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Federal Register

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Wednesday, May 4, 2022

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents.

ADMINISTRATIVE COMMITTEE OF THE FEDERAL REGISTER

1 CFR Part 12

Official Subscriptions to the Print Edition of the Federal Register

AGENCY: Administrative Committee of the Federal Register.

ACTION: Final rule.

SUMMARY: The Administrative Committee of the Federal Register is updating its regulations for official requests for specific issues or subscriptions to the print edition of the **Federal Register** as required by the Federal Register Printing Savings Act of 2017.

DATES: Effective May 4, 2022.

ADDRESSES: Docket materials are available for review at the Office of the Federal Register, 7 G Street NW, Suite A-734, Washington, DC 20401, 202-741-6030. Please contact the persons listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection of docket materials. The Office of the Federal Register's official hours of business are Monday through Friday, 8:45 a.m. to 5:15 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Katerina Horska, Director of Legal Affairs and Policy, or Miriam Vincent, Staff Attorney, Office of the Federal Register, at Fedreg.legal@nara.gov, or 202-741-6030.

SUPPLEMENTARY INFORMATION:

Background and Purpose

Under the Federal Register Act (44 U.S.C. Chapter 15), the Administrative Committee of the Federal Register (Administrative Committee, Committee, ACFR, or we) is responsible for issuing regulations governing **Federal Register** publications. This includes establishing the number of official print copies of the **Federal Register** that can be distributed to Members of Congress, officers and employees of the United States, or

Federal agencies (44 U.S.C. 1506). The ACFR sets out the number of official copies that Members of Congress and any other office of the United States are entitled to receive without charge in 1 CFR 12.1. This section also establishes how Federal offices of the United States request subscriptions to print copies of the **Federal Register**.

In January of 2018, the Federal Register Printing Savings Act of 2017 (Pub. L. 115-120) (the Act) updated 44 U.S.C. 1506 by changing subscription terms to yearly and placing other requirements on requests for official print copies of the **Federal Register**. Specifically, the Act prohibits the Government Publishing Office (GPO) from distributing the **Federal Register** without charge to Members of Congress or any other office of the United States unless they request a specific issue of the **Federal Register** or a subscription to the print edition of the **Federal Register** for that year. The Act also limits subscriptions to single-year terms. In addition, the Act requires the ACFR to issue regulations that notify Members of Congress and any other office of the United States of these restrictions and provide information on requesting official copies or subscriptions.

On December 30, 2020, we published a notice of proposed rulemaking (85 FR 86514), proposing to revise 1 CFR 12.1 to meet the requirements of the Act by setting out how Members of Congress and any other office of the United States may request an official copy or a subscription to the print edition of the **Federal Register**.

We received no comments.

Other Actions Taken To Implement the Act

Since the effective date of the Act, GPO has issued two Circular Letters related to its implementation. The first, GPO Circular Letter 1001, announced to official subscribers that GPO was creating a database to help implement the requirements of the Act (Gov't Publ'g Office, Circular Letter No. 1001 (2018), www.gpo.gov/how-to-work-with-us/agency/circular-letters/federal-register-printing-savings-act-of-2017). The second, GPO Circular Letter 1021, announced GPO's new online subscription portal for official distribution of the print edition of the **Federal Register** located at www.gpo.gov/frsubs (Gov't Publ'g Office, Circular Letter No. 1021 (2018),

www.gpo.gov/how-to-work-with-us/agency/circular-letters/federal-register-printing-savings-act-of-2017-2). On the portal's form, an office of the United States may sign up for a yearly subscription to the print edition of the **Federal Register**, with an option for the delivery of multiple copies to the office. The subscription will be valid for one calendar year, but must be renewed each January regardless of when initially requested. GPO will send subscribers a reminder that they will need to sign up for the next calendar year if they wish to continue to receive print copies of the daily **Federal Register**. If official subscribers do not use the portal to sign up, they will not receive print copies of the **Federal Register** at the start of the new calendar year. Currently, the portal also provides Members of Congress and other offices of the United States an email address (FRsubs@gpo.gov) for requesting specific issues of the daily **Federal Register**. However, future versions of the portal's form will allow Members of Congress and other offices of the United States to request specific issues of the daily **Federal Register**, in addition to subscriptions, directly through the portal.

To highlight these developments, GPO placed a direct link to the subscription portal on its homepage menu (Who We Are > Our Agency > Official Federal Register Subscription Form). We will also provide updates on any changes to the official distribution of print copies of the **Federal Register** on www.federalregister.gov and in the front matter of **Federal Register** issues.

We did not propose any changes to the process for requesting quantity overruns or extra copies. The paragraphs of § 12.1 governing those processes are re-designated as paragraphs (d) through (f) instead of paragraphs (b) through (d), but the processes themselves will remain the same. We also did not propose to change the paid subscription process in part 11. The Act did not affect the process for paid subscriptions, so this rule applies only to requests for distribution of the **Federal Register** without charge.

Regulatory Analysis

The Administrative Committee developed this rule after considering numerous statutes and Executive orders

related to rulemaking. Below is a summary of the Committee's determinations after analysis of these statutes and Executive orders with respect to this rulemaking.

Administrative Procedure Act

The Administrative Procedure Act (APA) requires a 30-day delay in the effective date of a rule unless the promulgating agency finds "good cause" for dispensing with the delay or another exception applies. 5 U.S.C. 553(d)(3). The Administrative Committee has determined that the good-cause exception applies to this rule.

The "primary purpose" for deferring the effective date of a rule is "to afford persons affected a reasonable time to prepare for the effective date of a rule or rules or to take other action which the issuance may prompt." *N. Arapahoe Tribe v. Hodel*, 808 F.2d 741, 752 (10th Cir. 1987) (quotation marks omitted); *Am. Fed'n of Gov't Emp., AFL-CIO v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981) (noting that a delay in the effective date "serve[s] the laudable purpose of informing affected parties and affording them a reasonable time to adjust to the new regulation"). The regulatory changes at issue in this rulemaking will not require any significant time for affected parties to alter their behavior because Members of Congress or other offices will immediately be able to use the online portal at www.gpo.gov/frsubs to request print subscriptions to the **Federal Register**. In addition, this rule has no effect on paid subscriptions, and it does not affect public access to the **Federal Register**, as the publication will remain freely available online at www.GovInfo.gov and www.federalregister.gov. Because the rule will have no significant effect on either requesting offices or the public more generally, regulated parties will not need time to come into compliance with the rule, and the good-cause exception under 5 U.S.C. 553(d)(3) applies.

Executive Orders 12866 and 13563

This rule has been drafted in accordance with Executive Order 12866, section 1(b), "The Principles of Regulation," and Executive Order 13563, "Improving Regulation and Regulatory Review." The Administrative Committee has determined that this rule is not a significant regulatory action as defined under section 3(f) of Executive Order 12866. Thus, this rule has not been reviewed by the Office of Management and Budget (OMB).

Regulatory Flexibility Act

This rule will not have a significant impact on small entities because it imposes no requirements on the public. Members of the public can access **Federal Register** publications for free through GPO's website, www.govinfo.gov/.

Federalism

This rule has no federalism implications under Executive Order 13132. It does not impose compliance costs on State or local governments or preempt State law.

Congressional Review

This rule is not a major rule as defined by 5 U.S.C. 804(2). The Administrative Committee will submit a rule report, including a copy of this final rule, to each House of the Congress and to the Comptroller General of the United States as required under the congressional review provisions of the Small Business Regulatory Enforcement Fairness Act of 1986. 5 U.S.C. 801(a).

List of Subjects in 1 CFR Part 12

Code of Federal Regulations, Federal Register, Government publications, Public Papers of Presidents of U.S., U.S. Government Manual, Daily Compilation of Presidential Documents.

For the reasons discussed in the preamble, under the authority at 44 U.S.C. 1506, the Administrative Committee of the Federal Register amends 1 CFR part 12 as follows:

PART 12—OFFICIAL DISTRIBUTION WITHIN FEDERAL GOVERNMENT

- 1. The authority citation for part 12 continues to read as follows:

Authority: 44 U.S.C. 1506; sec. 6, E.O. 10530, 19 FR 2709; 3 CFR, 1954–1958 Comp., p. 189.

- 2. Amend § 12.1 by:
 - a. Revising paragraph (a);
 - b. Redesignating paragraphs (b) through (e) as (d) through (g); and
 - c. Adding new paragraphs (b) and (c).

The revision and additions read as follows:

§ 12.1 Federal Register.

(a) The **Federal Register**, issued under the authority of the Administrative Committee, is officially maintained online and is available on at least one Government Publishing Office website.

(b) Requests for subscriptions to the **Federal Register** may be made as follows:

- (1) Requests from a Member of Congress or any other office of the United States for a specific issue or a subscription may be submitted via a

Government Publishing Office website or by email to an email address provided on that website.

- (2) Official subscription requests:
 - (i) May be made in the current year for that year or for the upcoming year;
 - (ii) Will expire at the end of each calendar year; and
 - (iii) Will not automatically continue into a new calendar year.

(c) Notifications regarding procedures for requesting official copies of specific issues or print subscriptions are available:

- (1) On a Government Publishing Office website dedicated to official subscriptions;
- (2) On www.federalregister.gov; and
- (3) In the front matter of the **Federal Register**, which is the text that precedes the main text of the daily issue of the **Federal Register**.

* * * * *

David S. Ferriero,

Chairperson, Administrative Committee of the Federal Register.

Hugh N. Halpern,

Member, Administrative Committee of the Federal Register.

Rosemary Hart,

Member, Administrative Committee of the Federal Register.

Approved:

Merrick B. Garland,

Attorney General.

David S. Ferriero,

Archivist of the United States.

[FR Doc. 2022–09563 Filed 5–3–22; 8:45 am]

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SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Docket No. SSA–2022–0016]

RIN 0960–AI66

Extension of Expiration Dates for Three Body System Listings

AGENCY: Social Security Administration.
ACTION: Final rule.

SUMMARY: We are extending the expiration dates of the following body systems in the Listing of Impairments (listings) in our regulations: Special Senses and Speech, Hematological Disorders, and Congenital Disorders That Affect Multiple Body Systems. We are making no other revisions to these body systems in this final rule. This extension ensures that we will continue to have the criteria we need to evaluate impairments in the affected body systems at step three of the sequential evaluation processes for initial claims and continuing disability reviews.

DATES: This final rule is effective on May 4, 2022.

FOR FURTHER INFORMATION CONTACT: Michael J. Goldstein, Director, Office of Medical Policy, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235-6401, (410) 965-1020.

For information on eligibility or filing for benefits, call our national toll-free number, 1-800-772-1213, or TTY 1-800-325-0778, or visit our internet site, Social Security Online, at <https://www.socialsecurity.gov>.

SUPPLEMENTARY INFORMATION:

Background

We use the listings in appendix 1 to subpart P of part 404 of 20 CFR at the third step of the sequential evaluation process to evaluate claims filed by adults and children for benefits based on disability under the title II and title XVI programs.¹ 20 CFR 404.1520(d), 416.920(d), 416.924(d). The listings are in two parts: Part A has listings criteria for adults and Part B has listings criteria for children. If you are age 18 or over, we apply the listings criteria in Part A when we assess your impairment or combination of impairments. If you are

under age 18, we first use the criteria in Part B of the listings when we assess your impairment(s). If the criteria in Part B do not apply, we may use the criteria in Part A when those criteria consider the effects of your impairment(s). 20 CFR 404.1525(b), 416.925(b).

Explanation of Changes

In this final rule, we are extending the dates on which the listings for the following three body systems will no longer be effective as set out in the following chart:

Body system listings	Current expiration date	New expiration date
Special Senses and Speech 2.00 and 102.00	June 3, 2022	June 5, 2026.
Hematological Disorders 7.00 and 107.00	June 3, 2022	June 5, 2026.
Congenital Disorders That Affect Multiple Body Systems 10.00 and 110.00	June 3, 2022	June 5, 2026.

We continue to revise and update the listings on a regular basis, including those body systems not affected by this final rule.² We intend to update the three listings affected by this final rule as necessary based on medical advances as quickly as possible, but may not be able to publish final rules revising these listings by the current expiration date. Therefore, we are extending the expiration dates listed above.

Regulatory Procedures

Justification for Final Rule

We follow the Administrative Procedure Act (APA) rulemaking procedures specified in 5 U.S.C. 553 in promulgating regulations. Section 702(a)(5) of the Social Security Act, 42 U.S.C. 902(a)(5). Generally, the APA requires that an agency provide prior notice and opportunity for public comment before issuing a final regulation. The APA provides exceptions to the notice-and-comment requirements when an agency finds there is good cause for dispensing with such procedures because they are impracticable, unnecessary, or contrary to the public interest.

We determined that good cause exists for dispensing with the notice and public comment procedures. 5 U.S.C. 553(b)(B). This final rule only extends the date on which the three body system listings will no longer be effective. It makes no substantive changes to our rules. Our current regulations³ provide that we may extend, revise, or promulgate the body system listings

again. Therefore, we determined that opportunity for prior comment is unnecessary, and we are issuing this regulation as a final rule.

In addition, for the reasons cited above, we find good cause for dispensing with the 30-day delay in the effective date of this final rule. 5 U.S.C. 553(d)(3). We are not making any substantive changes to the listings in these body systems. Without an extension of the expiration date for these listings, we will not have the criteria we need to assess medical impairments in these three body systems at step three of the sequential evaluation processes. We therefore find it is in the public interest to make this final rule effective on the publication date.

Executive Order 12866, as Supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and determined that this final rule does not meet the requirements for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB did not review it. We also determined that this final rule meets the plain language requirement of Executive Order 12866.

Regulatory Flexibility Act

We certify that this final rule does not have a significant economic impact on a substantial number of small entities because it affects only individuals.

Therefore, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act, as amended.

Paperwork Reduction Act

This final rule only extends the date for the medical listings cited above, but does not create any new or affect any existing collections, or otherwise change any content of the currently published rules. Accordingly, it does not impose any burdens under the Paperwork Reduction Act and does not require OMB approval.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.004, Social Security-Survivors Insurance; 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-age, Survivors and disability insurance, Reporting and recordkeeping requirements, Social Security.

The Acting Commissioner of the Social Security Administration, Kilolo Kijakazi, Ph.D., M.S.W., having reviewed and approved this document, is delegating the authority to electronically sign this document to Faye I. Lipsky, who is the primary Federal Register Liaison for SSA, for

¹ We also use the listings in the sequential evaluation processes we use to determine whether a beneficiary's disability continues. See 20 CFR 404.1594, 416.994, and 416.994a.

² We last extended the expiration dates of the three body system listings affected by this final rule on February 24, 2020 (85 FR 10278).

³ See the first sentence of appendix 1 to subpart P of part 404 of 20 CFR.

purposes of publication in the **Federal Register**.

Faye I. Lipsky,

Federal Register Liaison, Office of Legislation and Congressional Affairs, Social Security Administration.

For the reasons set out in the preamble, we are amending part 404 of chapter III of title 20 of the Code of Federal Regulations as set forth below.

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950—)

Subpart P—[Amended]

■ 1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a)–(b) and (d)–(h), 216(i), 221(a) and (h)–(j), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a)–(b) and (d)–(h), 416(i), 421(a) and (h)–(j), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 2. Amend appendix 1 to subpart P of part 404 in the introductory text by revising items 3, 8, and 11 to read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

■ 3. Special Senses and Speech (2.00 and 102.00): June 5, 2026.

* * * * *

8. Hematological Disorders (7.00 and 107.00): June 5, 2026.

* * * * *

11. Congenital Disorders That Affect Multiple Body Systems (10.00 and 110.00): June 5, 2026.

* * * * *

[FR Doc. 2022–09552 Filed 5–3–22; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2022–0073]

RIN 1625–AA08

Special Local Regulations; Annual Events in Captain of the Port Delaware Bay Zone

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing special local regulations for

four annual marine events in the Captain of the Port (COTP), Delaware Bay Zone. This action is necessary to protect participants, spectators, and vessels from the hazards associated with the varying types of marine events. This rulemaking prohibits persons and vessels from being in the regulated areas during the enforcement period unless authorized by the COTP or a designated representative.

DATES: This rule is effective June 3, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2022–0073 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email MST1 Jennifer Padilla, Waterways Management Division, Sector Delaware Bay, U.S. Coast Guard; telephone (215) 271–4889, email Jennifer.I.Padilla@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The four marine events included in this rule are held on a recurring basis on the navigable waters within the Captain of the Port, Delaware Bay Zone. Historically, the Coast Guard established annual temporary final regulations for each of these recurring events. In response, on February 17, 2022, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Special Local Regulations; Annual Events in Captain of the Port Delaware Bay Zone (87 FR 8994). There, we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to the special local regulations and recurring marine events. During the comment period that ended March 21, 2022 we received no comments.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70041. The Secretary has delegated ports and waterways authority, with certain reservations not applicable here, to the Commandant via DHS Delegation No.

00170.1(II)(70), Revision No. 01.2. The Commandant has further delegated these authorities within the Coast Guard as described in 33 CFR 1.05–1 and 6.04–6. The Coast Guard has determined that the events listed in this rule could pose a risk to participants or waterway users if normal vessel traffic were to interfere with the event. Possible hazards include risks of participant injury or death resulting from near or actual contact with non-participant vessels traversing through the regulated areas. In order to protect the safety of all waterway users, including event participants and spectators, this rule establishes special local regulations for the time and location of each marine event. This rule prevents vessels from entering, transiting, mooring or anchoring within areas specifically designated as regulated areas during the periods of enforcement unless authorized by the Captain of the Port (COTP), or designated Event Patrol Commander.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published February 17, 2022. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

The Coast Guard is adding four reoccurring special local regulations for annual marine events in the Captain of the Port Delaware Bay to 33 CFR 100.501 in Table 1 to Paragraph (i)(1). The Coast Guard will publish annual notice of the exact dates and times of the effective periods of the regulations. For each event, the notices will also provide the geographical description of each regulated area and other pertinent details concerning the nature of the events. This rule is necessary to protect participants, spectators, and vessels from the hazards associated with the varying types of marine events. During the enforcement periods of these special local regulations, non-participant persons or vessels are prohibited from entering into, remaining within, transiting through, or anchoring in the regulated area unless authorized by the Captain of the Port Delaware Bay or a designated representative of the Captain of the Port. The regulatory text appears at the end of this document.

Below is a description of the four reoccurring marine events that we are adding to Table 1 to Paragraph (i)(1) in 100.501.

1. Stockton Boat Race.

This marine event takes place one weekend in March or April at the location described below. The event is in Atlantic City, NJ, where the following area makes up the regulated area: All

navigable waters of the New Jersey Intracoastal Waterway in Atlantic City, NJ, within the polygon bounded by the following: Originating on the southwest portion at approximate position latitude 39°20'57" N, longitude 074°27'59" W; thence northeasterly along the shoreline to latitude 39°21'35" N, longitude 074°27'06" W; thence east across the mouth of Beach Thorofare to the shoreline at latitude 39°21'41" N, longitude 074°26'55" W; thence east along the shoreline to latitude 39°21'42" N, longitude 074°26'51" W; thence southeast across the New Jersey Intracoastal Waterway to the shoreline at latitude 39°21'43" N, longitude 074°26'41" W; thence southwest along the shoreline to approximate position latitude 39°20'55" N, longitude 074°27'57" W; thence north to the point of origin. The sponsor is Stockton University.

2. Escape the Cape Swim.

This marine event takes place on one Saturday or Sunday in June. The regulated area is in Lower Township, NJ, in the following area: All navigable waters of the Delaware Bay in Lower Township, NJ, bounded by a line drawn from: Latitude 39°0'57" N, longitude 074°56'56" W in Villas, NJ, thence west to latitude 39°00'59" N, longitude 074°57'15" W, thence south to latitude 38°58'08" N, longitude 074°58'11" W, thence east to latitude 38°58'04" N, longitude 074°57'52" W in North Cape May, NJ, thence north along the shoreline to the point of origin. The sponsor is DelMoSports.

3. Around the Island Paddle.

This marine event takes place on one Saturday or Sunday in June, July, or August. The regulated area location is in Cape May County, NJ. The following area is a moving regulated area: All waters within 50 yards in front of the lead safety vessel preceding the first event participants, to 50 yards behind the safety vessel trailing the last event participants, and 100 yards on either side of participant and safety vessels during the event. The regulated area will move with the safety vessels and participants as they transit the waters east through Cape May Harbor, south through Cape May Inlet, west through the Atlantic Ocean, north through the Delaware Bay, then east through Cape May Canal, and terminate at the Lost Fishermen's Memorial in Cape May Harbor. The regulated area will move at the pace of event patrol vessels and participants. The sponsor is the Desatnick Foundation.

4. Manasquan Inlet Intracoastal Tug.

This marine event takes place on one Saturday or Sunday in September or October. The location is Manasquan

Inlet, NJ. The following area makes up the regulated area: All waters of Manasquan Inlet extending 400 feet from either side of the rope located between approximate locations latitude 40°06'09" N, longitude 74°02'08" W and latitude 40°06'14" N, longitude 74°02'08" W. The sponsor is the Borough of Manasquan.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a "significant regulatory action" under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, scope, duration, and historical data concerning the scope and potential impact of these marine events. The special local regulation areas within this rule have been enforced on an annual basis through temporary final regulations. The regulated areas will be enforced in limited areas on six days out of the year, usually for only a few hours on those days. Specifically, the Manasquan Inlet Intracoastal Tug often schedules breaks during the event to temporarily let vessels pass through the inlet waterway entrance. Vessels will be able to contact the COTP for permission to transit the regulated areas or instructions for safely transiting around the area during enforcement periods.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this

rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the

Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have

determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves special local regulations at various locations and at various times to maintain the safety of event participants, spectators, and transiting vessel traffic. It is categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A memorandum for record (MFR) supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. In § 100.501, amend Table 1 to Paragraph (i)(1) by adding entries for “Stockton Boat Race”, “Escape the Cape Swim”, “Around the Island Paddle”, and “Manasquan Inlet Intracoastal Tug” at the end of the table to read as follows:

§ 100.501 Special Local Regulations; Marine Events Within the Fifth Coast Guard District.

* * * * *

TABLE 1 TO PARAGRAPH (i)(1)

Event	Regulated area	Enforcement period(s) ¹	Sponsor
* Stockton Boat Race	* All navigable waters of the New Jersey Intracoastal Waterway in Atlantic City, NJ within the polygon bounded by the following: Originating on the southwest portion at approximate position latitude 39°20'57" N, longitude 074°27'59" W; thence northeasterly along the shoreline to latitude 39°21'35" N, longitude 074°27'06" W; thence east across the mouth of Beach Thorofare to the shoreline at latitude 39°21'41" N, longitude 074°26'55" W; thence east along the shoreline to latitude 39°21'42" N, longitude 074°26'51" W; thence southeast across the New Jersey Intracoastal Waterway to the shoreline at latitude 39°21'43" N, longitude 074°26'41" W; thence southwest along the shoreline to approximate position latitude 39°20'55" N, longitude 074°27'57" W; thence north to the point of origin.	* One weekend in March or April.	* Stockton University.
* Escape the Cape Swim.	* All navigable waters of the Delaware Bay in Lower Township, NJ bounded by a line drawn from: Latitude 39°0'57" N, longitude 074°56'56" W in Villas, NJ, thence west to latitude 39°00'59" N, longitude 074°57'15" W, thence south to latitude 38°58'08" N, longitude 074°58'11" W, thence east to latitude 38°58'04" N, longitude 074°57'52" W in North Cape May, NJ, thence north along the shoreline to the point of origin.	* One Saturday or Sunday in June.	* DelMoSports.
* Around the Island Paddle.	* All waters within 50 yards in front of the lead safety vessel preceding the first event participants, to 50 yards behind the safety vessel trailing the last event participants, and 100 yards on either side of participant and safety vessels during the event. The regulated area will move with the safety vessels and participants as they transit the waters east through Cape May Harbor, south through Cape May Inlet, west through the Atlantic Ocean, north through the Delaware Bay, then east through Cape May Canal, and terminate at the Lost Fishermen’s Memorial in Cape May Harbor. The regulated area will move at the pace of event patrol vessels and participants.	* One Saturday or Sunday in June, July or August.	* Desatnick Foundation.
* Manasquan Inlet Intracoastal Tug.	* All waters of Manasquan Inlet extending 400 feet from either side of the rope located between approximate locations latitude 40°06'09" N, longitude 74°02'08" W and latitude 40°06'14" N, longitude 74°02'08" W.	* One Saturday or Sunday in September or October.	* Borough of Manasquan.

¹ As noted, the enforcement dates and times for each of the listed events in this table are subject to change. In the event of a change, or for enforcement periods listed that do not allow a specific date or dates to be determined, the Captain of the Port will provide notice to the public by publishing a Notice of Enforcement in the **Federal Register**, as well as, issuing a Broadcast Notice to Mariner.

* * * * *

Dated: April 26, 2022.

Jonathan D. Theel,*Captain, U.S. Coast Guard. Captain of the Port, Delaware Bay.*

[FR Doc. 2022-09502 Filed 5-3-22; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 100**

[Docket No. USCG-2022-0061]

Special Local Regulations: Miami Beach Air and Sea Show, Atlantic Ocean, Miami Beach, FL**AGENCY:** Coast Guard, DHS.**ACTION:** Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a special local regulation for the Miami Beach Air and Sea Show to provide for the safety of life on navigable waterways during this event. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulation in 33 CFR 100.702, Table 1 to § 100.702, Item 2, will be enforced from 9 a.m. until 5:30 p.m., each day from Friday May 27, 2022 through Sunday May 29, 2022.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Petty Officer Robert M. Olivas, Sector Miami Waterways Management Division, U.S. Coast Guard; telephone 305-535-4317, email *Robert.M.Olivas@uscg.mil*.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce a special local regulation in 33 CFR 100.702, Table 1 to § 100.702, Item 2, for the Miami Beach Air and Sea Show, from 9 a.m. until 5:30 p.m., each day from Friday May 27, 2022 through Sunday May 29, 2022. The Coast Guard is taking this action to provide for the safety of life on navigable waterways during the event. Our regulation for recurring marine events, Sector Miami, 33 CFR 100.702, Table 1 to § 100.702, Item 2, specifies the location of the regulated area which encompasses a portion of the Atlantic Ocean east of Miami Beach. During the enforcement periods, as reflected in § 100.702, if you are the operator of a vessel in the regulated area you must comply with directions from the Patrol

Commander or any Official Patrol displaying a Coast Guard ensign.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and marine information broadcasts.

Dated: April 28, 2022.

J.F. Burdian,*Captain, U.S. Coast Guard. Captain of the Port Miami.*

[FR Doc. 2022-09501 Filed 5-3-22; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165**

[Docket Number USCG-2022-0291]

RIN 1625-AA00

Safety Zones; Pensacola, Panama City, and Tallahassee, Florida**AGENCY:** Coast Guard, DHS.**ACTION:** Temporary final rule.

SUMMARY: The Coast Guard is establishing three temporary safety zones for the reentry of a capsule launched by Space Exploration Technologies Corporation (Space X) in support of the National Aeronautics and Space Administration (NASA) Crew-3 capsule recovery mission. These three temporary safety zones are located within the Coast Guard Sector Mobile area of responsibility offshore of Pensacola, Panama City, and Tallahassee, Florida. The purpose of this rule is to ensure the safety of vessels, mariners, and the navigable waters in the safety zones during a period when reentry is expected. This action is necessary to provide for the safe recovery of this capsule and astronauts in the U.S. Exclusive Economic Zone and implements a special activities provision of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021. This rule prohibits U.S. flagged vessels from entering the safety zones unless authorized by the Captain of the Port Mobile or a designated representative.

DATES: This rule is effective without actual notice from May 4, 2022 until May 15, 2022. For the purposes of enforcement, actual notice will be used from May 1, 2022 until May 4, 2022.

ADDRESSES: To view documents mentioned in this preamble as being

available in the docket, go to <https://www.regulations.gov>, type USCG-2022-0291 in the search box and click "Search." Next, in the Document Type column, select "Supporting & Related Material."

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Andrew Anderson, Sector Mobile Chief of Waterways (spw), U.S. Coast Guard; telephone (251) 441-5940, email *Andrew.S.Anderson@uscg.mil*.

SUPPLEMENTARY INFORMATION:**I. Table of Abbreviations**

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
EEZ Exclusive Economic Zone
FR Federal Register
NASA National Aeronautics and Space Administration
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code
Space X Space Exploration Technologies Corporation

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable and contrary to the public interest. The National Aeronautics and Space Administration (NASA) Crew-3 capsule recovery mission was approved and scheduled less than 30 days before the need for the three safety zones to be in place starting on May 1, 2022. Publishing an NPRM would be impracticable and contrary to the public interest since the missions would begin before completion of the rulemaking process, thereby inhibiting the Coast Guard's ability to protect against the hazards associated with the recovery missions.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to the public interest because

the temporary safety zones must be established by May 1, 2022, to mitigate safety concerns during the capsule recovery missions.

III. Legal Authority and Need for Rule

On January 1, 2021, the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (Pub. L. 116–283) (Authorization Act) was enacted. Its section 8343 (134 Stat. 4710) calls for the Coast Guard to conduct a 2-year pilot program to establish and implement a process to establish safety zones to address special activities in the Exclusive Economic Zone (EEZ).¹ These special activities include space activities carried out by United States citizens. Terms used to describe space activities, including *reentry site*, and *reentry vehicle*, are defined in 51 U.S.C. 50902.

The Captain of the Port Mobile has determined that potential hazards associated with the NASA Crew-3 capsule recovery mission presents a safety concern for anyone within the perimeter of the three safety zones. The safety zones will only be activated when a reentry vehicle is approaching a reentry site and will be deactivated once the reentry vehicle is removed from the reentry site. The purpose of this rule is to ensure the safety of astronauts, vessels, mariners, and the navigable waters in the safety zones before, during, and after the scheduled event. The Coast Guard is issuing this rule under authority of section 8343 of the Authorization Act and 46 U.S.C. 70034.

IV. Discussion of the Rule

The Coast Guard is establishing special activity temporary safety zones for reentry vehicles within any of the three reentry sites described in this rule. The Crew-3 recovery mission may occur within any of the following reentry sites in the Gulf of Mexico: Pensacola, Panama City, and Tallahassee, Florida.

Approximately one day before capsule reentry and recovery, Space X and NASA will determine which of the sites will be used. This determination is based on mission and environmental factors. After the determination is made, the respective COTP will use Local Notice to Mariners and Broadcast Notice to Mariners on VHF–FM channel 16 to inform the public of which safety zone is expected to be used.

The three temporary reentry sites in the EEZ are listed below and include all waters within the coordinates from surface to bottom. The coordinates are based on the projected reentry locations

as determined from telemetry data and modeling by Space X.

(1) Pensacola site:

Point 1	29.930° N	– 087.643° W
Point 2	29.930° N	– 087.357° W
Point 3	29.670° N	– 087.357° W
Point 4	29.670° N	– 087.° W

(2) Panama City site:

Point 1	29.846° N	– 086.326° W
Point 2	29.846° N	– 086.040° W
Point 3	29.586° N	– 086.040° W
Point 4	29.586° N	– 086.326° W

(3) Tallahassee site:

Point 1	29.413° N	– 084.342° W
Point 2	29.413° N	– 084.058° W
Point 3	29.153° N	– 084.058° W
Point 4	29.153° N	– 084.342° W

When the reentry site is activated as a safety zone, the COTP or a designated representative will be able to restrict vessel movement including but not limited to transiting, anchoring, or mooring within the safety zone to protect vessels from hazards associated with rocket and capsule recovery missions. Active restrictions are based on mission specific recovery exclusion areas provided by Space X and NASA, are temporary in nature, and would only be enacted and enforced at a reasonable time prior to and after a recovery. Because the safety zones are located in the EEZ, only United States flagged vessels are subject to safety zone enforcement. Other vessels are encouraged to remain outside the safety zone.

The COTP will inform the public of the activation or status of the safety zones by Local Notice to Mariners and Broadcast Notice to Mariners on VHF–FM channel 16.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a “significant regulatory action” under Executive Order 12866. Accordingly, this rule has not been reviewed by the

Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, duration, and scope of the safety zones. The safety zones are limited in size and location to only those areas where capsule re-entry is reasonably occurs. The safety zones are limited in scope, as vessel traffic will be able to safely transit around the safety zones which will impact a small part of the United States exclusive economic zone (EEZ) within the Gulf of Mexico.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

The safety zone activation and thus restriction to the public is expected to be approximately two hours per capsule recovery, and we anticipate one splash down during the effective period of this rule. Vessels would be able to transit around the activated safety zone location during this recovery. We do not anticipate any significant economic impact resulting from activation of the safety zones.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against

¹ The Coast Guard defines the Exclusive Economic Zone in 33 CFR 2.30.

small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the establishing of three temporary safety zones, one of which may be activated on

one occasion for approximately two hours between May 1, 2022 and May 15, 2022 for a Space X and NASA mission. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the ADDRESSES section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the FOR FURTHER INFORMATION CONTACT section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T07–0233 to read as follows:

§ 165.T08–0291 Safety Zones; Pensacola, Panama City, and Tallahassee, Florida.

(a) *Location.* The following areas are safety zones:

(1) *Pensacola site.* All waters from surface to bottom encompassed within the following coordinates connecting a line from Point 1, thence to Point 2, and thence to Point 3, connecting back to Point 4:

Point 1	29.930° N	–087.643° W
Point 2	29.930° N	–087.357° W
Point 3	29.670° N	–087.357° W
Point 4	29.670° N	–087.643° W

(2) *Panama City site.* All waters from surface to bottom encompassed within the following coordinates connecting a line from Point 1, thence to Point 2, and thence to Point 3, connecting back to Point 4:

Point 1	29.846° N	–086.326° W
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Point 2	29.846° N	–086.040° W
Point 3	29.586° N	–086.040° W
Point 4	29.586° N	–086.326° W

(3) *Tallahassee site.* All waters from surface to bottom encompassed within the following coordinates connecting a line from Point 1, thence to Point 2, and thence to Point 3, connecting back to Point 4:

Point 1	29.413° N	–084.342° W
Point 2	29.413° N	–084.058° W
Point 3	29.153° N	–084.058° W
Point 4	29.153° N	–084.342° W

(b) *Definitions.* As used in this section—

Designated representative means Coast Guard Patrol Commanders including Coast Guard coxswains, petty officers and other officers designated by or assisting the COTP Mobile in the enforcement of the safety zones.

Reentry Vehicle means a vehicle designed to return from Earth orbit or outer space to Earth, or a reusable launch vehicle designed to return from Earth orbit or outer space to Earth, substantially intact.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP’s designated representative.

(2) The COTP Mobile or other designated representative may restrict vessel movement including but not limited to transiting, anchoring, or mooring within these safety zones to protect vessels from hazards associated with rocket recoveries. These restrictions are temporary in nature and will only be enacted and enforced prior to and just after the recovery missions.

(3) Because the safety zones are within the United States Exclusive Economic Zone, only United States flagged vessels are subject to safety zone enforcement. Other vessels are encouraged to remain outside the safety zone.

(d) *Enforcement periods.* This rule will be enforced between May 1, 2022 and May 15, 2022, beginning a reasonable time before splashdown of a reentry vehicle in one of the areas described above, and will be deactivated once the area is no longer hazardous. The COTP will inform the public of which safety zone will be activated by Broadcast Notice to Mariners on VHF–FM channel 16.

Dated: April 29, 2022

LaDonn A. Allen,

Captain, Commander, Coast Guard Sector Mobile, Captain of the Port Mobile.

[FR Doc. 2022-09577 Filed 5-3-22; 8:45 am]

BILLING CODE 9110-04-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA-HQ-OAR-2021-0347; FRL-8470-01-OAR]

RIN 2060-AV25

Protection of Stratospheric Ozone: Listing of HFO-1234yf Under the Significant New Alternatives Policy Program for Motor Vehicle Air Conditioning in Nonroad Vehicles and Servicing Fittings for Small Refrigerant Cans

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Pursuant to the EPA's Significant New Alternatives Policy program, this action lists the refrigerant 2,3,3,3-tetrafluoroprop-1-ene, also known as HFO-1234yf or R-1234yf, as acceptable, subject to use conditions, in the motor vehicle air conditioning end-use for certain types of newly manufactured nonroad (also called off-road) vehicles, which includes some vehicles that are also considered heavy-duty vehicles. EPA is also adopting the current versions of the industry safety standards SAE J639, SAE J1739, and SAE J2844 by incorporating them by reference into the use conditions for the listings in nonroad vehicles and previous listings for certain onroad vehicles covered in final rules issued separately in March 2011 and December 2016. In addition, EPA is requiring unique servicing fittings for use with small refrigerant cans (two pounds or less) of 2,3,3,3-tetrafluoroprop-1-ene that are used to service onroad and nonroad vehicles. Finally, EPA is adding a reference to the Agency's regulations under the Toxic Substances Control Act for 2,3,3,3-tetrafluoroprop-1-ene for the listings in nonroad vehicles and previous listings for certain onroad vehicles.

DATES: This final rule is effective on June 3, 2022. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of June 3, 2022.

ADDRESSES: EPA has established a docket for this action under Docket ID

No. EPA-HQ-OAR-2021-0347. All documents in the docket are listed on the www.regulations.gov website. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Chenise Farquharson, Stratospheric Protection Division, Office of Atmospheric Programs (Mail Code 6205 T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202-564-7768; email address: farquharson.chenise@epa.gov. Notices and rulemakings under EPA's Significant New Alternatives Policy program are available on EPA's Stratospheric Ozone website at www.epa.gov/snap/snap-regulations.

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I. General Information

A. Executive Summary and Background

As proposed, EPA is listing 2,3,3,3-tetrafluoroprop-1-ene, also known as hydrofluoroolefin (HFO)-1234yf or R-1234yf, hereafter referred to as "HFO-1234yf," as acceptable, subject to use conditions, under the Significant New Alternatives Policy (SNAP) program, as of 30 days after publication of this final rule, for motor vehicle air conditioning (MVAC) systems¹ in the following types

¹ Under the SNAP program, MVAC systems are those systems that provide passenger comfort cooling for light-duty cars and trucks, heavy-duty vehicles (large pickups, delivery trucks, recreational vehicles, and semi-trucks), nonroad vehicles, buses, and rail vehicles. See final rules published on March 29, 2011 (76 FR 17488) and on December 1, 2016 (81 FR 86778). For informational purposes, we note that this includes systems that are also included in the definitions that apply under other provisions of EPA's regulations under title VI of the CAA. In this regard, we note that EPA's subpart F regulations at 40 CFR 82.152 define MVAC-like appliance to mean a mechanical vapor compression, open-drive compressor appliance with a full charge of 20 pounds or less of refrigerant used to cool the driver's or passenger's compartment of off-road vehicles or equipment. This includes, but is not limited to, the air-conditioning equipment found on agricultural or construction vehicles. This definition is not intended to cover appliances using R-22 refrigerant. By contrast, EPA's subpart F regulations at 40 CFR 82.152 define Motor vehicle air conditioner (MVAC) as "any appliance that is a motor vehicle air conditioner as defined in 40 CFR part 82, subpart B. The subpart B regulations at 40 CFR 82.32 provide that: Motor vehicle air conditioners means mechanical vapor compression refrigeration equipment used to cool the driver's or passenger's compartment of any motor vehicle. This definition is not intended to encompass the hermetically sealed refrigeration systems used on motor vehicles for refrigerated cargo and the air conditioning systems on passenger buses using HCFC-22 refrigerant. Further, the subpart B regulations at 40 CFR 82.32 provide that: Motor vehicle as used in this subpart means any vehicle which is self-propelled and designed for transporting persons or property on a street or highway, including but not limited to passenger cars, light duty vehicles, and heavy duty vehicles. This definition does not include a vehicle where final assembly of the vehicle has not been completed by the original equipment manufacturer.

of newly manufactured (hereafter “new”)² nonroad vehicles,³ including some vehicles that are also considered heavy-duty (HD)⁴ vehicles:

- Agricultural tractors with greater than 40 horsepower (HP);
- Self-propelled agricultural machinery;
- Compact equipment;
- Construction, forestry, and mining equipment; and
- Commercial utility vehicles.

EPA received four comments on the proposed rule from refrigerant suppliers and equipment manufacturers, and all commenters strongly supported finalizing the rule as proposed. The comment summaries and EPA’s responses to the comments are below in section II.F.

EPA has previously listed HFO-1234yf as acceptable, subject to use conditions, in new light-duty (LD) passenger cars and trucks (76 FR 17488; March 29, 2011) and new medium-duty passenger vehicles (MDPV), HD pickup trucks, and complete HD vans (81 FR 86778; December 1, 2016). The use conditions for those prior listings, which are intended to mitigate flammability and toxicity risks, require that MVAC systems designed to use HFO-1234yf meet the requirements of three technical safety standards developed by SAE International (SAE) (*i.e.*, SAE J639, SAE J1739, and SAE J2844). In this action, EPA is requiring the same use conditions, with certain updates discussed below, for MVAC systems designed to use HFO-1234yf in certain new nonroad vehicles. EPA is listing HFO-1234yf as acceptable, subject to use conditions, after its evaluation of human health and environmental information on various substitutes submitted to the SNAP program. In listing HFO-1234yf as acceptable, subject to use conditions, this action provides additional

² This is intended to mean a completely new refrigeration circuit containing a new compressor, evaporator, condenser, and refrigerant tubing.

³ In the past, EPA has referred to these vehicles as “off-road vehicles” under the SNAP program. In this action, we are aligning our terminology with that of other EPA programs and using the term “nonroad vehicle,” which is defined under CAA section 216 to mean “a vehicle that is powered by a nonroad engine and that is not a motor vehicle or a vehicle used solely for competition.” EPA’s regulations issued under that section of the Act defining a nonroad engine are codified at subpart A of 40 CFR part 1068.

⁴ Heavy-duty vehicles are often subdivided by vehicle weight classifications, as defined by the vehicle’s gross vehicle weight rating (GVWR), which is a measure of the combined curb (empty) weight and cargo carrying capacity of the truck. Heavy-duty vehicles have GVWRs above 8,500. See <https://www.epa.gov/emission-standards-reference-guide/vehicle-weight-classifications-emission-standards-reference-guide>.

flexibility for industry stakeholders by expanding the list of acceptable substitutes for certain types of nonroad vehicles.

EPA is also adopting the current versions of SAE J639, SAE J1739, and SAE J2844 by incorporating them by reference into the use conditions for the nonroad vehicles addressed in this action. EPA is also modifying the use conditions for the previous listings of HFO-1234yf in certain onroad vehicles to replace the references to older versions of the three SAE standards with references to the current versions. The current versions of the three standards are SAE J639 (revised November 2020), “Safety and Design Standards for Motor Vehicle Refrigerant Vapor Compression Systems;” SAE J1739 (revised January 2021), “Potential Failure Mode and Effects Analysis (FMEA) Including Design FMEA, Supplemental FMEA—MSR, and Process FMEA;” and SAE J2844 (revised January 2013), “R-1234yf (HFO-1234yf) New Refrigerant Purity and Container Requirements for Use in Mobile Air-Conditioning Systems.”

In addition, EPA is including a use condition, which requires unique servicing fittings, to provide for servicing MVAC systems in the nonroad vehicles addressed in this action, including use of small refrigerant cans (two pounds or less). For the previous listings of HFO-1234yf in certain onroad vehicles, EPA is revising the use conditions to require unique servicing fittings for use with small cans (two pounds or less).

Finally, EPA is including a reference to the Agency’s Significant New Use Rule (SNUR) for HFO-1234yf under the Toxic Substances Control Act (80 FR 37166, June 30, 2015) in Appendix B subpart G of part 82, under the ‘Comments’ column, for the listings of HFO-1234yf for the nonroad vehicles addressed in this action, as well as for all the previous listings of HFO-1234yf in certain onroad vehicles. The SNUR states that commercial users or consumers can only recharge MVAC systems with HFO-1234yf where the original charging of the system with HFO-1234yf was done by the Original Equipment Manufacturer (OEM).

The Agency is not modifying regulations promulgated under section 608 of the Clean Air Act (CAA). EPA notes that there are additional requirements that concern the sale or offer for sale of refrigerants, including a sales restriction under the regulations implementing CAA section 608, which can be found at 40 CFR part 82 subpart F. These regulations collectively comprise the national recycling and

emissions reduction program and may be commonly referred to as the stationary refrigeration and air conditioning management program. The general sales restriction provisions are codified at 40 CFR 82.154(c) and the specifications for self-sealing valves relevant to an exemption to the sales restriction for small cans of MVAC refrigerant are codified at 40 CFR 82.154(c)(2). This action does not modify the provisions under 40 CFR 82.154, including the restriction on the sale of substitute refrigerants and requirements for self-sealing valves.

B. SNAP Program Background

The SNAP program implements CAA section 612. Several major provisions of section 612 are:

1. Rulemaking

Section 612 requires EPA to promulgate rules making it unlawful to replace any class I (chlorofluorocarbon (CFC), halon, carbon tetrachloride, methyl chloroform, methyl bromide fluorocarbon, and chlorobromomethane) or class II (hydrochlorofluorocarbon (HCFC)) ozone-depleting substances (ODS) with any substitute that the Administrator determines may present adverse effects to human health or the environment where the Administrator has identified an alternative that (1) reduces the overall risk to human health and the environment and (2) is currently or potentially available.

2. Listing of Unacceptable/Acceptable Substitutes

Section 612(c) requires EPA to publish a list of the substitutes that it finds to be unacceptable for specific uses and to publish a corresponding list of acceptable substitutes for specific uses.

3. Petition Process

Section 612(d) grants the right to any person to petition EPA to add a substance to, or delete a substance from, the lists published in accordance with section 612(c).

4. 90-Day Notification

Section 612(e) directs EPA to require any person who produces a chemical substitute for a class I substance to notify the Agency not less than 90 days before a new or existing chemical is introduced into interstate commerce for significant new use as a substitute for a class I substance.⁵ The producer must

⁵ EPA’s SNAP regulations at 40 CFR 82.176 extend this requirement to substitutes for class II substances, providing that “[a]ny producer of a new substitute must submit a notice of intent to

also provide the Agency with the producer's unpublished health and safety studies on such substitutes.

The regulations for the SNAP program are promulgated at 40 CFR part 82, subpart G, and the Agency's process for reviewing SNAP submissions is described in regulations at 40 CFR 82.180. Under these rules, the Agency has identified five types of listing decisions: Acceptable; acceptable subject to use conditions; acceptable subject to narrowed use limits; unacceptable; and pending (40 CFR 82.180(b)). Use conditions and narrowed use limits are both considered "use restrictions," as described below. Substitutes that are deemed acceptable with no use restrictions (no use conditions or narrowed use limits) can be used for all applications within the relevant end-uses in the sector. After reviewing a substitute, the Agency may determine that a substitute is acceptable only if certain conditions in the way that the substitute is used are met to minimize risks to human health and the environment. EPA describes such substitutes as "acceptable subject to use conditions." (40 CFR 82.180(b)(2)). For some substitutes, the Agency may permit a narrowed range of use within an end-use or sector. For example, the Agency may limit the use of a substitute to certain end-uses or specific applications within an industry sector. EPA describes these substitutes as "acceptable subject to narrowed use limits." Under the narrowed use limit, users intending to adopt these substitutes "must ascertain that other alternatives are not technically feasible." (40 CFR 82.180(b)(3)).

In making decisions regarding whether a substitute is acceptable or unacceptable, and whether substitutes present risks that are lower than or comparable to risks from other substitutes that are currently or potentially available in the end-uses under consideration, EPA examines the criteria in 40 CFR 82.180(a)(7): (i) Atmospheric effects and related health and environmental impacts; (ii) general population risks from ambient exposure to compounds with direct toxicity and to increased ground-level ozone; (iii) ecosystem risks; (iv) occupational risks; (v) consumer risks; (vi) flammability; and (vii) cost and availability of the substitute.

Many SNAP listings include "comments" or "further information" to provide additional information on substitutes. Since this additional information is not part of the regulatory

decision, these statements are not binding for use of the substitute under the SNAP program. However, regulatory requirements so listed are binding as applicable under other regulatory programs (e.g., worker protection regulations promulgated by the U.S. Occupational Safety and Health Administration (OSHA)). The "further information" classification does not necessarily include all other legal obligations pertaining to the use of the substitute. While the items listed are not legally binding under the SNAP program, EPA encourages users of substitutes to apply all statements in the "further information" column in their use of these substitutes. In many instances, the information simply refers to sound operating practices that have already been identified in existing industry and/or building codes or standards. Thus, many of the statements, if adopted, would not require the affected user to make significant changes in existing operating practices.

For additional information on the SNAP program, visit the SNAP portion of EPA's Ozone Layer Protection website at <https://www.epa.gov/snap>. Copies of the full lists of acceptable substitutes for ODS in all industrial sectors are available at <https://www.epa.gov/snap/snap-substitutes-sector>. For more information on the Agency's process for administering the SNAP program or criteria for evaluation of substitutes, refer to the initial SNAP rulemaking published March 18, 1994 (59 FR 13044), codified at 40 CFR part 82, subpart G. SNAP decisions and the appropriate **Federal Register** citations are found at: <https://www.epa.gov/snap/snap-regulations>. Substitutes listed as unacceptable; acceptable, subject to narrowed use limits; or acceptable, subject to use conditions, are also listed in the appendices to 40 CFR part 82, subpart G.

In this action, EPA refers to listings made in a final rule issued on December 1, 2016, at 81 FR 86778 ("2016 Rule") in which the Agency listed HFO-1234yf as acceptable, subject to use conditions, in new MDPV, HD pickup trucks, and complete HD vans. The 2016 Rule also changed the listings for certain hydrofluorocarbons (HFCs) and blends from acceptable to unacceptable in various end-uses in the refrigeration and air conditioning, foam blowing, and fire suppression sectors. After a challenge to the 2016 Rule, the United States Court of Appeals for the District of Columbia Circuit ("the court") issued a partial vacatur of the 2016 Rule "only to the extent it requires manufacturers to replace HFCs that were previously and

lawfully installed as substitutes for ozone-depleting substances." ⁶ The court's decision on the 2016 Rule did not vacate the listing of HFO-1234yf for certain types of vehicles, and this final rule is not EPA's response to the court's decision on the 2016 Rule.

C. Does this action apply to me?

The following list identifies types of regulated entities that may be affected by this action and their respective North American Industrial Classification System (NAICS) codes:

- All Other Basic Organic Chemical Manufacturing (NAICS 325199)
- All Other General Merchandise Stores (NAICS 452990)
- All Other Miscellaneous Chemical Product and Preparation Manufacturing (NAICS 325998)
- Automotive Parts and Accessories Stores (NAICS 441310)
- Automotive Repair Shops Not Elsewhere Classified, Including Air Conditioning and Radiator Specialty Shops (NAICS 811198)
- Gasoline Stations with Convenience Stores (NAICS 447110)
- General automotive repair shops (NAICS 811111)
- Heavy Duty Truck Manufacturing (NAICS 336120)
- Industrial Gas Manufacturing (NAICS 32512)
- Motor Vehicle Body Manufacturing (NAICS 336211)
- Motor Vehicle Parts Manufacturing (NAICS 3363)
- Other Automotive Repair and Maintenance (NAICS 811119)
- Other Motor Vehicle Parts Manufacturing (NAICS 336390)
- Recyclable Material Merchant Wholesalers (NAICS 423930)
- Refrigeration Equipment and Supplies Merchant Wholesalers (NAICS 423740)

This list is not intended to be exhaustive but provides a guide for readers regarding types of entities likely to be regulated by this action. This list includes the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed above could also be regulated. To determine whether your facility, company, business, or organization could be affected by this action, you should carefully examine the regulations at 40 CFR part 82, subpart G. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

⁶ *Mexichem Fluor, Inc. v. EPA*, No. 17-1024, 760 Fed. Appx. 6, 9 (D.C. Cir., April 5, 2019).

introduce a substitute into interstate commerce 90 days prior to such introduction."

D. What acronyms and abbreviations are used in the preamble?

Below is a list of acronyms and abbreviations used in the preamble of this document:

AIHA—American Industrial Hygiene Association
 AC—Air Conditioning
 ACH—Air Changes Per Hour
 AEM—Association of Equipment Manufacturers
 ANSI—American National Standards Institute
 ASHRAE—American Society of Heating, Refrigerating and Air-Conditioning Engineers
 ASTM—American Society for Testing and Materials
 ATEL—Acute Toxicity Exposure Limit
 CAA—Clean Air Act
 CAS Reg. No.—Chemical Abstracts Service Registry Identification Number
 CBI—Confidential Business Information
 CFC—Chlorofluorocarbon
 CFD—Computational Fluid Dynamics
 CFR—Code of Federal Regulations
 CGA—Compressed Gas Association
 CO₂—Carbon Dioxide
 CRP—Cooperative Research Project
 DIY—Do-It-Yourself
 E.O.—Executive Order
 EPA—United States Environmental Protection Agency
 FCL—Flammability Concentration Limit
 FMEA—Failure Mode and Effects Analysis
 FR—Federal Register
 GHG—Greenhouse Gas
 GWP—Global Warming Potential
 GVWR—Gross Vehicle Weight Rating
 HCFC—Hydrochlorofluorocarbon
 HD—Heavy-Duty
 HD GHG—Heavy-Duty Greenhouse Gas
 HF—Hydrogen Fluoride
 HFC—Hydrofluorocarbon
 HFO—Hydrofluoroolefin
 HP—Horsepower
 ICF—ICF International, Inc.
 IPCC—Intergovernmental Panel on Climate Change
 LD—Light-Duty
 LD GHG—Light-Duty Greenhouse Gas
 LFL—Lower Flammability Limit
 MDPV—Medium-Duty Passenger Vehicle
 MVAC—Motor Vehicle Air Conditioning
 MY—Model Year
 NAAQS—National Ambient Air Quality Standards
 NAICS—North American Industrial Classification System
 NOAEL—No Observed Adverse Effect Level
 NRC—National Research Council
 OEM—Original Equipment Manufacturer
 ODP—Ozone Depletion Potential
 ODS—Ozone-depleting Substance
 OMB—Office of Management and Budget
 OSHA—Occupational Safety and Health Administration
 PPE—Personal Protective Equipment
 ppm—Parts Per Million
 PRA—Paperwork Reduction Act
 RCL—Reference Concentration Limit
 RFA—Regulatory Flexibility Act
 SAE—SAE International
 SDS—Safety Data Sheet
 SIP—State Implementation Plan

SNAP—Significant New Alternatives Policy
 SNUN—Significant New Use Notice
 SNUR—Significant New Use Rule
 STEL—Short-term Exposure Limit
 TFA—Trifluoroacetic Acid
 TLV—Threshold Limit Value
 TSCA—Toxic Substances Control Act
 TWA—Time Weighted Average
 UFL—Upper Flammability Limit
 UMRA—Unfunded Mandates Reform Act
 USGCRP—U.S. Global Change Research Program
 VOC—Volatile Organic Compounds
 WEEL—Workplace Environmental Exposure Limit

II. What is EPA finalizing in this action?

A. Listing of HFO-1234yf as Acceptable, Subject to use Conditions, for MVAC Systems in Certain new Nonroad Vehicles

As proposed, (86 FR at 68968; December 6, 2021), EPA is listing HFO-1234yf as acceptable, subject to use conditions, for MVAC systems in several types of new nonroad vehicles, specifically: Agricultural tractors greater than 40 HP; self-propelled agricultural machinery; compact equipment; construction, forestry, and mining equipment; and commercial utility vehicles. All MVAC refrigerants listed as acceptable are subject to use conditions requiring labeling and the use of unique fittings as described in Appendix B to subpart G of part 82—Substitutes Subject to Use Restrictions and Unacceptable Substitutes. EPA is listing HFO-1234yf as acceptable, subject to use conditions, in the five nonroad vehicle types. The use conditions require that MVAC systems designed to use HFO-1234yf meet the requirements of SAE J639, SAE J1739, and SAE J2844 to help ensure that use of HFO-1234yf does not have a significantly greater overall impact on human health and the environment than other alternatives for use in those vehicles. EPA is updating the existing use conditions that are currently required for the use of HFO-1234yf in MVAC systems in new LD vehicles, MDPVs, HD pickup trucks, and complete HD vans and applying them to all the MVAC systems addressed in this action. The use conditions are detailed below in section II.A.4, “What are the use conditions?”

1. What is the affected end-use?

Under SNAP, MVAC systems cool the passenger compartment of LD passenger vehicles and trucks, HD vehicles (e.g., large pickups, delivery trucks, and semi-trucks), off-road vehicles, buses, and passenger rail vehicles. These systems are typically charged during vehicle manufacture, and the main components

are connected by flexible refrigerant lines. Nonroad vehicles can be grouped into several categories (i.e., agriculture, construction, recreation, and many other purposes).⁷ The vehicle types addressed in this action include certain types of new nonroad vehicles, specifically:

- Agricultural tractors greater than 40 HP (including two-wheel drive (2WD), mechanical front-wheel drive (MFD), four-wheel drive (4WD), and track tractors) that are used for a number of agricultural applications such as farm work, planting, landscaping, and loading;^{8,9}
- Self-propelled agricultural machinery (including combines, grain and corn harvesters, sprayers, windrowers, and floaters) that are primarily used for harvesting, fertilizer, and herbicide operations;¹⁰
- Compact equipment (including mini excavators, turf mowers, skid-steer loaders, and tractors less than 40 HP) that are primarily used for agricultural operations and residential, commercial, and agricultural landscaping;¹¹
- Construction, forestry, and mining equipment (including excavators, bulldozers, wheel loaders, feller bunchers, log skidders, road graders, articulated trucks, sub-surface machines, horizontal directional drill, trenchers, and tracked crawlers) that are primarily used to excavate surface and subsurface materials during construction, landscaping, and road maintenance and building;¹² and
- Commercial utility vehicles that are primarily used for ranching, farming, hunting/fishing, construction, landscaping, property maintenance, railroad maintenance, forestry, and mining.¹³

These nonroad vehicles are almost exclusively used and operated by professionals (e.g., agricultural owners or skilled employees/operators) and vary by size, weight, use, and/or

⁷ EPA, 2021. Basic Information about the Emission Standards Reference Guide for On-road and Nonroad Vehicles and Engines. Available online at <https://www.epa.gov/emission-standards-reference-guide/basic-information-about-emission-standards-reference-guide-road> and in the docket for this rulemaking at <https://nepis.epa.gov/Exec/ZipPDF.cgi/P100K5U2.PDF?Dockey=P100K5U2.PDF>.

⁸ Wagner, 2021. May 24, 2021, email from John Wagner of the Association of Equipment Manufacturers to EPA. Available in the docket for this rulemaking.

⁹ AEM, 2021. Appendix A: Machine Forms as Classified by AEM Membership. Available in the docket for this rulemaking.

¹⁰ Ibid.

¹¹ Ibid.

¹² Ibid.

¹³ Ibid.

horsepower.¹⁴ For example, commercial utility vehicles typically weigh between 1,200 and 2,400 pounds, while agricultural tractors >40 HP typically weigh between 39,000 and 50,000 pounds.¹⁵ MVAC systems in these nonroad vehicles can have charge sizes ranging from 650 grams (23 ounces) to 3,400 grams (120 ounces) depending on the manufacturer and cab size, compared to a range of 390 grams (14 ounces) to 1,600 grams (56 ounces) for MVAC systems in light and medium duty passenger vehicles, HD pickups, and complete HD vans.¹⁷ Additionally, unlike onroad passenger vehicles, for example, nonroad vehicles are limited to non-highway terrain (e.g., fields, construction sites, forests, and mines), have more robust components, are operated at low working speeds, and there are typically a limited number of vehicles in the same location.

2. What are the ANSI/ASHRAE classifications for refrigerant flammability?

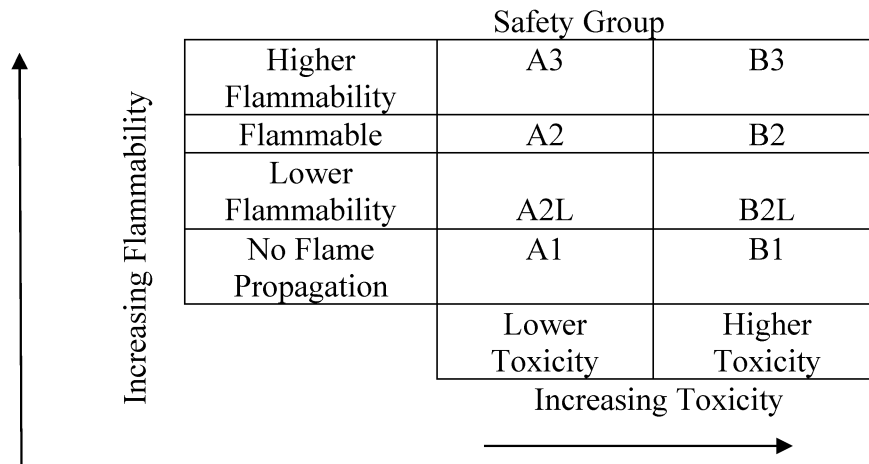
The American National Standards Institute/American Society of Heating,

Refrigerating and Air Conditioning Engineers (ANSI/ASHRAE) Standard 34–2019 assigns a safety group classification for each refrigerant which consists of two to three alphanumeric characters (e.g., A2L or B1). The initial capital letter indicates the toxicity, and the numeral denotes the flammability. ASHRAE classifies Class A refrigerants as refrigerants for which toxicity has not been identified at concentrations less than or equal to 400 ppm by volume, based on data used to determine threshold limit value-time-weighted average (TLV–TWA) or consistent indices. Class B signifies refrigerants for which there is evidence of toxicity at concentrations below 400 ppm by volume, based on data used to determine TLV–TWA or consistent indices.

Refrigerants are also assigned a flammability classification of 1, 2, 2L, or 3. Tests for flammability are conducted in accordance with American Society for Testing and Materials (ASTM) E681 using a spark ignition source at 140 °F (60 °C) and 14.7 psia (101.3 kPa)¹⁸. The

flammability classification “1” is given to refrigerants that, when tested, show no flame propagation. The flammability classification “2” is given to refrigerants that, when tested, exhibit flame propagation, have a heat of combustion less than 19,000 kJ/kg (8,169 Btu/lb.), and have a lower flammability limit (LFL) greater than 0.10 kg/m³. The flammability classification “2L” is given to refrigerants that, when tested, exhibit flame propagation, have a heat of combustion less than 19,000 kJ/kg (8,169 BTU/lb.), have an LFL greater than 0.10 kg/m³, and have a maximum burning velocity of 10 cm/s or lower when tested in dry air at 73.4 °F (23.0 °C) and 14.7 psia (101.3 kPa). The flammability classification “3” is given to refrigerants that, when tested, exhibit flame propagation and that either have a heat of combustion of 19,000 kJ/kg (8,169 BTU/lb.) or greater or have an LFL of 0.10 kg/m³ or lower. Using these safety group classifications, ANSI/ASHRAE Standard 34–2019 categorizes HFO-1234yf in the A2L Safety Group.

Figure 1. Refrigerant Safety Group Classification



3. How does HFO-1234yf compare to other refrigerants for these MVAC applications with respect to SNAP criteria?

When reviewing a substitute under SNAP, EPA compares the risk posed by

that substitute to the risks posed by other alternatives and considers whether that specific substitute under review poses significantly more risk than other available or potentially available alternatives for the same use. In the proposed rule (86 FR 68962;

December 6, 2021), EPA provided information on the environmental and health properties of HFO-1234yf and other substitutes in these MVAC applications and described the Agency’s comparative risk analysis, based on our criteria for review, including an

¹⁴ EPA, 2021. Basic Information about the Emission Standards Reference Guide for On-road and Nonroad Vehicles and Engines. Available online at <https://www.epa.gov/emission-standards-reference-guide/basic-information-about-emission-standards-reference-guide-road> and in the docket for this rulemaking.

¹⁵ Heavy-duty vehicles are often subdivided by vehicle weight classifications, as defined by the vehicle’s gross vehicle weight rating (GVWR),

which is a measure of the combined curb (empty) weight and cargo carrying capacity of the truck. Heavy-duty vehicles have GVWRs above 8,500. See <https://www.epa.gov/emission-standards-reference-guide/vehicle-weight-classifications-emission-standards-reference-guide>.

¹⁶ Wagner, 2021. May 24, 2021, email from John Wagner of the Association of Equipment Manufacturers to EPA. Available in the docket for this rulemaking.

¹⁷ ICF, 2016. Technical Support Document for Acceptability Listing of HFO-1234yf for Motor Vehicle Air Conditioning in Limited Heavy-Duty Applications. Available in the public docket for this rulemaking.

¹⁸ ASHRAE, 2019. ANSI/ASHRAE Standard 34–2019: Designation and Safety Classification of Refrigerants.

evaluation of environmental impacts, flammability, and toxicity. Redacted submissions that do not include information claimed as CBI by the submitter and supporting documentation for HFO-1234yf are provided in the docket for this rulemaking (EPA-HQ-OAR-2021-0347 at <https://www.regulations.gov>). EPA's assessments to examine the health and environmental risks of HFO-1234yf in each equipment type are also available in the docket for this rulemaking.^{19 20 21 22 23}

As explained more fully below, to help evaluate environmental, flammability, and toxicity risks resulting from the use of HFO-1234yf in certain types of new nonroad vehicles, EPA considered the Agency's analyses^{24 25 26 27 28 29 30 31 32} conducted in support of the 2011 (76 FR 17488; March 29, 2011) and 2016 (81 FR 86778; December 1, 2016) listing decisions for HFO-1234yf in MVAC systems, including information submitted during the public comment period of the proposal for the 2011 final decision (October 19, 2009; 74 FR 53445), such

¹⁹ ICF, 2021a. Risk Screen on Substitutes in Motor Vehicle Air Conditioning (Nonroad Vehicles—Agricultural Tractors Greater than 40 Horsepower) (New Equipment).

²⁰ ICF, 2021b. Risk Screen on Substitutes in Motor Vehicle Air Conditioning (Nonroad Vehicles—Self-Propelled Agricultural Machinery) (New Equipment).

²¹ ICF, 2021c. Risk Screen on Substitutes in Motor Vehicle Air Conditioning (Nonroad Vehicles—Compact Equipment) (New Equipment).

²² ICF, 2021d. Risk Screen on Substitutes in Motor Vehicle Air Conditioning (Nonroad Vehicles—Construction, Forestry, and Mining Equipment) (New Equipment).

²³ ICF, 2021e. Risk Screen on Substitutes in Motor Vehicle Air Conditioning (Nonroad Vehicles—Commercial Utility Vehicles) (New Equipment).

²⁴ EPA, 2005. Risk Analysis for Alternative Refrigerant in Motor Vehicle Air Conditioning.

²⁵ ICF, 2008a. Air Conditioning Refrigerant Charge Size to Passenger Compartment Volume Ratio Analysis.

²⁶ ICF, 2008b. Revised Characterization of U.S. Hybrid and Small Car Sales (Historical and Predicted) and Hybrid Vehicle Accidents.

²⁷ ICF, 2009a. Revised Final Draft Assessment of the Potential Impacts of HFO-1234yf and the Associated Production of TFA on Aquatic Communities and Local Air Quality.

²⁸ ICF, 2009b. Risk Screen on Substitutes for CFC-12 in Motor Vehicle Air Conditioning: Substitute: HFO-1234yf.

²⁹ ICF, 2010a. Summary of HFO-1234yf Emissions Assumptions.

³⁰ ICF, 2010b. Summary of Updates to the Vintaging Model that Impacted HFO-1234yf Emissions Estimates.

³¹ ICF, 2010c. Revised Assessment of the Potential Impacts of HFO-1234yf and the Associated Production of TFA on Aquatic Communities, Soil and Plants, and Local Air Quality.

³² ICF, 2010d. Sensitivity Analysis CMAQ results on projected maximum TFA rainwater concentrations and maximum 8-hr ozone concentrations.

as the SAE Cooperative Research Project's (CRP) risk assessments.^{33 34 35 36 37} These risk assessments are available in the docket for this rulemaking. The refrigerants to which HFO-1234yf was compared in the 2011 action for LD vehicles are the same refrigerants available for use in the nonroad vehicle types included in this action. In addition, EPA considered risk assessments^{38 39 40 41 42} conducted by the Association of Equipment Manufacturers (AEM), an industry consortium of construction and agriculture equipment manufacturers, and found these were consistent with the Agency's assessments to examine the health and environmental risks of HFO-1234yf in each vehicle type.

a. Environmental Impacts

The SNAP program considers a number of environmental criteria when evaluating substitutes: Ozone depleting potential (ODP); climate effects, primarily based on global warming potential (GWP); local air quality impacts, particularly potential impacts on smog formation from emissions of volatile organic compounds (VOC); and ecosystem effects, particularly from negative impacts on aquatic life. These and other environmental and health risks are discussed below.

HFO-1234yf is chemical substance identified as 2,3,3,3-tetrafluoroprop-1-ene (CAS Reg. No. 754-12-1). HFO-1234yf has a GWP of four,^{43 44} which is

³³ CRP, 2008. Risk Assessment for Alternative Refrigerants HFO-1234yf Phase II. Prepared for SAE International Cooperative Research Program 1234 by Gradient Corporation.

³⁴ CRP, 2009. Risk Assessment for Alternative Refrigerants HFO-1234yf and R-744 (CO₂) Phase III. Prepared for SAE International Cooperative Research Program 1234 by Gradient Corporation.

³⁵ DuPont and Honeywell. Guidelines for Use and Handling of HFO-1234yf (v8.0).

³⁶ Exponent. 2008. HFO-1234yf Refrigerant Concentration and Ignition Tests in Full-Scale Vehicle Passenger Cabin and Engine Compartment.

³⁷ CRP, 2013. SAE International Cooperative Research Project CRP1234-4 on R-1234yf Safety, Finishes Work and Presents Conclusions. Available online at: http://www.sae.org/servlets/pressRoom?OBJECT_TYPE=PressReleases&PAGE=showRelease&RELEASE_ID=2146.

³⁸ AEM, 2019. Risk Assessment for HFO-1234yf in Agricultural Tractors ≥ 40 HP including 2WD, MFD, 4WD and Track Type Equipment.

³⁹ AEM, 2020a. Risk Assessment for HFO-1234yf in Self-Propelled Agricultural Machinery including Combines, Forage Harvesters, Sprayers, and Windrowers.

⁴⁰ AEM, 2020b. Risk Assessment for HFO-1234yf in Compact Equipment (Examples include Tractors <40HP, Turf Equipment, Skid Steer, Mini-Excavators and Track Loaders)

⁴¹ AEM, 2020c. Risk Assessment for HFO-1234yf in Construction, Forestry and Mining Equipment.

⁴² AEM, 2020d. Risk Assessment for HFO-1234yf in Commercial Utility Vehicles.

⁴³ Nielsen *et al.*, 2007. Atmospheric chemistry of CF₃CF=CH₂: Kinetics and mechanisms of gas-phase

similar to or lower than the GWP of other alternatives for the nonroad vehicles addressed in this final rule. For example, its GWP is significantly lower than that of HFC-134a, the refrigerant most widely used in these vehicles today, which has a GWP of 1,430. As shown in Table 1, two other alternatives, HFC-152a⁴⁵ and CO₂,⁴⁶ have GWPs of 124 and 1, respectively.

Other acceptable refrigerants for the nonroad vehicles addressed in this action have GWPs ranging from 933 to 3,337. These include several blend refrigerants that are listed as acceptable, subject to use conditions, for these nonroad vehicles, including the HFC blends SP34E and R-426A (also known as RS-24) and the HCFC blends R-416A (also known as HCFC Blend Beta or FRIGC FR12), R-406A, R-414A (also known as HCFC Blend Xi or GHG-X4), R-414B (also known as HCFC Blend Omicron), HCFC Blend Delta (also known as Free Zone), Freeze 12, GHG-X5, and HCFC Blend Lambda (also known as GHG-HP). In a final rule issued July 20, 2015, at 80 FR 42870 ("2015 Rule"),⁴⁷ EPA listed the use of certain refrigerant blends, including the ones mentioned above, as unacceptable in new LD vehicles starting in MY 2017. EPA did not propose and is not finalizing a change of status for use of these refrigerant blends in MVACs in nonroad vehicles. Although EPA is not aware of the use of these refrigerant blends, they remain acceptable, subject to use conditions, for the nonroad vehicles addressed in this action. Also,

reactions with Cl atoms, OH radicals, and O₃. *Chemical Physics Letters* 439, 18–22. Available online at: http://www.cogci.dk/network/OJN_CF3CF=CH2.pdf.

⁴⁴ Papadimitriou *et al.*, 2007. CF₃CF=CH₂ and (Z)-CF₃CF=CHF: temperature dependent OH rate coefficients and global warming potentials. *Phys. Chem. Chem. Phys.*, 2007, Vol. 9, p. 1–13. Available online at: <http://pubs.rsc.org/en/Content/ArticleLanding/2008/CP/b714382f>.

⁴⁵ HFC-152a is listed as acceptable, subject to use conditions, for new vehicles only at 40 CFR part 82 subpart G; final rule published June 12, 2008 (73 FR 33304).

⁴⁶ CO₂ is listed as acceptable, subject to use conditions, for new vehicles only at 40 CFR part 82 subpart G; final rule published June 6, 2012 (77 FR 33315).

⁴⁷ The 2015 Rule, among other things, changed the listings for certain HFCs and blends from acceptable to unacceptable in various end-uses in the aerosols, refrigeration and air conditioning, and foam blowing sectors. After a challenge to the 2015 Rule, the United States Court of Appeals for the District of Columbia Circuit ("the court") issued a partial vacatur of the 2015 Rule "to the extent it requires manufacturers to replace HFCs with a substitute substance" (see *Mexichem Fluor, Inc. v. EPA*, 866 F.3d 451, 462 (D.C. Cir. 2017) and remanded the rule to the Agency for further proceedings. The court also upheld EPA's listing changes as being reasonable and not "arbitrary and capricious." See *Mexichem Fluor*, 866 F.3d at 462–63.

although they are listed as acceptable, subject to use conditions, EPA is not aware of the use or development of HFC-152a, CO₂, or any of the refrigerant blends above in new nonroad

vehicles.⁴⁸ Additionally, all MVAC refrigerants are subject to use conditions requiring labeling and the use of unique fittings, and the two lower-GWP alternatives currently approved for use

in nonroad vehicles (*i.e.*, HFC-152a and CO₂) are subject to additional use conditions mitigating flammability and toxicity as appropriate to the alternative.

TABLE 1: GWP, ODP, AND VOC STATUS OF HFO-1234YF COMPARED TO OTHER REFRIGERANTS IN MVAC SYSTEMS OF NONROAD VEHICLES ¹

Refrigerants	GWP	ODP	VOC status	Final decision
HFO-1234yf	4	0	No	Acceptable, subject to use conditions.
CO ₂ , HFC-152a, HFC-134a	1–1,430	0	No	No change.
Other refrigerants, including IKON A, R-414B, R-416A, R-426A, SP34E.	933–3,337	0–0.098	Yes ²	No change.

¹ The table does not include not-in-kind technologies listed as acceptable for the stated end-use.

² One or more constituents of the blend are VOC.

HFO-1234yf does not deplete the ozone layer. Similarly, HFC-134a, HFC-152a, CO₂, and the HFC blends SP34E and R-426A do not deplete the ozone layer; however, the HCFC blends have ODPs ranging from 0.012 to 0.056.

HFO-1234yf, HFC-134a, HFC-152a, and CO₂ are exempt from the EPA’s regulatory definition of VOC (see 40 CFR 51.100(s)) addressing the development of state implementation plans (SIPs) to attain and maintain the National Ambient Air Quality Standards (NAAQS). The HFC blends and some of the HCFC blends have one or more components that are VOC.

Another potential environmental impact of HFO-1234yf is its atmospheric decomposition to trifluoroacetic acid (TFA, CF₃COOH). TFA is a strong acid that may accumulate in soil, plants, and aquatic ecosystems over time and may have the potential to adversely impact plants, animals, and ecosystems.⁴⁹ For information on recent analyses and research that has been conducted on TFA, including EPA’s 2011 analysis, which was based on conservative emissions assumptions and a transition from HFC-134a to HFO-1234yf for all MVAC systems (not limited to LD vehicles), see section II.A.3.a of the proposed rule (86 FR at 68968; December 6, 2021). Taking into consideration the 2011 analysis and the research that has been conducted since, as discussed in section II.A.3.a in the proposed rule, EPA concludes that the use of HFO-1234yf in the nonroad vehicles addressed in this action does not pose a significant risk to the

environment from atmospheric decomposition to TFA.

Therefore, based on the consideration of all of these environmental impacts, EPA concludes that HFO-1234yf does not pose significantly greater risk to the environment than the other alternatives for use in new nonroad vehicles addressed in this action, and it poses significantly less risk than several of the alternatives with higher GWPs and ODPs.

b. Flammability

HFO-1234yf is a flammable refrigerant classified as A2L under ASHRAE 34–2013. HFC-134a, CO₂, and the refrigerant blends SP34E and R-426A (also known as RS-24) and the HCFC blends R-416A (also known as HCFC Blend Beta or FRIGC FR12), R-414A (also known as HCFC Blend Xi or GHG-X4), R-414B (also known as HCFC Blend Omicron), HCFC Blend Delta (also known as Free Zone), Freeze 12, GHG-X5, and HCFC Blend Lambda (also known as GHG-HP) are nonflammable refrigerants, while HFC-152a and R-406A are slightly more flammable than HFO-1234yf with an ASHRAE classification of A2. HFO-1234yf is flammable when its concentration in air is in the range of 6.2 percent to 12.3 percent by volume (62,000 ppm to 123,000 ppm).⁵⁰ In the presence of an ignition source (*e.g.*, static electricity, a spark resulting from a switch malfunction, or a cigarette), an explosion or a fire could occur when the concentration of HFO-1234yf exceeds its LFL of 62,000 ppm, posing a significant safety concern for workers and consumers if it is not handled carefully.

However, HFO-1234yf is difficult to ignite and, in the event of ignition, the flames would propagate slowly.⁵¹

With regards to flammability risks to workers, EPA’s risk screens evaluated the potential for a fire from release and ignition in workplace situations and work-site operations, such as during equipment manufacture, servicing and disposal or recycling of vehicle end-of-life for the five nonroad vehicles. EPA considered the characteristics that could be different from LD and other HD vehicles, such as differences in the engine compartment size, passenger cabins, and operating conditions, and how those might impact risks. In order to determine the potential flammability risks during servicing of the vehicle or in case of a release of refrigerant into the cab, concentrations of HFO-1234yf immediately following a 60 percent release of refrigerant over a period of one minute into the cab were compared to the LFL and upper flammability limit (UFL) for HFO-1234yf reported by ASHRAE Standard 34 (*i.e.*, 62,000 ppm and 123,000 ppm, respectively). The one-minute time duration is most appropriate for determining the risks of flammable refrigerants because the potential maximum instantaneous concentration can be estimated and compared to the LFL. Two key inputs to the models were the cab volume (*i.e.*, the space into which the refrigerant would leak) and the refrigerant charge size. Because passenger compartment volumes and refrigerant charge sizes can vary widely from model to model, the highest ratio of charge size to

⁴⁸ The CAA and EPA’s ODS regulations restrict the permissible uses of virgin HCFCs. With respect to refrigerants, virgin HCFC-22, HCFC-142b and blends containing HCFC-22 or HCFC-142b may now only be used to service existing appliances. Consequently, virgin HCFC-22, HCFC-142b and blends containing virgin HCFC-22 or HCFC-142b

may no longer be used as a refrigerant to manufacture new pre-charged appliances or appliance components or to charge new appliances assembled onsite.

⁴⁹ Other fluorinated compounds also decompose into TFA, including HFC-134a.

⁵⁰ Chemours, 2019. HFO-1234yf for Use as a Refrigerant. Significant New Alternatives Policy Program Submission to the U.S. Environmental Protection Agency.

⁵¹ HFO-1234yf has a high minimum ignition energy of 5,000–10,000 mJ and a low burning velocity of 1.5 cm/s (Koban, 2011).

compartment volume identified was used as the input into the models.

In the event of a leak, SAE Standard J2772 specifies that nonroad vehicles be manufactured such that the pressure differential between the air conditioning system and the cab allows only up to 60 percent of the refrigerant charge to be released into the cab.⁵² Independent testing of refrigerant releases from nonroad vehicles, according to SAE Standard J2772, found that the amount of refrigerant released following a line leak was much lower than 60 percent.

To represent a plausible worst-case scenario, EPA's box modeling assumed that 60 percent of the charge of the air conditioning systems for the five nonroad vehicles is released into the cab of the vehicles over a period of one minute. EPA's worst-case scenario box modeling resulted in the concentration of HFO-1234yf in the cab exceeding the LFL of 62,000 ppm by 2,100 ppm at the typical charge size (*i.e.*, 1.3 kilograms) and exceeding both the LFL (by 95,900 ppm) and the UFL (by 34,900 ppm) at the maximum charge size (*i.e.*, 3.2 kilograms), for the five nonroad vehicles. However, the estimated exposures were derived using conservative assumptions and represent worst-case scenarios with a low probability of occurrence, as the analyses assume a rapid release of refrigerant (*i.e.*, one minute), assume the minimum required fresh air intake, and do not consider the air recirculation rate for the nonroad vehicles or other variables that would potentially reduce the concentration levels in the air to below the flammable range for HFO-1234yf. Additionally, flammability concerns are further reduced due to the design of MVAC systems for the five vehicle types as described above in section II.A.1 and the low probability of collisions for these nonroad vehicles.

MVAC systems in the nonroad vehicles are robust and made to withstand strenuous operation, which lowers the potential for line leaks due to wear. According to AEM,^{53 54 55 56 57}

the operator's compartment in agricultural tractors greater than 40 HP; self-propelled agricultural machinery; compact equipment; and construction, forestry, and mining equipment is a completely self-contained unit which provides an additional level of safety in a collision event. For commercial utility vehicles, which are smaller than the other four nonroad vehicle types, AEM noted that the engine compartment is contained in the rear of the vehicle, under the cargo bed, with the main components of the MVAC system in the front of the cabin with only the compressor and two lines near the engine. The potential for collisions is also less likely because most of the vehicles are operated by trained professionals, typically at low speed, and are only driven on the highway to move from one site or nonroad location to another.

In addition to the plausible worst-case scenario analysis, which employs a simple box model, EPA's risk screens reference modeling conducted by AEM in the flammability assessments. The AEM consortium used two different models in its assessments: (1) A box model to examine worst-case scenarios for a wide variety of nonroad vehicles addressed in this proposal and (2) a computational fluid dynamics (CFD)^{58 59 60 61 62 63} model to more realistically represent the behavior of the leaked refrigerant in a nonroad vehicle. The AEM box model modeled the release of 60 percent of the refrigerant charge in the vehicles with varying charge and cab sizes and assumed a near-instantaneous leak of refrigerant over a period of 10 seconds. Six of the scenarios modeled in the box model resulted in the concentration of HFO-1234yf in the cab being equal to or exceeding the LFL; the concentrations from the remaining six scenarios were below the LFL. Similar to EPA's box modeling, the estimated exposures were derived using conservative assumptions

and represent worst-case scenarios with a low probability of occurrence, as the analyses assume a rapid release of refrigerant, assume the minimum required fresh air intake (*i.e.*, 43 m³/hour), and do not consider the air recirculation rate for the nonroad vehicles or other variables that would potentially reduce the concentration levels in the air to below the flammable range for HFO-1234yf.

Conversely, the maximum concentration reached in the AEM CFD model, which models a realistic leak scenario with the release of 60 percent of the refrigerant charge released in the nonroad vehicles for 1000 seconds of simulation, was significantly below the LFL for HFO-1234yf of 62,000 ppm. Construction, forestry, and mining vehicles were modeled to represent the five nonroad vehicles as they had the highest ratio of refrigerant charge to cabin volume among the five nonroad vehicles. AEM found that the maximum concentration of HFO-1234yf reached in the cab (*i.e.*, 25,700 ppm) is not likely to exceed the LFL for the five nonroad vehicles. The AEM CFD model reflects the real-world behavior of refrigerant in the cab given a worst-case leak scenario because it considers the refrigerant entry and exit points and assumes worst-case scenario conditions, including the most likely scenario where an operator is likely to ignite a cigarette, the highest charge-to-cab ratio, minimal fresh air flow, and maximum air velocity and refrigerant penetration. Additionally, the CFD modeling demonstrates the conservativeness of the worst-case scenario box modeling and how unlikely its results are; therefore, the worst-case scenario box models may be overstating the true risks associated with the use of HFO-1234yf in MVAC systems in the nonroad vehicles compared to real-world conditions as presented in the CFD model.

For these reasons, EPA concludes that the currently available assessments on the use of HFO-1234yf in new nonroad vehicles addressed in this action are sufficiently conservative to account for all probable flammability risks from the use of HFO-1234yf. Relying on a similar analysis considered in support of the 2011 and 2016 SNAP listings of HFO-1234yf in certain MVAC systems, verifying that more recent information is consistent with that analysis, and considering unique factors for the nonroad vehicle types, EPA concludes that the use of HFO-1234yf in the new nonroad vehicles addressed in this action does not pose significantly greater flammability risk than the other alternatives when used in accordance with the use conditions described below

⁵² SAE, 2019. Standard J2772: Measurement of Passenger Compartment Refrigerant Concentrations Under System Refrigerant Leakage Conditions. SAE International.

⁵³ AEM, 2019. Risk Assessment for HFO-1234yf in Agricultural Tractors ≥ 40 HP including 2WD, MFD, 4WD and Track Type Equipment.

⁵⁴ AEM, 2020a. Risk Assessment for HFO-1234yf in Self-Propelled Agricultural Machinery including Combines, Forage Harvesters, Sprayers, and Windrowers.

⁵⁵ AEM, 2020b. Risk Assessment for HFO-1234yf in Compact Equipment (Examples include Tractors <40HP, Turf Equipment, Skid Steer, Mini-Excavators and Track Loaders).

⁵⁶ AEM, 2020c. Risk Assessment for HFO-1234yf in Construction, Forestry, and Mining Equipment.

⁵⁷ AEM, 2020d. Risk Assessment for HFO-1234yf in Commercial Utility Vehicles.

⁵⁸ AEM, 2019. Risk Assessment for HFO-1234yf in Agricultural Tractors ≥ 40 HP including 2WD, MFD, 4WD and Track Type Equipment.

⁵⁹ AEM, 2020a. Risk Assessment for HFO-1234yf in Self-Propelled Agricultural Machinery including Combines, Forage Harvesters, Sprayers, and Windrowers.

⁶⁰ AEM, 2020b. Risk Assessment for HFO-1234yf in Compact Equipment (Examples include Tractors <40HP, Turf Equipment, Skid Steer, Mini-Excavators and Track Loaders).

⁶¹ AEM, 2020c. Risk Assessment for HFO-1234yf in Construction, Forestry, and Mining Equipment.

⁶² AEM, 2020d. Risk Assessment for HFO-1234yf in Commercial Utility Vehicles.

⁶³ AEM, 2020e. CFD Leak Modeling—Supplemental Information to Complement AEM Machine Form RAs.

in section II.A.4, which are intended to mitigate flammability risks, and recommendations in the safety data sheet (SDS) and EPA's risk screens.

c. Toxicity

Potential health effects of exposure to HFO-1234yf include drowsiness or dizziness. HFO-1234yf may also irritate the skin or eyes or cause frostbite, and at sufficiently high concentrations, HFO-1234yf may cause irregular heartbeat. HFO-1234yf could cause asphyxiation if air is displaced by vapors in a confined space. These potential health effects are common to many refrigerants.

The American Industrial Hygiene Association (AIHA) has established a Workplace Environmental Exposure Level (WEEL) of 500 ppm as an 8-hr TWA for HFO-1234yf. HFO-1234yf also has an acute toxicity exposure limit (ATEL) of 100,000 ppm and a refrigerant concentration limit (RCL) of 16,000 ppm, which are both established by ASHRAE. EPA anticipates that users will be able to meet the AIHA WEEL and ASHRAE ATEL and RCL, limits intended to reduce the risks of flammability in normally occupied, enclosed spaces, and address potential health risks by following requirements and recommendations in the manufacturer's SDSs and other safety precautions common to the refrigerant industry.

To evaluate human health and safety impacts, including asphyxiation and toxicity risks, from the use of HFO-1234yf in the five types of nonroad vehicles, the Agency estimated the potential exposures to HFO-1234yf in the event of a 60 percent release of refrigerant from the vehicles under reasonable worst-case scenarios described in the risk screens. In the event of a leak, SAE Standard J2772 specifies that nonroad vehicles be manufactured such that the pressure differential between the air conditioning system and the cab allows only up to 60 percent of the refrigerant charge to be released into the cab.⁶⁴ The analysis of asphyxiation risks considered whether a worst-case release of refrigerant under the cab would result in oxygen concentrations of 12 percent or less. The analysis found that impacts on oxygen concentrations did not present a significant risk of asphyxiation at the typical charge sizes, and that a 60 percent leak of refrigerant at the maximum charge sizes could result in

an oxygen concentration below 19.5 percent but above 12 percent. The estimated exposures were derived using conservative assumptions, however, and conditions resulting in oxygen levels under 12 percent⁶⁵ are only predicted to occur with charge sizes that are significantly larger than the maximum charge sizes provided by the submitter or cab sizes that are unlikely for the applications. Additionally, the worst-case scenarios did not consider conditions that are likely to occur that would increase oxygen levels to which individuals would be exposed, such as fresh air flow into the cab.

To assess the toxicity risks to end-users, 15-minute and 30-minute TWA exposures were estimated and compared to the standard toxicity limits. The estimated TWA exposures were fairly conservative as the analyses assume a rapid release of refrigerant (*i.e.*, one minute and 10 seconds for EPA's and AEM's box models, respectively), assume the minimum required ventilation rate (*i.e.*, 43 m³/hour), and do not consider the air recirculation rate for the vehicles or other variables that would potentially reduce the concentration levels in the air. EPA found that the estimated 15-minute and 30-minute TWA exposures for HFO-1234yf in MVAC systems in the nonroad vehicles are not likely to exceed the ATEL for HFO-1234yf of 100,000 ppm in a one-minute release scenario under EPA's worst-case scenario modeling assumptions. The end-use exposures estimated by AEM across all scenarios were also well below the ATEL for HFO-1234yf. Furthermore, these exposure estimates were derived using conservative assumptions that do not necessarily reflect a real-world leak scenario or the larger cab size where MVAC systems using HFO-1234yf would typically be installed.

Additionally, the estimated TWA exposure for HFO-1234yf determined from AEM's CFD modeling, which models a realistic leak scenario for the nonroad vehicles, was significantly below the ATEL for HFO-1234yf of 100,000 ppm. Construction, forestry, and mining vehicles were modeled to represent the five nonroad vehicles. As noted above, these vehicles are a more conservative and an approximately equivalent proxy for the other four nonroad vehicle types because they have the highest ratio of refrigerant charge to cabin volume among the five nonroad vehicles. Therefore, the toxicity risks from using HFO-1234yf in the five

nonroad vehicles is not likely to exceed the ATEL for the five nonroad vehicles.

Concerning workplace exposure during charging, servicing, and disposal of the nonroad vehicles addressed in this proposal, we expect that professional technicians have proper training and certification and have the proper equipment and knowledge to minimize their risks due to exposure to refrigerant from an MVAC system. Thus, worker exposure to HFO-1234yf is expected to be low. The vehicles are typically charged by the OEM. During air conditioning system manufacture (*i.e.*, charging at OEM location), points of release would be from connection/disconnection of temporary lines for charging and recovery equipment, although exposure during these activities is expected to be minimal due to the use of left-hand threaded fittings on storage cylinders, as specified in SAE Standard J2844, intended to help mitigate any releases and restrict the possibility of cross-contamination with other refrigerants.^{66 67 68 69 70} Furthermore, equipment containing HFO-1234yf is expected to be equipped with unique fittings for the low-side and high-side service ports of the MVAC system, according to SAE Standard J639, also intended to help mitigate any releases and restrict the possibility of cross-contamination with other refrigerants.⁷¹

Service of the vehicles is expected to take place in high-bays and/or outside (*e.g.*, out in the field or other outdoor site)⁷² rather than at a typical servicing center for LD vehicles, for example; therefore, exposure during servicing is expected to be less than during charging the MVAC system during manufacture. Therefore, occupational exposure during these activities was conservatively modeled based on charging. The modeled maximum 15-minute TWA exposures

⁶⁶ ICF, 2021a. Risk Screen on Substitutes in Motor Vehicle Air Conditioning (Nonroad Vehicles—Agricultural Tractors Greater than 40 Horsepower) (New Equipment).

⁶⁷ ICF, 2021b. Risk Screen on Substitutes in Motor Vehicle Air Conditioning (Nonroad Vehicles—Self-Propelled Agricultural Machinery) (New Equipment).

⁶⁸ ICF, 2021c. Risk Screen on Substitutes in Motor Vehicle Air Conditioning (Nonroad Vehicles—Compact Equipment) (New Equipment).

⁶⁹ ICF, 2021d. Risk Screen on Substitutes in Motor Vehicle Air Conditioning (Nonroad Vehicles—Construction, Forestry, and Mining Equipment) (New Equipment).

⁷⁰ ICF, 2021e. Risk Screen on Substitutes in Motor Vehicle Air Conditioning (Nonroad Vehicles—Commercial Utility Vehicles) (New Equipment).

⁷¹ *Ibid.*

⁷² Chemours, 2019. HFO-1234yf for Use as a Refrigerant. Significant New Alternatives Policy Program Submission to the U.S. Environmental Protection Agency.

⁶⁴ SAE, 2019. Standard J2772: Measurement of Passenger Compartment Refrigerant Concentrations Under System Refrigerant Leakage Conditions. SAE International.

⁶⁵ Twelve percent oxygen in air (*i.e.*, 120,000 ppm) is the No-Observed-Adverse-Effect-Level (NOAEL) for hypoxia (ICF, 1997).

for HFO-1234yf during charging were compared to the short-term exposure limit (STEL) of 1,500 ppm. EPA's modeling indicated that the short-term (15-minute) worker exposure concentrations of HFO-1234yf are not likely to exceed its STEL for the typical or maximum charge size in the vehicles during charging or servicing. Additionally, these exposure estimates are significantly lower than the RCL and ATEL of 16,000 ppm and 100,000 ppm, respectively, for HFO-1234yf, which are limits intended to reduce the risks of asphyxiation and acute toxicity hazards in normally occupied, enclosed spaces according to ASHRAE Standard 34.

EPA also determined that occupational exposure during disposal of all the vehicles, except for construction, forestry, and mining equipment, at the typical and maximum charge sizes is not likely to exceed the long-term (8-hour) WEEL for HFO-1234yf (*i.e.*, 500 ppm). Under the disposal release scenarios for construction, forestry, and mining equipment, the modeling showed that occupational exposure during disposal of MVAC systems containing HFO-1234yf at the maximum charge size (*i.e.*, 3.4 kilograms (120 ounces)) could potentially exceed the 8-hour long-term exposure limit by 10 ppm. The estimated exposures, however, were well below the RCL of 16,000 ppm for HFO-1234yf and were derived using conservative assumptions and represent a worst-case scenario with a low probability of occurrence. These MVAC systems are also disposed of by CAA section 608-certified personnel using proper industrial hygiene techniques while wearing PPE to maximize recovery efficiency and limit releases. EPA concludes that the manufacture, use, servicing, or disposal of HFO-1234yf MVAC systems in the new nonroad vehicles addressed in this action does not pose greater toxicity risk to workers than the other alternatives when used in accordance with the use conditions.

Additionally, EPA's review of potential toxicity risks of HFO-1234yf to the general population indicated that HFO-1234yf is not expected to pose significantly greater toxicity risk than other alternatives for the MVAC systems in the new nonroad vehicles addressed in this action. The general population is defined as non-personnel who are subject to exposure of the substitute near industrial facilities, including manufacturing or equipment production factories, equipment operating locations, or recycling centers, rather than personnel at end-use. EPA concludes that the use of HFO-1234yf in

the new nonroad vehicles addressed in this action does not pose significantly greater toxicity risk than the other alternatives when used in accordance with the use conditions described below in section II.A.4, which are intended to mitigate toxicity risks, and recommendations in the SDS and EPA's risk screens.

4. What are the use conditions?

All MVAC refrigerants listed as acceptable are subject to use conditions requiring labeling and the use of unique fittings. HFC-152a and CO₂ are subject to additional use conditions mitigating flammability and toxicity as appropriate to the alternative. Neither HFC-152a nor CO₂ can simply be "dropped" into existing MVAC systems because they are listed as acceptable only for new vehicles.

EPA is listing HFO-1234yf as acceptable, subject to use conditions, in MVAC systems in certain new nonroad vehicles because the use conditions are necessary to ensure that use of HFO-1234yf will not have a significantly greater overall impact on human health and the environment than other alternatives. EPA is updating the existing use conditions that are currently required for the use of HFO-1234yf in MVAC systems in new LD passenger cars and trucks, MDPVs, HD pickup trucks, and complete HD vans and then applying them to all the MVAC systems addressed in this action. Manufacturing and service personnel or consumers may not be familiar with refrigeration or AC equipment containing a flammable refrigerant. These use conditions will be sufficiently protective to ensure use of HFO-1234yf in these nonroad vehicles does not pose significantly greater risk than use of other alternatives.

The first use condition requires that HFO-1234yf may be used only in new MVAC systems which have been designed to address concerns unique to flammable refrigerants—*i.e.*, HFO-1234yf may not be used as a conversion or "retrofit" refrigerant for existing MVACs designed for other refrigerants. HFO-1234yf was not submitted under the SNAP program for use in retrofitted MVAC systems, and no information was provided on how to address hazards if HFO-1234yf were to be used in MVAC systems that were not designed for a flammable refrigerant. Therefore, under this use condition, HFO-1234yf may be used only in new MVACs that have been properly designed for its use.

The second use condition requires that MVAC systems designed to use HFO-1234yf in new agricultural tractors greater than 40 HP; self-propelled

agricultural machinery; compact equipment; construction, forestry, and mining equipment; and commercial utility vehicles must meet the requirements of SAE J639 (revised November 2020), "Safety Standards for Motor Vehicle Refrigerant Vapor Compression Systems." This standard sets safety standards that include unique fittings; a warning label indicating the refrigerant's identity and that it is a flammable refrigerant; and requirements for engineering design strategies that include a high-pressure compressor cutoff switch and pressure relief devices. This use condition also requires that for connections with refrigerant containers for use in professional servicing, use fittings must be consistent with SAE J2844 (revised January 2013), "R-1234yf (HFO-1234yf) New Refrigerant Purity and Container Requirements for Use in Mobile Air-Conditioning Systems," which specifies quick-connect fittings that are different from those for any other refrigerant. The low-side service port and connections will have an outside diameter of 14 mm (0.551 inches), and the high-side service port will have an outside diameter of 17 mm (0.669 inches), both accurate to within 2 mm. Under SAE J2844 (revised January 2013), containers of HFO-1234yf for use in professional servicing of MVAC systems must have a left-handed screw valve with a diameter of 0.5 inches and Acme (trapezoidal) thread with 16 threads per inch.

HFO-1234yf is mildly flammable (A2L classification) and, like other fluorinated refrigerants, can decompose to form the toxic compound hydrogen fluoride (HF) when exposed to flame or to sufficient heat. Consistent with the conclusion EPA drew at the time of the Agency's listing decision for HFO-1234yf in LD vehicles, EPA believes that the safety requirements that are included in SAE J639 sufficiently mitigate risks of both HF generation and refrigerant ignition (March 29, 2011; 76 FR 17488) for the nonroad vehicles addressed in this action. For example, SAE J639 provides for a pressure relief device designed to minimize direct impingement of the refrigerant and oil on hot surfaces and for design of the refrigerant circuit and connections to avoid refrigerant entering the passenger cabin. The pressure release device ensures that pressure in the system will not reach an unsafe level that might cause an uncontrolled leak of refrigerant, such as if the MVAC system is overcharged. The pressure release device will reduce the likelihood that refrigerant leaks would reach hot surfaces that might lead to either

ignition or formation of HF. These elements of the refrigerant circuit and connections are designed to prevent refrigerant from entering the passenger cabin if there is a leak. Keeping refrigerant out of the passenger cabin minimizes the possibility that there would be sufficient levels of refrigerant to reach flammable concentrations or that HF would be formed and transported where passengers might be exposed.

The third use condition requires the manufacturer of MVAC systems and vehicles to conduct Failure Mode and Effects Analysis (FMEA) as provided in SAE J1739 (revised January 2021), "Potential Failure Mode and Effects Analysis (FMEA) Including Design FMEA, Supplemental FMEA—MSR, and Process FMEA," and keep records of the FMEA on file for three years from the date of creation. SAE J1739 (revised January 2021) describes a FMEA as "a systematic group of activities intended to: (a) Recognize and evaluate the potential failure of a product/process and the effects and causes of that failure, (b) identify actions that could eliminate or reduce the change of the potential failure occurring, and (c) document the process." Through the FMEA, OEMs determine the appropriate protective strategies necessary to ensure the safe use of HFO-1234yf across their vehicle fleet. It is standard industry practice to perform the FMEA and to keep it on file while the vehicle is in production and for several years afterwards. As with the previous use condition, this use condition is intended to ensure that agricultural tractors greater than 40 HP; self-propelled agricultural machinery; compact equipment; construction, forestry, and mining equipment; and commercial utility vehicles manufactured with HFO-1234yf MVACs are specifically designed to minimize release of the refrigerant into the passenger cabin or onto hot surfaces that might result in ignition or in generation of HF.

B. Modifications to Use Conditions for MVAC Systems in Other Vehicle Types

For the previous listings of HFO-1234yf in the March 29, 2011 (76 FR 17488), and December 1, 2016 (81 FR 86778), final rules for MVAC systems in certain new vehicles, EPA is modifying the use conditions to replace the reference to older versions of SAE J639, SAE J1739, and SAE J2844.

First, EPA is replacing the reference to SAE J639 (revised 2011) in the March 2011 and December 2016 final rules with a reference to the 2020 version of the standard, "Safety and Design

Standards for Motor Vehicle Refrigerant Vapor Compression Systems." This is the most recent version of the SAE J639 standard, which was updated to include system design and safety-related requirements for secondary loop HFC-152a MVAC systems and to make general improvements for clarity.

Second, EPA is replacing the reference to SAE J1739 (adopted 2009) in the March 2011 and December 2016 final rules with a reference to the 2021 version of the standard, "Potential Failure Mode and Effects Analysis (FMEA) Including Design FMEA, Supplemental FMEA—MSR, and Process FMEA." The 2021 version is the most recent version of the SAE J1739 standard; it was revised to emphasize the process of FMEA selection, creation, documentation, reporting, and change management.

Finally, EPA is replacing the reference to SAE J2844 (revised 2011) in the March 2011 final rule with a reference to the 2013 version of the standard, "R-1234yf (HFO-1234yf) New Refrigerant Purity and Container Requirements for Use in Mobile Air-Conditioning Systems." This is the most recent version of the SAE J2844 standard; it was updated to add the requirements for certification according to SAE J2911, "Procedure for Certification that Requirements for Mobile Air Conditioning System Components, Service Equipment, and Service Technician Training Meet SAE J Standards."

C. Servicing Fittings for Small Cans of HFO-1234yf

EPA is including a use condition for HFO-1234yf to provide for servicing air conditioning systems. The use condition would require unique servicing fittings for use with small cans (two pounds or less) for servicing of MVAC systems containing HFO-1234yf in the nonroad vehicles addressed in this action, as well as servicing of the MVAC systems in the vehicles for which HFO-1234yf has already been listed as acceptable, subject to use conditions (*i.e.*, new LD passenger cars and trucks and new MDPVs, HD pickup trucks, and complete HD vans). The use condition is discussed below in section II.C.3, "What is the use condition?"

EPA previously listed HFO-1234yf as acceptable, subject to use conditions, for large containers of HFO-1234yf for professional servicing of MVAC systems (76 FR 17488, March 29, 2011; 77 FR 17344, March 26, 2012). Redacted submissions and supporting documentation for HFO-1234yf in small cans are provided in the docket for this rulemaking (EPA—HQ—OAR—2021—0347)

at <https://www.regulations.gov>. As explained in the proposed rule (86 FR 68962; December 6, 2021) and below, to help evaluate environmental, flammability, and toxicity risks resulting from the use of HFO-1234yf in small cans for MVAC servicing, EPA conducted a risk screen which is available in the docket for this rulemaking.⁷³

Servicing of MVAC systems containing HFO-1234yf with small refrigerant cans is expected to take place in a variety of locations, including professional and residential garages with differing sizes and ventilation rates. As discussed below in section II.C.3 regarding the use condition, small refrigerant cans must be equipped with a Standard Compressed Gas Association (CGA) 166 left-hand thread outlet connection valve in accordance with SAE Standard J2844.⁷⁴ The hose connected to the vehicle must also use the low side service port per SAE J639.

For additional context, we further note that separate from the requirements in this action, the sale of such small refrigerant cans would be subject to the regulatory requirements under CAA section 608, codified at 40 CFR 82.154. These regulations restrict the sale, distribution, and offer for sale or distribution of refrigerants, including non-exempt substitute refrigerants, like HFO-1234yf, to circumstances where certain requirements are met. Specific to the sale of small cans of refrigerant, 40 CFR 82.154(c)(1)(ix) provides that non-exempt substitute refrigerant for use in an MVAC, *e.g.*, HFO-1234yf, may be sold, including to DIYers, if it is in a container designed to hold two pounds or less of refrigerant which has a unique fitting, and, if manufactured or imported on or after January 1, 2018, has a self-sealing valve that complies with the self-sealing valve specifications codified at 40 CFR 82.154(c)(2). EPA is not modifying the existing CAA section 608 provisions under 40 CFR 82.154, including the restriction on sale of substitute refrigerants and requirements for self-sealing valves. For additional information, EPA directs readers to 40 CFR 82.152, where EPA defines a self-sealing valve as "a valve affixed to a container of refrigerant that automatically seals when not actively dispensing refrigerant and that meets or exceeds established performance criteria as identified in § 82.154(c)(2)."

⁷³ ICF, 2021f. Risk Screen on Substitutes in Motor Vehicle Air Conditioning (Small Cans). Substitute: HFO-1234yf.

⁷⁴ SAE J2844 container valve requirements are for HFO-1234yf service cylinders with a volume less than or equal to 23 kilograms.

1. What is the affected end-use?

As proposed, EPA is listing HFO-1234yf as acceptable, subject to a use condition, in small cans (two pounds or less) for servicing of MVAC systems in the nonroad vehicles addressed in this action, as well as in MVAC systems in the vehicles for which HFO-1234yf has already been listed as acceptable, subject to use conditions. For the existing listings in the March 29, 2011 (76 FR 17488), and December 1, 2016 (81 FR 86778), final rules, EPA is revising the use conditions to require unique servicing fittings for use with small cans.

2. How does HFO-1234yf compare to other refrigerants for these MVAC applications with respect to SNAP criteria?

a. Environmental Impacts

HFO-1234yf has a GWP of four,^{75 76} which is similar to or lower than the GWP of the other acceptable alternatives for use in small cans (*i.e.*, HFC-134a and CO₂). HFO-1234yf, HFC-134a, and CO₂ do not deplete the ozone layer, and are all exempt from the regulatory definition of VOC (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the NAAQS. For additional information on the environmental impacts of HFO-1234yf, see the discussion above in section II.A.3.a.

b. Flammability

As discussed above in section II.A.3.b, HFO-1234yf is classified as A2L under ASHRAE 34–2013, while HFC-134a and CO₂ are nonflammable refrigerants. HFO-1234yf is flammable when its concentration in air is in the range of 6.2 percent and 12.3 percent by volume (62,000 ppm to 123,000 ppm). Due to its flammability, small cans of HFO-1234yf for MVAC system servicing could pose a safety concern for workers and service personnel or consumers if they are not properly handled.

Servicing of MVAC systems with small refrigerant cans containing HFO-1234yf is expected to take place in either a professional garage bay or a residential garage. To determine the potential flammability risks of a

catastrophic release of refrigerant during professional and DIY MVAC system servicing using a small refrigerant can, EPA analyzed plausible worst-case scenarios to model a catastrophic release of HFO-1234yf⁷⁷ compared with the LFL of 62,000 ppm for HFO-1234yf.⁷⁸ Under these plausible worst-case scenarios, the full charge of the refrigerant can is assumed to be emitted into the professional garage bay and residential garage with 4.0 and 3.1 air changes per hour (ACH),⁷⁹ respectively, over the course of 15 minutes, which represents the approximate amount of time required to charge the MVAC system.⁸⁰ EPA found that the maximum instantaneous concentrations of HFO-1234yf in the lower 0.4 meters of the room did not exceed the LFL for HFO-1234yf (*i.e.*, 62,000 ppm) for small refrigerant cans (charge size of around 1kg (2 pounds) or less).⁸¹ EPA also found that the maximum instantaneous concentration exceeded 25 percent (15,500 ppm) of the LFL for HFO-1234yf for DIY servicing under one of the scenarios.⁸² However, the scenario was derived using conservative assumptions (*e.g.*, minimum room volume, vertical concentration gradient). Furthermore, small refrigerant cans are not likely to be used in spaces significantly smaller than those modeled in EPA's assessment, which are expected to be large enough to accommodate a vehicle and adequate space surrounding the vehicle for the user to access the MVAC unit. Finally, HFO-1234yf is difficult to ignite and, in the event of ignition, the flames would propagate slowly.⁸³

⁷⁷ In order to simulate the vertical concentration gradient of refrigerant following release, it is assumed that 95 percent of the leaked refrigerant mixes evenly into the lower 0.4 meters (1.3 feet) of the room, and the rest of the refrigerant mixes evenly in the remaining volume (Kataoka 2000).

⁷⁸ ICF, 2021f. Risk Screen on Substitutes in Motor Vehicle Air Conditioning (Small Cans). Substitute: HFO-1234yf.

⁷⁹ The air exchange rates were derived from the requirements in ANSI/ASHRAE Standard 62.1–2019, Table 6.1 (ANSI/ASHRAE 2019c). Ventilation requirements (presented as cubic feet per minute in the standard) were converted to ACH using the assumed room size in the residential garage scenario.

⁸⁰ Perrin Quarles Associates, Inc. (2007) suggests charging for up to 15 minutes to fully empty the contents of the refrigerant can is a best practice for DIY servicing of an MVAC system. This study also indicates that the transfer procedure used for a small refrigerant can (*e.g.*, holding upright, rotation method, and other flow control methods) influences the transfer time and resulting heel remaining in the can.

⁸¹ ICF, 2021f. Risk Screen on Substitutes in Motor Vehicle Air Conditioning (Small Cans). Substitute: HFO-1234yf.

⁸² *Ibid.*

⁸³ HFO-1234yf has a high minimum ignition energy of 5,000–10,000 mJ and a low burning velocity of 1.5 cm/s (Koban, 2011).

Therefore, the risk of fire is minimal if small refrigerant cans containing HFO-1234yf meet and are used to service vehicles in rooms with volumes in accordance with relevant safety standards as described below in section II.C.3.

Additionally, EPA considered the submitters' detailed assessments of the probability of events that might create a fire and approaches to mitigate risks. A CFD modeling was conducted by a submitter to simulate a severe refrigerant line leak from a 600-gram MVAC system in a garage bay of 84 m³ without forced ventilation and found that the flammable region of the refrigerant plume under the hood of the vehicle was small, ranging from 2 inches to a maximum of 10 inches, which quickly dispersed. Similarly, leaks from a small refrigerant can containing HFO-1234yf during MVAC servicing are not expected to accumulate under the vehicle hood in concentrations above the LFL for HFO-1234yf.

EPA concludes that the currently available assessments on the use of HFO-1234yf in small cans for professional and DIY servicing of MVAC systems are sufficiently conservative to account for all probable flammability risks from the use of HFO-1234yf. Therefore, the use of HFO-1234yf in small cans does not pose significantly greater flammability risk than the other alternatives when used in accordance with the use condition described below in section II.C.3, which is intended to mitigate flammability risks, and recommendations in the SDS and EPA's risk screen.

c. Toxicity

For a discussion of the potential health effects of HFO-1234yf, see the section II.A.3.c above. In evaluating potential asphyxiation and toxicity impacts of HFO-1234yf in small cans on human health, EPA considered both occupational risk and risk to the general population. EPA investigated the risk of asphyxiation and of exposure to toxic levels of HFO-1234yf for plausible worst-case scenarios. According to the results of EPA's asphyxiation assessment, the use of HFO-1234yf in small refrigerant cans does not present a significant risk of asphyxiation.⁸⁴ Conditions resulting in oxygen levels under 12 percent⁸⁵ would only occur with charge sizes that are significantly larger than the maximum charge size for

⁸⁴ ICF, 2021f. Risk Screen on Substitutes in Motor Vehicle Air Conditioning (Small Cans). Substitute: HFO-1234yf.

⁸⁵ Twelve percent oxygen in air (*i.e.*, 120,000 ppm) is the NOAEL for hypoxia (ICF 1997).

⁷⁵ Nielsen *et al.*, 2007. Atmospheric chemistry of CF₃CF=CH₂: Kinetics and mechanisms of gas-phase reactions with Cl atoms, OH radicals, and O₃. *Chemical Physics Letters* 439, 18–22. Available online at: http://www.cogci.dk/network/OJN_174_CF3CF=CH2.pdf.

⁷⁶ Papadimitriou *et al.*, 2007. CF₃CF=CH₂ and (Z)-CF₃CF=CHF: temperature dependent OH rate coefficients and global warming potentials. *Phys. Chem. Chem. Phys.*, 2007, Vol. 9, p. 1–13. Available online at: <http://pubs.rsc.org/en/Content/ArticleLanding/2008/CP/b714382f>.

small refrigerant cans or room sizes that are unlikely for the application. In addition, the charge sizes at which an asphyxiation concern would exist are also significantly larger (about 18 times) than the average charge size of an MVAC system.⁸⁶

To evaluate toxicity risks, EPA estimated 15-minute TWA exposures for HFO-1234yf in small cans and compared them to the standard toxicity limits. The estimated TWA values were conservative as the analysis did not consider opened windows or doors, fans operating, conditioned airflow (either heated or cooled), or other variables that would reduce the levels to which individuals would be exposed. The modeling results showed that the estimated 15-minute TWA exposures ranging from 3,100 ppm to 11,080 ppm are all lower than the RCL (*i.e.*, 16,000 ppm) and ATEL (*i.e.*, 100,000 ppm) for HFO-1234yf.

EPA also considered testing and air sampling conducted by a submitter to determine potential refrigerant exposure to professional servicing technicians or DIY users due to leakage of refrigerant cans in a small, closed garage with the condenser fan off and the vehicle hood partly open.⁸⁷ The various scenarios investigated included releases of 170 grams to 680 grams of refrigerant from both an inverted and upright can.⁸⁸ Refrigerant samples were taken under the vehicle at 0.15 meters above the floor (representing the potential breathing area of a technician present in that space) and in the engine compartment. The experimentally derived exposure estimates are also significantly lower than the RCL (*i.e.*, 16,000 ppm) and ATEL (*i.e.*, 100,000 ppm) for HFO-1234yf.

Additionally, EPA assessed the potential exposures to workers during disposal (*e.g.*, collection, transportation) of small refrigerant cans containing HFO-1234yf.⁸⁹ EPA determined that if proper handling and disposal guidelines

⁸⁶ EPA's Vintaging Model (EPA 2020) assumes the refrigerant charge size for MVACs to be 0.555–1 kilograms in light-duty vehicles and 0.79–1.14 kilograms in light-duty trucks.

⁸⁷ Honeywell International, Inc. 2012. Refrigerant exposure to service personnel or DIYers due to leakage of 12 oz charging cans or "small cans." Experiments Conducted at Honeywell's Research Laboratory in Buffalo, NY USA. January 2012.

⁸⁸ The orientation of the can during servicing determines the phase (*i.e.*, liquid or gas) of the refrigerant that is being transferred into the MVAC system. When the can is upright, the refrigerant transfers as a gas and when the can is inverted, the refrigerant transfers as a liquid (Perrin Quarles Associates, Inc., 2007). Refrigerant can instructions often direct users to hold the can upright or rotate its position during servicing.

⁸⁹ ICF, 2021f. Risk Screen on Substitutes in Motor Vehicle Air Conditioning (Small Cans). Substitute: HFO-1234yf.

are followed in accordance with good industrial hygiene practices and the SDS for HFO-1234yf, there is no significant risk to workers during the disposal of HFO-1234yf from MVAC systems or HFO-1234yf small refrigerant cans.

For potential toxicity risks of HFO-1234yf to the general population, EPA's analysis indicated that HFO-1234yf is not expected to present an unreasonable risk to human health in the general population when used as a refrigerant in small cans for MVAC servicing.

Based upon EPA's analysis, workplace and general population exposure to HFO-1234yf in small cans when used according to the use condition is not expected to exceed relevant exposure limits. Therefore, EPA concludes that the use of HFO-1234yf in small cans does not pose significantly greater toxicity risks than other acceptable refrigerants when used in accordance with the use condition described below in section II.C.3, which is intended to mitigate toxicity risks, and recommendations in the SDS and EPA's risk screen.

3. What is the use condition?

EPA's SNAP program has a longstanding approach of requiring unique fittings for use with each refrigerant substitute in MVAC systems. This is intended to prevent cross contamination of different refrigerants, to preserve the purity of recycled refrigerants, and ultimately to avoid venting of refrigerant consistent with requirements under CAA section 608(c), codified at 40 CFR 82.154(a). In the 1996 SNAP rule requiring the use of fittings on all refrigerants submitted for use in MVAC systems, EPA urged industry to develop mechanisms to ensure that the refrigerant venting prohibition under CAA section 608 and the implementing regulations at 40 CFR 82.154 are observed (61 FR 54032; October 16, 1996). EPA has issued multiple SNAP rules codified in the CFR requiring the use of fittings unique to a refrigerant for use on "containers of the refrigerant, on can taps, on recovery, recycling, and charging equipment, and on all [motor vehicle] air conditioning system service ports." (See appendices C and D to subpart G of 40 CFR part 82).

In this rule, EPA is establishing a use condition requiring that for connections with small cans (two pounds or less) of HFO-1234yf use fittings must be consistent with SAE J2844 (revised January 2013), which specifies quick-connect fittings that are different from those for any other refrigerant. The low-side service port and connections will

have an outside diameter of 14 mm (0.551 inches), and the high-side service port will have an outside diameter of 17 mm (0.669 inches), both accurate to within 2 mm. Under SAE J2844 (revised January 2013), small cans of HFO-1234yf (*e.g.*, for use in DIY servicing of MVAC systems) must have a left-handed screw valve with a diameter of 0.5 inches and Acme (trapezoidal) thread with 16 threads per inch.

D. Incorporation by Reference

As proposed, EPA is adopting the current versions of three technical safety standards developed by SAE by incorporating them by reference into the use conditions for the nonroad vehicles addressed in this action. EPA is also modifying the use conditions for the previous listings of HFO-1234yf in certain MVAC systems to incorporate by reference the most current versions of the three standards. The three standards are SAE J639 (revised November 2020), "Safety and Design Standards for Motor Vehicle Refrigerant Vapor Compression Systems;" SAE J1739 (revised January 2021), "Potential Failure Mode and Effects Analysis (FMEA) Including Design FMEA, Supplemental FMEA–MSR, and Process FMEA;" and SAE J2844 (revised January 2013), "R-1234yf (HFO-1234yf) New Refrigerant Purity and Container Requirements for Use in Mobile Air-Conditioning Systems." Section II.A.4 of this preamble discusses these standards in greater detail.

EPA finds, as in past rules, that it is appropriate to reference consensus standards that set conditions to reduce risk. As in past listings of flammable refrigerants, we find that such standards have already gone through a development phase that incorporates the latest findings and research. Likewise, such standards have gone through a vetting and refinement process that provides the affected parties an opportunity to comment. For the U.S. MVAC industry, EPA sees SAE standards in general as a pervasively used body of work to address risks, and these standards are the most applicable and recognized by the U.S. market.

Incorporation by reference allows federal agencies to comply with the requirement to publish rules in the **Federal Register** and the Code of Federal Regulations by referring to material already published elsewhere. The legal effect of incorporation by reference is that the material is treated as if it were published in the **Federal Register** and Code of Federal Regulations.

SAE J639, J1739, and J2844 are available for purchase by mail at: SAE

Customer Service, 400 Commonwealth Drive, Warrendale, PA 15096-0001; Telephone: 1-877-606-7323 in the U.S. or Canada (other countries dial 1-724-776-4970); internet address for SAE J639: https://www.sae.org/standards/content/j639_201112/; internet address for SAE J1739: https://www.sae.org/standards/content/j1739_202101/; internet address for SAE J2844: https://www.sae.org/standards/content/j2844_201301/. The cost of SAE J639, J1739, and J2844 is \$85 each for an electronic or hard copy. The cost of obtaining these standards is not a significant financial burden for manufacturers of MVAC systems, and purchase is not required for those selling, installing, or servicing the MVAC systems covered by these standards. Therefore, the EPA concludes that SAE J639, J1739, and J2844 are reasonably available.

E. What is the relationship between this SNAP rule and other federal rules?

1. Significant New Use Rule for HFO-1234yf Under the Toxic Substances Control Act

In a final rule published on March 29, 2011 (76 FR 17488), EPA noted that the listing of HFO-1234yf as acceptable, subject to use conditions, in new passenger cars and trucks did not apply to small cans. EPA stated that the Agency “would require additional information on consumer risk and a set of unique fittings from the refrigerant manufacturer for use with small cans or containers of HFO-1234yf before we would be able to issue a revised rule that allows for consumer filling, servicing, or maintenance of MVAC systems with HFO-1234yf”⁹⁰ and that use of small cans would need to be consistent with EPA’s final SNUR for HFO-1234yf under TSCA (October 27, 2010; 75 FR 65987). EPA has since revised the SNUR (80 FR 37166, June 30, 2015) to require the submission of a significant new use notice (SNUN) for commercial use of HFO-1234yf other than in passenger cars and vehicles in which the original charging of MVAC systems with HFO-1234yf was done by the OEM and use of HFO-1234yf in consumer products other than products used to recharge the MVAC systems in passenger cars and vehicles in which the original charging of MVAC systems with HFO-1234yf was done by the OEM, among other things. Manufacturers of

small cans of HFO-1234yf have also submitted a unique fitting specifically for use with small can taps and small refrigerant cans for EPA’s review. Today’s listing of HFO-1234yf would apply to small cans, weighing two pounds or less, for DIY or professional use. Consistent with the revised June 2015 SNUR for HFO-1234yf, commercial use or use in consumer products to recharge MVAC systems with HFO-1234yf in passenger cars and vehicles may only occur without submission of a SNUN and review by EPA if the OEM originally charged the system with HFO-1234yf.

EPA is including a reference to the June 2015 SNUR (80 FR 37166) in Appendix B subpart G of part 82, under the ‘Comments’ column, for the listings of HFO-1234yf for the nonroad vehicles addressed in this action. EPA is also modifying the existing listings of HFO-1234yf as acceptable, subject to use conditions, for various vehicle types, by including the reference to the June 2015 SNUR in the Comments column in Appendix B subpart G of part 82.

2. CAA Sections 608 and 609

Today’s action will not have any impact on EPA’s regulations under sections 608 or 609 of the Clean Air Act. Among other things, CAA section 608 prohibits individuals from knowingly venting or otherwise releasing into the environment any refrigerants except those specifically exempted in certain end uses, while maintaining, servicing, repairing, or disposing of air conditioning or refrigeration equipment. HFO-1234yf is not exempt from the venting prohibition in any application; therefore, knowing release of HFO-1234yf from MVAC systems in the nonroad vehicles addressed in this action, or any other MVAC system, by any person maintaining, servicing, repairing, or disposing of such systems is prohibited. MVAC end-of-life disposal and recycling specifications are also covered under CAA section 608 and EPA’s regulations issued under that section of the Act, which are codified at subpart F of 40 CFR part 82. In addition, as mentioned above in sections I.A and II.C, there are additional requirements that concern the sale or offer for sale of refrigerants, including a sales restriction under 40 CFR subpart F and specifically at 82.154(c)(1) and related specifications for self-sealing valves at 82.154(c)(2). This action does not modify the provisions under 40 CFR 82.154, including the restriction on sale of substitute refrigerants and requirements for self-sealing valves. The Agency is

not revising regulations promulgated under CAA section 608 in this action.

CAA section 609 establishes standards and requirements regarding the servicing or repair of MVAC systems. EPA has issued regulations implementing this statutory requirement and those regulations are codified at subpart B of 40 CFR part 82. Under section 609 and its implementing regulations, no person repairing or servicing motor vehicles for consideration⁹¹ may perform any service on an MVAC that involves the refrigerant without properly using approved refrigerant recovery or recovery and recycling equipment, and no such person may perform such service unless such person has been properly trained and certified. Refrigerant handling equipment must be certified by EPA or an independent organization approved by EPA. The statutory and regulatory provisions regarding MVAC servicing apply to all refrigerants, including HFO-1234yf.

3. Will this action affect EPA’s HD greenhouse gas standards?

The Phase 1 HD Greenhouse Gas (GHG) rule (76 FR 57106; September 15, 2011) set GHG standards for the HD industry in three discrete categories—combination tractors, HD pickups and vans, and vocational vehicles. The Phase 1 rule also set separate standards for engines that power vocational vehicles and combination tractors—based on the relative degree of homogeneity among vehicles within each category. As part of the Phase 1 HD GHG standards, EPA finalized a low leakage standard of 1.50 percent leakage per year for AC systems installed in HD pickup trucks and vans and combination tractors for model years 2014 and later. On October 25, 2016, EPA finalized Phase 2 HD GHG standards that built on the existing Phase 1 HD GHG standards (81 FR 73478). The nonroad vehicles for which EPA is listing HFO-1234yf are not regulated under the Phase 1 or Phase 2 HD GHG standards. Additionally, today’s action does not have a direct impact on the HD GHG standards, either for Phase 1 or Phase 2.

F. Response to Comments

EPA received four comments on the proposed rule from refrigerant suppliers and equipment manufacturers. All commenters strongly supported finalizing the rule as proposed, particularly the proposal to list

⁹¹ Service for consideration means receiving something of worth or value to perform service, whether in money, credit, goods, or services.

⁹⁰ EPA, 2011. Protection of Stratospheric Ozone: New Substitute in the Motor Vehicle Air Conditioning Sector Under the Significant New Alternatives Policy (SNAP) Program; Final Rule. March 29, 2011 (76 FR 17488). Available online at: <https://www.govinfo.gov/content/pkg/FR-2011-03-29/pdf/2011-6268.pdf>.

HFO-1234yf as acceptable, subject to use conditions, in certain nonroad vehicle air conditioning systems. One commenter noted that the similarities between the proposed use conditions for the nonroad vehicles and those required for certain onroad vehicles “will prevent confusion and help harmonize the industry as [HFO-]1234yf usage expands to nonroad vehicles.” Another commenter stated that the proposed listings of HFO-1234yf in the nonroad vehicles would “provide manufacturers with regulatory certainty so they can design and manufacture new equipment using HFO-1234yf and transition to lower GWP solutions.” EPA acknowledges the support for the proposed rule and is finalizing the listings and changes as proposed.

In the proposed rule, EPA requested information on the development of HFO-1234yf MVAC systems for types of nonroad or onroad HD vehicles not covered by this rulemaking, particularly onroad trucks (*i.e.*, Class 4–8 trucks between 14,001 and 33,000 or greater pounds). Two commenters supported the expanded use of HFO-1234yf in HD onroad trucks greater than 14,000 pounds. One commenter estimated that manufacturers would need at least five to ten years to fully transition from HFC-134a to HFO-1234yf and noted a few potential technical challenges. However, the commenter stated that “medium- and heavy-duty truck manufacturers are addressing the challenge with urgency,” and encouraged EPA to initiate rulemaking to list HFO-1234yf for HD onroad trucks greater than 14,000 pounds. EPA acknowledges the commenters’ support for the listing of HFO-1234yf in additional onroad vehicles and will consider these comments as it evaluates possible future actions.

III. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control number 2060–0226. The approved Information Collection Request includes five types

of respondent reporting and recordkeeping activities pursuant to SNAP regulations: Submission of a SNAP petition, filing a TSCA/SNAP Addendum, notification for test marketing activity, recordkeeping for substitutes acceptable subject to use restrictions, and recordkeeping for small volume uses. This rule contains no new requirements for reporting or recordkeeping.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, EPA concludes that the impact of concern for this rule is any significant adverse economic impact on small entities and that the agency is certifying that this rule will not have a significant economic impact on a substantial number of small entities if the rule has no net burden on the small entities subject to the rule. Because the use conditions are consistent with industry consensus standards, no change in business practice is required to meet the use conditions, resulting in no adverse impact compared to the absence of this final rule. Thus, the rule would not impose new costs on small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175.

Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action’s health and risk assessments are contained in the comparisons of toxicity for HFO-1234yf, as well as in the risk screens for HFO-1234yf. The risk screens are in the docket for this rulemaking.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

This action involves technical standards. EPA is adopting the current versions of three technical safety standards developed by SAE by incorporating them by reference into the use conditions for the nonroad vehicles addressed in this action. EPA is also modifying the use conditions for the previous listings of HFO-1234yf in MVAC systems to incorporate by reference the most current versions of the three standards. The use conditions ensure that HFO-1234yf does not present significantly greater risk to human health or the environment than other alternatives available for use in MVAC. Specifically, the three standards are:

1. *SAE J639: Safety and Design Standards for Motor Vehicle Refrigerant Vapor Compression Systems* (revised November 2020). This document establishes safety standards for HFO-1234yf MVAC systems that include unique fittings; a warning label indicating the refrigerant’s identity and that it is a flammable refrigerant; and requirements for engineering design strategies that include a high-pressure compressor cutoff switch and pressure relief devices. This standard is available at https://www.sae.org/standards/content/j639_201112/.

2. *SAE J1739: Potential Failure Mode and Effects Analysis (FMEA) Including Design FMEA, Supplemental FMEA–MSR, and Process FMEA* (revised January 2021). This standard describes potential FMEA in design and potential

FMEA in manufacturing and assembly processes. It requires manufacturers of MVAC systems and vehicles to conduct a FMEA and assists users in the identification and mitigation of risk by providing appropriate terms, requirements, ranking charts, and worksheets. This standard is available at https://www.sae.org/standards/content/j1739_202101/.

3. *SAE J2844: R-1234yf (HFO-1234yf) New Refrigerant Purity and Container Requirements for Use in Mobile Air-Conditioning Systems* (revised January 2013). This standard sets purity standards and describes container requirements, including fittings for refrigerant cylinders. For connections with refrigerant containers for use in professional servicing, use fittings must be consistent with SAE J2844 (revised January 2013). For connections with small refrigerant cans for consumer or professional use, use fittings must have a diameter of 0.5 inches, a thread pitch of 16 thread per inch, and a left thread direction, consistent with SAE J2844. This standard is available at https://www.sae.org/standards/content/j2844_201301/.

These standards may be purchased by mail at: SAE Customer Service, 400 Commonwealth Drive, Warrendale, PA 15096-0001; by telephone: 1-877-606-7323 in the United States or 724-776-4970 outside the United States or in Canada. The cost of SAE J639, SAE J1739, and SAE J2844 is \$85 each for an electronic or hardcopy. The cost of obtaining these standards is not a significant financial burden for manufacturers of MVAC systems and purchase is not required for those selling, installing, and servicing the systems. Therefore, EPA concludes that the use of SAE J639, SAE J1739, and SAE J2844 are reasonably available.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

A regulatory action may involve potential environmental justice concerns if it could: (1) Create new disproportionate impacts on people of color, communities of low-income, and/or indigenous peoples; (2) exacerbate existing disproportionate impacts on people of color, communities of low-income, and/or indigenous peoples; or (3) present opportunities to address existing disproportionate impacts on people of color, communities of low-income, and/or indigenous peoples through the action under development.

EPA believes that this action does not have disproportionately high and adverse human health or environmental

effects on people of color, communities of low-income and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The listings for HFO-1234yf in the vehicle types addressed in this action would provide additional lower-GWP alternatives for the MVAC end-use. By providing a lower-GWP alternative for this end-use, this final rule is also anticipated to reduce the use and eventual emissions of potent GHGs in this end-use, which could help to reduce the effects of climate change, including the public health and welfare effects on people of color, communities of low-income and/or indigenous peoples. This action's health and environmental risk assessments are contained in the comparison of health and environmental risks for HFO-1234yf, as well as in the risk screens that are available in the docket for this rulemaking. EPA's analysis indicates that other environmental impacts and human health impacts of HFO-1234yf are comparable to or less than those of other substitutes that are listed as acceptable for the same end-use. Based on these considerations, EPA expects that the effects on people of color, communities of low-income and/or indigenous peoples would not be disproportionately high and adverse.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

IV. References

Unless specified otherwise, all documents are available electronically through the Federal Docket Management System, Docket number EPA-HQ-OAR-2021-0347.

AEM, 2019. Risk Assessment for HFO-1234yf in Agricultural Tractors \geq 40 HP including 2WD, MFD, 4WD and Track Type Equipment.

AEM, 2020a. Risk Assessment for HFO-1234yf in Self-Propelled Agricultural Machinery including Combines, Forage Harvesters, Sprayers, and Windrowers.

AEM, 2020b. Risk Assessment for HFO-1234yf in Compact Equipment (Examples include Tractors <40HP, Turf Equipment, Skid Steer, Mini-Excavators and Track Loaders)

AEM, 2020c. Risk Assessment for HFO-1234yf in Construction, Forestry, and Mining Equipment.

AEM, 2020d. Risk Assessment for HFO-1234yf in Commercial Utility Vehicles.

AEM, 2020e. CFD Leak Modeling-Supplemental Information to Compliment AEM Machine Form RAs.

AEM, 2021. Appendix A: Machine Forms as Classified by AEM Membership.

ASHRAE, 2019. ANSI/ASHRAE Standard 34-2019: Designation and Safety Classification of Refrigerants.

Chemours, 2019. HFO-1234yf for Use as a Refrigerant. Significant New Alternatives Policy Program Submission to the U.S. Environmental Protection Agency.

CRP, 2008. Risk Assessment for Alternative Refrigerants HFO-1234yf Phase II. Prepared for SAE International Cooperative Research Program 1234 by Gradient Corporation.

CRP, 2009. Risk Assessment for Alternative Refrigerants HFO-1234yf and R-744 (CO₂) Phase III. Prepared for SAE International Cooperative Research Program 1234 by Gradient Corporation.

CRP, 2013. SAE International Cooperative Research Project CRP1234-4 on R-1234yf Safety, Finishes Work and Presents Conclusions. Available online at: http://www.sae.org/servlets/pressRoom?OBJECT_TYPE=PressReleases&PAGE=showRelease&RELEASE_ID=2146.

DuPont and Honeywell, 2008. Guidelines for Use and Handling of HFO-1234yf (v8.0).

EPA, 2005. Risk Analysis for Alternative Refrigerant in Motor Vehicle Air Conditioning.

EPA, 2011. Protection of Stratospheric Ozone: New Substitute in the Motor Vehicle Air Conditioning Sector Under the Significant New Alternatives Policy (SNAP) Program; Final Rule. March 29, 2011 (76 FR 17488). Available online at: <https://www.govinfo.gov/content/pkg/FR-2011-03-29/pdf/2011-6268.pdf>.

EPA, 2016. Protection of Stratospheric Ozone: Update to the Refrigerant Management Requirements Under the Clean Air Act. November 18, 2016. 81 FR 82272. Available online at: <https://www.regulations.gov/document?D=EPA-HQ-OAR-2015-0453-0125>.

EPA, 2021. Basic Information about the Emission Standards Reference Guide for On-road and Nonroad Vehicles and Engines. Available online at <https://www.epa.gov/emission-standards-reference-guide/basic-information-about-emission-standards-reference-guide-road>.

Exponent, 2008. HFO-1234yf Refrigerant Concentration and Ignition Tests in Full-Scale Vehicle Passenger Cabin and Engine Compartment.

ICF, 1997. Physiological Effects of Alternative Fire Protection Agents—Hypoxic Atmospheres Conference. Stephanie Skaggs prepared the proceedings of the conference held May 22, 1997 in New London, CT.

ICF, 2008a. Air Conditioning Refrigerant Charge Size to Passenger Compartment Volume Ratio Analysis.

ICF, 2008b. Revised Characterization of U.S. Hybrid and Small Car Sales (Historical and Predicted) and Hybrid Vehicle Accidents.

ICF, 2009a. Revised Final Draft Assessment of the Potential Impacts of HFO-1234yf and the Associated Production of TFA on Aquatic Communities and Local Air Quality.

ICF, 2009b. Risk Screen on Substitutes for CFC-12 in Motor Vehicle Air Conditioning: Substitute: HFO-1234yf.

ICF, 2010a. Summary of HFO-1234yf Emissions Assumptions.

- ICF, 2010b. Summary of Updates to the Vintaging Model that Impacted HFO-1234yf Emissions Estimates.
- ICF, 2010c. Revised Assessment of the Potential Impacts of HFO-1234yf and the Associated Production of TFA on Aquatic Communities, Soil and Plants, and Local Air Quality.
- ICF, 2010d. Sensitivity Analysis CMAQ results on projected maximum TFA rainwater concentrations and maximum 8-hr ozone concentrations.
- ICF, 2016. Technical Support Document for Acceptability Listing of HFO-1234yf for Motor Vehicle Air Conditioning in Limited Heavy-Duty Applications.
- ICF, 2021a. Risk Screen on Substitutes in Motor Vehicle Air Conditioning (Nonroad Vehicles Agricultural Tractors Greater than 40 Horsepower) (New Equipment).
- ICF, 2021b. Risk Screen on Substitutes in Motor Vehicle Air Conditioning (Nonroad Vehicles Self-Propelled Agricultural Machinery) (New Equipment).
- ICF, 2021c. Risk Screen on Substitutes in Motor Vehicle Air Conditioning (Nonroad Vehicles Compact Equipment) (New Equipment).
- ICF, 2021d. Risk Screen on Substitutes in Motor Vehicle Air Conditioning (Nonroad Vehicles—Construction, Forestry, and Mining Equipment) (New Equipment).
- ICF, 2021e. Risk Screen on Substitutes in Motor Vehicle Air Conditioning (Nonroad Vehicles Commercial Utility Vehicles) (New Equipment).
- ICF, 2021f. Risk Screen on Substitutes in Motor Vehicle Air Conditioning (Small Cans). Substitute: HFO-1234yf.
- Kataoka, O., Yoshizawa, M., & Hirakawa, T., 2000. Allowable Charge Limit of Flammable Refrigerants and Ventilation Requirements. Daikin Industries. International Refrigeration and Air Conditioning Conference. Paper 506. Available online at: <http://docs.lib.purdue.edu/iracc/506>.
- Nielsen, et al., 2007. Atmospheric chemistry of CF₃CF=CH₂: Kinetics and mechanisms of gas-phase reactions with Cl atoms, OH radicals, and O₃. *Chemical Physics Letters* 439, 18–22. Available online at: <http://>

www.cogci.dk/network/OJN_174_CF3CF=CH2.pdf.

- Papadimitriou, et al., 2007. CF₃CF=CH₂ and (Z)-CF₃CF=CHF: temperature dependent OH rate coefficients and global warming potentials. *Phys. Chem. Chem. Phys.*, 2007, Vol. 9, p. 1–13. Available online at: <http://pubs.rsc.org/en/Content/ArticleLanding/2008/CP/b714382f>.
- Perrin Quarles Associates, Inc., 2007. Disposable Container Heel Testing Study Report. Prepared for United States Environmental Protection Agency by Perrin Quarles Associates, Inc. March 21, 2007.
- SAE, 2013. Standard J2844: R-1234yf (HFO-1234yf) New Refrigerant Purity and Container Requirements for Use in Mobile Air-Conditioning Systems. (Revised January 2013).
- SAE, 2019. Standard J2772: Measurement of Passenger Compartment Refrigerant Concentrations Under System Refrigerant Leakage Conditions. SAE International. (Revised September 2019).
- SAE, 2020. Standard J639: Safety and Design Standards for Motor Vehicle Refrigerant Vapor Compression Systems. (Revised November 2020).
- SAE, 2021. Standard J1739: Potential Failure Mode and Effects Analysis (FMEA) Including Design FMEA, Supplemental FMEA–MSR, and Process FMEA. (Revised January 2021).
- Wagner, J., 2021. Email from John Wagner, Association of Equipment Manufacturers to Chenise Farquharson, EPA.

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Incorporation by reference, Recycling, Reporting and recordkeeping requirements, Stratospheric ozone layer, Motor vehicle air conditioning.

Michael S. Regan,
Administrator.

For the reasons set forth in the preamble, EPA amends 40 CFR part 82 as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

■ 1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

Subpart G—Significant New Alternatives Policy Program

■ 2. Appendix B to subpart G of part 82 is amended by

- a. In the table titled “Refrigerants—Acceptable Subject to Use Conditions”,
- i. Revising the entries for “CFC–12 Automobile Motor Vehicle Air Conditioning (New equipment in passenger cars and light-duty trucks only)”, “Motor vehicle air conditioning (newly manufactured medium-duty passenger vehicles)”, “Motor vehicle air conditioning (newly manufactured heavy-duty pickup trucks)”, and “Motor vehicle air conditioning (newly manufactured complete heavy-duty vans only)”; and
- ii. Adding entries, in the following order at the end of the table, for “Motor vehicle air conditioning (newly manufactured nonroad agricultural tractors with greater than 40 horsepower)”, “Motor vehicle air conditioning (newly manufactured nonroad self-propelled agricultural machinery)”, “Motor vehicle air conditioning (newly manufactured nonroad compact equipment)”, “Motor vehicle air conditioning (newly manufactured nonroad construction, forestry, and mining equipment)”, and “Motor vehicle air conditioning (newly manufactured nonroad commercial utility vehicles)”; and
- b. Removing “Note 1”.

The revisions and additions read as follows:

APPENDIX B TO SUBPART G OF PART 82—SUBSTITUTES SUBJECT TO USE RESTRICTIONS AND UNACCEPTABLE SUBSTITUTES REFRIGERANTS—ACCEPTABLE SUBJECT TO USE CONDITIONS

Application	Substitute	Decision	Conditions	Comments
CFC-12 Automobile Motor Vehicle Air Conditioning (New equipment in passenger cars and light-duty trucks only).	HFO-1234yf as a substitute for CFC-12.	Acceptable subject to use conditions.	As of June 3, 2022: (1) HFO-1234yf MVAC systems must adhere to all of the safety requirements of SAE J639, ^{4,7} including requirements for a flammable refrigerant warning label, high-pressure compressor cutoff switch and pressure relief devices, and unique fittings. For connections with refrigerant containers for use in professional servicing, use fittings must be consistent with SAE J2844. ^{6,7} For connections with small refrigerant cans for consumer or professional use, use fittings must have a diameter of 0.5 inches, a thread pitch of 16 thread per inch, and a left thread direction, consistent with SAE J2844.. (2) Manufacturers must conduct Failure Mode and Effect Analysis (FMEA) as provided in SAE J1739. ^{5,7} Manufacturers must keep the FMEA on file for at least three years from the date of creation.	Additional training for service technicians recommended. HFO-1234yf is also known as 2,3,3,3-tetrafluoro-prop-1-ene (CAS. Reg. No. 754-12-1). Consistent with EPA's Significant New Use Rule for HFO-1234yf under the Toxic Substances Control Act, commercial users or consumers can only recharge MVAC systems with HFO-1234yf where the original charging of the system with HFO-1234yf was done by the original equipment manufacturer. Refrigerant containers of HFO-1234yf for use in professional servicing are from 5 lbs. (2.3 L) to 50 lbs. (23 L) in size. Requirements for handling, storage, and transportation of compressed gases apply to this refrigerant, such as regulations of the Occupational Safety and Health Administration at 29 CFR 1910.101 and the Department of Transportation's requirements at 49 CFR 171-179. Requirements for handling, storage, and transportation of compressed gases apply to this refrigerant, such as regulations of the Occupational Safety and Health Administration at 29 CFR 1910.101 and the Department of Transportation's requirements at 49 CFR 171-179.
Motor vehicle air conditioning (newly manufactured medium-duty passenger vehicles).	HFO-1234yf	Acceptable subject to use conditions.	As of June 3, 2022: (1) HFO-1234yf MVAC systems must adhere to all of the safety requirements of SAE J639, ^{4,7} including requirements for a flammable refrigerant warning label, high-pressure compressor cutoff switch and pressure relief devices, and unique fittings. For connections with refrigerant containers for use in professional servicing, use fittings must be consistent with SAE J2844. ^{6,7} For connections with small refrigerant cans for consumer or professional use, use fittings must have a diameter of 0.5 inches, a thread pitch of 16 thread per inch, and a left thread direction, consistent with SAE J2844. (2) Manufacturers must conduct Failure Mode and Effect Analysis (FMEA) as provided in SAE J1739. ^{5,7} Manufacturers must keep the FMEA on file for at least three years from the date of creation.	Additional training for service technicians recommended. HFO-1234yf is also known as 2,3,3,3-tetrafluoro-prop-1-ene (CAS. Reg. No. 754-12-1). Consistent with EPA's Significant New Use Rule for HFO-1234yf under the Toxic Substances Control Act, commercial users or consumers can only recharge MVAC systems with HFO-1234yf where the original charging of the system with HFO-1234yf was done by the original equipment manufacturer.
Motor vehicle air conditioning (newly manufactured heavy-duty pickup trucks).	HFO-1234yf	Acceptable subject to use conditions.	As of June 3, 2022: (1) HFO-1234yf MVAC systems must adhere to all of the safety requirements of SAE J639, ^{4,7} including requirements for a flammable refrigerant warning label, high-pressure compressor cutoff switch and pressure relief devices, and unique fittings. For connections with refrigerant containers for use in professional servicing, use fittings must be consistent with SAE J2844. ^{6,7} For connections with small refrigerant cans for consumer or professional use, use fittings must have a diameter of 0.5 inches, a thread pitch of 16 thread per inch, and a left thread direction, consistent with SAE J2844. (2) Manufacturers must conduct Failure Mode and Effect Analysis (FMEA) as provided in SAE J1739. ^{5,7} Manufacturers must keep the FMEA on file for at least three years from the date of creation.	Additional training for service technicians recommended. HFO-1234yf is also known as 2,3,3,3-tetrafluoro-prop-1-ene (CAS No. 754-12-1). Consistent with EPA's Significant New Use Rule for HFO-1234yf under the Toxic Substances Control Act, commercial users or consumers can only recharge MVAC systems with HFO-1234yf where the original charging of the system with HFO-1234yf was done by the original equipment manufacturer.

APPENDIX B TO SUBPART G OF PART 82—SUBSTITUTES SUBJECT TO USE RESTRICTIONS AND UNACCEPTABLE SUBSTITUTES REFRIGERANTS—ACCEPTABLE SUBJECT TO USE CONDITIONS—Continued

Application	Substitute	Decision	Conditions	Comments
Motor vehicle air conditioning (newly manufactured complete heavy-duty vans only).	HFO-1234yf	Acceptable subject to use conditions.	As of June 3, 2022: (1) HFO-1234yf MVAC systems must adhere to all of the safety requirements of SAE J639, ^{4,7} including requirements for a flammable refrigerant warning label, high-pressure compressor cutoff switch and pressure relief devices, and unique fittings. For connections with refrigerant containers for use in professional servicing, use fittings must be consistent with SAE J2844. ^{6,7} For connections with small refrigerant cans for consumer or professional use, use fittings must have a diameter of 0.5 inches, a thread pitch of 16 thread per inch, and a left thread direction, consistent with SAE J2844. (2) Manufacturers must conduct Failure Mode and Effect Analysis (FMEA) as provided in SAE J1739. ^{5,7} Manufacturers must keep the FMEA on file for at least three years from the date of creation.	Additional training for service technicians recommended. HFO-1234yf is also known as 2,3,3,3-tetrafluoro-prop-1-ene (CAS No. 754-12-1). HFO-1234yf is acceptable for complete heavy-duty vans. Complete heavy-duty vans are not altered by a secondary or tertiary manufacturer. Consistent with EPA's Significant New Use Rule for HFO-1234yf under the Toxic Substances Control Act, commercial users or consumers can only recharge MVAC systems with HFO-1234yf where the original charging of the system with HFO-1234yf was done by the original equipment manufacturer.
Motor vehicle air conditioning (newly manufactured nonroad agricultural tractors with greater than 40 horsepower).	HFO-1234yf	Acceptable subject to use conditions.	As of June 3, 2022: (1) Systems must adhere to all of the safety requirements of SAE J639, ^{4,7} including requirements for a flammable refrigerant warning label, high-pressure compressor cutoff switch and pressure relief devices, and unique fittings. For connections with refrigerant containers for use in professional servicing, use fittings must be consistent with SAE J2844. ^{6,7} For connections with small refrigerant cans for consumer or professional use, use fittings must have a diameter of 0.5 inches, a thread pitch of 16 thread per inch, and a left thread direction, consistent with SAE J2844. (2) Manufacturers must conduct Failure Mode and Effect Analysis (FMEA) as provided in SAE J1739. ^{5,7} Manufacturers must keep the FMEA on file for at least three years from the date of creation.	Additional training for service technicians recommended. HFO-1234yf is also known as 2,3,3,3-tetrafluoro-prop-1-ene (CAS No. 754-12-1). Consistent with EPA's Significant New Use Rule for HFO-1234yf under the Toxic Substances Control Act, commercial users or consumers can only recharge MVAC systems with HFO-1234yf where the original charging of the system with HFO-1234yf was done by the original equipment manufacturer.
Motor vehicle air conditioning (newly manufactured nonroad self-propelled agricultural machinery).	HFO-1234yf	Acceptable subject to use conditions.	As of June 3, 2022: (1) HFO-1234yf MVAC systems must adhere to all of the safety requirements of SAE J639, ^{4,7} including requirements for a flammable refrigerant warning label, high-pressure compressor cutoff switch and pressure relief devices, and unique fittings. For connections with refrigerant containers for use in professional servicing, use fittings must be consistent with SAE J2844. ^{6,7} For connections with small refrigerant cans for consumer or professional use, use fittings must have a diameter of 0.5 inches, a thread pitch of 16 thread per inch, and a left thread direction, consistent with SAE J2844. (2) Manufacturers must conduct Failure Mode and Effect Analysis (FMEA) as provided in SAE J1739. ^{5,7} Manufacturers must keep the FMEA on file for at least three years from the date of creation.	Additional training for service technicians recommended. HFO-1234yf is also known as 2,3,3,3-tetrafluoro-prop-1-ene (CAS No. 754-12-1). Consistent with EPA's Significant New Use Rule for HFO-1234yf under the Toxic Substances Control Act commercial users or consumers can only recharge MVAC systems with HFO-1234yf where the original charging of the system with HFO-1234yf was done by the original equipment manufacturer.

APPENDIX B TO SUBPART G OF PART 82—SUBSTITUTES SUBJECT TO USE RESTRICTIONS AND UNACCEPTABLE SUBSTITUTES REFRIGERANTS—ACCEPTABLE SUBJECT TO USE CONDITIONS—Continued

Application	Substitute	Decision	Conditions	Comments
Motor vehicle air conditioning (newly manufactured nonroad compact equipment).	HFO-1234yf	Acceptable subject to use conditions.	As of June 3, 2022: (1) HFO-1234yf MVAC systems must adhere to all of the safety requirements of SAE J639, ^{4,7} including requirements for a flammable refrigerant warning label, high-pressure compressor cutoff switch and pressure relief devices, and unique fittings. For connections with refrigerant containers for use in professional servicing, use fittings must be consistent with SAE J2844. ^{6,7} For connections with small refrigerant cans for consumer or professional use, use fittings must have a diameter of 0.5 inches, a thread pitch of 16 thread per inch, and a left thread direction, consistent with SAE J2844). (2) Manufacturers must conduct Failure Mode and Effect Analysis (FMEA) as provided in SAE J1739. ^{5,7} Manufacturers must keep the FMEA on file for at least three years from the date of creation.	Additional training for service technicians recommended. HFO-1234yf is also known as 2,3,3,3-tetrafluoro-prop-1-ene (CAS No. 754-12-1). Consistent with EPA's Significant New Use Rule for HFO-1234yf under the Toxic Substances Control Act (80 FR 37166, June 30, 2015), commercial users or consumers can only recharge MVAC systems with HFO-1234yf where the original charging of the system with HFO-1234yf was done by the original equipment manufacturer.
Motor vehicle air conditioning (newly manufactured nonroad construction, forestry, and mining equipment).	HFO-1234yf	Acceptable subject to use conditions.	As of June 3, 2022: (1) HFO-1234yf MVAC systems must adhere to all of the safety requirements of SAE J639, ^{4,7} including requirements for a flammable refrigerant warning label, high-pressure compressor cutoff switch and pressure relief devices, and unique fittings. For connections with refrigerant containers for use in professional servicing, use fittings must be consistent with SAE J2844. ^{6,7} For connections with small refrigerant cans for consumer or professional use, use fittings must have a diameter of 0.5 inches, a thread pitch of 16 thread per inch, and a left thread direction, consistent with SAE J2844. (2) Manufacturers must conduct Failure Mode and Effect Analysis (FMEA) as provided in SAE J1739. ^{5,7} Manufacturers must keep the FMEA on file for at least three years from the date of creation.	Additional training for service technicians recommended. HFO-1234yf is also known as 2,3,3,3-tetrafluoro-prop-1-ene (CAS No. 754-12-1). Consistent with EPA's Significant New Use Rule for HFO-1234yf under the Toxic Substances Control Act, commercial users or consumers can only recharge MVAC systems with HFO-1234yf where the original charging of the system with HFO-1234yf was done by the original equipment manufacturer.
Motor vehicle air conditioning (newly manufactured nonroad commercial utility vehicles).	HFO-1234yf	Acceptable subject to use conditions.	As of June 3, 2022: (1) HFO-1234yf MVAC systems must adhere to all of the safety requirements of SAE J639, ^{4,7} including requirements for a flammable refrigerant warning label, high-pressure compressor cutoff switch and pressure relief devices, and unique fittings. For connections with refrigerant containers for use in professional servicing, use fittings must be consistent with SAE J2844. ^{6,7} For connections with small refrigerant cans for consumer or professional use, use fittings must have a diameter of 0.5 inches, a thread pitch of 16 thread per inch, and a left thread direction, consistent with SAE J2844. (2) Manufacturers must conduct Failure Mode and Effect Analysis (FMEA) as provided in SAE J1739. ^{5,7} Manufacturers must keep the FMEA on file for at least three years from the date of creation.	Additional training for service technicians recommended. HFO-1234yf is also known as 2,3,3,3-tetrafluoro-prop-1-ene (CAS No. 754-12-1). Consistent with EPA's Significant New Use Rule for HFO-1234yf under the Toxic Substances Control Act, commercial users or consumers can only recharge MVAC systems with HFO-1234yf where the original charging of the system with HFO-1234yf was done by the original equipment manufacturer.

⁴ SAE, J639 NOV2020, Safety and Design Standards for Motor Vehicle Refrigerant Vapor Compression Systems, Revised November 2020.

⁵ SAE, J1739 JAN2021, Potential Failure Mode and Effects Analysis (FMEA) Including Design FMEA, Supplemental FMEA-MSR, and Process FMEA, Revised January 2021.

⁶ SAE, J2844 JAN2013, R-1234yf (HFO-1234yf) New Refrigerant Purity and Container Requirements for Use in Mobile Air-Conditioning Systems, Revised January 2013.

⁷ The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. It is available for inspection at the EPA and at the National Archives and Records Administration (NARA). Contact EPA at: U.S. EPA's Air and Radiation Docket; EPA West Building, Room 3334, 1301 Constitution Ave. NW, Washington DC, 202-566-1742. For information on the availability of this material at NARA, email fr.inspection@nara.gov, or go to: www.archives.gov/federal-register/cfr/ibr-locations.html. Available from SAE International (SAE): SAE Customer Service, 400 Commonwealth Drive, Warrendale, PA 15096-0001; 1-877-606-7323 in the United States or 724-776-4970 outside the United States or in Canada; website: <https://www.sae.org/standards>.

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[FR Doc. 2022-08923 Filed 5-3-22; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF TRANSPORTATION**Pipeline and Hazardous Materials Safety Administration****49 CFR Parts 191 and 192**

[Docket No. PHMSA–2011–0023; Amdt. Nos. 191–31; 192–131]

RIN 2137–AF38

Pipeline Safety: Safety of Gas Gathering Pipelines: Extension of Reporting Requirements, Regulation of Large, High-Pressure Lines, and Other Related Amendments: Response to a Petition for Reconsideration; Technical Corrections; Issuance of Limited Enforcement Discretion

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule; response to petition for reconsideration; enforcement discretion; technical corrections.

SUMMARY: PHMSA is alerting the public to its April 1, 2022, response denying a petition for reconsideration of the final rule titled “Safety of Gas Gathering Pipelines: Extension of Reporting Requirements, Regulation of Large, High-Pressure Lines, and Other Related Amendments.” This final rule also makes clarifications and two technical corrections to that rulemaking. Lastly, this final rule memorializes a limited enforcement discretion in connection with that rulemaking’s amendment of the regulatory definition of “incidental gathering.”

DATES: This final rule is effective May 16, 2022. The limited enforcement discretion is effective May 16, 2022.

FOR FURTHER INFORMATION CONTACT: Technical questions: Steve Nanney, Senior Technical Advisor, by telephone at 713–272–2855.

General information: Sayler Palabrica, Transportation Specialist, by telephone at 202–366–0559.

SUPPLEMENTARY INFORMATION:**I. Response to Petition for Reconsideration**

On November 15, 2021, PHMSA published a final rule titled “Safety of Gas Gathering Pipelines: Extension of Reporting Requirements, Regulation of Large, High-Pressure Lines, and Other Related Amendments”¹ amending the Pipeline Safety Regulations at 49 CFR parts 191 and 192 to introduce reporting

requirements for previously unregulated Types C and R gas gathering pipelines along with safety standards for Type C gas gathering pipelines.

On December 15, 2021, the American Petroleum Institute and the GPA Midstream Association (collectively, “Petitioners”) submitted a Petition for Reconsideration of the final rule.² On April 1, 2022, PHMSA issued a letter to the Petitioners with an accompanying Appendix (“Response Letter”) responding to the arguments made in the Petition and denying the Petition and the Motion to Stay. The Response Letter is available in the docket for this rulemaking at Doc. No. PHMSA–2011–0023–0504.

II. Clarifications and Technical Corrections

Although PHMSA denied the Petition for reasons articulated in the Response Letter, Petitioners raised certain elements of the final rule that could benefit from clarification or technical correction to facilitate operator compliance efforts. Specifically, PHMSA is (1) issuing a technical correction amending the safety-related condition report requirements in § 191.23 consistent with statements in the preamble to the final rule, and (2) clarifying that operators may, when identifying Type C gas gathering lines pursuant to § 192.8, use the default specified minimum yield strength (“SMYS”) at § 192.107(b)(2) when the yield strength is not known. PHMSA is also issuing a technical correction amending § 192.8 to align the regulatory text with statements in the final rule facilitating operators’ consideration of maximum allowable operating pressure (“MAOP”) in making threshold determinations that gas gathering facilities qualify as Type C lines.

A. Technical Correction To Clarify That Certain Type C Gathering Lines Do Not Need To Report MAOP Exceedances

The final rule exempts all Type R gathering lines from part 191 requirements to report certain safety-related conditions, including when the pressure on a pipeline exceeds its MAOP. 86 FR at 63295 (revising § 191.23(b)(1)). However, the preamble to the final rule explained that exception was not meant to be limited to Type R gathering lines: Type C gathering lines with an outside diameter of less than 12.75 inches, which are not required by § 192.9(e)–(f) to establish

MAOP pursuant to § 192.619, were to be excepted from the safety-related condition reporting requirement. 86 FR at 63275. As the Petition pointed out, PHMSA inadvertently omitted regulatory language codifying that exception. PHMSA is therefore issuing a technical correction revising § 191.23(b)(1) to clarify that safety-related condition reporting of MAOP exceedances is not required for operators of gathering lines not required to establish an MAOP pursuant to §§ 192.9(e) and (f) and 192.619.

B. Clarification That Operators May Use a Default SMYS for Identifying Type C Gathering Lines

The final rule sets out in the Table 1 to § 192.8(c)(2) the criteria for an operator to use in making the threshold determination that its pipelines are Type C. 86 FR at 63296. Among those criteria is a comparison of hoop stress to SMYS. The Petition requested that PHMSA revise regulatory text to provide that operators may use the default yield strength specified at § 192.107(b)(2) for the SMYS input for determining whether a steel gas gathering line is a Type C gathering line.

As noted in the Response Letter, PHMSA declines to revise pertinent regulatory text as requested by the Petitioners. However, PHMSA agrees that there is value in clarifying that, in making the determination whether a gathering line is a Type C line pursuant to § 192.8(c), operators that do not know the yield strength of a steel gathering line may use the 24,000 pounds-per-square-inch default yield strength specified at § 192.107(b)(2) as a proxy for pipe SMYS used along with the pipeline operating hoop stress to determine the operating hoop stress percentage of pipe SMYS.

C. Technical Correction for Determining Pressure in Identifying Type C Gathering Lines

PHMSA also understands there is value in clarifying regulatory text pertaining to the operating pressure input in making the threshold determination of whether a gathering line is Type C pursuant to § 192.8(c). The final rule identifies operating pressure as an input to the threshold determination whether a pipeline facility is a Type C gathering line. 86 FR 63291 (“The Type C determination in § 192.8(c)(2) requires, at a minimum, knowledge only of . . . pressure of the pipeline.”), and 86 FR 63296 (codifying Table 1 to § 192.8(c)). However, PHMSA

² Doc. No. PHMSA–2011–0023–0493 (Dec. 20, 2021) (“Petition”). The Petition was accompanied by a Motion to Stay the rule (Doc. No. PHMSA–2011–0023–0492 (Dec. 20, 2021)).

¹ 86 FR 63266 (“Final Rule”).

inadvertently omitted from the final rule's regulatory text language codifying that operators would be able to reference historical operating pressure as an input to that threshold determination.

PHMSA therefore is issuing a technical correction to remedy this omission. Specifically, PHMSA is introducing § 192.8(c)(4), which provides that gas gathering line operators may, in connection with the threshold determination that a facility is a Type C gathering line when no MAOP has been calculated consistent with § 192.619(a) or (c)(1), use either (i) an MAOP calculated consistent with the methods at § 192.619(a) or (c)(1), or (ii) as a substitute for MAOP, the highest operating pressure to which the segment was subjected during the preceding five years.

III. Limited Enforcement Discretion for Existing Incidental Gathering Lines

PHMSA is also issuing a limited enforcement discretion addressing concerns raised in the Petition regarding the scope of the final rule's amendment of § 192.8 limiting the use of the "incidental gathering" designation. The final rule permitted continued use of an "incidental gathering" designation, which allows operators to designate lines downstream from the termination of any gathering function as a gathering line rather than as a transmission line. For pipelines that are new, replaced, relocated, or otherwise changed after May 16, 2022, however, the final rule limited incidental gathering to no more than 10 miles from the furthestmost downstream endpoint of gathering. (86 FR 63295 (codifying § 192.8(a)(5)).

Petitioners asked PHMSA to restrict the scope of this limitation to newly-constructed lines, as they note that its application to projects involving the replacement, relocation, or change of gas gathering lines currently considered "incidental gathering" would cause economic hardship on lines that would have to come into prompt compliance with the suite of part 192 requirements governing transmission lines.

As stated in the Response Letter, PHMSA declines at this time to amend the final rule to limit the scope of the incidental gathering distance limitation as requested by Petitioners. However, PHMSA understands that the broad scope of the final rule distance limitation may discourage operators of existing incidental gathering lines from undertaking much needed safety-improving repairs and replacement projects, which would subject those gathering lines to the more rigorous part 192 requirements for transmission lines.

Therefore, PHMSA will exercise its discretion, during the pendency of its consideration of amendments to § 192.8(a)(5) to be announced in a forthcoming supplemental notice of proposed rulemaking ("SNPRM") under RIN 2137-AF37,³ to enforce the final rule's ten-mile limitation on "incidental gathering" only in connection with gas gathering lines that are newly construction after May 16, 2022. PHMSA will not, during the pendency of that rulemaking, enforce the final rule's 10-mile limitation in connection with repair, replacement, or change of gathering lines existing on or before May 16, 2022 that are currently considered "incidental gathering" lines. PHMSA expects this limited enforcement discretion will remove any disincentive created by the final rule for operators of those legacy "incidental gathering" pipelines to undertake safety-enhancing replacement, relocation, or other projects on those lines while PHMSA considers within a rulemaking whether modification of § 192.8(a)(5) is warranted. PHMSA will memorialize this enforcement discretion within implementation material for PHMSA inspectors and recommend that its state partners do the same.

This document is a temporary notice of enforcement discretion. Regulated entities may rely on this notice as a temporary safeguard from Departmental enforcement as described herein. To the extent this notice includes guidance on how regulated entities may comply with existing regulations, it does not have the force and effect of law and is not meant to bind the regulated entities in any way. This enforcement discretion will remain in effect until further notice, aligned with the forthcoming SNPRM under RIN 2137-AF37. Nothing herein prohibits the PHMSA Office of Pipeline Safety from rescinding this limited exercise of its enforcement discretion and pursuing an enforcement action if it determines that a significant safety issue warrants doing so. Furthermore, nothing herein relieves operators from compliance with any other applicable provisions of PHMSA regulations or other law, and PHMSA reserves the right to exercise all of its other authorities.

IV. Regulatory Analyses and Notices

A. Statutory/Legal Authority

Statutory authority for this document's clarification and technical corrections to the final rule, as with the final rule itself (whose discussion of

statutory authority at section IV.A., 86 FR 63290, is incorporated herein by reference), is provided by the Federal Pipeline Safety Act (49 U.S.C. 60101 *et seq.*). The Secretary delegated his authority under the Federal Pipeline Safety Act to the PHMSA Administrator under 49 CFR 1.97.

PHMSA finds it has good cause to make those clarification and technical corrections without notice and comment pursuant to section 553(b) of the Administrative Procedure Act (APA, 5 U.S.C. 551, *et seq.*). Section 553(b)(B) of the APA provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. As explained above, the textual alterations herein consist of a pair of technical corrections codifying statements in the final rule preamble that were inadvertently omitted from its amendatory text; they make no substantive changes to the final rule but merely facilitate its implementation by aligning the regulatory text and explanatory material in the final rule's preamble. Because the final rule is the product of an extensive administrative record with numerous opportunities (including through written comments and the advisory committee) for public comment, PHMSA finds that additional comment on the technical corrections herein is unnecessary.

The May 16, 2022 effective date of the revisions contained in this notice is authorized under both section 553(d)(1) and (3) of the APA. Section 553(d)(1) provides that a rule should take effect "not less than 30 days" after publication in the **Federal Register** except for "a substantive rule which grants or recognizes an exemption or relieves a restriction," while section 553(d)(3) allows for earlier effectiveness for good cause found by the agency and published within the rule. 5 U.S.C. 553(d)(1), (3). "[T]he purpose of the thirty-day waiting period is to give affected parties a reasonable time to adjust their behavior before the final rule takes effect." *Omnipoint Corp. v. F.C.C.*, 78 F.3d 620, 630 (D.C. Cir. 1996). The technical correction at § 191.23(b)(1) relieves reporting requirements, the technical correction at § 192.8(c)(4) eases the threshold Type C determination by codifying an alternative method for calculating an operating pressure input, while the enforcement discretion expresses PHMSA's intent to limit enforcement of § 192.8(a)(5) to only certain categories (newly built incidental gathering lines)

³ Additional detail regarding the contents of that Supplemental Notice of Proposed Rulemaking will be announced in the Spring 2022 Unified Agenda.

provided for in that provision. Each relieves regulatory requirements of the final rule and, in accordance with 5 U.S.C. 553(d)(1), are effective May 16, 2022. Moreover, PHMSA finds that good cause under Section 553(d)(3) supports making the revisions effective May 16, 2022 because the technical corrections contained in this notice are entirely consistent with the final rule (which itself was published in November 2021) and in fact help promote timely compliance with the final rule's requirements before its May 16, 2022, effective date.

B. Executive Order 12866 and DOT Regulatory Policies and Procedures

This document has been evaluated in accordance with existing policies and procedures and is considered not significant under Executive Order 12866 ("Regulatory Planning and Review") and DOT Order 2100.6A ("Rulemaking and Guidance Procedures"); therefore, this notice has not been reviewed by the Office of Management and Budget (OMB) under Executive Order 12866. PHMSA finds that neither the clarifications nor the technical corrections herein (in all respects consistent with the final rule) neither impose incremental compliance costs nor adversely affect safety. Additionally, PHMSA found in the Regulatory Impact Analysis that the incidental gathering provision of the final rule would have a minor cost. To the extent the enforcement discretion statement contained in this notice results in fewer safety requirements applied to existing incidental gathering lines greater than 10 miles that are modified or replaced, the notice may lead to reduced costs of compliance and reduced safety and environmental benefits. However, the amount of existing incidental gathering lines 10 or more miles long is believed to be low and the portion of those lines that will be modified or replaced while the enforcement discretion is in effect is also likely to be low. Overall, PHMSA expects any impacts on the expected costs and benefits of the final rule will be negligible.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act, as amended by the Small Business Regulatory Flexibility Fairness Act of 1996 (5 U.S.C. 601 *et seq.*), generally requires Federal regulatory agencies to prepare a Final Regulatory Flexibility Analysis (FRFA) for a final rule subject to notice-and-comment rulemaking under the APA. 5 U.S.C. 604(a).⁴ The

Small Business Administration's implementing guidance explains that "[i]f an NPRM is not required, the RFA does not apply."⁵ Because PHMSA has "good cause" under the APA to forego comment on the technical corrections herein, no FRFA is required. Moreover, PHMSA prepared a FRFA for the final rule, which is available in the docket for this rulemaking;⁶ because the technical corrections herein will impose no new incremental compliance costs, PHMSA understands the analysis in that FRFA remains unchanged.

D. Paperwork Reduction Act

The clarifications and technical corrections in this notice impose no new or revised information collection requirements beyond those discussed in the final rule.

E. Unfunded Mandates Reform Act of 1995

PHMSA analyzed the clarifications and technical corrections in this notice under the factors in the Unfunded Mandates Reform Act of 1995 (UMRA, 2 U.S.C. 1501 *et seq.*) and determined that the technical corrections to the final rule herein do not impose enforceable duties on State, local, or Tribal governments or on the private sector of \$100 million or more, adjusted for inflation, in any one year. PHMSA prepared an analysis of the UMRA considerations in the final RIA for the final rule, which is available in the docket for the rulemaking.⁷ Because the clarifications and technical corrections herein will impose no new incremental compliance costs, PHMSA understands the analysis in that UMRA discussion for the final rule remains unchanged.

F. National Environmental Policy Act

The National Environmental Policy Act of 1969 (NEPA, 42 U.S.C. 4321 *et seq.*) requires Federal agencies to prepare a detailed statement on major Federal actions significantly affecting the quality of the human environment. PHMSA analyzed the final rule in accordance with NEPA, implementing Council on Environmental Quality regulations (40 CFR parts 1500–1508), and DOT implementing policies (DOT Order 610.1C, "Procedures for Considering Environmental Impacts") and determined the final rule would not

PHMSA has good cause to forego comment in adopting the technical correction herein.

⁴ Small Business Administration, "A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act" 55 (2017).

⁵ Doc. No. PHMSA–2011–0023–0488, at 34–35 (Nov. 14, 2021).

⁶ Doc. No. PHMSA–2011–0023–0488, at 35 (Nov. 14, 2021).

significantly affect the quality of the human environment.⁸ The clarifications and technical corrections to the final rule in this notice have no effect on PHMSA's earlier NEPA analysis as they are consistent, and merely facilitate compliance with, the final rule. PHMSA acknowledges that the limited enforcement discretion in Section III above could result in some existing "incidental" gas gathering lines that are replaced, relocated, or changed remaining subject to less rigorous part 192 safety requirements than if those lines were to be regulated as transmission lines consistent with the final rule's revisions to § 192.8. However, PHMSA expects that the enforcement discretion could improve public safety and environmental protection in some cases, as it removes potential inhibitions for some of those operators undertaking safety-enhancing repair, replacement, or change projects on their facilities. With these offsetting considerations in mind, PHMSA finds that the limited enforcement discretion herein would result in no significant impact on the human environment.

G. Privacy Act Statement

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at www.dot.gov/privacy.

H. Executive Order 13132 (Federalism)

PHMSA has analyzed this notice in accordance with the principles and criteria contained in Executive Order 13132 ("Federalism").⁹ The clarifications and technical corrections herein are consistent, and merely facilitate compliance with, the final rule, and do not have any substantial direct effect on the States, the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government beyond what was accounted for in the final rule. It does not contain any provision that imposes any substantial direct compliance costs on State and local governments, nor any new provision that preempts State law. Therefore, the consultation and funding

⁸ Final Environmental Assessment, Doc. No. PHMSA–2011–0023 (Nov. 2021).

⁹ 64 FR 43255 (Aug. 10, 1999).

⁴ This requirement is subject to exceptions—which are not in any event applicable here because

requirements of Executive Order 13132 do not apply.¹⁰

I. Executive Order 13211

PHMSA analyzed the final rule and determined that the requirements of Executive Order 13211 (“Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use”)¹¹ did not apply. The clarifications and technical corrections to the final rule herein are not a “significant energy action” under Executive Order 13211 either as they are not likely to have a significant adverse effect on supply, distribution, or energy use. Further, OMB has not designated these clarifications and revisions as a significant energy action.

J. Executive Order 13175

This document was analyzed in accordance with the principles and criteria contained in Executive Order 13175 (“Consultation and Coordination with Indian Tribal Governments”)¹² and DOT Order 5301.1 (“Department of Transportation Policies, Programs, and Procedures Affecting American Indians, Alaska Natives, and Tribes”). Because none of the clarifications and technical revisions have Tribal implications or impose substantial direct compliance costs on Indian Tribal governments, the funding and consultation requirements of Executive Order 13175 do not apply.

K. Executive Order 13609 and International Trade Analysis

Under Executive Order 13609 (“Promoting International Regulatory Cooperation”),¹³ agencies must consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary or may impair the ability of American business to export and compete internationally. In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The clarifications and technical corrections to the final rule in this notice do not impact international trade.

¹⁰ Moreover, PHMSA determined that the Final Rule did not impose substantial direct compliance costs on State and local governments.

¹¹ 66 FR 28355 (May 22, 2001).

¹² 65 FR 67249 (Nov. 6, 2000).

¹³ 77 FR 26413 (May 4, 2012).

L. Regulation Identifier Number (RIN)

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects

49 CFR Part 191

MAOP exceedance, Pipeline reporting requirements.

49 CFR Part 192

Integrity assessments, MAOP reconfirmation, Material verification, Pipeline safety, Predicted failure pressure, Reporting and record-keeping requirements, Risk assessment, Safety devices.

In consideration of the foregoing, PHMSA amends 49 CFR parts 191 and 192 as follows:

PART 191—TRANSPORTATION OF NATURAL AND OTHER GAS BY PIPELINE; ANNUAL, INCIDENT, AND OTHER REPORTING

■ 1. The authority citation for part 191 continues to read as follows:

Authority: 30 U.S.C. 185(w)(3), 49 U.S.C. 5121, 60101 *et seq.*, and 49 CFR 1.97.

■ 2. Section 191.23, as amended November 15, 2021, at 86 FR 63295, and effective May 16, 2022, is further amended by revising paragraph (b)(1) to read as follows:

§ 191.23 Reporting safety-related conditions.

* * * * *

(b) * * *

(1) Exists on a master meter system, a reporting-regulated gathering pipeline, a Type C gas gathering pipeline with an outside diameter of 12.75 inches or less, a Type C gas gathering pipeline covered by the exception in § 192.9(f)(1) of this subchapter and therefore not required to comply with § 192.9(e)(2)(ii), or a customer-owned service line;

* * * * *

PART 192—TRANSPORTATION OF NATURAL AND OTHER GAS BY PIPELINE: MINIMUM FEDERAL SAFETY STANDARDS

■ 3. The authority citation for part 192 continues to read as follows:

Authority: 30 U.S.C. 185(w)(3), 49 U.S.C. 5103, 60101 *et seq.*, and 49 CFR 1.97.

■ 4. Section 192.8, as amended November 15, 2021, at 86 FR 63295, and effective May 16, 2022, is further amended by adding paragraph (c)(4) to read as follows:

§ 192.8 How are onshore gathering pipelines and regulated onshore gathering pipelines determined?

* * * * *

(c) * * *

(4) For the purpose of identifying Type C lines in table 1 to paragraph (c)(2) of this section, if an operator has not calculated MAOP consistent with the methods at § 192.619(a) or (c)(1), the operator must either:

(i) Calculate MAOP consistent with the methods at § 192.619(a) or (c)(1); or
(ii) Use as a substitute for MAOP the highest operating pressure to which the segment was subjected during the preceding 5 operating years.

Issued in Washington, DC, on April 28, 2022, under authority delegated in 49 CFR 1.97.

Tristan H. Brown,

Deputy Administrator.

[FR Doc. 2022–09474 Filed 5–3–22; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 180117042–8884–02]

RIN 0648–XB936

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; inseason retention limit adjustment.

SUMMARY: NMFS has determined, based on consideration of the regulatory determination criteria regarding inseason adjustments, that the Atlantic bluefin tuna (BFT) daily retention limit that applies to Highly Migratory Species (HMS) Angling and HMS Charter/Headboat permitted vessels (when fishing recreationally for BFT) should be adjusted for the remainder of 2022. NMFS is adjusting the Angling category BFT daily retention limit from the default of one school, large school, or small medium BFT to: Two school BFT and one large school/small medium BFT per vessel per day/trip for private vessels with HMS Angling permits;

three school BFT and one large school/small medium BFT per vessel per day/trip for charter boat vessels with HMS Charter/Headboat permits when fishing recreationally; and six school BFT and two large school/small medium BFT per vessel per day/trip for headboat vessels with HMS Charter/Headboat permits when fishing recreationally. These retention limits are effective in all areas, except for the Gulf of Mexico, where targeted fishing for BFT is prohibited.

DATES: Effective May 6, 2022, through December 31, 2022.

FOR FURTHER INFORMATION CONTACT:

Larry Redd, Jr., larry.redd@noaa.gov, 301-427-8503, Nicholas Velseboer, nicholas.velseboer@noaa.gov, 978-675-2168, or Thomas Warren, thomas.warren@noaa.gov, 978-281-9347.

SUPPLEMENTARY INFORMATION: Atlantic HMS fisheries, including BFT fisheries, are managed under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*). The 2006 Consolidated Atlantic HMS Fishery Management Plan (FMP) and its amendments are implemented by regulations at 50 CFR part 635. Section 635.27 divides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) and as implemented by the United States among the various domestic fishing categories, per the allocations established in the 2006 Consolidated Atlantic HMS FMP and its amendments. NMFS is required under the MSA to provide U.S. fishing vessels with a reasonable opportunity to harvest quotas under relevant international fishery agreements such as the ICCAT Convention, which is implemented domestically pursuant to ATCA.

As described in § 635.27(a), the current baseline U.S. BFT quota is 1,247.86 mt (not including the 25-mt ICCAT allocated to the United States to account for bycatch of BFT in pelagic longline fisheries in the Northeast Distant Gear Restricted Area). The Angling category baseline quota is 232.4 mt. This baseline quota is further subdivided into subquotas by size class (see Table 1) as follows: 127.3 mt for school BFT, 99.8 mt for large school/small medium BFT, and 5.3 mt for large medium/giant BFT. Large school and small medium BFT traditionally have been managed as one size class, *i.e.*, a limit of one large school/small medium BFT (measuring 47 to less than 73 inches). Similarly, large medium and

giant BFT traditionally have been managed as one size class that is also known as the “trophy” class. Currently, the default Angling category daily retention limit of one school, large school, or small medium BFT is in effect and applies to HMS Angling and HMS Charter/Headboat permitted vessels (when fishing recreationally for BFT) (§ 635.23(b)(2)).

TABLE 1—BFT SIZE CLASSES

Size class	Curved fork length
School	27 to less than 47 inches (68.5 to less than 119 cm).
Large school.	47 to less than 59 inches (119 to less than 150 cm).
Small medium.	59 to less than 73 inches (150 to less than 185 cm).
Large medium.	73 to less than 81 inches (185 to less than 206 cm).
Giant	81 inches or greater (206 cm or greater).

Adjustment of Angling Category Daily Retention Limit

Under § 635.23(b)(3), NMFS may increase or decrease the Angling category retention limit for any size class of BFT after considering regulatory determination criteria under § 635.27(a)(8). Also under § 635.23(b)(3), recreational retention limits may be adjusted separately for specific vessel type, such as private vessels, headboats, or charter boats.

As discussed below, NMFS has considered all of the relevant determination criteria and their applicability to the change in the Angling category retention limit. After considering these criteria, NMFS has decided to adjust the Angling category retention limits as follows:

(1) For private vessels with HMS Angling permits, this action adjusts the limit upwards to two school BFT and one large school/small medium BFT per vessel per day/trip (*i.e.*, two BFT measuring 27 to less than 47 inches, and one BFT measuring 47 to less than 73 inches).

(2) For charter boat vessels with HMS Charter/Headboat permits, this action adjusts the limit upwards to three school BFT and one large school/small medium BFT per vessel per day/trip when fishing recreationally for BFT (*i.e.*, three BFT measuring 27 to less than 47 inches, and one BFT measuring 47 to less than 73 inches).

(3) For headboat vessels with HMS Charter/Headboat permits, this action adjusts the limit upwards to six school BFT and two large school/small medium BFT per vessel per day/trip when fishing recreationally for BFT (*i.e.*,

six BFT measuring 27 to less than 47 inches, and two BFT measuring 47 to less than 73 inches).

Regardless of the duration of a fishing trip, the daily retention limit applies upon landing. For example, whether a private vessel (fishing under the Angling category retention limit) takes a two-day trip or makes two trips in one day, the day/trip limit of two school BFT and one large school/small medium BFT applies and may not be exceeded upon landing.

Consideration of the Determination Criteria

Regarding the usefulness of information obtained from catches in the particular category for biological sampling and monitoring of the status of the stock (§ 635.27(a)(8)(i)), biological samples collected from BFT landed by recreational fishermen continue to provide NMFS with valuable parts and data for ongoing scientific studies of BFT age and growth, migration, and reproductive status. Additional opportunity to land BFT would support the continued collection of a broad range of data for these studies and for stock monitoring purposes.

NMFS also considered the catches of the Angling category quota to date and the likelihood of closure of that segment of the fishery if no adjustment is made (§ 635.27(a)(8)(ii)). Additionally, NMFS considered Angling category landings in 2020 and 2021, which were approximately 87 percent of the 232.4-mt annual Angling category quota in both 2020 and 2021, including landings of approximately 64 percent of the available school BFT quota in both 2020 and 2021, under the same daily retention limits as implemented in this action. Thus, absent retention limit adjustment, NMFS anticipates that the available 2022 Angling category quota would not be harvested under the default retention limit.

NMFS also considered the effects of the adjustment on the BFT stock and the effects of the adjustment on accomplishing the objectives of the 2006 Consolidated HMS FMP (§ 635.27(a)(8)(v) and (vi)). These retention limits would be consistent with established quotas and subquotas, which are implemented consistent with ICCAT recommendations, (established in Recommendation 17-06 and maintained in Recommendation 20-06), ATCA, and the objectives of the 2006 Consolidated HMS FMP and amendments. While not yet implemented, NMFS anticipates these retention limits would also be consistent with ICCAT Recommendation 21-07. In establishing

these quotas and subquotas and associated management measures, ICCAT and NMFS considered the best scientific information available, objectives for stock management and status, and effects on the stock. These retention limits are in line with these established management measures. It is also important that NMFS limit landings to the subquotas both to adhere to the FMP quota allocations and to ensure that landings are as consistent as possible with the pattern of fishing mortality (e.g., fish caught at each age) that was assumed in the latest stock assessment, and these retention limits are consistent with those objectives.

Another principal consideration in setting the retention limit is the objective of providing opportunities to harvest the available Angling category quota without exceeding the available quota, based on the objectives of the 2006 Consolidated HMS FMP and amendments, including to achieve optimum yield on a continuing basis and to allow all permit categories a reasonable opportunity to harvest the available BFT quota allocations (related to § 635.27(a)(8)(x)).

NMFS considered input on recreational limits from the HMS Advisory Panel at its May and September 2021 meetings and that ICCAT recommendations and HMS implementing regulations limit the allowance for landings of school bluefin tuna to 10 percent of the U.S. baseline quota (i.e., 127.3 mt). The 2021 school BFT landings represented approximately 6 percent of the total U.S. quota for 2021, well under the ICCAT recommended 10-percent limit. NMFS is not setting higher school BFT limits than the adjustments listed due to the potential risk of exceeding the ICCAT tolerance limit on school BFT and other considerations, such as potential effort shifts to BFT fishing as a result of current recreational retention limits for New England groundfish and striped bass as well as high variability in bluefin tuna availability.

Given that the Angling category landings fell short of the available quota in 2020 and 2021, even with the retention limit adjustments, and considering the regulatory criteria above, NMFS has determined that the Angling category retention limits applicable to HMS Angling and HMS Charter/Headboat permitted vessels should be adjusted upwards from the default levels.

NMFS has also concluded that implementation of separate limits for private, charter boat, and headboat vessels is appropriate, recognizing the different nature, socio-economic needs,

and recent landings results of the two components of the recreational BFT fishery. For example, charter operators historically have indicated that a retention limit greater than the default limit of one fish is vital to their ability to attract customers. In addition, Large Pelagics Survey estimates indicate that charter/headboat BFT landings averaged 31 percent of recent recreational landings for 2020 through 2021, with the remaining 69 percent landed by private vessels. NMFS has further concluded that a higher limit for headboats (than charter boats) is appropriate, given the limited number of headboats participating in the bluefin tuna fishery.

NMFS anticipates that the BFT daily retention limits in this action will result in landings during 2022 that would not exceed the available subquotas. Lower retention limits could result in substantial underharvest of the Angling category subquota, and increasing the daily limits further may risk exceeding the available quota, contrary to the objectives of the 2006 Consolidated HMS FMP and amendments.

Monitoring and Reporting

NMFS will continue to monitor the BFT fisheries closely through the mandatory landings and catch reports. HMS Angling and HMS Charter/Headboat permitted vessel owners are required to report the catch of all BFT retained or discarded dead, within 24 hours of the landing(s) or end of each trip, by accessing hmspermits.noaa.gov, using the HMS Catch Reporting app, or calling (888) 872-8862 (Monday through Friday from 8 a.m. until 4:30 p.m.). Depending on the level of fishing effort and catch rates of BFT, NMFS may determine that additional retention limit adjustments or closures are necessary to ensure available quota is not exceeded or to enhance scientific data collection from, and fishing opportunities in, all geographic areas. If needed, subsequent adjustments will be published in the **Federal Register**. In addition, fishermen may call the Atlantic Tunas Information Line at (978) 281-9260, or access hmspermits.noaa.gov, for updates on quota monitoring and inseason adjustments.

HMS Angling and HMS Charter/Headboat permit holders may catch and release (or tag and release) BFT of all sizes, subject to the requirements of the catch-and-release and tag-and-release programs at § 635.26. All BFT that are released must be handled in a manner that will maximize their survival, and without removing the fish from the water, consistent with requirements at

§ 635.21(a)(1). For additional information on safe handling, see the “Careful Catch and Release” brochure available at <https://www.fisheries.noaa.gov/resource/outreach-and-education/careful-catch-and-release-brochure>.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act and regulations at 50 CFR part 635 and is exempt from review under Executive Order 12866.

The Assistant Administrator (AA) for NMFS finds that it is impracticable and contrary to the public interest to provide prior notice of, and an opportunity for public comment on, this action for the following reasons:

The regulations implementing the 2006 Consolidated HMS FMP and amendments provide for inseason adjustments to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. Affording prior notice and opportunity for public comment to implement the daily retention limit for the remainder of 2022 at this time is impracticable. Based on available BFT quotas, fishery performance in recent years, and the availability of BFT on the fishing grounds, immediate adjustment to the Angling category BFT daily retention limit from the default levels is warranted to allow fishermen to take advantage of the availability of fish and of quota. NMFS could not have proposed these actions earlier, as it needed to consider and respond to updated landings data from the 2021 Angling category. If NMFS was to offer a public comment period now, after having appropriately considered those data, it could preclude fishermen from harvesting BFT that are legally available consistent with all of the regulatory criteria, and/or could result in selection of a retention limit inappropriately high or low for the amount of quota available for the period.

Fisheries under the Angling category daily retention limit are currently underway and thus prior notice would be contrary to the public interest. Delays in increasing daily recreational BFT retention limit would adversely affect those HMS Angling and HMS Charter/Headboat permitted vessels that would otherwise have an opportunity to harvest more than the default retention limit of one school, large school, or small medium BFT per day/trip and may exacerbate the problem of low catch rates and quota rollovers. Analysis of available data shows that adjustment

to the BFT daily retention limit from the default level would result in minimal risks of exceeding the ICCAT-allocated quota. Therefore, the AA finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for

public comment. For all of the above reasons, there is good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: April 29, 2022.

Jennifer M. Wallace,

*Director, Office of Sustainable Fisheries,
National Marine Fisheries Service.*

[FR Doc. 2022-09573 Filed 5-3-22; 8:45 am]

BILLING CODE 3510-22-P

Proposed Rules

Federal Register

Vol. 87, No. 86

Wednesday, May 4, 2022

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE-2017-BT-STD-0019]

Energy Conservation Program: Energy Conservation Standards for Consumer Products; Consumer Water Heaters; Reopening of Comment Period

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Request for information; reopening of public comment period.

SUMMARY: On March 1, 2022, the U.S. Department of Energy (DOE or the Department) published in the **Federal Register** a notification of availability of preliminary technical support document and request for comment regarding energy conservation standards for consumer water heaters. DOE received three requests to extend the public comment period by 60 days. DOE has reviewed these requests and is reopening the public comment period to allow comments to be submitted until May 16, 2022.

DATES: The comment period for the preliminary technical support document published in the **Federal Register** on March 1, 2022 (87 FR 11327) is reopened until May 16, 2022. Written comments, data, and information are requested and will be accepted on and before May 16, 2022.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at www.regulations.gov. Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE-2017-BT-STD-0019, by any of the following methods:

(1) *Federal eRulemaking Portal:* www.regulations.gov. Follow the instructions for submitting comments.

(2) *Email:* To ConsumerWaterHeaters2017STD0019@ee.doe.gov. Include docket number EERE-2017-BT-STD-0019 in the subject line of the message.

No telefacsimilies (“faxes”) will be accepted. For detailed instructions on submitting comments and additional information on this process, see **ADDRESSES** section.

Although DOE has routinely accepted public comment submissions through a variety of mechanisms, including postal mail and hand delivery/courier, the Department has found it necessary to make temporary modifications to the comment submission process in light of the ongoing COVID-19 pandemic. DOE is currently suspending receipt of public comments via postal mail and hand delivery/courier. If a commenter finds that this change poses an undue hardship, please contact Appliance Standards Program staff at (202) 586-1445 to discuss the need for alternative arrangements. Once the COVID-19 pandemic health emergency is resolved, DOE anticipates resuming all of its regular options for public comment submission, including postal mail and hand delivery/courier.

Docket: The docket for this activity, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at www.regulations.gov. All documents in the docket are listed in the www.regulations.gov index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket web pages can be found at: www.regulations.gov/docket/EERE-2017-BT-STD-0019. The docket web page contains instructions on how to access all documents, including public comments, in the docket.

FOR FURTHER INFORMATION CONTACT:

Ms. Julia Hegarty, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE-5B, 1000 Independence Avenue SW, Washington, DC 20585-0121. Telephone: (240) 597-6737. Email:

ApplianceStandardsQuestions@ee.doe.gov.

Mr. Eric Stas, U.S. Department of Energy, Office of the General Counsel, GC-33, 1000 Independence Avenue SW, Washington, DC 20585-0121. Telephone: (202) 586-5827. Email: Eric.Stas@hq.doe.gov.

For further information on how to submit a comment or review other

public comments and the docket, contact the Appliance and Equipment Standards Program staff at (202) 287-1445 or by email:

ApplianceStandardsQuestions@ee.doe.gov.

SUPPLEMENTARY INFORMATION: On March 1, 2022, DOE published in the **Federal Register** a notification of availability of preliminary technical support document and request for comment regarding energy conservation standards for consumer water heaters. DOE stated it would accept written comments, data, and information on the proposal by May 2, 2022. 87 FR 11327.

On April 8, 2022, and April 28, 2022, respectively, DOE received a comment from the Air Conditioning and Refrigeration Institute (AHRI) and a joint comment from the American Gas Association, American Public Gas Association, National Propane Gas Association, Spire Inc., Spire Missouri Inc., and Spire Alabama Inc. (collectively, the “Joint Commenters”), each requesting a 60-day extension of the public comment period on the basis that DOE had made public the preliminary Technical Support Document (“TSD”) one week after the notification was published in the **Federal Register**.¹ On April 28, 2022, DOE also received a comment from ONE Gas, Inc. requesting a 21-day extension of the public comment period to continue their review of the supplemental analytical tools relating to the preliminary analysis.²

DOE has reviewed the request and is reopening the comment period to allow additional time for interested parties to submit comments. In light of DOE’s one week delay in providing the preliminary TSD to the public, DOE believes that additional time is warranted, and that reopening the comment period until May 16, 2022, is sufficient. Therefore, DOE is reopening the comment period until May 16, 2022.

Signing Authority

This document of the Department of Energy was signed on April 29, 2022, by Kelly J. Speakes-Backman, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the

¹ See <https://www.regulations.gov/docket/EERE-2017-BT-STD-0019/comments>.

² See <https://www.regulations.gov/docket/EERE-2017-BT-STD-0019/comments>.

Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on April 29, 2022.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2022-09554 Filed 5-3-22; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE-2019-BT-STD-0036]

RIN 1904-AE82

Energy Conservation Program: Energy Conservation Standards for Consumer Boilers

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notification of availability of preliminary technical support document and request for comment.

SUMMARY: The U.S. Department of Energy (“DOE” or “the Department”) announces the availability of the preliminary analysis it has conducted for purposes of evaluating the need for amended energy conservation standards for consumer boilers, which is set forth in the Department’s preliminary technical support document (“TSD”) for this rulemaking. DOE will hold a public meeting via webinar to discuss and receive comment on its preliminary analysis. The meeting will cover the analytical framework, models, and tools used to evaluate potential standards; the results of preliminary analyses performed; potential energy conservation standard levels derived from these analyses (if DOE determines that proposed amendments are necessary); and any other relevant issues. In addition, DOE encourages written comments on these subjects.

DATES:

Comments: Written comments and information will be accepted on or before, July 5, 2022.

Meeting: DOE will hold a public meeting webinar on Thursday, June 16, 2022, from 1:00 p.m. to 4:00 p.m. See section IV, “Public Participation,” for webinar registration information, participant instructions, and information about the capabilities available to webinar participants.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at www.regulations.gov. Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE-2019-BT-STD-0036 and/or RIN 1904-AE82, by any of the following methods:

1. *Federal eRulemaking Portal:* www.regulations.gov. Follow the instructions for submitting comments.

2. *Email: ConsumerBoilers2019STD0036@ee.doe.gov.* Include docket number EERE-2019-BT-STD-0036 and/or RIN 1904-AE82 in the subject line of the message.

No telefacsimiles (“faxes”) will be accepted. For detailed instructions on submitting comments and additional information on this process, see section IV of this document.

Although DOE has routinely accepted public comment submissions through a variety of mechanisms, including postal mail and hand delivery/courier, the Department has found it necessary to make temporary modifications to the comment submission process in light of the ongoing coronavirus (COVID-19) pandemic. DOE is currently suspending receipt of public comments via postal mail and hand delivery/courier. If a commenter finds that this change poses an undue hardship, please contact Appliance Standards Program staff at (202) 586-1445 to discuss the need for alternative arrangements. Once the COVID-19 pandemic health emergency is resolved, DOE anticipates resuming all of its regular options for public comment submission, including postal mail and hand delivery/courier.

To inform interested parties and to facilitate this rulemaking process, DOE has prepared an agenda, a preliminary TSD, and briefing materials, which are available on the DOE website at: www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=32.

Docket: The docket for this activity, which includes **Federal Register** notices, comments, and other supporting documents/materials, is available for review at www.regulations.gov. All documents in the docket are listed in the www.regulations.gov index. However,

not all documents listed in the index may be publicly available, such as those containing information that is exempt from public disclosure.

The docket web page can be found at www.regulations.gov/#!docketDetail;D=EERE-2019-BT-STD-0036. The docket web page contains instructions on how to access all documents, including public comments, in the docket. See section IV for information on how to submit comments through www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Ms. Julia Hegarty, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE-5B, 1000 Independence Avenue SW, Washington, DC 20585-0121. Telephone: (240) 597-6737. Email: ApplianceStandardsQuestions@ee.doe.gov.

Mr. Eric Stas, U.S. Department of Energy, Office of the General Counsel, GC-33, 1000 Independence Avenue SW, Washington, DC 20585-0121. Telephone: (202) 586-5827. Email: Eric.Stas@hq.doe.gov.

For further information on how to submit a comment, review other public comments and the docket, or participate in the public meeting webinar, contact the Appliance and Equipment Standards Program staff at (202) 287-1445 or by email: ApplianceStandardsQuestions@ee.doe.gov.

SUPPLEMENTARY INFORMATION:

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I. Introduction

A. Authority

The Energy Policy and Conservation Act, as amended (“EPCA”),¹ Public Law 94–163 (42 U.S.C. 6291–6317, as codified), authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. Title III, Part B² of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles. (42 U.S.C. 6291–6309) These products include consumer boilers, the subject of this document. (42 U.S.C. 6292(a)(5))³

EPCA prescribed energy conservation standards for these products (42 U.S.C. 6295(f)(3)), and the statute directed DOE to conduct future rulemakings to determine whether to amend these standards. (42 U.S.C. 6295(f)(4)(C)) EPCA further provides that, not later than 6 years after the issuance of any final rule establishing or amending a standard, DOE must publish either a notification of determination that standards for the product do not need to be amended, or a notice of proposed rulemaking (“NOPR”) including new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6295(m)(1)) Not later than three years after issuance of a final determination not to amend standards, DOE must publish either a notice of determination that standards for the product do not need to be amended, or a NOPR including new proposed energy conservation standards (proceeding to a final rule, as appropriate). (42 U.S.C. 6295(m)(3)(B))

Pursuant to EPCA, any new or amended energy conservation standard must be designed to achieve the maximum improvement in energy efficiency that DOE determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) Furthermore, the new or amended standard must result in a significant conservation of energy. (42 U.S.C. 6295(o)(3)(B))

DOE is publishing this preliminary analysis to collect data and information

to inform its decision consistent with its obligations under EPCA.

B. Rulemaking Process

DOE must follow specific statutory criteria for prescribing new or amended standards for covered products, including consumer boilers. As noted, EPCA requires that any new or amended energy conservation standard prescribed by the Secretary of Energy (“Secretary”) be designed to achieve the maximum improvement in energy efficiency (or water efficiency for certain products specified by EPCA) that is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) Furthermore, DOE may not adopt any standard that would not result in the significant conservation of energy. (42 U.S.C. 6295(o)(3)(B))

Particularly in light of the climate crisis, the significance of energy savings offered by a new or amended energy conservation standard cannot be determined without knowledge of the specific circumstances surrounding a given rulemaking.⁴ For example, the United States has now rejoined the Paris Agreement on February 19, 2021. As part of that agreement, the United States has committed to reducing greenhouse gas (“GHG”) emissions in order to limit the rise in mean global temperature. As such, energy savings that reduce GHG emissions have taken on greater importance. Additionally, some covered products and equipment have most of their energy consumption occur during periods of peak energy demand. The impacts of these products on the U.S. energy infrastructure can be more pronounced than those of products with relatively constant demand. In evaluating the significance of energy savings, DOE considers differences in not only site energy use, but also primary energy and full-fuel-cycle (“FFC”) effects for different covered products and equipment when determining whether energy savings are significant. Primary energy and FFC effects include the energy consumed in electricity production (depending on load shape), in distribution and transmission, and in extracting, processing, and transporting primary fuels (*i.e.*, coal, natural gas, petroleum fuels), and, thus, present a more complete picture of the impacts of

energy conservation standards.⁵

Accordingly, DOE evaluates the significance of energy savings on a case-by-case basis.

The preliminary TSD details DOE’s analyses to estimate the amount of FFC energy savings which would be anticipated to result from technologically feasible improvements to consumer boiler efficiencies. Based on the amount of FFC savings, the corresponding reduction in emissions, and need to confront the global climate crisis, DOE has initially determined the energy savings estimated for the efficiency levels considered in this preliminary analysis are “significant” within the meaning of 42 U.S.C. 6295(o)(3)(B).

To determine whether a proposed new or amended energy conservation standard is economically justified, EPCA requires that DOE determine whether the benefits of the standard exceed its burdens by considering, to the greatest extent practicable, the following seven factors:

- (1) The economic impact of the standard on the manufacturers and consumers of the products subject to the standard;
- (2) The savings in operating costs throughout the estimated average life of the covered products in the type (or class) compared to any increase in the price, initial charges, or maintenance expenses for the covered products that are likely to result from the standard;
- (3) The total projected amount of energy (or as applicable, water) savings likely to result directly from the standard;
- (4) Any lessening of the utility or the performance of the products likely to result from the standard;
- (5) The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the standard;
- (6) The need for national energy and water conservation; and
- (7) Other factors the Secretary of Energy considers relevant.

(42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII))

DOE fulfills these and other applicable requirements by conducting a series of analyses throughout the rulemaking process. Table I.1 shows the individual analyses that are performed to satisfy each of the requirements within EPCA.

⁵ The FFC metric is discussed in DOE’s statement of policy and notice of policy amendment. 76 FR 51281 (August 18, 2011), as amended at 77 FR 49701 (August 17, 2012).

¹ All references to EPCA in this document refer to the statute as amended through the Infrastructure Investment and Jobs Act, Public Law 117–58 (Nov. 15, 2021).

² For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

³ DOE notes that consumer boilers are defined as a subcategory of covered consumer furnaces (*see* 42 U.S.C. 6291(23)).

⁴ *See* 86 FR 70892, 70901 (Dec. 13, 2021).

TABLE I.1—EPCA REQUIREMENTS AND CORRESPONDING DOE ANALYSIS

EPCA requirement	Corresponding DOE analysis
Significant Energy Savings	<ul style="list-style-type: none"> • Shipments Analysis. • National Impact Analysis. • Energy Use Analysis.
Technological Feasibility	<ul style="list-style-type: none"> • Market and Technology Assessment. • Screening Analysis. • Engineering Analysis.
Economic Justification:	
1. Economic impact on manufacturers and consumers	<ul style="list-style-type: none"> • Manufacturer Impact Analysis. • Life-Cycle Cost and Payback Period Analysis. • Life-Cycle Cost Subgroup Analysis. • Shipments Analysis.
2. Lifetime operating cost savings compared to increased cost for the product.	<ul style="list-style-type: none"> • Markups for Product Price Analysis.
3. Total projected energy savings	<ul style="list-style-type: none"> • Energy Analysis. • Life-Cycle Cost and Payback Period Analysis. • Shipments Analysis.
4. Impact on utility or performance	<ul style="list-style-type: none"> • National Impact Analysis. • Screening Analysis. • Engineering Analysis.
5. Impact of any lessening of competition	<ul style="list-style-type: none"> • Manufacturer Impact Analysis.
6. Need for national energy conservation	<ul style="list-style-type: none"> • Shipments Analysis. • National Impact Analysis.
7. Other factors the Secretary considers relevant	<ul style="list-style-type: none"> • Employment Impact Analysis. • Utility Impact Analysis. • Emissions Analysis. • Monetization of Emission Reductions Benefits.⁶ • Regulatory Impact Analysis.

Further, EPCA establishes a rebuttable presumption that a standard is economically justified if the Secretary finds that the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the energy savings during the first year that the consumer will receive as a result of the standard, as calculated under the applicable test procedure. (42 U.S.C. 6295(o)(2)(B)(iii))

EPCA also contains what is known as an “anti-backsliding” provision, which prevents the Secretary from prescribing any amended standard that either increases the maximum allowable energy use or decreases the minimum required energy efficiency of a covered product. (42 U.S.C. 6295(o)(1)) Also, the

Secretary may not prescribe an amended or new standard if interested persons have established by a preponderance of the evidence that the standard is likely to result in the unavailability in the United States in any covered product type (or class) of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States. (42 U.S.C. 6295(o)(4))

Additionally, EPCA specifies requirements when promulgating an energy conservation standard for a covered product that has two or more subcategories. DOE must specify a different standard level for a type or class of product that has the same function or intended use, if DOE determines that products within such group: (A) Consume a different kind of energy from that consumed by other covered products within such type (or class); or (B) have a capacity or other performance-related feature which other products within such type (or class) do not have and such feature justifies a higher or lower standard. (42 U.S.C. 6295(q)(1)) In determining whether a performance-related feature justifies a different standard for a group of products, DOE must consider such factors as the utility to the consumer of the feature and other factors DOE deems appropriate. *Id.* Any rule prescribing such a standard must include an explanation of the basis on which such

higher or lower level was established. (42 U.S.C. 6295(q)(2))

Finally, pursuant to the amendments to EPCA contained in the Energy Independence and Security Act of 2007 (“EISA 2007”), Public Law 110–140, any final rule for new or amended energy conservation standards promulgated after July 1, 2010, is required to address standby mode and off mode energy use. (42 U.S.C. 6295(gg)(3)) Specifically, when DOE adopts a standard for a covered product after that date, it must, if justified by the criteria for adoption of standards under EPCA (42 U.S.C. 6295(o)), incorporate standby mode and off mode energy use into a single standard, or, if that is not feasible, adopt a separate standard for such energy use for that product. (42 U.S.C. 6295(gg)(3)(A)-(B)) DOE’s current test procedures for consumer boilers address standby mode and off mode energy use. In this rulemaking, DOE intends to consider such energy use in any amended energy conservation standards it adopts in the final rule.

Before proposing a standard, DOE typically seeks public input on the analytical framework, models, and tools that DOE intends to use to evaluate potential standards for the product at issue and the results of preliminary analyses DOE performed for the product.

DOE is examining whether to amend the current energy conservation standards for consumer boilers pursuant

⁶On March 16, 2022, the Fifth Circuit Court of Appeals (No. 22–30087) granted the Federal government’s emergency motion for stay pending appeal of the February 11, 2022, preliminary injunction issued in *Louisiana v. Biden*, No. 21–cv–1074–JDC–KK (W.D. La.). As a result of the Fifth Circuit’s order, the preliminary injunction is no longer in effect, pending resolution of the federal government’s appeal of that injunction or a further court order. Among other things, the preliminary injunction enjoined the defendants in that case from “adopting, employing, treating as binding, or relying upon” the interim estimates of the social cost of greenhouse gases—which were issued by the Interagency Working Group on the Social Cost of Greenhouse Gases on February 26, 2021—to monetize the benefits of reducing greenhouse gas emissions. In the absence of further intervening court orders, DOE will revert to its approach prior to the injunction and present monetized benefits where appropriate and permissible under law.

to its obligations under EPCA. This document announces the availability of the preliminary TSD, which details the preliminary analyses and summarizes the preliminary results of DOE's analyses. In addition, DOE is announcing a public meeting webinar to solicit feedback from interested parties on its analytical framework, models, and preliminary results.

C. Deviations From Appendix A

In accordance with section 3(a) of 10 CFR part 430, subpart C, appendix A ("appendix A"), "Procedures, Interpretations, and Policies for Consideration of New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Certain Commercial/Industrial Equipment," DOE notes that it is deviating from the provision in appendix A regarding the pre-NOPR stages for an energy conservation standards rulemaking. See 86 FR 70892 (Dec. 13, 2021). Section 6(a)(2) of appendix A states that if the Department determines it is appropriate to proceed with a rulemaking, the preliminary stages of a rulemaking to issue or amend an energy conservation standard that DOE will undertake will be a framework document and preliminary analysis, or an advance notice of proposed rulemaking.

DOE is opting to deviate from this step by publishing a preliminary analysis without a framework document. A framework document is intended to introduce and summarize the various analyses DOE conducts

during the rulemaking process and requests initial feedback from interested parties. As discussed further in section II.B of this document, prior to this notification of the preliminary analysis, DOE published an early assessment review and request for information ("RFI") in the **Federal Register** in which DOE identified and sought comment on the analyses conducted in support of the most recent energy conservation standards rulemakings for consumer boilers. 86 FR 15804 (March 25, 2021; "March 2021 Early Assessment Review RFI"). In the March 2021 Early Assessment Review RFI, DOE sought data and information as to whether any new or amended rule would be cost-effective, economically justified, technologically feasible, or would result in a significant savings of energy. *Id.* DOE sought such data and information to assist in its consideration of whether (and if so, how) to amend the standards for consumer boilers. *Id.* Further, DOE provided an overview of the analysis it would use to evaluate new or amended energy conservation standards, including references to and requests for comment on the analyses conducted as part of the most recent energy conservation standards rulemakings. *Id.* As DOE is intending to rely on substantively the same analytical methods as in the most recent rulemaking, publication of a framework document would be largely redundant with the published March 2021 Early Assessment Review RFI. As such, DOE is not publishing a framework document.

Section 6(d)(2) of appendix A provides that the length of the public comment period for pre-NOPR rulemaking documents will vary depending upon the circumstances of the particular rulemaking, but will not be less than 75 calendar days. For this preliminary analysis, DOE has opted to provide a 60-day comment period. As stated, DOE requested comment in the March 2021 Early Assessment Review RFI on the previous energy conservation standards analyses. For this preliminary analysis, DOE has relied on many of the same analytical assumptions and approaches as used in the previous rulemaking and has determined that a 60-day comment period in conjunction with the prior comment period for the March 2021 Early Assessment Review RFI provides sufficient time for interested parties to review the preliminary analysis and develop comments.

II. Background

A. Current Standards

In a final rule published in the **Federal Register** on January 15, 2016 ("January 2016 Final Rule"), DOE prescribed the current energy conservation standards for consumer boilers, which are applicable to such products manufactured on and after January 15, 2021. 81 FR 2320, 2416–2417. These standards are set forth in the Code of Federal Regulations (CFR) at 10 CFR 430.32(e)(2) and are repeated here in Table II.1.

TABLE II.1—FEDERAL ENERGY CONSERVATION STANDARDS FOR CONSUMER BOILERS *

Product class	AFUE (percent) **	P _{W,SB} (watts) †	P _{W,OFF} (watts) †	Design requirements
Gas-fired Hot Water ...	84	9	9	Constant-burning pilot not permitted. Automatic means for adjusting water temperature required (except for boilers equipped with tankless domestic water heating coils).
Gas-fired Steam	82	8	8	Constant-burning pilot not permitted.
Oil-fired Hot Water	86	11	11	Automatic means for adjusting temperature required (except for boilers equipped with tankless domestic water heating coils).
Oil-fired Steam	85	11	11	None.
Electric Hot Water	None	8	8	Automatic means for adjusting temperature required (except for boilers equipped with tankless domestic water heating coils).
Electric Steam	None	8	8	None.

* A boiler that is manufactured to operate without any need for electricity or any electric connection, electric gauges, electric pumps, electric wires, or electric devices is not required to meet the AFUE or design requirements. Instead, such boilers must meet a minimum AFUE of 80 percent (for all classes except gas steam), and 75 percent for gas steam.

** AFUE stands for Annual Fuel Utilization Efficiency, as determined in 10 CFR 430.23(n)(2).

† P_{W,SB} and P_{W,OFF} stand for standby mode power consumption and off mode power consumption, respectively.

B. Current Process

On March 25, 2021, DOE published a notice in the **Federal Register** through a request for information (RFI) that it was initiating an early assessment review to determine whether any new or amended

standards would satisfy the relevant requirements of EPCA for a new or amended energy conservation standard for consumer boilers. 86 FR 15804. Specifically, through the published notice and RFI, DOE sought data and

information that could enable the agency to determine whether DOE should propose a "no new standard" determination because a more-stringent standard: (1) Would not result in a significant savings of energy; (2) is not

technologically feasible; (3) is not economically justified; or (4) any combination of foregoing. *Id.*

Comments received to date as part of the current process have helped DOE identify and resolve issues related to development of the preliminary analyses. Chapter 2 of the preliminary TSD summarizes and addresses the comments received.

III. Summary of the Analyses Performed by DOE

For the products covered in this preliminary analysis, DOE conducted in-depth technical analyses in the following areas: (1) Engineering; (2) markups to determine product price; (3) energy use; (4) life-cycle cost (“LCC”) and payback period (“PBP”); and (5) national impacts. The preliminary TSD that presents the methodology and results of each of these analyses is available at: www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=45.

DOE also conducted, and has included in the preliminary TSD, several other analyses that support the major analyses or are preliminary analyses that will be expanded if DOE determines that a NOPR is warranted to propose amended energy conservation standards. These analyses include: (1) The market and technology assessment; (2) the screening analysis, which contributes to the engineering analysis; and (3) the shipments analysis, which contributes to the LCC and PBP analysis and the national impact analysis (“NIA”). In addition to these analyses, DOE has begun preliminary work on the manufacturer impact analysis and has identified the methods to be used for the consumer subgroup analysis, the emissions analysis, the employment impact analysis, the regulatory impact analysis, and the utility impact analysis. DOE will expand on these analyses in the NOPR, should one be issued.

A. Market and Technology Assessment

DOE develops information in the market and technology assessment that provides an overall picture of the market for the products concerned, including general characteristics of the products, the industry structure, manufacturers, market characteristics, and technologies used in the products. This activity includes both quantitative and qualitative assessments, based primarily on publicly-available information. The subjects addressed in the market and technology assessment include: (1) A determination of the scope of the rulemaking and product classes, (2) manufacturers and industry structure, (3) existing efficiency

programs, (4) shipments information, (5) market and industry trends, and (6) technologies or design options that could improve the energy efficiency of the product.

DOE would note here a number of recent statutory interpretations that had bearing on the market and technology assessment for consumer boilers. On January 15, 2021, in response to a petition for rulemaking⁷ submitted by the American Public Gas Association, Spire, Inc., the Natural Gas Supply Association, the American Gas Association, and the National Propane Gas Association, DOE published a final interpretive rule (“the January 2021 Final Interpretive Rule”) in the **Federal Register** which determined that, in the context of residential furnaces, commercial water heaters, and similarly-situated products/equipment (which would include consumer boilers), use of non-condensing technology (and associated venting) constitute a performance-related “feature” under EPCA that cannot be eliminated through adoption of an energy conservation standard. 86 FR 4776.

In the March 2021 RFI, DOE sought information that would allow the agency to evaluate non-condensing technology (and the associated venting) consistent with the January 2021 Final Interpretive Rule, and whether separate product classes for non-condensing and condensing boilers is warranted. 86 FR 15804, 15805–15806 (March 25, 2021).

However, DOE has subsequently published a final interpretive rule that returns to the previous and long-standing interpretation (in effect prior to the January 15, 2021, final interpretive rule), under which the technology used to supply heated air or hot water is not a performance-related “feature” that provides a distinct consumer utility under EPCA. 86 FR 73947 (Dec. 29, 2021).

Accordingly, in conducting this preliminary analysis, DOE did not consider condensing technology to constitute a separate product class for consumer boilers.

See chapter 3 of the preliminary TSD for further discussion of the market and technology assessment.

B. Screening Analysis

DOE uses the following five screening criteria to determine which technology options are suitable for further consideration in an energy conservation standards rulemaking:

⁷ After receipt, DOE published the petition for rulemaking in the **Federal Register** for public comment. See 83 FR 54883 (Nov. 1, 2018).

(1) Technological feasibility.

Technologies that are not incorporated in commercial products or in working prototypes will not be considered further.

(2) *Practicability to manufacture, install, and service.* If it is determined that mass production and reliable installation and servicing of a technology in commercial products could not be achieved on the scale necessary to serve the relevant market at the time of the projected compliance date of the standard, then that technology will not be considered further.

(3) *Impacts on product utility or product availability.* If it is determined that a technology would have a significant adverse impact on the utility of the product for significant subgroups of consumers or would result in the unavailability of any covered product type with performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as products generally available in the United States at the time, it will not be considered further.

(4) *Adverse impacts on health or safety.* If it is determined that a technology would have significant adverse impacts on health or safety, it will not be considered further.

(5) *Unique-pathway proprietary technologies.* If a design option utilizes proprietary technology that represents a unique pathway to achieving a given efficiency level, that technology will not be considered further due to the potential for monopolistic concerns.

10 CFR part 430, subpart C, appendix A, sections 6(b)(3) and 7(b).

If DOE determines that a technology, or a combination of technologies, fails to meet one or more of the listed five criteria, it will be excluded from further consideration in the engineering analysis.

See chapter 4 of the preliminary TSD for further discussion of the screening analysis.

C. Engineering Analysis

The purpose of the engineering analysis is to establish the relationship between the efficiency and cost of consumer boilers. There are two elements to consider in the engineering analysis: (1) The selection of efficiency levels to analyze (*i.e.*, the “efficiency analysis”) and (2) the determination of product cost at each efficiency level (*i.e.*, the “cost analysis”). In determining the performance of higher-efficiency products, DOE considers technologies and design option combinations not eliminated by the screening analysis.

For each product class, DOE estimates the manufacturer production cost (“MPC”) for the baseline, as well as higher efficiency levels. The output of the engineering analysis is a set of cost-efficiency “curves” that are used in downstream analyses (*i.e.*, the LCC and PBP analyses and the NIA).

DOE converts the MPC to the manufacturer selling price (“MSP”) by applying a manufacturer markup. The MSP is the price the manufacturer charges its first customer when selling into the consumer boilers distribution channels. The manufacturer markup accounts for manufacturer non-production costs and profit margin. DOE developed the manufacturer markup by examining publicly-available financial information for manufacturers of the covered product.

See chapter 5 of the preliminary TSD for additional detail on the engineering analysis. See chapter 12 of the preliminary TSD for additional detail on the manufacturer markup.

D. Markups Analysis

The markups analysis develops appropriate markups (*e.g.*, retailer markups, distributor markups, contractor markups) in the distribution chain and sales taxes to convert MSP estimates derived in the engineering analysis to consumer prices, which are then used in the LCC and PBP analysis. At each step in the distribution channel, companies mark up the price of the product to cover business costs and profit margin.

DOE developed baseline and incremental markups for each actor in the distribution chain for consumer boilers. Baseline markups are applied to the price of products with baseline efficiency, while incremental markups are applied to the difference in price between baseline and higher-efficiency models (the incremental cost increase). The incremental markup is typically less than the baseline markup and is designed to maintain similar per-unit operating profit before and after new or amended standards.⁸

Chapter 6 of the preliminary TSD provides details on DOE’s development of markups for consumer boilers.

E. Energy Use Analysis

The purpose of the energy use analysis is to determine the annual

⁸Because the projected price of standards-compliant products is typically higher than the price of baseline products, using the same markup for the incremental cost and the baseline cost would result in higher per-unit operating profit. While such an outcome is possible, DOE maintains that in markets that are reasonably competitive, it is unlikely that standards would lead to a sustainable increase in profitability in the long run.

energy consumption of consumer boilers at different efficiencies in representative U.S. single-family homes, multi-family residences, and commercial buildings, and to assess the energy savings potential of increased consumer boiler efficiency. The energy use analysis estimates the range of energy use of consumer boilers in the field (*i.e.*, as they are actually used by consumers). In addition, the energy use analysis provides the basis for other analyses DOE performed, particularly assessments of the energy savings and the savings in consumer operating costs that could result from adoption of amended or new energy conservation standards.

Chapter 7 of the preliminary TSD addresses the energy use analysis.

F. Life-Cycle Cost and Payback Period Analyses

The effect of new or amended energy conservation standards on individual consumers usually involves a reduction in operating cost and an increase in purchase cost. DOE used the following two metrics to measure consumer impacts:

- The LCC is the total consumer expense of an appliance or product over the life of that product, consisting of total installed cost (manufacturer selling price, distribution chain markups, sales tax, and installation costs) plus operating costs (expenses for energy use, maintenance, and repair). To compute the operating costs, DOE discounts future operating costs to the time of purchase and sums them over the lifetime of the product.
- The PBP is the estimated amount of time (in years) it takes consumers to recover the increased purchase cost (including installation) of a more-efficient product through lower operating costs. DOE calculates the PBP by dividing the change in purchase cost at higher efficiency levels by the change in annual operating cost for the year that amended or new standards are assumed to take effect.

Chapter 8 of the preliminary TSD addresses the LCC and PBP analyses.

G. National Impact Analysis

The NIA estimates the national energy savings (“NES”) and the net present value (“NPV”) of total consumer costs and savings expected to result from amended standards at specific efficiency levels.⁹ DOE calculates the NES and NPV for the potential standard levels considered based on projections of annual product shipments, along with

⁹The NIA accounts for impacts in the 50 States and U.S. territories.

the annual energy consumption and total installed cost data from the energy use and LCC analyses. For the present analysis, DOE projected the energy savings, operating cost savings, product costs, and NPV of consumer benefits over the lifetime of consumer boilers sold from 2030 through 2059.

DOE evaluates the impacts of new or amended standards by comparing a case without such standards (“no-new-standards case”) with standards-case projections. The no-new-standards case characterizes energy use and consumer costs for each product class in the absence of new or amended energy conservation standards. For this projection, DOE considers historical trends in efficiency and various forces that are likely to affect the mix of efficiencies over time. DOE compares the no-new-standards case with projections characterizing the market for each product class if DOE adopted new or amended standards at specific energy efficiency levels for that class. For each efficiency level, DOE considers how a given standard would likely affect the market shares of product with efficiencies greater than the standard.

For the NIA, DOE uses a spreadsheet model to calculate the energy savings and the national consumer costs and savings from each efficiency level. Interested parties can review DOE’s analyses by changing various input quantities within the spreadsheet. The NIA spreadsheet model uses typical values (as opposed to probability distributions) as inputs. Critical inputs to this analysis include shipments projections, estimated product lifetimes, product installed costs and operating costs, product annual energy consumption, the base case efficiency projection, and discount rates.

DOE estimates a combined total of approximately 0.70 quads of potential full-fuel-cycle (FFC) energy savings at the max-tech efficiency levels for consumer boilers. Combined potential FFC energy savings at Efficiency Level (EL) 1 for all consumer boiler product classes analyzed are estimated to be approximately 0.09 quads.

Chapter 10 of the preliminary TSD addresses the NIA.

IV. Public Participation

DOE invites public engagement in this process through participation in the webinar and submission of written comments, data, and information. After the webinar and the closing of the comment period, DOE will consider all timely-submitted comments and additional information obtained from interested parties, as well as information obtained through further analyses.

Following such consideration, the Department will publish either a determination that the energy conservation standards for consumer boilers need not be amended or a NOPR proposing to amend those standards. The NOPR, should one be issued, would include proposed energy conservation standards for the products covered by this rulemaking, and members of the public would be given an opportunity to submit written and oral comments on the proposed standards.

A. Participation in the Public Meeting Webinar

The time and date for the webinar meeting are listed in the **DATES** section at the beginning of this document. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE's website: www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=45. Participants are responsible for ensuring their systems are compatible with the webinar software.

B. Procedure for Submitting Prepared General Statements for Distribution

Any person who has an interest in the topics addressed in this document, or who is representative of a group or class of persons that has an interest in these issues, may request an opportunity to make an oral presentation at the public meeting webinar. Such persons may submit requests to speak via email to the Appliance and Equipment Standards Program:

ApplianceStandardsQuestions@ee.doe.gov. Persons who wish to speak should include with their request a computer file in WordPerfect, Microsoft Word, PDF, or text (ASCII) file format that briefly describes the nature of their interest in this rulemaking and the topics they wish to discuss. Such persons should also provide a daytime telephone number where they can be reached.

Persons requesting to speak should briefly describe the nature of their interest in this rulemaking and provide a telephone number for contact. DOE requests persons selected to make an oral presentation to submit an advance copy of their statements at least two weeks before the public meeting webinar. At its discretion, DOE may permit persons who cannot supply an advance copy of their statement to participate, if those persons have made advance alternative arrangements with the Building Technologies Office. As necessary, requests to give an oral

presentation should ask for such alternative arrangements.

C. Conduct of the Public Meeting Webinar

DOE will designate a DOE official to preside at the public meeting webinar and may also use a professional facilitator to aid discussion. The meeting will not be a judicial or evidentiary-type public hearing, but DOE will conduct it in accordance with section 336 of EPCA (42 U.S.C. 6306). A court reporter will be present to record the proceedings and prepare a transcript. DOE reserves the right to schedule the order of presentations and to establish the procedures governing the conduct of the public meeting webinar. There shall not be discussion of proprietary information, costs or prices, market share, or other commercial matters regulated by U.S. anti-trust laws. After the public meeting webinar and until the end of the comment period, interested parties may submit further comments on the proceedings and any aspect of the rulemaking.

The public meeting webinar will be conducted in an informal, conference style. DOE will present a general overview of the topics addressed in this rulemaking, allow time for prepared general statements by participants, and encourage all interested parties to share their views on issues affecting this rulemaking. Each participant will be allowed to make a general statement (within time limits determined by DOE), before the discussion of specific topics. DOE will allow, as time permits, other participants to comment briefly on any general statements.

At the end of all prepared statements on a topic, DOE will permit participants to clarify their statements briefly and comment on statements made by others. Participants should be prepared to answer questions by DOE and by other participants concerning these issues. DOE representatives may also ask questions of participants concerning other matters relevant to this rulemaking. The official conducting the public meeting webinar will accept additional comments or questions from those attending, as time permits. The presiding official will announce any further procedural rules or modification of the above procedures that may be needed for the proper conduct of the public meeting webinar.

A transcript of the public meeting webinar will be included in the docket, which can be viewed as described in the *Docket* section at the beginning of this document. In addition, any person may

buy a copy of the transcript from the transcribing reporter.

D. Submission of Comments

DOE invites all interested parties, regardless of whether they participate in the public meeting webinar, to submit in writing no later than the date provided in the **DATES** section at the beginning of this document, comments, data, and information on matters addressed in this notification and on other matters relevant to DOE's consideration of potential amended energy conservation standards for consumer boilers. Interested parties may submit comments, data, and other information using any of the methods described in the **ADDRESSES** section at the beginning of this document.

Submitting comments via www.regulations.gov. The www.regulations.gov web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment itself or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. If this instruction is followed, persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to www.regulations.gov information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information ("CBI")). Comments submitted through www.regulations.gov cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through www.regulations.gov before

posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that www.regulations.gov provides after you have successfully uploaded your comment.

Submitting comments via email.

Comments and documents submitted via email also will be posted to www.regulations.gov. If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. No telefacsimiles (faxes) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, that are written in English, and that are free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information.

Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email two well-marked copies: One copy of the document marked "confidential" including all the information believed to be confidential, and one copy of the document marked "non-confidential" with the information believed to be confidential deleted. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information

provided in the comments (except information deemed to be exempt from public disclosure).

V. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notification of availability of the preliminary technical support document and request for comment.

Signing Authority

This document of the Department of Energy was signed on April 29, 2022, by Kelly J. Speakes-Backman, Principal Deputy Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE **Federal Register Liaison Officer** has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on April 29, 2022.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2022-09548 Filed 5-3-22; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1162 and 1166

[Docket Nos. FDA-2021-N-1349 and FDA-2021-N-1309]

Proposed Regulations To Establish Tobacco Product Standards for Menthol in Cigarettes and Characterizing Flavors in Cigars: Listening Sessions; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notification of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following virtual listening sessions entitled "Proposed Regulations to Establish Tobacco

Product Standards for Menthol in Cigarettes and Characterizing Flavors in Cigars: Listening Sessions." The purpose of the listening sessions is to discuss two proposed regulations that are published elsewhere in this issue of the **Federal Register**, a tobacco product standard that would prohibit menthol as a characterizing flavor in cigarettes ("Tobacco Product Standard for Menthol in Cigarettes"; Docket No. FDA-2021-N-1349) and a tobacco product standard that would prohibit characterizing flavors (other than tobacco) in all cigars ("Tobacco Product Standard for Characterizing Flavors in Cigars"; Docket No. FDA-2021-N-1309). FDA will provide information on the proposed rules to the public and provide the public an opportunity to provide open public comment.

DATES: The listening sessions will be held on two separate days on June 13 and 15, 2022. All requests to make open public comment must be received by June 6, 2022, at 11:59 p.m. Eastern Time.

FDA reminds the public that, in addition to providing comments through these meetings, commenters may submit either electronic or written comments on one or both of the proposed rules set out in the **SUMMARY** by July 5, 2022. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Additional details, such as the time of the listening sessions and registration information, will be posted soon at <https://www.fda.gov/tobacco-products>. The listening sessions will be held virtually and more information will be posted here: <https://www.fda.gov/tobacco-products>.

You may submit written comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 5, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-N-1349 for "Tobacco Product Standard for Menthol in Cigarettes" and/or Docket No. FDA-2021-N-1309 for "Tobacco Product Standard for Characterizing Flavors in Cigars." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information

redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the dockets to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: May Nelson, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 877-287-1373, CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Published elsewhere in this issue of the **Federal Register**, FDA is proposing two product standards: (1) A tobacco product standard that would prohibit menthol as a characterizing flavor in cigarettes ("Tobacco Product Standard for Menthol in Cigarettes"; Docket No. FDA-2021-N-1349) and (2) a tobacco product standard that would prohibit characterizing flavors (other than tobacco) in all cigars ("Tobacco Product Standard for Characterizing Flavors in Cigars"; Docket No. FDA-2021-N-1309). Characterizing flavors in tobacco products, including menthol, enhance taste and make them easier to use. Menthol's flavor and sensory effects reduce the harshness of cigarette smoking and make it easier for new users, particularly youth and young adults, to continue experimenting and progress to regular use. Characterizing flavors in cigars, such as strawberry, grape, cocoa, and fruit punch, increase appeal and make the cigars easier to use, particularly among youth and young adults. FDA is proposing these two tobacco product standards because they

would significantly reduce disease and death from combusted tobacco product use, the leading cause of preventable death in the United States.

There are over 18.5 million menthol cigarette smokers ages 12 and older in the United States. The proposed "Tobacco Product Standard for Menthol in Cigarettes" rule would reduce the appeal of cigarettes, particularly to youth and young adults, and thereby decrease the likelihood that nonusers who would otherwise experiment with menthol cigarettes would progress to regular smoking. In addition, this proposed tobacco product standard would improve the health and reduce the mortality risk of current menthol cigarette smokers by decreasing cigarette consumption and increasing the likelihood of cessation.

Over a half million youth in the United States use flavored cigars. The proposed "Tobacco Product Standard for Characterizing Flavors in Cigars" rule would reduce the appeal of cigars, particularly to youth and young adults, and thereby decrease the likelihood of experimentation, development of nicotine dependence, and progression to regular use. This proposed standard also would improve public health by increasing the likelihood that existing users of flavored cigars would quit.

FDA is issuing both proposed product standards to reduce the tobacco-related death and disease associated with menthol cigarette and flavored cigar use. The proposed standards also are expected to reduce tobacco-related health disparities and advance health equity.

II. Topics for Discussion at the Listening Sessions

The listening sessions will provide the public an opportunity to provide open public comment on the proposed product standard rules. Both proposed rules will be discussed at each session. Although the public can submit their questions and comments directly to the dockets, the listening sessions will enable FDA to share public information (*i.e.*, what is contained in the rules and related documents) and facilitate comment on the proposed rules.

After introductions, FDA will begin each listening session with an overview of both proposed rules. Then the registered speakers will have approximately 5 minutes each to share their comments on any topics related to the product standards. FDA is particularly interested in the areas where we specifically requested comment in the proposed rules and the associated preliminary regulatory impact analyses.

III. Participating in the Listening Sessions

Registration: To register to attend the free listening sessions, please visit the following website: <https://www.fda.gov/tobacco-products>. Registration information will be posted soon.

Live closed captioning will be provided during the listening sessions. Additional information on requests for special accommodations due to a disability will be provided during registration.

Requests to Provide Open Public Comment: During online registration you may indicate if you wish to make open public comments during the listening sessions. All requests to make open public comment must be received by June 6, 2022, at 11:59 p.m. Eastern Time. We will do our best to accommodate requests to make public comments. We are seeking to have a broad representation of ideas and perspectives presented at the meeting. FDA is especially interested to hear from those individuals or communities who may be less likely or less able to provide formal written comments through the standard process of docket submission. Individuals and organizations with common interests are urged to consolidate or coordinate their comments and request time for a joint presentation. FDA will determine the approximate time open public comments are to be provided and will notify all registrants who requested to make public comment ahead of the listening session. FDA will not accept presentation materials for the listening sessions. Instead, any materials can be submitted to the respective docket noted in the “Docket” section of this document before the end of the comment period.

Transcripts: Please be advised that as soon as transcripts of the listening sessions are available, they will be accessible at <https://www.regulations.gov>. They may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcripts and recordings will also be available on the internet at <https://www.fda.gov/tobacco-products>.

Dated: April 26, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-09302 Filed 4-28-22; 11:15 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2022–0056]

RIN 1625–AA08

Special Local Regulation: Pompano Race Weekend, Pompano Beach, FL

AGENCY: Coast Guard, Homeland Security (DHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is establishing a temporary special local regulation (SLR) on certain navigable waters of the Atlantic Ocean off Pompano Beach, FL, in connection with the Pompano Race Weekend event. The SLR is needed to protect personnel, vessels, and the marine environment from potential hazards associated with the high speed jet ski race. Entry of vessels or persons into the regulated area is prohibited unless specifically authorized by the Captain of the Port (COTP) Miami. We invite your comments on this proposed rulemaking. **DATES:** Comments and related material must be received by the Coast Guard on or before June 3, 2022.

ADDRESSES: You may submit comments identified by docket number USCG–2022–0056 using the Federal Decision Making Portal at <https://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email LTJG Benjamin Adrien, Sector Miami Waterways Management Division, U.S. Coast Guard at 305–535–4307 or Benjamin.D.Adrien@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

On January 24th, 2022, the National Watersports Association Racing organization notified the Coast Guard that it will be conducting a high speed jet ski race from 9 a.m. to 6 p.m. on June

25, 2022, and June 26, 2022. The race will be conducted off the beach in Pompano Beach, FL. The race will consist of fifteen high speed personal watercraft (jet ski) racing within a pre-designated course.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within 500 feet of the designated race course before, during, and after the scheduled event. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70041.

III. Discussion of Proposed Rule

The COTP is proposing to establish a temporary special local regulation (SLR) from 9 a.m. until 6 p.m. on June 25, 2022, and June 26, 2022. The SLR would cover certain navigable waters of the Atlantic Ocean off Pompano Beach, FL. The duration of the SLR is intended to protect personnel, vessels, and the marine environment in these navigable waters during the high speed jet ski race. The temporary SLR would prohibit all persons and vessels, except those persons and vessels participating in the race, from entering, transiting through, anchoring in, or remaining within the area unless authorized by the COTP Miami or a designated representative. Persons and vessels may request authorization to enter, transit through, anchor in, or remain within the race area by contacting the COTP Miami by telephone at (305) 535–4300, or a designated representative via VHF radio on channel 16. If authorization to enter, transit through, anchor in, or remain within the race area is granted by the COTP Miami or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the COTP Miami or a designated representative. The Coast Guard would provide notice of the special local regulation by a Broadcast Notice to Mariners, and on-scene designated representatives. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory

approaches that maximize net benefits. This NPRM has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the following reasons: (1) The temporary special local regulation (SLR) will be enforced for approximately 9 hours per day; a total of 18 hours; (2) although persons and vessels will not be able to enter, transit through, anchor in, or remain within the regulated area, without authorization from the COTP Miami or a designated representative, they may operate in the surrounding area during the enforcement period; (3) persons and vessels may still enter, transit through, anchor in, or remain within the regulated area during the enforcement period if authorized by the COTP Miami or a designated representative; and (4) the Coast Guard will provide advance notification of the temporary SLR to the local maritime community through the Local Notice to Mariners and Broadcast Notice to Mariners via VHF–FM.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the proposed rule would affect your small

business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132 (Federalism), if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the potential effects of this proposed rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland

Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a temporary SLR lasting approximately 9 hours on two separate days that will prohibit entry of persons or vessels during the Pompano Race Weekend event. Normally such actions are categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A preliminary Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision Making Portal at <https://www.regulations.gov>. To do so, go to <https://www.regulations.gov>, type USCG–2022–0056 in the search box and click “Search.” Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using <https://www.regulations.gov>, call or email the person in the **FOR FURTHER INFORMATION**

CONTACT section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select “Supporting & Related Material” in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the <https://www.regulations.gov> Frequently Asked Questions web page. We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to <https://www.regulations.gov> will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS’s eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. Add § 100.T799–0056 to read as follows:

§ 100.T799–0056 Special Local Regulation: Pompano Race Weekend; Atlantic Ocean, Pompano Beach, FL.

(a) *Location.* The following regulated area is established as a special local regulation in the Atlantic Ocean; Pompano Beach, FL. Coordinates are based on North American Datum 1983.

(1) *Regulated area.* All navigable waters of the Atlantic Ocean encompassed within the following points: Commence at Point A in position 26°13′54″ N, 080°05′18″ W; thence east to Point B in position 26°13′54″ N, 080°05′07″ W; thence north to Point C in position 26°14′07″ N, 080°05′07″ W; thence west to Point D in position 26°14′07″ N, 080°05′16″ W; thence southwest to Point A.

(2) [Reserved]

(b) *Definitions.* (1) The term *designated representative* means Coast

Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, State, and Local officers designated by or assisting the Captain of the Port (COTP) Miami in the enforcement of the regulated areas.

(2) The term *Patrol Commander* means a commissioned, warrant, or petty officer of the Coast Guard who has been designated by the respective Coast Guard Sector Commander to enforce this section.

(3) The term *spectators* means all persons and vessels not registered with the event sponsor as participants or official patrol vessels.

(c) *Regulations.* (1) All non-participant vessels or persons are prohibited from entering, transiting, anchoring in, or remaining within the regulated area unless authorized by the COTP or a designated representative.

(2) Persons and vessels desiring to enter, transit, anchor in, or remain within the regulated area may contact the COTP Miami by telephone at (305) 535–4472 or a designated representative via VHF–FM radio on channel 16, to request authorization. If authorization is granted, all persons and vessels receiving such authorization must comply with the instructions of the COTP Miami or a designated representative.

(3) The Coast Guard will provide notice of the regulated area through Broadcast Notice to Mariners via VHF–FM channel 16, on-scene designated representatives, and Local Notice to Mariners.

(d) *Enforcement period.* This section will be enforced from 9 a.m. until 6 p.m. on June 25, 2022, and June 26, 2022.

Dated: April 28, 2022.

J.F. Burdian,

Captain, U.S. Coast Guard, Captain of the Port Miami.

[FR Doc. 2022–09500 Filed 5–3–22; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2022–0164]

RIN 1625–AA08

Special Local Regulation: Riviera Race Weekend, Riviera Beach, FL

AGENCY: Coast Guard, Homeland Security (DHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is establishing a temporary special local regulation (SLR) on certain navigable waters of the Atlantic Ocean off Riviera Beach, FL, in connection with the Riviera Race Weekend event. The SLR is needed to protect personnel, vessels, and the marine environment from potential hazards associated with the high speed jet ski race. Entry of vessels or persons into the regulated area is prohibited unless specifically authorized by the Captain of the Port (COTP) Miami. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before June 3, 2022.

ADDRESSES: You may submit comments identified by docket number USCG–2022–0164 using the Federal Decision Making Portal at <https://www.regulations.gov>. See the “Public Participation and Request for Comments” portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email LTJG Benjamin Adrien, Sector Miami Waterways Management Division, U.S. Coast Guard at 305–535–4307 or Benjamin.D.Adrien@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

On February 17th, 2022, the National Watersports Association Racing organization notified the Coast Guard that it will be conducting a high speed jet ski race from 9 a.m. to 6 p.m. on June 4, 2022, and June 5, 2022. The race will be conducted off the beach in Riviera Beach, FL. The race will consist of fifteen high speed personal watercraft (jet ski) racing within a pre designated course.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within 500 feet of the designated race course before, during, and after the scheduled event. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034.

III. Discussion of Proposed Rule

The COTP is proposing to establish a temporary SLR from 9 a.m. until 6 p.m.

on June 4, 2022, and 5, 2022. The SLR would cover certain navigable waters of the Atlantic Ocean off Riviera Beach, FL. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters during the high speed jet ski race. The temporary SLR would prohibit all persons and vessels, except those persons and vessels participating in the race, from entering, transiting through, anchoring in, or remaining within the area unless authorized by the COTP Miami or a designated representative. Persons and vessels may request authorization to enter, transit through, anchor in, or remain within the race area by contacting the COTP Miami by telephone at (305) 535-4300, or a designated representative via VHF radio on channel 16. If authorization to enter, transit through, anchor in, or remain within the race area is granted by the COTP Miami or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the COTP Miami or a designated representative. The Coast Guard would provide notice of the special local regulation by a Broadcast Notice to Mariners, and on-scene designated representatives. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This NPRM has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the following reasons: (1) The temporary special local regulation (SLR) will be enforced for approximately 9 hours per day; a total of 18 hours; (2) although persons and vessels will not be able to enter, transit through, anchor in, or remain within the regulated area, without authorization from the COTP Miami or a designated representative, they may operate in the

surrounding area during the enforcement period; (3) persons and vessels may still enter, transit through, anchor in, or remain within the regulated area during the enforcement period if authorized by the COTP Miami or a designated representative; and (4) the Coast Guard will provide advance notification of the temporary (SLR) to the local maritime community through the Local Notice to Mariners and Broadcast Notice to Mariners via VHF-FM.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132 (Federalism), if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the potential effects of this proposed rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a temporary SLR lasting approximately 9 hours on two separate days that will prohibit entry of persons or vessels during the Riviera Race

Weekend event. Normally such actions are categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023-01-001-01, Rev. 1. A preliminary Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision Making Portal at <https://www.regulations.gov>. To do so, go to <https://www.regulations.gov>, type USCG-2022-0164 in the search box and click "Search." Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If you cannot submit your material by using <https://www.regulations.gov>, call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this proposed rule for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the previous paragraph, and then select "Supporting & Related Material" in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the <https://www.regulations.gov> Frequently Asked Questions web page. We review all comments received, but we will only post comments that address the topic of

the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to <https://www.regulations.gov> will include any personal information you have provided. For more about privacy and submissions to the docket in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 46 U.S.C. 70041; 33 CFR 1.05-1.

■ 2. Add § 100.T0799-0164 to read as follows:

§ 100.T0799-0164 **Special Local Regulation: Riviera Race Weekend; Atlantic Ocean, Riviera Beach, FL.**

(a) *Location.* The following regulated area is established as a special local regulation in the Atlantic Ocean; Riviera Beach, FL. Coordinates are based on North American Datum 1983.

(1) *Regulated area.* All navigable waters of the Atlantic Ocean encompassed within the following points: Commence at Point A in position 26°46'51" N, 080°01'53" W; thence east to Point B in position 26°46'51" N, 080°01'41" W; thence north to Point C in position 26°47'08" N, 080°01'41" W; thence west to Point D in position 26°47'08" N, 080°01'53" W; thence southwest to Point A.

(2) [Reserved]

(b) *Definitions.* (1) The term *designated representative* means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, State, and Local officers designated by or assisting the Captain of the Port (COTP) Miami in the enforcement of the regulated areas.

(2) The term *Patrol Commander* means a commissioned, warrant, or petty officer of the Coast Guard who has been designated by the respective Coast Guard Sector Commander to enforce this section.

(3) The term *spectators* means all persons and vessels not registered with

the event sponsor as participants or official patrol vessels.

(c) *Regulations.* (1) All non-participant vessels, spectators, and persons are prohibited from entering, transiting, anchoring in, or remaining within the regulated area unless authorized by the COTP or a designated representative.

(2) Persons and vessels desiring to enter, transit, anchor in, or remain within the regulated area may contact the COTP Miami by telephone at (305) 535-4472 or a designated representative via VHF-FM radio on channel 16, to request authorization. If authorization is granted, all persons and vessels receiving such authorization must comply with the instructions of the COTP Miami or a designated representative.

(3) The Coast Guard will provide notice of the regulated area through Broadcast Notice to Mariners via VHF-FM channel 16, on-scene designated representatives, and Local Notice to Mariners.

(d) *Enforcement period.* This section will be enforced from 9 a.m. until 6 p.m. each day on June 4, 2022, and June 5, 2022.

Dated: April 28, 2022.

J.F. Burdian,

Captain, U.S. Coast Guard, Captain of the Port Miami.

[FR Doc. 2022-09499 Filed 5-3-22; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Part 393

[Docket No. FMCSA-2022-0004]

Parts and Accessories Necessary for Safe Operations; Speed Limiting Devices

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Advance notice of supplemental proposed rulemaking.

SUMMARY: FMCSA announces its intent to proceed with a speed limiter rulemaking by preparing a supplemental notice of proposed rulemaking (SNPRM) to follow up on the National Highway Traffic Safety Administration's (NHTSA) and FMCSA's jointly issued September 7, 2016 notice of proposed rulemaking (NPRM) on this subject. The SNPRM will propose that motor carriers operating commercial motor vehicles

(CMVs) in interstate commerce with a gross vehicle weight rating (GVWR) or gross vehicle weight (GVW) of 11,794 kilograms or more (26,001 pounds or more), whichever is greater, that are equipped with an electronic engine control unit (ECU) capable of governing the maximum speed be required to limit the CMV to a speed to be determined by the rulemaking and to maintain that ECU setting for the service life of the vehicle. With this notice of intent, FMCSA requests public comments and data regarding the adjustment or reprogramming of ECUs.

DATES: Comments must be received on or before June 3, 2022.

ADDRESSES: You may submit comments identified by Docket Number FMCSA–2022–0004 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <https://www.regulations.gov/docket/FMCSA-2022-0004/document>. Follow the online instructions for submitting comments.

- *Mail:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.

- *Hand Delivery or Courier:* Dockets Operations, U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* (202) 493–2251.

FOR FURTHER INFORMATION CONTACT: Mr. Luke Loy, Office of Vehicle and Roadside Operations, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001; (202) 366–0676; MCPSV@dot.gov. If you have questions on viewing or submitting material to the docket, call Dockets Operations at (202) 366–9826.

SUPPLEMENTARY INFORMATION:

A. Submitting Comments

If you submit a comment, please include the docket number for this notification of intent (NOI) (FMCSA–2022–0004), indicate the specific section of this document to which your comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to <https://www.regulations.gov/docket/FMCSA-2022-0004/document>, click on this NOI, click “Comment,” and type your comment into the text box on the following screen.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period.

Confidential Business Information (CBI)

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to the NOI contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to the NOI, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission that constitutes CBI as “PROPIN” to indicate it contains proprietary information. FMCSA will treat such marked submissions as confidential under the Freedom of Information Act, and they will not be placed in the public docket of the NOI. Submissions containing CBI should be sent to Mr. Brian Dahlin, Chief, Regulatory Analysis Division, Office of Policy, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. Any comments FMCSA receives not specifically designated as CBI will be placed in the public docket for this rulemaking.

B. Viewing Comments and Documents

To view comments, as well as any documents mentioned in this NOI as being available in the docket, go to <https://www.regulations.gov/docket/FMCSA-2022-0004/document> and choose the document to review. To view comments, click this NOI, and click “Browse Comments.” If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy Act

DOT posts comments received without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at www.transportation.gov/privacy.

I. Background

NHTSA and FMCSA jointly published in the **Federal Register** on September 7, 2016, at (81 FR 61942) proposed regulations that would require vehicles with a GVWR of more than 11,793.4 kilograms (26,000 pounds) to be equipped with a speed limiting device set to a maximum speed to be specified in a final rule and would require motor carriers operating such vehicles in interstate commerce to maintain functional devices set to that speed for the service life of the vehicle (81 FR 61942).

Specifically, NHTSA proposed to establish a new Federal Motor Vehicle Safety Standard (FMVSS) requiring each vehicle with a GVWR of more than 11,793.4 kilograms (26,000 pounds), as manufactured and sold, to have its device set to a speed not greater than a specified speed and to be equipped with means of reading the vehicle’s current speed setting and the two previous speed settings (including the time and date the settings were changed) through its on-board diagnostic connection.

FMCSA proposed a complementary Federal Motor Carrier Safety Regulation (FMCSR) requiring each multipurpose passenger vehicle, truck, and bus and school bus with a GVWR of more than 11,793.4 kilograms (26,000 pounds)¹ to be equipped with a speed limiting device meeting the requirements of the proposed FMVSS applicable to the vehicle at the time of manufacture, including the requirement that the device be set to a speed not greater than a specified speed. Motor carriers operating such vehicles in interstate commerce would be required to maintain the speed limiting devices for the service life of the vehicle.

At the time the 2016 NPRM was published, NHTSA and FMCSA stated that all vehicles with electronic engine control units (ECUs) are generally electronically speed governed to prevent engine or other damage to the vehicle. This is because the ECU monitors an engine’s RPM (from which vehicle speed can be calculated) and also controls the supply of fuel to the engine.

¹ The jurisdictional definitions of GVW and GVWR applicable to NHTSA regulations are slightly different from the FMCSA definitions applicable to the SNPRM.

The NPRM stated that the information NHTSA analyzed indicated that ECUs have been installed in most heavy trucks since 1999, although the Agency was aware that some manufacturers were still installing mechanical controls through 2003 (81 FR 61947). Based on this background, it is likely the required means of achieving compliance with a speed limiter requirement would be to use the ECU to govern the speed of the vehicle rather than installing a mechanical means of doing so.

The Fall 2021 Unified Agenda of Regulatory and Deregulatory Actions,² published December 10, 2021, lists both speed limiter rules, from NHTSA (Regulation Identification Number 2127-AK92) and FMCSA (Regulation Identification Number 2126-AB63), as long-term actions. This notice informs the public that FMCSA intends to move forward with a separate motor carrier-based speed limiter rulemaking. FMCSA believes that placing the requirement on motor carriers will ensure compliance with the rule, and potentially avoid confusion on who is responsible. FMCSA believes the requirements can be met by the motor carriers but asks questions below to validate that approach. FMCSA will continue to consult with NHTSA during the development of this rule. If necessary, NHTSA will evaluate the need for additional regulatory actions concerning CMV manufacturer requirements to address issues raised during implementation that are beyond the scope of FMCSA's authority.

FMCSA Intention

FMCSA intends to issue an SNPRM that would, if adopted, impose speed limitations on certain CMVs subject to the FMCSRs. The rulemaking would propose that motor carriers operating certain *commercial motor vehicles*, as defined in 49 CFR 390.5, in interstate commerce that are equipped with an ECU capable of setting speed limits be required to limit the CMV to a speed to be determined by the rulemaking and to maintain that limit for the service life of the vehicle. The agency is considering making the rule only applicable to CMVs manufactured after a certain date, such as 2003, because this is the population of vehicles for which ECUs were routinely installed and may potentially be used to govern the speed of the vehicles. FMCSA seeks data below, to determine if that approach

should be revised in the forthcoming SNPRM. The agency is considering whether a retrofit requirement would be necessary and requests information below.

FMCSA is not yet proposing regulatory language to amend the FMCSRs in this notice. FMCSA does, however, solicit comments on the questions listed in Section II. REQUEST FOR PUBLIC COMMENTS, which will assist in the development of the SNPRM.

II. Request for Public Comments

FMCSA requests comments on the programming or adjustment of ECUs that could be made to impose speed limits on CMVs, including responses to the questions below.

General Questions: Setting and Maintaining ECUs

1. What percentage of the CMV fleet currently uses speed limiting devices?
2. If in use, at what maximum speed are the devices generally set?
3. What skill sets or training are needed for motor carriers' maintenance personnel to adjust or program ECUs to set speed limits?
4. What tools or equipment are needed to adjust or program ECUs?
5. How long would adjustment or reprogramming of an ECU take?
6. Where can the adjustment or reprogramming of an ECU be completed?
 - 6.a. Can the adjustment or reprogramming of an ECU be made on-site where the vehicle is ordinarily housed or garaged, or would it have to be completed at a dealership?
7. Do responses to questions 3 through 6 change based on the model year of the power unit?
8. Since publication of the NPRM, how has standard practice or technology changed as it relates to the ability to set speed limits using ECUs?
9. Are there any challenges or burdens associated with FMCSA publishing a rule without NHTSA updating the FMVSS?
 10. Should FMCSA revisit using the 2003 model year as the baseline requirement for the rule?
 11. Should FMCSA consider a retrofit requirement in the rule and, if so, should it be based on model year or other criteria, and what would the cost of such a requirement be?
 12. Should FMCSA include Classes 3-6 (*i.e.*, 10,001-26,001 lbs. GVWR) in the SNPRM?

Robin Hutcheson,
Deputy Administrator.

[FR Doc. 2022-09443 Filed 5-3-22; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS-R6-ES-2021-0134; FF09E21000 FXES1111090FEDR 223]

RIN 1018-BE98

Endangered and Threatened Wildlife and Plants; Threatened Species Status With Section 4(d) Rule for the Silverspot Butterfly

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), propose to list a subspecies of butterfly (*Speyeria nokomis nokomis*), a silverspot butterfly from Colorado, New Mexico, and Utah, as a threatened species under the Endangered Species Act of 1973, as amended (Act), with a rule issued under section 4(d) of the Act ("4(d) rule"). This document also serves as our 12-month finding on a petition to list the silverspot. After a review of the best available scientific and commercial information, we find that listing the subspecies is warranted. If we finalize this rule as proposed, it would add this subspecies to the List of Endangered and Threatened Wildlife and extend the Act's protections to the subspecies. We determined that designating critical habitat for this subspecies under the Act is not prudent.

DATES: We will accept comments received or postmarked on or before July 5, 2022. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date. We must receive requests for a public hearing, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by June 21, 2022.

ADDRESSES:

Written comments: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: <https://www.regulations.gov>. In the Search box, enter the docket number or RIN for this rulemaking (presented above in the document headings). For best results, do not copy and paste either number; instead, type the docket number or RIN into the Search box using hyphens. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, check the

² "Fall 2021 Unified Agenda of Regulatory and Deregulatory Actions." *Current Unified Agenda of Regulatory and Deregulatory Actions*, https://www.reginfo.gov/public/do/eAgendaMain?operation=OPERATION_GET_AGENCY_RULE_LIST Accessed December 22, 2021.

Proposed Rule box to locate this document. You may submit a comment by clicking on “Comment.”

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: FWS–R6–ES–2021–0134, U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on <https://www.regulations.gov>. This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

Availability of supporting materials: For this proposed rule, supporting materials are available at <https://www.regulations.gov> under Docket No. FWS–R6–ES–2021–0134, and at the Western Colorado Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Ann Timberman, Western Colorado Supervisor, U.S. Fish and Wildlife Service, Western Colorado Ecological Services Field Office, 445 West Gunnison Avenue, Grand Junction, CO 81501; telephone 970–628–7181. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Act, a species warrants listing if it meets the definition of an endangered species (in danger of extinction throughout all or a significant portion of its range) or a threatened species (likely to become endangered in the foreseeable future throughout all or a significant portion of its range). We have determined that the silverspot butterfly (*Speyeria nokomis nokomis*) meets the definition of a threatened species; therefore, we are proposing to list it as such. We have determined that designation of critical habitat is not prudent. Both listing a species as an endangered or threatened species and designating critical habitat can be completed only by issuing a rule through the Administrative Procedure Act rulemaking process.

What this document does. We propose to list the silverspot butterfly as a threatened species with a 4(d) rule.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species because of any of five factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. We have determined that habitat loss and fragmentation, incompatible livestock grazing, human-caused hydrologic alteration, genetic isolation, and the effects of climate change negatively affect the silverspot butterfly’s viability at a population level.

Section 4(a)(3) of the Act requires the Secretary of the Interior (Secretary) to designate critical habitat concurrent with listing to the maximum extent prudent and determinable. Section 3(5)(A) of the Act defines critical habitat as (i) the specific areas within the geographical area occupied by the species, at the time it is listed, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protections; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination by the Secretary that such areas are essential for the conservation of the species. Section 4(b)(2) of the Act states that the Secretary must make the designation on the basis of the best scientific data available and after taking into consideration the economic impact, the impact on national security, and any other relevant impacts of specifying any particular area as critical habitat. In the case of the silverspot butterfly, we found that designating critical habitat was not prudent, as explained later in this document.

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other concerned governmental agencies, Native American Tribes, the scientific community, industry, or any other interested parties concerning this proposed rule.

We particularly seek comments concerning:

(1) The subspecies’ biology, range, and population trends, including:

(a) Biological or ecological requirements of the subspecies, including habitat requirements for feeding, breeding, and sheltering;

(b) Genetics and taxonomy;

(c) Historical and current range, including distribution patterns;

(d) Historical and current population levels, and current and projected trends; and

(e) Past and ongoing conservation measures for the subspecies, its habitat, or both.

(2) Factors that may affect the continued existence of the subspecies, which may include habitat modification or destruction, overutilization, disease, predation, the inadequacy of existing regulatory mechanisms, or other natural or manmade factors.

(3) Biological, commercial trade, or other relevant data concerning any threats (or lack thereof) to this subspecies and existing regulations that may be addressing those threats.

(4) Additional information concerning the historical and current status, range, distribution, and population size of this subspecies, including the locations of any additional populations of this subspecies.

(5) Information on regulations that are necessary and advisable to provide for the conservation of the silverspot butterfly and that the Service can consider in developing a 4(d) rule for the subspecies. In particular, information concerning the extent to which we should include any of the Act’s section 9 prohibitions in the 4(d) rule or whether we should consider any additional exceptions from the prohibitions in the 4(d) rule.

(6) The reasons why we should or should not designate habitat as “critical habitat” under section 4 of the Act (16 U.S.C. 1531 *et seq.*), including information to inform the following factors that the regulations identify as reasons why designation of critical habitat may be not prudent:

(a) The species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species;

(b) The present or threatened destruction, modification, or curtailment of a species’ habitat or range is not a threat to the species, or threats to the species’ habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act;

(c) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for

a species occurring primarily outside the jurisdiction of the United States; or
(d) No areas meet the definition of critical habitat.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or a threatened species must be made “solely on the basis of the best scientific and commercial data available.”

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in **ADDRESSES**.

If you submit information via <https://www.regulations.gov>, your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on <https://www.regulations.gov>.

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on <https://www.regulations.gov>.

Because we will consider all comments and information we receive during the comment period, our final determinations may differ from this proposal. Based on the new information we receive (and any comments on that new information), we may conclude that the subspecies is endangered instead of threatened, or we may conclude that the subspecies does not warrant listing as either an endangered species or a threatened species. For critical habitat, we may conclude that designation of critical habitat is indeed prudent. In addition, we may change the parameters of the prohibitions or the exceptions to those prohibitions in the 4(d) rule if we conclude it is appropriate in light of comments and new information received. For example, we may expand the prohibitions to include prohibiting additional activities if we conclude that those additional activities are not compatible with conservation of the

subspecies. Conversely, we may establish additional exceptions to the prohibitions in the final rule if we conclude that the activities would facilitate or are compatible with the conservation and recovery of the subspecies.

Public Hearing

Section 4(b)(5) of the Act provides for a public hearing on this proposal, if requested. Requests must be received by the date specified in **DATES**. Such requests must be sent to the address shown in **FOR FURTHER INFORMATION CONTACT**. We will schedule a public hearing on this proposal, if requested, and announce the date, time, and place of the hearing, as well as how to obtain reasonable accommodations, in the **Federal Register** and local newspapers at least 15 days before the hearing. For the immediate future, we will provide these public hearings using webinars that will be announced on the Service’s website, in addition to the **Federal Register**. The use of these virtual public hearings is consistent with our regulations at 50 CFR 424.16(c)(3).

Previous Federal Actions

On July 3, 1978, we proposed to list *Speyeria nokomis nokomis* (with the common name “Great Basin silverspot butterfly”) as a threatened species with critical habitat under the Act (43 FR 28938). Due to a new range delineation (described in Background below), the former common name, Great Basin silverspot butterfly, is no longer valid as the subspecies is not found within the Great Basin; therefore, we will refer to the *S. n. nokomis* subspecies as “silverspot” in this proposed rule. On March 6, 1979, we withdrew the July 3, 1978, proposed rule, along with certain other proposed rules, because they did not meet requirements set forth in the Endangered Species Act Amendments of 1978 (Pub. L. 95–632, 92 Stat. 3751); see 44 FR 12382.

On May 22, 1984, we identified the silverspot as a category 2 candidate species (49 FR 21664). Category 2 candidate species comprised taxa for which information in the Service’s possession indicated that a proposal to list the species as endangered or threatened was possibly appropriate, but for which conclusive data on biological vulnerability and threat(s) were not currently available to support proposed rules at that time. Later candidate notices of review (CNOR) retained the subspecies as a category 2 candidate species (54 FR 554, January 6, 1989; 56 FR 58804, November 21, 1991; 59 FR 58982, November 15, 1994).

On February 28, 1996, we discontinued the designation of category 2 species as candidates in CNORs (61 FR 7596), and on December 5, 1996, we published a notice of final decision (61 FR 64481) to discontinue the practice of maintaining a list of species regarded as “category 2 candidates.” These actions resulted in the removal of the silverspot from the candidate list.

In 2013, WildEarth Guardians petitioned us to list the silverspot. On January 12, 2016, we published a 90-day finding (81 FR 1368) stating that the petition presented substantial scientific or commercial information indicating that the petitioned action may be warranted and announcing our intent to proceed with a status review. In 2021, we completed a species status assessment report for the silverspot (hereafter, SSA report) to compile the best scientific and commercial data available regarding the subspecies’ biology and factors that influence the subspecies’ viability (Service 2021, entire).

Supporting Documents

A species status assessment (SSA) team prepared an SSA report for the silverspot butterfly (Service 2021, entire). The SSA team was composed of Service biologists, in consultation with other species experts. The SSA report represents a compilation of the best scientific and commercial data available concerning the status of the subspecies, including the impacts of past, present, and future factors (both negative and beneficial) affecting the subspecies. In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing actions under the Act, we sought the expert opinions of four appropriate specialists regarding the SSA report. We received four responses. We also sent the SSA report to partners, including scientists with expertise in the subspecies, its habitat, and genetics, for review. The SSA report provides the scientific basis for this proposed listing rule.

I. Proposed Listing Determination Background

A thorough review of the taxonomy, life history, and ecology of the silverspot butterfly (hereafter, silverspot) is presented in the SSA report (Service 2021, pp. 4–24), and is briefly summarized here.

The silverspot is a relatively large butterfly with up to a 3-inch wingspan. Males typically have bright orange on

the upper side of the wing, while females typically have cream or light yellow with brown or black. The underside of the wing of both sexes has silvery-white spots, giving the subspecies' the common name of silverspot butterfly.

Based on recent genetic analysis, there are five silverspot butterfly subspecies including 10 major populations of *S. nokomis* throughout the United States and Mexico (Cong *et al.* 2019, entire). We established a new, more accurate range boundary for *S. n. nokomis* in this SSA based on the genetic analysis, which limits the distribution to east-central Utah through western and south-central Colorado and into north-central New Mexico (Service 2021, p. ii). The new range delineation shows that the subspecies does not occur in the Great Basin and thus the former common name, Great Basin silverspot butterfly, is no longer valid. We refer to the *S. n. nokomis* subspecies as "silverspot" in this proposed rule.

In the SSA report, we identified 10 populations of silverspot in our analysis, including the following: Archuleta, Conejos, Costilla, Garfield, La Plata, Mesa/Grand, Montrose/San Juan, and Ouray populations in Colorado and Utah; and the San Miguel/Mora and Taos populations in New Mexico (Service 2021, figure 14 and table 4). Populations of silverspot are known to occur between 5,200 feet (ft) (1,585 meters (m)) and 8,300 ft (2,530 m). The butterfly requires moist habitats in mostly open meadows with a variety of herbaceous and woody vegetation. Eggs are laid on or near the bog violet (*Viola nephrophylla/V. sororia* var. *affinis*), which the larvae feed on exclusively. A variety of flowering plants provide adult nectar sources. The butterfly completes its entire life cycle in one year.

Regulatory and Analytical Framework

Regulatory Framework

Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species is an endangered species or a threatened species. The Act defines an "endangered species" as a species that is in danger of extinction throughout all or a significant portion of its range, and a "threatened species" as a species that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether any species is an endangered species or a threatened

species because of any of the following factors:

- (A) The present or threatened destruction, modification, or curtailment of its habitat or range;
- (B) Overutilization for commercial, recreational, scientific, or educational purposes;
- (C) Disease or predation;
- (D) The inadequacy of existing regulatory mechanisms; or
- (E) Other natural or manmade factors affecting its continued existence.

These factors represent broad categories of natural or human-caused actions or conditions that could have an effect on a species' continued existence. In evaluating these actions and conditions, we look for those that may have a negative effect on individuals of the species, as well as other actions or conditions that may ameliorate any negative effects or may have positive effects.

We use the term "threat" to refer in general to actions or conditions that are known to or are reasonably likely to negatively affect individuals of a species. The term "threat" includes actions or conditions that have a direct impact on individuals (direct impacts), as well as those that affect individuals through alteration of their habitat or required resources (stressors). The term "threat" may encompass—either together or separately—the source of the action or condition or the action or condition itself.

However, the mere identification of any threat(s) does not necessarily mean that the species meets the statutory definition of an "endangered species" or a "threatened species." In determining whether a species meets either definition, we must evaluate all identified threats by considering the expected response by the species, and the effects of the threats—in light of those actions and conditions that will ameliorate the threats—on an individual, population, and species level. We evaluate each threat and its expected effects on the species, then analyze the cumulative effect of all of the threats on the species as a whole. We also consider the cumulative effect of the threats in light of those actions and conditions that will have positive effects on the species, such as any existing regulatory mechanisms or conservation efforts. The Secretary determines whether the species meets the Act's definition of an "endangered species" or a "threatened species" only after conducting this cumulative analysis and describing the expected effect on the species now and in the foreseeable future.

The Act does not define the term "foreseeable future," which appears in the statutory definition of "threatened species." Our implementing regulations at 50 CFR 424.11(d) set forth a framework for evaluating the foreseeable future on a case-by-case basis. The term "foreseeable future" extends only so far into the future as the Service can reasonably determine that both the future threats and the species' responses to those threats are likely. In other words, the foreseeable future is the period of time in which we can make reliable predictions. "Reliable" does not mean "certain"; it means sufficient to provide a reasonable degree of confidence in the prediction. Thus, a prediction is reliable if it is reasonable to depend on it when making decisions.

It is not always possible or necessary to define foreseeable future as a particular number of years. Analysis of the foreseeable future uses the best scientific and commercial data available and should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species' biological response include species-specific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

Analytical Framework

The SSA report documents the results of our comprehensive biological review of the best scientific and commercial data regarding the status of the species, including an assessment of the potential threats to the species. The SSA report does not represent a decision by the Service on whether the species should be proposed for listing as an endangered or threatened species under the Act. However, it does provide the scientific basis that informs our regulatory decisions, which involve the further application of standards within the Act and its implementing regulations and policies. The following is a summary of the key results and conclusions from the SSA report; the full SSA report can be found at Docket No. FWS-R6-ES-2021-0134 on <https://www.regulations.gov>.

To assess the silverspot's viability, we used the three conservation biology principles of resiliency, redundancy, and representation (Shaffer and Stein 2000, pp. 306–310). Briefly, resiliency supports the ability of the species to withstand environmental and demographic stochasticity (for example, wet or dry, warm or cold years), redundancy supports the ability of the species to withstand catastrophic events

(for example, droughts, large pollution events), and representation supports the ability of the species to adapt over time to long-term changes in the environment (for example, climate changes). In general, the more resilient and redundant a species is and the more representation it has, the more likely it is to sustain populations over time, even under changing environmental conditions. Using these principles, we identified the silverspot's ecological requirements for survival and reproduction at the individual, population, and subspecies levels, and described the beneficial and risk factors influencing the subspecies' viability.

The SSA process can be categorized into three sequential stages. During the first stage, we evaluated the individual subspecies' life-history needs. The next stage involved an assessment of the historical and current condition of the subspecies' demographics and habitat characteristics, including an explanation of how the subspecies arrived at its current condition. The final stage of the SSA involved making predictions about the subspecies' responses to positive and negative environmental and anthropogenic influences. Throughout all of these stages, we used the best available information to characterize viability as the ability of a species (or in this case, subspecies, which is a listable entity under the Act) to sustain populations in the wild over time. We use this information to inform our regulatory decision.

Summary of Biological Status and Threats

In this discussion, we review the biological condition of the subspecies and its resources, and the threats that influence the subspecies' current and future condition, in order to assess the subspecies' overall viability and the risks to that viability.

Species Needs

Individual Needs

Individual silverspot needs include wet meadows supported by springs, seeps, streams, or irrigated areas that contain the bog violet host plant for eggs and larvae and other herbaceous vegetation for cover and food resources. The butterflies may benefit from a light interspersed of willow or other shrubs for shade and for larval shelter. More dense willow and shrubs often surround open meadows where silverspots occur and, as long as the woody vegetation does not take over the meadows, the margins of denser stands can be beneficial for shade and shelter as well.

Population Needs

Populations need abundant individuals within habitat patches of adequate size and quality to maintain survival and reproduction. In general, the greater the suitable habitat acreage, and the greater the number of individuals within a population, the greater the resilience. Furthermore, colonies and populations need to be close enough to each other for individuals to breed with each other in order to maintain genetic diversity. Silverspots likely do not fly more than 5–10 miles (mi) (8–16 kilometers (km)) and would likely have difficulty finding another colony beyond this distance (Ellis 2020a, 2020b, 2020c, pers. comm.). Additionally, silverspots need the bog violet to be of sufficient extent and density to support colonies and populations. We define colonies to mean areas of abundant violets that produce butterflies, as well as surrounding habitat with nectar sources. If there is narrow but contiguous nectaring habitat up or down a drainage but without violets (or with only sparse violets), we consider those areas transitional corridors that are likely valuable for dispersal and genetic connectivity.

The silverspot and other *S. nokomis* subspecies can move between colonies within a continuous or nearly continuous riparian zone (Arnold 1989, pp. 10, 14; Fleishman *et al.* 2002, p. 708). For example, six colonies occurred along a 5-mi stretch in Unaweep Canyon that had likely genetic interchange (Ellis 1989, p. 3). However, these are considered separate colonies due to the natural or human-caused patchiness of bog violets up and down the canyon. In a mark-recapture study (Arnold 1989, pp. 10, 14, 21) in Unaweep Canyon, about 50 percent of the recaptured butterflies moved between two colonies separated by about 0.75 mi (1.2 km). Based on this work, it was speculated that silverspots could easily move at least 1 mile, and, based on this, Ellis (1989, p. 19) further speculated that there was exchange of individuals among all the Unaweep Canyon colonies every 1 to 5 years. This information also provided the basis for Ellis' professional judgement that colonies or populations farther than 5 to 10 mi (8 to 16 km) from each other are likely isolated (Ellis 2020a, 2020b, 2020c, pers. comm.).

Some silverspot populations have single colonies, while others have more than one colony, creating a metapopulation. A metapopulation structure is where individuals in colonies are close enough to interbreed

and can recolonize temporarily extirpated colonies. Colonies in a functioning metapopulation can be recolonized if local naturally occurring (stochastic) events cause extirpation of a colony. For instance, a flood may extirpate a colony, but if there is a nearby source for the bog violet and associated plant species, the area may return to suitable habitat condition and be recolonized by the butterfly.

Unfortunately, there is very little information on what an adequate-sized habitat patch for silverspot is, especially if there is only a single colony in a population. A professional estimate for minimum patch size of colonies is 2 acres (ac) (0.8 hectares (ha)) if the habitat has a reliable groundwater source and has high violet density; 5 ac (2 ha) if violets are less dense due to natural or human-caused variability within a patch (Ellis 2020c, pers. comm.). Although it is possible a single 2-acre or 5-acre patch of habitat could support the butterfly for a period of time, a more resilient population will likely contain at least three colonies of those sizes or greater. A three-colony metapopulation will have a better chance of survival by spreading the risk of extirpation if a natural event occurs at one or two of the colonies. Thus, the remaining one or two colonies can recolonize the extirpated sites assuming suitable habitat remains or reestablishes. Due to natural variability in soil and topographic conditions, we assume that most areas within the silverspot's range are likely to have a lower density of violets, rather than dense violets (Service 2021, p. 21). Consequently, under this assumption, a minimum amount of habitat for a sufficiently resilient population may be 12 ac (5 ha) and this can be made up of multiple colonies as long as they are at least 2 ac (0.8 ha) in size (Service 2021, p. 21). Due to its isolation, a single-colony population likely needs to have hundreds of acres of habitat in order to ensure there are enough butterflies to maintain genetic diversity and viability over the long term (Service 2021, p. 21). The specific minimum threshold for single colonies to maintain viability is unknown, but the larger the acreage is, the greater the resiliency and higher likelihood of viability.

There is also little information on the minimum number of silverspot individuals needed to sustain a colony. There have only been two demographic studies for silverspot that occurred at the same locations 10 years apart: 1979 and 1989 (Arnold 1989). The 1989 study found a daily estimate of between 48 and 260 butterflies with two different models at the Unaweep Seep colony

(Arnold 1989, pp. 6, 14). A combined population estimate at the Unaweep Seep colony and another upstream colony in Unaweep Canyon (which is considered two colonies due to intervening transitional habitat) resulted in a range of daily abundance from 594 to 2,689 butterflies. Quality of habitat may have as much weight in determining resiliency of a colony or population as does overall size of a habitat patch or number of individuals. Habitat quality could potentially be measured by density of violets. The Unaweep Seep study (Arnold 1989, p. 20) revealed that the larger colony with many individuals became extirpated, likely due to vegetative encroachment, while the upstream colony with more violets remained extant. Consequently, populations appear to have greater chance for survival when containing more violets.

Based on observation of grazed and burned properties in Unaweep Canyon, it was determined that occasional or well-managed grazing and burning likely benefit the violet by reducing willows, as well as reducing thatch buildup from grasses and sedges (Arnold 1989, p. 14; Ellis 1989, pp. 18, 19). Consequently, natural factors or management activities that lead to early seral stages or at least more open conditions where willow, grass, sedge or other vegetation does not outcompete violets is important to colonies and populations.

Single-colony populations likely need to have a very large habitat area, in the hundreds of acres, but might still need occasional immigration from other populations to maintain genetic diversity and resiliency for long-term persistence. Based on the scant evidence, the minimum number of individuals that are needed to sustain a silverspot colony or population is unknown, and even apparent natural but detrimental habitat factors, such as excessive growth of other plants, can cause extirpation of seemingly large colonies. Without additional study, it is not known what the minimum habitat size is to maintain viability, nor what density or abundance of bog violets or nectar sources is needed to sustain a colony or population, nor the maximum distance between colonies or populations that can be reached for genetic interchange to still be able to occur on a regular basis. Furthermore, it is unknown if very large single-colony populations can be sufficiently resilient without occasional genetic interchange from other populations.

In summary, to be adequately resilient, silverspot populations need water to sustain violets for the larvae, as

well as occasional or seasonal disturbance by grazing from native ungulates or domestic livestock, or burning, mowing, or non-catastrophic flooding, to occasionally remove vegetation that might otherwise crowd out the violets and other nectar plants for the adults. Furthermore, based on expert opinion and evidence from Arnold (1989) and Ellis (1989), the most resilient populations need to be at least 2 ac (0.8 ha) in size with dense violets or at least 5 ac (2 ha) in size with less dense violets, and need to have a few to several colonies within 0.75 to 5 mi (1.2 to 8 km) of each other and likely be not more than 10 mi (16 km) from each other (Ellis 2020c, pers. comm.).

Species Needs

To maintain viability, silverspots need to have a sufficient quality and quantity of habitat for adequately resilient populations, numerous populations to create redundancy in the event of catastrophic events, and broad enough genetic and ecological diversity to adapt to changing environmental conditions (representation). The subspecies will have a better chance of long-term viability if single-colony populations and even the metapopulations occasionally receive individuals from other populations such that genetic interchange occurs and they are able to adapt more readily to environmental changes.

Factors Influencing Subspecies Viability

We reviewed the potential risk factors (*i.e.*, threats, stressors) that could be affecting the silverspot now and in the future. In this proposed rule, we will discuss only those factors in detail that could meaningfully impact the status of the subspecies. Habitat loss and fragmentation, human-caused hydrologic alteration, livestock grazing, genetic isolation, exotic plant invasion, climate change, climate events, larval desiccation, and collecting are all factors that influence or could influence the subspecies' viability. Those risks that are not known to have effects on silverspot populations, such as disease, predation, prescribed burning or wildfire, and pesticides, are not discussed here but are evaluated in the SSA report.

Habitat Loss and Fragmentation

Habitat loss from golf course and housing development caused extirpation of two historical colonies north of Durango, Colorado (Ellis and Fisher 2020, pers. comm.). The remaining known site in the La Plata population has residential and commercial development across the

street from it, and one of two drainages supplying it water has relatively new housing and golf courses all around within 1.5 air miles (2.4 km), potentially degrading downstream silverspot habitat through hydrologic alteration. Housing development also appears to have been a contributing factor in extirpation of the Beulah, New Mexico, colony (Scott and Fisher 2014, p. 3). In Colorado, it is possible that Rifle Gap Reservoir and Dam degraded and fragmented habitat, as one butterfly was sighted at a small wetland downstream of the dam and the reservoir flooded and fragmented habitat upstream. Additional habitat alteration upstream and downstream from a variety of factors also has likely fragmented habitat. Many other colonies/populations have development around them that also either directly encroaches on the habitat or likely has caused degradation and fragmentation from homes, roads, hydrologic alteration and habitat conversion.

Agricultural habitat conversion can cause loss or fragmentation of habitat and typically involves mowing native meadows or growing exotic grasses for hay. Although it is unknown if all agricultural conversion has caused habitat to become unsuitable, aerial imagery reveals that agricultural conversion has been extensive within the silverspot's range. It has likely caused loss of unknown colonies over the last 150 years and has fragmented native habitat, reducing connectivity between colonies and populations. Annual haying may be less detrimental than haying two or three times a summer. A related subspecies in Arizona and New Mexico persisted for many years (Cong *et al.* 2019) even though haying occurs there once a year typically in late August or September (Smith 2019, pers. comm.).

Despite potential compatibility with annually mowing native hay fields, agricultural conversion to unsuitable crops or fragmentation of habitat has been extensive. Furthermore, residential and commercial development, and other development like roads, continues to limit and/or degrade habitat in or adjacent to existing colonies/populations. Habitat loss and fragmentation, therefore, has meaningfully reduced the viability of the subspecies.

Hydrologic Alteration

Hydrologic alteration is also a factor influencing the subspecies' viability. Hydrologic alteration can result from a variety of sources, including, but not limited to, diversions for agricultural and domestic use, erosion and stream

channel incision caused by livestock grazing, mining, roads, dredging and filling of wetlands, removal of beaver dams, and creation and operation of large human-made dams. For example, the only known colony in the Costilla population has a diversion ditch delimiting its south side that may have reduced the size of colony, and that ditch and other diversions have allowed for extensive agricultural development in the drainage that has altered native habitat and likely dropped the water table in much of the area. The Paradox colony in the Montrose/San Juan population also has had livestock grazing and water diversions occur over the last 30 years, which have degraded the quality of the wet meadow areas and lowered the water table (Ellis and Ireland 2018, pers. observation).

Many drainages in the Sacramento Mountains, where the Mescalero silverspot colony may have occurred (see SSA report), succumbed to incision of streams around 1900, in turn lowering water tables and eliminating wet meadow habitat (Cary 2020b, pers. comm.). Incision of stream channels occurred due to erosion from deforestation, conversion to agricultural and grazing lands, mining, etc. (Cary 2020b, 2020c, pers. comm.). Beavers were also eliminated around 1900 in the Sacramento Mountains (and other parts of the West), which also undoubtedly caused reduction of water tables and elimination of wet meadow habitat suitable for the silverspot and other wetland-dependent species (Cary 2020b, 2020c, pers. comm.). Hydrologic alteration that degrades riparian areas and lowers water tables from natural systems has occurred not only in the Costilla population, Montrose/San Juan population, and Sacramento Mountains, but extensively in the western United States, including much of the silverspot's range. Hydrologic alteration continues to limit suitable habitat and is a major factor influencing the viability of the subspecies.

Livestock Grazing

Livestock grazing may cause habitat loss and degradation if excessive, especially in the naturally scarce habitats of the silverspot (Hammond and McCorkle 1983, p. 219) and depending on the timing and intensity. Year-round grazing or heavy summer grazing is typically incompatible with silverspots because livestock graze on the violet leaves, nectar sources, and other vegetation necessary for the butterfly when the larvae and adults need them (Ellis 1999, p. 5). For example, an area adjacent to a known site in the Ouray population has

underlying hydrology and soils beneficial for silverspots, but the habitat is unsuitable due primarily to grazing and perhaps to a lesser extent occasional mowing for hay (Service 2021, figure 19). Light or moderate summer grazing (up to 20 or 30 percent vegetative utilization) may be acceptable, but total rest from grazing in the summer is preferred (Arnold 1989, p. 14; Ellis 2020d, pers. comm.).

If one or more kinds of vegetation are too dense, they can prevent the bog violet from persisting and thus cause extirpation of the butterfly. This occurred in the Unawep Seep colony in the Mesa/Grand population, perhaps primarily as a result of spike rush (*Eleocharis* spp.) invasion of meadows but also seemingly because of grass, sedge, and willow invasion (Arnold 1989, pp. 9, 14; Ellis 1999, pp. 3, 5, 6). It is unknown if this invasion would have occurred without grazing or if long-term grazing was the factor that shifted vegetation. Without occasional reduction or removal, herbaceous or woody vegetation could crowd out violets. Grazing is ongoing in suitable habitat for the subspecies and can limit availability of habitat throughout the range. Although it can be compatible, grazing is expected to continue to be a major factor influencing the subspecies' viability.

Genetic Isolation

Isolation can cause detrimental genetic and demographic effects and is a concern for the silverspot's population resiliency as well as redundancy and representation. Genetic isolation within the populations of silverspot analyzed in the SSA report does not currently appear to be an issue but may be in the future, especially if some populations become extirpated, leaving remaining populations even more isolated than in the current condition (Grishin 2020a, pers. comm.). Lower levels of genetic diversity can reduce the capacity of a population to respond to environmental change (*i.e.*, representation) and may lead to reduced population fitness, such as longevity and fecundity (Darvill *et al.* 2006, p. 608). Another silverspot subspecies, *S. n. apacheana*, has low genetic diversity, likely from genetic drift (disappearance of genes as individuals die), as a result of genetic isolation and small population sizes (Britten *et al.* 1994). Genetic exchange between and within populations can alleviate problems with genetic drift and augment populations demographically. In *S. n. apacheana*, routine dispersal distances up to 2.5 mi (3.9 km) were documented, and 26 percent of the recaptured butterflies had emigrated

from the initial patch of capture (Fleishman *et al.* 2002, p. 708). This migration appears to play an important role for *S. n. apacheana* populations both demographically and genetically (Britten *et al.* 2003, p. 232). Consequently, the ability or inability of individuals to migrate between colonies and populations is expected to also be of benefit or detriment, respectively, for silverspot.

Genetic isolation among populations of silverspot suggests reduced population fitness from genetic drift or for other reasons could be of concern in the future (Cong *et al.* 2019). All known silverspot populations are at least 24.5 mi (39 km) from each other and are genetically isolated from each other (Cong *et al.* 2019). Genetic analysis recently revealed that the Grand County colony is genetically similar to the Mesa County colonies and, hence, are part of the same population. Until recently (20–30 years ago), when Unawep Seep was extant, the Grand County colony and Unawep Seep colony in Mesa County were just under 20 mi (32 km) apart. Because alleles within genes can remain in the genome for hundreds or thousands of years, 20–30 years is a short time frame for separation of genetically similar colonies. Therefore, based on the latest scientific evidence (Cong *et al.* 2019), populations that are at least 20 miles apart are assumed to be separate populations. Currently, the distance between the two closest populations, which we know are genetically different and represent separate populations, is 24.5 air miles (39 km) (between the Taos and San Miguel/Mora populations in New Mexico). Consequently, and more specifically, the distance where populations of silverspot may not interbreed and thus may not support each other genetically or demographically appears to be somewhere between 20 and 24.5 air miles (32 and 39 km). The minimum distance of 20 mi (32 km), based on findings of Cong *et al.* (2019), was used in our analysis of genetic connectivity (see *Current Condition*, below).

Reasons for isolation, specifically whether from natural fragmentation or human habitat alteration, are not currently known for all colonies. It is also not known how long single colonies may have been isolated from each other. Like the large Taos colony of silverspot, if an isolated colony has enough area of habitat to support a large population, it may be resilient enough to survive without nearby colonies and thus maintain viability for a long time. However, many of the silverspot populations, whether single-colony or

multi-colony metapopulations, have limited amounts of habitat. It is unknown specifically how long it will take for low genetic diversity to become a threat to the silverspot, but isolation of populations indicates that loss of genetic diversity could be a threat at some point, if loss of populations through lack of demographic support does not occur first, and both are cause for concern for the subspecies' viability.

Exotic Plant Invasion

The Taos population has experienced some invasion by the exotic Siberian elm (*Ulmus pumila*). Because Siberian elm is widespread in the butterfly's range, we expect Siberian elm to increase if changes in climate reduce snowpack and water levels in the wet meadows of the Taos population (Cary 2020a, pers. comm.) or other populations. Similarly, the extirpated Unaweep Seep colony location was invaded by other exotic species, including Himalayan blackberry (*Rubus armeniacus*) and tree-of-heaven (*Ailanthus altissima*). Although not known to occupy other colonies at present, these plant species could invade other colonies (Plank 2020, pers. comm.). Other exotic woody or herbaceous species (such as Russian olive (*Elaeagnus angustifolia*), tamarisk (*Tamarix* spp.), or leafy spurge (*Euphorbia esula*)) can rapidly take over habitat and could eliminate bog violets and other native plants. However, there is currently little to no data on plants at the colonies (Ellis 1989, pp. 14–15).

Some nonnative thistles, such as Canada thistles (*Cirsium arvense*), occur in or around colonies and can create monocultures that create poor overall habitat conditions for the silverspot and bog violet by replacing native species (Ellis 1989, p. 14; Selby 2007, p. 30). Land managers in the West sometimes control the spread of exotic thistles, but Canada thistles (as well as native thistle) provide a nectar source for silverspots. Additionally, the adventive (exotic but not well-established) bull thistle (*C. vulgare*) and burdock (*Arctium minus*) can provide nectar sources (Ellis 1989, p. 14). Because silverspots use exotic thistles, aggressive control of them has been advised against (Fisher 2020b, pers. comm.). It does not appear that monocultures of Canada thistle or other exotic vegetation have replaced native vegetation beneficial for the butterfly at observed colonies (Ellis and Ireland 2018, pers. observation), but study of plant composition at all of the colonies is needed to determine levels of exotic plant presence. Exotic plant invasion is currently considered a minor factor because exotic species are not currently

known to be significantly influencing the subspecies' viability.

Climate Events

Climate events are defined in the SSA as events that would happen within the range of normal variability (*i.e.*, stochastic events). However, they may still cause reduction of habitat and number of butterflies. A record of other *Speyeria* in Utah indicates that too much rain can reduce numbers of butterflies but may be beneficial to violets, which can support greater numbers of butterflies the following year(s) (Myrup 2020b, pers. comm.). Similarly, floods may at least temporarily reduce habitat and vegetation as well as butterfly numbers. For instance, the Lake Fork River in northeast Utah flooded in spring 2019, limiting or causing extirpation of related silverspot butterflies at a known colony in the Uinta Mountains (Ellis *et al.* 2019, pers. observation) that had been there the year before (Myrup 2019, pers. comm.). However, the flood event was not outside the norm for past observed flood events in that drainage. This stochastic event provides an example of normal climate events that can cause reduction in numbers of individual butterflies or temporary extirpation of a colony but are not expected to cause permanent reduction or extirpation. Thus, climate events are not expected to reduce the subspecies' viability in the long term and are considered as a minor factor influencing the subspecies' viability.

Climate Change

The climate within the silverspot's range already appears to be changing as a result of increased greenhouse gas emissions, with earlier springs and warmer temperatures. Average temperatures in Colorado increased in the 30 years prior to 2014 by 2 degrees Fahrenheit (°F) (1.1 degrees Celsius (°C)), and by 2.5 °F (1.4 °C) in the last 50 years (Lukas *et al.* 2014, p. 2). Snowpack, as measured by snow water equivalent, has mostly been below average in Colorado since 2000. The timing of snowmelt and peak runoff has also shifted 1 to 4 weeks earlier in the last 30 years in Colorado. Furthermore, the Palmer Drought Severity Index has shown an increasing trend in soil-moisture drought conditions due to below average precipitation since 2000 and the warming trend (Lukas *et al.* 2014, p. 2). More recent analysis using National Oceanic and Atmospheric Administration (NOAA) temperature data shows that, since 1895, the average temperature in much of the northern half of the silverspot's range has

increased by, or more than, 3.6 °F (2 °C), and it is reported that average annual flows in the Colorado River Basin have declined by 20 percent over the past century (Eilperin 2020, entire). However, tree ring and other paleoclimate data indicate that there were more severe and sustained droughts prior to recent climate data (since 1900) (Lukas *et al.* 2014, pp. 2, 3). The butterfly has survived through the more severe past droughts and, despite noted changes in climate over the last 36 years, climate has thus far not been a detectable factor in reduction of the subspecies' viability. Consequently, at the present and for the current condition analysis in the SSA report, climate change is considered a minor factor. However, climate appears to be at the verge of becoming a major factor; see additional discussion of climate change under *Future Condition*, below.

Desiccation of Larvae

Desiccation of overwintering larvae may be a stressor if soil moisture and air humidity is too low or if larvae cannot remain hydrated. It is suspected that soil moisture and dead vegetation, along with some air flow, provide suitable conditions that prevent desiccation (Fisher 2020c, pers. comm.). Hydration also appears to be needed prior to first instar larvae overwintering and is achievable if water for drinking is freely available and if soil or air moisture is sufficient for absorption (Myrup 2020a, pers. comm.; Stout 2020, unpaginated). Snow cover may also provide some desiccation prevention and thermal cover, although it may not be a significant factor (Ellis 2020e, pers. comm.). Snow cover may be of benefit during extreme cold (Fisher 2020a, pers. comm.). In general, however, extreme cold in the silverspot's range is preceded by snow; thus, extreme cold may kill some larvae but is likely not a major factor that reduces the subspecies' viability.

Collecting

Collecting has occurred in silverspot colonies, and it is possible collecting in small colonies could negatively affect population resiliency (Ellis 1989, p. 15; Selby 2007, p. 31). We know of one example of a potential colony extirpation related to over-collection (Scott 2020, pers. comm.). However, collecting is not currently thought to be a significant stressor for silverspot since most colonies occur on private land, colony locations are largely unknown to the public, and current collecting pressure is not thought to be extensive (Ellis 2020f, pers. comm.). In terms of effect on the current condition of the

subspecies, collecting is currently considered a minor factor, and efforts should be taken to keep it a minor factor in the future. There is concern with collecting if public land, or even private land, colony locations are revealed in the future, but currently this factor does not appear to be significantly reducing the subspecies' viability. However, losing even one of the remaining populations to collection could have a substantial impact on the subspecies' redundancy and representation. We are concerned with the potentially detrimental effects to the subspecies from future collection if silverspot locations, especially smaller populations, are made public, which would facilitate increased collection and potentially cause collection to become a major factor affecting the subspecies' viability (see III. Critical Habitat, below).

Cumulative Effects

By using the SSA framework to guide our analysis of the scientific information documented in the SSA report, we have not only analyzed individual effects of factors on the subspecies, but we have also analyzed their potential cumulative effects. We incorporate the cumulative effects into our SSA analysis when we characterize the current and future condition of the subspecies. To assess the current and future condition of the subspecies, we undertake an iterative analysis that encompasses and incorporates the threats individually and then accumulates and evaluates the effects of all the factors that may be influencing the subspecies, including threats and conservation efforts. Habitat loss and fragmentation, human-caused hydrologic alteration, livestock grazing, genetic isolation, exotic plant invasion, climate change, climate events, larval desiccation, and collecting are all factors that influence or could influence the subspecies' viability. These factors also have the potential to act cumulatively to impact silverspot viability and their cumulative impacts were considered in our characterization of the subspecies' current and future condition in the SSA. Because the SSA framework considers not just the presence of the factors, but to what degree they collectively influence risk to the entire subspecies, our assessment integrates the cumulative effects of factors and replaces a standalone cumulative effects analysis.

Beneficial Factors

Mowing or Haying: Mowing or haying occasionally or once a year could be beneficial to open the canopy for violets, reduce a buildup of thatch from

dead vegetation, and keep woody vegetation from encroaching beyond what is suitable for the butterfly. Mowing or haying may approximate disturbance that would have occurred historically from native ungulate grazing and/or wildfire. Mowing in the early summer would allow for regrowth of vegetation and nectar sources suitable for the silverspot (Ellis 2020d, pers. comm.). However, mowing once in the late summer or early fall could potentially be compatible (Smith 2019, pers. comm.) but has a higher risk of reducing vegetation and nectar sources for that year's pupae and adults and possibly crushing pupae, eggs, and larvae. Occasional or once-yearly mowing can, nonetheless, be beneficial to reduce competition from other plants if adequate nectar sources remain in the field or if there are enough within a short distance around the field to supply nectar to adult silverspots.

Grazing: Winter and spring grazing (October to mid-April) can be beneficial to silverspots (Arnold 1989, pp. 14–15). This is because removal of thatch from the dead vegetation limits competition in the spring for the violets and can reduce woody vegetation so that it does not encroach beyond what is suitable for the butterfly. It also may approximate historical grazing patterns by native ungulates (deer and elk), which come down to lower valleys in the winter where there is less snow. Horses grazed an apparently healthy colony in the spring and summer (Arnold 1989, p. 14), so some light to moderate grazing in the spring or summer may be acceptable. In contrast, grazing when violets have emerged and are actively growing (spring and summer) may be detrimental if livestock readily consume or trample the violets and possibly eggs, larvae, and pupae.

Burning: Burning of meadows to reduce dead vegetation and reduce woody vegetation to suitable levels for the butterfly can also be beneficial and can possibly increase violet density (Arnold 1989, p. 14; Ellis 1989, p. 14).

Exotic Plant Invasion: Some exotic plants considered invasive or adventive may provide nectar sources that benefit silverspots (Ellis 1989, p. 14; Fisher 2020b, pers. comm.). However, especially with invasive plants, this may only be the case where native nectar sources have been substantially reduced or eliminated.

Conservation Efforts: The historical Unaweep Seep colony in the Mesa/Grand population was designated as a State Natural Area in 1983 (Ellis 1999, p. 2). The Bureau of Land Management (BLM) also established a Research Natural Area around it in 1983 (Ellis

1989, p. 1), and designated it as an Area of Critical Environmental Concern through their 2015 Resource Management Plan (Plank 2017, pers. comm.). Some monitoring, at least for the bog violet, occurred through 1999 (Ellis 1999, entire), but sometime after 1989 or possibly 1999, the colony became extirpated (Ellis 1999, pp. 2, 7). Habitat monitoring actions were recommended, but it is unclear whether any of them were ever implemented (Ellis 1999, pp. 8–9). Although the State of Colorado and the BLM implemented land conservation designations around the Unaweep Seep colony in the Mesa/Grand population, this colony has been extirpated for at least 20 years. Therefore, unless the bog violet and silverspot are translocated back to Unaweep Seep, the land designations do not benefit the silverspot. There are no other State regulatory mechanisms that benefit the butterfly in Colorado, New Mexico, or Utah. The Colorado Wildlife Action Plan (WAP) includes the silverspot butterfly, but there are no State statutes for management of the silverspot, so management would occur through cooperative efforts with other agencies or organizations.

The BLM (Colorado), U.S. Forest Service (USFS) Region 2 (Colorado), and USFS Region 3 (New Mexico) have the butterfly on their sensitive species lists. The USFS Region 4 (Utah) does not, but no silverspots are currently known on USFS land in Utah. No silverspot colonies are currently known on USFS land in Colorado or New Mexico either, but the elevational range of the subspecies includes some lower elevation USFS land. The BLM does not have the silverspot on its sensitive species lists in either Utah or New Mexico. If species are on BLM sensitive species lists, that means that the BLM works cooperatively with other Federal and State agencies and nongovernmental organizations to conserve these species and ensure that activities on public lands do not contribute to the need for their listing under the Act. Specific conservation objectives for BLM sensitive species are established in BLM land use plans. BLM's Grand Junction Field Office manages the Unaweep Seep property and mentions management of the area for the butterfly in their 2015 Resource Management Plan (Plank 2017, pers. comm.). The butterfly is not included in other BLM land use plans in any of the other BLM resource areas in Colorado, New Mexico, or Utah since the butterfly was not known to occur on BLM land in other areas until very recently (only one additional colony).

Only three silverspot colonies are known to occur on public land (including State lands), but there is potentially a fourth colony (unconfirmed) on public land based on recent bog violet locations for the Garfield population. Consequently, at present, any regulatory mechanisms or conservation efforts on State, BLM, and USFS lands, although contributing to conservation of silverspots, would have a low impact on the silverspot’s overall viability since the majority of populations and colonies are entirely or mostly on private land.

Current Condition

We assessed current conditions of silverspot populations in relation to the ecological requirements of this subspecies. Measurements available that are consistent across populations are habitat patch size, number of colonies, and approximate distance between colonies within a population from which genetic connectivity can be estimated. Additionally, the presence and potential influence of the three major habitat factors affecting the subspecies (habitat loss and fragmentation, grazing, and hydrologic

alteration) were derived from aerial imagery and/or on-the-ground knowledge. Therefore, these metrics are used to characterize the current resiliency condition of populations (see the SSA report’s section 3.5 “Current Condition by Population” on how metric ranks were derived; Service 2021).

Resiliency rankings and categories were established based on best available information and professional opinion of species experts. Habitat patch sizes are estimates based on expert opinion using aerial imagery based on best estimates of individual colony bog violet areas and primary nectar source areas. Determination of the number and status of colonies within a population was primarily based on expert input.

There are 10 populations comprised of 19 colonies of the silverspot butterfly. Two populations, Archuleta and Garfield, were not included in the genetic analysis by Cong *et al.* (2019) due to a lack of samples, but we consider them to be part of the silverspot butterfly subspecies due to their geographic proximity to confirmed populations.

Within the range and among all 10 populations, four known colonies have been extirpated. Three of these extirpations occurred relatively recently (in about the last 30 years) and one, Beulah, perhaps as long ago as 117 years (Scott and Fisher 2014, p. 3). Not including the extirpated colonies or stray sightings, and based on recent surveys or expert input, 19 colonies are considered extant that make up the 10 populations.

Resiliency for each population was scored using metrics for population size (in acres), number of colonies within populations, connectivity within populations, and habitat condition. Resiliency scores are categorized as follows: 0’s: Predicted extirpation (future scenarios only); 1’s: Very low resiliency; 2’s and 3’s: Low resiliency; 4’s to 6’s: Moderate resiliency; 7’s and above: High resiliency (Table 1). According to our current condition analysis in the SSA report, five populations have very low resiliency. One population has low resiliency, two populations have moderate resiliency, and two populations have high resiliency (Table 1).

TABLE 1—CURRENT CONDITION RESILIENCY RANKINGS FOR SILVERSPOT POPULATIONS

Population	Size in ac (ha)	Number of colonies	Population resiliency score
Archuleta	11.9 (4.8)	1	1
Conejos	39.2 (15.9)	1	3
Costilla	4.3 (1.7)	1	1
Garfield	1.0 (.4)	1	1
La Plata	5.2 (2.1)	1	1
Mesa/Grand	66.4 (26.9)	6	9
Montrose/San Juan	1.0 (.4)	2	4
Ourray	59.3 (24)	3	6
San Miguel/Mora	1.0 (.4)	1	1
Taos	521.2 (210.9)	2	8

With 10 populations spread across 284 air miles (457 km) north to south and 237 air miles (381 km) east to west, there appears to be adequate redundancy should catastrophic events occur that cause extirpation of one or a few populations. However, if catastrophic events cause extirpation of the populations with the highest resiliency (Mesa/Grand, Taos, and Ourray), it could be quite detrimental to the viability of the subspecies because six of the remaining populations have very low or low resiliency. Due to the uncertainty as to whether all populations are truly extant, and due to low resiliency of many populations, more populations with sufficient resiliency would contribute to the subspecies’ viability. However,

assuming all populations are still extant, we consider the current condition of the subspecies’ redundancy to be moderate.

Eight silverspot butterfly populations were identified based on genetic differentiation (Cong *et al.* 2019, entire). The other two populations were designated as such because they are more than 20 air miles (32 km) away from other populations (41 and 80 mi (66 and 129 km)) and it is likely populations more than 20 mi (32 km) apart are not genetically connected (Ellis 2020c, pers. comm.; Grishin 2020b, pers. comm.). It is likely these genetic differences provide some adaptability, or representation. However, since many of the populations are comprised of a single colony and all populations appear isolated from one

another, genetic drift could be causing limited genetic diversity, which is a concern for the subspecies. The 10 silverspot populations capture the genetic and ecological variation currently known for this subspecies. In general, the bog violet and butterfly occur in the same habitat across the range, but ecological representation adds to adaptive capacity since the silverspot occurs at different elevations, so that overall, the silverpot has low to moderate representation. Future analysis of ecological settings at all colonies/populations is needed to improve our understanding of representation across the subspecies’ range.

In summary, there are currently 19 colonies representing the 10

populations that are considered extant. In terms of resiliency, five populations are in very low condition, one in low condition, two in moderate condition, and two in high condition. Current redundancy is determined to be moderate, and representation is thought to be low to moderate.

Future Condition

In the SSA report, we forecast the resiliency of silverspot populations and the redundancy and representation of the subspecies over the next 30 years (to the year 2050) using a range of plausible future scenarios. We selected 30 years because climate model projections are relatively similar up to this point. Also, climate change impacts and human habitat impacts are likely to be the biggest drivers of changes to resiliency, redundancy, and representation for this subspecies. We used future climate projections developed for southern Colorado and northern New Mexico (Rangwala 2020a, 2020b). Four climate models captured the range of model projections; thus, we evaluate four future scenarios that capture the range of plausible futures. Three of the four models use representative concentration pathway (RCP; a greenhouse gas concentration trajectory) 4.5 and the fourth uses RCP8.5. RCP4.5 is considered a medium emissions scenario. RCP8.5 is considered a high emissions scenario. The higher the emissions, the greater chance the climate will change further from the 1971–2000 baseline. Current policies are projected to take us slightly above the RCP4.5 emission trends by mid-century (Hausfather and Peters 2020, p. 260). The climate models are presented in tables 5 and 6 in the SSA report (Service 2021).

Using the four climate scenarios, we developed four future condition scenarios to evaluate the future viability of the subspecies. In simple terms, the four scenarios include:

Scenario 1: Warm Climate with Conservation Efforts

Scenario 2: Hot and Dry Summers/Very Wet Winters with Conservation Efforts

Scenario 3: Very Hot and Very Dry Summers/Wet Winters with No Conservation Efforts

Scenario 4: Hot and Very Dry Summers/Dry Winters with No Conservation Efforts

In addition to the effects of climate change, we also considered effects of human-caused impacts. In evaluating the effects of scenarios on silverspot populations, if available information indicated hydrology of colonies/

populations will be impacted by human activity a negative habitat factor rank was applied to future resiliency scores (Service 2021, p. 46).

Because Scenarios 1 and 2 considered potential future conservation efforts, which are not certain to occur and are not formalized in any conservation agreements, we did not consider these scenarios when determining if the silverspot meets the Act's definition of an endangered species or of a threatened species. However, scenarios 1 and 2 will inform our strategies for recovery of the species. Therefore, our analysis in this proposed rule focuses on the future condition of the silverspot under scenarios 3 and 4, as summarized below. Refer to the SSA report for full descriptions of the future scenarios (Service 2021, chapter 4).

Scenario 3

Scenario 3 is characterized as follows:

- Some increase in direct habitat loss due to development occurs, particularly in colonies close to existing housing development.
- Habitat fragmentation due to agricultural conversion is not reduced.
- Light to heavy summer grazing occurs.
- No efforts are made to maintain current hydrology.
- All populations will have a negative habitat factor rank due to climate-related hydrologic alteration whether there is surrounding development or not.
- No translocations of butterflies are implemented, and genetic diversity remains in a likely low state.
- Climate emissions follow RCP8.5.

Scenario 4

Scenario 4 is characterized as follows:

- Some increase in direct habitat loss due to development occurs, particularly in colonies close to existing housing development.
- Habitat fragmentation due to agricultural conversion is not reduced.
- Light to heavy summer grazing occurs.
- No efforts are made to maintain current hydrology (but even if so, those efforts are ineffective in the face of extreme drought).
- All populations will have a negative habitat factor rank due to climate-related hydrologic factors regardless of absence of nearby development or agricultural activity or existing development and no conservation efforts.
- No translocations of butterflies are implemented, and genetic diversity remains in a likely low state.
- Climate emissions follow RCP4.5.

Results of Scenarios 3 and 4

Resiliency rankings for each population under Scenario 3 can be found in the SSA report (Service 2021, table 11; Table 2 below). Five of the previously ranked low or very low resiliency populations under current conditions are expected to become extirpated, one population has a very low resiliency, three are low resiliency, and the Ouray population retains a moderate resiliency passing the Mesa/Grand and Taos populations as the highest-ranking population. Extirpation of colonies will reduce resiliency and redundancy of populations, and will also undoubtedly decrease representation from the current condition, causing a decline in subspecies' viability compared to the current condition.

Resiliency rankings for each population under Scenario 4 can be found in the SSA report (Service 2021, table 12). As in Scenario 3, it is expected that climate change will cause extirpation of all small colonies/populations under 12 ac (5 ha). The size of habitat in remaining populations increases very slightly in Colorado populations compared to Scenario 3. Habitat decreases in the Taos population from Scenario 3 but not enough to change the size ranking. With there being slightly less evaporative stress and slightly less frequency of severe drought under Scenario 4 compared to Scenario 3, remaining populations may, in turn, be slightly more resilient. However, using the resiliency ranking metrics in the SSA report, the increase in resiliency in Scenario 4, compared to Scenario 3, is not sufficient to change the ranking of these populations. Consequently, resiliency rankings are the same as those in Scenario 3, with five extirpated populations, one very low and three low resiliency populations, and only one moderately resilient population. Redundancy of populations also remains low, and representation is also decreased from the current condition.

Summary of Current and Future Conditions

A comparison of the resiliency of each population for the current condition and future scenarios is presented below in Table 2 along with summaries of redundancy and representation (also Service 2021, table 13). Currently, we have determined that five of the 10 extant populations of silverspot are in a very low resiliency condition, one is low resiliency, two are moderate resiliency, and two of the largest populations are in high resiliency

condition. With 10 populations spread across the subspecies' range, there appears to be adequate redundancy should catastrophic events occur that cause extirpation of one or a few populations, and we consider current redundancy to be moderate for the silverspot. It is likely there is representation of adaptability due to the genetic differences observed among populations. However, many of the populations are composed of a single

colony, and all populations appear isolated genetically. In general, the bog violet and butterfly occur in the same habitat across the subspecies' range, but ecological representation adding to adaptive capacity through occurrence at different elevations gives a low-to-moderate subspecies representation currently.

Climate is predicted to change significantly over the next 30 years in scenarios 3 and 4, resulting in

conditions that cause resiliency, redundancy, representation to decrease, and thus the subspecies' viability is expected to decrease from the current condition. Resiliency rankings are the same for scenarios 3 and 4 with five extirpated populations, one very low and three low resiliency populations, and only one moderately resilient population. Redundancy of populations and representation are both reduced from the current condition.

TABLE 2—SUMMARY OF SILVERSPOT RESILIENCY, REDUNDANCY, AND REPRESENTATION FOR CURRENT CONDITION AND FOUR FUTURE SCENARIOS

Population	Current condition resiliency	Future scenario 3 resiliency	Future scenario 4 resiliency
Archuleta	1	0	0.
Conejos	3	2	2.
Costilla	1	0	0.
Garfield	1	0	0.
La Plata	1	0	0.
Mesa/Grand	9	3	3.
Montrose/San Juan	4	1	1.
Ouray	6	5	5.
San Miguel/Mora	1	0	0.
Taos	8	3	3.
Redundancy	Moderate	Very Low	Very Low.
Representation	Low-Moderate	Low	Low.

Determination of Silverspot's Status

Under the Act, the term "species" includes any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature (16 U.S.C. 1532(16)). Section 4 of the Act (16 U.S.C. 1533) and its implementing regulations (50 CFR part 424) set forth the procedures for determining whether a species meets the definition of an endangered species or a threatened species. The Act defines an "endangered species" as a species in danger of extinction throughout all or a significant portion of its range, and a "threatened species" as a species likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act requires that we determine whether a species meets the definition of endangered species or threatened species because of any of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

Status Throughout All of Its Range

We have carefully assessed the best scientific and commercial information available regarding the past, present, and future threats to the silverspot butterfly across its range in the United States. We found habitat loss and fragmentation (Factor A), incompatible livestock grazing (Factor A), human-caused hydrologic alteration (Factor A), and genetic isolation (Factor E) to be the main drivers of the subspecies' current condition, with the addition of the effects of climate change (Factor E) influencing future condition. These stressors all contribute to loss of habitat quantity and quality for the silverspot and for the bog violet, the plant on which silverspot larvae exclusively feed. These threats can currently occur anywhere in the range of the silverspot, and future effects of climate change are expected to be ubiquitous throughout the subspecies' range. The existing regulatory mechanisms (Factor D) do not significantly affect the subspecies or ameliorate these stressors; thus, these stressors continue and are predicted to increase in prevalence in the future.

Under the two future scenarios considered in this evaluation, we expect some populations to become extirpated and resiliency of the remaining populations to decrease. This would result in decreased redundancy and

representation in the future compared to the current condition.

We find that the silverspot is not currently in danger of extinction because the subspecies is still widespread with multiple populations of various sizes and resiliency spread across its range, capturing known genetic and ecological variation. Therefore, the subspecies currently has sufficient redundancy and representation to withstand catastrophic events and maintain adaptability to changes. However, we expect that the stressors, individually and cumulatively, will reduce resiliency, redundancy, and representation within all parts of the range within the foreseeable future in light of future climate change effects.

After evaluating threats to the subspecies and assessing the cumulative effect of the threats under the section 4(a)(1) factors, we find that the silverspot is likely to become endangered throughout all of its range within the foreseeable future. This finding is based on anticipated reductions in resiliency, redundancy, and representation in the future as a result of predicted loss and degradation of wet meadow habitat from the synergistic and cumulative interactions between climate change and other stressors. Climate change is predicted to increase temperatures and decrease water availability and snowpack

necessary to maintain the wet meadows that the silverspot and bog violet need. This, coupled with the continuation of other stressors that alter hydrology and cause habitat loss and fragmentation, is expected to impact the future viability of this subspecies. We can reasonably determine that both the future threats and the subspecies' responses to those threats are likely within a 30-year timeframe (*i.e.*, the foreseeable future). Thus, after assessing the best available information, we determine that the silverspot is not currently in danger of extinction but is likely to become in danger of extinction within the foreseeable future throughout all of its range.

Status Throughout a Significant Portion of Its Range

Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so in the foreseeable future throughout all or a significant portion of its range. The court in *Center for Biological Diversity v. Everson*, 2020 WL 437289 (D.D.C. Jan. 28, 2020) (*Center for Biological Diversity*), vacated the aspect of the Final Policy on Interpretation of the Phrase "Significant Portion of Its Range" in the Endangered Species Act's Definitions of "Endangered Species" and "Threatened Species" (79 FR 37578; July 1, 2014) that provided that the Service does not undertake an analysis of significant portions of a species' range if the species warrants listing as threatened throughout all of its range. Therefore, we proceed to evaluating whether the species is endangered in a significant portion of its range—that is, whether there is any portion of the species' range for which both (1) the portion is significant; and (2) the species is in danger of extinction in that portion. Depending on the case, it might be more efficient for us to address the "significance" question or the "status" question first. We can choose to address either question first. Regardless of which question we address first, if we reach a negative answer with respect to the first question that we address, we do not need to evaluate the other question for that portion of the species' range.

Following the court's holding in *Center for Biological Diversity*, we now consider whether there are any significant portions of the species' range where the species is in danger of extinction now (*i.e.*, endangered). In undertaking this analysis for the silverspot, we choose to address the status question first—we consider information pertaining to the geographic distribution of both the subspecies and

the threats that the subspecies faces to identify any portions of the range where the subspecies is endangered.

For the silverspot, we considered whether the threats are geographically concentrated in any portion of the subspecies' range at a biologically meaningful scale. We examined the following threats: Habitat loss and fragmentation; livestock grazing; human-caused hydrologic alteration; genetic isolation; climate change; climate events; invasion by nonnative plants; larval desiccation; and collecting. These are all factors that influence or could influence the subspecies' viability, including cumulative effects. All of these threats are similar in scope, scale, and distribution across the range of the subspecies. The spatial distribution of these threats is evenly distributed throughout the range and not concentrated in any particular area. However, there are a number of smaller populations distributed throughout the range that are currently in low resiliency condition and therefore could experience an elevated risk of extinction in the future (see Tables 1 and 2). However, these smaller populations are not concentrated in their location and are not at risk of extinction currently, as described in our analysis above. Rather their risk of extinction is influenced by the predicted future effects of habitat loss and degradation, climate change, and to a lesser extent the other stressors analyzed in this rule. Thus, there are no portions of the subspecies' range where the subspecies has a different status from its rangewide status. Therefore, no portion of the subspecies' range provides a basis for determining that the subspecies is in danger of extinction in a significant portion of its range, and we determine that the subspecies is likely to become in danger of extinction within the foreseeable future throughout all of its range. This is consistent with the courts' holdings in *Desert Survivors v. Department of the Interior*, No. 16-cv-01165-JCS, 2018 WL 4053447 (N.D. Cal. Aug. 24, 2018), and *Center for Biological Diversity v. Jewell*, 248 F. Supp. 3d, 946, 959 (D. Ariz. 2017).

Determination of Status

Our review of the best available scientific and commercial information indicates that the silverspot meets the Act's definition of a threatened species. Therefore, we propose to list the silverspot as a threatened species in accordance with sections 3(20) and 4(a)(1) of the Act.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened species under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and conservation by Federal, State, Tribal, and local agencies, private organizations, and individuals. The Act encourages cooperation with the States and other countries and calls for recovery actions to be carried out for listed species. The protection required by Federal agencies and the prohibitions against certain activities are discussed, in part, below.

The primary purpose of the Act is the conservation of endangered and threatened species and the ecosystems upon which they depend. The ultimate goal of such conservation efforts is the recovery of these listed species, so that they no longer need the protective measures of the Act. Section 4(f) of the Act calls for the Service to develop and implement recovery plans for the conservation of endangered and threatened species. The recovery planning process involves the identification of actions that are necessary to halt or reverse the species' decline by addressing the threats to its survival and recovery. The goal of this process is to restore listed species to a point where they are secure, self-sustaining, and functioning components of their ecosystems.

Recovery planning consists of preparing draft and final recovery plans, beginning with the development of a recovery outline and making it available to the public within 30 days of a final listing determination. The recovery outline guides the immediate implementation of urgent recovery actions and describes the process to be used to develop a recovery plan. Revisions of the plan may be done to address continuing or new threats to the species, as new substantive information becomes available. The recovery plan also identifies recovery criteria for review of when a species may be ready for reclassification from endangered to threatened ("downlisting") or removal from protected status ("delisting"), and methods for monitoring recovery progress. Recovery plans also establish a framework for agencies to coordinate their recovery efforts and provide estimates of the cost of implementing recovery tasks. Recovery teams (composed of species experts, Federal and State agencies, nongovernmental organizations, and stakeholders) are often established to develop recovery

plans. When completed, the recovery outline, draft recovery plan, and the final recovery plan will be available on our website (<https://www.fws.gov/angered>), or from our Western Colorado Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Implementation of recovery actions generally requires the participation of a broad range of partners, including other Federal agencies, States, Tribes, nongovernmental organizations, businesses, and private landowners. Examples of recovery actions include habitat restoration (e.g., restoration of native vegetation), research, captive propagation and reintroduction, and outreach and education. The recovery of many listed species cannot be accomplished solely on Federal lands because their range may occur primarily or solely on non-Federal lands. To achieve recovery of these species requires cooperative conservation efforts on private, State, and Tribal lands.

If this species is listed, funding for recovery actions will be available from a variety of sources, including Federal budgets, State programs, and cost-share grants for non-Federal landowners, the academic community, and nongovernmental organizations. In addition, pursuant to section 6 of the Act, the States of Colorado, New Mexico, and Utah would be eligible for Federal funds to implement management actions that promote the protection or recovery of the silverspot. Information on our grant programs that are available to aid species recovery can be found at: <https://www.fws.gov/grants>.

Although the silverspot is only proposed for listing under the Act at this time, please let us know if you are interested in participating in recovery efforts for this subspecies. Additionally, we invite you to submit any new information on this subspecies whenever it becomes available and any information you may have for recovery planning purposes (see **FOR FURTHER INFORMATION CONTACT**).

Section 7(a) of the Act requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as an endangered or threatened species and with respect to its critical habitat, if any is designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in destruction or adverse modification of proposed critical habitat. If a species is

listed subsequently, section 7(a)(2) of the Act requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into consultation with the Service.

Federal agency actions within the subspecies' habitat that may require conference or consultation or both as described in the preceding paragraph include management and any other landscape-altering activities on Federal lands administered by the U.S. Fish and Wildlife Service, Bureau of Land Management, Bureau of Indian Affairs, Bureau of Reclamation, National Park Service, and U.S. Forest Service; issuance of section 404 Clean Water Act (33 U.S.C. 1251 *et seq.*) permits by the U.S. Army Corps of Engineers; Natural Resources Conservation Service land management actions with private landowners and other Federal or State agencies; construction, maintenance, and funding of Federal or State roads or highways by the Federal Highway Administration; and possibly land management or other activities by other Federal agencies (such as the Office of Surface Mining, Reclamation, and Enforcement; Federal Energy Regulatory Commission; Western Area Power Administration; Federal Aviation Administration; Federal Communication Commission; Federal Emergency Management Agency; Environmental Protection Agency, and Animal and Plant Health Inspection Service).

It is our policy, as published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of a proposed listing on proposed and ongoing activities within the range of the species proposed for listing. The discussion below regarding protective regulations under section 4(d) of the Act complies with our policy.

II. Proposed Rule Issued Under Section 4(d) of the Act

Background

Section 4(d) of the Act contains two sentences. The first sentence states that the Secretary shall issue such regulations as she deems necessary and advisable to provide for the conservation of species listed as

threatened. The U.S. Supreme Court has noted that statutory language like "necessary and advisable" demonstrates a large degree of deference to the agency (see *Webster v. Doe*, 486 U.S. 592 (1988)). Conservation is defined in the Act to mean the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Additionally, the second sentence of section 4(d) of the Act states that the Secretary may by regulation prohibit with respect to any threatened species any act prohibited under section 9(a)(1), in the case of fish or wildlife, or section 9(a)(2), in the case of plants. Thus, the combination of the two sentences of section 4(d) provides the Secretary with wide latitude of discretion to select and promulgate appropriate regulations tailored to the specific conservation needs of the threatened species. The second sentence grants particularly broad discretion to the Service when adopting the prohibitions under section 9.

The courts have recognized the extent of the Secretary's discretion under this standard to develop rules that are appropriate for the conservation of a species. For example, courts have upheld rules developed under section 4(d) as a valid exercise of agency authority where they prohibited take of threatened wildlife, or include a limited taking prohibition (see *Alesea Valley Alliance v. Lautenbacher*, 2007 U.S. Dist. Lexis 60203 (D. Or. 2007); *Washington Environmental Council v. National Marine Fisheries Service*, 2002 U.S. Dist. Lexis 5432 (W.D. Wash. 2002)). Courts have also upheld 4(d) rules that do not address all of the threats a species faces (see *State of Louisiana v. Verity*, 853 F.2d 322 (5th Cir. 1988)). As noted in the legislative history when the Act was initially enacted, "once an animal is on the threatened list, the Secretary has an almost infinite number of options available to him [or her] with regard to the permitted activities for those species. He [or she] may, for example, permit taking, but not importation of such species, or he [or she] may choose to forbid both taking and importation but allow the transportation of such species" (H.R. Rep. No. 412, 93rd Cong., 1st Sess. 1973).

Exercising this authority under section 4(d), we have developed a proposed rule that is designed to address the silverspot's specific threats and conservation needs.

Although the statute does not require us to make a "necessary and advisable" finding with respect to the adoption of

specific prohibitions under section 9, we find that this rule as a whole satisfies the requirement in section 4(d) of the Act to issue regulations deemed necessary and advisable to provide for the conservation of the silverspot. As discussed above under Summary of Biological Status and Threats, we have concluded that the silverspot is likely to become in danger of extinction within the foreseeable future primarily due to the projected effects of climate change, habitat loss and fragmentation, incompatible livestock grazing, human-caused hydrologic alteration, and genetic isolation. The provisions of this proposed 4(d) rule would promote conservation of the silverspot by encouraging management of the landscape in ways that meet both land management considerations and the conservation needs of the silverspot. The provisions of this proposed rule are one of many tools that we would use to promote the conservation of the silverspot. This proposed 4(d) rule would apply only if and when we make final the listing of the silverspot as a threatened species.

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. In addition, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of proposed critical habitat.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Examples of actions that are subject to the section 7 consultation process are actions on State, Tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat—and actions on State, Tribal, local, or private lands that are not federally funded, authorized, or carried out by a Federal

agency—do not require section 7 consultation.

This obligation does not change in any way for a threatened species with a species-specific 4(d) rule. Actions that result in a determination by a Federal agency of “not likely to adversely affect” continue to require the Service’s written concurrence and actions that are “likely to adversely affect” a species require formal consultation and the formulation of a biological opinion.

Provisions of the Proposed 4(d) Rule

This proposed 4(d) rule would provide for the conservation of the silverspot by prohibiting the following activities, with certain exceptions (discussed below): Importing or exporting; possession and other acts with unlawfully taken specimens; delivering, receiving, transporting, or shipping in interstate or foreign commerce in the course of commercial activity; and selling or offering for sale in interstate or foreign commerce. In addition, anyone taking, attempting to take, or otherwise possessing a silverspot, or parts thereof, in violation of section 9 of the Act would be subject to a penalty under section 11 of the Act, with certain exceptions (discussed below).

Under the Act, “take” means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. Some of these provisions have been further defined in regulations at 50 CFR 17.3. Take can result knowingly or otherwise, by direct and indirect impacts, intentionally or unintentionally. Allowing incidental and intentional take in certain cases, such as for the purposes of scientific inquiry or monitoring, or to improve habitat availability and quality, would help preserve the silverspot’s remaining populations, slow their rate of decline, and decrease synergistic, negative effects from other stressors.

We may issue permits to carry out otherwise prohibited activities, including those described above, involving threatened wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.32. With regard to threatened wildlife, a permit may be issued for the following purposes: For scientific purposes, to enhance propagation or survival, for economic hardship, for zoological exhibition, for educational purposes, for incidental taking, or for special purposes consistent with the purposes of the Act. The statute also contains certain exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

We recognize the special and unique relationship with our State natural resource agency partners in contributing to conservation of listed species. State agencies often possess scientific data and valuable expertise on the status and distribution of endangered, threatened, and candidate species of wildlife and plants. State agencies, because of their authorities and their close working relationships with local governments and landowners, are in a unique position to assist us in implementing all aspects of the Act. In this regard, section 6 of the Act provides that we shall cooperate to the maximum extent practicable with the States in carrying out programs authorized by the Act. Therefore, any qualified employee or agent of a State conservation agency that is a party to a cooperative agreement with us in accordance with section 6(c) of the Act, who is designated by his or her agency for such purposes, would be able to conduct activities designed to conserve the silverspot that may result in otherwise prohibited take without additional authorization.

As discussed above under *Factors Influencing Subspecies Viability*, incompatible livestock grazing, exotic plant invasion, prescribed burning, and use of pesticides affect the status of the silverspot both negatively and positively depending on how, when, and where they are done. Accordingly, this proposed 4(d) rule addresses activities to facilitate conservation and management of the silverspot where they currently occur and may occur in the future by excepting them from the Act’s take prohibition under certain specific conditions. These activities are intended to increase management flexibility and encourage support for the conservation and habitat improvement of the silverspot. Under this proposed 4(d) rule, take would be prohibited, except for take incidental to an otherwise lawful activity caused by actions described in the exceptions to prohibitions in the proposed 4(d) rule for the purpose of silverspot conservation or recovery.

The proposed forms of allowable take are explained in more detail below. For all proposed forms of allowable take, reasonable care would have to be practiced to minimize the impacts from the actions. Reasonable care means limiting the impacts to the silverspot and its host plant (bog violet) by complying with all applicable Federal, State, and Tribal regulations for the activity in question; using methods and techniques that result in the least harm, injury, or death, as feasible; undertaking activities at the least impactful times (*e.g.*, conducting activities that might

impact habitat during the flight season) and locations, as feasible; ensuring the number of individuals affected does not impact the existing populations; ensuring no introduction of invasive plant species; and preserving the genetic diversity of populations.

Under the proposed 4(d) rule, incidental take of a silverspot butterfly would not be a violation of section 9 of the Act if it occurs as a result of the following activities. All activities and statements below only apply to habitat areas of silverspot that include wet meadow areas where bog violet are growing and immediately adjacent areas with nectar sources.

Livestock Grazing

By excepting take of silverspot caused by grazing, we would acknowledge the positive role that some ranchers have already played in conserving the silverspot butterfly and the importance of preventing any additional loss and fragmentation of native grasslands and riparian habitat. Grazing may be an effective tool to improve silverspot habitat by opening up the habitat and reducing vegetation that competes with bog violet when carefully applied in cooperation and consultation with private landowners, public land managers, and grazing experts. Moderate vegetative utilization (40–55 percent) in late fall to early spring (October 15 to May 31) would be excepted under this proposed 4(d) rule. Resting pastures that include silverspot habitat is preferred in summer through fall (June 1 to October 14), but light grazing (less than 30 percent utilization) during this time frame would also be excepted from take by reducing competition with the bog violet. Recovery of the silverspot will depend on the protection and restoration of high-quality habitats supporting the bog violet on private lands and on public lands that are grazed by private individuals under lease or other agreements.

Annual Haying or Mowing

Annual haying or mowing in early summer can be beneficial, or at least not detrimental, to silverspots by removing vegetation that competes with the bog violet. Therefore, we are proposing to except take from annual haying or mowing in silverspot habitat under the following conditions: Activities must occur in the early summer (June 30 or earlier), and blade height would need to be a minimum of 6 inches, with 8 inches or higher preferred in areas with bog violet to avoid cutting the violet leaves. The timing of cutting also applies to surrounding drier areas

important for nectaring, but blade height could be lower than 6 inches where the violet is not present. However, haying or mowing from July 1 through October would be detrimental due to removal of nectar sources and cover for all silverspot life stages, and therefore would not be excepted from the prohibitions in the proposed 4(d) rule in and adjacent to bog violet habitat.

Prescribed Burning

Spring burning can be beneficial to remove thatch that may reduce or prevent growth of the bog violet. Prescribed burning in the spring (March 1 to April 30) has limited impact to silverspots and would be excepted from take. Fall burning (October 15 to December 15) would also be excepted if the silverspot butterfly has been shown to not be present in a given year through adequate monitoring (*i.e.*, multiple surveys at times when butterflies are active).

Brush Control

Some woody vegetation interspersed in silverspot habitat or at the margins of habitat can be beneficial. However, if allowed to become too dense, woody vegetation can crowd out bog violets and nectar sources. Consequently, brush removal every 4 to 5 years would be excepted from take. Removal can be by mechanical means, burning, grazing, or herbicide application if in compliance with other excepted activities in the proposed 4(d) rule. If mechanical means such as a brush hog is used, the blade would need to be set to 8 inches or higher. If herbicides are used, an appropriate systemic herbicide to prevent regrowth would need to be applied to cut stems. Broadcast spraying in silverspot habitat would be prohibited because it may remove all nectar sources for the butterfly.

Noxious Weed Control

Although some noxious weeds like Canada thistle may provide nectar sources for silverspot, spot spraying, hand pulling, or mowing of noxious weeds would be excepted from take. High densities of noxious weeds can be detrimental to the bog violet and their control can benefit the silverspot. However, broadcast spraying in silverspot habitat would be prohibited because it may remove all nectar sources for the butterfly.

Fence Maintenance

Proposed excepted activities related to fence maintenance include replacement of poles and wire, and aboveground removal of woody vegetation along fence lines. Fences

help manage where cattle can graze and reduce unwanted impacts to bog violet habitat. Removal of woody vegetation can prevent encroachment of vegetation into bog violet habitat and reduces competition with bog violet. If removal of woody vegetation is done by machine, such as a brush hog, the machine blade would need to be set 8 inches or higher above ground to avoid or minimize damage to the butterfly's host plant (bog violet). We recommend a systemic herbicide applied to the cut stems of woody vegetation.

Maintenance of Other Structures

Maintenance of other existing structures within and immediately adjacent to silverspot habitat would be excepted if activities are kept within the confines of already disturbed ground so as to not disturb the subspecies or its habitat.

Nothing in this proposed 4(d) rule would change in any way the recovery planning provisions of section 4(f) of the Act, the consultation requirements under section 7 of the Act, or our ability to enter into partnerships for the management and protection of the silverspot. However, interagency cooperation may be further streamlined through planned programmatic consultations for the subspecies between us and other Federal agencies, where appropriate. We ask the public, particularly State agencies and other interested stakeholders that may be affected by the proposed 4(d) rule, to provide comments and suggestions regarding additional guidance and methods that the Service could provide or use, respectively, to streamline the implementation of this proposed 4(d) rule (see Information Requested, above).

III. Critical Habitat

Background

Critical habitat is defined in section 3 of the Act as:

- (1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features
 - (a) Essential to the conservation of the species, and
 - (b) Which may require special management considerations or protection; and
 - (2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.
- Our regulations at 50 CFR 424.02 define the geographical area occupied

by the species as an area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.*, range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.*, migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals). Additionally, our regulations at 50 CFR 424.02 define the word "habitat," for the purposes of designating critical habitat only, as the abiotic and biotic setting that currently or periodically contains the resources and conditions necessary to support one or more life processes of a species.

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Designation also does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the Federal agency would be required to consult with the Service under section 7(a)(2) of the Act. However, even if the Service were to conclude that the proposed activity would result in destruction or adverse modification of the critical habitat, the Federal action agency and the landowner are not required to abandon the proposed activity, or to restore or recover the species; instead, they must implement "reasonable and prudent

alternatives" to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific and commercial data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat). In identifying those physical or biological features that occur in specific occupied areas, we focus on the specific features that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity.

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. The implementing regulations at 50 CFR 424.12(b)(2) further delineate unoccupied critical habitat by setting out three specific parameters: (1) When designating critical habitat, the Secretary will first evaluate areas occupied by the species; (2) the Secretary will consider unoccupied areas to be essential only where a critical habitat designation limited to geographical areas occupied by the species would be inadequate to ensure the conservation of the species; and (3) for an unoccupied area to be considered essential, the Secretary must determine that there is a reasonable certainty both that the area will contribute to the conservation of the species and that the area contains one or more of those physical or biological features essential to the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available.

Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106-554; H.R. 5658)), and our associated Information Quality Guidelines provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

Prudency Determination

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, the Secretary shall designate critical habitat at the time the species is determined to be an endangered or threatened species. Our regulations (50 CFR 424.12(a)(1)) state that the Secretary may, but is not required to, determine that a designation would not be prudent in the following circumstances:

(i) The species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species;

(ii) The present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or threats to the species' habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act;

(iii) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States;

(iv) No areas meet the definition of critical habitat; or

(v) The Secretary otherwise determines that designation of critical habitat would not be prudent based on the best scientific data available.

Designation of critical habitat requires the publication of maps and a narrative description of specific critical habitat areas in the **Federal Register**. The degree of detail in those maps and boundary descriptions is greater than the general location descriptions provided in this proposal to list the silverspot as a threatened species. We

are concerned that designation of critical habitat would more widely announce the exact locations of silverspots to collectors. We believe that the publication of maps and descriptions outlining the locations of the silverspot would further facilitate unauthorized collection and trade, as collectors would know the exact locations where silverspots occur.

Although we do not have recent evidence of collection of the silverspot butterfly, we believe this is due to the public being largely unaware of where the silverspot butterfly occurs. Recent genetic studies reclassifying the multiple subspecies of *nokomis* may serve to increase interest in butterfly collection. In addition, collection of butterflies would be extremely difficult to detect, given the remote locations where the silverspot occurs. The silverspot has been collected in the past, and there is potential for collection pressure to increase if specific locations of populations were to become widely known (Ellis 2020e, pers. comm.; Scott 2020, pers. comm.). Butterflies in general are highly sought after by collectors in the illegal animal trade (Speart 2012, entire). Some experts have expressed concern that small populations/colonies of this subspecies could be impacted by collection pressure if it were to increase after the subspecies is listed (Scott 2020, pers. comm.). Experts have noted that individuals from small populations should not be collected (Scott 2020, pers. comm.). Many of the extant populations of the silverspot are small and currently in low resiliency condition, and therefore could be easily extirpated if collection pressure increased. The silverspot's annual life cycle also lends itself to increased negative population-level impacts if over-collection were to occur. We know of one example of a potential silverspot colony extirpation related to over-collection (combined with vegetation changes) (Scott 2020, pers. comm.). Many populations are on private land and locations of occupied colonies are currently not widely known. Therefore, publishing specific location information would provide a high level of assurance that any person going to a specific location would be able to successfully locate and collect silverspots given the subspecies' site fidelity and ease of capture once located. Identification of locations of populations through publication of a critical habitat designation for the silverspot can be expected to increase the degree of collection threat to the subspecies.

In conclusion, we find that the designation of critical habitat is not

prudent for the silverspot, in accordance with 50 CFR 424.12(a)(1), because the silverspot faces a threat of unauthorized collection and trade, and designation can reasonably be expected to increase the degree of these threats to the subspecies.

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

- (1) Be logically organized;
- (2) Use the active voice to address readers directly;
- (3) Use clear language rather than jargon;
- (4) Be divided into short sections and sentences; and
- (5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), need not be prepared in connection with listing a species as an endangered or threatened species under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In

accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. Thirty-eight Tribes with cultural claims or affiliation to land or with lands currently in the range of the silverspot were contacted via letter to solicit input on the SSA. One Tribe responded and stated that they do not have scientific data but would like to be kept informed of findings of the SSA. We have determined that critical habitat is not prudent for the silverspot, so no Tribal lands (or other lands) will be included in a proposed critical habitat designation.

References Cited

A complete list of references cited in this rulemaking is available on the internet at <https://www.regulations.gov> and upon request from the Western Colorado Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Fish and Wildlife Service's Species Assessment Team and the Western Colorado Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

- 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

- 2. Amend § 17.11, in paragraph (h), by adding an entry for “Butterfly, silverspot” to the List of Endangered and Threatened Wildlife in alphabetical order under INSECTS to read as follows:

§ 17.11 Endangered and threatened wildlife. (h) * * *

* * * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
* INSECTS	*	*	*	*
Butterfly, silverspot	<i>Speyeria nokomis nokomis</i> .	Wherever found	T	[Federal Register citation when published as a final rule]; 50 CFR 17.47(h). ^{4d}
*	*	*	*	*

■ 3. As proposed to be amended at 85 FR 1018 (January 8, 2020), 85 FR 64908 (October 13, 2020), and 86 FR 32859 (June 23, 2021), § 17.47 is further amended by adding a paragraph (h) to read as follows:

§ 17.47 Special rules—insects.

* * * * *

(h) Silverspot butterfly (*Speyeria nokomis nokomis*).

(1) *Prohibitions.* The following prohibitions that apply to endangered wildlife also apply to silverspot butterfly. Except as provided under paragraphs (h)(2) and (3) of this section and §§ 17.4 and 17.5, it is unlawful for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit another to commit, or cause to be committed, any of the following acts in regard to this species:

- (i) Import or export, as set forth at § 17.21(b) for endangered wildlife.
- (ii) Take, as set forth at § 17.21(c)(1) for endangered wildlife.
- (iii) Possession and other acts with unlawfully taken specimens, as set forth at § 17.21(d)(1) for endangered wildlife.
- (iv) Interstate or foreign commerce in the course of a commercial activity, as set forth at § 17.21(e) for endangered wildlife.
- (v) Sale or offer for sale, as set forth at § 17.21(f) for endangered wildlife.

(2) *General exceptions from prohibitions.* In regard to this species, you may:

- (i) Conduct activities as authorized by a permit under § 17.32.
- (ii) Take, as set forth at § 17.21(c)(2) through (c)(4) for endangered wildlife.
- (iii) Take as set forth at § 17.31(b).
- (iv) Possess and engage in other acts with unlawfully taken wildlife, as set forth at § 17.21(d)(2) for endangered wildlife.

(3) *Exceptions from prohibitions for specific types of incidental take.* You may take silverspot butterfly without a permit in wet meadow areas where bog violets (*Viola nephrophylla/V. sororia* var. *affinis*) are growing and immediately adjacent areas with nectar sources while carrying out the legally conducted activities set forth in this paragraph (h)(3), as long as the activities:

- (i) Are conducted with reasonable care. For the purposes of this paragraph, “reasonable care” means limiting the impacts to the silverspot and bog violet by complying with all applicable Federal, State, and Tribal regulations for the activity in question; using methods and techniques that result in the least harm, injury, or death, as feasible; undertaking activities at the least impactful times (e.g., conducting activities that might impact habitat during the flight season) and locations, as feasible; ensuring the number of individuals affected does not impact the existing populations; ensuring no introduction of invasive plant species; and preserving the genetic diversity of populations;
- (ii) Consist of one or more of the following:
 - (A) Grazing:
 - (1) Moderate grazing (40 to 55 percent vegetative utilization) in late fall to early spring (October 15 to May 31); or
 - (2) Light grazing (less than 30 percent vegetative utilization) in summer through fall (June 1 to October 14).
 - (B) Annual haying or mowing in silverspot habitat in the early summer (June 30 or earlier). Blade height must be a minimum of 6 inches, with 8 inches or higher preferred in areas with bog violet. In surrounding drier areas,

blade height may be lower than 6 inches where the violet is not present.

(C) Prescribed burning:

(1) In the spring (March 1 to April 30); or

(2) In the fall (October 15 to December 15), if the silverspot butterfly has been shown to not be present in a given year through adequate monitoring (i.e., multiple surveys at times when butterflies are active).

(D) Brush removal every 4 to 5 years. Removal can be by mechanical means, burning, grazing, or herbicide application if in compliance with other excepted activities in this paragraph (h)(3). If mechanical means such as a brush hog is used, the blade must be set to 8 inches or higher. If herbicides are used, an appropriate systemic herbicide to prevent regrowth must be applied to cut stems, but broadcast spraying is prohibited.

(E) Spot spraying, hand pulling, or mowing of noxious weeds. Broadcast spraying of noxious weeds is prohibited.

(F) Replacement of fence poles and wire, and aboveground removal of woody vegetation along fence lines. If removal of woody vegetation is done by machine, such as a brush hog, the machine blade must be set 8 inches or higher. We recommend a systemic herbicide applied to the cut stems of woody vegetation.

(G) Maintenance of other existing structures within and immediately adjacent to silverspot habitat if activities are kept within the confines of already disturbed ground.

Martha Williams,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2022–09446 Filed 5–3–22; 8:45 am]

BILLING CODE 4333–15–P

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

[Docket No. FCIC-22-0002]

Information Collection Request; Interpretations of Statutory and Regulatory Provisions and Written Interpretations of FCIC Procedures; Notice of Request for Renewal of a Currently Approved Information Collection

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Notice; request for comment.

SUMMARY: This notice announces a public comment period on the information collection requests (ICRs) associated with the interpretations of provisions of the Act or any regulation codified in the Code of Federal Regulations, and interpretations of policy provision not codified in the Code of Federal Regulations or any procedure used in the administration of the Federal crop insurance program.

DATES: Written comments on this notice will be accepted until close of business July 5, 2022.

ADDRESSES: FCIC prefers that comments be submitted electronically through the Federal eRulemaking Portal. You may submit comments, identified by Docket ID No. FCIC-22-0002, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Director, Product Administration and Standards Division, Risk Management Agency, United States Department of Agriculture, P.O. Box 419205, Kansas City, MO 64133-6205.

All comments received, including those received by mail, will be posted without change to <http://www.regulations.gov>, including any personal information provided, and can be accessed by the public. All comments

must include the agency name and docket number or Regulatory Information Number (RIN) for this rule. For detailed instructions on submitting comments and additional information, see <http://www.regulations.gov>. If you are submitting comments electronically through the Federal eRulemaking Portal and want to attach a document, we ask that it be in a text-based format. If you want to attach a document that is a scanned Adobe PDF file, it must be scanned as text and not as an image, thus allowing FCIC to search and copy certain portions of your submissions. For questions regarding attaching a document that is a scanned Adobe PDF file, please contact the RMA Web Content Team at (816) 823-4694 or by email at rmaweb.content@rma.usda.gov.

Privacy Act: Anyone is able to search the electronic form of all comments received for any dockets by the name of the person submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the complete User Notice and Privacy Notice for [Regulations.gov](http://www.regulations.gov) at <http://www.regulations.gov/#!privacyNotice>.

SUPPLEMENTARY INFORMATION:

Title: Interpretations of Statutory and Regulatory Provisions and Written Interpretations of FCIC Procedures.

OMB Number: 0563-0055.

Expiration Date of Approval: August 31, 2022.

Type of Request: Extension with a revision.

Abstract: FCIC is proposing to renew the currently approved information collection, OMB Number 0563-0055. It is currently up for renewal and extension for three years. The information collection requirements for this renewal package are necessary for FCIC to respond to requests for interpretations of provisions of the Federal Crop Insurance Act, policy provisions codified in the Code of Federal Regulations, policy provisions not codified in the Code of Federal Regulations, and procedures used in the administration of the Federal crop insurance program. This data is used to administer the provisions of 7 CFR part 400, subpart X in accordance with the Federal Crop Insurance Act, as amended.

We are asking the Office of Management and Budget (OMB) to extend its approval of our use of this

information collection activity for an additional 3 years.

The purpose of this notice is to solicit comments from the public concerning this information collection activity. These comments will help us:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies, e.g., permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 8 hours per response.

Respondents/Affected Entities: Parties affected by the information collection requirements included in this Notice are any producer (including their legal counsel) with a valid crop insurance policy and approved insurance provider (agents, loss adjusters, employees, contractors, or legal counsel) with agreement with FCIC.

Estimated annual number of respondents: 75.

Estimated annual number of responses per respondent: 1.

Estimated annual number of responses: 75.

Estimated total annual burden hours on respondents: 600.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, or other collection technologies, e.g., permitting electronic submission of responses.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Marcia Bunger,

Manager, Federal Crop Insurance Corporation.

[FR Doc. 2022-09576 Filed 5-3-22; 8:45 am]

BILLING CODE 3410-08-P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Produce Safety University Nomination and Course Evaluation

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This collection is a new collection for notification of Produce Safety University annual training to State agencies and nomination of participants to attend Produce Safety University.

DATES: Written comments must be received on or before July 5, 2022.

ADDRESSES: Comments may be sent to: Emma Kingsbury, Food and Nutrition Service, U.S. Department of Agriculture, 1320 Braddock Place, Alexandria, VA 22314. Comments may also be submitted via fax to the attention of Emma Kingsbury at 703-305-2955 or via email to emma.kingsbury@usda.gov. Comments will also be accepted through the Federal eRulemaking Portal. Go to <http://www.regulations.gov>, and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of this information collection should be directed to Emma Kingsbury at 703-305-2955.

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the

methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Produce Safety University Nomination and Course Evaluation.

Form Number: None.

OMB Number: 0584-NEW.

Expiration Date: To be determined.

Type of Request: New collection.

Abstract: Produce Safety University (PSU) is a training course designed to help child nutrition professionals identify and manage food safety risks associated with fresh produce. The PSU course is designed to be a train-the-trainer immersion course, where participants are expected to conduct further training with their peers using the information they obtain during PSU. The PSU curriculum covers all aspects of the fresh produce procurement chain, from growing and harvesting to storage and preparation through a combination of lecture, laboratory, and field-trip instruction. PSU was not held in 2020 due to the COVID-19 pandemic; during 2021 PSU transitioned to a virtual course, which included pre-recorded field-trip and laboratory components that participants were able to view these aspects virtually, while maintaining the full experience of PSU. Looking forward, PSU will likely continue through a hybrid approach, with both in-person sessions and virtual sessions offered annually.

The purpose of the proposed collection of information is twofold. The first is to electronically collect course nomination from child nutrition professionals and State agency staff to attend Produce Safety University (PSU). State agencies may nominate individuals to attend PSU and receive annual logistic information through a letter from FNS. The letter to States includes a link to the online course nomination. While nomination is voluntary, if a participant wishes to attend Produce Safety University, completion of the course nomination is mandatory. To ensure that PSU provides the most appropriate training content that is tailored to the audience, it is necessary to know the occupational make-up of each training co-hort. Therefore, job titles and the name of the organization nominees represent will be collected. Collecting this information on the course nomination will ensure that the Office of Food Safety offers this

training opportunity equally among each of the States and seven FNS Regions. Additional contact information is needed from participants to support their learning experience; when PSU training sessions are held virtually, physical course materials are shipped to each participant. These materials include slides, activities, and supplemental print resources, making address collection necessary.

The second aspect of the proposed collection of information involves program evaluation. The program evaluation involves three instruments, each designed to collect specific information from respondents at specific times. The Welcome Questions are given to confirmed PSU participants to assess where the training cohort lies in terms of knowledge and experience, which allows for the training team to make minor changes based on the foundational knowledge a group may have. The Course Evaluation involves questions following each session of PSU to assess if the session achieved its objective, and whether or not the time allotted was sufficient. The Course Evaluation also addresses how effective the training team and resources were in helping PSU participants grasp all information taught in the course. This information is crucial to ensure PSU is satisfying participants' expectations and supporting Child Nutrition program operators with accurate and helpful information. The Program Impact Evaluation is used to measure how the PSU courses have impacted participants six months after their completion of PSU. Since PSU is designed to be a train-the-trainer course, determining if graduates taught others on topics learned in PSU is essential to further the mission of the course. The Program Impact Evaluation is also used to inform resource development to support graduates in their efforts to train others on topics learned in PSU.

The Nomination Form for Produce Safety University (FNS-909) is currently approved under OMB# 0584-0611 FNS Fast Track Clearance for the Collection of Routine Customer Feedback, which expires on September 30, 2022. This fast track clearance is meant for one-time collections of customer feedback on a variety of programs. Since the original submission, FNS has decided that this will be an ongoing collection, so we are now seeking approval for this under a new OMB control number. FNS has also made changes to the collection since the original submission. Under OMB# 0584-0611, this collection has two instruments, the FNS-909 and a sample State Agency Letter, with a total of 218 responses and 55 burden hours. FNS

has made a number of changes as part of this new collection. These changes include the following: The FNS-909 is no longer the most appropriate instrument to collect the information from participants, and the new collection will not use the FNS-909. The proposed collection includes new questions outside of the FNS-909 scope. The new questions are necessary to determine nominee eligibility for training participation. We have also updated the course nomination from a paper to online format.

Affected Public: State, Local, and Tribal governments. Respondent groups identified include: (1) Child Nutrition program operators and (2) State agency staff.

Estimated Number of Respondents: The annual number of respondents is two-fold since those completing the course evaluations are a subset of those who completed the nomination form. The number of respondents to the State agency letter and nomination form is 285. This includes: 155 child nutrition professionals and 130 State agency staff. Approximately half of the State agency

staff read the letter but complete no further components of the collection. The course evaluations (welcome questions, course evaluations, and program impact evaluations) will be completed by a subset of respondents to the course nomination who were selected for participation in PSU. The total number of unique respondents for this collection is 285.

Estimated Number of Responses per Respondent: Each respondent will be asked to complete the nomination information one time. Respondents are asked to complete all three program evaluation instruments, however, since participation is voluntary, few participants choose to respond to all three program evaluation components. Because of this, FNS estimates that the frequency for the requirements in this collection will mainly be 1, although it may range anywhere from 1 to 4, depending on how many of the optional evaluation instruments the respondent decides to complete. Overall, FNS estimates that the number of responses per respondents across the entire collection is 2.256.

Estimated Total Annual Responses: 643 total annual responses. Following the course nomination, respondents may choose to voluntarily respond to other instruments (Welcome Questions, Course Evaluation, and Program Impact Evaluation). Therefore, the total number of responses across all instruments does not equal the number of unique respondents (see estimated annual burden table below for response breakdown).

Estimated Time per Response: The estimated time of response is 5 minutes (0.083 hours) for the State agency letter, 15 minutes (0.25 hours) for the course nomination, 10 minutes (0.167 hours) for Welcome Questions, 15 minutes for Course Evaluation, and 20 minutes (0.334 hours) for Program Impact Evaluation as shown in the table below. This is an annual average time of approximately 13 minutes (0.214 hours) per respondent across all of the items in the collection.

Estimated Total Annual Burden on Respondents: 138 hours. See the table below for estimated total annual burden for each type of respondent.

Respondent	Estimated number respondent	Responses annually per respondent	Total annual responses (Col. bxc)	Estimated avg. number of hours per response	Estimated total hours (Col. dxe)
Reporting Burden					
CN program operators—Course Nomination	155	1.00	155	0.25	38.8
CN program operators—Welcome Questions *	69	1.00	69	0.167	11.5
CN program operators—Course Evaluation *	98	1.00	98	0.25	24.5
CN program operators—Program Impact Evaluation *	57	1.00	57	0.334	19.0
Subtotal for Child Nutrition Program Operators	155	2.44516129	379	0.247522427	93.8
State agency—Stage Agency Letter	130	1.00	130	0.0835	10.8
State agency—Course Nomination **	65	1.00	65	0.25	16.3
State agency—Welcome Questions **	21	1.00	21	0.167	3.5
State agency—Course Evaluation **	31	1.00	31	0.25	7.8
State agency—Program Impact Evaluation **	17	1.00	17	0.334	5.7
Subtotal for State Agency Staff	130	2.030769231	264	0.166609848	44.0
Total for State, Local, or Tribal Government	285	2.256140351	643	0.214301711	137.8
Total Reporting Burden	285	2.256	643	0.214	138

* Indicates that the respondents are a subset of those responding to the course nomination and are not unique responses. There are 155 unique CN program operator respondents.

** Indicates that the respondents are a subset of those receiving the State Agency Letter and are not unique responses. There are 130 unique State agency respondents.

Cynthia Long,
Administrator, Food and Nutrition Service.
 [FR Doc. 2022-09529 Filed 5-3-22; 8:45 am]
BILLING CODE 3410-30-P

COMMISSION ON CIVIL RIGHTS
Notice of Public Meeting of the Minnesota Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of virtual business meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Minnesota Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a virtual business meeting via Webex at 12:00 p.m. CT on Tuesday, May 17, 2022. The purpose of

this meeting is to discuss the Committee's project on policing practices in the state.

DATES: The meeting will take place on Tuesday, May 17, 2022, at 12:00 p.m. CT.

FOR FURTHER INFORMATION CONTACT: David Barreras, DFO, at dbarreras@usccr.gov or (202) 656-8937.

SUPPLEMENTARY INFORMATION:

Link to Join (Audio/Visual): <https://tinyurl.com/4jdnf8c9>

Telephone (Audio Only): Dial (800) 360-9505 USA Toll Free; Access Code: 2762 953 3803

Committee meetings are available to the public through the conference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges.

Individuals who are deaf, deafblind, and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at (800) 877-8339 and providing the Service with the conference details found through registering at the web link above. To request additional accommodations, please email dbarreras@usccr.gov at least ten (10) days prior to the meeting.

Members of the public are also entitled to submit written comments; the comments must be received within 30 days following the meeting. Written comments may be emailed to Liliana Schiller at lschiller@usccr.gov. Persons who desire additional information may contact the Regional Programs Coordination Unit at (312) 353-8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit, as they become available, both before and after the meeting. Records of the meeting will be available via www.facadatabase.gov under the Commission on Civil Rights, Minnesota Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, <http://www.usccr.gov>, or may contact the Regional Programs Coordination Unit at the above phone number.

Agenda:

- I. Welcome & Roll Call
- II. Civil Rights Discussion
- III. Public Comment
- IV. Next Steps
- V. Adjournment

Dated: April 29, 2022.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2022-09561 Filed 5-3-22; 8:45 am]

BILLING CODE 6335-01-P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Current Population Survey, School Enrollment Supplement

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on February 18, 2022, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: U.S. Census Bureau, Department of Commerce.

Title: Current Population Survey, School Enrollment Supplement.

OMB Control Number: 0607-0464.

Form Number(s): None.

Type of Request: Regular submission. Request for a Revision of a Currently Approved Collection.

Number of Respondents: 54,000.

Average Hours per Response: 0.05.

Burden Hours: 2,700.

Needs and Uses: These data provide basic information on the school enrollment status of various segments of the population necessary as background for policy formulation and implementation. This supplement is the only annual source of data on public/private elementary and secondary school enrollment, as well as the characteristics of private school students and their families. As part of the Federal Government's efforts to collect data and provide timely information to government entities for policymaking decisions, this supplement provides national trends in enrollment and progress in school. Consequently, this supplement is the only source of historical data at the national level on the age distribution

and family characteristics of college students, and on the demographic characteristics of preprimary school enrollment.

Affected Public: Individuals or households.

Frequency: Annually.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13, United

States Code, Sections 8(b), 141, and 182 authorize the Census Bureau and Title 29, United States Code, Section 2 authorizes the Bureau of Labor Statistics to collect this information. The Education Sciences Reform Act of 2002 (ESRA, Title 20, United States Code, Section 9543) authorizes the National Center for Education Statistics to collect this information.

This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function and entering either the title of the collection or the OMB Control Number 0607-0464.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022-09536 Filed 5-3-22; 8:45 am]

BILLING CODE 3510-07-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-201-842]

Large Residential Washers From Mexico: Final Results of Antidumping Duty Administrative Review; 2020-2021

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that large residential washers (washers) from Mexico were not sold in the United States at less than normal value (NV) during the period of review (POR) February 1, 2020, through January 31, 2021.

DATES: Applicable May 4, 2022.

FOR FURTHER INFORMATION CONTACT: Tara Moran, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-3619.

SUPPLEMENTARY INFORMATION:

Background

This review covers one producer/exporter of the subject merchandise, Electrolux Home Products Corp. N.V. and Electrolux Home Products de Mexico, S.A. de C.V. (collectively, Electrolux). On February 24, 2022, Commerce published the *Preliminary Results* and invited interested parties to comment.¹ We received no comments from interested parties on the *Preliminary Results*. Commerce conducted this administrative review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The products covered by the order are all large residential washers and certain subassemblies thereof from Mexico. The products are currently classifiable under subheadings 8450.20.0040 and 8450.20.0080 of the Harmonized Tariff System of the United States (HTSUS). Products subject to this order may also enter under HTSUS subheadings 8450.11.0040, 8450.11.0080, 8450.90.2000, and 8450.90.6000. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to this scope is dispositive.²

Finals Results of the Review

We received no comments and are making no changes from the *Preliminary Results*. Therefore, as a result of this review, we continue to determine that the following weighted-average dumping margin exists for the respondent for the period February 1, 2020, through January 31, 2021:

Producer/exporter	Weighted-average dumping margin (percent)
Electrolux	0.00

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act, and 19 CFR 351.212(b)(1),

¹ See *Preliminary Results of Antidumping Duty Administrative Review; 2020-2021*, 87 FR 10336 (February 24, 2022), and accompanying Preliminary Decision Memorandum (PDM).

² For a full description of the scope of the order, see *Preliminary Results PDM*.

Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

Pursuant to 19 CFR 351.212(b)(1), Electrolux reported the entered value of its U.S. sales such that we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the examined sales to the total entered value of the sales for which entered value was reported. Where the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific assessment rate is zero or *de minimis*, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Commerce's "automatic assessment" practice will apply to entries of subject merchandise during the POR produced by Electrolux for which the company did not know that the merchandise it sold to the intermediary (*e.g.*, a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate of 36.52 percent³ if there is no rate for the intermediate company(ies) involved in the transaction.⁴

Commerce intends to issue liquidation instructions to CBP no earlier than 41 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the exporter listed above will be equal to the weighted-average dumping margin established in the final results of this

³ See *Large Residential Washers from Mexico and the Republic of Korea: Antidumping Duty Orders*, 78 FR 11148 (February 15, 2013).

⁴ For a full discussion of this practice, see *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for companies not participating in this review, the cash deposit rate will continue to be the company-specific cash deposit rate published for the most recently completed segment; (3) if the exporter is not a firm covered in this review, or the original less-than-fair-value (LTFV) investigation, but the producer is, then the cash deposit rate will be the cash deposit rate established for the most recently completed segment for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 36.52 percent, the all-others rate established in the LTFV investigation.⁵ These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

⁵ See *Large Residential Washers from Mexico and the Republic of Korea: Antidumping Duty Orders*, 78 FR 11148 (February 15, 2013).

Dated: April 26, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022-09523 Filed 5-3-22; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-580-809]

Circular Welded Non-Alloy Steel Pipe From the Republic of Korea: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2019-2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that the producers/exporters subject to this administrative review made sales of circular welded non-alloy steel pipe (CWP) from the Republic of Korea (Korea) at less than normal value during the period of review (POR), November 1, 2019, through October 31, 2020.

DATES: Applicable May 4, 2022.

FOR FURTHER INFORMATION CONTACT: Dusten Hom, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-5075.

SUPPLEMENTARY INFORMATION:

Background

On December 7, 2021, Commerce published the *Preliminary Results* of this administrative review.¹ The review covers 24 producers and/or exporters of subject merchandise. We invited interested parties to comment on the *Preliminary Results*. On March 23, 2022, Commerce extended the deadline for issuing these final results until April 27, 2022.² A summary of the events that occurred since Commerce published the *Preliminary Results*, as well as a full discussion of the issues raised by parties for these final results, are discussed in

¹ See *Circular Welded Non-Alloy Steel Pipe from the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2019-2020*, 86 FR 69225 (December 7, 2021) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

² See Memorandum, “Circular Welded Non-Alloy Steel Pipe from the Republic of Korea: Extension of Deadline for Final Results of Antidumping Duty Administrative Review; 2019-2020,” dated March 23, 2022.

the Issues and Decision Memorandum.³ Commerce conducted this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The merchandise subject to the order is circular welded non-alloy steel pipe and tube. Imports of the product are currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 7306.30.1000, 7306.30.5025, 7306.30.5032, 7306.30.5040, 7306.30.5055, 7306.30.5085, and 7306.30.5090. While the HTSUS subheadings are provided for convenience and customs purposes, the written description is dispositive. For a complete description of the scope of the order, see the Issues and Decision Memorandum.⁴

Analysis of Comments Received

All issues raised in the case and rebuttal briefs filed by parties in this review are listed in Appendix I to this notice and addressed in the Issues and Decision Memorandum. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <https://access.trade.gov>. In addition, a complete version of the Issues and Decision Memorandum can be accessed at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Changes Since the Preliminary Results

For reasons explained in the Issues and Decision Memorandum, we made no changes for the final results of review.

Final Determination of No Shipments

In the *Preliminary Results*, Commerce determined that HiSteel Co., Ltd (HiSteel) had no shipments of subject merchandise during the POR. No party commented on this issue and because we have not received any information to contradict our preliminary finding, we continue to find that HiSteel did not have any shipments of subject merchandise during the POR and intend to issue appropriate instructions to U.S. Customs and Border Protection (CBP) based on the final results of this review.

³ See Memorandum, “Issues and Decision Memorandum for the Final Results of the 2019-2020 Administrative Review of the Antidumping Duty Order on Circular Welded Non-Alloy Steel Pipe from the Republic of Korea,” dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

⁴ *Id.*

Rate for Non-Examined Companies
The statute and Commerce’s regulations do not address the establishment of a rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a market economy investigation, for guidance when calculating the rate for companies which were not selected for individual examination in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally “an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely {on the basis of facts available}.” In this review, we calculated weighted-average dumping margins for the mandatory respondents, Husteel Co., Ltd. (Husteel) and Hyundai Steel Company (Hyundai Steel), that are 4.07 and 1.97 percent, respectively, and we have assigned to the non-selected companies a rate of 3.21 percent, which is the weighted-average dumping margin of Husteel and Hyundai Steel, weighted by their publicly ranged U.S. sales values.⁵

Final Results of Review

We determine that the following weighted-average dumping margins exists for the period November 1, 2019, through October 31, 2020:

Producer/exporter	Weighted-average dumping margin (percent)
Husteel Co., Ltd	4.07

⁵ With two respondents under examination, Commerce normally calculates (A) a weighted-average of the dumping margins calculated for the examined respondents; (B) a simple average of the dumping margins calculated for the examined respondents; and (C) a weighted-average of the dumping margins calculated for the examined respondents using each company’s publicly-ranged U.S. sale quantities for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. See, e.g., *Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part*, 75 FR 53661, 53663 (September 1, 2010).

⁶ This company is also known as Hyundai Steel Corporation; Hyundai Steel; and Hyundai Steel (Pipe Division).

⁷ See Appendix II for a full list of these companies.

Producer/exporter	Weighted-average dumping margin (percent)
Hyundai Steel Company ⁶	1.97
Review-Specific Average Rate Applicable to the Following Companies	
Other Respondents ⁷	3.21

Disclosure

We intend to disclose the calculations performed in connection with these final results to parties in this proceeding within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b), Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. For any individually examined respondents whose weighted-average dumping margin is above *de minimis*, we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of the examined sales to that importer, and we will instruct CBP to assess antidumping duties on all appropriate entries covered by this. Where either the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific assessment rate is zero or *de minimis*, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

For entries of subject merchandise during the POR produced by Husteel or Hyundai Steel, for which they did not know that the merchandise was destined to the United States, and for all entries attributed to HiSteel, for which we found no shipments during the POR, we will instruct CBP to liquidate those entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.⁸

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the

⁸ See *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.*, within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review in the **Federal Register**, as provided for by section 751(a)(2) of the Act: (1) The cash deposit rate for companies subject to this review will be the rates established in these final results of the review; (2) for merchandise exported by producers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation but the producer is, then the cash deposit rate will be the rate established for the most recent period for the producer of the merchandise; (4) the cash deposit rate for all other producers or exporters will continue to be 4.80 percent,⁹ the all-others rate established in the investigation. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties has occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance

⁹ See *Notice of Antidumping Duty Orders: Certain Circular Welded Non-Alloy Steel Pipe from Brazil, the Republic of Korea (Korea), Mexico, and Venezuela, and Amendment to Final Determination of Sales at Less Than Fair Value: Certain Circular Welded Non-Alloy Steel Pipe from Korea*, 57 FR 49453 (November 2, 1992).

with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: April 26, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I—List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Changes Since the *Preliminary Results*
- V. No Shipments
- VI. Discussion of the Issues
 - Comment 1: Existence of Particular Market Situation (PMS)
 - Comment 2: Constructed Export Price (CEP) Offset
- VII. Recommendation

Appendix II—List of Companies Not Individually Examined

1. Aju Besteel
2. Bookook Steel
3. Chang Won Bending
4. Dae Ryung
5. Daewoo Shipbuilding & Marine Engineering (Dsme)
6. Daiduck Piping
7. Dong Yang Steel Pipe
8. Dongbu Steel¹⁰
9. Eew Korea Company
10. Hyundai Rb
11. Kiduck Industries
12. Kum Kang Kind
13. Kumsoo Connecting
14. Miju Steel Mfg.¹¹
15. Nexteel Co., Ltd.¹²
16. Samkang M&T
17. Seah Fs
18. Seah Steel¹³
19. Steel Flower
20. Vesta Co., Ltd.
21. Ycp Co.

[FR Doc. 2022–09553 Filed 5–3–22; 8:45 am]

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¹⁰ This company is also known as Dongbu Steel Co., Ltd.

¹¹ This company is also known as Miju Steel Manufacturing.

¹² This company is also known as Nexteel.

¹³ This company is also known as Seah Steel Corporation.

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Notification of Request for an Emergency Clearance; National Marine Fisheries Service, Office of Law Enforcement Cooperative Enforcement Program Partner Survey of Need (FY2022 Consolidated Appropriations Act Report)**

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance utilizing emergency review procedures in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. This Notice proposes the emergency/ expedited clearance to collect information regarding cooperative enforcement agreements with partner state and territorial law enforcement agencies as required by the recently issued the Consolidated Appropriations Act, 2022. NOAA requests emergency processing and OMB authorization to collect the information after publication of this Notice for a period of six (6) months.

Agency: National Oceanic and Atmospheric Administration (NOAA), Commerce.

Title: National Marine Fisheries Service, Office of Law Enforcement Cooperative Enforcement Program Partner Survey of Need.

OMB Control Number: 0648-XXXX.

Form Number(s): None.

Type of Request: Emergency submission, New Information Collection Request.

Number of Respondents: 29.

Average Hours per Response: 2 hours.

Burden Hours: 58.

Needs and Uses: NOAA's National Marine Fisheries Service (NMFS) Office of Law Enforcement (OLE) is sponsoring this congressionally mandated information collection. The information is collected under the authority of the Consolidated Appropriations Act of 2022 (117th Congress (221-2022)).

The purpose of the collection is to acquire, analyze, and report on detailed information about the OLE's Cooperative Enforcement Program (CEP) partner agencies' needs, as directed by Congress. The information will be collected from OLE's twenty-nine (29) Cooperative Enforcement Program

partner agencies and will ask questions related to shortages of trained personnel, maintaining maritime domain awareness, formal operational agreements with other Federal law enforcement agencies, and access to advanced technological enforcement tools, as directed by Congress. The partner agencies are located in twenty-eight (28) states and territories: Alaska, Alabama, American Samoa, California, Connecticut, Delaware, Florida, Georgia, Guam (two agencies), Hawaii, Louisiana, Massachusetts, Maryland, Maine, Michigan, Northern Mariana Islands, Mississippi, New Hampshire, New Jersey, New York, Oregon, Puerto Rico, Rhode Island, South Carolina, Texas, Virginia, Virgin Islands, Washington.

The information will be used to supply Congress with a detailed report describing the needs expressed by the Office of Law Enforcement's Cooperative Enforcement Program partner agencies. This is a unique one-time only collection of information from Office of Law Enforcement's Cooperative Enforcement Program partner agencies as directed by Congress.

As provided under 5 CFR 1320.13, NOAA is requesting emergency processing for cooperative enforcement program data. NOAA cannot reasonably comply with normal clearance procedures since the use of normal clearance procedures is reasonably likely to cause a congressionally mandated deadline to be missed. As required by the Consolidated Appropriations Act, 2022, NOAA is expected to submit a report to Congress no less than 180 days after enactment of the Act. Therefore, NOAA is requesting OMB approval as soon as possible (*i.e.*, 5 business days after publication of this Notice) for this collection of information.

Affected Public: State and territorial government natural resource law enforcement agencies who are members of Office of Law Enforcement's Cooperative Enforcement Program.

Frequency: Once.

Respondent's Obligation: Voluntary.

Legal Authority: 44 U.S.C. 3501-3520.

This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022-09578 Filed 5-3-22; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

[RTID 0648-XC001]

Pacific Fishery Management Council; Public Meetings and Public Hearing

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

SUMMARY: The Pacific Fishery Management Council (Pacific Council)'s Salmon Technical Team (STT) and Model Evaluation Workgroup (MEW) will hold a joint meeting on May 24, 2022 to discuss salmon topics in preparation for the June and September 2022 Pacific Council meetings. The meeting is open to the public.

DATES: The meeting will be held on Tuesday May 24, 2022, from 9 a.m. until 4 p.m., or until business is completed.

ADDRESSES: The meeting will be held at the Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220-1384, telephone: (503) 820-2280 (voice) or (503) 820-2299 (fax).

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220.

FOR FURTHER INFORMATION CONTACT: Ms. Robin Ehrlke, Staff Officer, Pacific Council; telephone: (503) 820-2410.

SUPPLEMENTARY INFORMATION: In preparation for the June 2022 Pacific Council meeting, the STT will discuss the work required and timeline necessary to investigate the accuracy of and consider potential improvements to recent preseason effort projections produced by the Klamath Ocean Harvest Model (KOHM) during the preseason management process.

In preparation for the September 2022 Pacific Council meeting, the STT and MEW will discuss the work required and timeline necessary to investigate the potential for improvements to forecasts of ocean exploitation rates for Southern Oregon/Northern California Coast (SONCC) coho salmon.

Discussions may include additional topics as time allows, including but not limited to administrative and ecosystem matters on the Pacific Council's June and September 2022 meetings, and various salmon related topics of pertinence.

Although non-emergency issues not contained in the STT meeting agendas may come before the STT for

discussion, those issues may not be the subject of formal STT action during these meetings. STT action will be restricted to those issues specifically listed in this document and to any issues arising after publication of this document requiring emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the STT's intent to take final action to address the emergency.

Specific meeting information, including instructions on how to join the meeting and system requirements will be provided in meeting announcements on the Pacific Council's website (see www.pcouncil.org). You may send an email to Mr. Kris Kleinschmidt (kris.kleinschmidt@noaa.gov) or contact him at (503) 820-2412 for technical assistance.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (kris.kleinschmidt@noaa.gov; (503) 820-2412) at least 10 days prior to the meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 29, 2022.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022-09531 Filed 5-3-22; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XB999]

Fisheries of the Gulf of Mexico; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of SEDAR 74 Post-Data Workshop Webinar for Gulf of Mexico Red Snapper.

SUMMARY: The SEDAR 74 assessment of Gulf of Mexico red snapper will consist of a Data workshop, a series of assessment webinars, and a Review workshop. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 74 Post-Data Workshop Webinar will be held May 23, 2022, from 10 a.m. to 12 p.m., Eastern.

ADDRESSES:

Meeting address: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see **FOR FURTHER INFORMATION CONTACT** below) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571-4366; email: Julie.neer@safmc.net.

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a multi-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report that compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report that describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS Management Division, and Southeast Fisheries Science Center. Participants include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion in the Post-Data Workshop Webinar are as follows:

Participants will review data for use in the assessment of Gulf of Mexico red snapper.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 29, 2022.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2022-09530 Filed 5-3-22; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF DEFENSE

Department of the Air Force

Amended Notice of Intent To Prepare an Environmental Impact Statement for Regional Special Use Airspace Optimization To Support Air Force Missions in Arizona

AGENCY: United States Air Force, Department of Defense.

ACTION: Amended Notice of Intent.

SUMMARY: On January 18, 2022, the Department of the Air Force (DAF) issued a Notice of Intent to prepare an Environmental Impact Statement (EIS) for Regional Special Use Airspace Optimization to Support Air Force Missions in Arizona (Vol. 87, No. 11 **Federal Register**, 2597, January 18, 2022). The Notice of Intent announced a 45-day formal scoping period through March 4, 2022, included the dates and locations of in-person scoping meetings, and solicited public comments on the DAF's proposed action. In response to public and stakeholder input received during the initial scoping period, the DAF has decided to extend the formal scoping comment period for this EIS. This Amended Notice of Intent extends the formal scoping comment period through June 3, 2022 to allow additional

time for the interested public to review the proposed action and submit scoping comments. No changes have been made to the proposed action. All handouts and displays are available on the project website (www.ArizonaRegionalAirspaceEIS.com). Comments submitted during the initial public scoping period from January 18–March 4, 2022 are currently being reviewed and do not need to be resubmitted. Further comments can be provided through the project website and via mail to the address listed below.

DATES: The extended public scoping comment period begins upon publication of this Notice. Further scoping comments are requested by June 3, 2022 to ensure full consideration in the Draft EIS in accordance with 40 CFR 1501.9.

ADDRESSES: Please mail public scoping comments to: Arizona Regional Airspace EIS, c/o Cardno, 501 Butler Farm Rd., Suite H, Hampton, VA 23666. Comments may also be submitted through the project website www.ArizonaRegionalAirspaceEIS.com.

FOR FURTHER INFORMATION CONTACT: Ms. Grace Keesling, Arizona Regional Airspace EIS, c/o Cardno, 501 Butler Farm Rd., Suite H, Hampton, VA 23666; Telephone: (210) 925–4534 at grace; or Email: keesling.1@us.af.mil.

Adriane Paris,

Air Force Federal Register Liaison Officer.

[FR Doc. 2022–09579 Filed 5–3–22; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP22–843–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Rate Schedule S–2 Tracker Filing eff 4/1/2022 to be effective 4/1/2022.

Filed Date: 4/27/22.

Accession Number: 20220427–5239.

Comment Date: 5 p.m. ET 5/9/22.

Docket Numbers: RP22–844–000.

Applicants: Discovery Gas Transmission LLC.

Description: Annual Imbalance Cash Out Report for 2021 of Discovery Gas Transmission LLC.

Filed Date: 4/27/22.

Accession Number: 20220427–5246.

Comment Date: 5 p.m. ET 5/9/22.

Docket Numbers: RP22–845–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Rate Schules GSS and LSS Tracker Filing eff 4/1/2022 to be effective 4/1/2022.

Filed Date: 4/27/22.

Accession Number: 20220427–5311.

Comment Date: 5 p.m. ET 5/9/22.

Docket Numbers: RP22–846–000.

Applicants: Bison Pipeline LLC.

Description: Compliance filing: 2022 Operational Purchases and Sales Report to be effective N/A.

Filed Date: 4/27/22.

Accession Number: 20220427–5313.

Comment Date: 5 p.m. ET 5/9/22.

Docket Numbers: RP22–847–000.

Applicants: Columbia Gas Transmission, LLC.

Description: § 4(d) Rate Filing: MU Mktg LLC—Replacement Contract NR 264870 264871 to be effective 4/1/2022.

Filed Date: 4/27/22.

Accession Number: 20220427–5331.

Comment Date: 5 p.m. ET 5/9/22.

Docket Numbers: RP22–849–000

Applicants: Ruby Pipeline, L.L.C.

Description: § 4(d) Rate Filing: Fuel LU and EPC Computation Update Filing to be effective 6/1/2022.

Filed Date: 4/28/22.

Accession Number: 20220428–5098.

Comment Date: 5 p.m. ET 5/10/22.

Docket Numbers: RP22–850–000.

Applicants: Southeast Supply Header, LLC.

Description: § 4(d) Rate Filing: 2022 SESH TUP/SBA Annual Filing to be effective 6/1/2022.

Filed Date: 4/28/22.

Accession Number: 20220428–5099.

Comment Date: 5 p.m. ET 5/10/22.

Docket Numbers: RP22–851–000.

Applicants: Cheyenne Plains Gas Pipeline Company, L.L.C.

Description: § 4(d) Rate Filing: Fuel and LU Annual Update and OPS Report to be effective 6/1/2022.

Filed Date: 4/28/22.

Accession Number: 20220428–5104.

Comment Date: 5 p.m. ET 5/10/22.

Docket Numbers: RP22–852–000.

Applicants: Wyoming Interstate Company, L.L.C.

Description: § 4(d) Rate Filing: FL&U Update Quarterly Filing to be effective 6/1/2022.

Filed Date: 4/28/22.

Accession Number: 20220428–5117.

Comment Date: 5 p.m. ET 5/10/22.

Docket Numbers: RP22–853–000.

Applicants: Transwestern Pipeline Company, LLC.

Description: § 4(d) Rate Filing: Housekeeping Filing on 4–28–22 to be effective 5/31/2022.

Filed Date: 4/28/22.

Accession Number: 20220428–5119.

Comment Date: 5 p.m. ET 5/10/22.

Docket Numbers: RP22–854–000.

Applicants: Sierrita Gas Pipeline LLC.

Description: § 4(d) Rate Filing: Quarterly Fuel and LU Update Filing to be effective 6/1/2022.

Filed Date: 4/28/22.

Accession Number: 20220428–5129.

Comment Date: 5 p.m. ET 5/10/22.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 28, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–09543 Filed 5–3–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP22–181–000]

Columbia Gas Transmission, LLC; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on April 19, 2022, Carolina Gas Transmission, LLC, 121 Moore Hopkins Lane, Columbia, South Carolina 29210 filed in the above referenced docket a prior notice pursuant to Section 157.205 and 157.210 of the Federal Energy Regulatory Commission's regulations under the Natural Gas Act, requesting authorization to construct, modify and operate certain facilities located in the Counties of Spartanburg, Dorchester and Charleston, South Carolina, under authorities granted by its blanket

certificate issued in Docket No. CP06–72–000.¹

Specifically, CGT requests that the Commission authorize its Moore-Dorchester Optimization Project (Project), which will allow CGT to provide 10,000 dekatherms per day (Dth/d) of firm transportation service from receipts to the Dominion Energy South Carolina, Inc. (DESC) delivery point in Charleston, South Carolina. The Project facilities proposed consist of restaging of existing compressor units, gas coolers, emergency use generator, and piping modifications at existing stations. The estimated cost for the Project is approximately \$5.5 million, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (<http://ferc.gov>) using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at FERCOnlineSupport@ferc.gov or call toll-free, (886) 208–3676 or TTY, (202) 502–8659.

Any questions concerning this application should be directed to Richard D. Jessee, Supervisor Gas Transmission Certificates, BHE GT&S., 6603 West Broad Street, Richmond, VA 23230, (866) 319–3382, richard.jessee@bhegts.com.

Pursuant to Section 157.9 of the Commission's Rules of Practice and Procedure,² within 90 days of this Notice the Commission staff will either: Complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for

this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Public Participation

There are three ways to become involved in the Commission's review of this project: You can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on June 27, 2022. How to file protests, motions to intervene, and comments is explained below.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,³ any person⁴ or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,⁵ and must be submitted by the protest deadline, which is June 27, 2022. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

³ 18 CFR 157.205.

⁴ Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

⁵ 18 CFR 157.205(e).

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure⁶ and the regulations under the NGA⁷ by the intervention deadline for the project, which is June 27, 2022. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at <https://www.ferc.gov/resources/guides/how-to/intervene.asp>.

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before June 27, 2022. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP22–181–000 in your submission.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to

⁶ 18 CFR 385.214.

⁷ 18 CFR 157.10.

¹ *Carolina Gas Transmission Corp.*, 116 FERC ¶ 61,049 (2006).

² 18 CFR (Code of Federal Regulations) 157.9.

Documents and Filings. New eFiling users must first create an account by clicking on “eRegister.” You will be asked to select the type of filing you are making; first select “General” and then select “Protest”, “Intervention”, or “Comment on a Filing”; or ⁸

(2) You can file a paper copy of your submission by mailing it to the address below.⁹ Your submission must reference the Project docket number CP22–181–000.

To mail via USPS, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

To mail via any other courier, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission,

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502–8258 or FercOnlineSupport@ferc.gov.

Protests and motions to intervene must be served on the applicant either by mail or email (with a link to the document) at: richard.jessee@bhegts.com, Richard D. Jessee, Supervisor Gas Transmission Certificates, BHE GT&S., 6603 West Broad Street, Richmond, VA 23230. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission’s Office of External Affairs, at (866) 208–FERC, or on the FERC website at www.ferc.gov using the “eLibrary” link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific

⁸ Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission’s website at www.ferc.gov under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

⁹ Hand-delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to www.ferc.gov/docs-filing/esubscription.asp.

Dated: April 28, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–09547 Filed 5–3–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG22–93–000.

Applicants: LI Solar Generation, LLC.

Description: LI Solar Generation, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 4/6/22.

Accession Number: 20220406–5259.

Comment Date: 5 p.m. ET 5/19/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2528–006.

Applicants: Aragonne Wind LLC.

Description: Notice of Change in Status of Aragonne Wind LLC.

Filed Date: 4/27/22.

Accession Number: 20220427–5390.

Comment Date: 5 p.m. ET 5/18/22.

Docket Numbers: ER10–2529–006; ER10–2534–007.

Applicants: Kumeyaay Wind LLC, Buena Vista Energy, LLC.

Description: Notice of Change in Status of Buena Vista Energy, LLC, et al.

Filed Date: 4/27/22.

Accession Number: 20220427–5389.

Comment Date: 5 p.m. ET 5/18/22.

Docket Numbers: ER20–2133–003.

Applicants: ISO New England Inc., Versant Power.

Description: Compliance filing; ISO New England Inc. submits tariff filing per 35: Versant Power; Changes to Schedule 21–VP in Compliance with Order No. 864 to be effective 1/27/2020.

Filed Date: 4/28/22.

Accession Number: 20220428–5234.

Comment Date: 5 p.m. ET 5/19/22.

Docket Numbers: ER22–1695–000.

Applicants: American Electric Power Service Corporation, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing; American Electric Power Service

Corporation submits tariff filing per 35.13(a)(2)(iii): AEP submits update to Attachment 1 of ILDSA, SA No. 1336 (4/27/22) to be effective 4/1/2022.

Filed Date: 4/27/22.

Accession Number: 20220427–5293.

Comment Date: 5 p.m. ET 5/18/22.

Docket Numbers: ER22–1696–000.

Applicants: AEP Texas Inc.

Description: § 205(d) Rate Filing; AEPTX-Barilla Solar 2nd A&R Generation Interconnection Agreement to be effective 4/11/2022.

Filed Date: 4/27/22.

Accession Number: 20220427–5330.

Comment Date: 5 p.m. ET 5/18/22.

Docket Numbers: ER22–1697–000.

Applicants: Southwest Power Pool, Inc.

Description: Compliance filing; Order No. 2222 Compliance Filing to be effective 12/31/9998.

Filed Date: 4/28/22.

Accession Number: 20220428–5171.

Comment Date: 5 p.m. ET 5/19/22.

Docket Numbers: ER22–1698–000.

Applicants: EDF Spring Field WPC, LLC.

Description: Baseline eTariff Filing; Initial Market-Based Rate Petition of EDF Spring Field to be effective 6/27/2022.

Filed Date: 4/28/22.

Accession Number: 20220428–5173.

Comment Date: 5 p.m. ET 5/19/22.

Docket Numbers: ER22–1699–000.

Applicants: Public Service Company of Colorado.

Description: § 205(d) Rate Filing; 2022–04–28 TSGT Facility Study-692–0.0.0 to be effective 4/29/2022.

Filed Date: 4/28/22.

Accession Number: 20220428–5177.

Comment Date: 5 p.m. ET 5/19/22.

Docket Numbers: ER22–1700–000.

Applicants: New York Independent System Operator, Inc., Niagara Mohawk Power Corporation.

Description: § 205(d) Rate Filing; New York Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii): 205: CRA between Niagara Mohawk and RG&E for Farmington Substation 168 (SA 2703) to be effective 4/1/2022.

Filed Date: 4/28/22.

Accession Number: 20220428–5192.

Comment Date: 5 p.m. ET 5/19/22.

Docket Numbers: ER22–1701–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing; 2022–04–28 SA 3823 UEC-Montgomery Solar FSA (J987) to be effective 6/28/2022.

Filed Date: 4/28/22.

Accession Number: 20220428–5194.

Comment Date: 5 p.m. ET 5/19/22.

Docket Numbers: ER22–1702–000.
Applicants: Niagara Mohawk Power Corporation, New York Independent System Operator, Inc.

Description: § 205(d) Rate Filing: Niagara Mohawk Power Corporation submits tariff filing per 35.13(a)(2)(iii): 205 NMPC SGAs between Bayside2704, Beta2705, Central2706, Creek2707, Helmet2708 to be effective 4/1/2022.

Filed Date: 4/28/22.

Accession Number: 20220428–5211.

Comment Date: 5 p.m. ET 5/19/22.

Docket Numbers: ER22–1703–000.
Applicants: Salem Harbor Power Development LP.

Description: § 205(d) Rate Filing: Name Change—Salem Harbor Power Development LP to be effective 4/29/2022.

Filed Date: 4/28/22.

Accession Number: 20220428–5233.

Comment Date: 5 p.m. ET 5/19/22.

Docket Numbers: ER22–1704–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2022–04–28 SA 3819 Ameren Missouri-Lutesville Solar FSA (J1107) to be effective 6/28/2022.

Filed Date: 4/28/22.

Accession Number: 20220428–5244.

Comment Date: 5 p.m. ET 5/19/22.

Docket Numbers: ER22–1705–000.
Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Notice of Cancellation of WMPA, SA No. 3928; Queue No. Z1–106 to be effective 4/29/2022.

Filed Date: 4/28/22.

Accession Number: 20220428–5258.

Comment Date: 5 p.m. ET 5/19/22.

Docket Numbers: ER22–1706–000.
Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Notice of Cancellation of WMPA, SA No. 3929; Queue No. Z1–107 to be effective 4/29/2022.

Filed Date: 4/28/22.

Accession Number: 20220428–5266.

Comment Date: 5 p.m. ET 5/19/22.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 28, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–09544 Filed 5–3–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2687–017]

Pacific Gas and Electric Company; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Application for Temporary Variance of Flushing Flow Requirements.

b. *Project No:* 2687–017.

c. *Date Filed:* April 5, 2022.

d. *Applicant:* Pacific Gas and Electric (licensee).

e. *Name of Project:* Pit No. 1 Hydroelectric Project.

f. *Location:* The project is located on the Pit and Fall rivers in Shasta County, California.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Jimmy Galloway, License Coordinator; Pacific Gas and Electric Company; Mail Code N11D, P.O. Box 770000, San Francisco, CA 94177; Phone: (530) 521–6798.

i. *FERC Contact:* Alicia Burtner, (202) 502–8038, Alicia.Burtner@ferc.gov.

j. *Deadline for filing comments, motions to intervene, and protests:* May 31, 2022.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at

FERCOnlineSupport@ferc.gov, (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include the docket number P–2687–017. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The licensee requests approval of a temporary variance of its requirements to provide sediment flushing flows pursuant to Condition 13 of the project water quality certification. The intent of the requirement was to control nuisance aquatic vegetation and impede mosquito reproduction in Fall River Pond. The flows are required to be released during one weekend each, in May or June, July, and August. However, the U.S. Fish and Wildlife Service determined in 2009 that the flows adversely affect the federally-endangered Shasta crayfish (*Pacifastacus fortis*) and its habitat. The licensee's Flushing Flow Effectiveness Monitoring Plan results have also shown that minimum instream flows have been more effective at suppressing and maintaining consistently low surface aquatic vegetation than flushing flows. As such, the licensee is requesting that no flushing flows be required in 2022.

l. *Locations of the Application:* This filing may be viewed on the Commission's website at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects.

At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID-19), issued by the President on March 13, 2020. For assistance, call 1-866-208-3676 or email FERCOnlineSupport@ferc.gov, for TTY, call (202) 502-8659. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. Comments, Protests, or Motions to Intervene: Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Filing and Service of Documents: Any filing must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: April 28, 2022.

Debbie-Anne A. Reese,
Deputy Secretary.

[FR Doc. 2022-09546 Filed 5-3-22; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2816-050; Project No. 12766-007]

North Hartland, LLC; Green Mountain Power Corporation; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the application for a new license for the North Hartland Hydroelectric Project No. 2816 (North Hartland Project), and the application for a new license for the Clay Hill Road Line 66 Transmission Project No. 12766 (Clay Hill Project), and has prepared an Environmental Assessment (EA) for the projects. The North Hartland Project is on the Ottauquechee River in Windsor County, Vermont, and occupies 20.8 acres of federal land administered by the U.S. Army Corps of Engineers. The Clay Hill Project serves as part of the primary transmission line for the North Hartland Project, and is located along Clay Hill Road in Windsor County, Vermont.

The EA contains staff's analysis of the potential environmental effects of the projects and concludes that licensing the projects, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

The Commission provides all interested persons with an opportunity to view and/or print the EA via the internet through the Commission's Home Page (<http://www.ferc.gov>) using the "eLibrary" link. Enter the docket number, excluding the last three digits in the docket number field, to access the document. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll-free at (866) 208-3676, or for TTY, (202) 502-8659.

You may also register online at <https://ferconline.ferc.gov/eSubscription.aspx> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 45 days from the date of this notice. The Commission strongly encourages electronic filings. Please file comments using the Commission's eFiling system at <https://ferconline.ferc.gov/>

eFiling.aspx. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <https://ferconline.ferc.gov/QuickComment.aspx>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P-2816-050 for the North Hartland Project and/or docket number P-12766-007 for the Clay Hill Project.

For further information, contact Bill Connelly at (202) 502-8587 or by email at william.connely@ferc.gov.

Dated: April 28, 2022.

Debbie-Anne A. Reese,
Deputy Secretary.

[FR Doc. 2022-09545 Filed 5-3-22; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OGC-2022-0406; FRL-9811-01-OGC]

Proposed Consent Decree, Unreasonable Delay Claim Regarding Discarded Polyvinyl Chloride Listing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed consent decree; request for public comment.

SUMMARY: In accordance with the Environmental Protection Agency (EPA) Administrator's March 18, 2022, Memorandum entitled Consent Decrees and Settlement Agreements to Resolve Environmental Claims Against the Agency, notice is hereby given of a proposed consent decree that resolves *Center for Biological Diversity v. U.S. Environmental Protection Agency, et al.*, a case in the United States District Court for the District of Columbia (1:21-cv-2210-JDB) that alleges EPA unreasonably delayed taking action on a petition to list discarded polyvinyl chloride (PVC) as hazardous waste under the Resource Conservation and Recovery Act (RCRA).

DATES: Written comments on the proposed consent decree must be received by June 3, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OGC-2022-0406 online at <https://www.regulations.gov> (EPA's preferred method). Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID number for this action. Comments received may be posted without change to <https://www.regulations.gov>, including any personal information provided. For detailed instructions on sending comments, see the "Additional Information about Commenting on the Proposed Consent Decree" heading under the **SUPPLEMENTARY INFORMATION** section of this document. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room is open to visitors by appointment only. Our Docket Center staff continues to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via <https://www.regulations.gov>, as there may be a delay in processing mail and faxes. Hand-deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the latest status information, please visit us online at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Clayton Cope, Solid Waste and Emergency Response Law Office, Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564-2647; email address: cope.clayton@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining a Copy of the Proposed Consent Decree

The official public docket for this action (identified by Docket ID No. EPA-HQ-OGC-2022-0406) contains a copy of the proposed consent decree.

The electronic version of the public docket for this action contains a copy of the proposed consent decree and is available through <https://www.regulations.gov>. You may use <https://www.regulations.gov> to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket

identification number then select "search."

II. Additional Information About the Proposed Consent Decree

Prior to this lawsuit being filed EPA received a petition from Plaintiff, dated July 24, 2014, to list discarded PVC as hazardous waste under RCRA. Plaintiff alleges EPA has failed to take action with respect to the petition within a reasonable time.

This proposed consent decree states that no later than January 20, 2023, pursuant to 40 CFR 260.20(c), EPA shall sign a tentative decision on Plaintiff's petition to classify discarded PVC as hazardous waste under RCRA. Furthermore, it states that no later than two years after the signature of the consent decree by CBD, April 12, 2024, EPA shall sign a final decision on Plaintiff's petition. Court approval of this proposed consent decree would resolve all claims in this case except for any claim for the costs of litigation, including attorneys' fees.

For a period of thirty (30) days following the date of publication of this document, the Agency will accept written comments relating to the proposed consent decree from persons who are not named as parties to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the proposed consent decree if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the APA or RCRA. Unless EPA or the Department of Justice determines that consent should be withdrawn, the terms of the proposed consent decree will be affirmed.

III. Additional Information About Commenting on the Proposed Consent Decree

Submit your comments, identified by Docket ID No. EPA-HQ-OGC-2022-0406 via <https://www.regulations.gov>. Once submitted, comments cannot be edited or removed from this docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at <https://www.regulations.gov> any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include

discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>. For additional information about submitting information identified as CBI, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document. Note that written comments containing CBI and submitted by mail may be delayed and deliveries or couriers will be received by scheduled appointment only.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the <https://www.regulations.gov> website to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an "anonymous access" system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment.

Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

Dated: April 26, 2022 .

Lorie Schmidt,

Associate General Counsel.

[FR Doc. 2022-09542 Filed 5-3-22; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-R05-SFUND-2022-0261; FRL-9619-01-R5]

Proposed CERCLA Administrative Prospective Purchaser Agreement and Proposed CERCLA Administrative Settlement Agreement [EPA Agreement Nos. V-W-22-C-004 and V-W-22-C-003]; Proposed Explanation of Significant Differences; U.S. Smelter and Lead Refinery, Inc. Site, East Chicago, Indiana**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice of proposed settlements; notice of explanation of significant differences; request for comment.

SUMMARY: In accordance with the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the terms of the proposed settlement agreements, the Environmental Protection Agency (EPA), Region 5, hereby gives notice of two proposed administrative settlements concerning the U.S. Smelter and Lead Refinery, Inc., Site in East Chicago, Indiana (the "Site"): (1) A proposed administrative Prospective Purchaser Agreement (the "PPA"); and (2) a proposed Administrative Settlement Agreement and Order on Consent (the "ASAOC"). The EPA proposes to enter into the PPA with Industrial Development Advantage of East Chicago, LLC as purchaser ("Purchaser"). The PPA requires Purchaser to perform remedial action on a portion of the Site. The EPA proposes to enter into the ASAOC with Atlantic Richfield Company, The Chemours Company FC, LLC, E.I. du Pont de Nemours and Company, U.S. Smelter and Lead Refinery, Inc., and United States Metals Refining Company as respondents ("Respondents") and with Arava Natural Resources Company, Inc., Mining Remedial Recovery Company, and Mueller Industries, Inc., as additional covered parties ("Additional Covered Parties"). The ASAOC requires the Respondents to pay \$18,000,000 in past response costs and provide financial assurance for the remedial action to be performed by Purchaser under the PPA. The State of Indiana joins the EPA as a party to both agreements. The EPA is also providing notice of a proposed Explanation of Significant Differences (ESD) for the portion of the Site that is the subject of the PPA. The EPA plans to finalize the proposed ESD after the two factual prerequisites for the selected contingent remedy provided in the Record of

Decision Amendment dated March 24, 2020 have been met. For thirty (30) days following the date of publication of this notice, the EPA will receive written comments on the settlements and the proposed ESD. The EPA will consider all comments received and may modify or withdraw its consent to the settlements if comments received disclose facts or considerations that indicate that the proposed settlements and the proposed ESD are inappropriate, improper, or inadequate. The EPA's response to any comments received will be available for public inspection at <https://www.epa.gov/uss-lead-superfund-site>.

DATES: Comments must be received on or before June 3, 2022.**ADDRESSES:** You may send comments, identified by Docket ID No. EPA-R05-SFUND-2022-0261, by either of the following methods:

- **Federal eRulemaking Portal:** <https://www.regulations.gov/> (our preferred method). Follow the online instructions for submitting comments.
- **Mail:** U.S. Environmental Protection Agency, ATTN: Charles Rodriguez, External Communications Office (RE-19J), 77 W Jackson Blvd., Chicago, Illinois 60604.

Instructions: All submissions received must include the Docket ID No. for this notice. Comments received may be posted without change to <https://www.regulations.gov/>, including any personal information provided. For detailed instructions on sending comments, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Steven P. Kaiser, Office of Regional Counsel, Environmental Protection Agency, telephone number: (312) 353-3804; email address: kaiser.steven@epa.gov.

SUPPLEMENTARY INFORMATION:**I. Public Participation***A. Where can I view the proposed settlement agreements and ESD?*

The proposed settlement agreements and proposed ESD are available electronically as part of Docket ID No. EPA-R05-SFUND-2022-0261, at https://www.regulations.gov, under "Supporting and Related Material." The proposed settlement agreements and proposed ESD can also be viewed at <https://www.epa.gov/uss-lead-superfund-site>. The proposed settlement agreements, proposed ESD, and related Site documents can be viewed in hardcopy at the East Chicago Public

Library, 2401 E Columbus Drive, East Chicago, IN 46312, (219) 397-2453; and the Robert A. Pastrick Library, 1008 W Chicago Ave., East Chicago, IN 46312, (219) 397-5505.

B. What should I know before I submit comments?

By this notice, the EPA is requesting comment on (1) the terms of the proposed PPA; (2) the terms of the proposed ASAOC; and (3) the proposed ESD. The EPA has previously accepted public comments on the proposed plan subsequently adopted in the Record of Decision Amendment dated March 24, 2020. The EPA's response to comments on the proposed plan is available at <https://semspub.epa.gov/work/05/955458.pdf>.

Submit your comments, identified by Docket ID No. EPA-R05-SFUND-2022-0261, at https://www.regulations.gov (our preferred method), or the other method identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

II. Background Information

This notice pertains to the U.S. Smelter and Lead Refinery, Inc. Superfund Site in East Chicago, Indiana. The Site is divided into two Operable Units, and Operable Unit 1 is further divided into three Zones. The portion of the Site affected by the proposed action is the area encompassed by the former West Calumet Housing Complex, Goodman Park, and a utility corridor located between Zone 1 and Zone 2 in Operable Unit 1 of the Site. This area is identified in the proposed agreements and proposed ESD as "Modified Zone 1."

The PPA and ASAOC provide for remediation of contaminated soils in

Modified Zone 1 to commercial/ industrial standards. A commercial/ industrial remedy is consistent with the contingent remedy described in the Record of Decision Amendment dated March 24, 2020 (the "ROD Amendment"). The ROD Amendment states that, if two conditions are satisfied, the EPA will issue an ESD to confirm that these two conditions have been met and will change the selected remedy for Modified Zone 1 from a residential cleanup to a commercial/ industrial cleanup. On May 26, 2020, the first condition was satisfied when the City of East Chicago changed the zoning designation for Modified Zone 1 from residential to light industrial. The Purchaser intends to acquire title to real property within Modified Zone 1 (the "Property") with the intent to redevelop it for commercial/industrial use. This acquisition will satisfy the second condition. Once the EPA receives notice that the Purchaser has acquired title to the Property, both conditions will be satisfied. The EPA will then issue the ESD and the PPA will become effective. Under the proposed PPA, Purchaser will remediate contaminated soils at the Property to commercial/industrial criteria as required by the ROD Amendment.

Under the proposed ASAOC, Respondents will provide financial assurance for the remedial action to be performed by Purchaser under the PPA, pay future federal and state oversight costs after application of an \$800,000 credit towards those costs, and pay \$18,000,000 in settlement of certain response costs incurred by the EPA at the Site. The Respondents and the Additional Covered Parties also agree to waive potential claims for reimbursement from the Hazardous Substance Superfund under Section 106(b) of CERCLA, 42 U.S.C. 9606(b).

In both the PPA and the ASAOC, the EPA covenants not to sue the Purchaser, Respondents, and Additional Covered Parties pursuant to Sections 106 and 107 of CERCLA, 42 U.S.C. 9606 and 9607, relating to Operable Unit 1. The EPA's covenants not to sue are subject to reservations. The settlement agreements also provide the Purchaser, Respondents, and Additional Covered Parties with protection from contribution actions or claims as provided by Section 113(f)(2) of CERCLA, 42 U.S.C. 9613(f)(2).

The EPA is providing notice of the proposed ASAOC in accordance with Section 122(i) of CERCLA, 42 U.S.C. 9622(i), which requires the Administrator to provide notice and an opportunity for comment when the EPA proposes to settle a claim pursuant to

Section 122(h) of CERCLA, 42 U.S.C. 9622(h). The EPA is providing notice of the proposed PPA in accordance with the terms of the PPA. Section 117(c) of CERCLA, 42 U.S.C. 9617(c), and 40 CFR 300.435(c)(2)(i) require EPA to issue an ESD when a settlement differs in any significant respect but does not fundamentally alter the remedy selected in the Record of Decision with respect to scope, performance, or cost. A formal public comment period is not required for an ESD.

Due to the interdependent nature of the three documents included in this notice, the EPA is requesting comment on all three documents simultaneously. The EPA will consider all comments received and may modify or withdraw its consent to the settlements if comments received disclose facts or considerations that indicate that the proposed settlements and proposed ESD are inappropriate, improper, or inadequate.

Douglas Ballotti,

Director, Superfund & Emergency Management Division, Region 5.

[FR Doc. 2022-09359 Filed 5-3-22; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meetings

TIME AND DATE: 10:00 a.m. on Thursday, May 5, 2022.

PLACE: The meeting is open to the public. Out of an abundance of caution related to current and potential coronavirus developments, the public's means to observe this Board meeting will be via a Webcast live on the internet and subsequently made available on-demand approximately one week after the event. Visit <https://youtu.be/FeRm7b-Xnss> to view the meeting. If you need any technical assistance, please visit our Video Help page at: <https://www.fdic.gov/video.html>.

Observers requiring auxiliary aids (e.g., sign language interpretation) for this meeting should call 703-562-2404 (Voice) or 703-649-4354 (Video Phone) to make necessary arrangements.

STATUS: Open.

MATTERS TO BE CONSIDERED: Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors will meet in open session to consider the following matter:

Discussion Agenda: Memorandum and resolution re: Notice of Proposed

Rulemaking on Revisions to the Community Reinvestment Act Regulations.

CONTACT PERSON FOR MORE INFORMATION: Requests for further information concerning the meeting may be directed to Debra A. Decker, Executive Secretary of the Corporation, at 202-898-8748.

Dated at Washington, DC, on May 2, 2022.
Federal Deposit Insurance Corporation.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2022-09639 Filed 5-2-22; 11:15 am]

BILLING CODE 6714-01-P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 87 FR 23862.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Tuesday, April 26, 2022 at 10:00 a.m. and its continuation at the conclusion of the open meeting on April 28, 2022.

CHANGES IN THE MEETING: Information the premature disclosure of which would be likely to have a considerable adverse effect on the implementation of a proposed Commission action.

* * * * *

CONTACT FOR MORE INFORMATION: Judith Ingram, Press Officer. Telephone: (202) 694-1220.

Authority: Government in the Sunshine Act, 5 U.S.C. 552b.

Laura E. Sinram,

Acting Secretary and Clerk of the Commission.

[FR Doc. 2022-09674 Filed 5-2-22; 4:15 pm]

BILLING CODE 6715-01-P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 87 FR 24162.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Thursday, April 28, 2022 at 10:00 a.m.

Hybrid meeting: 1050 First Street NE, Washington, DC (12th Floor) and virtual.

CHANGES IN THE MEETING: *The following matter was also considered:*

Audit Division Recommendation Memorandum on the UtePAC (A19-07).

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer. Telephone: (202) 694-1220.

Authority: Government in the Sunshine Act, 5 U.S.C. 552b.

Laura E. Sinram,

Acting Secretary and Clerk of the Commission.

[FR Doc. 2022–09667 Filed 5–2–22; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL TRADE COMMISSION

[File No. 221 0002]

Hikma Pharmaceuticals PLC/Custopharm, Inc.; Analysis of Agreement Containing Consent Orders To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis of Proposed Consent Orders to Aid Public Comment describes both the allegations in the complaint and the terms of the consent orders—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before June 3, 2022.

ADDRESSES: Interested parties may file comments online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Please write: “Hikma/Custopharm; File No. 221 0002” on your comment and file your comment online at <https://www.regulations.gov> by following the instructions on the web-based form. If you prefer to file your comment on paper, please mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Steven Wilensky (202–326–2650), Bureau of Competition, Federal Trade Commission, 400 7th Street SW, Washington, DC 20024.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis of Agreement Containing

Consent Orders to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC website at this web address: <https://www.ftc.gov/news-events/commission-actions>.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before June 3, 2022. Write “Hikma/Custopharm; File No. 221 0002” on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the <https://www.regulations.gov> website.

Due to protective actions in response to the COVID–19 pandemic and the agency’s heightened security screening, postal mail addressed to the Commission will be delayed. We strongly encourage you to submit your comments online through the <https://www.regulations.gov> website.

If you prefer to file your comment on paper, write “Hikma/Custopharm; File No. 221 0002” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580.

Because your comment will be placed on the publicly accessible website at <https://www.regulations.gov>, you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include sensitive personal information, such as your or anyone else’s Social Security number; date of birth; driver’s license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any “trade secret or any commercial or financial information which . . . is privileged or confidential”—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled “Confidential,” and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on <https://www.regulations.gov>—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at <https://www.ftc.gov> to read this Notice and the news release describing this matter. The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments it receives on or before June 3, 2022. For information on the Commission’s privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

Analysis of Agreement Containing Consent Orders To Aid Public Comment

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) from Hikma Pharmaceuticals PLC (“Hikma”), Custopharm, Inc. (“Custopharm”), Water Street Healthcare Partners, LLC (“Water Street”), Water Street Healthcare Partners III, L.P. (“Fund III”), Water Street Healthcare Partners IV (“Fund IV”), L.P., and Long Grove Pharmaceuticals, LLC (“Long Grove”) (collectively, “Respondents”). The purpose of the Consent Agreement is to remedy the anticompetitive effects that would likely result from Hikma’s acquisition of Custopharm (“the Proposed Acquisition”). Pursuant to an agreement dated September 27, 2021, Hikma proposes to acquire Custopharm in a transaction valued at approximately \$375 million. As part of the Proposed Acquisition, Custopharm agreed to carve out one of its pipeline products, injectable triamcinolone acetonide

(“TCA”), and transferred its TCA assets to Long Grove. The Commission alleges in its Complaint that the Proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by lessening future competition in the U.S. market for injectable TCA. The Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the Proposed Acquisition.

Under the terms of the proposed Decision and Order (“Order”), Respondent Hikma shall not acquire any rights or interests in TCA products or assets, or any rights or interests in the therapeutical equivalent or biosimilar of TCA products without the prior approval of the Commission. The Order requires Respondents Long Grove and Water Street to operate and maintain in the normal course of business the TCA assets previously operated by Custopharm for a period lasting until four years after the Order date.

The consent agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the consent agreement, modify it, or make final the proposed Order.

I. The Respondents

Respondent Hikma is a multinational pharmaceutical company with headquarters in London, England, and U.S. headquarters in Berkeley Heights, New Jersey. Hikma manufactures both branded and generic pharmaceutical products, including generic injectables.

Respondent Custopharm is incorporated in the State of Texas with its principal place of business located in Carlsbad, California. Water Street owns a majority of Custopharm. Custopharm develops generic pharmaceutical products but does not have any of its own manufacturing capabilities and manufactures its products exclusively through contract manufacturers. Those products are then sold through Custopharm’s commercial arm, Leucadia Pharmaceuticals.

Respondent Water Street Healthcare Partners, LLC is a private equity firm headquartered in Chicago, Illinois. Water Street is the General Partner of Respondents Fund III and Fund IV. Respondent Fund III is a private equity

fund managed by Water Street located in Chicago, Illinois. Fund III’s portfolio includes Custopharm. Respondent Fund IV is a private equity fund managed by Water Street located in Chicago, Illinois. Fund IV’s portfolio includes Long Grove. Respondent Long Grove is a pharmaceutical company launched in 2019 and headquartered in Rosemont, Illinois. Long Grove is owned by Fund IV.

II. The Relevant Market

In human pharmaceutical markets, prices generally decrease as the number of generic competitors increases. Prices continue to decrease incrementally with the entry of the second, third, fourth, and further pharmaceutical competitors. Accordingly, a reduction in the number of suppliers within each relevant market has a direct and substantial effect on pricing.

The Proposed Acquisition would reduce future competition in the market for injectable TCA. Injectable TCA is a corticosteroid used for severe skin conditions and inflammation. Only three competitors currently market injectable TCA: Bristol-Meyers Squibb, Amneal Biosciences, and Teva Pharmaceutical Industries. Hikma and Custopharm are two of a limited number of suppliers capable of entering the TCA market in the near future.

III. Entry

Entry into the market at issue would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. The combination of drug development times and regulatory requirements, including approval by the FDA, is costly and lengthy.

IV. Competitive Effects

The effect of the Proposed Acquisition, if consummated, is likely to substantially lessen competition by eliminating future competition between Hikma and Custopharm in the market for injectable TCA. The evidence shows that the Proposed Acquisition, absent a remedy, would eliminate an additional independent entrant in the currently concentrated market for injectable TCA, which would have enabled customers to negotiate lower prices. Customers and competitors have observed—and the pricing data confirms—that the price of pharmaceutical products decreases with new entry even after several other suppliers have entered the market. Thus, absent a remedy, the Proposed Acquisition likely would cause U.S. consumers to pay significantly higher prices for injectable TCA in the future.

V. The Proposed Order

The proposed Order effectively remedies the competitive concerns raised by the Proposed Acquisition for the pharmaceutical product at issue. The proposed Order requires that Hikma not acquire any rights or interests in TCA products or assets, or rights or interests in the therapeutical equivalent or biosimilar of TCA products without the prior approval of the Commission. The proposed Order also requires Water Street and Long Grove to operate and maintain in the normal course of business the TCA assets for a period lasting until four years after the date the Order is issued. The proposed Order also allows the Commission to appoint an individual to serve as Monitor to observe and report on Respondents’ compliance with their obligations set forth in the Order.

* * * * *

The purpose of this analysis is to facilitate public comment on the Consent Agreement and proposed Order to aid the Commission in determining whether it should make the proposed Order final. This analysis is not an official interpretation of the proposed Order and does not modify its terms in any way.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2022–09532 Filed 5–3–22; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly

unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—PAR 18–812, NIOSH Member Conflict Review.

Date: June 16, 2022.

Time: 1:00 p.m.–3:00 p.m., EDT.

Place: Teleconference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Michael Goldcamp, Ph.D., Scientific Review Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, Morgantown, West Virginia 26506, Telephone: (304) 285–5951; Email: MGoldcamp@cdc.gov.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–09580 Filed 5–3–22; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Solicitation of Nominations for Appointment to CDC’s Advisory Committee to the Director Data and Surveillance Workgroup

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is seeking nominations for membership on the Advisory Committee to the Director (ACD) Data and Surveillance Workgroup (DSW). The DSW will consist of approximately 15 members who are experts in fields associated with public health science and practice; policy development, analysis, and implementation; and surveillance and informatics.

DATES: Nominations for membership on the DSW workgroup must be received no later than May 16, 2022. Late

nominations will not be considered for membership.

ADDRESSES: All nominations (cover letters and curriculum vitae) should be emailed to DSWACD@cdc.gov with the subject line: “Nomination for CDC ACD DSW Workgroup.”

FOR FURTHER INFORMATION CONTACT: Rachel Holloway, MPH, Office of the Chief of Staff, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–10, Atlanta, Georgia 30329–4027; Telephone: (404) 639–7000; Email: DSWACD@cdc.gov.

SUPPLEMENTARY INFORMATION:

Background: The purpose of the ACD, CDC is to advise the Secretary, HHS, and the Director, CDC, on policy and broad strategies that will enable CDC to fulfill its mission of protecting health through health promotion, prevention, and preparedness. The ACD, CDC consists of up to 15 non-federal members, including the Chair, knowledgeable in areas pertinent to the CDC mission, such as health policy, public health, global health, preparedness, preventive medicine, the faith-based and community-based sector, and allied fields.

Purpose: The establishment and formation of the DSW is to provide input to the ACD, CDC on agency-wide activities related to the scope and implementation of CDC’s data modernization strategy across the agency, ultimately playing a key role in the agency’s work with public health, healthcare, and academic and private sector partners and with the promotion of equity. The DSW membership will consist of approximately 15 members. It will be co-chaired by two current ACD, CDC Special Government Employees. The DSW co-chairs will present their findings, observations, and work products at one or more ACD, CDC meetings for discussion, deliberation, and decisions (final recommendations to CDC).

Nomination Criteria: DSW members will serve terms ranging from six months to one year and be required to attend DSW meetings approximately 1–2 times per month (virtually or in person), and contribute time between meetings for research, consultation, discussion, and writing assignments.

Nominations are being sought for individuals who have the expertise and qualifications necessary to contribute to the accomplishments of the committee’s/workgroup’s objectives. Nominees will be selected based on expertise in the fields of public health science and practice; public health preparedness and response; public health policy development, analysis,

and implementation; public health surveillance and informatics; data analysis, data science, and forecasting; health information technology; and healthcare delivery from jurisdictional government agencies, non-government organizations, academia, and the private sector. To ensure a diverse workgroup composition, nominees with front line and field experience at the local, state, tribal, and territorial levels are encouraged to apply. This includes nominees with experience working for, and with, community-based organizations and other non-profit organizations. Federal employees will not be considered for membership. Selection of members is based on candidates’ qualifications to contribute to the accomplishment of the DSW’s objectives.

HHS policy stipulates that membership be balanced in terms of points of view represented and the workgroup’s function.

Appointments shall be made without discrimination based on age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens and cannot be full-time employees of the U.S. Government. Current participation on federal workgroups or prior experience serving on a federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships.

Interested candidates should submit the following items:

- A one-half to one-page cover letter that includes your understanding of, and commitment to, the time and work necessary; one to two sentences on your background and experience; and one to two sentences on the skills/perspective you would bring to the DSW.
- Current curriculum vitae which highlights the experience and work history being sought relevant to the criteria set forth above, including complete contact information (telephone numbers, mailing address, email address).

Nominations may be submitted by the candidate him or herself, or by the person/organization recommending the candidate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for

both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022-09538 Filed 5-3-22; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Solicitation of Nominations for Appointment to CDC's Advisory Committee to the Director (ACD) Laboratory Workgroup (LW)

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is seeking nominations for membership on the Advisory Committee to the Director (ACD) Laboratory Workgroup (LW). The LW will consist of up to 15 members who are experts in the fields of public health laboratory science and practice, laboratory quality management, diagnostic regulations, and laboratory testing and research.

DATES: Nominations for membership on the LW workgroup must be received no later than May 16, 2022. Late nominations will not be considered for membership.

ADDRESSES: All nominations (cover letters and curriculum vitae) should be emailed to LWACD@cdc.gov with the subject line: "Nomination for CDC ACD LW Workgroup."

FOR FURTHER INFORMATION CONTACT: Lauren Hoffmann, MA, Office of the Chief of Staff, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21-10, Atlanta, Georgia 30329-4027; Telephone: (404) 639-7000; Email: LWACD@cdc.gov.

SUPPLEMENTARY INFORMATION:

Background: The purpose of the ACD, CDC is to advise the Secretary, HHS, and the Director, CDC, on policy and broad strategies that will enable CDC to fulfill its mission of protecting health through health promotion, prevention, and preparedness. The ACD, CDC consists of up to 15 non-federal members, including the Chair, knowledgeable in areas pertinent to the CDC mission, such as health policy, public health, global health, preparedness, preventive medicine, the

faith-based and community-based sector, and allied fields.

Purpose: The establishment and formation of the LW is to provide input to the ACD, CDC on agency-wide activities related to laboratory quality management, continuous laboratory quality improvement, and laboratory diagnostic testing to support public health programs and investigations. The LW membership will consist of up to 15 members. It will be co-chaired by two current ACD, CDC Special Government Employees. The LW co-chairs will present their findings, observations, and work products at one or more ACD, CDC meetings for discussion, deliberation, and decisions (final recommendations to CDC).

Nomination Criteria: LW members will serve terms ranging from six months to one year and be required to attend LW meetings approximately 1-2 times per month (virtually or in person), and contribute time between meetings for research, consultation, discussion, and writing assignments.

Nominations are being sought for individuals who have the expertise and qualifications necessary to contribute to the accomplishments of the committee's/workgroup's objectives. Nominees will be selected based on expertise in the fields of public health laboratory science and practice, laboratory quality management, diagnostic regulations, and clinical laboratory testing and research. To ensure a diverse workgroup composition, nominees with front line and field experience at the local, state, tribal, and territorial levels are encouraged to apply. Federal employees will not be considered for membership. Selection of members is based on candidates' qualifications to contribute to the accomplishment of the LW's objectives.

HHS policy stipulates that membership be balanced in terms of points of view represented and the workgroup's function. Appointments shall be made without discrimination based on age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens and cannot be full-time employees of the U.S. Government. Current participation on federal workgroups or prior experience serving on a federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships.

Interested candidates should submit the following items:

- A one-half to one-page cover letter that includes your understanding of, and commitment to, the time and work necessary; one to two sentences on your background and experience; and one to two sentences on the skills/perspective you would bring to the LW.

- Current curriculum vitae which highlights the experience and work history being sought relevant to the criteria set forth above, including complete contact information (telephone numbers, mailing address, email address).

Nominations may be submitted by the candidate him or herself, or by the person/organization recommending the candidate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022-09537 Filed 5-3-22; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-10398 #59]

Medicaid and Children's Health Insurance Program (CHIP) Generic Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: On May 28, 2010, the Office of Management and Budget (OMB) issued Paperwork Reduction Act (PRA) guidance related to the "generic" clearance process. Generally, this is an expedited process by which agencies may obtain OMB's approval of collection of information requests that are "usually voluntary, low-burden, and uncontroversial collections," do not raise any substantive or policy issues, and do not require policy or methodological review. The process requires the submission of an

overarching plan that defines the scope of the individual collections that would fall under its umbrella. On October 23, 2011, OMB approved our initial request to use the generic clearance process under control number 0938–1148 (CMS–10398). It was last approved on April 26, 2021, via the standard PRA process which included the publication of 60- and 30-day **Federal Register** notices. The scope of the April 2021 umbrella accounts for Medicaid and CHIP State plan amendments, waivers, demonstrations, and reporting. This **Federal Register** notice seeks public comment on one or more of our collection of information requests that we believe are generic and fall within the scope of the umbrella. Interested persons are invited to submit comments regarding our burden estimates or any other aspect of this collection of information, including: the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by May 18, 2022.

ADDRESSES: When commenting, please reference the applicable form number (see below) and the OMB control number (0938–1148). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: CMS–10398 (#59)/OMB control number: 0938–1148, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may access CMS' website at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Following is a summary of the use and burden associated with the subject information collection(s). More detailed information can be found in the collection's supporting statement and associated materials (see **ADDRESSES**).

Generic Information Collections

1. *Title of Information Collection:* Medicaid Section 1115 Severe Mental Illness and Children with Serious Emotional Disturbance Demonstrations; *Type of Information Collection Request:* Revised; *Use:* As part of the meta-analysis, this April 2022 iteration proposes to add virtual interviews with leaders in the state Medicaid Agency and/or the single state agency for behavioral health in the states that have approved section 1115 SMI demonstrations. Otherwise, there are no changes to the active collection of information requirements that are associated with the Implementation Plan, the Monitoring Protocol, the Monitoring Report, and the Initial Availability Assessment. *Form Number:* CMS–10398 (#59) (OMB control number: 0938–1148); *Frequency:* Yearly, quarterly, once, and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 10; *Total Annual Responses:* 114; *Total Annual Hours:* 3,314. (For policy questions regarding this collection contact Danielle Daly at 443–379–3289.)

Dated: April 29, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–09572 Filed 5–3–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS–460]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the

Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by July 5, 2022.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement

and associated materials (see ADDRESSES).

CMS-460 Medicare Participating Physician or Supplier Agreement

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Title of Information Collection:* Medicare Participating Physician or Supplier Agreement; *Type of Information Collection Request:* Revision with change of a currently approved collection; *Use:* Form CMS-460 is the agreement a physician, supplier, or their authorized official signs to become a participating provider in Medicare Part B. By signing the agreement to participate in Medicare, the physician, supplier, or their authorized official agrees to accept the Medicare-determined payment for Medicare covered services as payment in full and to charge the Medicare Part B beneficiary no more than the applicable deductible or coinsurance for the covered services. For purposes of this explanation, the term “supplier” means certain other persons or entities, other than physicians, that may bill Medicare for Part B services (e.g., suppliers of diagnostic tests, suppliers of radiology services, durable medical suppliers (DME) suppliers, nurse practitioners, clinical social workers, physician assistants). Institutions that render Part B services in their outpatient department are not considered “suppliers” for purposes of this agreement. *Form Number:* CMS-460 (OMB control number: 0938-0373); *Frequency:* Annually; *Affected Public:* Private Sector, Business or other for-profits; *Number of Respondents:* 36,000; *Number of Responses:* 36,000; *Total Annual Hours:* 9,000. (For questions regarding this collection contact Mark G. Baldwin at 410-786-8139.)

Dated: April 29, 2022,
William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022-09574 Filed 5-3-22; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the National Vaccine Advisory Committee (NVAC) will hold an in-person meeting. The meeting will be open to the public and public comment will be heard during the meeting.

DATES: The meeting will be held June 15–16, 2022. The confirmed meeting times and agenda will be posted on the NVAC website at <http://www.hhs.gov/nvpo/nvac/meetings/index.html> as soon as they become available.

ADDRESSES: Instructions regarding attending this meeting will be posted online at: <http://www.hhs.gov/nvpo/nvac/meetings/index.html> at least one week prior to the meeting. Pre-registration is required for those who wish to attend the meeting or participate in public comment. Please register at <http://www.hhs.gov/nvpo/nvac/meetings/index.html>.

FOR FURTHER INFORMATION CONTACT: Ann Aikin, Acting Designated Federal Officer, at the Office of Infectious Disease and HIV/AIDS Policy, U.S. Department of Health and Human Services, Mary E. Switzer Building, Room L618, 330 C Street SW, Washington, DC 20024. Email: nvac@hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. 300aa-1), the Secretary of HHS was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Director of the

National Vaccine Program on matters related to the Program’s responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

The NVAC will hear presentations on innovation for immunization, vaccine safety, and communication, and surveillance. Please note that agenda items are subject to change, as priorities dictate. Information on the final meeting agenda will be posted prior to the meeting on the NVAC website: <http://www.hhs.gov/nvpo/nvac/index.html>.

Members of the public will have the opportunity to provide comment at the NVAC meeting during the public comment period designated on the agenda. Public comments made during the meeting will be limited to three minutes per person to ensure time is allotted for all those wishing to speak. Individuals are also welcome to submit written comments in advance. Written comments should not exceed three pages in length. Individuals submitting comments should email their written comments or their request to provide a comment during the meeting to nvac@hhs.gov at least five business days prior to the meeting.

Dated: April 5, 2022.

Ann Aikin,
Acting Designated Federal Official, Office of the Assistant Secretary for Health.

[FR Doc. 2022-09551 Filed 5-3-22; 8:45 am]

BILLING CODE 4150-44-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Membership on the National Vaccine Advisory Committee

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, Office of Infectious Disease and HIV/AIDS Policy.

ACTION: Notice.

SUMMARY: The Office of Infectious Disease and HIV/AIDS Policy (OIDP), a program office within the Office of the Assistant Secretary for Health, Department of Health and Human Services (HHS), solicits nominations of qualified candidates to be considered for appointment to the National Vaccine Advisory Committee (NVAC). The activities of this committee are governed by the Federal Advisory Committee Act (FACA).

The NVAC serves an advisory role, providing recommendations to the Assistant Secretary for Health in her capacity as the Director of the National

Vaccine Program. The committee studies and recommends ways to encourage the availability of an adequate supply of safe and effective vaccination products in the United States, as well as research priorities and other measures to enhance the safety and efficacy of vaccines. The committee also advises the Assistant Secretary for Health on the implementation of sections 300aa–2, 300aa–3, and 300aa–4 of the Public Health Service (PHS) Act, including government and non-government cooperation.

A copy of the NVAC charter that describes its structure and functions and lists of the current members can be reviewed on the NVAC website at: <http://www.hhs.gov/nvpo/nvac/index.html>.

Submission Process: Please email all submissions to nvac@hhs.gov. All nominations for membership on the committee must be received no later than 5:00 p.m. EDT on June 24, 2022.

FOR FURTHER INFORMATION CONTACT: Ann Aikin, Acting Designated Federal Officer, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, Office of Infectious Disease and HIV/AIDS Policy, Mary E. Switzer Building, Room L618, 330 C Street SW, Washington, DC 20024. Email: nvac@hhs.gov.

SUPPLEMENTARY INFORMATION:

Committee Function, Qualifications, and Information Required: As part of an ongoing effort to enhance deliberations and discussions with the public on vaccines and immunization, nominations are being sought for interested individuals to serve on the NVAC. Committee members provide peer review, consultation, advice, and recommendations to the Assistant Secretary for Health, in her capacity as the Director of the National Vaccine Program. Individuals selected for appointment to the NVAC will serve as voting members. The NVAC consists of 17 voting members: 15 public members and 2 representative members. Individuals selected for appointment to the NVAC can be invited to serve terms of up to four years. Selection of members is based on candidates' qualifications to contribute to the accomplishment of the NVAC's objectives. Interested candidates should demonstrate a willingness to commit time to NVAC activities and the ability to work constructively and effectively on committees.

Public Members: Public members are individuals who are appointed to the NVAC to exercise their independent best judgment on behalf of the government. It is expected that public

members will discuss and deliberate in a manner that is free from conflicts of interest. Public members to the NVAC shall be selected from individuals who are engaged in vaccine research or the manufacture of vaccines, or who are health care providers, members of parent organizations concerned with immunizations, representatives of state or local health agencies, or public health organizations.

Representative Members: Representative members are individuals appointed to the NVAC to provide the views of industry or a special interest group. NVAC representative members serve specifically to represent the viewpoints or perspectives of the vaccine manufacturing industry or groups engaged in vaccine research or the manufacture of vaccines.

This announcement is to solicit nominations of qualified candidates to fill positions in the public and representative member category of the NVAC. Applications received in response and not appointed may also be considered for future vacancies that occur.

Travel reimbursement provided to the committee: All NVAC members are authorized to receive reimbursement for travel expenses that are incurred to attend meetings and conduct authorized NVAC-related business, in accordance with standard government travel regulations. All other services that are performed by the public members outside the committee meetings shall be provided without compensation.

Expertise sought for the National Vaccine Advisory Committee: To enhance the diversity of expertise on the committee, OIDD seeks nominations of diverse individuals in the following disciplines/topic areas:

- Vaccine innovation and/or research and development;
- vaccine safety;
- vaccine access and financing;
- health information technologies and immunization information systems;
- immunization program implementation and management; and
- vaccine communications.

How to submit nominations: The following information should be included in the package of materials submitted for each nominee: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.*, specific attributes that qualify the nominee for service in this capacity); and a statement that the nominee is willing to serve as a member of the committee; (2) the nominator's name, address, daytime telephone number, home and/or work address, and email address; (3) a current

copy of the nominee's curriculum vitae (no longer than 10 pages); and (4) a short biographical sketch (no more than 350 words). All documentation must be received in a legible font, such as Times New Roman 12 point, for a nomination to be considered.

Please note that nominees will not receive updates on the status of their nomination, and the nomination process can take many months. Information on nominees appointed to the committee will be posted to the NVAC website at <http://www.hhs.gov/nvpo/nvac/members/index.html>.

Individuals can nominate themselves for consideration of appointment to the committee. Incomplete nominations will not be processed. Federal employees should not be nominated for appointment to this committee.

HHS makes efforts to ensure that the membership of federal advisory committees is balanced in terms of points of view represented and the committee's function. Likewise, HHS seeks a broad representation of individuals with diverse backgrounds to serve on HHS federal advisory committees. Appointment to NVAC will be made without discrimination based on age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Individuals appointed to serve as public members of federal advisory committees are classified as special government employees (SGEs). SGEs are government employees for purposes of the conflict-of-interest laws. Therefore, individuals appointed to serve as public members of NVAC are subject to an ethics review to determine whether they have any interests and/or activities in the private sector that may conflict with performance of their official duties as an NVAC member. Individuals appointed to serve as public members of the NVAC will be required to disclose information regarding financial holdings, consultancies, research grants and/or contracts, and the absence of an appearance of a loss of impartiality.

Authority: 42 U.S.C. 300aa–5, Section 2105 of the Public Health Service Act, as amended. The National Vaccine Advisory Committee is governed by the provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: April 5, 2022.

Ann Aikin,

Acting Designated Federal Official, Office of the Assistant Secretary for Health.

[FR Doc. 2022–09550 Filed 5–3–22; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2022-0001]

Amendments of Emergency and Major Disaster Declarations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice; emergency and major disaster declarations.

SUMMARY: This notice amends the notices of emergency and major disaster declarations declared from or having an incident period beginning between, January 1, 2020 and December 31, 2021.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street, SW, Washington, DC 20472, dean.webster@fema.dhs.gov, (202) 646-2833.

SUPPLEMENTARY INFORMATION: Pursuant to the H.R. 2471, Consolidated Appropriations Act, 2022, notwithstanding sections 403(b), 403(c)(4), 404(a), 406(b), 407(d), 408(g)(2), 428(e)(2)(B), and 503(a) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*), for any emergency or major disaster declared by the President under such Act with a declaration occurring or an incident period beginning between January 1, 2020, and December 31, 2021, the Federal share of assistance, including direct Federal assistance, provided under such sections shall be not less than 90 percent of the total eligible cost of such assistance. The following list of declarations are amended as follows:

Federal funds for Public Assistance, including direct Federal assistance, Hazard Mitigation, and Other Needs Assistance under the Individuals and Households Program, if such programs are authorized, shall be not less than 90 percent of total eligible costs.

Emergency Declarations

- Notice; Puerto Rico; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3426-EM.
- Notice; Michigan; Amendment No. 4 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3525-EM.
- Notice; Louisiana; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3527-EM.
- Notice; Hawaii; Amendment No. 2 to Notice of an Emergency Declaration; Docket

- ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3529-EM.
- Notice; Texas; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3530-EM.
- Notice; Virgin Islands; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3531-EM.
- Notice; Puerto Rico; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3532-EM.
- Notice; Florida; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3533-EM.
- Notice; North Carolina; Amendment No. 3 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3534-EM.
- Notice; Connecticut; Amendment No. 1 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3535-EM.
- Notice; Puerto Rico; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3537-EM.
- Notice; Louisiana; Amendment No. 4 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3538-EM.
- Notice; Mississippi; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3539-EM.
- Notice; Texas; Amendment No. 5 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3540-EM.
- Notice; Arkansas; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3541-EM.
- Notice; Oregon; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3542-EM.
- Notice; Louisiana; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3543-EM.
- Notice; Mississippi; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3544-EM.
- Notice; Alabama; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3545-EM.
- Notice; Florida; Amendment No. 3 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3546-EM.
- Notice; Louisiana; Amendment No. 3 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3547-EM.
- Notice; Mississippi; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3548-EM.
- Notice; Louisiana; Amendment No. 2 to Notice of an Emergency Declaration; Docket

- ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3549-EM.
- Notice; Mississippi; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3550-EM.
- Notice; Florida; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3551-EM.
- Notice; Tennessee; Amendment No. 1 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3552-EM.
- Notice; District of Columbia; Amendment No. 3 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3553-EM.
- Notice; Texas; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3554-EM.
- Notice; Oklahoma; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3555-EM.
- Notice; Louisiana; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3556-EM.
- Notice; Florida; Amendment No. 3 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3560-EM.
- Notice; Florida; Amendment No. 4 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3561-EM.
- Notice; Florida; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3562-EM.
- Notice; Rhode Island; Amendment No. 3 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3563-EM.
- Notice; Connecticut; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3564-EM.
- Notice; New York; Amendment No. 3 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3565-EM.
- Notice; Mashpee Wampanoag Tribe; Amendment No. 1 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3566-EM.
- Notice; Vermont; Amendment No. 1 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3567-EM.
- Notice; Louisiana; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3568-EM.
- Notice; Mississippi; Amendment No. 5 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3569-EM.
- Notice; California; Amendment No. 2 to Notice of an Emergency Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-3571-EM.

Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4637-DR.

- Notice; Alaska; Amendment No. 1 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4638-DR.

- Notice; Hawaii; Amendment No. 1 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4639-DR.

- Notice; Kansas; Amendment No. 2 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4640-DR.

- Notice; Nebraska; Amendment No. 1 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4641-DR.

- Notice; Iowa; Amendment No. 1 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4642-DR.

- Notice; Kentucky; Amendment No. 2 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4643-DR.

- Notice; Maine; Amendment No. 1 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4647-DR.

- Notice; Alaska; Amendment No. 1 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4648-DR.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2022-09299 Filed 5-3-22; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2022-0001]

Major Disaster Declarations; COVID-19 Pandemic

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice; major disaster declarations.

SUMMARY: This notice amends the notices of major disaster declarations and related determinations resulting from the Coronavirus Disease 2019 (COVID-19) pandemic beginning on January 20, 2020.

FOR FURTHER INFORMATION CONTACT:

Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, dean.webster@fema.dhs.gov, (202) 646-2833.

SUPPLEMENTARY INFORMATION: This notice applies to all major disaster declarations and related determinations resulting from the Coronavirus Disease 2019 (COVID-19) pandemic beginning on January 20, 2020. See detailed declarations list below.

Pursuant to the President's Memorandum on Maximizing Assistance to Respond to COVID-19, dated March 1, 2022, (87 FR 12391), and under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207(Stafford Act), FEMA applied the following for all COVID-19 related declarations:

Federal funds for emergency protective measures (Category B), including direct Federal assistance, under the Public Assistance program (Section 403) are authorized at 100 percent of total eligible costs for work performed from January 20, 2020, through July 1, 2022.

COVID-19 Declarations

- Notice; New York; Amendment No. 10 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4480-DR.

- Notice; Washington; Amendment No. 7 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4481-DR.

- Notice; California; Amendment No. 7 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4482-DR.

- Notice; Iowa; Amendment No. 7 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4483-DR.

- Notice; Louisiana; Amendment No. 5 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4484-DR.

- Notice; Texas; Amendment No. 5 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4485-DR.

- Notice; Florida; Amendment No. 5 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4486-DR.

- Notice; North Carolina; Amendment No. 6 to Notice of a Major Disaster Declaration;

Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4487-DR.

- Notice; New Jersey; Amendment No. 10 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4488-DR.

- Notice; Illinois; Amendment No. 8 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4489-DR.

- Notice; Missouri; Amendment No. 7 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4490-DR.

- Notice; Maryland; Amendment No. 8 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4491-DR.

- Notice; South Carolina; Amendment No. 6 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4492-DR.

- Notice; Puerto Rico; Amendment No. 11 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4493-DR.

- Notice; Michigan; Amendment No. 7 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4494-DR.

- Notice; Guam; Amendment No. 9 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4495-DR.

- Notice; Massachusetts; Amendment No. 6 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4496-DR.

- Notice; Kentucky; Amendment No. 6 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4497-DR.

- Notice; Colorado; Amendment No. 9 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4498-DR.

- Notice; Oregon; Amendment No. 8 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4499-DR.

- Notice; Connecticut; Amendment No. 7 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4500-DR.

- Notice; Georgia; Amendment No. 6 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4501-DR.

- Notice; District of Columbia; Amendment No. 8 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4502-DR.

- Notice; Alabama; Amendment No. 6 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4503-DR.

- Notice; Kansas; Amendment No. 7 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4504-DR.

- Notice; Rhode Island; Amendment No. 7 to Notice of a Major Disaster Declaration; Docket ID FEMA-2022-0001; Internal Agency Docket No. FEMA-4505-DR.

- Notice; Pennsylvania; Amendment No. 8 to Notice of a Major Disaster Declaration;

Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4506–DR.

- Notice; Ohio; Amendment No. 8 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4507–DR.
- Notice; Montana; Amendment No. 9 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4508–DR.
- Notice; North Dakota; Amendment No. 9 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4509–DR.
- Notice; Hawaii; Amendment No. 8 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4510–DR.
- Notice; Commonwealth of the Northern Mariana Islands; Amendment No. 9 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4511–DR.
- Notice; Virginia; Amendment No. 8 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4512–DR.
- Notice; Virgin Islands; Amendment No. 11 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4513–DR.
- Notice; Tennessee; Amendment No. 6 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4514–DR.
- Notice; Indiana; Amendment No. 8 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4515–DR.
- Notice; New Hampshire; Amendment No. 7 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4516–DR.
- Notice; West Virginia; Amendment No. 8 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4517–DR.
- Notice; Arkansas; Amendment No. 6 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4518–DR.
- Notice; Wisconsin; Amendment No. 8 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4520–DR.
- Notice; Nebraska; Amendment No. 7 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4521–DR.
- Notice; Maine; Amendment No. 7 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4522–DR.
- Notice; Nevada; Amendment No. 8 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4523–DR.
- Notice; Arizona; Amendment No. 8 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4524–DR.
- Notice; Utah; Amendment No. 9 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4525–DR.
- Notice; Delaware; Amendment No. 8 to Notice of a Major Disaster Declaration;

Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4526–DR.

- Notice; South Dakota; Amendment No. 9 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4527–DR.
 - Notice; Mississippi; Amendment No. 6 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4528–DR.
 - Notice; New Mexico; Amendment No. 6 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4529–DR.
 - Notice; Oklahoma; Amendment No. 6 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4530–DR.
 - Notice; Minnesota; Amendment No. 8 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4531–DR.
 - Notice; Vermont; Amendment No. 7 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4532–DR.
 - Notice; Alaska; Amendment No. 8 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4533–DR.
 - Notice; Idaho; Amendment No. 8 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4534–DR.
 - Notice; Wyoming; Amendment No. 9 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4535–DR.
 - Notice; American Samoa; Amendment No. 7 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4537–DR.
 - Notice; Seminole Tribe of Florida; Amendment No. 4 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4545–DR.
 - Notice; Navajo Nation; Amendment No. 6 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4582–DR.
 - Notice; Poarch Band of Creek Indians; Amendment No. 4 to Notice of a Major Disaster Declaration; Docket ID FEMA–2022–0001; Internal Agency Docket No. FEMA–4591–DR.
- The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidially Declared Disaster Areas; 97.049, Presidially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidially Declared Disasters); 97.039, Hazard Mitigation Grant.

Deanne Criswell,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2022–09298 Filed 5–3–22; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

**[FWS–R4–ES–2022–0046;
FXES1113040000EA–123–FF04EF1000]**

Receipt of Incidental Take Permit Application and Proposed Habitat Conservation Plan for the Alabama Beach Mouse, Baldwin County, AL; Categorical Exclusion

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comment and information.

SUMMARY: We, the Fish and Wildlife Service (Service), announce receipt of an application from Brett Real Estate Robinson Development Company, Inc. (applicant) for an incidental take permit (ITP) under the Endangered Species Act. The applicant requests the ITP to take the federally listed Alabama beach mouse incidental to construction in the City of Gulf Shores, Baldwin County, Alabama. We request public comment on the application, which includes the applicant's proposed habitat conservation plan (HCP), and the Service's preliminary determination that this HCP qualifies as low effect, categorically excluded under the National Environmental Policy Act. To make this determination, we used our environmental action statement and low-effect screening form, both of which are also available for public review.

DATES: We must receive your written comments on or before June 3, 2022.

ADDRESSES:

Obtaining Documents: You may obtain copies of the documents online in Docket No. FWS–R4–ES–2022–0046 at <https://www.regulations.gov>.

Submitting Comments: If you wish to submit comments on any of the documents, you may do so in writing by any of the following methods:

- *Online:* <https://www.regulations.gov>. Follow the instructions for submitting comments on Docket No. FWS–R4–ES–2022–0046.

- *U.S. mail:* Public Comments Processing, Attn: Docket No. FWS–R4–ES–2022–0046; U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: Mr. William Lynn, Project Manager, by telephone at 251-441-5868 or via email at william_lynn@fws.gov. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: We, the Fish and Wildlife Service (Service), announce receipt of an application from Brett Real Estate Robinson Development Company, Inc. (applicant) for an incidental take permit (ITP) under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The applicant requests the ITP to take the federally listed Alabama beach mouse (*Peromyscus polionotus ammobates*) (ABM) incidental to the construction of a single condominium tower with amenities (project) in the City of Gulf Shores, Baldwin County, Alabama. We request public comment on the application, which includes the applicant's proposed habitat conservation plan (HCP), and the Service's preliminary determination that this HCP qualifies as low-effect, categorically excluded, under the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*). To make this determination, we used our environmental action statement and low-effect screening form, both of which are also available for public review.

Project

The applicant requests a 50-year ITP to take ABM by converting approximately 0.061 acres (ac) of occupied ABM foraging and sheltering habitat incidental to the construction of a single condominium tower, with 110 beachfront units and amenities, on 0.84 ac of a 3.18-ac parcel in Baldwin County, Alabama. The parcel contains 0.713 ac of ABM-occupied suitable habitat.

The parcel was previously utilized in 2004 and 2005 for stockpiling of Hurricane(s) Ivan and Katrina debris. Most of the larger hurricane debris has been removed. However, the northern part of the parcel still contains considerable concrete and construction debris, which precludes the natural dune repair process.

As mitigation for incidental take of the ABM, the applicant proposes to preserve and enhance the remaining 0.652 ac of ABM-occupied habitat on the parcel. Additionally, the applicant

will restore a sandy area (0.073 ac) on the parcel to vegetated sand dunes. Outside the development footprint, the applicant will landscape 0.853 ac with native vegetation that may support ABM. After development is completed, the parcel will contain 2.34 ac of native habitat (0.853 ac open beach, 0.725 ac ABM habitat, and 0.762 ac native landscaping), which will be permanently managed as coastal dune habitat for the ABM. In addition, standard mitigation and minimization measures will be implemented on the parcel, including installing sea turtle-friendly lighting and tinted windows, landscaping with native vegetation, enhancing the frontal dune area, constructing a concrete driveway that will not spread widely as a result of storm surge, utilizing refuse-control measures during construction that also would be required of future residents, and restoring ABM habitat after tropical storms. Free-roaming cats and the use of exterior rodenticide will be prohibited within the development. There also will be monitoring of the on-site ABM population via fall, winter, and spring trapping surveys conducted quarterly for the life of the permit (50 years). Condominium unit owners will be required to pay a \$201-per-unit annual fee over the next 50 years into a mitigation fund set up by the condominium homeowners' association, and the accumulated fees will be used for predator control, monitoring, and/or improvement of Alabama beach mouse habitat on the parcel. The Service would require the applicant to ensure that funding for the HCP is available prior to engaging in any activities associated with the project.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, be aware that your entire comment—including your personal identifying information—may be made available to the public. While you may request that we withhold your personal identifying information, we cannot guarantee that we will be able to do so.

Our Preliminary Determination

The Service has made a preliminary determination that the applicant's project, including land clearing, infrastructure building, construction of the condominium tower and amenities, landscaping, and the proposed mitigation and minimization measures, would individually and cumulatively have a minor or negligible effect on the Alabama beach mouse and the environment. Therefore, we have

preliminarily concluded that the ITP for this project would qualify for categorical exclusion and that the HCP is low effect under our NEPA regulations at 43 CFR 46.205 and 46.210. A low-effect HCP is one that would result in (1) minor or negligible effects on federally listed, proposed, and candidate species and their habitats; (2) minor or negligible effects on other environmental values or resources; and (3) impacts that, when considered together with the impacts of other past, present, and reasonably foreseeable similarly situated projects, would not result in significant cumulative effects to environmental values or resources over time.

Next Steps

The Service will evaluate the application and the comments received to determine whether to issue the requested permit. We will also conduct an intra-Service consultation pursuant to section 7 of the ESA to evaluate the effects of the proposed take on the species. We will consider all of the preceding in determining whether the permit issuance criteria of section 10(a)(1)(B) of the ESA have been met. If met, the Service will issue ITP number ESPER0031364-0 to Brett Real Estate Robinson Development Company, Inc.

Authority

The Service provides this notice under section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.32) and NEPA (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR 1506.6 and 43 CFR 46.305).

William Pearson,

Field Supervisor, Alabama Ecological Service Field Office.

[FR Doc. 2022-09558 Filed 5-3-22; 8:45 am]

BILLING CODE 4333-15-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AA-9412, AA-9413, AA-9421, AA-9623, AA-9661, AA-9663, AA-9690, AA-9707, AA-9721, AA-9740, AA-9894; 22X.LLAK944000. L14100000.HY0000.P]

Alaska Native Claims Selection

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of decision approving lands for conveyance.

SUMMARY: The Bureau of Land Management (BLM) hereby provides constructive notice that it will issue an appealable decision approving conveyance of the surface estate in

certain lands to Calista Corporation, an Alaska Native regional corporation, pursuant to the Alaska Native Claims Settlement Act of 1971 (ANCSA). The lands approved for conveyance lie entirely within Clarence Rhode National Wildlife Range now known as the Yukon Delta Wildlife Refuge. As provided by ANCSA, ownership of the subsurface estate in the same lands will be retained by the United States.

DATES: Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the time limits set out in the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: You may obtain a copy of the decision from the Bureau of Land Management, Alaska State Office, 222 West Seventh Avenue, #13, Anchorage, AK 99513-7504.

FOR FURTHER INFORMATION CONTACT: Abby Muth, Land Law Examiner, BLM Alaska State Office, 907-271-3345 or amuth@blm.gov. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. The relay service is available 24 hours a day, 7 days a week, to leave a message or question with the BLM. The BLM will reply during normal business hours.

SUPPLEMENTARY INFORMATION: As required by 43 CFR 2650.7(d), notice is hereby given that the BLM will issue an appealable decision to Calista Corporation. The decision approves conveyance of surface estate in certain lands pursuant to ANCSA (43 U.S.C. 1601, *et seq.*), as amended. Ownership of the subsurface estate will be retained by the United States.

The lands are located within the Yukon Delta National Wildlife Refuge, in the following townships, and aggregate 78.31 acres: T. 15 N., R. 86 W., Seward Meridian (SM); T. 10 N., R. 88 W., SM; T. 15 N., R. 88 W., SM; T. 17 N., R. 88 W., SM; T. 18 N., R. 88 W., SM; T. 10 N., R. 89 W., SM; and T. 12 N., R. 89 W., SM.

The decision addresses public access easements, if any, to be reserved to the United States pursuant to Sec. 17(b) of ANCSA (43 U.S.C. 1616(b)), in the lands approved for conveyance.

The BLM will also publish notice of the decision once a week for four

consecutive weeks in "The Delta Discovery" newspaper.

Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the following time limits:

1. Unknown parties, parties unable to be located after reasonable efforts have been expended to locate, parties who fail or refuse to sign their return receipt, and parties who receive a copy of the decision by regular mail which is not certified, return receipt requested, shall have until June 3, 2022 to file an appeal.

2. Parties receiving service of the decision by certified mail shall have 30 days from the date of receipt to file an appeal.

Parties who do not file an appeal in accordance with the requirements of 43 CFR part 4 shall be deemed to have waived their rights. Notices of appeal transmitted by facsimile will not be accepted as timely filed.

Abby Muth,

Land Law Examiner, Adjudication Section.

[FR Doc. 2022-09524 Filed 5-3-22; 8:45 am]

BILLING CODE 4310-JA-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[223 LLUTG02000 L12200000.PM00000]

Notice of Public Meetings, San Rafael Swell Recreation Area Advisory Council, Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act, the Federal Advisory Committee Act, and the Federal Lands Recreation Enhancement Act, the U.S. Department of the Interior, Bureau of Land Management's (BLM) San Rafael Swell Recreation Area Advisory Council (Council) will meet as indicated below.

DATES: The Council will meet at the Emery County Courthouse on May 24, 2022, to depart for a field tour of the San Rafael Swell Recreation Area from 8:30 a.m. to 5:00 p.m. The Council will hold an in-person public meeting with a virtual participation option on May 25, 2022, from 8:30 a.m. to 12:30 p.m., with public comments accepted at 11:00 a.m.

The Council will hold an in-person public meeting with a virtual participation option on August 29, 2022, from 8:30 a.m. to 12:45 p.m., with public comments accepted at 11:00 a.m.

The meetings and field tour are open to the public.

ADDRESSES:

- On May 24, participants will meet at the Emery County Courthouse, 75 East Main Street, Castle Dale, UT 84513 for a field tour to the San Rafael Swell Recreation Area. The May 25 meeting will also be held at the Emery County Courthouse. Individuals that prefer to participate virtually must register in advance at <https://tinyurl.com/bdcs6nppn>.

- The August 29 meeting will be held at the Emery County Courthouse. Individuals that prefer to participate virtually must register in advance at <https://tinyurl.com/yckrjtfa>.

Written comments may be sent prior to each meeting either by mail to the BLM Green River District, Attn: Lance Porter, 170 South 500 West, Vernal, UT 84078, or by email: utprmail@blm.gov, with the subject line "San Rafael Swell Recreation Area Advisory Council Meeting."

FOR FURTHER INFORMATION CONTACT:

BLM Green River District Manager Lance Porter, telephone: (435) 781-4400 or email: utprmail@blm.gov. Persons in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The John D. Dingell, Jr. Conservation, Management, and Recreation Act (Pub. L. 116-9) established the San Rafael Swell Recreation Area Advisory Council to advise the Secretary of the Interior, through the BLM, in planning and managing the San Rafael Swell Recreation Area. The seven-member Council represents a wide range of interests including local government, recreational users, grazing allotment permittees, conservation organizations, people with expertise in historical uses of the recreation area, and Tribes.

The Council will host a field tour on May 24 to the San Rafael Swell Recreation Area, which features badlands of brightly colored and wildly eroded sandstone formations, deep canyons, and giant plates of stone tilted upright through massive geologic upheaval. The recreation area offers numerous recreational opportunities including hiking, biking, four-wheel driving, horseback, canyoneering, and river running. Members of the public are welcome on the field tour but must provide their own transportation and meals. Individuals who plan to attend

must RSVP at least one week in advance of the field tour to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individuals who need special assistance, such as sign language interpretation and other reasonable accommodations, also should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. The field tour will follow current Centers for Disease Control and Prevention COVID-19 guidance regarding social distancing and wearing of masks. Agenda items for the May 25 meeting include wild horse and burro management and special recreation permits. Agenda items for the August 29 meeting include a review of Areas of Critical Environmental Concern, land use plan amendments updates, and spring/summer visitor information updates.

Detailed meeting minutes will be maintained in the BLM Green River District Office and will be made available for public inspection and reproduction during regular business hours within 90 days following each meeting. Minutes will also be posted to the Council's web page <https://go.usa.gov/xzk5Q>. The amount of time for individual oral comments may be limited, depending on the total number of commenters. Written comments may also be sent to the BLM Green River District Manager at the address listed in the **ADDRESSES** section of this notice. All comments received will be provided to the Council.

Public Disclosure of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 CFR 1784.4-2.

Anita Bilbao,

Associate State Director.

[FR Doc. 2022-09522 Filed 5-3-22; 8:45 am]

BILLING CODE 4310-DQ-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[223.LLID910000.L18200000.XZ0000.241A0 MO #4500161655]

Notice of Public Meetings of the Idaho Resource Advisory Council and the Proposed Lava Ridge Wind Energy Project Subcommittee

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976 and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior Bureau of Land Management's (BLM) Idaho Resource Advisory Council (Idaho RAC) and the Proposed Lava Ridge Wind Energy Project Subcommittee (Lava Ridge Subcommittee) will meet as indicated below.

DATES: The BLM Idaho RAC and Lava Ridge Subcommittee will meet as follows:

- The Idaho RAC and Lava Ridge Subcommittee will host a field tour on Wednesday, June 15, 2022 from 8:00 a.m. to 5:30 p.m. Mountain Daylight Time.
- The Lava Ridge Subcommittee will host virtual meetings on Thursday, July 7, 2022; Thursday, August 25, 2022; and Thursday, September 22, 2022 from 9:00 a.m. to 5:00 p.m. Mountain Daylight Time.
- The Idaho RAC will host an in-person meeting on Wednesday, October 19, 2022 from 9:00 a.m. to 5:00 p.m. Mountain Daylight Time at the BLM Twin Falls District Office, 2878 Addison Avenue East, Twin Falls, Idaho, 83301. A virtual participation option will also be available. The entire meeting may be held virtually depending on public health recommendations in place at the time of the meeting. Public notice of the change will be posted on the RAC's web page 15 days in advance of the meeting.

The field tour and all meetings are open to the public and public comment periods will be held at each meeting and at the field tour.

ADDRESSES: The June 15 field tour will commence at 8:00 a.m. at the BLM Twin Falls District Office, 2878 Addison Avenue East, Twin Falls, Idaho, 83301. Participants will then travel to the Minidoka National Historic Site, Wilson Butte Cave, and Sid Butte. All virtual meetings will be held via the Zoom platform. Agendas, Zoom registration, and participation information will be available on the RAC's web page 30 days in advance of the meetings at

<https://www.blm.gov/get-involved/resource-advisory-council/near-you/idaho>.

FOR FURTHER INFORMATION CONTACT: MJ Byrne, 1387 South Vinnell Way, Boise, Idaho 83709; (208) 373-4006; mbyrne@blm.gov. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Idaho RAC is chartered, and the 15 members are appointed by the Secretary of the Interior. Their diverse perspectives are represented in commodity, non-commodity, and local interests. The Idaho RAC serves in an advisory capacity to BLM officials concerning issues relating to land use planning and management of public land resources located within the State of Idaho. The Idaho RAC formed the Lava Ridge Subcommittee to compile information, conduct research, and report their recommendations to the full Council for consideration. The BLM Shoshone Field Office is currently developing an Environmental Impact Statement to analyze the proposed Lava Ridge Wind Energy Project, a commercial-scale wind energy facility that is proposed to be constructed on BLM-managed public land in southern Idaho.

The June 15 Subcommittee and RAC field tour is to sites associated with the proposed Project. The public comment period for the Wednesday, June 15, 2022, field tour will be held at 4:45 p.m.

The July 7 Subcommittee meeting will focus on providing background information on the proposed Project, the NEPA process, and stakeholder perspective. The August 25 Subcommittee meeting will include a review of the Draft Environmental Impact Statement (DEIS) and presentations on alternatives. The September 22 Subcommittee meeting will focus on compiling information for consideration of the RAC on the DEIS alternatives. The October 19 RAC meeting will include State Director and District Office updates; a presentation on the Payette River System Draft Business Plan; an update on the proposed Project, a presentation on Subcommittee findings relating to the proposed Project, and development of associated RAC recommendations; and a presentation on Bipartisan Infrastructure Law implementation and projects.

The times that public comment periods will be held during the meetings will be specified in agendas that will be posted on the RAC's web page 30 days in advance of meetings. Contingent on the number of people who wish to comment during the public comment period, individual comments may be limited. Written comments may be submitted to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Comments received at least one week in advance of the meetings will be provided to the Idaho RAC and Lava Ridge Subcommittee members prior to the meetings. Please include "RAC comment" or "Lava Ridge Subcommittee comment" in your submission.

Before including your address, phone number, email address, or other personal identifying information in your comments, please be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comments to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Members of the public are welcome on the field tour but must provide their own transportation and meals. Individuals who plan to attend must RSVP at least one week in advance of the field tour to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individuals who need special assistance, such as sign language interpretation and other reasonable accommodations, also should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. The field tour will follow current Centers for Disease Control and Prevention COVID-19 guidance regarding social distancing and wearing of masks. Detailed summary minutes for the Idaho RAC and Lava Ridge Subcommittee meetings will be maintained in the BLM Idaho State Office and will be available for public inspection and reproduction during regular business hours within 30 days following the meetings. Previous minutes and agendas are also available on the RAC's web page at <https://www.blm.gov/get-involved/resource-advisory-council/near-you/idaho>.

(Authority: 43 CFR 1784.4-2)

Karen Kelleher,

Idaho State Director.

[FR Doc. 2022-09527 Filed 5-3-22; 8:45 am]

BILLING CODE 4310-GG-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AA-6987-D; 22X.LLAK944000.
L14100000.HY0000.P]

Alaska Native Claims Selection

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of decision approving lands for conveyance.

SUMMARY: The Bureau of Land Management (BLM) hereby provides constructive notice that it will issue an appealable decision approving conveyance of the surface estate in certain lands to Yak-Tat Kwaan, Incorporated for the Native village of Yakutat, pursuant to the Alaska Native Claims Settlement Act of 1971 (ANCSA). The subsurface estate in the same lands will be conveyed to Sealaska Corporation when the surface estate is conveyed to Yak-Tat Kwaan, Incorporated.

DATES: Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the time limits set out in the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: You may obtain a copy of the decision from the Bureau of Land Management, Alaska State Office, 222 West Seventh Avenue, #13, Anchorage, AK 99513-7504.

FOR FURTHER INFORMATION CONTACT: Dina L. Torres, Chief, Branch of Adjudication, BLM Alaska State Office, 907-271-5699, or dtorres@blm.gov. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: As required by 43 CFR 2650.7(d), notice is hereby given that the BLM will issue an appealable decision to Yak-Tat Kwaan, Incorporated. The decision approves conveyance of the surface estate in certain lands pursuant to ANCSA (43 U.S.C. 1601, *et seq.*). As provided by ANCSA, the subsurface estate in the same lands will be conveyed to Sealaska Corporation when the surface estate is conveyed to Yak-Tat Kwaan, Incorporated. The lands are located in the vicinity of Yakutat, Alaska, within Secs. 2 and 11, T. 28 S., R. 33 E., Copper

River Meridian, Alaska, and are described as:

U.S. Survey No. 13263, Alaska.
Containing 43.59 acres.

The decision addresses public access easements, if any, to be reserved to the United States pursuant to Sec. 17(b) of ANCSA (43 U.S.C. 1616(b)), in the lands described above.

The BLM will also publish notice of the decision once a week for four consecutive weeks in the Juneau Empire newspaper.

Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the following time limits:

1. Unknown parties, parties unable to be located after reasonable efforts have been expended to locate, parties who fail or refuse to sign their return receipt, and parties who receive a copy of the decision by regular mail which is not certified, return receipt requested, shall have until June 3, 2022 to file an appeal.

2. Parties receiving service of the decision by certified mail shall have 30 days from the date of receipt to file an appeal.

Parties who do not file an appeal in accordance with the requirements of 43 CFR part 4 shall be deemed to have waived their rights. Notices of appeal transmitted by facsimile will not be accepted as timely filed.

Dina L. Torres,

Chief, Branch of Adjudication.

[FR Doc. 2022-09525 Filed 5-3-22; 8:45 am]

BILLING CODE 4310-JA-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-PWRO-TUSK-33652; PPPWTUSK00,
PPMPSD1Z.YM0000]

Tule Springs Fossil Beds National Monument Advisory Council Notice of Public Meeting

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, the National Park Service is hereby giving notice that the Tule Springs Fossil Beds National Monument Advisory Council (Council) will meet as indicated below.

DATES: The meeting will be held on Wednesday, June 8, 2022, at 5:00 p.m. until 7:00 p.m. (PACIFIC).

ADDRESSES: The meeting will be held virtually and in person at the Ice Age Fossils State Park facility at 8660 N.

Decatur Blvd., North Las Vegas, Nevada 89085.

FOR FURTHER INFORMATION CONTACT:

Further information concerning the meeting may be obtained from Christa Johnston, Public Affairs Officer, Lake Mead National Recreation Area, 601 Nevada Way, Boulder City, Nevada 89005, via telephone at (702) 293-8691, or email at christa_johnston@nps.gov.

SUPPLEMENTARY INFORMATION: The Council was established pursuant to section 3092(a)(6) of Public Law 113-291 and in accordance with the provisions of the Federal Advisory Committee Act (5 U.S.C. Appendix 1-16). The purpose of the Council is to advise the Secretary of the Interior with respect to the preparation and implementation of the management plan.

Purpose of the Meeting: The Council agenda will include:

1. Minutes Review
2. Superintendent Updates will include: General Management Plan—Update of Workshop 1
3. Resource Management Updates
4. Old Business
5. New Business
6. Public Comments

The meeting is open to the public. Interested persons may make oral or written presentations to the Council during the business meeting or file written statements. Requests to address the Council should be made to the Superintendent prior to the meeting. Members of the public may submit written comments by mailing them to Ashley Pipkin, Acting Superintendent, Tule Springs Fossil Beds National Monument, 601 Nevada Way, Boulder City, NV 89005, or by email ashley_pipkin@nps.gov. All written comments will be provided to members of the Council. Due to time constraints during the meeting, the Council is not able to read written public comments submitted into the record. Depending on the number of people who wish to speak and the time available, the time for individual comments may be limited.

Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

Public Disclosure of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that

your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. Appendix 2.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2022-09505 Filed 5-3-22; 8:45 am]

BILLING CODE 4312-52-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1311]

Certain Centrifuge Utility Platform and Falling Film Evaporator Systems and Components Thereof; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on March 29, 2022, under section 337 of the Tariff Act of 1930, as amended, on behalf of Apeks, LLC of Johnstown, Ohio. The complaint was supplemented by letter on April 14, 2022. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain centrifuge utility platform and falling film evaporator systems and components thereof by reason of infringement of certain claims of U.S. Patent No. 10,814,338 (“the ‘338 patent”), U.S. Patent No. 11,014,098 (“the ‘098 patent”) and U.S. Patent No. 10,899,728 (“the ‘728 patent”). The complaint, as supplemented, further alleges that an industry in the United States exists as required by the applicable Federal Statute. The complainant requests that the Commission institute an investigation and, after the investigation, issue a general exclusion order, or in the alternative a limited exclusion order, and cease and desist orders.

ADDRESSES: The complaint, and supplement, except for any confidential information contained therein, may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. Hearing impaired individuals are advised that information on this matter can be obtained by

contacting the Commission’s TDD terminal on (202) 205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205-2000. General information concerning the Commission may also be obtained by accessing its internet server at <https://www.usitc.gov>.

FOR FURTHER INFORMATION CONTACT:

Pathenia M. Proctor, The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205-2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission’s Rules of Practice and Procedure, 19 CFR 210.10 (2021).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on April 28, 2022, ordered that—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 1, 10, and 14 of the ‘338 patent; claims 1, 10, and 18 of the ‘098 patent; and claims 1, 9, and 19 of the ‘728 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission’s Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or categories of accused products, which defines the scope of the investigation, are “(a) centrifuge utility platforms which combine closed-loop, alcohol extraction with mechanical centrifugation capable of targeting specific plant compounds, isolating the desired separation, and (b) falling film evaporators which distill and process solutions comprising extracts of botanical compounds (e.g., cannabinoids) and solvent to separate out the botanical oils and recover the solvent for reuse”;

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is:

Apeks, LLC, 31 Greenscape Court,
Johnstown, Ohio 43031

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Ambiopharm Inc., 1024 Dittman Court,
Beech Island, SC 29842

Calpha Industries Inc., 22732 Granite
Way Suite A, Laguna Hills, CA 92653

Comerg, LLC, 12620 N Cave Creek Rd.,
Phoenix, AZ 85022, USA

Ezhydro, 10255 Old Placerville Rd.,
Sacramento, CA 95827

Henan Lanphan Industry Co., Ltd.,
Room 801, Building B, CC Mall,
Jianshe, Road, Zhongyuan District,
Zhengzhou, Henan, Province, China,
450000

HX Labs, LLC, 34004 Texas St. SW,
Albany, OR 97321

Idea Makers, LLC, 722 S State St., Salt
Lake City, UT 84111

Lab1st Scientific and Industrial
Equipment, Inc., No. 248 Guanghua
Road, MinHang District, Shanghai
201612, China

Miracle Education Distributors, Inc.,
68366 Kieley Rd., Cathedral City, CA
92234, USA

Mountain Pure, LLC, 496 E 1750 N, Unit
E, Vineyard, UT 84057, USA

Redford Management, 4625 Alger St.,
Los Angeles, CA 90039

Ri Hemp Farms, LLC, 39 Nooseneck Hill
Rd., West Greenwich RI 02817

Shanghai Yuanhuai Industries Co. Ltd.,
No. 99 Shenbei Yi Rd., Songjiang
District, Shanghai City, China, 201612

Toption Instrument Co., Ltd., 21501
Room HeCheng, TaiBai Road, YanTa
District, Xi'an, Shaanxi Province,
China, 710000

Zhangjiagang Chunk Trading Corp. d/b/
a, Zhangjiagang Charme Trading Corp.
Ltd., Wang Xi Lu, Gusu Qu, Suzhou
Shi, Jiangsu Province, China, 215000

(c) The Office of Unfair Import
Investigations, U.S. International Trade
Commission, 500 E Street SW, Suite
401, Washington, DC 20436; and

(4) For the investigation so instituted,
the Chief Administrative Law Judge,
U.S. International Trade Commission,
shall designate the presiding
Administrative Law Judge.

Responses to the complaint and the
notice of investigation must be
submitted by the named respondents in
accordance with section 210.13 of the
Commission's Rules of Practice and
Procedure, 19 CFR 210.13. Pursuant to
19 CFR 201.16(e) and 210.13(a), as
amended in 85 FR 15798 (March 19,
2020), such responses will be
considered by the Commission if
received not later than 20 days after the
date of service by the complainant of the

complaint, as supplemented, and the
notice of investigation. Extensions of
time for submitting responses to the
complaint and the notice of
investigation will not be granted unless
good cause therefor is shown.

Failure of a respondent to file a timely
response to each allegation in the
complaint and in this notice may be
deemed to constitute a waiver of the
right to appear and contest the
allegations of the complaint and this
notice, and to authorize the
administrative law judge and the
Commission, without further notice to
the respondent, to find the facts to be as
alleged in the complaint, as
supplemented, and this notice and to
enter an initial determination and a
final determination containing such
findings, and may result in the issuance
of an exclusion order or cease and desist
order or both directed against the
respondent.

By order of the Commission.

Issued: April 28, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022-09508 Filed 5-3-22; 8:45 am]

BILLING CODE 7020-02-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1312]

Certain Mobile Electronic Devices; Institution of Investigation

AGENCY: U.S. International Trade
Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a
complaint was filed with the U.S.
International Trade Commission on
March 30, 2022, under section 337 of
the Tariff Act of 1930, as amended, on
behalf of Maxell, Ltd. of Japan.
Supplements to the complaint were
filed on April 13, 2022, and April 14,
2022. The complaint, as supplemented,
alleges violations of section 337 based
upon the importation into the United
States, the sale for importation, and the
sale within the United States after
importation of certain mobile electronic
devices by reason of infringement of
certain claims of U.S. Patent No.
7,199,821 (“the ‘821 Patent”); U.S.
Patent No. 7,324,487 (“the ‘487 Patent”);
U.S. Patent No. 8,170,394 (“the ‘394
Patent”); U.S. Patent No. 8,982,086 (“the
‘086 Patent”); and U.S. Patent No.
10,129,590 (“the ‘590 Patent”); and U.S.
Patent No. 10,244,284 (“the ‘284
Patent”). The complaint further alleges
that an industry in the United States

exists as required by the applicable
Federal Statute. The complainant
requests that the Commission institute
an investigation and, after the
investigation, issue a limited exclusion
order and a cease and desist order.

ADDRESSES: The complaint, except for
any confidential information contained
therein, may be viewed on the
Commission's electronic docket (EDIS)
at <https://edis.usitc.gov>. For help
accessing EDIS, please email
EDIS3Help@usitc.gov. Hearing impaired
individuals are advised that information
on this matter can be obtained by
contacting the Commission's TDD
terminal on (202) 205-1810. Persons
with mobility impairments who will
need special assistance in gaining access
to the Commission should contact the
Office of the Secretary at (202) 205-
2000. General information concerning
the Commission may also be obtained
by accessing its internet server at
<https://www.usitc.gov>.

FOR FURTHER INFORMATION CONTACT:

Pathenia M. Proctor, The Office of
Unfair Import Investigations, U.S.
International Trade Commission,
telephone (202) 205-2560.

SUPPLEMENTARY INFORMATION:

Authority: The authority for
institution of this investigation is
contained in section 337 of the Tariff
Act of 1930, as amended, 19 U.S.C.
1337, and in section 210.10 of the
Commission's Rules of Practice and
Procedure, 19 CFR 210.10 (2021).

Scope of Investigation: Having
considered the complaint, the U.S.
International Trade Commission, on
April 28, 2022, *ordered that—*

(1) Pursuant to subsection (b) of
section 337 of the Tariff Act of 1930, as
amended, an investigation be instituted
to determine whether there is a
violation of subsection (a)(1)(B) of
section 337 in the importation into the
United States, the sale for importation,
or the sale within the United States after
importation of certain products
identified in paragraph (2) by reason of
infringement of one or more of claims 1,
6, and 7 of the ‘821 patent; claims 1, 3,
and 4 of the ‘487 patent; claims 2, 4, 5,
7, and 8 of the ‘394 patent; claims 1, 2,
4, 6, 9-13, and 15 of the ‘086 patent;
claims 1, 5, 9, 11-14, 16-22, and 23-25
of the ‘590 patent; and claims 1, 3, 4, 7,
9, 10, and 18-20 of the ‘284 patent, and
whether an industry in the United
States exists as required by subsection
(a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of
the Commission's Rules of Practice and
Procedure, 19 CFR 210.10(b)(1), the
plain language description of the
accused products or category of accused

products, which defines the scope of the investigation, is “certain mobile electronic devices, *i.e.*, Motorola-branded smartphones”;

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is:

Maxell, Ltd., 1 Koizumi, Oyamazaki, Oyamazaki-cho, Otokuni-gun, Kyoto, 618–8525 Japan

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Lenovo Group Ltd., No. 6 Chuang Ye Road, Haidan District, Shangdi Information Industry Base, Beijing 100085, China

Lenovo (United States) Inc., 1009 Think Place, Morrisville, NC 27650

Motorola Mobility LLC, 600 N U.S. Highway 45, Libertyville, IL 60048.

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW, Suite 401, Washington, DC 20436; and

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission’s Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), as amended in 85 FR 15798 (March 19, 2020), such responses will be considered by the Commission if received not later than 20 days after the date of service by the complainant of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a the respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease

and desist order or both directed against the respondent.

By order of the Commission.

Issued: April 28, 2022.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2022–09510 Filed 5–3–22; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[OMB Control No. 1219–0039]

Proposed Extension of Information Collection; Gamma Radiation Surveys

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Request for public comments.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed collections of information in accordance with the Paperwork Reduction Act of 1995. This program helps to assure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments on the information collection for Gamma Radiation Surveys.

DATES: All comments must be received on or before July 5, 2022.

ADDRESSES: Comments concerning the information collection requirements of this notice may be sent by any of the methods listed below.

- *Federal E-Rulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments for docket number MSHA–2022–0021.

- *Mail/Hand Delivery:* Mail or visit DOL–MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, VA 22202–5452. Before visiting MSHA in person, call 202–693–9455 to make an appointment, in keeping with the Department of Labor’s COVID–19 policy. Special health precautions may be required.

- MSHA will post your comment as well as any attachments, except for information submitted and marked as

confidential, in the docket at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: S. Aromie Noe, Director, Office of Standards, Regulations, and Variances, MSHA, at MSHA.information.collections@dol.gov (email); 202–693–9440 (voice); or 202–693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

Gamma radiation occurs where radioactive materials are present. It has been associated with lung cancer and other debilitating occupational diseases. Natural sources include rocks, soils, and ground water. Gamma radiation hazards may be found near radiation sources at surface operations using X-ray machines, weightometers, nuclear and diffraction units. Nuclear gauges mounted outside tanks, pipes, bins, hoppers or other types of vessels use gamma rays to sense the level and density of liquids, slurries or solids. Gamma rays can penetrate the human body and can kill or damage cells in their path that can affect many of the body’s organs. The adverse health effects from exposure to gamma radiation can vary depending upon the type of cell affected and the extent of damage.

Under Section 103(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act), the Mine Safety and Health Administration (MSHA) is required to “. . . issue regulations requiring operators to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under any applicable mandatory health or safety standard promulgated under this Act.” In addition, 30 CFR 57.5047(a) requires that gamma radiation surveys be conducted annually in all underground mines where radioactive ores are mined. 30 CFR 57.5047(c) requires that gamma radiation dosimeters be provided for all persons exposed to average gamma radiation measurements in excess of 2.0 milliroentgens per hour in the working place. This paragraph also requires that the operator keep records of cumulative individual gamma radiation exposures.

II. Desired Focus of Comments

MSHA is soliciting comments concerning the proposed information collection related to Gamma Radiation Surveys. MSHA is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the

agency, including whether the information has practical utility;

- Evaluate the accuracy of MSHA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Suggest methods to enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

The information collection request will be available on <http://www.regulations.gov>. MSHA cautions the commenter against providing any information in the submission that should not be publicly disclosed. Full comments, including personal information provided, will be made available on www.regulations.gov and www.reginfo.gov.

The public may also examine publicly available documents at USDOL-Mine Safety and Health Administration, 201 12th South, Suite 4E401, Arlington, VA 22202-5452. Sign in at the receptionist's desk on the 4th floor via the East elevator. Before visiting MSHA in person, call 202-693-9455 to make an appointment, in keeping with the Department of Labor's COVID-19 policy. Special health precautions may be required. Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION** section of this notice.

III. Current Actions

This request for collection of information addresses provisions for conducting and recording Gamma Radiation Surveys. MSHA has updated the data with respect to the number of respondents, responses, burden hours, and burden costs supporting this information collection request.

Type of Review: Extension, without change, of a currently approved collection.

Agency: Mine Safety and Health Administration.

OMB Number: 1219-0039.

Affected Public: Business or other for-profit.

Number of Respondents: 3.

Frequency: On occasion.

Number of Responses: 3.

Annual Burden Hours: 6 hours.

Annual Respondent or Recordkeeper Cost: \$0.

Comments submitted in response to this notice will be summarized and

included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Song-ae Aromie Noe,

Certifying Officer.

[FR Doc. 2022-09540 Filed 5-3-22; 8:45 am]

BILLING CODE 4510-43-P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request; National Survey of College Graduates

AGENCY: National Center for Science and Engineering Statistics, National Science Foundation.

ACTION: Notice.

SUMMARY: The National Science Foundation (NSF) is announcing plans to renew this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting Office of Management and Budget (OMB) clearance of this collection for no longer than 3 years.

DATES: Written comments on this notice must be received by July 5, 2022 to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to the address below.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Suite E7400, Alexandria, Virginia 22314; telephone (703) 292-7556; or send email to splimpto@nsf.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including Federal holidays).

SUPPLEMENTARY INFORMATION:

Title of Collection: 2023 National Survey of College Graduates.

OMB Control Number: 3145-0141.

Expiration Date of Current Approval: November 30, 2023.

Type of Request: Intent to seek approval to extend an information collection for three years.

Abstract: Established within the NSF by the America COMPETES Reauthorization Act of 2010 § 505, codified in the National Science Foundation Act of 1950, as amended, the National Center for Science and Engineering Statistics (NCSES) serves as

a central Federal clearinghouse for the collection, interpretation, analysis, and dissemination of objective data on science, engineering, technology, and research and development for use by practitioners, researchers, policymakers, and the public.

The National Survey of College Graduates (NSCG) is designed to comply with these mandates by providing information on the supply and utilization of the nation's scientists and engineers. The purpose of the NSCG is to collect data that will be used to provide national estimates on the size, composition, and activities of the science and engineering workforce and changes in their employment, education, and demographic characteristics. The NSCG has been conducted biennially since the 1970s. The 2023 NSCG sample will be selected from the 2021 American Community Survey (ACS) and the 2021 NSCG. By selecting the sample from these two sources, the 2023 NSCG will provide coverage of the college graduate population residing in the United States.

The U.S. Census Bureau, as the agency responsible for the ACS, will serve as the NSCG data collection contractor for NCSES. The survey data collection is expected to begin in February 2023 and continue for approximately seven months. Data will be collected using web and mail questionnaires, and follow-up will be conducted with nonrespondents by computer-assisted telephone interviewing (CATI). The individual's response to the survey is voluntary. The survey will be conducted in conformance with Census Bureau statistical quality standards and, as such, the NSCG data will be afforded confidentiality protection under the applicable Census Bureau confidentiality statutes.

Use of the Information: NSF uses the information from the NSCG to prepare congressionally mandated reports such as *Women, Minorities and Persons with Disabilities in Science and Engineering* (<https://www.nsf.gov/statistics/women/>) and *Science and Engineering Indicators* (<https://nces.nsf.gov/indicators>), both of which are available online. A public release file of collected data, designed to protect respondent confidentiality, will be made available on the internet and will be accessible through an online data tool (<https://ncesdata.nsf.gov/ids/>).

Expected Respondents: A statistical sample of approximately 166,000 individuals (106,000 returning sample members and 60,000 new sample members) will be contacted in 2023. Of

the new sample members, 5,000 will form a non-production bridge panel, intended to quantify the potential impacts of question modifications on key survey estimates. Based on recent survey cycles, NCSSES expects the overall response rate to be 65 to 75 percent.

Estimate of Burden: The amount of time to complete the questionnaire may vary depending on an individual's educational history, employment status, and past response to the NSCG. The time to complete the 2021 NSCG web survey ranged from 19.6 minutes for some returning sample members to 27.3 minutes for members of the non-production bridge panel, and approximately 89% of respondents completed the web mode. Likewise, CATI interview times during the 2021 NSCG ranged from 32.5 minutes for some returning sample members to 42.2 minutes for new sample members, and about 4% of respondents completed via CATI. It was estimated that all forms of the 2021 NSCG paper questionnaire took 30 minutes to complete, and about 7% of respondents completed the paper form. Based on the 2021 cycle's survey completion times, it is estimated that it will take approximately 25 minutes, on average, to complete the 2023 NSCG questionnaire. NSF estimates that the average annual burden for the 2023 survey cycle over the course of the three-year OMB clearance period will be no more than 17,292 hours [(166,000 individuals × 75% response × 25 minutes)/3 years].

Comments: Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the NSF, including whether the information shall have practical utility; (b) the accuracy of the NSF's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, use, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Dated: April 8, 2022.

Suzanne H. Plimpton,
Reports Clearance Officer, National Science Foundation.

[FR Doc. 2022-09570 Filed 5-3-22; 8:45 am]

BILLING CODE 7555-01-P

OFFICE OF PERSONNEL MANAGEMENT

January 2022 Pay Schedules

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: The President adjusted the rates of basic pay and locality payments for certain Federal civilian employees effective in January 2022. The Executive order authorizes a 2.2 percent across-the-board increase for statutory pay systems and locality pay increases costing approximately 0.5 percent of basic payroll, reflecting an overall average pay increase of 2.7 percent. This notice serves as documentation for the public record.

FOR FURTHER INFORMATION CONTACT:

Kimberly Woods, Pay and Leave, Employee Services, Office of Personnel Management; (202) 606-2858 or *pay-leave-policy@opm.gov*.

SUPPLEMENTARY INFORMATION: On December 22, 2021, the President signed Executive Order (E.O.) 14061 (86 FR 73601), which implemented pay adjustments for certain Federal civilian employees in January 2022. E.O. 14061 provides an overall average pay increase of 2.7 percent for the statutory pay systems. This is consistent with the President's alternative pay plan issued under 5 U.S.C. 5303(b) and 5304a on August 27, 2021. The pay rates in E.O. 13970 have been superseded.

The publication of this notice satisfies the requirement in Section 5(b) of E.O. 14061 that the Office of Personnel Management (OPM) publish appropriate notice of the 2022 locality payments in the **Federal Register**.

Schedule 1 of E.O. 14061 provides the rates for the 2022 General Schedule (GS) and reflects a 2.2 percent increase from 2021. Executive Order 14061 also includes the percentage amounts of the 2022 locality payments. (See Section 5 and Schedule 9 of Executive Order 14061.)

General Schedule employees receive locality payments under 5 U.S.C. 5304. Locality payments apply in the United States (as defined in 5 U.S.C. 5921(4)) and its territories and possessions. In 2022, locality payments ranging from 16.20 percent to 42.74 percent apply to GS employees in the 54 locality pay areas. The 2022 locality pay area definitions can be found at: <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2022/locality-pay-area-definitions/>.

The 2022 locality pay percentages became effective the first day of the first pay period beginning on or after January

1, 2022 (January 2, 2022). An employee's locality rate of pay is computed by increasing his or her scheduled annual rate of pay (as defined in 5 CFR 531.602) by the applicable locality pay percentage. (See 5 CFR 531.604 and 531.609.)

Executive Order 14061 establishes the new Executive Schedule (EX), which incorporates a 2.2 percent increase required under 5 U.S.C. 5318 (rounded to the nearest \$100). By law, Executive Schedule officials are not authorized to receive locality payments.

Executive Order 14061 establishes the 2022 range of rates of basic pay for members of the Senior Executive Service (SES) under 5 U.S.C. 5382. The minimum rate of basic pay for the SES is \$135,468 in 2022. The maximum rate of the SES rate range is \$203,700 (level II of the Executive Schedule) for SES members who are covered by a certified SES performance appraisal system and \$187,300 (level III of the Executive Schedule) for SES members who are not covered by a certified SES performance appraisal system.

The minimum rate of basic pay for the senior-level (SL) and scientific and professional (ST) rate range was increased by 2.2 percent (\$135,468 in 2022), which is the amount of the across-the-board GS increase. The applicable maximum rate of the SL/ST rate range is \$203,700 (level II of the Executive Schedule) for SL or ST employees who are covered by a certified SL/ST performance appraisal system and \$187,300 (level III of the Executive Schedule) for SL or ST employees who are not covered by a certified SL/ST performance appraisal system. Agencies with certified performance appraisal systems for SES members and employees in SL and ST positions must also apply a higher aggregate limitation on pay—up to the Vice President's salary (\$261,400 in 2022.)

Note that section 747 of division E of the Consolidated Appropriations Act, 2022 (Pub. L. 117-103, March 15, 2022), contains a provision that continues the freeze on the payable pay rates for the Vice President and certain senior political appointees at the rates of pay and applicable limitations on payable rates of pay in effect on December 31, 2021. The section 747 pay freeze is scheduled to end on the last day of the last pay period that begins in calendar year 2022 (December 31, 2022, for those on the standard biweekly pay period cycle). Future Congressional action will determine whether the pay freeze continues beyond that date. OPM guidance on the continued pay freeze for certain senior political officials can

be found in CPM 2022–09 at <https://www.chcoc.gov/content/continued-pay-freeze-certain-senior-political-officials-6>.

Executive Order 14061 provides that the rates of basic pay for administrative law judges (ALJs) under 5 U.S.C. 5372 are increased by 2.2 percent (rounded to the nearest \$100) in 2022. The rate of basic pay for AL–1 is \$176,300 (equivalent to the rate for level IV of the Executive Schedule). The rate of basic pay for AL–2 is \$171,900. The rates of basic pay for AL–3/A through 3/F range from \$117,600 to \$162,900.

The rates of basic pay for members of Contract Appeals Boards are calculated as a percentage of the rate for level IV of the Executive Schedule. (See 5 U.S.C. 5372a.) Therefore, these rates of basic pay are increased by 2.2 percent in 2022.

On November 30, 2021, OPM issued a memorandum on behalf of the President’s Pay Agent (the Secretary of Labor and the Directors of the Office of Management and Budget and OPM) that continues GS locality payments for ALJs and certain other non-GS employee categories in 2022. By law, EX officials, SES members, employees in SL/ST positions, and employees in certain other equivalent pay systems are not authorized to receive locality payments. (Note: An exception applies to certain grandfathered SES, SL, and ST employees stationed in a nonforeign area on January 2, 2010. See CPM 2009–27 at <https://www.chcoc.gov/content/nonforeign-area-retirement-equity-assurance-act>.) The memo is available at <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2021/extension-of-locality-pay-memo-for-non-gs-employees-2022.pdf>.

On December 22, 2021, OPM issued a memorandum (CPM 2021–27) on the 2022 pay adjustments. (See <https://www.chcoc.gov/content/january-2022-pay-adjustments>.) The memorandum transmitted Executive Order 14061 and provided the 2022 salary tables, locality pay areas and percentages, and information on general pay administration matters and other related guidance. The “2022 Salary Tables” posted on OPM’s website at <http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/> are the official rates of pay for affected employees and are hereby incorporated as part of this notice.

Office of Personnel Management.

Stephen Hickman,

Federal Register Liaison.

[FR Doc. 2022–09559 Filed 5–3–22; 8:45 am]

BILLING CODE 6325–39–P

OFFICE OF PERSONNEL MANAGEMENT

Federal Prevailing Rate Advisory Committee Virtual Public Meeting

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: According to the provisions of section 10 of the Federal Advisory Committee Act, notice is hereby given that a virtual meeting of the Federal Prevailing Rate Advisory Committee will be held on Thursday, May 19, 2022. There will be no in-person gathering for this meeting.

DATES: The virtual meeting will be held on May 19, 2022, beginning at 10 a.m. (EST).

ADDRESSES: The meeting will convene virtually.

FOR FURTHER INFORMATION CONTACT: The public is invited to submit material in writing to the Chair on Federal Wage System pay matters felt to be deserving of the Committee’s attention. Additional information on these meetings may be obtained by contacting the Committee at Office of Personnel Management, Federal Prevailing Rate Advisory Committee, Room 7H31, 1900 E Street NW, Washington, DC 20415, (202) 606–2858. Contact Ana Paunoiu, 202–606–2858, or email pay-leave-policy@opm.gov.

SUPPLEMENTARY INFORMATION: The Federal Prevailing Rate Advisory Committee is composed of a Chair, five representatives from labor unions holding exclusive bargaining rights for Federal prevailing rate employees, and five representatives from Federal agencies. Entitlement to membership on the Committee is provided for in 5 U.S.C. 5347.

The Committee’s primary responsibility is to review the Prevailing Rate System and other matters pertinent to establishing prevailing rates under subchapter IV, chapter 53, 5 U.S.C., as amended, and from time to time advise the Office of Personnel Management.

Annually, the Chair compiles a report of pay issues discussed and concluded recommendations. These reports are available to the public. Reports for calendar years 2008 to 2019 are posted at <http://www.opm.gov/fprac>. Previous reports are also available, upon written request to the Committee.

This meeting is open to the public, with an audio option for listening. This notice sets forth the agenda for the meeting and the participation guidelines.

Meeting Agenda. The tentative agenda for this meeting includes the following Federal Wage System items:

- The definition of Monroe County, PA
- The definition of San Joaquin County, CA
- The definition of the Salinas-Monterey, CA, wage area
- The definition of the Puerto Rico wage area

Public Participation: The May 19, 2022, meeting of the Federal Prevailing Rate Advisory Committee is open to the public through advance registration. Public participation is available for the meeting. All individuals who plan to attend the virtual public meeting to listen must register by sending an email to pay-leave-policy@opm.gov with the subject line “May 19 FPRAC Meeting” no later than Tuesday, May 17, 2022.

The following information must be provided when registering:

- Name.
- Agency and duty station.
- Email address.
- Your topic of interest.

Members of the press, in addition to registering for this event, must also RSVP to media@opm.gov by April 17, 2022.

A confirmation email will be sent upon receipt of the registration. Audio teleconference information for participation will be sent to registrants the morning of the virtual meeting.

Office of Personnel Management.

Stephen Hickman,

Federal Register Liaison.

[FR Doc. 2022–09526 Filed 5–3–22; 8:45 am]

BILLING CODE 6325–38–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Notice of Request for Comment

AGENCY: Office of Science and Technology Policy.

ACTION: Notice of Request for Comment.

SUMMARY: On behalf of the National Science and Technology Council (NSTC), the In-space Servicing, Assembly, and Manufacturing (ISAM) Interagency Working Group coordinates science and technology policy, strategy, and federal research and development (R&D) pertaining to ISAM-related capabilities. NSTC operates under the auspices of the Office of Science and Technology Policy (OSTP). This coordinated effort aims to ensure that U.S. leadership in servicing, assembly, manufacturing capabilities in space and their applications is maintained and expanded for future use. OSTP requests

input from all interested parties on the In-space Servicing, Assembly and Manufacturing (ISAM) National Strategy,¹ and on specific U.S. Government actions or initiatives to advance the strategy's stated goals. Input received will inform the ISAM Interagency Working Group's development of an ISAM implementation plan.

DATES: Responses are due by June 30, 2022.

ADDRESSES: Interested individuals and organizations should submit comments electronically to Ezinne Uzo-Okoro at isam@ostp.eop.gov. Further information may be received by calling 202-456-4444.

Instructions: Response to this RFC is voluntary. Respondents need not reply to all questions listed. Each individual or institution is requested to submit only one response. OSTP and/or NSTC may post responses to this RFC, without change, on a Federal website. OSTP, therefore, requests that no business proprietary information, copyrighted information, or personally identifiable information be submitted in response to this RFC. Please note that the United States Government will not pay for response preparation, or for the use of any information contained in the response.

SUPPLEMENTARY INFORMATION: The ISAM Interagency Working Group has commenced the development of an implementation plan to be released in 2022. Pursuant to 42 U.S.C. 6622, OSTP is soliciting public input through this RFC to obtain recommendations from a wide range of stakeholders, including representatives from industry, academia, other relevant organizations and institutions, and the general public. Input provided in response to this RFC will inform OSTP and NSTC as they work with Federal departments and agencies and other stakeholders to develop an In-space Servicing, Assembly, and Manufacturing implementation plan. This implementation plan will identify key actions to advance the goals and objectives outlined in the ISAM national strategy published in April 2022. The national strategy can be found at: <https://www.whitehouse.gov/wp-content/uploads/2022/04/04-2022-ISAM-National-Strategy-Final.pdf>.

Implementing this strategy will help the United States realize the benefits of ISAM capabilities by taking steps to: improve coordination and collaboration

both within the USG, as well as among the USG, academia, industry, and international partners; send a clear and consistent demand signal to private industry in order to stimulate investment, mitigate risk, and address investor confidence; and establish and adopt ISAM standards to help promote growth. The strategy is organized around six goals: (1) Advance ISAM research and development, (2) prioritize expanding scalable ISAM infrastructure, (3) accelerate the emerging ISAM commercial industry, (4) promote international collaboration and cooperation, (5) prioritize environmental sustainability and (6) inspire the future space workforce.

OSTP seeks public input from the community of ISAM stakeholders on what priorities the government should focus on in the implementation plan. This includes actions for government-sponsored initiatives/coordination; the roles of academia, nonprofit, and industry actors in addressing these actions; and potential avenues for coordination between actors across public and private sectors.

Questions To Inform Development of the Implementation Plan

OSTP seeks responses to the following questions to improve government coordination and to provide long-term guidance for Federal programs and activities in support of the United States In-space Servicing, Assembly, and Manufacturing implementation plan.

(1) What specific technologies and capabilities require priority R&D focus to enable and advance the development of a suite of commercial ISAM capabilities over the next 10–15 years?

(2) What infrastructure, ground, space-based, or digital, or other non-monetary resources will be critical to enabling the advancement of ISAM capabilities and the commercial ISAM industry?

(3) What factors (e.g., demand for services, lack of regulation, government funding, USG space priorities and space architecture decisions, significant debris event) may accelerate or decelerate progress in the development and advancement of the ISAM industry?

(4) What are the most effective kinds of partnerships, between the U.S. Government, industry, and academia, that would advance ISAM industry maturity and ISAM capabilities? What partnership opportunities exist, both nationally and internationally, outside of the Federal Government?

(5) What are the highest priority actions that the USG can take over the

next five years to implement the goals outlined in the ISAM strategy?

Dated: April 29, 2022.

Stacy Murphy,

Operations Manager.

[FR Doc. 2022–09549 Filed 5–3–22; 8:45 am]

BILLING CODE 3271–F1–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–94814; File No. SR–NYSE–2022–04]

Self-Regulatory Organizations; New York Stock Exchange LLC; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Amend Rules 5P, 5.2(j)(8)(e), 8P, and 98

April 28, 2022.

On January 14, 2022, New York Stock Exchange LLC (“Exchange” or “NYSE”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”)¹ and Rule 19b–4 thereunder,² a proposed rule change to permit the listing and trading of certain exchange-traded products (“ETPs”) that overlie one or more NMS Stocks listed on the Exchange. The proposed rule change was published for comment in the **Federal Register** on January 31, 2022.³ On March 9, 2022, pursuant to Section 19(b)(2) of the Act,⁴ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.⁵ The Commission has received no comment letters on the proposal. This order institutes proceedings under Section 19(b)(2)(B) of the Act⁶ to determine whether to approve or disapprove the proposed rule change.

I. Summary Description of the Proposal⁷

The Exchange proposes to amend its rules regarding side-by-side trading, which is the trading of an equity

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Securities Exchange Act Release No. 94053 (Jan. 25, 2022), 87 FR 4982 (“Notice”).

⁴ 15 U.S.C. 78s(b)(2).

⁵ See Securities Exchange Act Release No. 94392, 87 FR 14592 (Mar. 15, 2022). The Commission designated May 1, 2022 as the date by which it should approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

⁶ 15 U.S.C. 78s(b)(2)(B).

⁷ For a complete description of the proposed rule change, see Notice, *supra* note 3.

¹ <https://www.whitehouse.gov/wp-content/uploads/2022/04/04-2022-ISAM-National-Strategy-Final.pdf>.

security and its related derivative product at the same physical location. Specifically, the Exchange proposes to exclude from its listing prohibitions in NYSE Rules 5P and 8P⁸ shares of an ETP that independently satisfies the quantitative generic listing criteria set forth in NYSE Rules 5.2(j)(3), Supplementary Material .01(a), NYSE Rule 5.2(j)(6)(B)(I); or proposed Rule 5.2(j)(8)(e)(1)(B), as well as shares of an ETP that independently satisfies the generic listing criteria set forth in NYSE Rules 8.100, Supplementary Material .01(a)(A) or 8.600, Supplementary Material .01(a).⁹

The Commission previously approved integrated market making and side-by-side trading for “broad-based” exchange traded funds, Trust-Issued Receipts, and related options.¹⁰ According to the Exchange, under Commission precedent, (1) integrated market making and side-by-side trading in both the ETP and related options is permissible—with no additional requirement for information barriers or physical or organizational separation—where the ETP is “broad-based,” *i.e.*, not readily susceptible to manipulation; (2) an ETP is broad-based when its the individual components are sufficiently liquid and well-capitalized and the product is not over-concentrated; and (3) to determine whether an ETP is broad-based, the Commission has relied on an exchange’s

listing standards.¹¹ In support of its proposal, the Exchange analyzes aspects of its existing—and in the case of Exchange-Traded Fund Shares, its proposed—listing criteria for shares of the specified ETPs and concludes that they are sufficiently “broad-based” to address potential manipulation concerns arising out of trading those shares on the same physical trading floor as one or more underlying NYSE-listed securities.¹²

The Exchange also proposes to amend a rule regarding integrated market making,¹³ which is the practice of the same person or firm making markets in an equity security and its related derivative product. NYSE assigns each of securities it lists to a Designated Market Maker (“DMM”), and trading is on the floor of the Exchange. Integrated market making could be implicated if NYSE starts listing ETPs with an underlying NYSE Component Security because each ETP would be assigned to a DMM and that DMM also may be assigned one or more NYSE Component Securities that underlie the ETP’s underlying index or portfolio. The Exchange proposes to narrow the definition of “related products” to exclude derivative instruments that overlie ETPs listed under NYSE Rules 5.2(j)(3), Supplementary Material .01(a); 5.2(j)(6)(B)(I); 5.2(j)(8)(e)(1)(B); 8.100, Supplementary Material .01(a)(A); 8.600 Supplementary Material .01(a); 8.601; or 8.900.

While informational advantage is a concern with respect to integrated market making,¹⁴ the Exchange asserts that there are sufficient safeguards in place to prohibit the misuse of material nonpublic information by a member organization that operates a DMM unit. Specifically, the Exchange asserts that Rule 98 contains narrowly tailored restrictions to address that DMMs while on the floor may have access to certain floor-based non-public information and requires DMM units to maintain procedures and controls to prevent the misuse of material, non-public information that are effective and appropriate for that member organization.¹⁵

According to the Exchange, trading on the Exchange is subject to a comprehensive regulatory program that includes a suite of surveillances and

routine examinations that review trading by DMMs and other market participants on the Exchange’s trading floor, including surveillances designed to monitor for trading ahead and manipulative activity.¹⁶ To assist Exchange surveillance of DMM trading activity, a member organization operating a DMM unit must daily provide the Exchange with net position information in DMM securities by the DMM unit and any independent trading unit of which it is part for such times and in the manner prescribed by the Exchange pursuant to Rule 98(c)(5).¹⁷ In addition, routine examinations are conducted consistent with the current exam-based regulatory program associated with Rule 98 that reviews member organizations operating DMM units for compliance with the above-described policies and procedures to protect against the misuse of material nonpublic information.¹⁸ Lastly, the Exchange asserts that DMM market making activity is not materially different from market making on other exchanges and that these existing programs are reasonably designed to address any concerns that may be raised by the trading of the specified listed ETPs that have underlying NYSE Component Securities.¹⁹

II. Proceedings To Determine Whether To Approve or Disapprove SR–NYSE–2019–54 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act²⁰ to determine whether the proposed rule change should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide comments on the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,²¹ the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change’s consistency with Section

⁸NYSE Rules 5P and 8P generally prohibit the Exchange from listing shares of an ETP that “has any component NMS Stock that is listed on the Exchange or that is based on, or represents an interest in, an underlying index or reference asset that includes an NMS Stock listed on the Exchange. NMS Stock is defined in Rule 600 of Regulation NMS, 17 CFR 242.600(b)(48) as “any NMS security other than an option.” “NMS Security” means any security or class of securities for which transaction reports are collected, processed, and made available pursuant to an effective transaction reporting plan, or an effective national market system plan for reporting transactions in listed options.” 17 CFR 242.600(b)(47). “NMS Security” refers to “exchange-listed equity securities and standardized options, but does not include exchange-listed debt securities, securities futures, or open-end mutual funds, which are not currently reported pursuant to an effective transaction reporting plan.” See Question 1.1 in the “Responses to Frequently Asked Questions Concerning Large Trader Reporting,” available at: <https://www.sec.gov/divisions/marketreg/large-trader-faqs.htm>.

⁹Shares of Active Proxy Portfolio Shares and Managed Portfolio Shares, which are issued by funds whose portfolios are not fully transparent, already are exempted from the general prohibition. See NYSE Rule 8P.

¹⁰See Securities Exchange Act Release No. 46213, 67 FR 48232 (SR–Amex–2002–21); see also Securities Exchange Act Release No. 62479 (July 9, 2010), 75 FR 41264 (July 15, 2010) (SR–Amex–2010–31) (approving side-by-side trading and integrated market making in the QQQ ETF and certain of its component securities where the QQQs met the composition and concentration measures to be classified as a broad-based ETF).

¹¹See Notice, *supra* note 3, 87 FR at 4983.

¹²See *id.*, 87 FR at 4984–85.

¹³Current NYSE Rule 98(c)(6) prohibits DMM units from operating as a specialist or market maker on the Exchange in “related products” unless specifically permitted in Exchange rules.

¹⁴See Securities Exchange Act Release No. 46213, *supra* note 10, 67 FR at 48235.

¹⁵See *id.*, 87 FR at 4986.

¹⁶See *id.*, 87 FR at 4987.

¹⁷See *id.*

¹⁸See *id.*

¹⁹See *id.*

²⁰15 U.S.C. 78s(b)(2)(B).

²¹*Id.*

6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be “designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade,” and “to protect investors and the public interest.”²²

The Commission asks that commenters address the sufficiency of the Exchange’s statements in support of the proposal, which are set forth in the Notice, in addition to any other comments they may wish to submit about the proposed rule change. In particular, the Commission seeks comment on the following questions and asks commenters to submit data where appropriate to support their views.

1. What are commenters’ views generally on whether the Exchange’s proposal to implement side-by-side trading and integrated market making for certain ETPs to be listed and traded on the Exchange is consistent with Section 6(b)(5) of the Act, which requires that the Exchange’s rules be designed to, among other things, prevent fraudulent and manipulative acts and practices?

2. Do the quantitative generic listing criteria of current Rules 5.2(j)(3), Supplementary Material .01(a) (applicable to Investment Company Units), 5.2(j)(6)(B)(I) (applicable to Equity Index-Linked Securities), and proposed Rule 5.2(j)(8), as well as the generic listing criteria of current NYSE Rules 8.100 (applicable to Portfolio Depositary Receipts) and 8.600 (applicable to Managed Fund Shares) adequately address the concerns reflected in the “broad-based” test previously articulated by the Commission with respect to side-by-side trading and integrated market making?²³ If not, why? Should the Commission consider other factors in reviewing side-by-side trading and integrated market making?

3. What are commenters’ views about whether the proposed changes to Rule 98 to exclude the specified ETPs listed on the Exchange from the definition of “related products” would remove impediments to and perfect the mechanism of a free and open market and a national market system? Do commenters agree that such changes would facilitate the assignment of listed ETPs, including ETPs with underlying NYSE Component Securities that meet the specified listing rules in Rules 5P and 8P, to DMMs and permit DMMs to

trade such listed ETPs consistent with existing Rules governing DMM trading? If so, why? If not, why not?

4. What informational advantage (if any) over other market participants with respect to trading an ETP or its underlying securities might a DMM (or other member) obtain as a result of the proposed implementation of side-by-side trading and integrated market making for ETPs with underlying NYSE Component Securities? What concerns, if any, do commenters have about the potential for a DMM (or other member) to misuse material, non-public information?

III. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposal is consistent with Section 6(b)(5) or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4, any request for an opportunity to make an oral presentation.²⁴

Interested persons are invited to submit written data, views, and arguments regarding whether the proposal should be approved or disapproved by May 25, 2022. Any person who wishes to file a rebuttal to any other person’s submission must file that rebuttal by June 8, 2022. The Commission asks that commenters address the sufficiency of the Exchange’s statements in support of the proposal, in addition to any other comments they may wish to submit about the proposed rule change.

Comments may be submitted by any of the following methods:

²⁴ Section 19(b)(2) of the Act, as amended by the Securities Act Amendments of 1975, Pub. L. 94–29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. See Securities Act Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

Electronic Comments

- Use the Commission’s internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR–NYSE–2022–04 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2022–04. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission’s Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2022–04 and should be submitted by May 25, 2022. Rebuttal comments should be submitted by June 8, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁵

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2022–09519 Filed 5–3–22; 8:45 am]

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²⁵ 17 CFR 200.30–3(a)(57).

²² 15 U.S.C. 78f(b)(5).

²³ See *supra* note 10.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-94812; File No. SR-CBOE-2022-020]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend the Operation of Its Flexible Exchange Options (“FLEX Options”) Pilot Program Regarding Permissible Exercise Settlement Values for FLEX Index Options

April 28, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”),¹ and Rule 19b-4 thereunder,² notice is hereby given that on April 20, 2022, Cboe Exchange, Inc. (the “Exchange” or “Cboe Options”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a “non-controversial” proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act³ and Rule 19b-4(f)(6) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the “Exchange” or “Cboe Options”) proposes to extend the operation of its Flexible Exchange Options (“FLEX Options”) pilot program regarding permissible exercise settlement values for FLEX Index Options. The text of the proposed rule change is provided below.

(additions are *italicized*; deletions are [bracketed])

* * * * *

Rules of Cboe Exchange, Inc.

* * * * *

Rule 4.21. Series of FLEX Options

(a) No change.

(b) *Terms*. When submitting a FLEX Order for a FLEX Option series to the System, the submitting FLEX Trader must include one of each of the following terms in the FLEX Order (all other terms of a FLEX Option series are the same as those that apply to non-

FLEX Options), provided that a FLEX Index Option with an index multiplier of one may not be the same type (put or call) and may not have the same exercise style, expiration date, settlement type, and exercise price as a non-FLEX Index Option overlying the same index listed for trading (regardless of the index multiplier of the non-FLEX Index Option), which terms constitute the FLEX Option series:

(1)–(4) No change.

(5) settlement type:

(A) No change.

(B) *FLEX Index Options*. FLEX Index Options are settled in U.S. dollars, and may be:

(i) No change.

(ii) p.m.-settled (with exercise settlement value determined by reference to the reported level of the index derived from the reported closing prices of the component securities), except for a FLEX Index Option that expires on any business day that falls on or within two business days of a third Friday-of-the-month expiration day for a non-FLEX Option (other than a QIX option) may only be a.m.-settled; however, for a pilot period ending the earlier of [May 2] *November 7, 2022* or the date on which the pilot program is approved on a permanent basis, a FLEX Index Option with an expiration date on the third-Friday of the month may be p.m.-settled;

(iii)–(iv) No change.

* * * * *

The text of the proposed rule change is also available on the Exchange’s website (<http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx>), at the Exchange’s Office of the Secretary, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On January 28, 2010, the Securities and Exchange Commission (the “Commission”) approved a Cboe Options rule change that, among other things, established a pilot program regarding permissible exercise settlement values for FLEX Index Options.⁵ The Exchange has extended the pilot period numerous times, which is currently set to expire on the earlier of May 2, 2022 or the date on which the pilot program is approved on a permanent basis.⁶ The purpose of this rule change filing is to extend the pilot program through the earlier of November 7, 2022 or the date on which the pilot program is approved on a permanent basis. This filing simply seeks to extend the operation of the pilot program and does not propose any

⁵ Securities Exchange Act Release No. 61439 (January 28, 2010), 75 FR 5831 (February 4, 2010) (SR-CBOE-2009-087) (“Approval Order”). The initial pilot period was set to expire on March 28, 2011, which date was added to the rules in 2010. See Securities Exchange Act Release No. 61676 (March 9, 2010), 75 FR 13191 (March 18, 2010) (SR-CBOE-2010-026).

⁶ See Securities Exchange Act Release Nos. 64110 (March 23, 2011), 76 FR 17463 (March 29, 2011) (SR-CBOE-2011-024); 66701 (March 30, 2012), 77 FR 20673 (April 5, 2012) (SR-CBOE-2012-027); 68145 (November 2, 2012), 77 FR 67044 (November 8, 2012) (SR-CBOE-2012-102); 70752 (October 24, 2013), 78 FR 65023 (October 30, 2013) (SR-CBOE-2013-099); 73460 (October 29, 2014), 79 FR 65464 (November 4, 2014) (SR-CBOE-2014-080); 77742 (April 29, 2016), 81 FR 26857 (May 4, 2016) (SR-CBOE-2016-032); 80443 (April 12, 2017), 82 FR 18331 (April 18, 2017) (SR-CBOE-2017-032); 83175 (May 4, 2018), 83 FR 21808 (May 10, 2018) (SR-CBOE-2018-037); 84537 (November 5, 2018), 83 FR 56113 (November 9, 2018) (SR-CBOE-2018-071); 85707 (April 23, 2019), 84 FR 18100 (April 29, 2019) (SR-CBOE-2019-021); 87515 (November 13, 2020), 84 FR 63945 (November 19, 2019) (SR-CBOE-2019-108); 88782 (April 30, 2020), 85 FR 27004 (May 6, 2020) (SR-CBOE-2020-039); 90279 (October 28, 2020), 85 FR 69667 (November 3, 2020) (SR-CBOE-2020-103); 91782 (May 5, 2021), 86 FR 25915 (May 11, 2021) (SR-CBOE-2021-031); and 93500 (November 1, 2021), 86 FR 61340 (November 5, 2021) (SR-CBOE-2021-064) (extending the pilot program through the earlier of May 2, 2022 or the date on which the pilot program is approved on a permanent basis). At the same time the permissible exercise settlement values pilot was established for FLEX Index Options, the Exchange also established a pilot program eliminating the minimum value size requirements for all FLEX Options. See Approval Order, *supra* note 5. The pilot program eliminating the minimum value size requirements was extended twice pursuant to the same rule filings that extended the permissible exercise settlement values (for the same extended periods) and was approved on a permanent basis in a separate rule change filing. See *id.*; and Securities Exchange Act Release No. 67624 (August 8, 2012), 77 FR 48580 (August 14, 2012) (SR-CBOE-2012-040) (Order Granting Approval of Proposed Rule Change Related to Permanent Approval of Its Pilot on FLEX Minimum Value Sizes).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴ 17 CFR 240.19b-4(f)(6).

substantive changes to the pilot program.

Under Rule 4.21(b), *Series of FLEX Options* (regarding terms of a FLEX Option),⁷ a FLEX Option may expire on any business day (specified to day, month and year) no more than 15 years from the date on which a FLEX Trader submits a FLEX Order to the System.⁸ FLEX Index Options are settled in U.S. dollars, and may be a.m.-settled (with exercise settlement value determined by reference to the reported level of the index derived from the reported opening prices of the component securities) or p.m.-settled (with exercise settlement value determined by reference to the reported level of the index derived from the reported closing prices of the component securities).⁹ Specifically, a FLEX Index Option that expires on, or within two business days of, a third Friday-of-the-month expiration day for a non-FLEX Option (other than a QIX option), may only be a.m. settled.¹⁰ However, under the exercise settlement values pilot, this restriction on p.m.-settled FLEX Index Options was eliminated.¹¹ As stated, the exercise settlement values pilot is currently set to expire on the earlier of May 2, 2022 or the date on which the pilot program is approved on a permanent basis.

Cboe Options is proposing to extend the pilot program through the earlier of November 7, 2022 or the date on which the pilot program is approved on a permanent basis. Cboe Options believes

⁷ In 2019, prior Rule 24A.4.01, covering the pilot program, was relocated to current Rule 4.21(b)(5). See Securities Exchange Act Release No. 87235 (October 4, 2019), 84 FR 54671 (October 10, 2019) (SR-CBOE-2019-084).

⁸ Except an Asian-settled or Cliquet-settled FLEX Option series, which must have an expiration date that is a business day but may only expire 350 to 371 days (which is approximately 50 to 53 calendar weeks) from the date on which a FLEX Trader submits a FLEX Order to the System.

⁹ See Rule 4.21(b)(5)(B); see also Securities Exchange Act Release No. 87235 (October 4, 2019), 84 FR 54671 (October 10, 2019) (SR-CBOE-2019-084). The rule change removed the provision regarding the exercise settlement value of FLEX Index Options on the NYSE Composite Index, as the Exchange no longer lists options on that index for trading, and included the provisions regarding how the exercise settlement value is determined for each settlement type, as how the exercise settlement value is determined is dependent on the settlement type.

¹⁰ For example, notwithstanding the pilot, the exercise settlement value of a FLEX Index Option that expires on the Tuesday before the third Friday-of-the-month could be a.m. or p.m. settled. However, the exercise settlement value of a FLEX Index Option that expires on the Wednesday before the third Friday-of-the-month could only be a.m. settled.

¹¹ No change was necessary or requested with respect to FLEX Equity Options. Regardless of the expiration date, FLEX Equity Options are settled by physical delivery of the underlying.

the pilot program has been successful and well received by its Trading Permit Holders and the investing public for the period that it has been in operation as a pilot. In support of the proposed extension of the pilot program, and as required by the pilot program's Approval Order, the Exchange has submitted to the Commission pilot program reports regarding the pilot, which detail the Exchange's experience with the program. Specifically, the Exchange provided the Commission with annual reports analyzing volume and open interest for each broad-based FLEX Index Options class overlying a third Friday-of-the-month expiration day, p.m.-settled FLEX Index Options series.¹² The annual reports also contained information and analysis of FLEX Index Options trading patterns. The Exchange also provided the Commission, on a periodic basis, interim reports of volume and open interest.

The Exchange believes there is sufficient investor interest and demand in the pilot program to warrant its extension. The Exchange believes that, for the period that the pilot has been in operation, the program has provided investors with additional means of managing their risk exposures and carrying out their investment objectives. Furthermore, the Exchange believes that it has not experienced any adverse market effects with respect to the pilot program, including any adverse market volatility effects that might occur as a result of large FLEX exercises in FLEX Option series that expire near Non-FLEX expirations and use a p.m. settlement (as discussed below).

In that regard, based on the Exchange's experience in trading FLEX Options to date and over the pilot period, Cboe Options continues to believe that the restrictions on exercise settlement values are no longer necessary to insulate Non-FLEX expirations from the potential adverse market impacts of FLEX expirations.¹³

¹² The annual reports also contained certain pilot period and pre-pilot period analyses of volume and open interest for third Friday-of-the-month expiration days, a.m.-settled FLEX Index series and third Friday-of-the-month expiration day Non-FLEX Index series overlying the same index as a third Friday-of-the-month expiration day, p.m.-settled FLEX Index option.

¹³ In further support, the Exchange also notes that the p.m. settlements are already permitted for FLEX Index Options on any other business day except on, or within two business days of, the third Friday-of-the-month. The Exchange is not aware of any market disruptions or problems caused by the use of these settlement methodologies on these expiration dates (or on the expiration dates addressed under the pilot program). The Exchange is also not aware of any market disruptions or problems caused by the use of customized options

To the contrary, Cboe Options believes that the restriction actually places the Exchange at a competitive disadvantage to its OTC counterparts in the market for customized options, and unnecessarily limits market participants' ability to trade in an exchange environment that offers the added benefits of transparency, price discovery, liquidity, and financial stability.

The Exchange also notes that certain position limit, aggregation and exercise limit requirements continue to apply to FLEX Index Options in accordance with Rules 8.35, *Position Limits for FLEX Options*, 8.42(g) *Exercise Limits* (in connection with FLEX Options) and 8.43(j), *Reports Related to Position Limits* (in connection with FLEX Options). Additionally, all FLEX Options remain subject to the general position reporting requirements in Rule 8.43(a).¹⁴ Moreover, the Exchange and

in the over-the-counter ("OTC") markets that expire on or near the third Friday-of-the-month and are p.m. settled. In addition, the Exchange believes the reasons for limiting expirations to a.m. settlement, which is something the SEC has imposed since the early 1990s for Non-FLEX Options, revolved around a concern about expiration pressure on the New York Stock Exchange ("NYSE") at the close that are no longer relevant in today's market. Today, the Exchange believes stock exchanges are able to better handle volume. There are multiple primary listing and unlisted trading privilege ("UTP") markets, and trading is dispersed among several exchanges and alternative trading systems. In addition, the Exchange believes that surveillance techniques are much more robust and automated. In the early 1990s, it was also thought by some that opening procedures allow more time to attract contra-side interest to reduce imbalances. The Exchange believes, however, that today, order flow is predominantly electronic and the ability to smooth out openings and closes is greatly reduced (e.g., market-on-close procedures work just as well as openings). Also, other markets, such as the NASDAQ Stock Exchange, do not have the same type of pre-opening imbalance disseminations as NYSE, so many stocks are not subject to the same procedures on the third Friday-of-the-month. In addition, the Exchange believes that NYSE has reduced the required time a specialist has to wait after disseminating a pre-opening indication. So, in this respect, the Exchange believes there is less time to react in the opening than in the close. Moreover, to the extent there may be a risk of adverse market effects attributable to p.m. settled options that would otherwise be traded in a non-transparent fashion in the OTC market, the Exchange continues to believe that such risk would be lessened by making these customized options eligible for trading in an exchange environment because of the added transparency, price discovery, liquidity, and financial stability available.

¹⁴ Rule 8.43(a) provides that "[i]n a manner and form prescribed by the Exchange, each Trading Permit Holder shall report to the Exchange, the name, address, and social security or tax identification number of any customer who, acting alone, or in concert with others, on the previous business day maintained aggregate long or short positions on the same side of the market of 200 or more contracts of any single class of option contracts dealt in on the Exchange. The report shall indicate for each such class of options, the number of option contracts comprising each such position and, in the case of short positions, whether covered

its Trading Permit Holder organizations each have the authority, pursuant to Rule 10.9, *Margin Required is Minimum*, to impose additional margin as deemed advisable. Cboe Options continues to believe these existing safeguards serve sufficiently to help monitor open interest in FLEX Option series and significantly reduce any risk of adverse market effects that might occur as a result of large FLEX exercises in FLEX Option series that expire near Non-FLEX expirations and use a p.m. settlement.

Cboe Options is also cognizant of the OTC market, in which similar restrictions on exercise settlement values do not apply. Cboe Options continues to believe that the pilot program is appropriate and reasonable and provides market participants with additional flexibility in determining whether to execute their customized options in an exchange environment or in the OTC market. Cboe Options continues to believe that market participants benefit from being able to trade these customized options in an exchange environment in several ways, including, but not limited to, enhanced efficiency in initiating and closing out positions, increased market transparency, and heightened counterparty creditworthiness due to the role of the Options Clearing Corporation as issuer and guarantor of FLEX Options.

If, in the future, the Exchange proposes an additional extension of the pilot program, or should the Exchange propose to make the pilot program permanent, the Exchange will submit, along with any filing proposing such amendments to the pilot program, an annual report (addressing the same areas referenced above and consistent with the pilot program's Approval Order) to the Commission at least two months prior to the expiration date of the program. The Exchange is required to submit an annual report at least yearly. Currently, the Exchange provides annual reports that cover the period from August 1st to July 31st of the applicable year. The Exchange will continue to provide reports covering this period annually and any additional report at least two months prior to the expiration date of the program covering the full prior year in the case that the Exchange is requesting permanent

or uncovered." For purposes of Rule 8.43, the term "customer" in respect of any Trading Permit Holder includes "the Trading Permit Holder, any general or special partner of the Trading Permit Holder, any officer or director of the Trading Permit Holder, or any participant, as such, in any joint, group or syndicate account with the Trading Permit Holder or with any partner, officer or director thereof." Rule 8.43(d).

approval of the program.¹⁵ The Exchange will also continue, on a periodic basis, to submit interim reports of volume and open interest consistent with the terms of the exercise settlement values pilot program as described in the pilot program's Approval Order.¹⁶ Additionally, the Exchange will provide the Commission with any additional data or analyses the Commission requests because it deems such data or analyses necessary to determine whether the pilot program is consistent with the Exchange Act. The Exchange is in the process of making public on its website all data and analyses previously submitted to the Commission under the pilot program, and will make public any data and analyses it submits to the Commission under the pilot program in the future.¹⁷

As noted in the pilot program's Approval Order, any positions established under the pilot program would not be impacted by the expiration of the pilot program.¹⁸

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the "Act") and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.¹⁹ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)²⁰ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in

¹⁵ For example, if the Exchange plans on submitting a proposal in October 2022 requesting permanent approval of the pilot program expiring November 7, 2022, the Exchange would have to submit an annual report no later than September 7, 2022 covering the full prior year.

¹⁶ The Exchange is required to submit the interim reports on a quarterly basis within 15 days of the end of each calendar quarter that the pilot is in effect.

¹⁷ Available at <https://www.cboe.com/aboutcboe/legal-regulatory/national-market-system-plans/pm-settlement-flex-pm-data>.

¹⁸ For example, a position in a p.m.-settled FLEX Index Option series that expires on the third Friday-of-the-month in January 2020 could be established during the exercise settlement values pilot. If the pilot program were not extended (or made permanent), then the position could continue to exist. However, the Exchange notes that any further trading in the series would be restricted to transactions where at least one side of the trade is a closing transaction. See Approval Order at footnote 3, *supra* note 5.

¹⁹ 15 U.S.C. 78f(b).

²⁰ 15 U.S.C. 78f(b)(5).

securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)²¹ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that the proposed extension of the pilot program, which permits an additional exercise settlement value, would provide greater opportunities for investors to manage risk through the use of FLEX Options. Further, the Exchange believes that it has not experienced any adverse effects from the operation of the pilot program, including any adverse market volatility effects that might occur as a result of large FLEX exercises in FLEX Option series that expire near Non-FLEX expirations and are p.m.-settled. The Exchange also believes that the extension of the exercise settlement values pilot does not raise any unique regulatory concerns. In particular, although p.m. settlements may raise questions with the Commission, the Exchange believes that, based on the Exchange's experience in trading FLEX Options to date and over the pilot period, market impact and investor protection concerns will not be raised by this rule change. The Exchange also believes that the proposed rule change would continue to provide Trading Permit Holders and investors with additional opportunities to trade customized options in an exchange environment (which offers the added benefits of transparency, price discovery, liquidity, and financial stability as compared to the over-the-counter market) and subject to exchange-based rules, and investors would benefit as a result.

B. Self-Regulatory Organization's Statement on Burden on Competition

Cboe Options does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes there is sufficient investor interest and demand in the pilot program to warrant its extension. The Exchange believes that, for the period that the pilot has been in operation, the program has provided investors with additional means of managing their risk exposures and carrying out their investment objectives. Furthermore, the Exchange believes that

²¹ *Id.*

it has not experienced any adverse market effects with respect to the pilot program, including any adverse market volatility effects that might occur as a result of large FLEX exercises in FLEX Option series that expire near Non-Flex expirations and use a p.m. settlement. Cboe Options believes that the restriction actually places the Exchange at a competitive disadvantage to its OTC counterparts in the market for customized options, and unnecessarily limits market participants' ability to trade in an exchange environment that offers the added benefits of transparency, price discovery, liquidity, and financial stability. Therefore, the Exchange does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act²² and Rule 19b-4(f)(6) thereunder.²³

A proposed rule change filed under Rule 19b-4(f)(6)²⁴ normally does not become operative for 30 days after the date of filing. However, pursuant to Rule 19b-4(f)(6)(iii),²⁵ the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that such waiver will allow the Exchange to extend the pilot program

and maintain the status quo, thereby reducing market disruption.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the pilot program to continue uninterrupted, thereby avoiding investor confusion that could result from a temporary interruption in the pilot program. For this reason, the Commission designates the proposed rule change to be operative upon filing.²⁶

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-CBOE-2022-020 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to File Number SR-CBOE-2022-020. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the

²⁶ For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-CBOE-2022-020, and should be submitted on or before May 25, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁷

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2022-09518 Filed 5-3-22; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-94810; File No. SR-NYSE-2021-45]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Withdrawal of Proposed Rule Change, as Modified by Amendment No. 2, to Adopt Listing Standards for Subscription Warrants Issued by a Company Organized Solely for the Purpose of Identifying an Acquisition Target

April 28, 2022.

On August 24, 2021, the New York Stock Exchange LLC ("NYSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act" or "Exchange Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to adopt listing standards for subscription warrants issued by a company organized solely for the purpose of identifying an acquisition target. The proposed rule change was

²⁷ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

²² 15 U.S.C. 78s(b)(3)(A).

²³ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

²⁴ 17 CFR 240.19b-4(f)(6).

²⁵ 17 CFR 240.19b-4(f)(6)(iii).

published for comment in the **Federal Register** on September 10, 2021.³

On September 30, 2021, pursuant to Section 19(b)(2) of the Act,⁴ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.⁵ On December 8, 2021, the Commission instituted proceedings under Section 19(b)(2)(B) of the Exchange Act⁶ to determine whether to approve or disapprove the proposed rule change.⁷

On March 1, 2022, the Exchange filed Amendment No. 2 to the proposed rule change, which replaced the proposed rule change as originally filed and superseded such filing in its entirety.⁸ On March 2, 2022, the Commission published notice of Amendment No. 2 to the proposed rule change.⁹ On March 4, 2022, the Commission extended the period for consideration of the proposed rule change to May 8, 2022.¹⁰ On April 26, 2022, the Exchange withdrew the proposed rule change (SR-NYSE-2021-45).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹¹

J. Matthew DeLesDernier,
Assistant Secretary.

[FR Doc. 2022-09517 Filed 5-3-22; 8:45 am]

BILLING CODE 8011-01-P

³ See Securities Exchange Act Release No. 92876 (September 3, 2021), 86 FR 50748. Comments received on the proposal are available on the Commission's website at: <https://www.sec.gov/comments/sr-nyse-2021-45/srnyse202145.htm>.

⁴ 15 U.S.C. 78s(b)(2).

⁵ See Securities Exchange Act Release No. 93221, 86 FR 55662 (October 6, 2021). The Commission designated December 9, 2021 as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to approve or disapprove, the proposed rule change.

⁶ 15 U.S.C. 78s(b)(2)(B).

⁷ See Securities Exchange Act Release No. 93741, 86 FR 71111 (December 14, 2021).

⁸ Amendment No. 2 is available at: <https://www.sec.gov/comments/sr-nyse-2021-45/srnyse202145-20118274-271197.pdf>. On February 17, 2022, the Exchange filed Amendment No. 1 to the proposed rule change. The Exchange withdrew Amendment No. 1 on March 1, 2022.

⁹ See Securities Exchange Act Release No. 94349, 87 FR 13036 (March 8, 2022).

¹⁰ See Securities Exchange Act Release No. 94363, 87 FR 13779 (March 10, 2022).

¹¹ 17 CFR 200.30-3(a)(12).

SMALL BUSINESS ADMINISTRATION

[License No. 03/03-0249]

Argosy Investment Partners IV, L.P.; Notice Seeking Exemption Under Section 312 of the Small Business Investment Act, Conflicts of Interest

Notice is hereby given that Argosy Investment Partners IV, L.P., 950 West Valley Road, Wayne, PA 19087, a Federal Licensee under the Small Business Investment Act of 1958, as amended ("the Act"), in connection with the financing of a small concern, has sought an exemption under Section 312 of the Act and Section 107.730, Financings which Constitute Conflicts of Interest of the Small Business Administration ("SBA") Rules and Regulations (13 CFR 107.730). Argosy Investment Partners IV, L.P. proposes to provide financing to Joliet Holdings, LLC, c/o MTN Capital Partners, 60 East 42nd Street, New York, NY 10165.

The financing is brought within the purview of § 107.730(a) and (d) of the Regulations because Odyssey Capital Group, L.P., an Associate of Argosy Investment Partners IV, L.P., owns more than ten percent of Joliet Holdings, LLC, and therefore this transaction is considered a financing of an Associate requiring prior SBA approval.

Notice is hereby given that any interested person may submit written comments on the transaction, within fifteen days of the date of this publication, to the Associate Administrator for Investment, U.S. Small Business Administration, 409 Third Street SW, Washington, DC 20416.

Bailey DeVries,

Associate Administrator, Office of Investment and Innovation.

[FR Doc. 2022-09515 Filed 5-3-22; 8:45 am]

BILLING CODE P

DEPARTMENT OF STATE

[Public Notice 11668]

Notice of Department of State Sanctions Actions Pursuant to the Countering America's Adversaries Through Sanctions Act (CAATSA) and the Protecting Europe's Energy Security Act (PEESA), as amended

SUMMARY: The Secretary of State has imposed sanctions on one entity and identified one vessel as blocked property pursuant to the Countering America's Adversaries Through Sanctions Act (CAATSA) and the Protecting Europe's Energy Security Act (PEESA), as amended.

DATES: The Secretary of State's determination and selection of certain sanctions to be imposed upon the one entity and one vessel identified in the **SUPPLEMENTARY INFORMATION** section pursuant to CAATSA were effective on January 19, 2021 and the Secretary of State's determination and imposition of sanctions to be imposed upon the one entity and one vessel identified in the **SUPPLEMENTARY INFORMATION** section pursuant to PEESA were effective on February 22, 2021.

FOR FURTHER INFORMATION CONTACT: Anthony Musa, mussad@state.gov, Phone: (202) 647-1925.

SUPPLEMENTARY INFORMATION: Pursuant to Section 232 of Countering America's Adversaries Through Sanctions Act (CAATSA), as delegated, the Secretary of State, in consultation with the Secretary of the Treasury, the Secretary of Commerce, the Secretary of Homeland Security, and the United States Trade Representative, and with the President of the Export-Import Bank, the Chairman of the Board of Governors of the Federal Reserve System, and other agencies and officials as appropriate, is authorized to impose on a person any of the sanctions described in Section 232 of Countering America's Adversaries Through Sanctions Act (CAATSA) upon determining that the person met any criteria set forth in sections 232(a)(1)-232(c) of Countering America's Adversaries Through Sanctions Act (CAATSA).

Pursuant to Section 7503(a)(1)(A) of PEESA, as amended, the Secretary of State, in consultation with the Secretary of the Treasury, shall submit every 90 days a report to the appropriate congressional committees that identifies vessels that engaged in pipe-laying or pipe-laying activities at depths of 100 feet or more below sea level for the construction of the Nord Stream 2 pipeline project, the Turkstream pipeline project, or any project that is a successor to either such project. Pursuant to Section 7503(a)(1)(B) of PEESA, as amended, the Secretary of State, in consultation with the Secretary of the Treasury shall also include in the report foreign persons that the Secretary of State, in consultation with the Secretary of the Treasury, determines have knowingly sold, leased, or provided, or facilitated selling, leasing, or providing, those vessels for the construction of such a project. Pursuant to Section 7503(c) of PEESA, as delegated, the Secretary of the Treasury, in consultation with the Secretary of State, shall exercise all powers granted to the President by the International Emergency Economic Powers Act to the

extent necessary to block and prohibit all transactions in all property and interests in property of any person identified under subsection (a)(1)(B) of PEESA if such property and interests in property are in the United States, come within the United States, or are or come within the possession or control of a United States person.

The Secretary of State has determined, pursuant to Section 232(a)(1) of Countering America's Adversaries Through Sanctions Act (CAATSA), that KVT-RUS, has knowingly, on or after July 15, 2020, made an investment described in subsection (b), or sold, leased, or provided to the Russian Federation, for the construction of Russian energy export pipelines, goods, services, technology, information, or support described in subsection (c), any of which has a fair market value of \$1,000,000 or more, or that during a 12 month period, have an aggregate fair market value of \$5,000,000 or more.

The Secretary of State has additionally determined, pursuant to Section 7503(a)(1)(B)(i) of Protecting Europe's Energy Security Act (PEESA), as amended, that KVT-RUS, has knowingly, on or after January 1, 2021, sold, leased, or provided, or facilitated selling, leasing, or providing, a vessel that engaged in pipe-laying or pipe-laying activities at depths of 100 feet or more below sea level for the construction of the Nord Stream 2 pipeline project.

Pursuant to sections 232(a)(1) and 235 of Countering America's Adversaries Through Sanctions Act (CAATSA) and E.O. 13849, the Secretary of State has selected the following sanctions to be imposed upon KVT-RUS:

- Order the United States Government not to issue any specific license and not to grant any other specific permission or authority to export any goods or technology to KVT-RUS (section 235(a)(2));

- Prohibit any transactions in foreign exchange that are subject to the jurisdiction of the United States and in which KVT-RUS has any interest (section 235(a)(7));

- Prohibit any transfers of credit or payments between financial institutions or by, through, or to any financial institution, to the extent that such transfers or payments are subject to the jurisdiction of the United States and involve any interest of KVT-RUS (section 235(a)(8));

- Prohibit any person from acquiring, holding, withholding, using, transferring, withdrawing, transporting, importing, or exporting any property that is subject to the jurisdiction of the

United States and with respect to which KVT-RUS has any interest (section 235(a)(9)(A)); dealing in or exercising any right, power, or privilege with respect to such property (section 235(a)(9)(B)); or conducting any transaction involving such property (section 235(a)(9)(C));

- Prohibit any United States person from investing in or purchasing significant amounts of equity or debt instruments of KVT-RUS (section 235(a)(10));

- Block all property and interests in property of KVT-RUS that are in the United States, that hereafter come within the United States, or that are or hereafter come within the possession or control of any United States person, and provide that such property and interests in property may not be transferred, paid, exported, withdrawn, or otherwise dealt in (E.O. 13849 Section 1(a)(iv)).

Pursuant to Section 7503(c) of PEESA, as amended, Sections 232(a)(1) and 235 of CAATSA, and E.O. 13849, KVT-RUS has been added to the Specially Designated Nationals and Blocked Persons List.

All property and interests in property of KVT-RUS subject to U.S. jurisdiction are blocked.

The following vessels subject to U.S. jurisdiction are blocked:
Fortuna (IMO 8674156)

Whitney Baird,

*Principal Deputy Assistant Secretary of State,
Bureau of Economic and Business Affairs,
Department of State. Bureau of Economic and
Business Affairs, Department of State.*

[FR Doc. 2022-09564 Filed 5-3-22; 8:45 am]

BILLING CODE 4710-AE-P

DEPARTMENT OF STATE

[Public Notice 11669]

Notice of Department of State Sanctions Actions Pursuant to the Protecting Europe's Energy Security Act

SUMMARY: The Secretary of State has imposed sanctions on one entity and one vessel pursuant to the Protecting Europe's Energy Security Act (PEESA), as amended and Executive Order 13049.

DATES: The Secretary of State's determination regarding the two entities, and imposition of sanctions on the entities and vessels identified in the **SUPPLEMENTARY INFORMATION** section were effective on November 23, 2021.

FOR FURTHER INFORMATION CONTACT: Anthony Musa, *mussad@state.gov*, Phone: (202) 647-1925.

SUPPLEMENTARY INFORMATION: Pursuant to Section 7503(a)(1)(A) of PEESA, as

amended, the Secretary of State, in consultation with the Secretary of the Treasury, shall submit every 90 days a report to the appropriate congressional committees that identifies vessels that engaged in pipe-laying or pipe-laying activities at depths of 100 feet or more below sea level for the construction of the Nord Stream 2 pipeline project, the Turkstream pipeline project, or any project that is a successor to either such project. Pursuant to Section 7503(a)(1)(B) of PEESA, as amended, the Secretary of State, in consultation with the Secretary of the Treasury shall also include in the report foreign persons that the Secretary of State, in consultation with the Secretary of the Treasury, determines have knowingly sold, leased, or provided, or facilitated selling, leasing, or providing, those vessels for the construction of such a project. Pursuant to Section 7503(c) of PEESA, as delegated, the Secretary of the Treasury, in consultation with the Secretary of State, shall exercise all powers granted to the President by the International Emergency Economic Powers Act to the extent necessary to block and prohibit all transactions in all property and interests in property of any person identified under subsection (a)(1)(B) of PEESA if such property and interests in property are in the United States, come within the United States, or are or come within the possession or control of a United States person. Pursuant to E.O. 13049, with respect to any foreign person identified by the Secretary of State, in consultation with the Secretary of the Treasury, in a report to the Congress pursuant to section 7503(a)(1)(B) of PEESA, all property and interests in property of such person that are in the United States, that hereafter come within the United States, or that are or hereafter come within the possession or control of any United States person are blocked and may not be transferred, paid, exported, withdrawn, or otherwise dealt in.

The Secretary of State has determined, pursuant to Section 7503(a)(1)(B)(i) of PEESA, as amended, that Transadria Ltd has knowingly, on or after January 1, 2021, sold, leased, or provided, or facilitated selling, leasing, or providing, a vessel that engaged in pipe-laying or pipe-laying activities at depths of 100 feet or more below sea level for the construction of the Nord Stream 2 pipeline project.

Pursuant to E.O. 13049 and Section 7503(c) of PEESA, as amended, this entity has been added to the Specially Designated Nationals and Blocked Persons List. All property and interest in property of this entity subject to U.S. jurisdiction is blocked.

The following vessel subject to U.S. jurisdiction is blocked:

Marlin (IMO 9396854) (Linked To: Transadria Ltd)

Whitney Baird,

Principal Deputy Assistant Secretary of State, Bureau of Economic and Business Affairs, Department of State.

[FR Doc. 2022-09566 Filed 5-3-22; 8:45 am]

BILLING CODE 4710-AE-P

DEPARTMENT OF STATE

[Public Notice 11667]

Notice of Department of State Sanctions Actions Pursuant to the Protecting Europe's Energy Security Act

SUMMARY: The Secretary of State has imposed sanctions on two entities and two vessels pursuant to the Protecting Europe's Energy Security Act (PEESA), as amended and Executive Order 13049.

DATES: The Secretary of State's determination regarding the two entities, and imposition of sanctions on the entities and vessels identified in the **SUPPLEMENTARY INFORMATION** section were effective on August 20, 2021.

FOR FURTHER INFORMATION CONTACT: Anthony Musa, *mussad@state.gov*, Phone: (202) 647-1925.

SUPPLEMENTARY INFORMATION: Pursuant to Section 7503(a)(1)(A) of PEESA, as amended, the Secretary of State, in consultation with the Secretary of the Treasury, shall submit every 90 days a report to the appropriate congressional committees that identifies vessels that engaged in pipe-laying or pipe-laying activities at depths of 100 feet or more below sea level for the construction of the Nord Stream 2 pipeline project, the Turkstream pipeline project, or any project that is a successor to either such project. Pursuant to Section 7503(a)(1)(B) of PEESA, as amended, the Secretary of State, in consultation with the Secretary of the Treasury, shall also include in the report foreign persons that the Secretary of State, in consultation with the Secretary of the Treasury, determines have knowingly sold, leased, or provided, or facilitated selling, leasing, or providing, those vessels for the construction of such a project, and foreign persons that the Secretary of State, in consultation with the Secretary of the Treasury, determines have knowingly provided for those vessels underwriting services or insurance or reinsurance necessary or essential for the completion of such a project. Pursuant to Section 7503(c) of PEESA, as delegated, the Secretary of

the Treasury, in consultation with the Secretary of State, shall exercise all powers granted to the President by the International Emergency Economic Powers Act to the extent necessary to block and prohibit all transactions in all property and interests in property of any person identified under subsection (a)(1)(B) of PEESA if such property and interests in property are in the United States, come within the United States, or are or come within the possession or control of a United States person. Pursuant to E.O. 13049, with respect to any foreign person identified by the Secretary of State, in consultation with the Secretary of the Treasury, in a report to the Congress pursuant to section 7503(a)(1)(B) of PEESA, all property and interests in property of such person that are in the United States, that hereafter come within the United States, or that are or hereafter come within the possession or control of any United States person are blocked and may not be transferred, paid, exported, withdrawn, or otherwise dealt in.

The Secretary of State has determined, pursuant to Section 7503(a)(1)(B)(i) of PEESA, as amended, that Joint Stock Company Nobility has knowingly, on or after January 1, 2021, sold, leased, or provided, or facilitated selling, leasing, or providing, a vessel that engaged in pipe-laying or pipe-laying activities at depths of 100 feet or more below sea level for the construction of the Nord Stream 2 pipeline project.

The Secretary of State has also determined, pursuant to Section 7503(a)(1)(B)(iii) of PEESA, as amended, that Konstanta, OOO has knowingly, on or after January 1, 2021, provided underwriting services or insurance or reinsurance to a vessel identified in section 7503(a)(1)(A).

Pursuant to E.O. 13049 and Section 7503(c) of PEESA, as amended, these entities have been added to the Specially Designated Nationals and Blocked Persons List. All property and interests in property of these entities subject to U.S. jurisdiction are blocked.

The following vessels subject to U.S. jurisdiction are blocked:

Ostap Sheremeta (IMO 9624225)
(Linked To: Joint Stock Company Nobility)

Ivan Sidorenko (IMO 9624213) (Linked To: Joint Stock Company Nobility)

Whitney Baird,

Principal Deputy Assistant Secretary of State, Bureau of Economic and Business Affairs, Department of State.

[FR Doc. 2022-09567 Filed 5-3-22; 8:45 am]

BILLING CODE 4710-AE-P

TENNESSEE VALLEY AUTHORITY

Agency Information Collection Activities: Information Collection Reinstatement; Comment Request

AGENCY: Tennessee Valley Authority.

ACTION: 60-Day notice of submission of information collection reinstatement approval and request for comments.

SUMMARY: The proposed information collection reinstatement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act of 1995. The Tennessee Valley Authority is soliciting public comments on this proposed collection reinstatement.

DATES: Comments should be sent to the Public Information Collection Clearance Officer no later than July 5, 2022.

ADDRESSES: Requests for information, including copies of the information collection proposed and supporting documentation, should be directed to the Public Information Collection Clearance Officer: Jennifer A. Wilds, Specialist, Records Compliance, Tennessee Valley Authority, 400 W Summit Hill Dr., CLK-320, Knoxville, Tennessee 37902-1401; telephone (865) 632-6580 or by email at *pra@tva.gov*.

SUPPLEMENTARY INFORMATION:

Type of Request: Reinstatement, with minor modification, of a previously approved information collection for which approval has expired.

Title of Information Collection: EnergyRight® Program.

OMB Approval Number: 3316-0019.

Frequency of Use: On occasion.

Type of Affected Public: Individuals or households and commercial businesses.

Small Businesses or Organizations Affected: Yes.

Federal Budget Functional Category Code: 455.

Estimated Number of Annual Responses: 33,500.

Estimated Total Annual Burden Hours: 8,650.

Estimated Average Burden Hours per Response: 0.3.

Need For and Use of Information:

This information is used by distributors of TVA power to assist in identifying and financing energy improvements for their electrical energy customers.

Rebecca L. Coffey,
Agency Records Officer.

[FR Doc. 2022-09504 Filed 5-3-22; 8:45 am]

BILLING CODE 8120-08-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****Noise Exposure Maps Notice for
Piedmont Triad International Airport,
Greensboro, North Carolina**

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: The FAA announces its determination that the noise exposure maps submitted by the Piedmont Triad Airport Authority for the Piedmont Triad International Airport are in compliance with applicable requirements.

APPLICABLE DATE: The effective date of the FAA's determination on the noise exposure maps is April 27, 2022.

FOR FURTHER INFORMATION CONTACT: Memphis Airports District Office, Tommy Dupree, Manager, Federal Aviation Administration, 2600 Thousand Oaks Blvd., Suite 2250, Memphis, Tennessee 38118, Telephone: (901) 322-8181.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA finds that the noise exposure maps submitted for the Piedmont Triad International Airport under the provisions of 49 U.S.C. 47501 et seq. (Aviation Safety and Noise Abatement Act) and 14 CFR part 150 are in compliance with applicable requirements of 14 CFR part 150, effective January 13, 2004.

Under 49 U.S.C. Section 47503 of the Aviation Safety and Noise Abatement Act (hereinafter referred to as "the Act"), an airport operator may submit to the FAA noise exposure maps which meet applicable regulations and which depict non-compatible land uses as of the date of submission of such maps, a description of projected aircraft operations during a forecast period that is at least five (5) years in the future, and the ways in which such operations will affect such maps. The Act requires such maps to be developed in consultation with interested and affected parties in the local community, government agencies, and persons using the airport. An airport operator who has submitted noise exposure maps that are found by the FAA to be in compliance with the requirements of 14 CFR part 150, promulgated pursuant to the Act, may submit a noise compatibility program for FAA approval which sets forth the measures the operator has taken or proposes to take to reduce existing non-compatible uses and prevent the introduction of additional non-compatible uses.

The FAA has completed its review of the noise exposure maps and accompanying documentation submitted by the Piedmont Triad Airport Authority. The documentation that constitutes the "Noise Exposure Maps" (NEM) as defined in Section 150.7 includes a 2020 Base Year NEM, Figure 7-1, and a 2025 Future Year NEM, Figure 7-2, located in Chapter 7 of the report. The figures contained within Chapter 7 are scaled to fit within the report context; however, the official, to scale, 2020 Base Year NEM and 2025 Future Year NEM are an attachment to the official report.

The Noise Exposure Maps contain current and forecast information including the depiction of the airport and its boundaries, the runway configurations, land uses such as single and two-family residential; multi-family residential; mixed residential and commercial; commercial and office; industrial and manufacturing; transportation, parking and utilities; public facilities and institutions; unclassified; open space, cemeteries, and outdoor recreation; vacant land; places of worship; schools; historic structures; hospitals; and day care/ assisted living facilities and those areas within the Day Night Average Sound Level (DNL) 65, 70 and 75 noise contours. Estimates of the residential population within the 2020 Base Year and 2025 Future Year noise contours are shown in Table 7-1 of Chapter 7 of the report. Figure 5-1 in Chapter 5 displays the location of noise monitoring sites. Flight track maps are provided in Figures 6-6 through 6-8 of Chapter 6. The type and frequency of aircraft operations, including nighttime operations and engine runups, are found in Tables 6-7 through 6-15 in Chapter 6.

As discussed in Chapter 9 of the report, the Piedmont Triad Airport Authority provided the general public the opportunity to review and comment on the NEMs. This public comment period opened on November 17, 2020 and closed on December 17, 2020. A public workshop was held on June 27, 2019 on the Part 150 process. A public workshop and hearing for the NEMs was held on December 8, 2020. All comments received during the public comment period and throughout the development of the NEMs, as well as responses to these comments, are contained in Appendix G of the report.

The FAA has determined that these noise exposure maps and accompanying documentation are in compliance with applicable requirements. This determination is effective on April 27, 2022.

FAA's determination on an airport operator's noise exposure maps is limited to a finding that the maps were developed in accordance with the procedures contained in Appendix A of 14 CFR part 150. Such determination does not constitute approval of the applicant's data, information or plans, or a commitment to approve a noise compatibility program or to fund the implementation of that program. If questions arise concerning the precise relationship of specific properties to noise exposure contours depicted on a noise exposure map submitted under Section 47503 of the Act, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties with regard to the depicted noise contours, or in interpreting the noise exposure maps to resolve questions concerning, for example, which properties should be covered by the provisions of Section 47506 of the Act. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under Part 150 or through FAA's review of noise exposure maps. Therefore, the responsibility for the detailed overlaying of noise exposure contours onto the map depicting properties on the surface rests exclusively with the airport operator that submitted those maps, or with those public agencies and planning authorities with which consultation is required under Section 47503 of the Act. The FAA has relied on the certification by the airport operator, under Section 150.21, that the statutorily required consultation has been accomplished.

Copies of the full noise exposure map documentation and of the FAA's evaluation of the maps are available for examination at the following locations: Federal Aviation Administration, Memphis Airports District Office, 2600 Thousand Oaks Blvd., Memphis, Tennessee 38118, and Piedmont Triad International Airport, 1000A Ted Johnson Parkway, Greensboro, North Carolina 27409.

FOR FURTHER INFORMATION CONTACT: Tommy Dupree, Manager, Memphis Airports District Office, Federal Aviation Administration, 2600 Thousand Oaks Blvd., Suite 2250, Memphis, TN 38118, Telephone: (901) 322-8181.

Issued in Memphis, TN, on April 27, 2022.

Tommy L. Dupree,
Manager, Memphis Airports District Office.

[FR Doc. 2022-09568 Filed 5-3-22; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**National Highway Traffic Safety Administration**

[Docket No. NHTSA–2022–0010]

Agency Information Collection Activities; Notice and Request for Comment; Confidential Business Information**AGENCY:** National Highway Traffic Safety Administration (NHTSA), DOT.**ACTION:** Notice and request for comments on a reinstatement, without change, of a previously approved collection of information.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) invites public comments about our intention to request approval from the Office of Management and Budget (OMB) for a reinstatement without change of a previously approved information collection. Before a Federal agency can collect certain information from the public, it must receive approval from OMB. Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections. This notice describes one collection of information for which NHTSA intends to seek OMB approval, relating to confidential business information.

DATES: Comments must be submitted on or before July 5, 2022.**ADDRESSES:** You may submit comments to the docket number identified in the heading of this document by any of the following methods:

- *Electronic Submissions:* Go to the Federal eRulemaking Portal at <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Fax:* (202) 493–2251.

- *Mail or Hand Delivery:* Docket Management, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays. To be sure someone is there to help you, please call (202) 366–9322 before coming.

Instructions: All submissions must include the agency name and docket number for this notice. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit <https://www.transportation.gov/privacy>.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> or the street address listed above. Follow the online instructions for accessing the dockets via internet.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Dan Rabinovitz in the Office of the Chief Counsel, Daniel.Rabinovitz@dot.gov, National Highway Traffic Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590. Please identify the relevant collection of information by referring to its title and OMB Control Number (Confidential Business Information, 2127–0025).

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) how to enhance the quality, utility, and clarity of the information to be collected; and (d) how to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. In compliance with these

requirements, NHTSA asks for public comments on the following proposed collection of information for which the agency is seeking approval from OMB.

Title: Confidential Business Information

OMB Control Number: 2127–0025
Form Number(s): N/A

Type of Request: Reinstatement without change of a previously approved information collection

Type of Review Requested: Regular
Requested Expiration Date of

Approval: 3 years from date of approval

Summary of the Collection of Information

Persons who submit information to the agency and seek to have the agency withhold some or all of that information from public disclosure, including under the Freedom of Information Act (FOIA), 5 U.S.C. 552, must provide the agency with sufficient support that justifies the confidential treatment of that information. A request for confidential treatment must meet the requirements set forth in 49 CFR part 512. For example, a request must be submitted to the Office of the Chief Counsel and include: (1) A letter to the Chief Counsel that contains supporting information to justify a request, per Part 512.8; (2) a certificate in support of a request for confidential treatment, per Part 512.4(b) and Appendix A; (3) the material claimed to include confidential business information—with proper confidential markings, per Part 512.6; and (4) a complete copy of the material—with redactions over the portions for which confidential treatment is claimed (*i.e.*, so it cannot be seen), and the rest of the material unredacted, per Part 512.5(a)(2).

Part 512 helps ensure that information submitted under a claim of confidentiality is properly evaluated under prevailing legal standards and, where appropriate, accorded confidential treatment. The requirements in Part 512 apply to all information submitted to NHTSA, except as provided in section 512.2(b), for which a determination is sought that the material is entitled to confidential treatment under 5 U.S.C. 552(b), most often because it constitutes confidential business information as described in 5 U.S.C. 552(b)(4), and should be withheld from public disclosure. To facilitate the evaluation process, in their requests for confidential treatment, submitters of information may make reference to certain limited classes of information specified in Appendix B that are presumptively treated as confidential, such as blueprints and engineering drawings, future specific

model plans (under limited conditions), and future vehicle production or sales figures for specific models (under limited conditions). Additionally, Appendix C's class determinations, which are specific to early warning reporting (EWR) data, grant presumptive confidentiality to certain EWR data, with exceptions including information on death, injury, and property damage claims and notices, which would be handled on an individual basis according to the procedures of Part 512.72 FR 59434 (Oct. 19, 2007).¹

Description of the Need for the Information and the Proposed or Actual Use of the Information

NHTSA receives confidential information for use in its activities, which include investigations, rulemaking actions, program planning and management, and program evaluation. The information is needed to ensure the agency has sufficient relevant information for decision-making in connection with these activities. Some of this information is submitted voluntarily, as in rulemaking, and some is submitted in response to compulsory information requests, as in investigations. If Part 512 were not in existence, the agency would still receive this confidential information, either through voluntary submissions or through compulsory submissions in response to agency requests issued pursuant to its information gathering powers. The only difference would be that the determinations of whether the information should be accorded confidential treatment would be less structured and, ultimately, more expensive and time-consuming for both the entities requesting confidentiality and the agency.

Affected Public

This collection of information applies to entities that submit to the agency information that the entities wish to have withheld from public disclosure, including under FOIA. Thus, the collection of information applies to entities that are subject to laws administered by the agency or agency regulations and are under an obligation to provide information to the agency. It also includes entities that voluntarily submit information to the agency. Such entities would include manufacturers of

motor vehicles and of motor vehicle equipment. Importers are considered to be manufacturers. It may also include other entities that are involved with motor vehicles or motor vehicle equipment but are not manufacturers.

Estimated Number of Respondents: 165

Frequency: On occasion.

Estimated Total Annual Burden Hours: 5,575 hours.

Potential submitters of requests for confidential treatment of information include vehicle manufacturers, equipment manufacturers, and registered importers. In recent years, NHTSA has received an average of approximately 500 requests for confidential treatment of information annually from approximately 75 unique requesters. Last year, however, NHTSA began receiving more requests for confidential treatment after NHTSA issued the Standing General Order 2021–01 (General Order) which requires certain named entities to submit reports on crashes involving ADS or Level 2 ADAS.² As a result, NHTSA estimates it will receive an additional 1,575 requests for confidential treatment each year from an estimated 110 unique respondents, for a total of 2,075 requests from 165 unique respondents (NHTSA estimates that there will be some overlap between respondents submitting requests in connection with General Order reporting and those submitting non-General Order requests). NHTSA estimates that most requests for confidential treatment have come, and will continue to come, from large manufacturers.

The agency receives requests for confidential treatment that vary in size—from requests that ask the agency to withhold as little as a portion of one page to voluminous electronic files. An entity requesting confidential treatment must provide a written statement in support of a request for confidential treatment that explains why the submitted information should be withheld from public disclosure, including the legal basis for withholding, along with a certification. See 49 CFR part 512. In the case of submissions by large manufacturers, which often consist of hundreds of

pages of information, it takes, on average, eight hours to prepare a submission. On the other hand, the typical small business that submits a single page document should only need about five (5) minutes to fully comply with the regulation. To estimate the total burden associated with this information collection, NHTSA has used the more conservative estimate that each non-General Order submission will take approximately 8 hours. Therefore, the non-General Order total annual burden is estimated at 4,000 hours (8 hours × 500 requests/year). Additionally, NHTSA estimates that each General Order submission will take approximately 1 hour.³ Therefore, the General Order total annual burden is estimated at 1,575 hours (1 hour × 1,575 requests/year). Finally, the combined total annual burden is estimated at 5,575 hours for 49 CFR part 512.

To calculate the labor cost associated with submitting requests for confidential treatment, NHTSA looked at wage estimates for the type of personnel involved with compiling and submitting the documents. NHTSA estimated the total labor costs associated with these burden hours by looking at the average wage for Paralegals and Legal Assistants. The Bureau of Labor Statistics (BLS) estimates that the average hourly wage for Paralegals and Legal Assistants (BLS Occupation code 23–2011) is \$27.22. The Bureau of Labor Statistics estimates that private industry workers' wages represent 70.4% of total labor compensation costs. Therefore, NHTSA estimates the hourly labor costs to be \$38.67 for BLS Occupation code 23–2011. Consequently, NHTSA estimates the total labor cost associated with the 5,575 burden hours to be \$215,585. This estimate was derived by multiplying the estimated annual burden of 5,575 hours with the mean hourly labor cost estimate for Paralegals and Legal Assistants of \$38.67 per hour. Table 1 provides a summary of the estimated burden hours and labor costs associated with those submissions.

³ NHTSA estimates that requests for confidential treatment pursuant to the General Order will only take 1 hour because NHTSA's online portal for General Order submissions helps automate the process for requests and the General Order only allows entities to request confidential treatment for three (3) fields per incident report. Consequently, the limited General Order requests for confidential treatment are, on average, remarkably smaller than the voluminous non-General Order requests.

¹ The collection of EWR data is covered under OMB Control No. 2127–0616.

² More information about the General Order is available on NHTSA's website at <https://www.nhtsa.gov/laws-regulations/standing-general-order-crash-reporting-levels-driving-automation-2-5> and in NHTSA's information collection request with OMB control number 2127–0754.

TABLE 1—BURDEN ESTIMATES

Annual responses	Estimated burden per response (hours)	Average hourly labor cost	Labor cost per submission	Total burden hours	Total labor costs
2,075	2.687	\$38.67	\$309.36	5,575	\$215,585

Since 49 CFR part 512 does not require those persons who request confidential treatment to keep copies of records or requests submitted to us, there are no associated recordkeeping burdens.⁴

Estimated Total Annual Burden Cost: \$165.

The only cost to respondents is expected to be postage costs. NHTSA estimates that each mailed response costs \$8.95 (priority flat rate envelope from USPS). Historically, Part 512 requests were submitted by mail. However, at the onset of the COVID-19 public health emergency, NHTSA began accepting Part 512 submissions electronically and requested that submissions not be mailed. NHTSA now estimates that no more than 1% of submissions are submitted by mail. Accordingly, NHTSA estimates the total annual costs for this information collection to be \$186 (2,075 submissions \times .01 \times \$8.95 = \$185.71, rounded to \$186).

Public Comments Invited: You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29.

Ann E. Carlson,
Chief Counsel.

[FR Doc. 2022-09516 Filed 5-3-22; 8:45 am]

BILLING CODE 4910-59-P

⁴NHTSA has a separate record retention regulation (49 CFR part 576) covered by a Paperwork Reduction Act clearance, OMB Control No. 2127-0042.

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. DOT- NHTSA-2022-0008]

Agency Information Collection Activities; Notice and Request for Comment; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments for a reinstatement of a previously approved information collection.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (PRA), this notice announces that the Information Collection Request (ICR) abstracted below will be submitted to the Office of Management and Budget (OMB) for review and approval. This document describes a collection of information for which NHTSA intends to seek OMB approval on generic clearance for qualitative feedback on agency service delivery. A **Federal Register** Notice with a 60-day comment period soliciting comments on the following information collection was published on January 13, 2022, 87FR2235. No comments were received.

DATES: Comments must be submitted on or June 3, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection, including suggestions for reducing burden, should be submitted to the Office of Management and Budget at www.reginfo.gov/public/do/PRAMain. To find this information collection, select "Currently under Review—Open for Public Comment" or use the search function.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Walter Culbreath, NIO-0300, (202)-366-1566, Office of the Chief Information Officer, W51-316, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590. Please identify the relevant collection of

information by referring to its OMB Control Number.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), a Federal agency must receive approval from the Office of Management and Budget (OMB) before it collects certain information from the public and a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. In compliance with these requirements, this notice announces that the following information collection request will be submitted OMB.

A **Federal Register** notice with a 60-day comment period soliciting public comments on the following information collection was published on January 13, 2022.

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Control Number: 2127-0682.

Form Number: To be determined by specific collections.

Type of Request: Reinstatement of a previously approved information collection.

Requested Expiration Date of Approval: 3 years from date of approval.

Summary of the Collection of Information: Executive Order 12862 directs Federal agencies to provide the highest quality service possible to the public. This proposed information collection provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery.

This feedback collected through this information collection will provide insights into customer or stakeholder perceptions, experiences and expectations; provide early warning of issues with service; or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. The feedback will allow for ongoing, collaborative, and actionable communication between the Agency and its customers and stakeholders. This information collection will also allow feedback to contribute directly to

the improvement of program management.

The Agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collection is voluntary.
 - The collection is low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and is low-cost for both the respondents and the Federal Government.
 - The collection is non-controversial and does not raise issues of concern to other Federal agencies.
 - Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future.
 - Personally identifiable information (PII) is collected only to the extent necessary and is not retained.
 - Information gathered is intended to be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency (if released, the agency must indicate the qualitative nature of the information).
 - Information gathered will not be used for the purpose of substantially informing influential policy decisions; and
 - Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.
- Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be

eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections under this request will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

Description of the Need for the Information and Proposed Use of the Information

Improving agency programs requires ongoing assessment of service delivery—systematic review of the operation of a program compared to a set of explicit or implicit standards—as a means of contributing to the continuous improvement of those programs. The Agency will collect, analyze, and interpret information gathered through this generic clearance to identify strengths and weaknesses of current services and make improvements in service delivery based on that feedback. The solicitation of feedback will target areas such as: timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information were not collected, vital feedback from customers and stakeholders on the Agency's services would be unavailable and the Agency would not know if adjustments would be warranted.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Estimated Number of Respondents: 113,582.

Frequency: On Occasion, per request.

Number of Responses: 113,582.

Estimated Total Annual Burden Hours: 20,204.

The 20,204 annual burden hours requested are based on the number of collections we expect to conduct over the requested period for this clearance.

Estimated Total Annual Burden Cost: \$0.

Participation in this collection is voluntary, and there are no costs to respondents beyond the time spent participating in the surveys.

Public Comments Invited: You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the

information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29.

Dated: April 29, 2022.

William Berry,

Director, Office of IT Compliance,

[FR Doc. 2022–09541 Filed 5–3–22; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Schedule F, (Form 1040)

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Schedule F (Form 1040), Profit or Loss From Farming.

DATES: Written comments should be received on or before July 5, 2022 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to omb.unit@irs.gov. Include 1545–1975 or Schedule F (Form 1040), Profit or Loss From Farming, in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this collection should be directed to LaNita Van Dyke, at 202–317–6009, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at Lanita.VanDyke@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Profit or Loss From Farming.

OMB Number: 1545–1975.

Form Number: Schedule F (Form 1040).

Abstract: Schedule F, (Form 1040) is used by individuals, estate or trust to report their farm income or loss and expenses. The data is used to verify that the items reported on the form are correct and also for general statistical use.

Current Actions: There is no change in the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations, Farming.

Estimated Number of Respondents: 26,546.

Estimated Time per Respondent: 19 hours.

Estimated Total Annual Burden Hours: 504,374.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 29, 2022.

Andres Garcia Leon,

Supervisory Tax Analyst.

[FR Doc. 2022–09575 Filed 5–3–22; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0095]

Agency Information Collection Activity: Pension Claim Questionnaire for Farm Income

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before July 5, 2022.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at www.Regulations.gov or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to nancy.kessinger@va.gov. Please refer to “OMB Control No. 2900–0095” in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email maribel.aponte@va.gov. Please refer to “OMB Control No. 2900–0095” in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 38 U.S.C. 1503 and 38 U.S.C. 1522.

Title: Pension Claim Questionnaire for Farm Income (21P–4165).

OMB Control Number: 2900–0095.

Type of Review: Revision of a currently approved collection.

Abstract: The Department of Veterans Affairs (VA) through its Veterans Benefits Administration (VBA) administers an integrated program of benefits and services, established by law, for Veterans, service personnel, and their dependents and/or beneficiaries.

Entitlement to pension benefits for Veterans and their surviving dependents is based on the family's countable annual income under the authority of 38 U.S.C. 1503 and under the authority of 38 U.S.C. 1522. VA Form 21P–4165 is used to gather the necessary information to evaluate the claimant's countable income and net worth related to the operation of a farm for the purpose of establishing entitlement to pension benefits and to evaluate a beneficiary's ongoing entitlement to pension benefits.

The respondent burden has decreased due to the estimated number of receivables averaged over the past year. No other changes have been made to this form.

Affected Public: Individuals and households.

Estimated Annual Burden: 109 hours.

Estimated Average Burden per Respondent: 30 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 218.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2022–09507 Filed 5–3–22; 8:45 am]

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Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 1166

Tobacco Product Standard for Characterizing Flavors in Cigars; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1166

[Docket No. FDA-2021-N-1309]

RIN 0910-AI28

Tobacco Product Standard for Characterizing Flavors in Cigars

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is proposing a tobacco product standard that would prohibit characterizing flavors (other than tobacco) in all cigars and their components and parts. Characterizing flavors in cigars, such as strawberry, grape, cocoa, and fruit punch, increase appeal and make the cigars easier to use, particularly among youth and young adults. Over a half million youth in the United States use flavored cigars. This proposed product standard would reduce the appeal of cigars, particularly to youth and young adults, and thereby decrease the likelihood of experimentation, development of nicotine dependence, and progression to regular use. FDA is taking this action to reduce the tobacco-related death and disease associated with cigar use. The proposed standard also is expected to reduce tobacco-related health disparities and advance health equity.

DATES: Submit either electronic or written comments on the proposed rule by July 5, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 5, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to

the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-N-1309 for "Tobacco Product Standard for Characterizing Flavors in Cigars." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on

<https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Courtney Smith or Nathan Mease, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 877-287-1373, CTPRegulations@fda.hhs.gov.

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I. Executive Summary

A. Purpose of the Proposed Rule

FDA is proposing a tobacco product standard that would prohibit characterizing flavors (other than tobacco) in cigars manufactured or sold in the United States. In developing this proposed rule, FDA carefully considered the scientific evidence and complex policy issues related to characterizing flavors in cigars.

Each year, an estimated 9,000 premature deaths are attributed to

regular cigar smoking, defined as smoking cigars on 15 or more of the past 30 days; approximately 5,200 of these premature deaths occur in regular cigar smokers who did not also smoke cigarettes. In 2019, not excluding use of other tobacco products, more young adults tried a cigar for the first time each day than tried a cigarette for the first time (3,163 cigar vs. 2,640 cigarette initiates per day). According to the 2020 National Youth Tobacco Survey (NYTS), an estimated 3.5 percent (960,000) of middle and high school students, including 5 percent (770,000) of high school students (grades 9–12) and 1.5 percent (180,000) of middle school students (grades 6–8), had smoked a cigar (cigar, cigarillo, or little cigar) in the preceding 30 days. Of particular concern is the number of youth smoking cigars with characterizing flavors. More than half (58.3 percent) of youth cigar smokers, or approximately 550,000 youth, reported using a flavored cigar during the past 30 days.

Researchers have found that characterizing flavors in cigars and other tobacco products play a key role in how users and nonusers, particularly youth, initiate, progress, and continue using tobacco products. Characterizing flavors in tobacco products increase the appeal of those tobacco products to youth and promote youth initiation, resulting in an increased likelihood that youth and young adults experimenting with flavored cigars will progress to regular cigar smoking. This proposed product standard is expected to reduce the appeal of cigars, particularly to youth and young adults, and thereby decrease the likelihood of experimentation, development of nicotine dependence, progression to regular use, and the resulting tobacco-related disease and death. The proposed standard also is anticipated to improve public health by increasing the likelihood of cessation among existing cigar smokers. And it will improve health outcomes within groups that experience disproportionate levels of tobacco use, including certain vulnerable populations, thus advancing health equity. For the reasons discussed in the preamble of this proposed rule, FDA finds that the proposed tobacco product standard would be appropriate for the protection of the public health.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule would prohibit characterizing flavors (other than tobacco) in cigars and cigar components and parts. Under the proposed rule, no person may manufacture, distribute, sell, or offer for distribution or sale,

within the United States a cigar or any of its components or parts that is not in compliance with the product standard. We also are proposing an effective date of 1 year after the date of publication of the final rule. We seek comment on all parts of this proposed rule.

Characterizing Flavor Prohibition—This proposed rule would prohibit the use of characterizing flavors in all cigars. FDA proposes to define “cigar” as a tobacco product that: (1) Is not a cigarette and (2) is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco. This rule would provide that a cigar or any of its components or parts (including the tobacco, filter, or wrapper, as applicable) must not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco) or an herb or spice, including, but not limited to, strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, coffee, mint, or menthol, that is a characterizing flavor of the tobacco product or tobacco smoke. Among the factors that FDA believes are relevant in determining whether a cigar has a characterizing flavor are:

- The presence and amount of artificial or natural flavor additives, compounds, constituents, or ingredients, or any other flavoring ingredient in a tobacco product, including its components or parts;
- The multisensory experience (*i.e.*, taste, aroma, and cooling or burning sensations in the mouth and throat) of a flavor during use of a tobacco product, including its components or parts;
- Flavor representations (including descriptors), either explicit or implicit, in or on the labeling (including packaging) or advertising of a tobacco product; and
- Any other means that impart flavor or represent that a tobacco product has a characterizing flavor.

However, cigars with tobacco as their characterizing flavor would not be subject to this proposed product standard’s prohibition. For those who experiment with cigars, especially youth and young adults, tobacco-flavored¹ cigars do not currently appear as attractive as cigars with other characterizing flavors. FDA is committed to monitoring the use of cigars with tobacco as their

¹ Throughout this document, FDA uses the terms “tobacco-flavored,” “non-flavored,” and “unflavored.” FDA relies on the specific term used by researchers when citing to individual studies; however, FDA generally considers a cigar that does not have a characterizing flavor other than tobacco to be “tobacco-flavored.”

characterizing flavor through surveillance of national representative data sources and other data to determine whether to take additional action in the future consistent with FDA’s authority.

Proposed Effective Date—FDA is proposing that any final rule that may issue based on this proposed rule become effective 1 year after the date of publication of the final rule. Therefore, after the effective date, no person may manufacture, distribute, sell, or offer for distribution or sale within the United States a cigar or any of its components or parts that is not in compliance with part 1166 (21 CFR part 1166). This regulation does not include a prohibition on individual consumer possession or use, and FDA cannot and will not enforce against individual consumers for possession or use of flavored cigars. FDA’s enforcement will only address manufacturers, distributors, wholesalers, importers, and retailers. State and local law enforcement agencies do not independently enforce the Federal Food, Drug, and Cosmetic Act (FD&C Act). These entities do not and cannot take enforcement actions against any violation of chapter IX of the Act or this regulation on FDA’s behalf. We recognize concerns about how State and local law enforcement agencies enforce their own laws in a manner that may impact equity and community safety

and seek comment on how FDA can best make clear the respective roles of FDA and State and local law enforcement.

C. Legal Authority

This proposed rule is being issued upon FDA’s authority to establish a tobacco product standard under section 907 of the FD&C Act (21 U.S.C. 387g), including its authority thereunder to require the reduction or elimination of a constituent (including a smoke constituent), or harmful component of tobacco products, and respecting the construction, components, ingredients, additives, constituents (including smoke constituents), and properties of the tobacco product (section 907(a)(3), (a)(4)(A)(ii), and (a)(4)(B)(i) of the FD&C Act); FDA’s authorities related to the sale and distribution of tobacco products under sections 907(a)(4)(B)(v) and 906(d) (21 U.S.C. 387f); FDA’s authorities related to adulterated and misbranded tobacco products under sections 902 and 903 (21 U.S.C. 387b and 387c); FDA’s authorities related to prohibited acts and penalties under sections 301 and 303 (21 U.S.C. 331 and 333); and FDA’s rulemaking authority under section 701 of the FD&C Act (21 U.S.C. 371).

D. Costs and Benefits

The quantified benefits of this proposed rule, if finalized, come from

reduced smoking-attributable mortality that are the result of cigar use among adult cigar smokers and reduced mortality from secondhand smoke among non-users. The costs of this proposed rule are those to firms to comply with the rule, to consumers impacted by the rule, and to the Government to enforce this product standard. In addition to benefits and costs, this rule will cause transfers from State governments, the Federal Government, and firms to consumers in the form of reduced revenue and tax revenue.

We estimate that the annualized benefits over a 40-year time horizon will equal \$7,024 million at a 7 percent discount rate, with a low estimate of \$3,962 million and a high estimate of \$10,140 million, and \$8,575 million at a 3 percent discount rate, with a low estimate of \$4,837 million and a high estimate of \$12,378 million.

Over a 40-year time horizon, we estimate that the annualized costs will equal \$112 million at a 7 percent discount rate, with a low estimate of \$9 million and a high estimate of \$216 million, and \$102 million at a 3 percent discount rate, with a low estimate of \$5 million and a high estimate of \$200 million.

II. Table of Abbreviations/Commonly Used Acronyms

Abbreviation/acronym	What it means
AI/ANs	American Indians or Alaskan Natives.
ANPRM	Advance notice of proposed rulemaking.
CDC	Centers for Disease Control and Prevention.
CFR	Code of Federal Regulations.
CO	Carbon monoxide.
COPD	Chronic obstructive pulmonary disease.
CPS I	Cancer Prevention Study I.
CPS II	Cancer Prevention Study II.
ENDS	Electronic Nicotine Delivery Systems.
E.O.	Executive order.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FDA	Food and Drug Administration.
FR	Federal Register.
HHS	U.S. Department of Health and Human Services.
IARC	International Agency for Research on Cancer.
IOM	Institute of Medicine.
LCCs	Little cigars and cigarillos.
LGBTQ+	Lesbian, Gay, Bisexual, Transgender, or Queer.
MI	Myocardial Infarction.
MSS	Minnesota Student Survey.
MYTS	Minnesota Youth Tobacco Survey.
NATS	National Adult Tobacco Survey.
NCI	National Cancer Institute.
NHANES	National Health and Nutrition Examination Survey.
NHIS	National Health Interview Survey.
NHIS-LMF	National Health Interview Survey-Linked Mortality Files.
NRC	National Research Council.
NSDUH	National Survey on Drug Use and Health.
NYC	New York City.
NYTS	National Youth Tobacco Survey.
OMB	Office of Management and Budget.
PAH	Polycyclic aromatic hydrocarbon.
PATH	Population Assessment of Tobacco and Health.

Abbreviation/acronym	What it means
RYO	Roll-your-own.
SE	Substantial equivalence.
TPSAC	Tobacco Products Scientific Advisory Committee.
TUS-CPS	Tobacco Use Supplement to the Current Population Survey.
WHO	World Health Organization.
YPLL	Years of potential life lost.
YRBS	Youth Risk Behavior Survey.

III. Background

A. Need for the Regulation

FDA is proposing to prohibit characterizing flavors² (other than tobacco) in cigars. Specifically, FDA is proposing a product standard that would prohibit a cigar or any of its components or parts (including the tobacco, filter, or wrapper, as applicable) from containing, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco) or an herb or spice, including, but not limited to, strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, coffee, mint, or menthol that is a characterizing flavor of the tobacco product or tobacco smoke.

Use of cigars³ overall has increased in recent years. Since 2000, sales of cigars have doubled from approximately 6.2 billion cigars in 2000 to more than 14 billion cigars in 2019 (Refs. 1 and 2). Each year, an estimated 9,000 premature deaths are attributed to regular cigar smoking (defined in the study as smoking cigars on 15 or more of the past 30 days); approximately 5,200 of these premature deaths occur in regular cigar smokers who do not also smoke cigarettes (Ref. 3). It is estimated that cigar-attributable annual healthcare expenditures amount to \$1.8 billion per year (Ref. 4). Analysis of 2014–2015 data from the Tobacco Use Supplement to the Current Population Survey (TUS-CPS) found that adult flavored-cigar smokers had greater odds of daily cigar smoking and smoking within 30 minutes of waking than non-flavored cigar smokers, after adjusting for age, sex, race/ethnicity, and multiple tobacco product use (Ref. 5).

²For the purposes of this proposed rule, we are using the terms “flavoring” in a tobacco product, a tobacco product with “flavors,” or a “flavored tobacco product” to refer to a tobacco product with characterizing flavors, which is the subject of this proposed rule.

³Throughout this document, FDA uses the terms “traditional,” “conventional,” “regular,” “large,” “little,” “filtered,” and “cigarillo” when discussing different types of cigars. FDA relies on the specific term used by researchers when citing a specific study. FDA uses the term “cigar” when not citing a specific study.

As discussed in section IV.B of this document, youth consumption of cigars is substantial, and nicotine dependence in cigar smokers could result from even a limited exposure to nicotine during adolescence (Ref. 6). According to the 2020 NYTS, an estimated 960,000 middle and high school students, including 5 percent (an estimated 770,000) of high school students (grades 9–12) and 1.5 percent (an estimated 180,000) of middle school students (grades 6–8), had smoked a cigar (cigar, cigarillo, or little cigar) on at least 1 day during the past 30 days (Ref. 7). Overall, the prevalence of cigar smoking among middle and high school students is comparable to the prevalence of cigarette smoking, with 4.6 percent (an estimated 710,000) of high school students and 1.6 percent (an estimated 190,000) of middle school students having smoked cigarettes on at least 1 day during the past 30 days (Ref. 7). For non-Hispanic Black⁴ students, cigar smoking prevalence (6.5 percent) is considerably greater than cigarette smoking (2.5 percent) (Ref. 7). Of particular concern is the number of youth smoking cigars with characterizing flavors. According to 2020 NYTS data analyzing flavored cigar use among youth, 58.3 percent of youth cigar smokers, or approximately 550,000 youth, reported using a flavored cigar during the past 30 days (Ref. 8).

Characterizing flavors in cigars and other tobacco products reduce the harshness, bitterness, and astringency of tobacco during inhalation and soothe irritation during use (Refs. 9–11). Characterizing flavors thus increase the youth⁵ appeal of those tobacco products

⁴Throughout this document, FDA uses both the terms “Black” and “African American.” The term “African American” is used to describe or refer to a person of African ancestral origins or who identifies as African American. “Black” is used to broadly describe or refer to a person who identifies with that term. Though both of these terms may overlap, they are distinct concepts (e.g., a Black person may not identify as African American). As a result, FDA relies on the specific term used by researchers when citing to specific studies. FDA uses the term “Black” when not citing to a specific study.

⁵Though age ranges for youth and young adults vary across studies, in general, “youth” or “adolescent” encompasses those 11–17 years of age, while those who are 18–25 years old are considered

and promote youth initiation, resulting in an increased likelihood that youth and young adults experimenting with flavored cigars will become addicted and progress to regular smoking (see sections IV.D and IV.E of this document). Recent evidence from an analysis of data from Wave 5 of the Population Assessment of Tobacco and Health (PATH) Study⁶ (2018–19) demonstrates that over half of youth (aged 12–17 years) who used cigars in the past 30 days identified flavors as a reason for use (Ref. 12). In addition, research has shown that characterizing flavors in tobacco products can trigger reward pathways in the brain that are responsible for reward-related learning, which may increase the attractiveness of flavored products to consumers and the probability of repeated use (Refs. 13–15).

FDA’s experience with manufacturers’ historical practices as well as the prohibition of characterizing flavors, other than menthol, in cigarettes (section 907(a)(1)(A) of the FD&C Act; 21 U.S.C. 387g(a)(1)(A)) is instructive for purposes of evaluating cigars’ characterizing flavors and this proposed product standard. Reflective of the appeal that flavored tobacco products have for youth and young adults, internal tobacco industry documents attest to cigar manufacturers’ historical practices of adding characterizing flavors to diminish the harshness of tobacco products’ taste with specific intent to appeal to young consumers (Refs. 16 and 17). Tobacco industry practices reflect the fact that non-tobacco flavors appear to enhance youth appeal (Refs. 9–11). Researchers have concluded that tobacco companies have engaged in a “calculated effort to blur the line between LCCs [little cigars and

“young adults” (even though, developmentally, the period between 18–20 years of age is often labeled late adolescence); those 26 years of age or older are considered “adults” or “older adults” (Ref. 17).

⁶The PATH Study is a collaboration between the Center for Tobacco Products, FDA and the National Institute on Drug Abuse, National Institutes of Health. It was launched in 2011 to inform FDA’s regulatory activities under the Tobacco Control Act. The PATH Study is an ongoing longitudinal cohort study on tobacco use behavior, attitudes and beliefs, and tobacco-related health outcomes. More information can be found at: <https://www.icpsr.umich.edu/web/NAHDAP/series/606>.

cigarillos] to increase appeal to cigarette smokers, and the use of flavours facilitated these efforts” (Ref. 16).

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act; Pub. L. 111–31) prohibited, among other things, cigarettes with characterizing flavors other than tobacco or menthol. In 2009, when the Act was passed, national cross-sectional data suggested that the use of flavored cigarettes was most prevalent among younger smokers (Ref. 18), which caused concern that the availability of flavored cigarettes was contributing to youth tobacco use (Ref. 19). Additional evidence available at that time showed that younger tobacco users and nonusers had greater positive expectancies (*e.g.*, beliefs that smoking will enhance positive affect and control weight) for flavored cigarettes compared to non-flavored cigarettes (Ref. 20), a finding that was consistent with evidence from internal industry documents showing that tobacco product manufacturers targeted flavored cigarettes toward young populations (Refs. 9, 10, and 21). Moreover, the Surgeon General has concluded that most smokers try, and become addicted to, cigarettes before adulthood (Ref. 17) and that smoking causes severe disease, disability, and death (Refs. 22 and 23).

As with cigarettes, first cigar use often occurs during youth or young adulthood (Refs. 24 and 25). In a cross-sectional analysis of data collected between 2011 and 2017 as part of a longitudinal study, among almost 10,000 young adult college students who had ever used cigars, the mean age of first cigar use was 13.6 years (Ref. 24). A longitudinal analysis of Waves 1–4 (2013–2017) of PATH Study data found the proportion of youth who initiate cigar use increases considerably between ages 15 and 20 years (Ref. 25). Whereas only 1.5 percent of 15-year-olds in the PATH Study (2013–2017) had ever used any cigar (*i.e.*, cigarillo, filtered cigar, or traditional cigar), by age 20, 31 percent had ever used any cigar, with the greatest increase in first use between 17 and 18 years of age (Ref. 25). Similarly, an analysis of harmonized data from five large national surveys found a consistent peak in cigar initiation among individuals aged 17–19 years (Ref. 26). The consistency of this age of initiation across all five studies increases the confidence in this finding and suggests cigar initiation extends into young adulthood (Ref. 26). A longitudinal study of Waves 1–3 (2013–2016) of PATH Study data found that 9.0 percent of youth (aged 12–17 years) and 12.0 percent of young adults (aged 18–24 years) started using cigars for the

first time between Wave 1 (2013–2014) and Wave 3 (2015–2016) (Ref. 27). In comparison, 3.3 percent of adults over 25 years old initiated cigar use in the same time period (Ref. 27). Study findings also indicate racial and ethnic disparities in cigar product use. Non-Hispanic Black youth were 47 percent more likely to initiate past 30-day cigarillo or filtered cigar use at earlier ages compared to non-Hispanic White youth (Ref. 25).

We also know that a majority of youth and young adults initiate with a flavored cigar compared to older adults based on data from Wave 5 (2018–2019) of the PATH Study (Ref. 12) and that first use of flavored cigars is associated with continued use of these products (Refs. 28 and 29). In a longitudinal analysis of Waves 1–4 (2013–2017) PATH Study data, youth whose first cigar was either a mint or menthol cigar or an “other” flavored cigar (*e.g.*, fruit, alcohol, chocolate, candy, and other flavor) were more likely to be a past-30-day cigar user at a subsequent wave (approximately 1 year later) compared to those who first used a non-flavored cigar. Similarly, young adults (aged 18–24 years) who first used a mint or menthol cigar or other flavored cigar were more likely to be a past-30-day cigar user at a subsequent wave compared to those first using a non-flavored cigar (Ref. 29).

Similar to cigarettes with characterizing flavors, cigars with characterizing flavors expose users to the highly addictive chemical nicotine and other toxic and carcinogenic chemicals found in combusted tobacco products. Little cigars, in particular, deliver similar (and sometimes higher) levels of nicotine, as well as similar (and sometimes higher) levels of carcinogens, compared to cigarettes (Refs. 30 and 31). People who smoke cigars regularly are at increased risk for many of the same diseases as cigarette smokers, including oral, esophageal, laryngeal, and lung cancer; cardiovascular diseases; and chronic obstructive pulmonary disease (COPD) (Ref. 32).

In particular, youth and young adult exposure to the nicotine in cigars can result in negative health effects. Exposure to nicotine can disrupt brain development, which continues through approximately age 25, and may lead to long-term adverse consequences for cognitive function into adulthood (Ref. 33). Nicotine exposure in adolescence may have lasting implications and can result in decreased attention, increased impulsivity, and various lasting mental health conditions (Ref. 34). Nicotine is highly addictive. Using nicotine in

adolescence may increase risk for future addiction to other drugs (Ref. 33).

FDA finds that this product standard is appropriate for the protection of the public health because it would reduce the appeal of cigars, particularly to youth and young adults, by eliminating flavorings that increase appeal, reduce the harshness and bitterness of cigars, and make them easier to smoke, thereby decreasing the likelihood that both nonusers would experiment with cigars and that current experimenters would continue to use cigars, as further discussed in sections IV.D and IV.E of this document. Furthermore, FDA finds that this product standard would decrease the likelihood that both nonusers and current experimenters would be exposed to the toxic and carcinogenic chemicals in cigars, develop nicotine dependence, and progress to regular tobacco use, as further discussed in sections IV.E and V.B of this document. Additionally, as discussed in section VI.B of this document, the proposed product standard could improve the health of current flavored cigar smokers by increasing their likelihood of smoking cessation or reduction. The population health benefits of the proposed product standard are discussed in detail in section VI of this document. Thus, based on the information discussed in the following sections of this document, FDA finds that the proposed tobacco product standard would be appropriate for the protection of the public health.

Reducing the appeal and use of cigars by eliminating characterizing flavors (other than tobacco) also is expected to substantially decrease tobacco-related health disparities and to equitably promote health across population groups. Tobacco-related health disparities are the differences observed in population groups regarding: the patterns (*e.g.*, initiation, dual or polyuse, cessation), prevention, and treatment of tobacco use; the risk, incidence, morbidity, mortality, and burden of tobacco-related illness; and capacity and infrastructure (*e.g.*, political systems, educational institutions), access to resources (*e.g.*, access to health services and programs), and environmental secondhand smoke exposure (Refs. 35–37). Tobacco-related health disparities affect those who have systematically experienced greater obstacles to health based on group membership due in part to the inequitable distribution of social, political, economic, and environmental resources (Refs. 37–39). Health equity is the attainment of the highest level of health for all people (Ref. 39). It is achieved by equally valuing all

individuals regardless of group membership; removing social, economic, and institutional obstacles to health; and addressing historical and contemporary injustices (Refs. 39–41). The advancement of health equity is integral to the reduction and elimination of tobacco-related health disparities, which affect those who have been denied opportunity and access to economic, political, and social participation. Members of underserved communities⁷ experience a disproportionate burden of cigar use in initiation, prevalence of use, current use, and frequency of use (see section V.A of this document), leading to observed tobacco-related health disparities within those communities. Such disparities in cigar use contribute to higher rates of observed tobacco-related morbidity and mortality among underserved communities and vulnerable populations,^{8,9} such as youth and young adults, some racial and ethnic populations, those with lower household income and educational attainment, and individuals who identify as lesbian, gay, bisexual, transgender, or queer (LGBTQ+),¹⁰ as further discussed in section V.F of this document. This proposed product standard is anticipated to promote better

⁷ As defined by Executive Order (E.O.) 13895, “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,” (86 FR 7009, January 25, 2021) the term “underserved communities” refers to populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life. In the context of tobacco products and tobacco-related health disparities, such communities may include populations disproportionately impacted by marketing and promotion targeted on the basis of such shared characteristics.

⁸ Throughout this document, the term “vulnerable populations” refers to groups that are susceptible to tobacco product risk and harm due to disproportionate rates of tobacco product initiation, use, burden of tobacco-related diseases, or decreased cessation. Examples of vulnerable populations include those with lower household income and educational attainment, certain racial or ethnic populations, individuals who identify as LGBTQ+, underserved rural populations, those pregnant or trying to become pregnant, those in the military or veterans, or those with behavioral health conditions.

⁹ Underserved communities are overrepresented in vulnerable populations.

¹⁰ Throughout this document, FDA uses the term “LGBTQ+” broadly when referring to lesbian, gay, bisexual, transgender, and queer (and other) communities. When we describe findings from the published literature, we refer specifically to the groups that are studied. For example, some authors examine tobacco-related outcomes for members who identify as lesbian, gay, bisexual, or transgender (LGBT) only; as such, the data are limited to those who identify as LGBT, and authors interpret the findings for those specific groups.

public health outcomes across population groups.

B. Relevant Regulatory History

In its implementation of the Tobacco Control Act over the past several years, FDA has engaged in close study and careful consideration of the scientific evidence and complex policy issues related to flavored tobacco products. FDA has issued an advance notice of proposed rulemaking (ANPRM) to solicit data and information about the roles of flavors in tobacco products, sponsored research on a variety of cigar- and flavors-related topics through contracts and interagency agreements with Federal partners, including the National Institutes of Health (NIH),¹¹ and undertaken its own scientific review related to the impact of characterizing flavors in cigar products. Among other things, FDA has considered the comments and information received in response to the ANPRM and scientific review in developing this proposed rule.

1. ANPRM

In July 2017, FDA announced a comprehensive approach to tobacco and nicotine regulation to protect youth and reduce tobacco-related disease and death (Ref. 42). As part of the public dialogue on the comprehensive approach, in March 2018, FDA issued three ANPRMs related to the regulation of nicotine in combustible cigarettes (83 FR 11818, March 16, 2018), flavors (including menthol) in tobacco products (83 FR 12294, March 21, 2018) (Flavors ANPRM), and premium cigars (83 FR 12901, March 26, 2018). In addition, FDA announced the availability of a draft concept paper, entitled “Illicit Trade in Tobacco Products after Implementation of a Food and Drug Administration Product Standard,” and sought public comment (83 FR 11754, March 16, 2018). This paper analyzes the potential for illicit trade markets to develop in response to a tobacco product standard (Ref. 43).

The Flavors ANPRM requested data and information about the role that flavors play in tobacco products (83 FR 12294). Specifically, the Flavors ANPRM requested comments, data, research results, or other information about, among other things, how flavors attract youth to initiate tobacco product use. While the Flavors ANPRM discussed potential product standards and a range of product types, it also specifically requested public input on

¹¹ Information on specific projects supported by FDA is available at <https://www.fda.gov/tobacco-products/tobacco-science-research/research> (search “cigars” or “flavors”).

the role of flavors in cigars. FDA received over 525,000 comments on the Flavors ANPRM, a large proportion of which were form letters related to 61 different organized campaigns. Five of these campaigns, which included a combined total of approximately 329,668 comments, were identified as being automatically generated “bot” comments. Some of the issues raised in the comments to the ANPRM are highlighted below.

Comments generally in support of the regulation of flavors in tobacco products stated that a product standard prohibiting the use of flavors in tobacco products would be appropriate for the protection of the public health. In particular, many comments argued that such a tobacco product standard would be appropriate for the following reasons: (1) To protect youth and young adults from becoming tobacco product users; (2) to prevent widened appeal of tobacco product use; and (3) to discourage addiction to tobacco products. FDA received many comments expressing concern about the use of flavors to capture new users, particularly children, into lifelong nicotine addiction by making tobacco products more appealing and/or palatable. Citing internal tobacco industry documents that have since been made public, many commenters, including several public health advocacy groups, some professional associations, and multiple State attorneys general, pointed out that the industry has a long and well-established history of deliberately targeting children through the development and/or marketing of flavored tobacco products.

FDA received many comments in support of the regulation of flavors in cigar products, specifically. These comments often noted that flavors are frequently added to cigars for the express purpose of making harsh products more palatable to new users. Citing national survey data trends and various recent studies, these commenters often noted that youth and young adults report flavors as a key reason for their use of cigars, including little cigars and cigarillos (LCCs), and that a substantial percentage of youth cigar smokers exclusively use flavored cigars.

FDA also received comments from individuals and representatives from the tobacco industry generally opposing the regulation of flavored tobacco products. These comments generally stated that such regulation was not likely to decrease the appeal of such tobacco products to youth nor have positive effects for society at large. Some comments opposed to a tobacco product

standard addressing flavors in cigars, specifically, stated that FDA had not presented the scientific basis for such a product standard, noting what they characterized as gaps in the scientific literature regarding usage patterns and consumer perceptions of flavored cigars, particularly among youth. Other comments from tobacco industry representatives conclude that any tobacco product standard for flavors in cigars should exclude premium cigars.

Many comments received from industry noted concern with how FDA would define “characterizing flavors,” arguing that any such definition must use clear and science-based criteria. Some comments argued that, without a definition for “characterizing flavors,” it could be difficult for industry to comply with a tobacco product standard. FDA also received comments in support of regulation suggesting that FDA define “characterizing flavor” in a way that makes the prohibition clear to manufacturers and retailers, protects public health, and prevents manufacturers from evading the intent of the product standard.

FDA has reviewed and closely considered the comments to the Flavors ANPRM, as well as additional evidence and information not available at the time of the Flavors ANPRM, in developing this proposed rule.

2. Scientific Review

As the body of evidence continues to grow, FDA recently undertook a review of the scientific evidence regarding the role characterizing flavors play in increasing the appeal and use of tobacco products, particularly cigars, among youth, young adults, and adults in the United States. This review, entitled “Scientific Assessment of the Impact of Flavors in Cigar Products,” summarizes findings from the peer-reviewed, publicly available scientific literature organized around three research questions: (1) How does the addition of characterizing flavors to tobacco products, including cigars, impact product appeal and product use; (2) how do characterizing flavors impact youth and young adult experimentation with tobacco products, including cigars, and do they make progression to regular tobacco use more likely; and (3) what impact do local and national policies restricting the sale of flavored cigars and other flavored tobacco products have on cigar sales and use? The “Scientific Assessment of the Impact of Flavors in Cigar Products” has been peer reviewed by independent external experts. Taking into consideration comments from this peer review (Ref. 44), FDA revised the scientific assessment, and the final peer-

reviewed scientific assessment is available in the docket for this proposed rule (Ref. 45). This scientific assessment informed the development of this proposed product standard.

C. Legal Authority

1. Product Standard Authority Generally

The Tobacco Control Act was enacted on June 22, 2009, amending the FD&C Act and providing FDA with the authority to regulate tobacco products. Section 901 of the FD&C Act (21 U.S.C. 387a) granted FDA the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own tobacco (RYO), and smokeless tobacco to protect the public health and to reduce tobacco use by youth. The Tobacco Control Act also gave the Agency authority to conduct rulemaking to “deem” any other tobacco products subject to chapter IX of the FD&C Act. In 2016, FDA issued a final rule deeming products meeting the statutory definition of “tobacco product” (including cigars), except accessories of the newly deemed products, to be subject to chapter IX of the FD&C Act, as amended by the Tobacco Control Act (81 FR 28974) (deeming final rule).

Among the tobacco product authorities provided to FDA is the authority to adopt tobacco product standards where FDA determines that such standard is appropriate for the protection of the public health (section 907(a)(3) of the FD&C Act). To establish a tobacco product standard, section 907(a)(3)(A) and (B) of the FD&C Act requires that FDA find that the standard is appropriate for the protection of the public health, taking into consideration scientific evidence concerning:

- The risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;
- The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
- The increased or decreased likelihood that those who do not use tobacco products will start using such products.

2. Authority To Prohibit Characterizing Flavors in Cigars

Section 907 of the FD&C Act authorizes FDA to issue tobacco product standards that are appropriate for the protection of the public health, including provisions that would require the reduction or elimination of a constituent (including a smoke constituent), or harmful component of

tobacco products and provisions respecting the construction, components, ingredients, additives, constituents (including smoke constituents), and properties of the tobacco product (section 907(a)(3), (a)(4)(A)(ii), and (a)(4)(B)(i) of the FD&C Act). This includes the authority to issue a new product standard prohibiting characterizing flavors in tobacco products pursuant to section 907(a)(3) and (4) and to amend or revoke an existing product standard pursuant to section 907(d)(4) of the FD&C Act. Section 907(a)(4)(B)(v) also authorizes FDA to include in a product standard a provision restricting the sale and distribution of a tobacco product to the extent that it may be restricted by a regulation under section 906(d) of the FD&C Act.

Pursuant to section 907(a)(3) and (c) of the FD&C Act, FDA is proposing this product standard that would require the elimination of characterizing flavors (other than tobacco) from cigars, because it would reduce the disease, disability, and death caused by tobacco use, and FDA has found the standard to be appropriate for the protection of the public health consistent with section 907(a)(3), (a)(4)(A)(ii), and (a)(4)(B)(i) of the FD&C Act. In addition, this proposed rule would prohibit the distribution, sale, and offer for distribution or sale of cigars with characterizing flavors (other than tobacco). Because this sale and distribution restriction would assist FDA in enforcing the standard and would ensure that manufacturers and retailers are selling product that complies with the standard, the Agency has found such restriction to be appropriate for the protection of the public health consistent with sections 907(a)(4)(B)(v) and 906(d) of the FD&C Act. FDA’s analysis showing that the proposed tobacco product standard is appropriate for the protection of the public health is discussed in section VI of this document.

FDA is proposing this product standard under the authorities discussed previously, along with section 701 of the FD&C Act, which provides FDA with the authority to “promulgate regulations for the efficient enforcement of this Act.”

D. FDA’s Consideration of Health Equity

Advancing health equity is a policy priority and an important component of fulfilling FDA’s mission to protect and promote public health. FDA and the Federal Government now recognize the advancement of health equity as “both a moral imperative and pragmatic policy,” as E.O. 13995 states.

Considerations related to health equity helped inform FDA's decision to prioritize this proposed product standard. In particular, FDA took into account the disproportionate toll flavored cigars have taken on certain population subgroups. We note that the expected health benefits of this proposed standard are expected to be greater in these subgroups than in the population more generally.

This proposed product standard easily clears the threshold of being appropriate for the protection of the public health, due to the large health benefits from the expected reduced initiation and increased cessation when looking at the population generally. We make this finding even without taking into account the specific expected greater health benefits from this product standard among certain population subgroups.

IV. Characterizing Flavors Impact Cigar Use, Particularly Among Youth and Young Adults

A. Recent Market Trends of Flavored Cigars in the United States

Congress passed the Tobacco Control Act in 2009 to address the premature death, disease, and other serious health conditions caused by tobacco use. The Tobacco Control Act gave FDA a mandate to reduce tobacco product dependence and use, particularly among youth (see section 3(2) and (9) of the Tobacco Control Act). Of particular importance for this proposed product standard, the Tobacco Control Act established a ban on characterizing flavors (other than tobacco or menthol) in cigarettes (section 907(a)(1)(A) of the FD&C Act). The legislative history of the Tobacco Control Act reflects that the goal of the Act's cigarette characterizing flavor ban was to eliminate one emerging group of tobacco products that was particularly appealing to youth (Ref. 46 at 37–38). Congress determined that banning cigarettes with characterizing flavors would benefit youth because flavored cigarettes were typically used by individuals experimenting with tobacco products, such as youth, and noted that such products were not typically used by regular adult smokers (Ref. 46 at 37–38). In 2009, FDA issued guidance on the statutory provision (see General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-questions-and-answers-ban-cigarettes-contain-certain-characterizing-flavors-edition-2>),

noting that “flavored products make it easier for new smokers to start smoking by masking the unpleasant flavor of tobacco” and that “[r]emoving these flavored products from the market is important because it removes an avenue that young people can use to begin regular tobacco use.” Research and data concerning the impact of Congress's decision to ban flavored cigarettes are instructive for purposes of evaluating cigars' characterizing flavors and this proposed product standard.

After the ban on characterizing flavors in cigarettes became effective, researchers noted that certain products previously marketed as cigarettes likely were modified or rebranded as “cigars” so that they could remain on the market in flavored varieties (e.g., Ref. 47). Little cigars are often indistinguishable from cigarettes given their shape, size, filters, and packaging (Refs. 48 and 49). An analysis of NYTS data from middle and high school students between 1999 and 2013 found that cigar use rose 34.4 percent following the ban on characterizing flavors in cigarettes (Ref. 50). The analysis found an overall decrease of 17 percent in the prevalence of youth cigarette smoking, fewer cigarettes smoked per month, and, despite the rise in cigar use, an overall reduction of 6 percent in the probability of using any type of tobacco (Ref. 50). A review of publicly available internal documents from a clove cigarette company found that the company started to develop a clove cigar product in 2007 in anticipation of the Tobacco Control Act and its ban on cigarettes with characterizing flavors, including clove-flavored cigarettes (Ref. 47). According to these documents, the goal was to be prepared for a product transition to allow for continual marketing of a clove-flavored combusted tobacco product (Ref. 47). Immediately following the prohibition on cigarette characterizing flavors, sales of clove cigars increased more than 1,400 percent between 2009 and 2012 (Ref. 47), strongly suggesting that users of clove cigarettes switched to clove cigars on the basis of flavor availability.

A similar trend in modifying or rebranding of products has been seen in several U.S. jurisdictions¹² where laws have been enacted to further restrict the sale of flavored tobacco products, including cigars. Subsequent to these restrictions on the sale of flavored tobacco products, researchers have noted the emergence of “concept” flavored named products that include

ambiguous names that imply flavor but do not explicitly indicate any particular flavor on the products labeling or packaging (e.g., purple, tropical sunset) (Refs. 51 and 52). Sales of concept flavors (e.g., sweet, jazz) increased from 2.2 percent of U.S. flavored cigar sales in 2009 to 21.4 percent of U.S. flavored cigar sales in 2020, a 33 percent average annual percentage change (Ref. 53).

Flavored cigars continue to maintain a substantial share of the cigar market. Researchers analyzing Nielsen data trends found that cigar dollar and unit sales in convenience stores increased by 23 percent and 50 percent, respectively, between 2008 and 2015, and that flavored cigar dollar sales—including, for example, those with characterizing flavors such as chocolate, mint, or rum—increased by 46.5 percent (Refs. 54 and 55). A more recent study also found that flavored cigar sales increased substantially between 2009 and 2020, while non-flavored cigar sales did not change (Ref. 53). Another study analyzing trends in cigars using Nielsen data found that during January 2016 to June 2020, monthly cigarillo unit sales, which represented 94.2 percent of total cigar unit sales during the study period, increased from about 131 million to 190 million (Ref. 56). Additionally, proprietary data gathered by Euromonitor International in March 2021 reveals that, in 2020, flavored cigars, including flavored cigarillos, accounted for approximately 19.1 percent of all cigar U.S. dollar sales and 41.9 percent of all cigar unit sales, suggesting that the average price of a single unit of flavored cigar was lower than that of a single unit of tobacco-flavored cigar in 2020.

Data suggest that due to both Congress's prohibition on cigarettes with characterizing flavors and the pressure placed on price-sensitive smokers (i.e., those smokers whose smoking behaviors change based on the cost of tobacco products) by increased taxation of cigarettes resulting from the 2009 Children's Health Insurance Program Reauthorization Act (Pub. L. 111–3), some price-sensitive cigarette smokers smoke cigars as a flavored, less expensive alternative to cigarettes (Ref. 57). In addition, the popularity of cigar products among young adults may be due to their lower price relative to cigarettes, lack of minimum pack size requirements, and exclusion from the advertising restrictions of the Tobacco Master Settlement Agreement (Ref. 54). Findings from a survey study indicated that affordability and flavors were the most commonly cited reasons for little cigar and cigarillo use among White and

¹²For more information on U.S. localities and the implementation of flavored tobacco product restrictions, see section IV.F of this document.

Black young adult ever users and past 30-day users (Ref. 58).

Given the current market share of flavored cigar products, research demonstrating how sales of flavored cigars increased in the years following the removal of flavored cigarettes, and how industry contributed to these shifts by marketing clove-flavored cigars nationally and introducing concept flavors, FDA is proposing to prohibit characterizing flavors (other than tobacco) in cigars to prevent youth and young adults from entering the market and progressing from experimentation to regular use of these products, and to promote cessation among existing users of these products.

B. Over Half a Million Youth, and Even More Young Adults, in the United States Use Flavored Cigars

Widespread use of flavored cigars by youth supports FDA's determination that this proposed rule would have a considerable positive impact on public health. Using NYTS 2020¹³ data, researchers estimated that approximately 960,000 U.S. middle and high school students had smoked a cigar in the prior month (Ref. 7). Overall, the prevalence of cigar smoking among middle and high school students is comparable to cigarette smoking, and for non-Hispanic Black students, cigar smoking prevalence (6.5 percent) is considerably greater than cigarette smoking (2.5 percent) (Ref. 7). In 2019, not excluding use of other tobacco products, more young adults tried a cigar for the first time each day than tried a cigarette for the first time (3,163 cigar vs. 2,640 cigarette) (Ref. 59 at Table A.3A). As discussed throughout this proposed rule, evidence is well documented of broad youth and young adult use of cigars and the reasons cited for their use. In addition, local policy evaluation studies of restrictions on the sale of flavored tobacco products, including cigars, found a decrease in overall tobacco use by youth (Refs. 51 and 60–62), further supporting the conclusion that prohibiting the use of characterizing flavors (other than tobacco) in cigars is likely to result in less cigar use and less tobacco product use overall, especially among youth and young adults.

Studies indicate that a substantial percentage of youth cigar users smoke flavored cigars. Data from Wave 5

(2018–2019) of the PATH Study indicate that among youth (aged 12–17 years) 44.0 percent of past 30-day cigar smokers reported using flavored cigars (*i.e.*, 33.9 percent of youth traditional cigar smokers, 46 percent of youth cigarillo users, and 50.2 percent of youth filtered cigar users reported past 30-day use of a flavored cigar) (Ref. 63). Data from the 2020 NYTS indicate that 58.3 percent of middle and high school students who smoke cigars (or approximately 550,000 youth), reported using a flavored cigar during the past 30 days (Ref. 8). The majority of youth cigar smokers identify the availability of cigar flavors as a leading reason for their cigar use (Refs. 64 and 65).

The data indicate a similar preference for flavors among young adults. According to Wave 5 (2018–2019) data from the PATH Study, approximately 630,000 young adults aged 18 to 24 years reported past month flavored cigar smoking (Ref. 63). An analysis of Wave 5 (2018–2019) PATH Study data indicated that among young adults (aged 18–24 years) who used cigars some or every day, 54.1 percent of traditional cigar users, 66.5 percent of cigarillo users, and 65.1 percent of filtered cigar users reported flavoring as a reason for cigar use (Ref. 12). Among young adult past 30-day cigar smokers 18–24 years old, 38.3 percent reported that the cigar product they smoked in the past 30 days was flavored (*i.e.*, 17.7 percent of young adult traditional cigar smokers, 46 percent of young adult cigarillo users, and 41 percent of young adult filtered cigar users reported past 30 day use of a flavored cigar) (Ref. 63). Since the brain continues development into an individual's mid-twenties, cigar use in both youth and young adulthood can harm the developing brain (Ref. 33). As discussed in section V.C of this document, nicotine can disrupt brain development and have long term consequences.

Studies illustrate some disparities in young adult flavored cigar use across population groups. Among a sample of college students aged 18–29 who used cigars in the past 30 days (n=523), Black, Asian, and Hispanic young adults were all significantly more likely to have used flavored cigars than White young adults (Ref. 66). Participants aged 18–24 years also had greater odds of using flavored cigars compared to participants aged 25–29 years (Ref. 66). Lastly, young adults who identified as lesbian, gay, or bisexual had higher odds of reporting past 30-day flavored large cigar and LCC use compared to respondents who identified as straight/heterosexual (Ref. 67).

The data also show that a substantial percentage of youth and young adult cigar users initiate with flavored cigars. Data from Wave 5 (2018–2019) of the PATH Study revealed that 60.4 percent of the youth participants (aged 12–17 years) and 63.2 percent of young adults (aged 18–24 years) who reported ever using cigars said that the first cigar they used was flavored, statistically significantly higher than the 41.9 percent of adults (aged 25 years and older) who have ever used cigars (Ref. 12).

C. Adult Use of Flavored Cigars in the United States

While the evidence is clear that youth and young adults use flavored cigars, it is important to note that older adults also use them. According to Wave 5 data (2018–2019) from the PATH Study, 36.0 percent of adult cigar smokers (adults aged 25 years and older who used cigars in the past 30 days), or over 3 million adults, reported use of a flavored cigar in one or more of the past 30 days (Ref. 63). When considering the type of cigar, reported use of a flavored cigar in the past 30 days occurred less frequently for adult traditional cigar smokers (19.7 percent) compared with adult smokers of all other cigar types (46.5 percent for cigarillos and 48.7 percent for filtered cigars) (Refs. 63).

Many adult cigar consumers also identify the availability of characterizing flavors as a reason for their cigar use. Among adults over 25 years old who used cigars every or some days, 54.8 percent of traditional cigar users, 69.6 percent of cigarillo users, and 71.4 percent of filtered cigar users reported flavoring as a reason for cigar use (Ref. 12). Among adults, studies suggest males are more likely than females to use cigars, with some differences across cigar types (Refs. 63, 66, 68, and 69). However, among cigar users, females are more likely to use flavored cigars. For example, a study of college students aged 18–29 years who had used cigars in the past 30 days found that 60.5 percent of cigar users were male, but, among cigar users, males were statistically significantly less likely to have used flavored cigars than females (Ref. 66). Likewise, in every wave of the PATH Study, adult males were more likely to use any cigar in the past 30 days, but among past-30-day cigar users, females were statistically significantly more likely to have used flavored cigar products (Ref. 63).

Furthermore, there are differences in adult use of flavored cigars across population groups. Among adults who were past-30-day users of any cigar type,

¹³The 2020 NYTS is a survey that was conducted after the Federal law went into effect prohibiting sales of tobacco products to those under the age of 21 (Further Consolidated Appropriations Act, 2020, Public Law 116–94, section 906(d) of the FD&C Act), thus potentially capturing some of the impacts of the new law.

non-Hispanic Black adults were statistically significantly more likely to have used a flavored cigar in the past 30 days compared to non-Hispanic White adults at every survey wave of the PATH Study (2013–2019) (Ref. 63). Likewise, at every wave of the PATH Study, among adults aged 25 years and older who had smoked cigars in the past 30 days, individuals with a college degree were statistically significantly less likely to use a flavored cigar (20.0 percent) than individuals categorized as having less than a high school diploma (44.9 percent), a high school diploma (37.4 percent), or some college (42.9 percent) (Ref. 63). Using 2009–2010 National Adult Tobacco Survey (NATS) data, adults who identified as lesbian, gay, bisexual, or transgender were also more likely to use flavored cigars (8.2 percent) compared to the national prevalence (2.8 percent) (Ref. 70).

This proposed rule, if finalized, could lead adult flavored cigar smokers to cease tobacco use, reduce tobacco use, or encourage them to switch to other, potentially less harmful tobacco products.

D. Characterizing Flavors Increase Appeal and Make Tobacco Products, Including Cigars, Easier To Use

Characterizing flavors increase the appeal of cigars and make them easier to use. Characterizing flavors are added to tobacco products, including cigars, for numerous reasons that relate to product appeal, such as to ensure pleasant flavor and taste; to reduce the harshness, bitterness, and astringency of tobacco during inhalation; and to soothe irritation during product use (Refs. 9–11). As documented by the Surgeon General, tobacco product manufacturers have historically added characterizing flavors to products with lower levels of free-nicotine content (*i.e.*, those products that have lower amounts of nicotine easily absorbed by the user) intended for use as “starter products” for new tobacco users (Ref. 17).

In particular, the addition of menthol as a characterizing flavor in combusted tobacco products, including cigars, can soothe irritation and increase appeal. Menthol is a flavor compound that when added to combusted tobacco products produces a minty taste and cooling sensation when inhaled (Ref. 71). Smokers report that mentholated products have a better taste, are smoother and more refreshing (Refs. 72–74). Menthol’s flavor and sensory effects reduce the harshness of smoking among new users and facilitates product use, particularly among youth and young adults (Refs. 29 and 74–76).

While much of the evidence on the role of flavors in increasing appeal focuses on cigarettes and tobacco products overall, internal industry documents also specifically discuss the role of flavors in cigars (Ref. 16). Internal tobacco industry documents illustrate cigar manufacturers’ historical practices of adding characterizing flavors to diminish the harshness of tobacco products’ taste with specific intent to appeal to young consumers (Refs. 16 and 17). A review of the Truth Tobacco Industry Documents, an archive of tobacco industry documents, showed that some flavors in cigars (*e.g.*, vanilla bean, peach, apricot, licorice, cocoa) may mask the bitterness of tobacco leaves, throat burn, and heavy taste, thereby facilitating inhalation, making smoking more tolerable for current users, and increasing palatability for new users. These documents illustrate that the effect of characterizing flavors in the appeal of other tobacco products is applicable to the effect of characterizing flavors in the appeal of cigar products. These documents also illustrate that the tobacco industry added flavors and changed some design characteristics of little cigars and cigarillos to facilitate inhalation and make smoking more tolerable for current smokers, as well as more palatable for new users, including youth (Refs. 16 and 77–79).

Flavors play an important role in attracting youth to tobacco products, including cigars (Refs. 55, 80, and 81). In survey and qualitative research, youth report that flavors in cigars are a leading reason for use. In 2018–2019 PATH Study data, 50.4 percent of youth participants (aged 12–17 years) who reported past 30-day cigar smoking identified flavors as a reason for use (Ref. 12). Results from qualitative research indicate that youth themselves acknowledge that flavorings impact their cigar use (Ref. 82). Similarly, some young adult participants mentioned that the flavors of little flavored cigars and cigarillos were particularly appealing, with one stating: “They taste basically like a strawberry. And I like the Tropical Fusion cause it’s like a coconut.” In a qualitative study involving focus groups of youth and young adults who used cigars (Ref. 83), the most appealing component of cigar packaging were aspects that indicated the flavor (*e.g.*, a flavor name or image), which was identified by nearly half of all participants, and participants indicated that the words describing the flavor (*e.g.*, “sweet”) were a reason to buy the product. In a qualitative study of adolescents (aged 15–18 years) (Ref.

84), both users of tobacco products (including users of cigars/cigarillos) and nonusers indicated flavors make tobacco products appealing and are a reason to use tobacco products. Participants indicated that both the taste and smell of flavored products were appealing (specifically mentioning minty, sweet, and fruit flavors) and noted that the smell of flavors could obscure the smell of tobacco.

Both younger and older adults similarly report flavors as a leading reason for cigar use. Among young adults (aged 18–24 years) in the PATH Study (2018–2019) who used cigars regularly and currently used cigars every or someday, 54.1 percent of current traditional cigar users, 66.5 percent of current cigarillo users, and 65.1 percent of current filtered cigar users reported flavoring as a reason for cigar use (Ref. 12). Likewise, adults aged 25 years and older report flavors as a leading reason for cigar use. Among adults aged 25 years and older in the PATH Study, 54.8 percent of current traditional cigar smokers, 69.6 percent of current cigarillo smokers, and 71.4 percent of current filtered cigar smokers reported flavoring as a reason for cigar use. There was not a statistically significant difference by age group in reporting flavors as a reason for use (Ref. 12).

Characterizing flavors increase susceptibility to use (a measure of how much individuals report being open or willing to use a tobacco product) in nonsmoking young adults, as documented in a 2020 study that tested cigarillo pack images containing the most popular characterizing flavors. Susceptibility to cigarillo use was statistically significantly greater among participants exposed to the packs with characterizing flavors (Ref. 85). Results from focus groups and semistructured interviews with 90 young adult past 30-day LCC-only, cigarette-only, and dual cigarette and LCC smokers provide insight about the appeal of characterizing flavors in certain cigars to youth and young adults (Ref. 82). Among study participants, the average age of initiation of LCC was 16.1 years, and nearly two-thirds of the participants reported first using an LCC that was flavored (Ref. 82). Participants frequently reported that smoking flavored LCCs relieved stress and that flavored LCC use sometimes depended on mood and was associated with boosted mood and gratification (Ref. 82). Participants frequently mentioned that flavored tobacco made smoking LCCs more palatable than smoking unflavored (or regular flavor) cigars (Ref. 82). For many participants, seeing or hearing the

phrase “little cigars or cigarillos” evoked thoughts about their favorite flavors (Ref. 82). In addition, for many participants, peers played an important role in continued experimentation because friends would often suggest flavors to one another (Ref. 82). Moreover, many participants stated that the appeal of the variety of available flavored LCCs on the market influenced their decision to try LCCs (Ref. 82). These studies indicate that flavors are an important factor in initiation and use of cigars among young adults.

Four systematic reviews of the scientific literature concluded that flavored tobacco products attract youth to the tobacco product (Refs. 86–89). Two of the systematic reviews included cigars and assessed studies on use and attitudes related to non-menthol flavored tobacco products (Refs. 88 and 89). The two reviews concluded that characterizing flavors were an appealing feature of tobacco products and that flavors influence perceptions, initiation, and progression to use of tobacco products, particularly among youth (Refs. 88 and 89).

The appeal of flavors in tobacco products, including cigars, is not only consistent across the literature on tobacco products, but is also consistent with the food literature. Physiologically, scientists have described how youth have a heightened preference for sweet food tastes and greater rejection of bitter food tastes; these preferences diminish with age (Refs. 90–93).

An FDA-funded scientific review of 474 articles published between 1931 and 2015 conducted to understand how youth and adults differ with respect to their preferences for characterizing flavors, primarily in food, concluded that preference for sweetness and saltiness is generally higher for children than it is for adults; and the level of sugar selected as most preferred in clinical experiments decreased between adolescence and adulthood (Ref. 94). The researchers hypothesized that the higher caloric needs of youth to sustain growth likely account for the more pronounced preference for sweetness in youth (Ref. 94).

Laboratory research has confirmed that the chemical-specific flavor sensory cues associated with fruit flavors in tobacco products are often the same as those found in popular candies (Refs. 95 and 96). While inhaling flavored chemicals is in many ways very different than ingesting flavored foods, researchers reviewed the levels of flavor chemicals in several brands of candy and Kool-Aid drink mix and concluded that the chemical amounts and combinations largely overlapped with

similarly labeled “cherry,” “grape,” “apple,” “peach,” and “berry” cigar and other tobacco products (Refs. 95 and 96).

Overall, FDA finds that evidence regarding the role of flavors in increasing appeal of cigars to youth and young adults, promoting progression to regular use, and increasing the addiction potential indicates that removing flavors from cigars would reduce initiation and use of such products, especially among youth and young adults. As a majority of adult regular tobacco users become dependent on or addicted to nicotine as youth and young adults, reducing initiation and use of cigar products in youth would reduce the likelihood that youth progress to nicotine dependence and regular use, as well as subsequent tobacco-related illness and death. Therefore, FDA anticipates that removing flavors from cigars would substantially reduce tobacco-related disease and death as a result of averted youth initiation.

E. Characterizing Flavors Increase Youth and Young Adult Experimentation With Tobacco Products, Including Cigars, and Make Progression to Regular Tobacco Use More Likely

Cigars are more commonly used among youth and young adults relative to other combusted tobacco products, including cigarettes. An analysis of PATH Study data found that new cigar use (*i.e.*, initiation since a prior wave of data collection) at Waves 2, 3, or 4 (2014–2017) was more common (14.5 percent youth, 19.7 percent young adults, 6.3 percent adults aged 25 and older) relative to new cigarette use (*i.e.*, initiation since a prior wave) (14.0 percent youth, 7.1 percent young adults, 1.1 percent adults aged 25 and older) (Ref. 29). Data from the 2019 National Survey on Drug Use and Health (NSDUH) found that each day 1,210 youth 12–17 years and 3,163 young adults aged 18 to 25 years tried a cigar for the first time (Ref. 59 at Table A.3A). In 2019, prevalence of past 30-day cigar use surpassed that of past 30-day cigarette use among U.S. high school students for the first time (Ref. 97). Flavors make tobacco products, including cigars, easier to use and reinforce tobacco use among youth and young adults. FDA finds that eliminating characterizing flavors (other than tobacco) in cigars would decrease the number of first-time users of cigars who progress to regular use.

The process of becoming a regular cigar smoker includes stages of experimentation, development of

nicotine dependence, and progression to regular use (Refs. 98 and 99). FDA finds that eliminating flavored cigar varieties would decrease the number of youth experimenting and the likelihood that youth will progress to regular, sustained use of tobacco products, and, thus, would reduce the risk of tobacco-related death and disease.

Experimentation with cigars can lead to nicotine dependence and regular use in less than one year. Longitudinal data from the nationally representative Truth Longitudinal Cohort (2014–2019) were used to examine the progression from cigar initiation to regular use among youth and young adults aged 15 to 25 years (Ref. 100). Nearly half (44.7 percent) of participants who initiated cigar use reported current (*i.e.*, past-30-day) cigar use 6 months after initiation (Ref. 100). Compared to participants who did not become past-30-day users 6 months after initiation, those who were past-30-day users engaged in a higher frequency of cigar use during the initial 6-month period, were younger, non-Hispanic African American, and were more likely to use other tobacco products. For example, non-Hispanic African American participants (relative to non-Hispanic White participants) had over twice the odds of past-30-day cigar use and had a higher average frequency of use (2.21 days/month vs. 1.34 days/month, respectively) 6 months after initiation of cigar use (Ref. 100).

Experimentation with flavored cigar use is associated with subsequent use. Another study used longitudinal data from Waves 1 (2013–2014) and 2 (2014–2015) of the PATH Study to assess whether there is a prospective association between first flavored use of a tobacco product and subsequent use of that specific product (Ref. 28). This analysis found that first use of any flavored cigar or first use of flavored cigarillos and filtered cigars (including menthol) at Wave 1 (2013–2014) of the nationally representative PATH Study was subsequently associated with daily or nondaily use of these products in young adults (aged 18–24 years) and adults (aged 25 years and older) 1 year later (2014–2015) compared with first non-flavored use (Ref. 28).

Studies have shown that menthol’s flavor and sensory effects reduce the harshness of smoking among new users and facilitate experimentation and progression to regular smoking of menthol products, particularly among youth and young adults (Refs. 29 and 74–76). A subsequent analysis using Waves 1–4 (2013–2017) of PATH Study data assessed the relationship between new use of a menthol/mint-flavored or other flavored (*e.g.*, fruit, alcohol,

chocolate, candy, and other flavor) cigar at Wave 2 or 3 with cigar use at a subsequent wave (Wave 3 or 4) compared to first use of a non-flavored cigar (Ref. 29). The analysis found that among youth (aged 12–17 years) and young adults (aged 18–24 years), first use of any menthol/mint-flavored or other flavored cigar (e.g., fruit, alcohol, chocolate, candy, and other flavor) was associated with greater odds of past 30-day use of these products at the subsequent wave compared with first use of a non-flavored (i.e., tobacco) cigar, even after controlling for sociodemographic variables (Ref. 29). Youth who first used a menthol/mint-flavored cigar or other flavored cigar were 72 percent (menthol/mint) and 47 percent (other flavor) more likely to be past-30-day cigar users at a subsequent wave (1 or more years later) compared to those first using a non-flavored cigar. Similarly, young adults (aged 18–24 years) who first used a menthol/mint-flavored cigar or other flavored cigar were 71 percent and 52 percent more likely to be past-30-day cigar users at a subsequent wave compared to those first using a non-flavored cigar (Ref. 29). For both youth and young adults, the association between the first flavor used and subsequent cigar use was not statistically significantly different for menthol/mint-flavored compared to other flavored cigars. Among adults (25 years and older), first use of an “other” flavored cigar (e.g., fruit, alcohol, chocolate, candy, and other flavor) was also associated with higher likelihood of subsequent past 30-day cigar use (Ref. 29). Overall, this study extends findings from the Wave 1 (2013–2014) to Wave 2 (2014–2015) PATH Study analysis (Ref. 28) finding that among youth and young adults newly using cigars, first use of any menthol/mint-flavored cigar or other flavored cigar is associated with greater continued use of these products at the subsequent wave compared with first use of non-flavored cigars (Ref. 29).

Several studies examining nicotine dependence found that smoking cigars fosters addiction by reducing cravings and the urge to smoke to a similar magnitude as cigarettes (Refs. 101–103). Cigars, like cigarettes, have also been shown to decrease acute nicotine withdrawal symptoms (e.g., craving, anxiousness) (Ref. 104). Available scientific data on nicotine’s addictiveness demonstrate that the adolescent brain is more vulnerable to developing nicotine dependence than the adult brain (Ref. 17). Exposure to substances such as nicotine can disrupt brain development and may lead to long-term consequences for cognitive

function (Refs. 105 and 106). Exposure to nicotine from cigarette smoking in adolescence is associated with changes in the brain that could increase the likelihood for addiction and dependence as adults (Ref. 34). Furthermore, nicotine exposure in adolescence may have lasting effects; it has been associated with decreased attention, increased impulsivity, and various lasting mental health conditions in adult smokers (Ref. 34). While research is not yet able to fully disentangle whether the association of nicotine with changes in attention and impulsivity are primarily a result of nicotine exposure or partially due to pre-existing vulnerability to changes in attention and impulsivity (Ref. 34), considerable research shows that exposure to nicotine in adolescence causes long-term changes in the brain, with implications for nicotine dependence, attention, and impulsivity, as well as other areas of cognitive function and substance use (Refs. 17 and 34). Researchers analyzing data from the 2017–2018 NYTS found that 43.1 percent of middle and high school students using cigars in the past 30 days reported nicotine dependence, including feeling a strong craving to use a tobacco product or using a tobacco product within 30 minutes of waking (Ref. 107). An analysis of Waves 1–4 (2013–2017) PATH data did not find a longitudinal association between first use of a menthol- or mint-flavored cigar and nicotine dependence scores (Ref. 29). Similarly, a cross-sectional analysis of 2017–2018 NYTS data found that exclusive use of cigars was associated with lower odds of reporting dependence compared to exclusive use of another product (Ref. 107). However, frequent cigar use (use on 20 or more days in the past 30 days) as well as current cigar use including both exclusive and polyuse of cigars was associated with increased odds of youth reporting nicotine dependence (Ref. 107). In this analysis, use of cigars in combination with other tobacco products was common: 76.1 percent of youth past 30-day cigar users used cigars in combination with one or two additional tobacco products (Ref. 107). Given the role of frequent use and polyuse in the relationship between cigar use among youth and dependence, the authors noted “the importance of examining behaviors related to use, as they can affect and/or exacerbate the risk of nicotine dependence” (Ref. 107).

Given that nicotine is highly addictive and present in all cigars, as youth experimenters continue to use these products, there is a risk of nicotine

dependence and progression to regular use, resulting in an increased risk of developing the many negative health consequences associated with regular cigar use. Based on the totality of the evidence, prohibiting characterizing flavors (other than tobacco) in cigars would reduce the appeal and ease of use of such products and is an important step toward reducing the likelihood of nicotine dependence, experimentation, and progression to regular use.

F. Real-World Experiences Demonstrate That Restricting Characterizing Flavors in Tobacco Products, Including Cigars, Decreases Tobacco Use

As previously discussed in section IV.A of this document, Congress passed the Tobacco Control Act in 2009 to address the premature death, disease, and other serious health conditions caused by tobacco use. To address the appeal and use of flavored combusted tobacco products among the Nation’s youth, in 2009, the Tobacco Control Act prohibited cigarettes with characterizing flavors other than tobacco or menthol. Researchers analyzed repeated cross-sectional data from the NYTS and concluded that the ban was associated with a 17 percent reduction in the probability of being a cigarette smoker and a 6 percent reduction in the probability of any tobacco use (i.e., cigarette, cigars, smokeless tobacco, or pipe tobacco) in the past 30 days among U.S. middle and high school students (Ref. 50). While cigarette smoking decreased among the Nation’s youth following implementation of the Tobacco Control Act, researchers noted that youth use of cigars and pipe tobacco, which remained available in flavored varieties, rose after implementation of the ban on characterizing flavors in cigarettes (Ref. 50).

While the prior analysis (Ref. 50) was limited in its ability to attribute changes in tobacco use, particularly flavored use, directly to the Federal restriction (as the NYTS was not designed to evaluate such a policy), recent evaluation studies implementing pre-post study designs with geographic comparisons provide real-world examples of how tobacco product use changes as a result of a sales restriction on characterizing flavors in tobacco products, including cigars. Such recent evaluations of restrictions on the sale of tobacco products with characterizing flavors in U.S. localities include studies of New York, NY (NYC); Providence, RI; Lowell, MA; Attleboro and Salem, MA; San Francisco, CA; Minneapolis and St. Paul, MN (Twin Cities); as well as Canada (See table 1, below,

summarizing the evaluation studies). Taken in totality, the real-world experience of state and local jurisdictions implementing sales restrictions on flavored tobacco

products provide insight into the likely responses of youth and young adults as well as current cigar smokers to a proposed product standard restricting characterizing flavors (other than

tobacco) in cigar products, including decreases in youth cigar use and cigar consumption among current cigar smokers.

TABLE 1—SUMMARY OF EVALUATION STUDIES ON SALES RESTRICTIONS INCLUDING FLAVORED CIGARS

Jurisdiction	Policy ¹	Effective or enforcement year	Retailer exemptions	Study design & reference	Sample size	Key outcome measures ² and findings
NYC, NY	Restriction includes all flavored products except menthol-, mint-, and wintergreen-flavored products. In 2020, restriction was expanded to include flavored Electronic Nicotine Delivery Systems (ENDS) products, including menthol-, mint-, and wintergreen-flavored ENDS products.	2010	Tobacco bars with ≥10% gross income from tobacco sales.	Pre/Post Design (Ref. 51).	Youth Tobacco Use: n=1708 (2010); n=8814 (2013).	<i>Sales:</i> Flavored cigars dollar sales declined. Cigar dollar sales of non-flavored cigars increased. <i>Youth (aged 13–17 years) Tobacco Use:</i> Youth had lower odds of ever trying a flavored tobacco product and of ever using tobacco products.
				Pre/Post Design with Comparison (Ref. 108).	N/A	<i>Sales:</i> Overall cigar unit sales declined. Flavored cigar unit sales declined. Flavored cigar unit sales increased in comparison counties.
Providence, RI	Restriction includes all flavored products except menthol, mint, and wintergreen flavors.	2013	All smoking bars ..	Pre/Post Design with Comparison (Ref. 109).	N/A	<i>Sales:</i> Decrease in flavored cigar unit sales. Decreases in overall cigar unit sales. Flavored cigar unit sales increased in the rest of the State. <i>Youth (10th and 12th grade students) Tobacco Use:</i> Youth current use of any tobacco product declined. <i>Youth (10th and 12th grade students) Cigar Use:</i> Youth current use of cigars/cigarillos declined.
				Post-only Design (Ref. 60).	n=2,150 (2012); n=2,062 (2016); n=2,223 (2018).	<i>Youth (9th–12th grade students) Flavored Tobacco Use:</i> Youth current use of any flavored tobacco products decreased in Lowell and increased in the comparison community, a statistically significant difference. <i>Youth (9th–12th grade students) Non-Flavored Tobacco Use:</i> Youth current use of any non-flavored tobacco products also decreased in Lowell and increased in the comparison community, a statistically significant difference.
Lowell, MA	Restriction includes all flavored products (except menthol, mint, or wintergreen).	2016	Adult-only (21+ years old) retail tobacco stores with ≥90% of sales from tobacco products.	Post-only Design with Comparison (Ref. 61).	Lowell: Baseline n=593; follow-up n=524. Malden (comparison community): baseline n=636; follow up n=646.	<i>Youth (9th–12th grade students) Flavored Tobacco Use:</i> Youth current use of any flavored tobacco products decreased in Lowell and increased in the comparison community, a statistically significant difference. <i>Youth (9th–12th grade students) Non-Flavored Tobacco Use:</i> Youth current use of any non-flavored tobacco products also decreased in Lowell and increased in the comparison community, a statistically significant difference.
Attleboro & Salem, MA.	Restriction includes all flavored products (except menthol, mint, or wintergreen).	2016 (Attleboro); 2017 (Salem).	Adult-only (21+ years old) retail tobacco stores with ≥90% of sales from tobacco products. All smoking bars ..	Pre/Post Design with Comparison (Ref. 110).	Attleboro: Baseline n=1413; follow up n=1565. Salem: Baseline n=480; follow up n=620. Gloucester (comparison municipality): Baseline n=539; follow up n=629.	<i>Youth (9th–12th grade students) Flavored Tobacco Use:</i> Statistically significantly smaller increases in current use of Flavored in Attleboro and Salem than in the comparison municipality. <i>Youth (9th–12th grade students) Non-Flavored Tobacco Use:</i> Significantly smaller increases in current use of non-flavored or menthol tobacco in Attleboro and Salem than in the comparison municipality.

TABLE 1—SUMMARY OF EVALUATION STUDIES ON SALES RESTRICTIONS INCLUDING FLAVORED CIGARS—Continued

Jurisdiction	Policy ¹	Effective or enforcement year	Retailer exemptions	Study design & reference	Sample size	Key outcome measures ² and findings
Twin Cities, MN	Restriction includes all flavored products (except menthol, mint, or wintergreen).	2016	Minneapolis: Adult-only (18 years and older) licensed tobacco product shops with ≥90% revenue from sale of tobacco. St. Paul: Adult-only (18 years and older) retail stores with ≥90% revenue from sale of tobacco.	Pre/Post Design with Comparison (Ref. 111).	Minnesota Youth Tobacco Survey: More than 4,000 students participated in the 2017 survey statewide.	<i>Youth (6th–12th grade students) Cigar Use:</i> Before and after the 2016 restriction on flavored tobacco products (except menthol, mint, and wintergreen), cigar use did not change in the Twin Cities but increased in the rest of the State.
	Restriction expanded to include menthol, mint, and wintergreen in 2018.	2018	Minneapolis: Sales of mint-, menthol-, and wintergreen-flavored tobacco products at adult only (21 years and older) liquor stores. St. Paul: Sales of mint-, menthol-, and wintergreen-flavored tobacco products at liquor stores that also hold a license for tobacco sales.	Pre/Post Design with Comparison (Ref. 111).	Minnesota Student Survey (8th, 9th, 11th grade students): More than 170,000 participating students in 2019.	<i>Youth (8th, 9th, 11th grade students) Cigar Use:</i> Before and after the 2018 restriction on flavored tobacco products, including menthol, mint, and wintergreen, cigar use declined more in the Twin Cities compared to the rest of the State.
San Francisco, CA ..	Restriction includes all flavored products (including menthol).	2019	None	Post-only Design (Ref. 62).	n=247	<i>Young Adult (aged 18–24 years) Cigar Use:</i> Statistically significant decrease in flavored cigar use. Decrease in overall cigar use, but the decline was not statistically significant. <i>Young Adult (aged 25–34 years) Cigar Use:</i> Decreases in overall cigar use and flavored cigar use, but the declines were not statistically significant.
				Pre/Post Design with Comparison (Ref. 52).	N/A	<i>Sales:</i> Statistically significant decreases in overall tobacco and flavored tobacco unit sales. Statistically significant decreases in overall cigar and flavored cigar unit sales. The comparison cities had more modest decreases or no statistically significant change.
Canada	Restriction includes flavored little cigars/cigarillos (except menthol); unflavored cigarillos minimum packs of 20.	2010	None	Pre/Post Design (Ref. 112).	N/A	<i>Sales:</i> Decreases in overall cigar and flavored cigar units sold. Increase in unflavored cigar units sold.
				Pre/Post Design (Ref. 113).	Over 46,000 observations.	<i>Youth (aged 15–24 years) Cigarillo Use:</i> Decreases in past 30-day cigarillo use.

¹ Tobacco products covered under flavored tobacco restrictions differed across jurisdictions, particularly in regard to menthol status and inclusion of ENDS.

² Outcome measures differed across studies, with some focused specifically on sales data, whereas others measured tobacco use (cigar specific and/or all tobacco use), across differing age groups.

In November 2010, NYC began enforcing a restriction on sales of all flavored tobacco products except for

menthol-flavored, mint-flavored, and wintergreen-flavored tobacco products; all e-cigarettes were excluded from the

sales restrictions. An evaluation of the impact on total cigar sales of NYC's flavor restriction found a considerable

reduction in overall sales, a proxy for overall consumption, after controlling for temporal trends in sales and the potential for purchases across the city border (Ref. 108). This evaluation used retail scanner data to assess changes in total cigar units sold before and after the NYC flavor restriction went into effect. For comparison, the analysis also examined sales in nine counties in New York and New Jersey proximal to NYC, as well as sales in the United States overall, over the same timeframe. In NYC, sales of all flavored tobacco products combined declined 27.1 percent, and sales of flavored cigars declined 22.3 percent at policy implementation. The NYC flavor restriction was associated with a statistically significant 11.6 percent decrease in total cigar sales in NYC immediately following policy implementation, while cigar sales in the comparison area and nationally did not statistically significantly change. The decrease in overall cigar sales observed in NYC suggests that consumers did not completely substitute non-flavored cigars for flavored cigars because of the restriction (Ref. 108). This study showed that the concurrent decrease in unit sales of flavored tobacco products and flavored cigars observed in NYC was not offset by an increase in non-flavored cigars or tobacco products not included in the restriction. Furthermore, these findings were similar to results from an earlier analysis of the NYC policy that used more limited data (Ref. 51). This more limited study analyzed data from stores with overall sales of at least \$2 million per year in NYC and found that the restriction was associated with an 86 percent decrease in flavored cigar dollar sales and only a 5 percent increase in unflavored cigar dollar sales (Ref. 51).

An evaluation of the impact of the NYC flavored tobacco restriction on youth tobacco use found that NYC youth (aged 13–17 years) had 37 percent lower odds of ever trying a flavored tobacco product in 2013 after the policy went into effect compared to youth in 2010. Similarly, in 2013, youth had 28 percent lower odds of ever using any tobacco product compared to youth before the policy went into effect (Ref. 51), suggesting that the decreases in overall sales and consumption of flavored tobacco products, including cigars, was also reflected in declines in youth tobacco experimentation. This study illustrated that youth tobacco use declined following the NYC sales restriction.

Providence, RI, implemented a sales restriction on tobacco products with characterizing flavors other than menthol, mint, or wintergreen in

January 2013 (Ref. 109). An evaluation in Providence, similar to the analysis in NYC, used retail scanner data to assess changes in total cigar units (both flavored and not flavored, including menthol, mint, and wintergreen flavors) sold before and after the Providence flavor restriction went into effect (Ref. 109). For comparison, the analysis also examined sales over the same time period in the rest of Rhode Island (Ref. 109). Sale of explicit flavor-named cigars (e.g., “cherry”) in Providence declined 93 percent, while “concept” flavor-named cigars (e.g., “jazz”) increased 74 percent after policy implementation compared to before policy implementation. Despite the increase in “concept” flavor-named cigar sales, flavored cigar sales decreased overall, suggesting that “concept” flavor-named cigar consumption did not entirely replace explicit flavored-named cigar consumption after the policy. The analysis found that average weekly sales of all flavored cigars decreased 51 percent following policy implementation in Providence compared to before policy implementation and increased 10 percent across the rest of the state during the same time period (Ref. 109). Average weekly sales of all cigars decreased 31 percent following policy implementation in Providence and decreased 6 percent across the rest of the state during the same time period (Ref. 109). This study illustrated that flavored cigar use decreased following policy implementation alongside an increase in sales in the rest of the state. While concept-flavored cigar sales increased in Providence and the rest of the State, the overall decline in flavored sales suggests that flavored cigar use was only partially offset by an increase in concept-flavored use.

Another evaluation of the Providence restrictions examined youth tobacco use including cigar use through a school-based survey of over 2,000 10th and 12th grade students at two time points after Providence’s sales restriction was in effect: 2016 (3 years post-restriction) and 2018 (5 years post-restriction) (Ref. 60). This analysis found that youth current use of any tobacco product declined, from 22.2 percent in 2016 to 12.1 percent in 2018; and current use of cigars/cigarillos declined from 7.1 percent in 2016 to 1.9 percent in 2018 (Ref. 60). This study illustrates a decline in youth cigar use after increased enforcement of the policy in Providence, which is consistent with the analysis of sales data in Providence (Ref. 109).

Lowell, MA, enacted a restriction on flavored tobacco except for menthol-, mint-, or wintergreen-flavored tobacco products in October 2016. One study assessed short-term (6-month) impact of the Lowell, MA, sales restriction on youth use of flavored tobacco using pre-post design with a comparison community (Malden, MA). The comparison community of Malden, MA, did not have a sales restriction and was similar to Lowell, MA, in demographics, retailer characteristics, and other point-of-sale policies (Ref. 61). The analysis evaluated youth use of flavored tobacco products in Lowell and Malden at baseline (November 2016–January 2017 in Lowell; September 2016 in Malden) and followup approximately 6 months later (May 2017 in Lowell; April 2017 in Malden). Youth current use of any flavored tobacco products decreased 2.4 percent in Lowell from baseline to followup periods and increased 3.1 percent in the comparison community without a sales restriction (Malden, MA) for a statistically significant estimated difference of –5.7 percent between the communities (Ref. 61). When considering the change in specific product use, ever use of flavored cigars and current use of flavored cigars decreased in Lowell and increased in the comparison community, although the changes were not statistically significant. In general, there were no statistically significant changes in youth use by specific tobacco products in Lowell, in the comparison city, or in the difference estimate between the communities when the models were adjusted for age, gender, and race and ethnicity (Ref. 61). Youth current use of any non-flavored tobacco products also decreased 1.9 percent in Lowell while increasing in the comparison city by a statistically significant 4.3 percent for a statistically significant estimated difference of –6.2 percent between the communities (Ref. 61). This study showed that youth use of flavored tobacco products declined potentially in response to a sales restriction in a Massachusetts community compared to a similar community without a sales restriction.

Another study evaluated the impact of flavored tobacco sales restrictions (excluding menthol, mint, and wintergreen) in Attleboro and Salem, MA, on tobacco use among high school students (Ref. 110). While youth tobacco use increased from baseline to followup in Attleboro and Salem and in the comparison municipality of Gloucester, MA, the increases in flavored tobacco use and non-flavored, mint, or menthol tobacco use were statistically

significantly smaller in Attleboro and Salem than the comparison municipality, suggesting that the policy mitigated increases in tobacco use (Ref. 110). This study found that youth tobacco use increased at a lower rate within the two municipalities covered by sales restrictions compared to the municipality without a restriction. Therefore, the study findings suggest that the flavored tobacco restriction may have prevented increases in tobacco use.

In 2016, Minneapolis and St. Paul, Minnesota, commonly referred to as the Twin Cities, also implemented sales restrictions that included all flavored tobacco products, including ENDS but excluded menthol, mint, and wintergreen flavors. These sales restrictions exempted adult-only (18 years and older) licensed tobacco product shops with at least 90 percent or greater revenue from sales of tobacco in Minneapolis and adult-only (18 years and older) retail stores with at least 90 percent or greater revenue from sales of tobacco in St. Paul. In 2018, the Twin Cities expanded the restrictions to include mint-, menthol-, and wintergreen-flavored tobacco products. However, sales of mint-, menthol-, and wintergreen-flavored tobacco products were permitted in adult-only (aged 21 years and older) liquor stores in Minneapolis and liquor stores that also hold a license for tobacco sales in St. Paul. An analysis of the Minnesota restrictions examined youth tobacco use prevalence in the seven-county Twin Cities metropolitan area, including Minneapolis and St. Paul, and compared it to the rest of the State of Minnesota using data from two cross-sectional surveys: The Minnesota Youth Tobacco Survey (MYTS) and the Minnesota Student Survey (MSS) (Ref. 111). The analysis used MYTS data from students in grades 6–12 to estimate tobacco use before (2014) and after (2017) the Twin Cities implemented flavor policies in 2016 that included all tobacco products but excluded menthol, mint, and wintergreen flavors. The analysis used MSS data from students in grades 8, 9, and 11 to assess changes in tobacco use before (2016) and after (2019) when the flavor restrictions were expanded to include mint, menthol, and wintergreen flavors. Using the MYTS data to assess youth tobacco use while the 2016 flavor restriction (excluding menthol, mint, and wintergreen) was in effect, the prevalence of tobacco product use overall and cigar use did not change in the Twin Cities among 6–12th graders; however, e-cigarette use increased 34.1 percent. In contrast, tobacco use prevalence overall, cigar

use, and e-cigarette use increased at greater rates in the rest of the state (+26.6 percent, +71.3 percent, and +114 percent, respectively). Using the MSS data to assess youth tobacco use after the 2019 flavor restriction (including menthol, mint, and wintergreen) was implemented, tobacco use and e-cigarette use among students in grades 8, 9, and 11 increased in the Twin Cities; however, the increase was smaller than the rest of the state (34.6 percent vs. 44.6 percent tobacco use increase; 49.5 percent vs. 88.9 percent e-cigarette increase). Cigar use declined more in the Twin Cities compared to the rest of the state (–42.4 percent and –23.7 percent, respectively). Cigarette use decreased more in the Twin Cities relative to the rest of the State (–40.5 percent and –22.6 percent, respectively). Use of any menthol or mint tobacco product decreased in both areas (–5.9 percent Twin Cities and –15.7 percent rest of state), and use of non-cigarette tobacco products (*e.g.*, cigars, smokeless tobacco, e-cigarettes, hookah) with flavors other than mint or menthol increased in both areas (+5 percent Twin Cities and +10.2 percent rest of state) (Ref. 111).

Given the differences in survey items, timing of data collection, and that the MYTS and MSS data included all seven counties of the Twin Cities metropolitan area, including some counties not implementing flavor restrictions, the observed prevalence changes may reflect contextual factors beyond the restrictions in the cities of Minneapolis and St. Paul. For example, the 2019 MSS data collection was shortly after the policies including mint, menthol, and wintergreen went into effect; therefore, the study may underestimate the effect of the policy on youth behavior change. However, the study observed stable and decreasing cigar use among youth across the surveys in the Twin Cities relative to the rest of the state, which suggests the sales restriction slowed youth cigar use.

In 2018, San Francisco, CA, enacted restrictions on flavored tobacco products. Changes following the 2018 San Francisco restriction on all flavored (including menthol) tobacco product sales were evaluated and compared with sales in two California comparison cities without such sales restrictions: San Jose and San Diego (Ref. 52). The analysis used Nielsen retail scanner sales data to estimate within-city changes in average weekly unit sales of tobacco products for San Francisco and comparison cities for three time periods: Pre-policy (June 2015–July 2018; pre-policy); policy enactment (July 2018–January 2019) and policy enforcement (January 2019–

December 2019).¹⁴ Sales of flavored tobacco products overall and of flavored cigars specifically decreased a statistically significant 96 percent from the pre-policy period through the enforcement period in San Francisco (Ref. 52). In the comparison cities, average weekly sales of flavored tobacco products either decreased more modestly, yet still statistically significantly (*e.g.*, 10 percent for all flavored products and 13 percent for flavored cigars in San Diego), or did not have a statistically significant change from pre-policy to policy enforcement, with the exception of flavored ENDS (which statistically significantly increased by 195 percent in San Jose and 118 percent in San Diego) and flavored smokeless tobacco (which statistically significantly increased by 3 percent in San Diego). Predicted average weekly total cigar sales decreased by 51 percent in San Francisco from pre-policy to policy enforcement, suggesting that there was not complete substitution of flavored cigars for non-flavored cigars (Ref. 52). This study observed a decline in overall tobacco product sales and flavored tobacco product sales, suggesting that there was not complete substitution of tobacco or non-flavored products for flavored products following the flavor restriction in San Francisco.

Another study evaluated the impact of the San Francisco restriction on all flavored (including menthol) tobacco products on use of cigars among a small convenience sample (n=247) of young adults aged 18–34 years who used tobacco products prior to the restriction (Ref. 62). After implementation of the flavor restriction in San Francisco, among young adults aged 18–24 years, there was a statistically significant decrease in use of flavored cigars (from 19.4 percent to 6.5 percent) and decrease in cigar use overall that was not statistically significant (Ref. 62). There were decreases in the prevalence of cigar use overall and use of flavored cigars among 25–34-year-old respondents, but the declines were not statistically significant. Among the 25–34 age group, there was a statistically significant decrease in flavored e-cigarette use (from 56.2 percent to 48.1 percent) and dual use of e-cigarettes with cigars (from 14.1 percent to 9.7 percent). This study showed among young adults, flavored cigar use may have declined following the San Francisco sales restriction, and the decrease was not offset by an increase in non-flavored cigar use.

¹⁴ Although enforcement of this policy was slated to begin in January 2019, compliance inspections with penalties did not commence until April 2019.

One study of San Francisco's flavored tobacco policy using 2019 Youth Risk Behavior Survey (YRBS) data reported that San Francisco's flavor restriction was associated with increased odds of cigarette smoking among high school students relative to other school districts (Ref. 114). However, another study reported a methodological mistake with these findings: data collection for the 2019 YRBS in San Francisco occurred in Fall 2018, prior to when the San Francisco flavor restriction was enforced in April 2019 (Ref. 115). As noted above, another study of the San Francisco policy observed an overall decline in tobacco product sales and total cigarette sales, suggesting that there was not complete substitution of tobacco or unflavored products for flavored products following the flavor restriction in San Francisco (Ref. 52).

In addition to the local U.S. jurisdictions discussed previously, a study of local level restrictions across Massachusetts from 2011–2017 found that counties with greater proportion of county residents covered by local policies that limit the sale of flavored tobacco products (excluding menthol) were associated with a decrease in the number of days high school students smoked cigarettes in the past 30 days and a decrease in the likelihood of their e-cigarette use (Ref. 116). This study illustrates the potential for flavor restrictions to reduce youth tobacco use.

Evaluations of a national flavored tobacco policy in Canada reinforce trends observed in jurisdictions that enacted flavored tobacco policies in the United States, including a decrease in cigar sales and a decrease in use of cigars among young people. In 2009, the government of Canada prohibited the use of characterizing flavors (excluding menthol) in cigarettes and cigars under 1.4 grams, or in any cigar that had a filter or non-spiral wrap. Using wholesale sales volumes, one evaluation examined trends in sales of flavored cigars during the 2004–2016 period, with equal periods of 6 years before and 6 years after enactment of the 2009 restriction (Ref. 112). The analysis found that overall cigar sales decreased 49.6 million units and sales of flavored cigars decreased 59 million units in the quarter immediately following policy enactment (*i.e.*, first quarter of 2010). Sales of cigars with no flavor descriptors increased 9.6 million units in the quarter immediately after policy implementation (Ref. 112). Another evaluation assessed the impact of Canada's 2010 ban on the sale of flavored cigarillos (Ref. 113). This evaluation analyzed data from the 2007

to 2011 Canadian Tobacco Use Monitoring Survey and found that the policy was associated with a statistically significant 2.3 percentage point decrease in past 30-day cigarillo use and a statistically significant 4.3 percentage point increase in past 30-day abstinence, defined as no cigar use in the prior 30 days among previous cigarillo users among young people aged 15 to 24 years. Cigarillo use declined in the older age group, 25 to 65 years, but the decline was not statistically significant. The study noted that there was some evidence of a small increase in use of cigars other than cigarillos or little cigars that were not included in the policy, and the analysis did not distinguish flavored cigarillo from unflavored cigarillos (Ref. 113).

Taken in totality, these studies of the impact of real-world restrictions on flavored tobacco products provide insight into the likely responses of youth and young adults as well as current cigar smokers to the proposed standard, including decreases in youth and adult cigar use. However, we acknowledge there are limitations to the application of these findings. One limitation includes the timing of data collection on cigar use. Some of the evaluation studies rely on data collection only after the policy with retrospective recall of cigar use prior to policy implementation. Furthermore, the duration of followup time varied between studies, and those with shorter followup times (*e.g.*, Refs. 61 and 62) may have underestimated the impact on cigar use. Limitations also include that some studies rely on aggregate tobacco sales information as a proxy for consumption, rather than data concerning individual-level tobacco use behaviors. Certain analyses used cigar sales as a proxy for consumption, given that sales and consumption tend to be highly correlated (Refs. 117–119). Furthermore, a number of noted studies used state or nationally representative surveys of youth and young adults to assess differences in tobacco use before and after policy implementation. Some of these studies were able to assess changes in cigar use specifically, while others assessed changes in overall tobacco use or flavored tobacco use more broadly. Lastly, smokers may have obtained flavored cigars through alternate means (*e.g.*, internet sales) that would not have been captured in sales data in these studies, or smokers may have switched to tobacco products not subject to restrictions, which may have resulted in an overestimation of the impacts of the restrictions, unless changes in overall tobacco use was

accounted for. Despite these limitations, these real-world evaluations provide important insight into how sales and tobacco use change in response to restrictions on flavored tobacco products, including cigars. These evaluation studies further demonstrate that the proposed prohibition on characterizing flavors (other than tobacco) in cigar products would reduce the rate of youth and young adult experimentation and progression to regular tobacco use and increase cessation among current cigar smokers. Section VI of this document draws on such findings to estimate the impact of the proposed rule on population health, including the likelihood that existing cigar smokers would stop smoking as well as the likelihood that nonusers would start smoking cigars.

G. Flavored Cigars Are Marketed Disproportionately in Underserved Communities and to Vulnerable Populations

Tobacco marketing activities—*e.g.*, advertising and promotions—are effective in promoting sales, increasing tobacco use, and engendering positive attitudes about tobacco companies and their products among youth, young adults, and other vulnerable populations (Refs. 37, 120, and 121). With regard to cigars, decades of targeted marketing activities have helped make cigars more appealing and affordable and contributed to the pervasive and enduring nature of disparities in cigar use in vulnerable populations.

A robust body of scientific evidence shows that tobacco is disproportionately marketed in underserved communities and to vulnerable populations, such as youth and young adults, some racial and ethnic populations, individuals who identify as LGBTQ+, pregnant persons, those with lower household income and educational attainment, and individuals with behavioral health conditions. Storefront and outdoor tobacco marketing as well as point-of-sale marketing are all disproportionately present in African American/Black, Hispanic/Latino, and low-income communities (Refs. 122–129). Additionally, tobacco companies have historically targeted African Americans, LGBTQ+ communities, and low-income populations by using strategies such as offering coupons and other price promotions to entice these groups to use tobacco products (Refs. 122 and 130). This evidence holds true for combusted tobacco products, including cigar and flavored cigar products.

Industry documents reveal that tobacco companies have for many

decades strategically marketed flavored cigars to encourage trial and initiation among vulnerable populations. For example, a 1969 industry report noted the introduction of new flavored cigar products “aimed directly at youth,” as well as marketing campaigns targeting youth by including special offers, such as record albums (Refs. 16 and 79). Similarly, a 1972 report on the findings of an industry consumer research study concluded that adding menthol and mint flavor to little cigars was appealing to young (not defined) study participants and recommended marketing this flavored cigar product at a lower price point than cigarettes in order to attract young users (Refs. 16 and 131). Industry documents also disclose that tobacco companies targeted Black consumers, including by offering sampling and distribution opportunities as well as publishing advertisements in Black-only newspapers (Refs. 16, 132, and 133). Furthermore, hip-hop artists, DJs, and music events are all avenues tobacco companies have used to attract African Americans to use flavored little cigars and cigarillos (Ref. 16). Industry market research also studied how to increase cigar use among young women, including the addition of flavors to improve palatability and mildness and thereby promote product trial. Segments of the industry used this information to inform marketing and product development targeted at women such as adding appealing flavors, reducing cigar size so they could fit into purses or pockets, and including celebrities in advertisements (Refs. 16 and 131).

The tobacco industry’s historic practice of marketing to vulnerable populations has resulted in long-term consequences for these communities. Scientific evidence indicates that tobacco marketing influences social norms around tobacco use, making tobacco use more socially acceptable and increasing the likelihood of tobacco use (Refs. 134–137). In underserved communities where the tobacco industry has disproportionately marketed over decades, these social norms are transferred through social networks of peers and generations of families, thereby contributing to present-day tobacco-related health disparities in these populations (Refs. 134, 135, 138, and 139). Furthermore, recent scientific evidence indicates that tobacco companies continue to target populations from underserved communities with cigar marketing, including flavored cigar marketing (see, e.g., Refs. 140–146). Across diverse marketing platforms, ranging from

traditional print media to online platforms, populations from underserved communities are disproportionately exposed to cigar advertisements.

Brick-and-mortar tobacco retailers are present in disproportionate numbers in neighborhoods of underserved communities, particularly in Black communities. Studies have found that the more Black residents there are in a census tract, the more tobacco retailers there are in that census tract, with a statistically significant positive association between tobacco retailer density and the proportion of residents who are Black (Refs. 124–127). Two systematic reviews and several studies found that tobacco retailers in predominately African American/Black neighborhoods were statistically significantly more likely to sell cigars and cigarillos, were statistically significantly more likely to have exterior advertisements for cigars and cigarillos, and were statistically significantly more likely to sell cigars and cigarillos at a lower price, as compared to tobacco retailers in other neighborhoods (Refs. 125, 127, and 146–149). Furthermore, two nationally representative studies found that retailers in Black neighborhoods were more likely to place interior advertisements at or below 3 feet off the floor, at a point where cigar advertisements are more visible to youth, compared to tobacco retailers in predominately non-Hispanic White neighborhoods (Refs. 143 and 144).

Higher exposure to tobacco advertisements and retailing are associated with disparities in tobacco use susceptibility and tobacco use among youth. For example, a nationally representative study of youth found that exposure to cigar advertisements at the point-of-sale was statistically significantly associated with high curiosity about using cigars, with non-Hispanic Black (14.8 percent) and Hispanic youth (11.9 percent) being statistically significantly more likely to be highly curious about cigars as compared to non-Hispanic White youth (7.6 percent). This finding raises concern because curiosity about using tobacco products predicts tobacco use susceptibility, tobacco use initiation, and progression to regular tobacco use among youth (Ref. 150). Similarly, a longitudinal study of middle and high school students found that recall of tobacco advertisements and products at the point-of-sale at baseline predicted current cigar use at a 6-month followup (Ref. 151). Additionally, one cross-sectional study found that youth who reported going to a corner, convenience,

or other retail store on the way to or from school frequently had statistically significantly higher odds of current use of cigars, little cigars, and cigarillos (Ref. 152).

Taken together, scientific evidence indicates that cigars and flavored cigars historically have been and continue to be disproportionately marketed in underserved communities and that the presence of flavors in cigars is intended to encourage trial and initiation and deter tobacco cessation. The differences found in exposure to flavored cigar marketing contribute to observed disparities in tobacco use and associated tobacco-related health disparities and health outcomes among vulnerable populations, as further discussed in section V.F of this document. While targeted marketing is only one factor in the development and perpetuation of flavored cigar use and related harms, this background helps to explain and provide critical context for the outcomes and disparities that undermine public health and are of great concern to FDA. FDA remains committed to improving health outcomes across the population as a whole, including within groups that experience disproportionate levels of tobacco use, such as the vulnerable populations discussed in this section.

V. Cigar Use Is Common, Addictive, and Harmful

A. Prevalence of Cigar Use Among Youth, Young Adults, and Older Adults in the United States

Patterns of cigar use differ markedly by age group, race and ethnicity, household income and educational attainment, and among others who have systematically experienced greater obstacles to health based due to the inequitable distribution of social, political, economic, and environmental resources, such as individuals who identify as LGBTQ+ and persons with disabilities.

1. Cigar Use Prevalence in Youth and Young Adults

Evidence from national surveys, including the Monitoring the Future study of 8th, 10th, and 12th grade students and the NYTS of middle and high school students, has suggested that, similar to cigarettes, cigar use has been on the decline among U.S. youth in recent years (Refs. 153 and 154). However, in 2020, cigars were the most commonly reported combusted tobacco product used by youth (Ref. 7). Nationwide, in 2020, nearly 1 million youth had smoked a cigar on at least 1 day during the past 30 days (Ref. 7). According to the 2020 NYTS, an

estimated 960,000 middle and high school students (3.5 percent), including 5.0 percent (770,000) of high school students (grades 9–12) and 1.5 percent (180,000) of middle school students (grades 6–8), had smoked a cigar (cigar, cigarillo, or little cigar) in the preceding 30 days (Ref. 7). The most recent NYTS data also found that, of those youth who use cigars, the largest proportion use cigarillos (44.1 percent), followed by regular cigars (33.1 percent), and little cigars (22.6 percent) (Ref. 8). Of note, 21.8 percent of youth who are current users report not knowing which cigar type they use (Ref. 8).

While there has been an overall downward trend in cigar use among youth in general, cigar use—particularly flavored cigar use—remains significant, and this decrease has not been equitably experienced as the popularity of cigar use remains disproportionately high among non-Hispanic Black youth (Ref. 7). Tobacco-related health disparities result, in part, from inequitable practices and denial of opportunities that prevent some communities from fully participating in aspects of economic, social, and civic life. These inequities influence vulnerabilities that some populations experience across the continuum of tobacco use. For example, disparities in initiation and prevalence of cigar use that are connected to inequitable treatment and opportunities likely contribute to and reinforce the continued tobacco-related vulnerabilities of Black youth as subsequent disparities are observed along the continuum of tobacco use for these youth. The 2020 NYTS data show that the popularity of cigars is especially high among non-Hispanic Black middle and high school students, as 6.5 percent reported past 30-day cigar use compared to 2.8 percent of non-Hispanic White students (Ref. 7). Additionally, the findings show that cigar use was statistically significantly higher than cigarette use among non-Hispanic Black high school students in 2020, with 9.2 percent reporting having smoked cigars during the past 30 days, compared with 2.8 percent reporting having smoked cigarettes (Ref. 7). Data also indicate that non-Hispanic Black youth have a higher risk than White youth of initiating cigar use at earlier ages. An analysis of 2013–2017 PATH Study youth (aged 12–17 years) data indicated that, when compared to non-Hispanic White youth, non-Hispanic Black youth were 47 percent more likely to initiate past 30-day cigarillo or filtered cigar use and 111 percent more likely to be “fairly regular” users of these products (Ref. 25). These observed disparities in cigar

use initiation are associated with higher levels of current cigar use and frequency of cigar use among Black youth and young adults. An analysis of data from a longitudinal cohort study found that once Non-Hispanic African American youth and young adults had initiated cigar use, they had twice the odds of current cigar use within 6 months relative to non-Hispanic Whites (Ref. 100). Also, within 6 months of initiation, the average frequency of use and days per month used was higher for non-Hispanic African Americans compared to non-Hispanic Whites (Ref. 100). Findings from the 2013 Cuyahoga County Youth Risk Behavior Survey indicate that non-Hispanic Black youth had statistically significantly higher odds of using cigars as compared to non-Hispanic White youth (Ref. 155). Disparities in cigar use among Black youth may also pose additional concerns due to the increased risk associated with polyuse with other combusted tobacco products. Cigarette smoking being perceived as harmful reduced the likelihood of cigar use among all racial and ethnic categories of youth except for non-Hispanic Black youth, who were statistically significantly more likely to be current cigar users if they perceived smoking cigarettes as harmful (Ref. 155). Moreover, use of cigars among Black youth disproportionately leads to cigarette smoking. In a nationally representative longitudinal study of youth, ever cigar use statistically significantly increased the odds of subsequent past-30-day cigarette use among non-Hispanic Black youth (Ref. 156). However, ever cigar use did not increase the odds of subsequent past 30-day cigarette use among non-Hispanic White youth (Ref. 156). This study found that 9.1 percent of cigarette initiation among non-Hispanic Black youth was directly attributable to cigar use, compared with only 3.9 percent among non-Hispanic White youth (Ref. 156).

Youth and young adults who identify as LGBTQ+ also face tobacco-related health disparities when compared with non-LGBTQ+ counterparts, including higher prevalence of tobacco product use as well as cigar use.¹⁵ In 2020, NYTS analysis found that past 30-day

¹⁵ FDA acknowledges that sexual orientation is distinct from gender identity and that discussion and consideration of these factors in the context of public health should recognize and account for that distinction. However, the relevant scientific studies cited herein do not provide data separated by sexual orientation and gender identity. Due to these study limitations, we discuss sexual orientation and gender identity in a combined manner, despite their important distinctions.

use of any tobacco product was higher among youth identifying as lesbian, gay, or bisexual than heterosexual youth (25.5 percent vs. 15.1 percent) (Ref. 7). Past 30-day cigar use was nearly twice as prevalent among youth identifying as lesbian, gay, or bisexual than heterosexual youth (6.0 percent vs. 3.1 percent) (Ref. 7). Findings from an analysis of Wave 3 PATH Study data (2015–2016) indicated that, similar to patterns among adults, lesbian and bisexual girls have even higher disparities and are more than twice as likely than their heterosexual peers to report ever using cigars (11.3 percent vs. 5.2 percent) and to have used cigars in the past 30 days (3.2 percent vs. 1.0 percent) (Ref. 157). An analysis of the 2015 YRBS data found that lesbian and bisexual girls have statistically significantly higher current use prevalence of cigars than their heterosexual peers (16.4 percent for lesbian girls, 10.2 percent for bisexual girls, 5.4 percent for heterosexual girls), as do gay and bisexual boys (20.0 percent for gay boys, 16.9 percent for bisexual boys, and 13.5 percent for heterosexual boys) (Ref. 158). Findings from a nationally representative cohort study indicated that young adults who identified as homosexual reported higher ever cigar use compared to young adults who identified as heterosexual (Ref. 159). Transgender youth also are statistically significantly more likely than non-transgender youth to report ever using any tobacco product (53.6 percent vs. 31.5 percent) including cigars (16.1 percent vs. 7.5 percent) and past 30-day use of more than one tobacco product, including cigars (10.2 percent vs. 3.5 percent) (Ref. 157). Study findings from a young adult cohort study indicated that past 30-day little cigars/cigarillos/bidis use was greater for young adults who identified as LGBT in comparison to those who did not identify as LGBT (Ref. 160).

Youth with disabilities also have higher rates of cigar use than their nondisabled peers. In one study of more than 20,000 11th graders in Oregon that controlled for sociodemographic risk factors of tobacco use, the proportion of little cigar use among students with at least one reported disability (7.0 percent) was statistically significantly higher than among students without a disability (5.4 percent) (Ref. 161).

2. Cigar Use in Adults

Cigars are also a popular tobacco product among adults. In the 2019 National Health Interview Survey (NHIS), 3.6 percent of adults 18 or older reported currently using cigars some or every day, behind cigarettes (14 percent)

and e-cigarettes (4.5 percent) (Ref. 68). Comparing 2011 to 2019, while past month cigarette smoking and cigar use were both statistically significantly lower in young adults (aged 18–25 years), the absolute decline in cigar use was less than the decline in cigarette use (33.5 percent in 2011 to 17.5 percent in 2019 for cigarettes; 10.9 percent in 2011 to 7.7 percent in 2019 for cigars) (Ref. 59). For adults (aged 26 years or older), cigarette use in 2011 was statistically significantly higher compared to in 2019; however, cigar use remained relatively stable and did not significantly change (21.9 percent in 2011 to 18.2 percent in 2019 for cigarettes; 4.2 percent in 2011 to 4.0 percent in 2019 for cigars) (Ref. 59). The 2019 NSDUH found that among adults aged 26 or older in 2019, 1,420 individuals initiated cigar use each day, considerably more than the 247 who initiated cigarette smoking each day in that year (Ref. 59).

Prevalence of cigar smoking, however, varied by the type of cigar smoked. Analysis of Wave 5 (2018–2019) data from the PATH Study found that, 4.8 percent of young adults (aged 18–24 years) used traditional cigars; 7.9 percent used cigarillos, and 2.4 percent used filtered cigars in the past 30 days (Ref. 63). According to the most recent data from the PATH Study (2018–2019), 3.5 percent of adults (aged 25 years and older) used traditional cigars, 3.3 percent used cigarillos, and 1.6 percent used filtered cigars in the past 30 days (Ref. 63).

Similar to youth and young adults, adults (aged 25 years and older) reported use of flavored cigars and are expected to benefit from the proposed product standard if finalized. Wave 5 (2018–2019) data from the PATH Study showed that 36.0 percent of adult cigar smokers (aged 25 years and older) reported past 30-day use of flavored cigar from 2018–2019 (Ref. 63). Among adult cigar smokers, a statistically significantly greater proportion of adult traditional cigar smokers (19.7 percent) reported use of a flavored cigar in the past 30 days compared with adult smokers of all other cigar types (46.5 percent for cigarillos and 48.7 percent for filtered cigars) (Ref. 63). The proportion of adults using flavored cigars within each of the cigar types did not differ over time across recent PATH Waves 4–5 (2016–2019) (Ref. 63).

A disproportionate proportion of cigar smoking occurs among vulnerable populations; this burden has grown over the past two decades. In the 2019 NHIS, 4.4 percent of non-Hispanic Black, 3.8 percent of non-Hispanic White, and 3.0 percent of Hispanic adults reported

some or everyday cigar use (Ref. 68). In an analysis of 2002–2016 NSDUH data for individuals aged 12 and older, non-Hispanic Black individuals were statistically significantly more likely than all other racial and ethnic groups to have used cigars in the past 30 days (Ref. 162). Decreases in prevalence of cigar use have not been observed in non-Hispanic Black adults as they have for other racial and ethnic groups (Ref. 162). There were no statistically significant changes in past 30-day use prevalence between 2002–2016 in the NSDUH data among non-Hispanic Black and non-Hispanic other/mixed race adults while there were decreases among both non-Hispanic White and Hispanic adults. Further, over this same time period, cigar use decreased among non-Hispanic White men and stayed the same among non-Hispanic White women, but it increased among non-Hispanic Black women and remained the same among non-Hispanic Black men (Ref. 162). When considering more recent NSDUH data, these racial and ethnic disparities have persisted, with the prevalence of past 30-day cigar smoking remaining statistically significantly higher among non-Hispanic Blacks compared to non-Hispanic Whites through 2019 (Ref. 59).

A recent analysis of PATH Study data from Wave 3 (2015–2016) showed differences in daily cigar smoking by racial and ethnic group (Ref. 163). Non-Hispanic Black individuals are statistically significantly more likely to report that they have ever been a “fairly regular” cigar smoker (5.4 percent) than non-Hispanic White cigar smokers (2.5 percent) and to report that they smoke cigars daily (1.9 percent), compared to non-Hispanic White cigar smokers (0.5 percent), with these differences being most pronounced for cigarillos (3.7 percent vs. 0.9 percent) (Ref. 163). Hispanic adults were more likely to smoke cigars within 30 minutes of waking, when compared with non-Hispanic Whites (Ref. 163). The analysis found a consistently higher prevalence of use for non-Hispanic Blacks, compared with non-Hispanic Whites for three cigar-smoking outcomes (past 30-day use, daily use, and established use) across all the cigar types (Ref. 163).

Differences in prevalence have been observed across cigar type and in the use of flavors across racial and ethnic populations. In the PATH Study, past 30-day cigarillo use was statistically significantly higher among non-Hispanic Black young adults (aged 18–24 years) and adults (aged 25 years and older) compared with non-Hispanic Whites and Hispanics at all waves (2013–2019) (Ref. 63). Past 30-day use of

flavored traditional cigars was statistically significantly higher among non-Hispanic Black older adults (aged 25 years and older) compared to non-Hispanic White adults at Waves 2–5 (2014–2019) and compared to Hispanic adults at Waves 2–3 (2014–2016) and Wave 5 (2018–2019) (Ref. 63). An analysis of survey data on college students indicated that Black young adults were three times more likely to smoke flavored cigars than White young adults (Ref. 66). Hispanic and Asian participants were also more likely to use flavored cigars over non-flavored cigars compared to non-Hispanic White participants (Ref. 66). Younger participants (aged 18–24 years) had greater odds of using flavored cigars when compared to older participants (aged 25–29 years) (Ref. 66).

Differences in prevalence of cigar use have also been observed across other population groups. Research indicates social gradient effects (where higher levels of household income and educational attainment are linked to better health outcomes and lower levels of household income and educational attainment are linked to poorer health outcomes) for cigar use. Data from the 2012–2013 NATS show that higher educational levels and higher annual household income generally were associated with lower prevalence of usual use of cigarillos, other mass market cigars, and of little filtered cigars (Ref. 164). Data from the PATH Study in 2018–2019 show that there was a statistically significant difference in past 30-day cigar use by education level as 7.3 percent of adults (aged 25 years and older) with less than a high school diploma smoked cigars in the past 30 days, compared to 3.8 percent of adults with a college degree or higher (Ref. 63). Among adults who used any cigar in the past 30 days, individuals with a college degree were statistically significantly less likely to use a flavored cigar (20.0 percent) than individuals categorized as having less than a high school diploma (44.9 percent), a high school diploma (37.4 percent), or some college (42.9 percent) (Ref. 63).

Tobacco-related cancers are a leading cause of death among adults experiencing homelessness (Ref. 165). In a study of 470 unhoused individuals, the analysis found that past 30-day use of all tobacco products was high and that 74.0 percent of respondents reported use of cigars and over half (55 percent) reported use of flavored cigars in the past 30 days (Ref. 166).

Adults over 18 with at least one chronic health condition (*e.g.*, heart disease, hypertension, stroke, diabetes, asthma, lung cancer, hepatitis, human

immunodeficiency virus infection, anxiety, depression, substance abuse) have been shown in one study to be more than one and a half times more likely than those without a chronic health condition to use cigars, with no statistically significant changes over time (Ref. 167). In particular, adults who have anxiety, depression, or substance use disorders have cigar use rates statistically significantly greater than those with no chronic health conditions (Ref. 167). This association holds for mentholated tobacco products, including cigars, which are used disproportionately by young adults (aged 18–34 years) who report mental health disorders, with past 30-day menthol tobacco product use being associated with greater odds of anxiety and depression when controlling for other tobacco and mental health risk factors (Ref. 168). Likewise, using Waves 1–4 (2013–2017) of PATH Study data, adults who reported past-year severe internalizing problems were more likely to have initiated use of flavored cigarillos since the prior PATH wave, and were also more likely to be past-30-day users of flavored cigarillos (Ref. 169).

Adults who identify as LGBTQ+ are more likely to use tobacco products, including cigars, and to meet the criteria for nicotine dependence when compared to their heterosexual and cisgender peers, with these associations being stronger for some racial and ethnic populations (Refs. 68, 157, 159, 160, and 170–173). For example, while adults who identified as gay/lesbian, bisexual, and “conflicting” (defined by study authors as those who identified as “heterosexual, had engaged in either no sexual behavior or exclusively heterosexual behavior, but reported some levels of same-sex attraction”) are more likely than their heterosexual peers to use tobacco and meet tobacco use disorder criteria, Hispanic and non-Hispanic Black bisexual adults have even stronger associations for current tobacco use than do their White bisexual peers (Ref. 172). Overlapping forms of disadvantage can interact to create and exacerbate tobacco-related health disparities. For example, discrimination experienced on the basis of gender identity or sexual orientation often overlaps with discrimination experienced on the basis of race or disability.¹⁶ As discussed in section IV.G of this document, the tobacco industry disproportionately targets its

marketing to those who identify as LGBTQ+ and some racial and ethnic populations. For example, adults who identify as lesbian, gay, bisexual, or transgender report higher rates of tobacco media exposure compared to their peers who do not identify as lesbian, gay, bisexual, or transgender (Ref. 141), which can lead to use of tobacco products, including cigars (Refs. 141 and 172).

Generally, findings indicate that adults who identify as lesbian, gay, bisexual, or transgender have a higher prevalence of experimental and current cigar use compared to their heterosexual peers (Refs. 159 and 173–175). Findings from an analysis of the 2012–2013 NATS data indicated that among women who identified as lesbian or gay, bisexual, or “something else” (an option provided in the study), cigar use was more than triple the rate of heterosexual women (Ref. 176). Data from the 2015–2017 NSDUH, indicate that lesbian and bisexual women had more than twice the odds of using cigars in the past year relative to heterosexual women (Ref. 170). These findings are consistent with those from a 2013 cross-sectional survey study showing that lesbian and bisexual women had more than twice the odds of current cigar use relative to heterosexual women (Ref. 173).

Adults who identify as transgender are more likely to use tobacco products, including cigars, than their cisgender peers. In a national cross-sectional online survey, transgender adults reported higher current (past 30-day) use of any cigarette/e-cigarette/cigar product (39.7 percent vs. 25.1 percent) (Ref. 177). This study also found that transgender adults had higher current use of cigars (26.8 percent vs. 9.3 percent), specifically, when compared with cisgender adults as well as statistically significantly higher odds of past 30-day tobacco product use for any cigarette/e-cigarette/cigar product and for cigars, compared to cisgender adults (Ref. 177).

These disparities also exist for flavored cigar use, as data from the 2009–2010 NATS indicated that adults who identify as lesbian, gay, bisexual, or transgender have a higher prevalence of flavored cigar use (8.2 percent) compared to the national prevalence (2.8 percent) and when compared to cigar users nationally (42.9 percent) (Ref. 70). Data from the 2011–2015 Truth Initiative Young Adult Cohort Study showed that respondents who identified lesbian, gay, or bisexual had higher odds of reporting past 30-day flavored large cigar and LCC use compared to respondents who identified as straight/heterosexual (Ref. 67).

3. Polyuse of Tobacco and Cigar Prevalence

FDA finds that recent trends toward polyuse of tobacco (*i.e.*, the use of two or more tobacco products) also support the Agency’s conclusion that this proposed rule would have positive impacts on public health. Polyuse increases exposure to nicotine (Ref. 178) and other harmful constituents of tobacco products and tobacco smoke. Using data from the 2017–2018 NYTS survey, one study found that 40.8 percent of middle and high school aged youth past 30-day tobacco users were using two or more tobacco products in the past month (Ref. 107). Among youth using cigars in the past 30 days, a majority, 76.1 percent, used cigars in combination with one or two additional tobacco products (Ref. 107). Among youth in the 2017–2018 NYTS data, cigarettes and e-cigarettes were the most common products used alongside cigars (Ref. 107).

The cumulative exposure from polyuse can sustain and may increase levels of tobacco dependence. A 2017–2018 analysis of NYTS data found that 43.1 percent of youth current cigar smokers, including polyusers, reported nicotine dependence, including feeling strong craving to use a tobacco product or using a tobacco product within 30 minutes of waking (Ref. 107). When looking at the association between cigar use and dependence, frequent cigar use (*i.e.*, use on 20 to 30 days in the past 30 days) was associated with increased odds of nicotine dependence as compared to less frequent users (Ref. 107). Exclusive use of cigars was associated with lower odds of dependence relative to exclusive use of another tobacco product. However, most youth cigar users in the study used cigars and one or more other tobacco products. When cigar use included polyuse and exclusive use, youth cigar use was associated with twice the odds of nicotine dependence (Ref. 107). Given the role of frequent and polyuse in the relationship between cigar use among youth and dependence, the authors note “. . . the importance of examining behaviors related to use, as they can affect and/or exacerbate the risk of nicotine dependence” (Ref. 107).

An analysis of tobacco dependence among daily cigarette, cigar, and e-cigarette users in the United States, using data from the 2012–2013 NATS, found that compared to cigarette-only smokers, dual cigarette and cigar smokers exhibited greater dependence, with a higher average number of cigarettes smoked per day (17.3 vs. 15.8), shorter times to first tobacco use

¹⁶ See, *e.g.*, E.O. 13988, “Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation” (86 FR 7023, January 25, 2021).

after waking (21.4 minutes vs. 25.9 minutes), and more frequent reporting of withdrawal and craving symptoms compared to exclusive cigarette smokers (Ref. 179). In addition, data from Wave 1 (2013–2014) of the PATH Study demonstrates that high nicotine dependence is two to three times more likely among poly users compared to dual and single product users (Ref. 180). Data from the 2012 and 2019–2020 NYTS also noted that reports of dependence were consistently associated with polyuse (Refs. 181 and 182).¹⁷ FDA anticipates this proposed product standard would help to reduce the number of cigar users and, therefore, the number of tobacco users who are

poly users and likely even more tobacco dependent.

B. Flavored Cigar Use Exposes Users to Additional Toxicants

All cigar users, including flavored cigar users, are exposed to toxicants, including more than 50 carcinogens in mainstream and sidestream cigar smoke (Ref. 183). In flavored combustible tobacco products, including cigars, additional toxicity can result from the chemicals formed when flavors are heated or burned (Refs. 184–187). For example, acetaldehyde, formaldehyde, and benzene were found during pyrolysis (*i.e.*, thermal decomposition or the process of breaking down a product

under the presence of heat) of 18 different cigarette flavor additives, and various polycyclic aromatic hydrocarbons (PAHs) were also detected during pyrolysis of cocoa (Ref. 188). Similar results would be expected for cigar flavor additives (Ref. 189). A study conducted by the Centers for Disease Control and Prevention (CDC) identified benzyl alcohol, piperonal, methyl cinnamate, and vanillin in strawberry cigar filler (Ref. 190). The table below summarizes examples of known respiratory and other relevant toxicities associated with these ingredients (and subcomponents) and their potential pyrolysis products.

TABLE 2—FLAVOR INGREDIENT PYROLYSIS AND POTENTIAL HEALTH HAZARDS

Flavor ingredient	Chemical reaction product	Health hazard of flavor ingredient
Benzaldehyde	Benzene, Carbon monoxide (CO) (Refs. 191 and 192)	Respiratory irritant and toxicant (Ref. 193).
Benzyl alcohol	Benzene, toluene (Refs. 194 and 195)	Acute inhalation toxicant; Nose, throat, and respiratory tract irritant (Ref. 196). Mutagen (Ref. 199).
Ethyl maltol	Acetaldehyde, acrolein, CO, formaldehyde, 1,3-butadiene, acetone, propionaldehyde, crotonaldehyde, methyl ethyl ketone (Refs. 197 and 198).	
Ethyl vanillin	Benzene, naphthalene (Ref. 200)	Respiratory irritant (Ref. 201).
Hexyl acetate	CO (Ref. 202)	Respiratory irritant (Ref. 203).
Methyl cinnamate ...	Styrene (Ref. 185)	Sensitization (Ref. 204).
Piperonal	1,3-butadiene/Butadiene, benzene (Ref. 188)	Mutagenic; hepatotoxic in rats (Ref. 205).
Vanillin	Benzene, catechol, naphthalene, phenol, o-cresols, toluene (Refs. 200 and 206).	Respiratory irritant (Ref. 207).

FDA expects that the proposed product standard, if finalized, would result in reduction or removal of such flavoring ingredients in cigars. Reducing flavoring ingredients in cigars and, thereby, reducing these toxicant levels in such products would reduce consumer exposure to these toxicants and help to protect consumers from the health effects of these toxicants.

C. Cigar Use Is Addictive

Through cigar smoke, nicotine can be absorbed by inhalation (like cigarettes) or through the oral mucosa (like smokeless tobacco). Multiple studies found that cigar smokers inhale (as evidenced by CO levels), and plasma nicotine levels are similar to those of cigarette smokers (Refs. 101–104 and 208).

All cigars contain nicotine, a highly addictive chemical. The Surgeon General has long recognized that the addictive nature of tobacco products is due to the presence of highly addictive nicotine that can be absorbed into the bloodstream and pass into the brain (*e.g.*, Ref. 121). Nicotine is “one of the

most addictive substances used by humans” (Ref. 209). Given that nicotine is highly addictive and present in all cigars, as experimenters continue to use these products, there is a risk of nicotine dependence and progression to regular use, resulting in an increased risk of developing the many negative health consequences associated with regular cigar use. Prohibiting characterizing flavors (other than tobacco) in cigars is an important step toward reducing experimentation and progression to regular use since it can reduce the appeal and ease of use of such products and, consequently, the likelihood of nicotine addiction.

The amount of nicotine delivered, and the means through which it is delivered, can either reduce or enhance nicotine’s potential for abuse and physiological effects (Ref. 6). Generally, the quicker the nicotine delivery, rate of absorption, and attainment of peak concentrations, the greater the potential that an individual will become addicted to nicotine (Ref. 6). Research has found that little cigars deliver nicotine levels that are similar to cigarettes and also

reduce users’ urge to smoke cigarettes (Ref. 6). Large cigars can deliver as much as ten times the nicotine of a filtered cigarette (Ref. 183). Factors determinative of cigars’ ability to deliver nicotine at a level capable of producing dependence include the age of initiation, the rate of nicotine absorption, the duration of exposure, the degree of cigar smoke inhalation, and the development of tolerance to nicotine (Ref. 210).

Cigar smoke contains many of the same harmful constituents as cigarette smoke—including nicotine (Ref. 183). A single cigar can contain as much tobacco as an entire pack of cigarettes, and nicotine yields from smoke from a cigar can be up to roughly eight times higher than yields from smoke from a non-filtered cigarette in machine smoking regimens—with delivery of 1.7 milligrams (mg) in non-filtered cigarettes compared to 3.8 mg in little cigars, 9.8 mg in cigarillos/other mass market cigars, and 13.3 mg in “premium” cigars (Ref. 183). Although the amount of nicotine taken in by a cigar user depends on various factors,

¹⁷ FDA is not aware of additional analyses that examine dependence in youth in NYTS data using 2013–2018 data.

such as how long the individual smokes the cigar, the number of puffs taken, and the degree of inhalation, a leading review of the science of cigar smoking concluded that “[c]igars are capable of providing high levels of nicotine at a sufficiently rapid rate to produce clear physiological and psychological effects that lead to dependence, even if the smoke is not inhaled” (Ref. 210).

Research indicates that most cigar smokers unknowingly inhale some amount of smoke, including cigar smokers who report that they do not inhale (Ref. 211; see Ref. 212). Youth more commonly use cigarillos and little filtered cigars that are designed to be inhaled, which may increase their risk of poor health outcomes as well as addiction (Refs. 32 and 183). Little cigars are often indistinguishable from cigarettes given their shape, size, filters, and packaging, and are perceived as being healthier than cigarettes (Refs. 48 and 49). Even if cigar smokers do not breathe or inhale smoke into their lungs, they are still subject to nicotine’s addictive effects through buccal absorption of nicotine or nicotine absorption through the lips due to cigar tobacco’s alkalinity (Refs. 211, 213–215). Cigar smoke dissolves in saliva and makes it possible for smokers to absorb sufficient amounts of nicotine to create dependence (Ref. 213).

Nicotine can exist in protonated and freebase, or unprotonated, forms; in the freebase form, it is most addictive because it is readily absorbed by the buccal mucosa, respiratory tissues, skin, and the gastrointestinal tract (Refs. 6 and 121). Freebase, unprotonated nicotine amounts are generally higher in cigars than cigarettes due to the higher pH of cigar smoke (Ref. 183). Nicotine absorbed across the buccal mucosa, the mouth’s membrane lining, can provide sustained amounts of freebase nicotine to the tobacco product user, which, along with the harshness of cigar smoke, may explain why cigar smokers are less likely to intend to inhale than cigarette smokers (Ref. 183). Cigars can deliver nicotine much like chewing tobacco or oral snuff, with nicotine extraction from the unburned tobacco absorbed directly through the buccal mucosa and lips (Ref. 183).

In addition, characterizing flavors may impact the effects of nicotine. In particular, characterizing flavors, including menthol, can activate the brain’s reward circuit, producing rewarding effects that, when added to tobacco products, can reinforce the effects of nicotine (Refs. 13 and 14). The use of sweet/candy and other characterizing flavors that appeal to youth produces a robust reinforcing

effect in young populations (Refs. 13 and 14). One animal study found that flavors can enhance the reinforcing effects of low nicotine doses in rodents (Ref. 216). The authors of this study suggest this effect may influence nicotine exposure and subsequent dependence. While flavors can activate the brain’s reward circuit and produce rewarding effects on their own (Ref. 14), these findings suggest that flavors and nicotine can interact to enhance the reinforcing effects of nicotine (Refs. 13, 216, and 217). Further studies demonstrate that menthol, like nicotine, binds to nicotinic receptors in the brain (Refs. 218 and 219) and menthol alone can increase the number of nicotinic receptors in the brain (Refs. 220 and 221). Increases in nicotinic receptors can lead to greater withdrawal and cravings (Ref. 222). Evidence demonstrates that menthol’s effects on nicotine in the brain are associated with behaviors indicative of greater addiction to nicotine (Refs. 220 and 223). In an analysis of 2019–2020 NYTS data, use of one or more flavored tobacco products, including menthol, during the past 30 days was associated with higher odds of reporting strong cravings and desire to use tobacco within 30 minutes of waking compared to use of an unflavored tobacco product (Ref. 182).

A cigar smoker’s age is another factor that affects susceptibility to nicotine addiction. The Surgeon General has noted that nicotine dependence in cigar smokers could result from even a limited exposure to nicotine during adolescence (Ref. 6). Analyses of data from the 2012 and 2019–2020 NYTS found that, although the percentage of middle and high school students reporting various measures of dependence was lower for cigars than for cigarettes, youth reported measures of nicotine dependence when exclusively using cigars (Refs. 181 and 182). The analysis of 2019–2020 NYTS data found that 14.8 percent of middle and high school students who only smoked cigars reported strong cravings for a tobacco product during the past 30 days (Ref. 182).

Prohibiting characterizing flavors (other than tobacco) in cigars would reduce the appeal of cigars, particularly among youth and young adults, and decrease the likelihood that nonusers would experiment with cigars. It also would decrease the likelihood that current experimenters would continue to use these products. Reducing the appeal of cigars and experimentation is particularly important because, as experimenters continue to use these products, they can develop dependence, leading to regular use and increasing

their risk of developing the many negative health consequences associated with regular cigar use.

D. Research Clearly Demonstrates a Causal Relationship Between Cigar Smoking and Death and Disease

Flavored cigar smokers, like all cigar smokers, are at increased risk for developing cancers of the mouth and throat, lung cancer, heart disease, and many other adverse health consequences, with some groups with higher rates of use at greater risk than others. As discussed in section V.C of this document, those who experiment with flavored cigars (due to their appeal and ease of use) can develop nicotine dependence, placing infrequent cigar smokers at risk of progression to regular use and to tobacco-related disease and death. Studies demonstrate that not only is cigar smoking causally associated with many of the same diseases as cigarette smoking, but cigar smoking risks can also exceed those causally associated with cigarette use depending on the number of cigars smoked and the depth of smoke inhalation (Ref. 32).

Cigar smoke contains many of the same harmful constituents as cigarette smoke, and cigar smoke may have even higher levels of several harmful compounds (Refs. 3, 23, and 224). For example, cigar smoke contains higher amounts of carcinogenic, tobacco-specific N-nitrosamines than cigarette smoke due to the relatively high concentration of nitrate in cigar tobacco, which leads to formation of cancer-causing nitrosamines during the fermentation process (Refs. 23; 183 at Chapter 3; and 224). Researchers have found urinary concentrations of NNAL (a hazardous tobacco-specific nitrosamine) measured in daily cigar smokers to be as high as those measured in daily cigarette smokers (Refs. 225 and 226). Like exposure to cigarette smoke, exposure to higher levels of cigar smoke for longer time periods increases the adverse health risks caused by cigar smoking (Ref. 6).

Using NATS data for 2009–2010, researchers have estimated that regular cigar smoking caused approximately 9,000 premature deaths or almost 140,000 years of potential life lost among adults 35 years or older (Ref. 3). A study of healthcare expenditures from 2000–2015 found that cigar-attributable health care expenditures for adults totaled \$1.75 billion per year, with \$284 million attributed to exclusive cigar smoking and \$1.5 billion attributed to non-exclusive cigar smoking (*i.e.*, cigar plus cigarette or smokeless tobacco use) (Ref. 4). The overall mortality rates for cigar smokers who inhale generally

approach the same mortality rates observed for cigarette smokers (Ref. 183 at 110–112). In addition, overall mortality rates for all cigar smokers (*i.e.*, those who report inhaling as well as those who report not inhaling cigar smoke) are higher than rates for those who have never smoked, although they are generally lower than the rates observed for cigarette smokers (Ref. 183 at 112). A recently published analysis using more contemporary data from the National Longitudinal Mortality Study, following participants for mortality from 1980 through the end of 2011, also found that exclusive cigar smokers had an elevated risk of all-cause mortality compared to never tobacco users, but lower than exclusive cigarette smokers (Ref. 227). Another similar analysis using the restricted-use National Health Interview Survey-Linked Mortality Files (NHIS-LMF), following participants for mortality from 2000 through 2015, observed that current, daily cigar smokers had elevated risk of all-cause mortality compared to never tobacco users (Ref. 228). In addition, researchers studying cigar smokers in 2009 and 2010 found that the average cigar or pipe smoker loses approximately 15 life-years (Ref. 3).

Given this causal relationship between cigar smoking and all-cause mortality, it is critical that FDA propose action to decrease the appeal and ease of cigar use, making it less likely that youth and young adults will experiment with cigars or progress to regular use. FDA also expects that the proposed product standard, if finalized, will cause a large number of existing cigar smokers to cease combusted tobacco product use (as discussed in section VI of this document) and, therefore, be less likely to suffer the negative health consequences of cigar smoking.

1. Cancers of the Mouth and Throat

The National Cancer Institute's (NCI's) Tobacco Control Monograph No. 9, which provides a comprehensive, peer-reviewed analysis of the trends in cigar smoking and potential public health consequences, identified a dose-response relationship for cigar smoking and certain types of cancer (Ref. 183 at 120–130). Specifically, NCI's Tobacco Control Monograph No. 9 identified a dose-response relationship for cigar smoking and oral, laryngeal, pharyngeal, and esophageal cancers, finding an increased risk of these diseases with greater numbers of cigars smoked per day and deeper inhalation (Refs. 183 and 229–232). Likewise, a systematic review of the mortality risks associated with cigar smoking that identified 22

studies observed similar dose trends (Ref. 32).

Cigar smoking can cause cancers of the mouth and throat even in smokers who report they do not inhale (Ref. 183). According to the NCI's Tobacco Control Monograph No. 9, the data clearly establish that cigar smoking is a cause of oral cancer (Ref. 183). Regular cigar smokers who have never smoked cigarettes, including those who report that they do not inhale, experience elevated risks for oral, laryngeal, pharyngeal, and esophageal cancers (Ref. 183). Although former cigarette smokers who currently smoke cigars are more likely to inhale more deeply than cigar smokers who never smoked cigarettes, “the mouth and oral cavity are exposed to the carcinogens in smoke whether the smoke is inhaled or not” (Ref. 183). The systematic review of the mortality risks associated with cigar smoking also noted that the relative mortality risk was still highly elevated for oral, esophageal, and laryngeal cancer among primary cigar smokers reporting no inhalation (Ref. 32). Cigar smokers, including those who do not inhale, have a similar risk of death from mouth and throat cancer as do cigarette smokers, with an overall risk 7 to 10 times higher than for those who have never smoked (Ref. 183). This similarity in risk is likely due to the similar doses of tobacco smoke delivered directly to the oral cavity and esophagus by cigars and cigarettes (Ref. 210). Cigar smokers are also more likely to develop mouth and throat cancer than those who have never smoked. In a large retrospective cohort study that included more than 17,000 men, researchers found that cigar smokers were nearly three times more likely than nonsmokers to develop cancer of the oropharynx and twice as likely to develop cancer of the upper aerodigestive tract (which includes oral cavity, pharynx, larynx, and esophagus) (Ref. 229). Those risks increased to roughly seven and five times, respectively, among those who smoked five or more cigars per day (Ref. 229).

The NCI's Tobacco Control Monograph No. 9 concluded that cigar smoking is a cause of laryngeal and esophageal cancers (Ref. 183). The likelihood of cigar smokers developing laryngeal cancer is similar to that of cigarette smokers who smoke fewer than 20 cigarettes per day (Ref. 233). The relative risk (*i.e.*, the risk of an outcome under study among exposed (smokers) compared to unexposed (nonsmokers)) of death from laryngeal cancer for those who smoke five or more cigars per day, or who inhale moderately or deeply, approaches the risk for cigarette smokers (Ref. 183). This similarity in

risk is likely due to the similar amounts of tobacco smoke delivered directly to the oral cavity and esophagus by cigars and cigarettes (Ref. 210). Regardless of whether smoke is inhaled, the mouths and tongues of cigar smokers are exposed to a high level of smoke (Ref. 210). The esophagus is exposed to the carcinogens of tobacco smoke, which collect on the mouth's surface and are swallowed with saliva, rendering cigar smoking a cause of esophageal cancer (Ref. 210). The risk of esophageal cancer is several times higher for cigar smokers than for those who have never smoked, and the relative risk of esophageal cancer is higher for cigar smokers than for cigarette smokers, even when cigar smokers are compared to the heaviest cigarette smokers (Ref. 234).

Several multinational research studies also have found that cigar smoking can cause oral and other cancers, even in those who do not inhale smoke. For example, the European Prospective Investigation into Cancer and Nutrition (EPIC) examined 102,395 men from Denmark, Germany, Spain, Sweden, and the United Kingdom and calculated the incidence of cancer in smokers who used cigars exclusively and cigar smokers who also smoked cigarettes (Ref. 235). According to the EPIC study findings, exclusive cigar smokers who report not inhaling had approximately a two-fold higher risk of lung, upper aerodigestive tract, and bladder cancers combined compared to those who never smoked (Ref. 235). This increased risk was raised to six- or seven-fold higher in cigar smokers who inhaled smoke compared to noninhalers (Ref. 235). This increased risk by comparison to never-smokers was lowest for smokers who had quit both cigarettes and cigars and higher for those who switched from cigarettes to only cigars, demonstrating the additional risk associated with cigar smoking compared to stopping smoking altogether (Ref. 235). Researchers confirmed a carcinogenic effect from cigar smoking with regard to upper aerodigestive tract cancers and found that the risk of these hazards increased with increased duration of smoking over the smoker's lifespan, increased intensity of use per week, and increased degree of smoke inhalation per episode (Ref. 235). A recently published international pooled cohort study found that ever cigar smokers had a non-significantly elevated risk of head and neck cancer and no elevated risk of esophageal cancer, although the numbers of cancer cases among ever cigar smokers were small at 12 for esophageal and 38 for head and neck cancer (Ref. 236). Such small sample

sizes, common in cancer studies given the relative rarity of the outcome, can limit the ability to observe a statistical association in the study.

In addition, the World Health Organization (WHO) International Agency for Research on Cancer (IARC) published a monograph evaluating the carcinogenic risk to humans from tobacco smoke and involuntary smoke exposure. The IARC explained: "Cigar and/or pipe smoking is strongly related to cancers of the oral cavity, oropharynx, hypopharynx, larynx, and esophagus, the magnitude of risk being similar to that from cigarette smoking. These risks increase with the amount of cigar . . . smoking and with the combination of alcohol and tobacco consumption" (Ref. 224).

2. Lung Cancer

The evidence clearly establishes that cigar smoking can cause lung cancer; the risk varies by number of cigars per day and level of exposure (Refs. 32; 183 at 119–120; and 224 at 1180). A recently published international pooled cohort study found that ever cigar smokers had a statistically significantly elevated risk of lung cancer (Ref. 236).

Like the dose-response relationship between cigar smoking and mouth and throat cancers, the risk of death and disease from lung cancer increases as the number of cigars smoked per day and the depth of smoke inhalation increases (Refs. 32, 183, and 237–239). Overall lung cancer risk for cigar smokers is lower than the overall risk for cigarette smokers (Refs. 229 and 240–243), but the risk of death from lung cancer for cigar smokers may be similar to the risk of death from lung cancer for cigarette smokers (Refs. 32, 229, and 237–242) once the rates are adjusted for differences in inhalation levels and quantity of cigars smoked daily (Ref. 183 at 120). Cigar smokers in the Cancer Prevention Study I (CPS I), conducted from 1959–1972, who smoked five or more cigars daily with moderate inhalation had a similar risk of death from lung cancer as did pack-a-day cigarette smokers (Ref. 183).

Former cigarette smokers who currently smoke cigars are more likely to inhale deeply than cigar smokers who have never smoked cigarettes, increasing their lung cancer risk (Ref. 23, citing Ref. 183). Although cigarette smokers who switch to smoking only cigars have lower lung cancer risks than they would have if they had continued smoking cigarettes, these risks appear to be substantially greater than for individuals who have quit smoking altogether (Refs. 183 at 155; 239; and 240).

Likewise, according to data from the Cancer Prevention Study II (CPS II, a 12-year study of 1.2 million men and women, in which an analysis was conducted on a subset of male participants from 1982 to 1994 who were asked about cigar use), the risk of lung cancer mortality was approximately five times higher for men who were current smokers of only cigars at the start of the followup study period compared with men who never smoked (Ref. 243). In an analysis of a subset of men who participated in the CPS II study, researchers found that men who smoked three or more cigars per day, who reported inhaling cigar smoke, or who had smoked cigars for 25 years or more experienced a statistically significantly greater risk of mortality from lung cancer than those men who reported less frequent cigar use, not inhaling, and smoking cigars for 25 years or less (Ref. 243). Even male cigar smokers who reported that they did not inhale were approximately three times more likely to die from lung cancer than those who never smoked (Ref. 243).

The type of cigar used also may impact the risk of lung cancer in cigar smokers. One large case-control study found that lung cancer patients had 12.7 times greater odds of being an exclusive cigarillo user than controls, compared to a 5.6 times greater odds of being an exclusive user of cigars other than cigarillos (the study was conducted in Europe, where cigarillos typically weigh 1.5 to 3 grams and traditional cigars weigh 2 to 8 grams) (Ref. 239). This difference was likely due to differences in inhalation, as the researchers found that cigarillo users were more likely to inhale than users of other cigars, and inhalers were at higher risk of lung cancer than noninhalers (Ref. 239). As cigarillo and filtered cigar use has increased (and cigarette use has decreased over this same period) in the United States, it is likely that smokers are using such products as substitutes for cigarettes and inhaling them as they would cigarettes (Refs. 101 and 183). Filtered cigars, for example, share many of the design characteristics of cigarettes (Ref. 49). Therefore, the risk of lung cancer for some cigar smokers may be similar to that for cigarette smokers.

3. Heart Disease and Aortic Aneurysm

Researchers have identified a pattern of elevated rates of death from coronary heart disease and aortic aneurysm among primary cigar smokers who smoke heavily or inhale deeply (Ref. 32). The CPS I (1959–1972), which evaluated nearly one million men and women in 25 states, found that the rate of death from coronary heart disease

increases with the number of cigars smoked and the depth of smoking inhalation (Refs. 32 and 183). Researchers also identified an elevated risk of developing coronary heart disease in those individuals who smoked five or more cigars per day and exhibited moderate or deep inhalation (Refs. 32, 183, and 244). CPS I data also suggest that cigar smokers are at an increased risk for aortic aneurysm, the risk rate approaching that observed for cigarette smokers (Refs. 32 and 183).

Researchers analyzing CPS II data also examined death rates resulting from coronary heart disease related to cigar smoking. The 1999 CPS II reviewed approximately 7,000 current cigar smokers, 7,000 former cigar smokers, and 113,000 men who had never regularly smoked tobacco to determine the risk of heart disease for cigar smokers (Ref. 210). Among men younger than 75 years old, current cigar smokers experienced a coronary heart disease death rate about one-third higher than those who had never smoked (Ref. 210).

Additional studies provide supporting evidence that cigar smokers have elevated rates of developing coronary heart disease compared with nonsmokers (Refs. 229, 241, and 245). One large study examined primary (*i.e.*, current, exclusive with no previous history of cigarette or pipe tobacco use) and secondary (*i.e.*, current, exclusive with previous history of cigarette or pipe tobacco use) cigar smokers compared with never smokers (Ref. 241). It found that both primary and secondary cigar smokers were at increased risk of major coronary heart disease compared to never smokers (Ref. 242). Secondary cigar smokers also had a higher risk of major stroke compared with never smokers (Ref. 241). Primary and secondary cigar smokers had similar risks of major coronary heart disease and stroke and experienced outcomes similar to those who smoked less than a pack of cigarettes per day (Ref. 241). In the recently published NHIS–LMF, current, daily cigar smokers had a non-significantly elevated risk of death due to coronary heart disease compared to never tobacco users (Ref. 228).

In addition, in 2010, the Surgeon General found that for older adult cigar smokers, particularly those who smoke more than one cigar per day or inhale the smoke, the risk of heart disease is moderately higher than that for nonsmokers (Ref. 6). In support of the Surgeon General's findings, one study conducted from 1964 to 1973 involved 17,774 men ranging in age from 30 to 85, of which 1,546 smoked cigars and 16,228 did not, all of whom reported

that they had never smoked cigarettes and did not currently smoke pipes (Ref. 229). This study determined that cigar smoking was associated with a moderate, but statistically significant, increase in the risk of coronary heart disease (Ref. 229).

International researchers have reached similar conclusions about the impact of cigar smoking on the risk of developing heart disease. For example, in a study of more than 12,000 Danish people aged 30 years and older that looked at the risk of first acute myocardial infarction (MI), researchers found the risk of first acute MI escalated with increasing depth of smoke inhalation and with increasing number of cigars smoked per day (Refs. 183 and 244). Another Danish study found the highest rates of myocardial infarction for smokers of cheroots (a type of cigar with ends that do not taper that is traditionally used in India and Burma) to be for those individuals who smoked six or more cheroots per day, with a relative risk of myocardial infarction of more than four times the risk of individuals who had never smoked (Ref. 183, citing Ref. 246).

4. Other Health Outcomes

Research studies have found that cigar smokers have approximately 40 to 45 percent higher risk of COPD than never tobacco users. A cohort study of Kaiser Permanente plan members found a relative risk of COPD diagnosis of 1.45 for cigar (Ref. 229), and CPS I data found a similar elevated relative risk of COPD among primary cigar smokers of 1.42 (Ref. 247).

The risk of bladder cancer in CPS I data was also approximately 40 percent higher for cigar smokers, with a relative risk of 1.38 (Ref. 247). In a recently published study using data from the Agricultural Health Study, ever cigar use was statistically significantly associated with risk of urinary cancer (Ref. 248).

There are other health outcomes attributable to cigar smoking that were not assessed using CPS I or II mortality data. For example, one study found statistically significant increased risks of colon and rectal cancers among cigar smokers in a cohort of nearly 250,000 World War I era veterans who were followed for mortality for 26 years (Ref. 249). While most research has focused on cigar-attributable mortality, limited research has addressed cigar-attributable morbidity. Besides dying from cigar-attributable disease, lifelong cigar smokers may live many years with serious medical conditions, such as cancers (Refs. 229 and 232), heart disease (Refs. 229 and 245), and

increased airflow obstruction (Ref. 124) that can lead to major physical impairments, and substantially reduce functioning and quality of life.

5. Impact on Individuals Who Report That They Do Not Inhale Smoke

Studies suggest that even cigar smokers who do not intend to inhale smoke, and who are unaware they are doing so, nonetheless inhale some amount of cigar smoke (Refs. 124 and 212). While inhaling cigar smoke poses much higher morbidity and mortality rates than not inhaling, substantial risks still exist for those cigar smokers who may not intentionally inhale smoke. Relative mortality risks for oral, esophageal, and laryngeal cancers are high even among those primary cigar smokers who reported that they do not inhale cigar smoke (Ref. 32; see Refs. 183, 230, and 247). Researchers found that the risk of stomach cancer mortality was also higher among cigar users who reported they did not inhale smoke when compared to individuals who did not use tobacco products (Ref. 250). Regardless of whether cigar smokers inhale, they are still subject to cigars' addictive and other adverse health effects through absorption of nicotine and other harmful constituents, including those discussed in section V.B of this document (Refs. 212 and 250). Buccal absorption of nicotine occurs even if cigar smoke is not inhaled, and cigar smokers may also absorb nicotine through the lips due to the alkalinity of cigar tobacco (Refs. 214 and 215). This greater nicotine yield and absorption increases the risk of nicotine addiction from cigar smoking.

E. Secondhand Tobacco Smoke, Including Cigar Smoke, Increases the Risks of Lung Cancer, Heart Disease, and Other Adverse Health Effects in Nonsmokers

Tobacco smoke inhaled by nonsmokers in indoor and outdoor spaces is most commonly referred to today as "secondhand smoke" but has also been referred to as "environmental tobacco smoke," "passive smoke," or "involuntary smoke." Extensive data exist regarding the dangers of involuntary exposure to tobacco smoke. It is well established that exposure to secondhand tobacco smoke causes premature death and disease in youth and adults who do not smoke (e.g., Refs. 251 and 252). Exposure to secondhand smoke has immediate adverse effects on the cardiovascular system and can cause lung cancer, coronary heart disease, and stroke (Ref. 251). By reducing the prevalence of cigar smoking, this

proposed standard also has benefits for those who do not use cigars.

Tobacco smoke contains over 7,000 compounds, and cigars generate more than 50 carcinogens in mainstream and sidestream smoke (Refs. 23, 183, and 251). Mainstream cigar smoke is the smoke one draws into the mouth from the butt end or mouthpiece of a cigar; sidestream cigar smoke is the smoke emitted from the burning cone of a cigar during the interval between puffs (Ref. 183). Secondhand smoke is a combination of sidestream smoke and exhaled mainstream smoke.

While the above data on secondhand smoke are related to cigarettes, evidence supports the conclusion that these data apply to secondhand cigar smoke, as well, and there is no basis to conclude that secondhand smoke from cigars is any less hazardous than secondhand smoke from cigarettes. Cigar smoke contains the same toxic substances as cigarette smoke, with varying concentrations of these constituents found in different cigar types and sizes (Ref. 183). Even though, on average, tobacco users smoke more cigarettes than cigars, the overall level of toxicants in secondhand smoke from cigars can be quantitatively higher than in the secondhand smoke from cigarettes (Ref. 183). Cigars also produce much higher levels of many indoor pollutants than cigarettes, which can be explained, at least in part, by the larger size of cigars and therefore greater amount of tobacco burned compared to cigarettes (Ref. 183). The smoke from one cigar can take 5 hours to dissipate, exposing household members to a considerable involuntary health risk (Ref. 183).

1. Lung Cancer and Secondhand Smoke

Exposure of nonsmokers to secondhand tobacco smoke has been shown to cause a statistically significant increase in urinary levels of metabolites of tobacco-specific nitrosamines, which are carcinogens that specifically link exposure to secondhand smoke with an increased risk for lung cancer (Ref. 251). Studies in rodents have demonstrated that 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone specifically induces lung tumors by systemic administration, which provides support that nitrosamines are major factors in the development of lung cancer (Ref. 251). According to the Surgeon General, there is sufficient evidence from which to infer a causal relationship between secondhand tobacco smoke exposure and lung cancer among lifetime nonsmokers (Ref. 251). Individuals living with smokers had a 20 to 30 percent increase in the risk of developing lung cancer from

secondhand smoke exposure, compared with individuals living with nonsmokers (Ref. 251). Based on the similarity of the toxic constituents in cigars and cigarettes, and the fact that cigars commonly share similar product design and mechanisms of smoke delivery as cigarettes, FDA's scientific judgment leads the Agency to expect that secondhand cigar smoke would produce effects similar to those produced by secondhand cigarette smoke. According to the World Health Organization's International Agency for Research on Cancer, a mass balance model developed for predicting secondhand tobacco smoke was used to obtain CO, respirable suspended particle, and PAH emission (Ref. 224). These observed factors demonstrated that cigars can be more potent sources of CO than cigarettes (Ref. 224). The study also demonstrated that although a single cigar may have lower emissions of respirable suspended particles and PAHs per gram of tobacco consumed than a cigarette, a cigar's larger size and longer smoking time results in greater total respirable suspended particles and PAH emission than a single cigarette (Refs. 224 and 253). Findings from the NCI Tobacco Control Monograph No. 9 also demonstrate that carcinogens linked to lung cancer would be expected to be present at comparable levels in cigar and cigarette smoke (Ref. 183). Little cigars with filter tips and regular cigars contain higher levels of certain nitrosamines in sidestream smoke than do filtered tip cigarettes (Ref. 183).

2. Heart Disease and Secondhand Smoke

The evidence cited in Surgeon General's Reports supports the conclusion that secondhand tobacco smoke exposure can cause heart disease and stroke. Although the research examining the effects of exposure specific to secondhand cigar smoke is more limited compared to cigarettes, evidence from a recently published study suggests that the risk of experiencing negative cardiovascular effects due to secondhand cigar smoke exposure is similar to the risk from secondhand cigarette smoke exposure (Ref. 254). It is reasonable to anticipate that the cardiovascular risks from secondhand cigar smoke would be similar to those of secondhand cigarette smoke due to the similar smoke profiles for cigars and cigarettes, the excess risk of coronary heart disease associated with active cigar smoking, and the low levels of toxicant exposure that can cause coronary heart disease (Ref. 251).

In a 2006 report regarding the health effects of exposure to secondhand

tobacco smoke, the Surgeon General concluded that exposure to secondhand tobacco smoke had immediate adverse effects on the cardiovascular systems and caused coronary heart disease (Ref. 251). The estimated increase in coronary heart disease risk from exposure to secondhand tobacco smoke is 25 to 30 percent above that of unexposed individuals (Ref. 251). Based on these data, the Surgeon General concluded that "the evidence is sufficient to infer a causal relationship between exposure to secondhand smoke and increased risks of coronary heart disease morbidity and mortality among both men and women" (Ref. 251).

3. Other Health Problems

Studies have concluded that secondhand tobacco smoke can cause other health problems, specifically for youth. Secondhand smoke exposure has been independently linked to increased inflammatory responses, oxidative stress, and endocrine disruption in youth (Refs. 255–257). Children exposed to secondhand smoke are also at an increased risk of sudden infant death syndrome, acute respiratory infections, ear problems, and more severe asthma (Ref. 23). In addition, smoking by parents can cause respiratory symptoms and slower lung growth in their children as compared to the children of non-smoking parents (Ref. 23). It is expected that these health effects would apply to secondhand cigar smoke exposure specifically, given the stated similarities between cigar smoke and other forms of tobacco smoke.

For all of these reasons and based on extensive evidence, it is clear that cigar use causes severe negative health consequences among users and nonusers. As discussed in section VI of this document, this proposed rule, if finalized, would help to prevent experimentation with cigars and progression to regular use, and increase cessation among current users, which would help to lessen the incidence of cigar-related negative health consequences.

F. Disparities in Tobacco Use, Including Cigar Use, Lead to Disparities in Tobacco-Related Morbidity and Mortality

As previously discussed, cigar smoking exposes users to the same toxic and carcinogenic compounds identified in cigarette smoke and is associated with many of the same health risks as cigarette smoking. As such, this section discusses the evidence to support how disparities in tobacco use shape disparities in tobacco-related morbidity and mortality. While the prevalence of

cigar use has decreased over time for non-Hispanic White persons, data from the 2002–2016 NSDUH show that cigar use has remained stable for non-Hispanic Black persons (aged 12 years and older) (Ref. 162), while 2000–2015 NHIS data show increased prevalence for non-Hispanic Black adults (aged 18 years and older) (Ref. 258). In addition, differences in cessation and quit attempts have been observed across population groups. Despite more attempts at quitting, Black cigarette smokers are less successful at quitting than White and Hispanic cigarette smokers (Refs. 38, 259, and 260). While less is known about disparities in cigar cessation, findings from 2013–2016 PATH data indicate that non-Hispanic Black cigar users had lower odds of discontinuing cigar use than non-Hispanic White users (Ref. 261). Collectively, these factors contribute to the disparities in tobacco-related health outcomes. While the etiology of chronic health conditions is multifactorial in nature, smoking has been found to be an important causal factor (Ref. 23) African American adults, and in particular African American men, experience the highest rates of incidence and mortality and lowest rates of survival from many tobacco-related cancers, such as lung and bronchus cancer and head and neck cancer, compared to those from other racial and ethnic groups (Refs. 262 and 263). Deaths from other tobacco-related conditions such as heart disease, stroke, and hypertension are higher among African Americans compared to other racial and ethnic groups (Refs. 264–269).

The higher levels of flavored cigar use among non-Hispanic Black cigar users exacerbate already-existing health disparities experienced by the Black community (Refs. 163 and 270). Levels of nicotine and other carcinogens in cigars may be higher than those in cigarettes and may be at levels that lead to increased risk of morbidity and mortality from conditions such as cancer, cardiovascular disease, and COPD (Refs. 3, 32, and 210).

Additionally, American Indians or Alaskan Natives (AI/ANs) have the highest prevalence of overall tobacco use compared to members of other racial and ethnic groups (Refs. 37, 38, 68, and 271). Prevalence of cigar smoking among AI/ANs is lower than prevalence among Blacks, but higher than among Hispanics and Asians (Ref. 271). It is well documented that AI/ANs suffer disproportionately from both lung cancer and cardiovascular diseases (Refs. 272 and 273). An analysis of 2001–2009 mortality data for people living in the Indian Health Service

Contract Health Service Delivery Area counties in the United States indicated that age-adjusted death rates, smoking-attributable fractions, and smoking-attributable mortality for all-cause mortality were statistically significantly higher among AI/AN populations than among Whites for adult men and women aged 35 years and older (Ref. 274). Cigarette smoking caused 21 percent of ischemic heart disease, 15 percent of other heart disease, and 17 percent of stroke deaths in AI/AN men, compared with 15 percent, 10 percent, and 9 percent, respectively, for White men (Ref. 274). Among AI/AN women, smoking caused 18 percent of ischemic heart disease deaths, 13 percent of other heart diseases deaths, and 20 percent of stroke deaths, compared with 9 percent, 7 percent, and 10 percent, respectively, among White women (Ref. 274).

Disparities in tobacco-related morbidity and mortality have also been observed for other population groups that have higher levels of tobacco use. Those with low household income and educational attainment bear a disproportionate burden of heart disease and stroke incidence and mortality (Refs. 275 and 276). National Health and Nutrition Examination Survey (NHANES) data from 2007 to 2010 indicate that prevalence of co-occurring obesity and smoking was linearly associated with educational attainment as women with the lowest levels of education had greater likelihood of being obese smokers than women with the highest levels of education (Ref. 277). Research has also demonstrated that individuals with behavioral health conditions and other medical comorbidities have higher prevalence of combusted tobacco use compared to those without these conditions (Refs. 167 and 278) and have increased risk of tobacco-related morbidity and mortality (Refs. 23, 279, and 280). Inpatient hospital admission data from 1990 to 2005 from California indicate that approximately half of the deaths in those who had been hospitalized for schizophrenia, bipolar disorder, or major depressive disorder were due to diseases causally linked to tobacco use (Ref. 279) and that the majority of deaths for those hospitalized for opioid-related conditions were related to tobacco and alcohol, not to opioids (Ref. 281). In a study of 470 unhoused individuals, the analysis found that past 30-day use of all tobacco products was high and that 74.0 percent of respondents reported use of cigars and over half (55 percent) reported use of flavored cigars in the past 30 days (Ref. 166). Tobacco-related cancers are a

leading cause of death among adults experiencing homelessness (Ref. 165).

Additionally, the burden of secondhand smoke exposure is experienced disproportionately among members from some racial and ethnic groups and people from lower household income and educational attainment backgrounds. Among nonsmokers ages 3 and older, findings from 2011–2018 NHANES data indicate that non-Hispanic Blacks and those living below the poverty level had the highest levels of secondhand smoke exposure compared to people of other races and those living above the poverty level, respectively; these disparities persisted across all years of the study analysis from 2011 to 2018 (Ref. 282). From 1999 to 2012, the percentage of the nonsmoking population ages 3 and older with detectable serum cotinine levels (defined in the study as levels ≥ 0.05 ng/mL to indicate secondhand smoke exposure) declined across all racial and ethnic groups (Ref. 283). However, a higher proportion of non-Hispanic Black nonsmokers continued to have detectable serum cotinine levels, compared to Mexican American and non-Hispanic White nonsmokers. For example, in 2011–2012, nearly 50 percent of non-Hispanic Black nonsmokers had detectable serum cotinine levels, compared with 22 percent of non-Hispanic White and 24 percent of Mexican American nonsmokers (Ref. 283).

Disparities in the secondhand smoke exposure are found across various environmental settings. These disparities speak to the interrelated influences of individual factors (e.g., age, race and ethnicity, income) and existing inequities in places where members from underserved communities are likely to reside, spend time, and work (Ref. 183). Findings drawn from the 2013–2016 NHANES data indicate that compared to non-Hispanic Whites, non-Hispanic Blacks had higher odds of secondhand smoke exposure in homes other than their own (Ref. 284). An analysis of NYTS data indicates that non-Hispanic Black and non-Hispanic White students both had higher prevalence of secondhand smoke exposure at home and in vehicles than Hispanic and non-Hispanic other students (Ref. 285). While secondhand smoke exposure in homes and vehicles declined from 2011 to 2018, secondhand smoke exposure in homes among non-Hispanic Black students did not change (Ref. 285). Home smoking bans (*i.e.*, household rules that restrict or ban smoking inside the home) can reduce secondhand smoke exposure. A study using 1995–2007 data from the

TUS–CPS found that among two parent households, higher levels of parental educational level and annual household income were associated with the higher reporting of a complete home ban as compared to lower levels of parental educational and annual household income (Ref. 286). Such findings are consistent with a higher degree of autonomy over the home environment for households with greater economic resources and housing flexibility, emphasizing the degree to which certain aspects of disadvantage (such as lower family income, lack of access to single-family housing, or lack of autonomy over the home environment) may compound tobacco-related health disparities. Workplace secondhand smoke exposure has also been shown to vary across population groups. Data from the 2010 and 2015 NHIS show that exposure to secondhand smoke in the workplace was disproportionately high among non-Hispanic Blacks, Hispanics, and workers with low education and low income (Ref. 287). Additionally, the study findings indicated that “blue-collar workers” (defined as those who performed manual labor such as manufacturing, mining, sanitation, and construction) experienced higher prevalence of secondhand smoke exposure as compared to “white-collar workers” (defined as those who primarily work in an office, with computer and desk setting, and perform professional, managerial, or administrative work) (Ref. 287).

The disparities observed in tobacco and cigar use, as well as disparities in secondhand smoke exposure, contribute to the disparities in tobacco-related morbidity and mortality experienced by some population groups. This proposed product standard is anticipated to reduce smoking-related morbidity and mortality for these vulnerable populations.

VI. Determination That the Standard Is Appropriate for the Protection of the Public Health

The Tobacco Control Act authorizes FDA to adopt tobacco product standards by regulation if it finds that a tobacco product standard is appropriate for the protection of the public health (section 907(a)(3)(A) of the FD&C Act). The notice of proposed rulemaking for such a product standard must set forth this finding with supporting justification, which FDA is doing here (section 907(c)(2)(A) of the FD&C Act).

In order to make this finding, FDA must consider scientific evidence concerning:

- The risks and benefits to the population as a whole, including users

and nonusers of tobacco products, of the proposed standard;

- The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
- The increased or decreased likelihood that those who do not use tobacco products will start using such products.

Section 907(a)(3)(B)(i) of the FD&C Act.

FDA has considered scientific evidence related to all three factors. Based on these considerations, as discussed below, we find that the proposed standard is appropriate for the protection of the public health because it would reduce the appeal of cigars, particularly to youth and young adults, thereby decreasing the likelihood both that nonusers would experiment with cigars and that current and future experimenters would continue to use cigars, develop an addiction to nicotine, and progress to regular use of cigars and/or other tobacco products. Additionally, FDA anticipates that the proposed standard would improve the health of some current smokers of flavored cigars by increasing the likelihood of cessation. Decreased experimentation, progression to regular use, and consumption would lead to lower disease and death in the U.S. population, including in certain populations that are disproportionately marketed to and bear a disparate burden of tobacco-related morbidity and mortality. In addition, the population as a whole would likely experience health benefits based on a likely decrease in morbidity and mortality resulting from secondhand smoke exposure.

A. The Likelihood That Nonusers Would Start Using Cigars

Flavors are a significant driver for youth and young adults to try cigars. In section IV of this document, we summarize evidence from multiple study designs, incorporating findings from qualitative research, and nationally representative cross-sectional and longitudinal observational studies that illustrate the appeal of flavored cigars among young people and the role characterizing flavors play in experimentation and continued cigar use. In this section, we discuss how, given this evidence and findings from policy evaluations of local and national jurisdictions, FDA expects the proposed standard on characterizing flavors (other than tobacco) in cigars would decrease experimentation and progression to regular use of cigars among current nonusers.

Youth and young adults consistently identify the availability of characterizing flavors as a leading reason for their cigar use (Refs. 64 and 65). In 2018–2019, 50.4 percent of youth (aged 12–17 years) participants in the PATH Study who reported past 30-day cigar smoking identified flavors as a reason for use (Ref. 12). Four systematic reviews of the scientific literature concluded that flavored tobacco products attract youth to the tobacco product (Refs. 86–89). Two of the reviews that included discussion of cigars concluded that characterizing flavors were an appealing feature of tobacco products and that flavors influence perceptions, initiation, and progression to use of tobacco products, particularly among youth (Refs. 88 and 89). Similarly, results from qualitative research indicate that youth and young adults themselves acknowledge that flavorings impact their cigar use, making smoking flavored cigars more palatable than smoking non-flavored cigars (Ref. 82). The appeal of flavors is also consistent with physiological studies assessing youth preference for flavors, including studies assessing the similarities between flavor chemicals in tobacco products with drink mixes and candy (Refs. 95 and 96). Overall, the literature is consistent on the appeal of flavors in tobacco products, including cigars (see section IV.D of this document). Diminishing the appeal of cigars by prohibiting the use of characterizing flavors (other than tobacco) is, therefore, appropriate for the protection of the public health, as it would decrease the likelihood of experimentation at younger ages and reduce the potential for onset of tobacco dependence during the progression to regular tobacco use. Furthermore, flavored cigar use exposes users to more toxicants than are present in non-flavored cigars and there is no evidence that flavored cigars present any countervailing benefits to public health.

Experimentation with cigars can lead to nicotine dependence and regular use, as discussed in section IV.E of this document. Based on nationally representative Truth Longitudinal Cohort data from 2014 to 2019, 44.7 percent of youth and young adults (aged 15–25 years) who initiated cigar use reported current (*i.e.*, past-30-day) cigar use 6 months after initiation (Ref. 100). When trying a cigar for the first time, the majority of youth cigar smokers report that the first cigar they used was flavored. Data from Wave 5 (2018–2019) of the PATH Study revealed that 60.4 percent of youth (aged 12–17 years) and 63.2 percent of young adults (aged 18–

24 years) who reported ever using cigars said that the first cigar they used was flavored (Ref. 12).

Using nationally representative longitudinal data from Waves 1 (2013–2014) and 2 (2014–2015) of the PATH Study, one study found that first use of a flavored cigar was associated with more likely subsequent cigar use 1 year later compared to first use of a non-flavored cigar in young adults (aged 18–24 years) and adults (aged 25 years and older) (Ref. 28). This analysis was extended using Waves 1–4 (2013–2017) of PATH Study data to assess the relationship between new use of a menthol- or mint-flavored cigar or other flavored (*e.g.*, fruit, alcohol, chocolate, candy, and other flavor) cigar with subsequent use compared to first use of a non-flavored cigar. The analysis found that among youth (aged 12–17 years) and young adults (aged 18–24 years), first use of any menthol- or mint-flavored or other flavored cigar was associated with current past 30-day use of flavored cigars at a later wave compared with first use of a non-flavored (*i.e.*, tobacco) cigar (Ref. 29). Specifically, youth who used a menthol/mint-flavored cigar or other flavored cigar were 72 percent (menthol/mint) and 47 percent (other flavor) more likely, respectively, to be using a cigar a year or more later compared to those first using a non-flavored cigar. Similarly, young adults (aged 18–24 years) who used a menthol/mint-flavored cigar or other flavored cigar were 71 percent (menthol/mint) and 52 percent (other flavor) more likely to be using a cigar a year or more later compared to those first using a non-flavored cigar. For both youth and young adults, the association between the first flavor used and subsequent cigar use was not statistically significantly different for menthol- or mint-flavored compared to other flavored cigars. These results are consistent with the evidence that flavors enhance the addictive effects of nicotine and make cigars easier to use, as discussed previously. FDA finds that eliminating flavored cigar varieties likely would decrease the number of youth and young adults experimenting and progressing to regular, sustained use of cigars.

Given that nicotine is highly addictive and present in all cigars, as experimenters continue to use these products, there is a risk of development of nicotine dependence and progression to regular use. Several studies found that cigars reduce craving and urge to smoke similar to cigarettes (Refs. 101–103). The adolescent brain is more vulnerable to developing nicotine

dependence than the adult brain. Nicotine can disrupt brain development and have long-term consequences, including decreasing attention and increasing impulsivity, which could promote the maintenance of nicotine use behavior (Ref. 288). Therefore, progressing to regular use during adolescence can have lasting consequences and signs of nicotine dependence are evident in young cigar users. Researchers analyzing data from the 2017–2018 NYTS found that 43.1 percent of middle and high school students using cigars in the past 30 days reported nicotine dependence, including feeling a strong craving to use a tobacco product or using a tobacco product within 30 minutes of waking (Ref. 107). Such results suggest that even infrequent experimentation can lead to early signs of dependence, which underscores the public health importance of decreasing the likelihood of cigar experimentation among youth and young adults in the United States.

It is also important to note the role that cigars play in polyuse patterns, and the subsequent development of dependence, among youth tobacco users. As polyuse increases, youth exposure to nicotine increases (Ref. 17), increasing the risk of dependence among young people (Refs. 181 and 182). When looking at the association between cigar use and dependence, exclusive use of cigars among youth in the 2017–2018 NYTS was associated with lower odds of nicotine dependence relative to exclusive use of another tobacco product. However, when youth cigar use included polyuse, which was more common for youth cigar users, current cigar use was associated with twice the odds of nicotine dependence compared to current use of any other tobacco product (Ref. 107). See section V.A.3 of this document for additional discussion regarding polyuse.

Similar to cigarette smoking, first cigar use often occurs during youth or young adulthood (Refs. 24 and 25). A longitudinal analysis of Waves 1–4 (2013–2017) of PATH Study data found an increasing probability of initiating cigar use between ages 15 and 20 years, with the greatest increase in first use between 17 and 18 years of age (Ref. 25).

FDA expects a substantial reduction in youth and young adult initiation and progression to regular use of cigars, which would ultimately protect many youth and young adults from a lifetime of addiction, disease, and death attributable to cigar smoking. There are multiple sources of evidence to inform the Agency's analysis of how the proposed standard would affect the likelihood that nonusers would start to

experiment and continue using cigars (Refs. 28, 29, and 100). First, many individuals who initiate cigar use transition to more regular use. One analysis of data from a nationally representative cohort found that 44.7 percent of youth and young adults who initiated cigar use became a regular user 6 months after first trying a cigar (Ref. 100). Next, several studies suggest that when individuals initiate cigar use, it is often with a flavored product. PATH researchers found that 60.4 percent of youth (aged 12–17 years) and 63.2 percent of young adults (aged 18–24 years) who reported ever using cigars said that the first cigar they used was flavored (Ref. 12). Lastly, analyses of PATH data also suggest that initiation with a flavored cigar is associated with a greater likelihood of progressing to regular use compared to initiation with a non-flavored cigar. In a cross-sectional analysis of the PATH study, young adult (aged 18–24 years) and adult ever tobacco users (aged 25 years and older) who initiated with a flavored cigar were more likely than those who initiated with a non-flavored cigar to be a current regular cigar user, after controlling for demographics, education, income, age at first tobacco use, substance use, and mental health indicators (Ref. 289). In a longitudinal analysis using Waves 1 to 4 (2013–2017) of PATH Study data, youth and young adults who used a mint or menthol cigar or other flavored cigar were more likely to be past-30-day cigar users at a subsequent wave compared to those first using a non-flavored cigar, after controlling for sociodemographics (Ref. 29). Together these study results indicate that experimentation with cigars is associated with progression to regular use, the majority of youth and young adults who initiate cigar use do so with flavored cigars, and initiating with flavored cigars (compared to non-flavored cigars) is associated with an increased risk of current and ongoing tobacco use, as compared to experimentation with non-flavored cigars. To the extent that youth and young adult cigar users using a flavored cigar on their first use would not otherwise initiate with non-flavored cigars or other tobacco products, the proposed standard would prevent future tobacco-related disease and death among these youth and young adults.

In addition to longitudinal studies illustrating the role of flavors in youth and young adults progressing from experimenting with flavored cigars to regular use, policy evaluations from local jurisdictions throughout the United States illustrate how a flavor

restriction can decrease youth cigar use. Section IV.F of this document discusses results from evaluation studies of restrictions on the sale of tobacco products with characterizing flavors in jurisdictions throughout the United States and in Canada. Studies of policies implemented in Providence, RI; New York, NY; Lowell, MA; Attleboro and Salem, MA; Minneapolis and St. Paul, MN; San Francisco, CA; and Canada focused on the impact of flavored tobacco sales restrictions on youth use of tobacco products, including cigars and are informative to FDA's consideration of how the proposed standard would impact the likelihood of tobacco use among youth.

In Providence, RI, at 3 years and 5 years following implementation of the city's restriction on flavored tobacco products except menthol, mint, and wintergreen, youth current use of any tobacco product had declined, from 22.2 percent in 2016 to 12.1 percent in 2018; and current use of cigars/cigarillos had declined from 7.1 percent in 2016 to 1.9 percent in 2018 (Ref. 60). Three years after implementation of a restriction on flavored tobacco products except menthol, mint, and wintergreen, in NYC in 2010, youth (13–17 years) had 37 percent lower odds of reporting having ever tried a flavored tobacco product, and 28 percent lower odds of ever using tobacco products in 2013 compared to 2010 (Ref. 51). Six months after enacting a restriction on flavored tobacco products except menthol in 2016, researchers in Lowell, MA, found that youth current use of any flavored tobacco products decreased in Lowell from baseline to followup (–2.4 percent), with a statistically significant difference between Lowell and an observed increase in flavored tobacco use in the comparison community (3.3 percent) (Ref. 61). In the Twin Cities, MN, two cross sectional studies were administered before and after implementation of a restriction on flavored tobacco products first excluding menthol, mint, and wintergreen in 2016 and then after the policy was expanded to include menthol, mint, and wintergreen in 2018 (Ref. 111). Comparing the two cities to the rest of the State, the study found that when the first policy was implemented the prevalence of cigar use did not change in the Twin Cities among 6th to 12th grade students, but cigar use increased 71.3 percent in the rest of the State. The analysis also found that between 2016 and 2019, when the flavor restriction also included menthol, cigar use among 8th, 9th, and 11th grade students declined more in the Twin

Cities compared to the rest of the State (Ref. 111). In San Francisco, CA, following implementation of the city's restriction on flavored tobacco products, including menthol, among a small convenience sample of young adults ages 18 to 24 years surveyed after policy implementation there was a statistically significant decrease in flavored cigar use (from 19.4 to 6.5 percent) (Ref. 62). An evaluation of a national flavored tobacco policy in Canada that restricted flavored tobacco products except menthol cigarettes and cigars under 1.4 grams (or in any cigar that had a filter or non-spiral wrap) is consistent with local flavored tobacco policies in the United States regarding decreased use of cigars among young people and found a statistically significant 2.3 percentage point decrease in past 30-day cigarillo use among young people aged 15 to 24 years 1 year after policy implementation (Ref. 113). Most of these studies of local flavored tobacco policies in the United States describe concerns with compliance and enforcement of the policies, noting potential increases in cross-border sales and observed retail sales of flavored product in defiance of implemented policies. FDA anticipates that a nationwide standard that prohibits the manufacture and sale of flavored cigars would likely have a greater impact in decreasing youth cigar use compared to that observed from policies from limited jurisdictions, because a nationwide product standard would eliminate the manufacture of these products as well as the opportunity for youth to easily travel to neighboring jurisdictions that do not have a flavor prohibition or use online retailers to purchase flavored cigars.

As described in section IV.B of this document, an estimated 960,000 youth reported past 30-day use of cigars in 2020, with an estimated 550,000 youth, reported using a flavored cigar during the past 30 days (Ref. 8). Given the measured decrease in youth tobacco use consistent across U.S. localities that have recently implemented restrictions on the sale of flavored tobacco, FDA expects that many of these youth would be discouraged from continued experimentation with cigars as a result of the proposed standard. In contrast to the locality restrictions discussed previously, FDA's proposed product standard would result in a comprehensive regulation restricting both the manufacturing and sale of cigars with characterizing flavors in the United States. Evaluations of retailer compliance following implementation of local flavor restrictions suggest that incomplete compliance led to

availability of violative products in retail environments, which likely diminished the impact of the restrictions (Refs. 108 and 109). Unlike a restriction on sales alone, the proposed standard would prohibit both the manufacture and sale of cigars with characterizing flavors (other than tobacco), and as a result, it would allow for a more complete prohibition of flavored cigar products from the market. It is therefore likely that the impact of the FDA product standard on youth and young adult cigar smoking would be greater than that observed among the evaluation studies discussed previously.

In summary, across varying study populations and research study designs, evidence shows that the presence of characterizing flavors in tobacco products enhances the appeal of tobacco products to young people and is associated with experimentation and progression to regular tobacco use. Characterizing flavors also can activate the brain's reward circuit and reinforce tobacco use. Prohibiting characterizing flavors (other than tobacco) in cigars would eliminate rewarding and reinforcing associations with the product among youth and would result in a marketplace that solely consists of (mostly already existing) cigar products that have harsher, more astringent cigar smoke that are likely less appealing to novice users. Evidence from five U.S. localities and Canada consistently indicate that prohibiting sales of flavored tobacco decreased youth and young adult use of tobacco, including cigars. In nationally representative estimates, most youth and young adults report initiating use with a flavored cigar (Ref. 12). In addition, results from a large national study observed a relationship between first use of a flavored cigar and regular cigar use in youth and young adults (Refs. 28 and 29). Therefore, a prohibition on characterizing flavors (other than tobacco) in cigars would reduce the likelihood that youth and young adults would initiate cigar use and also mean fewer youth and young adults progressing to regular cigar use. For these reasons, FDA expects that prohibiting characterizing flavors as described in this proposed rule would reduce the likelihood that youth would experiment with and continue to use cigars and would ultimately reduce future disease and death associated with long-term cigar smoking.

B. The Likelihood That Existing Users Would Reduce Cigar Consumption or Stop Cigar Smoking

FDA expects that the prohibition of characterizing flavors (other than

tobacco) in cigars, as proposed, would result in changes in tobacco use patterns among current smokers of flavored cigars. In addition to the long-term public health benefits that would accrue from the prevention or reduction of cigar smoking among youth and young adults, FDA anticipates that the proposed standard would increase the likelihood that some existing flavored cigar smokers would find tobacco-flavored cigars unappealing and consequently stop smoking cigars altogether, yielding health benefits from smoking cessation. For instance, current flavored cigar smokers may quit cigar use altogether, transition to tobacco-flavored cigars or other combusted tobacco products, or switch to other potentially less harmful tobacco products. Given the substantial proportion of existing cigar users using flavored cigars, the consistently high endorsement of characterizing flavors as a reason for use, empirical evidence of lower tobacco sales (as a proxy for consumption) following a flavored tobacco product restriction in multiple localities, and evidence suggesting decreased cigar use among adult consumers following implementation of flavor restrictions in two studied localities, FDA expects that the proposed standard would lead many flavored cigar smokers to reduce or stop using cigars.

In section IV.D of this document, we discussed how the addition of characterizing flavors improves the taste of tobacco and decreases the harshness of tobacco smoke. While the evidence shows that use of flavored tobacco products, including flavored cigars, is particularly concerning among youth and young adults, millions of adults report using flavored tobacco products (Ref. 63). According to Wave 5 (2018–2019) data from the PATH Study, among young adult past 30-day cigar smokers 18–24 years old, 38.3 percent reported that the cigar product they smoked in the past 30 days was flavored (Ref. 63). Similarly, among adult cigar smokers aged 25 years and older, 36.0 percent reported past 30-day use of a flavored cigar (Ref. 63). Many adult cigar consumers consistently identify the availability of characterizing flavors as a reason for their cigar use. An analysis of Wave 5 (2018–2019) PATH Study data indicated that among young adults (aged 18–24 years) who used cigars some or every day, 54.1 percent of traditional cigar users, 66.5 percent of cigarillo users, and 65.1 percent of filtered cigar users reported flavoring as a reason for cigar use (Ref. 12). Similarly, among adults over 25 years old who used cigars

every or some days, 54.8 percent of traditional cigar users, 69.6 percent of cigarillo users, and 71.4 percent of filtered cigar users reported flavoring as a reason for cigar use (Ref. 12). There was not a statistically significant difference by age group in reporting flavors as a reason for use (Ref. 12). In totality, such data from large national observational studies show that the availability of flavors is a contributing factor to young adult and adult cigar use. In addition, proprietary data gathered by Euromonitor International in March 2021 reveals that, in 2020, flavored cigars accounted for nearly half of all cigar sales in the United States (41.9 percent).

Data from three U.S. localities (Providence, RI; New York, NY; and San Francisco, CA)¹⁸ as well as Canada provide real-world evidence of the potential behavioral impacts the proposed product standard could have on cigar sales as a proxy for consumption with two localities (San Francisco, CA, and Canada) providing additional data suggesting a decline in cigar use among current cigar smokers. In Providence, following implementation of the city's restriction on flavored tobacco products, except menthol, mint, and wintergreen, there was a 31 percent decrease in total cigar sales of flavored and unflavored cigars and a 51 percent decrease in average weekly sales of flavored cigars in Providence following policy implementation (Ref. 109). Sale of explicit flavor-named cigars (*e.g.*, cherry) declined after policy implementation while concept flavor-named cigars (*e.g.*, "jazz") increased (Ref. 109). However, the increase in sales of concept flavor-named cigars did not completely offset the decrease in explicit flavor-named cigars (Ref. 109).

In New York, following implementation of a restriction on flavored tobacco products except menthol, mint, and wintergreen, in NYC in 2010, researchers found that the flavor restriction was associated with an approximate 15 percent to 20 percent reduction in total cigar sales in NYC, relative to the proximal area (Ref. 108). Flavored cigar sales in NYC declined 28 percent while sales of flavored cigars increased in the 10 non-NYC comparison counties surrounding the city (+3.2 percent) pre-post policy implementation (Ref. 108).

In San Francisco, CA, following implementation of the city's restriction

on flavored tobacco products, including menthol, sales of flavored tobacco products overall and of flavored cigars specifically decreased a statistically significant 96 percent from the pre-policy period and overall cigar sales decreased a statistically significant 51 percent (Ref. 52). There was a statistically significant decrease in the prevalence of flavored cigar use in a small convenience sample of young adults aged 18 to 34 years who used tobacco products prior San Francisco's restriction (Ref. 62). In Canada, following implementation of a national flavored tobacco policy that restricted flavored tobacco products except menthol cigarettes and cigars under 1.4 grams (or in any cigar that had a filter or non-spiral wrap), cigar sales decreased when comparing 6 years before policy enactment to 6 years after enactment (Ref. 112). In addition, following Canada's restriction on flavored cigarillos, young people aged 15 to 24 reported a significant increase in past 30-day abstinence in cigarillo use among prior cigarillo smokers (Ref. 113).

The findings from evaluations in these three U.S. localities and Canada, drawing on both changes in sales data as well as behavioral changes, including increased abstinence in use of cigars among previous smokers as discussed in this section, are applied by FDA to inform our conclusions about the extent to which flavored cigar smokers would quit smoking cigars under the proposed standard. The findings from Canada also, as discussed in section IV.F of this document, help to support these conclusions by FDA regarding the impact of the proposed standard on current cigar smokers. These data provide evidence of the general behavioral responses we would expect to see in response to the proposed standard; however, we acknowledge there are limitations to these findings. These limitations include a reliance on aggregate tobacco sales information as a proxy for consumption, rather than data concerning individual-level tobacco use behaviors; the potential that smokers obtained flavored cigars through alternate means (*e.g.*, internet sales) or switched to non-cigar products, which may have resulted in an overestimation of the impacts; and evidence of incomplete compliance with the restriction and exemptions for some retail establishments (*e.g.*, tobacco bars), which may have resulted in an underestimation of the impacts of the prohibition. In addition, evidence from the evaluations of the impact of local restrictions on the sale of flavored

tobacco products suggest that enforcement of such restrictions was not complete (see Refs. 108 and 109). Therefore, the estimated effect of local restrictions on flavored cigars may underestimate the effect of the proposed flavor standard since such standard would apply to cigar manufacturers as well as retailers, thus reducing the probability that violative products would make their way onto store shelves. Despite these limitations in generalizing findings from local jurisdictions, these real-world evaluations provide important insight into how sales and tobacco use change in response to restrictions on flavored tobacco products, including cigars. These evaluation studies provide important insight into how the proposed prohibition on characterizing flavors (other than tobacco) in cigar products could reduce the rate of youth and young adult experimentation and progression to regular tobacco use and increase cessation among current cigar smokers.

Additionally, the proposed product standard is anticipated to promote the public health by addressing the disproportionate burden of cigar use among current users from vulnerable populations and promoting better health outcomes within those groups. As described in section V.A of this document, compared to non-Hispanic White adults, non-Hispanic Black adults are more likely to report that they have ever been a "fairly regular" cigar smoker and to report that they smoke cigars daily (Ref. 163). Hispanic adults are more likely to smoke cigars within 30 minutes of waking than non-Hispanic White adults (Ref. 162). Adults who identify as LGBTQ+ are more likely to use tobacco products and to meet the criteria for nicotine dependence when compared to their heterosexual and cisgender peers with findings being more pronounced for some racial and ethnic groups such as LGBTQ+ persons who are Hispanic and non-Hispanic Black (Refs. 68, 157, 159, 160, and 170–173). As described in section V.F of this document, disparities in cigar use likely contribute to the disproportionate burden of tobacco-related morbidity and mortality that are observed for some population groups. For example, findings from 2013–2016 PATH data indicate that non-Hispanic Black cigar users had lower odds of discontinuing cigar use than non-Hispanic White users (Ref. 261); additionally, while cigar use has decreased over time for non-Hispanic White adults, the data indicate that cigar use has remained stable or increased for non-Hispanic Black adults

¹⁸ Study data from the Twin Cities, MN, Lowell, MA, and Attleboro and Salem, MA, only looked at youth use and not sales data and thus is not included in this aspect of the discussion.

over time (Refs. 162 and 179). African American adults experience some of the highest rates of morbidity and mortality from tobacco-related disease such as heart disease, stroke, and hypertension (Refs. 264–269), which may be attributed to the disproportionate levels of cigar use observed within that population. Based on these findings, the proposed product standard is anticipated to benefit the population as a whole by addressing disparities associated with cigar use, dependence, cessation, and, thus, tobacco-related morbidity and mortality.

The sum of the available evidence, including the current use of flavored cigars by millions of Americans, the consistently high acknowledgement of characterizing flavors as a reason for using cigars among youth and adults, and the empirical evidence of lower tobacco sales (as a proxy for consumption) and tobacco use prevalence data following flavored tobacco product restrictions in multiple U.S. jurisdictions as well as Canada, supports FDA's finding that the proposed product standard would lead many flavored cigar smokers to stop using combusted cigars, yielding considerable health benefits.

C. Benefits and Risks to the Population as a Whole

As discussed in section IV.D of this document, the presence of characterizing flavors enhances the appeal and ease of cigar use among youth and young adults. We expect that the proposed product standard, if finalized, would reduce tobacco-related harms by reducing this appeal and ease of use. Anticipated reductions in population harm would be realized through both long-term health benefits resulting from prevention of cigar uptake among youth and young adults as described in section VI.A of this document, as well as more immediate health benefits (e.g., improved breathing) resulting from increased cessation of cigar use among current flavored cigar smokers, as described in section VI.B of this document. In this section, we summarize the health effects of cigar smoking and describe analyses used to demonstrate anticipated population health benefits from the proposed standard in terms of decreased initiation and progression to regular use and decreased mortality attributable to cigar smoking in the United States.

Additionally, the proposed product standard is anticipated to improve health outcomes in populations that have historically experienced tobacco-related health disparities related to flavored tobacco product use and,

specifically, flavored cigar use. As described in section IV.G of this document, tobacco companies have strategically marketed flavored cigars to underserved communities over many decades. The tobacco industry continues to target these populations with tailored cigar marketing practices that contribute to and reinforce these longstanding and entrenched cigar disparities. As described in section V.A of this document, prevalence of cigar use is disproportionately high among certain population groups such as non-Hispanic Black youth (Ref. 7), youth who identify as lesbian, gay, bisexual, or transgender (Refs. 7, 157, and 158), and youth with disabilities (Ref. 161). After initiating cigar use, members of these vulnerable populations are more likely to progress to regular cigar use or display patterns of more frequent use (Ref. 100). Because nonusers, particularly youth, from vulnerable populations are more likely to experience adverse effects from prior cigar use, the proposed product standard is anticipated to promote improved health outcomes within these population groups.

1. Flavored Cigar Smoking and Adverse Health Effects

As described in section V.D of this document, cigar smoking, including flavored cigar smoking, causes many of the same serious health conditions as cigarette smoking (Ref. 32). As also noted, FDA has conducted and published a systematic review of cigar smoking-attributable mortality risks and estimates of regular cigar smoking-attributable mortality for the U.S. population (Refs. 3 and 32). NCI previously reviewed the studies that were available on cigar smoking mortality risks and reached similar general conclusions (Ref. 183). Both reviews found that cigar smoking causes oral, esophageal, pancreatic, laryngeal, and lung cancers, as well as coronary heart disease and aortic aneurysm (Refs. 32 and 183). These conclusions were based primarily on statistically significant risk estimates for primary cigar smokers who had never regularly used other tobacco products such as cigarettes that were calculated from American Cancer Society's CPS I and II data. The CPS I and II were large longitudinal cohort studies of cancer risk factors in the U.S. population that each enrolled at least one million participants (Ref. 290). The CPS I began in 1959 and the CPS II in 1982 (Ref. 290). Researchers assessed the mortality followup for participants through followup visits or linkage with the National Death Index (Refs. 243 and

290). Numerous studies have been published that analyze and quantify tobacco-attributable mortality risks using CPS I and II data, including studies of cigar smoking-attributable mortality risks (Refs. 243, 247, and 291). While findings using CPS I and CPS II data are representative of historical cohorts of U.S. residents, a more recent analysis was conducted using data from participants in the TUS–CPS from 1992 to 2011 in the National Longitudinal Mortality Study, following participants for mortality through the end of 2011 (Ref. 227). Results from this study regarding elevated risk of all-cause and cause-specific mortality among exclusive current cigar smokers compared to never tobacco users were generally consistent with estimates from CPS I and II (Ref. 227).

Research studies have found that cigar smokers have approximately 40 to 45 percent higher risk of COPD than never tobacco users (Refs. 229 and 247). Similarly, the risk of bladder cancer in CPS I data was also approximately 40 percent higher for cigar smokers (Ref. 247).

There may be other health outcomes attributable to cigar smoking that were not assessed using CPS I or II mortality data. For example, Heineman et al. found statistically significant increased risks of colon and rectal cancers among cigar smokers in a cohort of nearly 250,000 World War I era veterans who were followed for mortality for 26 years (Ref. 249). Patterns of flavored cigar use may have also changed over time and could contribute to health risks. While most research has focused on cigar-attributable mortality, limited research has addressed cigar-attributable morbidity. Besides dying from cigar-attributable disease, lifelong cigar smokers may live many years with serious medical conditions, such as cancers (Refs. 229 and 232), heart disease (Refs. 229 and 245), and increased airflow obstruction (Ref. 124) that can lead to major physical impairments, reduce functioning and quality of life, and produce appreciable health care costs and medical expenditures.

2. Estimated Impacts of the Proposed Standard on Cigar Smoking Initiation and Progression to Regular Use

As described throughout this document, the proposed standard is expected to have substantial public health benefits. Significant benefits are expected to come from the prevention of cigar smoking initiation and progression to regular use among youth and young adults, resulting in reduced morbidity and premature mortality. To estimate

these benefits, we have updated an analysis published by Rostron et al. in 2019 that examined the potential effects of the product standard on each cohort of 18-year-olds in the United States (Ref. 292). Beginning with the 4.26 million 18-year-olds in 2019 (Ref. 293), we estimate that 3.9 percent of these individuals were current cigar users at that age, based on PATH Study Wave 5 data of self-reported every day or someday cigar use (Ref. 12). We also use PATH data to estimate that 63.6 percent of these cigar smokers initiated cigar use with a flavored product, resulting in approximately 106,000 18-year-olds who currently use cigars and had initiated cigar use with a flavored product (Ref. 12).

We then estimate the proportion of these cigar users who would have initiated cigar smoking with non-flavored cigars in the absence of flavored cigars. Consistent with Rostron et al., we assume that the lower bound would be 35 percent, equal to the proportion of cigar users who currently initiate with non-flavored products, and that the upper bound would be 100 percent, which reflects complete substitution with non-flavored cigars. We use the midpoint of these values, 67.5 percent, as our main estimate, so 32.5 percent of those currently initiating with flavored cigars would be deterred from trying cigars, and we estimate that approximately 34,000 ($106,000 \times 32.5$ percent) cigar smoking initiates would be prevented by the product standard from initiating cigar use in this model. We also considered the possibility that flavored cigar initiates are more likely to continue cigar use than those who initiate with non-flavored products. PATH Study data from Waves 1 (2013–2014) and 2 (2014–2015) show that adult ever cigar users who initiated with flavored cigars are more likely to be current regular cigar users than ever users who initiated with non-flavored cigars, controlling for other relevant factors related to cigar use (Ref. 28). Similar estimates were obtained from analysis of Waves 2–4 (2014–2017) PATH Study data, although results were presented separately for mint- or menthol-flavored cigars and other flavored cigars (Ref. 29). We therefore estimate that approximately 26,000 [$106,000 \times (1.0 - 32.5$ percent) $\times (1.0 - (1.0/1.56^{19}))$] cigar smokers would be prevented from continuing to regular use by the product standard for a total

reduction of 60,000 current cigar smokers in each cohort of 18-year-olds.

Consistent with the prior analysis (Ref. 292), we account for the uncertainty inherent in estimating the impact of the proposed policy based on these data and conducted Monte Carlo simulations using @RISK statistical software to assess the effects of varying key data inputs. We conducted 1,000 simulations, with reductions in cigar initiation ranging from 0 to 65 percent and reductions in continuing use ranging from 22.5 percent ($1.0 - 1.0/1.29$) to 46.5 percent ($1.0 - 1.0/1.87$), among those who would have otherwise initiated cigar use with flavored cigars. Ninety percent of the resulting estimates were between 42,000 and 75,000 cigar users prevented in each cohort.

3. Estimated Impacts of the Proposed Standard on Mortality

In the preceding section, we describe the longer-term benefits of the proposed standard that would include prevention of disease and premature death among youth and young adults who are discouraged from taking up cigar smoking in the absence of access to the flavored cigars covered by the proposed standard. Over a shorter term, health benefits would come from decreased tobacco product use including cessation among those who currently use flavored cigars. In this section, our estimation of public health impacts focuses on the reduction in cigar-attributable deaths that would occur if such flavored cigars were removed from the market. To be clear, these estimates significantly understate the public health benefits because they do not include lives saved of youth and young adults who, as the result of the product standard, do not begin to smoke.

To estimate the potential impact of the proposed standard on mortality, we again updated a previously published analysis (Ref. 292), which began with an estimate of the current number of deaths that are attributable to regular cigar smoking in the United States on an annual basis. We then removed deaths due to dual cigar and cigarette use to specifically estimate mortality due to exclusive cigar smoking given that dual users may continue to use combusted tobacco products. Mortality estimates are not available for other combinations of polytobacco use involving cigars, but over 90 percent of cigar users who are polytobacco users use cigarettes (Ref. 294). Consistent with the prior analysis (Ref. 292), we applied a range of estimates for the reduction in total cigar consumption that reflects behavioral evidence from multiple localities' flavored tobacco restrictions as well as

information on the size of the flavored U.S. cigar market. These estimates were then translated to potential behavior change to estimate the number of deaths in the United States that would be prevented each year among exclusive regular cigar smokers as a result of the proposed standard.

We based our estimate of the annual mortality attributable to cigar smoking in the United States on a previously published analysis (Ref. 3). This analysis modified the Smoking-Attributable Mortality, Morbidity, and Economic Costs methodology, used by the CDC to estimate cigarette smoking-attributable mortality, to quantify the mortality burden of regular cigar smoking in the United States in 2010 for adults aged 35 years or older (Ref. 3). The analysis estimated that regular cigar smoking (defined in the study as smoking cigars on 15 or more of the past 30 days) was responsible for approximately 9,000 premature deaths annually and that 5,200 of these deaths occurred among regular cigar smokers who did not also currently smoke cigarettes (hereafter referred to as exclusive cigar smokers) (Ref. 3). Because it is possible that some dual cigarette and cigar smokers might replace their cigar use with cigarette use if flavored cigars were prohibited, our analysis used the latter estimate of 5,200 deaths as the basis for quantifying the benefits of the proposed standard. This is a conservative approach because it does not account for any health benefits among dual users who quit tobacco or cigar use as a result of the proposed standard. As data from the NHIS from 2000–2019 has shown relatively stable cigar use prevalence estimates among adults, this estimate of 5,200 premature deaths also serves as a general measure of the effects of exclusive regular cigar smoking (*i.e.*, non-dual) on mortality in the United States in subsequent years (Ref. 3). Although youth cigar smoking has declined in recent years, the long-term implications for regular cigar smoking in this population are unclear. These estimates are based on an expectation that the number of premature deaths from cigar use would remain constant over time in the absence of regulatory action. Conceivably, the number of cigar-attributable premature deaths could rise due to population growth even if cigar smoking rates remained constant, or the number could fall if cigar-smoking rates fell by more than the population growth.

We then estimated the fraction of deaths that would be avoided if the proposed standard were in effect as proposed. As discussed in section IV.F of this document, real-world experience

¹⁹This estimate is based on Reference 28 in which the adjusted prevalence ratio = 1.56, meaning that, after accounting for other factors in the model, such as demographics, individuals who initiated with flavored cigars were 56 percent more likely to currently use them.

regarding the impact of flavored tobacco restrictions across U.S. jurisdictions suggests that the removal of flavored cigars from the U.S. market would lead consumers who now smoke flavored cigars to alter their behavior and some of these individuals would reduce their use of cigars or quit smoking cigars completely, others would product switch entirely to other tobacco products. We used data from the Providence, NYC, and San Francisco areas because these cities' restrictions on the sale of flavored tobacco products provide the best available U.S. data on the effect of real-world, implemented restrictions on cigar sales, and thus consumption.²⁰ Several studies conducted analyses using Nielsen retail scanner data to assess changes in the number of cigars sold (both flavored and non-flavored) in Providence, NYC, and San Francisco before and after the flavor restrictions went into effect (Refs. 52, 108, and 109). For comparison, they also examined sales over the same timeframe in the rest of Rhode Island in the Providence analysis, in nine counties proximal to NYC, as well as sales in the United States overall, in the NYC analysis, and in San Diego and San Jose in the San Francisco analysis. Using a times series analysis, the study of Providence estimated the effect of the flavor restriction to be a 31 percent reduction in overall cigar sales (Ref. 109). This analysis also found that the restriction was associated with an approximate 15 percent to 20 percent reduction in overall NYC cigar sales, relative to the proximal area or the United States overall. The study of San Francisco found that the flavor restriction was associated with a 51 percent reduction in overall cigar sales (Ref. 52). Importantly, these decreases in overall cigar sales indicate that consumers did not completely substitute non-flavored cigars for flavored cigars because of the restriction (Ref. 108). The data also suggest that cross-border purchasing of flavored cigars was limited. For example, the NYC study found that flavored cigar sales in the ten-county area surrounding NYC declined after the implementation of NYC's flavor restriction, although the change was not statistically significant (Ref. 108).

We note that the decline in flavored and overall cigar sales occurred despite incomplete compliance in some localities, such as the NYC ordinance (Ref. 108). The NYC study found that

flavored cigars, specifically, continued to be sold at persistently high levels in NYC in violation of the restriction. FDA anticipates the proposed product standard would have a greater impact on public health than the NYC flavor sales restrictions. Unlike a restriction on sales alone, the proposed standard would prohibit both the manufacture and sale of cigars with characterizing flavors (other than tobacco), and as a result, it would allow for a more complete prohibition of flavored cigar products from the market. Moreover, FDA anticipates that this nationwide product standard would eliminate the opportunity for consumers to travel to local neighboring U.S.-based jurisdictions that do not have a flavor prohibition or use online retailers to purchase flavored cigars.

In our analysis, cigar sales are used as a proxy for consumption, given we expect sales and consumption to be highly correlated. We start with a 30 percent relative decrease in total cigar sales as our main estimate in the analysis, using a rounded estimate of 31 percent reduction in overall cigar sales observed in Providence, which provided the midrange of estimates from the three evaluation studies. For the reasons described in this section, FDA considers the impacts of the NYC flavor restriction on total cigar sales (*i.e.*, 15–20 percent reduction in overall cigar sales in NYC) to be a conservative estimate of what the reduction in total cigar consumption in the United States overall would be if the proposed standard were implemented. We therefore use an estimated 15 percent relative decline in total cigar sales as a lower bound of the impact of this proposed product standard as a conservative estimate, which would suggest some substitution with non-flavored cigars.

An alternate scenario is one in which the proposed flavored tobacco products are removed from the U.S. market after implementation of the proposed standard and no substitution of non-flavored cigars occurs among consumers. In this case, the impact of the proposed standard on total cigar consumption would be equivalent to the fraction of the total U.S. cigar market comprised of flavored cigars. Proprietary data gathered by Euromonitor International in March 2021 reveals that approximately 41.9 percent of 2020 cigar (including cigarillo) unit sales in the United States were for flavored varieties. In this alternative scenario, if there is no switching from flavored to non-flavored cigar varieties, then overall cigar sales, and subsequently consumption, would decrease by 41.9 percent. We use this

figure as the upper bound for the decrease in total cigar sales following implementation of the product standard. As noted, the reduction in cigar sales observed in San Francisco following implementation of a flavored tobacco product restriction was consistent with such a decrease at 51 percent (Ref. 52).

Next, we estimate the mortality effects of these reductions in cigar consumption. The proposed standard is expected to result in some consumers quitting smoking cigars entirely, others cutting back on cigar smoking. To estimate how reductions in consumption at the population-level may be distributed across individual consumer behaviors, we use data from studies of other tobacco control policies. These studies can inform estimates of potential effects of the proposed standard on cigar use. A robust evidence base exists to characterize the impact of tobacco taxes on consumption and behavior. Data from studies on the impacts of cigarette tax increases on smoking behaviors suggest that approximately half of observed reductions in cigarette sales are due to smokers quitting, while the remainder are due to reducing or cutting back on the number of cigarettes smoked (Ref. 295). For this analysis, we assume that, among exclusive cigar smokers who would change their smoking behavior due to the standard, approximately 50 percent would quit smoking entirely, while the other 50 percent would cut back. To be conservative, we assume there are no benefits in avoided mortality among those who cut back and avoided mortality is only counted among those who quit smoking entirely. This estimate may be somewhat conservative because some studies have found some health and mortality benefits from substantial reductions in cigarette consumption, although these benefits are less than those from complete smoking cessation (Refs. 296 and 297).

We use these inputs in our analysis. By multiplying the estimated 5,200 annual exclusive cigar attributable deaths previously described by 30 percent due to decline in cigar sales, and then reducing that value by 50 percent to reflect benefits only for those who quit entirely, we estimate that the proposed standard would result in approximately 800 annual averted deaths.²¹ We again conducted Monte Carlo simulations using @RISK statistical software to assess the effect of varying key data inputs. We ran 1,000

²⁰ Study data from Lowell, MA, and Attleboro and Salem, MA, only looked at youth use and not sales data and thus is not included in this aspect of the discussion.

²¹ All estimates are rounded to the nearest 100. See FDA's Preliminary Regulatory Impact Analysis (Ref. 298) for unrounded estimates.

simulations using 15 percent and 42 percent as the lower and upper bound of decreases in total cigar consumption and 25 percent and 75 percent as the lower and upper bound for the proportion of decreased consumption due to complete cessation, and 90 percent of the resulting estimates fell within a range of approximately 400 to 1,100 deaths averted annually.

FDA anticipates that a reduction in deaths attributable to cigar use would begin to accrue soon after implementation of the proposed standard (see Ref. 298 at section II.F). It would take time to fully realize the mortality benefit of the proposed standard, given that some cigar smokers may still die of a smoking-related disease due to previous use, even if they quit cigar use after the proposed standard is implemented. Given that lung cancer has been estimated to be responsible for the majority of deaths attributable to cigar smoking (Ref. 3), we base the timeframe for reduction in risk on this cause. Estimates from contemporary cohort data have found that full reductions in lung cancer risk after smoking cessation can take an extended time period; consequently, we used a time period of 30 years (Ref. 299). Reductions in risk from other causes such as cardiovascular disease are expected to be realized more quickly (Refs. 300 and 301). Benefits from reductions in cigar-related morbidity would also be expected to accrue more quickly.

We also estimate the years of life that would be gained due to the product standard. Nonnemaker et al. estimated that the approximately 9,000 annual deaths that are attributable to regular cigar smoking correspond to nearly 140,000 years of potential life lost (YPLL) (Ref. 3). This represents an average of 15.1 years of life lost per death. We multiply the approximately 774 deaths annually averted by the product standard by the 15.1 average years of life lost per attributable death and estimate that approximately 11,687 YPLLs are associated with the premature mortality that would be prevented by the product standard each year.

This analysis has concentrated on mortality effects, given the availability of specific estimates for cigar smoking-attributable mortality and mortality risks, but we also anticipate reductions in cigar smoking-attributable morbidity due to the product standard. It has been estimated that regular cigar smoking is directly responsible for approximately 9,000 deaths among U.S. adults annually (Ref. 3) and that cigarette smoking is directly responsible for

approximately 437,000 deaths annually among U.S. adults (Ref. 23 at 659). It has also been estimated that U.S. adults suffer from approximately 14 million major medical conditions due to cigarette smoking (Ref. 302). These figures suggest that current and former cigarette smokers are living with approximately 30 major medical conditions due to cigarette smoking for every premature death that occurs each year. Since regular cigar smoking causes premature death from some of the same conditions as cigarette smoking, we would expect a considerable disease burden attributable to cigar smoking among U.S. adults, along with reduction in this burden as a result of the proposed standard.

In addition, the population would experience health benefits based on a decrease in morbidity and mortality resulting from secondhand smoke exposure. According to the Surgeon General, there is sufficient evidence from which to infer a causal relationship between secondhand tobacco smoke exposure and lung cancer, as well as increased risks of coronary heart disease morbidity and mortality, among lifetime nonsmokers (Ref. 251 at 15). Individuals living with smokers had a 20 to 30 percent increase in the risk of developing lung cancer from secondhand smoke exposure (Ref. 251 at 15). Likewise, the estimated increase in coronary heart disease risk from exposure to secondhand tobacco smoke is 25 to 30 percent above that of unexposed individuals (Ref. 251 at 519). Based on the similarity of the toxic constituents in cigars and cigarettes, and the fact that cigars commonly share similar product design and mechanisms of smoke delivery as cigarettes, FDA's scientific judgment leads the Agency to expect that secondhand cigar smoke would produce effects similar to those produced by secondhand cigarette smoke, meaning that the proposed rule, if finalized, would decrease morbidity and mortality caused by secondhand exposure to cigar smoke.

These sections have focused on the potential benefit to the U.S. population as a whole from the proposed product standard, accounting for the potential decreased experimentation and progression to regular use among nonusers that would be prevented from trying flavored cigars, as well as potential decreased consumption or increased cessation among current flavored cigar smokers. Thus, we anticipate the proposed product standard would continue to produce reductions in morbidity and mortality over the long term, due in large part to the reduction in eventual adverse health

effects from cigars due to reduced initiation and use among young people.

One additional potential health benefit to continuing users of cigars that could result from the proposed product standard would be decreased exposure to potentially toxic flavor compounds, as discussed in section V.B of this document. In combusted tobacco products, such as cigarettes and cigars, toxicity can result from the chemicals formed when flavors are heated or burned (Refs. 184–187). For example, a study conducted by the CDC identified benzyl alcohol, piperonal, methyl cinnamate, and vanillin in strawberry cigar filler (Ref. 190) (see table 2 in this document for potential health hazards of these ingredients). While some flavoring compounds naturally occur in tobacco and the resulting standard may not fully eliminate such toxic exposures, reducing toxicant levels in these products would reduce consumer exposure and could protect consumers from the health effects of these toxicants, particularly from adverse respiratory effects.

4. Potential Risks to the Population as a Whole of the Proposed Cigar Flavors Product Standard Would Not Outweigh the Potential Benefits of the Proposed Product Standard

There are possible countervailing effects that could occur from the proposed product standard, if finalized. Possible countervailing effects on current tobacco users could include continued combusted tobacco product smoking and the possibility of illicit trade. As part of this rulemaking, FDA is required by the Tobacco Control Act to consider information submitted on such possible countervailing effects, including among vulnerable populations such as adolescent tobacco users and other population subgroups.

With the removal of characterizing flavors (other than tobacco) in cigar products, some cigar smokers may seek other sources of tobacco and/or nicotine. These could include nicotine replacement therapy products, which are products authorized by FDA to help people quit using tobacco products. However, some smokers may also transition to tobacco-flavored cigars, other combusted tobacco products, or other potentially less harmful tobacco products. As discussed in section VI.B of this document, if youth experimenters or users of flavored cigars were to switch to cigarettes or to other tobacco products as a result of flavored cigars no longer being available, it is possible that the benefits of the rule would be reduced. The availability of menthol cigarettes, if it continues after

flavored cigars are no longer available, may make this switch more likely and diminish the benefits. However, the proposed rule would not be expected to increase risks to individual or public health, since cigar and cigarette smokers suffer many of the same adverse health outcomes attributed to combusted tobacco use. In addition, FDA has considered the possibility that youth or adults will form a misperception that non-flavored cigars are safe or pose no substantial health risks (and that this misperception would impact behavior) because FDA has not similarly prohibited their continued availability. However, FDA is not aware of any evidence suggesting such misperceptions would or would not occur and will monitor for any such effects if this product standard is finalized. Should the Agency find evidence of such misperceptions, FDA would direct public education efforts toward such misperceptions and would consider taking other action as appropriate.

FDA recognizes that, while some flavored cigar users may switch to tobacco-flavored cigars, this potential countervailing effect would not outweigh the benefits from cigar users who quit smoking completely. FDA has no reason to believe that individuals switching from flavored (other than tobacco-flavored) cigars to other combusted tobacco products would be exposed to additional harm beyond their current exposure level. There is no available data to suggest, for example, that the prohibition of characterizing flavors (other than tobacco) in cigars would increase the frequency or depth of smoke inhalation of tobacco-flavored cigars, make tobacco-flavored cigars more toxic to individual users or those who inhale secondhand smoke, lead to increased initiation, or make it more difficult for current tobacco users to quit. As explained elsewhere in this document, it is anticipated that the toxicity of flavored cigars could likely be diminished if this proposed rule is finalized. FDA requests comments regarding additional evidence on the extent and magnitude that flavored cigar users could potentially switch to other tobacco products, including tobacco-flavored cigars.

In addition, FDA is considering whether illicit trade could occur as a result of a cigar flavor product standard and potential implications. Since the enactment of the Tobacco Control Act, FDA has been committed to studying and understanding the potential effects of a product standard on the illicit tobacco market. As part of FDA's consideration of possible regulations,

the Agency asked the National Research Council (NRC) and Institute of Medicine (IOM) of the National Academy of Sciences to assess the international illicit tobacco market, including variations by country; the effects of various policy mechanisms on the market; and the applicability of international experiences to the United States (Ref. 303). In 2015, the NRC/IOM issued its final report entitled "Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context, and Lessons from International Experiences" and concluded that "[o]verall, the limited evidence now available suggests that if conventional cigarettes are modified by regulations, the demand for illicit versions of them is likely to be modest" (Ref. 303 at 9). In addition, in March 2018, FDA issued a draft concept paper as an initial step in assessing the possible health effects of a tobacco product standard in the form of demand for contraband or nonconforming tobacco products (83 FR 11754, March 16, 2018). Among other things, the draft concept paper examined the factors that might support or hinder the establishment of a persistent illicit trade market related to a product standard but did not reach any conclusions regarding the potential demand that may develop due to a product standard (Ref. 43).

A study regarding a restriction on menthol cigarettes in Canada is instructive here. Researchers studied the effects of the first ever complete sales restriction of menthol cigarettes, which was issued in the Canadian province of Nova Scotia (Ref. 304). The researchers found that the menthol restriction did not result in an increase in illicit cigarettes seized (Ref. 304). The Nova Scotia tax authorities estimated that the "prevalence of illegal tobacco in the province had actually decreased, from 30 percent of all tobacco consumed in 2006–2007 to less than 10 percent in 2016–2017" (Ref. 304). This is evidence that a major change to the availability of certain tobacco products is not likely to lead to a surge in illicit tobacco product use.

FDA requests comments regarding whether and to what extent this proposed rule would result in an increase in illicit trade in flavored cigars and how any such increase could impact the marketplace or public health. If an illicit market develops after this proposed product standard is finalized, FDA has the authority to take enforcement actions and other steps regarding the sale and distribution of illicit tobacco products, including those imported or purchased online (see section VIII.C of this document for

additional information about FDA's enforcement authorities). FDA conducts routine surveillance of sales, distribution, marketing, and advertising related to tobacco products and takes corrective actions when violations occur. After this proposed product standard is finalized and goes into effect, it would be illegal to import cigars with characterizing flavors (other than tobacco), and such products would be subject to import examination and refusal of admission under the FD&C Act. Similarly, it would be illegal to sell or distribute flavored cigars, including those sold online, and doing so may result in FDA initiating enforcement or regulatory actions.

As previously noted, FDA's enforcement will only address manufacturers, distributors, wholesalers, importers, and retailers. This regulation does not include a prohibition on individual consumer possession or use, and FDA cannot and will not enforce against individual consumers for possession or use of flavored cigars. In addition, State and local law enforcement agencies do not independently enforce the FD&C Act. These entities do not and cannot take enforcement actions against any violation of chapter IX of the Act or this regulation on FDA's behalf. As noted previously, FDA recognizes concerns about how State and local law enforcement agencies enforce their own laws in a manner that may impact equity and community safety and seeks comments on how FDA can best make clear the respective roles of FDA and State and local law enforcement.

Based on the available evidence, FDA finds that, while there may be potential countervailing effects that could diminish the expected population health benefits of the proposed standard, such effects would be minimal. Therefore, these potential effects would not outweigh the potential benefits of the proposed product standard.

FDA requests additional information concerning the potential countervailing effects discussed in this section, as well as any other potential countervailing effects that could result from this rule, and how the potential countervailing effects could be minimized.

D. Conclusion

In this section, we have reviewed multiple lines of evidence to assess the likely impact of the proposed prohibition on characterizing flavors (other than tobacco) in cigars on current nonusers, tobacco users, and the U.S. population as a whole. With respect to the impact on nonusers, the Agency

anticipates prevention of initiation and progression to regular tobacco use among youth and young adults, as well as reductions in exposure to secondhand cigar smoke, although this population health benefit is not quantified in our calculations. With respect to youth initiation and use, the Agency anticipates that prohibiting characterizing flavors (other than tobacco) in cigars as proposed would eliminate the availability of products that are more appealing to novice users and avoid rewarding and reinforcing associations with the characterizing flavor among youth. In addition to decreased experimentation, this is expected to lead to decreased use. The best available evidence regarding the role of flavored cigars and progression to regular use suggests that youth initiating with flavored cigars are more likely to progress to regular use. Policy evaluations from local jurisdictions throughout the United States (NYC, NY; Providence, RI; Lowell, MA; Twin Cities, MN; and San Francisco, CA) showed that youth and young adult tobacco use decreased when flavored cigars were removed from the market. In order to prevent future addiction, disease, and death associated with long-term cigar smoking, FDA proposes to prohibit characterizing flavors (other than tobacco) in cigars.

FDA also anticipates that the proposed product standard would increase the likelihood that some of the estimated 3 million adult flavored cigar smokers would reduce the number of cigars they smoke or quit smoking cigars entirely instead of completely substituting non-flavored cigars for flavored cigars. Evidence shows that flavor availability is consistently a highly endorsed reason for cigar use among youth, young adult, and adult cigar smokers (Refs. 12 and 28). Characterizing flavors in tobacco products ensure pleasant flavor and taste, reduces the harshness, bitterness, and astringency of tobacco during inhalation and soothes irritation during cigar smoking. When flavored cigar products were removed from the market in NYC, Providence, San Francisco, and Canada analyses showed subsequent reductions in total cigar sales. Taken together, this suggests the proposed standard would lead some flavored cigar smokers to smoke fewer cigars or quit cigar use entirely, decreasing total cigar consumption notwithstanding any substitution with non-flavored cigars. Cigar smoking causes many of the same diseases as cigarette smoking, including oral, esophageal, pancreatic, laryngeal and lung cancers, as well as coronary

heart disease and aortic aneurysm (Refs. 32 and 183). Our evidence review indicates that, by increasing cessation among cigar smokers who would otherwise use a flavored tobacco product, the proposed standard would reduce cigar-attributable deaths and disease in the United States and would not result in any increase in deaths or disease from the use of other tobacco products. In addition to reductions in premature death, cigar smokers who quit would gain improved quality of life from the reduced risk or prevention of major medical conditions attributable to cigar smoking.

Additionally, FDA anticipates that the proposed tobacco standard will improve health outcomes within groups that experience disproportionate levels of tobacco use, including certain vulnerable populations. Longstanding disparities in cigar use are the result of decades of cigar marketing targeted at underserved communities and the role of flavors in nicotine addiction and dependence. FDA anticipates that the prohibition of characterizing flavors in cigars will reduce initiation and experimentation with cigar smoking (particularly by youth and young adults), decrease the likelihood of nicotine dependence and addiction, and increase the likelihood of cessation. These public health benefits are expected to be particularly pronounced among vulnerable populations who experience the disproportionate impact of cigar use.

In total, this evidence supports the conclusion that a prohibition on characterizing flavors (other than tobacco) in cigars would be appropriate for the protection of the public health. The Agency anticipates the proposed standard would result in decreased experimentation and progression to regular use among youth and young adults, and increased cessation among current cigar smokers, would lead to lower disease and death in the U.S. population in both the short term and long term, due to diminished exposure to tobacco smoke among both users and nonusers of cigars.

VII. Additional Considerations and Requests for Comments

A. Section 907 of the FD&C Act

FDA is required by section 907 of the FD&C Act to consider the following information submitted in connection with a proposed product standard:

- For a proposed product standard to require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a tobacco product because FDA has

found that the additive, constituent, or other component is or may be harmful, scientific evidence submitted by any party objecting to the proposed standard demonstrating that the proposed standard will not reduce or eliminate the risk of illness or injury (section 907(a)(3)(B)(ii) of the FD&C Act).

- Information submitted regarding the technical achievability of compliance with the standard, including with regard to any differences related to the technical achievability of compliance with such standard for products in the same class containing nicotine not made or derived from tobacco and products containing nicotine made or derived from tobacco (section 907(b)(1) of the FD&C Act).

- All other information submitted, including information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of chapter IX of the FD&C Act and the significance of such demand (section 907(b)(2) of the FD&C Act).

As required by section 907(c)(2) of the FD&C Act, FDA invites interested parties to submit a draft or proposed tobacco product standard for the Agency's consideration (section 907(c)(2)(B)) and information regarding structuring the standard so as not to advantage foreign-grown tobacco over domestically grown tobacco (section 907(c)(2)(C)). In addition, FDA invites the Secretary of Agriculture to provide any information or analysis which the Secretary of Agriculture believes is relevant to the proposed tobacco product standard (section 907(c)(2)(D) of the FD&C Act).

FDA is requesting all relevant documents and information described in this section with this proposed rule. Such documents and information may be submitted in accordance with the "Instructions" included in the preliminary information section of this document.

Section 907(d)(5) of the FD&C Act allows the Agency to refer a proposed regulation for the establishment of a tobacco product standard to the Tobacco Products Scientific Advisory Committee (TPSAC) at the Agency's own initiative or in response to a request for good cause made before the expiration of the comment period. If FDA opts to refer this proposed regulation to TPSAC, the Agency will publish a notice in the **Federal Register** announcing the TPSAC meeting to discuss this proposal.

B. Pathways to Market

To legally market a new tobacco product²² in the United States, a tobacco product must receive authorization from FDA permitting the marketing of the new tobacco product under one of three pathways: (1) The applicant obtains an order under section 910(c)(1)(A)(i) of the FD&C Act (21 U.S.C. 387j(c)(1)(A)(i)) (order after review of a premarket tobacco product application under section 910(b)); (2) the applicant obtains an order finding the new tobacco product substantially equivalent to a predicate tobacco product and in compliance with the requirements of the FD&C Act under section 910(a)(2)(A)(i) (order after review of a substantial equivalence (SE) report submitted under section 905(j) of the FD&C Act); or (3) the applicant makes a request under 21 CFR 1107.1 and obtains an exemption from the requirements related to SE (section 905(j)(3)(A)) (21 U.S.C. 387e(j)(3)(A)), and at least 90 days before commercially marketing the product, submits a report under section 905(j) including the information required in section 905(j)(1)(A)(ii) and (B) of the FD&C Act.

Applicants may be able to use the SE exemption pathway for products seeking to comply with this proposed standard by making a minor modification to an additive in their product, if FDA finds, among other things, that: (1) The modification is “minor”; (2) an SE Report is not necessary to ensure that permitting the product to be marketed would be appropriate for the protection of the public health; and (3) an exemption is otherwise appropriate (section 905(j)(3)(A) of the FD&C Act). For example, FDA has previously issued exemption orders for tobacco products where there was deletion of casing flavor or L-menthol from a combusted cigarette. However, to the extent manufacturers change their flavored cigars to comply with this rule, FDA requests comments regarding how they might satisfy the premarket review requirements of the Tobacco Control Act.

C. Considerations and Request for Comments on Scope of Products

As indicated throughout this document, FDA has determined that the proposed standard, which would apply to all flavored cigars (other than

tobacco) and their components or parts, is appropriate for the protection of the public health. The proposed scope of this rule—applying to all cigars, rather than only a subset of cigars—is important to protect public health and is justified by existing evidence. All cigars are combusted tobacco products that may be used by youth and that expose users to nicotine, a highly addictive substance, and many other toxic chemical constituents. Cigars are not a safe alternative to other tobacco products, including other combusted products such as cigarettes. In addition, these products pose no potential for positive net public health impact by means of reduced risk or harm.

Cigars may vary in size, from smaller cigars which may resemble cigarettes in size and shape, such as little cigars or cigarillos, to larger ones, such as cigars referred to as “premium” cigars. In August 2020, as part of its decision in *Cigar Association of America, et al. v. Food and Drug Administration, et al.* (*Cigar Association* case), the U.S. District Court for the District of Columbia “remand[ed] the [deeming final rule] to the FDA to consider developing a streamlined substantial equivalence process for premium cigars” and “enjoin[ed] the FDA from enforcing the premarket review requirements against premium cigars . . . until the agency has completed its review.” Under the terms of, and for the purposes of, the court’s order, a premium cigar is defined as a cigar that meets all of the following eight criteria:

1. Is wrapped in whole tobacco leaf;
2. contains a 100 percent leaf tobacco binder;
3. contains at least 50 percent (of the filler by weight) long filler tobacco (*i.e.*, whole tobacco leaves that run the length of the cigar);
4. is handmade or hand rolled;²³
5. has no filter, nontobacco tip, or nontobacco mouthpiece;
6. does not have a characterizing flavor other than tobacco;
7. contains only tobacco, water, and vegetable gum with no other ingredients or additives; and
8. weighs more than 6 pounds per 1,000 units.

While products subject to this court’s order meet the definition of “cigar” as set out in this proposed rule, they do not contain a characterizing flavor other than tobacco and contain no ingredients or additives outside of tobacco, water, and vegetable gum. As discussed, the proposed rule would prohibit the use of

characterizing flavors other than tobacco in all cigars. Therefore, products that meet this court order’s definition of “premium” cigar would not be affected by the proposed rule. All cigar products, regardless of shape and size, including those that are marketed as “premium” cigars, that include a characterizing flavor other than tobacco, would be prohibited by this proposed product standard.

FDA is also considering action to limit characterizing flavors in other tobacco products (see FDA’s ANPRM regarding the role flavors play in tobacco products (79 FR 12294, March 21, 2018) and FDA’s proposed rule prohibiting menthol as a characterizing flavor in cigarette products, published elsewhere in this issue of the **Federal Register**). FDA is proposing to limit the scope of this proposed standard to cigars, given their well-documented harms and the fact that flavored cigars clearly appeal to youth and young adults in large numbers, while undertaking additional efforts to evaluate and determine whether to prohibit or otherwise limit characterizing flavors in other tobacco products. Research also does not indicate any countervailing public health benefit impacts from characterizing flavors in cigars that might be affected by eliminating their use, in potential contrast to some non-combusted tobacco products. We request comments, data, and research regarding the proposed scope of this rule.

FDA considered including waterpipe tobacco products within the scope of this proposed product standard based on the fact that they are combusted tobacco products with a strong appeal to youth. According to the 2020 NYTS, 2.7 percent of high school students (or approximately 420,000 students) reported using waterpipe tobacco within the previous 30 days and 1.3 percent of middle school students (or approximately 160,000 students) reported waterpipe tobacco use in the prior month (Ref. 7). In addition, waterpipe tobacco use exposes users to nicotine and many toxic chemical constituents. The WHO study group on tobacco regulation has found that a waterpipe session, which typically lasts 20 to 80 minutes, can be the equivalent of smoking more than 100 cigarettes (Ref. 305, citing Ref. 306). However, at this time due to limited data—specifically limited data on how waterpipe tobacco might be used in the absence of non-tobacco characterizing flavors—FDA is not proposing to include waterpipe tobacco within the scope of this proposed product

²² Products that were commercially marketed in the United States as of February 15, 2007 (referred to as “pre-existing tobacco products,” previously referred to as “grandfathered products”), are not considered new tobacco products and do not require prior authorization to be legally marketed (section 910(a) of the FD&C Act).

²³ A product is “handmade or hand rolled” if no machinery was used apart from simple tools, such as a scissors to cut the tobacco prior to rolling.

standard. FDA requests information and data on how waterpipe tobacco might be used in the absence of non-tobacco characterizing flavors. FDA is continuing to study the health effects associated with waterpipe tobacco use, as well as use patterns generally, to evaluate and determine whether to prohibit characterizing flavors in waterpipe tobacco.

Similarly, FDA is aware of the dangers of pipe tobacco (excluding waterpipe tobacco) and considered including pipe tobacco in the proposed rule. However, FDA considered youth and young adult usage as a primary concern in determining the scope of this proposed product standard, and at this time the data is limited and appears to suggest that youth and young adults have a much lower prevalence of pipe tobacco use compared to cigar use. According to the 2020 NYTS, 0.7 percent of high school students (or approximately 110,000 students) reported using pipe tobacco within the previous 30 days and 0.4 percent of middle school students (or approximately 40,000 students) reported pipe tobacco use in the prior 30 days (Ref. 7). FDA is concerned that current data may underestimate the number of smokers who use pipe tobacco to roll their own cigarettes or cigars, but the lack of data on RYO tobacco use and the limitations in how national surveys assess loose pipe tobacco use impact our ability to draw conclusions regarding appeal of loose pipe tobacco among youth and adults at this time. Given the inherent differences in features of use of loose pipe tobacco compared to a pre-rolled cigar, FDA does not anticipate that flavored pipe tobacco would be a ready substitution for youth seeking to use flavored cigars. The current best available evidence indicates pipe tobacco is comparatively unpopular with youth, and findings from the few studies that looked at changes in pipe tobacco use following restrictions on flavors in other tobacco products were mixed (Refs. 50, 51, and 111). While youth use of any tobacco product is of concern, we are not proposing to include pipe tobacco at this time. FDA requests information and data to further inform the above considerations. We also note that FDA has issued Warning Letters to retailers illegally selling flavored tobacco products that bear the package description “pipe tobacco” but which, based on their overall presentation, meet the statutory definition of cigarette tobacco and/or RYO tobacco.

FDA is not including non-combusted tobacco products, such as ENDS and smokeless tobacco products, in the

scope of this proposed standard. As discussed previously, characterizing flavors in a variety of tobacco products have appealing effects, particularly among youth and young adults. And youth and young adult use of any tobacco product remains a significant concern for FDA. However, at this time, FDA is focusing this proposed rule on characterizing flavors in cigars because this action would help to prevent youth and young adults’ use of combusted tobacco products. Combusted tobacco products are responsible for the majority of death and disease due to tobacco use.

Accordingly, as part of its overall request for comments, FDA requests comments, including supporting data and research, regarding the following issues:

- Should this product standard cover waterpipe and/or pipe tobacco, in addition to cigars? Is there additional data or information that would support inclusion of waterpipe and/or pipe tobacco in this product standard?
- What are the advantages and/or disadvantages of covering other combusted tobacco products with this product standard? What evidence would support covering all combusted tobacco products? How should FDA define “combusted tobacco products” if the scope of the final product standard were expanded to include all combusted tobacco products?
- Is there a significant risk that, if FDA limits this standard to cigars, consumers would substitute and/or migrate to other combusted tobacco products, thereby undermining the public health benefits of this rule? What changes, if any, should FDA make to this proposal to protect against or minimize substitution and/or migration?

D. Request for Comments on the Potential Racial and Social Justice Implications of the Proposed Product Standard

FDA is aware of concerns by some that this proposed rule could lead to illicit trade in flavored cigars, increased policing, and criminal penalties in underserved communities. We reiterate that this regulation does not include a prohibition on individual consumer possession or use, and FDA cannot and will not enforce against individual consumer possession or use of flavored cigars. FDA’s enforcement of this proposed rule, if finalized, will only address manufacturers, distributors, wholesalers, importers, and retailers. State and local law enforcement agencies do not independently enforce the FD&C Act. These entities do not and cannot take enforcement actions against

any violation of chapter IX of the Act or this regulation on FDA’s behalf.

Recognizing concerns related to how State and local law enforcement agencies enforce their own laws in a manner that may impact equity and community safety, FDA requests comments, including supporting data and research, on any potential for this proposed rule to result, directly or indirectly, in disparate impacts within particular underserved communities or vulnerable populations. With respect to any potential disparate impacts, FDA requests comments and data on whether and how specific aspects of the rule, if finalized, might increase the likelihood of such outcomes beyond what would be expected to occur in the absence of the rule, and potential strategies for avoiding or addressing such impacts of the rule within the bounds of FDA’s authorities. FDA also requests comments and data related to the existence, nature, and degree of any change in police activity or community encounters with State or local law enforcement within a State, locality, or other jurisdiction following implementation of a prohibition of flavored cigars. Finally, FDA requests comment on any other policy considerations related to potential racial and social justice implications of the rule.

VIII. Description of the Proposed Rule

This proposed rule would establish a new part 1166 that would prohibit characterizing flavors (other than tobacco) in cigars. Part 1166 would describe the scope of the proposed regulation, applicable definitions, and the prohibition on use of characterizing flavors (other than tobacco) in cigars.

A. Scope (Proposed § 1166.1)

Proposed § 1166.1(a) would provide that this part sets out a tobacco product standard under the FD&C Act regarding the use of characterizing flavors in cigars.

Proposed § 1166.1(b) would prohibit the manufacture, distribution, sale, or offering for distribution or sale, within the United States of a cigar or any of its components or parts that is not in compliance with the tobacco product standard. This provision is not intended to restrict the manufacture of cigars intended for export. Consistent with section 801(e)(1) of the FD&C Act (21 U.S.C. 381(e)(1)), a tobacco product intended for export shall not be deemed to be in violation of section 907 or this product standard, if it meets the criteria enumerated in section 801(e)(1) of the FD&C Act, including not being sold or offered for sale in domestic commerce.

This proposed rule would prohibit the importation for sale or distribution in the United States of a finished cigar that violates this standard. As stated in section VII.C of this document, FDA is specifically requesting comment regarding the scope of this proposed rule.

B. Definitions (Proposed § 1166.3)

Proposed § 1166.3 provides the definitions for the terms used in the proposed rule. Several of these definitions are included in the FD&C Act or have been used in other regulatory documents.

- *Accessory*: FDA defined “accessory” in the final deeming final rule (81 FR 28974; codified at 21 CFR 1100.3). We are proposing to use that definition here as it applies to cigars to provide further understanding as to the scope of the proposed standard. Therefore, FDA proposes to define “accessory” in the context of part 1166 to mean any product that is intended or reasonably expected to be used with or for the human consumption of a cigar; does not contain tobacco or nicotine from any source and is not made or derived from tobacco; and meets either of the following: (1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a cigar or (2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a cigar but (i) solely controls moisture and/or temperature of a stored cigar or (ii) solely provides an external heat source to initiate but not maintain combustion of a cigar. A cigar “accessory” is not subject to chapter IX of the FD&C Act or to this proposed standard. Examples of cigar accessories include a humidor that solely controls the moisture and/or temperature of a stored product, as well as cigar tip cutters, holders, ashtrays, and cases. We note that a humidor that does more than *solely* control the moisture and/or temperature of a stored product (e.g., imparts a mint characterizing flavor to the stored product) could meet the definition of a “component” or “part” in proposed § 1166.3 and, therefore, would be covered under this proposed standard.

- *Cigar*: FDA proposes to define “cigar” as a tobacco product that: (1) Is not a cigarette and (2) is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco. This definition was used in the seven consent orders that the Federal Trade Commission (FTC) entered into with the largest mass marketers of cigars (see, e.g., *In re Swisher International, Inc.*,

Docket No. C–3964 (FTC August 18, 2000)) and also is codified at 21 CFR 1143.1.

- *Component or part*: FDA defined “component or part” in the deeming final rule. We have reiterated that definition here as it applies to cigars. Therefore, FDA proposes to define “component or part” in the context of part 1166 to mean any software or assembly of materials intended or reasonably expected: (1) To alter or affect the cigar’s performance, composition, constituents, or characteristics or (2) to be used with or for the human consumption of a cigar. The term excludes anything that is an accessory of a cigar. Examples of cigar components or parts that would be subject to this proposed product standard include liquids intended to add flavor, cigar blunt wraps, removable tips, mouthpieces, and filters. With respect to these definitions, FDA notes that “component” and “part” are separate and distinct terms within chapter IX of the FD&C Act. However, for purposes of this rule, FDA is using the terms “component” and “part” interchangeably and without emphasizing a distinction between the terms. FDA may clarify the distinctions between “component” and “part” in the future.

- *Person*: As defined in section 201(e) of the FD&C Act (21 U.S.C. 321(e)), the term “person” includes an individual, partnership, corporation, and association.

- *Tobacco product*: As defined in section 201(rr) of the FD&C Act, the term “tobacco product” is defined as any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term “tobacco product” does not mean an article that is: A drug under section 201(g)(1) (21 U.S.C. 321(g)); a device under section 201(h) (21 U.S.C. 321(h)); a combination product described in section 503(g) (21 U.S.C. 353(g)); or a food under section 201(f) of the FD&C Act (21 U.S.C. 321(f)) if such article contains no nicotine, or no more than trace amounts of naturally occurring nicotine.

- *United States*: As defined in section 900(22) of the FD&C Act, the term “United States” means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa,

Wake Island, Midways Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

C. Prohibition on Use of Characterizing Flavors in Cigars (Proposed § 1166.5)

Proposed § 1166.5 would establish a product standard prohibiting the use of characterizing flavors (other than tobacco) in cigars, similar to section 907(a)(1)(A) of the FD&C Act.²⁴ Specifically, proposed § 1166.5 would state that a cigar or any of its components or parts (including the tobacco, filter, or wrapper, as applicable) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco) or an herb or spice, including, but not limited to, strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, coffee, mint, or menthol, that is a characterizing flavor of the tobacco product or tobacco smoke.²⁵ As discussed in section VI of this document, FDA finds that this proposed product standard would be appropriate for the protection of the public health. FDA is proposing an effective date 1 year after the date of publication of the final rule, as discussed in section IX of this document.

We note that this proposed rule would prohibit the use of menthol as a characterizing flavor in cigars, whereas the statutory characterizing flavor ban for cigarettes excluded menthol from the prohibition. The sensory properties of menthol makes its addition to cigars concerning. Menthol is a flavor compound that when added to combusted tobacco products produces a minty taste and cooling sensation when

²⁴ Section 907(a)(1)(A) of the FD&C Act states that beginning 3 months after the date of enactment of the Tobacco Control Act, a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in section 907(a)(1)(A) of the Tobacco Control Act shall be construed to limit the Secretary of HHS’s authority to take action under this section or other sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this section.

²⁵ We note that the language in section 907(a)(1)(A) of the FD&C Act states that the characterizing flavor ban for cigarettes applies to cigarettes or “any of its component parts.” For purposes of this proposed product standard, we have used the phrase “any of its components or parts” and have defined “component or part” for clarity and consistency with the deeming final rule (81 FR 28974 at 28975).

inhaled (Ref. 71). Adding menthol to combusted tobacco products makes the products easier to inhale and less irritating. Smokers report that mentholated products have a better taste, are smoother and more refreshing (Refs. 72–74). Menthol's flavor and sensory effects reduce the harshness of smoking among new users and facilitate experimentation and progression to regular smoking of menthol products, particularly among youth and young adults (Refs. 29 and 74–76). As a result, the brain is repeatedly exposed to nicotine and susceptible to nicotine addiction (Ref. 222). Studies further demonstrate that menthol, like nicotine, binds to nicotinic receptors in the brain (Refs. 218 and 219) and menthol alone can increase the number of nicotinic receptors in the brain (Refs. 220 and 221). Increases in nicotinic receptors can lead to greater withdrawal and cravings (Ref. 222). Evidence demonstrates that menthol's effects on nicotine in the brain are associated with behaviors indicative of greater addiction to nicotine (Refs. 220 and 223).

For this proposed product standard, FDA also is concerned that a characterizing flavors prohibition that does not include menthol would shift the flavored cigar market to menthol-flavored cigars. FDA is addressing the use of menthol in cigarettes in its separate proposed tobacco product standard to prohibit the use of menthol as a characterizing flavor in cigarettes, published elsewhere in this issue of the **Federal Register**. We believe that including menthol within the scope of this proposed standard prohibition of characterizing flavors in cigar products would be appropriate for the protection of the public health regardless of whether a similar prohibition of menthol as a characterizing flavor in cigarettes is in place when this rule is finalized.

FDA would enforce the requirements of this proposed product standard under various sections of the FD&C Act, including sections 301, 303, 701(a), 902, and 903. Section 907(a)(4)(B)(v) of the FD&C Act states that product standards must, where appropriate for the protection of the public health, include provisions requiring that the sale and distribution of the tobacco products be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under section 906(d) of the FD&C Act. Similar to section 907, section 906(d) of the FD&C Act gives FDA authority to require restrictions on the sale and distribution of tobacco products by regulation if the Agency determines that such regulation

would be appropriate for the protection of the public health.

Failure to comply with any requirements prescribed by this product standard may result in FDA initiating enforcement or regulatory actions, including, but not limited to, warning letters, civil money penalties, no-tobacco-sale orders, criminal prosecution, seizure, and/or injunction. In addition, adulterated or misbranded tobacco products offered for import into the United States are subject to detention and refusal of admission. As previously discussed, FDA's enforcement will only address manufacturers, distributors, wholesalers, importers, and retailers. FDA cannot and will not enforce against individual consumers possession or use of flavored cigars.

Among the factors that FDA believes are relevant in determining whether a cigar product has a characterizing flavor are:

- The presence and amount of artificial or natural flavor additives, compounds, constituents, or ingredients, or any other flavoring ingredient in a tobacco product, including its components or parts;
- The multisensory experience (*i.e.*, taste, aroma, and cooling or burning sensations in the mouth and throat) of a flavor during use of a tobacco product, including its components or parts;
- Flavor representations (including descriptors), either explicit or implicit, in or on the labeling (including packaging) or advertising of a tobacco product;²⁶ and
- Any other means that impart flavor or represent that a tobacco product has a characterizing flavor.

FDA expects that the approach proposed in this rule—relying on specific, flexible factors to make a case-by-case determination as to characterizing flavor—would provide important clarity for FDA, regulated industry, and other stakeholders while also ensuring critical flexibility and enforceability to achieve the public health goals of this rule. FDA requests comments regarding these factors and other potential factors that the Agency might consider in determining whether a cigar has a characterizing flavor.

²⁶ If a cigar has a characterizing flavor (other than tobacco), but its labeling or advertising represents that it does not, then the product may be, among other things, misbranded under section 903 of the FD&C Act because its labeling or advertising is false or misleading. Similarly, if a cigar does not have a characterizing flavor, but its labeling or advertising represents that it does, then the product may be misbranded under section 903 of the FD&C Act because its labeling or advertising is false or misleading.

FDA also requests comments, including supporting data and research, regarding potential alternatives to prohibiting characterizing flavors (*e.g.*, prohibiting all flavor additives, compounds, constituents, or ingredients).

This proposed product standard would not prohibit tobacco-flavored cigars. Flavored tobacco products may differ in youth appeal—as discussed previously in this document, for those who experiment with cigars, tobacco-flavored cigars do not currently appear as attractive as cigars with other characterizing flavors. FDA expects that the tobacco flavor in a cigar, or its components or parts, need not be naturally inherent to the product to be considered “tobacco flavored” but rather may result from the addition of ingredients or other measures by the manufacturer to produce the presence of tobacco as its characterizing flavor.

Further, we note that this prohibition also would cover flavors that are separate from the cigar (*e.g.*, liquid flavors), including menthol, intended or reasonably expected to be added to cigars. For example, menthol can be added to the packaging of cigarettes to produce menthol cigarettes (and this can be done for cigars as well). Such flavors would be considered components or parts of cigars under § 1166.3, as they could be intended or reasonably expected: (1) Alter or affect the cigar's performance, composition, constituents, or characteristics or (2) be used with or for the human consumption of a cigar, and they would not be accessories of cigars. Therefore, the manufacture, distribution, sale, or offer for distribution or sale of such flavored products would be prohibited should this proposed rule be finalized.

IX. Proposed Effective Date

In accordance with section 907(d)(2) of the FD&C Act,²⁷ FDA proposes that any final rule that may issue based on this proposal become effective 1 year after the date of publication of the final rule. Therefore, after the effective date, no person may manufacture, distribute, sell, or offer for distribution or sale within the United States a cigar or any of its components or parts that is not in compliance with part 1166. This regulation does not include a

²⁷ Section 907(d)(2) of the FD&C Act states that a regulation establishing a tobacco product standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before 1 year after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health.

prohibition on individual consumer possession or use.

FDA finds this proposed standard appropriate for the protection of the public health because characterizing flavors in cigars increase appeal and makes them easier to use, which leads to an increased likelihood that youth and young adults will experiment with them and that those experimenting with cigars will become addicted and progress to regular smoking. Additional delay, past 1 year, would only increase the numbers of youth and young adults who experiment with and become regular smokers after experimenting with flavored cigars, would delay cessation by current smokers, and would exacerbate tobacco-related health disparities.

FDA also finds that a 1-year effective date will “minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade” pursuant to section 907(d)(2) of the FD&C Act. Some cigar manufacturers of currently marketed flavored cigars have tobacco-flavored versions that are either pre-existing tobacco products or new tobacco products that are required to obtain premarket authorization. FDA does not expect that this rule, if finalized, would result in many new tobacco products or would require extensive changes to manufacturing.

We also note that the Tobacco Control Act banned characterizing flavors in cigarettes with a 90-day effective date (section 907(a)(1)(A) of the FD&C Act). FDA is proposing a longer effective date here in accordance with section 907(d)(2) of the FD&C Act. FDA requests comments as to whether a shorter effective date, such as 90 days, would be necessary for the protection of the public health.

In setting the effective date, FDA will consider information submitted in connection with this proposal by interested parties, including manufacturers and tobacco growers, regarding the technical achievability of compliance with the standard, including information concerning the existence of patents that make it impossible to comply in the proposed 1-year time frame. While FDA does not expect that the proposed product standard would prompt extensive changes to manufacturing (given the likely compliance method of ending the addition of flavoring additives to cigar products), FDA requests comments and data regarding whether 1 year is sufficient to comply with this rule or whether this compliance period should be extended to provide additional time.

FDA is aware of retailers’ concerns regarding unsold inventory when any final rule goes into effect. FDA requests comments, including supportive data and research, regarding a sell-off period (e.g., 30 days after the effective date of a final rule) for retailers to sell through their current inventory of cigars with characterizing flavors (other than tobacco).

X. Preliminary Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under E.O. 12866, E.O. 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). E.O.s 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is an economically significant regulatory action as defined by E.O. 12866. As such, it has been reviewed by the Office of Information and Regulatory Affairs.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because businesses would incur costs to reallocate resources to products other than flavored cigars, we tentatively find that the proposed rule would have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would result in an expenditure in at least 1 year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The summary of costs and benefits is presented in table 3. The main quantified benefits of this proposed rule, if finalized, come from reduced smoking-attributable mortality that is

the result of cigar use among adult cigar smokers, and reduced mortality from secondhand smoke among non-users. Additional unquantified benefits include reduced smoking-attributable mortality among youth who are deterred from initiating under the proposed rule. Unquantified benefits also include medical cost savings, productivity loss savings, improved quality of life, and environmental impacts. These benefits occur because the proposed rule, if finalized, would discourage non-users from initiating flavored cigars, as well as decrease consumption and/or increase cessation among current flavored cigar users, and thus reduce the health consequences associated with such use. Reduced exposure to secondhand smoke would also produce such benefits among non-users. We estimate that the present value of the quantified benefits over a 40-year time horizon ranges between \$111,807 million and \$286,124 million, with a primary estimate of \$198,203 million at a 3 percent discount rate, and between \$52,827 million and \$135,188 million with a primary estimate of \$93,647 million at a 7 percent discount rate. The primary annualized quantifiable benefits equal \$8,575 million at a 3 percent discount rate and \$7,024 million at a 7 percent discount rate. Unquantified benefits are expected to provide additional benefits beyond those amounts.

The costs of this proposed rule are those to firms to comply with the rule, to consumers impacted by the rule, and to the government, in a form not necessarily reflected in budgets, to enforce this product standard. Retailers, manufacturers, and wholesalers face a one-time cost of \$239.9 (range of \$80.0 million to \$399.8 million) million to read and understand the rule and manufacturers face a one-time adjustment, or friction cost, of \$21.5 million (range of \$0.3 million to \$43.7 million) to reallocate productive resources currently devoted to the manufacture of flavored cigars to other tobacco products. Consumers who continue to use tobacco products will face a one-time search cost of \$61.7 million (range of \$30.8 million to \$92.5 million) to find new tobacco products as a replacement for the banned flavored cigar products. In addition, producers face annual lost producer surplus of \$88 million (range of \$0 million to \$175 million). Additional unquantified costs include the costs to consumers who switch from flavored to tobacco-flavored cigars and consumer surplus losses. The present value of the costs over a 40-year time horizon ranges between \$126 million and \$4,612 million with a

primary estimate of \$2,368 million for a 3 percent discount rate, and between \$118 million and \$2,883 million with a primary estimate of \$1,500 million at a 7 percent discount rate. The primary estimates for the annualized cost are \$102 million at a 3 percent discount rate and \$112 million at a 7 percent discount rate.

In addition to benefits and costs, this rule, if finalized, will cause transfers from state governments, Federal Government, and firms to consumers in the form of reduced revenue and tax revenue. The primary estimate for the annualized transfers from the Federal Government to consumers, in the form of reduced excise tax, is \$85 million.

The primary estimate for the annualized transfers from state governments to consumers, in the form of reduced excise tax, is \$129 million. The primary estimate for the annualized transfers from the firms to consumers, in the form of reduced revenue, is \$1,979 million. Transfers are summarized in table 3.

TABLE 3—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE
[Millions of 2020 dollars over a 40-year time horizon]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits:							
Annualized Monetized \$/year	\$7,024	\$3,962	\$10,140	2020	7	40	Reduced mortality among adult cigar smokers and non-users.
	8,575	4,837	12,378	2020	3	40	
Annualized Quantified					7		
					3		
Qualitative	Medical cost savings, productivity loss savings and improved quality of life, environmental impacts.						
Costs:							
Annualized Monetized \$/year	112	9	216	2020	7	40	Changes in consumer surplus for some flavored cigar smokers, including potential utility changes for consumers who switch from flavored to non-flavored cigars.
	102	5	200	2020	3	40	
Annualized Quantified					7		
					3		
Qualitative	Changes in consumer surplus for some flavored cigar smokers, including potential utility changes for consumers who switch from flavored to non-flavored cigars.						
Transfers:							
Federal Annualized Monetized \$/year	85	42	119	2020	7		
	85	42	119	2020	3		
From/To	From: Federal Government			To: Consumers			
Other Annualized Monetized \$/year	129	64	180	2020	7	40	
	129	64	180	2020	3	40	
From/To	From: State Governments			To: Consumers			
Other Annualized Monetized \$/year	1,979	1,033	2,717	2020	7	40	
	1,979	1,033	2,717	2020	3	40	
From/To	From: Firms			To: Consumers			

Effects:
State, Local or Tribal Government: States would transfer some cigar excise tax revenue back to consumers. We are not aware of any cigar manufacturers that are tribally-affiliated and/or operate on tribal land.
Small Business: There are about 50 small businesses. Each small business would experience about \$1.9 million in annual costs at both a 3 and 7% discount rate.
Wages: No effect.
Growth: No effect.

We have developed a comprehensive Preliminary Regulatory Impact Analysis that assesses the impacts of the proposed rule. The full analysis of economic impacts is available in the docket for this proposed rule (see Ref. 298) and at <https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations>.

XI. Analysis of Environmental Impact

The Agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not

required. The Agency’s finding of no significant impact and the evidence supporting that finding is available in the docket for this proposed rule (see Refs. 307 and 308) and may be seen in Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <https://www.regulations.gov>. Under FDA’s regulations implementing the National Environmental Policy Act (21 CFR part 25), an action of this type would require an environmental assessment under 21 CFR 25.20.

XII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 is not required. This proposed rule refers to previously approved collections of information. The collections of information in 21 CFR part 1114 have been approved under OMB control number 0910–0879 (expires December 31, 2024); the collections of information in 21 CFR part 1107 have been approved under OMB control number 0910–0684

(expires September 30, 2022); the collections of information in section 905(j) of the FD&C Act have been approved under OMB control number 0910–0673 (expires November 30, 2024); and the collections in FDA’s guidance entitled “Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States As of February 15, 2007,” have been approved under OMB control number 0910–0775 (expires August 31, 2022).

XIII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13132. Section 4(a) of the Executive order requires Agencies to “construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” We have determined that the proposed rule, if finalized, would not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

This rule is being issued under section 907(a) of the FD&C Act, which enables FDA to prescribe regulations relating to tobacco product standards, and the sale and distribution restriction in this rule is also being issued under section 906(d) of the FD&C Act, which enables FDA to prescribe regulations restricting the sale and distribution of a tobacco product. If this proposed rule is made final, the final rule would create requirements whose preemptive effect would be governed by section 916 of the FD&C Act, entitled “Preservation of State and Local Authority.”

Section 916 of the FD&C Act broadly preserves the authority of states and localities to protect the public against the harms of tobacco use. Specifically, section 916(a)(1) of the FD&C Act establishes a general presumption that FDA requirements do not preempt or otherwise limit the authority of states, localities, or tribes to, among other things, enact and enforce laws regarding tobacco products that relate to certain activities (e.g., sale, distribution) and

that are in addition to or more stringent than requirements established under chapter IX of the FD&C Act.

Section 916(a)(2)(A) of the FD&C Act is an express preemption provision that establishes an exception to the preservation of State and local governmental authority over tobacco products established in section 916(a)(1). Specifically, section 916(a)(2)(A) of the FD&C Act provides that “[n]o State or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to tobacco product standards”

However, section 916(a)(2)(B) limits the applicability of section 916(a)(2)(A) of the FD&C Act, narrowing the scope of state and local requirements that are subject to express preemption. In particular, paragraph (a)(2)(B) provides that preemption under paragraph (a)(2)(A) does not apply to state or local “requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products.”

If this proposed rule is finalized as proposed, the final rule would create requirements that fall within the scope of section 916(a)(2)(A) of the FD&C Act because they are “requirements under the provisions of the chapter relating to tobacco product standards.” Accordingly, the preemptive effect of those requirements on any state or local requirement would be determined by the nature of the state or local requirement at issue—specifically, whether the state or local requirement is preserved under section 916(a)(1) of the FD&C Act, and/or excepted under section 916(a)(2)(B) of the FD&C Act (such as if it relates to the “sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products”). State and local prohibitions on the sale and distribution of flavored tobacco products, including flavored cigars, would not be preempted by this rule, if finalized, because such prohibitions would be preserved by section 916(a)(1) of the FD&C Act or, as applicable, excepted from express preemption by section 916(a)(2)(B) of the FD&C Act. FDA invites comments on how state or local laws may be implicated if this proposed rule is finalized.

XIV. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. The Agency solicits comments from tribal officials on any potential impact on Indian tribes from this proposed action.

XV. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

- *1. Tynan, M.A., T. McAfee, G. Promoff, et al., “Consumption of Cigarettes and Combustible Tobacco—United States, 2000–2011.” *Morbidity and Mortality Weekly Report*, 61(30):565–569, 2012. Available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6130a1.htm>.
2. Euromonitor International, “Passport: Cigars, Cigarillos and Smoking Tobacco in the US.” 2020. Available at <https://www.euromonitor.com/cigars-cigarillos-and-smoking-tobacco-in-the-us/report>.
3. Nonnemaker, J., B. Rostron, P. Hall, et al., “Mortality and Economic Costs from Regular Cigar Use in the United States, 2010.” *American Journal of Public Health*, 104(9):e86–e91, 2014. Available at <https://doi.org/10.2105/AJPH.2014.301991>.
4. Wang, Y., H. Sung, T. Yao, et al., “Health Care Utilization and Expenditures Attributable to Cigar Smoking Among US Adults, 2000–2015.” *Public Health Reports*, 133(3):329–337, 2018. Available at <https://doi.org/10.1177/0033354918769873>.
- *5. Odani, S., B. Armour, I.T. Agaku, “Flavored Tobacco Product Use and Its Association with Indicators of Tobacco Dependence Among US Adults, 2014–2015.” *Nicotine & Tobacco Research*,

- 22(6):1004–1015, 2020. Available at <https://doi.org/10.1093/ntr/ntz092>.
- *6. HHS, *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General*. Atlanta, GA: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2010.
- *7. Gentzke, A.S., T.W. Wang, A. Jamal, et al., “Tobacco Product Use Among Middle and High School Students—United States, 2020.” *Morbidity and Mortality Weekly Report*, 69(50):1881–1888, 2020. Available at <http://dx.doi.org/10.15585/mmwr.mm6950a1>.
8. Parns, T.A., S.K. Head, M.D. Sawdey, et al., “Characteristics of Past 30-Day Cigar Smoking, U.S. Adolescents, 2020.” *American Journal of Preventive Medicine*, 62(1):e39–e44, 2022. Available at <https://doi.org/10.1016/j.amepre.2021.06.011>.
9. Carpenter, C.M., G.F. Wayne, J.L. Pauly, et al., “New Cigarette Brands with Flavors that Appeal to Youth: Tobacco Marketing Strategies.” *Health Affairs*, 24(6):1601–1610, 2005. Available at <https://doi.org/10.1377/hlthaff.24.6.1601>.
10. Cummings, K.M., C.P. Morley, J.K. Horan, et al., “Marketing to America’s Youth: Evidence From Corporate Documents.” *Tobacco Control*, 11(Suppl. 1):i5–i17, 2002. Available at https://tobaccocontrol.bmj.com/content/11/suppl_1/i5.
11. Manning, K.C., K.J. Kelly, M.L. Comello, et al., “Flavoured Cigarettes, Sensation Seeking and Adolescents’ Perceptions of Cigarette Brands.” *Tobacco Control*, 18(6):459–465, 2009. Available at <https://doi.org/10.1136/tc.2009.029454>.
- *12. FDA, “Memorandum of Summary of Internal Analyses of Flavoured Cigars Using Wave 5 of the Population Assessment of Tobacco and Health (PATH) Study.” Silver Spring, MD: HHS, FDA, Center for Tobacco Products, 2021.
13. Palmatier, M.I., J.E. Lantz, L.C. O’Brien, et al., “Effects of Nicotine on Olfactogustatory Incentives: Preference, Palatability, and Operant Choice Tests.” *Nicotine & Tobacco Research*, 15(9):1545–1554, 2013. Available at <https://doi.org/10.1093/ntr/ntt016>.
14. Touzani, K., R.J. Bodnar, and A. Scalfani, “Neuropharmacology of Learned Flavor Preferences.” *Pharmacology Biochemistry and Behavior*, 97(1):55–62, 2010. Available at <https://doi.org/10.1016/j.pbb.2010.06.001>.
15. Audrain-McGovern, J., A.A. Strasser, and E.P. Wileyto, “The Impact of Flavoring on the Rewarding and Reinforcing Value of E-Cigarettes with Nicotine Among Young Adult Smokers.” *Drug and Alcohol Dependence*, 166:263–267, 2016. Available at <https://doi.org/10.1016%2Fj.drugaldep.2016.06.030>.
16. Kostygina, G., S.A. Glantz, and P.M. Ling, “Tobacco Industry Use of Flavours to Recruit New Users of Little Cigars and Cigarillos.” *Tobacco Control*, 25(1):66–74, 2016. Available at <https://doi.org/10.1136/tobaccocontrol-2014-051830>.
- *17. HHS, *Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General*. Atlanta, GA: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012.
18. Klein, S.M., G.A. Giovino, D.C. Barker, et al., “Use of Flavored Cigarettes Among Older Adolescent and Adult Smokers: United States, 2004–2005.” *Nicotine & Tobacco Research*, 10(7):1209–1214, 2008. Available at <https://doi.org/10.1080/14622200801263159>.
- *19. FDA, “Candy and Fruit Flavored Cigarettes Now Illegal in United States; Step Is First Under New Tobacco Law.” *FDA.gov*. Accessed January 12, 2017. <http://wayback.archive-it.org/7993/20170112124205/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm183211.htm>.
20. Ashare, R.L., L.W. Hawk, K.M. Cummings, et al., “Smoking Expectancies for Flavored and Non-Flavored Cigarettes Among College Students.” *Addictive Behaviors*, 32(6):1252–1261, 2007. Available at <https://doi.org/10.1016/j.addbeh.2006.08.011>.
21. Lewis, M.J. and O. Wackowski, “Dealing With an Innovative Industry: A Look at Flavored Cigarettes Promoted by Mainstream Brands.” *American Journal of Public Health*, 96(2):244–251, 2006. Available at <https://doi.org/10.2105/AJPH.2004.061200>.
- *22. HHS, *The Health Consequences of Smoking: Chronic Obstructive Lung Disease: A Report of the Surgeon General*. DHHS Publication No. (PHS) 84–50205. Rockville, MD: HHS, Public Health Service, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 1984.
- *23. HHS, *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*. Atlanta, GA: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.
24. Do, E.K., E.C. Prom-Wormley, B.F. Fuemeler, et al., “Associations Between Initial Subjective Experiences with Tobacco and Self-Reported Recent Use in Young Adulthood.” *Substance Use & Misuse*, 53(14):2291–2298, 2018. Available at <https://doi.org/10.1080/10826084.2018.1473435>.
- *25. Chen, B., K.L. Sterling, M.A. Bluestein, et al., “Age of Initiation of Cigarillos, Filtered Cigars and/or Traditional Cigars Among Youth: Findings from the Population Assessment of Tobacco and Health (PATH) Study, 2013–2017.” *PLoS ONE*, 15(12):e0243372, 2020. Available at <https://doi.org/10.1371/journal.pone.0243372>.
- *26. Fishbein, H., D. Bauer, Q. Yu, et al., “Harmonizing Cigar Survey Data Across Tobacco Centers of Regulatory Science, Center for Tobacco Products, and Population Assessment of Tobacco and Health Studies: The Cigar Collaborative Research Group.” *Nicotine & Tobacco Research*, 23(1):212–218, 2021. Available at <https://doi.org/10.1093/ntr/ntz201>.
27. Stanton, C.A., E. Sharma, E.L. Seaman, et al., “Initiation of Any Tobacco and Five Tobacco Products Across 3 Years Among Youth, Young Adults and Adults in the USA: Findings from the PATH Study Waves 1–3 (2013–2016).” *Tobacco Control*, 29(Suppl. 3):s178–s190, 2020. Available at <https://doi.org/10.1136/tobaccocontrol-2019-055573>.
- *28. Villanti, A.C., A.L. Johnson, A.M. Glasser, et al., “Association of Flavored Tobacco Use with Tobacco Initiation and Subsequent Use Among US Youth and Adults, 2013–2015.” *JAMA Network Open*, 2(10):e1913804, 2019. Available at <https://doi.org/10.1001/jamanetworkopen.2019.13804>.
29. Villanti, A.C., A.L. Johnson, M.J. Halenar, et al., “Menthol and Mint Cigarettes and Cigars: Initiation and Progression in Youth, Young Adults and Adults in Waves 1–4 of the PATH Study, 2013–2017.” *Nicotine & Tobacco Research*, 23(8):1318–1326, 2021. Available at <https://doi.org/10.1093/ntr/ntaa224>.
30. Hamad, S.H., N.M. Johnson, M.E. Tefft, et al., “Little Cigars vs. 3R4F Cigarette: Physical Properties and HPHC Yields.” *Tobacco Regulatory Science*, 3(4):459–478, 2017. Available at <https://doi.org/10.18001/TRS.3.4.7>.
31. Goel, R., N. Trushin, S.M. Reilly, et al., “A Survey of Nicotine Yields in Small Cigar Smoke: Influence of Cigar Design and Smoking Regimens.” *Nicotine & Tobacco Research*, 20(10):1250–1257, 2018. Available at <https://doi.org/10.1093/ntr/ntx220>.
- *32. Chang, C.M., C.G. Corey, B.L. Rostron, et al., “Systematic Review of Cigar Smoking and All Cause and Smoking Related Mortality.” *BMC Public Health*, 15:390, 2015. Available at <https://doi.org/10.1186/s12889-015-1617-5>.
- *33. HHS, *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*. Atlanta, GA: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.
34. England, L.J., K. Aagaard, M. Bloch, et al., “Developmental Toxicity of Nicotine: A Transdisciplinary Synthesis and Implications for Emerging Tobacco Products.” *Neuroscience & Biobehavioral Reviews*, 72:176–189, 2017. Available at <https://doi.org/10.1016/j.neubiorev.2016.11.013>.
35. Fagan, P., G. King, D. Lawrence, et al., “Eliminating Tobacco-Related Health Disparities: Directions for Future Research.” *American Journal of Public Health*, 94(2):211–217, 2004. Available at <https://doi.org/10.2105/ajph.94.2.211>.
- *36. Fagan, P., E.T. Moolchan, D. Lawrence, et al., “Identifying Health Disparities Across the Tobacco Continuum.” *Addiction*, 102(Suppl. 2):5–29, 2007. Available at <https://doi.org/10.1111/j.1360-0443.2007.01952.x>.
- *37. National Cancer Institute, *A Socioecological Approach to Addressing Tobacco-Related Health Disparities*.

- Tobacco Control Monograph No. 22. NIH Publication No. 17-CA-8035A. Bethesda, MD: HHS, National Institutes of Health, National Cancer Institute, 2017. Available at <https://cancercontrol.cancer.gov/brp/tcrb/monographs/monograph-22>.
- *38. HHS, *Tobacco Use Among U.S. Racial/Ethnic Minority Groups: African Americans, American Indians and Alaska Natives, Asian Americans and Pacific Islanders, Hispanics: A Report of the Surgeon General*. Atlanta, GA: HHS, CDC, National Center for Chronic Disease and Health Prevention and Health Promotion, Office on Smoking and Health, 1998.
- *39. HHS, "Healthy People 2020: Disparities." *HealthyPeople.gov*. Accessed February 15, 2022. <https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities>.
- *40. Braveman, P., E. Arkin, T. Orleans, et al., "What is Health Equity?" *Behavioral Science & Policy*, 4(1):1-14, 2018. Available at <https://behavioralpolicy.org/articles/what-is-health-equity/>.
- *41. Peterson, A., V. Charles, D. Yeung, et al., "The Health Equity Framework: A Science- and Justice-Based Model for Public Health Researchers and Practitioners." *Health Promotion Practice*, 22(6):741-746, 2020. Available at <https://doi.org/10.1177/1524839920950730>.
- *42. FDA, "FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death." *FDA.gov*. Accessed March 13, 2022. <https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death>.
- *43. FDA, "Illicit Trade in Tobacco Products After Implementation of an FDA Product Standard." Silver Spring, MD: HHS, FDA, Center for Tobacco Products, 2018. Available at <https://www.fda.gov/files/tobacco%20products/published/Illicit-Trade-in-Tobacco-Products-After-Implementation-of-an-FDA-Product-Standard.pdf>.
- *44. FDA, "Final Summary Report: External Letter Peer Review of FDA's Scientific Assessment of the Impact of Flavors in Cigar Products." Prepared by Versar, Inc. for FDA, Center for Tobacco Products, 2022.
- *45. FDA, "Scientific Assessment of the Impact of Flavors in Cigar Products." Silver Spring, MD: HHS, FDA, Center for Tobacco Products, 2022.
- *46. U.S. Congress. House. Committee on Energy and Commerce. *Family Smoking Prevention and Tobacco Control Act (H.R. 1256)*. House Report Number 111-58. 111th Cong., 1st sess., March 26, 2009.
47. Delnevo, C.D. and M. Hrywna, "Clove Cigar Sales Following the US Flavoured Cigarette Ban." *Tobacco Control*, 24(e4), 2015. Available at <https://doi.org/10.1136/tobaccocontrol-2013-051415>.
48. Delnevo, C.D. and M. Hrywna, "'A Whole 'Nother Smoke' or a Cigarette in Disguise: How RJ Reynolds Reframed the Image of Little Cigars." *American Journal of Public Health*, 97(8):1368-1375, 2007. Available at <https://doi.org/10.2105/AJPH.2006.101063>.
49. Caruso, R.V., R.J. O'Connor, M.J. Travers, et al., "Design Characteristics and Tobacco Metal Concentrations in Filtered Cigars." *Nicotine & Tobacco Research*, 17(11):1331-1336, 2015. Available at <https://doi.org/10.1093/ntr/ntu341>.
50. Courtemanche, C.J., M.K. Palmer, M.F. Pesko, "Influence of the Flavoured Cigarette Ban on Adolescent Tobacco Use." *American Journal of Preventive Medicine*, 52(5):e139-e146, 2017. Available at <https://doi.org/10.1016/j.amepre.2016.11.019>.
51. Farley, S.M. and M. Johns, "New York City Flavoured Tobacco Product Sales Ban Evaluation." *Tobacco Control*, 26:78-84, 2016. Available at <https://doi.org/10.1136/tobaccocontrol-2015-052418>.
52. Gammon, D.G., T. Rogers, J. Gaber, et al., "Implementation of a Comprehensive Flavoured Tobacco Product Sales Restriction and Retail Tobacco Sales." *Tobacco Control*, 2021. Available at <https://doi.org/10.1136/tobaccocontrol-2021-056494>.
53. Delnevo, C.D., E. Miller Lo, D.P. Giovenco, et al., "Cigar Sales in Convenience Stores in the U.S., 2009-2020." *Journal of the American Medical Association*, 326(23):2429-2432, 2021. Available at <https://doi.org/10.1001/jama.2021.19692>.
54. Delnevo, C.D., D.P. Giovenco, E.J. Miller Lo, "Changes in the Mass-Merchandise Cigar Market Since the Tobacco Control Act." *Tobacco Regulatory Science*, 3(Suppl. 1):S8-S16, 2017. Available at [https://doi.org/10.18001/trs.3.2\(suppl1\).2](https://doi.org/10.18001/trs.3.2(suppl1).2).
55. Delnevo, C.D., D.P. Giovenco, B.K. Ambrose, et al., "Preference for Flavoured Cigar Brands Among Youth, Young Adults and Adults in the USA." *Tobacco Control*, 24(4):389-394, 2015. Available at <https://doi.org/10.1136/tobaccocontrol-2013-051408>.
56. Wang, X., Y. Kim, M. Borowiecki, et al., "Trends in Cigar Sales and Prices, by Product and Flavor Type—the United States, 2016-2020." *Nicotine & Tobacco Research*, ntab238:1-7, 2021. Available at <https://doi.org/10.1093/ntr/ntab238>.
57. Casseus, M., J. Garmon, M. Hrywna, et al., "Cigarette Smokers' Classification of Tobacco Products." *Tobacco Control*, 25(6):628-630, 2016. Available at <https://doi.org/10.1136/tobaccocontrol-2015-052535>.
58. Dunn, D.S., A.L. Johnson, K.L. Sterling, et al., "Differences in Reasons for Little Cigar/Cigarillo Use Across White and Black/African American Young Adult Users." *Addictive Behaviors*, 118:106884, 2021. Available at <https://doi.org/10.1016/j.addbeh.2021.106884>.
- *59. Substance Abuse and Mental Health Services Administration (SAMHSA), *Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health*. HHS Publication No. PEP20-07-01-001, NSDUH Series H-55. Rockville, MD: HHS, SAMHSA, Center for Behavioral Health Statistics and Quality, 2020. Available at https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP20-07-01-001-PDF.pdf.
- *60. Pearlman, D.N., J.A. Arnold, G.A. Guardino, et al., "Advancing Tobacco Control Through Point of Sale Policies, Providence, Rhode Island." *Preventing Chronic Disease*, 16:E129, 2019. Available at <https://doi.org/10.5888/pcd16.180614>.
61. Kingsley, M., C.M. Setodji, J.D. Pane, et al., "Short-Term Impact of a Flavoured Tobacco Restriction: Changes in Youth Tobacco Use in a Massachusetts Community." *American Journal of Preventive Medicine*, 57(6):741-748, 2019. Available at <https://doi.org/10.1016/j.amepre.2019.07.024>.
- *62. Yang, Y., E.N. Lindblom, R.G. Salloum, et al., "The Impact of a Comprehensive Tobacco Product Flavor Ban in San Francisco Among Young Adults." *Addictive Behaviors Report*, 11:100273, 2020. Available at <https://doi.org/10.1016/j.abrep.2020.100273>.
- *63. HHS, NIH, National Institute on Drug Abuse and HHS, FDA, Center for Tobacco Products. "PATH Study Data Tables and Figures." Inter-University Consortium for Political and Social Research, 2021. Retrieved on April 18, 2022, from <https://www.icpsr.umich.edu/web/pages/NAHDAP/path-study-tables-home.html>.
64. Ambrose, B.K., H.R. Day, B. Rostron, et al., "Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014." *Journal of the American Medical Association*, 314(17):1871-1873, 2015. Available at <https://doi.org/10.1001/jama.2015.13802>.
65. Nyman, A.L., K.L. Sterling, S.R. Weaver, et al., "Little Cigars and Cigarillos: Users, Perceptions, and Reasons for Use." *Tobacco Regulatory Science*, 2(3):239-251, 2016. Available at <https://doi.org/10.18001/TRS.2.3.4>.
66. Hinds, J.T., X. Li, A. Loukas, et al., "Flavored Cigars Appeal to Younger, Female, and Racial/Ethnic Minority College Students." *Nicotine & Tobacco Research*, 20(3):347-354, 2018. Available at <https://doi.org/10.1093/ntr/ntx041>.
67. Glasser, A.M., A.I. Johnson, S.W. Rose, et al., "Correlates of Cigar Use by Type and Flavor Among US Young Adults: 2011-2015." *Tobacco Regulatory Science*, 3(Suppl. 1):S59-S71, 2017. Available at [https://doi.org/10.18001/TRS.3.2\(Suppl1\).7](https://doi.org/10.18001/TRS.3.2(Suppl1).7).
- *68. Cornelius, M.E., T.W. Wang, A. Jamal, et al., "Tobacco Product Use Among Adults—United States, 2019." *Morbidity and Mortality Weekly Report*, 69(46):1736-1742, 2020. Available at <http://doi.org/10.15585/mmwr.mm6946a4>.
- *69. Corey, C.G., E. Holder-Hayes, A.B. Nguyen, et al., "US Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar

- Type: Findings from the Population Assessment of Tobacco And Health (PATH) Study, 2013–2014.” *Nicotine & Tobacco Research*, 20(12):1457–1466, 2018. Available at <https://doi.org/10.1093/ntr/ntx209>.
- *70. King, B.A., S.R. Dube, and M.A. Tynan, “Flavored Cigar Smoking Among U.S. Adults: Findings from the 2009–2010 National Adult Tobacco Survey.” *Nicotine & Tobacco Research*, 15(2):608–614, 2013. Available at <https://doi.org/10.1093/ntr/nts178>.
71. Kamatou, G.P., I. Vermaak, A.M. Viljoen, et al., “Menthol: A Simple Monoterpene with Remarkable Biological Properties.” *Phytochemistry*, 96:15–25, 2013. Available at <https://doi.org/10.1016/j.phytochem.2013.08.005>.
72. Wiseman, E.J. and D.E. McMillan, “Rationale for Cigarette Smoking and for Mentholation Preference in Cocaine- and Nicotine-Dependent Outpatients.” *Comprehensive Psychiatry*, 39(6):358–363, 1998. Available at [https://doi.org/10.1016/S0010-440X\(98\)90048-7](https://doi.org/10.1016/S0010-440X(98)90048-7).
73. Richter, P., D. Beistle, L. Pederson, et al., “Small-Group Discussions on Menthol Cigarettes: Listening to Adult African American Smokers in Atlanta, Georgia.” *Ethnicity & Health*, 13(2):171–182, 2008. Available at <https://doi.org/10.1080/13557850701784694>.
74. Wackowski, O.A., K.R. Evans, M.B. Harrell, et al., “In Their Own Words: Young Adults’ Menthol Cigarette Initiation, Perceptions, Experiences and Regulation Perspectives.” *Nicotine & Tobacco Research*, 20(9):1076–1084, 2018. Available at <https://doi.org/10.1093/ntr/ntx048>.
75. Kreslake, J.M., G.F. Wayne, H.R. Alpert, et al., “Tobacco Industry Control of Menthol in Cigarettes and Targeting of Adolescents and Young Adults.” *American Journal of Public Health*, 98(9):1685–1692, 2008. Available at <https://doi.org/10.2105/AJPH.2007.125542>.
- *76. Klausner, K., “Menthol Cigarettes and Smoking Initiation: A Tobacco Industry Perspective.” *Tobacco Control*, 20(Suppl. 2):ii12–ii19, 2011. Available at <https://doi.org/10.1136/tc.2010.041954>.
- *77. Triest, F.J., “Function of Tobacco Flavor.” US Tobacco Records in Smokeless Tobacco, Date Unknown. Available at <https://www.industrydocuments.ucsf.edu/docs/#id=jmvm0046>.
- *78. Triest, F.J., “Our Affiliates Buy, Sort, Pack or Process Each Kind of Tobacco to Give You the Best of Quality.” US Tobacco Records in Smokeless Tobacco, 1966. Available at <https://www.industrydocuments.ucsf.edu/docs/#id=ynhd0044>.
- *79. RJ Reynolds. “Product Profile: Cigars.” RJ Reynolds Records, Master Settlement Agreement, 1969. Available at <http://legacy.library.ucsf.edu/tid/gmz49d00>.
80. Harrell, M.B., A. Loukas, C.D. Jackson, et al., “Flavored Tobacco Product Use Among Youth and Young Adults: What If Flavors Didn’t Exist?” *Tobacco Regulatory Science*, 3(2):168–173, 2017. Available at <https://doi.org/10.18001/TRS.3.2.4>.
- *81. Cullen, K.A., S.T. Liu, J.K. Bernat, et al., “Flavored Tobacco Product Use Among Middle and High School Students—United States, 2014–2018.” *Morbidity and Mortality Weekly Report*, 68(39):839–844, 2019. Available at <http://dx.doi.org/10.15585/mmwr.mm6839a2>.
82. Sterling, K.L., C.S. Fryer, M. Nix, et al., “Appeal and Impact of Characterizing Flavors on Young Adult Small Cigar Use.” *Tobacco Regulatory Science*, 1(1):42–53, 2015. Available at <https://doi.org/10.18001/TRS.1.1.5>.
83. Kong, G., D.A. Cavallo, K.W. Bold, et al., “Adolescent and Young Adult Perceptions on Cigar Packaging: A Qualitative Study.” *Tobacco Regulatory Science*, 3(3):333–346, 2017. Available at <https://doi.org/10.18001/TRS.3.3.9>.
- *84. Liu, J., D. Ramamurthi, and B. Halpern-Felsher, “Inside the Adolescent Voice: A Qualitative Analysis of the Appeal of Different Tobacco Products.” *Tobacco Induced Diseases*, 19:15, 2021. Available at <https://doi.org/10.18332/tid/132856>.
85. Avishai, A., C. Meernik, A.O. Goldstein, et al., “Impact and Mechanisms of Cigarillo Flavor Descriptors on Susceptibility to Use Among Young Adult Nonusers of Tobacco.” *Journal of Applied Social Psychology*, 50(12):699–708, 2020. Available at <https://doi.org/10.1111/jasp.12706>.
- *86. Meernik, C., H.M. Baker, S.D. Kowitz, et al., “Impact of Non-Menthol Flavours in E-Cigarettes on Perceptions and Use: An Updated Systematic Review.” *British Medical Journal*, 9(10):e031598, 2019. Available at <https://doi.org/10.1136/bmjopen-2019-031598>.
- *87. Zare, S., M. Nemati, and Y. Zheng, “A Systematic Review of Consumer Preference for E-Cigarette Attributes: Flavor, Nicotine Strength, and Type.” *PLoS One*, 13(3):e0194145, 2018. Available at <https://doi.org/10.1371/journal.pone.0194145>.
88. Feirman, S.P., D. Lock, J.E. Cohen, et al., “Flavored Tobacco Products in the United States: A Systematic Review Assessing Use and Attitudes.” *Nicotine & Tobacco Research*, 18(5):739–749, 2016. Available at <https://doi.org/10.1093/ntr/ntv176>.
- *89. Huang, L., H.M. Baker, C. Meernik, et al., “Impact of Non-Menthol Flavours in Tobacco Products on Perceptions and Use Among Youth, Young Adults and Adults: A Systematic Review.” *Tobacco Control*, 26(6):709–719, 2017. Available at <https://doi.org/10.1136/tobaccocontrol-2016-053196>.
90. Mennella, J.A., M.Y. Pepino, and D.R. Reed, “Genetic and Environmental Determinants of Bitter Perception and Sweet Preferences.” *Pediatrics*, 115(2):e216–e222, 2005. Available at <https://doi.org/10.1542/peds.2004-1582>.
91. Desor, J.A. and G.K. Beauchamp, “Longitudinal Changes in Sweet Preferences in Humans.” *Physiology & Behavior*, 39(5):639–641, 1987. Available at [https://doi.org/10.1016/0031-9384\(87\)90166-1](https://doi.org/10.1016/0031-9384(87)90166-1).
92. Enns, M.P., T.B. Van Itallie, and J.A. Grinker, “Contributions of Age, Sex and Degree of Fatness on Preferences and Magnitude Estimations for Sucrose in Humans.” *Physiology & Behavior*, 22(5):999–1003, 1979. Available at [https://doi.org/10.1016/0031-9384\(79\)90346-9](https://doi.org/10.1016/0031-9384(79)90346-9).
93. De Graaf, C. and E.H. Zandstra, “Sweetness Intensity and Pleasantness in Children, Adolescents, and Adults.” *Physiology & Behavior*, 67(4):513–520, 1999. Available at [https://doi.org/10.1016/S0031-9384\(99\)00090-6](https://doi.org/10.1016/S0031-9384(99)00090-6).
94. Hoffman, A.C., R.V. Salgado, C. Dresler, et al., “Flavour Preferences in Youth Versus Adults: A Review.” *Tobacco Control*, 25:ii32–ii39, 2016. Available at <https://doi.org/10.1136/tobaccocontrol-2016-053192>.
95. Brown, J.E., W. Luo, L.M. Isabelle, et al., “Candy Flavorings in Tobacco.” *New England Journal of Medicine*, 370(23):2250–2252, 2014. Available at <https://doi.org/10.1056/NEJMc1403015>.
96. Chen, C., L.M. Isabelle, W.B. Pickworth, et al., “Levels of Mint and Wintergreen Flavorants: Smokeless Tobacco Products vs. Confectionery Products.” *Food and Chemical Toxicology*, 48(2):755–763, 2010. Available at <https://doi.org/10.1016/j.fct.2009.12.015>.
- *97. Wang, T.W., A.S. Gentzke, M.R. Creamer, et al., “Tobacco Product Use and Associated Factors Among Middle and High School Students—United States, 2019.” *Morbidity and Mortality Weekly Report Surveillance Summaries*, 68(12):1–22, 2019. Available at <http://doi.org/10.15585/mmwr.ss6812a1>.
98. Leventhal, H. and P.D. Cleary, “The Smoking Problem: A Review of the Research and Theory in Behavioral Risk Modification.” *Psychological Bulletin*, 88(2):370–405, 1980. Available at <https://doi.org/10.1037/0033-2909.88.2.370>.
99. Flay, B.R., “Youth Tobacco Use: Risks, Patterns and Control.” In *Nicotine Addiction: Principles and Management*. Orleans, C.T. and J. Slade (Eds.), 365–384. New York, NY: Oxford University Press, 1993.
100. Cantrell, J., S. Xu, J. Kreslake, et al., “Cigar Use Progression Among New Cigar Initiators: A Two-Part Growth Curve Analysis Among a Youth and Young Adult Cohort.” *Nicotine & Tobacco Research*, 24(1):1–9, 2022. Available at <https://doi.org/10.1093/ntr/ntab143>.
101. Koszowski, B., Z.R. Rosenberry, A. Kanu, et al., “Nicotine and Carbon Monoxide Exposure from Inhalation of Cigarillo Smoke.” *Pharmacology Biochemistry and Behavior*, 139(Part A):7–14, 2015. Available at <https://doi.org/10.1016/j.pbb.2015.10.007>.
102. Pickworth, W.B., Z.R. Rosenberry, and B. Koszowski, “Toxicant Exposure from Smoking a Little Cigar: Further Support for Product Regulation.” *Tobacco Control*, 26(3):269–276, 2017. Available at <https://tobaccocontrol.bmj.com/content/26/3/269>.
103. Rosenberry, Z.R., W.B. Pickworth, and B. Koszowski, “Large Cigars: Smoking Topography and Toxicant Exposure.” *Nicotine & Tobacco Research*, 20(2):183–

- 191, 2018. Available at <https://doi.org/10.1093%2Fntnr%2Fntw289>.
104. Blank, M.D., C.O. Cobb, T. Eissenberg, et al., "Acute Effects of 'Hyping' a Black&Mild Cigarillo." *Nicotine & Tobacco Research*, 18(4):460–469, 2016. Available at <https://doi.org/10.1093/ntr/ntv063>.
105. Chamberlain, S.R., B.L. Odlaug, L.R.N. Schreiber, et al., "Association Between Tobacco Smoking and Cognitive Functioning in Young Adults." *The American Journal on Addictions*, 21(Suppl. 1):S14–S19, 2012. Available at <https://doi.org/10.1111/j.1521-0391.2012.00290.x>.
- * 106. Chen, R., A. Clifford, L. Lang, et al., "Is Exposure to Secondhand Smoke Associated with Cognitive Parameters of Children and Adolescents?—A Systematic Literature Review." *Annals of Epidemiology*, 23(10):652–661, 2013. Available at <https://doi.org/10.1016/j.annepidem.2013.07.001>.
107. Gomez, Y., M. Creamer, K.F. Trivers, et al., "Patterns of Tobacco Use and Nicotine Dependence Among Youth, United States, 2017–2018." *Preventative Medicine*, 141:106284, 2020. Available at <https://doi.org/10.1016/j.jpmed.2020.106284>.
108. Rogers, T., E.M. Brown, T.M. McCrae, et al., "Compliance with a Sales Policy on Flavoured Non-Cigarette Tobacco Products." *Tobacco Regulatory Science*, 3(2 Suppl. 1):S84–S93, 2017. Available at [https://doi.org/10.18001/TRS.3.2\(Suppl1\).9](https://doi.org/10.18001/TRS.3.2(Suppl1).9).
109. Rogers, T., A. Feld, D.G. Gammon, et al., "Changes in Cigar Sales Following Implementation of a Local Policy Restricting Sales of Flavoured Non-Cigarette Tobacco Products." *Tobacco Control*, 29:412–419, 2020. Available at <https://tobaccocontrol.bmj.com/content/29/4/412>.
110. Kingsley, M., C.M. Setodji, J.D. Pane., et al., "Longer-Term Impact of the Flavoured Tobacco Restriction in Two Massachusetts Communities: A Mixed-Methods Study." *Nicotine & Tobacco Research*, 23(11):1928–1935, 2021. <https://doi.org/10.1093/ntr/ntab115>.
111. Olson, L.T., E.M. Coats, T. Rogers, et al., "Youth Tobacco Use Before and After Local Sales Restrictions on Flavoured and Menthol Tobacco Products in Minnesota." *Journal of Adolescent Health*, Epub ahead of print: March 7, 2022. Available at <https://doi.org/10.1016/j.jadohealth.2022.01.129>.
- * 112. Chaiton, M.O., R. Schwartz, G. Tremblay, et al., "Association of Flavoured Cigar Regulations with Wholesale Tobacco Volumes in Canada: An Interrupted Time Series Analysis." *Tobacco Control*, 28:457–461, 2019. Available at <http://dx.doi.org/10.1136/tobaccocontrol-2018-054255>.
113. Nguyen, H.V. and P. Grootendorst, "Intended and Unintended Effects of Restrictions on the Sale of Cigarillos to Youth: Evidence from Canada." *Tobacco Control*, 24:382–388, 2015. Available at <https://tobaccocontrol.bmj.com/content/24/4/382.info>.
- * 114. Friedman, A.S., "A Difference-in-Differences Analysis of Youth Smoking and a Ban on Sales of Flavoured Tobacco Products in San Francisco, California." *JAMA Pediatrics*, 175(8):863–865, 2021. Available at <https://doi.org/10.1001/jamapediatrics.2021.0922>.
115. Liu, J., L. Hartman, A. S.L. Tan, et al., "Youth Tobacco Use Before and After Flavoured Tobacco Sales Restrictions in Oakland, California and San Francisco, California." *Tobacco Control*, Epub ahead of print: March 17, 2022. Available at <https://doi.org/10.1136/tobaccocontrol-2021-057135>.
116. Hawkins, S.S., C. Kruzik, M. O'Brien, et al., "Flavoured Tobacco Product Restrictions in Massachusetts Associated with Reductions in Adolescent Cigarette and E-Cigarette Use." *Tobacco Control*, Epub ahead of print: January 27, 2021. Available at <https://doi.org/10.1136/tobaccocontrol-2020-056159>.
117. Cotti, C., E. Nesson, and N. Tefft, "The Effects of Tobacco Control Policies on Tobacco Products, Tar, and Nicotine Purchases Among Adults: Evidence from Household Panel Data." *American Economic Journal: Economic Policy*, 8(4):103–123, 2016. Available at <https://doi.org/10.1257/pol.20150268>.
118. Zheng, Y., C. Zhen, J. Nonnemaker, et al., "Advertising, Habit Formation, and U.S. Tobacco Product Demand." *American Journal of Agricultural Economics*, 98(4):1038–1054, 2016. Available at <https://doi.org/10.1093/ajae/aaw024>.
119. Zheng, Y., C. Zhen, D. Dench, et al., "U.S. Demand for Tobacco Products in a System Framework." *Health Economics*, 26(8):1067–1086, 2017. Available at <https://doi.org/10.1002/hec.3384>.
- * 120. National Cancer Institute, *The Role of the Media in Promoting and Reducing Tobacco Use*. Tobacco Control Monograph No. 19. NIH Publication No. 07–6242. Bethesda, MD: HHS, National Institutes of Health, National Cancer Institute, June 2008. Available at <https://cancercontrol.cancer.gov/brp/tcrb/monographs/monograph-19>.
- * 121. HHS, *The Health Consequences of Smoking: Nicotine Addiction: A Report of the Surgeon General*. DHHS Publication No. (CDC) 88–8406. Rockville, MD: HHS, Public Health Service, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 1988.
122. Seidenberg, A.B., R.W. Caughey, V.W. Rees, et al., "Storefront Cigarette Advertising Differs by Community Demographic Profile." *American Journal of Health Promotion*, 24(6):e26–e31, 2010. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3086453/>.
123. Primack, B.A., J.E. Bost, S.R. Land, et al., "Volume of Tobacco Advertising in African American Markets: Systematic Review and Meta-Analysis." *Public Health Reports*, 122(5):607–615, 2007. Available at <https://doi.org/10.1177/003335490712200508>.
124. Rodriguez, D., H.A. Carlos, A.M. Adachi-Mejia, et al., "Predictors of Tobacco Outlet Density Nationwide: A Geographic Analysis." *Tobacco Control*, 22(5):349–355, 2013. Available at <https://doi.org/10.1136/tobaccocontrol-2011-050120>.
125. Lee, J.G. L., L. Henriksen, S.W. Rose, et al., "A Systematic Review of Neighborhood Disparities in Point-of-Sale Tobacco Marketing." *American Journal of Public Health*, 105(9):e8–e18, 2015. Available at <https://doi.org/10.2105/AJPH.2015.302777>.
126. Lee, J.G. L., D.L. Sun, N.M. Schleicher, et al., "Inequalities in Tobacco Outlet Density by Race, Ethnicity and Socioeconomic Status, 2012, USA: Results from the ASPIRE Study." *Journal of Epidemiology & Community Health*, 71(5):487–492, 2017. Available at <https://doi.org/10.1136/jech-2016-208475>.
- * 127. Cruz, T.B., S.W. Rose, B.A. Lienemann, et al., "Pro-Tobacco Marketing and Anti-Tobacco Campaigns Aimed at Vulnerable Populations: A Review of the Literature." *Tobacco Induced Diseases*, 17(September):68, 2019. Available at <https://doi.org/10.18332/tid/111397>.
128. Fakunle, D. O., F.C. Curriero, P.J. Leaf, et al., "Black, White, or Green? The Effects of Racial Composition and Socioeconomic Status on Neighborhood-Level Tobacco Outlet Density." *Ethnicity & Health*, 26(7):1–16, 2019. Available at <https://doi.org/10.1080/13557858.2019.1620178>.
- * 129. Rose, S.W., A. Anesetti-Rothermel, S. Westneat, et al., "Inequitable Distribution of FTP Marketing by Neighborhood Characteristics: Further Evidence for Targeted Marketing." *Nicotine & Tobacco Research*, ntab222:1–9, 2021. Available at <https://doi.org/10.1093/ntr/ntab222>.
130. Fallin, A., A.J. Goodin, B.A. King, "Menthol Cigarette Smoking Among Lesbian, Gay, Bisexual, and Transgender Adults." *American Journal of Preventative Medicine*. 48(1):93–97, 2015. Available at <https://doi.org/10.1016/j.amepre.2014.07.044>.
- * 131. Harlow, G.E., "Consumer Research Report: Consumer Attitudes Toward Menthol from Mint Leaves (MRD #72–0524)." RJ Reynolds Records, Master Settlement Agreement, 1972. Available at <https://www.industrydocuments.ucsf.edu/docs/ymyn0096>.
- * 132. BBDO, "Ethnic Marketing Opportunities for Long Johns." American Tobacco Records, Master Settlement Agreement, 1975. Available at <https://www.industrydocuments.ucsf.edu/docs/zrlx0147>.
- * 133. Jackson, C.A., "Long Johns Special Advertising and Promotional Campaign." American Tobacco Company Records, Master Settlement Agreement, 1975. Available at <https://www.industrydocuments.ucsf.edu/docs/zrlx0147>.
134. Hinds, J.T., A. Loukas, and C.L. Perry, "Explaining Sexual Minority Young Adult Cigarette Smoking Disparities." *Psychology of Addictive Behaviors*, 33(4):371–381, 2019. Available at <https://doi.org/10.1037/adb0000465>.
135. Berg, C.J., E. Stratton, G.L. Schauer, et al., "Perceived Harm, Addictiveness, and

- Social Acceptability of Tobacco Products and Marijuana Among Young Adults: Marijuana, Hookah, and Electronic Cigarettes Win." *Substance Use & Misuse*, 50(1):79–89, 2015. Available at <https://doi.org/10.3109/10826084.2014.958857>.
136. Gunther, A.C., D. Bolt, D.L.G. Borzekowski, et al., "Presumed Influence on Peer Norms: How Mass Media Indirectly Affect Adolescent Smoking." *Journal of Communication*, 56(1):52–68, 2006. Available at <https://doi.org/10.1111/j.1460-2466.2006.00002.X>.
137. Wakefield, M., B. Flay, M. Nichter, et al., "Role of the Media in Influencing Trajectories of Youth Smoking." *Addiction*, 98(Suppl. 1):79–103, 2003. Available at <https://doi.org/10.1046/j.1360-0443.98.s1.6.x>.
138. Etcheverry, P.E. and C.R. Agnew, "Romantic Partner and Friend Influences on Young Adult Cigarette Smoking: Comparing Close Others' Smoking and Injunctive Norms Over Time." *Psychology of Addictive Behaviors*, 22(3):313–325, 2008. Available at <https://doi.org/10.1037/0893-164X.22.3.313>.
139. Christakis, N.A. and J.H. Fowler, "The Collective Dynamics of Smoking in a Large Social Network." *New England Journal of Medicine*, 358(21):2249–2258, 2008. Available at <https://doi.org/10.1056/NEJMs0706154>.
140. Tan, A.S.L., E.P. Hanby, A. Sanders-Jackson, et al., "Inequities in Tobacco Advertising Exposure Among Young Adult Sexual, Racial and Ethnic Minorities: Examining Intersectionality of Sexual Orientation with Race and Ethnicity." *Tobacco Control*, 30(1):84–93, 2021. Available at <https://doi.org/10.1136/tobaccocontrol-2019-055313>.
141. Emory, K., F.O. Buchting, D.R. Trinidad, et al., "Lesbian, Gay, Bisexual, and Transgender (LGBT) View It Differently Than Non-LGBT: Exposure to Tobacco-Related Couponing, E-Cigarette Advertisements, and Anti-Tobacco Messages on Social and Traditional Media." *Nicotine & Tobacco Research*, 21(4):513–522, 2019. Available at <https://doi.org/10.1093/ntr/nty049>.
- * 142. Moran, M.B., K. Heley, J.P. Pierce, et al., "Ethnic and Socioeconomic Disparities in Recalled Exposure to and Self-Reported Impact of Tobacco Marketing and Promotions." *Health Communication*, 34(3):280–289, 2019. Available at <https://doi.org/10.1080/10410236.2017.1407227>.
143. Ribisl, K.M., H. D'Angelo, A.L. Feld, et al., "Disparities in Tobacco Marketing and Product Availability at the Point of Sale: Results of a National Study." *Preventive Medicine*, 105:381–388, 2017. Available at <https://doi.org/10.1016/j.ypmed.2017.04.010>.
144. Kong, A.Y., T.L. Queen, S.D. Golden, et al., "Neighborhood Disparities in the Availability, Advertising, Promotion, and Youth Appeal of Little Cigars and Cigarillos, United States, 2015." *Nicotine & Tobacco Research*, 22(12):2170–2177, 2020. Available at <https://doi.org/10.1093/ntr/ntaa005>.
145. Henriksen, L., E. Andersen-Rodgers, X. Zhang, et al., "Neighborhood Variation in the Price of Cheap Tobacco Products in California: Results From Healthy Stores for a Healthy Community." *Nicotine & Tobacco Research*, 19(11):1330–1337, 2017. Available at <https://doi.org/10.1093/ntr/ntx089>.
- * 146. Smiley, S.L., N. Kintz, Y.L. Rodriguez, et al., "Disparities in Retail Marketing for Little Cigars and Cigarillos in Los Angeles, California." *Addictive Behaviors Report*, 9:100149, 2019. Available at <https://doi.org/10.1016/j.abrep.2018.100149>.
147. Cantrell, J., J.M. Kreslake, O. Ganz, et al., "Marketing Little Cigars and Cigarillos: Advertising, Price, and Associations with Neighborhood Demographics." *American Journal of Public Health*, 103(10):1902–1909, 2013. Available at <https://doi.org/10.2105/AJPH.2013.301362>.
148. Roberts, M.E., M.L. Berman, M.D. Slater, et al., "Point-of-Sale Tobacco Marketing in Rural and Urban Ohio: Could the New Landscape of Tobacco Products Widen Inequalities?" *Preventive Medicine*, 81:232–235, 2015. Available at <https://doi.org/10.1016/j.ypmed.2015.08.024>.
149. Giovenco, D.P., T.E. Spillane, J.M. Merizier, "Neighborhood Differences in Alternative Tobacco Product Availability and Advertising in New York City: Implications for Health Disparities." *Nicotine & Tobacco Research*, 21(7):896–902, 2019. Available at <https://doi.org/10.1093/ntr/nty244>.
- * 150. Portnoy, D.B., C.C. Wu, C. Tworek, et al., "Youth Curiosity About Cigarettes, Smokeless Tobacco, and Cigars: Prevalence and Associations with Advertising." *American Journal of Preventive Medicine*, 47(2 Suppl. 1):S76–S86, 2014. Available at <https://doi.org/10.1016/j.amepre.2014.04.012>.
151. Pasch, K.E., N.E. Nicksic, S.C. Opara, et al., "Recall of Point-of-Sale Marketing Predicts Cigar and E-Cigarette Use Among Texas Youth." *Nicotine & Tobacco Research*, 20(8):962–969, 2018. Available at <https://doi.org/10.1093/ntr/ntx237>.
152. Trapl, E.S., L.D. Yoder, J.L. Frank, et al., "Individual, Parental, and Environmental Correlates of Cigar, Cigarillo, and Little Cigar Use Among Middle School Adolescents." *Nicotine & Tobacco Research*, 18(5):834–841, 2016. Available at <https://doi.org/10.1093/ntr/ntv201>.
- * 153. Johnston, L.D., R.A. Miech, P.M. O'Malley, et al., *Monitoring the Future National Survey Results on Drug Use: 1975–2021: 2021 Overview, Key Findings on Adolescent Drug Use*. Ann Arbor, MI: The University of Michigan, Institute for Social Research, 2022. Available at <http://monitoringthefuture.org/pubs/monographs/mtf-overview2021.pdf>.
- * 154. Wang, T.W., A. Gentzke, S. Sharapova, et al., "Tobacco Use Among Middle and High School Students—United States, 2011–2017." *Morbidity and Mortality Weekly Report*, 67(22):629–633, 2018. Available at <http://dx.doi.org/10.15585/mmwr.mm6722a3>.
155. Trapl, E.S. and S.J. Koopman Gonzalez, "Attitudes and Risk Perceptions Toward Smoking Among Adolescents Who Modify Cigar Products." *Ethnicity & Disease*, 28(3):135–144, 2018. Available at <https://doi.org/10.18865/ed.28.3.135>.
- * 156. Stokes, A.C., A.E. Wilson, D.J. Lundberg, et al., "Racial/Ethnic Differences in Associations of Non-Cigarette Tobacco Product Use with Subsequent Initiation of Cigarettes in US Youths." *Nicotine & Tobacco Research*, 23(6):900–908, 2021. Available at <https://doi.org/10.1093/ntr/ntaa170>.
157. Johnson, S.E., E.K. O'Brien, B. Coleman, et al., "Sexual and Gender Minority U.S. Youth Tobacco Use: Population Assessment of Tobacco and Health (PATH) Study Wave 3, 2015–2016." *American Journal of Preventive Medicine*, 57(2):256–261, 2019. Available at <https://doi.org/10.1016/j.amepre.2019.03.021>.
158. Dai, H., "Tobacco Product Use Among Lesbian, Gay, and Bisexual Adolescents." *Pediatrics*, 139(4):e20163276, 2017. Available at <https://doi.org/10.1542/peds.2016-3276>.
159. Rath, J.M., A.C. Villanti, R.A. Rubenstein, et al., "Tobacco Use by Sexual Identity Among Young Adults in the United States." *Nicotine & Tobacco Research*, 15(11):1822–1831, 2013. Available at <https://doi.org/10.1093/ntr/ntt062>.
160. Ganz, O., A.L. Johnson, A.M. Cohn, et al., "Tobacco Harm Perceptions and Use Among Sexual and Gender Minorities: Findings from a National Sample of Young Adults in the United States." *Addictive Behaviors*, 81:104–108, 2018. Available at <https://doi.org/10.1016/j.addbeh.2018.01.032>.
- * 161. Senders, A. and W. Horner-Johnson, "Disparities in E-Cigarette and Tobacco Use Among Adolescents With Disabilities." *Preventing Chronic Disease*, 17:200161, 2020. Available at <https://doi.org/10.5888/pcd17.200161>.
162. Weinberger, A.H., C.D. Delnevo, J. Zhu, et al., "Trends in Cigar Use in the United States, 2002–2016: Diverging Trends by Race/Ethnicity." *Nicotine & Tobacco Research*, 22(4):583–587, 2020. Available at <https://doi.org/10.1093/ntr/ntz060>.
163. Chen-Sankey, J.C., E.L. Mead-Morse, D. Le, et al., "Cigar-Smoking Patterns by Race/Ethnicity and Cigar Type: A Nationally Representative Survey Among U.S. Adults." *American Journal of Preventive Medicine*, 60(1):87–94, 2021. Available at <https://doi.org/10.1016/j.amepre.2020.07.005>.
- * 164. Corey, C.G., B.A. King, B.N. Coleman, et al., "Little Filtered Cigar, Cigarillo, and Premium Cigar Smoking Among Adults—United States, 2012–2013." *Morbidity and Mortality Weekly Report*, 63(30):650–654, 2014. Available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6330a2.htm>.
165. Baggett, T.P., Y. Chang, B.C. Porneala, et al., "Disparities in Cancer Incidence, Stage, and Mortality at Boston Health Care for the Homeless Program." *American Journal of Preventive*

- Medicine*, 49(5):694–702, 2015. Available at <https://doi.org/10.1016/j.amepre.2015.03.038>.
- *166. Alizaga, N.M., M. Hartman-Filson, H. Elser, et al., “Alternative Flavored and Unflavored Tobacco Product Use and Cigarette Quit Attempts Among Current Smokers Experiencing Homelessness.” *Addictive Behavior Reports*, 12:100280, 2020. Available at <https://doi.org/10.1016/j.abrep.2020.100280>.
167. Stanton, C.A., D.R. Keith, D.E. Gaalema, et al., “Trends in Tobacco Use Among US Adults with Chronic Health Conditions: National Survey on Drug Use and Health 2005–2013.” *Preventative Medicine*, 92:160–168, 2016. Available at <https://doi.org/10.1016/j.jypmed.2016.04.008>.
- *168. Cohn, A.M., A.L. Johnson, E. Hair, et al., “Menthol Tobacco Use Is Correlated with Mental Health Symptoms in a National Sample of Young Adults: Implications for Future Health Risks and Policy Recommendations.” *Tobacco Induced Diseases*, 14(January):1, 2016. Available at <https://doi.org/10.1186/s12971-015-0066-3>.
169. Ganz, O., A.M. Cohn, R.D. Goodwin, et al., “Internalizing Problems Are Associated with Initiation and Past 30-Day Use of Flavored Tobacco Products.” *Addictive Behaviors*, 125:107162, 2022. Available at <https://doi.org/10.1016/j.addbeh.2021.107162>.
170. Schuler, M.S. and R.L. Collins, “Sexual Minority Substance Use Disparities: Bisexual Women at Elevated Risk Relative to Other Sexual Minority Groups.” *Drug and Alcohol Dependence*, 206:107755, 2020. Available at <https://doi.org/10.1016/j.drugalcdep.2019.107755>.
171. Blossnich, J., T. Jarrett, K. Horn, “Disparities in Smoking and Acute Respiratory Illnesses Among Sexual Minority Young Adults.” *Lung*, 188:401–407, 2010. Available at <https://doi.org/10.1007/s00408-010-9244-5>.
172. Freitag, T.M., J.C. Chen-Sankey, D.A. Duarte, et al., “Variations in Substance Use and Disorders Among Sexual Minorities by Race/Ethnicity.” *Substance Use Misuse*, 56(7):921–928, 2021. Available at <https://doi.org/10.1080/10826084.2021.1899225>.
173. Emory, K., Y. Kimm, F. Buchting, et al., “Intragroup Variance in Lesbian, Gay, and Bisexual Tobacco Use Behaviors: Evidence That Subgroups Matter, Notably Bisexual Women.” *Nicotine & Tobacco Research*, 18(6):1494–1501, 2016. Available at <https://doi.org/10.1093/ntr/ntv208>.
- *174. Agaku, I.T., B.A. King, C.G. Husten, et al., “Tobacco Product Use Among Adults—United States, 2012–2013.” *Morbidity and Mortality Weekly Report*, 63(25):542–547, 2014. Available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6325a3.htm>.
- *175. Wheldon, C.W. and K.P. Wiseman, “Tobacco Use Among Transgender and Gender Non-Conforming Adults in the United States.” *Tobacco Use Insights*, 12:1–8, 2019. Available at <https://doi.org/10.1177/1179173X19849419>.
176. Johnson, S.E., E. Holder-Hayes, G.K. Tessman, et al., “Tobacco Product Use Among Sexual Minority Adults: Findings From the 2012–2013 National Adult Tobacco Survey.” *American Journal of Preventative Medicine*, 50(4):e91–e100, 2016. Available at <https://doi.org/10.1016/j.amepre.2015.07.041>.
177. Buchting, F.O., K.T. Emory, Scout, et al., “Transgender Use of Cigarettes, Cigars, and E-Cigarettes in a National Study.” *American Journal of Preventative Medicine*, 53(1):e1–e7, 2017. Available at <https://doi.org/10.1016/j.amepre.2016.11.022>.
178. Bombard, J.M., L.L. Pederson, J.J. Koval, et al., “How Are Lifetime Polytobacco Users Different than Current Cigarette-Only Users? Results from a Canadian Young Adult Population.” *Addictive Behaviors*, 34(12):1069–1072, 2009. Available at <https://doi.org/10.1016/j.addbeh.2009.06.009>.
- *179. Rostron, B.L., M.J. Schroeder, and B.K. Ambrose, “Dependence Symptoms and Cessation Intentions Among U.S. Adult Daily Cigarette, Cigar and E-Cigarette Users, 2012–2013.” *BMC Public Health*, 16:814, 2016. Available at <https://doi.org/10.1186/s12889-016-3510-2>.
180. Strong, D.R., J. Pearson, S. Ehlike, et al., “Indicators of Dependence for Different Types of Tobacco Product Users: Descriptive Findings from Wave 1 (2013–2014) of the Population Assessment of Tobacco and Health (PATH) Study.” *Drug and Alcohol Dependence*, 178:257–266, 2017. Available at <https://doi.org/10.1016/j.drugalcdep.2017.05.010>.
- *181. Apelberg, B.J., C.G. Corey, A.C. Hoffman, et al., “Symptoms of Tobacco Dependence Among Middle and High School Tobacco Users: Results from the 2012 National Youth Tobacco Survey.” *American Journal of Preventative Medicine*, 47(2 Suppl. 1):S4–S14, 2014. Available at <https://doi.org/10.1016/j.amepre.2014.04.013>.
- *182. FDA, “Memorandum of Summary of Internal Analyses of Nicotine Dependence Using Data from the 2019–2020 National Youth Tobacco Survey (NYTS).” Silver Spring, MD: HHS, FDA, Center for Tobacco Products, 2022.
- *183. National Cancer Institute. *Cigars: Health Effects and Trends*. Tobacco Control Monograph No. 9. NIH Publication No. 98–4302. Bethesda, MD: HHS, National Institutes of Health, National Cancer Institute, 1998. Available at <https://cancercontrol.cancer.gov/brp/tcrb/monographs/monograph-09>.
184. Paschke, M., C. Hutzler, F. Henkler, et al., “Oxidative and Inert Pyrolysis On-Line Coupled to Gas Chromatography with Mass Spectrometric Detection: On the Pyrolysis Products of Tobacco Additives.” *International Journal of Hygiene and Environmental Health*, 219(8):780–791, 2016. Available at <https://doi.org/10.1016/j.ijheh.2016.09.002>.
185. Baker, R.R. and L.J. Bishop, “The Pyrolysis of Tobacco Ingredients.” *Journal of Analytical and Applied Pyrolysis*, 71(1):223–311, 2004. Available at [https://doi.org/10.1016/S0165-2370\(03\)00090-1](https://doi.org/10.1016/S0165-2370(03)00090-1).
186. Baker, R.R., J.R. Pereira da Silva, and G. Smith, “The Effect of Tobacco Ingredients on Smoke Chemistry. Part II: Casing Ingredients.” *Food and Chemical Toxicology*, 42(Suppl.):S39–S52, 2004. Available at <https://doi.org/10.1016/j.fct.2003.08.009>.
187. Baker, R.R. and L.J. Bishop, “The Pyrolysis of Non-Volatile Tobacco Ingredients Using a System that Simulates Cigarette Combustion Conditions.” *Journal of Analytical and Applied Pyrolysis*, 74(1–2):145–170, 2005. Available at <https://doi.org/10.1016/j.jaap.2004.10.011>.
188. Coggins, C.R.E., E.J. Sena, T.B. Langston, et al., “A Comprehensive Evaluation of the Toxicology of Cigarette Ingredients: Aromatic Carbonyl Compounds.” *Inhalation Toxicology*, 23(Suppl. 1):90–101, 2011. Available at <https://doi.org/10.3109/08958378.2010.542581>.
- *189. Wang, A., B. Cai, L. Fu, et al., “Analysis of Pyrolysis Characteristics and Kinetics of Cigar Tobacco and Flue-Cured Tobacco by TG–FTIR.” *Contributions to Tobacco & Nicotine Research*, 30(1):29–43, 2021. Available at <https://doi.org/10.2478/ctnr-2021-0004>.
190. Lisko, J.G., S.B. Stanfill, C.H. Watson “Quantitation of Ten Flavor Compounds in Unburned Tobacco Products.” *Analytical Methods* 6(13):4698–4704, 2014. Available at <https://doi.org/10.1039/C4AY00271G>.
191. Hurd, C.D. and C.W. Bennett, “The Pyrolysis of Benzaldehyde and of Benzyl Benzoate.” *Journal of the American Chemical Society*, 51(4):1197–1201, 1929. Available at <https://doi.org/10.1021/ja01379a030>.
192. Vasilou, A.K., J.H. Kim, T.K. Ormond, et al., “Biomass Pyrolysis: Thermal Decomposition Mechanisms of Furfural and Benzaldehyde.” *The Journal of Chemical Physics*, 139(10):104310, 2013. Available at <https://doi.org/10.1063/1.4819788>.
- *193. National Center for Biotechnology Information, PubChem Annotation Record for BENZALDEHYDE, Source: Hazardous Substances Data Bank (HSDB). Accessed February 21, 2022. <https://pubchem.ncbi.nlm.nih.gov/source/hsdb/388>.
194. Dhont, J., “Pyrolysis and Gas Chromatography for the Detection of the Benzene Ring in Organic Compounds.” *Nature*, 192:747–748, 1961.
195. Urakami, K., C. Kobayashi, Y. Miyazaki, et al., “Degradation Products Generated by Sonication of Benzyl Alcohol, a Sample Preparation Solvent for the Determination of Residual Solvents in Pharmaceutical Bulks, on Capillary Gas Chromatography.” *Chemical and Pharmaceutical Bulletin*, 48(9):1299–1303, 2000. Available at <https://doi.org/10.1248/cpb.48.1299>.
- *196. National Center for Biotechnology Information, PubChem Compound Summary for CID 244, Benzyl Alcohol.

- Accessed February 21, 2022. <https://pubchem.ncbi.nlm.nih.gov/compound/Benzyl-Alcohol>.
197. Baker, R.R., "The Generation of Formaldehyde in Cigarettes—Overview and Recent Experiments." *Food and Chemical Toxicology*, 44(11), 1799–1822, 2006. Available at <https://doi.org/10.1016/j.fct.2006.05.017>.
198. Talhout, R., A. Opperhuizen, J.G.C. van Amsterdam, "Sugars as Tobacco Ingredient: Effect on Mainstream Smoke Composition." *Food and Chemical Toxicology*, 44(11):1789–1798, 2006. Available at <https://doi.org/10.1016/j.fct.2006.06.016>.
199. Bjeldanes, L.F. and H. Chew, "Mutagenicity of 1,2-Dicarbonyl Compounds: Maltol, Kojic Acid, Diacetyl and Related Substances." *Mutation Research*, 67:367–371, 1979.
200. Shin, E., M.R. Nimlos, and R.J. Evans, "A Study of the Mechanisms of Vanillin Pyrolysis by Mass Spectrometry and Multivariate Analysis." *Fuel*, 80(12):1689–1696, 2001. Available at [https://doi.org/10.1016/S0016-2361\(01\)00055-2](https://doi.org/10.1016/S0016-2361(01)00055-2).
- *201. National Center for Biotechnology Information, PubChem Annotation Record for ETHYL VANILLIN, Source: Hazardous Substances Data Bank (HSDB). Accessed February 21, 2022. <https://pubchem.ncbi.nlm.nih.gov/source/hsdb/945>.
- *202. Sigma-Aldrich, Safety Data Sheet: Hexyl Acetate. Sigma-Aldrich: St. Louis, MO, November 26, 2021. Accessed February 22, 2022. <https://www.sigmaaldrich.com/US/en/product/aldrich/w256528>.
- *203. National Center for Biotechnology Information, PubChem Annotation Record for n-Hexyl Acetate, Source: Hazardous Substances Data Bank (HSDB). Accessed February 21, 2022. <https://pubchem.ncbi.nlm.nih.gov/source/hsdb/5641>.
204. Bhatia, S.P., G.A. Wellington, J. Cocchiara, et al., "Fragrance Material Review on Methyl Cinnamate." *Food and Chemical Toxicology*, 45(1 Suppl. 1):S113–S119, 2007. Available at <http://doi.org/10.1016/j.fct.2007.09.077>.
- *205. National Center for Biotechnology Information, PubChem Annotation Record for Piperonal, Source: Hazardous Substances Data Bank (HSDB). Accessed February 21, 2022. <https://pubchem.ncbi.nlm.nih.gov/source/hsdb/581>.
- *206. Stotesbury, S.J., L.J. Willoughby, and A. Couch, "Pyrolysis of Cigarette Ingredients Labelled with Stable Isotopes." *Beiträge zur Tabakforschung International*, 19(2), 55–64, 2000. Available at <https://doi.org/10.2478/cttr-2013-0696>.
- *207. National Center for Biotechnology Information, PubChem Annotation Record for VANILLIN, Source: Hazardous Substances Data Bank (HSDB). Accessed February 21, 2022. <https://pubchem.ncbi.nlm.nih.gov/source/hsdb/1027>.
208. Blank, M.D., A. Nasim, A. Hart, et al., "Acute Effects of Cigarillo Smoking." *Nicotine & Tobacco Research*, 13(9):874–879, 2011. Available at <https://doi.org/10.1093/ntr/nt070>.
- *209. Institute of Medicine (IOM), *Ending the Tobacco Problem: A Blueprint for the Nation*. R.J. Bonnie, K. Stratton, R.B. Wallace, Eds. Washington, DC: The National Academies Press, 2007. Available at <https://doi.org/10.17226/11795>.
210. Baker, F., S.R. Ainsworth, J.T. Dye, et al., "Health Risks Associated With Cigar Smoking." *Journal of the American Medical Association*, 284(6):735–740, 2000. Available at <https://doi.org/10.1001/jama.284.6.735>.
211. Rodriguez, J., R. Jiang, W.C. Johnson, et al., "The Association of Pipe and Cigar Use with Cotinine Levels, Lung Function, and Airflow Obstruction: A Cross-Sectional Study." *Annals of Internal Medicine*, 152(4):201–210, 2010. Available at <https://doi.org/10.7326/0003-4819-152-4-201002160-00004>.
212. McDonald, I.J., R.S. Bhatia, and P.D. Hollett, "Deposition of Cigar Smoke Particles in the Lung: Evaluation with Ventilation Scan Using ^{99m}Tc-Labeled Sulfur Colloid Particles." *Journal of Nuclear Medicine*, 43(12):1591–1595, 2002. Available at <https://jnm.snmjournals.org/content/43/12/1591.long>.
213. Weglicki, L.S., "Tobacco Use Assessment: What Exactly Is Your Patient Using and Why Is It Important to Know?" *Ethnicity & Disease*, 18(3 Suppl. 3):s3–1–s3–6, 2008. Available at <https://pubmed.ncbi.nlm.nih.gov/18785400/>.
214. Henningfield, J.E., M. Hariharan, and L.T. Kozlowski, "Nicotine Content and Health Risks of Cigars." *Journal of the American Medical Association*, 276(23):1857–1858, 1996. Available at <https://doi.org/10.1001/jama.1996.03540230007003>.
215. Henningfield, J.E., R.V. Fant, A. Radzius, et al., "Nicotine Concentration, Smoke pH and Whole Tobacco Aqueous pH of Some Cigar Brands and Types Popular in the United States." *Nicotine & Tobacco Research*, 1(2):163–168, 1999. Available at <https://doi.org/10.1080/1462299050011271>.
216. Palmatier, M.I., A.L. Smith, E.M. Odineal, et al., "Nicotine Self-Administration with Tobacco Flavor Additives in Male Rats." *Nicotine & Tobacco Research*, 22(2):224–231, 2020. Available at <https://doi.org/10.1093/ntr/ntz053>.
217. Charnitkov, S., S.T. Pittenger, N. Swalve, et al., "Conditioned Enhancement of the Nicotine Reinforcer." *Experimental and Clinical Psychopharmacology*, 29(4), 385–394, 2021. Available at <https://doi.org/10.1037/pha0000370>.
218. Wickham, R.J., "The Biological Impact of Menthol on Tobacco Dependence." *Nicotine & Tobacco Research*, 22(10):1676–1684, 2020. Available at <https://doi.org/10.1093/ntr/ntz239>.
219. Shahoei, R. and E. Tajkhorshid, "Menthol Binding to the Human $\alpha 4\beta 2$ Nicotinic Acetylcholine Receptor Facilitated by Its Strong Partitioning in the Membrane." *Journal of Physical Chemistry*, 124(10):1866–1880, 2020. Available at <https://doi.org/10.1021/acs.jpcc.9b10092>.
- *220. Alsharari, S.D., J.R. King, J.C. Nordman, et al., "Effects of Menthol on Nicotine Pharmacokinetic, Pharmacology and Dependence in Mice." *PLoS ONE*, 10(9):e0137070, 2015. Available at <https://doi.org/10.1371/journal.pone.0137070>.
221. Henderson, B.J., T.R. Wall, B.M. Henley, et al., "Menthol Alone Upregulates Midbrain nAChRs, Alters nAChR Subtype Stoichiometry, Alters Dopamine Neuron Firing Frequency, and Prevents Nicotine Reward." *Journal of Neuroscience*, 36(10):2957–2974, 2016. Available at <https://doi.org/10.1523/JNEUROSCI.4194-15.2016>.
222. Benowitz, N.L., "Nicotine Addiction." *New England Journal of Medicine*, 362(24):2295–2303, 2010. Available at <https://doi.org/10.1056/NEJMr0809890>.
- *223. Henderson, B.J., T.R. Wall, B.M. Henley, et al., "Menthol Enhances Nicotine Reward-Related Behavior by Potentiating Nicotine-Induced Changes in nAChR Function, nAChR Upregulation, and DA Neuron Excitability." *Neuropsychopharmacology*, 42:2285–2291, 2017. Available at <https://doi.org/10.1038/npp.2017.72>.
224. IARC, *Tobacco Smoke and Involuntary Smoking*. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, No. 83. Lyon (FR): IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, 2004. Available at <https://publications.iarc.fr/Book-And-Report-Series/Iarc-Monographs-On-The-Identification-Of-Carcinogenic-Hazards-To-Humans/Tobacco-Smoke-And-Involuntary-Smoking-2004>.
225. Chen, J., A. Ketterman, B.L. Rostron, et al., "Biomarkers of Exposure Among U.S. Cigar Smokers: An Analysis of 1999–2012 National Health and Nutrition Examination Survey (NHANES) Data." *Cancer Epidemiology, Biomarkers & Prevention*, 23(12):2906–2915, 2014. Available at <https://doi.org/10.1158/1055-9965.EPI-14-0849>.
226. Chang, C.M., B.L. Rostron, J.T. Chang, et al., "Biomarkers of Exposure Among U.S. Adult Cigar Smokers: Population Assessment of Tobacco and Health (PATH) Study Wave 1 (2013–2014)." *Cancer Epidemiology, Biomarkers & Prevention*, 28(5):943–953, 2019. Available at <https://doi.org/10.1158/1055-9965.EPI-18-0539>.
227. Christensen, C.H., B. Rostron, C. Cosgrove, et al., "Association of Cigarette, Cigar, and Pipe Use with Mortality Risk in the US Population." *JAMA Internal Medicine*, 178(4):469–476, 2018. Available at <https://doi.org/10.1001/jamainternmed.2017.8625>.
- *228. Inoue-Choi, M., M.S. Shiels, T.S. McNeel, et al., "Contemporary Associations of Exclusive Cigarette, Cigar, Pipe, and Smokeless Tobacco Use

- With Overall and Cause-Specific Mortality in the United States." *JNCI Cancer Spectrum*, 3(3), 2019. Available at <https://doi.org/10.1093/jncics/pkz036>.
229. Iribarren, C., I.S. Tekawa, S. Sidney, et al., "Effect of Cigar Smoking on the Risk of Cardiovascular Disease, Chronic Obstructive Pulmonary Disease, and Cancer in Men." *New England Journal of Medicine*, 340(23):1773–1780, 1999. Available at <https://doi.org/10.1056/NEJM199906103402301>.
230. Wyss, A., M. Hashibe, S. Chuang, et al., "Cigarette, Cigar, and Pipe Smoking and the Risk of Head and Neck Cancers: Pooled Analysis in the International Head and Neck Cancer Epidemiology Consortium." *American Journal of Epidemiology*, 178(5):679–690, 2013. Available at <https://doi.org/10.1093/aje/kwt029>.
231. Blot, W.J., J.K. McLaughlin, D.M. Winn, et al., "Smoking and Drinking in Relation to Oral and Pharyngeal Cancer." *Cancer Research*, 48(11):3282–3287, 1988. Available at <https://pubmed.ncbi.nlm.nih.gov/3365707/>.
- *232. Garrote, L.F., R. Herrero, R.M. Ortiz Reyes, et al., "Risk Factors for Cancer of the Oral Cavity and Oro-Pharynx in Cuba." *British Journal of Cancer*, 85(1):46–54, 2001. Available at <https://doi.org/10.1054/bjoc.2000.1825>.
233. Stockwell, H.G. and G.H. Lyman, "Impact of Smoking and Smokeless Tobacco on the Risk of Cancer of the Head and Neck." *Head & Neck Surgery*, 9(2):104–110, 1986. Available at <https://doi.org/10.1002/hed.2890090206>.
234. Ferraroni, M., E. Negri, C. La Vecchia, et al., "Socioeconomic Indicators, Tobacco and Alcohol in the Aetiology of Digestive Tract Neoplasms." *International Journal of Epidemiology*, 18(3):556–562, 1989. Available at <https://doi.org/10.1093/ije/18.3.556>.
235. McCormack, V.A., A. Agudo, C.C. Dahm, et al., "Cigar and Pipe Smoking and Cancer Risk in the European Prospective Investigation into Cancer and Nutrition (EPIC)." *International Journal of Cancer*, 127(10):2402–2411, 2010. Available at <https://doi.org/10.1002/ijc.25252>.
236. Malhotra, J., C. Borron, N.D. Freedman, et al., "Association Between Cigar or Pipe Smoking and Cancer Risk in Men: A Pooled Analysis of Five Cohort Studies." *Cancer Prevention Research*, 10(12):704–709, 2017. Available at <https://doi.org/10.1158/1940-6207.CAPR-17-0084>.
237. Joly, O.G., J.H. Lubin, and M. Caraballoso, "Dark Tobacco and Lung Cancer in Cuba." *Journal of the National Cancer Institute*, 70(6):1033–1039, 1983. Available at <https://doi.org/10.1093/jnci/70.6.1033>.
238. Lubin, J.H., B.S. Richter, and W.J. Blot, "Lung Cancer Risk With Cigar and Pipe Use." *Journal of the National Cancer Institute*, 73(2):377–381, 1984. Available at <https://doi.org/10.1093/jnci/73.2.377>.
239. Boffetta, P., G. Pershagen, K.H. Jockel, et al., "Cigar and Pipe Smoking and Lung Cancer Risk: A Multicenter Study From Europe." *Journal of the National Cancer Institute*, 91(8):697–701, 1999. Available at <https://doi.org/10.1093/jnci/91.8.697>.
240. Higgins, I.T.T., C.M. Mahan, and E.L. Wynder, "Lung Cancer Among Cigar and Pipe Smokers." *Preventive Medicine*, 17(1):116–128, 1988. Available at [https://doi.org/10.1016/0091-7435\(88\)90077-1](https://doi.org/10.1016/0091-7435(88)90077-1).
241. Shaper, A.G., S.G. Wannamethee, and M. Walker, "Pipe and Cigar Smoking and Major Cardiovascular Events, Cancer Incidence and All-Cause Mortality in Middle-Aged British Men." *International Journal of Epidemiology*, 32(5):802–808, 2003. Available at <https://doi.org/10.1093/ije/dyg206>.
242. Abelin, T. and O.R. Gsell, "Relative Risk of Pulmonary Cancer in Cigar and Pipe Smokers." *Cancer*, 20(8):1288–1296, 1967.
243. Shapiro, J.A., E.J. Jacobs, and M.J. Thun, "Cigar Smoking in Men and Risk of Death from Tobacco-Related Cancers." *Journal of the National Cancer Institute*, 92(4):333–337, 2000. Available at <https://doi.org/10.1093/jnci/92.4.333>.
244. Nyboe, J., G. Jensen, M. Appleyard, et al., "Smoking and the Risk of First Acute Myocardial Infarction." *American Heart Journal*, 122(2):438–447, 1991. Available at [https://doi.org/10.1016/0002-8703\(91\)90997-V](https://doi.org/10.1016/0002-8703(91)90997-V).
245. Matroos, A., K. Magnus, and J. Strackee, "Fatal and Nonfatal Coronary Attacks in Relation to Smoking in Some Dutch Communities." *American Journal of Epidemiology*, 109(2):145–151, 1979. Available at <https://doi.org/10.1093/oxfordjournals.aje.a112669>.
246. Gyntelberg, F., P.B. Pedersen, L. Lauridsen, et al., "Smoking and Risk of Myocardial Infarction in Copenhagen Men Aged 40–59 with Special Reference to Cherooot Smoking." *The Lancet*, 317(8227):987–989, 1981. Available at [https://doi.org/10.1016/S0140-6736\(81\)91743-8](https://doi.org/10.1016/S0140-6736(81)91743-8).
- *247. Shanks, T.G. and D.M. Burns, "Disease Consequences of Cigar Smoking." In *Cigars: Health Effects and Trends*, National Cancer Institute, Chapter 4. Tobacco Control Monograph No. 9. NIH Publication No. 98–4302. Bethesda, MD: HHS, National Institutes of Health, National Cancer Institute, 1998. Available at <https://cancercontrol.cancer.gov/brp/tcrb/monographs/monograph-09>.
248. Andreotti, G., N.D. Freedman, D.T. Silverman, et al., "Tobacco Use and Cancer Risk in the Agricultural Health Study." *Cancer Epidemiology, Biomarkers & Prevention*, 26(5):769–778, 2017. Available at <https://doi.org/10.1158/1055-9965.EPI-16-0748>.
249. Heineman, E.F., S. Hoar Zahm, J.K. McLaughlin, et al., "Increased Risk of Colorectal Cancer Among Smokers: Results of a 26-Year Follow-Up of US Veterans and a Review." *International Journal of Cancer*, 59(6):728–738, 1994. Available at <https://doi.org/10.1002/ijc.2910590603>.
- *250. Chao, A., M.J. Thun, S.J. Henley, et al., "Cigarette Smoking, Use of Other Tobacco Products and Stomach Cancer Mortality in US Adults: The Cancer Prevention Study II." *International Journal of Cancer*, 101(4):380–389, 2002. Available at <https://doi.org/10.1002/ijc.10614>.
- *251. HHS, *The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General*. Atlanta, GA: HHS, CDC, Coordinating Center for Health Promotion, National Center for Chronic Disease Prevention and Health Promotion, Office of Smoking and Health, 2006.
- *252. IOM, *Secondhand Smoke Exposure and Cardiovascular Effects: Making Sense of the Evidence*. Washington, DC: The National Academies Press, 2010. Available at <https://doi.org/10.17226/12649>.
253. Klepeis, N.E., W.R. Ott, and J.L. Repace, "The Effect of Cigar Smoking on Indoor Levels of Carbon Monoxide and Particles." *Journal of Exposure Analysis and Environmental Epidemiology*, 9(6):622–635, 1999. Available at <https://doi.org/10.1038/sj.jea.7500065>.
254. Liu, J., X. Wang, S. Narayan, et al., "Impairment of Endothelial Function by Little Cigar Secondhand Smoke." *Tobacco Regulatory Science*, 2(1):56–63, 2016. Available at <https://doi.org/10.18001/TRS.2.1.6>.
- *255. Moore, B.F., M.L. Clark, A. Bachand, et al., "Interactions Between Diet and Exposure to Secondhand Smoke on the Prevalence of Childhood Obesity: Results From NHANES, 2007–2010." *Environmental Health Perspectives*, 124(8):1316–1322, 2016. Available at <http://dx.doi.org/10.1289/ehp.1510138>.
256. Barnoya, J. and S.A. Glantz, "Cardiovascular Effects of Secondhand Smoke: Nearly as Large as Smoking." *Circulation*, 111(20):2684–2698, 2005. Available at <https://doi.org/10.1161/CIRCULATIONAHA.104.492215>.
257. Tziomalos, K. and F. Charoulis, "Endocrine Effects of Tobacco Smoking." *Clinical Endocrinology*, 61(6):664–674, 2004. Available at <https://doi.org/10.1111/j.1365-2265.2004.02161.x>.
- *258. Rostron, B.L., C.G. Corey, and R.M. Gindi, "Cigar Smoking Prevalence and Morbidity Among US Adults, 2000–2015." *Preventive Medicine Reports*, 14:100821, 2019. Available at <https://doi.org/10.1016/j.pmedr.2019.100821>.
- *259. Babb, S., A. Malarcher, G. Schauer, et al., "Quitting Smoking Among Adults—United States, 2000–2015." *Morbidity and Mortality Weekly Report*, 65(52):1457–1464, 2017. Available at <https://doi.org/10.15585/mmwr.mm6552a1>.
260. Kulak, J.A., M.E. Cornelius, G.T. Fong, et al., "Differences in Quit Attempts and Cigarette Smoking Abstinence Between Whites and African Americans in the United States: Literature Review and Results From the International Tobacco Control U.S. Survey." *Nicotine & Tobacco Research*, 18(Suppl. 1):S79–S87, 2016. Available at <https://doi.org/10.1093/ntr/ntv228>.
261. Kasza, K.A., K.C. Edwards, Z. Tang, et al., "Correlates of Tobacco Product

- Cessation Among Youth and Adults in the USA: Findings from the PATH Study Waves 1–3 (2013–2016).” *Tobacco Control*, 29:s203–s215, 2020. Available at <https://doi.org/10.1136/tobaccocontrol-2019-055255>.
262. Schabath, M.B., W.D. Cress, and T. Muñoz-Antonia, “Racial and Ethnic Differences in the Epidemiology and Genomics of Lung Cancer.” *Cancer Control*, 23(4):338–346, 2016. Available at <https://doi.org/10.1177/107327481602300405>.
- *263. National Cancer Institute. “Cancer Statistics: Cancer Disparities.” *SEER.Cancer.gov*. Accessed June 4, 2021. <https://seer.cancer.gov/statfacts/html/disparities.html>.
- *264. Keenan, N.L. and K.M. Shaw, “Coronary Heart Disease and Stroke Deaths—United States, 2006.” *Morbidity and Mortality Weekly Report Supplements*, 60(1):62–66, 2011. Available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/su6001a13.htm>.
265. Safford, M.M., T.M. Brown, P.M. Muntner, et al., “Association of Race and Sex with Risk of Incident Acute Coronary Heart Disease Events.” *Journal of the American Medical Association*, 308(17):1768–1774, 2012. Available at <https://doi.org/10.1001/jama.2012.14306>.
- *266. Singh, G.K., M. Siahpush, R.E. Azuine, et al., “Widening Socioeconomic and Racial Disparities in Cardiovascular Disease Mortality in the United States, 1969–2013.” *International Journal of Maternal and Child Health and AIDS*, 3(2):106–118, 2015. Available at <https://doi.org/10.21106/ijma.44>.
- *267. National Center for Health Statistics, “Racial and Ethnic Disparities in Heart Disease.” *Health, United States Spotlight*, 2019. Accessed February 21, 2022. https://www.cdc.gov/nchs/hus/spotlight/HeartDiseaseSpotlight_2019_0404.pdf.
- *268. Van Dyke, M., S. Greer, E. Odom, et al., “Heart Disease Death Rates Among Blacks and Whites Aged ≥35 Years—United States, 1968–2015.” *Morbidity and Mortality Weekly Report Surveillance Summaries*, 67(5):1–11, 2018. Available at <https://doi.org/10.15585/mmwr.ss6705a1>.
- *269. CDC, “Vital Signs: Avoidable Deaths from Heart Disease, Stroke, and Hypertensive Disease—United States, 2001–2010.” *Morbidity and Mortality Weekly Report*, 62(35):721–727, 2013. Available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a4.htm>.
270. Chen-Sankey, J.C., K. Choi, T.R. Kirchner, et al., “Flavored Cigar Smoking Among African American Young Adult Dual Users: An Ecological Momentary Assessment.” *Drug and Alcohol Dependency*, 196:79–85, 2019. Available at <https://doi.org/10.1016/j.drugalcdep.2018.12.020>.
- *271. Odani, S., B.S. Armour, C.M. Graffunder, et al., “Prevalence and Disparities in Tobacco Product Use Among American Indians/Alaska Natives—United States, 2010–2015.” *Morbidity and Mortality Weekly Report*, 66(50):1374–1378, 2017. Available at <https://doi.org/10.15585/mmwr.mm6650a2>.
- *272. Eichner, J.E., W. Wang, Y. Zhang, et al., “Tobacco Use and Cardiovascular Disease Among American Indians: The Strong Heart Study.” *International Journal of Environmental Research and Public Health*, 7(10):3816–3830, 2010. Available at <https://doi.org/10.3390/ijerph7103816>.
273. Lee, E.T., T.K. Welty, R. Fabsitz, et al., “The Strong Heart Study—A Study of Cardiovascular Disease in American Indians: Design and Methods.” *American Journal of Epidemiology*, 132(6):1141–1155, 1990. Available at <https://doi.org/10.1093/oxfordjournals.aje.a115757>.
274. Mowery, P.D., S.R. Dube, S.L. Thorne, et al., “Disparities in Smoking-Related Mortality Among American Indians/Alaska Natives.” *American Journal of Preventive Medicine*, 49(5):738–744, 2015. Available at <https://doi.org/10.1016/j.amepre.2015.05.002>.
275. Hamad, R., J. Penko, D.S. Kazi, et al., “Association of Low Socioeconomic Status with Premature Coronary Heart Disease in US Adults.” *JAMA Cardiology*, 5(8):899–908, 2020. Available at <https://doi.org/10.1001/jamacardio.2020.1458>.
276. Gutierrez, J. and O.A. Williams, “A Decade of Racial and Ethnic Stroke Disparities in the United States.” *Neurology*, 82(12):1080–1082, 2014. Available at <https://doi.org/10.1212/WNL.000000000000237>.
277. Vurbic, D., V.S. Harder, R.R. Redner, et al., “Co-Occurring Obesity and Smoking Among U.S. Women of Reproductive Age: Associations with Educational Attainment and Health Biomarkers and Outcomes.” *Preventive Medicine*, 80:60–66, 2015. Available at <https://doi.org/10.1016/j.ypmed.2015.05.020>.
278. Smith, P. H., C. M. Mazure, and S. A. McKee, “Smoking and Mental Illness in the US Population.” *Tobacco Control*, 23(e2):e147–e153, 2014. Available at <https://doi.org/10.1136/tobaccocontrol-2013-051466>.
279. Callaghan, R.C., S. Veldhuizen, T. Jeysingh, et al., “Patterns of Tobacco-Related Mortality Among Individuals Diagnosed with Schizophrenia, Bipolar Disorder, or Depression.” *Journal of Psychiatric Research*, 48(1):102–110, 2014. Available at <https://doi.org/10.1016/j.jpsychires.2013.09.014>.
- *280. Prochaska, J.J., S. Das, and K.C. Young-Wolff, “Smoking, Mental Illness, and Public Health.” *Annual Review of Public Health*, 38:165–185, 2017. Available at <https://doi.org/10.1146/annurev-publhealth-031816-044618>.
281. Veldhuizen, S. and R.C. Callaghan, “Cause-Specific Mortality Among People Previously Hospitalized with Opioid-Related Conditions: A Retrospective Cohort Study.” *Annals of Epidemiology*, 24(8):620–624, 2014. Available at <https://doi.org/10.1016/j.annepidem.2014.06.001>.
282. Shastri, S.S., R. Talluri, and S. Shete, “Disparities in Secondhand Smoke Exposure in the United States: National Health and Nutrition Examination Survey 2011–2018.” *JAMA Internal Medicine*, 181(1):134–137, 2021. Available at <https://doi.org/10.1001/jamainternmed.2020.3975>.
- *283. Homa, D.M., L.J. Neff, B.A. King, et al., “Vital Signs: Disparities in Nonsmokers’ Exposure to Secondhand Smoke—United States, 1999–2012.” *Morbidity and Mortality Weekly Report*, 64(4):103–108, 2015. Available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6404a7.htm>.
284. Azagba, S., K. Latham, and L. Shan, “Sociodemographic Differences in Secondhand Smoke Exposure in the United States.” *Health Education & Behavior*, 47(4):602–610, 2020. Available at <https://doi.org/10.1177/1090198120925414>.
- *285. Walton, K., A.S. Gentzke, R. Murphy-Hoefer, et al., “Exposure to Secondhand Smoke in Homes and Vehicles Among US Youths, United States, 2011–2019.” *Preventing Chronic Disease*, 17:E103, 2020. Available at <https://dx.doi.org/10.5888/2Fpcd17.200107>.
286. Zhang, X., A.P. Martinez-Donate, D. Kuo, et al., “Trends in Home Smoking Bans in the USA, 1995–2007: Prevalence, Discrepancies and Disparities.” *Tobacco Control*, 21(3):330–336, 2012. Available at <https://tobaccocontrol.bmj.com/content/21/3/330.short>.
287. Dai, H., and J. Hao, “The Prevalence of Exposure to Workplace Secondhand Smoke in the United States: 2010 to 2015.” *Nicotine & Tobacco Research*, 19(11):1300–1307, 2017. Available at <https://doi.org/10.1093/ntr/ntw306>.
288. Counotte, D.S., A.B. Smit, T. Pattij, et al., “Development of the Motivational System During Adolescence, and Its Sensitivity to Disruption by Nicotine.” *Developmental Cognitive Neuroscience*, 1(4):430–443, 2011. Available at <https://doi.org/10.1016/j.dcn.2011.05.010>.
289. Villanti, A.C., A.L. Johnson, B.K. Ambrose, et al., “Flavored Tobacco Product Use in Youth and Adults: Findings from the First Wave of the PATH Study (2013–2014).” *American Journal of Preventive Medicine*, 53(2):139–151, 2017. Available at <https://doi.org/10.1016/j.amepre.2017.01.026>.
- *290. Thun, M.J., C. Day-Lally, D.G. Myers, et al., “Trends in Tobacco Smoking and Mortality from Cigarette Use in Cancer Prevention Studies I (1959 through 1965) and II (1982 through 1988).” In *Changes in Cigarette-Related Disease Risks and Their Implication for Prevention and Control*, National Cancer Institute, Chapter 4. Tobacco Control Monograph No. 8. NIH Publication No. 97–4213. Bethesda, MD: HHS, National Institutes of Health, National Cancer Institute, 1997. Available at <https://cancercontrol.cancer.gov/brp/tcrb/monographs/monograph-08>.
291. Jacobs, E.J., M.J. Thun, L.F. Apicella, et al., “Cigar Smoking and Death From Coronary Heart Disease in a Prospective Study of US Men.” *Archives of Internal Medicine*, 159(20):2413–2418, 1999.

- Available at <https://doi.org/10.1001/archinte.159.20.2413>.
- *292. Rostron, B.L., C.G. Corey, E. Holder-Hayes, et al., "Estimating the Potential Public Health Impact of Prohibiting Characterizing Flavors in Cigars Throughout the US." *International Journal of Environmental Research and Public Health*, 16(18):3234, 2019. Available at <https://doi.org/10.3390/ijerph16183234>.
- *293. U.S. Census Bureau. "Annual Estimates of the Resident Population by Single Year of Age and Sex for the United States: April 1, 2010 to July 1, 2019 (NC-EST2019-SYA SEXN)." *Census.gov*. Accessed October 7, 2021. <https://www.census.gov/newsroom/press-kits/2020/population-estimates-detailed.html>.
294. Sung, H., Y. Wang, T. Yao, et al., "Polytobacco Use of Cigarettes, Cigars, Chewing Tobacco, and Snuff Among US Adults." *Nicotine & Tobacco Research*, 18(5):817–826, 2016. Available at <https://doi.org/10.1093%2Fnt%2Fntv147>.
295. IARC, *Effectiveness of Tax and Price Policies for Tobacco Control*. IARC Handbooks of Cancer Prevention, Tobacco Control, Vol. 14. Lyon (FR): IARC, 2011. Available at <https://publications.iarc.fr/Book-And-Report-Series/Iarc-Handbooks-Of-Cancer-Prevention/Effectiveness-Of-Tax-And-Price-Policies-For-Tobacco-Control-2011>.
296. Godtfredsen, N.S., E. Prescott, and M. Osler, "Effect of Smoking Reduction on Lung Cancer Risk." *Journal of the American Medical Association*, 294(12):1505–1510, 2005. Available at <https://doi.org/10.1001/jama.294.12.1505>.
- *297. Hart, C., L. Gruer, and L. Bauld, "Does Smoking Reduction in Midlife Reduce Mortality Risk? Results of 2 Long-Term Prospective Cohort Studies of Men and Women in Scotland." *American Journal of Epidemiology*, 178(5):770–779, 2013. Available at <https://doi.org/10.1093/aje/kwt038>.
- *298. FDA, Preliminary Regulatory Impact Analysis; Initial Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis, Tobacco Product Standard for Characterizing Flavors in Cigars; Proposed Rule.
299. Thun, M.J., B.D. Carter, N.D. Feskanich, et al., "50-Year Trends in Smoking-Related Mortality in the United States." *New England Journal of Medicine*, 368(4):351–364, 2013. Available at <https://doi.org/10.1056/NEJMsa1211127>.
- *300. HHS, *The Health Benefits of Smoking Cessation: A Report of the Surgeon General*. DHHS Publication No. (CDC) 90–8416. Rockville, MD: HHS, Public Health Service, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 1990.
- *301. HHS, *Smoking Cessation: A Report of the Surgeon General*. Atlanta, GA: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2020.
302. Rostron, B.L., C.M. Chang, and T.F. Pehachek, "Estimation of Cigarette Smoking-Attributable Morbidity in the United States." *JAMA Internal Medicine*, 174(12):1922–1928, 2014. Available at <https://doi.org/10.1001/jamainternmed.2014.5219>.
303. National Research Council and Institute of Medicine of the National Academies, *Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context, and Lessons from International Experiences*. Washington, DC: The National Academies Press, 2015. Available at <https://doi.org/10.17226/19016>.
304. Stoklosa, M., "No Surge in Illicit Cigarettes After Implementation of Menthol Ban in Nova Scotia." *Tobacco Control*, 28(6):701–703, 2019. Available at <https://doi.org/10.1136/tobaccocontrol-2018-054552>.
- *305. WHO Study Group on Tobacco Product Regulation, *Tobacco Regulatory Advisory: Waterpipe Tobacco Smoking: Health Effects, Research Needs and Recommended Actions by Regulators*. WHO Tobacco Control Papers. Geneva (Switzerland): World Health Organization, Tobacco Free Initiative, 2005. Available at <https://www.who.int/publications/i/item/advisory-note-waterpipe-tobacco-smoking-health-effects-research-needs-and-recommended-actions-by-regulators>.
306. Shihadeh, A., S. Azar, C. Antonios, et al., "Towards a Topographical Model of Narghile Water-Pipe Café Smoking: A Pilot Study in a High Socioeconomic Status Neighborhood of Beirut, Lebanon." *Pharmacology Biochemistry and Behavior*, 79(1):75–82, 2004. Available at <https://doi.org/10.1016/j.pbb.2004.06.005>.
- *307. FDA, "Finding of No Significant Impact: Tobacco Product Standard for Flavors in Cigars." Silver Spring, MD: HHS, FDA, Center for Tobacco Products, 2022.
- *308. FDA, "Environmental Assessment for Tobacco Product Standard for Flavors in Cigars." Silver Spring, MD: HHS, FDA, Center for Tobacco Products, 2022.

Subpart B—Tobacco Product Standard for Flavors in Cigars

1166.5 Prohibition on use of characterizing flavors in cigars.

Authority: 21 U.S.C. 331, 333, 371(a), 387b, 387c, 387f(d), 387g(a).

Subpart A—General Provisions

§ 1166.1 Scope.

(a) This part sets out a tobacco product standard under the Federal Food, Drug, and Cosmetic Act regarding the use of characterizing flavors in cigars.

(b) No person may manufacture, distribute, sell, or offer for distribution or sale, within the United States a cigar or any of its components or parts that is not in compliance with this part.

§ 1166.3 Definitions.

For purposes of this part:

Accessory means any product that is intended or reasonably expected to be used with or for the human consumption of a cigar; does not contain tobacco or nicotine from any source and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a cigar; or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a cigar; but

(i) Solely controls moisture and/or temperature of a stored cigar; or

(ii) Solely provides an external heat source to initiate but not maintain combustion of a cigar.

Cigar means a tobacco product that:

(1) Is not a cigarette; and

(2) Is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco.

Component or *part* means any software or assembly of materials intended or reasonably expected:

(1) To alter or affect the cigar's performance, composition, constituents, or characteristics; or

(2) To be used with or for the human consumption of a cigar. The term excludes anything that is an accessory of a cigar.

Person includes an individual, partnership, corporation, and association.

Tobacco product means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in

List of Subjects in 21 CFR Part 1166

Labeling, Smoke, Smoking, Tobacco, Tobacco products.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that chapter I of title 21 of the Code of Federal Regulations be amended by adding part 1166 to subchapter K to read as follows:

PART 1166—PRODUCT STANDARD: FLAVORS IN CIGARS

Subpart A—General Provisions

Sec.

1166.1 Scope.

1166.3 Definitions.

manufacturing a component, part, or accessory of a tobacco product). The term “tobacco product” does not mean an article that under the Federal Food, Drug, and Cosmetic Act is: A drug (section 201(g)(1)); a device (section 201(h)); a combination product (section 503(g)); or a food under section 201(f) if such article contains no nicotine, or no more than trace amounts of naturally occurring nicotine.

United States means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam,

the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

Subpart B—Tobacco Product Standard for Flavors in Cigars

§ 1166.5 Prohibition on use of characterizing flavors in cigars.

A cigar or any of its components or parts (including the tobacco, filter, or wrapper, as applicable) shall not contain, as a constituent (including a

smoke constituent) or additive, an artificial or natural flavor (other than tobacco) or an herb or spice, including, but not limited to, strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, coffee, mint, or menthol, that is a characterizing flavor of the tobacco product or tobacco smoke.

Dated: April 22, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 1162

Tobacco Product Standard for Menthol in Cigarettes; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1162

[Docket No. FDA-2021-N-1349]

RIN 0910-A160

Tobacco Product Standard for Menthol in Cigarettes

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing a tobacco product standard that would prohibit menthol as a characterizing flavor in cigarettes. Tobacco use is the leading preventable cause of death and disease in the United States. Menthol's flavor and sensory effects increase appeal and make menthol cigarettes easier to use, particularly among youth and young adults. There are over 18.5 million menthol cigarette smokers ages 12 and older in the United States. This proposed product standard would reduce the appeal of cigarettes, particularly to youth and young adults, and thereby decrease the likelihood that nonusers who would otherwise experiment with menthol cigarettes would progress to regular smoking. In addition, the proposed tobacco product standard would improve the health and reduce the mortality risk of current menthol cigarette smokers by decreasing cigarette consumption and increasing the likelihood of cessation. FDA is taking this action to reduce the tobacco-related death and disease associated with menthol cigarette use. The proposed standard also is expected to reduce tobacco-related health disparities and advance health equity.

DATES: Submit either electronic or written comments on the proposed rule by July 5, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 5, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-N-1349 for "Tobacco Product Standard for Menthol in Cigarettes." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential

with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Beth Buckler or Eric Mandle, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 877-287-1373, CTPRegulations@fda.hhs.gov.

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I. Executive Summary

A. Purpose of the Proposed Rule

FDA is proposing a tobacco product standard that would prohibit menthol as a characterizing flavor in cigarettes. In developing this proposed rule, FDA carefully considered the scientific evidence and complex policy issues related to menthol cigarettes. As described in the preamble of this rule, FDA has conducted multiple scientific reviews related to menthol cigarettes, issued two advance notices of proposed rulemaking (ANPRMs) to solicit data and information about menthol cigarettes, considered a citizen petition requesting that FDA ban menthol as a characterizing flavor in cigarettes, and sponsored research on a variety of menthol-related topics.

Each year, 480,000 people die prematurely from a smoking-attributable disease, making tobacco use the leading cause of preventable death and disease in the United States. In 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) banned characterizing flavors in

cigarettes, other than tobacco or menthol, based on their appeal to youth, in order to reduce the number of children and adolescents who smoke cigarettes. As a result, menthol cigarettes are the only cigarettes with a characterizing flavor still marketed in the United States.

In 2019, there were more than 18.5 million current smokers of menthol cigarettes ages 12 and older in the United States. Although menthol cigarette smoking is widespread in the United States, menthol cigarettes are used at a particularly high rate by youth, young adults, and certain other vulnerable populations such as African American and other racial and ethnic groups. Menthol is a flavor compound added to cigarettes, which produces a minty taste and cooling sensation when inhaled. Menthol's flavor and sensory effects reduce the harshness of cigarette smoking and make it easier for new users, particularly youth and young adults, to continue experimenting and progress to regular use. In addition, data show that menthol cigarettes contribute to greater nicotine dependence in youth and young adults than non-menthol cigarettes. By prohibiting menthol as a characterizing flavor in cigarettes, this proposed product standard would reduce the appeal of cigarettes, particularly to youth and young adults, who are more likely to try a menthol cigarette as their first cigarette than a non-menthol cigarette. And because almost all daily smokers started smoking before the age of 25, it would thereby decrease the likelihood that nonusers who would otherwise experiment with menthol cigarettes would progress to regular smoking. By prohibiting menthol as a characterizing flavor in cigarettes, FDA expects a significant reduction in the likelihood of youth and young adult initiation and progression to regular cigarette smoking, which is expected to prevent future cigarette-related disease and death.

In addition, the proposed tobacco product standard would improve the health and reduce the mortality risk of current menthol cigarette smokers by substantially decreasing cigarette consumption and increasing the likelihood of cessation. Published modeling studies have estimated a 15.1 percent reduction in smoking prevalence within 40 years if menthol cigarettes were no longer available in the United States. These studies also estimate that 324,000 to 654,000 smoking attributable deaths overall (92,000 to 238,000 among African Americans) would be avoided within 40 years. FDA expects the public health benefit of this rule to be particularly

pronounced among vulnerable populations, including youth and young adults, as well as Black smokers, who have the highest prevalence of menthol cigarette smoking and experience a disproportionate burden of the related harms. For the reasons discussed in the preamble of this proposed rule, FDA finds that the proposed tobacco product standard would be appropriate for the protection of the public health. Additionally, this proposed product standard is expected to substantially decrease tobacco-related health disparities and to advance health equity across population groups.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule would prohibit the use of menthol as a characterizing flavor in cigarettes and cigarette components and parts, including those that are sold separately to consumers. Specifically, the rule would provide that a cigarette or any of its components or parts (including the tobacco, filter, wrapper, or paper, as applicable) shall not contain, as a constituent (including a smoke constituent) or additive, menthol that is a characterizing flavor of the tobacco product or tobacco smoke. Under the proposed rule, no person may manufacture, distribute, sell, or offer for distribution or sale, within the United States a cigarette or cigarette component or part that is not in compliance with the product standard. Among the factors that FDA believes are relevant in determining whether a cigarette has a characterizing flavor are:

- The presence and amount of artificial or natural flavor additives, compounds, constituents, or ingredients, or any other flavoring ingredient in a tobacco product, including its components or parts;
- The multisensory experience (*i.e.*, taste, aroma, and cooling or burning sensations in the mouth and throat) of a flavor during use of a tobacco product, including its components or parts;
- Flavor representations (including descriptors), either explicit or implicit, in or on the labeling (including packaging) or advertising of tobacco products; and
- Any other means that impart flavor or represent that the tobacco products has a characterizing flavor.

FDA is proposing that any final rule that may issue based on this proposed rule become effective 1 year after the date of publication of the final rule. Therefore, after the effective date, no person may manufacture, sell, or offer for sale or distribution within the United States a cigarette or any of its components or parts that is not in

compliance with part 1162. This regulation does not include a prohibition on individual consumer possession or use, and FDA cannot and will not enforce against individual consumers for possession or use of menthol cigarettes. FDA’s enforcement will only address manufacturers, distributors, wholesalers, importers, and retailers. State and local law enforcement agencies do not independently enforce the Federal Food, Drug and Cosmetic Act (FD&C Act). These entities do not and cannot take enforcement actions against any violation of chapter IX of the Act or this regulation on FDA’s behalf. We recognize concerns about how State and local law enforcement agencies enforce their own laws in a manner that may impact equity and community safety and seek comment on how FDA can best make clear the respective roles of FDA and State and local law enforcement.

C. Legal Authority

Section 907 of the FD&C Act (21 U.S.C. 387g) prohibited characterizing flavors, other than menthol and tobacco,

in cigarettes. Section 907 expressly preserved FDA’s ability to prohibit menthol as an exercise of FDA’s authorities to revise or issue tobacco product standards, including provisions that would require the reduction or elimination of a constituent (including a smoke constituent), or harmful component of tobacco products; and provisions respecting the construction, components, ingredients, additives, constituents (including smoke constituents), and properties of the tobacco product (section 907(a)(2), (a)(3), (a)(4)(A)(ii), and (a)(4)(B)(i) of the FD&C Act). FDA’s authorities related to the sale and distribution of tobacco products are established under sections 907(a)(4)(B)(v) and 906(d) (21 U.S.C. 387f(d)) of the FD&C Act.

D. Costs and Benefits

The quantified benefits of this proposed rule come from lower smoking-attributable mortality in the U.S. population due to diminished exposure to tobacco smoke for both users and nonusers of cigarettes. The costs of this proposed rule are those to

firms to comply with the rule, to consumers impacted by the rule, and to the government to enforce this product standard. In addition to benefits and costs, this rule will cause transfers from State governments, Federal Government, and firms to consumers in the form of reduced revenue and tax revenue.

We estimate that the annualized benefits over a 40-year time horizon will equal \$220 billion at a 7 percent discount rate, with a low estimate of \$102 billion and a high estimate of \$334 billion, and \$232 billion at a 3 percent discount rate, with a low estimate of \$108 billion and a high estimate of \$353 billion.

Over a 40-year time horizon, we estimate that the annualized costs will equal \$307 million at a 7 percent discount rate, with a low estimate of \$16 million and a high estimate of \$601 million, and \$291 million at a 3 percent discount rate, with a low estimate of \$9 million and a high estimate of \$573 million.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
Addiction Review	Scientific Review of the Effects of Menthol in Cigarettes on Tobacco Addiction: 1980–2021.
ANPRM	Advance notice of proposed rulemaking.
CARDIA	Coronary Artery Risk Development in Young Adults.
CFR	Code of Federal Regulations.
CPS II	Cancer Prevention Study II.
CTP	FDA’s Center for Tobacco Products.
EE	Expert Elicitation.
ENDS	Electronic Nicotine Delivery Systems.
E.O.	Executive order.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FDA	Food and Drug Administration.
FR	Federal Register.
FTC	Federal Trade Commission.
HHS	U.S. Department of Health and Human Services.
HTP	Heated Tobacco Product.
IOM	Institute of Medicine.
LGBTQ+	Lesbian, gay, bisexual, transgender, or queer.
Nav Guide	Navigation Guide Systematic Review Methodology.
NCI	National Cancer Institute.
NHANES	National Health and Nutrition Examination Survey.
NHIS	National Health Interview Survey.
NRC	National Research Council.
NSDUH	National Survey on Drug Use and Health.
NYC	New York City.
NYAHS	National Young Adult Health Survey.
NYTS	National Youth Tobacco Survey.
PATH	Population Assessment of Tobacco and Health.
PRIA	Preliminary Regulatory Impact Analysis.
RYO	Roll-your-own.
SAVM	Smoking and Vaping Model.
SGR	Surgeon General Report.
SIDS	Sudden infant death syndrome.
Tobacco Control Act	Family Smoking Prevention and Tobacco Control Act.
TPSAC	Tobacco Product Scientific Advisory Committee.
TUS–CPS	Tobacco Use Supplement to the Current Population Survey.
YRBS	Youth Risk Behavior Survey.

III. Background

A. Need for the Regulation

FDA is proposing to prohibit menthol as a characterizing flavor in cigarettes. Cigarette smoking is the leading cause of preventable death and disease in the United States and is responsible for more than 480,000 premature deaths per year (Ref. 1). Menthol is a flavor compound that is added to cigarettes, which produces a minty taste and cooling sensation when inhaled (Ref. 2). These sensory properties contribute to smoker perceptions that menthol cigarettes are easier to inhale, are less irritating, have a better taste, are smoother and more refreshing than non-menthol cigarettes (Refs. 3–5). Menthol's flavor and sensory effects reduce the harshness of cigarette smoking among new users and facilitate experimentation and progression to regular smoking of menthol cigarettes, particularly among youth and young adults (Refs. 6–7, 5, 8). As a result, the brain is repeatedly exposed to nicotine and susceptible to nicotine addiction (Ref. 9).

In addition to its flavor and sensory effects, menthol contributes to a greater risk of nicotine dependence by enhancing the addictive effects of nicotine in the brain by affecting mechanisms involved in nicotine addiction (Refs. 10–13). Clinical data show that menthol cigarette smokers have higher levels of brain nicotinic receptors compared to non-menthol smokers (Ref. 14). Studies demonstrate that menthol, like nicotine, binds to nicotinic receptors in the brain (Refs. 15 and 16), and menthol alone can increase the number of nicotinic receptors in the brain (Refs. 10 and 11). Evidence demonstrates that the combined effects of menthol and nicotine in the brain are associated with behaviors indicative of greater addiction to nicotine compared to nicotine alone (Refs. 10 and 12).

Youth and young adults are particularly susceptible to becoming addicted to nicotine. Due to its ongoing development, the adolescent brain, which continues to develop until about age 25, is more vulnerable to nicotine's effects than the adult brain (Refs. 17–19). The combined effects of nicotine and menthol in the developing brain make youth who smoke menthol cigarettes particularly vulnerable to the effects of menthol on nicotine dependence.

Data from multiple studies across different populations and time periods demonstrate that menthol cigarettes contribute to greater nicotine

dependence in youth and young adults¹ than non-menthol cigarettes (Refs. 20–28). Menthol is a significant contributor to experimentation and progression to regular cigarette smoking among this population (Refs. 25, 29–31, 8). This is of particular concern since the vast majority of smoking initiation occurs during adolescence (Refs. 32, 8, 31, 33) and youth and young adults are more likely to try a menthol cigarette as their first cigarette than a non-menthol cigarette (Refs. 8, 31, and 33).

In addition to the impacts on progression to regular use and dependence, menthol contributes to reduced cessation success, particularly among Black smokers² (Refs. 34–41) (see section IV.D of this document). A number of nationally representative studies among young adult and adult smokers show that menthol in cigarettes contributes to reduced cessation success (Refs. 34–35, 42, 36–38, 40, 43). Among Black smokers, this effect is consistent across large nationally representative studies, smaller clinical studies of smokers, reviews of the menthol and cessation literature, and meta-analyses, which examined outcomes from multiple menthol and cessation studies. Although findings among smokers in the general population produce more mixed results than findings specific to Black smokers, the strongest studies on the general population support an effect of menthol on reduced cessation. For example, two recent studies using data from the nationally representative longitudinal Population Assessment of Tobacco and Health (PATH) study found that menthol is associated with reduced smoking cessation across multiple years of followup (Refs. 40 and 43).

In 2019, there were more than 18.5 million current smokers of menthol cigarettes ages 12 and older in the United States (Ref. 44). Data show that menthol cigarettes are used at a particularly high rate by youth (aged

12–17), young adults (aged 18–25), and other vulnerable populations³ such as African American and other racial and ethnic groups (Ref. 44). Prohibiting menthol as a characterizing flavor in cigarettes would help to decrease the nicotine addiction resulting from menthol cigarette use, and thereby, decrease disease and death.

In 2009, the Tobacco Control Act established the “Special Rule for Cigarettes” (section 907(a)(1)(A) of the FD&C Act (Special Rule for Cigarettes)).⁴ The Special Rule for Cigarettes banned characterizing flavors in cigarettes, other than tobacco or menthol, based on their appeal to youth, in order to reduce the number of children and adolescents who smoke cigarettes (see H.R. Rep. No. 111–58, pt. 1, at 37 (2009)). As a result, menthol cigarettes are the only cigarettes with a characterizing flavor still marketed in the United States.

In establishing the Special Rule for Cigarettes, Congress noted that, “[g]iven the number of open questions related to menthol cigarettes, the legislation authorizes the Secretary to ban or modify the use of menthol in cigarettes based on scientific evidence” (H.R. Rep. No. 111–58, pt. 1, at 39 (2009)). Specifically, the Tobacco Control Act authorizes FDA to adopt or revise product standards where FDA determines that such standard is appropriate for the protection of the public health (section 907(a)(2) and (3) of the FD&C Act).

After careful consideration of the scientific evidence, FDA is proposing to prohibit the use of menthol as a characterizing flavor in cigarettes in

³ Throughout the preamble of this proposed rule, the term “vulnerable populations” refers to groups that are susceptible to tobacco product risk and harm due to disproportionate rates of tobacco product initiation, use, burden of tobacco-related diseases, or decreased cessation. Examples of vulnerable populations include those with lower household income and educational attainment, certain racial or ethnic populations, individuals who identify as LGBTQ+, underserved rural populations, those pregnant or trying to become pregnant, those in the military or veterans, or those with behavioral health conditions or substance use disorders.

⁴ Section 907(a)(1)(A) of the FD&C Act states that beginning 3 months after the date of enactment of the Tobacco Control Act, a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph (section 907(a)(1)(A) of the Tobacco Control Act) shall be construed to limit the Secretary of HHS's authority to take action under this section or other sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this section.

¹ Though age ranges for youth and young adults vary across studies, in general, “youth” or “adolescent” encompasses those 11–17 years of age, while those who are 18–25 years old are considered “young adults” (even though, developmentally, the period between 18–20 years of age is often labeled late adolescence); those 26 years of age or older are considered “adults” or “older adults” (Ref. 32).

² Throughout the preamble of this proposed rule, FDA uses both the terms “Black” and “African American.” The term “African American” is used to describe or refer to a person of African ancestral origins or who identifies as African American. “Black” is used to broadly describe or refer to a person who identifies with that term. Though both of these terms may overlap, they are distinct concepts (e.g., a Black person may not identify as African American). As a result, FDA relies on the specific term used by researchers when citing to specific studies. FDA uses the term “Black” when not citing to a specific study.

order to reduce the death and disease caused by cigarette use. For the reasons described in the preamble of this rule, FDA finds that this product standard would be appropriate for the protection of the public health because it would prohibit menthol cigarettes, which will reduce initiation rates of smoking cigarettes, particularly for youth and young adults, and thereby decrease the likelihood that nonusers of cigarettes who experiment with these tobacco products would progress to regular cigarette smoking. Additionally, the proposed tobacco product standard is anticipated to improve the health of current smokers of menthol cigarettes by decreasing cigarette consumption and increasing the likelihood of cessation among this population. Published modeling studies have estimated that 324,000 to 654,000 smoking attributable deaths would be avoided by the year 2060 if menthol cigarettes were no longer available in the United States (Refs. 45 and 46). These figures significantly understate the public-health benefits because they undercount lives saved of youth and young adults who, as the result of the menthol ban, do not begin to smoke. Beyond averted deaths, societal benefits would include reduced smoking-related morbidity and health disparities, diminished exposure to secondhand smoke among non-smokers, decreased potential years of life lost, decreased disability, and improved quality of life among former smokers. FDA expects the public health benefit of this rule to be particularly pronounced among vulnerable populations, including youth and young adults, as well as Black smokers, who have the highest prevalence of menthol cigarette smoking and experience a disproportionate burden of the related harms.

This proposed product standard is also expected to substantially decrease tobacco-related health disparities and to advance health equity across population groups. Tobacco-related health disparities are the differences observed in population groups regarding: The patterns (*e.g.*, initiation, dual or polyuse, cessation), prevention, and treatment of tobacco use; the risk, incidence, morbidity, mortality, and burden of tobacco-related illness; and in capacity and infrastructure (*e.g.*, political systems, educational institutions), access to resources (*e.g.*, health services and programs), and environmental secondhand smoke exposure (Refs. 47–49). Tobacco-related health disparities affect those who have systematically experienced greater obstacles to health based on group

membership due to the inequitable distribution of social, political, economic, and environmental resources (Refs. 50, 49, and 51). Health equity is the attainment of the highest level of health for all people (Ref. 51). It is achieved by equally valuing all individuals regardless of group membership; removing social, economic, and institutional obstacles to health; and addressing historical and contemporary injustices (Refs. 51–53). The advancement of health equity is integral to the reduction and elimination of tobacco-related health disparities, which result from denied opportunity and access to economic, political, and social participation (Refs. 49 and 54).

Despite significant declines in cigarette smoking since 1964, “very large disparities in tobacco use remain across groups defined by race, ethnicity, educational level, and socioeconomic status and across regions of the country” (Ref. 1). Menthol cigarettes contribute to these disparities in cigarette use (Refs. 55–56, 21–24, 57–59) and the resulting disparities in health outcomes (Refs. 60–63, 50, 49). Members of underserved communities,⁵ such as African American and other racial and ethnic populations, individuals who identify as LGBTQ+, pregnant persons, those with lower household income or educational attainment, and individuals with behavioral health disorders are more likely to report smoking menthol cigarettes than other population groups (Refs. 64–67, 55, 57–59, 68–69, 44, 70–71). Due to this increased prevalence of menthol cigarette smoking, members of underserved communities bear a disproportionate burden of tobacco-related morbidity and mortality (see section V.C of this document). This proposed product standard is anticipated to promote better public health outcomes across population groups.

B. Relevant Regulatory History of Menthol Cigarettes

In its implementation of the Tobacco Control Act over the past several years, FDA has engaged in close study and

⁵ As defined by Executive Order (E.O.) 13985, “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,” (86 FR 7009, January 25, 2021) the term “underserved communities” refers to populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life. In the context of tobacco products and tobacco-related health disparities, such communities may include populations disproportionately impacted by marketing and promotion targeted on the basis of such shared characteristics.

careful consideration of the scientific evidence and complex policy issues related to menthol cigarettes. FDA has conducted multiple scientific reviews related to menthol cigarettes, issued two ANPRMs to solicit data and information about menthol cigarettes, considered a citizen petition requesting that FDA ban menthol as a characterizing flavor in cigarettes, and sponsored research on a variety of menthol-related topics through contracts and interagency agreements with Federal partners, including the National Institutes of Health (NIH).⁶ Among other things, FDA has considered the comments and information received in response to the scientific reviews, ANPRMs, and citizen petition in developing this proposed rule.

1. Scientific Reviews

In March 2010, FDA’s Tobacco Product Scientific Advisory Committee (TPSAC) undertook a review of the available evidence concerning menthol cigarettes and solicited and received input from many public commenters, including researchers, tobacco industry representatives, consultants to the tobacco industry, and public health experts. As required by section 907(e) of the FD&C Act, on March 23, 2011, TPSAC submitted its report and recommendation to the Secretary of HHS on the impact of the use of menthol in cigarettes on the public health, including use among children, African Americans, Hispanics, and other racial and ethnic populations (Ref. 72).^{7, 8} In addition, the nonvoting

⁶ Information on specific projects supported by FDA is available at <https://www.fda.gov/tobacco-products/tobacco-science-research/research> (search “menthol” or “flavors”).

⁷ Based on evidence available at that time, TPSAC concluded that removing menthol cigarettes from the market would benefit the public health and noted that the statute provides a “variety of mechanisms for FDA to consider, if it concludes that it should pursue this recommendation,” but it offered “no specific suggestions for FDA to follow-up” on its recommendations (Ref. 72 at 225). TPSAC also noted that, although the FD&C Act requires FDA to consider information submitted on potential countervailing effects of any proposed product standard, such as the creation of a black market, the advisory committee was not “constituted to carry out analyses of the potential for and impact of a black market for menthol cigarettes” and did not analyze that issue (Ref. 72). Therefore, “FDA would need to assess the potential for contraband menthol cigarettes as required by the [FD&C] Act.” (Ref. 72).

⁸ Two tobacco companies challenged the TPSAC menthol report in court, alleging that certain TPSAC members had conflicts of interest that led them to shape the recommendations in a manner that injured the tobacco companies. In 2014, the U.S. District Court for the District of Columbia held that TPSAC members were improperly appointed. *Lorillard, Inc. v. FDA*, 56 F. Supp. 3d 37 (D.D.C. 2014). The court ordered FDA to reconstitute TPSAC and enjoined FDA from using the TPSAC

industry representatives of TPSAC submitted a separate document reflecting the tobacco industry perspective (Ref. 73).

Shortly thereafter, independent of TPSAC's work and report, including the nonvoting industry representatives' report, experts within FDA's Center for Tobacco Products (CTP) conducted an evaluation of the available science related to the impact of the use of menthol in cigarettes on public health. This evaluation is titled "Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes" (Preliminary Evaluation) and has been peer reviewed (Ref. 74). FDA evaluated peer-reviewed literature, tobacco industry submissions and other materials provided to TPSAC, secondary data analyses, and CTP's own analyses of relevant large data sets (Ref. 74). The Preliminary Evaluation concluded that menthol in cigarettes is likely associated with increased smoking initiation and progression to regular smoking, increased dependence, and reduced cessation success, particularly among African American smokers (Ref. 74).

As the body of evidence has continued to grow, FDA recently undertook an updated robust review of the science on menthol in cigarettes. This review, titled "Scientific Review of the Effects of Menthol in Cigarettes on Tobacco Addiction: 1980–2021" (Ref. 75) (Addiction Review), covers the peer-reviewed, publicly available literature spanning the period from 1980 to April 30, 2021, and focuses on the impact of menthol cigarettes on outcomes related to addiction, including progression to

menthol report. *Id.* at 57. This holding was vacated by the U.S. Court of Appeals for the D.C. Circuit on the ground that the tobacco companies failed to show any imminent injury from the report. *R.J. Reynolds Tobacco Co. v. FDA*, 810 F.3d 827, 832 (D.C. Cir. 2016).

Because of the pendency of this lawsuit at the time FDA began to develop the Preliminary Evaluation discussed below, FDA did not rely on the findings in the TPSAC menthol report in conducting its independent review of the scientific evidence related to menthol. Similarly, in connection with developing this proposed rule, FDA has reviewed the TPSAC menthol report, as well as the industry perspective document submitted by the non-voting industry representatives on TPSAC, but did not rely directly on any findings or recommendations in the TPSAC menthol report. Although the conclusions reached in the TPSAC menthol report are generally consistent with the determinations reached by FDA in support of this proposed rule, FDA conducted an independent analysis of the scientific evidence, including evidence that has developed since the report issued more than 10 years ago. FDA also notes that it has reviewed but did not rely on an additional analysis that builds on modeling prepared in connection with the TPSAC menthol report. That evidence is discussed in the Evaluation of Potential Impacts.

regular use, dependence, and cessation. The Addiction Review has been peer reviewed by independent external experts. Taking into consideration comments from this peer review (Ref. 76), FDA revised the Addiction Review, and the final peer-reviewed document is available in the docket for this proposed rule (Ref. 75).

FDA's process for this scientific evaluation is described in detail in the Addiction Review (see Ref. 75). In sum, FDA used several scientific publication databases to retrieve articles published between 1980 and April 30, 2021, and developed a screening process, including eligibility criteria, to identify articles for inclusion in the final review (Ref. 75). FDA scored the individual quality of each study using the "QualSyst" systematic review tool (Ref. 75). For the weight of evidence approach, FDA adapted and used the Navigation Guide Systematic Review Methodology (NavGuide), an integrated Cochrane-style risk of bias analysis and weight of evidence approach (Ref. 75). The NavGuide approach was selected due to the rigor of its systematic review methods (*e.g.*, specifying explicit study questions, conducting a comprehensive search, rating the quality and strength of the evidence according to consistent criteria). The approach also allowed for combining the results of clinical and nonclinical evidence into a single conclusion about the effects of menthol on the outcomes of interest (Ref. 75). This weight of the evidence approach allowed FDA to assess the quality of the available evidence and determine the role of menthol in cigarettes on the sensory effects of smoking, as well as the impact of menthol in cigarettes on the progression to regular use, dependence, and cessation.

The Addiction Review found the totality of evidence from 1980 to 2021 supports that: (1) The sensory effects of menthol are associated with positive subjective smoking experiences, such as those that mask and reduce the harshness of cigarette smoking; these effects facilitate continued smoking, (2) menthol is associated with progression to regular cigarette smoking in youth and young adults, (3) menthol in cigarettes is associated with greater dependence among youth, (4) menthol is likely associated with reduced cessation success among the general population, and (5) menthol in cigarettes is associated with reduced cessation success among African American cigarette smokers (Ref. 75). FDA has considered the Addiction Review conclusions based on weighted scientific evidence in the development of this proposed product standard.

In addition, FDA undertook a review of scientific evidence related to the potential impacts of a menthol product standard. This review, titled "Review of Studies Assessing the Potential Impact of Prohibiting Menthol as a Characterizing Flavor in Cigarettes" (Ref. 77) (Evaluation of Potential Impacts), is comprised of three distinct evaluations. Section 1 describes the results of a reproducible, transparent, and documented review of the scientific evaluation literature regarding the tobacco use behaviors of young people, tobacco use behaviors of adults, sales of tobacco products, illicit sales of tobacco products, and user modification of tobacco products (Ref. 77). Section 2 describes the scientific evidence relevant to consumers' product choices and intended use behaviors in response to a hypothetical menthol cigarette ban (Ref. 77). And section 3 summarizes and evaluates modeling studies that quantify the effects of a menthol cigarette ban to inform an assessment of the potential behavioral responses to a menthol product standard (Ref. 77).

The Evaluation of Potential Impacts has been peer reviewed by independent external experts. Taking into consideration comments from this peer review (Ref. 76), FDA revised the Evaluation of Potential Impacts, and the final peer-reviewed document is available in the docket for this proposed rule (Ref. 77). As with the Addiction Review, FDA has considered this scientific review in the development of this proposed product standard.

2. ANPRMs

In July 2013, FDA issued an ANPRM to obtain information related to the potential regulation of menthol in cigarettes, including any data, research, or other information that may inform regulatory actions FDA might take with respect to menthol in cigarettes (78 FR 44484, July 24, 2013) (Menthol ANPRM). FDA sought data and information on a number of complex questions, including whether FDA should consider establishing a tobacco product standard for menthol in menthol cigarettes; if so, what level of menthol would be appropriate for the protection of public health; whether FDA should address menthol in other tobacco products; whether alternatives and substitutes might appear on the market and how those substances might be regulated; whether and how restrictions on advertising and promotion of menthol cigarettes would influence consumer behavior; and whether there was evidence that illicit trade in menthol cigarettes would become a significant problem if menthol

cigarettes were banned (78 FR 44484 at 44485). The Menthol ANPRM also requested comment on the Preliminary Evaluation and made available an addendum with articles published since the evaluation was submitted for peer review in 2011 (id.).

In July 2017, FDA announced a comprehensive approach to tobacco and nicotine regulation to protect youth and reduce tobacco-related disease and death (Ref. 78). As part of the public dialogue on the comprehensive approach, in March 2018, FDA issued three ANPRMs related to the regulation of nicotine in combustible cigarettes (83 FR 11818, March 16, 2018), flavors (including menthol) in tobacco products (83 FR 12294, March 21, 2018) (Flavors ANPRM), and premium cigars (83 FR 12901, March 26, 2018). In addition, FDA announced the availability of a draft concept paper titled “Illicit Trade in Tobacco Products after Implementation of a Food and Drug Administration Product Standard,” and sought public comment (83 FR 11754, March 16, 2018). This paper analyzes the potential for illicit trade markets to develop in response to a tobacco product standard (Ref. 79 at 2).

The Flavors ANPRM requested data and information about the role that flavors play in tobacco products (83 FR 12294). With regard to menthol, FDA requested additional data or information about the role of menthol in cigarettes, including the role menthol plays in: (1) Smoking initiation, (2) the likelihood of smoking cessation in youth, young adults, and adults, (3) the likelihood that menthol smokers would switch to another tobacco product or start dual use with another tobacco product, instead of quitting smoking, if a tobacco product standard prohibited or limited menthol in cigarettes, and (4) the use of tobacco products other than cigarettes (e.g., electronic nicotine delivery systems (ENDS) and cigars) (83 FR 12294 at 12299).

3. Comments to the ANPRMs

While the Menthol ANPRM and the Flavors ANPRM discussed two different potential product standards and a range of product types, both specifically requested public input on the role of menthol in cigarettes. FDA received over 174,000 comments on the Menthol ANPRM, with approximately 165,000 of those comments submitted as part of 41 different organized campaigns. FDA also received over 525,000 comments on the Flavors ANPRM, a large proportion of which were form letters related to 61 different organized campaigns. Some of the issues raised in the comments to the ANPRMs are highlighted below.

Comments generally in support of any proposed menthol product standard stated that a product standard would protect the health of smokers and non-smokers, provide current menthol cigarette smokers an incentive to quit smoking, and protect youth, African Americans, and other vulnerable populations from the dangers of menthol cigarettes. FDA received many comments suggesting a specific, nonzero allowable level of menthol in cigarettes; many comments suggested a prohibition on menthol at any level and noted this would be the easiest standard to enforce. Other comments, without specifying a specific level or amount, argued that FDA should determine the nonzero allowable level of menthol in cigarettes. Many others urged FDA to adopt a product standard prohibiting menthol as a characterizing flavor in cigarettes without specifying a specific level or amount. Many of the comments in favor of prohibiting menthol as a characterizing flavor stated that FDA should be responsible for determining the definition of “characterizing flavor” to avoid reliance on industry practices or standards. Regardless of the formulation of a product standard, many comments stated that any menthol product standard is technically achievable and noted the prior ban on other characterizing flavors (other than tobacco and menthol) in cigarettes.

Many comments stated that a product standard should apply to menthol (natural or artificial) and any additive, constituent, artificial or natural flavor, component, or insert which conveys menthol or flavoring to cigarettes or cigarette smoke, including through the tobacco or something other than the tobacco itself. These commenters often noted that there are additives beyond natural and synthetic menthol that can create a similar flavor and sensation in cigarettes.

FDA also received comments from individuals and members of the tobacco industry generally opposing the establishment of any product standard for menthol cigarettes. These comments generally stated there was insufficient scientific evidence to support a menthol product standard. Industry comments also argued menthol cigarettes do not present a greater health risk when compared to non-menthol cigarettes, arguing that menthol does not increase the risk of disease or increase markers for dependence and addiction. Some comments opposed to a menthol product standard stated it would not be appropriate for the protection of the public health, as a standard would not lead to an increase in cessation and would result in consumers adding

menthol to non-menthol cigarettes or the use of illicit or unregulated products.

Many comments received from industry noted concern with how FDA would define “characterizing flavors,” arguing that any such definition must use clear and science-based criteria. Some comments argued that, without a definition for “characterizing flavors,” it could be difficult for industry to comply with a menthol product standard. FDA also received comments from industry suggesting that any standard apply only to known natural or synthetic menthol additives currently used in the manufacture of cigarettes, stating that it was not logical for a product standard to apply to unknown additives or additives not currently in use.

FDA has reviewed and closely considered the comments to the ANPRMs, as well as additional evidence and information not available at the time of the ANPRMs, in developing this proposed rule.

4. Citizen Petition

On April 12, 2013, the Tobacco Control Legal Consortium (now known as the Public Health Law Center) submitted a citizen petition on behalf of themselves, several other public health organizations, and an individual requesting that FDA ban menthol as a characterizing flavor in cigarettes (Ref. 80). FDA issued an interim response in 2013, stating that the Agency had not yet reached a decision on the petition “because it raises significant, complex issues requiring extensive review and analysis by Agency officials” (Ref. 81).

In 2020, the African American Tobacco Control Leadership Council and several other public health organizations filed a lawsuit alleging that FDA unreasonably delayed addressing menthol as a characterizing flavor in cigarettes and responding to the citizen petition. *Compl., African Am. Tobacco Control Leadership Council v. U.S. Dep’t. of Health & Human Servs.*, No. 20–cv–04012 (N.D. Cal. June 17, 2020), ECF No. 1. Before any action by the court, FDA committed to responding to the petition by a date certain. Subsequently, the U.S. District Court of the Northern District of California held that section 907(a)(5) of the FD&C Act “does not necessarily require that FDA modify the [Special Rule for Cigarettes], but a *determination* of whether the [Special Rule for Cigarettes] should be modified is required by the statute.” Order Granting in Part and Denying in Part Motion To Dismiss, *African Am. Tobacco Control Leadership Council v. U.S. Dep’t. of*

Health & Human Servs., ECF No. 34 at 8 (emphasis in original).

On January 14, 2021, the Petitioners submitted a citizen petition supplement pursuant to 21 CFR 10.30(g) to update the administrative record with research developed since 2013 on the impact of menthol in cigarettes. The supplement identified and discussed evidence related to the following topics: Menthol's impact on youth initiation, adult and youth cessation, the impact on non-users of menthol cigarettes caused by secondhand smoke exposure, thirdhand smoke exposure, tobacco waste pollution, the disproportionate impact that menthol has had on several populations (e.g., African Americans), evaluation data from several jurisdictions that have implemented prohibitions on menthol, technical achievability, and illicit trade (Ref. 82).

On April 29, 2021, FDA issued its final response to the citizen petition and included in its response a determination that the Special Rule for Cigarettes should be changed to include menthol (Ref. 83). In its response, FDA stated that it interpreted the petition "as a request that the Agency engage in the rulemaking process by proposing a rule to prohibit menthol as a characterizing flavor in cigarettes." FDA granted the request, stating it intends to issue a proposed rule to prohibit menthol as a characterizing flavor in cigarettes (Ref. 83). FDA also stated that it intends to work with HHS to enlist and collaborate with other entities at the Federal, Tribal, State, and local levels who provide support to menthol smokers who quit or want to quit as a result of a prohibition of menthol as a characterizing flavor in cigarettes going into effect (Ref. 83). To reach this decision, the Agency considered, among other things, the petition, the January 2021 supplement filed by the Petitioners that updated the administrative record with research developed since 2013 on the impact of menthol cigarettes, and the comments submitted to the petition docket (Ref. 83).

C. Legal Authority

1. Product Standard Authority Generally

The Tobacco Control Act was enacted on June 22, 2009, amending the FD&C Act and providing FDA with the authority to regulate tobacco products to protect the public health, including reducing tobacco use by youth (Pub. L. 111–31). Section 901 of the FD&C Act (21 U.S.C. 387a) granted FDA the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco as well

as any other tobacco product FDA deemed by regulation.

Among the tobacco product authorities provided to FDA is the authority to revise or adopt tobacco product standards where FDA determines that such standard is appropriate for the protection of the public health (section 907(a)(2) and (3) of the FD&C Act). This includes a tobacco product standard to prohibit the use of menthol as a characterizing flavor. To establish a tobacco product standard, section 907(a)(3)(A) and (B) of the FD&C Act requires that FDA find that the standard is appropriate for the protection of the public health, taking into consideration scientific evidence concerning:

- The risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;
- The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
- The increased or decreased likelihood that those who do not use tobacco products will start using such products.

2. Authority To Prohibit Menthol as a Characterizing Flavor in Cigarettes

The Tobacco Control Act established the Special Rule for Cigarettes that prohibited cigarettes or any of its component parts from containing, as a constituent (including smoke constituent) or additive, an artificial or natural flavor or an herb or spice that is a characterizing flavor of the tobacco product or tobacco smoke (section 907(a)(1)(A) of the FD&C Act). This rule exempted menthol from the prohibition but stated that "nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol" (id.). Further, section 907(a)(2) states that FDA "may revise" the Special Rule in accordance with the rulemaking provisions outlined in section 907 of the FD&C Act.

Section 907 of the FD&C Act authorizes FDA to issue tobacco product standards that are appropriate for the protection of the public health, including provisions that would require the reduction or elimination of a constituent (including a smoke constituent), or harmful component of tobacco products and provisions respecting the construction, components, ingredients, additives, constituents (including smoke constituents), and properties of the tobacco product (section 907(a)(3),

(a)(4)(A)(ii), and (a)(4)(B)(i) of the FD&C Act). This includes the authority to issue a new product standard prohibiting characterizing flavors in tobacco products pursuant to section 907(a)(3) and (4) and to amend or revoke an existing product standard pursuant to section 907(d)(4) of the FD&C Act. Section 907(a)(4)(B)(v) also authorizes FDA to include in a product standard a provision restricting the sale and distribution of a tobacco product to the extent that it may be restricted by a regulation under section 906(d) of the FD&C Act. Similar to section 907(a)(4)(B)(v), section 906(d) of the FD&C Act gives FDA authority to require restrictions on the sale and distribution of tobacco products by regulation if the Agency determines that such regulation would be appropriate for the protection of the public health. Section 701 of the FD&C Act (21 U.S.C. 371) provides FDA with the authority to "promulgate regulations for the efficient enforcement of" the FD&C Act.

Pursuant to section 907(a)(2) and (3) and (c) of the FD&C Act, FDA is proposing this tobacco product standard that would prohibit menthol as a characterizing flavor in cigarettes, because it would reduce the tobacco-related death and disease associated with menthol cigarette use, and FDA has found the standard to be appropriate for the protection of the public health consistent with section 907(a)(3), (a)(4)(A)(ii), and (a)(4)(B)(i). In addition, this proposed rule would prohibit the distribution, sale, and offer for distribution or sale of cigarettes with menthol as a characterizing flavor. This sale and distribution restriction would also assist FDA in enforcing the standard and would ensure that manufacturers, distributors, and retailers are selling product that complies with the standard. For these reasons, the Agency has found such restriction to be appropriate for the protection of the public health consistent with sections 907(a)(4)(B)(v) and 906(d) of the FD&C Act. FDA's analysis showing that the proposed tobacco product standard is appropriate for the protection of the public health is discussed in section V of this document.

D. FDA's Consideration of Health Equity

Advancing health equity is a policy priority and an important component of fulfilling FDA's mission to protect and promote public health. FDA and the Federal Government now recognize the advancement of health equity as "both a moral imperative and pragmatic policy," as E.O. 13995 states.

Considerations related to health equity helped inform FDA's decision to

prioritize this proposed product standard. In particular, FDA took into account the disproportionate toll menthol cigarettes have taken on certain population subgroups. We note that the expected health benefits of this proposed standard are expected to be greater in these subgroups than in the population more generally.

This proposed product standard easily clears the threshold of being appropriate for the protection of the public health, due to the large health benefits from the expected reduced initiation and increased cessation when looking at the population generally. We make this finding even without taking into account the specific expected greater health benefits from this product standard among certain population subgroups.

IV. Menthol Cigarette Use Is Common, Addictive, and Harmful

A. Background

Menthol is a flavor additive widely used in consumer and medicinal products, including cigarettes (Refs. 1 at 782, 84). It is a compound that can be derived from plants or synthetically produced and has a minty taste and cooling properties (Refs. 84 and 2). Menthol is added to cigarettes in a variety of ways (e.g., sprayed on the cut tobacco during blending; placed in a capsule in the filter) and eventually diffuses throughout the cigarette (Refs. 84–86). Menthol may be present in cigarettes not labeled as menthol cigarettes (Refs. 87, 84–85, 88–89).

The first menthol cigarette was marketed in the late 1920s, and the menthol share of the cigarette market has continued to increase since then (Refs. 90–92). Federal Trade Commission (FTC) data on market share of the largest cigarette manufacturers indicate that the menthol cigarette market increased from 16 percent in 1963 to 29 percent in 1979 (Ref. 92). From 1980 to 2009, it remained relatively constant ranging from 25 to 29 percent (Ref. 92) and, from 2010 to 2019, it increased from 31 to 37 percent (Ref. 92). Market trend research evaluating mass retail and convenience store cigarette sales indicates that, from 2011–2015, 31.5 percent of the cigarette market was menthol (Ref. 93). Estimates of cigarette consumption from 2000 to 2018 in the United States show an overall decline of 46 percent in cigarette consumption (435.6 to 235.6 billion), but the decline was greater among non-menthol (52.9 percent; 322.8 billion to 152.0 billion cigarettes) than menthol cigarettes (26.1 percent; 112.8 billion to 83.3 billion cigarettes) (Ref. 94).

B. Menthol Smoking Is Widespread and Disproportionately Impacts Youth, Young Adults, and Other Vulnerable Populations in the United States

In 2019, there were more than 18.5 million current smokers of menthol cigarettes ages 12 and older in the United States (Ref. 44). Although menthol cigarette smoking is widespread in the United States, menthol cigarettes are used at a particularly high rate among youth, young adults, and other vulnerable populations such as African Americans and other racial and ethnic groups (Ref. 44).

In 2019, researchers estimated that approximately 1.15 million U.S. middle and high school students had smoked a cigarette in the prior month based on data from the NYTS, a nationally representative survey (Ref. 95). Of these youth smokers, 46.7 percent reported smoking a menthol cigarette in the prior month, representing an estimated 530,000 youths (Ref. 95). Additionally, data from the 2019 NSDUH estimates that nearly 5.7 million U.S. young adults aged 18–25 years were current smokers, of which 51 percent (2.96 million young adults) smoked menthol cigarettes (Refs. 96 and 44). Using the same 2019 NSDUH data, an additional 39.4 million older adults (aged 26 and older) were current cigarette smokers, of which, 39 percent were current menthol smokers (15.4 million older adults) (Refs. 96 and 44).

The disproportionate use of menthol cigarettes by youth and young adult smokers compared to older adults has been consistent over time and across multiple studies with nationally representative populations. A study that examined changes in menthol smoking prevalence among cigarette smokers using NSDUH data from 2004 to 2014 found that the prevalence of past-month menthol smoking between 2008–2010 and 2012–2014 was highest among youth smokers aged 12–17 years (52.5 percent to 53.9 percent), followed by young adult smokers aged 18–25 years (43.6 percent to 50 percent), adult smokers aged 26–34 (34.6 percent to 43.9 percent), adult smokers aged 35–49 (30.3 percent to 32.3 percent), and adult smokers aged 50 and older (30.6 percent to 32.9 percent) (Ref. 57). In 2019 NSDUH data, past-month menthol use among cigarette smokers was highest among young adults aged 18–25 years (51 percent), followed by youth aged 12–17 years (48.6 percent) and older adults aged 26 and older (39 percent) (Ref. 44). Results from a study of Wave 2 data from the PATH Study (2014–2015) support these data and indicate

age-related differences in past-month menthol cigarette smoking, with a higher proportion of youth aged 12–17 years (46.6 percent) and young adult aged 18–24 years (50 percent) cigarette smokers being menthol smokers compared to older adults aged 25 and older (34.4 percent) (Ref. 97). While data on trends of cigarette smoking from NYTS show a decline in overall cigarette smoking and in menthol cigarette smoking among middle and high school student smokers from 2011 to 2018, nearly half reported smoking menthol cigarettes in 2018 (Ref. 56).

African American smokers, regardless of age, are disproportionately more likely to smoke menthol cigarettes than smokers of any other race (Refs. 55–56, 21–24, 57–59, 44), and are also more likely than other racial and ethnic groups to try a menthol cigarette as their first cigarette, regardless of age (Refs. 33, 25, and 31).

Findings from 2018 NYTS data show that, among middle and high school students who were current cigarette smokers, 51.4 percent of non-Hispanic Black youth and 50.6 percent of Hispanic youth reported smoking menthol cigarettes, compared to 42.8 percent of non-Hispanic White youth (Ref. 56). Statistically significant differences in this proportion by race and ethnicity have been observed in the NYTS over the 2011–2018 period. While declines in menthol cigarette use from 2011–2018 have been observed among non-Hispanic White youth, declines were not observed among non-Hispanic Black youth or Hispanic youth (Ref. 56). Similarly, among all adults, data from the National Health Interview Survey (NHIS) indicate that cigarette smoking decreased from 20.9 percent in 2005 to 15.1 percent in 2015 (Ref. 70). While there was a significant decrease in the prevalence of menthol cigarette smoking overall (5.3 percent in 2005 to 4.4 percent in 2015), the prevalence of menthol cigarette smoking did not decrease among male smokers, adult smokers aged 25–34, adult smokers aged 55 and older, non-Hispanic Asian smokers, Hispanic smokers, or smokers who had less than a high school education (Ref. 70). Additionally, this study highlights that while the prevalence of all cigarette smoking and menthol smoking, specifically, have decreased over time (2005–2015), the prevalence of menthol smoking in 2015 remained highest among specific groups, such as non-Hispanic Blacks (11.9 percent) (Ref. 70).

A systematic literature review of menthol smoking by gender found that female smokers are more likely to smoke menthol cigarettes compared to men

(Ref. 98). Additionally, in another study of trends in menthol smoking from 2004 to 2014, the NSDUH data showed that women are significantly more likely to smoke menthol cigarettes than men (Ref. 57). This is consistent with data from the 2019 NSDUH, which indicated that a higher proportion and number of female cigarette smokers smoked menthol (44.8 percent; 9.49 million) than male cigarette smokers (37.1 percent; 9.10 million) (Ref. 44). High levels of menthol cigarette smoking have also been reported in pregnant smokers. An analysis of 2006 to 2015 participant data from two racially and ethnically diverse cohorts of pregnant smokers with lower educational attainment and lower household income indicated high prevalence of menthol use in both cohorts (85 percent and 87 percent) (Ref. 71).

Study findings indicate that individuals who identify as lesbian, gay, or bisexual are more likely to report smoking menthol cigarettes compared to those who identify as heterosexual, as well as other disparities related to gender identity or sexual orientation.^{9 10} A study examining menthol use by LGBT status found a higher prevalence and a higher likelihood of smoking menthol cigarettes among LGBT smokers compared to heterosexual smokers, and that these differences in use were even greater among LGBT female respondents compared to heterosexual women (Ref. 69). In national data from the 2019 NSDUH, only 6.9 percent of those identifying as straight or heterosexual reported smoking menthol (15.95 million) compared to 14 percent of those identifying as lesbian, gay, or bisexual (2.04 million) (Ref. 44). An analysis of pooled data from the 2015–2019 NSDUH indicate that compared to heterosexual/straight respondents, respondents who identified as gay males, lesbian/gay females, or bisexual females reported higher prevalence of past 30-day smoking (Ref. 99). Additionally, compared to heterosexual/straight respondents, gay males, and bisexual males, findings indicated that lesbian/gay females and bisexual females had higher menthol preference (defined as past 30-day use of menthol

cigarettes among those who smoked cigarettes in the past 30-days) (Ref. 99).

Study findings show social gradient effects (where higher levels of indicators such as household income are linked to better health outcomes and lower levels are linked to poorer health outcomes) for menthol cigarette use (Refs. 44, 57, and 59). In 2019 NSDUH data, the prevalence of menthol smoking was 13.5 percent among those with a total family income less than \$20,000, 8.4 percent between \$20,000 and \$49,999, 6 percent between \$50,000 and \$74,999, and 3.6 percent above \$75,000 (Ref. 44). In another study of 2012–2014 NSDUH data, among past 30-day smokers, 43.7 percent of smokers with household income less than \$30,000 smoked menthol cigarettes compared to 32.1 percent of smokers with household incomes greater than \$75,000 (Ref. 57). Additionally, a study using 2018 NSDUH data found that menthol preference among cigarette smokers was 46.8 percent among those living in poverty,¹¹ 42.3 percent among those with income up to two times above the Federal Poverty Threshold, and 35.8 percent among those with income more than two times above the Federal Poverty Threshold (Ref. 59).

Menthol cigarette use is also higher among adults with behavioral health conditions or illness (Refs. 44, 100, 68, 59, 101). In 2019 NSDUH data, 17.4 percent of adults age 18 and older who reported past-month serious psychological stress reported past-month menthol smoking compared to only 6.6 percent of those who did not report past month serious psychological distress (Ref. 44). An analysis of young adults (aged 18–30 years) with a serious mental illness who were receiving treatment for smoking cessation, more than half (58 percent) smoked menthol cigarettes (Ref. 101). In national data, a study utilizing 2008/2009 NSDUH data also found that cigarette smokers with mental health symptoms were

significantly more likely to smoke menthol cigarettes than smokers who report mild or no mental health symptoms (Ref. 68). Another national study of women aged 18–34 years indicated that menthol smokers had higher odds of reporting anxiety or depression compared to non-menthol smokers (Ref. 100). Lastly, an analysis of young adults (aged 18–30 years) receiving treatment for smoking cessation also found that of those with severe mental illness, more than half (58 percent) smoked menthol cigarettes (Ref. 101).

C. Menthol in Cigarettes Increases Smoking Initiation, Increases Progression to Regular Use, and Contributes to Nicotine Dependence

1. Menthol's Flavor and Sensory Properties Make Cigarette Smoking Easier and the Initial Response to Cigarettes More Palatable

Menthol is a flavor compound that is added to cigarettes, which produces a minty taste and cooling sensation when inhaled (Ref. 2). As a result of its sensory properties, menthol can reduce irritation (Refs. 102 and 103), reduce coughing (Refs. 104 and 105), and relieve pain (Ref. 106). For this reason, compared to non-menthol cigarettes, menthol smokers perceive menthol cigarettes as easier to smoke, less irritating, smoother and more refreshing, and having a better taste (Refs. 4–5, 107–108). Such flavor and sensory effects of menthol reduce the harshness of cigarette smoking among new users, facilitating experimentation and regular use, particularly among younger smokers (Refs. 6, 7, and 5).

An individual initiates smoking upon first trying a cigarette, even if they take just one or two puffs (Ref. 32). The vast majority of smoking initiation occurs during adolescence (Ref. 32). Initiation can progress to repeated experimentation, where individuals continue to occasionally try cigarettes, but do not smoke every day, and then to smoking regularly (Ref. 32). When an individual first tries a menthol cigarette, the flavor and sensory effects of menthol make initial smoking experiences more palatable. This makes it easier for new users, particularly youth and young adults, to continue experimenting with smoking and progress to regular use. The 2019 NSDUH found that each day, approximately 1,500 youth (under the age of 18 years) and 2,600 young adults (aged 18–25 years) first smoke a cigarette (Ref. 96). Results from Waves 1–4 of the PATH Study (2013–2017) and the Truth Initiative Young Adult Cohort Study show that youth (aged 12–17

⁹ Throughout the preamble of this proposed rule, FDA uses the terminology cited in the scientific studies.

¹⁰ The relevant scientific studies cited herein do not provide data separated by sexual orientation and gender identity. Due to these study limitations, we discuss sexual orientation and gender identity in a combined manner, despite their important distinctions.

¹¹ “Living in poverty” was determined and recoded in the NSDUH public use file based on a person’s family income relative to poverty thresholds. The full definition of this variable can be found in the 2019 NSDUH codebook at: <https://www.datafiles.samhsa.gov/sites/default/files/field-uploads-protected/studies/NSDUH-2019/NSDUH-2019-datasets/NSDUH-2019-DS0001/NSDUH-2019-DS0001-info/NSDUH-2019-DS0001-info-codebook.pdf>. The U.S. Census Bureau assigns a poverty threshold for each combination of family size and number of children in the household. To be at 100 percent of the poverty threshold is equivalent to having a family income that is the same as the poverty threshold. A poverty level less than 100 percent indicates having a family income less than the poverty threshold and therefore defined by the Federal Government as living in poverty. A poverty level greater than 100 percent indicates having a family income greater than the poverty threshold.

years) and young adults (aged 18–24 years) are more likely to try a menthol cigarette as their first cigarette than a non-menthol cigarette (Refs. 8, 31, and 33). A separate cross-sectional analysis of Wave 1 PATH Study data (2013–2014) also found that among ever cigarette smokers (*i.e.*, those who reported ever trying a cigarette, even one or two puffs), nearly 43 percent of youth (aged 12–17 years) and 45 percent of young adults (aged 18–24 years) reported that the first cigarette they smoked was mentholated, compared to 30 percent of adults (aged 25 years and older) (Ref. 109).

Consistent with the evidence that menthol makes cigarettes easier to use and reinforces tobacco use among new users, results from Wave 2 of the PATH Study (2014–2015) indicate that youth (aged 12–17 years) and young adults (aged 18–24 years) who initiate smoking with menthol cigarettes are more likely to report having a pleasant first smoking experience compared to smokers who initiate with non-menthol cigarettes (Ref. 110). Smokers in the study who reported a pleasant first smoking experience were more likely to smoke regularly (Ref. 110). In another study, young adult smokers (aged 18–24 years) reported that the taste of menthol (*e.g.*, “minty”, “cool”, “refreshing”) made cigarettes “less harsh” and “easier to inhale” than non-menthol cigarettes, and these factors influenced their initial preference for menthol cigarettes (Ref. 5). A study evaluating the sensory experiences of first cigarette use among young adult and adult smokers (aged 18–34 years) also found that fewer menthol smokers reported experiencing nausea during their first smoking experience compared to non-menthol smokers (Ref. 33). Regular menthol smokers also cite the flavor and sensory factors as primary reasons for continuing to smoke menthol cigarettes (Refs. 4, 5, and 111).

Evidence from tobacco industry documents indicates that the industry has been adding menthol to cigarettes because of perceptions among new users that menthol cigarettes are less harsh and easier to smoke (Ref. 7). These documents indicate that menthol has traditionally been added to cigarettes as a design feature to attract new youth and young adult smokers (Refs. 7 and 6). For example, a 1987 document from one company states: “Menthol brands have been said to be good starter products because new smokers appear to know that menthol covers up some of the tobacco taste and they already know what menthol tastes like, *vis-à-vis* candy” (Ref. 112). Additionally, a 1978 document about a traditionally menthol-

only cigarette brand states that the brand is “being purchased by Black people (all ages), young adults (usually college age), but the base of our business is the high school student” (Ref. 113). Menthol cigarettes continue to be used disproportionately by youth and new smokers (Ref. 44).

These findings support that menthol’s flavor and sensory effects make cigarettes easier to smoke by masking the harshness and irritation of tobacco and reducing unpleasant smoking experiences that can deter new users from repeated experimentation.

2. Menthol Enhances Nicotine Addiction in the Brain

Menthol enhances the effects of nicotine in the brain by affecting mechanisms involved in nicotine addiction. Nicotine is the primary chemical in tobacco products that causes addiction through its psychoactive and reinforcing effects (Ref. 114). Nicotine addiction occurs as the result of repeated exposure to nicotine, which induces changes in the brain (Refs. 115, 9, and 116). Addiction to nicotine can lead to symptoms of nicotine dependence, which may include tolerance to the effects of nicotine, withdrawal symptoms upon cessation of use, and craving cigarettes (Refs. 9 and 1).

Upon inhaling smoke from a burning cigarette, nicotine is absorbed into the lungs and rapidly travels to the brain. Once in the brain, nicotine produces its initial effects by binding to nicotinic receptors, the primary targets for nicotine in the brain, and inducing release of the chemical dopamine (Refs. 115 and 9). Dopamine plays a major role in the pleasurable and reinforcing effects of smoking that promote continued use (Refs. 115 and 9). After repeated exposure to nicotine, nicotinic receptors become less responsive, prompting an increase in the number of brain nicotinic receptors; this process has been implicated in the development of nicotine addiction (Ref. 9).

A clinical study that analyzed brain images of adult non-smokers, menthol smokers, and non-menthol smokers found that menthol cigarette smokers have higher levels of brain nicotinic receptors than non-menthol smokers (Ref. 14). Studies in rodents have been used to provide insight into a mechanism for how menthol produces this effect in the brains of smokers. The nicotinic receptor composition, distribution, and function in the rodent brain is comparable to that of humans, and rodents can be trained to perform a variety of behavioral tasks (Refs. 117–119). Therefore, rodents serve as an

appropriate model to examine the behavioral effects of nicotine and the effects of nicotine in the brain.

Studies demonstrate that menthol, like nicotine, binds to nicotinic receptors in the brain (Refs. 15 and 16), and menthol alone can increase the number of nicotinic receptors in the brain (Refs. 10 and 11). Consistent with clinical findings in menthol smokers (Ref. 14), animal studies also demonstrate that menthol in combination with nicotine increases the number of nicotinic receptors in the brain to a greater extent than nicotine alone (Refs. 10–12). This effect in the brain was accompanied by greater intensity of nicotine withdrawal signs in rodents treated with nicotine and menthol compared to those treated with nicotine alone (Ref. 10). Menthol also enhances nicotine’s effects on dopamine in the rodent brain. Animal studies demonstrate that nicotine-induced dopamine release is greater in the presence of menthol (Ref. 13). Additionally, menthol enhances nicotine-induced increases in dopamine cell activity to a greater extent than nicotine alone; these changes were associated with differences in behavioral responses to the rewarding effects of nicotine, where menthol-treated rodents exhibited greater reward for nicotine than those treated with nicotine alone (Ref. 12). These findings demonstrate that menthol’s effects on nicotine in the brain are associated with behaviors indicative of greater addiction to nicotine.

In combination with menthol’s flavor and sensory effects, menthol’s interaction with nicotine in the brain plays a role in making it easier to experiment, progress to regular smoking and dependence, and harder to quit smoking.

3. The Adolescent Brain Is Particularly Vulnerable to the Effects of Nicotine

Youth and young adults are particularly susceptible to becoming addicted to nicotine. Due to its ongoing development, the adolescent brain, which continues to develop until about age 25, is more vulnerable to nicotine’s effects than the adult brain (Refs. 17–19). The 1994, 2012, 2014, and 2020 Surgeon General’s Reports on smoking and health note that almost 90 percent of current adult regular smokers initiated smoking before age 18, and 99 percent initiated smoking before the age of 25, which is the approximate age at which the brain has completed development (Refs. 120, 32, 1, 245). Though age ranges for youth and young adults vary across studies, in general, “youth” or “adolescent” encompasses

those 11–17 years of age, while those who are 18–25 years old are considered “young adults” (even though, developmentally, the period between 18–20 years of age is often labeled late adolescence); those 26 years of age or older are considered “adults” (Ref. 32).

Studies in adolescent and adult rodents show that adolescents are more sensitive to the rewarding and reinforcing effects of nicotine than adults (Refs. 121–124). In particular, animal studies highlight that early adolescence is a critical period for vulnerability to nicotine addiction (Refs. 125–127). Studies have also found that nicotine exposure during adolescence induces changes in the brain that either do not occur in animals exposed to nicotine in adulthood or are observed to a lesser extent following adult nicotine exposure. For example, studies using adolescent and adult rodents show that nicotine exposure during adolescence induces changes in gene expression, changes in brain structure and activity, and greater, more widespread increases in brain nicotinic receptor expression compared to exposure in adulthood (Refs. 128–131). These effects of nicotine on the developing brain largely occur in brain regions involved in addiction, learning, and memory (Refs. 132–133, 129, 131). Rodent studies also support that many of these changes remain after nicotine exposure has ended, and persist into adulthood (Refs. 133, 132, 130, 17–18).

Studies among youth support the findings from animal studies and show that adolescence is a vulnerable period for nicotine addiction. Youth who initiate tobacco use at earlier ages are more likely than those initiating at older ages to report current daily smoking and symptoms of tobacco dependence (Refs. 134–136). Researchers in a 4-year study of sixth grade students found that the most susceptible youth lose autonomy (*i.e.*, independence in their actions) regarding tobacco within 1 or 2 days of first inhaling from a cigarette (Ref. 137). The study also found that “[e]ach of the nicotine withdrawal symptoms appeared in some subjects *prior* to daily smoking” (Ref. 137) (emphasis added). Ten percent of youth showed signs of dependence to tobacco use within 1 or 2 days of first inhaling from a cigarette, and half had done so by the time they were smoking seven cigarettes per month (Ref. 137). Another study that followed 12–13 year old adolescents over 6 years found that 19.4 percent of adolescents who smoked weekly were nicotine dependent (Ref. 138). In a study of nicotine dependence among recent onset adolescent smokers (9th and 10th grade students), individuals

who smoked cigarettes only 1 to 3 days of the past 30 days experienced nicotine dependence symptoms such as loss of control over smoking and irritability after not smoking for a while (Ref. 139). Overall, these findings demonstrate that, due to ongoing brain development, youth and young adults who experiment with smoking are at greater risk of becoming addicted to nicotine and maintaining tobacco product use into adulthood (Refs. 17, 18, and 32). Therefore, due to the combined effects of nicotine and menthol in the developing brain, youth who smoke menthol cigarettes are particularly vulnerable to the effects of menthol on progression to regular use and dependence.

4. Menthol Facilitates Experimentation and Progression to Regular Cigarette Use Among Youth and Young Adults

Consistent with the impact of menthol in cigarettes on smoking ease and nicotine addiction, menthol cigarettes have been shown to facilitate progression to regular use in new smokers, particularly in youth and young adults. A longitudinal study that evaluated smoking behaviors in middle and high school students over the course of 3 years (2000–2003) found that youth who initiate smoking with menthol cigarettes are more likely to progress to regular cigarette smoking compared to youth who initiate smoking with non-menthol cigarettes (Ref. 25). These findings are supported by nationally representative data from the Evaluation of Public Education Campaign on Teen Tobacco longitudinal national youth survey, which examined youth over 3 years (2013–2016) (Ref. 30). Youth in the study who reported experimenting with menthol cigarettes in a prior year were more likely to report progressing to regular smoking than youth who smoked non-menthol cigarettes (Ref. 30). Additionally, data from the 2011 National Young Adult Health Survey (NYAHS) found that young adult (aged 18–34 years) current menthol smokers had double the odds of reporting an increase in cigarette smoking over the previous year compared to non-menthol smokers (Ref. 29).

Similarly, longitudinal data from Waves 1 and 2 of the PATH Study (2013–2015) were used to evaluate the association of flavored tobacco use with product initiation among youth (aged 12–17 years), young adults (aged 18–24 years), and older adults (aged 25 and older) over a 10–13 month timeframe (Ref. 31). The study found that among all age groups, those that first used a menthol cigarette were more likely to

report any past 12-month or past 30-day smoking at followup compared to those who reported a non-menthol cigarette as the first cigarette smoked (Ref. 31). Further, among those in all age groups, those whose first cigarette was menthol were more likely to report smoking every day in the past 30 days at followup compared to smokers who initiated with non-menthol cigarettes (Ref. 31). Expanding on these findings, longitudinal data across Waves 1–4 of PATH data (2013–2017) showed that among young adults, those who smoked menthol as the first cigarette were more likely to report continued smoking over the past 12 months compared to smokers who initiated with non-menthol cigarettes (Ref. 8).

Overall, the evidence supports that menthol facilitates repeated experimentation and progression to regular smoking among youth and young adults. This finding is consistent across different populations and time periods, including in studies that assess large, nationally representative populations.

5. Menthol Contributes to Nicotine Dependence in Young People

Data from multiple studies across different populations and time periods demonstrate that menthol cigarettes contribute to greater nicotine dependence in youth (Refs. 20–28). One longitudinal study evaluated middle and high school students over 3 years (2000–2003) in 83 schools in 7 communities across 5 states. Data from the study show that youth who initiated smoking with menthol cigarettes scored higher on a scale of dependence than youth who initiated with non-menthol cigarettes (Ref. 25). Nationally representative data from the 2000 and 2002 NYTS found that youth who smoked menthol cigarettes on at least 1 day in the past month reported higher scores on a scale of nicotine dependence compared to non-menthol smokers (Ref. 21). In addition, studies using 2004 and 2006 NYTS data found that, compared to youth non-menthol smokers, youth menthol smokers report multiple indicators of nicotine dependence, including higher levels of craving for cigarettes, needing a cigarette within one hour after smoking, and increased feelings of restlessness and irritability without smoking (Refs. 22 and 24). Pooled NYTS analyses (2017–2020) also indicate that youth menthol smokers have greater odds of experiencing tobacco cravings and using tobacco within 30 minutes of waking than non-menthol smokers (Ref. 28). Similarly, results from Wave 2 PATH Study data (2014–2015) show that youth menthol

smokers report higher levels of craving, tolerance to the effects of nicotine, and affiliative attachment (feeling “alone” without cigarettes), indicating that youth menthol smokers are more physically dependent on nicotine and experience greater emotional attachment to cigarettes than youth non-menthol smokers (Ref. 26).

Studies also demonstrate that youth menthol smokers smoke more frequently than non-menthol smokers, indicating an increased risk of being more nicotine dependent than non-menthol smokers. Youth who smoke more frequently display greater symptoms of nicotine dependence (Ref. 138). Compared to smokers of “other brands” (at the time of the study “other brands” may have included non-menthol flavored and unflavored cigarettes), youth menthol smokers have reported greater levels of smoking, including having smoked more total cigarettes, smoking on more days and more cigarettes in a month, having smoked more recently, and having ever smoked daily (Ref. 23). Nationally representative data also indicate that higher proportions of youth menthol smokers report smoking more frequently compared to non-menthol smokers (Refs. 56, 27, and 28). In analyses of pooled 2016–2018 NYTS data, higher proportions of youth menthol smokers reported smoking on more days during the month, smoking more cigarettes per day, and smoking 100 or more cigarettes in their lifetime compared to non-menthol smokers (Ref. 56). These findings are supported by 2017–2020 NYTS data, which show that youth menthol smokers have greater odds of smoking 10–30 days out of the month compared to non-menthol smokers (Refs. 27 and 28). Furthermore, 2017 and 2018 NYTS data indicate that, compared to youth non-menthol smokers, youth menthol smokers are more likely to report intentions to continue smoking cigarettes in the following year (Ref. 27).

Some studies have not found a significant difference in dependence outcomes between youth menthol and non-menthol smokers. One study, using data from the Development and Assessment of Nicotine Dependence in Youths study, examined the relationship between the first smoking experience and the development of nicotine dependence symptoms in youth and did not find a difference in dependence level between menthol and non-menthol smokers (Ref. 140). A study that used PATH data to examine the association between first use of menthol cigarettes and nicotine dependence scores at a subsequent

wave, also did not find a relationship between menthol cigarette use and dependence among youth (Ref. 8). Furthermore, a nationally representative study that evaluated associations between menthol use and dependence among youth (aged 15–19 years) in the 2003 and 2006–2007 Tobacco Use Supplement to the Current Population Survey (TUS–CPS) and youth (aged 12–19 years) in the 1999–2010 National Health and Nutrition Examination Survey (NHANES) did not find an association between menthol smoking and level of dependence (Ref. 141).

Studies that found no effect of menthol on dependence in youth constitute a smaller number of studies in the totality of evidence. The few studies (discussed in the previous paragraph) that did not find an effect of menthol in cigarettes on greater dependence in youth were either not nationally representative or had other limitations that reduced the generalizability or influenced the validity of the findings. These study limitations include small samples sizes, which may reduce ability to detect significant between-group differences; failure to report sample sizes for populations assessed; and survey data that included participants beyond the typical age range for youth studies (age 12–17 years), which reduces generalizability of the findings to youth.

Based on the number and strength of the studies that support the conclusion that menthol is associated with greater dependence among youth and the limitations of the evidence that did not find an effect of menthol on youth dependence, the totality of evidence supports that menthol in cigarettes contributes to greater dependence among youth. This conclusion is supported by multiple nationally representative studies that were designed to collect and evaluate survey data on tobacco use in youth populations.

D. Menthol in Cigarettes Makes Quitting Smoking More Difficult

1. Menthol Contributes to Reduced Cessation Success, Particularly Among Black Smokers

A number of nationally representative studies among young adult and adult smokers show that menthol in cigarettes contributes to reduced cessation success (Refs. 34–35, 42, 36–38, 40, 43). A study from the 2003 and 2006–2007 TUS–CPS examined quit attempts and quit rates in menthol and non-menthol smokers (Ref. 37). Overall, quit attempts were 8.8 percent higher among menthol smokers compared to non-menthol smokers, but

menthol smokers had 3.5 percent lower rates of quitting within the past year and 6 percent lower rates of quitting within the past 5 years compared to non-menthol smokers (Ref. 37). Young adults (aged 18–24 years) who smoked menthol cigarettes made more quit attempts than menthol smokers of older adult age groups (aged 25 and older) and had higher rates of quitting for 3 months to 1 year than non-menthol smokers; however, when evaluating longer term quitting (*i.e.*, within the past 5 years) young adult menthol smokers were less likely to have successfully quit smoking than non-menthol smokers (Ref. 37). Taken together, these findings suggest that short-term quitting does not translate to long-term success in quitting among young adult menthol smokers. Other studies that used 2003 and 2006–2007 TUS–CPS data examined the role of menthol in cessation and found that, compared to non-menthol smokers, menthol smokers were less likely to have successfully quit smoking for at least 6 months (Ref. 42) and were less likely to report having quit smoking in the past 5 years (Ref. 36). Data from the 2010–2011 TUS–CPS also found that menthol smokers were less likely than non-menthol smokers to report having abstained from smoking for 1–3 years (Ref. 38).

Additionally, longitudinal studies demonstrate that menthol smokers have more difficulty quitting compared to non-menthol smokers. One PATH Study using data from Waves 1–4 (2013–2017) found that, after 12 months, quit rates were significantly lower among daily menthol smokers (4 percent) compared to daily non-menthol smokers (5.3 percent) after adjusting for age, sex, race and ethnicity, education, nicotine dependence, and past quit attempts (Ref. 40). Daily menthol smokers also had 24 percent lower odds of quitting smoking compared to non-menthol smokers (Ref. 40). Another PATH Study using data from Waves 1–4 (2013–2017) evaluated short-term (30-day) and long-term (12-month) smoking abstinence among menthol and non-menthol smokers who had attempted to quit smoking in the past 12 months (Ref. 43). Menthol smoking decreased the probability of 30-day smoking abstinence by 28 percent and the probability of 12 month smoking abstinence by 53 percent compared to smoking non-menthol cigarettes after adjusting for race, sex, age and frequency of smoking (Ref. 43). The Coronary Artery Risk Development in Young Adults (CARDIA) study, which evaluated smoking cessation behavior in young adult smokers (age 18–30 years)

across 15 years (1985–2000), also found that menthol smokers were more likely to report continued smoking at two consecutive followups and were almost twice as likely to have relapsed compared to non-menthol smokers (Ref. 142).

Short- and long-term clinical longitudinal studies of cessation also show that menthol smokers are less likely than non-menthol smokers to achieve cessation success (Refs. 143–147). A short-term cessation study found that menthol smokers were more likely than non-menthol smokers to relapse within 48 hours of quitting smoking (Ref. 147). A long-term cessation study evaluated the effectiveness of smoking cessation therapies and tested smokers for cessation success at several timepoints throughout the study (Ref. 146). Menthol smoking was associated with reduced likelihood of successful quitting at the 4-week, 8-week, and 26-week followup assessments (Ref. 146). These findings are supported by data from studies of smokers interested in quitting smoking, which show that menthol smokers are less likely to achieve cessation success than non-menthol smokers at study followups ranging from 3 weeks to 6 months (Refs. 148, 143–145).

Evidence from nationally representative studies show that the effect of menthol on reduced cessation success is particularly evident among Black smokers (Refs. 34–38, 40). Data from the 2005 NHIS Cancer Control Supplement were used to examine racial and ethnic differences in menthol cigarette smoking and found that African American menthol smokers had a significantly decreased likelihood of quitting smoking compared to African American and White non-menthol smokers (Ref. 35). Data from the 2005 and 2010 NHIS were also used to evaluate the association between menthol cigarette smoking and likelihood of being a former smoker (Ref. 38). Black menthol smokers were less likely than Black non-menthol smokers to report not having smoked in the past year (Ref. 38). Additional analyses of 2005 NHIS and 2003 and 2006–2007 TUS–CPS data found that, compared to Black non-menthol smokers, Black menthol smokers were less likely to report smoking “not at all” at the time of the survey and less likely to report having quit smoking in the past 5 years (Refs. 34 and 36).

Longitudinal studies using Waves 1–4 PATH data (2013–2017) and data from the CARDIA Study also demonstrate that African American menthol smokers have more difficulty quitting compared

to African American non-menthol smokers. These studies evaluated the effect of menthol on cessation at multiple timepoints in the same population of smokers. A recent study using nationally representative PATH data found that, after 12 months, quit rates were significantly lower among African American daily menthol smokers (3 percent) compared to African American daily non-menthol smokers (6.2 percent) (Ref. 40). Among Black daily smokers, menthol smokers also had 53 percent lower odds of quitting smoking compared to non-menthol smokers after controlling for age, sex, education, nicotine dependence, and past quit attempts (Ref. 40). Additionally, the CARDIA study measured smoking cessation behaviors in young adult (aged 18–30 years) menthol and non-menthol smokers from four U.S. cities over 15 years (1985–2000) (Ref. 142). After adjusting for health insurance status and other factors, the study found that African American menthol smokers were less likely to report having sustained cessation at two consecutive followups than African American non-menthol smokers (Ref. 142). Among African Americans, menthol smokers were also more likely to have relapsed back to smoking (Ref. 142).

Clinical longitudinal studies have also evaluated short- and long-term cessation success in current smokers and smokers seeking treatment to quit. These studies show that among African Americans, menthol smokers are less likely than non-menthol smokers to remain abstinent from smoking (Refs. 149–152, 146). A cessation study in African American smokers determined that the smokers who had quit by the end of the 7-week study treatment were more likely to smoke non-menthol cigarettes, compared to menthol cigarettes (Ref. 152). Furthermore, a long-term cessation study found that, among African American smokers, menthol smokers were significantly less likely to have quit at the 6-month followup assessment (Ref. 151). Another clinical study in African American smokers found that menthol smokers were less likely to have quit smoking at the 6-month followup than non-menthol smokers (Ref. 150). Data from the 2003 and 2006–2007 TUS–CPS also found that African American menthol smokers made more quit attempts and had higher rates of quitting for 3 months to 1 year than smokers of other racial and ethnic groups; however, when evaluating quitting in the past 5 years, quit success was lower among African American

menthol smokers compared to other racial/ethnic groups (Ref. 37).

Taken together, these findings suggest that short term quitting does not translate to long term success in quitting among African American menthol smokers. Furthermore, studies using 2006–2007 and 2010–2011 TUS–CPS data show that African American menthol smokers are more likely to make a quit attempt than African American non-menthol smokers, but these attempts do not necessarily translate into successful cessation (Refs. 153 and 154). Additionally, a community-based survey of African American adults in Minnesota aimed to understand African Americans’ perceptions of menthol cigarettes and reasons for unsuccessful quit attempts among menthol smokers (Ref. 155). Menthol smokers in the study were more likely than non-menthol smokers to perceive menthol as harder to quit. Forty-five percent of menthol smokers who reported a failed quit attempt reported craving as the reason for the unsuccessful attempt (Ref. 155).

Some studies do not show that menthol smokers have more difficulty quitting than non-menthol smokers (Refs. 156–159, 67, 160, 64, 29, 161–163). For example, data from the 2003 and 2006–2007 TUS–CPS that evaluated smoking abstinence at 2 weeks did not find a difference in cessation success between menthol and non-menthol smokers (Ref. 64). Data from the nationally representative 2011 NYAHS study of young adults (aged 18–34 years) who self-reported past year smoking behaviors also did not find significant differences in the proportion of menthol and non-menthol smokers who reported quitting (Ref. 29). Among longitudinal studies, some studies have reported no difference in quit rates or odds of quitting between menthol and non-menthol smokers at 6-month, 7-month, 12-month, and 5-year followup assessments based on individual self-report (Refs. 159, 158, 156, 163). In another longitudinal study, researchers analyzed data from a randomized controlled trial of smoking cessation that tested breath carbon monoxide to confirm self-reported smoking status at an 8-week follow-up assessment (Ref. 161). The study found no difference in smoking abstinence rates between menthol and non-menthol smokers (Ref. 161).

Two meta-analyses of the literature that combined the results of multiple menthol and cessation studies, as well as one systemic literature review, all found statistically significant reductions in the likelihood of cessation among African American menthol smokers, and

two of the three found reductions for cessation in the general population (Refs. 39, 41, and 164). These studies highlight the large amount of variability across the different studies in this body of literature. For example, across menthol and cessation studies, populations varied by sociodemographic factors such as race or ethnicity, gender, and geographic region; studies ranged from large nationally representative samples to small clinical trials of cessation; studies varied by the followup timepoints at which they assessed cessation, ranging from 48 hours to 15 years; studies did not use the same methods or definitions to measure cessation; and studies did not control for the same factors that may influence cessation outcomes (e.g., demographics, nicotine dependence, use behaviors). This variability may in part explain the inconsistencies across study findings related to menthol and cessation.

Of studies that evaluated menthol in populations of current and former smokers, studies which found that menthol smokers have more difficulty quitting were more likely to be longitudinal, allowing for assessments of cessation across multiple time points among the same individuals, and generally had longer followup periods than studies that found no effect of menthol on cessation success. Several studies which found that menthol reduces cessation success also confirmed whether menthol smokers had quit at followup assessments by testing for indicators of cigarette smoking in saliva and/or through breath carbon monoxide, in addition to individual self-report. An individual's self-report of quitting may not always be accurate (e.g., individuals may not remember correctly or may not be truthful in responding); therefore, studies that also test for indicators of cigarette smoking through biochemical verification, such as levels of carbon monoxide in breath and/or nicotine metabolites in blood, urine, or saliva, provide strong evidence to validate individual responses (Ref. 165). Furthermore, the meta-analyses of the cessation literature only included studies published through 2017 (Refs. 39 and 41). Two recent studies using data from the nationally representative, longitudinal PATH Study, are thus not included in these meta-analyses; both PATH studies suggest that menthol smoking is associated with reduced smoking cessation across multiple years of data (Refs. 40 and 43). Therefore, despite some contrary findings, the studies that utilized designs that

allowed for long-term assessments of menthol and cessation success and that used multiple methods to confirm smoking status at followups were more likely to find an effect of menthol on reduced cessation success in the general population.

2. Menthol's Interaction With Nicotine in the Brain Makes it Harder To Quit Smoking

Addiction to nicotine makes it difficult to quit smoking (Ref. 1). As discussed in section IV.C.2, repeated exposure to nicotine through smoking leads to an increase in nicotinic receptor levels in the brains of smokers; this process is associated with the development of nicotine addiction (Ref. 9). When an individual stops smoking, such as overnight or when attempting to quit, the nicotine levels in the brain decrease as the body clears nicotine, but the number of nicotinic receptors does not (Ref. 115). The combination of high levels of nicotinic receptors and low levels of nicotine in the brain produces the discomfort smokers feel when experiencing symptoms of nicotine withdrawal (Ref. 115). This is consistent with reports that smokers with greater brain nicotinic receptor levels have more difficulty quitting than smokers with lower brain nicotinic receptor levels (Ref. 166).

Clinical and animal studies show that menthol enhances brain nicotinic receptor levels to a greater extent than nicotine alone (Refs. 14, 10, and 11). These changes occur in brain regions involved in the development of nicotine addiction (Refs. 10–12). Therefore, menthol's ability to enhance the effects of nicotine in the brain contributes to why menthol smokers have greater difficulty quitting smoking compared to non-menthol smokers.

3. Conclusion

The totality of scientific evidence on menthol and cessation supports the conclusion that menthol cigarettes contribute to reduced cessation success, particularly among Black smokers. This effect of menthol among Black smokers is consistent across large nationally representative studies, smaller clinical studies of smokers, reviews of the menthol and cessation literature, and meta-analyses, which examined outcomes from multiple menthol and cessation studies. Findings among smokers in the general population produce more mixed results, which may be attributed in part to heterogeneity across study designs, methods, and populations; however, the evidence that supports an effect of menthol on reduced cessation success includes

longitudinal studies that evaluated quitting outcomes in the same population of smokers for up to 15 years and studies of up to 6 months that tested for indicators of continued cigarette smoking to strengthen the validity of individual self-report.

When considering the evidence from nationally representative surveys, longitudinal studies that evaluated cessation outcomes over time, and menthol's effects on nicotinic receptors in the brain, the totality of evidence supports that menthol in cigarettes contributes to reduced cessation success, particularly among Black smokers.

E. Menthol Cigarettes Are Marketed Disproportionately in Underserved Communities and to Vulnerable Populations

Tobacco marketing activities (e.g., advertising and promotions) are effective in promoting sales, increasing tobacco use, and engendering positive attitudes about tobacco products among youth, young adults, and other vulnerable populations (Refs. 167, 32, and 49). With regard to menthol cigarettes, decades of targeted marketing activities have helped to make menthol cigarettes more appealing and affordable and contributed to the pervasive and enduring nature of disparities in menthol cigarette smoking observed in vulnerable populations, particularly the Black community.

Tobacco industry research on menthol cigarettes illustrates that the industry “carefully researched the menthol segment of the market” and “added [menthol] to cigarettes in part because it is known to be an attractive feature to inexperienced smokers” (Ref. 7). In addition, evidence shows the tobacco industry employed a wide range of marketing activities, including branding, advertising and promotion, product placement, and pricing, to promote sales and increase menthol cigarette use by certain populations.

For example, research indicates that in the 1960s and 1970s, the tobacco industry's menthol cigarette advertising and promotion heavily targeted the African American community by use of darker-skinned models, tailored messaging and language, and reliance on media such as magazines with a high Black readership (Refs. 168, 90, and 92). Industry research identified the cultural values, geographic location, and taste preferences of Black smokers, which was then used to inform tobacco product branding (e.g., “Kool” cigarettes), culturally-tailored imagery in advertisements, and locations to

reach and appeal to Black menthol smokers (Refs. 169, 168, 90–91).

Over many decades, tobacco companies continued to employ marketing strategies to promote menthol cigarette use among youth, young adults, and underserved communities, such as low-income Black communities. The strategies used to target underserved communities included discounts (Ref. 170), distribution of free samples (Refs. 168, 171, and 172), and advertising in nightclubs, bars, and special events (Ref. 171). The tobacco industry also marketed menthol cigarettes to low-income Black communities and youth, including Black teens as young as 16 years of age, by selling menthol cigarettes in smaller package quantities to encourage trial and initiation, and to provide a lower price point (Refs. 173 and 174).

Recent scientific evidence indicates that tobacco companies market menthol cigarettes in the retail environment to continually appeal to underserved communities. For example, menthol marketing is more prevalent in neighborhoods that have more Black and low-income residents (Refs. 170 and 175). Furthermore, tobacco retailers in predominantly Black neighborhoods are more likely to advertise discount promotions for menthol cigarettes, and sell menthol cigarettes at a lower price, as compared to tobacco retailers in predominantly White neighborhoods (Refs. 175, 170, and 176). Menthol marketing is also more visible in neighborhoods with predominately Black residents as compared to predominately White neighborhoods, as well as in urban neighborhoods (Ref. 175). A recent nationally representative study of tobacco retailers in the contiguous United States found that retail menthol advertising was more common in neighborhoods with more Black and low-income residents (Ref. 177). Furthermore, price promotions for Newport brand menthol cigarettes were more common in retailers in neighborhoods with more Black residents (Ref. 177).

Higher exposure to tobacco advertisements and retailing are associated with disparities in tobacco use susceptibility and tobacco use among youth. For example, youth who live or go to school in neighborhoods where tobacco retailers are disproportionately present are more susceptible to smoking (Refs. 178 and 179), are more likely to experiment with smoking (Refs. 180 and 179), and are more likely to smoke currently (Ref. 181).

Taken together, scientific evidence indicates that menthol cigarettes have

historically and continue to be disproportionately marketed in underserved communities and contribute to the longstanding disparities in menthol cigarette smoking and health outcomes observed in vulnerable populations, particularly the Black community. While targeted marketing is only one factor in the development and perpetuation of menthol cigarette use and related harms, this background helps to explain and provide critical context for the outcomes and disparities that undermine public health and are of concern to FDA. Addressing how these products disproportionately affect vulnerable populations supports the Agency's mission of promoting public health.

V. Determination That the Standard Is Appropriate for the Protection of the Public Health

The Tobacco Control Act authorizes FDA to revise or adopt tobacco product standards by regulation if it finds that such tobacco product standards are appropriate for the protection of the public health (section 907(a)(2) and (a)(3)(A) of the FD&C Act). The notice of proposed rulemaking for such a product standard must set forth this finding with supporting justification, which FDA is doing here (section 907(c)(2)(A) of the FD&C Act).

In order to make this finding, FDA must consider scientific evidence concerning:

- The risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;
- The increased or decreased likelihood that existing users of tobacco products will stop using such products; and
- The increased or decreased likelihood that those who do not use tobacco products will start using such products.

(Section 907(a)(3)(B)(i) of the FD&C Act)

FDA has considered scientific evidence related to all three factors. Based on these considerations, as discussed below, we find that the proposed standard is appropriate for the protection of the public health because the prohibition of menthol as a characterizing flavor in cigarettes: Decreases the likelihood that nonsmokers would experiment with cigarettes, develop tobacco dependence symptoms, and progress to regular cigarette smoking and/or use of other tobacco products, while also decreasing the likelihood that current smokers would continue to smoke cigarettes. Cigarettes are the most toxic consumer

product when used as intended and adding menthol as a characterizing flavor makes cigarettes more appealing and easier to smoke. The proposed standard is anticipated to decrease the likelihood of menthol cigarette experimentation and the subsequent progression to regular, established cigarette smoking and cigarette consumption. Further, the proposed standard is anticipated to improve the health of current smokers of menthol cigarettes by increasing the likelihood of cessation, which would lead to lower disease and death in the U.S. population due to diminished exposure to tobacco smoke for both users and nonusers of cigarettes. Prohibiting menthol as a characterizing flavor in cigarettes would reduce the death and disease caused by cigarette use.

A. The Likelihood That Nonusers Would Start Using Cigarettes

Menthol in cigarettes is a significant contributor to youth and young adult initiation of cigarette smoking. In this section, we summarize evidence from multiple study designs, incorporating findings from longitudinal studies, national surveys, policy evaluations, and qualitative research that illustrate the role menthol plays in facilitating initiation and experimentation of cigarettes. We also discuss how the proposed prohibition on menthol as a characterizing flavor in cigarettes would decrease experimentation and thus, reduce progression to regular cigarette smoking among current nonusers.

Menthol is a flavor compound that is added to cigarettes, which produces a minty taste and cooling sensation when inhaled (Ref. 2). These sensory properties are pleasing and drive smoker beliefs that menthol cigarettes have a better taste, are smoother and more refreshing, are easier to inhale, and are less irritating than non-menthol cigarettes (Refs. 3–5). These properties also mask the harshness of smoking for new smokers and facilitate repeated experimentation and progression to regular smoking of menthol cigarettes, particularly among youth and young adults (Refs. 6–7, 5, 8).

When an individual tries a menthol cigarette, the sensory effects associated with menthol make initial and continued smoking experiences more palatable. In a focus group study conducted with young adult (aged 18–24) menthol smokers, participants reported that the taste of menthol made cigarettes as “minty”, “cool”, and “refreshing”, stating that these factors influenced their initial preference for menthol cigarettes (Ref. 5). Further, these young adults indicated that they

continued to smoke menthol cigarettes because they taste and smell better than non-menthol cigarettes (Ref. 5). In addition, a study evaluating the sensory experiences of first cigarette use among young adult smokers found that fewer menthol smokers reported experiencing nausea during their first smoking experience compared to non-menthol smokers (Ref. 33). Evidence from tobacco industry documents also support that menthol is added to cigarettes in part because it is known to be an attractive feature to new and younger inexperienced smokers who perceive menthol cigarettes as less harsh and easier to smoke than non-menthol cigarettes (Ref. 7).

The increased likelihood of initiation of menthol cigarettes is reflected in the high proportion of youth and young adults who report that their first cigarette was menthol as compared to older adult smokers and the high proportion of past 30-day menthol smoking among youth as compared to older adult smokers (Refs. 8, 31, 33, 65–66, 182–183, 55–57, 44, 95). National studies and data also show that younger smokers (aged approximately 12–25 years) are more likely to smoke menthol cigarettes than older adult smokers (aged 26 and older) (Refs. 65–66, 182–183, 57, 55, 44). Among middle and high school students, the prevalence of current past 30-day menthol cigarette smoking decreased from 2011 to 2018 in NYTS data (Ref. 56), however approximately 47 percent of youth who smoke cigarettes reported smoking menthol cigarettes in 2019 (Ref. 95). Baseline findings from PATH Study data indicate similar findings, with nearly 43 percent of youth (12 to 17 years of age) and 45 percent of young adult (18 to 24 years of age) ever cigarette smokers (*i.e.*, those young adults who have used a tobacco product even once or twice in their lifetimes) reported that the first cigarette they smoked was mentholated (Ref. 31). In a followup study examining Waves 1–4 (2013–2017) of PATH data, youth (aged 12–17 years) and young adult (aged 18–24 years) new smokers (smokers who reported trying a cigarette for the first time between any adjacent waves) were more likely to report smoking menthol cigarettes than adults aged 25 and older (Ref. 8). These findings are consistent across studies encompassing different populations and time periods, including studies that assess large, nationally representative populations (Refs. 65–66, 182–183, 55–57, 44, 95, 31, 8). Data indicating youth and young adults are more likely to smoke menthol cigarettes points to the importance of the

proposed product standard in protecting these vulnerable populations.

Experimentation with cigarettes can lead to nicotine dependence, which in turn increases the likelihood that experimenters will progress to regular cigarette smoking. As discussed in section IV.C of this document, studies have long provided clear evidence that signs of nicotine dependence in youth can arise soon after they first start smoking cigarettes, even among intermittent users (Refs. 184, 137, and 135). Such results suggest that even infrequent experimentation can lead to early signs of dependence, which underscores the public health importance of decreasing the likelihood of cigarette experimentation among youth and young adults in the United States.

Menthol's flavor, sensory effects, and interaction with nicotine in the brain contribute to an even greater risk of nicotine dependence by facilitating repeated experimentation and progression to regular smoking. Youth who smoke menthol cigarettes have statistically significant higher scores for several indicators of nicotine dependence (*i.e.*, craving, affiliative attachment, and tolerance) compared to youth who smoke non-mentholated cigarettes (Ref. 26). Pooled data from 2017–2020 NYTS of past 30-day youth cigarette smokers also indicates menthol smokers have greater risk of smoking more frequently (20–30 days per month versus 1–5 days per month) and more cigarettes per day (11+ versus 1–5), and that they report higher levels of dependence (cravings for tobacco and wanting tobacco within 30 minutes of waking) and have lower intentions to quit smoking (Ref. 28).

The reported dependence on tobacco, even at low levels of use, puts adolescents at greater risk of continuing to use tobacco products into adulthood (Refs. 135 and 185). The adolescent brain, which continues to develop until about age 25, is particularly vulnerable to nicotine's addictive effects (Refs. 17, 18, and 32). Several studies among adolescent and young adult cigarette smokers have shown that early dependence symptoms are predictive of smoking continuation and progression or failed cessation attempts (Refs. 186 and 187). The addition of menthol as a characterizing flavor used in cigarettes enhances nicotine addiction, particularly for youth and young adults, through a combination of its flavor, sensory effects, and interaction with nicotine in the brain.

If this proposed rule is finalized, menthol as a characterizing flavor would not be available to mask the

harshness of smoking cigarettes and make initial smoking experiences more appealing for new users. FDA anticipates that implementation of the proposed standard would result in fewer youth and young adults experimenting repeatedly with cigarettes, becoming nicotine dependent, and progressing to regular cigarette smoking. Through these impacts alone, the proposed standard is appropriate for the protection of the public health, as it would lead to a significant reduction in the number of new regular cigarette smokers and the well-documented health impacts associated with regular cigarette smoking.

If this proposed rule is finalized, FDA expects a significant reduction in youth initiation and progression to regular cigarette smoking, which would ultimately protect youth from a lifetime of addiction and disease, and premature death, attributable to cigarette smoking. To the extent that youth and young adults in the United States who would have initiated with menthol cigarettes do not initiate with non-menthol cigarettes or other tobacco products, the proposed standard would prevent future cigarette-related disease and death.

FDA's expectation of a significant reduction in youth initiation and progression to regular cigarette smoking is supported by real-world experience of youth tobacco use prevalence decreasing following implementation of policies restricting the sales of flavored tobacco products. Two nationally representative studies assessing the impact of the Special Rule for Cigarettes (section 907(a)(1)(A) of the FD&C Act), which banned non-menthol flavored cigarettes, both found that youth cigarette smoking rates decreased following implementation. In a study using 2002–2017 NSDUH quarterly data with older adults (aged 50 and older) as a comparison group, there was a temporary increase (“temporary” was undefined in the study) in the odds of past 30-day cigarette smoking and past 30-day menthol cigarette smoking in youth and young adults immediately after the Special Rule went into effect (Ref. 188). Following the temporary increase, odds of past 30-day cigarette smoking and past 30-day menthol cigarette smoking in youth and young adults decreased through 2017 (Ref. 188). No increase in odds of past 30-day cigarette smoking and past 30-day menthol cigarette smoking was observed immediately after the Special Rule went into effect or following through 2017 among older adults (ages 50 and older). The study estimated the total effect of the Special Rule for Cigarettes and

found that the flavored cigarette ban overall was associated with a significant reduction in cigarette smoking for youth (ages 12–17), young adults (ages 18–25), and adults (ages 26–49), but not older adults (ages 50 and older). This includes reductions in menthol cigarette smoking among youth and youth adults likely due to the overall effect the Special Rule had on decreasing rates of smoking among these groups over time.

Another nationally representative study examining tobacco use among U.S. middle and high school students before and after the Special Rule for Cigarettes banning non-menthol flavored cigarettes, found an overall decrease in the prevalence of youth cigarette smoking, fewer number of cigarettes smoked per month, and an overall reduction in the probability of using any type of tobacco (Ref. 189). Adjusting for demographic variables, national-level tax inclusive price indices for cigarettes and non-cigarette tobacco products, youth unemployment rate, and time trends, there was a 17.1 percent reduction in the probability of middle and high school students being a cigarette smoker after the Special Rule for Cigarettes (Ref. 189). Additionally, middle and high school smokers reported smoking 59 percent fewer cigarettes per month after the Special Rule for Cigarettes (Ref. 189). While there were increases in the use of some types of tobacco products, including cigars (34.4 percent) and pipe tobacco (54.6 percent) that remained available in flavored varieties, the probability of using any type of tobacco overall was reduced by 6 percent (Ref. 189).

In recent years, several U.S. localities and some states have placed restrictions on the sale of menthol cigarettes in addition to restrictions on the sale of other flavored tobacco products. Results from evaluations of these policies provide evidence of decreases in use and sales of tobacco products after policy implementation (Refs. 190–193). In 2018, Minneapolis and St. Paul, Minnesota, expanded their sales restrictions on flavored tobacco products (including e-cigarettes) to include menthol, mint, and wintergreen tobacco products. An evaluation of this sales restriction found decreases in youth cigarette (3.8 percent to 2.3 percent), cigar (2.7 percent to 1.6 percent), smokeless tobacco (1.6 percent to 1.2 percent), and hookah (2.4 percent to 1.3 percent) product use after policy implementation in the Twin Cities metro area, which includes Minneapolis and St. Paul (Ref. 192). An increase in youth e-cigarette prevalence from 10.5 percent to 15.7 percent occurred after the policy in the Twin Cities, but this

increase was lower than the rest of the State of Minnesota where e-cigarette prevalence increased from 10.0 percent to 18.8 percent (Ref. 192). Although prevalence of youth overall tobacco use increased after the policy in the Twin Cities from 12.2 percent to 16.5 percent and increased in the rest of the State from 13.9 percent to 20.1 percent, these increases were driven by youth e-cigarette use and align with national youth tobacco use trends (Ref. 192). Importantly, the increases in youth overall tobacco use after the policy were lower in the Twin Cities than in the rest of the State, suggesting that the policy mitigated increases in overall tobacco use.

In July 2018, San Francisco, California, implemented a sales restriction on all flavored tobacco products, including menthol cigarettes. The San Francisco Department of Public Health announced that enforcement would begin January 2019 and enforcement with routine retailer compliance inspections began April 2019 (Ref. 194). An evaluation of the impact of the San Francisco policy on tobacco product sales, a proxy for consumption, found that total tobacco sales decreased by a statistically significant 25 percent from before policy implementation (July 2015–July 2018) to a post-policy enforcement period (January–December 2019) (Ref. 190). This study also found a statistically significant decrease in the overall sales of flavored tobacco products (from 39,350 average weekly unit sales to 1,546 average weekly unit sales), including menthol cigarettes (from 21,463 average weekly unit sales to 860 average weekly unit sales), to low levels after policy enforcement (Ref. 190). Findings that total tobacco sales and flavored tobacco sales decreased post policy suggest that consumers did not completely substitute non-flavored tobacco products for flavored tobacco products, and that such a policy can be implemented effectively and reduce sales of products as intended.

Changes in sales of tobacco products in San Francisco after policy enforcement were also reflected in young adult tobacco use patterns. A retrospective study of a convenience sample of young adult ever tobacco users in San Francisco found a statistically significant lower prevalence of overall tobacco use among 18-to 24-year-olds (from 100 percent to 82.3 percent) and 25-to 34-year-olds (from 100 percent to 92.4 percent) about 11 months after policy enforcement (November 2019) (Ref. 191).

One study on San Francisco's flavored tobacco policy using Youth Risk

Behavior Survey (YRBS) data reported that San Francisco's flavor restriction was associated with increased odds of cigarette smoking among high school students relative to other school districts (Ref. 195). However, another study reported a methodological mistake with these findings: Data collection for the 2019 YRBS in San Francisco occurred in Fall 2018, prior to when the San Francisco flavor restriction was enforced in April 2019 (Ref. 196). As previously noted, another study of the San Francisco policy observed an overall decline in tobacco product sales and total cigarette sales, suggesting that there was not complete substitution of tobacco or unflavored products for flavored products following the flavor restriction in San Francisco (Ref. 190).

In June 2020, Massachusetts implemented a statewide sales restriction on flavored tobacco products (including menthol cigarettes) (Ref. 193). An evaluation of retail sales data assessed State-level cigarette sales per 1000 people in Massachusetts and comparison states without statewide flavor sales restrictions (Ref. 193). After the flavor sales restriction, the adjusted sales of cigarettes in Massachusetts versus the comparison states decreased by 372.27 packs per 1000 people for menthol cigarettes and by 282.65 pack per 1000 people for all cigarettes (Ref. 193).

In addition to state and local menthol sales restrictions, in recent years many provinces in Canada have implemented menthol sales restrictions. An evaluation of provincial menthol sales restrictions in Canada on youth and adult cigarette use found that provincial menthol sales restrictions were associated with decreases in menthol cigarette smoking (Ref. 197). While this study found that provincial menthol sales restrictions were not associated with an overall change in youth and adult past 30-day cigarette use, this finding is inconsistent with the authors' supplemental analysis that found decreases in menthol cigarette sales and no effect on non-menthol cigarette sales post-implementation (Ref. 197). The study also found an increase in adult self-reported purchasing of cigarettes from First Nations reserves, which were exempt from the sales restriction (Ref. 197). This purchasing behavior was not assessed among youth. In the United States, however, the proposed menthol product standard would apply nationwide, including on Tribal lands, which likely would increase the effectiveness of a nationwide menthol standard as compared to Canada.

In addition to the studies discussed in this section, as of November 2021, at least 145 localities in the United States have passed restrictions on the sale of menthol cigarettes in addition to other flavored tobacco products (Ref. 198). FDA requests comments and data on the impact of these menthol cigarette sales restrictions on non-users and users of tobacco products.

Evaluations of local non-menthol flavored tobacco product sales restrictions also provide evidence of decreases in the use and sales of tobacco products after policy implementation (Refs. 199–203). In November 2010, New York City (NYC) began enforcing a sales restriction on all flavored tobacco products except for menthol-flavored, mint-flavored, and wintergreen-flavored tobacco products; all e-cigarettes were excluded from the sales restrictions. An evaluation of the impact of the policy on youth tobacco product use found that NYC youth (aged 13–17 years) had 37 percent lower odds of ever trying a flavored tobacco product in 2013 after the policy was enforced compared to youth in 2010. Similarly, youth in 2013 had 28 percent lower odds of ever using any tobacco products compared to youth before the policy was enforced (Ref. 199). Changes in youth flavored tobacco use patterns were also reflected in changes in overall sales of flavored tobacco products. Analyses of tobacco product sales found a statistically significant decline in sales of overall flavored tobacco products following policy implementation and enforcement (Refs. 199 and 200). Similar to findings in NYC, an evaluation of a policy restricting the sale of flavored tobacco products, including e-cigarettes and excluding menthol cigarettes, in Providence, Rhode Island, found a decrease in any tobacco product use among high school students after active enforcement of the policy began (Ref. 202). More specifically, this analysis found that youth current use of any tobacco product declined from 22.2 percent in 2016 to 12.1 percent in 2018 (Ref. 202).

In October 2016, Lowell, Massachusetts, a small locality, began enforcing a sales restriction on all flavored tobacco products, except for menthol; e-cigarettes were included in the sales restriction. An evaluation of the short-term (6-month) impact of the policy found that youth use of any flavored tobacco products and any non-flavored or menthol tobacco products decreased in Lowell from baseline to followup and increased in the comparison community; statistically significant decreases in both any flavored and any non-flavored or

menthol tobacco use were observed when comparing changes from baseline to followup between the two communities (Ref. 201). More specifically, youth self-reported current use of any non-flavored tobacco products decreased 1.9 percent in Lowell while increasing in the comparison city by a statistically significant 4.3 percent for a statistically significant estimated difference of –6.2 percent between the communities (Ref. 201). These data suggest that overall, youth did not switch to non-flavored or menthol tobacco products and that the policy helped reduce use of tobacco products among youth (Ref. 201).

Additionally, a study of local level restrictions across Massachusetts from 2011–2017 found that counties with a greater proportion of county residents covered by local policies that limit the sale of flavored tobacco products (excluding menthol) were associated with a decrease in the number of days smoked in the past 30 days and a decrease in the likelihood of e-cigarette use among high school students (Ref. 203). Another study evaluated the impact of flavored tobacco sales restrictions (excluding menthol) in Attleboro and Salem, Massachusetts, on tobacco use among high school students (Ref. 204). While youth use of flavored tobacco products and nonflavored or menthol tobacco products increased from baseline to followup in Attleboro and Salem and in the comparison municipality, the increases were significantly smaller in Attleboro and Salem than the comparison municipality, suggesting that the policy mitigated increases in flavored and nonflavored or menthol tobacco use (Ref. 204). Furthermore, while no changes in youth overall tobacco use were observed after a sales restriction on flavored tobacco products (excluding menthol, mint, and wintergreen products) in Minneapolis and St. Paul, Minnesota (18.1 percent to 17.6 percent), significant increases in the prevalence of youth overall tobacco use were observed in the rest of the state (12.4 percent to 15.7 percent), suggesting that the policy may have prevented increases in overall tobacco use (Ref. 192). As discussed previously, after this sales restriction was expanded to include menthol, mint, and wintergreen tobacco products, increases in youth overall tobacco use were lower in the Twin Cities than in the rest of the State, suggesting that the expanded policy diminished increases in overall tobacco use (Ref. 192).

FDA acknowledges there may be limitations to relying on aggregate tobacco sales information as a proxy for

consumption. In addition, overall sales data are more likely to be driven by adult than adolescent use, given the larger size of the adult population as well as the tendency for youth to acquire tobacco via social sources (Ref. 205). However, studies have shown that sales and consumption tend to be highly correlated (Refs. 206–208). Additionally, sales data provide information on purchases of tobacco products in a defined area (which could include neighboring jurisdictions) (Refs. 200 and 209) and can serve as a proxy for consumption of tobacco products after policy implementation.

Evaluations of local policies may underestimate the potential impact of a national policy. Depending on availability of tobacco products in jurisdictions neighboring those where local policies were passed, users and non-users may easily be able to access tobacco products from these locations. Even with these limitations, FDA finds sales and local policy evaluation data useful and supportive in informing our expectations about the impact of the proposed product standard on tobacco product use and potential product substitution. Overall, the evidence supports that sales and use of tobacco products decrease as a result of flavored tobacco product sales restrictions. FDA anticipates that a nationwide standard that prohibits the manufacture and sale of menthol cigarettes would likely have a greater impact in decreasing youth cigarette use compared to that observed from policies from limited jurisdictions, because a nationwide product standard would eliminate the manufacture of these products as well as the opportunity to easily travel to neighboring jurisdictions within the United States that do not have a menthol sales restriction or use online retailers to purchase menthol cigarettes.

Although there are limitations in attributing public health outcomes to the evaluations described in this section, such evaluations are useful to understand the anticipated effect of the proposed menthol product standard. Findings from these evaluations generally suggest that youth use of cigarettes would decrease following implementation of the proposed product standard. With reduced menthol cigarette smoking, we would see reduced smoking-related morbidity and mortality along with diminished exposure to secondhand smoke among non-smokers, decreased potential years of life lost, decreased disability, and improved quality of life for the current and future generations to come. For these reasons, FDA expects that prohibiting menthol as a characterizing

flavor in cigarettes would reduce the likelihood that youth and young adults would initiate with and progress to regular menthol cigarette smoking, thereby protecting many youth from a lifetime of addiction and disease, and premature death, attributable to cigarette smoking. From the expected impact on non-users alone, especially youth and young adults, this proposed product standard is appropriate for the protection of public health.

B. The Likelihood That Existing Menthol Cigarette Users Would Reduce Cigarette Consumption or Stop Cigarette Smoking

In addition to the long-term public health benefits that would accrue from the prevention or reduction of menthol cigarette smoking among youth and young adults, FDA anticipates that the proposed standard would increase the likelihood that many existing menthol cigarette smokers would stop smoking cigarettes altogether, yielding health benefits from smoking cessation. FDA expects that the proposed prohibition of menthol as a characterizing flavor in cigarettes would result in substantial changes in tobacco use patterns among current tobacco users. Current menthol smokers would either: (1) Quit smoking or tobacco use altogether; (2) transition to non-menthol cigarettes or other combusted tobacco products; or (3) switch to other tobacco products, including potentially less harmful products. Given the large proportion of menthol cigarette use among smokers, the role of menthol in reducing cessation success among cigarette smokers, and the empirical evidence published through 2021 from policies restricting the sales of flavored tobacco products in the United States and Canada, FDA expects that the proposed product standard would lead many menthol cigarette smokers to stop using cigarettes.

As discussed previously, menthol's flavor and sensory properties influence initiation and continued experimentation (see section IV.C of this document). Additionally, these sensory properties are a major factor for a smoker's continued use of menthol cigarettes. Smokers note that menthol in cigarettes impacts their sensory experience, including the perception of a better tasting, smoother, and more refreshing cigarette that is easier to inhale and produces a cooling effect in the mouth and throat; smokers report that these sensory effects from menthol contribute to their continued smoking (Refs. 3–5, 107–108). In a qualitative study, young adult menthol smokers (aged 18–24) reported that the taste of menthol made cigarettes “minty”,

“cool”, and “refreshing”, stating that these factors influenced their initial preference for menthol cigarettes (Ref. 5). They perceived menthol cigarettes as smoother, less harsh, and “easier to inhale” than non-menthol cigarettes, which were generally regarded as strong, harsh, and “gross” (Ref. 5). They also reported that menthol cigarettes deliver a “fuller” smoke and “hit hard,” and seemingly require fewer cigarettes to feel “satisfied” (Ref. 5). Among adult smokers aged 18 and older, another recent study found menthol cigarette smoking to be associated with self-reported subjective reward, satisfaction, and throat hit (Ref. 108). Similar findings have been noted in youth. In a PATH Study of Wave 1 data, youth cigarette smokers (aged 12–17), regardless of menthol use status, reported that menthol cigarettes are easier to smoke (Ref. 107). The menthol product standard, if finalized, would prohibit menthol as a characterizing flavor in cigarettes, eliminating menthol's sensory cue, thereby reducing the reinforcing appeal of cigarettes for current menthol smokers, and encouraging current menthol smokers to quit smoking.

The sensory effects of menthol serve to reinforce the effects of nicotine. While nicotine dependence is the driving factor for all tobacco use, including cigarettes, menthol's enhancement of nicotine dependence and the sensory properties of menthol contribute to continued use of menthol cigarettes, making it even more difficult to quit smoking (Refs. 1, 34–35, 42, 36–37). While there is some inconsistency in the literature regarding menthol's role on smoking cessation, when considering the evidence from systematic reviews, national surveys, longitudinal studies that evaluated cessation outcomes over time, and menthol's effects on nicotinic receptors in the brain, the totality of evidence supports that menthol in cigarettes contributes to reduced cessation success among smokers, particularly among Black smokers (Refs. 34–35, 42, 36–41).

Data from TUS–CPS found that in 2007, reporting a quit attempt in the past year was 8.8 percent higher among menthol smokers (41.4 percent) compared to non-menthol smokers (38.1 percent), but menthol smokers had 3.9 percent lower rates of quitting within the past year (menthol: 4.2 percent versus non-menthol: 4.4 percent) and 11.3 percent lower rates of quitting within the past 5 years (menthol: 18.8 percent versus non-menthol: 21.1 percent) compared to non-menthol smokers (Ref. 37). After adjusting for covariates, including nicotine

dependence and race/ethnicity, the likelihood of quitting was 3.5 percent lower for quitting in the past year and 6 percent lower for quitting in the past 5 years in menthol compared with nonmenthol smokers (Ref. 37). Similar results have been noted in more recent data from Waves 1–4 of the PATH Study (2013–2018), which found that daily adult menthol smokers (ages 18 and older) had 24 percent lower odds of quitting smoking compared to daily non-menthol smokers (Ref. 40). Another PATH study evaluated short-term (30-day) and long-term (12-month) smoking abstinence among menthol and non-menthol smokers who had attempted to quit smoking in the past 12 months (Ref. 43). Menthol smoking decreased the probability of 30-day smoking abstinence by 28 percent and the probability of 12-month smoking abstinence by 53 percent compared to smoking non-menthol cigarettes (Ref. 43). The majority of cigarette smokers in the United States report wanting to quit smoking (2015 NHIS: 68.0 percent) (Ref. 210), and thus, in response to the proposed product standard, many menthol cigarette smokers may seek to quit tobacco altogether or switch to other, potentially less harmful products.

FDA expects that, if this proposed rule is finalized and menthol is prohibited as a characterizing flavor in cigarettes, many menthol cigarette smokers will either quit smoking or switch to a non-combusted tobacco product, such as ENDS. In an expert elicitation study estimating transitions in use under both menthol ban and status quo scenarios, the panel of experts estimated that an additional 20.1 percent of menthol smokers ages 35 to 54 would cease combustible tobacco use over 2 years under a menthol ban compared to the status quo, with about half (10.3 percent) switching to ENDS and about half (10 percent) quitting all tobacco use (Ref. 211). The expert panel also estimated that an additional 30.1 percent of menthol smokers ages 18 to 24 would cease combustible tobacco use over 2 years, with 15.6 percent switching to ENDS and 12.3 percent quitting all tobacco use (Ref. 211). Some menthol cigarette smokers may switch to non-menthol cigarettes. The expert elicitation study suggested that among menthol smokers age 35 to 54, 45.7 percent would become non-menthol cigarette smokers (compared to 4.6 percent under the status quo) while 3.7 percent would become non-menthol cigar smokers (compared to no change under the status quo) (Ref. 211). The expert elicitation study and the resulting population modeling study,

which utilized the expert elicitation, are discussed in further detail in section V.C.5 of this document.

Among Hispanic and Latino smokers, studies also suggest that menthol smokers have more difficulty quitting than non-menthol smokers (Refs. 34, 151, 42, 36). Data from cross-sectional surveys using nationally representative online cohorts of U.S. adults indicated that Hispanic, non-Hispanic African American, and non-Hispanic other (those who identified with more than two races) adults were more supportive of a menthol ban than non-Hispanic White adults (Ref. 212) and that, among menthol smokers, both African American and Hispanic adults were more supportive of a menthol ban than White adults (Ref. 213). African American adults and Hispanic adults are two of the three racial and ethnic groups that, in 2019, had the highest prevalence of menthol cigarette smoking.

Prohibiting menthol as a characterizing flavor in cigarettes would likely result in increased cigarette cessation among members of historically underserved communities, including Black smokers, due to increased quit attempts and lower likelihood of switching to non-menthol cigarettes. A recent review of the literature found that among smokers, African American menthol smokers had lower odds of smoking cessation compared to non-menthol smokers (Ref. 41). As discussed above, the totality of evidence supports that menthol in cigarettes contributes to reduced cessation success. Data from national surveys suggests that menthol likely plays a role in making quitting particularly difficult for African American cigarette smokers (Refs. 34–37, 40). A focus group study among Black smokers found that taste was the main reason for continuing to smoke a particular brand and was a reason for smoking menthol rather than non-menthol cigarettes (Ref. 4). Additionally, participants agreed that menthol cigarettes were “refreshing”, “soothing”, and “smooth” while non-menthol cigarettes were “strong” or “harsh” (Ref. 4). Participants’ preference for menthol cigarettes in this study was so strong that non-menthol cigarettes were viewed as a cessation aid (Ref. 4). These findings support that prohibiting menthol as a characterizing flavor in cigarettes will reduce the appeal of cigarettes, lead to reduced initiation and experimentation, and reduce the likelihood of subsequent progression to regular, established smoking and smoking dependence among vulnerable populations.

While a menthol restriction is anticipated to benefit the general population, the benefits of a menthol restriction on smoking cessation are likely to be more pronounced among Black menthol smokers, as they are less likely to switch to non-menthol cigarettes. Older and more recent studies are consistent in their findings that there would be increased likelihood of quitting smoking altogether for many menthol smokers under a menthol ban. A 1993 study of adult cigarette smokers found that 56 percent of Black smokers, compared to 28 percent of White smokers, responded that they would not smoke non-menthol cigarettes if they could not smoke menthol cigarettes (Ref. 214). While all menthol smokers in a nationally representative study had lower odds of smoking cessation compared to non-menthol smokers, when stratified by race and ethnicity, African American menthol smokers had the lowest odds of smoking cessation of any group (Ref. 40). A 2011–2016 analysis of data from the Truth Initiative Young Adult Cohort showed that among past 30-day menthol smokers, African American smokers had greater odds of reporting that they would quit smoking if menthol cigarettes were unavailable compared to White smokers (Ref. 215). Another study evaluating the effect of a menthol sales restriction in seven Canadian provinces indicated that non-White cigarette smokers were more likely than White cigarette smokers to make a quit attempt (Ref. 216). Additionally, one experimental study recruited 29 current menthol adult smokers who were not currently using cessation treatments and were not trying to quit (Ref. 217). Participants were switched from smoking their usual brand menthol cigarettes to a matched-brand non-menthol cigarette and were monitored multiple times across 2 weeks to model a potential ban of menthol cigarettes (Ref. 217). After switching to non-menthol cigarettes, participants had significantly lower nicotine dependence scores and greater increases in quitting motivation and confidence (Ref. 217). Findings from this study indicated that Black smokers had greater reductions in cigarettes per day when compared to non-Black smokers (defined as Hispanic, White, or “Other” smokers) (Ref. 217). Taken together, these research findings suggest that the proposed menthol product standard could help to reduce tobacco-related health disparities as experienced by vulnerable populations.

Findings from surveys asking menthol cigarette smokers what they would do if menthol cigarettes were to be banned

are consistent with the Agency’s expectation that many menthol smokers would attempt to quit smoking following the implementation of the proposed menthol standard. A recent literature review examined such surveys and based on responses from U.S. menthol smokers, concluded that banning menthol cigarettes would increase quit attempts and switching to potentially less harmful tobacco products (Ref. 218). Across several surveys, menthol smokers have said that if menthol cigarettes were no longer available, they would consider quitting smoking altogether (Refs. 213, 219–223, 215). For example, a 2010 nationally representative survey found that approximately 39 percent of adult menthol cigarette smokers said they would “try to stop smoking” if menthol cigarettes were banned (Ref. 213). In a 2014 survey, adult menthol smokers in Minnesota were asked whether they would quit smoking if menthol cigarettes were no longer sold in U.S. stores (Ref. 221). Just under half (46.4 percent) of menthol smokers responded that they would quit smoking (Ref. 221). A longitudinal survey from 2011–2016 of young adult menthol smokers found that an average of 23.5 percent of menthol smokers reported that they would most likely quit smoking and not use any other tobacco product in response to a menthol ban (Ref. 215).

In another study of adolescent and adult cigarette smokers, more than 35 percent of menthol smokers indicated their intentions to try to quit smoking if a ban of menthol in cigarettes was enacted (Ref. 219). Two studies report higher proportions of non-Hispanic Black menthol smokers indicating their intentions to quit smoking than non-Hispanic White menthol smokers following a menthol cigarette flavor ban; however, these differences were not statistically significant in either study (Refs. 219 and 213). In a longitudinal study of young adults, non-Hispanic Black participants had significantly higher odds of reporting that they would most likely quit smoking if menthol cigarettes were no longer available compared to non-Hispanic White participants (Ref. 215). A study in Ontario, Canada, that compared individuals’ behavioral intentions before a menthol sales restriction was implemented with actual responses 1 year after implementation found 38 percent of those with behavioral intentions to quit cigarettes in response to a menthol ban reported quitting 1 year after the menthol ban was implemented (Ref. 224). Fifteen percent of those who planned to switch to non-

menthol cigarettes, 34 percent of those who planned to switch to other flavored tobacco products, 19 percent of those who planned to switch to contraband, and 24 percent of those who were unsure of their response before the menthol ban also reported quitting cigarettes 1 year after the menthol ban (Ref. 224).

An additional study asked U.S. adult menthol smokers to complete a hypothetical shopping task in a virtual store under one of four experimental conditions that simulated various policy scenarios (1—no ban, 2—replacement of menthol cigarettes and ads with green replacement versions (*i.e.*, the term “menthol cigarettes” is replaced with the term “green cigarettes”), 3—menthol cigarette ban, 4—all menthol tobacco product ban) and assessed tobacco purchases (Ref. 225). This study found that participants in scenarios with a menthol cigarette ban and all menthol tobacco product bans were less likely to purchase cigarettes than participants who were exposed to no ban (Ref. 225). This finding supports FDA’s expectation that many menthol cigarette smokers would quit smoking altogether after implementation of a menthol product standard.

Real-world experience from Canada’s laws prohibiting the sale of menthol tobacco products provides information on the potential behavioral impacts the menthol product standard could have on cigarette use in the United States. Studies evaluating the impact of these laws have found increased reports of quit attempts and quitting smoking following policy implementation (Refs. 226, 224, 227, 216). These findings are consistent with the Agency’s expectation that, following implementation, the proposed menthol product standard would increase the number of menthol cigarette smokers who quit cigarette use. After menthol sales restrictions in Quebec, Ontario, Prince Edward Island, Newfoundland, and Labrador, and a nationwide restriction covering British Columbia, Saskatchewan, and Manitoba, smokers from these provinces reported high rates of quit attempts and quitting smoking (Refs. 226, 224, 227, 216). In a study of Ontario 1 year after policy implementation, 56 percent of study participants who were smokers before the sales restriction reported making a quit attempt and 19 percent reported quitting smoking (Ref. 224). In a study of smokers from the Canadian provinces previously mentioned, 21.5 percent of pre-ban menthol smokers reported quitting smoking (defined as those who had currently quit or cut down to smoking less than monthly) after policy

implementation (Ref. 216). Another study of adult smokers from Canadian provinces that implemented menthol sales restrictions found a small non-significant increase in the likelihood of ever trying to quit following policy implementation (Ref. 197). While the percent of smokers who reported quitting post-policy in these studies varies based on the length of time after policy implementation, geographic location, and definition of quitting, the percent of quitting post-policy in these studies was higher than the percent of current smokers from Ontario who reported quitting smoking 30 days or longer pre-policy in 2014 (7.9 percent) (Ref. 228). This suggests the various Canadian menthol sales restrictions contributed to increases in the number of smokers who quit smoking. The high rates of quit attempts and quitting smoking in Canada after menthol sales restrictions support FDA’s expectation that a ban on menthol cigarettes would increase the likelihood that existing menthol cigarette smokers will stop smoking cigarettes altogether. For reference, in 2018 in the United States, recent successful quitting (quit smoking for ≥ 6 months during the past year) was 7.5 percent among those who were either current smokers who smoked for ≥ 2 years or former smokers who quit during the past year (Ref. 229). Even if only a portion of the increase in cessation seen in Canada is experienced in the United States as a result of the proposed menthol standard, there would still be a significant net public health benefit.

Further supporting FDA’s expectation that a prohibition on menthol cigarettes would increase quitting by menthol cigarette smokers is evidence from Canada that menthol smokers there report higher rates of quit attempts and quitting smoking than non-menthol smokers (Refs. 224, 227, and 216). Studies from Ontario 1 year and 2 years after policy implementation found a higher likelihood of quit attempts and quitting smoking among those who reported smoking menthol cigarettes daily before the sales restriction (baseline) when compared with smokers who reported smoking non-menthol cigarettes daily (Refs. 224 and 227). Similarly, in a study looking across seven Canadian provinces with menthol sales restrictions, menthol smokers were more likely than non-menthol smokers to make a quit attempt and remain quit (quit greater than 6 months at follow-up and were long-term quitters who stopped smoking before the nationwide ban and remained quit) (Ref. 216). In addition, there is evidence that previous

menthol smoking is not associated with relapse (Refs. 227 and 216). This suggests that menthol sales restrictions help those who quit smoking menthol cigarettes to stay quit. Taken together, the results from these studies support FDA’s expectation that menthol smokers will achieve quit rates similar to or higher than non-menthol smokers because of a menthol product standard.

Findings on cessation from Ontario are consistent with analyses of tobacco manufacturer wholesale sales data and retail scanner data (Refs. 230 and 231). These data are often used as a proxy for cigarette consumption. An analysis of wholesale cigarette sales data in 10 Canadian provinces found an overall decrease of 4.6 percent in total cigarette sales after menthol cigarette bans (Ref. 232). Another analysis of tobacco manufacturer wholesale sales data showed that total cigarette sales declined by 128 million units following the Ontario menthol sales restriction compared to British Columbia, a Canadian province demographically similar to Ontario that did not have a menthol sales restriction in place at the time of the study, in which no significant changes were observed (Ref. 230).

There are considerations in relying on: (1) Canadian-based data to inform U.S. policy and (2) tobacco manufacturer wholesale sales and retail sales data as a proxy for consumption. With regard to the Canadian-based data to inform U.S. policy, it is important to note that menthol cigarettes comprise a larger proportion of cigarettes sales in the United States (*e.g.*, 26 percent in the United States versus 4 percent in Canada in 2001) and that a larger proportion of Black cigarette smokers in the United States use menthol cigarette brands (*e.g.*, 78.4 percent of Black cigarette smokers in the United States versus 9.8 percent of Black cigarette smokers in Canada in 2002) (Ref. 88). Therefore, findings from Canada likely underestimate the impact of a menthol cigarette ban in the United States. Findings from Canada’s menthol sales restrictions corroborate evidence from evaluations of flavored tobacco product sales restrictions in the United States (*e.g.*, Massachusetts; Providence, RI; New York City, NY; San Francisco, CA) that found that sales and use of tobacco products covered by the flavor restriction decreased after implementation (Refs. 193, 200, 199, 209, 190).

With regard to relying on tobacco manufacturer wholesale sales and retail sales data as a proxy for consumption, such data do not completely reflect individual-level tobacco use behaviors.

For example, smokers may have obtained cigarettes through channels not included in the Ontario sales data (e.g., other provinces) or switched to non-restricted products, which may result in an overestimation of the impacts. The analysis of tobacco manufacturer wholesale data found a significant decline in the overall cigarette sales in Ontario in the month following Ontario's menthol sales restriction. This was followed by a statistically significant increase in the sales of overall cigarettes driven by an increase in non-menthol cigarettes in Ontario, suggesting a slight rebound effect; however, overall cigarette sales approximately 8 months following the menthol sales restriction were lower than study baseline (October 2012) (Ref. 230). Similarly, an analysis of retail sales data found a small increase (0.4 percent) in sales of non-menthol cigarettes in the 6 months following policy implementation (Ref. 231). In spite of this limitation, considering sales data with the self-report data suggests increased smoking cessation occurred as a result of the sales restriction.

As mentioned previously, several U.S. localities have placed restrictions on the sale of menthol cigarettes in addition to restrictions on the sale of flavored tobacco products. FDA is aware of two studies that report on the impact of the policy in San Francisco on cessation. The first, a retrospective study with a relatively small convenience sample of young adult ever tobacco users in San Francisco found of 20 exclusive menthol cigarette smokers before the policy, 5 percent (n=1) quit any tobacco use after the policy and, among 61 menthol cigarette and other tobacco users before the policy, 3.3 percent (n=2) quit after the policy (Ref. 191). A second study examining the impact of the same policy among clients enrolled in a San Francisco residential substance use disorder treatment facility found that participants surveyed about 5 months after the policy (n=102) were statistically significantly less likely to report menthol as the usual cigarette smoked compared to participants surveyed before the policy (Ref. 233). This study found no evidence that the policy was associated with decreased number of cigarettes per day or increased readiness to quit among current smokers (Ref. 233). The marginal effects observed in this study are not entirely unanticipated. Smoking prevalence rates are substantially higher among individuals with substance use disorder compared to those in the general population (Refs. 234–237), and these individuals report increased

nicotine dependence levels (Ref. 238) and have less success at quitting smoking than individuals without substance use disorders (Refs. 239 and 240). Additionally, studies show that drugs of abuse may have unique pharmacological interactions with nicotine, increasing the reinforcing effects of both smoking and drug use among these populations (Refs. 241–244). This population with substance use disorder may have been less sensitive to the regional menthol ban compared to the general population due to their unique risk factors and pervasive patterns of tobacco use.

Taken together, these two San Francisco studies provide limited evidence of the impact of a menthol cigarette sales restriction on cessation in the United States (Refs. 191 and 233). Both studies rely on convenience samples and do not include a control group (Refs. 191 and 233) limiting their generalizability to people other than study participants. In addition, the retrospective study of a convenience sample of young adult ever tobacco users in San Francisco (Ref. 191), only collects data after the policy was implemented. Given this, FDA relies more on the evidence from Canada which includes multiple longitudinal cohort studies of the general population at different time points following policy implementation and in various locations that have implemented menthol sales restrictions to inform expectations on the impact of the proposed product standard on cessation.

As discussed previously, evaluations of local policies may underestimate the potential impact of a national policy. Depending on availability of tobacco products in jurisdictions neighboring those where local policies were passed, users and non-users may easily be able to access tobacco products from these locations. For example, in the study examining clients enrolled in San Francisco residential substance use disorder treatment facilities, 50 percent of menthol smokers reported purchasing menthol cigarettes in San Francisco after the menthol sales restriction (Ref. 233). Overall, the evidence supports that following a menthol sales restriction or ban, adult menthol cigarette smokers' quit attempts and quitting smoking increases. FDA anticipates that a nationwide standard that prohibits the manufacture and sale of menthol cigarettes would likely have a greater impact in increasing cigarette smokers' quit attempts and quitting smoking compared to that observed from policies from limited jurisdictions, because a nationwide product standard would eliminate the manufacture of these

products as well as the opportunity to easily travel to neighboring jurisdictions within the United States that do not have a menthol sales restriction or use online retailers to purchase menthol cigarettes. While the 2020 Surgeon General's Report, "Smoking Cessation", concluded that "the evidence is suggestive but not sufficient to infer that restricting the sale of certain types of tobacco products . . . increases smoking cessation . . .," this assessment was based on empirical evidence published through 2019 (Ref. 245). Numerous studies have been published since the 2020 Surgeon General's Report and were considered in FDA's assessment of the impact of a proposed product standard on cessation. The recently published evaluation studies have examined the impact of menthol sales restrictions in multiple Canadian provinces (Refs. 216, 230, 227, 231–232, 197) and state and local jurisdictions in the United States (Refs. 190–191, 233, 193). When these studies are considered with the evaluation evidence published before 2020, FDA concludes that there is substantial evidence of increases in quit attempts and quitting by adult smokers after a menthol cigarette sales restriction (Refs. 77, 197, and 193). Further, recent longitudinal data from the PATH study and a systematic review of the literature all indicate that menthol cigarette smoking is associated with reduced cessation success compared to non-menthol smokers (Refs. 40, 43, and 41). Thus, by banning menthol cigarettes, FDA expects to increase smoking cessation across the population. This is further evidenced by expert elicitation and simulation studies, which assessed and modeled menthol restrictions in the United States, resulting in substantial estimated public health benefits (Refs. 46 and 211). These findings, all more recent than the 2020 Surgeon General's Report, suggest that a menthol ban is appropriate for the protection of the public health.

The sum of the available evidence, including the interaction of menthol and nicotine in the brain, the continued use of menthol cigarettes by millions of Americans, the difficulties of quitting smoking for menthol smokers, and the empirical evidence from policies restricting the sales of menthol cigarettes in Canada and flavored tobacco products in the United States, suggest that the proposed standard would lead many menthol cigarette smokers to stop using cigarettes, yielding considerable health benefits. There are currently more than 18.5 million menthol cigarette smokers ages

12 and older in the United States (Ref. 44). Thus, even small changes in initiation and cessation would result in a significant reduction in the burden of death and disease caused by smoking. Further, given the high concentration of menthol cigarette smoking among underserved communities, the effect of the standard on reducing cigarette smoking would be expected to be greater in these populations. From the expected public health impact on current adult menthol cigarette smokers alone, this proposed product standard is appropriate for the protection of the public health.

As discussed in section III.B.4 of this document, FDA intends to work with HHS to enlist and collaborate with other entities at the Federal, Tribal, State, and local levels who provide support to menthol smokers who quit or want to quit as a result of a prohibition of menthol as a characterizing flavor in cigarettes going into effect.

C. Benefits and Risks to the Population as a Whole

We expect that the proposed menthol product standard, if finalized, would reduce tobacco-related harms. As discussed in section IV of this document, the addition of menthol as a characterizing flavor to cigarettes makes it easier to start smoking, easier to continue smoking, and harder to quit smoking. By prohibiting the addition of menthol as a characterizing flavor to cigarettes sold in the United States, FDA anticipates that reductions in population harm would be realized through long-term health benefits resulting from prevention of cigarette uptake and progression to regular cigarette smoking among youth and young adults, as described in section V.A of this document, as well as shorter-term health benefits resulting from increased cessation of cigarette smoking among current menthol smokers, as described in section V.B of this document. Each of these impacts alone would result in significant health benefits to the U.S. population. In totality, they provide overwhelming evidence that the proposed standard would result in substantial health benefits over both the short- and long-term. In this section, we summarize the health benefits of never progressing to regular cigarette smoking, the health benefits of quitting smoking, the potential health benefits of switching from cigarettes to potentially less harmful tobacco products, and the health benefits of not being exposed to secondhand smoke. We also describe findings from population modeling studies that estimate the public health

impact of the proposed standard. Finally, we describe potential risks of the product standard, including risks of countervailing effects of the tobacco standard such as increasing demand for contraband.

1. Given the Harmful Effects of Cigarette Smoking, Never Progressing to Regular Smoking Prevents Death and Disease

Never progressing to regular cigarette smoking prevents death and disease caused by smoking. Any effects of a menthol ban on preventing youth, young adult, and even adult never smokers from initiating/experimenting and progressing to regular cigarette smoking will have a population health benefit. According to the 2014 Surgeon General's Report, "The Health Consequences of Smoking: 50 Years of Progress", which summarizes thousands of peer-reviewed scientific studies and is itself peer-reviewed, smoking remains the leading preventable cause of death in the United States, and cigarettes have been shown to cause an ever-expanding number of diseases and health conditions (Ref. 1). As stated in the report, "cigarette smoking has been causally linked to disease of nearly all organs of the body, to diminished health status, and to harm to the fetus" and "[t]he the burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products" (Ref. 1 at 37).

The 2014 Surgeon General's Report estimates that 16 million people live with diseases caused by smoking cigarettes (Ref. 1). Comparing mortality to morbidity, for every person who dies from smoking, 30 more are living with a smoking-attributable disease (Ref. 1). Smoking is causally associated with a number of diseases affecting nearly all organs in the body, such as numerous types of cancer, heart disease, stroke, lung diseases such as chronic obstructive pulmonary disease, and diabetes, in addition to putting individuals at increased risk for tuberculosis, certain eye diseases, and immune system issues (Ref. 1). Furthermore, maternal smoking is causally associated with multiple adverse fetal outcomes, including fetal growth restriction and low birth weight, premature rupture of the membranes, placenta previa, placental abruption, preterm birth, preeclampsia, reduction of lung function in infants, and sudden infant death syndrome (SIDS) (Ref. 1).

A study using 2006–2012 data from the NHIS estimated that 6.9 million U.S. adults had a combined 10.9 million self-reported smoking-attributable medical conditions, highlighting that smoking

cigarettes often causes co-morbid diseases (Ref. 246). The study noted that the morbidity estimates are likely underestimates due to underreporting of diseases in surveys and the lack of assessment of several major medical conditions (Ref. 246). Thus, it is likely that the true morbidity burden in the United States is substantially more than these estimates.

An analysis of the National Longitudinal Mortality Study, a longitudinal population-based, nationally representative health survey with mortality data from the National Death Index, found that exclusive regular cigarette smokers had substantially higher all-cause mortality risks than never tobacco users (Ref. 247). Another analysis, which examined NHIS data, found that life expectancy was shortened by more than 10 years among current cigarette smokers, compared with those who had never smoked (Ref. 248). Even non-daily smokers have higher mortality risk than never smokers. A recent study pooled data from the 1991, 1992, and 1995 NHIS and were linked to data from the National Death Index through 2011 (Ref. 249). The study indicated that lifelong non-daily smokers, who had smoked cigarettes on a median of 15 days and 50 cigarettes per month, had a 72 percent higher overall mortality risk resulting in about a 5-year shorter lifespan, than never smokers (Ref. 249). The study also found a gradient in number of cigarettes smoked among non-daily users, with higher mortality risks observed among lifelong non-daily smokers who reported 31–60 cigarettes per month and more than 60 cigarettes per month than never smokers, but no difference among those who smoked 11–30 cigarettes per month (Ref. 249). Daily smokers in the study had an even higher mortality risk and shorter survival (about 10 years less) than never smokers (Ref. 249).

As previously discussed, menthol cigarette smoking facilitates progression to regular cigarette smoking among youth and young adults. African American smokers are more likely than smokers from other racial and ethnic groups to try a menthol cigarette as their first cigarette, regardless of age (Refs. 33, 25, and 31). FDA anticipates that a menthol restriction will prevent a substantial number of youth, and especially Black youth, from initiating menthol cigarette smoking, thereby decreasing progression to regular cigarette smoking, resulting in reduced tobacco-related morbidity and mortality associated with menthol cigarette smoking.

2. Given the Harmful Effects of Cigarette Smoking, Quitting Smoking Reduces Death and Disease

Quitting cigarette smoking, including menthol cigarettes, substantially reduces the likelihood of tobacco-related death and disease. As stated in the 2004 Surgeon General's Report, "[q]uitting smoking has immediate as well as long-term benefits, reducing risks for diseases caused by smoking and improving health in general" (Ref. 250). The 2020 Surgeon General's Report also concluded, "[s]moking cessation is beneficial at any age. Smoking cessation improves health status and enhances quality of life." (Ref. 245). As previously noted, FDA expects that, if this proposed rule is finalized, there will be a significant increase in smoking cessation in the U.S. population (see section V.B).

The benefits associated with smoking cessation happen quickly (Ref. 250). Within 2 to 12 weeks of quitting smoking, an individual's lung function and blood circulation improve (Ref. 250). During the first 1 to 9 months after cessation, coughing and shortness of breath decrease (Ref. 250). Within several months of quitting smoking, individuals can expect improvement in lung function (Ref. 250).

The benefits continue for those who remain smoke-free. Smoking cessation reduces the risk of cancers and other diseases (Ref. 245). For example, the risk of fatal lung cancer in adults over 55 is about 25 times higher among smokers relative to people who have never smoked (Ref. 251). After 10–15 years of abstinence from smoking, the risk of lung cancer is about 50 percent of the risk for individuals who continue to smoke (Ref. 245). The risk of cancer of the mouth, throat, esophagus, stomach, bladder, cervix, pancreas, liver, kidney, colon, rectum, and the risk of acute myeloid leukemia also decreases (Refs. 252 and 245). The evidence is also sufficient to infer that the risk of stroke decreases after smoking cessation, and approaches that of never smokers over time (Ref. 245). Furthermore, the evidence is sufficient to infer that the relative risk of coronary heart disease among former smokers compared with never smokers falls rapidly after cessation and then declines more slowly (Ref. 245).

Even smokers who quit smoking after the onset of life-threatening disease experience health benefits from cessation. Quitting smoking after a diagnosis reduces the chance of recurrences and future health problems. For example, people who quit smoking after having a heart attack can reduce

their chances of having a second heart attack by 50 percent (Ref. 252). For those persons who have already developed cancer, quitting smoking reduces the risk of developing a second cancer (Refs. 253–256). Additionally, quitting smoking after a diagnosis of lung cancer reduces the risk of cancer progression and mortality (Ref. 257). Researchers also estimate that for current smokers diagnosed with coronary heart disease, quitting smoking reduces the risk of death overall, and reduces the risk of recurrent heart attacks and cardiovascular death by 30 to 40 percent (Refs. 245 and 256). The 2020 Surgeon General's Report concluded that quitting smoking reduces the risk of fatal stroke, and earlier reports have also said that it is reasonable to assume that quitting smoking would reduce the risk of recurrent strokes (Refs. 245 and 256). Quitting smoking also helps the body tolerate the surgery and treatments, such as chemotherapy and radiation, associated with certain smoking-related diseases (Refs. 250, 253, 256, 258) and reduces the risk of respiratory infections compared to continued smoking (Refs. 256 and 259).

Given the reduction in risk of smoking-related death and disease associated with cessation, those who successfully quit smoking increase their life expectancy. Using data from the Cancer Prevention Study II (CPS II), an ongoing study of 1.2 million adults, scientists have found that men who smoked at 35 years old and continued to smoke until death had a life expectancy of 69.3 years, compared with a life expectancy of 76.2 years for those who stopped smoking at age 35 (Ref. 260). After adjusting for the subsequent quit rate among current smokers at baseline (to account for the possibility that some current smokers at baseline quit smoking or some former smokers relapsed during followup and, thus, were incorrectly classified as continuing smokers in the unadjusted analysis), the life expectancy for male former smokers increased to 77.8 years (a life extension of 8.5 years) (Ref. 260). Women who smoked at 35 years old and continued to smoke until death had a life expectancy of 73.8 years, compared with a life expectancy of 79.7 years for those who stopped smoking at age 35 (Ref. 260). After adjustment for the subsequent quit rate among current smokers at baseline, the life expectancy for female former smokers increased to 81 years (a life extension of 7.7 years) (Ref. 260). Further, a man aged 60 to 64 who smokes 20 cigarettes (one pack) or more per day and then quits smoking

reduces his risk of dying during the next 15 years by 10 percent (Ref. 256).

While cessation is beneficial for all ages, the health benefits are greatest for people who stop smoking at earlier ages (Refs. 256 and 250). Scientists in the United Kingdom found those who quit smoking at age 30 reduce their risk of dying prematurely from smoking-related diseases by more than 90 percent (Refs. 261 and 262). Those who quit at age 50 reduce their risk of dying prematurely by 50 percent compared to those who continue to smoke (Ref. 262). Using data from the NHIS, researchers also estimated that life expectancy in the United States would increase 4 years among smokers quitting cigarettes at 55 to 64 years of age, and 10 years among smokers quitting cigarettes at 25 to 34 years of age (Ref. 248). Scientists using the CPS II data (while accounting for the possibility that some current smokers at baseline quit smoking and some former smokers relapsed during followup) found that even smokers who quit at age 65 had an expected life increase of 2 years for men and 3.7 years for women (Ref. 260).

As discussed previously, there is a lower quit rate among smokers of menthol cigarettes than there is for non-menthol cigarettes. FDA anticipates that prohibiting menthol as a characterizing flavor in cigarettes would improve smoking cessation outcomes in adult smokers and result in longer life expectancies for more individuals. Additionally, FDA anticipates that this proposed product standard will benefit vulnerable populations by reducing tobacco-related morbidity and mortality by improving quitting and cessation among these populations. As previously discussed, the role of menthol in cigarettes in reducing cessation success among smokers is more pronounced among certain population groups, in particular, among Black smokers. Additionally, research has shown that cigarette smokers from underserved communities bear a disproportionate burden of tobacco-related morbidity and mortality. African Americans, and in particular African American men, experience the highest rates of incidence and mortality from tobacco-related cancers compared to people from other racial and ethnic groups (Refs. 263 and 264). Additionally, mortality due to tobacco-related disease such as heart disease, stroke, and hypertension is higher among African Americans compared to other racial and ethnic groups (Refs. 265–270, 50). Furthermore, as previously discussed, compared to White smokers, Black smokers report they may be more likely to quit smoking altogether if menthol

cigarettes were unavailable following a menthol restriction (Refs. 214, 215, and 217). Based on these collective findings, FDA anticipates that the proposed product standard will improve smoking cessation outcomes among vulnerable populations, in particular, Black smokers, leading to a reduction in adverse tobacco-related health effects in these populations.

3. Given the Harmful Effects of Cigarette Smoking, Switching to a Potentially Less Harmful Nicotine Delivery Product May Reduce Death and Disease

FDA recognizes that smokers who choose to switch completely to a potentially less harmful nicotine delivery product to maintain their nicotine dose also could, to the extent that those products result in less harm, significantly reduce their risk of tobacco-related death and disease (Ref. 271). The least harmful nicotine delivery products available to smokers are the pharmaceutical nicotine replacement therapies already approved by FDA as both safe and effective cessation tools, many of which are available in a variety of flavors, including mint, which could appeal to menthol smokers. However, smokers may also transition to tobacco products which utilize other forms of nicotine delivery in place of smoking combusted cigarettes. These include smokeless tobacco, dissolvable products, and ENDS products, among others.

In surveys, some menthol cigarette smokers and some dual users of menthol cigarettes and ENDS report intending to use ENDS if menthol cigarettes were no longer available (Refs. 221, 272, and 222). Experimental marketplace studies also suggest that, in addition to taking other actions, some menthol smokers may switch partially or fully to ENDS in the event of a menthol cigarette ban (Refs. 273 and 225). These empirical findings are consistent with the 2020 Surgeon General's Report, titled "Smoking Cessation," and several systematic reviews, which suggest that some adult cigarette smokers report using ENDS to try to reduce or quit smoking (Refs. 245, 274–276). The literature also suggests that cigarette smokers who use ENDS more frequently (versus less frequently) have improved success in switching, however the long-term patterns of use remain unknown (Refs. 271, 277–279).

In an expert elicitation study estimating effects of a menthol ban on transitions in use, the panel of experts estimated that among menthol smokers aged 35 to 54 years, 55.1 percent would remain combustible tobacco users (a reduction of 20.1 percent from the status

quo), with another 20 percent switching to a "novel nicotine delivery product," defined in the study as ENDS or heated tobacco products (HTPs) (a 10.3 percent increase from the status quo), and about 22.5 percent quitting all tobacco use (a 10.0 percent increase from the status quo) (Ref. 211). Additionally, the experts estimated that among those aged 12 to 24 years who would have initiated as menthol cigarette smokers, under the menthol ban, 41.1 percent would still initiate combustible tobacco use (including non-menthol cigarettes, cigars, or illegal menthol cigarettes), while 17.6 percent would instead initiate with a "novel nicotine delivery product," such as ENDS or HTPs; the result is a 58.9 percent reduction in combustible tobacco initiation from the status quo (Ref. 211). Additional details of the expert elicitation study and resulting population model study can be found in section V.C.5 of this document.

Data from the 2017 Ontario menthol sales restriction did not show increases in menthol smokers' self-reported use of e-cigarettes (Ref. 280) or increases in retail sales of e-cigarettes (Ref. 231) following policy implementation. To the extent that this may occur following implementation of this product standard, FDA recognizes that completely switching from combusted tobacco products to ENDS has the potential to reduce some tobacco-related disease risks among individual users (Ref. 271). However, cessation of all tobacco products leads to the greatest reduction in tobacco-related disease and death (Ref. 245).

4. Having Fewer People Smoke Cigarettes Will Reduce Smoking-Related Death and Disease Associated With Secondhand Smoke Exposure

Secondhand smoke exposure is harmful to the health of non-smokers. The 2006 Surgeon General's Report, "The Health Consequences of Involuntary Exposure to Secondhand Smoke," concluded that "secondhand smoke exposure causes premature death and disease in children and in adults who do not smoke" (Ref. 281). Exposure to secondhand smoke is a cause of cancer and respiratory and cardiovascular disease (Ref. 1). According to the 2014 Surgeon General's Report, more than 437,000 premature deaths per year are caused by active cigarette smoking, and an additional 41,280 premature deaths among adults aged 35 years and older are due to secondhand smoke (Ref. 1). Specifically, the 2014 Surgeon General's Report estimated secondhand smoke causes approximately 7,330 deaths from lung cancer and 33,950 deaths from

coronary heart diseases in non-smokers annually (Ref. 1).

Secondhand smoke is particularly harmful to children. The 2014 Surgeon General's Report estimated that secondhand smoke is associated with 150,000 to 300,000 lower respiratory tract infections in infants and children under 18 months of age, 790,000 doctor's office visits related to ear infections per year, and 202,000 asthma cases each year (Refs. 282 and 1). In 2014, the Surgeon General reported 400 SIDS deaths related to perinatal smoking or exposure to secondhand smoke; the "Reproductive Outcomes" section describes the impact of perinatal smoking (Ref. 1). Children of parents who smoke, when compared with children of nonsmoking parents, have an increased frequency of respiratory infections like pneumonia and bronchitis (Ref. 256). Children exposed to tobacco smoke in the home are also more likely to develop acute otitis media (middle ear infections) and persistent middle ear effusions (fluid behind the eardrum) (Ref. 256).

More recent data from the 2013–2014 NHANES estimates that approximately 58 million American non-smokers (1 in 4) were exposed to secondhand smoke, including 14 million children (Ref. 283). Approximately half of all U.S. children aged 3 to 18 years are exposed to cigarette smoke regularly at home or other locations that still permit smoking (Ref. 1). In 2019, approximately one-quarter of middle and high school students reported breathing in secondhand smoke in their homes or in a vehicle (Ref. 284).

The burden of secondhand smoke exposure is experienced disproportionately among members of some racial or ethnic groups and lower income groups. Among nonsmokers age 3 and older, findings from 2011–2018 NHANES data indicate that non-Hispanic Black persons and those living below the poverty level had the highest levels of secondhand smoke exposure compared to people of other races and those living above the poverty level, respectively; these disparities persisted across all years of the study analysis from 2011 to 2018 (Ref. 285). From 1999 to 2012, the percentage of the nonsmoking population age 3 and older exposed to secondhand smoke (defined in the study as levels 0.05–10 ng/mL) declined across all racial and ethnic groups (Ref. 286). However, a significantly higher proportion of non-Hispanic Black nonsmokers continued to have detectable serum cotinine levels, compared to Mexican American and non-Hispanic White nonsmokers. For example, in 2011–2012, nearly 50

percent of non-Hispanic Black nonsmokers had detectable serum cotinine levels, compared with 22 percent of non-Hispanic White and 24 percent of Mexican American nonsmokers (Ref. 286).

Disparities in the secondhand smoke exposure are found across various environmental settings. These disparities speak to the interrelated influences of individual factors (*e.g.*, age, race and ethnicity, income) and existing inequities in places where members from underserved communities are likely to reside, spend time, and work (Ref. 49). Findings drawn from the 2013–2016 NHANES data indicate that compared to non-Hispanic Whites, non-Hispanic Blacks had higher odds of secondhand smoke exposure in homes other than their own (Ref. 27). An analysis of NYTS data indicates that non-Hispanic Black and non-Hispanic White students both had higher prevalence of secondhand smoke exposure at home and in vehicles than Hispanic and non-Hispanic other students (Ref. 284). While secondhand smoke exposure in homes and vehicles significantly declined from 2011 to 2018, secondhand smoke exposure in homes among non-Hispanic Black students did not change (Ref. 284). Home smoking bans (or household rules that restrict or ban smoking inside the home) can reduce secondhand smoke exposure. A study using 1995–2007 data from the TUS–CPS found that among two parent households, higher levels of parental educational level, higher levels of annual household income, and both parents being Hispanic, non-Hispanic, Other race, or other combinations of parents of different race/ethnicities were associated with the higher reporting of a complete home ban as compared to lower levels of parental educational, lower levels of annual household income, and both parents being non-Hispanic White, respectively (Ref. 287). Such findings are consistent with a higher degree of autonomy over home environment for households with greater economic resources and housing flexibility, emphasizing the degree to which certain aspects of disadvantage (such as lower family income, lack of access to single-family housing, or lack of autonomy over the home environment) may compound tobacco-related health disparities. Workplace secondhand smoke exposure has also been shown to vary across population groups. Data from the 2010 and 2015 NHIS show that exposure to secondhand smoke in the workplace was disproportionately high among non-Hispanic Blacks, Hispanics, and

workers with low education and low income (Ref. 288). Additionally, the study findings indicated that “blue-collar workers” (defined as those who performed manual labor such as manufacturing, mining, sanitation, and construction) experienced higher prevalence of secondhand smoke exposure as compared to “white-collar workers” (defined as those who primarily work in an office, with computer and desk setting, and perform professional, managerial, or administrative work) (Ref. 288). The proposed product standard is anticipated to reduce smoking-related morbidity and mortality for these vulnerable populations, especially youth.

FDA expects that the proposed menthol product standard would reduce the number of smokers and decrease non-smokers’ exposures to secondhand smoke. As evidenced by evaluations of smoke-free policies, decreasing exposure to secondhand smoke will reduce exposure to tobacco smoke pollution and decrease smoking-related death and disease (Refs. 289 and 290).

5. Results From Simulation Models Are Consistent With the Findings That Prohibiting Menthol Cigarettes Would Benefit the Population’s Health

The population health benefit of prohibiting menthol cigarettes has been examined in several simulation studies conducted in the past decade (Refs. 46, 211, 291, 45). A 2021 study by Levy et al. simulated the future benefit of a menthol cigarette ban on the U.S. population as a whole over the 2021–2060 period (Ref. 46). This model compared a *Status Quo Scenario*, in which no menthol ban was implemented, to a simulated *Menthol Ban Scenario* in which a complete ban on menthol cigarettes and cigars was implemented in 2021.¹² Additionally, as part of the model, it took into account the use of ENDS products (“nicotine vaping products”) by smokers and non-

smokers over the study period (Refs. 46, 211, and 291).

The simulation used the Smoking and Vaping Model (SAVM), a model capable of simulating the population health effects of cigarette smoking and ENDS use for specific birth cohorts. For this study, the model was extended to evaluate non-menthol and menthol cigarettes separately, with the following use states captured in the model compartments: (1) Never users, (2) menthol smokers, (3) non-menthol smokers, (4) exclusive ENDS users, (5) former smokers using ENDS, (6) former smokers, and (7) former ENDS users.

The SAVM first utilized historical data from the NHIS (1965–2013) for estimates of smoking prevalence (specific model inputs can be found in the manuscript) (Refs. 46, 211, and 291). The model projected prevalence estimates of never, current, and former smoking by age and gender beginning in 2013. The model was then recalibrated using 2013–2018 NHIS data to improve model estimates of smoking prevalence after ENDS products became more widely available around 2013. Next, age- and gender-specific rates of smoking initiation (*i.e.*, any initiation of regular cigarette smoking by age 40) and cessation (*i.e.*, cessation of regular cigarette smoking for 2 years, including those who temporarily use ENDS but ultimately quit all tobacco use), cigarettes-to-ENDS switching (*i.e.*, cessation of regular cigarette smoking with initiation of regular ENDS smoking), and initiation of ENDS use (*i.e.*, initiation of regular ENDS use without regular cigarette smoking) were modeled using PATH Study data, with separate rates of initiation, cessation and switching for menthol and non-menthol smokers. To simplify the model, dual users of cigarettes and ENDS were not modeled separately from current smokers. Smokers who switched to ENDS before age 35 were treated the same as exclusive ENDS users, while smokers who switched to ENDS age 35 or later were considered separately as former smokers using ENDS.

Additionally, the transitions modeled were unidirectional; relapse (*i.e.*, reinitiating regular cigarette smoking or ENDS use after entering any group containing former smokers/users) was not considered in the model. Although age- and gender-specific effects were modeled, other sources of population heterogeneity, such as race, ethnicity, socioeconomic status, and geographical location, were not simulated.

Based on PATH Study data and other publications, the ratio of menthol to non-menthol cessation was modeled as 0.8 and the ratio of menthol to non-

¹² The *Menthol Ban Scenario* models a ban of menthol in cigarettes and cigars, but includes only the benefits attributed to the menthol cigarette ban. Cigars are covered in the model because it is assumed that menthol cigarette smokers could simply switch to menthol cigars if a menthol cigarette ban was put in place and if menthol cigars were still available. FDA’s expectation is that, even if menthol was not prohibited as a characterizing flavor in cigars, this rule would still reduce initiation and experimentation of cigarette smoking, decrease nicotine dependence and addiction, and increase cessation among current menthol cigarette smokers. However, since FDA is concurrently pursuing a proposed rule, published elsewhere in this issue of the *Federal Register*, that would prohibit characterizing flavors (other than tobacco) in cigars, the *Menthol Ban Scenario* is directly applicable.

menthol switching was modeled as 0.9, in effect modeling menthol cigarette smokers as 20 percent less likely to quit smoking and 10 percent less likely to switch to ENDS than non-menthol smokers (Refs. 46 and 211). Based on PATH Study data, all cigarettes-to-ENDS switching was assumed to decline 10 percent annually from 2018. The excess relative risk of mortality for ENDS products compared to cigarettes was set at 0.15, in effect modeling the mortality risk of ENDS use as 15 percent of the mortality risk of cigarette smoking over the same period.

To estimate the specific effects of a menthol ban on current and future tobacco use, an expert elicitation (EE) was conducted (Ref. 211). The EE used a systematic approach to identify eleven leading academic experts on topics related to the impacts of menthol flavor bans in tobacco products. Experts estimated a number of behaviors under a menthol ban, such as continued (illicit) menthol product use, menthol to non-flavored product switching, switching to other nicotine products (e.g., ENDS, smokeless tobacco products), and tobacco cessation. These estimates were adapted to fit the simpler structure of the SAVM. For example, transitions from cigarettes to HTPs were treated as transitions to ENDS, while transitions from menthol cigarettes to non-menthol cigars were treated as a transition to non-menthol cigarettes. Transitions to smokeless tobacco products were also treated as transitions to non-menthol cigarettes. Experts estimated the effects of a menthol ban for youth and young adults ages 12–24 who would otherwise have initiated menthol smoking by age 24 (i.e., counterfactual menthol smokers), which were used to calculate the ongoing initiation rates beginning with the simulated ban in 2021 in the *Menthol Ban Scenario*. Among menthol smokers in both the *Status Quo Scenario* and *Menthol Ban Scenario*, experts estimated transitions over a 2-year period for ages 18–24 and 35–54, which were modeled as mean net differences applied to menthol smokers up to age 30 and over age 30, respectively. The ban was assumed to have no effects on non-menthol smokers. In the expert elicitation study, it is likely that when the experts were answering survey questions around tobacco use behaviors under a future menthol ban, they considered the products available in the market at the time. The marketplace of products may change over time due to a variety of reasons, and it is possible that changes in the marketplace, if known, may impact experts' judgements

about how menthol smokers and non-users at risk for initiation may act in response to a menthol ban.

The model estimated smoking-attributable deaths averted and life-years lost averted over the 2021–2060 period (Ref. 46). Compared to the *Status Quo Scenario*, in which no menthol ban was implemented, under the *Menthol Ban Scenario* the estimated overall smoking prevalence declined 14.7 percent by 2026 and 15.1 percent by 2060. This overall decrease was due to a sharp reduction in menthol smoking (down 92.5 percent by 2026, and 96.5 percent by 2060), coupled with a smaller increase in non-menthol smoking (up 47.4 percent by 2026, and 58.0 percent by 2060) over the same time period. The ban was also estimated to increase ENDS use 22.6 percent by 2026, up to a 26.5 percent relative increase by 2060. Totaling the effects, the model estimated 654,000 premature deaths and 11,300,000 life-years lost averted by 2060.

The study authors also conducted several sensitivity analyses to determine which model parameters had the greatest influence on outcome estimates (Ref. 46). Increasing the ratio of menthol to non-menthol cessation rate from 0.8 to 1.0, in effect making menthol cigarettes no harder to quit than non-menthol cigarettes, had the greatest impact on the model estimates, resulting in decreasing deaths averted by 29.5 percent (to 461,000) and life-years lost averted by 24.2 percent (to 8.58 million). Eliminating the 10 percent annual declines in cigarette-to-ENDS switching from the model, in effect increasing the appeal of complete switching for smokers in later years of the model, reduced deaths averted by 20.5 percent (to 520,000) and life-years lost averted by 21.9 percent (to 8.83 million). Other sensitivity analyses included 10 percent absolute increases and decreases in the excess relative risk of ENDS products to cigarettes, and 10 percent relative changes in smoking initiation, smoking cessation, time-independent cigarette-to-ENDS switching, ENDS initiation, and ENDS cessation. All of these sensitivity analyses resulted in modest (under 10 percent) changes to model-predicted deaths and life-years lost averted.

In addition to the SAVM study, a 2011 study by Levy et al. that simulated the future benefit of a menthol cigarette ban was also consistent with the findings of other studies. This study estimated potential impacts of a U.S. menthol ban on future smoking prevalence and smoking attributable mortality for the total population, and for African Americans specifically (Ref.

45). The model used data from the 2003 TUS–CPS to characterize current smoking status, initiation and cessation rates by cigarette type, various other sources to characterize smoking relapse rates, and CPS II to characterize mortality risks, which were treated as equivalent for menthol and non-menthol smokers. The analysis simulated the 2010–2050 period, with a menthol ban going into effect in 2011. The study compared three menthol ban scenarios against a status quo scenario with no menthol ban:

1. 10 percent of menthol smokers quit permanently and 10 percent who would have initiated as menthol smokers do not take up smoking.

2. 20 percent of menthol smokers quit permanently and 20 percent who would have initiated as menthol smokers do not take up smoking, and

3. 30 percent of menthol smokers quit permanently and 30 percent who would have initiated as menthol smokers do not take up smoking.

The study estimated that by 2050, under these menthol ban scenarios, 324,000 (scenario 1) to 634,000 (scenario 3) smoking attributable deaths would have been averted in the United States overall, while relative declines in smoking prevalence were expected to range from 4.8 percent to 9.7 percent, under scenarios 1 and 3, respectively. Among African Americans, by 2050, an estimated 92,000 to 238,000 smoking attributable deaths would have been prevented, while relative declines in smoking prevalence ranged from 9.1 percent to 24.8 percent (under scenarios 1 and 3, respectively) (Ref. 45).

In conclusion, population health models simulating menthol ban policies are consistent with a substantial public health benefit. The 2021 simulation by Levy et al., using the SAVM model, estimated approximately 650,000 premature deaths averted and 11.3 million life-years lost averted in the first 40 years of a menthol cigarette and cigar ban beginning in 2021 (Refs. 46, 211, and 291). The prevalence of smoking was also estimated to decline 15.1 percent in that period. Sensitivity analyses demonstrated that lower cessation among menthol smokers compared to non-menthol smokers was a notable driver of the public health impact of the simulated menthol ban. The overall findings were consistent with the 2011 simulation by Levy et al. that estimated 324,000–634,000 premature deaths averted under a similar ban and time period (Ref. 45).¹³

¹³ The Further Consolidated Appropriations Act, 2020, made it unlawful for any retailer to sell a

6. Public Health Benefits Not Addressed in the Smoking and Vaping Model

While the SAVM projections of the potential impact from a menthol product standard suggest a significant public health benefit to the United States resulting from substantial reductions in smoking prevalence, these analyses do not address other additional benefits.

First, the SAVM simulation does not account for increased quality of life from decreased tobacco-related morbidity. The Surgeon General has reported that about 30 individuals will suffer from at least one smoking-related disease for every person that dies from smoking each year (Ref. 245). Researchers in one study estimated that individuals are living with 14 million major smoking-related conditions in the United States, including more than 7.4 million cases of chronic obstructive pulmonary disease, nearly 2.3 million heart attacks, 1.8 million cases of diabetes, nearly 1.2 million stroke events, more than 300,000 cases of lung cancer, and nearly 1 million cases of other smoking-attributable cancers (bladder, cervix, colon/rectum, kidney, larynx, mouth, tongue, lip, throat, pharynx, stomach) (Ref. 246). Another study, which examined disparities in tobacco-related cancer incidence and mortality, found that tobacco-related mortality decreased between 2004 and 2013, however tobacco-related cancer incidence and mortality rates remain highest among African Americans, accounting for more than 39,000 deaths annually between 2009 and 2013 (Ref. 293). Cigarette smoking, in addition to causing disease, can diminish overall health status, leading to higher risks for surgical complications, including wound healing and respiratory complications, increased absenteeism from work, and greater use of health care services (Ref. 1). Increased smoking cessation, reduced cigarette consumption, and lower progression to regular cigarette smoking would reduce not only the mortality from smoking, but it also would reduce the enormous burden of cigarette-attributable disease in the United States.

tobacco product to any person younger than 21 years of age (Pub. L. 116–94, section 603 (2019)). The quantitative estimates of the impact of a menthol ban on premature mortality presented in these studies do not take into account the impact of T21. However, given the long lag period between smoking initiation and premature mortality from smoking, any impact of T21 on the mortality benefits described in this rule would not be observed for decades into the future. See section II.C.4.a of the Preliminary Regulatory Impact Analysis (PRIA) for a discussion of T21 impacts on premature smoking-attributable deaths averted (Ref. 292).

Second, the SAVM simulation does not account for the public health impacts of reduced secondhand smoke exposure. Exposure to secondhand smoke is a cause of cancer, respiratory, and cardiovascular disease (Ref. 1). Secondhand smoke exposure is currently estimated to be responsible for over 41,000 deaths annually in the United States (Ref. 1). Reducing secondhand smoke exposure through increased smoking cessation, reduced cigarette consumption, and lower progression to regular cigarette smoking would reduce the more than 7,300 lung cancer deaths and nearly 34,000 coronary heart disease deaths annually attributed to secondhand smoke (Ref. 1). Exposure to secondhand smoke can also cause adverse health effects in infants and children. Exposure to cigarette smoke among children and adolescents can trigger asthma attacks and lead to more frequent respiratory infections compared to those not exposed to smoke (Ref. 1). Prenatal tobacco exposure and postnatal secondhand smoke exposure increase the risks of fetal deaths, fetal growth restriction/low birth weight, respiratory conditions, and SIDS (Ref. 1).

Third, the SAVM simulation does not isolate differential effects as experienced by vulnerable populations. Menthol cigarette use, and the disease and death linked to such use, is disproportionately high among members of vulnerable populations such as African Americans and other racial and ethnic groups, those with lower household income, and those who identify as LGBTQ+ (Refs. 55–57, 21–24, 44). As a result, a menthol restriction is expected to confer larger benefits among these vulnerable populations by promoting improved public health outcomes. For example, studies have shown that after switching to non-menthol cigarettes, Black menthol smokers had greater reductions in cigarettes per day when compared to non-Black menthol smokers (Ref. 217). In comparison to White smokers, a higher prevalence of Black smokers report they would not smoke a non-mentholated cigarette if they could not smoke a mentholated cigarette (Ref. 214), a higher prevalence of Black menthol smokers reported intentions to quit following a menthol restriction (Refs. 219 and 215), and Black menthol smokers had lower odds of reporting that they would switch to a non-menthol brand (Ref. 213). Prior modeling has shown that by 2050, following a 2011 menthol ban, an estimated 92,000 to 238,000 smoking attributable deaths among African

Americans would have been prevented, comprising almost one-third of the total deaths averted by the ban (Ref. 45). The relative reduction in African Americans' smoking prevalence in 2050 was also projected to range between 9.1 and 24.8 percent compared to the status quo of no menthol ban (Ref. 45).

Finally, the analysis does not account for reductions in harms caused by smoking-related fires. Lower prevalence of cigarette smoking, and reduced cigarette consumption are likely to decrease the occurrence of fires caused by smoking materials, including cigarettes and other lighted tobacco products. Even though all states have instituted laws requiring fire-safety-compliant cigarette paper (adoption began in 2003 with all states adopting these laws by 2012), smoking remained the second leading cause of residential fire deaths in the United States in 2018 (Ref. 294). In 2011, an estimated 90,000 fires in the United States were caused by smoking materials, of which 17,600 occurred in the home (Ref. 295). Between 2012 and 2016, there were an average of 18,100 home structure fires per year started by smoking material, accounting for around 1 in 20 of all home fires (5 percent) (Ref. 296). The fatality rate for smoking-related residential building fires is seven times greater than for nonsmoking related fires (Ref. 297). Moreover, smoking materials remain the leading cause of fatal home fires in the United States and smokers themselves are not the only victims (Refs. 295 and 296). One out of every four fatal victims of smoking-material fires were not the smoker whose cigarette initiated the fire (Ref. 298). Reductions in smoking as a result of the proposed standard are likely to have an impact on the 590 deaths and over 1,100 injuries from smoking-attributable structure fires (Ref. 296).

We note that, while the impact of a proposed rule prohibiting menthol as a characterizing flavor in cigarettes is likely to be sizable, there is uncertainty in precisely quantifying the effects. Although the exact magnitude of the effects of the proposed ban are uncertain, because of the sheer number of smokers currently using menthol cigarettes—an estimated 18.5 million persons ages 12 and older (Ref. 44)—even modest decreases in the percentage of the population initiating smoking and increases in the percentage of the population quitting smoking would save many lives.

7. Potential Risks to the Population as a Whole of the Proposed Menthol Product Standard Would Not Outweigh the Potential Benefits of the Proposed Product Standard

There are possible countervailing effects that could occur from the proposed product standard, if finalized. Potential risks to the population, however, would generally only occur among individuals currently using tobacco or smoking cigarettes as FDA concludes there are little to no risks to nonusers of tobacco. These potential risks do not offset the anticipated benefits of the rule. The countervailing effects on current tobacco users could include continued combusted tobacco product smoking, smokers seeking to add menthol to their combusted tobacco product, and the possibility of illicit trade. As part of this rulemaking, FDA is required by the Tobacco Control Act to consider information submitted on such possible countervailing effects, including among vulnerable populations and other population subgroups.

With the removal of menthol cigarettes from the tobacco marketplace, some cigarette smokers may seek other sources of tobacco and/or nicotine. These could include nicotine replacement therapy products, non-menthol cigarettes, other combusted tobacco products, or other potentially less harmful tobacco products. Findings from evaluations of menthol sales restrictions in Canada suggest some users switch to non-menthol cigarettes and flavored combusted tobacco products following a menthol sales restriction (Refs. 226, 231, 230, 216, 193, 197).

FDA acknowledges that the availability of flavored cigars may impact the public health benefits of the proposed rule. FDA's expectation is that, even if menthol is not prohibited as a characterizing flavor in cigars, this rule would reduce initiation of and experimentation with cigarette smoking, decrease nicotine dependence and addiction to cigarettes, and increase the likelihood of cessation among current menthol cigarette smokers. It is also unlikely that all current or potential users of menthol cigarettes would switch to or initiate with menthol cigars. In studies assessing the potential impacts of banning menthol cigarettes, a minority of menthol smokers indicated that they might switch to flavored cigars (Refs. 219, 273, and 225). However, FDA is concurrently proposing a product standard to prohibit characterizing flavors (other than tobacco) in cigars, which would decrease the likelihood

that menthol smokers would switch to cigars as a result of the proposed menthol cigarette standard. Working with others in HHS, FDA is currently exploring options to ensure that smokers who would like to quit cigarettes or would like to quit tobacco product use completely in response to the proposed standard will be aware of and have access to resources that provide cessation support.

FDA recognizes that, while some smokers may switch to non-menthol flavored cigarettes, the risks of this won't outweigh the benefits from smokers who quit smoking completely. FDA has no reason to believe that individuals switching from menthol cigarettes to other combusted tobacco products would be exposed to additional harm beyond their current exposure level. FDA requests comments regarding additional evidence on the extent and magnitude that menthol smokers will switch to other combusted tobacco products.

With the removal of menthol cigarettes from the tobacco marketplace, some users could seek out products that will add menthol to non-menthol cigarettes (e.g., drops, capsules, filter tips for RYO tobacco, or cards that can be inserted into a cigarette pack or pouch of rolling tobacco) (Refs. 226, 299, and 300),¹⁴ which would reduce the benefits of the proposed rule. A study of smokers from Ontario found that, before the menthol sales restriction, 4.4 percent of daily menthol smokers had previously tried flavored additives (including flavor cards, drops, oils, or other additives to add menthol to tobacco) (Ref. 299). One month after the menthol sales restriction in Ontario, 5.1 percent of daily menthol smokers had tried flavored additives, 1 year after 12.5 percent had, and 2 years after 9.5 percent had (Ref. 299). However, products used to alter or affect the cigarette's performance, composition, constituents, or characteristics are components and parts of the cigarette would also be subject to this rule. Thus, to the extent that flavor cards, drops, oils, or other additives that are components and parts of a cigarette contain menthol as a characterizing flavor, such products would be prohibited under proposed § 1162.3. Therefore, FDA does not anticipate a substantial number of individuals would utilize such products.

¹⁴ While we recognize that some smokers could try to add menthol e-cigarette liquids (or e-liquids) to non-menthol cigarettes, we believe that the amount of e-liquid needed to impart a menthol characterizing flavor would make the cigarette unsmokeable.

Even if some people were to modify their non-menthol cigarettes in response to a menthol cigarette prohibition, FDA does not expect this behavior to result in significant additional harm beyond what menthol cigarette smokers are already being exposed to. Furthermore, with many other tobacco products available on the marketplace and the prohibition of products used to alter or affect the cigarette's performance, composition, constituents, FDA does not expect that many individuals would attempt to modify non-menthol cigarettes and thus, FDA does not expect that this potential countervailing effect would significantly reduce the impact of the rule (Ref. 299).

Finally, the removal of menthol cigarettes from the marketplace could result in some people seeking menthol cigarettes through the illicit trade market. FDA is considering whether illicit trade could occur as a result of a menthol product standard and potential implications.

Since the enactment of the Tobacco Control Act, FDA has been committed to studying and understanding the potential effects of a product standard on the illicit tobacco market. As part of FDA's consideration of possible regulations, the Agency asked the National Research Council (NRC) and Institute of Medicine (IOM) of the National Academy of Sciences to assess the international illicit tobacco market, including variations by country; the effects of various policy mechanisms on the market; and the applicability of international experiences to the United States (Ref. 301). In 2015, the NRC/IOM issued its final report titled "Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context, and Lessons from International Experiences" and concluded "[o]verall, the limited evidence now available suggests that if conventional cigarettes are modified by regulations, the demand for illicit versions of them is likely to be modest." (Ref. 301 at 9). In addition, in March 2018, FDA issued a draft concept paper as an initial step in assessing the possible health effects of a tobacco product standard in the form of demand for contraband or nonconforming tobacco products (83 FR 11754). Among other things, the draft concept paper examined the factors that might support or hinder the establishment of a persistent illicit trade market related to a product standard but did not reach any conclusions regarding the potential demand that may develop due to a product standard (Ref. 79).

The recent implementation of local menthol restrictions in the United States and restrictions outside of the United

States provides real-world experience regarding the potential for illicit trade of menthol cigarettes. Evidence from Canada, England, and the United States suggest that the impact of the proposed rule on the illicit market would not be significant (Refs. 302, 226, 224, 216, 200, 209, 191, 303, 197). For example, a study evaluating a restriction on sales of menthol cigarettes in Nova Scotia, Canada found that the policy did not result in an increase in illicit cigarette seized (Ref. 302). The researchers noted that according to local Canadian authorities there were only a few small seizures of menthol cigarettes in the year following the policy (with the nature of the data analyzed indicating that seizures were from businesses only, not individual users, though the study is not clear on this point), and that there were no further seizures of menthol cigarettes after the first year (Ref. 302). Studies asking smokers about their responses to menthol sales restrictions in Canada find a small percentage that continue to use and purchase menthol cigarettes (Refs. 226, 224, and 216). When menthol smokers were asked where they purchased menthol cigarettes after menthol sales restrictions, a majority reported purchasing from First Nations Reserves (54.7 percent), which were generally exempted from the sales restrictions, followed by retail stores (31.0 percent); few reported purchasing menthol cigarettes online (7.5 percent) (Ref. 216). The study, however, was not able to determine the proportion of menthol cigarettes purchased by cigarette smokers post-policy that were contraband (Ref. 216). The authors also noted it is unclear how smokers were able to purchase menthol cigarettes at retail stores and hypothesized that smokers could be reporting the purchase of non-menthol cigarettes that were rebranded as menthol replacements with color on the pack or in the brand name to suggest menthol-like qualities (Ref. 216). Another study of a local Canadian menthol sales restriction found that one month following implementation of Ontario's menthol sales restriction, 14.1 percent of smokers reported using menthol cigarettes purchased from a First Nations reserve, other province, other country, or online (Ref. 226). A study of young adult ever tobacco users in San Francisco found that a small percentage reported purchasing flavored tobacco products illegally in San Francisco (5 percent) and purchasing flavored tobacco products online (15 percent) after the policy; however, this was a

retrospective study with a relatively small convenience sample (Ref. 191).

These results are consistent with the expert elicitation study discussed previously (Ref. 211). In the expert elicitation study, 50.5 percent of menthol smokers were expected to remain combusted tobacco product users, with 40.3 percent becoming non-menthol cigarette smokers, and 3.7 percent becoming non-menthol cigar smokers; however, the experts also estimated that 6.5 percent would continue to use illicit menthol cigarettes (Ref. 211).

Taken together, these studies provide evidence that a major change to the availability of products covered by this proposed rule (see section VII.A) is not likely to lead to a surge in illicit menthol cigarette use. In reaching this conclusion, FDA has considered several factors that are likely to affect the potential for illicit trade. For example, FDA anticipates that a nationwide standard that prohibits the manufacture and sale of menthol cigarettes, coupled with FDA's authority to take enforcement actions and other steps regarding the sale and distribution of illicit tobacco products, would eliminate the manufacture and distribution of these products. FDA also expects that a nationwide product standard would eliminate the opportunity to easily travel to neighboring jurisdictions within the United States that do not have such menthol sales restrictions or use online retailers to purchase menthol cigarettes. FDA thus anticipates that the rule would result in much less illicit trade than observed in the case of a state or local requirement and that any such trade would be significantly outweighed by the benefits of the rule.

If an illicit market develops after this proposed menthol standard is finalized, FDA has the authority to take enforcement actions and other steps regarding the sale and distribution of illicit tobacco products, including those imported or purchased online (see section VII.C of this document for additional information about FDA's enforcement authorities). FDA conducts routine surveillance of sales, distribution, marketing, and advertising related to tobacco products and takes corrective actions when violations occur. After this proposed menthol standard is finalized and goes into effect, it would be illegal to import menthol cigarettes and such products would be subject to import examination and refusal of admission under the FD&C Act. Similarly, it would be illegal to sell or distribute menthol cigarettes, including those sold online, and doing

so may result in FDA initiating enforcement or regulatory actions. We note that the Prevent All Cigarette Trafficking Act of 2009 (PACT Act) establishes restrictions that make cigarettes generally nonmailable through the U.S. Postal Service, subject to certain exceptions (18 U.S.C. 1716E). Outside of these exceptions, the U.S. Postal Service cannot accept or transmit any package that it knows, or has reasonable cause to believe, contains nonmailable cigarettes, smokeless tobacco, or ENDS.

As previously noted, FDA's enforcement will only address manufacturers, distributors, wholesalers, importers, and retailers. This regulation does not include a prohibition on individual consumer possession or use, and FDA cannot and will not enforce against individual consumers for possession or use of menthol cigarettes. In addition, State and local law enforcement agencies do not independently enforce the FD&C Act. These entities do not and cannot take enforcement actions against any violation of chapter IX of the Act or this regulation on FDA's behalf. As noted previously, FDA recognizes concern about how State and local law enforcement agencies enforce their own laws in a manner that may impact equity and community safety and seeks comments on how FDA can best make clear the respective roles of FDA and State and local law enforcement.

Based on the available evidence, FDA finds that, while there may be potential countervailing effects that could diminish the expected population health benefits of the proposed standard, such effects would be significantly outweighed by the potential benefits of the proposed menthol product standard.

In this section, FDA has cited studies describing the potential countervailing effects of the proposed product standard. FDA requests additional information concerning the potential countervailing effects discussed in this section, as well as any other potential countervailing effects that could result from this rule, and how the potential countervailing effects could be minimized. FDA is particularly interested in receiving comments, including supporting data and research, regarding whether and to what extent this proposed rule would result in an increase in illicit trade in menthol cigarettes and how any such increase could impact the marketplace or public health.

D. Conclusion

FDA has considered scientific evidence related to the likely impact of the proposed rule prohibiting use of menthol as a characterizing flavor in cigarettes on current nonusers, current users, and the U.S. population as a whole. Based on these considerations, we find that the proposed tobacco product standard is appropriate for the protection of the public health because it would reduce the appeal and ease of smoking cigarettes, particularly for young people and new users, thereby decreasing the likelihood that nonusers of cigarettes who experiment with these tobacco products would progress to regular cigarette smoking. Additionally, the proposed tobacco product standard is anticipated to improve the health of current smokers of menthol cigarettes by decreasing cigarette consumption, increasing the likelihood of cessation among this population, and decreasing secondhand smoke exposure among current smokers and non-smokers. These positive public health impacts will also address the significant health disparities linked to menthol cigarettes.

Tobacco use is the leading preventable cause of disease and death in the United States (Ref. 1). As over 18.5 million Americans ages 12 and older smoke menthol cigarettes (Ref. 44), even modest reductions in the percentage of people initiating and modest increases in the percentage of people quitting smoking would lead to substantial reductions in the over 480,000 annual deaths and approximately 16 million cases of disease attributed to combustible tobacco products in the United States, as well as the economic and societal costs associated with such illness and death.

Each day in the United States, more than 1,500 youth under the age of 18 smoke their first cigarette (Ref. 96). Additionally, nearly 90 percent of adult current daily cigarette smokers in the United States report having smoked their first cigarette by the age of 18 (Ref. 1). Nicotine is a highly addictive substance, and multiple studies have shown that symptoms of nicotine dependence can arise early after youth start smoking cigarettes, even among infrequent users (Refs. 184, 137, and 135). Menthol in cigarettes enhances nicotine addiction through a combination of its flavor, sensory effects, and interaction with nicotine in the brain, facilitating repeated experimentation with cigarettes and progression to regular cigarette smoking, which repeatedly exposes the brain to nicotine (Refs. 6 and 9).

Evidence shows that adding menthol to cigarettes soothes irritation from nicotine and smoke inhalation, particularly among new smokers (Ref. 7). Data from the 2013–2014 PATH Study indicate that 43 percent of youth (aged 12–17 years), 45 percent of young adults (aged 18–24 years) and 30 percent of adults (aged 25 years and older) that have ever smoked a cigarette reported that their first tobacco product was mentholated (Ref. 31). Results from national studies also consistently show a preference for smoking menthol cigarettes among youth and young adult smokers, compared to older smokers, and existing research suggests that the likelihood of progressing to regular, established smoking is higher among youth who initiate with menthol smoking compared to those starting with non-menthol cigarettes (Refs. 25, 29–31, 8). The result is that nearly half of youth (48.6 percent) and young adults (51 percent) and two in five (39 percent) adult smokers report smoking menthol cigarettes (Ref. 44).

Prohibiting the use of menthol as a characterizing flavor in cigarettes would help to decrease future addiction, disease, and death among youth at risk of tobacco use. FDA anticipates that the proposed standard would produce substantial health benefits. Even small changes in initiation and cessation would result in a significant reduction in the burden of death and disease in the United States caused by smoking, including reductions in smoking-related morbidity and mortality, diminished exposure to secondhand smoke among non-smokers, decreased potential years of life lost, decreased disability, and improved quality of life for the current and future generations to come.

While preventing initiation to regular cigarette smoking by even modest amounts carries the greatest potential from this proposed standard to improve population health in the long term, FDA anticipates that the proposed standard would produce substantial short-term health benefits resulting from decreased cigarette consumption and increased cessation among current menthol cigarette smokers. In the United States, there are currently over 18.5 million smokers of menthol cigarettes ages 12 and older (Ref. 44). As previously described, the health benefits of smoking cessation are substantial. A published population modeling study estimated that as many as 654,000 smoking attributable deaths would be avoided by the year 2060 if menthol cigarettes were no longer available (Ref. 46). Beyond averted deaths, societal benefits would include reduced smoking-related morbidity and health

disparities, diminished exposure to secondhand smoke among non-smokers, decreased potential years of life lost, decreased disability, and improved quality of life among former smokers.

FDA's expectation that the proposed product standard would be appropriate for the protection of the public health is reasonable and well-supported by scientific evidence. Cigarettes are the most toxic consumer product, when used as intended, and adding menthol as a characterizing flavor makes cigarettes more appealing and easier to smoke. Given the existing scientific evidence described in sections IV and V of this document, FDA expects that implementing the proposed menthol product standard would result in reduced smoking initiation and progression among youth and young adults, and increased smoking cessation among current cigarette smokers. Across the population, these changes in cigarette smoking behaviors would lead to lower disease and death in the United States in both the short term, and in the future, due to diminished exposure to tobacco smoke among both smokers and non-smokers.

FDA anticipates the proposed product standard also will improve health outcomes among vulnerable populations. As previously described, menthol cigarette use, and the disease and death linked to such use, is disproportionately high among members of vulnerable populations such as African Americans and other racial and ethnic groups, those with lower household income, and those who identify as LGBTQ+ (Refs. 55–57, 21–24, 44). For example, out of all non-Hispanic Black smokers, nearly 85 percent smoke menthol cigarettes, compared to 30 percent of non-Hispanic White smokers who smoke menthol cigarettes (Ref. 44). As a result, these population groups with the greatest menthol cigarette use would be expected to experience the greatest benefit from the proposed product standard through its impact on reducing youth initiation of and experimentation with cigarette smoking, decreasing the likelihood of nicotine dependence and addiction, and increasing the likelihood of cessation. Accordingly, the proposed product standard is anticipated to promote better public health outcomes across population groups.

VI. Additional Considerations and Requests for Comments

A. Section 907 of the FD&C Act

FDA is required by section 907 of the FD&C Act to consider the following

information submitted in connection with a proposed product standard:

- For a proposed product standard to require the reduction or elimination of an additive, constituent (including smoke constituent), or other component of a tobacco product because FDA has found that the additive, constituent (including a smoke constituent), or other component is or may be harmful, scientific evidence submitted by any party objecting to the proposed standard demonstrating that the proposed standard will not reduce or eliminate the risk of illness or injury (section 907(a)(3)(B)(ii) of the FD&C Act).

- Information submitted regarding the technical achievability of compliance with the standard, including with regard to any differences related to the technical achievability of compliance with such standard for products in the same class containing nicotine not made or derived from tobacco and products containing nicotine made or derived from tobacco (section 907(b)(1) of the FD&C Act).

- All other information submitted, including information concerning the countervailing effects of the tobacco product standard on the health of adolescent tobacco users, adult tobacco users, or nontobacco users, such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of chapter IX of the FD&C Act and the significance of such demand (section 907(b)(2) of the FD&C Act).

As required by section 907(c)(2) of the FD&C Act, FDA invites interested persons to submit a draft or proposed tobacco product standard for the Agency's consideration (section 907(c)(2)(B)) and information regarding structuring the standard so as not to advantage foreign-grown tobacco over domestically grown tobacco (section 907(c)(2)(C)). In addition, FDA invites the Secretary of Agriculture to provide any information or analysis which the Secretary of Agriculture believes is relevant to the proposed tobacco product standard (section 907(c)(2)(D) of the FD&C Act).

FDA is requesting all relevant documents and information described in this section with this proposed rule. Such documents and information may be submitted in accordance with the "Instructions" included in the preliminary information section of this document.

Section 907(d)(5) of the FD&C Act allows the Agency to refer a proposed regulation for the establishment of a tobacco product standard to TPSAC at the Agency's own initiative or in response to a request that demonstrates

good cause for a referral and is made before the expiration of the comment period. If FDA opts to refer this proposed regulation to TPSAC, the Agency will publish a notice in the **Federal Register** announcing the TPSAC meeting to discuss this proposal.

B. Request for Comments on the Potential Racial and Social Justice Implications of the Proposed Product Standard

FDA is aware of concerns raised by some that this proposed rule could lead to illicit trade in menthol cigarettes, increased policing, and criminal penalties in underserved communities, including Black communities, which tend to have higher rates of menthol cigarette use and experience greater tobacco-related morbidity and mortality. We reiterate that this regulation does not include a prohibition on individual consumer possession or use, and FDA cannot and will not enforce against individual consumer possession or use of menthol cigarettes. FDA's enforcement of this proposed rule will only address manufacturers, distributors, wholesalers, importers, and retailers. State and local law enforcement agencies do not independently enforce the FD&C Act. These entities do not and cannot take enforcement actions against any violation of chapter IX of the Act or this regulation on FDA's behalf.

Recognizing concerns related to how State and local law enforcement agencies enforce their own laws in a manner that may impact equity and community safety, FDA requests comments, including supporting data and research, on any potential for this proposed rule to result, directly or indirectly, in disparate impacts within particular underserved communities or vulnerable populations. With respect to any potential disparate impacts, FDA requests comments and data on whether and how specific aspects of the rule, if finalized, might increase the likelihood of such outcomes beyond what would be expected to occur in the absence of the rule, and potential strategies for avoiding or addressing such impacts of the rule within the bounds of FDA's authorities. FDA also requests comments and data related to the existence, nature and degree of any change in police activity or community encounters with State or local law enforcement within a State, locality or other jurisdiction following implementation of a prohibition of menthol cigarettes. Finally, FDA requests comment on any other policy considerations related to potential racial

and social justice implications of the rule.

VII. Description of the Proposed Regulation

We are proposing to establish a new 21 CFR part 1162 (part 1162) that would prohibit menthol as a characterizing flavor in cigarettes. Part 1162 would describe the scope of the proposed regulation, applicable definitions, and the prohibition on use of menthol as a characterizing flavor in cigarettes.

A. Scope (Proposed § 1162.1)

Proposed § 1162.1(a) would provide that this part sets out a tobacco product standard under the FD&C Act regarding the use of menthol as a characterizing flavor in cigarettes. We are proposing that this product standard would cover all products meeting the definition of "cigarette" in section 900(3) of the FD&C Act (21 U.S.C. 387(3)) (proposed § 1162.3 includes a definition of cigarette). This includes all types, sizes, nicotine strengths and formulations of cigarettes, cigarette tobacco and RYO tobacco, as well as HTPs that meet the definition of a cigarette in the FD&C Act (cigarettes that are HTPs).

In general, as discussed in this document, menthol as a characterizing flavor in tobacco products enhances product appeal, usability, and addictiveness and has played a role in creating and perpetuating tobacco-related health disparities. While these effects raise concerns in the context of any tobacco product—none of which is without risk—FDA recognizes that certain products that meet the definition of cigarette in the FD&C Act may present different considerations with respect to this proposed product standard. For example, certain cigarettes may produce significantly fewer or lower levels of toxicants or have significantly reduced potential for creating or sustaining addiction. Recognizing that tobacco products exist on a continuum of risk, with combusted cigarettes being the deadliest, FDA recognizes that certain, specific products meeting the definition of a cigarette (*e.g.*, some that are not combusted or are minimally addictive) may pose less risk to individual users or to population health than other products meeting the definition of a cigarette. FDA also notes that there is wide variability even within certain types of cigarettes, such as variability in toxicants or youth appeal among HTPs or minimally addictive cigarettes.¹⁵

¹⁵ For additional information about the variability of tobacco products, see the Premarket Tobacco Product Applications and Recordkeeping

Accordingly, FDA is considering options that would allow certain products that present different considerations to seek exemptions from the product standard on a case-by-case basis.

Section 910 of the FD&C Act provides that those seeking to market new tobacco products via a premarket tobacco application may justify a deviation from a product standard to which it does not conform. However, no similar provision exists for pre-existing products or products that already are authorized under, or that seek authorization under, other pathways, *i.e.*, the substantial equivalence pathway or exemption from substantial equivalence. FDA is considering whether a final product standard rule should include a provision for requesting an exemption from the standard for certain products within particular categories, on a case-by-case basis, consistent with the potential for differential public health impacts among products meetings the definition of “cigarette”, as discussed above.

Accordingly, we are requesting comments on exemptions, including: (1) Whether the final rule should include a provision that allows for firms to request an exemption from the standard for specific products of certain types (*e.g.*, noncombusted, reduced nicotine), on a case-by-case basis; (2) for what types of products should firms be eligible to request an exemption; (3) for an exemption provision, how should the Agency evaluate exemption requests, and what data and information should firms be required to submit for this; and (4) if an exemption provision should apply to products currently on the market at the time of the final rule’s effective date, how the exemption process should work (*e.g.*, require that any exemption request be received within 180 days of publication so the Agency has time to make a determination before the effective date). As part of this, comments could address or account for impact on industry, impact on the Agency’s use of resources and the Agency’s ability to protect public health, as well as situations where the commenter believes an exemption would or would not be appropriate.

Proposed § 1162.1(b) would prohibit the manufacture, distribution, sale, or offering for distribution or sale, in the United States of a cigarette or any of its components or parts that is not in

compliance with the tobacco product standard. This provision is not intended to restrict the manufacture of cigarettes with menthol as a characterizing flavor intended for export. Consistent with section 801(e)(1) of the FD&C Act (21 U.S.C. 381(e)(1)), a tobacco product intended for export shall not be deemed to be in violation of section 907 of the FD&C Act or this product standard, if it meets the criteria enumerated in section 801(e)(1), including not being sold or offered for sale in domestic commerce.

B. Definitions (Proposed § 1162.3)

Proposed § 1162.3 provides the definitions for the terms used in the proposed rule. Several of these definitions are included in the FD&C Act or are used in other regulations.

- *Accessory*: FDA defined “accessory” in the deeming final rule (81 FR 28974, May 10, 2016; codified at § 1100.3 (21 CFR 1100.3)). We are proposing to use that definition here as it applies to cigarettes to provide further understanding as to the scope of the proposed standard. Therefore, FDA proposes to define “accessory” in the context of part 1162 to mean any product that is intended or reasonably expected to be used with or for the human consumption of a cigarette; does not contain tobacco or nicotine from any source, and is not made or derived from tobacco; and meets either of the following: (1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a cigarette; or (2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a cigarette but (i) solely controls moisture and/or temperature of a stored cigarette; or (ii) solely provides an external heat source to initiate but not maintain combustion of a cigarette. An example of a cigarette “accessory” is an ashtray.

- *Cigarette*: As defined in section 900(3) of the FD&C Act, the term “cigarette”: (1) Means a product that: (i) Is a tobacco product and (ii) meets the definition of the term “cigarette” in section 3(1) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332(1)) and (2) includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as RYO tobacco.

- *Cigarette tobacco*: As defined in section 900(4) of the FD&C Act, the term “cigarette tobacco” means any product that consists of loose tobacco that is

intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under 21 CFR chapter I also apply to cigarette tobacco.

- *Component or part*: FDA defined “component or part” in the deeming final rule (§ 1100.3). We are proposing to use that definition here as it applies to cigarettes. Therefore, FDA proposes to define “component or part” in the context of part 1162 to mean any software or assembly of materials intended or reasonably expected: (1) To alter or affect the cigarette’s performance, composition, constituents or characteristics or (2) to be used with or for the human consumption of a cigarette. The term excludes anything that is an accessory of a cigarette. Examples of cigarette components or parts that would be subject to this proposed product standard include cigarette paper, filters, and flavor additives. With respect to these definitions, FDA notes that “component” and “part” are separate and distinct terms within chapter IX of the FD&C Act. However, for purposes of this rule, FDA is using the terms “component” and “part” interchangeably and without emphasizing a distinction between the terms. FDA may clarify the distinctions between “component” and “part” in the future.

- *Person*: As defined in section 201(e) of the FD&C Act (21 U.S.C. 321(e)), the term “person” includes an individual, partnership, corporation, and association.

- *Roll-your-own tobacco*: As defined in section 900(15) of the FD&C Act, the term “roll-your-own tobacco” means any tobacco product which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

- *Tobacco product*: As defined in section 201(rr) of the FD&C Act, the term “tobacco product” is defined as any product that is made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term “tobacco product” does not mean an article that is: A drug under section 201(g)(1); a device under section 201(h); a combination product described in section 503(g) of the FD&C Act (21 U.S.C. 353(g)); or a food under section 201(f) if such article contains no

Requirements (PMTA) final rule (86 FR 55300, October 5, 2021) available at <https://www.federalregister.gov/documents/2021/10/05/2021-21011/premarket-tobacco-product-applications-and-recordkeeping-requirements>.

nicotine, or no more than trace amounts of naturally occurring nicotine.

- *United States*: As defined in section 900(22) of the FD&C Act, the term “United States” means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midways Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

C. Prohibition on Use of Menthol as a Characterizing Flavor in Cigarettes (Proposed § 1162.5)

Proposed § 1162.5 would establish a tobacco product standard prohibiting the use of menthol as a characterizing flavor in cigarettes. Specifically, proposed § 1162.5 would state that a cigarette or any of its components or parts (including the tobacco, filter, wrapper, or paper, as applicable) shall not contain, as a constituent (including a smoke constituent) or additive, menthol that is a characterizing flavor of the tobacco product or tobacco smoke.¹⁶ This proposal takes into consideration, among other information, the comments received by FDA on the ANPRMs and citizen petition, including comments urging FDA to ban menthol as a characterizing flavor in cigarettes, comments arguing for a total ban on menthol in cigarettes, comments recommending that any product standard for menthol also cover additives and components which convey menthol flavoring, and comments opposing any product standard for menthol in cigarettes. As discussed in section V of this document, FDA finds that this proposed product standard, which would prohibit menthol as a characterizing flavor in cigarettes, would be appropriate for the protection of the public health.

FDA would enforce the requirements of this proposed product standard under various sections of the FD&C Act, including sections 301, 303, 902, and 903. Section 907(a)(4)(B)(v) of the FD&C Act states that product standards must, where appropriate for the protection of the public health, include provisions requiring that the sale and distribution of the tobacco products be restricted but only to the extent that the sale and

distribution of a tobacco product may be restricted under section 906(d). Similar to section 907(a)(4)(B)(v), section 906(d) of the FD&C Act gives FDA authority to require restrictions on the sale and distribution of tobacco products by regulation if the Agency determines that such regulation would be appropriate for the protection of the public health. Because this sale and distribution restriction of menthol cigarettes would also assist FDA in enforcing the standard and would ensure that manufacturers, distributors, and retailers are selling product that complies with the standard, the Agency has found the restriction to be appropriate for the protection of the public health consistent with sections 907(a)(4)(B)(v) and 906(d) of the FD&C Act.

Failure to comply with any requirements prescribed by this product standard may result in FDA initiating enforcement or regulatory actions, including, but not limited to, warning letters, civil money penalties, no-tobacco-sale orders, criminal prosecution, seizure, and/or injunction. In addition, adulterated or misbranded tobacco products offered for import into the United States are subject to detention and refusal of admission. As previously discussed, FDA’s enforcement will only address manufacturers, distributors, wholesalers, importers, and retailers. FDA cannot and will not enforce against individual consumer possession or use of menthol cigarettes.

Among the factors that FDA believes are relevant in determining whether a cigarette has a characterizing flavor are:

- The presence and amount of artificial or natural flavor additives, compounds, constituents, or ingredients, or any other flavoring ingredient in a tobacco product, including its components or parts;
- The multisensory experience (*i.e.*, taste, aroma, and cooling or burning sensations in the mouth and throat) of a flavor during use of a tobacco product, including its components or parts;
- Flavor representations (including descriptors), either explicit or implicit, in or on the labeling (including packaging) or advertising of tobacco products;¹⁷ and

¹⁷ If a cigarette has a characterizing flavor (other than tobacco), but its labeling or advertising represents that it does not, then the product may be, among other things, misbranded under section 903 of the FD&C Act because its labeling or advertising is false or misleading. Similarly, if a product does not have a characterizing flavor, but its labeling or advertising represents that it does, then the product may be misbranded under section 903 of the FD&C Act because its labeling or advertising is false or misleading.

- Any other means that impart flavor or represent that the tobacco product has a characterizing flavor.

FDA expects that the approach proposed in this rule—relying on specific, flexible factors to make a case-by-case determination as to a characterizing flavor of menthol—would provide important clarity for FDA, regulated industry, and other stakeholders while also ensuring critical flexibility and enforceability to achieve the public health goals of this rule. FDA requests comments regarding these factors and other potential factors that the Agency might consider in determining whether a cigarette has menthol as a characterizing flavor.

FDA also requests comments, including supporting data and research, regarding any alternatives to prohibiting menthol as a characterizing flavor (*e.g.*, prohibiting all menthol flavor additives, compounds, constituents, or ingredients).

We note that this prohibition also would cover menthol flavoring that is separate from the cigarette. For example, menthol can be added to non-menthol cigarettes via drops, capsules, filter tips for RYO tobacco, or cards that can be inserted into a cigarette pack or pouch of rolling tobacco (Refs. 299 and 300). Such menthol flavorings would be considered components or parts of cigarettes under proposed § 1162.3, as they could be intended or reasonably expected to: (1) Alter or affect the cigarette’s performance, composition, constituents, or characteristics or (2) be used with or for the human consumption of a cigarette, and they would not be accessories of cigarettes. Therefore, the manufacture, distribution, sale, or offer for distribution or sale of such products would be prohibited should this proposed rule be finalized.

VIII. Proposed Effective Date

In accordance with section 907(d)(2) of the FD&C Act,¹⁸ FDA proposes that any final rule that may issue based on this proposal become effective 1 year after the date of publication of the final rule. Therefore, after the effective date, no person may manufacture, sell, or offer for sale or distribution within the United States a cigarette or any of its components or parts that is not in compliance with part 1162. This

¹⁸ Section 907(d)(2) of the FD&C Act states that a regulation establishing a tobacco product standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before 1 year after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health.

¹⁶ We note that the language in section 907(a)(1)(A) of the FD&C Act states that the Special Rule for Cigarettes applies to cigarettes or “any of its component parts.” For purposes of this standard, we have used the phrase “any of its components or parts” and have defined “component or part” for clarity and consistency with the deeming final rule (81 FR 28974 at 28975).

regulation does not include a prohibition on individual consumer possession or use.

FDA finds this proposed standard appropriate for the protection of the public health because it would reduce the ease of smoking cigarettes, particularly for young people and new users, thereby decreasing the likelihood that nonusers who experiment with these products would progress to regular smoking. In addition, the proposed tobacco product standard would improve the health of current menthol cigarette smokers by decreasing cigarette consumption and increasing the likelihood of cessation. Additional delay, past 1 year, would only increase the numbers of youth and young adults who experiment with menthol cigarettes and become regular smokers, delay cessation by current smokers, and exacerbate tobacco-related health disparities.

FDA also finds that a 1-year effective date will “minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade” pursuant to section 907(d)(2) of the FD&C Act. As discussed in the preliminary economic analysis (Ref. 292), FDA believes that most currently marketed menthol cigarettes are available for purchase in currently marketed non-menthol versions. Therefore, FDA does not expect that this rule, if finalized, would result in many new tobacco product applications. For these reasons, FDA believes that the availability of currently marketed non-menthol versions of currently marketed menthol cigarettes would minimize the economic loss to, and disruption of, domestic and international trade.

We also note that the Tobacco Control Act banned characterizing flavors in cigarettes with a 90-day effective date (section 907(a)(1)(A) of the FD&C Act). FDA is proposing a longer effective date here in accordance with section 907(d)(2) of the FD&C Act. FDA requests comments as to whether a shorter effective date, such as 90 days, would be necessary for the protection of the public health. In setting the effective date, FDA will consider information submitted in connection with this proposal by interested parties, including manufacturers and tobacco growers, regarding the technical achievability of compliance with the standard, and including information concerning the existence of patents that make it impossible to comply in the proposed 1-year timeframe.

FDA is aware of retailers’ concerns regarding unsold inventory when any final rule goes into effect. FDA requests

comments, including supportive data and research, regarding a sell-off period (e.g., 30 days after the effective date of a final rule) for retailers to sell through their current inventory of menthol cigarettes.

IX. Preliminary Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under Executive Order (E.O.) 12866, E.O. 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). E.O.s 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is an economically significant regulatory action as defined by E.O. 12866. As such, it has been reviewed by the Office of Information and Regulatory Affairs.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because a portion of business revenues may revert back to consumers who currently purchase menthol cigarettes, we find that the rule may have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule, if finalized, would result in expenditures that meet or exceed this amount.

B. Summary of Costs and Benefits

The summary of benefits and costs is presented in Table 1. The proposed rule, if finalized, would establish a tobacco product standard prohibiting the use of menthol as a characterizing flavor in cigarettes. The quantified benefits of this proposed rule come from lower smoking-attributable mortality in the

U.S. population due to diminished exposure to tobacco smoke for both users and nonusers of cigarettes. Qualitative benefits include: decreased illness and associated reductions in medical costs (both publicly and privately funded), decreased productivity loss, and improved health-related quality of life for menthol smokers and non-smokers; reductions in smoking-related fires; and reductions in cigarette butt litter and associated harms to the environment. We estimate that the present value of the monetized benefits over a 40-year time horizon ranges between \$2,529 billion and \$8,253 billion (primary estimate of \$5,428 billion) at a 3 percent discount rate, and range between \$1,369 billion and \$4,470 billion (primary estimate of \$2,941 billion) at a 7 percent discount rate. The primary annualized benefits equal \$232 billion at a 3 percent discount rate and \$220 billion at a 7 percent discount rate. Unquantified benefits are expected to provide additional benefits beyond those amounts and additional health and related benefits are expected to occur outside the time horizon used in this analysis.

The proposed rule, if finalized, would also create costs for firms, consumers and the Federal Government. Firms face one-time costs to read and review the rule (undiscounted primary estimate of \$186.6 million with a range of \$56.0 million to \$349.9 million), and may face one-time costs for reallocation, friction, and adjustment in the cigarette product market (undiscounted primary estimate of \$235.9 million with a range of \$0.2 million to \$471.9 million). Firms may also face costs due to producer surplus loss over the 40 year time horizon (undiscounted primary estimate of \$10,628 million with a range of \$0 to \$21,256). Consumers may face one-time search costs of \$359.3 million (undiscounted, range of \$179.7 million to \$539.0 million) to find substitute tobacco products as a replacement for menthol cigarettes. The FDA may face annual costs associated with enforcement of the proposed product standard (undiscounted range from \$0 to \$1.3 million, primary estimate \$0.7 million per year). Qualitative costs may include changes in consumer surplus for some menthol cigarette product users, including potential utility changes for smokers of menthol cigarette products who switch from menthol to non-menthol cigarette products. We estimate that the present value of monetized costs over a 40-year time horizon ranges between \$223.0 million and \$13,421.6 million (primary

estimate of \$6,805.9 million) for a 3 percent discount rate, and between \$208.0 million and \$8,051.3 million (primary estimate of \$4,113.2 million) at a 7 percent discount rate. The primary estimates for the annualized cost are \$291 million at a 3 percent discount rate and \$307 million at a 7 percent discount rate. In addition to benefits and costs, this rule, if finalized, will create

significant transfers from State governments, Federal Government, and firms to consumers in the form of reduced revenue and tax revenue. The primary estimates for annualized transfers related to Federal taxes are \$2.0 billion at a 3 percent discount rate and \$2.0 billion at a 7 percent discount rate. The primary estimates for the annualized transfers related to State

taxes are \$3.7 billion at a 3 percent discount rate and \$3.7 billion at a 7 percent discount rate. The primary estimates for the annualized transfers between cigarette product manufacturers and consumers are \$13.3 billion at a 3 percent discount rate and \$13.0 billion at a 7 percent discount rate. Benefits, costs, and transfers are summarized in Table 1.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE
[\$ Millions of 2020 dollars over a 40 year time horizon]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits:							
Annualized Monetized (\$m/year)	\$220,000	\$102,000	\$334,000	2020	7	40	
	232,000	108,000	353,000	2020	3	40	
Annualized Quantified							
Qualitative	<i>Qualitative benefits include:</i> Decreased illness and associated reductions in medical costs (both publicly and privately funded), decreased productivity loss, and improved health-related quality of life for menthol smokers and non-smokers; reductions in smoking-related fires; and reductions in cigarette butt litter and associated harms to the environment.						
Costs:							
Annualized Monetized (\$m/year)	307	16	601	2020	7	40	
	291	9	573	2020	3	40	
Annualized Quantified							
Qualitative	Changes in consumer surplus may occur for some menthol smokers.						
Transfers:							
Federal Annualized Monetized (\$m/year)	2,000	1,000	2,000	2020	7	40	
	2,000	1,000	2,000	2020	3	40	
	From: Federal Government			To: Consumers			
State Annualized Monetized (\$m/year)	4,000	3,000	4,000	2020	7	40	
	4,000	3,000	4,000	2020	3	40	
	From: State Government			To: Consumers			
Other Annualized Monetized (\$m/year)	13,000	9,000	15,000	2020	7	40	
	13,000	9,000	15,000	2020	3	40	
	From: Cigarette Product Manufacturers			To: Consumers and Manufacturers of Other Tobacco Products			

Effects:

- State, Local, or Tribal Government:* See transfers for estimated State excise tax impacts. See distributional effects for discussions of impacts to tribally-affiliated manufacturers and/or manufacturers operating on tribal lands.
- Small Business:* Small menthol cigarette manufacturers are expected to face one-time costs for reading and understanding the rule and for planning and implementing reallocation procedures for menthol cigarette production lines. Small menthol cigarette manufacturers would also face revenue transfers as consumers cease purchasing menthol cigarette products.
- Wages:* No effect.
- Growth:* No effect.

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full analysis of economic impacts is available in the docket for this proposed rule (see Ref. 292) and at <https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations>.

X. Analysis of Environmental Impact

The Agency has carefully considered the potential environmental effects of this action. FDA has concluded that the

action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The Agency's finding of no significant impact and the evidence supporting that finding is available in the docket for this proposed rule (see Refs. 304 and 305) and may be seen in the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <https://www.regulations.gov>. Under FDA's regulations implementing the National

Environmental Policy Act (21 CFR part 25), an action of this type would require an environmental assessment under 21 CFR 25.20.

XI. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) is not required.

XII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13132. Section 4(a) of the Executive order requires Agencies to “construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” We have determined that the proposed rule, if finalized, would not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the rule does not contain policies that have federalism implications as defined in the E.O. and, consequently, a federalism summary impact statement is not required.

This rule is being issued under section 907 of the FD&C Act, which enables FDA to prescribe regulations relating to tobacco product standards, and the sale and distribution restriction in this rule is also being issued under section 906(d) of the FD&C Act, which enables FDA to prescribe regulations restricting the sale and distribution of a tobacco product. If this proposed rule is made final, the final rule would create requirements whose preemptive effect would be governed by section 916 of the FD&C Act, entitled “Preservation of State and Local Authority.”

Section 916 broadly preserves the authority of states and localities to protect the public against the harms of tobacco use. Specifically, section 916(a)(1) establishes a general presumption that FDA requirements do not preempt or otherwise limit the authority of States, localities, or tribes to, among other things, enact and enforce laws regarding tobacco products that relate to certain activities (*e.g.*, sale, distribution) and that are in addition to or more stringent than requirements established under chapter IX of the FD&C Act.

Section 916(a)(2)(A) of the FD&C Act is an express preemption provision that establishes an exception to the preservation of State and local governmental authority over tobacco products established in section 916(a)(1). Specifically, section 916(a)(2)(A) of the FD&C Act provides that “[n]o State or political subdivision of a State may establish or continue in

effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this chapter relating to tobacco product standards”

However, section 916(a)(2)(B) of the FD&C Act limits the applicability of section 916(a)(2)(A), narrowing the scope of state and local requirements that are subject to express preemption. In particular, paragraph (a)(2)(B) provides that preemption under paragraph (a)(2)(A) does not apply to State or local “requirements relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products.”

If this proposed rule is finalized as proposed, the final rule would create requirements that fall within the scope of section 916(a)(2)(A) because they are “requirements under the provisions of the chapter relating to tobacco product standards.” Accordingly, the preemptive effect of those requirements on any state or local requirement would be determined by the nature of the state or local requirement at issue—specifically, whether the state or local requirement is preserved under section 916(a)(1), and/or excepted under section 916(a)(2)(B) (such as if it relates to the “sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products”). State and local prohibitions on the sale and distribution of flavored tobacco products, such as menthol cigarettes, would not be preempted by this rule, if finalized, because such prohibitions would be preserved by FD&C Act section 916(a)(1) or, as applicable, excepted from express preemption by FD&C Act section 916(a)(2)(B). FDA invites comments on how State or local laws may be implicated if this proposed rule is finalized.

XIII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from

tribal officials on any potential impact on Indian Tribes from this proposed action.

XIV. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

- *HHS. “The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General.” Atlanta, GA: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014. Available at https://www.ncbi.nlm.nih.gov/books/NBK179276/pdf/Bookshelf_NBK179276.pdf.
- Kamatou, G.P., I. Vermaak, A.M. Viljoen, et al. “Menthol: A Simple Monoterpene with Remarkable Biological Properties.” *Phytochemistry*, 96:15–25, 2013. Available at <https://doi.org/10.1016/j.phytochem.2013.08.005>.
- Wiseman, E.J. and D.E. McMillan. “Rationale for Cigarette Smoking and for Mentholation Preference in Cocaine- and Nicotine-Dependent Outpatients.” *Comprehensive Psychiatry*, 39(6):358–363, 1998. Available at [https://doi.org/10.1016/S0010-440X\(98\)90048-7](https://doi.org/10.1016/S0010-440X(98)90048-7).
- Richter, P., D. Beistle, L. Pederson, et al. “Small-Group Discussions on Menthol Cigarettes: Listening to Adult African American Smokers in Atlanta, Georgia.” *Ethnicity & Health*, 13(2):171–182, 2008. Available at <https://doi.org/10.1080/13557850701784694>.
- Wackowski, O.A., K.R. Evans, M.B. Harrell, et al. “In Their Own Words: Young Adults’ Menthol Cigarette Initiation, Perceptions, Experiences and Regulation Perspectives.” *Nicotine & Tobacco Research*, 20(9):1076–1084, 2018. Available at <https://doi.org/10.1093/ntr/ntx048>.
- Kreslake, J.M., G.F. Wayne, H.R. Alpert, et al. “Tobacco Industry Control of Menthol in Cigarettes and Targeting of Adolescents and Young Adults.” *American Journal of Public Health*, 98:1685–1692, 2008. Available at <https://doi.org/10.2105/AJPH.2007.125542>.
- *Klausner, K. “Menthol Cigarettes and Smoking Initiation: A Tobacco Industry Perspective.” *Tobacco Control*, 20(Suppl

- 2) ii12-ii19, 2011. Available at <https://doi.org/10.1136/tc.2010.041954>.
8. Villanti, A.C., A.L. Johnson, M. Halenar, et al. "Menthol and Mint Cigarettes and Cigars: Initiation and Progression in Youth, Young Adults and Adults in Waves 1–4 of the PATH Study, 2013–2017." *Nicotine & Tobacco Research*, 23(8): 1318–1326, 2021. Available at <https://doi.org/10.1093/ntr/ntaa224>.
 9. Benowitz, N.L. "Nicotine Addiction." *The New England Journal of Medicine*, 362(24):2295–2303, 2010. Available at <https://doi.org/10.1056/NEJMra0809890>.
 10. * Alsharari, S.D., J.R. King, J.C. Nordman, et al. "Effects of Menthol on Nicotine Pharmacokinetic, Pharmacology and Dependence in Mice." *PLoS ONE*, 10(9):e0137070, 2015. Available at <https://doi.org/10.1371/journal.pone.0137070>.
 11. * Henderson, B.J., T.R. Wall, B.M. Henley, et al. "Menthol Alone Upregulates Midbrain Nachrs, Alters Nachr Subtype Stoichiometry, Alters Dopamine Neuron Firing Frequency, and Prevents Nicotine Reward." *The Journal of Neuroscience*, 36(10):2957–2974, 2016. Available at <https://doi.org/10.1523/JNEUROSCI.4194-15.2016>.
 12. * Henderson, B.J., T.R. Wall, B.M. Henley, et al. "Menthol Enhances Nicotine Reward-Related Behavior by Potentiating Nicotine-Induced Changes in Nachr Function, Nachr Upregulation, and Da Neuron Excitability." *Neuropsychopharmacology*, 42:2285–2291, 2017. Available at <https://doi.org/10.1038/npp.2017.72>.
 13. Zhang, M., E. Harrison, L. Biswas, et al. "Menthol Facilitates Dopamine-Releasing Effect of Nicotine in Rat Nucleus Accumbens." *Pharmacology, Biochemistry and Behavior*, 175:47–52, 2018. Available at <https://doi.org/10.1016/j.pbb.2018.09.004>.
 14. Brody, A.L., A.G. Mukhin, J.L. Charite, et al. "Up-Regulation of Nicotinic Acetylcholine Receptors in Menthol Cigarette Smokers." *International Journal of Neuropsychopharmacology*, 16(5):957–966, 2013. Available at <https://doi.org/10.1017/S1461145712001022>.
 15. * Wickham, R.J. "The Biological Impact of Menthol on Tobacco Dependence." *Nicotine & Tobacco Research*, 22(10):1676–1684, 2020. Available at <https://doi.org/10.1093/ntr/ntz239>.
 16. Shahoei, R. and E. Tajkhorshid. "Menthol Binding to the Human A4B2 Nicotinic Acetylcholine Receptor Facilitated by Its Strong Partitioning in The Membrane." *Journal of Physical Chemistry*, 124(10):1866 – 1880, 2020. Available at <https://doi.org/10.1021/acs.jpcc.9b10092>.
 17. * Goriounova, N.A. and H.D. Mansvelder. "Short- and Long-Term Consequences of Nicotine Exposure During Adolescence for Prefrontal Cortex Neuronal Network Function." *Cold Spring Harbor Perspectives in Medicine*, 2:a012120, 2012. Available at <https://doi.org/10.1101/cshperspect.a012120>.
 18. * Yuan, M., S.J. Cross, SE Loughlin, et al. "Nicotine and the Adolescent Brain." *The Journal of Physiology*, 593(16):3397–3412, 2015. Available at <https://doi.org/10.1113/jp270492>.
 19. * HHS. "E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General." Atlanta, GA: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016. Available at https://www.cdc.gov/tobacco/data_statistics/sgr/e-cigarettes/pdfs/2016_sgr_entire_report_508.pdf.
 20. Collins, C.C. and E.T. Moolchan. "Shorter Time to First Cigarette of the Day in Menthol Adolescent Cigarette Smokers." *Addictive Behaviors*, 31(8):1460–1464, 2006. Available at <https://doi.org/10.1016/j.addbeh.2005.10.001>.
 21. Hersey, J.C., SW Ng, J.M. Nonnemaker, et al. "Are Menthol Cigarettes a Starter Product for Youth?" *Nicotine & Tobacco Research*, 8(3):403–413, 2006. Available at <https://doi.org/10.1080/14622200600670389>.
 22. Wackowski, O. and C.D. Delnevo. "Menthol Cigarettes and Indicators of Tobacco Dependence Among Adolescents." *Addictive Behaviors*, 32(9):1964–1969, 2007. Available at <https://doi.org/10.1016/j.addbeh.2006.12.023>.
 23. Muilenburg, J.L. and J.S. Legge. "African American Adolescents and Menthol Cigarettes: Smoking Behavior Among Secondary School Students." *Journal of Adolescent Health*, 43(6):570–575, 2008. Available at <https://doi.org/10.1016/j.jadohealth.2008.08.017>.
 24. Hersey, J., J. Nonnemaker, and G. Homs. "Menthol Cigarettes Contribute to the Appeal and Addiction Potential of Smoking for Youth." *Nicotine & Tobacco Research*, 12(2):S136–S146, 2010. Available at <https://doi.org/10.1093/ntr/ntq173>.
 25. Nonnemaker J., J. Hersey, G. Homs, et al. "Initiation with Menthol Cigarettes and Youth Smoking Uptake." *Addiction*, 108(1):171–8, 2013. Available at <https://doi.org/10.1111/j.1360-0443.2012.04045.x>.
 26. Cwalina, S.N., A. Majmundar, J.B. Unger, et al. "Adolescent Menthol Cigarette Use and Risk of Nicotine Dependence: Findings from the National Population Assessment on Tobacco and Health (PATH) Study." *Drug and Alcohol Dependence*, 206:107715, 2020. Available at <https://doi.org/10.1016/j.drugalcdep.2019.107715>.
 27. Azagba, S., J. King, L. Shan, et al. "Cigarette Smoking Behavior Among Menthol and Nonmenthol Adolescent Smokers." *Journal of Adolescent Health*, 66(5):545–550, 2020. Available at <https://doi.org/10.1016/j.jadohealth.2019.11.307>.
 28. Mantey, D.S., O.G. Chido-Amajuoyi, O. Omega-Njemnobi, et al. "Cigarette Smoking Frequency, Quantity, Dependence, and Quit Intentions During Adolescence: Comparison of Menthol and Non-Menthol Smokers (National Youth Tobacco Survey 2017–2020)." *Addictive Behaviors* 121:106986, 2021. Available at <https://doi.org/10.1016/j.addbeh.2021.106986>.
 29. Delnevo, C.D., A.C. Villanti, O.A. Wackowski, et al. "The Influence of Menthol, E-Cigarettes and Other Tobacco Products on Young Adults' Self-Reported Changes in Past Year Smoking." *Tobacco Control*, 25:571–574, 2016. Available at <https://doi.org/10.1136/tobaccocontrol-2015-052325>.
 30. Nonnemaker, J., S.P. Feirman, A. MacMonegle, et al. "Examining the Role of Menthol Cigarettes in Progression to Established Smoking Among Youth." *Addictive Behaviors*, 98(2019):106045, 2019. Available at <https://doi.org/10.1016/j.addbeh.2019.106045>.
 31. * Villanti, A.C., A.L. Johnson, A.M. Glasser, et al. "Association of Flavored Tobacco Use with Tobacco Initiation and Subsequent Use Among US Youth and Adults, 2013–2015." *JAMA Network Open*, 2(10):e1913804, 2019. Available at <https://doi.org/10.1001/jamanetworkopen.2019.13804>.
 32. * HHS. "Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General." Atlanta, GA: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012. Available at https://www.ncbi.nlm.nih.gov/books/NBK99237/pdf/Bookshelf_NBK99237.pdf.
 33. D'Silva, J., A.M. Cohn, A.L. Johnson, et al. "Differences in Subjective Experiences to First Use of Menthol and Nonmenthol Cigarettes in a National Sample of Young Adult Cigarette Smokers." *Nicotine & Tobacco Research*, 20(9):1062–1068, 2018. Available at <https://doi.org/10.1093/ntr/ntx181>.
 34. Gundersen, D.A., C.D. Delnevo, and O. Wackowski "Exploring the Relationship Between Race/Ethnicity, Menthol Smoking, and Cessation, in a Nationally Representative Sample of Adults." *Preventive Medicine*, 49(6):553–557, 2009. Available at <https://doi.org/10.1016/j.ypmed.2009.10.003>.
 35. * Stahre, M., K.S. Okuyemi, A.M. Joseph, et al. "Racial/Ethnic Differences in Menthol Cigarette Smoking, Population Quit Ratios and Utilization of Evidence-Based Tobacco Cessation Treatments." *Addiction*, 105(Suppl. 1):75–83, 2010. Available at <https://doi.org/10.1111/j.1360-0443.2010.03200.x>.
 36. Delnevo, C.D., D.A. Gundersen, M. Hrywna, et al. "Smoking-Cessation Prevalence Among U.S. Smokers of Menthol Versus Non-Menthol Cigarettes." *American Journal of Preventive Medicine*, 41(4):357–365, 2011. Available at <https://doi.org/10.1016/j.amepre.2011.06.039>.
 37. Levy, D.T., K. Blackman, J. Tauras, et al. "Quit attempts and Quit Rates Among Menthol and Nonmenthol Smokers in the United States." *American Journal of Public Health*, 101:1241–1247, 2011. Available at <https://doi.org/10.2105/AJPH.2011.300178>.
 38. * Sulsky, S.L., W.G. Fuller, C. Van Landingham, et al. "Evaluating the

- Association Between Menthol Cigarette Use and the Likelihood of Being A Former Versus Current Smoker.” *Regulatory Toxicology and Pharmacology*, 70(1):231–241, 2014. Available at <https://doi.org/10.1016/j.yrtph.2014.07.009>.
39. * Sanders, E., R. Weitkunat, and R. Dempsey. “Menthol Cigarettes, Time to First Cigarette, and Smoking Cessation.” *Contributions to Tobacco Research*, 27(5):4–32, 2017. Available at <https://doi.org/10.1515/cttr-2017-0003>.
40. Mills, S.D., Y. Hao, K. Ribisl, et al. “The Relationship Between Menthol Cigarette Use, Smoking Cessation, and Relapse: Findings from Waves 1 to 4 of the Population Assessment of Tobacco and Health Study.” *Nicotine & Tobacco Research*, 23(6):966–975, 2021. Available at <https://doi.org/10.1093/ntr/ntaa212>.
41. * Smith, P.H., B. Assefa, S. Kainth, et al. “Use of Mentholated Cigarettes and Likelihood of Smoking Cessation in the United States: A Meta-Analysis.” *Nicotine & Tobacco Research*, 22(3):307–316, 2020. Available at <https://doi.org/10.1093/ntr/ntz067>.
42. * Trinidad, D.R., E. Pérez-Stable, K. Messer, et al. “Menthol Cigarettes and Smoking Cessation Among Racial/Ethnic Groups in the United States.” *Addiction*, 105(1): 84–94, 2010. Available at <https://dx.doi.org/10.1111%2Fj.1360-0443.2010.03187.x>.
43. * Leas, E.C., T. Benmarhnia, D.R. Strong, et al. “Effects of Menthol Use and Transitions in Use on Short-Term and Long-Term Cessation from Cigarettes Among US Smokers.” *Tobacco Control*, 0:1–6, 2021. Available at <https://doi.org/10.1136/tobaccocontrol-2021-056596>.
44. * FDA, “Memorandum of Summary of Internal Analyses Using Data From the 2019 National Survey on Drug Use and Health on Menthol Cigarette Smoking.” Silver Spring, MD: HHS, FDA, Center for Tobacco Products, 2022.
45. Levy, D.T., J. Pearson, A. Villanti, et al. “Modeling the Future Effects of a Menthol Ban on Smoking Prevalence and Smoking-Attributable Deaths in the United States.” *American Journal of Public Health*, 101:1236–1240, 2011. Available at <https://doi.org/10.2105/AJPH.2011.300179>.
46. Levy, D.T., R. Meza, Z. Yuan, et al. “Public Health Impact of a US Ban on Menthol in Cigarettes and Cigars: A Simulation Study.” *Tobacco Control*, 2021. Available at <https://doi.org/10.1136/tobaccocontrol-2021-056604>.
47. Fagan, P., G. King, D. Lawrence, et al. “Eliminating Tobacco-Related Health Disparities: Directions for Future Research.” *Am J Public Health*, 94(2):211–217, 2004. Available at <https://doi.org/10.2105/ajph.94.2.211>.
48. * Fagan, P., E.T. Moolchan, D. Lawrence, et al. “Identifying Health Disparities Across the Tobacco Continuum.” *Addiction*, 102 Suppl. 2:5–29, 2007. Available at <https://doi.org/10.1111/j.1360-0443.2007.01952.x>.
49. * National Cancer Institute. “A Socioecological Approach to Addressing Tobacco-Related Health Disparities.” *National Cancer Institute Tobacco Control Monograph 22*. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute. NIH Publication No. 17–CA–8035A, 2017. Available at <https://cancercontrol.cancer.gov/brp/tcrb/monographs/monograph-22>.
50. * HHS. “Tobacco Use Among U.S. Racial/Ethnic Minority Groups: A Report of the Surgeon General.” Atlanta, GA: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 1998. Available at https://www.cdc.gov/tobacco/data_statistics/sgr/1998/complete_report/pdfs/complete_report.pdf.
51. * HHS. “Healthy People 2020: Disparities.” HHS, Office of Disease Prevention and Health Promotion. *HealthyPeople.gov*. Accessed November 12, 2021. Available at <https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities>.
52. * Braveman, P., E. Arkin, T. Orleans, et al. “What is Health Equity?” *Behavioral Science & Policy*, 4(1):1–14, 2018. Available at <https://behavioralpolicy.org/wp-content/uploads/2018/12/What-is-Health-Equity.pdf>.
53. * Peterson, A., V. Charles, D. Yeung, et al. “The Health Equity Framework: A Science and Justice-Based Model for Public Health Researchers and Practitioners.” *Health Promotion Practice*, 1–6, 2020. Available at <https://doi.org/10.1177/1524839920950730>.
54. * Centers for Disease Control and Prevention. “Best Practices for Comprehensive Tobacco Control Programs.” CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014. Available at <https://www.cdc.gov/tobacco/stateandcommunity/guides/pdfs/2014/comprehensive.pdf>.
55. * Caraballo, R.S. and K. Asman. “Epidemiology of Menthol Cigarette Use in the United States.” *Tobacco Induced Diseases*, 9(Suppl. 1):S1, 2011. Available at <https://doi.org/10.1186/1617-9625-9-S1-S1>.
56. * Sawdey, M.D., J.T. Chang, K.A. Cullen, et al. “Trends and Associations of Menthol Cigarette Smoking Among US Middle and High School Students—National Youth Tobacco Survey, 2011–2018.” *Nicotine & Tobacco Research*, 22(10):1726–1735, 2020. Available at <https://doi.org/10.1093/ntr/ntaa054>.
57. * Villanti, A., P.D. Mowery, C.D. Delnevo, et al. “Changes in the Prevalence and Correlates of Menthol Cigarette Use in the USA, 2004–2014.” *Tobacco Control*, 25:ii14–ii20, 2016. Available at <https://doi.org/10.1136/tobaccocontrol-2016-053329>.
58. Weinberger, A.H., D.P. Giovenco, J. Zhu, et al. “Racial/Ethnic Differences in Daily, Nondaily, and Menthol Cigarette Use and Smoking Quit Ratios in the United States: 2002 to 2016.” *Preventive Medicine*, 125:32–39, 2019. Available at <https://doi.org/10.1016/j.ypmed.2019.04.009>.
59. * Delnevo, C.D., O. Ganz, R.D. Goodwin, et al. “Banning Menthol Cigarettes: A Social Justice Issue Long Overdue.” *Nicotine & Tobacco Research*, 22(10):1673–1675, 2020. Available at <https://doi.org/10.1093/ntr/ntaa152>.
60. Alexander, L.A., D.R. Trinidad, K.K. Sakuma, et al. “Why We Must Continue to Investigate Menthol’s Role in the African American Smoking Paradox.” *Nicotine & Tobacco Research*, 18(Suppl. 1):S91–S101, 2016. Available at <https://doi.org/10.1093/ntr/ntv209>.
61. Benowitz, N.L., E.J. Pérez-Stable, B. Herrera, et al. “Slower Metabolism and Reduced Intake of Nicotine from Cigarette Smoking in Chinese-Americans.” *Journal of the National Cancer Institute*, 94(2):108–115, Jan. 16, 2002. Available at <https://pubmed.ncbi.nlm.nih.gov/11792749/>.
62. Garten, S. and R.V. Falkner. “Role of Mentholated Cigarettes in Increased Nicotine Dependence and Greater Risk Tobacco-Attributable Disease.” *Preventive Medicine* 38 793–798, 2004. Available at <https://doi.org/10.1016/j.ypmed.2004.01.019>.
63. Hooper, M., W. Zhao, M. Byrne, et al. “Menthol Cigarette Smoking and Health, Florida 2007 BRFSS.” *American Journal of Health Behavior*, 35(1):3–14, 2011. Available at <https://doi.org/10.5993/AJHB.35.1.1>.
64. * Fagan, P., E.T. Moolchan, A. Hart, et al. “Nicotine Dependence and Quitting Behaviors Among Menthol and Non-Menthol Smokers with Similar Consumptive Patterns.” *Addiction*, 105(Suppl. 1):55–74, 2010. Available at <https://doi.org/10.1111/j.1360-0443.2010.03190.x>.
65. * Fernander, A., M. Rayens, M. Zhang, et al. “Are Age of Smoking Initiation and Purchasing Patterns Associated with Menthol Smoking?” *Addiction*, 105(Suppl. 1):39–45, 2010. Available at <https://doi.org/10.1111/j.1360-0443.2010.03188.x>.
66. * Lawrence, D., A. Rose, P. Fagan, et al. “National Patterns and Correlates of Mentholated Cigarette Use in the United States.” *Addiction*, 105(Suppl. 1), 13–31, 2010. Available at <https://doi.org/10.1111/j.1360-0443.2010.03203.x>.
67. * Cubbin, C., M. Soobader, and F.B. LeClere. “The Intersection of Gender and Race/Ethnicity in Smoking Behaviors Among Menthol and Non-Menthol Smokers in the United States.” *Addiction*, 105(Suppl. 1):32–38, 2010. Available at <https://doi.org/10.1111/j.1360-0443.2010.03191.x>.
68. Hickman, N.J., K.L. Delucchi, and J.J. Prochaska. “Menthol Use Among Smokers with Psychological Distress: Findings from the 2008 and 2009 National Survey on Drug Use and Health.” *Tobacco Control*, 23:7–13, 2014. Available at <https://doi.org/10.1136/tobaccocontrol-2012-050479>.
69. Fallin, A., A.J. Goodin, B. King. “Menthol Cigarette Smoking Among Lesbian, Gay,

- Bisexual, and Transgender Adults.” *Am J Prev Med.*, 48(1):93–97, 2015. Available at <https://doi.org/10.1016/j.amepre.2014.07.044>.
70. * Mattingly, D.T., J.L. Hirschtick, R. Meza, et al. “Trends in Prevalence and Sociodemographic and Geographic Patterns of Current Menthol Cigarette Use Among U.S. Adults, 2005–2015.” *Preventive Medicine Reports*, 20:101227, 2020. Available at <https://doi.org/10.1016/j.pmedr.2020.101227>.
71. Stroud, L.R., C. Vergara-Lopez, M. McCallum, et al. “High Rates of Menthol Cigarette Use among Pregnant Smokers: Preliminary Findings and Call for Future Research.” *Nicotine & Tobacco Research*, 22(10):1711–1717, 2020. Available at <https://doi.org/10.1093/ntr/ntz142>.
72. * FDA Tobacco Products Scientific Advisory Committee. “Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations.” Silver Spring, MD: HHS, FDA, Center for Tobacco Products, Tobacco Products Scientific Advisory Committee, 2011. Available at <https://wayback.archive-it.org/7993/20170405201731/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf>.
73. * Non-Voting Industry Representatives on TPSAC and Other Tobacco Industry Stakeholders. “Menthol Cigarettes: No Disproportionate Impact on Public Health.” *The Industry Menthol Report*, 2011. Available at <https://wayback.archive-it.org/7993/20170406091740/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM249320.pdf>.
74. * FDA. “Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes.” Silver Spring, MD: HHS, FDA, Center for Tobacco Products, 2013. Available at <https://www.fda.gov/media/86497/download>.
75. * FDA. “Scientific Review of the Effects of Menthol in Cigarettes on Tobacco Addiction: 1980–2021.” Silver Spring, MD: HHS, FDA, Center for Tobacco Products, 2022. Available at <https://www.fda.gov/media/157642/download>.
76. * FDA. “Peer Review Summary Report: External Peer Review of the FDA Scientific Evaluation of the Possible Health Effects of Menthol Versus Nonmenthol Cigarettes.” 2011. Available at <https://www.fda.gov/media/86018/download>.
77. * FDA. “Review of Studies Assessing the Potential Impact of Prohibiting Menthol as a Characterizing Flavor in Cigarettes.” Silver Spring, MD: HHS, FDA, Center for Tobacco Products, 2022. Available at <https://www.fda.gov/media/157643/download>.
78. * FDA. “FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death.” *FDA.gov*. July 27, 2017. Available at <https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death>.
79. * FDA. “Illicit Trade in Tobacco Products after Implementation of a FDA Product Standard.” 2018. Available at <https://www.fda.gov/files/tobacco%20products/published/Illicit-Trade-in-Tobacco-Products-After-Implementation-of-an-FDA-Product-Standard.pdf>.
80. * Tobacco Control Legal Consortium et al. “Citizen Petition to the FDA Related to Prohibiting Menthol as a Characterizing Flavor in Cigarettes.” April 12, 2013 (Docket No. FDA–2013–P–0435–0001). Available at <https://www.regulations.gov/docket/FDA-2013-P-0435/document>.
81. * FDA. Letter, FDA/CTP Response to Tobacco Control Legal Consortium et al. October 7, 2013 (Docket No. FDA–2013–P–0435–0088). Available at <https://www.regulations.gov/docket/FDA-2013-P-0435/document>.
82. * Tobacco Control Legal Consortium, et al. “Supplement to Citizen Petition: ‘Prohibit Menthol as a Characterizing Flavor of Cigarettes and Cigarette Smoke.’” January 14, 2021 (Docket No. FDA–2013–P–0435–0001). Available at <https://www.regulations.gov/document/FDA-2013-P-0435-0106>.
83. * FDA. Letter, FDA Response to Menthol Citizen Petition. April 29, 2021 (Docket No. FDA–2013–P–0435–0106). Available at <https://www.regulations.gov/docket/FDA-2013-P-0435/document>.
84. World Health Organization. “Banning Menthol in Tobacco Products.” Geneva, Switzerland: World Health Organization Study Group on Tobacco Product Regulation, 2016.
85. Perfetti, T.A. and H.H. Gordin. “Just Noticeable Differences Studies with Menthol and Non-Menthol.” *Tobacco Science*, 29:57–66, 1985.
86. * Borschke, A. J. “Review of Technologies Relating to Menthol Use in Cigarettes.” Philip Morris Records; Master Settlement Agreement, 1993. Available at <https://www.industrydocuments.ucsf.edu/docs/tncy0002>.
87. * Ai, J., K.M. Taylor, J.G. Lisko, et al. “Menthol Content in US Marketed Cigarettes.” *Nicotine & Tobacco Research*, 18(7):1575–1580, 2016. Available at <https://doi.org/10.1093%2Fntn%2Fntv162>.
88. Giovino, G.A., S. Sidney, J.C. Gfroerer, et al. “Epidemiology of Menthol Cigarette Use.” *Nicotine & Tobacco Research*, 6(1), 2004. Available at <https://doi.org/10.1080/14622203710001649696>.
89. Henningfield, J., N. Benowitz, K. Ahijevych, et al. “Does menthol enhance the addictiveness of cigarettes? An agenda for research.” *Nicotine & Tobacco Research*, 5(1):9–11, 2003. Available at <https://doi.org/10.1080/1462220031000070543>.
90. Gardiner, P.S. “The African Americanization of Menthol Cigarette Use in the United States.” *Nicotine & Tobacco Research*, 6(1) S55–S65, 2004. Available at <https://doi.org/10.1080/14622200310001649478>.
91. Sutton, C.D. and R.G. Robinson. “The Marketing of Menthol Cigarettes in the United States: Populations, Messages, and Channels.” *Nicotine & Tobacco Research*, 6(Suppl. 1) S82–S91, 2004. Available at <https://doi.org/10.1080/14622203310001649504>.
92. * Federal Trade Commission. *Cigarette Report for 2019*. Washington, DC: Federal Trade Commission, 2021. Available at <https://www.ftc.gov/reports/federal-trade-commission-cigarette-report-2019-smokeless-tobacco-report-2019>.
93. * Kuiper, N., D. Gammon, B. Loomis, et al. “Trends in Sales of Flavored and Menthol Tobacco Products in the United States During 2011–2015.” *Nicotine & Tobacco Research*, 20(6):698–706, 2018. Available at <https://doi.org/10.1093/ntr/ntx123>.
94. * Delnevo, C.D., D.P. Giovenco, and A.C. Villanti. “Assessment of Menthol and Nonmenthol Cigarette Consumption in the US, 2000 to 2018.” *JAMA Network Open*, 3(8):e2013601, 2020. Available at <https://doi.org/10.1001/jamanetworkopen.2020.13601>.
95. * Wang, T., A. Gentzke, M. Creamer, et al. “Tobacco Product Use and Associated Factors Among Middle and High School Students—United States, 2019.” *Morbidity and Mortality Weekly Report*, 68(12):1–22, 2019. Available at <https://www.cdc.gov/mmwr/volumes/68/ss/ss6812a1.htm>.
96. * Substance Abuse and Mental Health Services Administration. “Key Substance Use and Mental Health Indicators in the United States: Results from the 2019 National Survey on Drug Use and Health (HHS Publication No. PEP20–07–01–001, NSDUH Series H–55).” Rockville, MD: Center for Behavioral Health Statistics and Quality, 2020. Available at <https://nsduhweb.rti.org/respweb/homepage.cfm>.
97. Rose, S.W., A. Johnson, A.M. Glasser, et al. “Flavour Types Used by Youth and Adult Tobacco Users in Wave 2 of The Population Assessment of Tobacco and Health (Path) Study 2014–2015.” *Tobacco Control*, 29(4):432–446, 2020. Available at <https://doi.org/10.1136/tobaccocontrol-2018-054852>.
98. Smith, P.H., E. Akpara, R. Haq, et al. “Gender and Menthol Cigarette Use in the United States: A Systematic Review of the Recent Literature (2011–May 2017).” *Current Addiction Reports*, 4(4):431–438, 2017. Available at <https://doi.org/10.1007/s40429-017-0175-6>.
99. Ganz, O. and C.D. Delnevo. “Cigarette Smoking and the Role of Menthol in Tobacco Use Inequalities for Sexual Minorities.” *Nicotine & Tobacco Research*, 23(11) 1942–1946, 2021. Available at <https://doi.org/10.1093/ntr/ntab101>.
100. * Cohn, A.M., A.L. Johnson, E. Hair, et al. “Menthol Tobacco Use Is Correlated with Mental Health Symptoms in a National Sample of Young Adults: Implications for Future Health Risks and Policy Recommendations.” *Tobacco Induced Diseases*, 14(1), 2016. Available

- at <https://doi.org/10.1186/s12971-015-0066-3>.
101. Brunette, M.F., J.C. Ferron, P. Geiger, et al. "Menthol Cigarette Use in Young Adult Smokers with Severe Mental Illnesses." *Nicotine & Tobacco Research*, 21(5):691–694, 2019. Available at <https://doi.org/10.1093/ntr/nty064>.
 102. * Willis, D.N., B. Liu, M.A. Ha, et al. "Menthol Attenuates Respiratory Irritation Responses to Multiple Cigarette Smoke Irritants." *The Federation of American Societies for Experimental Biology Journal*, 25(12):4434–4444, 2011. Available at <https://doi.org/10.1096/fj.11-188383>.
 103. * Ha, M.A., G.J. Smith, J.A. Cichock, et al. "Menthol Attenuates Respiratory Irritation and Elevates Blood Cotinine in Cigarette Smoke Exposed Mice." *PLOS ONE*, 2015. Available at <https://doi.org/10.1371/journal.pone.0117128>.
 104. Wise, P., P. Breslin, and P. Dalton. "Sweet Taste and Menthol Increase Cough Reflex Thresholds." *Pulmonary Pharmacology & Therapeutics*, 25: 236–241, 2012. Available at <https://doi.org/10.1016/j.pupt.2012.03.005>.
 105. * Plevkova, J.M., M. Kollarik, I. Poliacek, et al. "The Role of Trigeminal Nasal Trpm8—Expressing Afferent Neurons in the Antitussive Effects of Menthol." *Journal of Applied Physiology*, 115: 268–274, 2013. Available at <https://doi.org/10.1152/jappphysiol.01144.2012>.
 106. Liu, B., L. Fan, S. Balakrishna, et al. "TRPM8 is the Principal Mediator of Menthol-Induced Analgesia of Acute and Inflammatory Pain." *PAIN*, 154(10):2169–2177, 2013. Available at <https://doi.org/10.1016/j.pain.2013.06.043>.
 107. Cohn, A.M., S.W. Rose, J. D'Silva, et al. "Menthol Smoking Patterns and Smoking Perceptions Among Youth: Findings from the Population Assessment of Tobacco and Health Study." *American Journal of Preventive Medicine*, 56(4):e107–e116, 2019. Available at <https://doi.org/10.1016/j.amepre.2018.11.027>.
 108. Cohn, A.M., O. Ganz, A.A. Dennhardt, et al. "Menthol Cigarette Smoking is Associated with Greater Subjective Reward, Satisfaction, and "Throat Hit," But Not Greater Behavioral Economic Demand." *Addictive Behaviors*, 101(2020):106108, 2020. Available at <https://doi.org/10.1016/j.addbeh.2019.106108>.
 109. Villanti, A.C., A.L. Johnson, B. Ambrose, et al. "Flavored Tobacco Product Use in Youth and Adults: Findings from the First Wave of the Path Study (2013–2014)." *American Journal of Preventive Medicine*, 53(2):139–151, 2017. Available at <https://doi.org/10.1016/j.amepre.2017.01.026>.
 110. Cohn, A. and J. D'Silva. "Menthol Smoking and Subjective Response to the First Cigarette Smoked." *Tobacco Regulatory Science*, 5(6):554–566, 2019. Available at <https://doi.org/10.18001/TRS.5.6.7>.
 111. D'Silva, J., E. O'Gara, C.S. Fryer, et al. "Because There's Just Something About That Menthol": Exploring African American Smokers' Perspectives on Menthol Smoking and Local Menthol Sales Restrictions." *Nicotine & Tobacco Research*, 23(2):357–363, 2021. Available at <https://doi.org/10.1093/ntr/ntaa164>.
 112. * Cantrell, Dan V. "U.S. Exhibit 30,792, Report, 'Kool Isn't Getting the Starters/236' DAN V. CANTRELL, BROWN & WILLIAMSON TOBACCO CORP., February 17, 1987." *Depositions and Trial Testimony (DATTA); RICO Privilege Downgrades Collection*. 1987. Available at <https://www.industrydocuments.ucsf.edu/docs/xskv0035>.
 113. * Achey, Ted L. "U.S Exhibit 22,357, Memo, 'Product Information' TED L. ACHEY, LORILLARD INC., August 30, 1978." *Depositions and Trial Testimony (DATTA); RICO Privilege Downgrades Collection*. 1978. Available at <https://www.industrydocuments.ucsf.edu/docs/fhhv0035>.
 114. * HHS. "The Health Consequences of Smoking: Nicotine Addiction: A Report of the Surgeon General." Atlanta, GA: HHS, CDC, Office on Smoking and Health, 1988. Available at <https://collections.nlm.nih.gov/ext/document/101584932X423/PDF/101584932X423.pdf>.
 115. * Dani, J.A. and S. Heinemann. "Molecular and Cellular Aspects of Nicotine Abuse." *Neuron*, 16(5):905–908, 1996. Available at [https://doi.org/10.1016/S0896-6273\(00\)80112-9](https://doi.org/10.1016/S0896-6273(00)80112-9).
 116. * Dani, J.A., D. Jenson, J.I. Broussard, et al. "Neurophysiology of Nicotine Addiction." *Journal of Addiction Research & Therapy*, 20(Suppl. 1), 2011. Available at <https://doi.org/10.4172/2155-6105.S1-001>.
 117. Gotti, C., M. Moretti, A. Gaimarri, et al. "Heterogeneity and Complexity of Native Brain Nicotinic Receptors." *Biochemical Pharmacology*, 74(8):1102–1111, 2007. Available at <https://doi.org/10.1016/j.bcp.2007.05.023>.
 118. O'Dell, L.E. and T.V. Khroyan. "Rodent Models of Nicotine Reward: What Do They Tell Us About Tobacco Abuse in Humans?" *Pharmacology Biochemistry and Behavior*, 91(4):481–488, 2009. Available at <https://doi.org/10.1016/j.pbb.2008.12.011>.
 119. Malin, D., and P. Goyarzu "Rodent Models of Nicotine Withdrawal Syndrome." *Nicotine Psychopharmacology*, 402–427, 2009. Available at https://doi.org/10.1007/978-3-540-69248-5_14.
 120. * HHS. "Preventing Tobacco Use Among Young People: A Report of the Surgeon General." Atlanta, GA: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 1994.
 121. Torres, O.V., H.A. Tejada, L.E. Natividad, et al. "Enhanced Vulnerability to the Rewarding Effects of Nicotine During the Adolescent Period of Development." *Pharmacology Biochemistry and Behavior*, 90(4):658–663, 2008. Available at <https://doi.org/10.1016/j.pbb.2008.05.009>.
 122. Levin, E.D., S.S. Slade, C. Wells, et al. "Threshold of Adulthood for the Onset of Nicotine Self-Administration in Male and Female Rats." *Behavioural Brain Research*, 225(2):473–481, 2011. Available at <https://doi.org/10.1016/j.bbr.2011.08.005>.
 123. de la Pena, J.B., H.M. Ahsan, C.J. Botanas, et al. "Adolescent Nicotine Or Cigarette Smoke Exposure Changes Subsequent Response to Nicotine Conditioned Place Preference And Self-Administration." *Behavioral Brain Research*, 272(1):156–164, 2014. Available at <https://doi.org/10.1016/j.bbr.2014.06.044>.
 124. Dannenhoffer, C.A. and L.P. Spear. "Age Differences in Conditioned Place Preferences and Taste Aversions to Nicotine." *Developmental Psychobiology*, 58(5):660–666, 2016. Available at <https://doi.org/10.1002/dev.21400>.
 125. Adriani, W., S. Macri, R. Pacifici, et al. "Peculiar Vulnerability to Nicotine Oral Self-Administration in Mice During Early Adulthood." *Neuropsychopharmacology*, 27(2):212–224, 2002. Available at [https://doi.org/10.1016/S0893-133X\(02\)00295-6](https://doi.org/10.1016/S0893-133X(02)00295-6).
 126. Kota, D., S.E. Robinson, and M.I. Damaj. "Enhanced Nicotine Reward in Adulthood After Exposure to Nicotine During Early Adolescence in Mice." *Biochemical Pharmacology*, 78(7):873–879, 2009. Available at <https://doi.org/10.1016/j.bcp.2009.06.099>.
 127. Cao, J., J.D. Bulluzzi, S.E. Loughlin, et al. "Locomotor and Stress Responses to Nicotine Differ in Adolescent and Adult Rats." *Pharmacology Biochemistry and Behavior*, 96(1):82–90, 2010. Available at <https://doi.org/10.1016/j.pbb.2010.04.010>.
 128. Trauth, J., F. Seidler, S. Ali, et al. "Adolescent Nicotine Exposure Produces Immediate and Long-Term Changes in CNS Noradrenergic and Dopaminergic Function." *Brain Research*, 892:269–280, 2001. Available at [https://doi.org/10.1016/S0006-8993\(00\)03227-3](https://doi.org/10.1016/S0006-8993(00)03227-3).
 129. * Counotte, D.S., N.A. Goriunova, M. Moretti, et al. "Adolescent Nicotine Exposure Transiently Increases High-Affinity Nicotinic Receptors and Modulates Inhibitory Synaptic Transmission in Rat Medial Prefrontal Cortex." *FASEB Journal*, 26(5):1810–1820, 2012. Available at <https://doi.org/10.1096/fj.11-198994>.
 130. McDonald, C.G., A.K. Eppolito, J.M. Brielmaier, et al. "Evidence for Elevated Nicotine-Induced Structural Plasticity in Nucleus Accumbens of Adolescent Rats." *Brain Research*, 1151:211–218, 2007. Available at <https://doi.org/10.1016/j.brainres.2007.03.019>.
 131. Schochet, T., A. Kelley, and C. Landry. "Differential Expression of Arc mRNA and Other Plasticity-Related Genes Induced by Nicotine in Adolescent Rat Forebrain." *Neuroscience*, 135(1): 285–297, 2005. Available at <https://doi.org/10.1016/j.neuroscience.2005.05.057>.
 132. Trauth, J., F. Seidler, E. McCook, et al. "Adolescent Nicotine Exposure Causes Persistent Upregulation of Nicotinic Cholinergic Receptors in Rat Brain

- Regions." *Brain Research*, 851:9–19, 1999. Available at [https://doi.org/10.1016/S0006-8993\(99\)01994-0](https://doi.org/10.1016/S0006-8993(99)01994-0).
133. Doura, M.B., T.V. Luu, N. Lee, et al. "Persistent Gene Expression Changes in Ventral Tegmental Area of Adolescent But Not Adult Rats in Response to Chronic Nicotine." *Neuroscience*, 170(2):503–513, 2010. Available at <https://doi.org/10.1016/j.neuroscience.2010.06.071>.
134. * Sharapova, S., C. Reyes-Guzman, T. Singh, et al. "Age of Tobacco Use Initiation and Association with Current Use and Nicotine Dependence Among US Middle and High School Students, 2014–2016." *Tobacco Control*, 29(1):49–54, 2020. Available at <https://doi.org/10.1136/tobaccocontrol-2018-054593>.
135. * Apelberg, B.J., C.G. Corey, A.C. Hoffman, et al. "Symptoms of Tobacco Dependence Among Middle and High School Tobacco Users: Results from the 2012 National Youth Tobacco Survey." *American Journal of Preventive Medicine*, 47(2, Suppl. 1):S4–S14, 2014. Available at <https://doi.org/10.1016/j.amepre.2014.04.013>.
136. * Dierker, L.D., J.S. Swendsen, J.R. Rose, et al. "Transitions to Regular Smoking and Nicotine Dependence in the Adolescent National Comorbidity Survey (NCS–A)." *Annals of Behavioral Medicine*, 43:394–401, 2012. Available at <https://doi.org/10.1007/s12160-011-9330-9>.
137. * DiFranza, J.R., J.A. Savageau, K. Fletcher, et al. "Symptoms of Tobacco Dependence After Brief Intermittent Use: The Development and Assessment of Nicotine Dependence in Youth-2 Study." *JAMA*, 161(7):704–710, 2007. Available at <https://jamanetwork.com/journals/jamapediatrics/fullarticle/570706>.
138. O'Loughlin, J., J. DiFranza, R.F. Tyndale, et al. "Nicotine-Dependence Symptoms Are Associated with Smoking Frequency in Adolescents." *American Journal of Preventive Medicine*, 25(3):0749–3797, 2003. Available at [https://doi.org/10.1016/S0749-3797\(03\)00198-3](https://doi.org/10.1016/S0749-3797(03)00198-3).
139. Rose J.S., L.C. Dierker, E. Donny. "Nicotine Dependence Symptoms Among Recent Onset Adolescent Smokers." *Drug and Alcohol Dependence*, 106(2–3):126–32, 2010. Available at <https://doi.org/10.1016/j.drugalcdep.2009.08.012>.
140. DiFranza, J.R., J.A. Savageau, K. Fletcher, et al. "Recollections and Repercussions of the First Inhaled Cigarette." *Addictive Behaviors*, 29:261–272, 2004. Available at <https://doi.org/10.1016/j.addbeh.2003.08.002>.
141. * Curtin, G.M., S.I. Sulsky, C.V. Landingham, et al. "Primary Measures of Dependence Among Menthol Compared to Non-Menthol Cigarette Smokers in the United States." *Regulatory Toxicology and Pharmacology*, 69(3):451–466, 2014. Available at <https://doi.org/10.1016/j.yrtph.2014.05.011>.
142. * Pletcher, M.J., B.J. Hulley, T. Houston, et al. "Menthol Cigarettes, Smoking Cessation, Atherosclerosis, and Pulmonary Function." *Archives of Internal Medicine*, 166:1915–1922, 2006. Available at <https://doi.org/10.1001/archinte.166.17.1915>.
143. Reitzel, L.R., E. Cromley, Y. Li, et al. "The Effect of Tobacco Outlet Density and Proximity on Smoking Cessation." *American Journal of Public Health*, 101(2):315–320, 2011. Available at <https://dx.doi.org/10.2105%2FAJPH.2010.191676>.
144. * Reitzel, L.R., Y. Li, D.W. Stewart, et al. "Race Moderates the Effect of Menthol Cigarette Use on Short-Term Smoking Abstinence." *Nicotine & Tobacco Research*, 15(5):883–889, 2013. Available at <https://doi.org/10.1093/ntr/nts335>.
145. Rojewski, A.M., B.A. Toll, and S. O'Malley. "Menthol Cigarette Use Predicts Treatment Outcomes of Weight-Concerned Smokers." *Nicotine & Tobacco Research*, 16(1):115–119, 2014. Available at <https://doi.org/10.1093/ntr/ntt137>.
146. Smith, S.S., M.C. Fiore, and T.B. Baker. "Smoking Cessation in Smokers Who Smoke Menthol and Non-Menthol Cigarettes." *Addiction*, 109(12):2107–2117, 2014. Available at <https://doi.org/10.1111/add.12661>.
147. Muench, C. and L.M. Juliano. "Predictors of Smoking Lapse During a 48-Hour Laboratory Analogue Smoking Cessation Attempt." *Psychology of Addictive Behaviors*, 31(4):415–422, 2017. Available at <https://doi.org/10.1037/adb0000246>.
148. Bover, M.T., J. Foulds, M.B. Steinberg, et al. "Waking at Night to Smoke as a Marker for Tobacco Dependence: Patient Characteristics and Relationship to Treatment Outcome." *International Journal of Clinical Practice*, 62(2):182–190, 2008. Available at <https://doi.org/10.1111/j.1742-1241.2007.01653.x>.
149. Okuyemi, K.S., J.S. Ahluwalia, M. Ebersole-Robinson, et al. "Does Menthol Attenuate the Effect of Bupropion Among African American Smokers?" *Addiction*, 98:1387–1393, 2003. Available at <https://doi.org/10.1046/j.1360-0443.2003.00443.x>.
150. Okuyemi, K.S., B. Faseru, L.S. Cox, et al. "Relationship Between Menthol Cigarettes and Smoking Cessation Among African American Light Smokers." *Addiction*, 102(12):1979–1986, 2007. Available at <https://doi.org/10.1111/j.1360-0443.2007.02010.x>.
151. Gandhi, K., J. Foulds, M. Steinberg, et al. "Lower Quit Rates Among African American and Latino Menthol Cigarette Smokers at a Tobacco Treatment Clinic." *International Journal of Clinical Practice*, 63(3): 360–367, 2009. Available at <https://doi.org/10.1111/j.1742-1241.2008.01969.x>.
152. Faseru, B., N.L. Nollen, M.S. Mayo, et al. "Predictors of Cessation in African American Light Smokers Enrolled in a Bupropion Clinical Trial." *Addictive Behaviors*, 38:1796–1803, 2013. Available at <https://doi.org/10.1016/j.addbeh.2012.11.010>.
153. Keeler, C., W. Max, V. Yerger, et al. "The Association of Menthol Cigarette Use with Quit Attempts, Successful Cessation, and Intention to Quit Across Racial/Ethnic Groups in the United States." *Nicotine & Tobacco Research*, 19(12):1450–1464, 2017. Available at <https://doi.org/10.1093/ntr/ntw215>.
154. Keeler, C., W. Max, V. Yerger, et al. "Effects of Cigarette Prices on Intention to Quit, Quit Attempts, and Successful Cessation Among African American Smokers." *Nicotine & Tobacco Research*, 22(4):1–10, 2018. Available at <https://doi.org/10.1093/ntr/nty149>.
155. Kingsbury, J.H., K. Mehrotra, J. D'Silva, et al. "Perceptions of Menthol Cigarettes and Reasons for Unsuccessful Quits in An African American Community Sample." *Journal of Immigrant and Minority Health*, 23:137–144, 2021. Available at <https://doi.org/10.1007/s10903-020-01028-z>.
156. * Hyland, A., S. Garten, G. Giovino, et al. "Mentholated Cigarettes and Smoking Cessation: Findings from COMMIT." *Tobacco Control*, 11:135–139, 2002. Available at <https://doi.org/10.1136/tc.11.2.135>.
157. Murray, R.P., J.E. Connett, M.A. Skeans, et al. "Menthol Cigarettes and Health Risks in Lung Health Study Data." *Nicotine & Tobacco Research*, 9(1):101–107, 2007. Available at <https://doi.org/10.1080/14622200601078418>.
158. Fu, S.S., K.S. Okuyemi, M.R. Partin, et al. "Menthol Cigarettes and Smoking Cessation During an Aided Quit attempt." *Nicotine & Tobacco Research*, 10(3):457–462, 2008. Available at <https://doi.org/10.1080/14622200801901914>.
159. Blot, W.J., S.S. Cohen, M. Aldrich, et al. "Lung Cancer Risk Among Smokers of Menthol Cigarettes." *Journal of the National Cancer Institute*, 103(10):810–816, 2011. Available at <https://doi.org/10.1093/jnci/djr102>.
160. D'Silva, J., R.G. Boyle, R.L. Lien, et al. "Cessation Outcomes Among Treatment-Seeking Menthol and Nonmenthol Smokers." *American Journal of Preventive Medicine*, 43(5S3):S242–S248, 2012. Available at <https://doi.org/10.1016/j.amepre.2012.07.033>.
161. Jao, N.C., A.K. Veluz-Wilkins, M.J. Smith, et al. "Does Menthol Cigarette Use Moderate the Effect of Nicotine Metabolism on Short-Term Smoking Cessation?" *Experimental and Clinical Psychopharmacology*, 25(3):216–222, 2017. Available at <https://doi.org/10.1037/pha0000124>.
162. Tanner, N.T., N.A. Thomas, R. Ward, et al. "Association of Cigarette Type and Nicotine Dependence in Patients Presenting for Lung Cancer Screening." *Chest Journal*, 158(5):2184–2191, 2020. Available at <https://doi.org/10.1016/j.chest.2020.05.608>.
163. Schneller, L.M., M. Bansal-Travers, M.C. Mahoney, et al. "Menthol Cigarettes and Smoking Cessation among Adult Smokers in the US." *American Journal of Health Behavior*, 44(2): 252–256, 2020. Available at <https://doi.org/10.5993/AJHB.44.2.12>.
164. * Villanti, A.C., L.K. Collins, R.S. Niaura, et al. "Menthol Cigarettes and the Public Health Standard: A

- Systematic Review.” BMC Public Health, 17:983, 2017. Available at <https://doi.org/10.1186/s12889-017-4987-z>.
165. * Hilberink, S., J.E. Jacobs, S. Opstal, et al. “Validation of Smoking Cessation Self-Reported By Patients with Chronic Obstructive Pulmonary Disease.” International Journal of General Medicine, 4:85–90, 2011. Available at <https://doi.org/10.2147/IJGM.S15231>.
166. Brody, A.L., A.G. Mukhin, M.S. Mamoun, et al. “Brain Nicotinic Acetylcholine Receptor Availability and Response to Smoking Cessation Treatment: A Randomized Trial.” JAMA Psychiatry, 71(7):797–805, 2014. Available at <https://doi.org/10.1001/jamapsychiatry.2014.138>.
167. * National Cancer Institute. “The Role of the Media in Promoting and Reducing Tobacco Use. Tobacco Control Monograph No. 19.” Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute. NIH Pub. No. 07–6242, June 2008. Available at <https://cancercontrol.cancer.gov/brp/tcrb/monographs/monograph-19>.
168. Cruz, T.B., L.T. Wright, and G. Crawford. “The Menthol Marketing Mix: Targeted Promotions for Focus Communities in the United States.” Nicotine & Tobacco Research, 12(Suppl. 2):S147–S153, 2010. Available at <https://doi.org/10.1093/ntr/ntq201>.
169. Balbach, E.D., R.J. Gasior, and E.M. Barbeau. “R.J. Reynolds’ Targeting of African Americans: 1988–2000.” American Journal of Public Health, 93(5):822–827, 2003. Available at <https://doi.org/10.2105/AJPH.93.5.822>.
170. * Cruz, T.B., S.W. Rose, B.A. Lienemann, et al. “Pro-Tobacco Marketing and Anti-Tobacco Campaigns Aimed at Vulnerable Populations: A Review of the Literature.” Tobacco Induced Diseases, 17:68, 2019. Available at <https://doi.org/10.18332/tid/111397>.
171. Yerger, V.B., J. Przewoznik, and R.E. Malone. “Racialized Geography, Corporate Activity, and Health Disparities: Tobacco Industry Targeting of Inner Cities.” Journal of Health Care for the Poor and Underserved, 18(4):10–18, 2007. Available at <https://doi.org/10.1353/hpu.2007.0120>.
172. * Phillip Morris. “Benson & Hedges Part-Time Inner City Sampling Program.” Philip Morris Records; Master Settlement Agreement, 1985. Available at <https://www.industrydocuments.ucsf.edu/docs/xqxx0111>.
173. * Gravely, L. “Black Smoker Likelihood of Buying Ten (10) Cigarette Package Size of Kool.” Marketing to Minorities, Military, and Gays MSA Collection, 1985. Available at <https://www.industrydocuments.ucsf.edu/docs/kmlk0045>.
174. * Persoskie, A., E.A. Donaldson, and C. Ryant. “How Tobacco Companies Have Used Package Quantity for Consumer Targeting.” BMJ, 28(4):9, 2018. Available at <https://tobaccocontrol.bmj.com/content/28/4/365>.
175. Lee, J.G., L. Henriksen, SW Rose, et al. “A Systematic Review of Neighborhood Disparities in Point-Of-Sale Tobacco Marketing.” American Journal of Public Health, 105:e8–e18, 2015. Available at <https://doi.org/10.2105/AJPH.2015.302777>.
176. Kephart, L., G. Song, P. Henley, et al. “The Association Between Neighborhood Racial Composition and Menthol Cigarette Pricing in Boston, MA.” Health & Place, 58:102144, 2019. Available at <https://doi.org/10.1016/j.healthplace.2019.102144>.
177. Mills, S.D., L. Henriksen, S.D. Golden, et al. “Disparities in Retail Marketing for Menthol Cigarettes in the United States, 2015.” Health & Place, 53:62–70, 2018. Available at <https://doi.org/10.1016/j.healthplace.2018.06.011>.
178. Mennis J. and M. Mason. “Tobacco Outlet Density and Attitudes Towards Smoking Among Urban Adolescent Smokers.” Substance Abuse, 37(4):521–525, 2016. Available at <https://doi.org/10.1080/08897077.2016.1181135>.
179. Robertson L., C. Cameron, R. McGee, et al. “Point-of-Sale Tobacco Promotion and Youth Smoking: A Meta-Analysis.” Tobacco Control, 25(e2):e83–e89, 2016. Available at <https://doi.org/10.1136/tobaccocontrol-2015-052586>.
180. McCarthy, M., M. Siahpush, R.A. Shaikh, et al. “Social Disparities in Unaided Quit Attempts Among Daily Current and Former Smokers: Results From the 2010–2011 Tobacco Use Supplement to the Current Population Survey.” Nicotine & Tobacco Research, 18(8):1705–1710, 2016. Available at <https://doi.org/10.1093/ntr/ntw007>.
181. Henriksen, L., N.C. Schleicher, A.L. Dauphinee, et al. “Targeted Advertising, Promotion, and Price for Menthol Cigarettes in California High School Neighborhoods.” Nicotine & Tobacco Research, 14(1):116–21, 2012. Available at <https://doi.org/10.1093/ntr/ntn122>.
182. Rock, V., S. Davis, S. Thorne, et al. “Menthol Cigarette Use among Racial and Ethnic Groups in the United States, 2004–2008.” Nicotine & Tobacco Research, S117–S124, 2010. Available at <https://doi.org/10.1093/ntr/ntq204>.
183. * Giovino, G.A., A.C. Villanti, P.D. Mowert, et al. “Differential Trends in Cigarette Smoking in the USA: Is Menthol Slowing Progress?” Tobacco Control, 24:28–37, 2015. Available at <https://doi.org/10.1136/tobaccocontrol-2013-051159>.
184. Kandel, D., M.C. Hu, P. Griesler, et al. “On the Development of Nicotine Dependence in Adolescence.” Drug and Alcohol Dependence, 91(1):26–39., 2007. Available at <https://dx.doi.org/10.1016%2Fj.drugalcdep.2007.04.011>.
185. Gomez, Y., M. Creamer, K.F. Trivers, et al. “Patterns of Tobacco Use and Nicotine Dependence Among Youth, United States, 2017–2018.” Preventive Medicine, 141 106284, 2020. Available at <https://doi.org/10.1016/j.jpmed.2020.106284>.
186. Sledjeski, E.M., L.C. Dierker, D. Costello, et al. “Predictive Validity of Four Nicotine Dependence Measures in a College Sample.” Drug and Alcohol Dependence, 87(1):10–19, 2007. Available at <https://doi.org/10.1016/j.drugalcdep.2006.07.005>.
187. Walker, J.F. and P.D. Loprinzi. “Longitudinal Examination of Predictors of Smoking Cessation in a National Sample of U.S. Adolescent and Young Adult Smokers.” Nicotine & Tobacco Research, 16(6):820–827, 2014. Available at <https://doi.org/10.1093/ntr/ntu005>.
188. Rossheim, M.E., M.D. Livingston, J.R. Krall, et al. “Cigarette Use Before and After the 2009 Flavored Cigarette Ban.” Journal of Adolescent Health, 67(3):432–437, 2020. Available at <https://doi.org/10.1016/j.jadohealth.2020.06.022>.
189. Courtemanche, C.J., M.K. Palmer, and M.F. Pesko. “Influence of the Flavored Cigarette Ban on Adolescent Tobacco Use.” American Journal of Preventive Medicine, 52(5):e139–e146, 2017. Available at <https://doi.org/10.1016/j.amepre.2016.11.019>.
190. Gammon, D.G., T. Rogers, J. Gaber, et al. “Implementation of a Comprehensive Flavoured Tobacco Product Sales Restriction and Retail Tobacco Sales.” Tobacco Control, 0:1–7, 2021. Available at <https://doi.org/10.1136/tobaccocontrol-2021-056494>.
191. * Yang, Y., E.N. Lindblom, R.G. Salloom, et al. “The Impact of a Comprehensive Tobacco Product Flavor Ban in San Francisco Among Young Adults.” Addictive Behaviors Reports, 11:100273, 2020. Available at <https://doi.org/10.1016/j.abrep.2020.100273>.
192. Olson, L.T., E.M. Coats, T. Rogers, et al. “Youth Tobacco Use Before and After Local Sales Restrictions on Flavored and Menthol Tobacco Products in Minnesota.” Journal of Adolescent Health, 2022. Available at <https://doi.org/10.1016/j.jadohealth.2022.01.129>.
193. Asare S., M.A., J.L. Westmaas, et al. “Association of Cigarette Sales with Comprehensive Menthol Flavor Ban in Massachusetts.” JAMA Internal Medicine 182(2):231–234, 2022. Available at <https://doi:10.1001/jamainternmed.2021.7333>.
194. Vyas, P., P. Ling, B. Gordon, et al. “Compliance with San Francisco’s Flavoured Tobacco Sales Prohibition.” Tobacco Control, 30:227–230, 2021. Available at <https://doi.org/10.1136/tobaccocontrol-2019-055549>.
195. * Friedman, A.S. “A Difference-In-Differences Analysis of Youth Smoking and a Ban on Sales of Flavoured Tobacco Products in San Francisco, California.” JAMA Pediatrics, 175(8):863–865, 2021. Available at <https://dx.doi.org/10.1001%2Fjamapediatrics.2021.0922>.
196. Liu, J., A.S.L. Tan, J.P. Winickoff, et al. “Youth Tobacco Use Before and After Flavoured Tobacco Sales Restrictions in Oakland, California and San Francisco, California.” Tobacco Control, Published Online First, 17 March 2022. Available at <http://dx.doi.org/10.1136/tobaccocontrol-2021-057135>.
197. Carpenter, C.S., & Nguyen, H.V. “Intended and unintended effects of banning menthol cigarettes.” The Journal

- of Law and Economics, 64(3), 629–650, 2021. Available at <https://doi.org/10.1086/713978>.
198. * Campaign for Tobacco-Free Kids. “States and Localities That Have Restricted The Sale of Flavored Tobacco Products.” January 6, 2022. Available at <https://www.tobaccofreekids.org/assets/factsheets/0398.pdf>.
199. Farley, S.M. and M. Johns. “New York City Flavoured Tobacco Product Sales Ban Evaluation.” *Tobacco Control*, 26:78–84, 2017. Available at <https://doi.org/10.1136/tobaccocontrol-2015-052418>.
200. Rogers, T., E.M. Brown, T.M. McCrae, et al. “Compliance with A Sales Policy on Flavored Non-Cigarette Tobacco Products.” *Tobacco Regulatory Science*, 3(Suppl 1):84–93, 2017. Available at [https://doi.org/10.18001/TRS.3.2\(Suppl1\).9](https://doi.org/10.18001/TRS.3.2(Suppl1).9).
201. Kingsley, M., C.M. Setodji, J.D. Pane, et al. “Short-Term Impact of a Flavored Tobacco Restriction: Changes in Youth Tobacco Use in a Massachusetts Community.” *American Journal of Preventive Medicine*, 57(6):741–748, 2019. Available at <https://doi.org/10.1016/j.amepre.2019.07.024>.
202. * Pearlman, D.N., J.A. Arnold, G.A. Guardino, et al. “Advancing Tobacco Control Through Point of Sale Policies, Providence, Rhode Island.” *Preventing Chronic Disease*, 16:180614, 2019. Available at <https://doi.org/10.5888/pcd16.180614>.
203. * Hawkins, S.S., C. Kruzik, M. O’Brien, et al. “Flavoured Tobacco Product Restrictions in Massachusetts Associated with Reductions in Adolescent Cigarette and E-Cigarette Use.” *Tobacco Control*, 0:1–4, 2021. Available at <https://doi.org/10.1136/tobaccocontrol-2020-056159>.
204. Kingsley, M., C.M. Setodji, J.D. Pane, et al. “Longer-Term Impact of the Flavored Tobacco Restriction in Two Massachusetts Communities: A Mixed-Methods Study.” *Nicotine & Tobacco Research*, 23(11): 1928–1935, 2021. Available at <https://doi.org/10.1093/ntr/ntab115>.
205. Liu, S.T., K. Snyder, M.A. Tynan, et al. “Youth Access to Tobacco Products in the United States, 2016–2018.” *Tobacco Regulatory Science*, 5(6):491–501, 2019. Available at <https://doi.org/10.18001/TRS.5.6.2>.
206. * Cotti, C., E. Nesson, and N. Tefft (2016). “The effects of tobacco control policies on tobacco products, tar, and nicotine purchases among adults: Evidence from household panel data”. *American Economic Journal: Economic Policy*, 8(4), 103–23, 2016. Available at <http://dx.doi.org/10.1257/pol.20150268>.
207. Zheng, Y., C. Zhen, J. Nonnemaker, J., et al. “Advertising, habit formation, and US tobacco product demand.” *American Journal of Agricultural Economics*, 98(4), 1038–1054, 2016. Available at <https://doi.org/10.1093/ajae/aaw024>.
208. Zheng, Y., C. Zhen, D. Dench, D., et al. “US demand for tobacco products in a system framework.” *Health Economics*, 26(8), 1067–1086, 2017. Available at <https://doi.org/10.1002/hec.3384>.
209. Rogers, T., A. Feld, D.G. Gammon, et al. “Changes in Cigar Sales Following Implementation of a Local Policy Restricting Sales of Flavoured Non-Cigarette Tobacco Products.” *Tobacco Control*, 29(4):412–419, 2020. Available at <https://doi.org/10.1136/tobaccocontrol-2019-055004>.
210. * Babb, S., A. Malarcher, G. Schauer, et al. “Quitting Smoking Among Adults—United States, 2000–2015.” *Morbidity and Mortality Weekly Report*, 65(52):1457–1464, 2017. Available at <https://doi.org/10.15585/mmwr.mm6552a1>.
211. Levy, D.T., C.J. Cadham, L.M. Sanchez-Romero, et al. “An Expert Elicitation on the Effects of a Ban on Menthol Cigarettes and Cigars in the United States.” *Nicotine & Tobacco Research*, 23(11): 1911–1920, 2021. Available at <https://doi.org/10.1093/ntr/ntab121>.
212. * Czaplicki, L., B. Schillo, S.W. Rose, et al. “National Support for a Menthol Cigarette Sales Ban.” *Public Health Reports*, 136(2):183–191, 2021. Available at <https://doi.org/10.1177%2F0033354920966004>.
213. Pearson, J.L., D.B. Abrams, R.S. Niaura, et al. “A Ban on Menthol Cigarettes: Impact on Public Opinion and Smokers’ Intention to Quit.” *American Journal of Public Health*, 102:e107–e114, 2012. Available at <https://doi.org/10.2105/AJPH.2012.300804>.
214. Hymowitz, N., C. Mouton, and H. Edkholdt. “Menthol Cigarette Smoking in African Americans and Whites.” *Tobacco Control*, 4(2):194–195, 1995. Available at <http://dx.doi.org/10.1136/tc.4.2.194b>.
215. Rose, S.W., O. Ganz, Y. Zhou, et al. “Longitudinal Response to Restrictions on Menthol Cigarettes Among Young Adult US Menthol Smokers, 2011–2016.” *American Journal of Public Health*, 109:1400–1403, 2019. Available at <https://doi.org/10.2105/AJPH.2019.305207>.
216. * Chung-Hall, J., G.T. Fong, G. Meng, et al. “Evaluating the Impact of Menthol Cigarette Bans on Cessation and Smoking Behaviours in Canada: Longitudinal Findings from the Canadian Arm of the 2016–2018 ITC Four Country Smoking and Vaping Surveys.” *Tobacco Control*, 0:1–8, 2021. Available at <https://doi.org/10.1136/tobaccocontrol-2020-056259>.
217. Bold, K.W., P. Jatlow, L.M. Fucito, et al. “Evaluating the Effect of Switching to Non-Menthol Cigarettes Among Current Menthol Smokers: An Empirical Study of a Potential Ban of Characterising Menthol Flavour in Cigarettes.” *Tobacco Control*, 29:624–630, 2020. Available at <https://doi.org/10.1136/tobaccocontrol-2019-055154>.
218. * Cadham, C.J., L.M. Sanchez-Romero, N.L. Fleicher, et al. “The Actual and Anticipated Effects of a Menthol Cigarette Ban: A Scoping Review.” *BMC Public Health*, 20:1055, 2020. Available at <https://doi.org/10.1186/s12889-020-09055-z>.
219. O’Connor, R.J., M. Bansal-Travers, L.P. Carter, et al. “What Would Menthol Smokers Do If Menthol in Cigarettes Were Banned? Behavioral Intentions and Simulated Demand.” *Addiction*, 107:1330–1338, 2012. Available at <https://doi.org/10.1111/j.1360-0443.2012.03822.x>.
220. Wackowski, O.A., M.T. Manderski, and C.D. Delnevo. “Young Adults’ Behavioral Intentions Surrounding a Potential Menthol Cigarette Ban.” *Nicotine & Tobacco Research*, 16(6):876–880, 2014. Available at <https://doi.org/10.1093/ntr/ntu003>.
221. * D’Silva, J., M.S. Amato, R.G. Boyle, et al. “Quitting and Switching: Menthol Smokers’ Responses to a Menthol Ban.” *Tobacco Regulatory Science*, 1(1):54–60, 2015. Available at <https://doi.org/10.18001/TRS.1.1.6>.
222. * Wackowski, O.A., C.D. Delnevo, and J.L. Pearson. “Switching to E-Cigarettes in the Event of a Menthol Cigarette Ban.” *Nicotine & Tobacco Research*, 17(10):1286–1287, 2015. Available at <https://doi.org/10.1093/ntr/ntv021>.
223. * Hartman, A. “What Menthol Smokers Report They Would Do If Menthol Cigarettes Were No Longer Sold.” Presentation to FDA Tobacco Products Scientific Advisory Committee Meeting, Silver Spring, MD, January 10–11, 2011. Available at <https://wayback.archive-it.org/7993/20170113150718/http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM240176.pdf>.
224. Chaiton, M.O., I. Nicolau, R. Schwartz, et al. “Ban on Menthol-Flavoured Tobacco Products Predicts Cigarette Cessation at 1 Year: A Population Cohort Study.” *Tobacco Control*, 29:341–347, 2020. Available at <https://doi.org/10.1136/tobaccocontrol-2018-054841>.
225. Guillory, J., A.E. Kim, J.M. Nonnemaker, et al. “Effect of Menthol Cigarette and Other Menthol Tobacco Product Bans on Tobacco Purchases in the RTI iShoppe Virtual Convenience Store.” *Tobacco Control*, 29(4):452–459, 2020. Available at <https://doi.org/10.1136/tobaccocontrol-2019-054997>.
226. Chaiton, M.O., R. Schwartz, J.E. Cohen, et al. “Association of Ontario’s Ban on Menthol Cigarettes with Smoking Behavior 1 Month After Implementation.” *JAMA Internal Medicine*, 178(5):710–711, 2018. Available at <https://doi.org/10.1001/jamainternmed.2017.8650>.
227. Chaiton, M.O., R. Schwartz, J.E. Cohen, et al. “Prior Daily Menthol Smokers More Likely to Quit 2 Years After a Menthol Ban Than Non-Menthol Smokers: A Population Cohort Study.” *Nicotine & Tobacco Research*, 23(9):1584–1589, 2021. Available at <https://doi.org/10.1093/ntr/ntab042>.
228. * Ontario Tobacco Research Unit. *Smoke-Free Ontario Strategy Monitoring Report*. Toronto, Canada: Ontario Tobacco Research Unit, Special Report, March 2017. Available at <https://www.otru.org/documents/2017-smoke-free-ontario-strategy-monitoring-report/>.
229. * Creamer, M.R., T.W. Wang, S. Babb, et al. “Tobacco Product Use and Cessation

- Indicators Among Adults—United States, 2018.” *Morbidity and Mortality Weekly Report*, 68(45):1013–1019, 2019. Available at <https://doi.org/10.15585/mmwr.mm6845a2>.
230. * Chaiton, M.O., R. Schwartz, J. Shuldiner, et al. “Evaluating a Real World Ban on Menthol Cigarettes: An Interrupted Time-Series Analysis of Sales.” *Nicotine & Tobacco Research*, 22(4):576–579, 2020. Available at <https://doi.org/10.1093/ntr/ntz041>.
231. Brown, E.M., D.G. Gammon, T. Rogers, et al. “Changes in Retail Sales in Tobacco Products in Ontario After a Menthol Sales Restriction.” *Tobacco Control*, tobaccocontrol–2021–056489, 2021. Available at <https://doi.org/10.1136/tobaccocontrol-2021-056489>.
232. * Chaiton M.O., R. Schwartz, A. Kundu, et al. “Analysis of Wholesale Cigarette Sales in Canada After Menthol Cigarette Bans.” *JAMA Network Open*, 4(11):e2133673, 2021. Available at <https://doi:10.1001/jamanetworkopen.2021.33673>.
233. * Guldish, J.R., E.R. Straus, T. Le, et al. “Menthol Cigarette Use in Substance Use Disorder Treatment Before and After Implementation of a County-Wide Flavoured Tobacco Ban.” *Tobacco Control*, 30:616–622, 2021. Available at <https://doi.org/10.1136/tobaccocontrol-2020-056000>.
234. Guldish, J., E. Passalacqua, B. Tajima, et al. “Smoking Prevalence in Addiction Treatment: A Review.” *Nicotine & Tobacco Research*, 13(6):401–411, 2011. Available at <https://doi.org/10.1093/ntr/ntz048>.
235. Guldish, J., E. Passalacqua, A. Pagano, et al. “An International Systematic Review of Smoking Prevalence in Addiction Treatment.” *Addiction*, 111(2):220–230, 2016. Available at <https://doi.org/10.1111/add.13099>.
236. McClure, E.A., S.P. Acquavita, K.E. Dunn, et al. “Characterizing Smoking, Cessation Services, and Quit Interest Across Outpatient Substance Abuse Treatment Modalities.” *Substance Abuse & Treatment*, 46(2), 2014. Available at <https://doi.org/10.1016/j.jsat.2013.07.009>.
237. Parker, M.A., S. Sigmon, and A. Villanti. “Higher Smoking Prevalence Among United States Adults with Co-Occurring Affective and Drug Use Diagnosis.” *Addictive Behaviors*, 99:106112, 2019. Available at <https://doi.org/10.1016/j.addbeh.2019.106112>.
238. Parker, M.A., J.M. Streck, and S.C. Sigmon. “Associations Between Opioid and Nicotine Dependence in Nationally Representative Samples of United States Adult Daily Smokers.” *Drug and Alcohol Dependence*, 186(2018):167–170, 2018. Available at <https://doi.org/10.1016/j.drugalcdep.2018.01.024>.
239. Richter, K., C. Gibson, J. Ahluwalia, et al. “Tobacco Use and Quit Attempts Among Methadone Maintenance Clients.” *American Journal of Public Health*, 91:296–299, 2001. Available at <https://dx.doi.org/10.2105%2Fajph.91.2.296>.
240. Richter, K.P., H.K. Ahluwalia, M.C. Mosier, et al. “A Population-Based Study of Cigarette Smoking among Illicit Drug Users in The United States.” *Addiction*, 97, 861–869, 2002. Available at <https://doi.org/10.1046/j.1360-0443.2002.00162.x>.
241. Chait, L.D. and R.R. Griffiths. “Effects of Methadone on Human Cigarette Smoking and Subjective Ratings.” *The Journal of Pharmacology and Experimental Therapeutics*, 229(3):636–640, 1984. Available at <https://jpet.aspetjournals.org/content/229/3/636>.
242. Henningfield, J. and R. Griffiths. “Cigarette Smoking and Subjective Response: Effects of D-Amphetamine.” *Clin. Pharmacol. Ther.*, 30(4):497–505, 1981. Available at <https://doi.org/10.1038/clpt.1981.194>.
243. Schmitz, J., J. Grabowski, and H. Rhoades. “The Effects of High and Low Doses of Methadone on Cigarette Smoking.” *Drug and Alcohol Dependence*, 34:237–242, 1994. Available at [https://doi.org/10.1016/0376-8716\(94\)90162-7](https://doi.org/10.1016/0376-8716(94)90162-7).
244. Spiga, R., J. Schmitz, and J. Day. “Effects of Nicotine on Methadone Self-Administration in Humans.” *Drug and Alcohol Dependence*, 50(2):157–165, 1998. Available at [https://doi.org/10.1016/S0376-8716\(98\)00020-9](https://doi.org/10.1016/S0376-8716(98)00020-9).
245. * HHS. “Smoking Cessation: A Report of the Surgeon General.” Atlanta, GA: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2020. Available at <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>.
246. * Rostron, B.L., C.M. Chang, and T.F. Pechacek. “Estimation of Cigarette Smoking-Attributable Morbidity in the United States.” *JAMA Internal Medicine*, 174(12):1922–1928, 2014. Available at <https://doi.org/10.1001/jamainternmed.2014.5219>.
247. Christensen, C.H., B. Rostron, C. Cosgrove, et al. “Association of Cigarette, Cigar, and Pipe Use with Mortality Risk in the US Population.” *JAMA Internal Medicine*, 178(4):469–476, 2018. Available at <https://doi.org/10.1001/jamainternmed.2017.8625>.
248. Jha, P., C. Ramasundaramhettige, V. Landsman, et al. “21st-Century Hazards of Smoking and Benefits of Cessation in The United States.” *The New England Journal of Medicine*, 368:341–50, 2013. Available at <https://doi.org/10.1056/NEJMsa1211128>.
249. Inoue-Choi, M., T.S. McNeel, P. Hartge, et al. “Non-Daily Cigarette Smokers: Mortality Risks in The United States.” *American Journal of Preventive Medicine*, 56(1):27–37, 2019. Available at <https://doi.org/10.1016/j.amepre.2018.06.025>.
250. * HHS. “The Health Consequences of Smoking: A Report of the Surgeon General.” Atlanta, GA: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2004. Available at https://www.cdc.gov/tobacco/data_statistics/sgr/2004/complete_report/index.htm.
251. Thun M., B. Carter, D. Feskanich, et al. “50-Year Trends in Smoking-Related Mortality in the United States.” *The New England Journal of Medicine*, 368(4):351–364, 2013. Available at <https://doi.org/10.1056/NEJMsa1211127>.
252. * World Health Organization. “Tobacco: Health Benefits of Smoking Cessation.” February, 25, 2020. Accessed November 3, 2021. <https://www.who.int/news-room/questions-and-answers/item/tobacco-health-benefits-of-smoking-cessation>.
253. * McBride, C. and J. Ostroff. “Teachable Moments for Promoting Smoking Cessation: The Context of Cancer Care and Survivorship.” *Cancer Control*, 10(4):325–333, 2003. Available at <https://doi.org/10.1177/107327480301000407>.
254. * Travis, L.B., C.S. Rabkin, L.M. Brown, et al. “Cancer Survivorship—Genetic Susceptibility and Second Primary Cancers: Research Strategies and Recommendations.” *Journal of the National Cancer Institute*, 98(1):15–25, 2006. Available at <https://doi.org/10.1093/jnci/djj001>.
255. * Parsons, A., A. Daley, R. Begh, et al. “Influence of Smoking Cessation After Diagnosis of Early Stage Lung Cancer on Prognosis: Systematic Review of Observational Studies with Meta-Analysis.” *BMJ*, 340:b5569, 2010. Available at <https://doi.org/10.1136/bmj.b5569>.
256. * HHS. “The Health Benefits of Smoking Cessation: A Report of the Surgeon General.” Atlanta, GA: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 1990. Available at https://www.google.com/books/edition/The_Health_Benefits_of_Smoking_Cessation/9bkJtXVCkdMC?hl=en&gbpv=1&printsec=frontcover.
257. Sheikh, M., A. Mukeriyah, O. Shangina, et al. “Postdiagnosis Smoking Cessation and Reduced Risk for Lung Cancer Progression and Mortality: A Prospective Cohort Study.” *Annals of Internal Medicine*, 174(9):1232–1239, 2021. Available at <https://doi.org/10.7326/M21-0252>.
258. * Kaiser, E.G., J.J. Prochaska, and M.S. Kendra. “Tobacco Cessation in Oncology Care.” *Oncology*, 95:129–137, 2018. Available at <https://doi.org/10.1159/000489266>.
259. * Rosoff, D.B., J. Yoo, and F.W. Lohoff. “Smoking is Significantly Associated with Increased Risk of COVID-19 and Other Respiratory Infections.” *Communications Biology*, 4(1230), 2021. Available at <https://doi.org/10.1038/s42003-021-02685-y>.
260. * Taylor, D., V. Hasselblad, J. Henley, et al. “Benefits of Smoking Cessation for Longevity.” *American Journal of Public Health*, 92(6):990–996, 2002.
261. Peto, R., S. Darby, H. Deo, et al. “Smoking, Smoking Cessation, and Lung Cancer in the UK since 1950: Combination of National Statistics with

- Two Case-Control Studies.” *BMJ*, 321:323–9, 2000. Available at <https://doi.org/10.1136/bmj.321.7257.323>.
262. Doll, R., R. Peto, J. Boreham, et al. “Mortality in Relation to Smoking: 50 Years’ Observations on Male British Doctors.” *BMJ Online First*, 2004. Available at <https://doi.org/10.1136/bmj.38142.554479.AE>.
263. * Schabath, M., W. Cress, and T. Muñoz-Antonia. “Racial and Ethnic Differences in the Epidemiology of Lung Cancer and the Lung Cancer Genome.” *Cancer Control*, 23(4): 338–346, 2016. Available at <https://doi.org/10.1177/107327481602300405>.
264. * National Cancer Institute. “SEER Cancer Statistics Factsheets: Cancer Disparities.” National Cancer Institute. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, Surveillance, Epidemiology, and End Results Program. Accessed July 7, 2021. Available at <https://seer.cancer.gov/statfacts/html/disparities.html>.
265. * Keenan N.L. and K.M. Shaw. “Coronary heart disease and stroke deaths—United States, 2006.” *Morbidity and Mortality Supplement*, 60(1):62–6, Jan. 14, 2011. Available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/su6001a13.htm>.
266. * Safford, M., T. Brown, P. Muntner, et al. “Association of Race and Sex with Risk of Incident Acute Coronary Heart Disease Events.” *Journal of American Medical Association*, 308(17), 2012. Available at <https://doi.org/10.1001/jama.2012.14306>.
267. * Singh, G., M. Siahpush, R. Azuine, et al. “Widening Socioeconomic and Racial Disparities in Cardiovascular Disease Mortality in The United States, 1969–2013.” *International Journal of MCH and AIDS*, 3(2):106–118, 2015.
268. * HHS. “Health, United States, 2019.” Hyattsville, MD: HHS, CDC, National Center for Health Statistics. Health, United States, 2019. Available at https://www.cdc.gov/nchs/hus/index.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fnchs%2Fhus.htm.
269. * Van Dyke, M., S. Greer, E. Odom, et al. “Heart Disease Death Rates Among Blacks and Whites Aged ≥35 Years—United States, 1968–2015.” *Morbidity and Mortality Weekly Report*, 67(5), 2018. Available at <http://dx.doi.org/10.15585/mmwr.ss6705a1>.
270. * Centers for Disease Control and Prevention. “Vital Signs: Avoidable Deaths from Heart Disease, Stroke, and Hypertensive Disease—United States, 2001–2010.” *Morbidity and Mortality Weekly Report*, 62(35):721–727, 2013. Available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a4.htm>.
271. National Academies of Sciences, Engineering, and Medicine. “Public Health Consequences of E-Cigarettes.” Washington, DC: The National Academies Press, 2018. Available at <https://doi.org/10.17226/24952>.
272. Pacek, L.R., O. Rass, M.M. Sweitzer, et al. “Young Adult Dual Combusted Cigarette and E-cigarette Users’ Anticipated Responses to Hypothetical E-cigarette Market Restrictions.” *Substance Use & Misuse*, 54(12):2033–2042, 2019. Available at <https://doi.org/10.1080/10826084.2019.1626435>.
273. Denlinger-Apte, R.L., R.N. Cassidy, K.B. Carey et al. “The Impact of Menthol Flavoring in Combusted Tobacco on Alternative Product Purchasing: A Pilot Study Using the Experimental Tobacco Marketplace.” *Drug and Alcohol Dependence*, 218:108390, 2021. Available at <https://doi.org/10.1016/j.drugalcdep.2020.108390>.
274. Wang, R.J., S. Bhadriraju, and S.A. Glantz. “E-Cigarette Use and Adult Cigarette Smoking Cessation: A Meta-Analysis.” *Research and Analysis*, 111(2), 2021. Available at <https://dx.doi.org/10.2105%2FAJPH.2020.305999>.
275. Hartmann-Boyce, J., H. McRobbie, N. Lindson, et al. “Electronic Cigarettes for Smoking Cessation (Review).” *Cochrane Database of Systematic Reviews*, 9:CD010216, 2021. Available at <https://doi.org/10.1002/14651858.CD010216.pub6>.
276. * El Dib, R., E.A. Suzumura, E.A. Aki, et al. “Electronic Nicotine Delivery Systems and/or Electronic Non-nicotine Delivery Systems for Tobacco Smoking Cessation or Reduction: A Systematic Review and Meta-analysis.” *BMJ*, 7:e012680, 2017. Available at <https://doi.org/10.1136/bmjopen-2016-012680>.
277. Coleman, B., B. Rostron, S.E. Johnson, et al. “Transitions in electronic cigarette use among adults in the Population Assessment of Tobacco and Health (PATH) Study, Waves 1 and 2 (2013–2015).” *Tobacco Control*, 28:50–59, 2019. Available at <http://dx.doi.org/10.1136/tobaccocontrol-2017-054174>.
278. Levy, D.T., Z. Yuan, Y. Luo, et al. “The Relationship of E-Cigarette Use to Cigarette Quit Attempts and Cessation: Insights from a Large, Nationally Representative U.S. Survey.” *Nicotine Tobacco Research*, 20(8):931–939, 2018. Available at <https://doi.org/10.1093/ntr/ntx166>.
279. Giovanco, D.P. and C.D. Delnevo. “Prevalence of Population Smoking Cessation by Electronic Cigarette Use Status in a National Sample of Recent Smokers.” *Addictive Behaviors*, 76:129–134, 2018. Available at <https://doi.org/10.1016/j.addbeh.2017.08.002>.
280. Chaiton, M.O., I. Papadhima, R. Schwartz, et al. “Product Substitution After a Real World Menthol Ban: A Cohort Study.” *Tobacco Regulatory Science*, 6(3):205–212, 2020. Available at <https://doi.org/10.18001/TRS.6.3.5>.
281. * HHS. “The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General.” Atlanta, GA: HHS, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2006. Available at https://www.ncbi.nlm.nih.gov/books/NBK44324/pdf/Bookshelf_NBK44324.pdf.
282. * California Environmental Protection Agency. “Proposed Identification of Environmental Tobacco Smoke as a Toxic Air Contaminant.” CEPA, Air Resources Board, Office of Environmental Health Hazard Assessment, 2005. Available at <https://escholarship.org/uc/item/8hk6960q>.
283. * Tsai, J., D. Homa, A. Gentzke, et al. “Exposure to Secondhand Smoke Among Nonsmokers—United States, 1988–2014.” *Morbidity and Mortality Weekly Report*, 67(48):1342–1346, 2018. Available at <http://dx.doi.org/10.15585/mmwr.mm6748a3>.
284. * Walton, K., A. Gentzke, B. Kenemer, et al. “Exposure to Secondhand Smoke in Homes and Vehicles Among US Youths, United States, 2011–2019.” *Preventing Chronic Disease*, 17:200107, 2020. Available at <http://dx.doi.org/10.5888/pcd17.200107>.
285. * Shastri, S., R. Talluri, S. Shete. “Disparities in Secondhand Smoke Exposure in the United States: National Health and Nutrition Examination Survey 2011–2018.” *JAMA Internal Medicine*, 181(1):134–137, 2021. Available at <https://doi.org/10.1001/jamainternmed.2020.3975>.
286. * Homa, D., L. Neff, B. King, et al. “Vital Signs: Disparities in Nonsmokers’ Exposure to Secondhand Smoke—United States, 1999–2012.” *Morbidity and Mortality Weekly Report*, 64(4), 2015. Available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6404a7.htm>.
287. Zhang, X., N. Jones, D. Kuo, et al. “Trends in Home Smoking Bans in the USA, 1995–2007: Prevalence, Discrepancies, and Disparities.” *Tobacco Control*, 21:330–336, 2012. Available at <http://dx.doi.org/10.1136/tc.2011.043802>.
288. Dai, H. and Jianqiang Hao. “Prevalence of Exposure to Workplace Secondhand Smoke in the United States: 2010 to 2015.” *Nicotine & Tobacco Research*, 19(11):1300–1307, 2016. Available at <https://doi.org/10.1093/ntr/ntw306>.
289. International Agency for Research and Cancer. “Evaluating the Effectiveness of Smoke-Free Policies.” *IARC Handbooks of Cancer Prevention, Tobacco Control*, Vol. 13. Lyon (FR): IARC, 2009. Available at <https://publications.iarc.fr/Book-And-Report-Series/Iarc-Handbooks-Of-Cancer-Prevention/Evaluating-The-Effectiveness-Of-Smoke-free-Policies-2009>.
290. * Centers for Disease Control and Prevention. “The Community Guide: Tobacco Use: Smoke Free Policies.” Available at <https://www.thecommunityguide.org/findings/tobacco-use-and-secondhand-smoke-exposure-smoke-free-policies>.
291. * Levy, D.T., J. Tam, L.M. Sanchez-Romero, et al. “Public Health Implications of Vaping in the USA: The Smoking and Vaping Simulation Model.” *Population Health Metrics*, 19:19, 2021. Available at <https://doi.org/10.1186/s12963-021-00250-7>.
292. * FDA. Preliminary Regulatory Impact Analysis; Initial Regulatory Flexibility

- Analysis; Unfunded Mandates Reform Act Analysis, Tobacco Product Standard for Menthol in Cigarettes; Proposed Rule.
293. * Henley, S., C. Thomas, S. Sharapova, et al. "Vital Signs: Disparities in Tobacco-Related Cancer Incidence and Mortality—United States, 2004–2013." *Morbidity and Mortality Weekly Report*, 65(44), 2016. Available at <http://dx.doi.org/10.15585/mmwr.mm6544a3>.
294. * U.S. Fire Administration. "Fire Estimate Summary: Residential Building Fire Trends (2009–2018)." Emmitsburg, MD: Federal Emergency Management Agency, U.S. Fire Administration, National Fire Data Center, March 2020. Available at https://www.usfa.fema.gov/downloads/pdf/statistics/res_bldg_fire_estimates.pdf.
295. * Hall, J. "Smoking-Material Fire Problem Fact Sheet." NFPA Fire Analysis & Research, 2013. Available at <https://www.nfpa.org/-/media/Files/News-and-Research/Fire-statistics-and-reports/Fact-sheets/smokingfactsheet.ashx>.
296. * Ahrens, M. "Home Fires Started by Smoking." National Fire Protection Association Research, 2019. Available at <https://www.nfpa.org/News-and-Research/Data-research-and-tools/US-Fire-Problem/Smoking-Materials>.
297. * U.S. Fire Administration. "Smoking-Related Fires in Residential Buildings (2008–2010)." *Topical Fire Report Series*, 13(6), 2012. Available at <https://www.usfa.fema.gov/downloads/pdf/statistics/v13i6.pdf>.
298. Hall, J. "U.S. Smoking-Material Fire Problem." NFPA Fire Analysis & Research, 2008. Available at <https://library.nfpa.org/GeniePLUS/GeniePLUS/Portal/Public.aspx>.
299. Chaiton, M.O., R. Schwartz, J.E. Cohen, et al. "The Use of Flavour Cards and Other Additives After a Menthol Ban in Canada." *Tobacco Control*, 30:601–602, 2020. Available at <https://doi.org/10.1136/tobaccocontrol-2020-055698>.
300. * Hiscock, R., K. Silver, Mateusz Zatoński, et al. "Tobacco Industry Tactics to Circumvent and Undermine the Menthol Cigarette Ban in the UK." *Tobacco Control*, 29:e138–e142, 2020. Available at <http://dx.doi.org/10.1136/tobaccocontrol-2020-055769>.
301. National Research Council and Institute of Medicine of the National Academies. "Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context, and Lessons from International Experiences." Washington, DC: The National Academies Press, 2015. Available at <https://doi.org/10.17226/19016>.
302. Stoklosa, M. "No Surge in Illicit Cigarettes After Implementation of Menthol Ban in Nova Scotia." *Tobacco Control*, 28:701–703, 2019. Available at <https://doi.org/10.1136/tobaccocontrol-2018-054552>.
303. Kock, L., L. Shahab, I. Bogdanovica, et al. "Profile of Menthol Cigarette Smokers in the Months Following the Removal of These Products From the Market: A Cross-Sectional Population Survey in

England." *Tobacco Control*, Published Online First: 17 November 2021. Available at <http://dx.doi.org/10.1136/tobaccocontrol-2021-057005>.

304. * FDA. "Finding of No Significant Impact: Tobacco Product Standard for Menthol in Cigarettes." Silver Spring, MD: HHS, FDA, Center for Tobacco Products, 2022.
305. * FDA. "Environmental Assessment of the Tobacco Product Standard for Menthol in Cigarettes." Silver Spring, MD: HHS, FDA, Center for Tobacco Products, 2022.

List of Subjects in 21 CFR Part 1162

Labeling, Smoke, Smoking, Tobacco, Tobacco products.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that chapter I of title 21 of the Code of Federal Regulations be amended by adding part 1162 to subchapter K to read as follows:

PART 1162—PRODUCT STANDARD: MENTHOL IN CIGARETTES

Subpart A—General Provisions

Sec.

1162.1 Scope.

1162.3 Definitions.

Subpart B—Product Standard for Menthol in Cigarettes

1162.5 Prohibition on use of menthol as a characterizing flavor in cigarettes.

Authority: 21 U.S.C. 331, 333, 371(a), 387b, 387c, 387f(d), 387g.

Subpart A—General Provisions

§ 1162.1 Scope.

(a) This part sets out a tobacco product standard under the Federal Food, Drug, and Cosmetic Act regarding the use of menthol as a characterizing flavor in cigarettes.

(b) No person may manufacture, distribute, sell, or offer for distribution or sale, within the United States a cigarette or any of its components or parts that is not in compliance with this part.

§ 1162.3 Definitions.

For purposes of this part:

Accessory means any product that is intended or reasonably expected to be used with or for the human consumption of a cigarette; does not contain tobacco or nicotine from any source, and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a cigarette; or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a cigarette; but

- (i) Solely controls moisture and/or temperature of a stored cigarette; or
- (ii) Solely provides an external heat source to initiate but not maintain combustion of a cigarette.

Cigarette, as used in this part:

(1) Means a product that:

- (i) Is a tobacco product; and
- (ii) Meets the definition of the term "cigarette" in section 3(1) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1332(1)); and

(2) Includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

Cigarette tobacco means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this chapter also apply to cigarette tobacco.

Component or *part* means any software or assembly of materials intended or reasonably expected:

(1) To alter or affect the cigarette's performance, composition, constituents, or characteristics; or

(2) To be used with or for the human consumption of a cigarette. The term excludes anything that is an accessory of a cigarette.

Person includes an individual, partnership, corporation, or association.

Roll-your-own tobacco means any tobacco product which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

Tobacco product means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). The term "tobacco product" does not mean an article that under the Federal Food, Drug, and Cosmetic Act is: A drug (section 201(g)(1)); a device (section 201(h)); a combination product (section 503(g)); or a food under section 201(f) if such article contains no nicotine, or no more than trace amounts of naturally occurring nicotine.

United States means the 50 States of the United States of America and the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, Johnston Atoll, the Northern Mariana Islands, and any other trust territory or possession of the United States.

Subpart B—Product Standard for Menthol in Cigarettes

§ 1162.5 Prohibition on use of menthol as a characterizing flavor in cigarettes.

A cigarette or any of its components or parts (including the tobacco, filter, wrapper, or paper, as applicable) shall not contain, as a constituent (including a smoke constituent) or additive,

menthol that is a characterizing flavor of the tobacco product or tobacco smoke.

Dated: April 22, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2022-08994 Filed 4-28-22; 11:15 am]

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Part IV

Department of Energy

Federal Energy Regulatory Commission

18 CFR Part 35

Building for the Future Through Electric Regional Transmission Planning and Cost Allocation and Generator Interconnection; Proposed Rule

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket No. RM21-17-000]

Building for the Future Through Electric Regional Transmission Planning and Cost Allocation and Generator Interconnection

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Energy Regulatory Commission (Commission) proposes to reform both the pro forma Open Access Transmission Tariff and the pro forma Large Generator Interconnection Agreement to remedy deficiencies in the Commission’s existing regional transmission planning and cost allocation requirements. Specifically, the proposal would require public utility transmission providers to; conduct long-term regional transmission planning on a sufficiently forward-looking basis to meet transmission needs driven by changes in the resource mix and demand; more fully consider dynamic line ratings and advanced power flow control devices in regional transmission planning processes; seek the agreement of relevant state entities within the transmission planning region regarding the cost allocation method or methods that will apply to transmission

facilities selected in the regional transmission plan for purposes of cost allocation through long-term regional transmission planning; adopt enhanced transparency requirements for local transmission planning processes and improve coordination between regional and local transmission planning with the aim of identifying potential opportunities to “right-size” replacement transmission facilities; and revise their existing interregional transmission coordination procedures to reflect the long-term regional transmission planning reforms proposed in this NOPR. In addition, the proposal would not permit public utility transmission providers to take advantage of the construction-work-in-progress incentive for regional transmission facilities selected for purposes of cost allocation through long-term regional transmission planning and would permit the exercise of federal rights of first refusal for transmission facilities selected in a regional transmission plan for purposes of cost allocation, conditioned on the incumbent transmission provider with the federal right of first refusal for such regional transmission facilities establishing joint ownership of the transmission facilities.

DATES: Comments are due July 18, 2022 and Reply Comments are due August 17, 2022.

ADDRESSES: Comments, identified by docket number, may be filed in the following ways. Electronic filing

through https://www.ferc.gov, is preferred.

• Electronic Filing: Documents must be filed in acceptable native applications and print-to-PDF, but not in scanned or picture format.

• For those unable to file electronically, comments may be filed by USPS mail or by hand (including courier) delivery.

○ Mail via U.S. Postal Service Only: Addressed to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

○ Hand (including courier) delivery: Deliver to: Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

The Comment Procedures Section of this document contains more detailed filing procedures.

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I. Introduction

1. In this Notice of Proposed Rulemaking (NOPR), the Federal Energy Regulatory Commission (Commission) is proposing, pursuant to its authority under section 206 of the Federal Power Act (FPA),¹ to reform its electric regional transmission planning and cost allocation requirements. The proposed reforms are intended to remedy deficiencies in the Commission’s existing regional transmission planning and cost allocation requirements to ensure that Commission-jurisdictional rates remain just and reasonable and not unduly discriminatory or preferential.

2. This NOPR builds on Order Nos. 888,² 890,³ and 1000,⁴ in which the

¹ 16 U.S.C. 824e. Section 206 requires that Commission-jurisdictional rates, terms, and conditions, including those for transmission services, be just and reasonable and not unduly discriminatory or preferential. The phrase “Commission-jurisdictional rates,” as used in this NOPR, includes rates, terms, and conditions.

² *Promoting Wholesale Competition Through Open Access Non-Discriminatory Transmission Services by Pub. Utils.; Recovery of Stranded Costs by Publ. Utils. & Transmitting Utils.*, Order No. 888, 61 FR 21540 (May 10, 1996), FERC Stats. & Regs. ¶ 31,036 (1996) (cross-referenced at 75 FERC ¶ 61,080), *order on reh’g*, Order No. 888–A, 62 FR 12274 (Mar. 14, 1997), FERC Stats. & Regs. ¶ 31,048 (cross-referenced at 78 FERC ¶ 61,220), *order on reh’g*, Order No. 888–B, 81 FERC ¶ 61,248 (1997), *order on reh’g*, Order No. 888–C, 82 FERC ¶ 61,046 (1998), *aff’d in relevant part sub nom. Transmission Access Pol’y Study Group v. FERC*, 225 F.3d 667 (D.C. Cir. 2000), *aff’d sub nom. N. Y. v. FERC*, 535 U.S. 1 (2002).

³ *Preventing Undue Discrimination & Preference in Transmission Serv.*, Order No. 890, 72 FR 12266 (Mar. 15, 2007), 118 FERC ¶ 61,119, *order on reh’g*, Order No. 890–A, 73 FR 2984 (Jan. 16, 2008), 121 FERC ¶ 61,297 (2007), *order on reh’g*, Order No. 890–B, 123 FERC ¶ 61,299 (2008), *order on reh’g*, Order No. 890–C, 74 FR 12540 (Mar. 25, 2009), 126 FERC ¶ 61,228, *order on clarification*, Order No. 890–D, 129 FERC ¶ 61,126 (2009).

⁴ *Transmission Planning & Cost Allocation by Transmission Owning & Operating Pub. Utils.*, Order No. 1000, 76 FR 49842 (Aug. 11, 2011), 136 FERC ¶ 61,051 (2011), *order on reh’g*, Order No.

Commission incrementally developed the requirements that govern regional transmission planning and cost allocation processes to ensure that Commission-jurisdictional rates remain just and reasonable and not unduly discriminatory or preferential.

3. With respect to regional transmission planning, as discussed in more detail below, the reforms proposed in this NOPR would require public utility transmission providers to conduct long-term regional transmission planning on a sufficiently forward-looking basis to meet transmission needs driven by changes in the resource mix and demand.⁵ As part of this long-term regional transmission planning, public utility transmission providers would be required to: (1) Identify transmission needs driven by changes in the resource mix and demand through the development of long-term scenarios that satisfy the requirements set forth in this NOPR, including accounting for low-frequency, high-impact events such as extreme weather events; (2) evaluate the benefits of regional transmission facilities to meet these needs over a time horizon that covers, at a minimum, 20 years starting from the estimated in-service date of the transmission facilities; and (3) establish transparent

1000–A, 77 FR 32184 (May 31, 2012), 139 FERC ¶ 61,132, *order on reh’g and clarification*, Order No. 1000–B, 141 FERC ¶ 61,044 (2012), *aff’d sub nom. S.C. Pub. Serv. Auth. v. FERC*, 762 F.3d 41 (D.C. Cir. 2014).

⁵ A public utility transmission provider means a public utility that owns, controls, or operates transmission facilities. The term public utility transmission provider should be read to include a public utility transmission owner when the transmission owner is separate from the transmission provider, as is the case in regional transmission organizations (RTO) and independent system operators (ISO). The term “public utility” means “any person who owns or operates facilities subject to the jurisdiction of the Commission” 16 U.S.C. 824(e).

and not unduly discriminatory criteria to select transmission facilities in the regional transmission plan for purposes of cost allocation that more efficiently or cost-effectively address these transmission needs in collaboration with states and other stakeholders. We do not propose in this NOPR to change Order No. 1000’s requirements for public utility transmission providers with respect to existing reliability and economic planning requirements. Additionally, we propose to require that public utility transmission providers more fully consider dynamic line ratings and advanced power flow control devices in regional transmission planning processes.

4. With respect to transmission cost allocation, the reforms proposed in this NOPR would require that public utility transmission providers in each transmission planning region seek the agreement of relevant state entities within the transmission planning region regarding the cost allocation method or methods that will apply to transmission facilities selected in the regional transmission plan for purposes of cost allocation through long-term regional transmission planning⁶ and revise their OATTs to include those method or methods.

5. We also propose to not permit public utility transmission providers to take advantage of the construction-work-in-progress (CWIP) incentive for regional transmission facilities selected for purposes of cost allocation through long-term regional transmission planning.

6. With respect to federal rights of first refusal, the reforms proposed in this NOPR would amend Order No. 1000’s requirements, in part, to permit

⁶ This NOPR refers to such facilities as “Long-Term Regional Transmission Facilities”.

the exercise of federal rights of first refusal for transmission facilities selected in a regional transmission plan for purposes of cost allocation, conditioned on the incumbent transmission provider with the federal right of first refusal for such regional transmission facilities establishing joint ownership of the transmission facilities consistent with the proposal below.

7. With respect to transparency and coordination, we propose to require public utility transmission providers to adopt enhanced transparency requirements for local transmission planning processes and improve coordination between regional and local transmission planning with the aim of identifying potential opportunities to “right-size” replacement transmission facilities.

8. With respect to interregional transmission coordination and cost allocation, the reforms proposed in this NOPR would require that public utility transmission providers revise their existing interregional transmission coordination procedures to reflect the long-term regional transmission planning reforms proposed in this NOPR.

9. The proposed reforms in this NOPR related to regional transmission planning and cost allocation requirements, like those of Order Nos. 890 and 1000, are focused on the transmission planning process, and not on any substantive outcomes that may result from this process. Taken together, these proposed reforms would work together to remedy deficiencies in the Commission’s existing regional transmission planning and cost allocation requirements. This, in turn, would fulfill our statutory obligation to ensure that Commission-jurisdictional rates remain just and reasonable and not unduly discriminatory or preferential.

10. The Advance Notice of Proposed Rulemaking (ANOPR),⁷ the Commission also sought comment on reforms related to cost allocation for interconnection-related network upgrades, interconnection queue processes, interregional transmission coordination and planning, and oversight of transmission planning and costs. While this NOPR does not propose broad or comprehensive reforms directly related to these topics, we will continue to review the record developed to date and expect to address possible inadequacies through subsequent proceedings that propose reforms, as warranted, related

to these topics. In addition, concurrent with the issuance of this NOPR, we notice a technical conference on Transmission Planning and Cost Management.

11. We seek comment on the reforms proposed herein and encourage commenters to identify enhancements to those reforms that could better support development of more efficient or cost-effective transmission facilities than is the case under the Commission’s existing regional transmission planning and cost allocation requirements.

II. Background

A. Historical Framework: Order Nos. 888, 890, and 1000

12. Over the last several decades, the Commission has taken multiple significant actions on transmission planning and cost allocation, including issuing Order Nos. 888, 890, and 1000. In 1996, the Commission issued Order No. 888, which implemented open access to transmission facilities owned, operated, or controlled by a public utility and included certain minimum requirements for transmission planning. In 2007, the Commission issued Order No. 890 to address deficiencies in the *pro forma* OATT that it identified after more than 10 years of experience since Order No. 888. Among other OATT reforms, the Commission required all public utility transmission providers’ local transmission planning processes to satisfy nine transmission planning principles: (1) Coordination; (2) openness; (3) transparency; (4) information exchange; (5) comparability; (6) dispute resolution; (7) regional participation; (8) economic planning studies; and (9) cost allocation for new projects.⁸

13. Then, in 2011, the Commission recognized the need for further transmission planning reforms with its issuance of Order No. 1000. The Commission based the reforms it adopted in Order No. 1000 on changes in the energy industry, its experience implementing Order No. 890, and a robust record developed through technical conferences and comments from a diverse range of stakeholders.⁹ The Commission stated in Order No. 1000 that “the electric industry is currently facing the possibility of substantial investment in future transmission facilities to meet the challenge of maintaining reliable service

at a reasonable cost.”¹⁰ In establishing the requirements of Order No. 1000, the Commission found that the existing requirements of Order No. 890 were not adequate, noting that Order No. 1000 “expands upon the reforms begun in Order No. 890 by addressing new concerns that have become apparent in the Commission’s ongoing monitoring of these matters.”¹¹ The Commission then enumerated multiple concerns that it had regarding existing transmission planning practices, including concerns about: (1) The lack of an affirmative obligation to develop a transmission plan evaluating if a regional transmission facility “may be more efficient or cost-effective than solutions identified in local transmission planning processes;” (2) the lack of a requirement to address Public Policy Requirements;¹² (3) the federal right of first refusal for incumbent transmission developers to build upgrades to their existing transmission facilities; (4) the lack of procedures to identify and evaluate the benefits of interregional transmission facilities; and (5) cost allocation for regional and interregional transmission facilities.¹³

14. Order No. 1000 included a package of reforms to ensure that the transmission planning and cost allocation requirements embodied in the *pro forma* OATT were adequate to support the development of more efficient or cost-effective transmission facilities.¹⁴ The reforms in Order No. 1000 fell into the following categories: Regional transmission planning; transmission needs driven by Public Policy Requirements; nonincumbent transmission developer reforms; regional and interregional cost allocation, including a set of principles for each category of cost allocation; and interregional transmission coordination. The reforms focused on the process by which public utility transmission providers engage in regional transmission planning and associated cost allocation rather than on the outcomes of the process.¹⁵

¹⁰ *Id.* P 2.

¹¹ *Id.* P 22.

¹² Public Policy Requirements are requirements established by local, state or federal laws or regulations (*i.e.*, enacted statutes passed by the legislature and signed by the executive and regulations promulgated by a relevant jurisdiction, whether within a state or at the federal level). *Id.* P 2. Order No. 1000–A clarified that Public Policy Requirements include local laws or regulations passed by a local governmental entity, such as a municipal or county government. Order No. 1000–A, 139 FERC ¶ 61,132 at P 319.

¹³ Order No. 1000, 136 FERC ¶ 61,051 at P 3.

¹⁴ *Id.* PP 11–12, 42–44; Order No. 1000–A, 139 FERC ¶ 61,132 at PP 3, 4–6.

¹⁵ Order No. 1000, 136 FERC ¶ 61,051 at P 12.

⁷ *Building for the Future Through Electric Regional Transmission Planning & Cost Allocation & Generator Interconnection*, 86 FR 40266 (July 15, 2021), 176 FERC ¶ 61,024 (2021) (ANOPR); *see infra* P 18 (briefly summarizing the ANOPR).

⁸ Order No. 890, 118 FERC ¶ 61,119 at PP 418–601.

⁹ Order No. 1000, 136 FERC ¶ 61,051 at P 3. The term “stakeholder” means any interested party. *Id.* P 151 n.143.

15. Among other regional transmission planning reforms in Order No. 1000, the Commission required that the following Order No. 890 transmission planning principles apply to regional transmission planning processes: (1) Coordination; (2) openness; (3) transparency; (4) information exchange; (5) comparability; (6) dispute resolution; and (7) economic planning studies.¹⁶

16. In addition, with respect to the Order No. 1000 reforms, there is a distinction between a transmission facility “included” in a regional transmission plan and a transmission facility “selected” in a regional transmission plan for purposes of cost allocation. A transmission facility selected in a regional transmission plan for purposes of cost allocation is a transmission facility that has been selected pursuant to a transmission planning region’s¹⁷ Commission-approved regional transmission planning process for inclusion in a regional transmission plan for purposes of cost allocation because it is a more efficient or cost-effective transmission facility needed to meet regional transmission needs. Both regional transmission facilities and interregional transmission facilities are eligible for potential “selection” in a regional transmission plan for purposes of cost allocation.¹⁸ A regional transmission facility is a transmission facility located entirely in one transmission planning region.¹⁹ An interregional transmission facility is one that is located in two or more transmission planning regions.²⁰

17. Transmission facilities selected in a regional transmission plan for purposes of cost allocation often will not comprise all of the transmission facilities that are included in a regional transmission plan.²¹ Some transmission facilities are merely “rolled up” and listed in a regional transmission plan without going through an analysis at the regional level, and therefore, are not eligible for selection and regional cost allocation.²² For example, a local

transmission facility is a transmission facility located solely within a public utility transmission provider’s retail distribution service territory or footprint that is not selected in the regional transmission plan for purposes of cost allocation.²³ Thus, a local transmission facility may be rolled up and “included” in a regional transmission plan for informational purposes, but it is not “selected” in a regional transmission plan for purposes of cost allocation.

B. ANOPR and Technical Conference

18. In July 2021, the Commission issued an ANOPR presenting potential reforms to improve the regional transmission planning and cost allocation and generator interconnection processes. In issuing the ANOPR, the Commission noted that, more than a decade after Order No. 1000, it was time to review its regulations governing regional transmission planning and cost allocation and generator interconnection processes to determine whether reforms are needed to ensure Commission-jurisdictional rates remain just and reasonable and not unduly discriminatory or preferential.²⁴ The Commission noted that the electricity sector is transforming as the generation fleet shifts from resources located close to population centers toward resources that may often be located far from load centers. The Commission also highlighted the growth of new resources seeking to interconnect to the transmission system and that the differing characteristics of those resources are creating new demands on the transmission system. The Commission explained that ensuring just and reasonable Commission-jurisdictional rates as the resource mix changes, while maintaining grid reliability, remains the Commission’s priority in adopting requirements for the regional transmission planning and cost allocation and generator interconnection processes. As a result, the Commission issued the ANOPR to consider whether there should be changes in the regional transmission planning and cost allocation and generator interconnection

processes and, if so, which changes are necessary to ensure that Commission-jurisdictional rates remain just and reasonable and not unduly discriminatory or preferential and that reliability is maintained.

19. On November 15, 2021, the Commission convened a staff-led technical conference (November 2021 Technical Conference or Technical Conference) to examine in detail issues and potential reforms related to regional transmission planning as described in ANOPR. Specifically, the Technical Conference included three panels covering issues related to factors to consider in long-term scenarios, consideration of longer-term scenarios in regional transmission planning processes, and identifying geographic zones with high renewable resource potential for use in regional transmission planning processes.²⁵ After the Technical Conference, the Commission invited all interested persons to file comments after the Technical Conference to address issues raised during the Technical Conference.

C. Joint Federal-State Task Force on Electric Transmission

20. On June 17, 2021, the Commission established a Joint Federal-State Task Force on Electric Transmission (Task Force) to formally explore broad categories of transmission-related topics.²⁶ The Commission explained that the development of new transmission infrastructure implicates a host of different issues, including how to plan and pay for these facilities. Given that federal and state regulators each have authority over transmission-related issues and the impact of transmission infrastructure development on numerous different priorities of federal and state regulators, the Commission determined that the area is ripe for greater federal-state coordination and cooperation.²⁷ The Task Force is comprised of all FERC Commissioners as well as representatives from 10 state commissions nominated by the National Association of Regulatory Utility Commissioners (NARUC), with two originating from each NARUC region.²⁸

¹⁶ The Commission did not include the regional participation or cost allocation transmission planning principles with respect to regional transmission planning processes because those issues were addressed by other reforms in Order No. 1000. *Id.* P 151.

¹⁷ A transmission planning region is one in which public utility transmission providers, in consultation with stakeholders and affected states, have agreed to participate for purposes of regional transmission planning and development of a single regional transmission plan. *Id.* P 160.

¹⁸ *Id.* P 63.

¹⁹ *Id.* n.374.

²⁰ *Id.*

²¹ *Id.* P 63.

²² *Id.* PP 7, 226, 318.

²³ *Id.* P 63. The Commission clarified in Order No. 1000–A that a local transmission facility is one that is located within the geographical boundaries of a public utility transmission provider’s retail distribution service territory, if it has one; otherwise the area is defined by the public utility transmission provider’s footprint. In the case of an RTO/ISO whose footprint covers the entire region, a local transmission facility is defined by reference to the retail distribution service territories or footprints of its underlying transmission owning members. Order No. 1000–A, 139 FERC ¶ 61,132 at P 429.

²⁴ ANOPR, 176 FERC ¶ 61,024 at P 3.

²⁵ *Building for the Future Through Elec. Reg’l Transmission Planning & Cost Allocation & Generator Interconnection*, Further Supplemental Notice of Technical Conference, Docket No. RM21–17–000 (issued Nov. 12, 2021) (attaching agenda).

²⁶ *Joint Fed.-State Task Force on Elec. Transmission*, 175 FERC ¶ 61,224, at PP 1, 6 (2021).

²⁷ *Id.* P 2.

²⁸ An up-to-date list of Task Force members, as well as additional information on the Task Force, is available on the Commission’s website at: <https://www.ferc.gov/TFSOET>. Public materials related to the Task Force, including transcripts from public

21. The Task Force will convene for multiple formal meetings and has thus far met twice—on November 10, 2021, and on February 16, 2022. The discussion at the November meeting was focused on incorporating state perspectives into regional transmission planning. The Task Force members discussed: Whether the existing regional transmission planning processes adequately plan for future transmission needs, including those of states in meeting their energy-related goals; what methods are currently employed to provide states a role in regional transmission planning processes and whether reforms are needed to increase consideration and incorporation of state perspectives and energy-related goals in those processes; transparency in existing regional transmission planning processes; and criteria for use in selecting transmission facilities, including the proper role for states in selection of transmission facilities identified during regional transmission planning processes.²⁹

22. The February meeting included discussion of specific categories and types of transmission benefits that transmission providers should consider for the purposes of transmission planning and cost allocation. The Task Force Members discussed: Whether and how the three categories and types of transmission (to address transmission needs driven by reliability, economic considerations, and Public Policy Requirements) that are considered for the purposes of transmission planning and cost allocation should be expanded or changed; whether these categories are being adequately considered or can be improved upon; if there any specific benefits being considered by public utility transmission providers today that should be more widely adopted by other public utility transmission providers and whether certain benefits are unique to specific regions; and how the certainty of benefits should be addressed, such as whether and how benefits need to be quantified. The Task Force Members also discussed at the February meeting cost allocation principles, methodologies, and decision processes, such as whether the current cost allocation methodologies used by public utility transmission providers allocate costs roughly commensurate with estimated benefits, and if not, how should this be improved; under what set of benefits—both existing and

meetings, are available in the Commission's eLibrary in Docket No. AD21-15-000.

²⁹ *Joint Fed.-State Task Force on Elec. Transmission*, Notice of Meeting, Docket No. AD21-15-000 (issued Oct. 27, 2021) (attaching agenda).

expanded—would states be amenable to bearing the costs of transmission that is expected to deliver those estimated benefits to ratepayers; and whether there is sufficient opportunity for stakeholders, including states, to collaborate in the development and approval of cost allocation methodologies to build consensus among and increase buy-in from stakeholders within a transmission planning region, and if not, how this can be improved.³⁰

D. High-Level Overview of ANOPR Comments

23. The Commission received many comments from a diverse set of parties in response to the ANOPR.³¹ One hundred and seventy five parties, including federal agencies, state regulatory commissions, state policy makers and other state representatives, ratepayer advocates, municipalities, RTOs/ISOs, RTO/ISO market monitors, public utility transmission providers, transmission-dependent utilities, electric cooperatives, municipal power providers, independent power producers, transmission developers, generation trade associations, transmission trade associations, industry interest groups, consumer interest groups, energy policy and law interest groups, individual businesses, landowners, and individuals, filed initial comments that totaled over 4,000 pages without attachments. A similarly diverse set of 95 parties filed reply comments that totaled nearly 2,000 pages.

III. Need for Reform

24. Over the last 25 years, the Commission has undertaken a series of significant reforms to ensure that transmission planning and cost allocation processes result in Commission-jurisdictional rates that are just and reasonable and not unduly discriminatory or preferential.³² It has now been more than a decade since Order No. 1000—the Commission's last significant regional transmission planning and cost allocation rule—and there is mounting evidence that the Commission's regional transmission planning and cost allocation requirements may be inadequate to ensure Commission-jurisdictional rates remain just and reasonable and not unduly discriminatory or preferential.

³⁰ *Joint Fed.-State Task Force on Elec. Transmission*, Notice of Meeting, Docket No. AD21-15-000 (issued Feb. 2, 2022) (attaching agenda).

³¹ See Appendix A for a list of commenters and the abbreviated names of commenters that are used in this ANOPR.

³² See *supra* PP 12–14.

In particular, although public utility transmission providers are required to participate in regional transmission planning and cost allocation processes under Order No. 1000, we are concerned that those processes may not be planning transmission on a sufficiently long-term, forward-looking basis to meet transmission needs driven by changes in the resource mix and demand.

25. As a result, the regional transmission planning and cost allocation processes that public utility transmission providers adopted to comply with Order No. 1000 may not be identifying the more efficient or cost-effective transmission facilities. We are concerned that the absence of sufficiently long-term, comprehensive transmission planning processes appears to be resulting in piecemeal transmission expansion to address relatively near-term transmission needs. We are concerned that continuing with the status quo approach may cause public utility transmission providers to undertake relatively inefficient investments in transmission infrastructure, the costs of which are ultimately recovered through Commission-jurisdictional rates.³³ That dynamic may result in transmission customers paying more than necessary to meet their transmission needs, customers forgoing benefits that outweigh their costs, or some combination thereof—either or both of which could potentially render Commission-jurisdictional rates unjust and unreasonable or unduly discriminatory or preferential. As the Commission has an obligation under the FPA to ensure that those rates are just and reasonable and not unduly discriminatory or preferential, we are proposing reforms to remedy these potential deficiencies in the Commission's existing regional transmission planning and cost allocation requirements.

26. As explained in the next section, we believe that there are substantial potential benefits of long-term regional transmission planning and cost allocation to identify and plan for transmission needs driven by changes in the resource mix and demand. But, as explained below, expansion of the high voltage transmission system is apparently increasingly occurring outside of the regional transmission planning process, and in a piecemeal fashion through other avenues, such as the generator interconnection process primarily in response to individual (or a small cluster of) interconnection requests rather than through regional

³³ *S.C. Pub. Serv. Auth.*, 762 F.3d at 56–59.

transmission planning and cost allocation processes.

27. In light of those concerns, we propose reforms to require public utility transmission providers to conduct long-term regional transmission planning on a sufficiently long-term, forward-looking basis to identify and plan for transmission needs driven by changes in the resource mix and demand. Absent such reforms, we are concerned that meeting transmission needs driven by changes in the resource mix and demand through short-term, piecemeal transmission expansion will result in unjust and unreasonable and unduly discriminatory and preferential Commission-jurisdictional rates for customers. Specifically, without these reforms, we believe that regional transmission planning processes are unlikely to identify the more efficient or cost-effective solutions to transmission needs driven by changes in the resource mix and demand. Thus, we preliminarily find that these reforms are necessary to ensure that Commission-jurisdictional rates remain just and reasonable and not unduly discriminatory or preferential.

A. Potential Benefits of Long-Term Regional Transmission Planning and Cost Allocation To Identify and Plan for Transmission Needs Driven by Changes in the Resource Mix and Demand

28. A robust, well-planned transmission system is foundational to ensuring an affordable, reliable supply of electricity.³⁴ Due to continuing changes in both supply and demand, ongoing investment in transmission facilities is necessary to ensure the transmission system continues to serve load in a reliable³⁵ and economically efficient fashion. Such investments also support enhanced reliability, as larger, more integrated transmission systems result in a diversity of supply and demand conditions and a certain degree of redundancy that allows the system to better withstand failures during

³⁴ 16 U.S.C. 824, 824d, 824e; see also U.S. DOE Comments at 2 (stating that “strengthening and expanding existing transmission infrastructure, particularly the development of regional and inter-regional transmission projects, is key to continued access to reliable, resilient, lower-cost, and clean electricity for all”).

³⁵ See, e.g., Testimony of James B. Robb Before the U.S. Senate Energy and Natural Resources Committee, *Reliability, Resiliency, and Affordability of Electric Service in the United States Amid the Changing Energy Mix and Extreme Weather Events*, at 9 (Mar. 11, 2021), <https://www.nerc.com/news/Headlines%20DL/NERC%20Reliability%20Hearing%20Testimony%203-11-21%20-%20Final.pdf> (testifying that more transmission infrastructure is required to ensure reliability and resilience of the bulk power system in light of changing conditions); MISO Comments at 40.

unexpected events.³⁶ Proactive, forward-looking transmission planning that considers evolving supply and demand conditions more comprehensively can enable potential reliability problems and economic constraints to be identified and resolved before they affect the transmission system,³⁷ which can facilitate the selection of more efficient or cost-effective transmission facilities to meet transmission needs.

29. In addition, transmission can unlock the forces of competition, changing who can sell to whom, eliminating barriers to entry, and mitigating market power.³⁸ That, in turn, can provide a host of benefits for customers, including cost-savings from greater access to low-cost power and a wider range of resources.³⁹

³⁶ U.S. DOE Comments at 18; NERC Comments at 16–17; ACOE Comments, Ex. 4, *Transmission Makes the Power System Resilient to Extreme Weather*; Mark Chupka & Pearl Donohoo-Vallett, *Recognizing the Role of Transmission in Electric System Resilience* (May 2018).

³⁷ MISO’s Multi-Value Project (MVP) regional transmission planning process, for example, eliminated the need for approximately \$300 million in reliability transmission facilities, resolving reliability violations and mitigating system instability conditions, through a forward-looking approach. Midcontinent Independent System Operator, *MTEP17 MVP Triennial Review: A 2017 review of the public policy, economic, and qualitative benefits of the Multi-Value Project Portfolio*, at 11, 33 (Sept. 2017) (MTEP17 Review).

³⁸ Johannes Pfeifenberger et al., The Brattle Group and Grid Strategies, *Transmission Planning for the 21st Century: Proven Practices that Increase Value and Reduce Costs*, at 48–49 (Oct. 2021), <https://gridprogress.files.wordpress.com/2021/10/transmission-planning-for-the-21st-century-proven-practices-that-increase-value-and-reduce-costs-7.pdf> (Brattle-Grid Strategies Oct. 2021 Report); Policy Integrity Comments at 13 (citing Mohamed Awad et al., *The California ISO Transmission Economic Assessment Methodology (TEAM): Principles and Applications to Path 26*, at 3 (“A new transmission project can enhance competition by both increasing the total supply that can be delivered to consumers and the number of suppliers that are available to serve load.”)); PIOs Comments at 48 (quoting F.A. Wolak, World Bank, *Managing Unilateral Market Power in Electricity*, Policy Research Working Paper; No. 3691, at 8 (2005) (“Expansion of the transmission network typically increases the number of independent wholesale electricity suppliers that are able to compete to supply electricity at locations in the transmission network served by the upgrade”).

³⁹ See, e.g., PJM Interconnection, L.L.C., *PJM Value Proposition* (2019), <https://www.pjm.com/about-pjm/-/media/about-pjm/pjm-value-proposition.aspx> (PJM’s planning of resource adequacy over a large region is estimated to result in savings of \$1.2–1.8 billion.); Midcontinent Independent System Operator, *Value Proposition* (2020), <https://www.misoenergy.org/about/miso-strategy-and-value-proposition/miso-value-proposition/> (MISO estimates \$517–572 million in savings from more efficient use of existing assets and \$2.5–3.2 billion from reduced need for additional assets.); Southwest Power Pool, *SPP’s Value of Transmission: 2021 Report and Update* (Jan. 5, 2022) (SPP estimates \$382.7 million in adjusted product costs savings in 2020 due to transmission investment.).

Transmission infrastructure can also serve as a form of insurance for the uncertainties of the future, because a more robust, integrated transmission system has the potential to afford consumers the benefits of competition and enhanced reliability even if supply and demand fundamentals change over time.⁴⁰

30. Given these potential benefits, it should be no surprise that investments in more efficient or cost-effective transmission infrastructure can yield substantial benefits to consumers.⁴¹ For example, MISO’s MVP transmission planning process resulted in transmission facilities that are estimated to generate \$2.20 to \$3.40 of benefit per dollar invested.⁴²

31. MISO achieved these benefits by proactively planning over a 20-year period for two key drivers of transmission needs: The impacts of changing state laws on the resource mix, and a large increase in the number of generator interconnection requests.⁴³ To mitigate the uncertainties of such projections of need, MISO relied on scenarios to consider a range of potential future conditions⁴⁴ and

⁴⁰ U.S. Dept. of Energy, *National Electric Transmission Congestion Study*, at 11 (Sept. 2015) (stating transmission expansion can strengthen and increase the flexibility of the overall network and “create real options to use the transmission system in ways that were not originally envisioned”); Vikram S. Budhraj et al., *Improving Electricity Resource Planning Processes by Considering the Strategic Benefits of Transmission*, 22 ELEC. J. 54 (Mar. 2009), (high voltage transmission affords “mitigation of risks as a form of insurance against extreme events”).

⁴¹ See, e.g., Southwest Power Pool, *The Value of Transmission* (Jan. 2016), <https://www.spp.org/value-of-transmission/> (A 2016 study of 348 transmission projects in SPP constructed between 2012 and 2014 found the overall ratio of benefits to costs to be at least 3.5 to 1.); NextEra Comments at 95 (citing ACEG, *Texas as a National Model for Bringing Clean Energy to the Grid* (Oct. 2017), <https://cleanenergygrid.org/texas-national-model-bringing-clean-energy-grid/>) (Transmission developed due to Texas’s Competitive Renewable Energy Zone planning process estimated to save \$1.7 billion each year in production costs alone, far surpassing its \$6.9 billion cost.); Brattle-Grid Strategies Oct. 2021 Report at 4–8 & app. A (describing evidence showing that well-planned transmission expansion resulted in lower total cost to construct the needed transmission facilities).

⁴² MTEP17 Review at 4.

⁴³ Midcontinent Independent System Operator, *RGOS: Regional Generation Outlet Study* at 2 (Nov. 19, 2010) (RGOS Study). MISO staff and stakeholders determined that allowing the transmission expansion needed to accommodate these requests to occur through the generator interconnection process “would not be an efficient means for building a cost-effective transmission system either immediately, over the next 5–10 year period or in the foreseeable future beyond that time-frame.” *Id.*

⁴⁴ MISO relied on stakeholder surveys of likely renewable energy needs over the next 20 years, and calculations of the new generation that would be needed in order to achieve state renewable portfolio

disclosed the assumptions and inputs underlying each.⁴⁵ The MVP process then identified a portfolio of “no regrets” transmission projects that were projected to provide multiple kinds of reliability and economic benefits under all the alternate future scenarios studied.⁴⁶ At each stage of the MVP process, MISO invested in significant stakeholder engagement and collaboration, from developing the technical parameters underlying its scenarios and the weights to give to each, to the metrics and methodology used to evaluate the portfolio of transmission projects.⁴⁷

32. Although, as illustrated by the MVP example, transmission infrastructure can provide significant benefits to consumers, there are often substantial barriers to developing more efficient or cost-effective transmission facilities. For example, as the Commission has long recognized, “vertically-integrated utilities do not have an incentive to expand the grid to accommodate new entries or to facilitate the dispatch of more efficient competitors.”⁴⁸ Further, because large-scale transmission investments that geographically extend or strengthen the integration of the transmission system are both costly and tend to produce widespread benefits, there is significant risk that free ridership problems inhibit their development.⁴⁹ In any event, the logistics alone of coordinating among multiple public utility transmission providers within a region, seeking support across what is often multiple state jurisdictions, and attaining sufficient certainty over who will pay the costs of the needed transmission facilities can thwart investments in more efficient or cost-effective transmission expansion.⁵⁰

33. We are concerned that these barriers continue to stymie investment in more efficient or cost-effective transmission facilities. In particular, we are concerned that public utility transmission providers are not engaging in the type of long-term, more comprehensive regional transmission planning and cost allocation processes—like the process used to plan the MISO MVPs—that is necessary to increase the likelihood that such highly beneficial transmission infrastructure is

developed. Without this kind of transmission planning and cost allocation process, opportunities to meet transmission needs more efficiently or cost-effectively may be lost. Customers may be forced to pay for less efficient or cost-effective investment in transmission facilities that, for example, achieve lower cost-benefit ratios than would otherwise be achieved with long-term, more comprehensive regional transmission planning and cost allocation. In short, absent reforms, we are concerned customers may be paying more for less.

B. Unjust and Unreasonable and Unduly Discriminatory and Preferential Commission-Jurisdictional Rates

34. The evidence suggests that sufficiently long-term, forward-looking regional transmission planning and cost allocation to meet transmission needs driven by changes in the resource mix and demand is not occurring in most transmission planning regions on a regular or consistent basis. As such, consumers may not be seeing the benefits such as enhanced reliability, improved resource adequacy, access to lower cost and diverse resources, and other benefits that result from regional transmission planning and cost allocation processes that identify, select, and allocate the costs of the more efficient or cost-effective transmission solutions to transmission needs driven by changes in the resource mix and demand. We preliminarily find that the failure of existing regional transmission planning and cost allocation processes to perform this type of transmission planning and cost allocation is resulting in unjust, unreasonable, unduly discriminatory, and preferential Commission-jurisdictional rates.

35. More specifically, we preliminarily find that reforms are needed to the Commission’s existing regional transmission planning and cost allocation requirements because they fail to require public utility transmission providers to: (1) Perform a sufficiently long-term assessment of transmission needs; (2) adequately account on a forward-looking basis for known determinants of transmission needs driven by changes in the resource mix and demand; and (3) consider the broader set of benefits and beneficiaries of transmission facilities planned to meet those transmission needs. We believe that these deficiencies may be resulting in unjust and unreasonable and unduly discriminatory and preferential Commission-jurisdictional rates to the extent that they lead to public utility transmission providers failing to identify transmission needs

driven by changes in the resource mix and demand, failing to select more efficient or cost-effective transmission facilities to meet those transmission needs, and failing to allocate the costs of transmission facilities selected in the regional transmission plan for purposes of cost allocation to meet those transmission needs in a manner that is at least roughly commensurate with the estimated benefits.

1. The Transmission Investment Landscape Today

36. We begin with the facts on the ground: The evidence suggests that long-term regional transmission planning and cost allocation to identify and plan for transmission needs driven by changes in the resource mix and demand is not occurring in most transmission planning regions on a regular or consistent basis. Rather, the status quo appears to be resulting in a disproportionate share of transmission facilities to meet transmission needs driven by changes in the resource mix and demand being developed outside regional transmission planning and cost allocation processes, resulting in less efficient and cost-effective transmission development. Significant expansion of the transmission system instead appears to occur through interconnection-related network upgrades⁵¹ constructed as a result of generator interconnection requests. Because the generator interconnection process is not designed to consider how to more efficiently or cost-effectively address transmission needs beyond the interconnection request(s) being studied, it cannot achieve the economies of scale in transmission investment needed to

⁵¹ The Commission’s *pro forma* large generator interconnection agreement (LGIA) defines Network Upgrades as: “the additions, modifications, and upgrades to the Transmission Provider’s Transmission System required at or beyond the point at which the Interconnection Facilities connect to the Transmission Provider’s Transmission System to accommodate the interconnection of the Large Generating Facility to the Transmission Provider’s Transmission System.” *Pro forma LGIA Art. 1 (Definitions)*; see also *Standardization of Generator Interconnection Agreements & Proc.*, Order No. 2003, 68 FR 49846 (Aug. 19, 2003), 104 FERC ¶ 61,103, at P 21 (2003) (describing network upgrades developed through the generator interconnection process as those interconnection facilities located at or beyond the point where the interconnection customer’s generating facility interconnects to the transmission provider’s transmission system), *order on reh’g*, Order No. 2003–A, 106 FERC ¶ 61,220, *order on reh’g*, Order No. 2003–B, 109 FERC ¶ 61,287 (2004), *order on reh’g*, Order No. 2003–C, 111 FERC ¶ 61,401 (2005), *aff’d sub nom. Nat’l Ass’n of Regul. Util. Comm’rs v. FERC*, 475 F.3d 1277 (D.C. Cir. 2007), *cert. denied*, 552 U.S. 1230 (2008). We refer to network upgrades developed through the generator interconnection process as interconnection-related network upgrades.

standards by 2027. MISO also identified the location of expected “renewable energy zones” with potential to achieve high capacity factors for use in its analysis. *Id.* at 26–29.

⁴⁵ See, e.g., MTEP17 Review at 16.

⁴⁶ *Id.* at 13.

⁴⁷ MISO Comments at 9.

⁴⁸ Order No. 890, 118 FERC ¶ 61,119 at P 57.

⁴⁹ Order No. 1000, 136 FERC ¶ 61,051 at P 486.

⁵⁰ *Id.* PP 498–501.

integrate significant quantities of new generation resources while maintaining Commission-jurisdictional rates that are just and reasonable and not unduly discriminatory or preferential. Transmission expansion in this incremental manner may miss the potential for more efficient or cost-effective transmission facilities to solve transmission needs driven by changes in the resource mix and demand, as well as to afford system-wide benefits that may not be achieved through piecemeal, one-off transmission upgrades. Robust long-term regional transmission planning, on the other hand, may enable the same needs to be met more efficiently or cost-effectively, or identify transmission facilities that meet those same needs while generating additional benefits. Today's incremental transmission planning may also fail to consider opportunities to "right size" certain replacement transmission facilities and thereby fail to identify the potential for more efficient or cost-effective regional transmission facilities.

37. The problems with the status quo are evident in the dramatic increase in recent years (and continuing upward trend) in investment in transmission facilities through the generator interconnection process in the form of interconnection-related network upgrades. The evidence demonstrates a sharp growth in both the total cost of interconnection-related network upgrades and in the cost of such upgrades relative to generation project costs. It appears that the average cost of interconnection-related network upgrades is increasing over time as the transmission system is fully subscribed and demand for interconnection service outpaces transmission investment. Recent studies of the total cost of network upgrades needed to interconnect new generation resources reflect this trend. In the generator interconnection study MISO published in July 2020, MISO identified the need for nearly \$2.5 billion in interconnection-related network upgrades to interconnect 9.2 GW of generation in MISO South.⁵² In MISO's 2020 interconnection queue outlook, MISO reported that it expects new generation resources in MISO West will need over \$3 billion in interconnection-related network upgrades and noted a

similar trend in other MISO sub-regions.⁵³ In its most recent system impact study for generator interconnection, published in April 2021, SPP identified the need for over \$4.6 billion in network upgrades to interconnect 10.4 GW of generation.⁵⁴

38. The dramatic increase in the cost of interconnection-related network upgrades per kilowatt (kW) of an interconnection customer's generating capacity may also be problematic. For example, interconnection-related network upgrade costs in MISO West went from approximately \$300/kW in 2016 to nearly \$1,000/kW in 2017.⁵⁵ The trend is evident in other parts of the country as well.⁵⁶ The costs of interconnection-related network upgrades seem to have become an ever-growing percentage of the total capital costs of new generation projects. According to one report, interconnection costs for new renewable resources were less than 10% of total generation project costs until a few years ago, but recently these costs have risen to as much as 50–100% of the total generation project costs.⁵⁷ At the same

⁵³ Americans For A Clean Energy Grid, *Disconnected: The Need for a New Generator Interconnection Policy*, at 14 (Jan. 2021), <https://acore.org/wp-content/uploads/2021/01/Disconnected-The-Need-for-a-New-Generator-Interconnection-Policy-1.14.21.pdf> (ACEG Jan. 2021 Interconnection Report) (attached to ACORE Comments as Exhibit 2); NextEra Comments at 16 (citing Midcontinent Independent System Operator, *2020 Interconnection Queue Outlook*, at 9 (2020), <https://cdn.misoenergy.org/MISO2020InterconnectionQueueOutlook445829.pdf> (MISO 2020 Queue Outlook)).

⁵⁴ ICF Sept. 2021 Report at 2.

⁵⁵ ACEG Jan. 2021 Interconnection Report at 14; NextEra Comments at 16 (citing MISO 2020 Queue Outlook at fig. 7).

⁵⁶ E.g., ACEG Jan. 2021 Interconnection Report at 14 & tbl. 2 (showing that, as of 2019, interconnection costs in PJM for constructed wind and solar projects were \$19.07/kW and 61.83/kW, respectively, as compared to a greater than 100% increase to \$54/kW and \$131.90/kW, respectively, for projects newly proposed today); NextEra Comments at 16–17 (stating that interconnection-related network upgrade cost estimates have nearly tripled for newly proposed wind projects, and more than doubled for solar projects in PJM); see also ACEG Jan. 2021 Interconnection Report at 16 (illustrating an increase in average interconnection-related network upgrade costs in NYISO from \$67/kW in 2013 to \$124/kW in 2019). Compare ACEG Jan. 2021 Interconnection Report at 15 (identifying interconnection-related network upgrade costs in 2013 in SPP as \$89/kW) with ICF Sept. 2021 Report at 2 (citing interconnection-related network upgrade costs of \$448/kW for interconnection customers studied in SPP's system impact study published in April 2021).

⁵⁷ ACEG Jan. 2021 Interconnection Report at 6; see also *id.* at 13 (stating that the rising interconnection costs of wind projects in MISO recently reached approximately 23% of the capital cost of the project); *id.* at 15 (identifying the increase in interconnection-related network upgrade costs in SPP between 2013 and 2017 as representing an increase from around 8% to over

time, interconnection-related network upgrades appear to have transitioned from primarily small transmission facilities that serve the needs of a limited number of interconnection customers to the size and scope of what has traditionally been considered high voltage transmission facilities. For example, interconnection-related network upgrades have recently included demolishing and rebuilding multiple 500 kV transmission lines⁵⁸ and constructing long, double-circuit, 765 kV transmission lines,⁵⁹ all at significant cost to the interconnection customer—and ultimately to consumers.

39. In contrast to the significant investment in transmission facilities through the generator interconnection process, the regional transmission planning and cost allocation processes have yielded limited investment in regional transmission facilities. Transmission developers in the United States invested \$20 to \$25 billion annually in transmission facilities from 2013 to 2020.⁶⁰ Yet only a limited portion of these investments have gone toward regional transmission facilities since Order No. 1000. In fact, investment in regional transmission facilities in some regions has declined compared to prior Order No. 1000.⁶¹ Moreover, across all the non-RTO/ISO regions, there has not yet been a single transmission facility selected in a regional transmission plan for purposes

43% of the capital cost of wind generation); NextEra Comments at 17 (similar).

⁵⁸ See ACEG Jan. 2021 Interconnection Report at 15 (describing interconnection-related network upgrades for a 120 MW solar plus storage project in southern Virginia to interconnect to PJM that cost as much as \$12,086/kW).

⁵⁹ See *id.* (describing one interconnection-related network upgrade in SPP identified in the system impact study published in April 2021); ICF Sept. 2021 Report at 3 (same); NextEra Comments at 17 (same).

⁶⁰ Brattle-Grid Strategies Oct. 2021 Report at 2 (citing Johannes Pfeifenberger & John Tsoukalis, The Brattle Group, *Transmission Investment Needs and Challenges*, at slide 2 (June 1, 2021), <https://www.brattle.com/wp-content/uploads/2021/10/Transmission-Investment-Needs-and-Challenges.pdf>); Johannes Pfeifenberger et al., The Brattle Group, *Cost Savings Offered by Competition in Electric Transmission: Experience to Date and the Potential for Additional Customer Value*, at 2–3 & fig.1 (Apr. 2019), https://www.brattle.com/wp-content/uploads/2021/05/16726_cost_savings_offered_by_competition_in_electric_transmission.pdf (Brattle Apr. 2019 Competition Report).

⁶¹ See, e.g., Rob Gramlich & Jay Caspary, Americans for a Clean Energy Grid, *Planning for the Future*, at 25 & fig. 8 (Jan. 2021) (included as Ex. 1 to ACORE Comments) (ACEG Jan. 2021 Planning Report) (charting the annual investment in regional transmission facilities in RTOs/ISOs from 2010 to 2018); ACORE Comments at 4 (citing Ex. 1, ACEG Jan. 2021 Planning Report at 25).

⁵² ICF Resources, LLC, *Just and Reasonable? Transmission Upgrades Charged to Interconnecting Generators Are Delivering System-Wide Benefits*, at 2 (Sept. 9, 2021), <https://acore.org/wp-content/uploads/2021/09/Just-Reasonable-Transmission-Upgrades-Charged-to-Interconnecting-Generators-Are-Delivering-System-Wide-Benefits.pdf> (ICF Sept. 2021 Report) (attached to ACORE Comments as Exhibit 5).

of cost allocation since implementation of Order No. 1000.⁶²

40. The vast majority of investment in transmission facilities since the issuance of Order No. 1000 has been in local transmission facilities.⁶³ For example, transmission investment to resolve local needs accounted for almost 80% of total transmission investment in MISO from 2018 to 2020.⁶⁴ Similarly, in PJM, about two-thirds of the total transmission investment in the region went to resolving local needs.⁶⁵

41. This evidence runs counter to the Commission's expectation that, in light of growing demand for transmission, the regional transmission planning and cost allocation reforms adopted in Order No. 1000 should have resulted in investment in more efficient or cost-effective transmission facilities over time. In Order No. 1000, the Commission recognized a growing need for transmission investment to ensure reliability and integrate new resources in light of industry trends changing the demands placed on the transmission system.⁶⁶ The Commission concluded that increasing transmission needs amplified the need for and importance of effective transmission planning and cost allocation processes to identify transmission needs and select regional transmission facilities where they are more efficient or cost-effective than the alternatives.⁶⁷

42. In sum, the evidence suggests that improvements to the Commission's

regional transmission planning and cost allocation requirements may be needed to realize the full potential of the benefits to be achieved through the planning and development of regional transmission facilities. Today, transmission needs driven by changes in the resource mix and demand appear to be largely addressed outside the regional transmission process—e.g., through generator interconnection processes—through mechanisms that are not designed to consider regional transmission needs and identify and select the more efficient or cost-effective transmission facility to meet those needs. We believe that this may result in an inefficient expansion of the transmission system to meet transmission needs driven by changes in the resource mix and demand.

43. To the extent public utility transmission providers may not be identifying the more efficient or cost-effective transmission facilities needed to meet underlying transmission needs, including needs driven by changes in the resource mix and demand, over time, consumers may ultimately bear the costs of inefficient piecemeal transmission expansion. Moreover, this concern may be exacerbated when wholesale electricity rates reflect the costs of the interconnection-related network upgrades that address needs that could have been more efficiently or cost-effectively addressed through effective regional transmission planning and cost allocation. Additionally, relying on generator interconnection processes to identify transmission facilities to address transmission needs driven by changes in the resource mix and demand leaves other benefits on the table as well, as described earlier,⁶⁸ some of which are almost always (if not exclusively) achieved through the development of regional transmission facilities (e.g., avoiding emergency operations and lost load, especially during extreme weather events, and increased wholesale market competition). We preliminarily find that this paradigm results in Commission-jurisdictional rates that are unjust and unreasonable and unduly discriminatory and preferential.

44. While the reforms adopted in Order No. 1000 were an important first step towards improved regional transmission planning and cost allocation, we preliminarily find that further reforms are necessary to ensure that public utility transmission providers engage in regional transmission planning and cost allocation on a sufficiently long-term,

forward-looking basis to meet transmission needs driven by changes in the resource mix and demand. In Order No. 1000, the Commission was focused in particular on: The lack of an affirmative obligation for public utility transmission providers “to develop a regional transmission plan that reflects the evaluation of whether alternative regional solutions may be more efficient or cost-effective than solutions identified in local transmission planning processes;” the absence of a “requirement that public utility transmission providers consider transmission needs at the local or regional level driven by Public Policy Requirements;” the potential for federal rights of first refusal to discourage investment by nonincumbent transmission developers; the limited procedures in place for interregional transmission coordination and cost allocation; and the failure of many cost allocation methods “to account for the beneficiaries of new transmission facilities.”⁶⁹ Order No. 1000 was aimed at ensuring two things: (1) That regional transmission planning processes “consider and evaluate, on a non-discriminatory basis, possible transmission alternatives and produce a transmission plan that can meet transmission needs more efficiently and cost-effectively;” and (2) “that the costs of transmission solutions chosen to meet regional transmission needs are allocated fairly to those who receive benefits from them.”⁷⁰ To that end, the Commission adopted reforms that set forth the minimum requirements to achieve these goals, requirements that were noteworthy at the time and required public utility transmission providers to expend substantial time and effort to comply.

45. We believe that it is time to take the next step. The generation fleet is changing rapidly. In many cases, this is taking the form of a shift from large, centralized resources located close to population centers toward renewable resources (sometimes in combination with electric storage resources) that are often, but not always, located far from load centers where access to their fuel source, such as the wind or the sun, is greatest.⁷¹ The growth in these resource

⁶² LS Power Oct. 12 Comments, app. I, at 18 & n.57; FERC, Staff Report, *2017 Transmission Metrics*, at 19 (Oct. 6, 2017), <https://www.ferc.gov/sites/default/files/2020-05/transmission-investment-metrics.pdf>.

⁶³ See generally ACEG Jan. 2021 Planning Report at 25–26, 71 (describing investment in local transmission facilities nationwide since implementation of Order No. 1000). In MISO, investment in local transmission facilities went from \$1.1 billion per year from 2010 to 2013, to \$2.7 billion per year from 2014 to 2019. Harvard ELI Comments at 20 & n.89; see also ACEG Jan. 2021 Planning Report at 104 (charting MISO transmission investment by project type from 2010 to 2019); ACPA and ESA Comments at 22 (showing \$247 million invested in nine regional transmission projects versus \$16.6 billion in 2,165 local transmission projects in MISO between 2016 and 2020). In PJM, investment in local transmission facilities went from \$1.25 billion per year from 2005 to 2013, to \$3.79 billion per year from 2014 to 2020. During the same time periods, investment in regional transmission facilities decreased from \$2.76 billion per year to \$1.65 billion per year. Harvard ELI Comments at 21 n.92; PIOs Comments at 33 n.98 (citing PJM Transmission Expansion Advisory Committee, *Project Statistics* (May 12, 2020)); Ari Peskoe, *Is the Utility Transmission Syndicate Forever?*, 42 Energy L.J. 1, 51 n.324 (2021), https://www.eba-net.org/assets/1/6/5_-_%5BPeskoe%5D%5B1-66%5D.pdf.

⁶⁴ Brattle-Grid Strategies Oct. 2021 Report at 2–3.

⁶⁵ LS Power October 12 Comments, Ex. 9, at 7.

⁶⁶ See Order No. 1000–A, 139 FERC ¶ 61,132 at P. 5.

⁶⁷ See *id.*

⁶⁸ See *supra* PP 28–32.

⁶⁹ Order No. 1000, 136 FERC ¶ 61,051 at P. 3.

⁷⁰ *Id.* P. 4. The interregional transmission coordination and cost allocation requirements were aimed at the same objectives with respect to possible transmission solutions located in neighboring transmission planning regions. *Id.*

⁷¹ In its 2021 Long-Term Reliability Assessment, NERC reports over 504 GW of nameplate capacity from new solar and wind in development through 2031. In contrast, confirmed coal-fired, nuclear, and natural-gas-fired retirements through the year 2026

types is driven by many factors, including: (1) The improved economics of certain renewable resources;⁷² (2) increased customer demand for such resources, including among major corporations;⁷³ (3) utility commitments to procure most or all of their electricity from renewable and/or non-emitting resources;⁷⁴ and (4) federal, state, and local policies incentivizing various forms of generation resources and other technologies.⁷⁵ Similarly, changes in electric demand and associated load profiles are occurring as load-serving entities shift to meet increasing needs due to the electrification of our power system as well as new large loads associated with evolving industrial and commercial needs such as the growth in data centers.⁷⁶ Moreover, transmission system operators are also increasing their reliance on regional and interregional transmission facilities to ensure operational stability in light of the rising share of variable resources in the resource mix and increasingly frequent extreme weather events.⁷⁷

total approximately 48.4 GW. NERC, *2021 Long-Term Reliability Assessment*, at 30, 35 (Dec. 2021).

⁷² See Lawrence Berkeley National Laboratory, *Wind Energy Technology Data Update: 2020 Edition*, at 66 (Aug. 2020) (noting the average levelized cost of wind energy for commercial wind generation has decreased from \$90 per MWh in 2009, to \$35 per MWh in 2019); Lawrence Berkeley National Laboratory, *Utility-Scale Solar Data Update: 2020 Edition*, at 32 (Nov. 2020) (noting the average levelized power purchase agreement price for utility-scale solar generation has decreased from approximately \$160 per MWh in 2009, to approximately \$40 per MWh in 2020).

⁷³ See National Renewable Energy Laboratory (NREL), *H2 2020 Solar Industry Update*, at 31 (2021) (stating that U.S. corporate solar contracts were up 34% annually in 2020, and 7.4 times higher over 5 years).

⁷⁴ See Deloitte, *Insights, Utility Decarbonization Strategies, Renew, Reshape, and Refuel to Zero*, at 4 (2020) (indicating 43 of 55 utilities surveyed have emissions reductions targets and 22 have net-zero or carbon-free electricity goals); Esther Whieldon, S&P Global Market Intelligence, *Path to net zero: 70% of biggest US utilities have deep decarbonization targets*, at 3–6 (2020) (indicating based on a review of utilities' climate goals and decarbonization plans that, as of December 2020, 70% of the 30 largest utilities have net-zero carbon targets, or are moving to comply with similarly aggressive state mandates).

⁷⁵ See Lawrence Berkeley National Laboratory, *U.S. Renewables Portfolio Standards 2021 Status Update: Early Release*, at 9 (Feb. 2021) (stating renewable portfolio standards exist in 30 states and the District of Columbia, and apply to 58% of total U.S. retail electricity sales).

⁷⁶ For example, the electrification of end uses that currently rely on other energy sources is expected, under a moderate scenario that does not factor in public policy drivers, to increase electricity demand by 2050 to about 25% above today's level. ACEG Jan. 2021 Planning Report at 35 (discussing National Renewable Energy Laboratory's "medium electrification" case); see also AEE Comments at 14–18 (describing local, state, and federal policies, technical and economic trends that are leading to increased electrification).

⁷⁷ For example, during Winter Storm Uri in February 2021, SPP and MISO were able to avoid

Lastly, in recognition of the benefits of regional power markets, regional integration efforts have expanded since Order No. 1000, as illustrated by the creation of the Western Energy Imbalance Market (EIM) and SPP Integrated Marketplace in 2014.⁷⁸ These changes in the resource mix and demand, operational challenges, and increasing regional integration increase the importance of engaging in regional transmission planning and cost allocation to meet long-term transmission needs more efficiently or cost-effectively.

46. A diverse range of stakeholders, including state and regulatory entities,⁷⁹ consumer interest groups,⁸⁰ transmission owners,⁸¹ independent

major power shortfalls during the extreme cold by importing electricity from the east. During the event, MISO imported nearly 9,000 MW from PJM and several thousand MW from the Tennessee Valley Authority. ACORE Comments, Ex. 4, *Transmission Makes the Power System Resilient to Extreme Weather*, at 7.

⁷⁸ Moreover, we note that efforts for further regional integration of power markets continue today. See, e.g., Kassia Micek, *Megawatt Daily, Three Colorado utilities to join SPP's Western Energy Imbalance Service Market* (Jan. 26, 2022) ("Three Colorado utilities announced plans to join [SPP's] Western Energy Imbalance Service market and continue studying long-term solutions to join or develop an organized wholesale market.").

⁷⁹ See, e.g., NARUC Comments at 5 ("NARUC identifies opportunities for reforms that may result in more efficient transmission planning and investment to the benefit of consumers, all while preserving jurisdictional authorities."); NASEO Comments at 1 ("NASEO shares the Commission's concern that the current approach to planning and allocating the costs of transmission facilities may lead to an inefficient, piecemeal expansion of the transmission grid."); NESCOE Comments at 35 ("NESCOE appreciates the Commission's leadership in recognizing a need for longer-term and comprehensive regional transmission analysis to account for this changing resource mix."); Kansas Commission Comments at 5 (stating "the KCC believes that improvements can be made to optimize regional transmission planning policies and proceedings").

⁸⁰ Iowa Consumer Advocate Comments at 1 (recognizing "an urgent need to review existing processes and identify opportunities for reform" and that failure to do so could "negatively impact reliability, and result in rates that are unjust and unreasonable"); Consumers Council Comments at 3–4 (stating reforms are "crucial" and that "since Order No. 1000 was implemented, several inefficiencies and unintended consequences have emerged in transmission planning"); District of Columbia's Office of the People's Counsel Comments at 2 (arguing there are "significant flaws" in the regional transmission planning process in PJM).

⁸¹ See, e.g., NY TOs Comments at 14 ("In conclusion, the NY TOs support the ANOPR's goals of proactive, multi-value scenario modeling and recognize that further refinements to New York's transmission planning processes and modeling will likely be needed to integrate renewables and to maintain reliability."); SoCal Edison Comments at 3 (asserting that "enhancements are necessary" to CAISO's regional transmission planning structure); AEP Comments at 2 (encouraging the Commission "to consider broad reforms for both transmission planning and generator interconnections").

power producers,⁸² and various trade⁸³ and non-government organizations,⁸⁴ identify the need to build on existing regional transmission planning and cost allocation processes. A still broader range of stakeholders acknowledge, at a minimum, that there is scope for improvements in existing regional transmission planning and cost allocation processes.⁸⁵ While RTOs/ISOs defend the sufficiency of their regional transmission planning and cost allocation processes, all recognize the potential for reforms to respond to ongoing developments in the electric industry⁸⁶ and, in some instances, they have initiated analysis and other early steps toward proposing reforms.⁸⁷

⁸² See, e.g., Enel Comments, attach. (*Plugging In: A Roadmap for Modernizing & Integrating Interconnection and Transmission Planning*) at 4 (arguing certain deficiencies result in inadequate building of transmission and result in cost-inefficient solutions for load); Northwest and Intermountain Comments at 3–4 (pointing to limitations in existing Order No. 1000 processes and advocating additional reforms are needed to ensure just and reasonable transmission rates).

⁸³ See, e.g., Joint Statement in Support of Large Scale Transmission at 1 (ACORE, ACPA, ACEG, AEE, National Electrical Manufacturers Association, and SEIA, among other signatories, support reforms to transmission planning and cost allocation policies); WIRES Comments at 7–18 (advocating for several reforms to regional transmission planning and cost allocation processes, and against others).

⁸⁴ See, e.g., R Street Comments at 1 (stating "planning processes require an overhaul"); Policy Integrity Comments at 1 (arguing "current approaches to transmission planning and cost allocation are failing to capture [] large potential benefits").

⁸⁵ See, e.g., EPSA Comments at 2, 4 (asserting reforms will be necessary to accommodate the evolving transmission system and longer-term regional transmission planning is warranted); Industrial Customers Comments at 13 (stating "[t]o be sure, there is room for improvement"); Northern VA Coop Comments at 2 (noting "improvement is possible").

⁸⁶ MISO Comments at 7 (arguing its transmission planning process is serving its intended purpose but acknowledging "improvements may be made"); SPP Comments at 9 (stating "SPP realized there was a need to more strategically consider broader changes to SPP's transmission planning process"); PJM Reply Comments at 6 (stating "it is appropriate to enhance the long-term planning process to consider scenario planning and the interaction of many system enhancement drivers"); ISO-NE Comments at 26 (noting "improvements may be needed to optimize transmission solutions for reliability, economic, and public policy based needs"); NYISO Comments at 2 ("NYISO sees an opportunity to build on the existing successes of its processes and to evolve them to address current conditions."); CAISO Comments at 2 (supporting the goal of enhancing regional transmission planning and generator interconnection processes to account for the transmission needs of a changing resource mix).

⁸⁷ See, e.g., SPP Comments at 10 (SPP Board of Directors-appointed team identified critical issues with existing transmission planning process including sub-optimal transmission plans; deficiency in collective quantification of cost-causers and beneficiaries which create free rider situations; and failure to consider congestion costs and other economic impacts in processes used to

2. Deficiencies in the Commission's Existing Regional Transmission Planning and Cost Allocation Requirements

47. We preliminarily find deficiencies in the Commission's existing regional transmission planning and cost allocation requirements are resulting in Commission-jurisdictional rates that are unjust and unreasonable and unduly discriminatory and preferential. In particular, we preliminarily find that the Commission's regional transmission planning and cost allocation requirements fail to require public utility transmission providers to: (1) Perform a sufficiently long-term assessment of transmission needs; (2) adequately account on a forward-looking basis for known determinants of transmission needs driven by changes in the resource mix and demand; and (3) consider the broader set of benefits and beneficiaries of regional transmission facilities planned to meet those transmission needs. We believe that these deficiencies may be resulting in unjust and unreasonable and unduly discriminatory and preferential Commission-jurisdictional rates to the extent that they lead public utility transmission providers to fail to identify transmission needs driven by changes in the resource mix and demand, select more efficient or cost-effective transmission facilities to meet those transmission needs, and allocate the costs of transmission facilities selected in the regional transmission plan for purposes of cost allocation to meet those transmission needs in a manner that is at least roughly commensurate with the estimated benefits. We address each deficiency in turn.

48. The first deficiency—that the Commission's existing regional transmission planning and cost allocation requirements do not require public utility transmission providers to perform a sufficiently long-term assessment of transmission needs—is reflected across multiple components of existing regional transmission planning processes, from the degree to which studies that inform assessment of transmission needs are forward looking, to whether forward-looking assessments actually inform selection and cost allocation of regional transmission facilities. Existing regional transmission planning and cost allocation processes typically look out and plan for transmission needs based on a relatively

identify needed upgrades.); ISO-NE Comments at 14–16 (initiating a 2050 Transmission Study at the request of ISO-NE states and efforts to incorporate a new forward-looking, scenario-based transmission planning tool).

near-term horizon. While some existing regional transmission planning and cost allocation processes may incorporate studies or assessments that have a longer forward-looking period, these are typically for informational purposes and do not result in identification of long-term regional transmission needs, assessment of transmission alternatives to meet those needs, or selection of transmission facilities in the regional transmission plan for purposes of cost allocation.⁸⁸ Such studies or assessments may be one-off, available only upon request, or conducted at irregular intervals.⁸⁹ Additionally, many forward-looking studies treat key variables that affect transmission needs, such as generation additions and retirements, as fixed over the full time horizon of the study, even though these variables are likely to change.⁹⁰ Such studies are therefore unlikely to adequately assess transmission needs over the longer-term horizon, as they do not attempt to assess the likelihood that conditions contributing to transmission needs change.⁹¹

49. While it is reasonable for regional transmission planning and cost allocation processes to include near-term study of the transmission system, the absence of any longer-term assessment of transmission needs that may form the basis for selection and cost allocation may prevent public utility transmission providers from considering regional transmission

⁸⁸ For example, SPP is required under its tariff to conduct a 20-year study of transmission at least every five years but is prohibited from using that study as the basis for authorizing construction of a transmission solution. SPP Market Monitor Comments at 4 (citing SPP, OATT, attach. O, § IV.2 (8.0.0), § IV.2.a).

⁸⁹ For example, in response to state requests, ISO-NE recently initiated a stakeholder process to respond to the problem that “[t]he current processes do not support the performance of state-requested transmission analysis based on state-developed scenarios, inputs and assumptions, nor do they support transmission analysis beyond the ten-year horizon.” ISO-NE, *Attachment K Revisions: Extended-Term Planning*, Transmission Committee, at slide 3 (Sept. 28, 2021), https://www.iso-ne.com/static-assets/documents/2021/09/a07_tc_2021_09_28_atk_ext_trans_presentation.pdf; see also Indicated PJM TOs Comments at 25 (stating “the PJM Tariff does not provide concrete time windows for scenario planning”).

⁹⁰ Policy Integrity Comments at 29.

⁹¹ PJM's long-term assessment of the transmission system ostensibly considers a 15-year horizon, for example, but does not account for changes to the generation mix beyond a 5-year period. See PSEG Comments at 11 (stating that “in practice only new resources that are near the end of the interconnection queue process and have signed an Interconnection Service Agreement are considered in the RTEP base case”); Union of Concerned Scientists Comments at 10 & n.11 (“Generation additions are unchanged in the 15-year study period, as the input assumption has no additional information that would expand the set of generators included in the forecast.”).

facilities that may be more efficient or cost-effective in light of changing transmission needs.⁹² The failure to assess longer-term transmission needs is particularly problematic given the long-lead times necessary to construct large (e.g., high voltage or long distance) transmission facilities, the potential for economies of scale in transmission investment, and the long life of transmission assets, which will continue to serve transmission needs well beyond a 5- or 10-year planning horizon—all of which suggest that relying solely on shorter-term studies may fail to identify transmission needs and undervalue the benefits of transmission investments to meet those needs. Moreover, the likelihood that near-term assessments will fail to identify more efficient or cost-effective regional transmission facilities is higher during periods, as the sector is now experiencing, in which the need for transmission is expected to grow considerably.⁹³

50. The second deficiency is that existing requirements fail to ensure that public utility transmission providers adequately account on a forward-looking basis for known determinants of transmission needs driven by changes in the resource mix and demand. This is closely related to the first deficiency in the sense that both relate to the failure of the existing requirements to result in processes that adequately plan for the foreseeable future. Orders Nos. 890 and 1000 afforded flexibility to public utility transmission providers to determine the inputs, assumptions, and methodologies that are used in analyses of the transmission system to identify transmission needs and produce a regional transmission plan. In the absence of clear standards, public utility transmission providers have adopted widely divergent approaches to

⁹² U.S. DOE Comments at 10 (stating failure to plan transmission far enough ahead results in “adverse implications for system reliability, resilience, consumers’ electricity rates, and the achievement of clean energy goals”); MISO Reply Comments at 5 (“[G]iven long-term needs of an evolving system, additional transmission is necessary to reliably serve customers now and into the future. These challenges require immediate action and further delay only increases the risk that system enhancements may not be in place in the timeframe needed.”).

⁹³ U.S. DOE Comments at 10 (“Relying on successive small transmission expansion projects to meet foreseeable long-term needs may lead to the need for expensive retrofits (at customers’ expense) at a later date. Economies of scale and network economies suggest that an initial larger-scale buildout will often represent a lower-cost solution.”); see also Policy Integrity Comments at 29 (citing Álvaro García-Cerzo et al., *Robust Transmission Network Expansion Planning Considering Non-Convex Operational Constraints*, 98 Energy Econ. (June 2021)).

determining the factors that are relevant to regional transmission planning and addressing uncertainty in these variables. The result is that public utility transmission providers in some transmission planning regions do a better job than others in accounting for changes in the resource mix and demand when performing transmission planning studies. We are concerned that the reality is that none do so in a manner that ensures the consideration of more efficient or cost-effective transmission facilities to meet transmission needs driven by changes in the resource mix and demand.

51. While we recognize the inevitable uncertainty in forecasting, a number of factors that increasingly shape the resource mix and demand are known in advance and have reasonably predictable effects, especially in the aggregate. For example, the economics of new and existing generating facilities has predictable effects on the resource mix, including which existing generating facilities are likely to retire and which type of new generating facility is likely to be built to replace them. Similarly, state laws, utility integrated resource plans and resource procurements, and other regulatory actions necessarily implicate the resource mix and demand for Commission-jurisdictional services.⁹⁴ There are other known determinants of transmission needs as well, including factors affecting electricity demand (e.g., electrification trends, energy efficiency improvements, and demand response deployments), the risk of extreme weather, information derived from the generator interconnection process about needed transmission expansion, and the locations where transmission needs are likely to be particularly acute or concentrated because of desirable siting conditions for new generating facilities. Yet it appears that existing regional transmission planning processes may undervalue or entirely omit consideration of some or all of these factors.⁹⁵

⁹⁴ See AEE Comments at 10 (explaining that the majority of U.S. electricity customers take service from a load-serving entity subject to legally binding requirements that affect the resource mix).

⁹⁵ See SPP Market Monitor Comments at 3 & n.5 (describing that even SPP's more forward-looking scenario analysis of an emerging technology case in its Integrated Transmission Plan presently underestimates the actual growth of renewables so much that "[w]ind capacity in service today (29.8 GW) already exceeds wind levels projected in both 2019 ITP futures that go out to 2029"); AEE Comments at 18 (MISO projects electrification effect on load in its long-term regional transmission planning, but how other transmission providers account for electrification trends is not consistent or transparent.); Brattle-Grid Strategies Oct. 2021 Report at 36 (stating that production cost

52. We believe that engaging in regional transmission planning without adequate consideration of such factors may be leading to transmission investment that is not more efficient or cost-effective and, in turn, Commission-jurisdictional rates that are unjust and unreasonable and unduly discriminatory and preferential.⁹⁶ We believe that this deficiency may delay planning for the transmission system's changing operational needs until shortly before those needs manifest, despite the fact that the continued shift in the resource mix and changes in demand can be reasonably forecast based on known factors. As explained above, the lack of sufficient long-term transmission planning appears to be resulting in significant transmission investment in recent years occurring through generator interconnection processes to satisfy near-term transmission needs, resulting in piecemeal development of transmission facilities that may not more efficiently or cost-effectively meet transmission needs driven by changes in the resource mix and demand. We expect the problems created by this deficiency to only grow more acute as the factors that impact the resource mix and demand are poised to continue increasing in their impact on transmission needs.

53. The third potential deficiency is that public utility transmission providers may not identify a sufficiently broad set of benefits—and beneficiaries—associated with regional transmission facilities planned to meet transmission needs driven by changes in the resource mix and demand. Failing to adequately identify and consider the benefits of such transmission facilities may lead to sub-optimal or inefficient investment therein. In particular, the cost-benefit analyses that are used as part of the selection process may fail to identify more efficient or cost-effective transmission facilities for selection in

simulations that are typically used to estimate the economic benefit of regional transmission facilities assumes no extreme weather events); U.S. DOE Comments, app. B (*National Laboratories' Supplemental Information to Comments of Department of Energy to Advance Notice of Proposed Rulemaking (ANOPR)*) at 79 (stating an array of tools exist to identify and analyze high-value zones).

⁹⁶ NERC Comments at 17–18 (“Coordination and better certainty around anticipated future resource mix during transmission planning and interconnection studies could improve reliability assessments associated with the changing resource mix[.]”); ACPA and ESA Comments at 29 (claiming the current approach “delays overall investment in the transmission system”); AEE Comments at 8 (arguing existing transmission planning processes’ failure to capture “documented and predictable trends in electricity demand and threats to the reliability, resilience, and sufficiency of the bulk electricity system” warrant reforms).

the regional transmission plan for purposes of cost allocation because they provide an inaccurate portrayal of the comparative benefits of different transmission facilities. In addition, by not considering an expanded set of benefits and beneficiaries, cost allocation methods may fail to assign the costs of such facilities to beneficiaries in a manner that is at least roughly commensurate with the benefits they derive from them.⁹⁷

54. We recognize that, in addressing these deficiencies, the Commission would be requiring public utility transmission providers to plan on a longer-term and more comprehensive basis. As discussed below, we acknowledge that such transmission planning may entail a more complex set of considerations compared to existing regional transmission planning requirements, which, in turn, may increase the importance of ensuring that the cost allocations method for projects identified and developed through these processes are perceived as fair.⁹⁸ As discussed below, we are proposing to address these concerns in part through greater state involvement, particularly in the development of cost allocation methods.

55. In sum, we preliminarily find that the deficiencies in the Commission's existing regional transmission planning and cost allocation requirements that we identify in this NOPR are resulting in Commission-jurisdictional rates that are unjust and unreasonable and unduly discriminatory and preferential. To address the enumerated deficiencies and ensure that Commission-jurisdictional rates are just and reasonable and not unduly discriminatory or preferential, we propose reforms to these requirements, as described in detail in the sections that follow.

IV. Regional Transmission Planning

56. We preliminarily find that reforms to public utility transmission providers' regional transmission planning processes are necessary to ensure that Commission-jurisdictional rates are just and reasonable and not unduly discriminatory or preferential. As discussed below, the regional transmission planning reforms proposed in this NOPR would require that public utility transmission providers conduct regional transmission planning on a

⁹⁷ *Ill. Commerce Comm'n v. FERC*, 576 F.3d 470, 477 (7th Cir. 2009). Order No. 1000, 136 FERC ¶ 61,051 at PP 622, 639 (requiring costs of regional transmission facilities to be allocated in a manner that is at least roughly commensurate with estimated benefits).

⁹⁸ See *infra* P-235–.

sufficiently long-term, forward-looking basis to identify and plan for transmission needs driven by changes in the resource mix and demand. As part of this long-term regional transmission planning, public utility transmission providers would be required, in coordination with states, to: (1) Identify transmission needs driven by changes in the resource mix and demand through the development of long-term scenarios that satisfy the requirements set forth in this NOPR; (2) evaluate the benefits of regional transmission facilities to meet identified transmission needs driven by changes in the resource mix and demand over a time horizon that covers, at a minimum, 20 years starting from the estimated in-service date of the transmission facilities; and (3) establish transparent and not unduly discriminatory criteria to select regional transmission facilities in the regional transmission plan for purposes of cost allocation that more efficiently or cost-effectively address these transmission needs driven by changes in the resource mix and demand. Additionally, we propose to require that public utility transmission providers more fully consider dynamic line ratings and advanced power flow control devices in regional transmission planning processes.

A. Overview of Existing Regional Transmission Planning Processes

57. Public utility transmission providers currently plan their transmission systems to meet reliability, economic, and Public Policy Requirements needs identified through their regional transmission planning process, consistent with Order Nos. 890 and 1000.⁹⁹ The next few paragraphs provide a brief overview of how public utility transmission providers currently conduct regional transmission planning.

1. Reliability Needs

58. Public utility transmission providers within transmission planning regions conduct planning studies to help ensure the ability of the transmission system to meet minimum performance requirements under a variety of contingencies to provide reliable service to customers. These studies cover the near-term, which is years 1 through 5, and the long-term, which covers years 6 through year 10 and beyond.¹⁰⁰ Long-term transmission planning varies by public utility transmission provider; for example,

studies conducted by RTOs/ISOs may range 10, 15, to 20 years¹⁰¹ into the future depending on the transmission planning region's regional transmission planning process and test for violations of established North American Electric Reliability Corporation (NERC) reliability requirements.¹⁰² Additional regional and local reliability criteria may also apply in specific transmission planning regions. In order to meet applicable reliability planning criteria, the regional transmission planning process focuses on studying and producing a transmission system that is robust enough to withstand a range of probable contingencies (e.g., the sudden loss of a generator or higher-voltage transmission facilities) while reliably serving customer demand and preventing cascading outages.¹⁰³ Generally, public utility transmission providers identify areas of the transmission system that they predict will not be in compliance with reliability criteria and develop plans to

¹⁰¹ Long-term planning for reliability by RTO/ISO varies as follows: CAISO at least 10 years (CAISO, CASIO eTariff, § 24.2 (Nature of the Transmission Planning Process) (6.0.0)); ISO-NE between 5 and 10 years (ISO-NE, Transmission, Markets and Services Tariff, attach. K (Regional System Planning Process) (27.0.0), § 3.3 (RSP Planning Horizon and Parameters)); MISO maximum of 20 years (MISO, FERC Electric Tariff, attach. FF (Transmission Expansion Planning Protocol) (85.0.0), § I.C.8.a); NYISO years 4 through 10 (NYISO, NYISO Tariffs, NYISO OATT, § 31.1, attach. Y (New York Comprehensive System Planning Process) (26.0.0)); PJM 10 years (PJM, Intra-PJM Tariffs, OA Schedule 6, § 1.4 (Contents of the Regional Transmission Expansion Plan) (2.1.0), § 1.4.b); and, SPP 10 and 20 years (Southwest Power Pool, Inc., OATT, attach. Y, § III (The Integrated Transmission Planning Assessment) (8.0.0), § IV (Other Planning Studies) (8.0.0)).

¹⁰² For example, Reliability Standard TPL-001-4 requires that Transmission Planners conduct an annual planning assessment of their region's portion of the bulk electric system and document summarized results of the steady state analyses, short circuit analyses, and stability analyses. TPL-001-4 also requires that Transmission Planners conduct these analyses using a model of their systems operating under a wide variety of potential conditions to see under what, if any, conditions the system will fail to meet reliability criteria. TPL-001-4 lays out the variety of these conditions, including system peak, off-peak, single contingency, multiple contingencies (both sequential and simultaneous), severe contingencies on adjacent systems, sensitivity analyses to underlying model assumptions, and extreme events. Transmission Planner is defined as "the entity that develops a long-term (generally one year and beyond) plan for the reliability (adequacy) of the interconnected bulk electric transmission systems within its portion of the Planning Authority area." NERC, Glossary of Terms Used in NERC Reliability Standards (June 28, 2021), https://www.nerc.com/pa/Stand/Glossary%20of%20Terms/Glossary_of_Terms.pdf.

¹⁰³ The regional transmission planning process will identify the necessary transmission system facilities (which have varying costs and lead times for when they can be placed into service) that are needed to achieve reliable transmission system operations.

achieve compliance. Public utility transmission providers examine potential transmission facilities to mitigate identified reliability criteria violations for their feasibility, impact, and comparative costs, culminating in a recommended regional transmission plan.¹⁰⁴

2. Economic Needs

59. Public utility transmission providers within transmission planning regions also plan transmission facilities to meet economic needs. In Order No. 1000, the Commission recognized that Order No. 890 placed no affirmative obligation on public utility transmission providers to perform economic planning studies absent a request by stakeholders.¹⁰⁵ To remedy this deficiency, the Commission required in Order No. 1000 that, in addition to economic planning studies requested by stakeholders, public utility transmission providers evaluate, through a regional transmission planning process and in consultation with stakeholders, regional transmission facilities that might meet the needs of the transmission planning region more efficiently or cost-effectively than transmission facilities identified by individual public utility transmission providers in their local transmission planning process.¹⁰⁶ These regional transmission facilities could include transmission facilities needed to meet reliability requirements, address economic considerations, and/or meet transmission needs driven by Public Policy Requirements.¹⁰⁷ As Order No. 890 explains, the purpose of economic transmission planning is to plan transmission to alleviate congestion through the integration of new generation resources or an expansion of the regional transmission system, by an amount that justifies its cost, usually by a defined threshold.¹⁰⁸ Examples of regional transmission facilities driven by economic needs include transmission facilities that relieve historical or projected transmission congestion and allow lower-cost power to flow to consumers.

3. Transmission Needs Driven by Public Policy Requirements

60. In Order No. 1000, the Commission required public utility transmission providers to consider transmission needs driven by Public Policy Requirements in their local and regional transmission planning

¹⁰⁴ ANOPR, 176 FERC ¶ 61,024 at P 14.

¹⁰⁵ Order No. 1000, 136 FERC ¶ 61,051 at PP 3, 81, 147.

¹⁰⁶ *Id.* P 148.

¹⁰⁷ *Id.* PP 147-148.

¹⁰⁸ Order No. 890, 118 FERC ¶ 61,119 at P 549.

⁹⁹ ANOPR, 176 FERC ¶ 61,024 at P 13.

¹⁰⁰ NERC, Glossary of Terms Used in NERC Reliability Standards (June 28, 2021), https://www.nerc.com/pa/Stand/Glossary%20of%20Terms/Glossary_of_Terms.pdf.

processes.¹⁰⁹ However, the requirement in Order No. 1000 to consider transmission needs driven by Public Policy Requirements is limited, and the Commission provided public utility transmission providers with flexibility in how to meet the requirement. For example, Order No. 1000 does not require that a separate class of transmission facilities be created in the regional transmission planning process to address transmission needs driven by Public Policy Requirements,¹¹⁰ nor does it mandate the consideration of any particular transmission need driven by a Public Policy Requirement.¹¹¹ In addition, while Order No. 1000 requires that public utility transmission providers consider transmission needs driven by Public Policy Requirements proposed by stakeholders, it provides flexibility on how active public utility transmission providers themselves choose to be in identifying such needs.¹¹² As a result, the process for identifying and considering transmission needs driven by Public Policy Requirements varies from transmission planning region to transmission planning region.

B. Comments

61. In response to the ANOPR, the Commission received many comments on the need to reform regional transmission planning processes. Many comments support long-term regional transmission planning.¹¹³ Some

¹⁰⁹ Order No. 1000, 136 FERC ¶ 61,051 at PP 203, 222; Order No. 1000-A, 139 FERC ¶ 61,132 at P 208.

¹¹⁰ Order No. 1000, 136 FERC ¶ 61,051 at P 220 (explaining that the requirements in Order No. 1000 related to transmission needs driven by Public Policy Requirements are intended to “provide flexibility for public utility transmission providers to develop procedures appropriate for their local and regional transmission planning processes”).

¹¹¹ *Id.* P 215.

¹¹² Order No. 1000-A, 139 FERC ¶ 61,132 at P 322.

¹¹³ *E.g.*, CAISO Comments at 5; MISO Comments at 41; ISO-NE Comments at 23; NYISO Comments at 26–28; PJM Comments at 3–4; SPP Comments at 6; AEP Comments at 4; Ameren Comments at 5; BP Comments at 3–4; Exelon Comments at 2; National Grid Comments at 4; NextEra Comments at 56; PG&E Comments at 2; Indicated PJM TOs Comments at 3; PSEG Comments at 10–11; SDG&E Comments at 2; SCE Comments at 3–4; Shell Comments at 7; VEIR Comments at 14; Xcel Comments at 19–20; WIRES Comments at 7; EDP Renewables Comments at 4; EDF Comments at 5; EPSA Comments at 6; ITC Comments at 4; New England for Offshore Wind Comments at 1; Certain TDUs Comments at 7; ACORE Comments at 6; ACPA and ESA Comments at 44; AEE Comments at 3; EEI Comments at 12–14; Consumers Council Comments at 9; Harvard ELI Comments at 33; Nature Conservancy Comments at 2–3; PIOs Comments at 60; Resale Iowa Comments at 14; REBA Comments at 17; NARUC Comments at 6; California Public Utility Commission Comments at 5; Michigan Commission Comments at 2–3; Minnesota Department of Commerce Comments at

transmission developers and incumbent public utility transmission providers support efforts to reform aspects of existing regional transmission planning processes, with some recommending that the Commission impose prescriptive planning requirements.¹¹⁴ Some state commissions and consumer advocates also support the need to reform regional transmission planning processes, but express concern about potential costs and ensuring that such costs are allocated commensurate with estimated benefits.¹¹⁵

62. Some RTOs/ISOs assert that their current regional transmission planning processes already incorporate many of the potential reforms discussed in the ANOPR and ask that the Commission provide sufficient flexibility and avoid being too prescriptive should it undertake those reforms.¹¹⁶ ISO-NE states that forward-looking scenario planning is underway in ISO-NE and asks that the Commission not require a one-size-fits-all approach.¹¹⁷ NYISO urges the Commission to consider that in NYISO, incremental, yet meaningful, reforms can implement many of the goals of the ANOPR, and asks that the Commission recognize the need for regional variation so that each RTO/ISO

5; New Jersey Commission Comments at 10–11; District of Columbia Office of the People’s Counsel Comments at 22–23; Oregon Public Utility Commission Comments at 1; NEPOOL Comments at 6–7; SPP RSC Comment at 2; NASUCA Comments at 4; Iowa Office Of Consumer Advocate Comments at 2; Massachusetts Attorney General Comments at 2; State of Massachusetts Comments at 2; NESCOE Comments at 5–6; NASEO Comments at 1–2; City of New York Comments at 4; APPA Comments at 9; American Municipal Power Comments at 33–34; California Municipal Utilities Association Comments at 7; Public Systems Comments at 17; U.S. DOE Comments at 12, 16; Association of Fish and Wildlife Agencies Comments at 3; *see also* ACEG Reply Comments, app. A (identifying 174 entities supporting planning for a future resource mix).

¹¹⁴ For example, AEP, SoCal Edison, and NextEra support a 20-year planning horizon. AEP Comments at 1–2, 7–8; SoCal Edison Comments at 4; NextEra Comments at 70, 79–80. Exelon, PSEG, and NextEra support requirements for public utility transmission providers to include state statutes and goals in their scenarios. Exelon Comments at 12–20; PSEG Comments at 3–6; NextEra Comments at 80. LS Power and Resale Iowa support a requirement that all facilities above 100 kV be regionally planned. LS Power Oct. 12 Comments at 49–60; Resale Iowa Comments at 8. NextEra supports requiring public utility transmission providers to use an expanded set of transmission benefits and to designate renewable energy development zones. NextEra Comments at 92–101. Avangrid supports requiring public utility transmission providers to plan for offshore wind development. Avangrid Comments at 21–23.

¹¹⁵ District of Columbia’s Office of the People’s Counsel Comments at 1–5; NARUC Comments at 5–7, 46–47; NASUCA Comments at 3–5; Iowa Consumer Advocate Comments at 2.

¹¹⁶ CAISO Comments at 3–5; MISO Comments at 2–4.

¹¹⁷ ISO-NE Comments at 2, 13–16.

can improve its regional transmission planning process in light of its regional needs.¹¹⁸

63. The market monitors express mixed views on more comprehensive or long-term transmission planning. The PJM Market Monitor expresses a concern around the lack of certainty and quality of additional information being included in regional transmission planning that may impose additional uncertainty on the regional transmission planning process.¹¹⁹ Potomac Economics expresses concern regarding mandating long-term regional transmission planning that requires public utility transmission providers to speculate on certain future conditions, but notes improvements could be made to the regional transmission planning process to account for near-term emerging trends that are less uncertain than longer-term factors.¹²⁰ In contrast, the SPP Market Monitor expresses a concern that SPP’s regional transmission planning process is not planning for generation resources of the future.¹²¹

C. Proposed Reforms

1. Long-Term Regional Transmission Planning

a. Need for Reform

64. We are concerned that existing regional transmission planning processes may not be planning on a sufficiently long-term, forward-looking basis to meet transmission needs driven by changes in the resource mix and demand, leading to the piecemeal and inefficient development of new transmission facilities in a manner that is not more efficient or cost-effective. As discussed above, existing regional transmission planning processes typically look out and plan for transmission needs based on a relatively short time horizon.¹²² While some existing regional transmission planning processes may incorporate studies or assessments that have a longer forward-looking period, these are typically for informational purposes and do not result in identification of long-term regional transmission needs, assessment of transmission alternatives to meet

¹¹⁸ NYISO Comments at 2–4.

¹¹⁹ PJM Market Monitor Comments at 2–3.

¹²⁰ Potomac Economics Comments at 4.

¹²¹ SPP Market Monitor Comments at 4.

¹²² *Supra* Need for Reform: Unjust and Unreasonable and Unduly Discriminatory and Preferential Commission-Jurisdictional Rates. For example, PJM’s Regional Transmission Expansion Plan (RTEP) baseline assessment looks out over a 5-year period, the NorthernGrid Regional Transmission Plan has a 10-year planning horizon, and SPP’s Integrated Transmission Plan (ITP) also addresses a 10-year horizon.

those needs, or selection of transmission facilities in the regional transmission plan for purposes of cost allocation.¹²³ In lieu of such a long-term outlook, transmission needs driven by changes in the resource mix and demand are largely addressed through generator interconnection processes.¹²⁴ However, such processes are not designed to evaluate the need for larger, regional transmission facilities to address transmission needs driven by changes in the resource mix and demand, resulting in a piecemeal expansion of the electric transmission system.

65. Implementation challenges associated with long-term transmission planning—such as determining the appropriate time horizon, selecting a set of factors to forecast the future resource mix and demand, and choosing the appropriate method to account for uncertainty—make it unlikely that public utility transmission providers will engage in such transmission planning voluntarily and regularly. However, such challenges do not diminish the importance of long-term transmission planning. Moreover, even if long-term regional transmission planning is performed, failing to consider an adequate time horizon, set of factors to forecast the future resource mix and demand, and sufficient method to account for uncertainty—may result in transmission planning that is inadequate in identifying more efficient or cost-effective transmission facilities due a less comprehensive and accurate understanding of the areas impacted by transmission needs driven by changes in the resource mix and demand. Accordingly, we believe that reforms may be necessary to require public utility transmission providers to identify transmission needs driven by changes in the resource mix and demand.

66. We are also concerned that existing regional transmission planning requirements may be inadequate to ensure that public utility transmission providers adequately assess the benefits of regional transmission facilities planned to meet transmission needs driven by changes in the resource mix and demand. In Order No. 1000, the Commission declined to prescribe particular definitions of or a uniform approach to identifying benefits and beneficiaries, in order to allow flexibility for public utility transmission providers to develop cost allocation methods for their transmission planning

regions.¹²⁵ However, transmission facilities may provide a wide variety of benefits to transmission customers, particularly for regional transmission facilities addressing large, systemic changes in the electric industry. We recognize that when public utility transmission providers fail to consider a broader set of benefits for transmission facilities meeting transmission needs driven by changes in the resource mix and demand, they may fail to select transmission facilities in their regional transmission plans for purposes of cost allocation that meet the transmission planning region's transmission needs more efficiently or cost-effectively.

67. As described in the ANOPR, existing regional transmission planning and cost allocation processes generally examine categories of transmission needs separately from one another based on the driver of the relevant transmission need, be it reliability, economic considerations, or Public Policy Requirements.¹²⁶ As a general matter, public utility transmission providers only calculate the set of benefits specific to that category of transmission need for purposes of determining whether a regional transmission facility meets the criteria for selection. However, the literature and experience demonstrates a panoply of benefits beyond those currently considered by all public utility transmission providers in existing regional transmission planning and cost allocation processes.¹²⁷ Failing to provide for the allocation of costs of transmission facilities selected in a regional transmission plan for purposes of cost allocation to address transmission needs driven by changes in the resource mix and demand in a way that aligns with a reasonable set of benefits through the transmission planning process could lead to needed transmission facilities not being built, adversely affecting ratepayers. Accordingly, we propose a list of benefits for public utility transmission providers to consider when assessing a

broader set of benefits during long-term regional transmission planning, and require public utility transmission providers to provide certain information, as described below, about the benefits they will use.

b. Proposed Reform

68. To help to ensure just and reasonable and not unduly discriminatory or preferential Commission-jurisdictional rates, we propose to require that public utility transmission providers participate in a regional transmission planning process that includes Long-Term Regional Transmission Planning,¹²⁸ meaning regional transmission planning on a sufficiently long-term, forward-looking basis to identify transmission needs driven by changes in the resource mix and demand, evaluate transmission facilities to meet such needs, and identify and evaluate transmission facilities for potential selection in the regional transmission plan for purposes of cost allocation as the more efficient or cost-effective transmission facilities to meet such needs.

69. As discussed further below, we propose several specific requirements on how public utility transmission providers would be required to implement the requirement to conduct Long-Term Regional Transmission Planning. Specifically, we propose to require that public utility transmission providers in each transmission planning region: (1) Identify transmission needs driven by changes in the resource mix and demand through the development of Long-Term Scenarios¹²⁹ that satisfy the requirements set forth in this NOPR; (2) evaluate the benefits of regional transmission facilities to meet these needs over a time horizon that covers, at a minimum, 20 years starting from the estimated in-service date of the transmission facilities; and (3) establish transparent and not unduly discriminatory criteria to select transmission facilities in the regional transmission plan for purposes of cost

¹²⁵ Order No. 1000, 136 FERC ¶ 61,051 at PP 624–625.

¹²⁶ ANOPR, 176 FERC ¶ 61,024 at P 85.

¹²⁷ See generally Paul L. Joskow, *Facilitating Transmission Expansion to Support Efficient Decarbonization of the Electricity Sector*, Economics of Energy & Environmental Policy, Vol. 10, No. 2 (June 2021); Johannes Pfeifenberger et al., *The Value of Diversifying Uncertain Renewable Generation through the Transmission System*, Boston University Institute for Sustainable Energy (Sept. 1, 2020); Johannes Pfeifenberger et al., *The Brattle Group, Toward More Effective Transmission Planning: Addressing the Costs and Risks of an Insufficiently Flexible Electricity Grid* (Apr. 2015); Judy Chang et al., *The Brattle Group, The Benefits of Electric Transmission: Identifying and Analyzing the Value of Investments* (2013).

¹²⁸ For example, two features of Long-Term Regional Transmission Planning included in these proposed reforms are the development of scenarios with a 20-year planning horizon to be reassessed and revised every three years, with each such reassessment providing the basis for identification and evaluation of transmission facilities for potential selection in the regional transmission plan for purposes of cost allocation.

¹²⁹ We use the term Long-Term Scenarios in this NOPR to describe a tool to identify transmission needs driven by changes in the resource mix and demand, and enable the evaluation of transmission facilities to meet such needs, across multiple scenarios that incorporate different assumptions about the future electric power system over a sufficiently long-term, forward-looking transmission planning horizon.

¹²³ See *infra* P 94.

¹²⁴ See *supra* P 36.

allocation that more efficiently or cost-effectively address these transmission needs in collaboration with states and other stakeholders. We discuss each of these requirements in greater detail below.

70. Taken together, these proposed requirements would establish a more comprehensive and proactive approach to regional transmission planning, ensuring that public utility transmission providers plan for transmission needs driven by changes in the resource mix and demand. The Long-Term Regional Transmission Planning proposed in this NOPR is meant to require regional transmission planning based on a multitude of drivers of long-term transmission needs, as detailed below, and result in selection of more efficient or cost-effective transmission facilities in the regional transmission plan for purposes of cost allocation to meet those needs.

71. We recognize that benefits from transmission facilities may change over time due to the inherent uncertainty in Long-Term Regional Transmission Planning and actual use of transmission facilities. We note that long-term benefits may be more stable or evenly distributed over time if they are evaluated for a portfolio of transmission facilities rather than for a single transmission facility. We propose to provide public utility transmission providers with the flexibility to propose to use a portfolio approach in the evaluation of benefits and selection of transmission facilities in the regional transmission plan for purposes of cost allocation through their Long-Term Regional Transmission Planning, as discussed below in this NOPR.

72. The reforms proposed in this NOPR inevitably interact with the existing regional transmission planning and cost allocation processes required by Order No. 1000 to more efficiently or cost-effectively meet transmission needs driven by the transmission planning region's reliability, economic, and Public Policy Requirements. With respect to transmission needs associated either with maintaining reliability or for addressing economic considerations and their associated cost allocation, we do not propose in this NOPR to change Order No. 1000's requirements for public utility transmission providers to create a regional transmission plan that will identify transmission facilities that more efficiently or cost-effectively meet the region's reliability and economic requirements.¹³⁰ In other words, public utility transmission providers may

continue to rely on their existing regional transmission planning and cost allocation processes to comply with Order No. 1000's requirements related to transmission needs driven by reliability concerns or economic considerations.

73. With respect to transmission needs driven by Public Policy Requirements, while we do not propose to change the existing Order No. 1000 requirement to consider transmission needs driven by Public Policy Requirements in the regional transmission planning process,¹³¹ we propose to clarify that public utility transmission providers will comply with this existing Order No. 1000 requirement through the Long-Term Regional Transmission Planning that we propose to require in this NOPR. Specifically, we propose that public utility transmission providers would be deemed to comply with the existing Order No. 1000 requirement to consider transmission needs driven by Public Policy Requirements in their regional transmission planning process through the proposed requirement to conduct Long-Term Regional Transmission Planning. As discussed in the Factors section below, we propose to require that public utility transmission providers incorporate state or federal laws or regulations, meaning enacted statutes (*i.e.*, passed by the legislature and signed by the executive) and regulations promulgated by a relevant jurisdiction, whether within a state or at the federal level,¹³² that affect the future resource mix and demand into the development of Long-Term Scenarios. Thus, we preliminarily find that under the reforms proposed herein, public utility transmission providers that comply with the Long-Term Regional Transmission Planning requirements established in any final rule in this proceeding will comply with the requirement in Order No. 1000 that they participate in a regional transmission planning process that considers, and has associated cost allocation provisions related to, transmission needs driven by Public Policy Requirements.

74. That said, we understand that public utility transmission providers in some transmission planning regions have developed processes to consider

transmission needs driven by Public Policy Requirements through their regional transmission planning processes that they may wish to retain. Therefore, we propose to allow public utility transmission providers to propose to continue using some or all aspects of the existing regional transmission planning and cost allocation processes they use to consider transmission needs driven by Public Policy Requirements. However, such continued use of existing regional transmission planning and cost allocation processes would not supplant public utility transmission providers' obligations to comply with the Long-Term Regional Transmission Planning requirements established in any final rule in this proceeding. Moreover, in their filing to comply with any final rule, public utility transmission providers seeking to retain existing regional transmission planning and cost allocation processes to consider transmission needs driven by Public Policy Requirements through their regional transmission planning processes would have to demonstrate that continued use of any such processes does not interfere or otherwise undermine the Long-Term Regional Transmission Planning that we propose to require in this NOPR by demonstrating that continued use of such processes is consistent with or superior to any final rule issued in this proceeding.

75. Finally, we preliminarily find that public utility transmission providers could propose a regional transmission planning process that plans for reliability needs, economic needs, transmission needs driven by Public Policy Requirements, and transmission needs driven by changes in the resource mix and demand simultaneously through a combined approach. Public utility transmission providers proposing to address all such transmission needs in a single regional transmission planning process would bear the burden of demonstrating continued compliance with Order No. 1000 in addition to compliance with the requirements of any final rule in this proceeding; to do so, they would be required to demonstrate that such process is consistent with or superior to the requirements of both Order No. 1000 and any final rule issued in this proceeding.

76. Further, we propose to require that Long-Term Regional Transmission Planning comply with the following existing Order Nos. 890 and 1000 transmission planning principles: (1) Coordination; (2) openness; (3) transparency; (4) information exchange;

¹³¹ See *id.* PP 203–224 (discussing the requirement to consider transmission needs driven by Public Policy Requirements in regional transmission planning processes). This proposal would also leave unchanged the existing requirement for public utility transmission providers to consider transmission needs driven by Public Policy Requirements in their local transmission planning processes.

¹³² See *id.* P 2.

¹³⁰ See Order No. 1000, 136 FERC ¶ 61,051 at P 11.

(5) comparability; and (6) dispute resolution.¹³³

77. We seek comment on the requirements proposed in this section of the NOPR. In particular, we seek comment on the proposed requirement for public utility transmission providers to participate in a regional transmission planning process that includes Long-Term Regional Transmission Planning.

78. As part of this Long-Term Regional Transmission Planning, we propose to require that public utility transmission providers identify transmission needs driven by changes in the resource mix and demand through the development of Long-Term Scenarios that satisfy the specific requirements that we more fully enumerate below. We propose that public utility transmission providers: (1) Use a transmission planning horizon no less than 20 years into the future in developing Long-Term Scenarios and reassess and revise those scenarios at least once every three years; (2) incorporate into their Long-Term Scenarios a set of Commission-identified categories of factors that may drive transmission needs driven by changes in the resource mix and demand; (3) develop a plausible and diverse set of at least four Long-Term Scenarios; (4) use “best available data” in developing their Long-Term Scenarios; and (5) consider whether to identify geographic zones with the potential for development of large amounts of new generation.

i. Development of Long-Term Scenarios for Use in Long-Term Regional Transmission Planning

79. In the ANOPR, the Commission expressed concern that regional transmission planning processes may not adequately model future scenarios to ensure that those scenarios incorporate sufficiently long-term and comprehensive forecasts of future transmission needs.¹³⁴ The Commission stated that, to the extent that regional transmission planning processes consider generation development in scenario analyses, they tend to include in their baseline reliability model only those generators that have completed facilities studies, and thus are far along in the generator interconnection process and will likely come online in the short term.¹³⁵ The Commission stated that such a short-term outlook may under-forecast longer-term transmission needs and that more efficient or cost-effective transmission facilities that address

longer-term needs may never be developed.¹³⁶ The Commission sought comment on whether reforms are needed regarding how the regional transmission planning processes model scenarios to ensure they incorporate sufficiently long-term and comprehensive forecasts of future transmission needs.¹³⁷

(a) Comments

80. Many commenters responding to the ANOPR support scenario planning.¹³⁸ All RTOs/ISOs express support for long-term scenario-based planning as a current or future practice; some request that the Commission allow for regional flexibility.¹³⁹ SERTP states that its “bottom-up” regional transmission planning process already assesses a multitude of scenarios as part of each public utility transmission provider’s integrated resource planning process and that it could perform additional, hypothetical scenario planning to inform decision makers.¹⁴⁰

81. Many public utility transmission providers support the idea of scenario planning.¹⁴¹ Most of these public utility transmission providers support targeted reforms that specify guardrails, or baselines, in scenario planning. For example, some public utility transmission providers list the

¹³⁶ *Id.* P 47.

¹³⁷ *Id.* P 46.

¹³⁸ *E.g.*, ACEG Comments at 5; ACPA and ESA Comments at 46–47; AEE Comments at 36; AEP Comments at 9–11; Ameren Comments at 5; APPA Comments at 7–9; Arizona Commission Comments at 2; Avangrid Comments at 11–12; Certain TDUs Comments at 11; Consumers Council Comments at 8–9; Union of Concerned Scientists Comments at 42; East Kentucky Comments at 4–7; EDF Comments at 3; EEI Comments at 24–26; Eversource Comments at 8; Exelon Comments at 11–19; Massachusetts Attorney General Comments at 13; NARUC Comments at 10–11; National Grid Comments at 11–17; Nature Conservancy Comments at 2–5; NESCOE Comments at 39–40; New England for Offshore Wind Comments at 2; NextEra Comments at 70–83; Northwest and Intermountain Comments at 6–8; Oregon Commission Comments at 1; PG&E Comments at 5–6; PIOs Comments at 76–81; Indicated PJM TOs Comments at 24–26; Policy Integrity Comments at 25–40; PSEG Comments at 6–18; Resale Iowa Comments at 14; SAFE Comments at 11; SDG&E Comments at 3–4; Shell Comments at 7; State Agencies Comments at 21; State of Massachusetts Comments at 10–15; Tenaska Comments at 12–13; U.S. DOE Comments at 21–22; WIRES Comments at 7–8; VEIR Comments at 13–17; Xcel Comments at 19–20.

¹³⁹ CAISO Comments at 42–44; MISO Comments at 7, 49; SPP Comments at 7; NYISO Comments at 27–31; PJM Comments at 41–42, 45–46; ISO–NE Comments at 13–17, 20–22.

¹⁴⁰ *See* SERTP Comments at 8, 14–17; SERTP Reply Comments at 11.

¹⁴¹ *E.g.*, AEP Comments at 9–11; Ameren Comments at 5; Eversource Comments at 8; Exelon Comments at 11–19; National Grid Comments at 11–17; NextEra Comments at 70–83; PG&E Comments at 5–6; PSEG Comments at 6–18; SDG&E Comments at 3–4; Xcel Comments at 19–20.

minimum set of factors they think should be included in a scenario planning requirement.¹⁴² Other public utility transmission providers support scenario planning so long as it is strictly informational, limited, or non-binding.¹⁴³ Some public utility transmission providers equate scenario planning to their existing integrated resource plans.¹⁴⁴

82. NARUC supports scenario planning as a means to evaluate the system needs to integrate state-directed resources.¹⁴⁵ Other state commissions and state representatives express their support for scenario planning as necessary to identify system needs and transmission facilities to address them.¹⁴⁶ A few state commissions do not support the Commission imposing specific scenario planning requirements, or only support the Commission providing guardrails, because they believe state regulatory officials in collaboration with public utility transmission providers are in the best position to evaluate the needs of each region or because they believe the current processes work sufficiently well.¹⁴⁷ The PJM Market Monitor and Potomac Economics do not comment specifically on use of scenarios, but acknowledge the uncertainty associated with transmission planning and accuracy of inputs into the transmission planning process.¹⁴⁸ The SPP Market Monitor states that one of its biggest challenges related to the transmission planning process has been persuading stakeholders to adopt an additional scenario as part of SPP’s 10-year Integrated Transmission Planning Assessment.¹⁴⁹

83. Several consumer and trade organizations support scenario planning to assess uncertainty about future

¹⁴² *E.g.*, National Grid Comments at 4–9; Exelon Comments at 12–16.

¹⁴³ *E.g.*, Southern Comments at 36–37; Arizona Public Service Comments at 2–4; Xcel Comments at 20.

¹⁴⁴ *E.g.*, Berkshire Comments at 12–13.

¹⁴⁵ NARUC Comments at 6, 10–11.

¹⁴⁶ *E.g.*, Arizona Commission Comments at 2; Oregon Commission Comments at 8–9; Massachusetts Attorney General Comments at 5–15.

¹⁴⁷ *E.g.*, Mississippi Commission Comments at 3; Nebraska Commission Comments at 3–4; Michigan Commission Comments at 7.

¹⁴⁸ PJM Market Monitor Comments at 2–3; Potomac Economics Comments at 3–4; *see also Joint Fed.-State Task Force on Elec. Transmission*, Technical Conference, Docket No. AD21–15–000, Tr. 59:17–24 (Andrew French) (Nov. 10, 2021) (November Joint Task Force Tr.) (commenting that in SPP, futures projections of renewables have “probably not been based on data or reality” but “have been more of a consensus of what stakeholders are willing to accept” with the result being that those projects have been too low).

¹⁴⁹ SPP Market Monitor Comments at 3.

¹³³ *See id.* PP 146, 151.

¹³⁴ ANOPR, 176 FERC ¶ 61,024 at P 31.

¹³⁵ *Id.*

transmission needs.¹⁵⁰ Some commenters call for a national uniform framework for scenario planning.¹⁵¹

(b) Proposed Reform

84. We propose to require that public utility transmission providers develop and use Long-Term Scenarios as part of Long-Term Regional Transmission Planning. We propose to define Long-Term Scenarios as a tool to identify transmission needs driven by changes in the resource mix and demand—and enable the evaluation of transmission facilities to meet such transmission needs—across multiple scenarios that incorporate different assumptions about the future electric power system over a sufficiently long-term, forward-looking transmission planning horizon. A scenario is a hypothetical sequence of events that includes assumptions used to forecast transmission needs. Assumptions used to forecast transmission needs driven by changes in the resource mix and demand include: Forecasts of the level and pattern (*i.e.*, hourly and seasonal variability) of future electricity demand; the quantity, location, and type of resource additions and retirements; and other relevant forecasts about the electric power system that are used as inputs to the transmission model and determine the need for new transmission facilities over the transmission planning horizon. Other relevant assumptions might include forecasts for natural gas prices, increasing outage trends due to extreme weather and climatic trends, and other future events. We also propose to require that public utility transmission providers use Long-Term Scenarios to evaluate potential regional transmission facilities needed to meet transmission needs driven by changes in the resource mix and demand to identify the more efficient or cost-effective regional transmission facilities.

85. In the next section of this NOPR, we propose specific requirements that public utility transmission providers would need to meet in developing Long-Term Scenarios. We propose to require each public utility transmission provider to amend the regional transmission planning process in its OATT to explicitly describe the open and transparent process that it will use

¹⁵⁰ *E.g.*, ACEG Comments at 5; ACPA and ESA Comments at 46; AEE Comments at 36; APPA Comments at 4; Business Council for Sustainable Energy Comments at 4; Union of Concerned Scientists Comments at 42–44; Consumers Council Comments at 8–9; Iowa Consumer Advocate Comments at 32; Nature Conservancy Comments at 3; WIREs Comments at 7.

¹⁵¹ *See, e.g.*, NARUC Comments at 17; PIOs Comments at 103; Policy Integrity Comments 29–40; U.S. DOE Comments at 33.

to develop Long-Term Scenarios that meet these requirements.

86. We preliminarily find that requiring public utility transmission providers to develop and utilize multiple Long-Term Scenarios, as further specified below, as part of Long-Term Regional Transmission Planning will allow public utility transmission providers to identify and plan to more efficiently or cost-effectively meet transmission needs driven by changes in the resource mix and demand. Specifically, we believe that using Long-Term Scenarios in the regional transmission planning process will help public utility transmission providers to account for the inherent uncertainty involved in identifying transmission needs driven by changes in the resource mix and demand and evaluating more efficient or cost-effective transmission facilities needed to meet those needs.

87. As discussed above, Long-Term Regional Transmission Planning is critical to ensuring more efficient or cost-effective transmission development to meet transmission needs driven by changes in the resource mix and demand.¹⁵² However, such transmission planning necessarily relies on forecasts of future system conditions, such as the state of the resource mix and the level of demand. These conditions may be reasonably predictable in the near term, but as the transmission planning horizon extends further into the future, they become increasingly imprecise. By utilizing multiple Long-Term Scenarios, public utility transmission providers will have a better understanding of potential future transmission needs under multiple reasonably likely scenarios, allowing them to assess the implications of changing market conditions and policies. They can also manage uncertainties about future system conditions and better identify more efficient or cost-effective regional transmission facilities by evaluating which transmission facilities are beneficial under multiple scenarios. Doing so will mitigate the risks of under-building or over-building transmission facilities that are identified through Long-Term Regional Transmission Planning.

88. We preliminarily find that the development of Long-Term Scenarios as part of the regional transmission planning process will ensure that public utility transmission providers adequately assess the potential benefits of regional transmission facilities that

¹⁵² *Supra* Need for Reform: Potential Benefits of Long-Term Regional Transmission Planning and Cost Allocation to Identify and Plan for Transmission Needs Driven by Changes in the Resource Mix and Demand.

may meet the needs of a transmission planning region more efficiently or cost-effectively than transmission planning without Long-Term Scenarios. We preliminarily find that a regional transmission planning process that does not develop Long-Term Scenarios that meet the requirements described below fails to properly identify transmission needs driven by changes in the resource mix and demand, which may lead to piecemeal and inefficient development of new transmission facilities. In addition, we preliminarily find that failing to develop Long-Term Scenarios means that transmission facilities needed to meet transmission needs driven by changes in the resource mix and demand are more likely to be identified in the generator interconnection process instead of the regional transmission planning process, similarly leading to the increased potential for piecemeal and inefficient transmission development, as described above.¹⁵³ For these reasons, we preliminarily find that requiring public utility transmission providers to develop Long-Term Scenarios that meet the requirements described below will ensure that Commission-jurisdictional rates are just and reasonable and not unduly discriminatory or preferential.

89. We clarify that we do not propose to require that public utility transmission providers use Long-Term Scenarios in their regional transmission planning processes to address near-term reliability and economic transmission needs. In other words, we do not propose to require that public utility transmission providers modify their existing regional transmission planning processes that plan for reliability and economic transmission needs to incorporate Long-Term Scenarios.

90. We seek comment on the requirements proposed in this section of the NOPR. In particular, we seek comment on whether public utility transmission providers should be required to incorporate some form of scenario analysis into their existing reliability and economic regional transmission planning processes to identify more efficient or cost-effective transmission facilities than are identified through those processes today.

(1) Long-Term Scenarios Requirements

91. We propose to require that public utility transmission providers comply with specified minimum requirements in developing Long-Term Scenarios,

¹⁵³ *Supra* Need for Reform: Deficiencies in the Commission's Existing Regional Transmission Planning and Cost Allocation Requirements.

which we preliminarily find will help to ensure Long-Term Regional Transmission Planning results in Commission-jurisdictional rates that are just and reasonable and not unduly discriminatory or preferential. We expect these proposed minimum requirements will allow public utility transmission providers to better identify transmission needs driven by changes in the resource mix and demand and evaluate regional transmission facilities to more efficiently or cost-effectively meet those needs. Specifically, as discussed further below, we propose to require that public utility transmission providers: (1) Use a transmission planning horizon no less than 20 years into the future in developing Long-Term Scenarios and reassess and revise those scenarios at least once every three years; (2) incorporate a set of Commission-identified categories of factors that may affect transmission needs driven by changes in the resource mix and demand into their Long-Term Scenarios; (3) develop a plausible and diverse set of at least four Long-Term Scenarios; (4) use “best available data” (as defined in the Specificity of Data Inputs section below) in developing their Long-Term Scenarios; and (5) consider whether to identify geographic zones with the potential for development of large amounts of new generation.

(i) Transmission Planning Horizon and Frequency

92. The transmission planning horizon is the number of years into the future that public utility transmission providers look when developing Long-Term Scenarios. For example, a transmission planning horizon of 20 years means that the public utility transmission provider develops Long-Term Scenarios to identify and plan to meet transmission needs that will materialize up to 20 years in the future. We believe that, to be just and reasonable, the transmission planning horizon used in Long-Term Regional Transmission Planning should extend far enough into the future that public utility transmission providers can identify transmission needs that could be met with more efficient or cost-effective regional transmission facilities, *i.e.*, the transmission planning horizon should capture the longer-term benefits of addressing transmission needs driven by changes in the resource mix and demand.

93. In addition, we believe that the Long-Term Scenarios used in Long-Term Regional Transmission Planning should not remain static over time. Instead, they should be periodically re-evaluated and re-developed to ensure

that they reflect recent forecasts of future system conditions. Frequency is how often public utility transmission providers reassess whether the data inputs and factors included in their previously developed Long-Term Scenarios need to be updated and then revise their Long-Term Scenarios as needed to reflect updated data inputs and factors. Reassessing and revising scenarios is appropriate as technology, markets, and factors that affect the future resource mix and demand change. Frequent scenario reassessment and revision could help address some of the uncertainty and risks associated with under-building or over-building transmission facilities over a long-term transmission planning horizon. However, developing scenarios can be costly and time-consuming for both public utility transmission providers and their stakeholders. Frequent scenario reassessment and revision might also be unnecessary if the data inputs and factors into scenario development do not change much over the time period between studies. Thus, we believe that there may be a need to balance the benefits of updating Long-Term Scenarios with the burdens associated with such updates when deciding how frequently to do so. In order to prevent overlap of Long-Term Scenarios that are developed every three years, we also propose to require that the development of Long-Term Scenarios be completed within three years—*i.e.*, before the next three-year assessment commences.

94. Based on our review of public information and ANOPR comments, our understanding is that some transmission planning regions currently use longer-term transmission planning horizons for regional transmission planning. For instance, CAISO selects transmission facilities in its regional transmission plan for purposes of cost allocation based on a 10-year transmission planning horizon and recently initiated an effort to conduct informational high-level technical studies with a 20-year horizon as part of its regional transmission planning process.¹⁵⁴ NYISO uses a 20-year transmission planning horizon to evaluate scenarios in its regional transmission planning process for transmission needs driven by Public Policy Requirements and for its Outlook.¹⁵⁵ However, NYISO uses a

¹⁵⁴ CAISO Comments at 44–46.

¹⁵⁵ NYISO Comments at 10, 36–37. The Outlook is a report by which NYISO summarizes the current assessments, evaluations, and plans in its biennial Comprehensive System Planning Process; produces a 20-year projection of congestion on the New York State Transmission System; identifies, ranks, and groups congested elements; and assesses the

10-year or shorter transmission planning horizon for its regional transmission planning process for reliability and economic needs. SPP conducts its Integrated Transmission Planning Assessment with a 10-year transmission planning horizon and conducts an informational 20-year assessment using scenarios every five years.¹⁵⁶ MISO’s current Long Range Transmission Planning effort uses a 20-year transmission planning horizon.¹⁵⁷ PJM uses a 15-year transmission planning horizon for its long-term analysis as part of its regional transmission planning processes.¹⁵⁸ All other transmission planning regions currently use a 10-year transmission planning horizon for their regional transmission planning processes,¹⁵⁹ consistent with NERC’s definition of the Long-Term Transmission Planning Horizon.¹⁶⁰ ISO–NE has stated that it plans to use a longer transmission planning horizon in future transmission planning studies.¹⁶¹ We understand that transmission planning regions that currently use scenarios with longer-term transmission planning horizons (longer than 10 years) typically do so only for informational purposes or in a limited application and not commonly to select transmission facilities in regional transmission plans for purposes of cost allocation.

(01) Comments

95. Comments in response to the ANOPR support a range of possible transmission planning horizons, from five years to beyond 30 years. Some commenters claim that a transmission planning horizon of 10 years is sufficient because that is typically

potential benefits of addressing the identified congestion. *See id.* at 10.

¹⁵⁶ SPP Comments at 3; SPP, OATT, attach. O, § IV.2 (4.0.0), § IV.2.a.

¹⁵⁷ MISO Comments at 36.

¹⁵⁸ PJM Comments at 41.

¹⁵⁹ *E.g.*, Southeastern Regional Transmission Planning, 2021 Regional Transmission Planning Analyses, at 2 (Nov. 17, 2021), <https://www.southeasternrtp.com/docs/general/2021/2021-SERTP-Regional-Transmission-Planning-Analyses-Summary-Final.pdf>; WestConnect Regional Transmission Planning, 2020–21 Planning Cycle Final Regional Study Plan, at 7 (Mar. 18, 2020), <https://doc.westconnect.com/Documents.aspx?NID=18668&d=1>; NorthernGrid, Regional Transmission Plan for the 2020–2021 NorthernGrid Planning Cycle, at 5 (Dec. 8, 2021), https://www.northerngrid.net/private-media/documents/2020-2021_Regional_Transmission_Plan.pdf.

¹⁶⁰ *See* NERC, Glossary of Terms Used in NERC Reliability Standards (June 28, 2021), https://www.nerc.com/files/glossary_of_terms.pdf (defining Long-Term Transmission Planning Horizon as the “[t]ransmission planning period that covers years six through ten or beyond when required to accommodate any known longer lead time projects that may take longer than ten years to complete”).

¹⁶¹ ISO–NE Comments at 13–17.

enough time to identify, design, and build needed transmission facilities or because it is consistent with NERC standards and some state integrated resource plans.¹⁶² Other commenters claim that a longer transmission planning horizon, most frequently 20 years, is needed to appropriately identify and plan for future transmission needs.¹⁶³ Commenters that support a longer transmission planning horizon commonly also support shorter-term interim assessments. Panelists at the November 2021 Technical Conference that supported a specific transmission planning horizon contended that a 20-year transmission planning horizon is appropriate because that transmission planning horizon may be needed for siting, permitting, and construction of transmission facilities or because states have longer-term policy goals.¹⁶⁴ Some panelists stated that such a transmission planning horizon should be used in informational studies and that a shorter transmission planning horizon (*e.g.*, 10 years) should be used to select transmission facilities, while other panelists stated that public utility transmission providers should use a 20-year or greater transmission planning horizon to select transmission facilities.¹⁶⁵

96. Commenters discussing frequency generally support the Commission requiring that scenarios be reassessed and revised between every two to five years, and up to seven years, to balance the benefits and costs of revisiting the scenarios.¹⁶⁶ AEP recommends that the

¹⁶² *E.g.*, Exelon Comments at 16–17; NRECA Comments at 19–20. Similarly, ITC supports a 5 to 10-year transmission planning horizon. ITC Comments at 12–13.

¹⁶³ For example, BP supports a 15-year transmission planning horizon. BP Comments at 4. Public Systems supports a 15- to 20-year transmission planning horizon. Public Systems Comments at 18–22. NextEra, AEP, Northwest and Intermountain, and the Oregon Commission support a 20-year transmission planning horizon. NextEra Comments at 70; Northwest and Intermountain Comments at 4, 16; Oregon Commission Comments at 8–9. NYISO supports the Commission granting discretion, up to 20 years. NYISO Comments at 34–37. ACPA and ESA, AEE, U.S. DOE, Competitive Energy, District of Columbia's Office of the People's Counsel, Massachusetts Attorney General, and VEIR support a transmission planning horizon longer than 20 years. ACPA and ESA Comments at 43–45; AEE Comments at 32; U.S. DOE Comments at 12–15, 27–28; Competitive Energy Comments at 37–40; District of Columbia's Office of the People's Counsel Comments at 22–25; Massachusetts Attorney General Comments at 5–15; VEIR Comments at 13–17.

¹⁶⁴ November 2021 Technical Conference Transcript (Tr.) at 129–137.

¹⁶⁵ *Id.* at 129–137.

¹⁶⁶ For example, NextEra supports every two years, ITC supports every three to five years, Exelon and Competitive Energy support every five to seven years, AEP supports at least every three years, and

Commission require all public utility transmission providers to reassess scenarios at the same time to promote consistent results and comparability among regions.¹⁶⁷ Panelists at the November 2021 Technical Conference, including PJM, MISO, and AEP, supported a frequency of at least every three years.¹⁶⁸

(02) Proposed Requirement

97. We propose to require that public utility transmission providers develop Long-Term Scenarios as part of Long-Term Regional Transmission Planning using no less than a 20-year transmission planning horizon. In addition, we propose to require that public utility transmission providers develop Long-Term Scenarios at least every three years, by reassessing whether the data inputs and factors incorporated in their previously developed Long-Term Scenarios need to be updated and then revising their Long-Term Scenarios as needed to reflect updated data inputs and factors. We also propose to require that the development of Long-Term Scenarios be completed within three years, before the next three-year assessment commences.

98. We preliminarily find that a 20-year transmission planning horizon requirement strikes a reasonable balance between the current near-term transmission planning horizons used in many transmission planning regions and the 30-year or longer transmission planning horizon proposed by some commenters. The 30-year or longer transmission planning horizon is criticized by other commenters as speculative or too uncertain. We also believe that a 20-year transmission planning horizon requirement may be reasonable because some public utility transmission providers use a 20-year transmission planning horizon in existing regional transmission planning processes. In addition, we believe that a 20-year planning horizon would allow for sufficient time to identify, plan, and obtain siting and permitting approval and to construct regional transmission facilities to meet long-term regional transmission needs including those that may take longer than the average amount of time to go from planning to in-service.¹⁶⁹ Finally, we believe that a

the SPP Market Monitor supports a 10-year study every year. NextEra Comments at 79; ITC Comments at 12; Exelon Comments at 17; Competitive Energy Comments at 37–40; SPP Market Monitor Comments at 3–4.

¹⁶⁷ AEP Comments at 10–11.

¹⁶⁸ November 2021 Technical Conference Tr. at 138–140.

¹⁶⁹ The time needed to plan, obtain siting and permitting approval for, and construct regional

20-year transmission planning horizon would allow public utility transmission providers to better leverage economies of scale by sizing transmission facilities to meet not only nearer-term needs but also longer-term transmission needs driven by changes in the resource mix and demand over time. By assessing transmission needs over a longer time horizon—for example, starting in year six¹⁷⁰ through year 20 of the transmission planning horizon—Long-Term Regional Transmission Planning should be able to identify more efficient or cost-effective regional transmission facilities to address these needs.

99. We preliminarily find that a three-year frequency requirement balances the need of public utility transmission providers to reassess changes in the resource mix and demand as technology, markets, and policies have the potential to rapidly change,¹⁷¹ with the burden of developing Long-Term Scenarios that can take a year or longer. We believe that this three-year frequency requirement will allow public utility transmission providers to identify new transmission needs driven by changes in the resource mix and demand during the interim years of the transmission planning period, and update previously identified transmission needs, if warranted.

100. We seek comment on whether using a 20-year transmission planning horizon for Long-Term Scenarios is appropriate to allow public utility transmission providers to identify transmission needs driven by changes in the resource mix and demand and to evaluate regional transmission facilities to more efficiently or cost-effectively meet such transmission needs. We also seek comment on whether a frequency of no less than three years for reassessing and revising, as necessary, the data inputs and factors incorporated in previously developed Long-Term Scenarios appropriately balances the benefits and burdens of such updates. In addition, we seek comment on whether a three-year frequency requirement for

transmission facilities takes an average of 10 years. *See, e.g.*, MISO, *2021 MISO Transmission Expansion Planning*, at 12 (2021) (“Transmission facilities take an average of 10 years to go from planning to in-service.”). Larger-scale and greenfield transmission facilities may take longer to go from planning to in-service.

¹⁷⁰ As indicated above in this NOPR, NERC defines the long-term transmission planning horizon as covering year six through year 10 and beyond.

¹⁷¹ For example, the annual capacity of new interconnection requests grew 42% from 2017 to 2020, and 123% since 2015. *See* Lawrence Berkeley National Lab, *Generation, Storage, and Hybrid Capacity in Interconnection Queues Interactive Visualization* (May 2021), <https://emp.lbl.gov/generation-storage-and-hybrid-capacity>.

reassessing and revising, as necessary, the data inputs and factors incorporated in previously developed Long-Term Scenarios allows for public utility transmission providers to update their assumptions in time to assess transmission needs driven by changes in the resource mix and demand, and whether this requirement helps to balance the risks of under-building or over-building regional transmission facilities. Finally, we also seek comment on the proposal to require that the development of Long-Term Scenarios be completed within three years, and whether this proposed requirement prevents the overlap of the three-year assessments.

(ii) Factors

101. Factors shaping the electric power system are used as inputs to develop scenarios for regional transmission planning. Factors represent long-term drivers and trends that inform the expected composition of the future resource mix and demand that may not be captured by the inputs of a basic model of the transmission system. Factors inform changes in the data inputs of models of the transmission system but are not direct data inputs of such models. For example, a state energy law driving procurement of generation is a factor, and technology changes driving a long-term trend towards certain resource types is also a factor, whereas the estimated impact that these factors will have on the future resource mix and demand is a data input of a model of the transmission system. Incorporating the appropriate set of factors to forecast the future resource mix and demand when developing Long-Term Scenarios is essential to ensuring that Long-Term Regional Transmission Planning can identify more efficient or cost-effective regional transmission facilities to meet transmission needs driven by changes in the resource mix and demand. Importantly, incorporating more accurate inputs into Long-Term Scenarios enables a better understanding of transmission needs driven by changes in the resource mix and demand, which in turn allows public utility transmission providers to better evaluate the benefits of regional transmission facilities that would meet those needs. Currently, public utility transmission providers consider different sets of factors in the development of scenarios as part of their regional transmission planning processes, to the extent that they develop scenarios. For example, MISO's Futures study includes federal and state climate and clean energy laws and

regulations, federal and state climate and clean energy goals that have not been enacted into law, utility energy and climate goals, assumptions on the potential to electrify various types of technologies/loads, data and forecasts developed by various national labs or U.S. agencies, and assumptions on resource retirements.¹⁷²

102. The ANOPR sought comment on what factors shaping the resource mix are appropriate to use for transmission planning purposes, such as, for example: (1) Federal, state, and local climate and clean energy laws and regulations; (2) federal, state, and local climate and clean energy goals that have not been enacted or promulgated into law or regulation; (3) utility and corporate energy and climate goals; (4) trends in technology costs within and outside of the electricity supply industry, including shifts toward electrification of buildings and transportation; and (5) resource retirements.¹⁷³

(01) Comments

103. Commenters in response to the ANOPR generally support the factors that the Commission listed in the ANOPR as shaping the resource mix. Such commenters highlight the importance of: Public policies;¹⁷⁴ decarbonization commitments;¹⁷⁵ resource retirements;¹⁷⁶ the scale, location, and adoption rate of distributed energy resources (including batteries);¹⁷⁷ state-approved utility integrated resource plans;¹⁷⁸ weather

¹⁷² MISO Comments at 41–43.

¹⁷³ ANOPR, 176 FERC ¶ 61,024 at P 46.

¹⁷⁴ *E.g.*, EEI Comments at 13–14; ACPA and ESA Comments at 28–29; Competitive Energy Comments at 38; City of New York Comments at 7–9; Union of Concerned Scientists Comments at 41–44; Minnesota Commission Comments at 4; National Grid Comments at 4–9; New Jersey Commission Comments at 13–15; NRECA Comments at 17–19; Indicated PJM TOs Comments at 25–26; SDG&E Comments at 3–4; VEIR Comments at 13–14; WIRES Comments at 8; SEIA Comments at 5.

¹⁷⁵ *E.g.*, ACPA and ESA Comments at 43–45; Amazon Comments at 3; Competitive Energy Comments at 38; City of New York Comments at 7–9; Minnesota Commission Comments at 4; PIOs Comments at 80; RMI Comments at 2–3; SDG&E Comments at 3–4; VEIR Comments at 13–14.

¹⁷⁶ *E.g.*, ACPA and ESA Comments at 43–45; Ameren Comments at 5–8; Competitive Energy Comments at 38; Union of Concerned Scientists Comments at 41–44; EEI Comments at 13–14; NARUC Comments at 10; Northern Virginia Cooperative Comments at 7–8; NRECA Comments at 17–19; NYISO Comments at 27–31; Rail Electrification Comments at 12–13; SEIA Comments at 5.

¹⁷⁷ *E.g.*, EEI Comments at 13–14; NARUC Comments at 10; PG&E Comments at 6; U.S. DOE Comments at 12–15; SEIA Comments at 5.

¹⁷⁸ *E.g.*, ACPA and ESA Comments at 43–45; Entergy Comments at 14–15; NRECA Comments at 11, 17–19; Union of Concerned Scientists Comments at 41–44; Minnesota Commission

trends; climate risk; and reliability or resilience against extreme weather¹⁷⁹ as factors shaping future transmission needs that public utility transmission providers should model in developing scenarios. Additionally, some commenters argue that scenarios should explicitly account for additional load from electrification of transportation and buildings and include an estimation of clean energy demand preferences from transmission customers in the region.¹⁸⁰ Some commenters request that the Commission allow for regional flexibility and not be overly prescriptive on factors for scenario planning.¹⁸¹ City of New York proposes that New York State's statutory goals should be part of the baseline scenario, rather than an informational scenario or treated as a mere consideration.¹⁸² Exelon states that a state policy “not enshrined into law” by the legislature should be one of the possible futures that should be considered, even if somewhat “discounted” for being aspirational.¹⁸³ ACPA and ESA recommend that the “business-as-usual” base case include existing future resource plans of the utilities in the planning area and any local, state, or federal policy requirements,¹⁸⁴ and Berkshire states that many of the factors listed in the ANOPR are already under consideration in states where integrated resource plans are required.¹⁸⁵ Industrial Customers states that transmission investment should not be based on speculative factors.¹⁸⁶ Similarly, Potomac Economics expresses concern with mandating long-term planning studies involving speculation on a

Comments at 4; OMS Comments at 5–6; Rail Electrification Comments at 12–13.

¹⁷⁹ *E.g.*, AEP Comments at 7–11; AES Ohio Comments at 2–4; Oregon Commission Comments at 9–10; District of Columbia's Office of the People's Counsel Comments at 22–25; East Kentucky Comments at 8; Exelon Comments at 12, 15–16; LS Power Oct. 12 Comments at 41–46; Massachusetts Attorney General Comments at 13–21; PIOs Comments at 80; PJM Comments at 25–26; REBA Comments at 19–26, 33.

¹⁸⁰ *E.g.*, Ameren Comments at 5–8; EEI Comments at 13–14; PIOs Comments at 80–81; PJM Comments at 25–26; Rail Electrification Comments at 12–13; REBA Comments at 19–26, 33; SEIA Comments at 5; Massachusetts Attorney General Comments at 5–15; U.S. DOE Comments at 12–18; *see also* November Joint Task Force Tr. 112:1–10 (Andrew French) (asserting that anything that indicates there is demand should be considered within the transmission planning process).

¹⁸¹ Duke Comments at 5–7; PJM Comments at 9; ISO–NE Comments at 20–21; MISO Comments at 41.

¹⁸² City of New York Comments at 6–7.

¹⁸³ Exelon Comments at 12, 15–16.

¹⁸⁴ ACPA and ESA Comments at 46.

¹⁸⁵ Southern Comments at 3–5; Berkshire Comments at 12–13.

¹⁸⁶ Industrial Customers Comments at 20–33.

variety of factors.¹⁸⁷ The PJM Market Monitor acknowledges the uncertainty associated with transmission planning and accuracy of inputs and expresses concern with planning for anticipated new generation.¹⁸⁸

(02) Proposed Requirement

104. We propose to require that public utility transmission providers incorporate specific categories of factors in the development of Long-Term Scenarios as part of Long-Term Regional Transmission Planning. Specifically, we propose to require that public utility transmission providers incorporate, at a minimum, the following categories of factors into the development of Long-Term Scenarios: (1) Federal, state, and local laws and regulations that affect the future resource mix and demand;¹⁸⁹ (2) federal, state, and local laws and regulations on decarbonization and electrification;¹⁹⁰ (3) state-approved utility integrated resource plans and expected supply obligations for load serving entities;¹⁹¹ (4) trends in technology and fuel costs within and outside of the electricity supply industry, including shifts toward electrification of buildings and transportation;¹⁹² (5) resource

retirements;¹⁹³ (6) generator interconnection requests and withdrawals;¹⁹⁴ and (7) utility and corporate commitments and federal, state, and local goals that affect the future resource mix and demand.¹⁹⁵

105. We preliminarily find that incorporating, at a minimum, these categories of factors in the development of Long-Term Scenarios is appropriate because these categories of factors affect the future resource mix and demand, and their incorporation in Long-Term Scenarios is therefore essential to identifying transmission needs driven by changes in the resource mix and demand through Long-Term Regional Transmission Planning. Directly below, we discuss our proposed requirements governing how public utility transmission providers must incorporate each category of factors into Long-Term Scenarios. We note that we are proposing to require that public utility transmission providers incorporate, at a minimum, these categories of factors into the development of Long-Term Scenarios. To the extent public utility transmission providers would like to incorporate additional categories of factors into the development of Long-Term Scenarios, we propose to require that they demonstrate that the incorporation of more than the minimum is consistent with or superior to any final rule in this proceeding.

106. First, we propose to require that each Long-Term Scenario that public utility transmission providers use in Long-Term Regional Transmission Planning incorporate and be consistent with federal, state, and local laws and regulations that affect the future resource mix and demand; federal, state, and local laws and regulations on decarbonization and electrification; and state-approved integrated resource plans and expected supply obligations for load serving entities. We preliminarily find that it is reasonable to require public utility transmission providers to assume legally binding obligations and state utility regulator-approved plans are followed and expected supply

obligations for load serving entities are fully met. Public utility transmission providers may not discount the factors included in the categories of federal, state, and local laws and regulations that affect the future resource mix; federal, state, and local laws and regulations on decarbonization and electrification; and state-approved integrated resource plans and expected supply obligations for load serving entities.

107. Second, we propose to require that each Long-Term Scenario that public utility transmission providers use in Long-Term Regional Transmission Planning include trends in technology and fuel costs within and outside of the electricity supply industry, including shifts toward electrification of buildings and transportation; resource retirements; and generator interconnection requests and withdrawals. For these particular categories of factors, we propose to grant public utility transmission factors flexibility in how they incorporate each factor into Long-Term Scenarios so long as public utility transmission providers identify and publish specific factors for each of these categories as further described below. As discussed in the Coordination of Regional Transmission Planning and Generator Interconnection Processes section below, we propose to require that public utility transmission providers consider in their Long-Term Regional Transmission Planning regional transmission facilities that address interconnection-related transmission needs that the public utility transmission provider has identified multiple times in the generator interconnection process but that have never been constructed due to the withdrawal of the underlying interconnection request(s). We propose to require that public utility transmission providers must incorporate the specific interconnection-related needs identified through that reform, in addition to one or more factors that more generally characterize generator interconnection withdrawals, as a factor in the generator interconnection requests and withdrawals category of factors in their development of Long-Term Scenarios.

108. Finally, we propose to require that each Long-Term Scenario incorporate utility and corporate goals and federal, state, and local goals that affect the future resource mix. However, we acknowledge that these categories of factors are less binding and more likely to change over time, and therefore their impact on the future resource mix and demand are less certain. For this reason, we preliminarily find that it may be

¹⁸⁷ Potomac Economics Comments at 4.

¹⁸⁸ PJM Market Monitor Comments at 2–3; see also November Joint Task Force Tr. at 69:18–22 (Jason Stanek) (discussing the need to account for the fact that there will be some uncertainty if planning on a longer term horizon).

¹⁸⁹ For example, consistent with the Governor's executive order, the New Jersey Board of Public Utilities has developed a solicitation schedule to procure 7,500 MW of offshore wind resources by 2035. See New Jersey Commission Comments at 1. New York State Department of Environmental Conservation has promulgated emissions regulations that will cause many of the peaking generating facilities in New York City to retire. See City of New York Comments at 8. By "state or federal laws or regulations," we mean enacted statutes (*i.e.*, passed by the legislature and signed by the executive) and regulations promulgated by a relevant jurisdiction, whether within a state, municipality, or at the federal level.

¹⁹⁰ For example, five of the six New England states are statutorily required to reduce economy-wide greenhouse gas emissions by at least 80% below 1990 levels by 2050. NESCOE Comments at 8. New York law requires all new passenger cars and trucks in the state to be zero-emissions vehicles by 2035. City of New York Comments at 8.

¹⁹¹ For example, North Carolina's vertically-integrated investor-owned electric utilities participate in a biennial integrated resource plan process, in which they develop and file with the North Carolina Commission a forecast of load, supply-side resources, and demand-side resources over a 15-year period. North Carolina Commission Reply Comments at 17.

¹⁹² For example, MISO's latest Futures Report included assumptions on the potential to electrify various types of technologies/loads and data on technology costs from the National Renewable Energy Laboratory (NREL) Annual Technology Baseline dataset, the EIA, and DOE. MISO Comments at 43 (citing MISO, *MISO Futures Report*, at 30–38 (Dec. 2021)).

¹⁹³ For example, CAISO evaluates potential generation capacity retirements when developing the unified planning assumptions and study plan during phase one of its regional transmission planning process. CAISO Comments at 18.

¹⁹⁴ For example, in 2019, approximately 4.75 of 5 GW of generator interconnection requests that had been a part of the MISO West 2017 study group withdrew from the generator interconnection queue. ACORE Comments, Ex. 2 at 17.

¹⁹⁵ For example, two-thirds of Fortune 100 companies and roughly half of Fortune 500 companies have set renewable energy or related sustainability targets. ACPA and ESA Comments at 28. By "goal," we mean any commitment or statement expressed in writing that is not a law or regulation.

appropriate for public utility transmission providers to discount such goals to account for this uncertainty. In other words, public utility transmission providers would not be required to assume that utility and corporate goals and federal, state, and local goals that affect the future resource mix will be fully met.

109. We propose to require that public utility transmission providers identify and publish on an Open Access Same-Time Information System (OASIS) or other public website a list of the factors that fall into each of the required categories of factors that they will incorporate in their development of Long-Term Scenarios. That is, public utility transmission providers would be responsible for identifying all the factors they know of and are considering incorporating in the development of Long-Term Scenarios as part of Long-Term Regional Transmission Planning. We also propose to require that public utility transmission providers revise the regional transmission planning processes in their OATTs to outline an open and transparent process that provides stakeholders, including states,¹⁹⁶ with a meaningful opportunity to propose potential factors that public utility transmission providers must incorporate in their development of Long-Term Scenarios, such as specific laws, regulations, goals, and commitments, and to provide input on how to appropriately discount factors that are less certain.

110. We note that, under Order No. 1000, public utility transmission providers must already have procedures in their OATTs that give stakeholders a meaningful opportunity to submit proposed transmission needs driven by Public Policy Requirements and that allow public utility transmission providers to identify, out of the larger set of potential transmission needs driven by Public Policy Requirements that stakeholders propose, those needs for which transmission facilities will be evaluated.¹⁹⁷ Therefore, public utility transmission providers may be able to modify and expand these existing procedures for identifying transmission needs driven by Public Policy Requirements to meet these proposed requirements regarding the

identification of factors for incorporation into Long-Term Scenarios.

111. We propose this reform because we believe that incorporation of the categories of factors set forth above in developing Long-Term Scenarios would help facilitate the identification of transmission needs driven by changes in the resource mix and demand, which we preliminarily find is necessary to ensure just and reasonable and not unduly discriminatory or preferential Commission-jurisdictional rates. Absent a requirement to incorporate these categories of factors into the development of Long-Term Scenarios, public utility transmission providers may not incorporate known inputs that will likely affect the future resource mix and demand. Additionally, public utility transmission providers may not adequately identify transmission needs driven by changes in the resource mix and demand and evaluate the potential benefits of regional transmission facilities that may more efficiently or cost-effectively meet such needs. As an additional benefit, this requirement would provide clarity to public utility transmission providers and stakeholders on what factors must be considered in scenario development.

112. We seek comment on whether and how the categories of factors listed above adequately capture factors expected to drive changes in the resource mix and demand.

(iii) Number and Range of Long-Term Scenarios

113. In Long-Term Regional Transmission Planning, the number and range of Long-Term Scenarios developed determines the scope of possible future conditions for the electric power system and allows public utility transmission providers to identify the transmission needs for each possible future reflected in the scenarios. Developing a range of scenarios with different assumptions allows public utility transmission providers to consider a variety of potential scenarios and associated transmission needs driven by changes in the resource mix and demand and, in turn, possibly different regional transmission facilities to more efficiently or cost-effectively meet those needs. However, modeling multiple scenarios requires additional time and effort, and may add to the costs of Long-Term Regional Transmission Planning. We are cognizant of these tradeoffs in developing our proposed reforms.

114. In developing scenarios, it is possible to create a base case scenario that is a business-as-usual scenario, or a

most likely scenario, and compare that to alternative scenarios that are considered to be less likely to occur. These alternative scenarios typically depart from the base case by considering different assumptions. For example, an alternative scenario might differ from a base case in how it considers the location and quantity of resource additions or retirements. In addition, it is possible to develop specific scenarios to determine potential transmission needs. For example, it is possible to develop a scenario that assumes a greater amount of distributed energy resource additions compared to a business-as-usual case, a scenario that assesses conditions associated with extreme weather events, or a scenario that explores the possibility of additional resource development in an identified geographic zone, as well as a scenario that combines these assumptions.

115. Currently, MISO developed three scenarios, called futures, that it intends to use as part of its Long-Range Transmission Planning.¹⁹⁸ MISO makes a different assumption about load growth, the extent to which state and utility goals that are not legislated are met, and the future resource mix for each future.¹⁹⁹ CAISO creates a base case scenario reflecting the assumptions about resource locations that are most likely to occur and one or more stress scenarios to compare to the base case scenario.²⁰⁰ SPP currently develops a base reliability scenario and two scenarios as part of its 10-year Integrated Transmission Planning assessment and four scenarios as part of its 20-year Integrated Transmission Planning assessment.²⁰¹ NYISO currently develops multiple scenarios (high/low load, high/low natural gas price, 70% zero-emissions by 2030) for its regional transmission planning process.²⁰²

116. The ANOPR sought comment on whether consideration should be given to multiple future scenarios and whether and how public utility transmission providers should account for an array of different future scenarios when identifying more efficient or cost-effective transmission facilities in regional transmission plans.²⁰³

117. The ANOPR also sought comment on how the regional

¹⁹⁶ See NARUC Comments at 5–6 (“NARUC . . . supports exploring reforms that will better align regional transmission planning with state needs and ensure meaningful opportunities for the state to provide direction and inputs or otherwise have their law and policies appropriately reflected through the transmission planning process—all while benefitting electricity consumers.”).

¹⁹⁷ Order No. 1000, 136 FERC ¶ 61,051 at PP 206–207; Order No. 1000–A, 139 FERC ¶ 61,132 at P 335.

¹⁹⁸ MISO Comments at 8, 80.

¹⁹⁹ MISO, *MISO Futures Report*, at 4 (Dec. 2021).

²⁰⁰ CAISO Comments at 45.

²⁰¹ SPP, *2020 Integrated Transmission Planning Assessment Report*, at 8 (Oct. 2020); SPP Market Monitor Comments at 3–4; SPP, *2022 20-Year Assessment Scope*, at 2–4 (Feb. 2, 2021).

²⁰² NYISO Comments at 28–29.

²⁰³ ANOPR, 176 FERC ¶ 61,024 at P 48.

transmission planning process should consider the probabilities of scenarios.²⁰⁴ The Commission also asked “whether greater use of probabilistic transmission planning approaches may better assess the benefits of regional transmission facilities” and whether “more advanced approaches, such as stochastic²⁰⁵ techniques, may provide an opportunity to consider a broader array of potential future conditions.”²⁰⁶

(01) Comments

118. Some commenters responding to the ANOPR discuss the number and range of scenarios that should be used in regional transmission planning. U.S. DOE recommends a national standard set of scenarios, including business-as-usual, high/medium/low load growth, high/medium/low reliance on distributed energy resources and demand response, and high decarbonization.²⁰⁷ ACPA and ESA recommend a business-as-usual base case and alternative scenarios with adjusted assumptions on increased commitments to decarbonization, increased electrification of transportation and other uses such as home heating, and increased fuel prices.²⁰⁸ Oregon Commission recommends that the Commission require study of a scenario in which there is a federal-level climate/clean energy policy.²⁰⁹ Eversource states that regions should have flexibility in defining scenarios, and that states should have a major role in defining scenarios.²¹⁰ Nebraska Commission generally opposes the Commission specifying scenario requirements.²¹¹

119. In terms of the number of scenarios, ACPA and ESA argue that the Commission should require public utility transmission providers to use three to four scenarios, including a business-as-usual case.²¹² AEP recommends at least three robust and standardized scenarios.²¹³ NextEra also recommends that the Commission require public utility transmission providers to consider at least three scenarios ranging from a business-as-usual case to a transformative scenario featuring economy-wide national net

zero emissions.²¹⁴ And Nature Conservancy contends that the Commission should require at least four.²¹⁵ Avangrid proposes the number of scenarios should be sufficient to support reasoned decision-making but not so exhaustive to complicate and slow down planning.²¹⁶ LS Power asserts that there is a need for a plan that uses a broad range of plausible scenarios.²¹⁷

120. In terms of probabilistic planning methods in developing scenarios, commenters to the ANOPR identify the benefits of probabilistic planning, which can include the ability to recognize multiple facility outages at a single time, to prepare for and recover from extreme weather events, and to address uncertainties about operational outcomes (like variable generation) and over a long time horizon.²¹⁸ In light of these benefits, some commenters recommend that the Commission require public utility transmission providers to adopt probabilistic planning methods.²¹⁹ PG&E states that the planning toolkit must now evolve to include more probabilistic tools that appropriately reflect the variable nature of the resource mix and other uncertainties in the forecast.²²⁰ U.S. DOE states that probabilistic planning, along with other factors, is likely to contribute to the development of a transmission system that reliably meets system needs at just and reasonable rates.²²¹ Other commenters support the use of probabilistic planning methods where feasible or appropriate and do not recommend the Commission require public utility transmission providers to adopt probabilistic planning methods at this time.²²² PJM, CAISO, and MISO

²¹⁴ NextEra Comments at 71–71, 75–77.

²¹⁵ Nature Conservancy Comments at 3.

²¹⁶ Avangrid Comments at 12–14.

²¹⁷ LS Power Oct. 12 Comments at 33–36.

²¹⁸ E.g., California Commission Comments at 71; NARUC Comments at 11 (stating that probabilistic approaches can provide “more insight into the benefits and risks of different decisions; and the importance and relationship between various uncertainties”); MISO Comments at 36 (stating that “probabilistic planning has many benefits and should be explored”); PG&E Comments at 3 (stating that probabilistic planning “appropriately reflect[s] the variable nature of the resource mix and other uncertainties in the forecast”).

²¹⁹ AES Ohio Comments at 2–3; PIOs Comments at 79; California Commission Comments at 66; VEIR Comments at 15–16.

²²⁰ PG&E Comments at 3.

²²¹ U.S. DOE Comments at 20.

²²² EI Comments at 25; NARUC Comments at 10 (“[P]robabilistic analysis should be used, where feasible without significantly burdening the planning process.”); WIREs Comments at 8–9; National Grid Comments at 71; *see also Joint Fed.-State Task Force on Elec. Transmission*, Technical Conference, Docket No. AD21–15–000, Tr. 71:12–72:5 (Clifford Rechtschaffen) (Feb. 16, 2022)

identify the value of probabilistic planning methods yet acknowledge that complex issues remain involving data availability, computational intensity, and stakeholder consensus.²²³ Minnesota Commission states that probabilistic approaches are likely to be problematic in the stakeholder process because of the uncertainty and wide-ranging stakeholder opinions about the future.²²⁴

(02) Proposed Requirement

121. We propose to require that public utility transmission providers develop at least four distinct Long-Term Scenarios as part of Long-Term Regional Transmission Planning. We propose to require that each of these Long-Term Scenarios incorporate, at a minimum, the categories of factors listed in the requirement above. As discussed in the Factors section above, we propose that each Long-Term Scenario must be consistent with federal, state, and local laws and regulations that affect the future resource mix; federal, state, and local laws and regulations on decarbonization and electrification; and state-approved integrated resource plans. However, each Long-Term Scenario may vary according to assumptions about the remaining categories of factors described above, as well as with respect to other characteristics of the future electric power system. We do not propose to require the development of a specific Long-Term Scenario or specific set of Long-Term Scenarios, nor do we propose to require that public utility transmission providers identify the relative likelihood of different Long-Term Scenarios except where a public utility transmission provider develops a base case scenario, as described more fully below.

122. We preliminarily find that using at least four distinct Long-Term Scenarios is a reasonable lower bound for the number of Long-Term Scenarios that public utility transmission providers must evaluate in Long-Term Regional Transmission Planning. This minimum number of Long-Term Scenarios will help ensure that public utility transmission providers conduct Long-Term Regional Transmission Planning that identifies more efficient or cost-effective regional transmission facilities to meet transmission needs

(February Joint Task Force Tr.) (supporting increasing use of probabilistic and other analytical approaches where feasible to account for uncertainty in quantification of benefits and effectively plan for the longer term).

²²³ PJM Comments at 64–66; MISO Comments at 46–47; CAISO Comments at 48.

²²⁴ Minnesota Commission Comments at 4.

²⁰⁴ *Id.*

²⁰⁵ Stochastic models are frameworks for addressing optimization problems that involve uncertainty.

²⁰⁶ ANOPR, 176 FERC ¶ 61,024 at P 49.

²⁰⁷ U.S. DOE Comments at 12–15.

²⁰⁸ ACPA and ESA Comments at 46.

²⁰⁹ Oregon Commission Comments at 8–9.

²¹⁰ Eversource Comments at 9.

²¹¹ Nebraska Commission Comments at 3–4.

²¹² ACPA and ESA Comments at 46.

²¹³ AEP Comments at 11–12.

driven by changes in the resource mix and demand. For example, public utility transmission providers could develop a base case and three alternatives or a low-, medium-, and high-level assumption for the factors that public utility transmission providers (and their stakeholders) believe to be important to conduct Long-Term Regional Transmission Planning to more efficiently or cost-effectively meet transmission needs driven by changes in the resource mix and demand, along with a scenario that accounts for a high-impact, low-frequency event (as discussed below).

123. Furthermore, we propose to require that public utility transmission providers in each transmission planning region develop a plausible and diverse set of Long-Term Scenarios.²²⁵ That is to say, the set of at least four Long-Term Scenarios must be: (1) Plausible, that is they must reasonably capture probable future outcomes, and (2) diverse in the sense that public utility transmission providers can distinguish distinct transmission facilities or distinct benefits of similar transmission facilities in each scenario. If a public utility transmission provider produces a base case scenario, that scenario should be consistent with what the public utility transmission provider determines to be the most likely scenario to occur. Consistent with the Order No. 890 transparency transmission planning principle,²²⁶ we propose to require that public utility transmission providers in each transmission planning region publicly disclose (subject to any applicable confidentiality protections) information and data inputs they use to create each Long-Term Scenario. This transparency requirement will allow stakeholders to understand how each scenario differs. Similarly, consistent with the Order Nos. 890 and 1000 coordination transmission planning principle,²²⁷ we propose to require that

public utility transmission providers in each transmission planning region give stakeholders the opportunity to provide timely and meaningful input into the identification of which Long-Term Scenarios are developed. We propose to require that public utility transmission providers revise the regional transmission planning processes in their OATTs to outline an open and transparent process that provides stakeholders, including states, with a meaningful opportunity to propose which future outcomes are probable and can be captured through assumptions made in the development of Long-Term Scenarios. We further propose to require that public utility transmission providers explain on compliance how their process will identify a plausible and diverse set of Long-Term Scenarios.

124. We propose to require that at least one of the four distinct Long-Term Scenarios that public utility transmission providers in each transmission planning region use in Long-Term Regional Transmission Planning must account for uncertain operational outcomes that determine the benefits of or need for transmission facilities during high-impact, low-frequency events. We propose to allow public utility transmission providers to determine which high-impact, low-frequency event should be modeled in this Long-Term Scenario as part of Long-Term Regional Transmission Planning based on our understanding that each transmission planning region may see a need to evaluate a different type of high-impact, low-frequency event. High-impact, low-frequency events may include extreme weather events or events associated with potential cyber attacks. This Long-Term Scenario accounting for a high-impact, low-frequency event can be developed, for example, by assuming greater-than-expected electricity demand and greater-than-expected generation or transmission outages. We propose that the use of probabilistic transmission planning or stochastic techniques would satisfy this requirement, but do not propose to require either approach at this time.²²⁸

fully in the transmission planning process. The transmission planning process must provide for the timely and meaningful input and participation of customers and other stakeholders regarding the development of transmission plans, allowing customers and other stakeholders to participate in the early stages of development. Order No. 890, 118 FERC ¶ 61,119 at PP 451–454.

²²⁸ For the purpose of an improved record, we clarify that we consider probabilistic transmission planning approaches to include any transmission planning approach that uses a probability distribution to assign probabilities to one or more inputs to the transmission model. These inputs can

125. We note that public utility transmission providers can develop sensitivities for every Long-Term Scenario to assess how outcomes modeled in Long-Term Scenarios may depend on an assumption about electric power system model inputs that does not vary across scenarios (e.g., higher natural gas prices).²²⁹ Such sensitivities can provide valuable information about the need for and benefits of potential transmission facilities; however, they can be burdensome to develop if applied to every scenario.

126. We seek comment on whether four Long-Term Scenarios will provide public utility transmission providers with enough information to identify transmission needs driven by changes in the resource mix and demand and evaluate transmission facilities for potential selection in the regional transmission plan for purposes of cost allocation that may more efficiently or cost-effectively meet those needs or whether additional Long-Term Scenarios should be required. In addition, we seek comment on whether public utility transmission providers should be required to develop sensitivities for each Long-Term Scenario to identify more efficient or cost-effective transmission facilities for selection in the regional transmission plan for purposes of cost allocation as part of Long-Term Regional Transmission Planning.

(iv) Specificity of Data Inputs

127. Data inputs are numbers that characterize assumptions about future conditions of the transmission system under each scenario over the

include shorter-term operational inputs (like wind generation or generation outages). See, e.g., Li, W., *Probabilistic Planning of Transmission Systems: Why, How and an Actual Example*, at 1, 2008 IEEE Power and Energy Society General Meeting—Conversion and Delivery of Electrical Energy in the 21st Century (2008). Stochastic techniques include adaptive transmission planning techniques that identify transmission facilities that optimize transmission net-benefits over a time horizon under market and regulatory uncertainty about the future. See, e.g., Ho, J., et al., *Planning transmission for uncertainty: Applications and lessons for the western interconnection*, at 21, The Western Electricity Coordinating Council (2016) (answering “What is stochastic transmission planning?”).

²²⁹ See, e.g., SPP, *2020 Integrated Transmission Planning Assessment Report*, at 146–154 (Oct. 2020). <https://www.spp.org/documents/63434/2020%20integrated%20transmission%20plan%20report%20v1.0.pdf>; NYISO, *2020 Reliability Needs Assessment*, at 89–92 (Nov. 2020). <https://www.nyiso.com/documents/20142/2248793/2020-RNAREport-Nov2020.pdf>. A sensitivity represents a single assumption about a short-term input or factor (some input with a value that may change throughout a day or year). A scenario represents an assumption about a longer-term input or factor (e.g., resource retirements and additions or public policies). See, e.g., Brattle-Grid Strategies Oct. 2021 Report at 64.

²²⁵ We note that different assumptions about the factors and data inputs used to develop Long-Term Scenarios and other characteristics of the future electric power system determine whether the set of Long-Term Scenarios are plausible and diverse.

²²⁶ The transparency transmission planning principle requires public utility transmission providers to reduce to writing and make available the basic methodology, criteria, and processes used to develop transmission plans. Public utility transmission providers must make sufficient information available to enable customers and other stakeholders to replicate the results of transmission planning studies. Order No. 890, 118 FERC ¶ 61,119 at P 471. Order No. 1000 applied this and other Order No. 890 transmission planning principles to regional transmission planning processes. Order No. 1000, 136 FERC ¶ 61,051 at P 151.

²²⁷ The coordination transmission planning principle requires public utility transmission providers to provide customers and other stakeholders with the opportunity to participate

transmission planning horizon. Using reasonable data inputs is key to effective Long-Term Regional Transmission Planning because data inputs can drive the results of transmission planning models, both in terms of the transmission needs identified and the more efficient or cost-effective transmission facilities to address those needs. For example, the long-term load forecast can lead to more planned transmission if the assumed growth rate is increased. Similarly, the assumed dates of generation retirements can be a critical factor in determining when new transmission will be needed. Given how sensitive transmission planning models can be to changes in assumptions, using robust data inputs is critical to identifying more efficient or cost-effective regional transmission facilities.

128. In the ANOPR, the Commission asked what inputs should be considered in modeling anticipated future generation.²³⁰ More specifically, the Commission asked which data inputs public utility transmission providers would need to model to represent new generation sources, such as renewable resources, in order to reflect their actual performance.²³¹

(01) Comments

129. In response to the ANOPR, several public utility transmission providers commented on the data inputs used in their existing regional transmission planning processes.²³² PJM recommends that the Commission require disclosure of data inputs and their assumptions.²³³ ACEG, AEE, and PIOs advocate for a new rule that specifies that public utility transmission providers use best available data inputs and best practices for load forecasts.²³⁴ Rail Electrification recommends that the Commission insist on best available data and most plausible futures.²³⁵ Union of Concerned Scientists states that the failure to use the best available data will lead to the failure to identify more efficient and cost-effective transmission alternatives.²³⁶ U.S. DOE recommends the Commission consider the need to standardize modeling inputs to increase consistency and comparability across

planning processes and lists the potential inputs it thinks the Commission should consider.²³⁷ U.S. DOE also provides information on the array of tools and data developed by national laboratories which can be used as inputs in transmission planning.²³⁸ NARUC states that better sharing of data between states and the RTOs/ISOs would be beneficial.²³⁹ RMI states that state-of-the-art cost data and forecasts are of paramount importance in planning for new transmission.²⁴⁰ NERC says that improved transmission planning for reliability requires better data collection especially electromagnetic transient data.²⁴¹ Entergy believes that the transmission models used should incorporate realistic and objectively reasonable future assumptions.²⁴² Certain TDUs believes public utility transmission providers should regularly update planning models with the most recent integrated resource plan data available.²⁴³ The PJM Market Monitor asserts that decisions made about the transmission grid must reflect accurate information while remaining flexible enough to incorporate new information as it becomes available.²⁴⁴

(02) Proposed Requirement

130. We propose to require that public utility transmission providers use “best available data inputs” when developing Long-Term Scenarios. By “best available,” we do not imply that there is a single “best” value for each data input that public utility transmission providers must use, but rather that best practices are used to develop that data input.

131. We propose to define “best available data inputs” as data inputs that are timely²⁴⁵ and developed using diverse and expert perspectives, adopted via a process that satisfies the transparency planning principle described above,²⁴⁶ and that reflect the list of factors that public utility transmission providers must incorporate into Long-Term Scenarios. An example of data inputs that could meet this requirement are the long-term load forecasts of demand that RTOs/ISOs currently use for predicting long-term resource adequacy. Another example of

data inputs that could meet this requirement are the most recent data on renewable energy potential and distributed energy resources developed by national labs.²⁴⁷

132. We propose to require that public utility transmission providers in each transmission planning region update all data inputs each time they reassess and revise, as necessary, their Long-Term Scenarios, which, as explained above, we propose to require they do at least every three years. As indicated in the Long-Term Regional Transmission Planning section above, we also propose to require that the Order Nos. 890 and 1000 transmission planning principles apply to the process through which public utility transmission providers determine which data inputs to use in their Long-Term Scenarios. For example, consistent with the coordination transmission planning principle in Order Nos. 890 and 1000, we propose to require that public utility transmission providers in each transmission planning region give stakeholders the opportunity to provide timely and meaningful input concerning which data inputs to use in Long-Term Scenarios.

133. We preliminarily find that a requirement to use the best available data inputs is necessary to ensure that public utility transmission providers are regularly updating data inputs and then using timely and accurate data inputs to inform Long-Term Scenarios. As stated above, data inputs can drive the results of Long-Term Regional Transmission Planning, and as a result, directly affect which transmission facilities may be selected in the regional transmission plan for purposes of cost allocation and, in turn, Commission-jurisdictional rates.

134. We seek comment on whether the proposed definition of best available data inputs will allow for public utility transmission providers to identify the more efficient or cost-effective transmission facilities for selection in the regional transmission plan for purposes of cost allocation using Long-Term Scenarios. We seek comment on whether the proposed definition of best available data inputs should be expanded to include an evaluation of the data source entities’ historical accuracy in identifying and projecting trends that impact the resource mix and demand. We also seek comment as to

²³⁰ ANOPR, 176 FERC ¶ 61,024 at P 48.

²³¹ *Id.* P 50.

²³² As examples, CAISO and PJM mention generation retirements, MISO mentions forced outage rates, and CAISO, NYISO, and SPP mention load and capacity forecasts. CAISO Comments at 18; MISO Comments at 47; NYISO Comments at 6; PJM Comments at 42; SPP Comments at 3.

²³³ PJM Comments, attach. K at 4.

²³⁴ ACEG Comments, attach. C at 10; AEE Reply Comments at 4; PIOs Reply Comments at 43–44.

²³⁵ Rail Electrification Comments at 13.

²³⁶ Union of Concerned Scientists Comments at 31.

²³⁷ U.S. DOE Comments at 12–13.

²³⁸ *Id.* at attach. B.

²³⁹ NARUC Comments at 42.

²⁴⁰ RMI Comments at 3.

²⁴¹ NERC Comments at 10.

²⁴² Entergy Comments at 17.

²⁴³ Certain TDUs Comment at 11.

²⁴⁴ PJM Market Monitor Comments at 6.

²⁴⁵ Timely data inputs are based on the most current information.

²⁴⁶ See *supra* note 226.

²⁴⁷ See, e.g., U.S. DOE Comments, attach. B at 79, 94 (discussing NREL’s Renewable Energy Potential model and Distributed Generation Market Demand model). We note that such granular data may be useful to public utility transmission providers to the extent public utility transmission providers do not already have such granular data that meet this requirement.

whether stakeholders and public utility transmission providers would find value in or believe it is necessary for the Commission to facilitate the development of data inputs that meet this proposed requirement by identifying or standardizing the best available data inputs that meet this proposed requirement.²⁴⁸

(v) Identification of Geographic Zones

135. In the ANOPR, the Commission sought comment on whether it should require public utility transmission providers to establish, as part of their regional transmission planning processes, a process that identifies geographic zones that have the potential for the development of large amounts of new generation, particularly renewable resources. The Commission also sought comment on whether and how such a process might interrelate with existing regional transmission planning and cost allocation processes, and how long-term scenario planning may be used in this process or other relevant regional transmission planning and cost allocation processes.²⁴⁹ The Commission also noted that the Texas' CREZ initiative, MISO's MVPs, and a Commission-approved CAISO proposal are examples of such identification of geographic zones in transmission planning and development initiatives.²⁵⁰

(01) Comments

136. Several commenters responded to the Commission's request for comments related to the identification of geographic zones. Starting with the RTOs/ISOs, CAISO states that, while it supports the idea of finding zones of renewable energy, there are many ways to do this, and each region should be allowed to find its own solution. CAISO states that active involvement and buy-in of state regulators in identifying zones of renewable energy is critical to mitigate the risk of over-building transmission and to facilitate state siting approvals for transmission facilities. CAISO suggests that an open season could be used to identify interest in a new transmission line.²⁵¹

137. NYISO supports the identification of pockets where future generation would be developed and

²⁴⁸ *Id.* at 12–14 (arguing the Commission should standardize modeling input assumptions and establish core scenarios); Harvard ELI Comments at 34 (stating the Commission could work with the U.S. DOE to develop industry-wide standards for scenario planning which would include data inputs).

²⁴⁹ ANOPR, 176 FERC ¶ 61,024 at P 57.

²⁵⁰ *Id.* PP 55–56.

²⁵¹ CAISO Comments at 49–54.

where new transmission is needed. NYISO states that it already has such an identification process.²⁵²

138. ISO–NE states that it has a process in place to identify regions of renewable energy that it calls ISO–NE Clustering, which it says is similar to the process CAISO used in its Tehachapi approach. ISO–NE states that long-term planning for transmission to renewable-rich areas should not replace the generator interconnection process.²⁵³

139. PJM argues that if the Commission creates a geographic zone requirement, the RTOs/ISOs should have the flexibility to establish a process for their region.²⁵⁴ Additionally, PJM suggests that sub-zones of renewable energy could be visualized in a heat map.²⁵⁵

140. MISO opposes prescriptive requirements to identify zones of renewable energy because it argues that the regions should have the flexibility to work with stakeholders to identify zones. MISO also argues that there are potential problems in identifying regions of renewable energy because (1) what counts as renewable energy is not clear, and (2) where the zones of renewable energy resources are not clear, in part because a state's desire to develop resources may force generation development in other states with lower resource potential. MISO states that the MVP process was a success, in part, due to the Regional Generation Outlet Study, which was a successful collaboration between MISO and the states within the MISO region that might not have worked as well if MISO and the states had not had the flexibility to develop it the way that they did.²⁵⁶ MISO states that the MISO MVPs, ERCOT's CREZ, and the CAISO examples all reflect local solutions based on unique factors in each location. MISO points out that ERCOT and CAISO are each single-state RTOs/ISOs, which makes their experience not directly comparable to MISO's.²⁵⁷

141. U.S. DOI supports the creation of geographic zones as a means to improve the efficiency of transmission planning overall but cautions that any

²⁵² NYISO Comments at 31–33.

²⁵³ ISO–NE Comments at 21–25 (citing *Cal. Indep. Sys. Operator*, 118 FERC ¶ 61,226, *order on clarification*, 120 FERC ¶ 61,180 (2007) (granting request for waiver to conduct a “targeted” cluster study to identify the significant transmission infrastructure necessary to interconnect approximately 4,500 MW of primarily wind resources in the remote Tehachapi Wind Resource Area of the system)).

²⁵⁴ PJM Comments at 12–13.

²⁵⁵ *Id.* at 41–42.

²⁵⁶ MISO Comments at 53–56.

²⁵⁷ *Id.* at 56–58.

requirement must consider environmental impacts and habitats of species that are of conservation concern.²⁵⁸ Similarly, U.S. DOE argues that while the creation of geographic zones is a step in the right direction, additional agreement is needed on which generation resources would actually be developed, which market areas need to be served, and which transmission facilities are needed to connect them reliably and efficiently.²⁵⁹ However, U.S. DOE states that Texas' CREZ model has worked well since it establishes clear regulatory pathways and cost allocation en masse.

142. Some commenters oppose a geographic zone requirement. Consumer Organizations assert that a “top down” approach from the Commission has the potential to saddle customers with unnecessary costs from constructing “roads to nowhere” that may never be utilized.²⁶⁰ East Kentucky argues that a Commission-required geographic zone requirement would create an uneven playing field for generation resources that seek to interconnect outside a designated geographic zone.²⁶¹ APPA argues that instead of requiring geographic zones, the Commission should permit load-serving entities to identify geographic zones when developing their resource plans, which is more of a “bottom up” approach.²⁶² OMS and NESCOE both assert that each region already has an existing process to identify zones of renewable resource potential and that the Commission should not require anything further.²⁶³ WIRES states that a requirement to identify zones of renewable energy is not needed and regions should have the flexibility to find their own solutions.²⁶⁴ Xcel notes that such a requirement exceeds the Commission's authority under the FPA because states have the final say over construction of new generation, as well as transmission facility siting and permitting.²⁶⁵

143. Ohio Commission states that the Commission lacks jurisdiction to require the creation of new zones.²⁶⁶ Michigan

²⁵⁸ U.S. DOI Comments at 1–3.

²⁵⁹ U.S. DOE Comments at 24, 74; *see also* November Joint Task Force Tr 108:23–109:8, 110:13–18 (Gladys Brown-Dutrieuille) (suggesting identification of geographic zones as one long-term transmission planning principle FERC could work with states to develop to “facilitate integration of optimal resources in transmission”).

²⁶⁰ Consumer Organizations Comments at 21.

²⁶¹ East Kentucky Comments at 8–9.

²⁶² APPA Comments at 17.

²⁶³ OMS Comments at 8–9; NESCOE Comments at 46–47.

²⁶⁴ WIRES Comments at 41–42.

²⁶⁵ Xcel Comments at 5–10.

²⁶⁶ Ohio Commission Comments at 6–10.

Commission cautions that if the Commission requires a geographic zone concept, the notion that geographic zones must be “rich in renewable resources” would unreasonably shift costs to consumers that do not receive commensurate benefits.²⁶⁷ NRECA states that the decision to establish geographic zones should be left to the regional transmission planning processes to resolve, subject to input from state and local governing bodies and to ultimate Commission oversight and approval on a case-by-case basis to ensure that zone selection and cost allocations are consistent with Order No. 1000.²⁶⁸

144. LPPC argues that a geographic zone requirement should consider guardrails that will assist in limiting undue risk and financial exposure for those customers that may not use the planned facilities.²⁶⁹ SoCal Edison argues that geographic zones should entail providing federal funds to disproportionately burdened communities.²⁷⁰ Shell argues that coastal public utility transmission providers should be required to explain how their transmission planning processes accommodate the unique obstacles impeding offshore wind transmission and generation.²⁷¹ Orsted states that the scale and location of future offshore wind generation is well known, and RTOs/ISOs should be required to plan cost-effective transmission to bring offshore wind power to market.²⁷² Union of Concerned Scientists argue that if the Commission requires geographic zones, it should revise Order No. 1000’s provision for local and regional transmission planning processes to explicitly provide for the recognition of Public Policy Requirements established by state or federal laws or regulations, including federal leasing for the development of generation, that will drive transmission and interconnection in resource-rich zones.²⁷³

(02) Proposed Requirement

145. We propose to require each public utility transmission provider, as part of its regional transmission planning process, to consider whether to: (1) Identify, with stakeholder input, specific geographic zones within the transmission planning region that have the potential for development of large

amounts of new generation; (2) assess generation developers’ commercial interest in developing generation within the identified geographic zones; and (3) incorporate designated zones, and the identified commercial interest in each zone, into Long-Term Scenarios.

146. We preliminarily find that requiring the consideration and potential identification of geographic zones within Long-Term Scenarios assists public utility transmission providers, transmission developers, and generation developers to coordinate their activities. We believe that public utility transmission providers would be able to better identify transmission needs driven by changes in the resource mix and demand by considering geographic zones that have the potential for the development of large amounts of new generation and where developers have already shown commercial interest. Using the information gained through the process described below to identify such geographic zones, public utility transmission providers in each transmission planning region could then plan transmission facilities that would serve large concentrations of new generation in a more efficient or cost-effective manner.

147. As step one of the geographic zone process, we propose to require that public utility transmission providers consider whether to establish and include in the regional transmission planning process outlined in their OATTs the method that they will use to identify geographic zones within the transmission planning region. We propose to require that this method use best available data, including atmospheric, meteorological, geophysical, and other surveys, to identify geographic zones with potential for development of large amounts of new generation. We also propose to require that public utility transmission providers in each transmission planning region use this information to create a set of draft geographic zones, and that they post on their OASIS or other public websites maps of the draft geographic zones, as well the information used to create the draft geographic zones, for stakeholders’ input.

148. As part of proposed step one, after the public utility transmission providers in each transmission planning region identify and post any draft geographic zones and related information, we propose to require them to provide all stakeholders, including relevant federal and state siting authorities, with a meaningful opportunity to provide input on the draft geographic zones. We believe that input from federal and state siting

authorities is particularly important because we also propose to require that public utility transmission providers in each transmission planning region use this stakeholder engagement to identify known siting, permitting, or other anticipated development challenges or opportunities associated with the draft geographic zones. We believe that obtaining information related to siting and permitting early in the geographic zone development process will help public utility transmission providers to identify draft zones where the anticipated generation resources are most likely to materialize.

149. In addition, we propose to require that public utility transmission providers in each transmission planning region consider this stakeholder feedback and modify the draft geographic zones as appropriate to produce a final list of designated geographic zones within the transmission planning region.²⁷⁴ As the final part of proposed step one, we propose to require that public utility transmission providers in each transmission planning region post on their OASIS or other public websites maps of the designated geographic zones and information related to the designation of those zones, including the explanation of changes from the draft to final list.

150. In step two of the geographic zone process, we propose to require that public utility transmission providers in each transmission planning region assess generation developers’ commercial interest in developing generation within each designated geographic zone. Specifically, we propose to require that public utility transmission providers include in their OATTs as part of their regional transmission planning process a method to assess generation developers’ commercial interest in developing generation within each designated geographic zone that considers the following: (1) The generation developer’s existing energy resources within the zone; (2) the number and size of any interconnection requests from developers with completed facilities study agreements for generation located within the zone; (3) a generation developer’s leasing agreements with landowners within the zone; (4) a generation developer’s letters of credit associated with generation it may develop in the zone; (5) any merchant or other entity commitments to build

²⁷⁴ We note that, while we refer to multiple “zones,” subsequent to stakeholder feedback, the final list may contain only one designated geographic zone.

²⁶⁷ Michigan Commission Comments at 12–14.

²⁶⁸ NRECA Comments at 21–23.

²⁶⁹ LPPC Comments at 14–15.

²⁷⁰ SoCal Edison Comments at 10.

²⁷¹ Shell Comments at 8–9.

²⁷² Orsted Comments at 8.

²⁷³ Union of Concerned Scientists Comments at 32–37.

(including deposits or payments to secure or fund) transmission facilities that would serve generation within the zone; (6) a generation developer's power purchase agreements with a credit-worthy counterparty associated with generation within the zone; and (7) any other factors for which generation developers have provided evidence as indications of commercial interest in developing generation within the zone. We propose this step two requirement because we believe it will indicate how much of the geographic zone's resource hosting potential generation developers are interested in pursuing, which is useful for improving the accuracy of Long-Term Scenarios as public utility transmission providers in each transmission planning region incorporate information about designated geographic zones into such scenarios as part of step three.

151. In step three of the geographic zone process, we propose to require that public utility transmission providers in each transmission planning region incorporate the information from step one and step two regarding the designated geographic zones into their Long-Term Scenarios. We believe this information will be useful to public utility transmission providers in each transmission planning region as they identify and run different Long-Term Scenarios as part of the requirement to conduct Long-Term Regional Transmission Planning to address transmission needs driven by changes in the resource mix and demand. Specifically, we propose to require that public utility transmission providers revise the regional transmission planning process in their OATTs to describe how the designated geographic zones, the information they used to designate the geographic zones, and the information about generation developers' commercial interest in developing generation within each zone are integrated into their Long-Term Scenarios. We believe that integrating this information into Long-Term Scenarios will allow public utility transmission providers in each transmission planning region to better identify transmission needs driven by changes in the resource mix and demand, as well as more efficient or cost-effective regional transmission facilities to meet those needs.

152. We acknowledge that public utility transmission providers in multi-state transmission planning regions may face unique challenges and differing energy policy interests or preferences in complying with this proposed requirement.

153. We seek comment on how public utility transmission providers in multi-state transmission planning regions may reconcile or account for differing energy policy interests or preferences in implementing this proposed requirement, while respecting and not overriding those state preferences.

ii. Coordination of Regional Transmission Planning and Generator Interconnection Processes

154. As discussed above, we preliminarily find that current regional transmission planning processes fail to plan for transmission needs driven by changes in the resource mix and demand. Instead, public utility transmission providers typically account for such transmission needs through interconnection-related network upgrades identified through the generator interconnection process. Based on the comments received in response to the ANOPR, we believe that there may be a need for better coordination between the regional transmission planning and cost allocation and generator interconnection processes. To this end, we propose to require that public utility transmission providers consider as part of their Long-Term Regional Transmission Planning regional transmission facilities that address interconnection-related needs that the public utility transmission provider identified multiple times in the generator interconnection process but that have never been constructed due to the withdrawal of the underlying interconnection request(s).

(a) ANOPR

155. In the ANOPR, the Commission asserted that the interaction between a public utility transmission provider's current generator interconnection process and its regional transmission planning and cost allocation processes appears to be limited.²⁷⁵ The Commission also observed that the primary interaction between a public utility transmission provider's current generator interconnection process and its regional transmission planning and cost allocation processes is that the baseline regional transmission planning models generally only incorporate interconnection projects that are near the end of the generator interconnection process and have completed an interconnection facilities study.²⁷⁶

156. The ANOPR sought comment on whether reforms are necessary to improve coordination between the regional transmission planning and cost

allocation and generator interconnection processes.²⁷⁷ In particular, the ANOPR sought comment on whether interconnection requests that trigger the need for interconnection-related network upgrades that may provide regional transmission benefits could be studied in a way that accounts for the potential broader transmission benefits in coordination with the regional transmission planning process.²⁷⁸ The ANOPR also sought comment on whether it may be possible and beneficial to combine certain aspects of the regional transmission planning and generator interconnection processes.²⁷⁹

(b) Comments

157. Each of the RTOs/ISOs filed comments in response to the ANOPR related to the coordination of their regional transmission planning and cost allocation and generator interconnection processes. CAISO states that it includes interconnection-related network upgrades identified during its interconnection study process and that meet specific voltage and/or capital cost thresholds as an input into the regional transmission planning process. CAISO asserts that it does so to ensure that it identifies and approves all major transmission additions and upgrades under a single comprehensive process and allocates the available amount of transmission capacity to the proposed generating facilities in each area.²⁸⁰ PJM states that it leverages opportunities to address supplemental projects and new interconnection service requests through its baseline transmission projects. For instance, when increasing the capabilities of a regional transmission facility would obviate the need for an interconnection-related network upgrade, PJM factors the interconnection customer's incremental need into the transmission project and the interconnection customer is only responsible for the costs of the incremental portion of the transmission facility.²⁸¹ ISO-NE explains how its regional transmission planning and generator interconnection processes are coordinated presently but acknowledges that improvements may be necessary to optimize transmission solutions.²⁸² NYISO and SPP each identify an ongoing or potential stakeholder process to improve the coordination of the generator interconnection and regional

²⁷⁷ ANOPR, 176 FERC ¶ 61,024 at *Id.* P 65.

²⁷⁸ ANOPR, 176 FERC ¶ 61,024 at *Id.* P 66.

²⁷⁹ ANOPR, 176 FERC ¶ 61,024 at P 66. *Id.*

²⁸⁰ CAISO Comments at 71–72.

²⁸¹ PJM Comments at 17–18.

²⁸² ISO-NE Comments at 25–26.

²⁷⁵ ANOPR, 176 FERC ¶ 61,024 at P 23.

²⁷⁶ ANOPR, 176 FERC ¶ 61,024 at P 23. *Id.*

transmission planning processes.²⁸³ MISO explains how its generator interconnection and regional transmission planning processes are currently related to each other and contends that the regional transmission planning process is the right avenue to determine more holistic transmission needs but considers the generator interconnection process more appropriate to focus on the specific needs associated with interconnecting new generation.²⁸⁴

158. Several commenters support better coordination between the regional transmission planning and cost allocation and generator interconnection processes, including the need for similar timelines and assumptions.²⁸⁵ Anbaric and Public Systems ask the Commission to require a regional transmission planning assessment if an interconnection study identifies significant interconnection-related network upgrades beyond the interconnection facility line needed to reach a substation and any directly interconnected substation upgrades to “shift the evaluation of development of needed upgrades to the [regional transmission] planning process.”²⁸⁶ Anbaric and Public Systems state that the needed upgrades could be eligible for competitive bidding as part of the regional transmission planning process. Similarly, Duke suggests that public utility transmission providers can identify an *ex ante* measure, such as the change in the levelized cost of a transmission network upgrade, to determine whether an interconnection-related network upgrade should be incorporated into its regional transmission plan for purposes of cost allocation according to a defined cost allocation method.²⁸⁷

159. Enel outlines a detailed proposal for consolidating the generator interconnection and regional transmission planning processes to limit generator interconnection studies to focus on direct, localized impacts of new generation and directly assign costs for interconnection-related network upgrades to generators when the cost causation relationship is “strong and

justified.”²⁸⁸ Under Enel’s proposal, interconnection requests that meet significant readiness criteria required by the public utility transmission provider, such as a non-refundable cash deposit or letter of credit in the amount of 100% of the costs of the “local” interconnection-related network upgrades, would be included in the regional transmission planning process after the public utility transmission provider conducts a basic interconnection study (e.g., Energy Resource Interconnection Study).²⁸⁹ AEE states that implementing Enel’s proposal would help resolve the cost allocation and market entry barrier problems associated with the current funding paradigm for interconnection-related network upgrades and could also help unburden constrained and backlogged interconnection queues that are creating barriers to entry.²⁹⁰

160. Other commenters oppose further coordination of the generator interconnection and regional transmission planning processes.²⁹¹ Some consumer groups express a general concern that coordination reforms would shift costs of generator interconnection to consumers.²⁹² Finally, some commenters expect that a regional transmission planning process that better accounts for anticipated future generation would address generator interconnection issues that are due to a lack of coordination, or co-optimization, of the two processes.²⁹³

(c) Need for Reform

161. For the reasons set forth below, we believe that there may be a need for better coordination between regional transmission planning and cost allocation and generator interconnection processes to ensure just and reasonable and not unduly discriminatory or preferential Commission-jurisdictional rates. As the Commission explained in the ANOPR, the interaction between regional transmission planning and cost allocation processes on the one hand and the generator interconnection

process on the other appears limited—the baseline regional transmission planning models generally only incorporate interconnection projects that have completed an interconnection facilities study, and are therefore near the end of the generator interconnection process.²⁹⁴ But where transmission system needs are repeatedly identified through generator interconnection processes, we believe that more efficient or cost-effective transmission expansion could be achieved through regional transmission planning and cost allocation that allocates costs in a manner that is at least roughly commensurate with estimated benefits and eliminates a potential barrier to entry for new generation resources.

162. We are most concerned with the prevalence of interconnection-related network upgrades being repeatedly identified in the generator interconnection process in multiple interconnection queue cycles in a short period of time (e.g., five years) but not being developed because the interconnection request(s) driving the need for the upgrade are all withdrawn. As explained above, there has been a dramatic increase in recent years in the level of spending on interconnection-related network upgrades, driving the cost of interconnecting new generation to the transmission system higher and higher.²⁹⁵ The evidence suggests that this trend is leading to more and more interconnection customers withdrawing their interconnection requests in the face of significant costs associated with interconnection-related network upgrades. According to a January 2021 report, “the high cost of interconnection is increasing the rate at which generators drop out of the interconnection queue.”²⁹⁶ For example, between January 2016 and July 2020, 245 generation projects in advanced stages in the MISO generator interconnection process withdrew from the queue, with the project developers citing high interconnection-related network upgrade costs as the primary reason for their withdrawal.²⁹⁷ While interconnection customers may choose to withdraw from the interconnection queue for a number of reasons, in recent

²⁸³ Enel Comments at 3.

²⁸⁴ Enel Comments, *Id.* attach. 1 (Plugging In) at 12. Enel proposes that the Transfer Distribution Factor is a good metric for determining electrical distance from a generation facility and what constitutes “local.” See Enel Comments, attach. 1 (Plugging In) *id.* at 6.

²⁸⁵ AEE Comments at 52–53.

²⁸⁶ Southern Comments at 38–39; US Chamber of Commerce Comments at 4; *see also* ACORE Comments at 26–27; APPA Comments at 22–23; Berkshire Comments at 10–11; CAISO Comments at 70; LPPC Comments at 18; ITC Comments at 31.

²⁸⁷ Industrial Customers Comments at 25; Consumer Organizations Comments at 26.

²⁸⁸ EEI Comments at 37; Exelon Comments at 33–34; Policy Integrity Comments at 27–28; Indicated PJM TOs Comments at 27.

²⁸⁹ ANOPR, 176 FERC ¶ 61,024 at P 23.

²⁹⁰ *Supra* section and Unreasonable and Unduly Discriminatory and Preferential Commission-Jurisdictional Rates (detailing the sharp rise in total investment in interconnection-related network upgrades along with the jump in the cost per kW for newly interconnecting generators to interconnect).

²⁹¹ ACEG Jan. 2021 Interconnection Report at 17.

²⁹² *Id.* (naming the high cost of interconnection-related network upgrades as the fundamental problem that interconnection queue reform has failed to address thus far).

²⁸³ NYISO Comments at 41; SPP Comments at 9–11.

²⁸⁴ MISO Comments at 75–76.

²⁸⁵ *See, e.g.*, AEP Comments at 30–31; APPA Comments at 22; Certain TDUs Comments at 18; NARUC Comments at 6, 11, 18; NERC Comments at 17–18; NewSun Comments at 24; Northwest and Intermountain Comments at 33; OMS Comments at 11–13; Indicated PJM TOs Comments at 27; REBA Comments at 2–3; SDG&E Comments at 5.

²⁸⁶ Anbaric Comments at 23; Public System Comments at 6–7, 19.

²⁸⁷ Duke Comments at 8–9.

years, the deciding factor has become the interconnection customer's "sticker shock" at its cost responsibility for interconnection-related network upgrades.²⁹⁸

163. When interconnection customers withdraw from the interconnection queue, the identified interconnection-related network upgrades associated with those interconnection customers remain unbuilt and the underlying interconnection-related needs go unaddressed. In many cases, when the interconnection-related need is not addressed via development of interconnection-related network upgrades in one interconnection queue cycle, the same interconnection-related need—and oftentimes the same or a substantially similarly interconnection-related network upgrade—will appear in interconnection studies for different interconnection requests or clusters in subsequent interconnection queue cycles. This scenario can occur even if subsequent interconnection requests or clusters vary considerably from previous interconnection requests or clusters in terms of size, fuel type, technical specifications, or location. One study, which analyzed 12 specific interconnection-related network upgrades identified by MISO and SPP, found that SPP identified three of the upgrades in two interconnection queue cycles and one in three interconnection queue cycles, and MISO identified three of the upgrades in two interconnection queue cycles and two in three interconnection queue cycles.²⁹⁹ In other words, both SPP and MISO were repeatedly identifying the same interconnection-related network upgrades as interconnection customers withdrew from the interconnection queue, leaving next-in-line interconnection customers to address the same interconnection-related needs.

164. Where interconnection-related needs are repeatedly identified in interconnection studies, the implication may be that the area, despite the potentially prohibitive interconnection costs, is otherwise desirable for generators to locate (*e.g.*, it is located close to fuel sources). At the same time, the recurrent need for an interconnection-related network upgrade is unlikely to go away without someone investing in the transmission system in that location. As interconnection customers that have invested time and resources in proposing a project, entering the interconnection queue, and engaging in the generator interconnection process

choose to withdraw rather than fund the interconnection-related network upgrades, it becomes more and more likely that it will never be economic for an interconnection customer (or small cluster of interconnection customers) to resolve the interconnection-related need.

165. At the same time, interconnection-related network upgrades can provide widespread transmission benefits that extend beyond the interconnection customer.³⁰⁰ As a result, planning these transmission upgrades exclusively through the generator interconnection process may result in a mismatch between the beneficiaries of the transmission upgrade and those to whom the costs are allocated. In other words, by upgrading the transmission system in a piecemeal fashion through the generator interconnection process, the current transmission planning paradigm appears to impose costs on interconnection customers for transmission facilities that would provide benefits beyond those received by the interconnection customer. This paradigm can present a potential barrier to entry for new generation resources that might otherwise be economic if not for the cost of interconnection-related network upgrades. We believe that reforms may be necessary to allow for the consideration of transmission facilities to meet interconnection-related needs repeatedly identified in the generator interconnection process through Long-Term Regional Transmission Planning and Cost Allocation process instead, which we believe would result in more efficient or cost-effective transmission expansion, cost allocation for such transmission facilities that is at least roughly commensurate with estimated benefits, and elimination of a barrier to entry for new generation resources. In turn, we expect that these reforms would ensure just and reasonable and not unduly discriminatory or preferential Commission-jurisdictional rates.

(d) Proposed Reform

166. We propose to require that public utility transmission providers consider

³⁰⁰ See, *e.g.*, CAISO Comments at 52–53 (stating that in CAISO "transmission facilities at 200 kV and above are eligible for regional cost allocation," including location-constrained resources interconnection facilities, because "this voltage threshold . . . recognizes that high voltage transmission facilities support and provide benefits to all customers to the CAISO grid"); Order No. 2003, 104 FERC ¶ 61,103 at P 65 (stating that "[f]acilities beyond the Point of Interconnection [*i.e.*, interconnection-related network upgrades] are part of the Transmission Provider's Transmission System and benefit all users"); ACORE Comments, Ex. 5, at 4–7.

in their Long-Term Regional Transmission Planning regional transmission facilities that address certain interconnection-related needs that the public utility transmission provider has identified multiple times in the generator interconnection process but that have never been constructed due to the withdrawal of the underlying interconnection request(s). In particular, we propose to require that public utility transmission providers evaluate for selection in the regional transmission plan for purposes of cost allocation regional transmission facilities to address interconnection-related needs that have been identified in the generator interconnection process as requiring interconnection-related network upgrades where: (1) The public utility transmission provider has identified interconnection-related network upgrades in interconnection studies to address those interconnection-related needs in at least two interconnection queue cycles during the preceding five years (beginning at the time of the withdrawal of the first underlying interconnection request); (2) the interconnection-related network upgrade identified to meet those interconnection-related needs has a voltage of at least 200 kV and/or an estimated cost of at least \$30 million; (3) those interconnection-related network upgrades have not been developed and are not currently planned to be developed because the interconnection request(s) driving the need for the upgrade has been withdrawn; and (4) the public utility transmission provider has not identified an interconnection-related network upgrade to address the relevant interconnection-related need in an executed generator interconnection agreement or in a generator interconnection agreement that the interconnection customer requested that the public utility transmission provider file unexecuted with the Commission.

167. We propose to require that public utility transmission providers in each transmission planning region consider regional transmission facilities to address interconnection-related needs pursuant to this reform through the proposed Long-Term Regional Transmission Planning. We recognize that the Long-Term Regional Transmission Planning proposal requires that public utility transmission providers incorporate interconnection queue withdrawals into Long-Term Scenario development. Consequently, we propose to require that public utility transmission providers in each transmission planning region incorporate the specific

²⁹⁸ See ACORE Comments at 12.

²⁹⁹ ICF Sept. 2021 Report at 25–26.

interconnection-related needs identified through this reform as a factor used to develop Long-Term Scenarios.

168. We preliminarily find that this requirement will support the establishment of just and reasonable and not unduly discriminatory or preferential Commission-jurisdictional rates by addressing a potential barrier to integrating new sources of generation that may otherwise continue to exist absent such requirements in the regional transmission planning process.

Additionally, to the extent that such transmission facilities are selected in the regional transmission plan for purposes of cost allocation, this proposal would provide an avenue to allocate these regional transmission facilities' costs more broadly in recognition of their more widespread benefits (as identified through the regional transmission planning process), helping to ensure that their costs are allocated in a manner that is at least roughly commensurate with the estimated benefits that they provide. We believe that the criteria proposed above that the public utility transmission provider must use to identify the interconnection-related needs that should be considered in the regional transmission planning process will help to ensure that the associated interconnection-related network upgrades are likely to have produced benefits beyond those provided to the interconnection customers whose interconnection requests the interconnection-related network upgrades are needed to accommodate. It is important to note that we are not proposing that all interconnection-related needs that satisfy the above criteria must result in transmission facilities being selected in the regional transmission plan for purposes of cost allocation; rather, those regional transmission facilities would have to independently satisfy the criteria for such selection in Long-Term Regional Transmission Planning as the more efficient or cost-effective transmission facility.

169. As noted above, we propose that the first qualifying criterion for this potential reform is that the public utility transmission provider has identified a needed interconnection-related network upgrade in generator interconnection studies to address the same interconnection-related need in at least two interconnection queue cycles during the preceding five years. The five-year look-back for each interconnection-related need would begin on the date that an interconnection customer with an interconnection study that identifies an

interconnection-related network upgrade that meets the voltage or cost estimate threshold withdraws its interconnection request.³⁰¹ We propose to choose this starting point because, arguably, this is the earliest point at which the transmission provider will have notice that the costs associated with an identified interconnection-related network upgrade may have caused a withdrawal. We also believe that this criterion appropriately limits the scope of this requirement to those interconnection-related needs that are likely to persist, are not unique to a single interconnection customer's request, and have the potential, if evaluated through the regional transmission planning process, to provide more widespread benefits to transmission customers.

170. We propose that the initial five-year time period begin five calendar years prior to the initial effective date of the accepted tariff provisions proposed to comply with this reform. Thus, upon the acceptance of such tariff provisions in a Commission or delegated letter order, the public utility transmission provider would consider interconnection-related network upgrades identified to address the same interconnection-related need in at least two interconnection queue cycles in the five calendar years prior to the effective date established in the order accepting those tariff revisions. Thus, if the Commission adopts this proposal, the public utility transmission provider should not look back to a point earlier than that date and, going forward, this requirement would apply to any repeat identification of an interconnection-related need identified in at least two interconnection queue cycles in the immediately preceding five calendar years. We believe that such a limitation would prevent consideration of regional transmission facilities (more specifically, interconnection-related network upgrades) identified using data that may be stale by the time the public utility transmission providers in a transmission planning region consider regional transmission facilities to address the identified interconnection-

³⁰¹ We propose that when an interconnection-related network upgrade is identified for the interconnection of more than one interconnection customer in an interconnection queue cycle, the withdrawal of all interconnection customers assigned to that interconnection-related network upgrade qualifies as one withdrawal. The withdrawal of a single interconnection customer when other interconnection customers assigned to the interconnection-related network upgrade remain in the interconnection queue cycle does not qualify as a withdrawal of an interconnection queue interconnection request for the purposes of this reform.

related needs in their regional transmission planning process. We believe that five years is short enough to provide public utility transmission providers with accurate information on interconnection-related needs and also long enough for public utility transmission providers to identify the same interconnection-related need, which is likely to persist, in at least two interconnection queue cycles.

171. We do not propose to limit this reform to interconnection-related network upgrades that are identical to those identified in prior interconnection queue cycles. Instead, we propose to focus on the relevant interconnection-related needs that those upgrades are intended to address. To this point, we propose to require that public utility transmission providers in each transmission planning region consider whether the interconnection-related need for which the public utility transmission provider identified the interconnection-related network upgrade is the same in multiple interconnection queue cycles. That is, if an interconnection-related need is driving the identification of an interconnection-related network upgrade on the transmission system in one interconnection queue cycle and an interconnection-related network upgrade with, for example, a different voltage, starting point, or ending point is identified in the next interconnection queue cycle to address the same interconnection-related need, then the first criterion would be satisfied. We believe that this approach will appropriately account for differences in technology, study assumptions, system topology, and/or interconnection requests that may occur over time that may result in different interconnection-related network upgrades to address the same interconnection-related need.

172. We also propose to limit the scope of this reform to those interconnection-related network upgrades that have a voltage of at least 200 kV and/or an estimated cost of at least \$30 million. We note that we have previously found a 200 kV voltage threshold to be just and reasonable in the context of an analogous provision in CAISO's tariff.³⁰² With respect to the

³⁰² Section 24.4.6.5 of CAISO's Comprehensive Transmission Planning Process provides that interconnection-related network upgrades identified in the generator interconnection process that are not already included in a signed LGIA may be assessed in the Comprehensive Transmission Planning Process if they "consist of new transmission lines 200 kV or above, and have capital costs of \$100 million or greater; . . . [are] a new 500 kV substation that has capital costs of \$100 million or greater; or, . . . have a capital cost

\$30 million estimated cost threshold, evidence suggests that requiring interconnection customers to be responsible for this level of costs from a single interconnection-related network upgrade can lead to withdrawal from the interconnection queue, signaling that this level may be an appropriate dividing line for consideration in regional transmission planning processes.³⁰³

173. To avoid shifting costs inappropriately from generators in the generator interconnection process to transmission customers through the regional transmission planning process, we further propose to limit the scope of interconnection-related needs to be considered in the regional transmission planning process to those interconnection-related needs not addressed by interconnection-related network upgrades memorialized in an executed generator interconnection agreement (or in a generator interconnection agreement that the interconnection customer requested to be filed unexecuted with the Commission). This proposed limitation would ensure that public utility transmission providers only consider in their regional transmission planning process interconnection-related network upgrades that remain unconstructed despite the existence of a demonstrated interconnection-related need. We reiterate that regional transmission facilities identified through this process would have to independently satisfy the public utility transmission provider's criteria for selection in the regional transmission plan for purposes of cost allocation as the more efficient or cost-effective transmission solution.

of \$200 million or more." CAISO, Tariff, section 24.4.6.5 (LGIP Network Upgrades) (1.0.0).

³⁰³ The ACEG Report notes that 3.5 of 5 GW of renewable energy projects in the MISO West 2017 study group dropped out because each project "faced transmission costs in the range of tens to hundreds of millions of dollars." ACEG Report See Americans for a Clean Energy Grid, *Disconnected: The Need for New Generator Interconnection Policy*, at 17. (Jan. 2021). We also note that the ICF Report indicates that the Wichita-Benton 345 kV line in SPP South, which has appeared in two different interconnection queue cycles and has not been constructed, has an estimated cost of \$32.1 million. See ICF Report Resources, LLC, *Just & Reasonable? Transmission Upgrades Charged to Interconnection Generators are Delivering System-Wide Benefits*, at 5, 26. (Sep. 2021). As a further reference point, wind and solar industry advocates claim that "the 'implied cost threshold' beyond which new generators are often no longer financially viable is . . . an average of about \$100,000 per megawatt of installed capacity." See American Wind Energy Association, Clean Grid Alliance, and SELA, *Generator Contributions to Transmission Expansion*, at 2 (August 2020), https://cleangridalliance.org/uploads/media/uploads/source/Generator_Contrib_Xmission-V3a-FINAL.pdf.

174. We seek comment on the requirements proposed in this section of the NOPR. In particular, we seek comment on whether this proposed reform could delay the processing of existing interconnection queues and what reforms, if any, would be necessary to ensure that the generator interconnection and regional transmission planning processes are not significantly delayed by this proposed reform. We also seek comment on the appropriateness of the criteria that we propose a public utility transmission provider must use to identify the interconnection-related needs that should be considered in the regional transmission planning process, and whether there are alternative criteria public utility transmissions providers may use to identify significant interconnection-related needs that warrant consideration in the regional transmission planning process. Finally, we seek comment on how this proposed reform should interact with existing regional transmission planning processes and the Long-Term Regional Transmission Planning proposed herein.

iii. Evaluation of the Benefits of Regional Transmission Facilities

175. As discussed above, we propose to require that public utility transmission providers in each transmission planning region identify transmission needs driven by changes in the resource mix and demand using Long-Term Scenarios that meet the requirements proposed above. As explained in this section, once the public utility transmission providers in a transmission planning region have identified the region's transmission needs driven by changes in the resource mix and demand, we propose to require that, as part of public utility transmission providers' identification and evaluation of more efficient or cost-effective regional transmission facilities that may resolve those transmission needs in the regional transmission planning process, public utility transmission providers must: (1) Evaluate the benefits of regional transmission facilities to meet identified transmission needs driven by changes in the resource mix and demand, identify which benefits they will use in Long-Term Regional Transmission Planning, explain how they will calculate those benefits, and explain how the benefits will reasonably reflect the benefits of regional transmission facilities to meet identified transmission needs driven by changes in the resource mix and demand; and (2) evaluate the benefits of regional transmission facilities over a time horizon that covers, at a minimum,

20 years starting from the estimated in-service date of the transmission facilities. Further, we propose to allow (but not require) public utility transmission providers to evaluate the benefits of a portfolio of regional transmission facilities instead of doing so on a facility-by-facility basis. Finally, we identify and describe a broad set of benefits that we believe public utility transmission providers could consider using in Long-Term Regional Transmission Planning (Long-Term Regional Transmission Benefits) to reasonably capture the benefit of regional transmission facilities to meet identified transmission needs driven by changes in the resource mix and demand.

(a) Evaluations of Long-Term Regional Transmission Benefits

176. In Order No. 1000, the Commission neither prescribed a particular definition of "benefits" or "beneficiaries," nor required consideration of any specific benefits. Instead, the Commission stated that the proper context for consideration of such matters would be on review of compliance proposals.³⁰⁴ The Commission stated that allowing greater flexibility to accommodate a variety of approaches better advanced the goals of Order No. 1000.³⁰⁵ The Commission also stated that, in determining the beneficiaries of transmission facilities, a regional transmission planning process could consider benefits including, but not limited to, the extent to which transmission facilities, individually or in the aggregate, provide for maintaining reliability and sharing reserves, production cost savings and congestion relief, and/or meeting Public Policy Requirements.³⁰⁶ The result is that there are no specific requirements for public utility transmission providers to consider any particular benefit or set of benefits in evaluating transmission facilities for selection in the regional transmission plan for purposes of cost allocation as the more efficient or cost-effective solution to a regional transmission need.

177. In the ANOPR, the Commission sought comment on whether the Commission should require public utility transmission providers to use a minimum set of benefits to identify more efficient or cost-effective regional transmission facilities, and what those benefits should be.³⁰⁷ The Commission

³⁰⁴ Order No. 1000, 136 FERC ¶ 61,051 at P 624.

³⁰⁵ *Id.* PP 624–625.

³⁰⁶ *Id.* P 622.

³⁰⁷ ANOPR, 176 FERC ¶ 61,024 at P 53.

sought comment as to whether the existing regional transmission planning and cost allocation processes fully accounted for the full suite of benefits, including hard-to-quantify benefits. Further, the Commission sought comment on the types of benefits provided by transmission facilities needed to meet the transmission needs of the changing resource mix, as well as the manner in which those benefits can be quantified, if at all. The Commission also sought comment on how public utility transmission providers can document and account for benefits if those benefits cannot be quantified, but are real.³⁰⁸

(1) Comments

178. Many commenters support consideration of a wider set of benefits than those currently used to evaluate transmission facilities for potential selection in the regional transmission plan for purposes of cost allocation.³⁰⁹ Further, many commenters support the consideration of all possible benefits of regional transmission facilities when discussing benefits in the context of the current approach to separately consider reliability, economic, and public policy benefits—however, even some commenters that support maintaining the Order No. 1000 framework acknowledge that the benefits assessed could be expanded.³¹⁰ Commenters that support requiring consideration of an expanded set of transmission benefits argue that existing regional transmission

planning processes are unjust and unreasonable because they ignore the full range of transmission benefits and therefore fail to select net beneficial transmission facilities, leading to underinvestment in transmission and higher consumer costs in the long run.³¹¹ PIOs assert that the Commission should conduct a survey of all potential benefits that can result from multi-value, scenario-based planning and should require that public utility transmission providers consider those benefits for regional transmission planning.³¹² Numerous commenters point to a list of transmission benefits identified by The Brattle Group as providing a useful framework for delineating a minimum set of benefits that the Commission could require public utility transmission providers to consider when evaluating alternative regional transmission facilities.³¹³

179. Many commenters generally request regional flexibility to consider benefits. Ameren opposes requiring a specific set of benefits, arguing that such a reform could lead to controversy and delays.³¹⁴ Consumer Organizations and District of Columbia's Office of the People's Counsel express that, if additional benefits are added to the equation, additional costs to communities and landowners (for example, additional farm production costs, local road use, and local emergency services) should be, too.³¹⁵ Consumer Organizations and LPPC assert that it is not within the Commission's authority to create "new speculative benefits" in an effort to broaden cost allocation.³¹⁶ District of Columbia's Office of the People's Counsel urges that greater specificity is needed regarding what is a benefit.³¹⁷ APPA does not support considering environmental benefits associated with particular types of resources in planning

transmission facilities and allocating costs.³¹⁸

180. MISO states that it has adopted benefit metrics such as avoided/deferred reliability projects and reduced MISO-SPP settlement costs that go beyond adjusted production cost savings. However, MISO states that it has not been able to adopt other metrics explored in the stakeholder process, including: (1) Transmission outage and transmission energy losses; and (2) reduced capacity cost due to reduced peak load losses and future capacity expansion deferral due to increased capacity import and export limits.³¹⁹ MISO seeks flexibility on benefits that are considered to reflect changing circumstances but calls for direction or guidance from the Commission on identification and quantification of challenging benefits like resilience.³²⁰

181. NYISO supports identifying economic benefits when studying reliability projects. NYISO states that the current economic calculation is based on net production cost savings and does not consider other economic benefits such as installed capacity cost savings to load-serving entities.³²¹

182. The PJM Market Monitor claims that PJM incorrectly defines the benefits of proposed market efficiency transmission projects, resulting in uneconomic transmission upgrades. In particular, the PJM Market Monitor argues that PJM uses speculative transmission-related benefits over a 15-year period while limiting the analysis to the existing generation fleet and existing patterns of fuel costs and congestion, which eliminates the possibility that new generation could respond to market signals and meet the same needs.³²² The PJM Market Monitor cautions against considering congestion reduction or localized locational marginal price reductions as an economic benefit to a potential transmission project without accurately

³⁰⁸ *Id.* P 70.

³⁰⁹ ACOE Comments at ii; AEE Comments at 31–32; ACEG Comments at 6–8; ACPA and ESA Comments at 75; AEP Comments at 14; Amazon Comments at 4; Anbaric Comments at 29; Avangrid Comments at 9; Business Council for Sustainable Energy Comments at 2; Citizens Energy Comments at 6–7; City of New York Comments at 3–4; Union of Concerned Scientists Comments at 66–75; Consumers Council Comments at 4, 16; Duke Comments at 12; EDF Comments at 8–10; EEI Comments at 33; ITC Comments at 28–34; Massachusetts Attorney General Comments at 24–25; New Jersey Commission at 13–14, 17–19; NextEra Comments at 83–88; Northwest and Intermountain Comments at 35–38; Orsted Comments at 6–7; PIOs Comments at 30, 60; Policy Integrity Comments at 43; PSEG Comments at 25–27; REBA Comments at 17; RMI Comments at 4; SEIA Comments at 9; Shell Comments at 18–20; State Agencies Comments at 21–22; State of Massachusetts Comments at 16–17; U.S. DOE Comments at 7–9, 23–24; WIRES Comments at 18; *see also Joint Fed.-State Task Force on Elec. Transmission*, Transcript of Feb. 16, 2022 Meeting, Docket No. AD21–15–000, at 19:15–18, 22:9–12 (Comm'r Rechtschaffen) (supporting expanded list of benefits and arguing that a more comprehensive benefit-cost analysis would lead to better transmission planning).

³¹⁰ City of New York Comments at 7; PIOs Comments at 81–82; EEI Comments at 24–25; PG&E Comments at 8–9; Anbaric Comments at 29; Union of Concerned Scientists Comments at 38; State of Massachusetts Comments at 16–19; Orsted Comments at 6–7; RMI Comments at 4.

³¹¹ *See, e.g.*, ACEG Comments at 31–32 & app. A; ACOE Comments at 31–32 & Ex. 6; ACPA and ESA Comments at 24–27; NextEra Comments at 84–86; PIOs Comments at 82; PIOs Reply Comments at 55.

³¹² PIOs Comments at 30; *see also* Orsted Comments at 6.

³¹³ *See, e.g.*, ACEG Comments at 34 & app. A; ACOE Comments at 34 & Ex. 6; ACPA and ESA Comments at 24–26; EDF Comments at 9; NextEra Comments at 84–86; PIOs Comments at 34 & Ex. A; RMI Comments at 4; U.S. DOE Comments at 37; WIRES Comments at 2; ACEG Reply Comments at 11; Enel Reply Comments at 3–4; PIOs Reply Comments at 55; *see also* February Joint Task Force Tr 49:8–13 (Ted Thomas) (stating that The Brattle Group list of benefits is "characterized by rigor").

³¹⁴ Ameren Comments at 9–11.

³¹⁵ Consumer Organizations Comments at 18–19; District of Columbia's Office of the People's Counsel Comments at 26–27.

³¹⁶ Consumer Organizations Comments at 18; LPPC Comments at 20–23.

³¹⁷ District of Columbia's Office of the People's Counsel Comments at 3–4.

³¹⁸ APPA Comments at 15–16.

³¹⁹ MISO Comments at 23–26.

³²⁰ *Id.* at 52–53; *see also* February Joint Task Force Tr 20:5–8, 21:4–12 (Clifford Rechtschaffen) (suggesting that the reliability category should be expanded to include resilience, particularly in light of extreme events in the West and increasingly intense hurricanes in the East), 51:10–15 (Matthew Nelson) (stating that having commonality in terminology for benefits and where they are considered would be valuable), 69:16–18 (Jason Stanek) (concluding that if there is a fourth category of benefits, it may be resilience), 73:1–4 (Riley Allen) (arguing for not ignoring difficult to quantify benefits but rather for finding sensible ways to quantify them).

³²¹ NYISO Comments at 27–31, 34–37; *see also* February Joint Task Force Tr 20:9–12 (Clifford Rechtschaffen) (advocating for expanding the economic category to include improved connectivity to lower-cost generation).

³²² PJM Market Monitor Comments at 10.

accounting for how the congestion dollars are or are not returned to load through the financial transmission rights (or their equivalent).³²³

(2) Proposed Reform

183. At this time, consistent with Order No. 1000, we decline to propose to prescribe any particular definition of “benefits” or “beneficiaries,” nor require use of any specific benefits.³²⁴ Instead, we continue to acknowledge the benefits of regional flexibility, and consistent with Order No. 1000, propose to consider such matters on review of compliance proposals.³²⁵ Nevertheless, we acknowledge the support for the adoption of a common set of minimum benefits, and we propose a list of Long-Term Regional Transmission Benefits described below that public utility transmission providers may consider in Long-Term Regional Transmission Planning and cost allocation processes. In addition, we propose to require that public utility transmission providers identify on compliance the benefits they will use in Long-Term Regional Transmission Planning, how they will

calculate those benefits, and how the benefits will reasonably reflect the benefits of regional transmission facilities to meet identified transmission needs driven by changes in the resource mix and demand. As part of this compliance obligation, public utility transmission providers should explain the rationale for using the benefits identified.

184. We believe that the Long-Term Regional Transmission Benefits discussed below account for many of the benefits that regional transmission facilities to address transmission needs driven by changes in the resource mix and demand identified as part of Long-Term Regional Transmission Planning are most likely to provide. However, we clarify that this list of potential benefits is not mandatory or exhaustive and public utility transmission providers would have flexibility to propose what benefits to use as part of their Long-Term Regional Transmission Planning. For example, public utility transmission providers may wish to use benefits previously accepted by the Commission for existing regional transmission

planning processes that are not included in the Long-Term Regional Transmission Benefits discussed herein.

185. We believe that the following set of Long-Term Regional Transmission Benefits may be useful in evaluating transmission facilities for selection in the regional transmission plan for purposes of cost allocation as the more efficient or cost-effective solutions to meet transmission needs driven by changes in the resource mix and demand: (1) Avoided or deferred reliability transmission projects and aging infrastructure replacement; (2) either reduced loss of load probability or reduced planning reserve margin; (3) production cost savings; (4) reduced transmission energy losses; (5) reduced congestion due to transmission outages; (6) mitigation of extreme events and system contingencies; (7) mitigation of weather and load uncertainty; (8) capacity cost benefits from reduced peak energy losses; (9) deferred generation capacity investments; (10) access to lower-cost generation; (11) increased competition; and (12) increased market liquidity.

TABLE 1—LONG-TERM REGIONAL TRANSMISSION BENEFITS

Benefit	Description
Avoided or deferred reliability transmission facilities and aging transmission infrastructure replacement.	Reduced costs of avoided or delayed transmission investment otherwise required to address reliability needs or replace aging transmission facilities.
Reduced loss of load probability [OR next benefit]	Reduced frequency of loss of load events by providing additional pathways for connecting generation resources with load (if planning reserve margin is constant), resulting in benefit of reduced expected unserved energy by customer value of lost load.
Reduced planning reserve margin [OR prior benefit]	While holding loss of load probabilities constant, system operators can reduce their resource adequacy requirements (<i>i.e.</i> , planning reserve margins), resulting in a benefit of reduced capital cost of generation needed to meet resource adequacy requirements.
Production cost savings	Reduction in production costs, including savings in fuel and other variable operating costs of power generation, that are realized when transmission facilities allow for the increased dispatch of suppliers that have lower incremental costs of production, displacing higher-cost supplies; also reduction in market prices as lower-cost suppliers set market clearing prices; when adjusted to account for purchases and sales outside the region, called adjusted production cost savings.
Reduced transmission energy losses	Reduced energy losses incurred in transmittal of power from generation to loads, thereby reducing total energy necessary to meet demand.
Reduced congestion due to transmission outages	Reduced production costs during transmission outages that significantly increase transmission congestion.
Mitigation of extreme events and system contingencies	Reduced production costs during extreme events, such as unusual weather conditions, fuel shortages, and multiple or sustained generation and transmission outages, through more robust transmission system reducing high-cost generation and emergency procurements necessary to support the system.
Mitigation of weather and load uncertainty	Reduced production costs during higher than normal load conditions or significant shifts in regional weather patterns.
Capacity cost benefits from reduced peak energy losses	Reduced energy losses during peak load reduces generation capacity investment needed to meet the peak load and transmission losses.
Deferred generation capacity investments	Reduced costs of needed generation capacity investments through expanded import capability into resource-constrained areas.

³²³ *Id.* at 11.

³²⁴ See Order No. 1000, 136 FERC ¶ 61,051 at PP 624–625.

³²⁵ See *id.* P 624.

TABLE 1—LONG-TERM REGIONAL TRANSMISSION BENEFITS—Continued

Benefit	Description
Access to lower-cost generation	Reduced total cost of generation due to ability to locate units in a more economically efficient location (e.g., low permitting costs, low-cost sites on which plants can be built, access to existing infrastructure, low labor costs, low fuel costs, access to valuable natural resources, locations with high-quality renewable energy resources).
Increased competition	Reduced bid prices in wholesale electricity markets due to increased competition among generators and reduced overall market concentration/market power.
Increased market liquidity	Reduced transaction costs (e.g., bid-ask spreads) of bilateral transactions, increased price transparency, increased efficiency of risk management, improved contracting, and better clarity for long-term transmission planning and investment decisions through increased number of buyers and sellers able to transact with each other as a result of transmission expansion.

186. Below, we describe each benefit along with examples of how each benefit may be calculated. We clarify that these are just examples, and we are not proposing to require that public utility transmission providers use any specific benefits or calculate those benefits in a particular manner when conducting Long-Term Regional Transmission Planning. At this time, we are only proposing to require public utility transmission providers to identify what benefits they will use in Long-Term Regional Transmission Planning and explain how they will be calculated and how the benefits will reasonably reflect the benefits of regional transmission facilities to meet identified transmission needs driven by changes in the resource mix and demand.

187. We seek comment on each of the Long-Term Regional Transmission Benefits discussed in this section of the NOPR. Additionally, we seek comment on how to ensure that each type of benefit is distinct such that the list of benefits does not “double count” benefits. We also seek comment on the application of the Long-Term Regional Transmission Benefits in non-RTO/ISO regions.

188. Finally, we seek comment on whether public utility transmission providers should be required to use some or all of the Long-Term Regional Transmission Benefits as a minimum set of benefits for their Long-Term Regional Transmission Planning process.

(3) Description of Long-Term Regional Transmission Benefits

189. The benefits of transmission facilities identified in Long-Term Regional Transmission Planning may include a set of benefits related to avoided or deferred reliability transmission facilities and aging transmission infrastructure replacement, which we describe as reduced costs on

avoided or delayed transmission investment otherwise required to address reliability needs or replace aging transmission facilities. The Commission has recognized that regional transmission planning could lead to the development of transmission facilities that span the service territories of multiple public utility transmission providers, which in turn would obviate the need for transmission facilities that would otherwise be identified in multiple local transmission plans.³²⁶

190. The Commission has accepted accounting for such “avoided costs” as part of a method for identifying beneficiaries and allocating costs in almost all the regional cost allocation methods in non-RTO/ISO regions. Using this method, public utility transmission providers in a transmission planning region determine the beneficiaries of a regional transmission facility or portfolio of facilities by identifying the local and regional transmission facilities that a new proposed regional transmission facility or portfolio of facilities would displace. The method defines the benefits of the regional transmission facility or facilities as the costs that public utility transmission providers in the transmission planning region “avoid” because they no longer need to build the displaced local and regional transmission facilities. The method allocates costs among public utility transmission providers whose local or regional transmission facilities the new proposed regional transmission facility or facilities would displace in proportion to their share of the total benefits (i.e., the total avoided costs). If the new proposed regional transmission facility or facilities do not displace any local or regional transmission facilities in existing local or regional transmission plans, the avoided cost method determines the benefits of the

applicable facilities by considering the costs of local or regional transmission facilities that would otherwise be needed to meet the same need that the new proposed regional transmission facility will meet.³²⁷

191. In calculating this benefit, public utility transmission providers in each transmission planning region could first identify transmission facilities that could defer or replace an identified reliability transmission solution. Avoided cost benefits could be calculated by comparing the cost of transmission facilities required to address the reliability need without the proposed regional transmission facility to the cost of transmission facilities needed to address the reliability need assuming the regional transmission solution were in place.³²⁸

192. Similarly, this benefit could also include the separate benefits stream caused by a deferral of replacement of other transmission facilities through identification and selection for purposes of cost allocation in the regional transmission plan of a transmission facility or facilities. This could be measured through calculation of the present value savings for the period of deferral of additional replacement transmission facilities multiplied by their estimated capital cost.

193. A number of public utility transmission providers already evaluate the avoided or deferred costs of reliability transmission projects. For example, SPP uses a power flow model to analyze the ability of potential economic and Public Policy transmission facilities to meet the same thermal reliability needs addressed by a potential reliability transmission facility. The costs of these avoided or delayed reliability transmission

³²⁷ See, e.g., *S.C. Elec. & Gas Co.*, 143 FERC ¶ 61,058, at P 232 (2013).

³²⁸ Brattle-Grid Strategies Oct. 2021 Report at 37.

³²⁶ Order No. 1000, 136 FERC ¶ 61,051 at P 81.

facilities are used to determine the reliability benefit of the potential economic or Public Policy Requirements transmission facilities.³²⁹ Public utility transmission providers could also use avoided costs to calculate the benefits of replacing aging transmission facilities. NYISO, for example, estimates the benefits associated with the replacement of aging transmission facilities by quantifying the savings of not having to refurbish the facilities in the future.³³⁰

194. Another potential benefit of regional transmission infrastructure is reduced frequency of loss of load events by providing additional pathways for connecting generation resources with load in regions that can be constrained by weather events and unplanned outages (if planning reserve margin is not changed despite lower loss of load events), as well as improved physical reliability benefits by reducing the likelihood of load shed events; or reduced planning reserve margin, which we propose to define as the reduction in capital costs of generation needed to meet resource adequacy requirements (*i.e.*, planning reserve margins) while holding loss of load probability constant. There is an overlap between reduced loss of load probability benefits and reduced planning reserve margin benefits, such that a single transmission facility can either reduce loss of load events if the planning reserve margin is unchanged or allow for the reduction in planning reserve margins if loss of load events remain constant, but not both simultaneously.

195. As for reduction in loss of load probability benefits, transmission investments, even those not made to satisfy a reliability need, generally enhance the reliability of the transmission system by increasing transfer capability, which, in turn, reduces the likelihood that a public utility transmission provider will be unable to serve its load due to a shortage of generation over a given period. This enhancement in reliability can be measured as a reduction in loss of load probability, or the likelihood of system demand exceeding generation over a given period. One example of how a reduction of loss of load probability benefit could be calculated can be found in a report by SPP's Metrics Task Force. The report proposes quantifying the incremental increase in system reliability by determining the reduction in expected unserved energy between

the base case and the change case, obtaining the value of lost load, and multiplying these two values to obtain the monetary benefit of enhanced reliability associated with a transmission expansion.³³¹

196. A lower planning reserve margin requirement is another way to demonstrate a resource adequacy benefit. Investments in transmission capacity can reduce the system-wide planning reserve margin requirement of the system-wide or reserve margin requirement within individual resource adequacy zones of a transmission planning region, which can reduce the need for generation capital expenditures. It is important to note that, due to the overlap between the benefit obtained from a reduction in reserve margin requirements and the benefit associated with loss of load probability, only one of these benefits should be calculated for a transmission investment, but not both simultaneously.

197. RTOs/ISOs have calculated the transmission benefits of reduced planning reserve margins. MISO, for example, calculated a reduction in planning reserves associated with its MVP portfolio, which reduced the need for future generation buildout to meet reserve requirements, by using loss of load expectation reliability simulations. MISO estimated that its MVP portfolio was expected to reduce the required planning reserve margin by up to one percentage point, which translated into a projected savings of \$1.0 to \$5.1 billion in benefits over 10 years.³³²

198. Another potential benefit of regional transmission infrastructure is production cost savings, which we describe as savings in fuel and other variable operating costs of power generation that are realized when transmission facilities allow for displacement of higher-cost supplies through the increased dispatch of suppliers that have lower incremental costs of production, as well as a reduction in market prices as lower-cost suppliers set market clearing prices.³³³

199. Most regional transmission planning processes currently estimate production cost savings. Generally, within RTOs/ISOs, security-constrained production cost models simulate the hourly operations of the electric system

and the wholesale electricity market by emulating how system operators would commit and dispatch generation resources to serve load at least cost, subject to transmission and operating constraints. The traditional method for estimating the changes in adjusted production costs associated with proposed transmission facilities (or portfolio of facilities) is to compare the adjusted production costs with and without those facilities. Analysts typically call the market simulations without the proposed transmission facilities the "Base Case" and the simulations with those facilities the "Change Case."

200. Approaches used to calculate production cost savings vary. MISO uses production cost savings (adjusted for import costs and export revenues) to allocate the costs of its Market Efficiency Projects to cost allocation zones based on each zone's share of the total adjusted production cost savings.³³⁴ NYISO and PJM, in contrast, use reductions to load energy payments (adjusted to reflect the reduced value of transmission congestion contracts) to allocate the costs of economic transmission facilities.³³⁵

201. Non-RTO/ISO regions, without centrally organized energy markets, rely on other tools to perform analyses of production cost savings. For example, WestConnect's regional cost allocation method for regional transmission facilities driven by economic considerations identifies the benefits and beneficiaries of a proposed regional transmission facility or facilities by modeling the potential of the transmission facilities to support more economic bilateral transactions between generators and loads in the region. Specifically, WestConnect considers the transactions between loads and lower-cost generation that a proposed regional transmission facilities could support and, accounting for the costs associated with transmission service, identifies the transactions that are likely to occur. WestConnect then estimates any resulting cost savings (in the form of reductions in production costs and reserve sharing requirements) and

³³⁴ See MISO, FERC Electric Tariff, Attach. FF, Benefit Metrics § (I)(A)(1) (33.0.0).

³³⁵ See *PJM Interconnection L.L.C.*, 142 FERC ¶ 61,214, at P 416 (2013) (PJM First Regional Compliance Order); *New York Independent System Operator Corp.*, 143 FERC ¶ 61,059 at PP 268, 269, n.516 (2013) (NYISO First Regional Compliance Order); NYISO, NYISO Tariffs, OATT, attach. Y, § 31.5 (27.0.0), § 31.5.4.3.2. For high voltage economic transmission facilities, PJM allocates 50% of the costs in accordance with its economic analysis and allocates the other 50% of the costs on a load-ratio share basis.

³³¹ SPP, *Benefits for the 2013 Regional Cost Allocation Review*, at 25 (Sept. 13, 2012).

³³² MISO, *Proposed Multi Value Project Portfolio: Business Case Workshop*, at 36–38 (Sept. 19 & 29, 2011).

³³³ When this calculation is adjusted to account for purchases and sales outside the region, we propose to define this as adjusted production cost savings.

³²⁹ SPP *Benefit Metrics Manual*, SPP Engineering, at 15 (Nov. 6, 2020).

³³⁰ The Brattle Group, *Benefit-Cost Analysis of Proposed New York AC Transmission Upgrades*, The Brattle Group, at 114 (Sept. 15, 2015).

allocates the costs of the regional transmission facilities on that basis.³³⁶

202. Another set of potential benefits of regional transmission infrastructure is benefits related to reduced transmission energy losses, which we describe as reduced total energy necessary to meet demand stemming from reduced energy losses incurred in transmittal of power from generation to loads. These benefits include the reduced energy losses incurred when transmitting power from generation to loads.

203. Production cost savings metrics used today typically exclude reduced transmission energy losses and the other three production cost savings-related benefits in our proposed list described further below. Including these additional benefits can produce a more robust set of congestion and production cost benefits that can be quantified and integrated into the method for calculating production cost savings, and, therefore, help to ensure that the more efficient or cost-effective transmission facilities are selected in the regional transmission plan for purposes of cost allocation through Long-Term Regional Transmission Planning.

204. To measure reduced transmission energy losses, public utility transmission providers could: (1) Simulate losses in production cost models; (2) estimate changes in losses with power flow models for a range of hours; or (3) estimate how the cost of supplying losses will likely change with marginal loss charges. For example, American Transmission Company (ATC) measured reduced transmission energy losses based on changes in marginal loss charges and loss refund estimates using the marginal loss component from the PROMOD³³⁷ electric market simulation software simulations for the Paddock-Rockdale 345 kV Access Project,³³⁸ which produced cost reduction benefits using adjusted production cost analysis. Also, SPP's analysis for its Regional Cost Allocation Review (RCAR) process estimated energy loss reductions through post-processing the marginal loss component of the locational

marginal prices in PROMOD simulation results.³³⁹

205. Another set of potential benefits of regional transmission infrastructure is benefits related to reduced congestion due to transmission outages, which we describe as reduced production costs resulting from avoided congestion during transmission outages. Such benefits include reduced production costs during transmission outages that significantly increase transmission congestion. Production cost simulations typically consider planned generation outages and, in most cases, a random distribution of unplanned generation outages. In contrast, they do not generally reflect transmission outages, planned or unplanned.³⁴⁰ Public utility transmission providers could measure this benefit, for example, by either building a data set of a normalized outage schedule (not including extreme events) that can be introduced into simulations or by inducing system constraints more frequently. In its RCAR process, SPP measured the benefits of reducing congestion resulting from transmission outages. There, SPP modeled outage events and new constraints based on these outages in PROMOD for a 2025 case year, and then conducted PROMOD simulations to calculate adjusted production cost savings for a base case and the change case including the transmission line.³⁴¹ In another example, SPP calculated the financial value of reducing congestion caused by outages based on a rerun of its entire day-ahead and real-time market.

206. Another set of potential benefits of regional transmission infrastructure is benefits related to mitigation of extreme events and system contingencies, which we describe as reductions in production costs resulting from reduced high-cost generation and emergency procurements necessary to support the transmission system during extreme events (such as unusual weather conditions, fuel shortages, or multiple or sustained

generation and transmission outages) and system contingencies. These benefits include reduced production costs during extreme events facilitated by a more robust transmission system that reduces high-cost generation and emergency procurements necessary to support the system.

207. Public utility transmission providers can measure benefits from the mitigation of extreme events and system contingencies by calculating the probability-weighted production cost savings through production cost simulation for a set of extreme historical market conditions. One example is CAISO's analysis of Devers-Palo Verde Line No. 2 (PVD2), where CAISO modeled several contingencies to determine the value of the line during high-impact, low-probability events.³⁴² Another example is ATC's production cost simulation analysis of insurance benefits for the ATC Paddock-Rockdale transmission line. ATC found that probability-weighted savings from reducing production and power purchase costs during a number of simulated extreme events offset 20% of total project costs.³⁴³ Finally, a Grid Strategies study found development of an additional 1,000 MW of transmission capacity into Texas would have fully paid for itself over four days during Winter Storm Uri and the same into MISO would have saved \$100 million during the same time period.³⁴⁴

208. Another set of potential benefits of regional transmission infrastructure is benefits related to mitigation of weather and load uncertainty, which we describe as reduced production costs during higher-than-normal load conditions or significant shifts in regional weather patterns. This is beyond the effects of extreme weather described above and may account for, for example, regional and sub-regional load variances that will occur due to changing weather patterns. This ignores the potential benefit of transmission expansions under more normal system operating conditions, such as when the system experiences higher-than-normal load conditions or significant shifts in

³³⁶ *Pub. Serv. Co. of Colo.*, 142 FERC ¶ 61,206, at P 314 (2013).

³³⁷ PROMOD is a generator and portfolio modeling system. <https://www.hitachienergy.com/us/en/offering/product-and-system/energy-planning-trading/market-analysis/promod>.

³³⁸ ATC explains that the marginal loss component for transmitting internal generation to load is the marginal loss charge differential between load and generation, and the loss refund returns half of that amount. ATC, Planning Analysis of the Paddock-Rockdale Project, Docket No. 137-CE-149, app. C, Ex. 1, at 34-38 (Wisc. Pub. Serv. Comm'n Apr. 5, 2007).

³³⁹ SPP, Regional Cost Allocation Review (RCAR II), at 5 (July 11, 2016), <https://www.spp.org/documents/46235/rcar%20%20report%20final.pdf>.

³⁴⁰ Brattle-Grid Strategies Oct. 2021 Report at 79.

³⁴¹ SPP, Regional Cost Allocation Review (RCAR II), at 51-52. To estimate incremental savings associated with mitigation of transmission outage costs, SPP analyzed outage cases in PROMOD for the 2025 study year. SPP developed cases based on 12 months of historical SPP transmission data. SPP said that because of the high volume of historical transmission outage data (approximately 7,000 outage events) and based on the expectation that many outages would not lead to significant increases in congestion, SPP only modeled a subset of outage events. The events selected were those expected to create significant congestion and met at least one of three conditions. *Id.* at 51.

³⁴² *Opinion Granting Certificate of Public Convenience and Necessity, In the Matter of the Application of Southern California Edison Company (U 338-E) for a Certificate of Public Convenience and Necessity Concerning the Devers-Palo Verde No. 2 Transmission Line Project*, Application 05-04-015 (Cal. Comm'n Jan. 27, 2007).

³⁴³ ATC, Planning Analysis of the Paddock-Rockdale Project, Docket No. 137-CE-149, app. C, Ex. 1, at 4, 50-53 (Wisc. Pub. Serv. Comm'n Apr. 5, 2007).

³⁴⁴ M. Goggin, Grid Strategies, LLC, *Transmission Makes the Power System Resilient to Extreme Weather* (July 2020).

regional weather patterns that change the relative power consumption levels across multiple regions or sub-regions.

209. One example of the mitigation of weather and load uncertainty benefits is the simulations that ERCOT performed for normal loads, higher-than-normal loads, and lower-than-normal loads for a Houston import project, which showed increased benefits with a probability-weighted average for all three simulated load conditions.³⁴⁵ To measure this benefit, production cost model inputs under high and low load conditions can be used to develop regional variations of relative benefits under these conditions. Production cost benefits can then be modeled based upon a probability weighted average anticipating varying load conditions, with the increment over a base case representing additional production cost savings.

210. Another set of potential benefits of regional transmission infrastructure is capacity cost benefits related to reduced peak energy losses, which we describe as reduced generation capacity investment needed to meet peak load.

211. Capacity cost savings from reduced peak energy losses benefits refer to the ability of proposed transmission facilities to lessen the amount of transmission system energy losses during peak-load conditions which, over time, would decrease the need for new generation capacity installations or purchases. To the extent that new transmission facilities result in changes to generation dispatch and flows, transmission system energy losses will also change. If transmission system losses are reduced via the new transmission facilities, public utility transmission providers will not have to construct or procure additional generation to satisfy installed capacity requirements for peak-load conditions. If there is a reduction in energy losses during peak conditions, this would result in, presumably, lowered investments for generation capacity resources to meet the peak load. For example, Entergy found that potential transmission facilities in its footprint could reduce peak-load transmission losses and associated needed generation investment by 2% of total transmission facility costs.³⁴⁶ We note that capacity cost savings from reduced peak energy

losses only attempt to evaluate benefits for peak-load conditions.

212. One potential way to calculate capacity cost savings from reduced peak energy losses is to calculate the present value of capital cost savings associated with the reduction in installed generation requirements.³⁴⁷ To arrive at the value of capital cost savings associated with these savings, the estimated net cost of new entry (Net CONE) (*i.e.*, the cost of new peaking generating capacity net of operating margins earned in energy and ancillary services markets when the region is resource constrained) would be multiplied by the reduction in installed generation capacity requirements. The resulting value would represent the avoided cost of procuring more generation to cover transmission system losses during peak-load conditions that would be passed on to consumers via lowered generation capacity costs.

213. Another set of potential benefits of regional transmission infrastructure is benefits related to deferred generation capacity investments, which we describe as reduced costs of needed generation capacity investments realized through expanded import capability into resource-constrained areas.

214. Deferred generation capacity investments benefits reflect the value of increased transfer capability, provided by new transmission facilities, that either defers or negates the need to invest in generation capacity resources within a transmission planning region by increasing import capability from neighboring regions into resource-constrained areas. By expanding the transmission system's capacity to deliver energy to load centers, public utility transmission providers may avoid additional generation capacity investments closer to load centers. We note, for example, an ITC study examining transmission facilities between the eastern, non-ERCOT region of Texas that can import energy from Arkansas and Louisiana. The study highlighted that, by enabling imports of surplus energy from Arkansas and Louisiana, additional generation capacity investments were not needed in the eastern, non-ERCOT region of Texas.³⁴⁸

215. One potential manner of calculating deferred generation capacity investments is to calculate the present value of generation capacity cost savings resulting from deferred generation investments, based on Net CONE. Specifically, the total value of deferred

generation investments could be determined by multiplying the change in the public utility transmission provider's installed capacity requirement by Net CONE. The value of deferred generation capacity investments would ultimately benefit consumers through lower generation capacity costs.

216. Another set of potential benefits of regional transmission infrastructure is benefits related to access to lower-cost generation, which we describe as reduced total cost of needed generation due to the ability to locate generating units in a more economically efficient location (*e.g.*, low permitting costs, low-cost sites on which plants can be built, access to existing infrastructure, low labor costs, low fuel costs, access to valuable natural resources). In other words, this refers to the value of savings that may accrue to consumers who, because of a new regional transmission facility or portfolio of facilities, are able to access lower cost generation resources that they would have been unable to otherwise. For example, if the new regional transmission facilities extend to generation located farther from load centers that may be lower-cost compared to generation located closer to load centers that may be higher-priced, the new regional transmission facilities will provide savings to consumers via increased access lower-cost generation. We note, for example, that CAISO found that its proposed PVD2 transmission project, which provided an additional link between Arizona and California, permitted CAISO to meet reliability requirements through imports of lower-cost, new generation in Arizona.³⁴⁹

217. One potential way to calculate benefits from access to lower-cost generation enabled by a regional transmission facility or portfolio of facilities would be calculating them akin to how production cost savings are calculated. Specifically, public utility transmission providers could calculate the reduction in total generation investment costs by comparing the status quo (*i.e.*, higher-cost local generation) to a future (*i.e.*, lower-cost distant generation) where the proposed new regional transmission facilities allow for the import of those lower-cost generation. By allowing for the import of lower-cost generation, consumers

³⁴⁵ ERCOT, *Economic Planning Criteria: Question 1: 1/7/2011 Joint CMWG/PLWG Meeting*, at 10 (Mar. 4, 2011). The \$57.8 million probability-weighted estimate is calculated based on ERCOT's simulation results for three load scenarios and Luminant Energy estimated probabilities for the same scenarios.

³⁴⁶ ITC Holdings Co., Joint Application, Docket No. EC12-145-000, at Ex. ITC-600, 77-78 (Test. of Pfeifenberger) (filed Sept. 24, 2012).

³⁴⁷ *Id.*

³⁴⁸ *Id.* at 58-59.

³⁴⁹ *Opinion Granting Certificate of Public Convenience and Necessity, In the Matter of the Application of Southern California Edison Company (U 338-E) for a Certificate of Public Convenience and Necessity Concerning the Devers-Palo Verde No. 2 Transmission Line Project*, Application 05-04-015 (Cal. Comm'n Jan. 27, 2007).

would benefit via reduced total cost of generation.

218. While we acknowledge calculating benefits from access to lower-cost generation may be similar to methodologies for calculating production cost savings, we believe that calculating production cost savings using traditionally used methodologies would not adequately capture benefits associated with capacity cost savings. Such methodologies do not account for capacity cost savings since they do not consider load variances during hotter or colder than normal weather conditions; do not consider transmission system outages or other situations where less than the full transfer capability of the transmission facility is available; do not consider extreme events like multiple generator outages; and do not capture “real-world” operational issues such as forecasting errors or unexpected loop flows.³⁵⁰ Additionally, we believe that calculating access to lower-cost generation benefits, as Brattle Group explains, may require additional or separate analysis by public utility transmission providers since accurately capturing the aforementioned benefits may require a different generation mix than specified in the production cost simulations between the Base Case (e.g., with generation located in lower-quality or higher-cost locations) and the Change Case (e.g., with more generation located in higher-quality or lower-cost locations).³⁵¹

219. Another set of potential benefits of regional transmission infrastructure is benefits related to increased competition. We describe increased competition as reduced bid prices in wholesale electricity markets due to increased competition among generators and reduced overall market concentration. Regional transmission facilities can increase competition in, and the liquidity of, wholesale electric power markets by increasing the number of wholesale electricity suppliers that are able to compete to supply electricity at locations in the transmission network served by the transmission facility,³⁵² which helps to ensure just and reasonable Commission-jurisdictional rates.

220. More specifically, to the extent that certain portions of a transmission

planning region remain import-constrained, such that a single resource, or even a small number of resources, can have an outsized influence on the price of energy paid by load by increasing the price in their offer to sell energy, additional transmission capacity may reduce such influence, and thereby create benefits to transmission customers in the form of reduced energy prices.

221. Some public utility transmission providers have considered this benefit for certain transmission facilities. For example, CAISO evaluated the PVD2 and Path 26 Upgrade projects, and ATC evaluated its Paddock-Rockdale project, for increased competition benefits.³⁵³ We highlight three possible methods to calculate increased competition benefits, all of which ATC employed in evaluating the benefits of the Paddock-Rockdale Project, as examples of how public utility transmission providers could calculate this benefit. The first two methods that ATC employed are similar in that ATC estimated the change in a measure of market concentration (i.e., the extent to which the largest supplier is pivotal)—called the Residual Supplier Index³⁵⁴—which assumes a certain percentage of load is subject to market-based pricing, and measured the subsequent effect on generators’ ability to offer above their marginal costs (measured as a price-cost markup) and related energy prices. ATC calculated the change in the Residual Supplier Index using an assumed change in import capability to the area served by the new transmission facility.

222. The first method ATC employed to calculate the increased competition benefit, called the “Modified MISO IMM Method,” draws from two key

³⁵³ *Opinion Granting Certificate of Public Convenience and Necessity, In the Matter of the Application of Southern California Edison Company (U 338-E) for a Certificate of Public Convenience and Necessity Concerning the Devers-Palo Verde No. 2 Transmission Line Project*, Application 05-04-015 (Cal. Comm’n Jan. 27, 2007); CAISO, *Transmission Economic Assessment Methodology*, Chapter 4 (Jun. 2004); ATC, *Planning Analysis of the Paddock-Rockdale Project*, at 44–49 (Apr. 5, 2007).

³⁵⁴ The Residual Supplier Index is calculated as the ratio of residual supply (i.e., total supply minus the capacity of the largest supplier in the market) to the total demand. If the Residual Supplier Index is less than 1.0, it means the largest supplier is “pivotal,” meaning that a load cannot be served without the largest supplier making available at least some of its capacity. With inelastic demand, a pivotal supplier theoretically would be able to set the market price at any desired level above the competitive price. See von der Fehr, Nils-Henrik & David Harbord, *Spot Market Competition in the UK Electricity Industry*, *Economic Journal*, at 103, 531–46 (1993); ATC, *Planning Analysis of the Paddock-Rockdale Project*, Docket No. 137-CE-149, app. C, Ex. 1, at 44 & n.11 (Wisc. Pub. Serv. Comm’n Apr. 5, 2007).

assumptions to determine price mark-ups. First, the Modified MISO IMM Method requires an estimate of the pivotal supplier’s price-cost markup for the area served by the transmission facility for all times when the supplier is pivotal.³⁵⁵ Second, this method assumes that the price-cost markup increases linearly as the Residual Supplier Index falls below 1.2,³⁵⁶ such that there is no price-cost markup where the Residual Supplier Index for an hour is above 1.2 (i.e., no improved competition benefit) and the price markup is half the estimated price-cost markup from the first assumption where the Residual Supplier Index for an hour is less than 1.0. Finally, this method assumes that the pivotal supplier is the marginal resource that sets the energy price when the Residual Supplier Index is below 1.2. The difference in price-cost markup for hours when the Residual Supplier Index is below 1.2 provides the benefits from increased competition.

223. The second potential method to calculate increased competition benefits that ATC employed, the “Modified CAISO Method,” estimates the energy price impacts of a new transmission facility by using regression analysis to find the relationship between historical market structure and price-bid markups. CAISO first developed this regression equation and its coefficients in its 2004 report evaluating the economic viability of certain transmission upgrades, including the PVD2 and Path 26 Upgrade projects.³⁵⁷ CAISO’s study also used two binary indicator variables: One for the summer period in CAISO and another for peak hours. We note that public utility transmission providers using the Modified CAISO approach may find that coefficients developed using data specific to the transmission planning region where the public utility transmission provider is located are more appropriate and may also wish to include more independent variables specific to their respective transmission planning regions.

³⁵⁵ In the case of the Paddock-Rockdale Project, the MISO independent market monitor had designated the area as a “Narrow Constrained Area” and estimated that, whenever a resource became pivotal in that area its offer would exceed its marginal costs by up to \$36/MWh. While the MISO independent market monitor provided such an estimate for the Paddock-Rockdale Project, we do not suggest that any specific entity conduct the necessary study deriving this estimate (e.g., the public utility transmission providers in a transmission planning region could also conduct such a study).

³⁵⁶ This assumption is based on a study analyzing summer 2000 peak hourly data from the California Power Exchange. Sheffrin, A., (2002), “Predicting Market Power Using the Residual Supplier Index,” Mimeo, Department of Market Analysis, CAISO.

³⁵⁰ TC Holdings, Joint Application, Docket No. EC12-145-000, Ex. No. ITC-600, at 54–55 (filed Sept. 24, 2012) (Pfeifenberger, Direct Testimony on behalf of ITC Holdings).

³⁵¹ Brattle-Grid Strategies Oct. 2021 Report at 46–47.

³⁵² F.A. Wolak, *Managing Unilateral Market Power in Electricity*, Policy Research Working Paper, No. 3691. World Bank, Washington, DC, at 8 (2005).

224. The third potential method to calculate increased competition benefits, the “Bidding Behavior Method,” relies on a simulation model that optimizes bidding behavior from a supplier perspective given each supplier’s supply portfolio and load obligations. This model could be based on the theoretical incentive that suppliers have to increase price-cost markups in proportion to the absolute value of the slope of residual demand (*i.e.*, total demand less the supply of all other resources serving the same load).³⁵⁸ Public utility transmission providers in a transmission planning region would develop a study estimating market prices for a future period matching the planning horizon as load, generation supply, transmission constraints, and import capability changed. Public utility transmission providers in a transmission planning region would also assume that a percentage of load was exposed to congestion.

225. Finally, another set of potential benefits of regional transmission infrastructure is benefits related to increased market liquidity. We describe increased market liquidity as enabling a larger number of entities, both buyers and sellers, to participate in a market. By increasing the number of market participants, both buyers and sellers, transmission facilities may provide benefits through reduced transaction costs (*e.g.*, bid-ask spreads) of bilateral transactions, increased pricing transparency, increased efficiency of risk management, improved contracting, and better clarity for long-term transmission planning and investment decisions.³⁵⁹ The primary increased market liquidity benefit to transmission customers is the decrease in energy prices. For example, bid-ask spreads for bilateral trades at less liquid hubs have been found to be between \$0.50 to \$1.50/MWh higher than the bid-ask spreads at more liquid hubs.³⁶⁰ Public utility transmission providers could quantify increased market liquidity benefits to transmission customers by estimating (1) how additional transmission facilities may increase liquidity and (2) how increased

liquidity may reduce bid-asks spreads or energy prices.

(b) Evaluation of Transmission Benefits Over Longer Time Horizon

(1) Comments

226. Several commenters responding to the ANOPR recommend that the Commission allow or require public utility transmission providers to evaluate the benefits of transmission facilities over a longer time horizon.³⁶¹ For example, ACPA and ESA argue that proper economic analysis entails an analysis of the benefits of a proposed transmission facility over the asset’s life, which is at least 40 years for transmission lines.³⁶² Other commenters, however, raise concerns with attempts to forecast future transmission system conditions in order to consider potential benefits on a longer time horizon.³⁶³ For example, Xcel argues that planning for the future is inherently uncertain, and that the benefits of transmission facilities can change over time.³⁶⁴

(2) Proposed Reform

227. We propose to require that public utility transmission providers in each transmission planning region evaluate, as part of Long-Term Regional Transmission Planning, the benefits of regional transmission facilities over a time horizon that covers, at a minimum, 20 years starting from the estimated in-service date of the transmission facilities. For example, if Long-Term Regional Transmission Planning identifies transmission facilities that are estimated to be in-service in year 10 of the 20-year long-term transmission planning horizon, then the estimate of benefits for those same transmission facilities will commence at year 10 and

cover an additional 20 years. We believe that 20 years may strike an appropriate balance that reasonably illustrates the benefits a transmission facility is likely to provide over its useful life, which can exceed 40 years, while recognizing the inherent difficulties in attempting to predict system conditions too far into the future. Moreover, we note that some public utility transmission providers currently conduct long-term transmission planning over a 20-year horizon, and thus have some experience with modelling and making assumptions over this period, though such modelling is typically for informational purposes and not to select transmission facilities in the regional transmission plan for purposes of cost allocation.³⁶⁵

228. We propose to require that public utility transmission providers evaluate benefits over this time horizon in all stages of Long-Term Regional Transmission Planning, which includes evaluating regional transmission facilities, selecting more efficient or cost-effective regional transmission facilities in the regional transmission plan for purposes of cost allocation, and allocating the costs of such transmission facilities in a manner that is at least roughly commensurate with estimated benefits. We also note that for consistency and a matching comparison of benefits and costs over time, to the extent that public utility transmission providers estimate the costs of transmission facilities beyond the in-service date of the transmission facilities, we propose that they should estimate those future costs over the same time horizon as the estimated benefits.

229. Finally, while we propose to establish a minimum requirement for the time horizon over which benefits must be evaluated, we clarify that public utility transmission providers may propose approaches that exceed this minimum requirement. In particular, while we believe that 20 years may strike a reasonable balance, we also believe that a time horizon longer than 20 years for the evaluation of benefits may be consistent with the long life of transmission facilities—

³⁶¹ See, *e.g.*, NYISO Comments at 34–37 (stating that NYISO limits consideration of benefits to 10 years and recommending that the Commission grant public utility transmission providers discretion to plan for up to 20 years of needs and benefits); see also NextEra Comments at 79–80 (recommending a similar length of time for consideration of benefits as for scenario planning); see also February Joint Task Force Tr 20:23–25 (Clifford Rechtschaffen) (arguing that the Commission should extend the timeframe over which benefits are calculated to be 15–20 years or longer), 24:4–8 (Matthew Allen) (advocating for recognizing benefits over at least a 20-year timeframe given the long life of transmission assets).

³⁶² ACPA and ESA Comments at 44–45; see also PIOs Comments at 121–122.

³⁶³ Entergy Comments at 10–11; see also EEI Comments at 30–31 (arguing for maintaining the Commission’s policies on abandoned plant recovery because of the additional uncertainty inherent in longer-term transmission planning); Minnesota Commerce Comments at 3 (stating that future uncertainty is compounded by the rapid pace of technological change).

³⁶⁴ Xcel Comments at 20 n.52.

³⁶⁵ See MISO, *LRTP Business Case*, Long Range Transmission Planning Workshop, at slide 7 (Jan. 21, 2022, Revised Feb. 2, 2022), <https://cdn.misoenergy.org/20220121%20LRTP%20Workshop%20Item%2004%20Business%20Case%20Presentation619895.pdf>; CAISO, *20-Year Transmission Outlook* (Draft Jan. 31, 2022), <https://www.caiso.com/Initiative/Documents/Draft20-YearTransmissionOutlook.pdf>; SPP Engineering, *2021 SPP Transmission Expansion Plan Report* (Jan. 11, 2021), <https://spp.org/documents/56611/2021%20step%20report.pdf>.

³⁵⁸ See, *e.g.*, F.A. Wolak, *Measuring the competitiveness benefits of a transmission investment policy: The case of the Alberta electricity market* 86 Energy Policy 426–444 (June 2015); N. Ryan, *The Competitive Effects of Transmission Infrastructure in the Indian Electricity Market*, 13 American Economic Journal: Microeconomic 2, 202–42 (May 2021).

³⁵⁹ Brattle-Grid Strategies Oct. 2021 Report at 50.

³⁶⁰ *Id.*

which generally exceeds 20 years by a substantial margin—and also consistent with the fact that transmission facilities provide significant benefits over their entire useful life.³⁶⁶ To the extent public utility transmission providers would like to evaluate transmission benefits beyond the proposed minimum time horizon, we propose to require that they demonstrate that their proposal is consistent with or superior to any final rule in this proceeding.

230. We seek comment on the requirements proposed in this section of the NOPR.

(c) Evaluation of the Benefits of Portfolios of Transmission Facilities

231. In the ANOPR, the Commission sought comment on whether public utility transmission providers would identify more efficient or cost-effective transmission facilities in their regional transmission planning processes if they evaluated the benefits of a portfolio of transmission facilities collectively rather than individual transmission facilities separately.³⁶⁷

(1) Comments

232. Many commenters recommend that the Commission permit or require public utility transmission providers to use a portfolio approach when evaluating the benefits of transmission facilities.³⁶⁸ Under such an approach, public utility transmission providers would evaluate multiple transmission facilities in an aggregated, integrated fashion rather than doing so on a facility-by-facility basis. For example, U.S. DOE argues that a portfolio approach is more likely to result in an accurate evaluation of the benefits of transmission facilities than would an approach requiring evaluation of each facility individually,³⁶⁹ while PIOs claim that facility-by-facility rather than portfolio-based evaluation underestimates the benefits of regional transmission facilities.³⁷⁰ Other commenters explain that public utility transmission providers could achieve administrative efficiencies using a portfolio approach, which can help

avoid the necessity of running the same analyses on each facility.³⁷¹

(2) Proposed Reform

233. We propose to afford public utility transmission providers in each transmission planning region the flexibility to propose to use a portfolio approach in the evaluation of benefits of regional transmission facilities through their Long-Term Regional Transmission Planning. Evaluating the benefits of a portfolio of regional transmission facilities appears to contain several advantages compared to evaluating the benefits of each proposed regional transmission facility individually. Several commenters explain that future benefits may be more stable or evenly distributed over time if they are evaluated for a portfolio of transmission facilities.³⁷² These comments are consistent with the fact that benefits from transmission facilities may change over time due to the inherent uncertainty in Long-Term Regional Transmission Planning and actual use of transmission facilities. An example of the evaluation of expanded benefits for a portfolio of transmission facilities is the MISO MVP Portfolio, which is a collection of 17 distinct transmission facilities, for which MISO evaluated a collective distribution of benefits.³⁷³ Given the suite of minimum benefits proposed above, we believe that evaluating these benefits across a portfolio of transmission facilities as opposed to each individual transmission facility may result in significant administrative efficiencies for public utility transmission providers. Moreover, we believe that a more stable or even distribution of benefits from a portfolio of transmission facilities may also facilitate agreement on regional cost allocation that is at least roughly commensurate with estimated benefits.

234. Accordingly, we encourage this practice by public utility transmission providers. We clarify that public utility transmission providers that propose such an approach must include in their OATTs provisions describing how they would analyze the benefits of regional transmission facilities under a portfolio approach and whether the portfolio approach would be used for Long-Term

Regional Transmission Planning universally to address transmission needs driven by changes in the resource mix and demand or would be used only in certain specified instances.

235. We recognize that a variety of commenters request that we require the use of a portfolio approach. While we recognize the advantages to a portfolio approach, we also acknowledge that the transition to a portfolio approach may represent a significant change for many public utility transmission providers and that the potential benefits may not warrant such a change in all instances.³⁷⁴ We seek comment as to whether there are certain circumstances for which the Commission should require the use of a portfolio approach.

iv. Selection of Regional Transmission Facilities

236. Order No. 1000 requires public utility transmission providers to include in their OATTs a transparent and not unduly discriminatory process for evaluating whether to select a proposed regional transmission facility in the regional transmission plan for purposes of cost allocation.³⁷⁵ Order No. 1000 does not mandate that public utility transmission providers select any transmission facility,³⁷⁶ and the Commission declined for the most part to set minimum standards for the criteria used to select a transmission facility in a regional transmission plan for purposes of cost allocation. However, the Commission required that a public utility transmission provider's selection criteria be transparent and not unduly discriminatory.³⁷⁷

237. In the ANOPR, the Commission sought comment on whether and how public utility transmission providers should use information developed through long-term scenario planning to identify and select transmission facilities that meet future needs. In addition, the Commission sought comment on how public utility transmission providers should evaluate the benefits of proposed transmission facilities in their regional transmission planning processes, and whether the maximization of net benefits is an appropriate criterion for selecting transmission facilities in the regional transmission plan for purposes of cost

³⁶⁶ ACPA and ESA Comments at 44–45; *see also* WIREs Comments at 7–8 (recommending accounting for benefits of transmission facilities over their useful lives).

³⁶⁷ ANOPR, 176 FERC ¶ 61,024 at PP 53, 89, 91.

³⁶⁸ ITC Comments at 11; State Agencies Comments at 21; ELCON Reply Comments at 3–4; *see also* Southern Comments at 13–14 (stating that vertically-integrated utilities already use a portfolio approach).

³⁶⁹ U.S. DOE Comments at 40–41.

³⁷⁰ PIOs Comments at 50–51.

³⁷¹ ACEG Reply Comments at 5, 8; ITC Comments at 6, 11, 28.

³⁷² U.S. DOE Comments at 40–41; *see also* February Joint Task Force Tr 24:15–22 (Matthew Allen) (stating his belief that transmission planners should be looking at projects and benefits on a portfolio basis to identify synergies).

³⁷³ MISO, Multi Value Project Portfolio Results and Analyses at 1–6 (2012), <https://cdn.misoenergy.org/2011%20MVP%20Portfolio%20Analysis%20Full%20Report117059.pdf>.

³⁷⁴ *See, e.g.*, February Joint Task Force Tr. 76:10–12 (Kimberly Duffley) (asking that the Commission recognize regional differences that may result in portfolio projects working for one region but not for all regions).

³⁷⁵ Order No. 1000, 136 FERC ¶ 61,051 at PP 328–331; Order No. 1000–A, 139 FERC ¶ 61,132 at P 452.

³⁷⁶ Order No. 1000, 136 FERC ¶ 61,051 at P 331.

³⁷⁷ *See* Order No. 1000–A, 139 FERC ¶ 61,132 at P 455.

allocation.³⁷⁸ Finally, the Commission sought comment on whether public utility transmission providers would select more efficient or cost-effective transmission facilities in their regional transmission planning processes if they selected a portfolio of transmission facilities collectively.³⁷⁹

(a) Comments

238. With respect to the selection of transmission facilities in a regional transmission plan for purposes of cost allocation, commenters responding to the ANOPR provided a wide range of feedback. Several commenters emphasize that scenario planning should ensure the selection of more efficient or cost-effective transmission facilities,³⁸⁰ while others argue that scenario planning should be solely for informational purposes.³⁸¹ Certain commenters believe that Commission guidance on selection criteria is essential,³⁸² while others argue that the Commission instead should provide flexibility for public utility transmission providers to adopt selection criteria.³⁸³

239. Many commenters also recommend that the Commission permit or require public utility transmission providers to use a portfolio approach when selecting transmission facilities.³⁸⁴ U.S. DOE explains that the benefits of individual transmission facilities typically are distributed unevenly across a region, whereas

portfolios of transmission facilities generally would be expected to confer benefits more broadly and evenly.³⁸⁵

240. With respect to specific selection criteria or methods, several commenters support an approach that would select transmission facilities with the highest level of net benefits instead of facilities with the highest benefit-cost ratio,³⁸⁶ whereas other commenters support maintaining the maximum 1.25 benefit-cost ratio permitted by Order No. 1000.³⁸⁷ Other commenters recommend a “least-regrets” approach to selecting transmission facilities, in which public utility transmission providers would select a transmission facility identified through scenario planning as beneficial across many or all scenarios.³⁸⁸

(b) Proposed Reform

241. We propose to require that public utility transmission providers, as part of the Long-Term Regional Transmission Planning that we propose to require in this NOPR, include in their OATTs: (1) Transparent and not unduly discriminatory criteria, which seek to maximize benefits to consumers over time without over-building transmission facilities, to identify and evaluate transmission facilities for potential selection in the regional transmission plan for purposes of cost allocation that address transmission needs driven by changes in the resource mix and demand, consistent with the discussion below; and (2) a process to coordinate with the relevant state entities in developing such criteria.

242. Subject to certain minimum requirements, we propose to provide public utility transmission providers the flexibility to propose the selection criteria that they, in consultation with their stakeholders, believe will ensure that more efficient or cost-effective regional transmission facilities to address the region’s transmission needs driven by changes in the resource mix and demand ultimately are selected in

the regional transmission plan for purposes of cost allocation. As stated in Order No. 1000, to comply with Order Nos. 890 and 1000 transmission planning principles, the evaluation process must result in a determination that is sufficiently detailed for stakeholders to understand why a particular transmission project was selected or not selected in the regional transmission plan for purposes of cost allocation to address transmission needs driven by changes in the resource mix and demand.³⁸⁹ Further, we propose that the evaluation process and, specifically, the selection criteria must seek to maximize benefits to consumers over time without over-building transmission facilities.

243. We believe that this proposed flexibility would help accommodate the regional differences described in comments in response to the ANOPR, such as the different transmission needs each transmission planning region may have, the factors driving those needs, or market structures. We also believe that providing flexibility to public utility transmission providers in this regard would allow public utility transmission providers, in consultation with their stakeholders, to determine criteria for assessing the efficiency or cost-effectiveness of various regional transmission facilities, whether by reference, for example, to a benefit-cost ratio or by aggregate net benefits.³⁹⁰

244. Further, we believe this proposed flexibility would allow public utility transmission providers in each transmission planning region to develop selection criteria that could sufficiently balance individual state interests within each transmission planning region. We believe that providing an opportunity for state involvement in regional transmission planning processes is becoming more important as states take a more active role in shaping the resource mix and demand, which, in turn, means that those state actions are increasingly affecting the long-term transmission needs for which we are proposing to require public utility transmission providers to plan in this NOPR. Given the important role states play and the wide variety of potential approaches to selection criteria, we propose, as part of this requirement, that public utility transmission providers must consult with and seek support from the relevant state entities, as defined below, within their

³⁷⁸ ANOPR, 176 FERC ¶ 61,024 at P 53.

³⁷⁹ See *id.* PP 89, 91.

³⁸⁰ AEP Comments at 10; Ameren Reply Comments at 3; see also Anbaric Comments at 32 (recommending that the Commission impose deadlines to ensure that transmission planning processes select offshore wind transmission facilities rather than allowing results to “languish in protracted stakeholder processes”); AEE Reply Comments at 7–8 (requesting the adoption of transparency and enforcement mechanisms that would ensure the selection of transmission facilities that meet regional needs).

³⁸¹ See PJM Comments at 44 (stating that PJM’s proposed long-term transmission planning process will “inform stakeholder discussions”); see also Xcel Energy Comments at 20 (“The Commission should not require all issues identified in the holistic planning process to result in planned projects.”).

³⁸² PJM Comments at 46; see also City of New York Comments at 11 (arguing that the Commission should adopt common project selection criteria); Policy Integrity Comments at 17 (recommending greater uniformity in selection criteria); Massachusetts Attorney General Comments at 25 (arguing that consumer protection requires that selection criteria be “clear, real, and objective”).

³⁸³ MISO Comments at 32; National Grid Comments at 14–15; American Municipal Power Comments at 15.

³⁸⁴ ITC Comments at 9, 11, 33; NARUC Comments at 12; PIOs Comments at 50–51; State Agencies Comments at 21; AEP Reply Comments at 33; ELCON Reply Comments at 3–4; see also Southern Comments at 13–14 (stating that vertically-integrated utilities already use a portfolio approach).

³⁸⁵ U.S. DOE Comments at 40–41.

³⁸⁶ ITC Comments at 11; ACEG Comments at 5–6; Policy Integrity Comments at 44–46; AEP Comments at 16.

³⁸⁷ NARUC Comments at 12, 22–24 (advocating for maximizing benefit-cost ratio and retaining the benefit-cost ratio permitted by Order No. 1000); Entergy Comments at 18 (asking the Commission to retain the ability to have a benefit-cost ratio up to 1.25); Mississippi Commission Comments at 13–14 (arguing for a strict benefit-cost ratio of no less than 1.25 for economic projects with the possibility of a higher benefit-cost ratio for specific projects); Entergy Reply Comments at 12–13 (asserting that a higher benefit-cost ratio may be appropriate for a longer-term planning horizon).

³⁸⁸ National Grid Comments at 16; American Municipal Power Comments at 32; PIOs Comments at 79; Chamber of Commerce Comments at 4; WIRES Comments at 7–8; AEP Comments at 9–10.

³⁸⁹ Order No. 1000, 136 FERC ¶ 61,051 at P 328.

³⁹⁰ We do not propose to change the Order No. 1000 requirement that public utility transmission providers may not impose a benefit-cost ratio requirement higher than 1.25. See *id.* P 646.

transmission planning region's footprint to develop the selection criteria. These selection criteria would be used in Long-Term Regional Transmission Planning to evaluate a transmission facility (or a portfolio of regional transmission facilities) for potential selection in the regional transmission plan for purposes of cost allocation.

245. While we propose significant flexibility in the development of selection criteria, we believe that certain minimum requirements must be in place for public utility transmission providers, their stakeholders, and states. The selection criteria must be transparent and not unduly discriminatory, and must aim to ensure that more efficient or cost-effective transmission facilities are selected in the regional transmission plan for purposes of cost allocation to address transmission needs driven by changes in the resource mix and demand. Public utility transmission providers should seek to maximize benefits to consumers over time without over-building transmission facilities. Public utility transmission providers should propose specific selection criteria to achieve this balance over time. We note, as discussed above, that regional transmission planning and cost allocation processes generally have resulted in few regionally planned transmission facilities being selected and ultimately built.³⁹¹ However, the reforms proposed in this NOPR seek to better ensure that the more efficient or cost-effective regional transmission facilities are identified through Long-Term Regional Transmission Planning and acknowledge commenters' concerns about over-building due to uncertainties of future transmission system conditions.³⁹² We acknowledge the inherent uncertainty involved in predicting future transmission needs and emphasize that we are not proposing to require public utility transmission providers to achieve, *ex post*, any particular outcome but rather to adopt an evaluation process that, *ex ante*, aims to maximize consumer benefits over time without over-building transmission facilities.

³⁹¹ *Supra* Need For Reform: The Transmission Investment Landscape Today (explaining in some transmission planning regions, regional transmission investment declined after issuance of Order No. 1000, while in other regions, regional transmission planning processes have not resulted in the selection of a single regional transmission facility); *see also* Minnesota Commerce Comments at 3 (arguing the risk of status quo is worse than the risk of over-building).

³⁹² *See, e.g.*, NASUCA Comments at 3–5; November 2021 Technical Conference Tr. at 29 (testimony of Dr. Patton).

246. Public utility transmission providers would bear the burden on compliance of demonstrating that their proposed selection criteria satisfy the Order Nos. 890 and 1000 transmission planning principles in the context of Long-Term Regional Transmission Planning, even if public utility transmission providers propose to use selection criteria that they also use in their existing regional transmission planning process.³⁹³ Likewise, public utility transmission providers would bear the burden on compliance of demonstrating that their proposed selection criteria seek to maximize benefits to consumers over time without over-building transmission facilities. Moreover, we propose to require that public utility transmission providers demonstrate on compliance that they developed their proposed selection criteria in consultation with the relevant state entities in their transmission planning region's footprint.

247. We propose that, consistent with Order No. 1000, the developer of a transmission facility selected in the regional transmission plan for purposes of cost allocation through Long-Term Regional Transmission Planning to address transmission needs driven by changes in the resource mix and demand would be eligible to use the applicable cost allocation method for the Long-Term Regional Transmission Facility.³⁹⁴ We also propose that the existing transmission developer requirements would apply, including that the developer of the selected regional transmission facility must submit a development schedule that indicates the required steps, such as the granting of state approvals necessary to develop and construct the transmission facility such that it meets the transmission needs of the transmission planning region.³⁹⁵ To the extent the

³⁹³ For example, if public utility transmission providers in a transmission planning region propose to use existing selection criteria, they should explain on compliance how those criteria also are just and reasonable with respect to the selection of regional transmission facilities identified to address transmission needs driven by changes in the resource mix and demand.

³⁹⁴ We note that the applicable cost allocation method for a Long-Term Regional Transmission Facility may not be *ex ante*, as discussed in the Regional Transmission Cost Allocation section below.

³⁹⁵ Order No. 1000–A, 139 FERC ¶ 61,132 at P 442. The Commission also stated that, as part of the ongoing monitoring of the progress of a transmission facility once it is selected, the public utility transmission providers in a transmission planning region must establish a date by which state approvals to construct must have been achieved that is tied to when construction must begin to timely meet the need that the facility is selected to address. If such critical steps have not been achieved by that date, then the public utility

relevant state entities in a transmission planning region agree to a State Agreement Process, as described in the Regional Transmission Cost Allocation section below, the development schedule should also include relevant steps related to that process.³⁹⁶

248. Given the longer-term nature of transmission needs driven by changes in the resource mix and demand, we note that the required development schedule may make it unnecessary for the developer of a transmission facility selected in the regional transmission plan for purposes of cost allocation to take actions or incur expenses in the near-term if the transmission facility will not need to be in service in the near-term. We also note that, with respect to a transmission facility selected in the regional transmission plan for purposes of cost allocation to meet transmission needs driven by changes in the resource mix and demand, public utility transmission providers may make its selection status subject to the outcomes of subsequent Long-Term Regional Transmission Planning cycles, such that a previously selected transmission facility is no longer needed. Public utility transmission providers should include in their selection criteria how they will address the selection status of a previously selected transmission facility based on the outcomes of subsequent Long-Term Regional Transmission Planning cycles.

249. Consistent with our approach to benefits analysis, we clarify that public utility transmission providers would have the flexibility to propose to use a portfolio approach in selecting regional transmission facilities in the regional transmission plan for purposes of cost allocation that address transmission needs driven by changes in the resource mix and demand. Public utility transmission providers that propose such an approach would have to include in their OATTs provisions describing whether the selection criteria would apply to one proposed regional transmission facility or to a portfolio of regional transmission facilities; and whether the portfolio approach would be used for Long-Term Regional Transmission Planning universally to address transmission needs driven by changes in the resource mix and

transmission providers in a transmission planning region may "remove the transmission facility from the selected category and proceed with reevaluating the regional transmission plan to seek an alternative solution." *Id.*

³⁹⁶ *Infra* P 302 (describing cost allocation requirements for Long-Term Regional Transmission Planning).

demand or would be used only in certain specified instances.

250. We preliminarily find that the development and analysis of Long-Term Scenarios cannot remedy the deficiencies in the Commission's existing regional transmission planning requirements without the inclusion of transparent and not unduly discriminatory selection criteria that are used to evaluate transmission facilities (or portfolios of transmission facilities) for potential selection in the regional transmission plan for purposes of cost allocation. Absent such criteria, public utility transmission providers' Commission-jurisdictional rates may be unjust and unreasonable and unduly discriminatory and preferential.

251. As noted above, we recognize the inherent uncertainty involved in predicting future transmission needs, including those driven by changes in the resource mix and demand, and many commenters express concern that imperfect information may lead to selecting transmission facilities in the regional transmission plan for purposes of cost allocation that become stranded assets. However, we believe that there are selection criteria that public utility transmission providers could adopt, following consultation with stakeholders and with relevant state entities in their transmission planning region's footprint, to minimize these risks while allowing for investment in transmission facilities that more efficiently or cost-effectively meet transmission needs driven by changes in the resource mix and demand. For example, under a least-regrets approach, public utility transmission providers in a transmission planning region would select a transmission facility (or portfolio of transmission facilities) in their regional transmission plan for purposes of cost allocation that is net-beneficial in most or all Long-Term Scenarios, even if other transmission facilities have more net benefits or a higher benefit-cost ratio in a single Long-Term Scenario. Another approach is a weighted-benefits approach, in accordance with which public utility transmission providers in a transmission planning region would select a transmission facility (or portfolio of regional transmission facilities) in their regional transmission plan for purposes of cost allocation based on its probability-weighted average benefits, where probabilities have been assigned to each Long-Term Scenario studied.³⁹⁷

³⁹⁷ Brattle-Grid Strategies Oct. 2021 Report at 59–60.

252. We seek comment on the requirements proposed in this section of the NOPR. In addition, we seek comment on whether relevant state entities should have the opportunity to voluntarily fund the cost of, or a portion of the cost of, a Long-Term Regional Transmission Facility³⁹⁸ to enable such facility to satisfy the public utility transmission provider's selection criteria (e.g., any benefit-cost threshold), and if so, whether the Commission's final rule in this proceeding should include requirements to facilitate such an opportunity for the relevant state entities.³⁹⁹ Commenters on this issue should also address preferred approaches to implement such a voluntary funding opportunity for relevant state entities for Long-Term Regional Transmission Facilities. For example, we seek comment on what mechanism would be appropriate to document agreement from the relevant state entities to voluntarily fund (e.g., commit customers within the state to fund) the cost of, or a portion of the cost of, a Long-term Regional Transmission Facility to enable such facility to satisfy the public utility transmission provider's selection criteria; whether a public utility transmission provider should be required to include a pro forma agreement for such an opportunity in its OATT for facilitation purposes; how the Commission and the public utility transmission providers would be assured that the commitment by the relevant state entity is sufficiently binding; and whether another manner for relevant state entities to make and fulfill such a commitment would be preferable. We also seek comment on what stage in the regional transmission planning process is the most appropriate point for such an opportunity for the relevant state entities. We also seek comment on whether such opportunity for the relevant state entities to voluntarily fund the cost of, or the portion of the

³⁹⁸ As noted *infra* note 507, we propose to define a Long-Term Regional Transmission Facility as a transmission facility identified as part of Long-Term Regional Transmission Planning and selected in the regional transmission plan for purposes of cost allocation to address transmission needs driven by changes in the resource mix and demand.

³⁹⁹ For Long-Term Regional Transmission Facilities, such an opportunity for the relevant state entities could enable them to assign a value to achieving of their particular policy goals while ensuring that their customers bear the corresponding costs. As the New Jersey Commission suggests, "some states ascribe additional 'value' to the achievement of public policy goals, backed by a willingness to bear the costs associated with those benefits." NJ Commission, Comments, Docket No. AD21–15–000, at 4 (filed Apr. 1, 2022). See also Maryland Energy Admin Comments at 8–9; Maryland Commission Reply Comments at 2.

cost of, a Long-Term Regional Transmission Facility should be limited to relevant state entities or should be expanded to include interconnection customers.⁴⁰⁰

c. Implementation of Long-Term Regional Transmission Planning

253. We recognize that the timing of the proposed Long-Term Regional Transmission Planning requirement has the potential to overlap with public utility transmission providers' near-term assessment of transmission needs captured by existing regional transmission planning processes. We propose that public utility transmission providers must explain on compliance how the initial timing sequence for Long-Term Regional Transmission Planning interacts with existing regional transmission planning efforts. We recognize the possibility that there may be overlap in the time horizon for the proposed Long-Term Regional Transmission Planning and existing near-term regional transmission planning processes and that they will likely inform each other. It is also possible that, in some cases, transmission facilities selected in a regional transmission plan for purposes of cost allocation to address transmission needs driven by changes in the resource mix and demand may provide near-term reliability or economic benefits and thus potentially displace regional transmission facilities that are under consideration as part of existing regional transmission planning processes.

254. We seek comment on the requirement proposed in this section of the NOPR. In particular, we seek comment on whether there is a need to coordinate the initial timing sequences between Long-Term Regional Transmission Planning and the existing near-term regional transmission planning processes.

255. We also seek comment on whether the Commission should host a periodic forum for public utility transmission providers, transmission experts, relevant federal and state agencies, and other stakeholders to share best practices in implementing Long-Term Regional Transmission Planning as proposed herein. The Commission could, for example, host a tri-annual technical conference focused on topics such as choice of best

⁴⁰⁰ We note that some commenters have suggested that interconnection customers similarly be afforded an opportunity to voluntarily contribute funds to a Long-Term Regional Transmission Facility so as to facilitate its selection. Enel Comments at 12–14; ACPA and ESA Comments at 75–79.

available data, principles for developing plausible scenarios, and techniques for evaluating benefits of proposed transmission facilities. We seek comment on the benefits such a forum might provide, and, if implemented, how such a forum should be structured and the frequency on which it should be held.

2. Consideration of Dynamic Line Ratings and Advanced Power Flow Control Devices in Long-Term Regional Transmission Planning

a. ANOPR

256. In the ANOPR, the Commission sought comment on whether the development of longer-term scenarios for planning purposes should be pursued and, if so, whether and how Grid-Enhancing Technologies (GETs)⁴⁰¹ should be accounted for in determining what transmission is needed under such scenarios.⁴⁰² The Commission solicited input on how it could require greater consideration of GETs and asked commenters to describe any challenges that exist in establishing such a requirement and how they might be addressed.⁴⁰³

b. Comments

257. The majority of commenters on the ANOPR support the Commission requiring public utility transmission providers to consider GETs in the regional transmission planning process, emphasizing that advanced technologies can optimize existing transmission corridors and provide cost-effective solutions for consumers.⁴⁰⁴ NARUC states that an effective transmission planning process should maximize the use of existing transmission and build new transmission only where necessary or economic, asserting that the transmission planning process needs a clear pathway for consideration of alternative transmission solutions, including GETs.⁴⁰⁵

⁴⁰¹ For purposes of a prior workshop, Commission staff stated that GETs increase the capacity, efficiency, or reliability of transmission facilities. Commission staff further stated that these technologies include but are not limited to: (1) Power flow control and transmission switching equipment; (2) storage technologies; and (3) advanced line rating management technologies. *Grid-Enhancing Technologies*, Notice of Workshop, Docket No. AD19-19-000 (issued Sept. 9, 2019).

⁴⁰² ANOPR, 176 FERC ¶ 61,024 at P 48.

⁴⁰³ *Id.* P 158.

⁴⁰⁴ See, e.g., National Grid Comments at 32; PJM Comments at 59-62; State of Massachusetts Comments at 20; see also *Joint Fed.-State Task Force on Elec. Transmission*, Transcript of Nov. 10, 2021 Meeting, Docket No. AD21-15-000, at 97:5-11 (Chair Scripps) (supporting consideration of GETs in regional transmission planning).

⁴⁰⁵ NARUC Comments at 9.

258. Some commenters, such as Duke, EEI, and MISO Transmission Owners, either oppose the use of GETs in regional transmission planning, do not see it as a fit for regional transmission planning for transmission needs driven by changes in the resource mix and in demand, or urge caution, as they assert that the technologies are not always substitutes for transmission facilities.⁴⁰⁶ AEP notes that GETs should be considered as long as they are evaluated on an equal footing, for example, evaluating technology life span on equal footing.⁴⁰⁷

259. Market monitors, such as the PJM Market Monitor, emphasize the value that dynamic line ratings⁴⁰⁸ and other GETs could add in maximizing existing transmission capacity but express caution about how they would be implemented and compensated.⁴⁰⁹ Potomac Economics sees some benefit to GETs in helping transmission owners avoid inefficient transmission upgrade costs to mitigate congestion but expresses concern about mandating long-term planning studies that would involve RTOs/ISOs or transmission providers “speculating on” GETs.⁴¹⁰

260. RTOs/ISOs generally indicate that they currently consider the use of GETs in the regional transmission planning process. CAISO supports the use of GETs in the regional transmission planning process.⁴¹¹ MISO indicates that its current regional transmission planning process allows for the consideration of GETs, but also indicates that these technologies alone will not be able to address the changing needs of the transmission system.⁴¹² PJM states that, as part of its regional transmission planning process, it evaluates GETs proposals, to the extent submitted, in a manner not materially different from its evaluation of other project proposals.⁴¹³ PJM also notes that it conducts an advanced technology pilot program as a testing ground for new technologies that require integration into PJM operations and

⁴⁰⁶ Duke Comments at 13; EEI Comments at 7; MISO TOs Comments at 46-47.

⁴⁰⁷ AEP Comments at 15.

⁴⁰⁸ A dynamic line rating is “a transmission line rating that applies to a time period of not greater than one hour and reflects up-to-date forecasts of inputs such as (but not limited to) ambient air temperature, wind, solar heating, transmission line tension, or transmission line sag.” *Managing Transmission Line Ratings*, Order No. 881, 177 FERC ¶ 61,179, at PP 235, 238 (2021); 18 CFR 35.28(b)(14).

⁴⁰⁹ PJM Market Monitor Comments at 13.

⁴¹⁰ Potomac Economics Comments at 4.

⁴¹¹ CAISO Comments at 113-114.

⁴¹² MISO Comments at 45-46.

⁴¹³ PJM Comments at 59-60.

markets.⁴¹⁴ Additionally, SPP states that it supports the use of certain GETs where they can be appropriately used in regional transmission planning. It contends that it has considered certain GETs in the regional transmission planning process, but notes that certain technologies, such as dynamic line ratings or topological controls, have historically not lent themselves readily to utilization in the regional transmission planning process.⁴¹⁵

261. RTOs/ISOs, notably MISO and PJM, also discuss the importance of ensuring that public utility transmission providers understand any GETs that may be deployed on the system and their limitations, as well as understanding the challenges of integrating GETs into existing systems; for example, whether there is a need to change telemetry, modeling, other operating tools, and protocols, all of which necessitate careful consideration.⁴¹⁶ PJM notes the value of its ongoing Advanced Technology Pilot Program in addressing implementation challenges and identifying system risks associated with GETs. Expressing concerns about the deployment of GETs by nonincumbent transmission developers, PJM recommends that the Commission request that the industry, via NERC and/or U.S. DOE, develop a technology application guide addressing where, when, and how to apply GETs.⁴¹⁷ MISO states that it is important not to overstate the capabilities of GETs in the regional transmission planning process, as these technologies generally cannot substitute for long-term investment in transmission facilities that are needed to address the evolving resource mix, and notes the inherent uncertainty in forecasting power flows and congestion longer into the future.⁴¹⁸

262. A few commenters set forth criteria that public utility transmission providers should be required to consider in the regional transmission planning process to promote the use of GETs. These include: Optimizing the utilization of existing and new transmission facilities;⁴¹⁹ requiring energy efficiency as a design criterion for every transmission capital project;⁴²⁰ and requiring public utility transmission providers to show where they have incorporated GETs in their

⁴¹⁴ *Id.* at 60.

⁴¹⁵ SPP Comments at 12.

⁴¹⁶ MISO Comments at 28; PJM Comments at 62-63.

⁴¹⁷ PJM Comments at 60-63.

⁴¹⁸ MISO Comments at 45-46.

⁴¹⁹ Certain TDUs Comments at 22.

⁴²⁰ CTC Global Comments at 6.

regional transmission planning process where they are cost-effective.⁴²¹

263. Other commenters offer specific suggestions on how GETs could be implemented. TAPS urges the Commission to “[m]ake more explicit the mandate to consider GETs as part of regional planning processes,” arguing that Order No. 1000’s requirement to consider non-transmission alternatives “appears insufficient to ensure robust consideration of GETs in the planning process.”⁴²² In addition, TAPS recommends that the Commission expand the MISO/PJM Targeted Market Efficiency Process to the regional transmission planning process to promote the use of GETs for quick fixes identified in the regional transmission planning process.⁴²³

264. PJM suggests that the Commission require RTOs/ISOs and non-RTO/ISO transmission planning regions to “develop a robust process to account for the potential for [GETs] to be integrated into the planning processes as part of both near-term and long-range expansion options before requiring that new greenfield transmission be built.”⁴²⁴ Along similar lines, WATT Coalition suggests that for proposed transmission projects with an initial cost estimate above \$10 million, the Commission should require the transmission planning region to show documentation of its evaluation of alternative solutions utilizing GETs.⁴²⁵

265. EDF offers a specific application for GETs implementation, suggesting that the Commission encourage and even require that GETs be proposed to address outages that have a material impact on market efficiency, reliability, and resiliency. EDF notes that transmission system upgrades are often associated with multi-month outages, which can have a severe impact on market efficiency and suggests that GETs be proposed in combination with traditional upgrades or to minimize the impact of outages that can result from the construction of transmission upgrades.⁴²⁶ WATT Coalition builds on this notion, suggesting that the Commission require transmission owners and planning authorities to propose solutions, including GETs, that minimize the impacts of long duration outages.⁴²⁷

266. WATT Coalition encourages the Commission to require the periodic

publication of a report on grid utilization to show transmission usage data in order to provide system planners with a “more holistic profile of their system capacity, establishing a new dataset for targeted GETs deployment and associated consumer savings.”⁴²⁸ Arizona Commission adds that an independent transmission monitor could use information collected to provide feedback on how public utility transmission providers consider GETs.⁴²⁹

c. Need for Reform

267. Since Order No. 1000, commercially available technologies to make transmission systems operate more efficiently or cost-effectively have greatly advanced. This influx of new and improved technologies has the potential to improve the operation of new and existing transmission facilities and defer new transmission investments. As such, the consideration of new technological innovations in regional transmission planning processes could help to ensure that these processes are identifying more efficient or cost-effective regional transmission facilities and in turn, that Commission-jurisdictional rates are just and reasonable.

268. When the Commission issued Order No. 1000, integrating these new technologies was not a major focus of the rule, partly because many new technologies were either still in development or not yet widely in use. After more than a decade, the technologies available today may help to ensure that the transmission system operates more efficiently or cost-effectively. However, Order No. 1000-compliant regional transmission planning processes do not appear to have kept time with technology advancements and potentially need to be updated to ensure that they are appropriately considering these new technologies.

269. Recently, in Order No. 881, which required more accurate transmission line ratings in near-term transmission service through the use of ambient-adjusted transmission line ratings,⁴³⁰ the Commission highlighted the benefits of dynamic line ratings, including permitting greater power flows than would otherwise be allowed, aiding in the detection of situations where power flows should be reduced to maintain safe and reliable operations, and avoiding unnecessary wear on

transmission equipment.⁴³¹ Other benefits of dynamic line ratings that the Commission emphasized in Order No. 881 include strategic deployments and targeted applications in which dynamic line ratings can provide net benefits to customers by increasing the accuracy and power carrying capabilities of a line.⁴³² While the Commission declined to mandate dynamic line ratings in Order No. 881, it required RTOs/ISOs to establish and maintain systems and procedures necessary to allow transmission owners to electronically update transmission line ratings for ambient-adjusted ratings, which could facilitate the use of dynamic line ratings.⁴³³ In addition, the Commission issued a Notice of Inquiry to continue to explore the implementation of dynamic line ratings.⁴³⁴ This Notice of Inquiry sought comment on: Whether and how the required use of dynamic line ratings is needed to ensure just and reasonable Commission-jurisdictional rates; potential criteria for dynamic line ratings requirements; the benefits, costs, and challenges of implementing dynamic line ratings; the nature of potential dynamic line ratings requirements; and potential timeframes for implementing dynamic line ratings requirements.⁴³⁵

270. At a recent workshop held by Commission staff,⁴³⁶ participants highlighted the benefits of advanced power flow control devices,⁴³⁷ such as their ability to modify a transmission line’s electrical characteristics to increase or decrease power flowing through the line without increasing the capacity of the line. Participants also highlighted that optimal transmission switching acts to completely open or close off routes to power flow. Finally, participants noted that advanced power

⁴³¹ *Id.* P 253.

⁴³² *Id.*

⁴³³ *Id.* P 255.

⁴³⁴ *Implementation of Dynamic Line Ratings*, 178 FERC ¶ 61,110 (2022).

⁴³⁵ *Id.* P 1.

⁴³⁶ *Grid-Enhancing Technologies*, Notice of Workshop, Docket No. AD19-19-000 (issued Sept. 9, 2019).

⁴³⁷ Advanced power flow control devices serve a transmission function. These devices can help the system operator control power flows over a given path and can include phase shifting transformers (also known as phase angle regulators) and devices or systems necessary for implementing optimal transmission switching. Advanced power flow control devices allow power to be pushed and pulled to alternate lines with spare capacity leading to maximum utilization of existing transmission capacity. See T. Bruce Tsuchida et al., *The Brattle Group, Unlocking the Queue with Grid-Enhancing Technologies*, at 19–20 (Feb. 1, 2021), https://watt-transmission.org/wp-content/uploads/2021/02/Brattle_Unlocking-the-Queue-with-Grid-Enhancing-Technologies_Final-Report_Public-Version.pdf90.pdf.

⁴²¹ PIOs Comments at 97.

⁴²² TAPS Comments at 2.

⁴²³ *Id.* at 22.

⁴²⁴ PJM Comments at 63.

⁴²⁵ WATT Coalition Comments at 4.

⁴²⁶ EDF Comments at 16–18.

⁴²⁷ WATT Coalition Comments at 5.

⁴²⁸ *Id.*

⁴²⁹ Arizona Commission Reply Comments at 12.

⁴³⁰ Order No. 881, 177 FERC ¶ 61,179 at P 34.

flow control devices, including optimal transmission switching, provide the tools to effectively control and route power to lines that have more capacity than those that do not, which can reduce congestion, reduce costs to consumers, and increase reliability of the transmission system.

271. To address the issues described above, we propose reforms to require public utility transmission providers to more fully consider two specific technologies—dynamic line ratings and advanced power flow control devices—in regional transmission planning processes.

d. Proposed Reform

272. In order to help ensure that regional transmission planning processes identify more efficient or cost-effective transmission facilities for selection in the regional transmission plan for purposes of cost allocation, we propose to require that public utility transmission providers in each transmission planning region more fully consider in regional transmission planning and cost allocation processes two specific technologies: The incorporation into transmission facilities of dynamic line ratings and advanced power flow control devices. We believe that selecting transmission facilities that incorporate dynamic line ratings or advanced power flow control devices in the regional transmission plan for purposes of cost allocation may offer a more efficient or cost-effective alternative to other regional transmission facilities in certain instances.

273. Specifically, we believe it is possible that selecting transmission facilities that incorporate such technologies serving a transmission function in the regional transmission plan for purposes of cost allocation could be more efficient or cost-effective than a proposed regional transmission facility that does not use such technologies. For example, selecting in the regional transmission plan for purposes of cost allocation a transmission facility that is designed with the equipment necessary to support dynamic line ratings may provide greater benefits through reduced production costs than a similar transmission facility that does not include such equipment. Likewise, selecting in the regional transmission plan for purposes of cost allocation a transmission facility that incorporates an advanced power flow control device may provide greater production costs benefits under transmission outage scenarios than another transmission facility.

274. To facilitate greater use of these technologies where warranted, we propose to require that public utility transmission providers in each transmission planning region consider for each identified regional transmission need whether selecting transmission facilities in the regional transmission plan for purposes of cost allocation that incorporate dynamic line ratings or advanced power flow control devices would be more efficient or cost-effective than transmission facilities that do not incorporate these technologies. Specifically, such consideration should include first, whether incorporating dynamic line ratings or advanced power flow control devices into existing transmission facilities could meet the same regional transmission need more efficiently or cost-effectively than other potential transmission facilities. Second, when evaluating transmission facilities for potential selection in the regional transmission plan for purposes of cost allocation, the public utility transmission providers in the transmission planning region must also consider whether incorporating dynamic line ratings and advanced power flow control devices as part of any potential regional transmission facility would be more efficient or cost-effective. We propose that this requirement apply in all aspects of the regional transmission planning processes, including the existing regional transmission planning processes for near-term regional transmission needs and Long-Term Regional Transmission Planning, as proposed in this NOPR. As is the case for any other transmission facility selected in the regional transmission plan for purposes of cost allocation, we propose that the costs to incorporate dynamic line ratings or advanced power flow control devices that are selected in the regional transmission plan for purposes of cost allocation—whether as an addition to an existing transmission facility or as part of a new regional transmission facility—will be allocated using the applicable regional cost allocation method.

275. As required by Order No. 1000, the evaluation process must culminate in a determination that is sufficiently detailed for stakeholders to understand why a particular transmission facility was selected or not selected in the regional transmission plan for purposes of cost allocation.⁴³⁸ This process must now include the consideration of dynamic line ratings and advanced power flow control devices and why

⁴³⁸ Order No. 1000, 136 FERC ¶ 61,051 at P 328; Order No. 1000–A, 139 FERC ¶ 61,132 at P 267.

they were not incorporated into selected regional transmission facilities.

276. As discussed above, the ANOPR requested comment on GETs as a larger category of transmission technologies. While we recognize that there are likely other novel technologies that public utility transmission providers could consider as they develop their regional transmission plans, we are not proposing to mandate their consideration at this time. We believe that there is enough operational experience with dynamic line ratings and power flow control devices such that public utility transmission providers should be able to adequately consider their operations in the regional transmission planning process. In addition, the nature of dynamic line ratings and advanced power flow control devices allows for consideration in regional transmission planning and cost allocation processes in a way that may not be possible for other technologies.⁴³⁹

277. We seek comment on the requirements proposed in this section of the NOPR. We also seek comment on whether there are other transmission technologies serving a transmission function that should be considered in regional transmission planning and cost allocation processes. Finally, we seek comment on whether non-RTO/ISO transmission planning regions should be required to update their energy management systems or make other similar changes if dynamic line ratings are identified as a more efficient or cost-effective transmission facility selected in the regional transmission plan for purposes of cost allocation.⁴⁴⁰

V. Regional Transmission Cost Allocation

278. We preliminarily find that reforms to public utility transmission providers' regional cost allocation methods are necessary to ensure that Commission-jurisdictional rates are just and reasonable and not unduly discriminatory or preferential. As discussed below, we propose to require that public utility transmission providers in each transmission planning region seek the agreement of relevant state entities within the transmission planning region regarding the cost allocation method or methods that will

⁴³⁹ For example, while transmission topology optimization can serve a useful function in optimizing system flows and deferring transmission investment in the short-term, system conditions over 5 to 20 years in the future may be too uncertain to rely on system reconfiguration to address identified transmission needs.

⁴⁴⁰ Cf. 18 CFR 35.25(g)(13)(i) (requiring each RTO/ISO to maintain systems and procedures to accept and utilize dynamic line ratings data).

apply to transmission facilities selected in the regional transmission plan for purposes of cost allocation through Long-Term Regional Transmission Planning and revise their OATTs to include the method or methods.⁴⁴¹

279. We also propose a reform to facilitate an additional opportunity for involvement of state regulators in decisions about how the costs of transmission facilities selected in a regional transmission plan for purposes of cost allocation through Long-Term Regional Transmission Planning will be allocated. Specifically, this reform would require public utility transmission providers in each transmission planning region to add a time period for states to negotiate an alternate cost allocation method for a transmission facility selected in the regional transmission plan for purposes of cost allocation through Long-Term Regional Transmission Planning.

A. Background

280. In Order No. 890, the Commission noted that for a transmission planning process to comply with the final rule, it must address the allocation of costs of new transmission facilities. The Commission required public utility transmission providers and their stakeholders to develop a new cost allocation method, if needed, for any new transmission facilities that did not fall under public utility transmission providers' existing cost allocation methods.⁴⁴² The Commission stated that such methods should consider: (1) Whether a proposed cost allocation method fairly assigns costs among participants, including those that cause them to be incurred and those that otherwise benefit from them; (2) whether a proposed cost allocation method provides adequate incentives to construct new transmission; and (3) whether a proposed cost allocation method is generally supported by the region's state authorities and participants.⁴⁴³

281. In Order No. 1000, the Commission determined that, while existing cost allocation methods may have sufficed in the past, changing circumstances in the industry led to the need for changes to cost allocation

requirements.⁴⁴⁴ The Commission observed that, as transmission needs increased, the challenges in allocating the cost of transmission appeared to grow more acute.⁴⁴⁵ The Commission further found that, in "the absence of clear cost allocation rules for regional transmission facilities, there is a greater potential that public utility transmission providers and nonincumbent transmission developers may be unable to develop transmission facilities that are determined by the region to meet their needs."⁴⁴⁶ As a result, the Commission required each public utility transmission provider to have in place a method, or set of methods, for allocating the costs of new transmission facilities selected in the regional transmission plan for purposes of cost allocation and established a set of six cost allocation principles that public utility transmission providers' regional cost allocation methods must satisfy.⁴⁴⁷ The Commission determined that this principles-based approach requires the allocation of the costs of new transmission facilities in a manner that is at least roughly commensurate with the benefits received by those that pay those costs while allowing for regional flexibility.⁴⁴⁸

282. The six regional transmission cost allocation principles adopted in Order No. 1000 are: (1) The costs of transmission facilities selected in a regional transmission plan for purposes of cost allocation must be allocated to those within the transmission planning region that benefit from those facilities in a manner that is at least roughly commensurate with estimated benefits; (2) those that receive no benefit from transmission facilities, either at present or in a likely future scenario, must not be involuntarily allocated any of the costs of those transmission facilities; (3) a benefit to cost threshold ratio, if adopted, cannot exceed 1.25 to 1; (4) costs must be allocated solely within the transmission planning region unless another entity outside the region voluntarily assumes a portion of those costs; (5) the method for determining benefits and identifying beneficiaries must be transparent; and (6) there may be different regional cost allocation methods for different types of transmission facilities, such as those needed for reliability, congestion relief, or to achieve Public Policy

Requirements.⁴⁴⁹ The Commission declined to require that public utility transmission providers adopt a universal or comprehensive definition of "benefits" and "beneficiaries" of regional transmission facilities, instead permitting regional flexibility and examining each transmission planning region's definitions on compliance.⁴⁵⁰

283. While the Commission determined that generator interconnection was outside the scope of Order No. 1000, it also stated that public utility transmission providers could propose a regional transmission cost allocation method that allocates costs directly to generators as beneficiaries, but any effort to do so must be consistent with the Order No. 2003 generator interconnection process.⁴⁵¹ No public utility transmission providers have proposed a regional cost allocation method that allocates costs directly to generators, instead allocating all costs of transmission facilities selected in a regional transmission plan for purposes of cost allocation to transmission customers.

284. On compliance, public utility transmission providers in each transmission planning region adopted varying regional transmission cost allocation methods to comply with the cost allocation principles of Order No. 1000. The majority of these methods allocate the costs of transmission facilities selected in a regional transmission plan for purposes of cost allocation that address reliability needs separately from those that address economic needs, and separately from those that address transmission needs driven by Public Policy Requirements.

285. Some public utility transmission providers' Order No. 1000-compliant regional transmission cost allocation methods identify benefits across a portfolio of transmission facilities rather than on a facility-by-facility basis. An example of a transmission planning region accounting for broader benefits is MISO, which accounts for the following benefits in their MVP portfolio:⁴⁵²

- Economic: increased market efficiency (congestion and fuel savings and operating reserves), deferred generation investment (system planning

⁴⁴⁹ Order No. 1000, 136 FERC ¶ 61,051 at PP 622, 637, 646, 657, 668, 685.

⁴⁵⁰ *Id.* P 624.

⁴⁵¹ Order No. 1000-A, 139 FERC ¶ 61,132 at P 680.

⁴⁵² MISO, *Multi-Value Project Portfolio, Detailed Business Case*, <https://cdn.misoenergy.org/2011%20MVP%20Portfolio%20Detailed%20Business%20Case117056.pdf>. More general benefits requirements for MVP Projects are described at MISO, FERC Electric Tariff, Attachment FF, Section ILC.2, .5.

⁴⁴¹ We are not proposing to require any changes to existing interregional cost allocation methods for interregional transmission facilities that are selected in the regional transmission plan for purposes of cost allocation and that the Commission previously accepted as compliant with Order No. 1000.

⁴⁴² Order No. 890, 118 FERC ¶ 61,119 at PP 557-558.

⁴⁴³ *Id.* P 559.

⁴⁴⁴ Order No. 1000, 136 FERC ¶ 61,051 at P 497.

⁴⁴⁵ *Id.* P 498.

⁴⁴⁶ *Id.* P 558.

⁴⁴⁷ *Id.*

⁴⁴⁸ *Id.* P 10; Order No. 1000-A, 139 FERC ¶ 61,132 at P 647.

reserve margins and transmission line losses), and other capital benefits (wind turbine investment and future transmission investment);⁴⁵³

- Reliability: transmission line overloads and system voltage constraints mitigated, transient stability benefits, mitigation of fault conditions that could cause system instability, voltage stability, increased transfer capacity, increased transfer capability;⁴⁵⁴

- Policy: reliably enables the delivery of energy in support of policy mandates.⁴⁵⁵

B. ANOPR

286. In the ANOPR, the Commission recognized that reforms to regional transmission planning cannot be successful without ensuring that transmission providers and customers alike are able to identify the types of benefits these transmission facilities can provide and also identify the beneficiaries that would receive those benefits, along with the relative proportion of benefits that accrue to each of those beneficiaries.⁴⁵⁶ Acknowledging that cost allocation methods can be “difficult and controversial,” particularly for regional transmission facilities that may be both more costly and have potentially broad benefits, the Commission sought comment on whether there should be reforms to cost allocation in regional transmission planning and cost allocation processes.⁴⁵⁷

287. Additionally, the Commission noted that one way to add oversight to the regional transmission planning and cost allocation processes could be to involve state commissions in those processes.⁴⁵⁸ For example, the Commission pointed to SPP’s Regional State Committee (RSC), which provides collective state regulatory agency input in areas under the RSC’s primary responsibilities and on matters of regional importance related to the development and operation of the bulk electric transmission system. Pursuant to the SPP Bylaws, “with respect to transmission planning, the RSC will determine whether transmission upgrades for remote resources will be included in the regional transmission planning process and the role of transmission owners in proposing transmission upgrades in the regional

planning process.”⁴⁵⁹ The Commission sought comment on whether this type of model, or other models that may be proposed, could be expanded to other regions and other topics; for example, whether a state-led committee could, *inter alia*, provide insight into regional transmission facility costs and cost allocation methods.⁴⁶⁰

C. Comments

288. In response to the ANOPR, the Commission received comments from a broad range of stakeholders, generally recognizing the importance of cost allocation to successful development of more efficient or cost-effective regional transmission facilities and advocating different ways to reduce the likelihood that controversy regarding who pays for regional transmission facilities obstructs their development and to ensure the costs of regional transmission facilities are allocated roughly commensurate with benefits.

289. In their comments, many state regulators and groups advocate for increased state involvement in cost allocation decisions.⁴⁶¹ NARUC explains that most states think that more should be done to encourage and incent states with similar public policy profiles to use the State Agreement Approach, which it says has the benefit of being a stakeholder-driven product that enjoys significant state support.⁴⁶² NARUC further asserts that planners could provide a platform for states with similar policy objectives to better coordinate and agree upon cost allocation, while urging that regions should “retain the flexibility to develop innovative approaches to allocating the costs.”⁴⁶³ NESCOE asserts that states need to occupy a central role in cost allocation, consistent with applicable state requirements.⁴⁶⁴ NESCOE calls for state decision making in the evaluation and selection of projects providing

public policy benefits and for a robust role in the regional transmission planning processes.⁴⁶⁵ Some commenters note that they are already pursuing cost allocation reforms with transmission planning regions.⁴⁶⁶ Arizona Commission contends that, because state commissions are already tasked with ensuring retail rates are just and reasonable for their ratepayers, increased state commission involvement in cost allocation processes would better allow state commissions to establish just and reasonable retail rates.⁴⁶⁷ New Jersey Commission states that to enable cost allocation reforms the Commission could mandate public utility transmission providers institute a process for states to submit portions of their public policies for consideration into PJM’s RTEP.⁴⁶⁸ Mississippi Commission notes that where one or more states have common economic development, environmental, or other goals, and require transmission investment to achieve those goals, the cost of such projects could be allocated to those states in an agreed upon amount.⁴⁶⁹ Northwest and Intermountain notes that a strong state role is particularly important in non-RTO/ISO regions.⁴⁷⁰ ACPA and ESA state that a Commission approach to cost allocation could include cost contributions from states and interconnection customers.⁴⁷¹

290. But while there is broad agreement on the importance of states’ role in cost allocation, a number of states indicate that it is difficult for them to participate in a timely manner in the regional transmission planning and cost allocation processes to address concerns regarding cost allocation.⁴⁷² District of Columbia’s Office of the People’s Counsel calls for the Commission to facilitate “the participation of any group that may be subject to cost allocation in early planning stages to determine which outcome best serves the needs of all the customers in that region.”⁴⁷³ Other state commissions also call for greater involvement in cost allocation

⁴⁵³ MISO, *Multi-Value Project Portfolio, Detailed Business Case* at 27.

⁴⁵⁴ *Id.* at 17–19.

⁴⁵⁵ *Id.* at 21.

⁴⁵⁶ ANOPR, 176 FERC ¶ 61,024 at P 84.

⁴⁵⁷ *Id.* PP 83–89.

⁴⁵⁸ ANOPR, 176 FERC ¶ 61,024 at P 176.

⁴⁵⁹ ANOPR, 176 FERC ¶ 61,024 at P 176 *Id.* (citing SPP, *Governing Documents Tariff, Bylaws, Section 7.2 (Regional State Committee)* (1.0.0)).

⁴⁶⁰ ANOPR, 176 FERC ¶ 61,024 at P 177.

⁴⁶¹ Members of the Task Force similarly advocated for state regulatory involvement in cost allocation processes, emphasizing that states are not merely stakeholders. *See, e.g., Joint Fed.-State Task Force on Elec. Transmission*, Transcript of Feb. 16, 2022 Meeting, Docket No. AD21–15–000, at 107:1–6 (Chair French), 108:17–18 (Comm’r Duffley), 109:2 (Chair Nelson), 110:4–5, 15–16 (Chair Stanek), 112:3–5 (Comm’r Rechtschaffen).

⁴⁶² NARUC Comments at 25; *see also* Ohio Commission Comments at 15 (noting the PJM State Agreement Approach and related “hard work and progress that has already been made in incorporating state policy goals into transmission planning in the PJM region.”); Pennsylvania Commission Comments at 6 (similarly calling for respect of the State Agreement Approach).

⁴⁶³ NARUC Comments at 25–26.

⁴⁶⁴ NESCOE Comments at 21–25.

⁴⁶⁵ *Id.* at 49.

⁴⁶⁶ NESCOE Comments *Id.* at 47–48; MISO Comments at 8, 21.

⁴⁶⁷ Arizona Commission Comments at 7; *see also* SPP RSC Comments at 10 (urging the Commission to seek approaches that enhance state authority rather than diminishing or diluting it).

⁴⁶⁸ New Jersey Commission Comments at 12–15.

⁴⁶⁹ Mississippi Commission Comments at 14.

⁴⁷⁰ Northwest and Intermountain Comments at 28–30.

⁴⁷¹ ACPA and ESA Comments at 75.

⁴⁷² District of Columbia’s Office of the People’s Counsel Comments at 4–5.

⁴⁷³ *Id.* at 5.

decisions.⁴⁷⁴ Maryland Energy Admin asserts that earlier state involvement in cost allocation for the Artificial Island transmission facility, for example, could have “avoided significant delays and additional costs, including some that were ultimately assigned to ratepayers.”⁴⁷⁵ Other commenters note that failure to gain state support for selection and cost allocation for transmission facilities can result in states subsequently blocking or delaying transmission facilities selected in regional transmission planning and cost allocation processes through subsequent state siting proceedings.⁴⁷⁶

291. Many commenters support consideration of a wider set of benefits than those currently used to evaluate transmission facilities in the regional transmission plan for purposes of cost allocation.⁴⁷⁷ PIOs advocate that the Commission conduct a survey of all potential benefits that can result from multi-value, scenario-based planning and require that public utility transmission providers consider those benefits for regional cost allocation as well as for regional transmission planning.⁴⁷⁸ U.S. DOE states that the Commission should establish a minimum set of potential benefits (and costs) to be considered, to ensure that they are taken into account in both project selection and in the allocation of costs for selected projects, adding this practice would help ensure that benefits not currently fully valued will be more appropriately incorporated in the planning process and foster consistency among planning regions.⁴⁷⁹ Certain TDUs express that cost allocation

reforms must be equitable for consumers.⁴⁸⁰

292. Some RTOs/ISOs support the Commission requiring public utility transmission providers to consider a broader set of transmission benefits. For example, NYISO states that requiring public utility transmission providers to adopt a broader range of evaluation and selection criteria in their transmission planning processes would enable them to consider the reliability, economic, and public policy benefits of proposed solutions to a transmission need regardless of the underlying driver of the need, which would enhance their ability to select the more efficient or cost-effective transmission solution.⁴⁸¹ SPP states that the Commission should adopt a minimum, standardized set of benefit metrics for all public utility transmission providers to ensure that transmission is valued consistently between regions and to allow for an apples-to-apples comparison of potential projects.⁴⁸² CAISO and MISO state that the Commission could consider requiring public utility transmission providers to consider the resilience benefits of transmission.⁴⁸³ If the Commission expands the set of benefits that public utility transmission providers must consider, PJM urges the Commission to provide clear decision criteria on whether and when it is appropriate for public utility transmission planners to order construction of new transmission for anticipated future generation not yet in the interconnection queue.⁴⁸⁴ If the Commission requires the consideration of a broader set of transmission benefits, several RTOs/ISOs urge the Commission to provide for regional flexibility.⁴⁸⁵

293. Minnesota Commerce acknowledges that cost allocation is a central factor in determining whether to build needed regional transmission.⁴⁸⁶ Many commenters state that existing regional transmission cost allocation methods are sound and/or should continue.⁴⁸⁷ At least one commenter suggests that ultimate cost allocation

reforms should not unintentionally disrupt settled methods.⁴⁸⁸

294. Some commenters suggest special cost allocation methods for transmission facilities resulting from scenario-based planning. Exelon asserts that the default cost allocation method for transmission projects resulting from scenario-based planning should reflect a load-ratio share method,⁴⁸⁹ but that the Commission should allow suitable substitute cost allocations as agreed to by the participating states to reflect the particular aggregation of benefits provided by the portfolio.⁴⁹⁰ On the other hand, Michigan Commission notes that postage stamp cost allocation is highly divisive.⁴⁹¹

295. Some commenters state that further analysis is necessary to determine if prescriptive action by the Commission is necessary and whether alteration of Order No. 1000’s six regional transmission cost allocation principles is warranted.⁴⁹² AEP urges that benefits and methodologies to measure those benefits should be consistent throughout regions.⁴⁹³

296. Some commenters propose cost allocation pursuant to benefits related to anticipated future generation, resilience, and/or climate and environmental benefits.⁴⁹⁴ APPA states that, to the extent that regions shift their transmission planning processes to place a greater emphasis on anticipated future generation or otherwise modify existing planning protocols towards a more holistic analysis, it may be appropriate to consider conforming changes to cost allocation methods.⁴⁹⁵

⁴⁷⁴ Arizona Commission Comments at 7; Maryland Energy Administration Admin Comments at 2.

⁴⁷⁵ Maryland Energy Administration Admin Comments at 3.

⁴⁷⁶ Exelon Comments at 31–32.

⁴⁷⁷ ACOE Comments at ii; AEE Comments at 31–32; ACEG Comments at 6–8; ACPA and ESA Comments at 75; AEP Comments at 14; Amazon Comments at 4; Anbaric Comments at 29; Avangrid Comments at 9; Business Council for Sustainable Energy Comments at 2; Citizens Energy Comments at 6–7; City of New York Comments at 3–4; Union of Concerned Scientists Comments at 66–75; Consumers Council Comments at 4, 16; Duke Comments at 12; EDF Comments at 8–10; EEI Comments at 33; ITC Comments at 28–34; Massachusetts Attorney General Comments at 24–25; New Jersey Commission Comments at 13–14, 17–19; NextEra Comments at 83–88; Northwest and Intermountain Comments at 35–38; Orsted Comments at 6–7; PIOs Comments at 30, 60; Policy Integrity Comments at 43; PSEG Comments at 25–27; REBA Comments at 17; RMI Comments at 4; SEIA Comments at 9; Shell Comments at 18–20; State Agencies Comments at 21–22; State of Massachusetts Comments at 16–17; U.S. DOE Comments at 7–9, 23–24; WIREs Comments at 18.

⁴⁷⁸ PIOs Comments at 30; *see also* Orsted Comments at 6.

⁴⁷⁹ U.S. DOE Comments at 23.

⁴⁸⁰ Certain TDUs Comments at 5–6.

⁴⁸¹ NYISO Reply Comments at 10–11.

⁴⁸² SPP Comments at 14.

⁴⁸³ CAISO Comments at 85–88; MISO Comments at 85.

⁴⁸⁴ PJM Comments at 8.

⁴⁸⁵ CAISO Comments at 85; MISO Comments at 85; NYISO Comments at 35–36.

⁴⁸⁶ Minnesota Commerce Comments at 6–7 (noting cost allocation is one of the more difficult barriers to new transmission development); *see also* November 2021 Technical Conference Tr. at 79.

⁴⁸⁷ *See, e.g.,* NASUCA Comments at 6; North Carolina Commission Comments at 23; Ohio Commission Comments at 12–13; SERTP Comments at 4, 21–23; SoCal Edison Comments at 6.

⁴⁸⁸ *See* NESCOE Comments at 50.

⁴⁸⁹ Under the load-ratio share regional cost allocation method, the costs of new transmission facilities are allocated based on some measure of system usage, whether at peak or overall. Specifically, load-ratio share cost allocation methods include both demand charge approaches and volumetric (energy) approaches. Under the demand charge approach, costs are allocated in proportion to each transmission customer’s contribution to the system peak load (which can be coincident or non-coincident peak). In contrast, under the volumetric approach, costs are allocated based on each transmission customer’s share of total system usage. *See* CAISO, *Review Transmission Access Charge Structure Issue Paper*, at 18, tbl. 2: Summary of ISO/RTO approaches to transmission charges (June 30, 2017).

⁴⁹⁰ Exelon Comments at 30–31.

⁴⁹¹ Michigan Commission Comments at 20.

⁴⁹² *See, e.g.,* EEI Comments at 32–33; NARUC Comments at 22; *see also* *Joint Fed.-State Task Force on Elec. Transmission*, Transcript of Feb. 16, 2022 Meeting, Docket No. AD21–15–000, at 36:12–13 (Chair Brown Dutrieuille) (reiterating NARUC’s comments that the Order No. 1000 cost allocation principles should remain in place).

⁴⁹³ AEP Comments at 15.

⁴⁹⁴ *See, e.g.,* ACEG Comments at 6–7; Consumers Council Comments at 16–17; WIREs Comments at 18–19; PSEG Comments at 5.

⁴⁹⁵ APPA Comments at 15–16.

D. Need for Reform

297. The Commission has previously recognized that knowing how the costs of transmission facilities would be allocated is critical to the development of new transmission infrastructure.⁴⁹⁶ Without such clarity, the likelihood that transmission facilities selected in a regional transmission plan for purposes of cost allocation will be developed is diminished, undermining the entire purpose of the regional transmission planning process, namely, the development of more efficient or cost-effective transmission facilities.⁴⁹⁷ Yet, identifying a cost allocation method that is perceived as fair, especially within transmission planning regions that encompass several states, remains challenging. Litigation contesting regional transmission cost allocation methods persists.⁴⁹⁸ Moreover, even where the cost allocation method is reasonably settled, regional transmission facilities face significant uncertainty and risk of not reaching construction if certain stakeholders—in particular, a state regulator responsible for permitting transmission facilities—do not perceive the regional transmission facilities' value as commensurate with their costs.⁴⁹⁹

298. We are concerned that these challenges are likely to be exacerbated in the context of Long-Term Regional Transmission Planning and Cost Allocation. We recognize that, by requiring a longer-term planning horizon, consideration of multiple scenarios, and accounting for the longer-term factors that affect transmission needs, Long-Term Regional Transmission Planning entails a more complex set of considerations as compared to existing regional transmission planning requirements. We are concerned that this increased complexity could make cost allocation decisions more contentious, which may risk undermining the development of more efficient or cost-effective regional transmission facilities to address transmission needs driven by changes in the resource mix and demand. For example, we anticipate that

⁴⁹⁶ Order No. 1000, 136 FERC ¶ 61,051 at P 496 (discussing findings in Order No. 890).

⁴⁹⁷ *Id.*

⁴⁹⁸ See, e.g., *Long Island Power Auth. v. FERC*, 27 F.4th 705, 709 (D.C. Cir. 2022) (addressing a “long-running dispute” over regional transmission cost allocation in PJM); *Pub. Serv. Elec. & Gas Co. v. FERC*, 989 F.3d 10 (D.C. Cir. 2021) (addressing dispute over cost allocation for particular transmission upgrades).

⁴⁹⁹ See, e.g., *Transource Pa., LLC v. Dutrieuille*, Case No. 1:2021cv01110 (filed June 22, 2021, M.D. Pa.) (lawsuit challenging state commission's denial of an application for siting and construction of regional transmission facilities).

stakeholders, including state regulators, may diverge in their views of which scenarios best reflect future transmission needs, and these conflicting perceptions may lead to disagreements regarding who should pay for selected transmission facilities.

299. For these reasons, we preliminarily find that the cost allocation requirements for transmission facilities identified and selected in the regional transmission plan through Long-Term Regional Transmission Planning proposed in this proceeding may differ in part from those established in Order No. 1000. In particular, we believe that providing state regulators with a formal opportunity to develop a cost allocation method for regional transmission facilities selected through Long-Term Regional Transmission Planning could help increase stakeholder—and state—support for those facilities, which, in turn, may increase the likelihood that those facilities are sited and ultimately developed with fewer costly delays and better ensure just and reasonable Commission-jurisdictional rates.

300. The Commission has long recognized the critical role of states in transmission planning.⁵⁰⁰ The Commission recently issued a Policy Statement addressing state efforts to develop transmission facilities through voluntary agreements to plan and pay for those facilities.⁵⁰¹ In the statement, the Commission recognized that such voluntary agreements may allow state-prioritized transmission facilities to be planned and built more quickly than would comparable facilities that are planned through the regional transmission planning process, and encouraged elimination to barriers to such agreements.⁵⁰² The Commission has also recently taken action to further federal-state coordination and cooperation in this area through the

⁵⁰⁰ See Order No. 1000, 136 FERC ¶ 61,051 at P 688 (citing Order No. 890, 118 FERC ¶ 61,119 at P 574). In 2015, the Commission accepted NYISO's proposal to facilitate the timely participation of the New York State Public Service Commission (New York Commission) in review of transmission facilities proposed to address transmission needs driven by Public Policy Requirements. Under NYISO's process, the New York Commission is provided a time period during which it may propose a cost allocation method or negotiate a cost allocation method with the developer of such a proposed transmission facility before the Order No. 1000-compliant *ex ante* regional cost allocation method is applied. See *NY Indep. Sys. Operator, Inc.*, 151 FERC ¶ 61,040, at PP 119–121 (2015).

⁵⁰¹ *State Voluntary Agreements to Plan and Pay for Transmission Facilities*, 175 FERC ¶ 61,225 (2021).

⁵⁰² *Id.* PP 2, 6.

establishment of the Task Force.⁵⁰³ The Commission included in the list of topics that the Task Force may consider: (1) “[E]xploring potential bases for one or more states to use FERC-jurisdictional transmission planning processes to advance their policy goals, including multi-state goals;” and (2) “[e]xploring opportunities for states to voluntarily coordinate in order to identify, plan, and develop regional transmission solutions.”⁵⁰⁴ The Task Force, comprised of FERC Commissioners and state regulators, discussed the role of states in regional transmission planning and cost allocation processes at two meetings thus far, and numerous state regulators and other stakeholders filed comments in response to the ANOPR on this topic. The general consensus is that involving state regulators when it comes to allocating the costs of new regional transmission facilities is particularly important given states' role in siting those transmission facilities, including consideration of the costs and benefits when making state public interest determinations.⁵⁰⁵

301. We believe that facilitating involvement of state regulators in the cost allocation process, as further described below, would allow states to voluntarily coordinate to advance their policy goals through needed transmission development and may minimize delays and additional costs that can be associated with siting proceedings that follow the regional transmission planning and cost allocation processes at the federal level.⁵⁰⁶ We believe that providing an opportunity for state involvement in regional transmission planning cost allocation processes is becoming more important as states take a more active role in shaping the resource mix and demand, which, in turn, means that those state actions are increasingly affecting the long-term transmission

⁵⁰³ See *Joint Fed.-State Task Force on Elec. Transmission*, 175 FERC ¶ 61,224 at PP 1–2 (establishing the Task Force).

⁵⁰⁴ *Id.* P 6.

⁵⁰⁵ See NARUC Comments at 27, 46–47; NESCOE Comments at 21–25; Arizona Commission Comments at 7; SPP RSC Comments at 10; Maryland Energy Admin Comments at 2; *Joint Fed.-State Task Force on Elec. Transmission*, Transcript of Feb. 16, 2022 Meeting, Docket No. AD21–15–000, at 102:13–24 (Chair Thomas), 110:24–111:8 (Comm'r Allen), 111:24–112:5 (Comm'r Rechtschaffen), 134:4–9 (Chair Stanek) (including in the list of three overarching themes from the meeting that of state consultation—soliciting state input, at a minimum—on cost allocation).

⁵⁰⁶ E.g., Maryland Energy Admin Comments at 3 (pointing to significant delays and costs associated with the Artificial Island transmission facility); Exelon Comments at 31–32 (speaking generally to states blocking or delaying transmission development through siting).

needs for which we are proposing to require public utility transmission providers to plan in this NOPR.

E. Proposed Reform

1. State Involvement in Cost Allocation for Long-Term Regional Transmission Facilities⁵⁰⁷

302. We propose to require that public utility transmission providers in each transmission planning region revise their OATTs to include either (1) a Long-Term Regional Transmission Cost Allocation Method⁵⁰⁸ to allocate the costs of Long-Term Regional Transmission Facilities, or (2) a State Agreement Process⁵⁰⁹ by which one or more relevant state entities may voluntarily agree to a cost allocation method, or (3) a combination thereof.⁵¹⁰ We propose to require that the Long-Term Regional Transmission Cost Allocation Method and any cost allocation method resulting from the State Agreement Process for Long-Term Regional Transmission Facilities comply with the existing six Order No.

⁵⁰⁷ We propose to define a Long-Term Regional Transmission Facility as a transmission facility identified as part of Long-Term Regional Transmission Planning and selected in the regional transmission plan for purposes of cost allocation to address transmission needs driven by changes in the resource mix and demand.

⁵⁰⁸ We propose to define a Long-Term Regional Transmission Cost Allocation Method as an *ex ante* regional cost allocation method that would be included in each public utility transmission provider's OATT as part of Long-Term Regional Transmission Planning. The developer of a Long-Term Regional Transmission Facility would be entitled to use the Long-Term Regional Transmission Cost Allocation Method if it is the applicable method.

⁵⁰⁹ We propose to define a State Agreement Process as an *ex post* cost allocation process that would be included in each public utility transmission provider's OATT as part of Long-Term Regional Transmission Planning, which may apply to an individual Long-Term Regional Transmission Facility or a portfolio of such Facilities grouped together for purposes of cost allocation. After a Long-Term Regional Transmission Facility is selected in the regional transmission plan for purposes of cost allocation, the State Agreement Process would be followed to establish a cost allocation method for that facility (if agreement can be reached). If the Commission subsequently approves the cost allocation method that results from the State Agreement Process, the developer of the Long-Term Regional Transmission Facility would be entitled to use that cost allocation method if it is the applicable method.

⁵¹⁰ For example, a "combination" approach may entail (i) providing a Long-Term Regional Transmission Cost Allocation Method for certain types of Long-Term Regional Transmission Facilities and providing a State Agreement Process for others; or (ii) providing for cost allocation for a Long-Term Regional Transmission Facility, portfolio, or type of such facilities partially based on a Long-Term Regional Transmission Cost Allocation Method and partially based on funding contributions in accordance with a State Agreement Process.

1000 regional cost allocation principles.⁵¹¹

303. In order to comply with this proposed requirement, public utility transmission providers in each transmission planning region would be required to seek the agreement of relevant state entities within the transmission planning region regarding the Long-Term Regional Transmission Cost Allocation Method, State Agreement Process, or a combination thereof. We propose to require public utility transmission providers in each transmission planning region to explain how the proposed Long-Term Transmission Cost Allocation Method, the proposed State Agreement Process, or a combination thereof either: (1) Reflect the agreement of the relevant state entities, or (2) to the extent agreement cannot be obtained, an explanation of the good faith efforts by the relevant public utility transmission provider to seek agreement from such entities. We seek comment below on how to resolve the potential inability of the relevant parties to come to agreement, noting that it will ultimately be necessary for public utility transmission providers to have a cost allocation method on file with the Commission for transmission facilities selected through Long-Term Regional Transmission Planning, and recognizing a State Agreement Process or combination cost allocation method would not comply with this proposed rule unless the relevant public utility transmission providers has obtained agreement from the relevant state entities.

a. Agreement of Relevant State Entities

304. We propose to define relevant state entities for purposes of the Long-Term Regional Transmission Planning cost allocation requirements as any state entity responsible for utility regulation or siting electric transmission facilities within the state or portion of a state located in the transmission planning region, including any state entity as may be designated for that purpose by the law of such state. Although, as discussed below, we propose to provide public utility transmission providers flexibility in determining what constitutes state agreement, we preliminarily find that, for each state, a single entity should be designated as the voting or representative entity to avoid confusion or over-representation by a

⁵¹¹ We are not proposing to require any changes to existing interregional cost allocation methods for interregional transmission facilities that are selected in the regional transmission plan for purposes of cost allocation and that the Commission previously accepted as compliant with Order No. 1000.

single state in a multi-state voting process.

305. We propose to require that public utility transmission providers in each transmission planning region seek agreement from the relevant state entities regarding the approach to cost allocation for Long-Term Regional Transmission Facilities. Specifically, public utility transmission providers in each transmission planning region must seek to determine whether, for all or a subset of Long-Term Regional Transmission Facilities, the relevant state entities agree to (1) a Long-Term Regional Transmission Cost Allocation Method; (2) a State Agreement Process; (3) forgo a role in determining the cost allocation approach for Long-Term Regional Transmission Facilities; or (4) some combination thereof.

306. We further propose to afford public utility transmission providers in each transmission planning region flexibility in the process by which they seek agreement from the relevant state entities. In addition, we propose to require public utility transmission providers to provide the state entities with flexibility with regard to defining what constitutes "agreement" among the relevant state entities on the cost allocation approach for Long-Term Regional Transmission Facilities. For example, states may choose to apply the existing provisions for engaging with the relevant state entities.⁵¹² In other cases, the relevant state entities may elect to engage in new or different ways to reach and communicate agreement regarding a cost allocation approach for Long-Term Regional Transmission Facilities.⁵¹³

307. We note that the relevant state entities may forgo a role in determining the cost allocation approach for all or a subset of Long-Term Regional Transmission Facilities. In the event that the relevant state entities do so, we propose to require public utility transmission providers to propose a Long-Term Regional Transmission Cost Allocation Method consistent with the requirements of Order No. 1000, including the prohibition on relying on voluntary agreement among states or

⁵¹² For example, states in ISO-NE may consider NESCOE's by-laws in defining the threshold of agreement among relevant state entities. Likewise, states in MISO may consider OMS procedures to define agreement and rely on existing processes by which OMS conveys its positions to MISO.

⁵¹³ As discussed *infra* in Proposed Compliance Procedures, we propose to establish an extended compliance period to accommodate meaningful engagement with states with respect to this Long-Term Regional Transmission Planning cost allocation reform.

participant funding.⁵¹⁴ Relevant state entities may also fail to reach agreement on a cost allocation method for all or a portion of Long-Term Regional Transmission Facilities, and we request comments below on the appropriate outcome in that situation.

308. We clarify that we are not proposing to impose any requirements on states to participate in processes to establish regional cost allocation methods for Long-Term Regional Transmission Facilities. The Commission has no authority over relevant state entities in this regard and, as such, those entities need not engage on a cost allocation approach if they do not wish to do so. Instead, we propose only to require that public utility transmission providers in each transmission planning region seek the agreement of the relevant state entities, and demonstrate in their compliance filings how either the proposed Long-Term Regional Transmission Cost Allocation Method, the proposed State Agreement Process, or combination thereof: (1) Reflects the agreement of the relevant state entities, or (2) to the extent agreement cannot be obtained, reflects good faith efforts by the relevant public utility transmission provider to seek agreement from such entities.

309. We seek comment on whether the proposed definition of relevant state entities is appropriate. We also seek comment on the proposal to afford relevant states entities the flexibility to define agreement among relevant state entities, or whether it is preferable for the Commission to adopt a specific definition of such agreement.

310. We further recognize that it is possible that relevant states entities may seek to agree to a cost allocation approach but be unable to achieve agreement, or may be unwilling to seek agreement to a cost allocation approach but do not agree to forgo their role in developing a cost allocation approach for Long-Term Regional Transmission Facilities. We request comment on the appropriate outcome when the relevant state entities fail to agree on a cost allocation method for all or a portion of Long-Term Regional Transmission Facilities. Specifically, we request comment on whether in such circumstances the public utility transmission providers should be required to establish a Long-Term Regional Transmission Cost Allocation

Method, the relevant state entities should be afforded additional time to endeavor to reach agreement, or the Commission should instead have the responsibility to establish the Long-Term Regional Transmission Cost Allocation Method.⁵¹⁵

b. State Agreement Process

311. We preliminarily find that a State Agreement Process by which one or more relevant state entities voluntarily agree to a cost allocation method for Long-Term Regional Transmission Facilities (or portfolio of facilities) after it is selected in the regional transmission plan for purposes of cost allocation may be a just and reasonable approach to cost allocation for such regional transmission facilities. The State Agreement Process may apply to all Long-Term Regional Transmission Facilities or only a subset thereof.

312. We further propose to require that a cost allocation method that results from the State Agreement Process and is filed by the public utility transmission providers must comply with the existing six Order No. 1000 regional cost allocation principles.⁵¹⁶ We preliminarily find that compliance with such principles will help to ensure that Commission-jurisdictional rates resulting from any State Agreement Process will be just and reasonable and not unduly discriminatory or preferential.

313. If the relevant state entities decide on a State Agreement Process, we also propose to require that the public utility transmission providers in each transmission planning region detail the process by which the relevant state entities would reach voluntary

agreement regarding the cost allocation for Long-Term Regional Transmission Facilities pursuant to the State Agreement Process, including the timeline for such processes. For example, the public utility transmission providers in each transmission planning region could specify, as part of the Long-Term Regional Transmission Planning in their OATTs the procedures by which such voluntary agreements by the relevant state entities may be filed with the Commission for consideration under FPA section 205. Such procedures should set forth a process by which the relevant state entities would agree to funding contributions and the mechanism by which such costs would be allocated (*e.g.*, through a *pro forma* contract).

314. Finally, we note that, to the extent public utility transmission providers believe their existing cost allocation approaches comply with the requirements adopted in any final rule in this proceeding, including those related to the agreement of relevant state entities, we propose that they may make such demonstration in their compliance filings in response to any final rule. In addition, we propose to apply the cost allocation reforms we propose in this NOPR only to new Long-Term Regional Transmission Facilities and, therefore, these proposed reforms would not provide grounds for re-litigation of cost allocation decisions for transmission facilities that are selected in the regional transmission plan for purposes of cost allocation prior to the effective date of any final rule in this proceeding,⁵¹⁷ nor would they apply to the cost allocation methods associated with regional transmission facilities that address shorter-term transmission needs driven by reliability and/or economic considerations. We believe the proposed cost allocation requirements for Long-Term Regional Transmission Facilities will help to ensure just and reasonable Commission-jurisdictional rates by increasing the likelihood that more efficient or cost-effective regional transmission facilities to address transmission needs driven by changes in the resource mix and demand are developed, and with fewer delays. The proposed reforms would enable relevant state entities, such as state regulators and siting authorities, who seek greater involvement in cost allocation for Long-Term Regional Transmission Facilities an opportunity to do so. Where relevant state entities in a multi-state

⁵¹⁵ In Order No. 1000, the Commission determined that, in the event public utility transmission providers in a region fail to reach agreement on a cost allocation method, it would use the record in the compliance filing to determine the cost allocation method. Order No. 1000, 136 FERC ¶ 61,051 at P 607.

⁵¹⁶ As noted, *supra*, those cost principles are: (1) The costs of transmission facilities selected in a regional transmission plan for purposes of cost allocation must be allocated to those within the transmission planning region that benefit from those facilities in a manner that is at least roughly commensurate with estimated benefits; (2) those that receive no benefit from transmission facilities, either at present or in a likely future scenario, must not be involuntarily allocated any of the costs of those transmission facilities; (3) a benefit to cost threshold ratio, if adopted, cannot exceed 1.25 to 1; (4) costs must be allocated solely within the transmission planning region unless another entity outside the region voluntarily assumes a portion of those costs; (5) the method for determining benefits and identifying beneficiaries must be transparent; and (6) there may be different regional cost allocation methods for different types of transmission facilities, such as those needed for reliability, congestion relief, or to achieve Public Policy Requirements.

⁵¹⁴ Under this proposed requirement, the Long-Term Regional Transmission Cost Allocation Method that public utility transmission providers would be required to submit would only apply to the subset of Long-Term Regional Transmission Facilities for which the relevant state entities did not determine a cost allocation approach.

⁵¹⁷ The Commission took a similar approach with respect to its cost allocation reforms in Order No. 1000. See Order No. 1000, 136 FERC ¶ 61,051 at P 565.

transmission planning region are able to agree upon an approach to allocate the costs of Long-Term Regional Transmission Facilities needed to meet these longer-term transmission needs, applying that approach is likely to decrease the controversy over development of such facilities, by, for example, making the relevant state entities more confident that ratepayers in the state are receiving benefits at least roughly commensurate with their share of the cost of such facilities. In so doing, the engagement of relevant state entities may help to reduce instances in which a Long-Term Regional Transmission Facility is selected, has an established *ex ante* cost allocation method that applies to it, but nevertheless fails to be developed because it cannot receive a necessary state regulatory approval. After all, states retain siting authority over transmission facilities and will review whether Long-Term Regional Transmission Facilities are consistent with the public interest and state siting regulations.

315. We recognize that, if states agree to a State Agreement Process instead of a Long-Term Regional Transmission Cost Allocation Method, certain Long-Term Regional Transmission Facilities selected in the regional transmission plan for purposes of cost allocation would lack a clear *ex ante* cost allocation method. We continue to believe that the availability of an *ex ante* cost allocation method helps to ensure the development of more efficient or cost-effective regional transmission facilities identified in the regional transmission planning process.⁵¹⁸ However, given the increased uncertainty of Long-Term Regional Transmission Planning and potential for divergent views on the benefits of meeting transmission needs driven by changes in the resource mix and demand, we believe that applying a cost allocation approach agreed to by the relevant state entities may be just and reasonable and support the viability of Long-Term Regional Transmission Facilities.

316. We recognize that in Order No. 1000, the Commission explained that reliance on participant funding as a regional cost allocation method “increases the incentive of any individual beneficiary to defer investment in the hopes that other beneficiaries will value a transmission project enough to fund its development” and would therefore not comply with

the regional cost allocation principles adopted in Order No. 1000.⁵¹⁹

317. Nevertheless, we preliminarily find that allowing a State Agreement Process for Long-Term Regional Transmission Facilities, where agreed to by the relevant state entities, appropriately balances the concerns about increased free ridership problems against the benefit of greater state involvement in determining the cost allocation of Long-Term Regional Transmission Facilities.⁵²⁰ As discussed above, we are proposing to require public utility transmission providers to engage in transmission planning over a longer time-horizon than we have previously required. Although we preliminarily find that such reforms are necessary to ensure just and reasonable rates, we recognize that the precise quantification and allocation of the benefits of Long-Term Regional Transmission Facilities may be more uncertain than transmission facilities that are planned on a shorter-term basis and/or based on a more limited set of benefits. As such, we recognize that state entities charged with siting transmission facilities within their state may, at least in certain circumstances, take a more skeptical approach to evaluating applications to site Long-Term Regional Transmission Facilities. We believe that providing relevant state entities an opportunity for involvement in establishing a cost allocation method, including through use of a State Agreement Process, would help to address any such concerns on the part of state regulators, increasing the likelihood that Long-Term Regional Transmission Facilities are actually developed, and without delay. Accordingly, we preliminarily find that this potential benefit outweighs concerns about free-ridership with respect to the reforms proposed herein.

318. We seek comment on the requirements proposed in this section of the NOPR. We also seek comment on whether the Commission should require, instead of the reforms proposed in this section of the NOPR, public utility transmission providers to include a Long-Term Regional Transmission Cost Allocation Method in their OATTs.

⁵¹⁹ Order No. 1000, 136 FERC ¶ 61,051 at P 723. Under a participant funding approach to cost allocation, the costs of a transmission facility are allocated only to those entities that volunteer to bear those costs. *Id.* P 486 n.375.

⁵²⁰ *Id.* P 586 (stating regional cost allocation principles, including “[t]hose that receive no benefit from transmission facilities, either at present or in a likely future scenario, must not be involuntarily allocated the costs of those facilities.”).

2. Time Period in Long-Term Regional Transmission Planning Cost Allocation Processes for State-Negotiated Alternate Cost Allocation Method

319. Additionally, we propose to require that public utility transmission providers establish a process, detailed in their OATTs, to provide a state or states (in multi-state transmission planning regions) a time period to negotiate a cost allocation method for a transmission facility (or portfolio of facilities) selected for purposes of cost allocation through Long-Term Regional Transmission Planning that is different than any *ex ante* regional cost allocation method that would otherwise apply. During this time period for a state-negotiated alternate cost allocation method, if a state or all states within the transmission planning region in which the selected regional transmission facility will be located unanimously agree on an alternate cost allocation method, the public utility transmission provider may elect to file it with the Commission for consideration under FPA section 205. As discussed above, we anticipate the public utility transmission provider may elect to file an alternate cost allocation method because doing so increases the likelihood that relevant stakeholders perceive the cost allocation as fair and that the needed regional transmission facilities are actually constructed.

320. If the relevant state or states cannot agree on an alternate cost allocation method memorialized in writing within a specified timeframe after a transmission facility is selected in the regional transmission plan for purposes of cost allocation through Long-Term Regional Transmission Planning (*e.g.*, 90 days), then the transmission developer will be entitled to use any *ex ante* regional cost allocation method that would otherwise apply for that regional transmission facility.

321. Providing states with a time period to propose alternate cost allocation methods could help facilitate the timely development of more efficient or cost-effective regional transmission facilities. For example, allowing states to negotiate an alternate cost allocation method for selected regional transmission facilities at a time when details of the transmission facilities are known could facilitate agreements on the cost allocation for new regional transmission facilities because states would have better knowledge of relevant facts, including benefits and costs, regarding the transmission facilities for which they are negotiating cost allocation.

⁵¹⁸ *Id.* P 499; Order No. 1000–A, 139 FERC ¶ 61,132 at P 52.

Moreover, state siting proceedings may proceed more efficiently if states have better information about the costs and benefits of such regional transmission facilities.

322. We propose to require that public utility transmission providers add to their OATTs provisions that describe a time period for state involvement in regional cost allocation for transmission facilities selected in Long-Term Regional Transmission Planning, including when this time period will occur, what its duration will be, and that any alternate cost allocation method must be submitted to the Commission for review and approval under FPA section 205 prior to taking effect. When filed, the Commission will evaluate the alternate cost allocation method to ensure that it is just and reasonable and allocates costs in a manner that is at least roughly commensurate with estimated benefits. If the Commission rejects a state-proposed cost allocation method, the transmission developer of the transmission facility selected in the regional transmission plan for purposes of cost allocation through Long-Term Regional Transmission Planning would be entitled to use the applicable *ex ante* regional cost allocation method that would have applied to it in the absence of the proposed alternative cost allocation method, just as it would be absent this proposed provision for an alternate cost allocation method.

323. We recognize the tension between a proposal for a time period for state-negotiated cost allocation within an Order No. 1000-compliant regional transmission planning process and the Commission's *ex ante* cost allocation approach, which we do not propose to remove, including the potential for delay as compared to the *ex ante* approach. We propose to prescribe a 90-day time period for state-negotiated cost allocation memorialized in writing, which is consistent with the period for state cost allocation negotiation that the Commission accepted in NYISO's filing described above.

324. We seek comment on the requirements proposed in this section of the NOPR, including the timing and duration of any time period for state-negotiated cost allocation for transmission facilities selected in the regional transmission plan for purposes of cost allocation through Long-Term Regional Transmission Planning. We also seek comment on whether there should be a requirement for a time period for state involvement in regional cost allocation for transmission facilities selected in existing near-term reliability

and economic regional transmission planning processes.

3. Identification of Benefits Considered in Cost Allocation for Long-Term Regional Transmission Facilities

325. We are concerned that the Commission's existing regional transmission planning and cost allocation requirements may result in public utility transmission providers undervaluing the benefits of Long-Term Regional Transmission Facilities for purposes of allocating the costs of such facilities to beneficiaries in a manner that is roughly commensurate with estimated benefits. The current approach of considering only a subset of categories of benefits based on the type of transmission need that is being studied may result in inaccurate valuation of a transmission facility's benefits in Long-Term Regional Transmission Planning. We are also concerned that considering only a subset of benefits in assigning the cost of Long-Term Regional Transmission Facilities may contribute to the risk of free rider problems that impede development of the more efficient or cost-effective regional transmission facilities. At the same time, as discussed above, we consider it important that cost allocation should reflect the views of stakeholders, and the state entities with a role in permitting transmission facilities in particular, and believe that the involvement of states in cost allocation increases the likelihood that Long-Term Regional Transmission Facilities are actually developed.

326. Nevertheless, we acknowledge the support for the adoption of a common set of minimum benefits, and we propose for consideration a list of Long-Term Regional Transmission Benefits described above for public utility transmission providers to apply in Long-Term Regional Transmission Planning and Cost Allocation processes. In addition, we propose to require that public utility transmission providers identify on compliance the benefits they will use in any *ex ante* cost allocation method associated with Long-Term Regional Transmission Planning, how they will calculate those benefits, and how the benefits will reasonably reflect the benefits of regional transmission facilities to meet identified transmission needs driven by changes in the resource mix and demand. As part of this compliance obligation, public utility transmission providers should explain the rationale for using the benefits identified.

327. We request comment on this proposed requirement. We also request comment on whether the Commission

should require that public utility transmission providers account for the full list of benefits described in the Evaluation of the Benefits of Regional Transmission Facilities section above in Long-Term Regional Transmission Planning, or whether no change to the benefits currently used in existing regional transmission planning processes is needed.

VI. Construction Work in Progress Incentive

A. Background

328. In the Energy Policy Act of 2005,⁵²¹ Congress added section 219 to the FPA, directing the Commission to establish, by rule, incentive-based rate treatments to promote capital investment in certain transmission infrastructure. The Commission subsequently issued Order No. 679 in 2006, which sets forth processes by which a public utility may seek transmission rate incentives pursuant to FPA section 219.⁵²²

329. In Order No. 679, the Commission adopted several incentive-based rate treatments to promote capital investment in certain transmission infrastructure and to address impediments faced by those investing in transmission. The Commission found that the long-lead time to construct new transmission and associated cash flow difficulties presented an impediment to new transmission investment.⁵²³ To remove this impediment, the Commission adopted its proposal to allow for the recovery of 100% of CWIP costs in rate base in certain circumstances (CWIP Incentive).⁵²⁴ Allowing transmission developers to include construction costs in rate base prior to commercial operation provides utilities with additional cash flow in the form of an immediate earned return, rather than delaying recovery of those costs until the plant is placed into service.⁵²⁵ In Order No. 679, the Commission acknowledged that the CWIP Incentive was a departure from the existing ratemaking doctrine that rates should be based on plant costs that

⁵²¹ Public Law 109–58, 1241, 119 Stat. 594 (2005).

⁵²² *Promoting Transmission Inv. through Pricing Reform*, Order No. 679, 116 FERC ¶ 61,057, *order on reh'g*, Order No. 679–A, 117 FERC ¶ 61,345 (2006), *order on reh'g*, 119 FERC ¶ 61,062 (2007).

⁵²³ *Id.* P 9.

⁵²⁴ The Commission has also provided that any public utility engaged in the sale of electric power for resale can file to include in rate base up to 50% of CWIP, subject to limitations. *Construction Work in Progress for Public Utilities; Inclusion of Costs in Rate Base*, Order No. 298, FERC Stats. & Regs. ¶ 30,455 (1983), *order on reh'g*, 25 FERC ¶ 61,023 (1983).

⁵²⁵ Order No. 679, 116 FERC ¶ 61,057 at n.70.

are “used and useful.”⁵²⁶ However, the Commission clarified that “the Commission can depart from the norm as long as it reasonably balances consumers’ interest in fair rates against investors’ interest in maintaining financial integrity and access to capital markets.”⁵²⁷

B. Need for Reform

330. As indicated above in this NOPR, under the proposed Long-Term Regional Transmission Planning reforms, we seek to strike a balance between the risk of over- and under-investment regarding the selection of transmission facilities in the regional transmission plan for purposes of cost allocation that address transmission needs driven by changes in the resource mix and demand. We acknowledge that there is likely to be more uncertainty in Long-Term Regional Transmission Planning, *e.g.*, requiring public utility transmission providers to conduct Long-Term Regional Transmission Planning over a minimum of 20 years (compared to the current practice of 6–15 years), than in the existing regional transmission planning processes.

331. In light of the incremental uncertainty associated with the proposed Long-Term Regional Transmission Planning, we preliminarily find that additional protection for ratepayers may be necessary to reasonably balance consumers’ interest in just and reasonable rates against investors’ interest in earning a return on their investments and reduce the risk to ratepayers of potentially financing over-investment in regional transmission facilities.⁵²⁸ The Commission previously found that the CWIP Incentive is beneficial to ease the financial pressures associated with transmission development by providing up-front regulatory certainty, rate stability, and improved cash flow, which in turn can result in higher credit ratings and lower capital costs.⁵²⁹ These benefits mainly accrue to the public utility transmission providers and their shareholders during construction, while ratepayers mainly receive the benefits from completed transmission facilities under a more stable rate environment. Specifically, during the construction of the regional transmission facilities, ratepayers do not receive benefits from the regional transmission facilities,

while simultaneously ratepayers directly finance the construction under the CWIP Incentive. Should the regional transmission facilities not be placed in service, then ratepayers will have financed the construction of such facilities that were not used and useful, while ultimately receiving no benefits from such facilities.

332. Given the Long-Term Regional Transmission Planning reforms proposed in this NOPR and the incremental uncertainty and risk that Long-Term Regional Transmission Facilities may not become “used and useful,” we are concerned that the CWIP Incentive, if made available for Long-Term Regional Transmission Facilities, may shift too much risk to consumers to the benefit of public utility transmission providers in a manner that renders Commission-jurisdictional rates unjust and unreasonable.

C. Proposed Reform

333. To address the concerns identified above, we propose to not permit public utility transmission providers to take advantage of the CWIP Incentive for Long-Term Regional Transmission Facilities. We note that public utility transmission providers may still book costs incurred during the pre-construction or construction phase as Allowance for Funds Used During Construction (AFUDC) and only recover those costs after the project is in service to customers, in accordance with generally accepted utility accounting principles for AFUDC.⁵³⁰

334. We seek comment on the requirements proposed in this section of the NOPR. In particular, we seek comment on whether this proposed reform would reasonably balance consumer and investor interests.

VII. Exercise of a Federal Right of First Refusal in Commission-Jurisdictional Tariffs and Agreements

335. Order No. 1000 instituted a number of reforms regarding the participation of nonincumbent transmission developers in the regional transmission planning process, which,

⁵³⁰ We further note that our proposal regarding the CWIP Incentive for Long-Term Regional Transmission Facilities does not affect Commission policy and regulations established before Order No. 679. That is, public utility transmission providers would still be allowed to request 50% CWIP in rate base, as is permitted pursuant to 18 CFR 35.25(c)(3), subject to an FPA section 205 filing detailing how the request meets the requirements of Order No. 298. We believe that the ability to include 50% CWIP in rate base, if requested and granted, reflects a more reasonable sharing of risks and benefits than the CWIP Incentive for Long-Term Regional Transmission Facilities given the greater uncertainty inherent in Long-Term Regional Transmission Planning, as proposed in this NOPR.

as a whole, facilitate competition for transmission development.⁵³¹ As explained in more detail below, we continue to require compliance with Order No. 1000’s nonincumbent transmission developer reforms, and we maintain our commitment to transmission development rules and policies that align with or advance the goals of those reforms, or otherwise ensure just and reasonable Commission-jurisdictional rates and limit opportunities for undue discrimination by public utility transmission providers.

336. However, in light of the experience gained since the issuance of Order No. 1000 and the comments received in response to the ANOPR, we propose to amend Order No. 1000’s nonincumbent transmission developer requirements, in part. As described in more detail below, we propose to permit the exercise of federal rights of first refusal for transmission facilities selected in a regional transmission plan for purposes of cost allocation, conditioned on the incumbent transmission provider with the federal right of first refusal for such regional transmission facilities establishing joint ownership of the transmission facilities consistent with the proposal below.

A. Background

1. Order No. 1000’s Nonincumbent Transmission Developer Reforms and Federal Right of First Refusal Elimination Mandate

337. In instituting nonincumbent transmission developer reforms, the Commission in Order No. 1000 distinguished between incumbent transmission developers (also called incumbent transmission providers) and nonincumbent transmission developers. An incumbent transmission developer/provider is an entity that develops a transmission facility within its own retail distribution service territory or footprint. A nonincumbent transmission developer refers to two categories of transmission developer: (1) A transmission developer that does not have a retail distribution service territory or footprint; and (2) a public utility transmission provider that proposes a transmission facility outside of its existing retail distribution service territory or footprint, where it is not the incumbent for purposes of that facility.⁵³²

338. Among its nonincumbent transmission developer reforms, Order No. 1000 requires that each public

⁵³¹ See *ISO New Eng. Inc.*, 169 FERC ¶ 61,054, at PP 1–2 (2019) (citations omitted); see also Order No. 1000, 136 FERC ¶ 61,051 at PP 225–344.

⁵³² Order No. 1000, 136 FERC ¶ 61,051 at P 225.

⁵²⁶ *Id.* PP 116–117.

⁵²⁷ *Id.* P 117 (quoting *Jersey Cent. Power & Light Co. v. FERC*, 810 F.2d 1168, 1178 (D.C. Cir. 1987)).

⁵²⁸ See, *e.g.*, *NextEra Energy Transmission Sw., LLC*, 178 FERC ¶ 61,082 (2022) (Christie, Comm’r, concurring).

⁵²⁹ Order No. 679, 116 FERC ¶ 61,057 at P 115.

utility transmission provider eliminate provisions in Commission-jurisdictional tariffs and agreements that establish a federal right of first refusal for an incumbent transmission provider with respect to entirely new transmission facilities selected in a regional transmission plan for purposes of cost allocation.⁵³³

339. This requirement from Order No. 1000 does not apply to local transmission facilities, which are defined as transmission facilities located solely within an incumbent transmission provider's retail distribution service territory or footprint that are not selected in the regional transmission plan for purposes of cost allocation.⁵³⁴ The requirement also does not apply to the right of an incumbent transmission provider to build, own, and recover costs for upgrades to its own existing transmission facilities, regardless of whether an upgrade has been selected in the regional transmission plan for purposes of cost allocation.⁵³⁵ In addition, the Commission noted that the requirement does not remove, alter, or limit an incumbent transmission provider's use and control of its existing rights-of-way under state law.⁵³⁶ The Commission has

⁵³³ *Id.* P 313; Order No. 1000–A, 139 FERC ¶ 61,132 at P 426 (“The concept is that there should not be a federally established monopoly over the development of an entirely new transmission facility that is selected in a regional transmission plan for purposes of cost allocation to others.”). The phrase “a federal right of first refusal” refers only to rights of first refusal that are created by provisions in Commission-jurisdictional tariffs or agreements. Order No. 1000–A, 139 FERC ¶ 61,132 at P 415. Before Order No. 1000, some RTO/ISO governing documents and other utility tariffs and agreements included federal rights of first refusal, which “gave incumbent utilities the option to construct any new transmission facilities in their particular service areas, even if the proposal for new construction came from a third party.” *S.C. Pub. Serv. Auth.*, 762 F.3d at 72.

⁵³⁴ Order No. 1000, 136 FERC ¶ 61,051 at PP 63, 226, 258, 318. In addition, the Commission clarified in Order No. 1000–A that a transmission facility whose costs are 100% allocated to the public utility transmission provider in whose retail distribution service territory or footprint the facility is located is not considered to be selected in the regional transmission plan for purposes of cost allocation and could remain subject to a federal right of first refusal. Order No. 1000–A, 139 FERC ¶ 61,132 at PP 423–424; *see also id.* P 427.

⁵³⁵ Order No. 1000, 136 FERC ¶ 61,051 at PP 226, 319; Order No. 1000–A, 139 FERC ¶ 61,132 at P 426. Upgrades to existing transmission facilities include, for example, tower change outs or reconductoring, regardless of whether or not an upgrade has been selected in the regional transmission plan for purposes of cost allocation. Order No. 1000, 136 FERC ¶ 61,051 at P 319. The Commission clarified in Order No. 1000–A that the term “upgrade” means an improvement to, addition to, or replacement of a part of, an existing transmission facility. The term does not refer to an entirely new transmission facility. Order No. 1000–A, 139 FERC ¶ 61,132 at P 426.

⁵³⁶ Order No. 1000, 136 FERC ¶ 61,051 at PP 226, 319.

also permitted exemptions from the federal right of first refusal elimination mandate for immediate need reliability projects.⁵³⁷

340. In adopting Order No. 1000's nonincumbent transmission developer reforms, the Commission identified several reasons why it believed that eliminating federal rights of first refusal from Commission-jurisdictional tariffs and agreements was necessary and appropriate to ensure that Commission-jurisdictional rates are just and reasonable. The Commission found that federal rights of first refusal “creat[e] a barrier to entry,” and that their existence could lead to the loss of nonincumbent transmission developer investment opportunities to incumbent transmission providers, which “discourages nonincumbent transmission developers from proposing alternative solutions for consideration at the regional level” in regional transmission planning processes.⁵³⁸ The Commission found that administering transmission planning processes with federal rights of first refusal “may result in the failure to consider more efficient or cost-effective solutions to regional needs” and thus their elimination may give “customers . . . the benefits of competition in transmission development, and associated potential savings.”⁵³⁹ The Commission also expressed concern that federal rights of first refusal could allow an incumbent transmission provider “to act in its own economic self-interest,” which in general would not support permitting “new entrants to develop transmission facilities, even if proposals submitted by new entrants would result in a more efficient or cost-effective solution to the region's needs.”⁵⁴⁰

341. The Commission also found that elimination of federal rights of first refusal was “necessary to address opportunities for undue discrimination and preferential treatment against nonincumbent transmission developers within regional transmission planning

⁵³⁷ *See, e.g., PJM Interconnection, L.L.C.*, 174 FERC ¶ 61,117, at P 3 (2021); *Sw. Power Pool, Inc.*, 171 FERC ¶ 61,213, at P 3 (2020); *Midcontinent Indep. Sys. Operator, Inc.*, 173 FERC ¶ 61,203, at P 1 (2020); *ISO New Eng. Inc.*, 171 FERC ¶ 61,211, at P 1, 3 (2020); *N.Y. Indep. Sys. Operator, Inc.*, 171 FERC ¶ 61,082, at PP 30–34 (2020).

⁵³⁸ Order No. 1000, 136 FERC ¶ 61,051 at PP 229, 256–257, 284, 320.

⁵³⁹ *Id.* PP 284–286, 291; *see also id.* PP 229, 315. The Commission reasoned, in part, that “[g]reater participation by transmission developers in the transmission planning process may lower the cost of new transmission facilities, enabling more efficient or cost-effective deliveries by load serving entities and increased access to resources.” *Id.* P 291.

⁵⁴⁰ *Id.* P 256.

processes.”⁵⁴¹ While the Commission did not dispute the claim that incumbent transmission providers may have some inherent advantages over nonincumbent transmission developers in the transmission development context,⁵⁴² the Commission found that these claimed incumbent advantages were “strengths” that could be deployed by incumbent transmission providers to their benefit in competitive transmission development processes, and not a reason to forgo holding those processes.⁵⁴³

342. Importantly, while the Commission declined to eliminate federal rights of first refusal for upgrades to existing transmission facilities and local transmission facilities, among other specific types of transmission facilities,⁵⁴⁴ and has permitted exemptions for immediate need reliability projects,⁵⁴⁵ the Commission did not otherwise qualify or limit the federal right of first refusal elimination mandate within its defined scope (*i.e.*, as applied to entirely new transmission facilities selected in a regional transmission plan for purposes of cost allocation).⁵⁴⁶ Instead, the

⁵⁴¹ Order No. 1000–A, 139 FERC ¶ 61,132 at P 361; *see also* Order No. 1000, 136 FERC ¶ 61,051 at PP 269, 286. The Commission also reiterated that “if a regional transmission planning process does not consider and evaluate transmission projects proposed by nonincumbents that regional transmission planning process cannot meet the Order No. 890 transmission planning principle of being ‘open.’” Order No. 1000, 136 FERC ¶ 61,051 at P 229.

⁵⁴² *See* Order No. 1000, 136 FERC ¶ 61,051 at P 260 (acknowledging that incumbent transmission providers “may have unique knowledge of their own transmission systems, familiarity with the communities they serve,” and other potential transmission development advantages); *see also id.* PP 241, 250 (summarizing other contentions “that incumbent transmission owners are better situated to build new transmission facilities”).

⁵⁴³ *Id.* P 260.

⁵⁴⁴ *See supra* notes 534–536 and associated text. The Commission explained, in part, that its decision in this regard would “continue[] to permit an incumbent . . . to meet its reliability needs or service obligations” through local transmission facilities, and the Commission hoped that this exemption would also, in part, address concerns that Order No. 1000's reforms would “adversely impact the collaborative nature of current regional transmission planning processes.” *See* Order No. 1000, 136 FERC ¶ 61,051 at PP 258, 262.

⁵⁴⁵ *See supra* note 537 and associated text.

⁵⁴⁶ *See, e.g.,* Order No. 1000–A, 139 FERC ¶ 61,132 at P 426 (“The concept is that there should not be a federally established monopoly over the development of an entirely new transmission facility that is selected in a regional transmission plan for purposes of cost allocation to others.”); *id.* P 360 (finding on rehearing that “the Commission's decision to require public utility transmission providers to adopt the nonincumbent transmission developer reforms was an appropriate, and adequately tailored, remedy” and noting that the Commission did not accept the position of some commenters that “supported eliminating all federal rights of first refusal” but rather it “determined that

Commission ordered, with limited exceptions, the elimination of federal rights of first refusal for entirely new transmission facilities selected in a regional transmission plan for purposes of cost allocation, regardless of the specifics of or the circumstances under which such federal rights of first refusal had been or could be used.

2. Experience Since Order No. 1000

343. Since the Commission issued Order No. 1000, all public utility transmission providers across the country have adopted and many have administered competitive transmission development processes for the selection of transmission facilities in a regional transmission plan for purposes of cost allocation.⁵⁴⁷ Though public utility transmission providers in all transmission planning regions must participate in their respective regional transmission planning processes, the degree to which competitive transmission development processes have led to specific transmission facility selection, investment, and development activities since Order No. 1000—and the proportion of such processes that resulted in the selection of a nonincumbent transmission developer's proposal—varies significantly by region.⁵⁴⁸

344. Importantly, recent transmission investment trends suggest that despite increased investment in transmission facilities overall, in many transmission planning regions there has been comparatively limited investment in transmission facilities selected in a regional transmission plan for purposes of cost allocation as a result of a competitive process; transmission investment has instead largely been concentrated in transmission facilities generally not subject to competitive transmission development processes.⁵⁴⁹

incumbent transmission providers should be able to maintain an existing federal right of first refusal for certain types of new transmission projects”).

⁵⁴⁷ See FERC, Staff Report, *2017 Transmission Metrics*, at 8 (Oct. 6, 2017), <https://www.ferc.gov/sites/default/files/2020-05/transmission-investment-metrics.pdf> (describing the two general types of competitive transmission development processes, the “competitive bidding model” and the “sponsorship model”); see also Competition Coalition Comments at 14–15 (same).

⁵⁴⁸ See FERC, Staff Report, *2017 Transmission Metrics*, at 23–26 (Oct. 6, 2017), <https://www.ferc.gov/sites/default/files/2020-05/transmission-investment-metrics.pdf>; see also Brattle Apr. 2019 Competition Report at 5, 8 fig. 2, 28 fig. 10 (included as Ex. 2 to LS Power Oct. 12 Comments).

⁵⁴⁹ See Competition Coalition Comments at 9–10 (describing growth trend in overall transmission investment); NextEra Comments at 99–101 (estimating that only a small fraction of overall transmission investment in RTO/ISO regions between 2013–2020 was awarded as the result of a

In particular, recent transmission investment appears to be concentrated in local transmission facility development or regional transmission facilities subject to an exception from competitive transmission development processes, such as immediate need reliability projects or upgrades to existing transmission facilities, as opposed to investment in regional transmission facilities selected in a regional transmission plan for purposes of cost allocation that serve a wider set of transmission needs and are subject to competitive transmission development processes.⁵⁵⁰

3. ANOPR

345. In the ANOPR, the Commission recognized the possibility that “the current transmission planning processes may be resulting increasingly in transmission facilities addressing a narrow set of transmission needs, often located in a single transmission owner’s footprint.”⁵⁵¹ The Commission also recognized that to “the extent that the requirements of the regional transmission planning process result in transmission providers expanding predominately local transmission facilities, that process may fail to identify more efficient or cost-effective transmission facilities needed to accommodate anticipated future generation.”⁵⁵² The Commission sought “to better understand how the reforms of the federal right of first refusal in Order No. 1000 have shaped the type and characteristics of transmission facilities developed through regional and local transmission planning processes, such as a relative increase in investment in local transmission facilities or the diversity of projects resulting from competitive bidding processes.”⁵⁵³

4. Comments

346. In response, many commenters address issues related to competitive transmission development processes, federal rights of first refusal, and how Order No. 1000’s reforms may have

competitive process); Brattle Apr. 2019 Competition Report at 1, 3, 5–8, 25 (same).

⁵⁵⁰ See APPA Comments at 20; AEE Comments at 22–23; LS Power Reply Comments at 41–44; see also California Commission Comments at 14–16 (discussing investment in “self-approved projects”); EEI Comments at 6 (referring in part to “a near standstill in transmission development for regional projects”); Brattle-Grid Strategies Oct. 2021 Report at 19–20 (explaining that concentration on local transmission facilities and the incentives given to transmission owners may create “a bias against larger regional solutions even if they are more innovative and cost-effective”).

⁵⁵¹ ANOPR, 176 FERC ¶ 61,024 at P 37.

⁵⁵² *Id.*

⁵⁵³ *Id.*

shaped transmission development decisions and investments in recent years. Included among these comments are critiques of the Commission’s Order No. 1000 nonincumbent transmission developer reforms, which contend that those reforms have not achieved their predicted benefits; these critiques tend to associate that track record at least in part with Order No. 1000’s federal right of first refusal elimination policy.⁵⁵⁴

347. However, commenters are divided regarding the steps that they believe the Commission should take in response to the concerns and trends described above. Several commenters support increasing the scope and number of competitive transmission development processes by expanding Order No. 1000’s federal right of refusal elimination mandate to other types of transmission facilities. For example, the Competition Coalition and the California Commission call for more competition in regional transmission planning, design, and construction, which they predict will lower costs to customers as transmission investment increases.⁵⁵⁵ Similarly, LS Power contends that the implementation of current regional transmission planning processes has resulted in increasingly local transmission planning to the detriment of regional transmission planning, that a focus on local transmission needs leads to piecemeal solutions, and that the proper response is to expand competitive transmission development processes to address a greater number of transmission facilities.⁵⁵⁶ NARUC similarly recommends that the Commission encourage the use of current competitive processes and discourage over-investment in local transmission facilities to help maximize regional and

⁵⁵⁴ *E.g.*, MISO Comments at 26–27, 29–30 (asserting that “Order No. 1000 requirements for competitive development of projects selected in a regional plan for purposes of cost allocation [have] . . . seen only limited success” and describing the challenges MISO has faced in implementing those mandates); WIRES Comments at 11–12, 16 (asserting that the “introduction of competition . . . has not lived up to expectations” and addressing the Commission’s articulated concerns about the possibility that “current policies and processes are not appropriately incentivizing the development and construction of larger regional facilities”); Harvard ELI Comments at 17–18, 20–21 (contending that “Order No. 1000-compliant regional processes . . . have not fulfilled their promise” and did not “lead to an increase in regional projects”).

⁵⁵⁵ Competition Coalition Comments at 4, 11; see also *id.* at 4 nn.4–5 (citing Brattle Apr. 2019 Competition Report at 13, 19); California Commission Comments at 24–25, 34–35, 42–43.

⁵⁵⁶ LS Power Oct. 12 Comments at 28, 31–33, 35, 85–111 (citations omitted); see also LS Power Reply Comments at 2–39 (collecting statements from similar comments (citations omitted)).

interregional benefits.⁵⁵⁷ PIOs assert that the Commission must require public utility transmission providers to plan for local transmission needs as part of the regional transmission planning process.⁵⁵⁸ The PJM Market Monitor indicates that there is not yet a transparent, robust, and clearly defined mechanism to permit competition to build transmission projects, to ensure that competitors provide a total project cost cap, or to obtain least cost financing through the capital markets. The PJM Market Monitor claims that the Commission should build upon Order No. 1000 to remove barriers to nonincumbent transmission development and create more opportunities for competition between incumbent transmission providers and nonincumbent transmission providers.⁵⁵⁹ The Chairman of the Kentucky Commission states that more transmission facilities and needs should be subject to competition.⁵⁶⁰

348. In contrast, other commenters urge the Commission to move in the opposite direction, arguing that the existence of competitive transmission development processes leads to delays and added costs while the elimination of federal rights of first refusal for transmission facilities selected in a regional transmission plan for purposes of cost allocation has failed to produce the benefits that the Commission expected.⁵⁶¹ For example, EEI urges the Commission to recognize that “transmission is not being built” and to act to “remove the complex and costly competitive processes” that, in EEI’s view, delay transmission

⁵⁵⁷ NARUC Comments at 55–56; *see also* Environmental Advocates Comments at 15–18 (arguing, in part, that reliance on projects not subject to competition “can forestall regional projects by making transmission planning and construction into a piecemeal process”).

⁵⁵⁸ PIOs Reply Comments at 13.

⁵⁵⁹ PJM Market Monitor Comments at 8. For example, the PJM Market Monitor criticizes the lack of oversight of supplemental projects in PJM, noting that the need for supplemental projects should be clearly defined within PJM’s transmission planning process and there should be a transparent, robust, and clearly defined mechanism to permit competition to build supplemental projects. *Id.* at 8–9.

⁵⁶⁰ Chairman of the Kentucky Commission Kent A. Chandler Reply Comments at 3–4.

⁵⁶¹ *See* EEI Comments at 21–23; *see also id.* at 23–24 (urging the Commission to recognize that “transmission is not being built” and to act to “remove the complex and costly competitive processes” that, in EEI’s view, delay transmission development); *See* EEI Comments at 21–23; *see also* Eversource Comments at 13–14 (arguing that, in its experience, competitive transmission development processes have created delays, and that it is unclear what benefits can be shown from such processes); Indicated PJM TOs Comments at 4 (arguing in part that Order No. 1000’s nonincumbent transmission developer reforms have “fostered conflict and litigation, with the associated expense and delays”).

development.⁵⁶² ITC asserts that significant time and resources are required to conduct competitive transmission development processes, yet those processes “deliver few if any savings to customers, let alone savings which justify their costs.”⁵⁶³ Accordingly, ITC advocates for allowing public utility transmission providers to adopt or reinstate a federal right of first refusal in light of “the urgency of the need for new transmission investment.”⁵⁶⁴

B. Need for Reform

349. As noted above, recent investment appears to be concentrated in transmission facilities not subject to Order No. 1000 competitive transmission development processes, which are often developed within individual incumbent transmission provider retail distribution service territories or footprints or address narrow regional transmission needs, as opposed to investment in regional transmission facilities selected in a regional transmission plan for purposes of cost allocation that serve a wider set of transmission needs and are subject to competitive transmission development processes.⁵⁶⁵ Indeed, despite the fact that multiple industry studies estimate that regionally planned transmission expansion would yield numerous consumer benefits,⁵⁶⁶ transmission investment through the regional transmission planning and cost allocation processes has not necessarily increased since implementation of Order No. 1000; in fact, in some transmission planning regions, investment in regionally planned transmission has declined.⁵⁶⁷ The

⁵⁶² EEI Comments at 23–24.

⁵⁶³ ITC Comments at 13–15 & nn.8–9 (citing Concentric Energy Advisors, *Building New Transmission, Experience to Date Does Not Support Expanding Solicitations* (June 2019) (included as attach. B to EEI Reply Comments)).

⁵⁶⁴ *Id.* at 13.

⁵⁶⁵ *See supra* note 550 and associated text.

⁵⁶⁶ *See, e.g.,* Rob Gramlich & Jay Caspary, Americans for a Clean Energy Grid, *Planning for the Future*, at app. A (Jan. 2021) (included as Ex. 1 to ACORE Comments) (ACEG Jan. 2021 Planning Report); at app. A; Brattle, *Offshore Transmission in New England: The Benefits of a Better Planned Grid* (May 2020), https://www.brattle.com/wp-content/uploads/2021/05/18939_offshore_transmission_in_new_england_-_the_benefits_of_a_better-planned_grid_brattle.pdf (Brattle Offshore Transmission Study).

⁵⁶⁷ *See, e.g.,* ACEG Jan. 2021 Planning Report at 25 & fig. 8 (charting the annual regionally planned transmission investment in RTOs/ISOs from 2010 to 2018); ACORE Comments at 4 (citing Ex. 1, ACEG Jan. 2021 Planning Report at 25). For example, investment in regional transmission facilities in PJM averaged \$2.76 billion from 2005 to 2013 and dropped to \$1.65 billion from 2014 to 2020. Harvard ELI Comments at 21 & n.92 (citations omitted); *see also* PJM, Transmission Expansion

record here further indicates that regional transmission facilities subject to a competitive transmission development process represent only a small portion of total transmission investment in recent years across several transmission planning regions.⁵⁶⁸

350. This trend may be related to Order No. 1000’s nonincumbent transmission developer reforms. While Order No. 1000 anticipated and generally sought to facilitate greater and more efficient or cost-effective investment in regional transmission facilities,⁵⁶⁹ some observers at the time expressed concern that Order No. 1000’s reforms “could ultimately discourage” existing “transmission owners from seeking regional cost allocation for their local projects,” and thereby unintentionally encourage “more local transmission projects” serving more local needs, even where broader regional transmission facilities may be more efficient or cost-effective.⁵⁷⁰ Thus, given the investment trends observed since Order No. 1000’s implementation, it is possible that the Commission’s Order No. 1000 nonincumbent transmission developer reforms may in fact be inadvertently *discouraging* investment in and development of regional transmission facilities to some extent. Incumbent transmission providers, as a result of those reforms, may be presented with perverse investment incentives that do not adequately encourage those incumbent transmission providers to develop and advocate for transmission facilities that benefit more than just their own local retail distribution service territory or footprint. Due to these concerns, we propose to revisit and reform the Commission’s rules and policies regarding the elimination of federal rights of first refusal, as described in this section.

C. Proposed Reform

1. Approach To Reform

351. In light of the experience gained since the issuance of Order No. 1000 and the comments received in response to the ANOPR, we propose to amend Order No. 1000’s nonincumbent transmission developer reforms in part,

Advisory Committee, *2019 Project Statistics*, at 3 (May 12, 2020), <https://www.pjm.com/-/media/committees-groups/committees/teac/2020/20200512/20200512-item-10-2019-project-statistics.ashx>.

⁵⁶⁸ *See, e.g.,* Brattle Apr. 2019 Competition Report at 19 fig. 6.

⁵⁶⁹ *See* Order No. 1000, 136 FERC ¶ 61,051 at PP 2–3, 46.

⁵⁷⁰ *See, e.g., id.* (Moeller, Comm’r, dissenting in part).

so as to permit the exercise of federal rights of first refusal for transmission facilities selected in a regional transmission plan for purposes of cost allocation, conditioned on the incumbent transmission provider with the federal right of first refusal for such regional transmission facilities establishing joint ownership of the transmission facilities consistent with the proposal below. We propose to use the discretion afforded by FPA section 309 to “amend, and rescind such orders, rules, and regulations as [the Commission] may find necessary or appropriate” in implementing the FPA, including FPA section 205.⁵⁷¹ to amend Order No. 1000’s findings and mandates in part. Specifically, we preliminarily find that Order No. 1000 remains correct regarding the *unconditional* exercise of federal rights of first refusal for entirely new transmission facilities selected in a regional transmission plan for purposes of cost allocation—the unconditional use of federal rights of first refusal for such facilities remains unjust and unreasonable given the likelihood that the presence and exercise of those rights may prevent the realization of more efficient or cost-effective transmission solutions to regional transmission needs.⁵⁷²

352. However, in light of the years of experience since the issuance of Order No. 1000 and the comments received in response to the ANOPR, we preliminarily find that Order No. 1000’s remedy—requiring the elimination of *all*

⁵⁷¹ 16 U.S.C. 825h (“The Commission shall have power to perform any and all acts, and to prescribe, issue, make, amend, and rescind such orders, rules, and regulations as it may find necessary or appropriate to carry out the provisions of this chapter.”); *see also id.* section 824d(a)–(b) (requiring that “all rules and regulations affecting or pertaining to” jurisdictional rates “be just and reasonable” and free from “undue preference or advantage”); *Am. Pub. Power Ass’n v. FPC*, 522 F.2d 142, 144, 145–47 (D.C. Cir. 1975) (affirming Commission action taken under FPA section 309 to change rules regarding cost basis for wholesale electric power rates, observing in part that “ratemaking methodologies perceived to produce just and reasonable results in the past may be scrapped in favor of other methodologies now perceived to be preferable” (citation omitted)); *La. Regional Transmission Organizations*, Order No. 2000, FERC Stats. & Regs. ¶ 31,089, at 30,993 (1999) (cross-referenced at 89 FERC ¶ 61,285) (relying in part on section 205 in a rulemaking order that enabled voluntary reforms), *order on reh’g*, Order No. 2000–A, FERC Stats. & Regs. ¶ 31,092 (2000) (cross-referenced at 90 FERC ¶ 61,201), *aff’d sub nom. Pub. Util. Dist. No. 1 of Snohomish Cty. v. FERC*, 272 F.3d 607 (DC Cir. 2001); *La. Pub. Serv. Comm’n v. Entergy Corp.*, Opinion No. 519–A, 153 FERC ¶ 61,188, at P 15 (2015) (“The Commission, which is responsible for determining what is ‘just and reasonable’ under the FPA, necessarily has broad discretion to take into account all factors that affect that determination.”).

⁵⁷² *See* Order No. 1000, 136 FERC ¶ 61,051 at PP 5, 7, 226.

federal rights of first refusal for entirely new transmission facilities selected in a regional transmission plan for purposes of cost allocation—was overly broad. Order No. 1000 may have overlooked the possibility that, as an alternative to elimination of federal rights of first refusal for transmission facilities selected in a regional transmission plan for purposes of cost allocation, conditions could be applied to the use of federal rights of first refusal for such facilities that would make their exercise just and reasonable and not unduly discriminatory or preferential.

353. Accordingly, we preliminarily find that, while Order No. 1000’s nonincumbent transmission developer reforms have a sound theoretical basis,⁵⁷³ in requiring the elimination of *all* federal rights of first refusal for entirely new transmission facilities selected in a regional transmission plan for purposes of cost allocation, the remedy prescribed by Order No. 1000 failed to recognize that at least some of the most notable expected benefits from competitive transmission development processes (e.g., new transmission developer market entry, greater innovation in and potentially lower costs of transmission development) could be achieved or at least reasonably approximated through other means. We believe that it may be possible that allowing public utility transmission providers to propose conditional federal rights of first refusal consistent with the proposal below may help public utility transmission providers address potentially flawed investment incentives that may be restraining otherwise more efficient or cost-effective regional transmission facility development. Therefore, under FPA sections 309 and 205, we preliminarily find it necessary or appropriate to carry out the provisions of the FPA to amend Order No. 1000 in part as described in this section.

354. Should the Commission proceed to amend Order No. 1000’s findings and mandates as described above, following the issuance of any final rule in this docket, we propose to allow public utility transmission providers to propose, pursuant to FPA section 205, new federal rights of first refusal for incumbent transmission providers, provided that such rights are conditioned on the incumbent transmission provider with the federal right of first refusal for such regional transmission facilities establishing joint ownership of the transmission facilities consistent with the proposal below. We believe that this reform will help to

⁵⁷³ *See supra* notes 538 to 541 and associated text.

ensure just and reasonable Commission-jurisdictional rates and limit opportunities for undue discrimination by public utility transmission providers. We preliminarily continue to find that unconditional federal rights of first refusal for incumbent transmission providers are unjust and unreasonable, and unduly discriminatory and preferential.

355. In making this proposal, however, we do not intend to require the establishment of any particular federal rights of first refusal. Given the nature of our proposed action, public utility transmission providers would not be obligated to adopt the conditional federal rights of first refusal described in this section. Instead, Order No. 1000’s findings and mandates would be amended such that joint ownership conditions may presumptively be found to ensure just and reasonable Commission-jurisdictional rates and limit opportunities for undue discrimination by public utility transmission providers, if imposed upon the exercise of an incumbent transmission provider’s federal right of first refusal for transmission facilities selected in a regional transmission plan for purposes of cost allocation. We believe that this approach would permit justified variations from an otherwise one-size-fits-all federal rights of first refusal policy, and thereby would allow for regional flexibility, without imposing new federal rights of first refusal requirements on all public utility transmission providers. Public utility transmission providers would have the opportunity in their regular course of business to consider whether this type of a conditional federal right of first refusal would, if adopted, help improve their particular regional transmission planning process or help address potentially misaligned incentives regarding regional and local transmission facility investment.

356. We also propose to allow public utility transmission providers that establish conditional federal rights of first refusal as recognized in any final rule adopted in this proceeding to make other corresponding adjustments to the timing and procedural requirements of their competitive transmission development processes that are just and reasonable and not unduly discriminatory or preferential. More specifically, to accommodate changes in federal rights of first refusal provisions regarding certain transmission facilities selected in a regional transmission plan for purposes of cost allocation, we propose to permit changes to existing tariff provisions that were adopted to comply with the following requirements

of Order No. 1000: The federal rights of first refusal elimination requirement;⁵⁷⁴ the qualification requirement;⁵⁷⁵ the information requirement;⁵⁷⁶ and the access to use the regional cost allocation method(s) requirement.⁵⁷⁷ The degree to which changes to such tariff provisions will be necessary will depend on the specifics of the future proposal made by a particular public utility transmission provider. In allowing these corresponding adjustments, we intend for public utility transmission providers to provide robust openness and transparency safeguards regarding the exercise of conditional federal rights of first refusal, to help ensure just and reasonable Commission-jurisdictional rates and to limit and detect instances of potential undue discrimination.⁵⁷⁸

357. Also, we envision that conditional federal right of first refusal proposals would seek to establish federal rights of first refusal true to their name—a process whereby an incumbent transmission provider may, at its own election, choose to exercise a right to be designated to use the regional cost allocation method for a particular transmission facility or set of transmission facilities within its retail

⁵⁷⁴ The federal right of first refusal elimination requirement means the requirement that each public utility transmission provider eliminate provisions in Commission-jurisdictional tariffs and agreements that establish a federal right of first refusal for an incumbent transmission provider with respect to transmission facilities selected in a regional transmission plan for purposes of cost allocation. See Order No. 1000, 136 FERC ¶ 61,051 at P 313.

⁵⁷⁵ The qualification requirement means the requirement that each public utility transmission provider revise its OATT to demonstrate that the regional transmission planning process in which it participates has established appropriate qualification criteria for determining an entity's eligibility to propose a transmission facility for selection in the regional transmission plan for purposes of cost allocation, whether that entity is an incumbent transmission provider or a nonincumbent transmission developer. See *id.* P 323.

⁵⁷⁶ The information requirement means the requirement that each public utility transmission provider identify in its OATT the information that a prospective transmission developer must submit in support of a transmission project the developer proposes in the regional transmission planning process. See *id.* P 325.

⁵⁷⁷ The access to use the regional cost allocation method(s) requirement means the requirement that each public utility transmission provider participate in a regional transmission planning process that provides that a nonincumbent transmission developer has an opportunity comparable to that of an incumbent transmission provider to allocate the cost of a transmission facility selected in the regional transmission plan for purposes of cost allocation through a regional cost allocation method or methods. See *id.* PP 332, 335.

⁵⁷⁸ See, e.g., *PJM Interconnection, L.L.C.*, 174 FERC ¶ 61,117 at PP 3–4 (describing the criteria for and process regarding immediate need reliability projects).

distribution service territory or footprint that is selected in a regional transmission plan for purposes of cost allocation,⁵⁷⁹ subject to applicable conditions. Should the incumbent transmission provider choose not to exercise its right, we envision that a public utility transmission provider would then proceed to follow its competitive transmission development process to select a qualified transmission developer to use the regional transmission cost allocation method for the selected regional transmission facilities.⁵⁸⁰

2. Conditional Federal Rights of First Refusal for Certain Jointly-Owned Transmission Facilities

358. We propose to preliminarily find presumptively just and reasonable and not unduly discriminatory or preferential the establishment of a federal right of first refusal for transmission facilities selected in a regional transmission plan for purposes of cost allocation, conditioned on joint-ownership requirements, as more fully described in this section. We propose that an incumbent transmission provider may establish qualifying joint ownership structures with unaffiliated nonincumbent transmission developers as defined in Order No. 1000,⁵⁸¹ or with another unaffiliated entity, including another incumbent transmission provider, if the joint ownership structure meets the requirements outlined in this section, including the requirement that the joint ownership structure offer a meaningful level of participation and investment in proposed transmission facilities to the incumbent transmission provider's unaffiliated partners.⁵⁸² We believe this proposed reform could address the potentially misaligned incentives for

⁵⁷⁹ See *S.C. Pub. Serv. Auth.*, 762 F.3d at 72 & n.6.

⁵⁸⁰ If the competitive transmission development process does not yield a qualified transmission developer to use the regional transmission cost allocation method for the selected regional transmission facilities, and if necessary, the incumbent transmission provider may be obligated to build those selected regional transmission facilities. See *PJM Interconnection, L.L.C.*, 142 FERC ¶ 61,214, at P 224 (2013) (explaining that Order No. 1000 did not limit “mechanisms to impose an obligation to build transmission facilities in a regional transmission plan”); e.g., CAISO, CASIO eTariff, § 24.6.4, (Inability to Complete the Transmission Solution) (2.0.0) (granting CAISO the discretion, regarding reliability driven transmission solutions an Approved Project Sponsor is unable to construct, to either “direct the Participating TO in whose PTO Service Territory or footprint either terminus of the transmission solution is located . . . to build the transmission solution, or the CAISO may open a new solicitation for Project Sponsors to finance, own, and construct the transmission solution”).

⁵⁸¹ See *supra* P 337.

⁵⁸² See *infra* PP 365, 371.

regional transmission facility development faced by incumbent transmission providers while still largely ensuring at least some of the potential cost-related benefits of competitive transmission development processes.

a. Background

359. In Order No. 1000, in response to comments requesting that the Commission consider joint transmission ownership as a financing and cost allocation tool, the Commission stated that specific financing techniques such as joint ownership were beyond the scope of that proceeding. While the Commission declined to “specifically address joint ownership as a cost allocation tool,” it did note that transmission developers were “free to consider joint ownership when proposing and developing a transmission project.”⁵⁸³ The Commission also reiterated its belief that “there are benefits to joint ownership of transmission facilities, particularly large backbone facilities, both in terms of increasing opportunities for investment in the transmission grid, as well as ensuring nondiscriminatory access to the transmission grid by transmission customers.”⁵⁸⁴ Since Order No. 1000, joint proposals or joint ownership arrangements between incumbent transmission providers and nonincumbent transmission developers have been an option generally available to qualified transmission developers participating, pursuant to public utility transmission provider tariffs, in competitive transmission development processes.⁵⁸⁵

b. Comments

360. Although the Commission did not specifically ask about jointly-owned

⁵⁸³ Order No. 1000, 136 FERC ¶ 61,051 at P 776.

⁵⁸⁴ *Id.* (citing Order No. 890, 118 FERC ¶ 61,119 at P 593).

⁵⁸⁵ See, e.g., CAISO, CASIO eTariff, § 24.5.2 (Project Sponsor Application and Information Requirements) (6.0.0), § 24.5.2.1 (Opportunity for Collaboration); *id.* 24.15.1 Transmission Additions and Upgrades under TCA (0.0.0), section 24.15.1 (referencing “transmission additions and upgrades [that] are jointly developed by Participating TOs and non-Participating TOs”); MISO, FERC Electric Tariff, attach. FF (Transmission Expansion Planning Protocol) (85.0.0), § VIII.D.4.2. (Joint-Developer Proposal); PJM, Intra-PJM Tariffs, OA Schedule 6, § 1.5 (Procedure for the Development of the Regional Transmission Expansion Plan) (28.0.0), § 1.5.6(I) (“Nothing herein shall prevent any Transmission Owner or other entity designated to construct, own and/or finance a recommended transmission enhancement or expansion from agreeing to undertake its responsibilities under such designation jointly with other Transmission Owners or other entities.”).

transmission facilities in the ANOPR,⁵⁸⁶ some commenters address the topic of jointly-owned transmission facilities. For example, SDG&E discusses its partnership with nonincumbent transmission developers to develop and construct two new transmission lines, known as the Sunrise Powerlink and Sycamore-Peñasquitos projects.⁵⁸⁷

361. In its comments, TAPS supports joint transmission ownership arrangements, which TAPS argues have been effective for getting transmission facilities constructed.⁵⁸⁸ Among other potential benefits of joint transmission ownership arrangements, TAPS argues that these arrangements improve coordination by leveraging relationships and knowledge among the joint-owning parties for transmission siting, obtaining approval from state-level retail regulators, easing cost allocation issues by spreading or socializing costs among the joint-owning parties, spreading risk more evenly, and likely lessening disputes related to transmission planning and cost allocation that the Commission may otherwise have to adjudicate.⁵⁸⁹ Joint ownership arrangements, TAPS explains, can be structured in various ways, including as an inclusive transmission-only company, or shared-system arrangement, or other type of joint venture, including structures where ownership among two or more utilities is held in proportion to each participant's load ratio share of connected customer load.⁵⁹⁰

362. TAPS asserts that while the Commission has previously found that joint transmission ownership arrangements are beneficial and encouraged more entities to consider these types of arrangements,⁵⁹¹ there are few joint transmission ownership arrangements today. TAPS warns that the Commission's objective of modifying transmission planning and expansion requirements to accommodate the changing resource mix, while minimizing costs to consumers, would be thwarted if costs are unnecessarily increased; that objective may also be thwarted if needed transmission projects are not

timely built because those projects face greater financial or siting risk without joint ownership, which may relate to federal rights of first refusal requirements.⁵⁹²

363. In order to foster joint transmission ownership arrangements, TAPS recommends that the Commission make changes to transmission planning processes, including by permitting public utility transmission providers to bid out the cost of construction and associated capital requirements regarding regional and interregional transmission facilities selected in regional transmission plans, which would be designed to identify ownership partners among the existing load-serving entities in the transmission planning region. TAPS recommends that, to the extent the Commission makes a finding on joint transmission ownership arrangements, the Commission should structure competitive bidding processes such that they provide transmission-dependent utilities in the project's footprint with opportunities to participate in supplying their fair share of capital for certain projects.⁵⁹³

364. While TAPS does not explicitly request that the Commission permit the establishment of a conditional federal right of first refusal for constructing transmission facilities under certain joint transmission ownership arrangements, TAPS contends that in general there is significant interest from willing partners that could work together with incumbent transmission providers to construct a transmission facility, and that the structure of competitive transmission development processes should "advance[] the role of inclusive joint ownership."⁵⁹⁴

c. Proposed Reform

365. We preliminarily find presumptively just and reasonable and not unduly discriminatory or preferential the establishment of a federal right of first refusal for transmission facilities selected in a regional transmission plan for purposes of cost allocation, conditioned on the incumbent transmission provider with the federal right of first refusal for such regional transmission facilities establishing joint ownership of the transmission facilities consistent with this subsection. We propose that an incumbent transmission provider may establish qualifying joint ownership with unaffiliated nonincumbent transmission developers as defined in

Order No. 1000,⁵⁹⁵ or another unaffiliated entity, including another incumbent transmission provider, if otherwise consistent with this subsection. These potential joint ownership partners could include unaffiliated public power entities, unaffiliated load-serving entities such as transmission-dependent municipally-owned utilities or electric cooperatives, other unaffiliated third parties that do not have (or are operating outside of) their retail distribution service territory or footprint, or another unaffiliated entity, including another incumbent transmission provider.

366. We expect that public utility transmission providers seeking to adopt this reform will need to include in their tariffs a detailed process for the exercise of a conditional right of first refusal for regional transmission facilities that will be jointly owned. Relatedly, we believe that an incumbent transmission provider's conditional federal right of first refusal—whether exercised or not regarding any particular transmission facility—should not significantly delay the regional transmission planning process, nor should it result in prolonged uncertainty regarding which transmission facilities will (or, alternatively, will not) be subject to competitive transmission development processes.

367. We envision, as an example, the following process for the exercise of a conditional federal right of first refusal for regional transmission facilities that will be jointly owned. First, the public utility transmission providers in a transmission planning region will identify a regional transmission need (under the sponsorship model) or identify a regional transmission need and select a transmission facility in the regional transmission plan for purposes of cost allocation to meet that need (under the competitive bidding model).⁵⁹⁶

368. Second, before public utility transmission providers in each transmission planning region initiate competitive transmission development processes, public utility transmission providers in each transmission planning region will give an opportunity for an incumbent transmission provider possessing a relevant conditional federal right of first refusal to indicate its intent to invoke that right and submit a jointly-owned regional transmission facility

⁵⁸⁶ See ANOPR, 176 FERC ¶ 61,024 at P 37.

⁵⁸⁷ SDG&E Comments at 4–5.

⁵⁸⁸ TAPS Comments at 8 (citing TAPS 2021 White Paper (June 25, 2021), <https://www.tapsgroup.org/wp-content/uploads/2021/09/TAPS-Inclusive-Joint-Ownership-White-Paper.pdf> (TAPS 2021 White Paper)).

⁵⁸⁹ *Id.* at 9–11.

⁵⁹⁰ *Id.* at 8–9 & nn.9–11.

⁵⁹¹ *Id.* at 12; TAPS 2021 White Paper at 7–8 (citing in part Order No. 1000, 136 FERC ¶ 61,051 at P 776; *Promoting Transmission Inv. Through Pricing Reform*, Policy Statement, 77 FR 69754 (Nov. 21, 2012), 141 FERC ¶ 61,129 (2012)).

⁵⁹² TAPS Comments at 13–15, 52–53.

⁵⁹³ *Id.* at 13–15.

⁵⁹⁴ *Id.* at 12, 14–15, 52–53.

⁵⁹⁵ See *supra* P 337.

⁵⁹⁶ See FERC, Staff Report, 2017 *Transmission Metrics*, at 8 (Oct. 6, 2017), <https://www.ferc.gov/sites/default/files/2020-05/transmission-investment-metrics.pdf> (describing the two general types of competitive transmission development processes).

proposal in partnership with one or more unaffiliated entities.

369. Third, given that the potentially relevant conditional federal right of first refusal and process for exercising it has been established in Commission-jurisdictional tariffs and agreements, upon receipt of a jointly-owned regional transmission facility proposal, the public utility transmission providers in the transmission planning region would confirm the parties' rights and responsibilities associated with the jointly-owned transmission facility proposal and its conformance with tariff provisions implementing the option proposed in this subsection. Here, we envision that the parties participating in the jointly-owned regional transmission facility proposal would have to demonstrate that their proposal commits the parties to a joint-ownership arrangement consistent with this subsection and that it meets the requirements of the applicable regional transmission planning process as outlined in the public utility transmission providers' tariffs on file with the Commission. For instance, the parties to a jointly-owned regional transmission facility proposal would have to provide sufficient detail to adequately delineate their respective financial interests and relationship as partners, and to demonstrate that the parties either individually or jointly meet all other applicable requirements. Public utility transmission providers in the transmission planning region should, at the conclusion of this step in the process, notify stakeholders and the public (*e.g.*, through posting on a public website) that either the jointly-owned regional transmission facility proposal conforms with tariff provisions implementing the conditional right of first refusal and, thus, a relevant conditional right of first refusal has been exercised, or, alternatively, that the public utility transmission providers in the transmission planning region will proceed to initiate a competitive transmission development process given that the jointly-owned regional transmission facility proposal does not conform with such tariff provisions. If a jointly-owned regional transmission facility proposal is not or cannot be confirmed as conforming with the public utility transmission provider's Commission-jurisdictional tariffs and agreements that relate to the incumbent transmission provider's conditional federal right of first refusal, or otherwise does not qualify for selection in the regional transmission plan for purposes of cost allocation, public utility transmission providers in the

transmission planning region shall proceed to follow their otherwise applicable competitive transmission development process.

370. Finally, public utility transmission providers in the transmission planning region would proceed to evaluate the jointly-owned regional transmission facility proposal without going through the competitive transmission development process. In a transmission planning region with a sponsorship model, this means that public utility transmission providers would evaluate in their regional transmission planning process the jointly-owned regional transmission facility proposal for potential selection in the regional transmission plan for purposes of cost allocation without soliciting any sponsored transmission facility proposals. In a transmission planning region with a competitive bidding model, where the transmission facility has already been selected in the regional transmission plan for purposes of cost allocation, this means that public utility transmission providers would evaluate the jointly-owned regional transmission facility proposal through the regional transmission planning process without soliciting other proposals to develop the already-selected regional transmission facility.

371. As part of this proposal and in general, we believe that the benefits of joint ownership would not be achieved if an incumbent transmission provider partnered with an affiliated entity to submit a proposal, or if that incumbent transmission provider limited the input or ownership share of its intended partners to less than a meaningful level. Instead, we intend for incumbent transmission providers pursuing joint-ownership proposals to offer unaffiliated entities a reasonable chance at meaningful participation and investment in the proposed regional transmission facility. Therefore, we propose that to qualify for the presumption advanced in this proposal, incumbent transmission providers with a conditional federal right of first refusal would not be allowed to partner with affiliated entities, and would not be allowed to structure joint-ownership arrangements such that unaffiliated entities were offered less than a meaningful level of participation and investment in the proposed regional transmission facility. While we do not propose to limit potentially qualifying joint ownership structures to those already employed in the industry, we note that a meaningful level of participation and investment in proposed facilities has been or could be offered to unaffiliated entities under

various types of joint ownership structures that have been established or proposed.⁵⁹⁷

372. We believe that a conditional federal right of first refusal for jointly-owned transmission facilities as described in this subsection may help facilitate openness in the regional transmission planning process, decrease potential financial and siting risks, and increase the likelihood that transmission facilities selected in a regional transmission plan for purposes of cost allocation are successfully and cost-effectively developed. First, if a conditional federal right of first refusal was available for jointly-owned regional transmission facilities, the greater development certainty that a federal right of first refusal could provide for the development of a transmission facility could help incentivize interested parties (including incumbent transmission providers and potential unaffiliated partners) to consider a jointly-owned transmission facility and leverage the combined transmission development strengths of the parties, potentially including the parties' knowledge of siting and permitting processes or other strengths. Joint ownership arrangements could, consistent with Commission precedent, help increase opportunities for investment in the transmission system, as well as ensure not unduly discriminatory access to the transmission system by transmission customers.⁵⁹⁸ Indeed, we believe that jointly-owned regional transmission facilities, which may involve the participation of multiple nearby load-serving entities and potentially those that are public power entities, may increase collaboration within the regional transmission planning process consistent with Order No. 679.⁵⁹⁹

373. Second, given the nature of a joint-ownership arrangement, individual parties working together may achieve efficiencies in addressing their collective transmission needs and, therefore, achieve lower overall costs compared to developing transmission facilities to resolve more individualized needs in a more piecemeal manner as is the case today. Relatedly, the entities in

⁵⁹⁷ See, *e.g.*, *supra* PP 360–364 (discussing examples of joint ownership structures employed or identified by ANOPR commenters, including those based on load-ratio share); see also *infra* note 604 and associated text (describing the inclusive transmission-only company or shared-system agreement concepts).

⁵⁹⁸ See Order No. 1000, 136 FERC ¶ 61,051 at P 776; see also Order No. 890, 118 FERC ¶ 61,119 at PP 593–594.

⁵⁹⁹ See *Promoting Transmission Inv. through Pricing Reform*, Order No. 679, 71 FR 43294 (July 31, 2006), 116 FERC ¶ 61,057, at PP 354, 355 (2006).

a joint ownership arrangement might bring different strengths to the process of developing a regional transmission facility, potentially reducing the costs for development or leveraging their expertise to design a more efficient or cost-effective transmission facility than the partners would have designed separately, thus benefiting customers. We note, for example, that while SDG&E's Sunrise Powerlink and Sycamore-Peñasquitos projects addressed multiple reliability needs for CAISO's transmission system, these transmission facilities also enabled the transmission facility's other joint owner the option to lease a portion transfer capability of the transmission facility.⁶⁰⁰ In short, we believe that this joint ownership proposal may help promote innovative transmission ownership structures for transmission development, as well as innovative regional transmission facilities that more efficiently or cost-effectively address regional transmission needs, which in turn would help ensure just and reasonable Commission-jurisdictional rates.

374. Third, jointly-owned regional transmission facilities, by spreading the risks and responsibilities of developing transmission facilities among multiple parties, may act as a useful hedging tool against expected longer-term, future transmission system development costs by allowing the parties to offset near-term expenditures on constructing transmission facilities necessary to maintain reliability.

375. Thus, we preliminarily find that a conditional federal right of first refusal for regional transmission facilities that will be jointly owned, as described in this subsection, could address the potentially misaligned incentives for transmission facility development faced by incumbent transmission providers while still largely ensuring the potential cost-related benefits of competitive transmission development processes. Given that jointly-owned transmission facilities appear to offer many benefits, we preliminarily find that customers may benefit from such a conditional federal right of first refusal through the selection of more efficient or cost-effective transmission facilities in the regional transmission plan for purposes of cost allocation. Indeed, we believe

that joint ownership arrangements may help achieve several of the goals that competitive transmission development processes are intended to serve today.⁶⁰¹

376. In particular, we believe that this proposal would offer nonincumbent transmission developers and other potential unaffiliated entities the opportunity to partner with an incumbent transmission provider and thereby achieve market entry and greater diversity of participation and perspectives in transmission ownership. Moreover, to exercise their conditional federal right of first refusal under this proposed reform, incumbent transmission providers would be required to share ownership and investment opportunities with other partners, potentially including other transmission developers, limiting an incumbent transmission provider's ability to use federal rights of first refusal to serve only its own economic interests.

377. As described above, we are concerned that today's processes place unintended emphasis on the development of local transmission facilities or other transmission facilities not subject to competitive transmission development processes, potentially at the expense of regional transmission facility development, given trends observed since the issuance of Order No. 1000.⁶⁰² We believe that this joint ownership-focused conditional federal right of first refusal proposal may help address that issue while advancing the goals of Order No. 1000.

378. We seek comment on the requirements proposed in this section of the NOPR. In particular, we request that commenters address how this proposed conditional right of first refusal aligns with or advances the goals of Order No. 1000's reforms,⁶⁰³ or otherwise ensures just and reasonable Commission-jurisdictional rates and limits opportunities for undue discrimination by public utility transmission providers.

379. We also seek comment regarding the administrability of and implementation challenges associated with the establishment and exercise of joint ownership-focused conditional federal rights of first refusal, including what specific requirements the Commission should impose on joint-

ownership agreements or on the process of formulating them. We also seek comment on whether limiting this option to proposals that form or expand an inclusive transmission-only company or shared-system arrangement is necessary to ensure just and reasonable Commission-jurisdictional rates and limited opportunities for undue discrimination by public utility transmission providers.⁶⁰⁴ We seek comment as well regarding whether all transmission-dependent utilities or load-serving entities in a particular public utility transmission provider's service territory where a proposed regional transmission facility would be located should be given the opportunity to participate in a joint ownership arrangement that allows those transmission-dependent utilities or load-serving entities to supply up to their fair share (e.g., load-ratio share) of capital for certain regional transmission facilities.⁶⁰⁵

380. We also seek comment on the standards, such as ownership share percentages or load-ratio share offer requirements, that should govern whether particular joint ownership arrangements qualify for the presumption identified here because such standards would help achieve the benefits described above. Accordingly, we seek comment on whether any additional requirements beyond those mentioned above would be necessary to prevent the exertion of undue influence over the transmission development process or joint ownership arrangement by any project entity (including an incumbent transmission provider), avoid greater risks of project cancellation or abandonment, or otherwise protect customer interests.

381. Relatedly, we seek comment on eligibility and participation criteria related to jointly-owned transmission facilities and partners that should be permitted to qualify for the presumption proposed in this section, and any

⁶⁰⁴ In its comments and related white paper, TAPS cites Vermont Transco LLC and American Transmission Company LLC as inclusive transmission-only companies where instead of retaining direct ownership of separate transmission facilities, investor-owned and public power or cooperative utilities alike own membership units or equity stakes in one jointly-owned transmission company. See TAPS Comments at 8 nn.8-9; see also TAPS 2021 White Paper at 2. As TAPS further explains, under "shared-system arrangements, . . . transmission facilities of two or more utilities are planned and operated jointly, as a single system, pursuant to a long-term agreement. Ownership is generally in proportion to each participant's load ratio share of connected customer load, which can be achieved in a variety of ways, e.g., owning an undivided share of the entire joint system; owning discrete facilities; owning new facilities." See TAPS Comments at 8 n.10.

⁶⁰⁵ See TAPS Comments at 14-15.

⁶⁰⁰ See SDG&E Comments at 4-5; see also

California State Water Project Reply Comments at 12 n.44 (discussing the Sycamore-Peñasquitos Project (citations omitted)); *Citizens Sycamore-Peñasquitos Transmission LLC*, 164 FERC ¶ 61,149, at PP 5-6 (2018) (same); *Citizens Sunrise Transmission LLC*, 138 FERC ¶ 61,129, at PP 3-10 (2012) (discussing the Sunrise Powerlink Project); *Citizens Energy Corp.*, 129 FERC ¶ 61,242, at P 5 (2009) (same).

⁶⁰¹ See *supra* notes 538 to 541 and associated text.

⁶⁰² See *supra* note 550; see also WIRES Comments at 11-12, 16 (asserting that the "introduction of competition . . . has not lived up to expectations" and addressing the Commission's articulated concerns about the possibility that "current policies and processes are not appropriately incentivizing the development and construction of larger regional facilities").

⁶⁰³ See *supra* notes 538 to 543 and associated text.

transparency, informational, or screening processes that may be required.⁶⁰⁶ While transmission developers already must satisfy qualification criteria to be eligible to use the regional transmission cost allocation method for regional transmission facilities selected in a regional transmission plan for purposes of cost allocation, we seek comment on whether this proposal necessitates specialized eligibility criteria or particular joint ownership partner selection processes to ensure just and reasonable Commission-jurisdictional rates and limit opportunities for undue discrimination by public utility transmission providers.⁶⁰⁷

382. Finally, we seek comment regarding whether the Commission should pursue broader reform to its rules and regulations governing federal rights of first refusal. In particular, we seek comment on whether the Commission should consider fully restoring the federal rights of first refusal eliminated in Order No. 1000 and, if so, how the Commission should go about doing so. We recognize that pursuing reforms focused on joint ownership alone may not fully address the potential issues that commenters have raised regarding competitive transmission development processes. Therefore, we seek comment both on the joint ownership-focused conditional federal rights of first refusal reform proposed above and on whether more significant changes to Order No. 1000's federal right of first refusal elimination mandate would help ensure just and reasonable Commission-jurisdictional rates while limiting opportunities for undue discrimination by public utility transmission providers.

⁶⁰⁶ For example, MISO's tariff requires information regarding the responsibilities and liabilities of each party to a joint-developer transmission project proposal. See MISO, FERC Electric Tariff, attach. FF (Transmission Expansion Planning Protocol) (85.0.0), § VIII.D.4.2. (Joint-Developer Proposal); *id.* § VIII.D.5.1.1. (Identification of RFP Respondents).

⁶⁰⁷ For example, we note that SDG&E's Sycamore-Peñasquitos Project was developed in partnership with Citizens Energy and required both SDG&E and Citizens Energy to enter into a Development, Coordination, and Option Agreement to provide for their rights, responsibilities, and future options related to the Sycamore-Peñasquitos Project. See *Citizens Sycamore-Peñasquitos Transmission LLC*, 164 FERC ¶ 61,149 at P 7.

VIII. Enhanced Transparency of Local Transmission Planning Inputs in the Regional Transmission Planning Process and Identifying Potential Opportunities to Right-Size Replacement Transmission Facilities

A. Background

383. Generally, the transmission facilities that public utility transmission providers include in their individual local transmission plans are incorporated into regional transmission plans as inputs, with minimal opportunity for stakeholder review in the regional transmission planning process. That is because the analysis of local transmission plans in the regional transmission planning process is limited mainly to a reliability analysis to ensure that local transmission plans do not negatively affect the reliability of the regional transmission system.

384. As noted earlier, the Commission in Order No. 1000 defined a local transmission facility as a transmission facility located solely within a public utility transmission provider's retail distribution service territory or footprint that is not selected in the regional transmission plan for purposes of cost allocation.⁶⁰⁸ The Commission did not require that the transmission facilities in a public utility transmission provider's local transmission plan be subject to approval at the regional or interregional level, unless that public utility transmission provider seeks to have any of those facilities selected as regional transmission facilities in the regional transmission plan for purposes of cost allocation.⁶⁰⁹

385. As existing transmission infrastructure ages, transmission owners must assess the state of their transmission systems and the condition of their transmission assets to determine whether and, if so, how to replace existing transmission facilities that have reached the end of their useful lives. The Commission has found that a replacement of an existing transmission facility that does not incrementally increase that facility's capacity is not subject to the transmission planning requirements of Order No. 890 or Order No. 1000 because an in-kind replacement⁶¹⁰ of an existing

transmission facility does not represent an expansion or enhancement of the transmission system.⁶¹¹ Therefore, under this precedent there is no requirement that public utility transmission providers provide information about potential in-kind replacements of existing transmission facilities in either their local or regional transmission planning processes. Some RTO/ISO transmission planning regions may assess a planned in-kind replacement of an existing transmission facility to ensure that it does not cause adverse reliability impacts,⁶¹² but regional transmission planning processes generally do not evaluate whether the planned in-kind replacement transmission facility could be modified to more efficiently or cost-effectively address regional transmission needs. However, we note that some public utility transmission providers do provide stakeholders with reports detailing the justification and quantity of replacement transmission

(*e.g.*, a 345 kV transmission facility that is replaced with a 345 kV transmission facility).

⁶¹¹ See *S. Cal. Edison Co.*, 164 FERC ¶ 61,160, at P 31 (2018) ("While Order No. 890 does not explicitly define the scope of 'transmission planning,' the Commission adopted the transmission planning requirements in Order No. 890 to remedy opportunities for undue discrimination in *expansion* of the transmission grid." (citing Order No. 890, 118 FERC ¶ 61,119 at PP 57–58, 421–422)); *Cal. Pub. Utils. Comm'n v. Pac. Gas & Elec. Co.*, 164 FERC ¶ 61,161, at P 68 (2018); *PJM Interconnection, L.L.C.*, 172 FERC ¶ 61,136, at P 12, 89, *order on reh'g*, 173 FERC ¶ 61,225 (2020); *PJM Interconnection, L.L.C.*, 173 FERC ¶ 61,242, at P 54 (2020), *order on reh'g*, 176 FERC ¶ 61,053 (2021). The Commission has further clarified that there may be instances in which a transmission owner's replacement of an existing transmission facility may result in an incidental increase in transmission capacity that is not reasonably severable from that replacement, *e.g.*, that occurs as a function of advancements in technology of the replaced equipment. In such cases, the Commission stated, the incidental increase in transmission capacity would not render the in-kind replacement of an existing transmission facility a transmission expansion that is subject to the transmission planning requirements of Order No. 890. *Cal. Pub. Utils. Comm'n v. Pac. Gas & Elec. Co.*, 164 FERC ¶ 61,161 at P 68.

⁶¹² See, *e.g.*, PJM Manual 14B: PJM Regional Transmission Planning Process at 19–20 ("It should also be noted that prior to integrating a Supplemental Project into the RTEP base case PJM performs a 'do no harm study' to evaluate whether a proposed Supplemental Project will adversely impact the reliability of the Transmission System as represented in the planning models used in all other PJM reliability planning studies. If as a result of the do no harm study, system upgrades are required, such upgrades will be considered part of the Supplemental Project and are the responsibility of the Transmission Owner sponsoring the Supplemental Project."); see also MISO Business Practice Manual, Transmission Planning, Manual No. 020 at 22–23 ("In its role as the Planning Coordinator (PC), MISO will evaluate all bottom-up projects submitted by Transmission Owner(s) and validate that the projects represent prudent solutions to one or more identified Transmission Issues.").

⁶⁰⁸ *Supra* P 17.

⁶⁰⁹ Order No. 1000–A, 139 FERC ¶ 61,132 at P 190.

⁶¹⁰ For the purposes of this NOPR, we define an "in-kind replacement" as a new transmission facility that does not expand the capacity of the existing transmission facility that is being replaced unless the incidental increase in transmission capacity occurs as a function of advancements in technology of the replaced equipment and is thus not reasonably severable from that replacement.

facilities.⁶¹³ Further, as discussed above, some public utility transmission providers do assess the benefits of deferred or avoided infrastructure, including asset replacements that would otherwise be needed.⁶¹⁴

386. The Commission in Order 1000—A clarified that it was not eliminating the right of an owner of a transmission facility to improve its own existing transmission facility.⁶¹⁵ Order No. 1000 also allows an incumbent transmission provider to meet its reliability needs or service obligations by choosing to build new transmission facilities that are located solely within its retail distribution service territory or footprint and that are not selected in a regional transmission plan for purposes of cost allocation.⁶¹⁶ Such transmission facilities' costs are allocated to the retail distribution service territory or footprint in which the facility is located through the incumbent transmission provider's individual transmission service rates in its OATT or through the zonal rates in an RTO/ISO OATT.

B. ANOPR

387. In the ANOPR, the Commission sought comment on whether individual incumbent transmission provider practices regarding replacement of existing transmission facilities sufficiently align with the directive to ensure evaluation of alternative transmission solutions and whether these practices sufficiently consider the more efficient or cost-effective ways to serve future needs.⁶¹⁷ Additionally, the Commission sought comment on whether sufficient transparency exists around replacement decisions made by transmission providers to allow an assessment of these decisions in the regional transmission planning process.

388. In the ANOPR, the Commission also sought comment on local transmission planning to better understand how the reforms of the federal right of first refusal in Order No. 1000 have shaped the type and characteristics of transmission facilities developed through regional and local transmission planning processes, such as a relative increase in investment in local transmission facilities or the diversity of projects resulting from

competitive regional transmission planning processes.⁶¹⁸

389. The Commission requested comment on whether the current regional and local transmission planning processes provide sufficient transparency for stakeholders to understand how best to obtain information and fully participate in the various processes.⁶¹⁹ The Commission, for example, theorized that in non-RTO/ISO regions, individual transmission owning members' local transmission planning processes may not be as well-publicized or follow as well-understood processes to provide information as in RTO/ISO regions. Based on this example, the Commission inquired whether customers and other stakeholders may benefit from enhanced oversight of local transmission planning.

C. Comments

390. Numerous commenters state that the vast majority of investment for transmission facilities in recent years has increasingly been focused on local level transmission facilities (typically less than 100–250 kV), and in replacing existing transmission facilities.⁶²⁰

391. Several commenters generally agree that the process for replacing aging transmission facilities needs additional improvements related to transparency and to increase the potential that multiple transmission system needs are addressed.⁶²¹ The California Commission argues that because the decision to order replacement transmission facilities is delegated to incumbent transmission owners, there is no process to evaluate whether replacement transmission facilities could be a “like-for-like” replacement or whether the replacement transmission facility may be upgraded via a new design or capacity.⁶²² NARUC argues that the Commission should require public utility transmission providers to apply Order No. 890 transparency principles to replacement transmission facilities to guard against incumbent public utility transmission

providers' incentive to overinvest in replacement transmission facilities.⁶²³ The New Jersey Commission asserts that by evaluating replacement transmission facilities through the regional transmission planning process, a potentially broader transmission solution may be identified thus obviating the need for a smaller-scale replacement transmission facility.⁶²⁴

392. ACEG notes that much of the nation's transmission facilities are over 50 years old and that the lack of a broader view of transmission planning in terms of replacement of existing, aging transmission facilities, coupled with a changing generation mix, will lead to a suboptimal transmission infrastructure network.⁶²⁵ Eversource argues that, going forward, the Commission should encourage flexibility by breaking down transmission planning silos so that an existing or planned transmission facility can be “upsized” to address multiple system needs like transmission facility conditions while also anticipating clean energy goals.⁶²⁶ LS Power argues that the Commission should require NERC to develop a new requirement that transmission providers must give notice when an existing transmission facility has reached the end of its useful life.⁶²⁷ PIOs explain that the routine of in-kind replacement of aging transmission facilities misses opportunities for better utilizing existing rights-of-way so as to meet multiple transmission system needs, which increases costs and inefficiencies.⁶²⁸

393. Likewise, many commenters argue that the current relationship between local and regional transmission planning processes must be reformed. Some consumer groups, state commissions, market monitors, and renewable energy developers and organizations argue that the local transmission planning process is broken.⁶²⁹ These entities argue that the local transmission planning process lacks transparency and oversight and is inappropriately influenced by incumbent transmission owners. To correct these flaws, these commenters

⁶¹³ See *PJM Interconnection, L.L.C.*, 172 FERC ¶ 61,136 at 21.

⁶¹⁴ *Supra* Table 1—Long-Term Regional Transmission Benefits.

⁶¹⁵ Order No. 1000—A, 139 FERC ¶ 61,132 at P 426.

⁶¹⁶ *Id.* PP 366, 379, 425, 428; Order No. 1000, 136 FERC ¶ 61,051 at P 262; Order No. 1000—A, 139 FERC ¶ 61,132 at PP 366, 379, 425, 428.

⁶¹⁷ ANOPR, 176 FERC ¶ 61,024 at P 171.

⁶¹⁸ ANOPR, 176 FERC ¶ 61,024 at P 37.

⁶¹⁹ *Id.* P 162.

⁶²⁰ ACOE Comments at 19–23; AEE Comments at 41–43; ACPA and ESA Comments at 30; American Municipal Power Comments at 22–24; APPA Comments at 20; California Commission Comments at 31–37; Union of Concerned Scientists Comments at 24–31; Harvard ELI Comments at 20–21; LS Power Oct. 12 Comments at 36–37; Michigan Commission Comments at 8–9; NARUC Comments at 55–56; New Jersey Commission Comments at 3–7; Pennsylvania Commission Comments at 16–17; Policy Integrity Comments at 16.

⁶²¹ *E.g.*, District of Columbia's Office of the People's Counsel Comments at 11–12; EDF Comments at 12.

⁶²² California Commission Comments at 17–18.

⁶²³ NARUC Comments at 15, 48–29.

⁶²⁴ New Jersey Commission Comments at 12–13.

⁶²⁵ ACEG Jan. 2021 Planning Report at 18–24.

⁶²⁶ Eversource Comments at 10.

⁶²⁷ LS Power Oct. 12 Comments at 43–44.

⁶²⁸ PIOs Comments at 50 (citing Brattle-Grid Strategies Oct. 2021 Report at 3).

⁶²⁹ ACEG Comments at 4–6 (citing Brattle Report at 25); AEE Comments at 41–49; Union of Concerned Scientists Comments at 24–31; Eversource Comments at 15–18; New Jersey Commission Comments at 4–6; LS Power Oct. 12 Comments at 49–62; PJM Market Monitor Comments at 9., Harvard ELI Reply Comments at 12–16.

are in favor of lowering voltage thresholds for regional transmission planning processes, such that more transmission facilities would be planned through that process rather than local transmission planning processes.⁶³⁰ Some of those commenters further urge the Commission to require transmission owners and providers to provide information and metrics about their local systems to the transmission planning process, and to do so within a timeframe that allows opportunity for real engagement with stakeholders, because without such a requirement, transmission owners and providers may be inhibiting the sharing of information relevant to the regional transmission planning processes.⁶³¹

394. The PJM Market Monitor recommends that PJM should clearly define the need for local transmission projects within the regional transmission planning process and that there should be a transparent, robust, and clearly defined mechanism to permit competition to build the project.⁶³² Some commenters go so far as to argue that there should be no separation between local and regional transmission planning processes at all.⁶³³

395. Other commenters identify the potential for less significant changes. AEP recommends that, to the extent the Commission reforms local transmission planning processes by increasing transparency and oversight, the Commission apply the practices and principles of PJM's Attachment M-3 process for Supplemental Projects across all other regions, including non-RTO/ISO regions.⁶³⁴

396. Alternatively, some commenters contend that existing processes are adequate. Some commenters argue that existing processes adequately address replacements of aging transmission facilities. CAISO notes that, while only

participating transmission owners oversee replacement transmission facilities that do not expand the capacity of transmission facilities, CAISO continues to evaluate and approve transmission facilities that do expand the transmission system.⁶³⁵ MISO TOs assert that replacement transmission facilities are evaluated through the MISO regional transmission planning process already and that MISO is obligated to seek combining replacement transmission facilities with other transmission facility projects where it is efficient and cost-effective to do so.⁶³⁶ PJM TOs note that they provide PJM with a list of candidates for replacement transmission facilities so that PJM can determine if the replacement transmission project may also address a larger, regional need.⁶³⁷

397. Additionally, some commenters argue that existing processes provide for an appropriate level of coordination between regional and local planning. The Alabama Commission, Duke, Southern, the Louisiana Commission, and the Ohio Commission,⁶³⁸ assert jurisdictional arguments in opposition to enhanced or expanded local transmission planning processes. These commenters argue that the Commission should not intervene in retail activities that are subject to state-level regulatory bodies.

D. Need for Reform

398. We are concerned that local transmission planning processes may lack adequate provisions for transparency and meaningful input from stakeholders, and that regional transmission planning processes may not adequately coordinate with local transmission planning processes.⁶³⁹ In Order No. 890, the Commission required that public utility transmission providers' local transmission planning processes comply with nine transmission planning principles, including coordination, openness, transparency, and information exchange.⁶⁴⁰ The Commission further explained that to satisfy the

coordination principle, public utility transmission providers must facilitate the timely and meaningful input and participation of customers in the development of transmission plans and, more specifically, that "customers must be included at the early stages of the development of the transmission plan and not merely given an opportunity to comment on transmission plans that were developed in the first instance without their input."⁶⁴¹ At times, the Commission has found it necessary to review local transmission planning processes to ensure stakeholders' opportunity to engage in them is meaningful.⁶⁴² However, implementation of these principles in local transmission planning processes appears to remain uneven, as commenters from regions across the country raise concerns about the transparency of and the opportunity for real engagement in various aspects of local transmission planning processes and their interaction with regional transmission planning processes.⁶⁴³ We are concerned that the lack of minimal standards or specified procedures to implement these principles may contribute to inadequate transparency and opportunities for stakeholders to engage in local transmission planning processes. In addition, we believe that reforms to better ensure more consistent implementation of these principles may be timely and important in light of the significant investments in transmission that now occur through local transmission planning processes.⁶⁴⁴

399. In addition, we are concerned that, given the age of the nation's transmission infrastructure, many incumbent transmission providers are replacing aging transmission infrastructure as it reaches the end of its useful life without evaluating whether those replacement transmission facilities could be modified (*i.e.*, right sized) to more efficiently or cost-effectively address regional transmission needs, and, more generally, that public utility transmission providers developing

⁶³⁰ California Commission Comments at 39–43; Competition Coalition Comments at 16; LS Power Oct. 12 Comments at 49–53.

⁶³¹ See *e.g.*, Union of Concerned Scientists Comments at 24–31; see also Environmental Advocates Comments at 22; Northwest and Intermountain Comments at 49.

⁶³² PJM Market Monitor Comments at 9.

⁶³³ American Municipal Power Comments at 32; City of New York Comments at 20–21; LS Power Oct. 12 Comments at 61–62; New Jersey Commission Comments at 11–13.

⁶³⁴ AEP Comments at 43–44 (citing *PJM Interconnection, L.L.C.*, 172 FERC ¶ 61,136 (2020)). Briefly, PJM's Attachment M-3 process for Supplemental Projects refers to the additional transparency and stakeholder input rules around transmission facilities that are not eligible for selection in the regional transmission plan for purposes of cost allocation but, though classified as local transmission facilities, nonetheless impact the identification and selection of regional transmission facilities.

⁶³⁵ CAISO Comments at 55–56.

⁶³⁶ MISO TOs Comments at 21–22.

⁶³⁷ PJM TOs Comments at 13–14.

⁶³⁸ Alabama Commission Comments at 2; Duke Comments at 2–4; Southern Comments at 22–33; Louisiana Commission Comments at 4–9; Ohio Commission Comments at 1–6.

⁶³⁹ See Order No. 1000, 136 FERC ¶ 61,051 at P 148 (providing that regional planning processes should identify "alternative transmission solutions that might meet the needs of the transmission planning region more efficiently or cost-effectively than solutions identified by individual utility transmission providers in their local transmission planning process").

⁶⁴⁰ Order No. 890, 118 FERC ¶ 61,119 at PP 418–601.

⁶⁴¹ *Id.* P 454.

⁶⁴² See, *e.g.*, *Monongahela Power Co.*, 156 FERC ¶ 61,134 (2016).

⁶⁴³ NARUC Comments at 14 (stating current planning processes may not be sufficiently transparent "in every region"); Massachusetts Attorney General Comments at 11 (stating it requires "herculean" efforts to review transmission project proposals); Resale Iowa Comments at 7 (claiming "[c]ustomers and other third parties have little or no input into alternative evaluation and project selection of these local projects"); Northwest and Intermountain Comments at 6 (stating "local utilities' transmission plans are incorporated into regional transmission planning processes as inputs with little opportunity for stakeholder comment").

⁶⁴⁴ See *supra* P 40; note 63.

regional transmission plans may lack the information necessary to identify the benefits regional transmission facilities may provide in deferring or eliminating the need for in-kind replacements.⁶⁴⁵ Specifically, as described in the background section, in-kind replacements of existing transmission facilities are managed by individual incumbent transmission providers according to their company practices; there is no requirement that public utility transmission providers plan these in-kind replacement transmission facilities through an Order No. 890-compliant transmission planning process.⁶⁴⁶ While a transmission provider may be able to meet its needs associated with an aging asset through an in-kind replacement, there may be circumstances under which “right-sizing” the planned transmission replacement would result in a more efficient or cost-effective transmission facility to meet both the need for the transmission provider to replace the existing transmission facility and transmission needs identified through Long-Term Regional Transmission Planning. Because in-kind replacement of existing transmission facilities is not subject to any transmission planning process, we are concerned that, absent reform, there may be a lack of coordination between regional transmission planning processes and in-kind replacement of existing transmission facilities to identify whether these replacement transmission facilities could be modified to more efficiently or cost-effectively address transmission needs identified through Long-Term Regional Transmission Planning. This lack of coordination may result in a regional transmission planning process that fails to identify

opportunities to right size planned in-kind replacement transmission facilities and may result in the development of duplicative or unnecessary transmission facilities that increase costs to consumers and render Commission-jurisdictional rates unjust and unreasonable.

E. Proposed Reform

400. We propose to require that public utility transmission providers in each transmission planning region revise the regional transmission planning process in their OATTs with additional provisions to enhance transparency of: (1) The criteria, models, and assumptions that they use in their local transmission planning process, (2) the local transmission needs that they identify through that process, and (3) the potential local or regional transmission facilities that they will evaluate to address those local transmission needs. Under this proposed reform, public utility transmission providers would be required to establish an iterative process that would ensure that stakeholders have meaningful opportunities to participate and provide feedback on local transmission planning throughout the regional transmission planning process. Leveraging the existing stakeholder processes for regional transmission planning, we propose to require that the regional transmission planning process include at least three stakeholder meetings concerning the local transmission planning process of each public utility transmission provider that is a member of the transmission planning region before each public utility transmission provider’s local transmission plan can be incorporated into the transmission planning region’s planning models, as described further below.

401. Specifically, prior to the submission of local transmission planning information to the transmission planning region for inclusion in the regional transmission planning process, public utility transmission providers in each transmission planning region would be required to convene, collectively, as part of the regional transmission planning process, a stakeholder meeting to review the criteria, assumptions, and models related to each public utility transmission provider’s local transmission planning (Assumptions Meeting). Next, no fewer than 25 calendar days after the Assumptions Meeting, public utility transmission providers that are members of the transmission planning region would be required to convene, collectively, as part

of the regional transmission planning process, a stakeholder meeting to review identified reliability criteria violations and other transmission needs that drive the need for local transmission facilities (Needs Meeting). Finally, no fewer than 25 calendar days after the Needs Meeting, public utility transmission providers that are members of the transmission planning region would be required to convene, collectively, as part of the regional transmission planning process, a stakeholder meeting to review potential solutions to those reliability criteria violations and other transmission needs (Solutions Meeting). Additionally, we propose to require that all materials for stakeholder review during these three meetings be publicly posted and that stakeholders have opportunities before and after each meeting to submit comments.

402. We preliminarily find that these proposed requirements will result in needed additional transparency into local transmission planning processes, which inform the regional transmission planning process in a transmission planning region. We believe that these proposed requirements are needed to ensure just and reasonable Commission-jurisdictional rates because the information provided will better facilitate the identification of regional transmission facilities that may be more efficient or cost-effective than proposed local transmission facilities through the regional transmission planning process. We also believe that these proposed requirements are needed to ensure just and reasonable and not unduly discriminatory or preferential Commission-jurisdictional rates because the information provided will enable customers and other stakeholders alike to evaluate or replicate the findings of public utility transmission providers so as to reduce after-the-fact disputes regarding whether local transmission planning has been conducted in an unjust and unreasonable or unduly discriminatory or preferential fashion.⁶⁴⁷

403. We also propose to require that, as part of each Long-Term Regional Transmission Planning cycle, public utility transmission providers in each transmission planning region evaluate whether transmission facilities operating at or above 230 kV that an individual public utility transmission provider that owns the transmission facility anticipates replacing in-kind with a new transmission facility during the next 10 years can be “right-sized” to more efficiently or cost-effectively address regional transmission needs

⁶⁴⁵ For example, we note a recent PJM analysis estimates that roughly two-thirds of all PJM transmission system assets are more than 40 years old, with some transmission facilities approaching 90 years old. See PJM Interconnection, L.L.C., *The Benefits of the PJM Transmission System* at 5 (April 16, 2019), <https://www.pjm.com/-/media/library/reports-notices/special-reports/2019/the-benefits-of-the-pjm-transmission-system.pdf>. Moreover, AEP estimates that approximately 30 percent of all its transmission assets will need to be replaced over the next ten10 years. See AEP, *Wolfe Utilities, Midstream, & Clean Energy Conference*, at 40 (Sept. 30, 2021), <https://www.aep.com/Assets/docs/investors/events/presentationsandwebcasts/WolfeConferencePresentation093021.pdf>. <https://www.aep.com/Assets/docs/investors/events/presentationsandwebcasts/WolfeConferencePresentation093021.pdf>.

⁶⁴⁶ *S. Cal. Edison Co.*, 164 FERC ¶ 61,160 at P 33; *Cal. Pub. Utils. Comm’n v. Pac. Gas & Elec. Co.*, 164 FERC ¶ 61,161 at P 68; *PJM Interconnection, L.L.C.*, 172 FERC ¶ 61,136 at PP 12, 89; *PJM Interconnection, L.L.C.*, 173 FERC ¶ 61,242 at P 54.

⁶⁴⁷ Order No. 890, 118 FERC ¶ 61,119 at P 471.

identified in Long-Term Regional Transmission Planning. By “right-sizing” we mean the process of modifying a public utility transmission provider’s in-kind replacement of an existing transmission facility to increase that facility’s transfer capability. Right-sizing could include, for example, increasing the transmission facility’s voltage level, adding circuits to the towers (e.g., redesigning a single-circuit line as a double-circuit line), or incorporating advanced technologies (such as advanced conductor technologies).⁶⁴⁸

404. As part of this proposed reform, first, we propose to require that, at a specified point early in each Long-Term Regional Transmission Planning cycle, each public utility transmission provider submit, as part of the regional transmission planning process, a list of each existing transmission facility operating at or above 230 kV that the public utility transmission provider owns and that it estimates may need to be replaced with a new in-kind transmission facility over the next 10 years, starting from the point in the transmission planning cycle when the list is compiled (which we refer to as “in-kind replacement estimates”).⁶⁴⁹

405. Second, we propose to require that public utility transmission providers in each transmission planning region, as part of Long-Term Regional Transmission Planning, review and evaluate whether the existing transmission facilities included in each public utility transmission owner’s in-kind replacement estimates can be right-sized to address a transmission need identified in Long-Term Regional Transmission Planning.

406. We preliminarily find that an existing transmission facility operating at or above 230 kV that a public utility transmission provider indicates may need to be replaced over the next 10 years is the type of facility that is best suited to be considered for right-sizing as part of Long-Term Regional Transmission Planning. We believe that in-kind replacement transmission facilities that will operate at or above 230 kV are the most likely candidates

for right-sizing, *i.e.*, are most susceptible to modification that could more efficiently or cost-effectively meet transmission needs identified through Long-Term Regional Transmission Planning. We also believe that 10 years is an appropriate timeframe to evaluate potential in-kind replacements for right-sizing to balance the long lead times necessary to construct large transmission facilities with the uncertainty associated with the exact timing when aging transmission assets may need to be replaced. A right-sized replacement transmission facility has the potential to both meet the individual public utility transmission provider’s responsibility to maintain the reliability of its existing transmission system and address a regional transmission need(s) identified in Long-Term Regional Transmission Planning more efficiently or cost-effectively. In addition, a right-sized replacement transmission facility may defer or displace the need for other transmission facilities, including both new transmission facilities and in-kind replacement of existing transmission facilities, thus representing a benefit to the public utility transmission provider and its customers. We believe that if opportunities for right-sized replacement transmission facilities are not considered, regional transmission planning processes may not select the more efficient or cost-effective transmission facilities in the regional transmission plan for purposes of cost allocation to meet transmission needs identified through Long-Term Regional Transmission Planning.⁶⁵⁰

407. The process under this proposed reform would entail the following steps. First, sufficiently early in each Long-Term Regional Transmission Planning cycle, each public utility transmission provider would submit its in-kind replacement estimates for use in Long-Term Regional Transmission Planning. Then, if a right-sized replacement transmission facility is identified as a potential solution to a Long-Term Regional Transmission Planning need, that right-sized replacement transmission facility would be evaluated in the same manner as any other proposed transmission facility to determine whether it is the more efficient or cost-effective transmission facility to address the transmission

need. If a right-sized replacement transmission facility addresses the public utility transmission provider’s need to replace an existing transmission facility, meets all the applicable selection criteria included in Long-Term Regional Transmission Planning, and is found to be the more efficient or cost-effective solution to a transmission need identified through Long-Term Regional Transmission Planning, then the right-sized replacement transmission facility may be selected in the regional transmission plan for purposes of cost allocation.⁶⁵¹

408. Although the right-sized replacement transmission facility may be selected in the regional transmission plan for purposes of cost allocation, it is necessary that a selected right-sized replacement transmission facility be subject to different rules with respect to the elimination of a federal right of first refusal than other regional transmission facilities. Absent reform, if a public utility transmission provider’s estimated in-kind replacement were right-sized and then selected in the regional transmission plan for purposes of cost allocation to meet transmission needs identified through Long-Term Regional Transmission Planning, the right-sized replacement transmission facility might then be subject to the transmission planning region’s competitive transmission development process. However, the public utility transmission provider would not necessarily be bound by that right-sizing decision made by the region, unless the public utility transmission provider was selected to develop the right-sized replacement transmission facility. This is because nothing in this proposed rule would alter existing law concerning the public utility transmission provider’s ability to proceed with developing its planned in-kind replacement transmission facility without the right-sizing, in spite of the potential efficiencies of right-sizing identified in the regional transmission planning process.⁶⁵² This may reduce the opportunities for the regional transmission planning process to identify more efficient or cost-effective solutions to transmission needs identified through Long-Term Regional Transmission Planning and potentially lead to duplicative or inefficient transmission development.

⁶⁴⁸ Grid Strategies LLC, *Advanced Conductors on Existing Transmission Corridors to Accelerate Low Cost Decarbonization*, at 2 (Mar. 2022), <https://gridprogress.files.wordpress.com/2022/03/advanced-conductors-on-existing-transmission-corridors-to-accelerate-low-cost-decarbonization.pdf>.

⁶⁴⁹ We note that in RTOs/ISOs, the RTO/ISO is the public utility transmission provider. Each individual transmission-owning member of the RTO/ISO generally has the responsibility to maintain its own existing transmission facilities and thus have the obligation to provide replacement estimates to the RTO/ISO.

⁶⁵⁰ We note that benefits associated with right-sizing potential replacement transmission facilities to address transmission needs identified through Long-Term Regional Transmission Planning should be evaluated the same as any potential transmission facility that could address that transmission need. See *supra* Regional Transmission Planning: Proposed Reforms, Evaluation of the Benefits of Regional Transmission Facilities.

⁶⁵¹ See *supra* Regional Transmission Planning: Proposed Reforms, Selection of Regional Transmission Facilities.

⁶⁵² Similarly, nothing in this proposed rule would alter existing law concerning subsequent proceedings involving an in-kind asset replacement, e.g., state-law siting proceedings.

409. In addition, requiring in-kind replacement estimates to cover the next 10 years, starting from the point in the transmission planning cycle when the list is compiled, may lengthen the time horizon over which in-kind replacement needs are assessed, compared to current practices where in-kind replacement needs may be assessed on a shorter-term or nearer-term basis.⁶⁵³ Accordingly, areas of uncertainty that could lessen the accuracy of a public utility transmission provider's in-kind replacement estimates should be minimized where possible. In particular, such an approach that looks out over 10 years, would allow the public utility transmission provider to formulate in-kind replacement estimates with greater certainty as to its own future role in meeting that transmission need. Therefore, for any right-sized replacement transmission facility that is selected in the regional transmission plan for purposes of cost allocation to meet transmission needs identified through Long-Term Regional Transmission Planning, we propose to require the establishment of a federal right of first refusal for the public utility transmission provider that included the in-kind replacement transmission facility in its in-kind replacement estimates, which would extend to any portion of such a transmission facility located within the applicable public utility transmission provider's retail distribution service territory or footprint.

410. With respect to cost allocation, we propose that if a right-sized replacement transmission facility is selected in the regional transmission plan for purposes of cost allocation, only the incremental costs of right-sizing the transmission facility will be eligible to use the applicable Long-Term Regional Transmission Cost Allocation Method. We propose that the costs the incumbent transmission provider would have otherwise incurred to construct the in-kind replacement transmission facility be allocated in a manner consistent with the allocation that would have otherwise occurred for the in-kind replacement. We preliminarily find that it is just and reasonable and not unduly discriminatory or preferential for only the portion of the

costs associated with right-sizing a right-sized replacement transmission facility that is selected in the regional transmission plan for purposes of cost allocation to be eligible to use the Long-Term Regional Transmission Cost Allocation Method because it is the right-sizing of the in-kind replacement transmission facility that allows the transmission facility to meet the transmission need(s) identified in Long-Term Regional Transmission Planning. In addition, the customers of the public utility transmission provider that would be allocated the costs associated with the original in-kind replacement transmission facility would have otherwise been responsible for paying those costs had the replacement transmission facility not been right-sized.

411. We note that Order No. 1000 allows a public utility transmission provider to meet its reliability needs or service obligations by choosing to build new transmission facilities that are located solely within its retail distribution service territory or footprint and that are not selected in the regional transmission plan for purposes of cost allocation.⁶⁵⁴ Similarly, nothing in the reforms that we propose here alters existing law concerning a public utility transmission provider's existing rights and responsibilities with respect to maintaining, and when necessary replacing, existing transmission facilities. Thus, the proposed requirements for public utility transmission providers to provide greater transparency and stakeholder process surrounding local transmission planning and in-kind replacement estimates would not create an obligation for an incumbent transmission provider to actually replace any existing transmission facilities. We believe that this clarification is important given that decisions related to replacement of existing transmission facilities may change as a public utility transmission provider gets better information about the condition of its transmission facilities.

412. Even if a right-sized replacement transmission facility is selected in the regional transmission plan for purposes of cost allocation to meet transmission needs identified in Long-Term Regional Transmission Planning, that selection does not alter existing law concerning any existing rights and responsibilities a public utility transmission provider may have to replace as needed its existing transmission facilities with in-kind

replacement transmission facilities. For example, a public utility transmission provider could inform the transmission planning region that, notwithstanding the selection of a right-sized replacement transmission facility in the regional transmission plan for purposes of cost allocation, the public utility transmission provider has chosen to build the original in-kind replacement transmission facility instead. In such cases, as we explain earlier,⁶⁵⁵ we understand that, depending on the rules of the particular regional transmission planning process, the in-kind replacement transmission facility may be *included* in the regional transmission plan for informational purposes, but not *selected* in the regional transmission plan for purposes of cost allocation.

413. Our proposal to only allow the incremental costs of right-sizing replacement transmission facilities to be eligible to use the applicable Long-Term Regional Transmission Cost Allocation Method emphasizes the need for transparency in regional transmission planning processes so as to clearly determine which right-sized replacement transmission facilities have been selected in the regional transmission plan for purposes of cost allocation.⁶⁵⁶ Therefore, we propose to require public utility transmission providers in each transmission planning region to amend their regional transmission planning processes to provide transparency with respect to which right-sized replacement transmission facilities have been selected in the regional transmission plan for purposes of cost allocation (and thus found to be a more efficient or cost-effective transmission facility to meet regional transmission needs) and which transmission facilities are simply included in the regional transmission plan for informational (and not cost allocation) purposes. We believe that this additional transparency would inform interested parties, including state regulators, regarding the degree to which a right-sized replacement transmission facility was evaluated through Long-Term Regional Transmission Planning. As such, we believe that this additional transparency ensures just and reasonable Commission-jurisdictional rates because the information provided will enable customers and other stakeholders alike to evaluate or replicate the findings related to right-sized replacement transmission facilities or in-kind

⁶⁵³ See, e.g., PJM, Intra-PJM Tariffs, OATT, attach. M-3, OATT Attachment M-3 (1.0.0), § (d)(1)(iii) (providing that every year "each Transmission Owner will provide to PJM a Candidate [End-of-Life (EOL)] Needs List comprising its non-public confidential, non-binding projection of up to 5 years of EOL Needs that it has identified under the Transmission Owner's processes for identification of EOL Needs" and that each "Transmission Owner may change its projection as it deems necessary and will update it annually").

⁶⁵⁴ Order No. 1000, 136 FERC ¶ 61,051 at P 262; Order No. 1000-A, 139 FERC ¶ 61,132 at PP 366, 379, 425, 428.

⁶⁵⁵ See *supra* P 412.

⁶⁵⁶ See *supra* Regional Transmission Planning: Proposed Reforms, Selection of Regional Transmission Facilities.

replacement transmission facilities so as to reduce after-the-fact disputes regarding transmission system needs or cost allocation.

414. We seek comment on the requirements proposed in this section of the NOPR. In particular, we seek comment on whether the Commission should impose any requirements regarding how the relevant public utility transmission providers would determine incremental costs of right-sizing the transmission facility.

415. We also seek comment on whether there is additional information from transmission owners that would help public utility transmission providers to identify whether there are estimated in-kind replacements of an existing transmission facility that could be right-sized to address a transmission need identified in Long-Term Regional Transmission Planning. If so, we seek comment what level of burden such a requirement would impose on the transmission owners required to provide that information, and what level of burden is justified given the potential benefits of such information. Moreover, we seek comment on whether there is additional information beyond a list of in-kind replacement estimates that public utility transmission providers need to calculate such benefits and, if so, how that information could be obtained.

IX. Interregional Transmission Coordination and Cost Allocation

416. In the ANOPR, the Commission asked several questions about the value and logistics of reforms to interregional transmission coordination, planning, and cost allocation. The Commission continues to examine those issues, including review of comments to the ANOPR, and to consider possible reforms. As such, we do not, at this time, propose changes to the existing interregional transmission coordination and cost allocation requirements of Order No. 1000. However, we propose to require that public utility transmission providers revise their existing interregional transmission coordination procedures adopted in compliance with Order No. 1000 to apply them to the proposed Long-Term Regional Transmission Planning reforms in this NOPR, as discussed below.

A. Background

417. In Order No. 1000, the Commission set out a number of requirements for interregional transmission coordination and

interregional cost allocation.⁶⁵⁷ Order No. 1000 requires public utility transmission providers in neighboring transmission planning regions to develop and implement procedures to provide for: (1) The sharing of information regarding the respective transmission needs of each region and potential solutions to those needs; and (2) the identification and joint evaluation of interregional transmission facilities that may be more efficient or cost-effective transmission facilities needed to meet those regional needs.⁶⁵⁸

418. With regard to the evaluation of interregional transmission facilities, Order No. 1000 requires public utility transmission providers in neighboring transmission planning regions to develop and implement formal procedures to identify and jointly evaluate transmission facilities that are proposed to be located in neighboring transmission planning regions.⁶⁵⁹ The Commission clarified that the developer of an interregional transmission facility must first propose its transmission facility in the regional transmission planning processes of each of the neighboring transmission planning regions in which the transmission facility is proposed to be located. The submission of the interregional transmission facility in each regional transmission planning process triggers the procedure under which the public utility transmission providers, acting through their regional transmission planning process, jointly evaluate the proposed transmission project.⁶⁶⁰

419. The Commission further required, *inter alia*, that interregional transmission coordination procedures must have a process by which differences in the data, models, assumptions, planning horizons, and criteria used to study a proposed transmission project can be identified and resolved for purposes of jointly evaluating the proposed interregional transmission facility.⁶⁶¹

420. With regard to transmission facility selection, Order No. 1000 requires that an interregional transmission facility must be selected in both of the relevant regional transmission plans for purposes of cost allocation in order to be eligible for

interregional cost allocation.⁶⁶² The Commission further clarified that based on the information gained during the joint evaluation of an interregional transmission project, each transmission planning region will determine, for itself, whether to select those interregional transmission facilities within its footprint in the regional transmission plan for purposes of cost allocation.⁶⁶³

421. With respect to interregional cost allocation, the Commission required that each public utility transmission provider in a transmission planning region must have, together with the public utility transmission providers in its own transmission planning region and a neighboring transmission planning region, a common method or methods for allocating the costs of a new interregional transmission facility among the beneficiaries of that transmission facility in the two neighboring transmission planning regions in which the transmission facility is located.⁶⁶⁴ The Commission also defined six interregional cost allocation principles that apply to, and only to, a cost allocation method or methods for a new interregional transmission facility.⁶⁶⁵

B. ANOPR

422. In the ANOPR, the Commission asked several questions about the value and logistics of reforms to interregional transmission coordination, planning, and cost allocation. Specifically, the Commission sought comment on whether greater interregional or state-regional coordination is required to address other topics in the ANOPR, including long-term regional transmission planning, identifying geographic zones that have the potential for the development of large amounts of new generation, and incentives for transmission development.⁶⁶⁶ The Commission also sought comment on how a regional states committee or other organized body of state officials should participate in the development and evaluation of assumptions or criteria used for interregional transmission coordination.⁶⁶⁷ Further, the Commission sought comment on whether to require joint transmission planning processes for neighboring transmission planning regions, rather than simply joint coordination, and

⁶⁵⁷ In Order No. 1000, the Commission defined an interregional transmission facility as a transmission facility that is located in two or more transmission planning regions. Order No. 1000, 136 FERC ¶ 61,051 at P 482 n.374.

⁶⁵⁸ *Id.* PP 393–399.

⁶⁵⁹ *Id.* P 436.

⁶⁶⁰ *Id.*

⁶⁶¹ *Id.* P 437; Order No. 1000–A, 139 FERC ¶ 61,132 at PP 506, 510.

⁶⁶² Order No. 1000, 136 FERC ¶ 61,051 at P 400; Order No. 1000–A, 139 FERC ¶ 61,132 at P 509.

⁶⁶³ Order No. 1000, 136 FERC ¶ 61,051 at PP 443, 635.

⁶⁶⁴ *Id.* P 578.

⁶⁶⁵ *Id.* P 603.

⁶⁶⁶ ANOPR, 176 FERC ¶ 61,024 at PP 57, 62–64.

⁶⁶⁷ *Id.* P 64.

whether the Commission should establish interregional reliability planning criteria.⁶⁶⁸

C. Comments

423. Some commenters urge the Commission to require substantial changes to the existing interregional transmission coordination requirements established in Order No. 1000.⁶⁶⁹ Other commenters instead urge the Commission to maintain the existing interregional transmission coordination requirements.⁶⁷⁰

D. Need for Reform

424. In establishing the Order No. 1000 interregional transmission coordination and cost allocation requirements, the Commission considered the requirements of Order No. 890, determining that the transmission planning requirements of Order No. 890 were too narrowly focused geographically and failed to provide for adequate analysis of the benefits associated with interregional transmission facilities in neighboring transmission planning regions.⁶⁷¹ The Commission stated that “in the absence of coordination between transmission planning regions, public utility transmission providers may be unable to identify more efficient or cost-effective solutions to the individual needs identified in their respective local and regional transmission planning processes, potentially including interregional transmission facilities.”⁶⁷² Therefore, the Commission concluded that interregional transmission coordination reforms were necessary. The Commission stated that “[c]lear and transparent procedures that result in the

sharing of information regarding common needs and potential solutions across the seams of neighboring transmission planning regions will facilitate the identification of interregional transmission facilities that more efficiently or cost-effectively could meet the needs identified in individual regional transmission plans.”⁶⁷³

425. Based upon our experience since Order No. 1000 and the record in this proceeding, we continue to believe that there is a significant need for interregional transmission coordination. We therefore preliminarily find that it is necessary to revise the existing Order No. 1000 interregional transmission coordination requirements to apply them to the proposed Long-Term Regional Transmission Planning reforms in this NOPR to ensure that interregional transmission coordination is just and reasonable. We believe that the reforms we propose here will ensure that the information sharing and evaluation of interregional transmission facilities required as part of the existing interregional transmission coordination procedures will continue to occur with respect to all aspects of the regional transmission planning process, including the proposed Long-Term Regional Transmission Planning.

E. Proposed Reform

426. We propose to require that public utility transmission providers revise their existing interregional transmission coordination procedures to reflect the Long-Term Regional Transmission Planning reforms proposed in this NOPR.⁶⁷⁴

427. Specifically, we propose to require that public utility transmission providers in neighboring transmission planning regions revise their existing interregional coordination procedures (and regional transmission planning processes as needed) to provide for: (1) The sharing of information regarding the respective transmission needs identified in the Long-Term Regional Transmission Planning that we propose to require in that section above, as well as potential transmission facilities to meet those needs; and (2) the identification and joint evaluation of interregional transmission facilities that may be more efficient or cost-effective transmission facilities to address transmission needs identified through

Long-Term Regional Transmission Planning.

428. We also propose to require that public utility transmission providers in neighboring transmission planning regions revise their interregional transmission coordination procedures (and regional transmission planning processes as needed) to allow an entity to propose an interregional transmission facility in the regional transmission planning process as a potential solution to transmission needs identified through Long-Term Regional Transmission Planning. We believe that this will align the existing requirement for an entity to propose an interregional transmission facility in the regional transmission planning processes of each of the neighboring transmission planning regions in which the transmission facility is proposed to be located with the proposed requirement for public utility transmission providers to conduct Long-Term Regional Transmission Planning as part of their regional transmission planning processes.

429. This proposed reform aims to ensure that transmission needs driven by changes in the resource mix and demand identified through Long-Term Regional Transmission Planning can be considered in existing interregional transmission coordination and cost allocation processes.⁶⁷⁵ Doing so will ensure that there is an opportunity for the public utility transmission providers in neighboring transmission planning regions to consider whether there are interregional transmission facilities that could more efficiently or cost-effectively meet the transmission needs identified through Long-Term Regional Transmission Planning, in turn helping to ensure just and reasonable Commission-jurisdictional rates.

X. Proposed Compliance Procedures

430. Given the necessity to coordinate with the relevant state entities and other stakeholders on the proposed reforms, we propose an extended compliance period. We propose to require that each public utility transmission provider submit a compliance filing within eight months of the effective date of any final rule in this proceeding revising its OATT and other document(s) subject to the Commission’s jurisdiction as necessary to demonstrate that it meets the proposed requirements set forth in

⁶⁶⁸ *Id.* PP 62–63.

⁶⁶⁹ *See, e.g.*, ACEG Comments at 4–5; ACORE Comments at 27; ACPA and ESA Comments at 51–52; Advanced Power Comments at 2; AEE Comments at 31; AEP Comments at 18–24; Amazon Comments at 2; American Municipal Power Comments at 33; Anbaric Comments at 30–32; Avangrid Comments at 20–21; Arizona Commission Comments at 4; Competition Coalition Comments at 20; Consumers Council Comments at 10–11; EDF Comments at 8; Eversource Comments at 18–19; Kansas Commission Comments at 2; LS Power Oct. 12 Comments at 63; NARUC Comments at 16–19; Nature Conservancy Comments at 9–10; New Jersey Commission Comments at 2; NY TOs Comments at 25–26; Northwest and Intermountain Comments at 30; PG&E Comments at 7; PIOs Comments at 70–72; Policy Integrity Comments at 16–18; REBA Comments at 17; Resale Iowa Comments at 15; RMI Comments at 3–4; State Agencies Comments at 28–30; State of Massachusetts Comments at 21; U.S. DOE Comments at 25–26; Xcel Comments at 22.

⁶⁷⁰ *See, e.g.*, APPA Comments at 5; CAISO Comments at 6–8, 59–63; LPPC Comments at 24–26; MISO Comments at 2–3, 15–16; MISO TOs Comments at 16–18; NYISO Comments at 56–57; PJM Comments at 68.

⁶⁷¹ Order No. 1000, 136 FERC ¶ 61,051 at P 369.

⁶⁷² *Id.* P 368.

⁶⁷³ *Id.*

⁶⁷⁴ As noted earlier, we are not proposing to require any changes to existing interregional cost allocation methods for interregional transmission facilities that are selected in the regional transmission plan for purposes of cost allocation and that the Commission previously accepted as compliant with Order No. 1000.

⁶⁷⁵ *See* Order No. 1000, 136 FERC ¶ 61,051 at PP 99–117 (explaining the Commission’s legal basis for requiring interregional transmission coordination and interregional cost allocation).

this NOPR and are included in any final rule in this proceeding.⁶⁷⁶

431. The Commission would assess whether each compliance filing satisfies the proposed requirements outlined above and issue additional orders as necessary to ensure that each public utility transmission provider meets the requirements of any final rule in this proceeding.

432. We propose that transmission providers that are not public utilities would have to adopt the requirements of this NOPR as a condition of maintaining the status of their safe harbor tariff or otherwise satisfying the reciprocity requirement of Order No. 888.⁶⁷⁷

433. The Commission will ensure that jurisdictional entities comply with these NOPR requirements upon final action of the Commission and has the authority to conduct audits to evaluate such compliance. Section 302(C) of the Federal Power Act allows the Commission staff to examine the books, accounts, memoranda, and records of any person who controls directly or indirectly, a licensee or public utility subject to the jurisdiction of the Commission insofar as they relate to transactions with or the business of such licensee or public utility.

XI. Information Collection Statement

434. The information collection requirements contained in this NOPR are subject to review by the Office of Management and Budget (OMB) under section 3507(d) of the Paperwork Reduction Act of 1995.⁶⁷⁸ OMB's regulations require approval of certain information collection requirements imposed by agency rules.⁶⁷⁹ Upon approval of a collection of information, OMB will assign an OMB control number and expiration date. Respondents subject to the filing requirements of this rule will not be penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number.

435. This NOPR would, pursuant to section 206 of the FPA, reform the Commission's *pro forma* OATT and the Commission's *pro forma* LGIP to correct deficiencies in the Commission's existing regional transmission planning

and cost allocation requirements so that the transmission system can better support wholesale power markets and thereby ensure that Commission-jurisdictional rates remain just and reasonable and not unduly discriminatory or preferential.

436. Interested persons may obtain information on the reporting requirements by contacting Ellen Brown, Office of the Executive Director, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426 via email (DataClearance@ferc.gov) or telephone (202) 502-8663.

437. The Commission solicits comments on the Commission's need for this information, whether the information will have practical utility, the accuracy of the burden estimates, ways to enhance the quality, utility, and clarity of the information to be collected or retained, and any suggested methods for minimizing respondents' burden, including the use of automated information techniques.

438. Please send comments concerning the collections of information and the associated burden estimates to the Office of Information and Regulatory Affairs, Office of Management and Budget, through www.reginfo.gov/public/do/PRAMain. Attention: Federal Energy Regulatory Commission Desk Officer. Please identify the OMB Control Numbers 1902-0233 and 1902-0096 in the subject line of your comments. Comments should be sent within 60 days of publication of this notice in the **Federal Register**.

439. Please submit a copy of your comments on the information collections to the Commission via the eFiling link on the Commission's website at <https://www.ferc.gov>. Comments on the information collection that are sent to FERC should refer to Docket No. RM21-17-000.

440. *Title:* Electric Transmission Facilities (FERC-917) and Electric Rate Schedules and Tariff Filings (FERC-516).

441. *Action:* Proposed revision of collections of information in accordance with Docket No. RM21-17-000 and request for comments.

442. *OMB Control Nos.:* 1902-0233 (FERC-917) and 1902-0096 (FERC-516).

443. *Respondents:* Public utility transmission providers, including RTOs/ISOs, and public utility transmission owners.

444. *Frequency of Information Collection:* One time during Year 1. Occasional times during subsequent years, at least once every three years.

445. *Necessity of Information:* The reforms in this Proposed Rule will correct deficiencies in the Commission's existing regional transmission planning and cost allocation requirements so that the transmission system can better support wholesale power markets and thereby ensure that Commission-jurisdictional rates remain just and reasonable and not unduly discriminatory or preferential.

446. *Internal Review:* The Commission has reviewed the changes and has determined that such changes are necessary. These requirements conform to the Commission's need for efficient information collection, communication, and management within the energy industry. The Commission has specific, objective support for the burden estimates associated with the information collection requirements.

447. Our estimates are based on the NERC Compliance Registry as of March 3, 2022, which indicates that there are 48 transmission service providers⁶⁸⁰ and 118 transmission owners that are registered within the United States and are subject to this proposed rulemaking.⁶⁸¹

448. *Public Reporting Burden:* The burden and cost estimates below are based on the need for applicable entities to revise documentation, already required by the Commission's *pro forma* OATT and the Commission's *pro forma* LGIP.

449. The Commission estimates that the NOPR would affect the burden⁶⁸² and cost of FERC-917 and FERC-516 as follows:

⁶⁸⁰ The transmission service provider (TSP) function is a NERC registration function which is similar to the transmission provider that is referenced in the *pro forma* OATT. The TSP function is being used as a proxy to estimate the number of transmission providers that are impacted by this proposed rulemaking.

⁶⁸¹ The number of entities listed from the NERC Compliance Registry reflects the omission of the Texas RE registered entities. Note that 41 transmission owners in non-RTO/ISO regions are also transmission service providers, so in total there are 125 entities subject to this proposed rulemaking.

⁶⁸² "Burden" is the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 CFR 1320.3.

⁶⁷⁶ See Appendix B for the proposed *pro forma* Attachment K consistent with this NOPR.

⁶⁷⁷ Order No. 888, FERC Stats. & Regs. ¶ 31,036 at 31,760-63.

⁶⁷⁸ 44 U.S.C. 3507(d).

⁶⁷⁹ 5 CFR 1320.11.

PROPOSED CHANGES IN NOPR IN DOCKET NO. RM21-17-000⁶⁸³

Area of modification A	Annual number of respondents B	Total annual estimated number of responses C	Average burden hours & cost ⁶⁸⁴ per response D	Total estimated burden hours & total estimated cost (column C × column D) E
FERC-917, Electric Transmission Facilities (OMB Control No. 1902-0233)				
Participate in Long-Term Regional Transmission Planning, which includes developing Long-Term Scenarios, evaluating the benefits of regional transmission facilities, and establishing criteria in consultation with states to select transmission facilities in the regional transmission plan for purposes of cost allocation.	125 (TSPs and TOs)	125	Year 1: 150 hours; \$11,275 Subsequent Years: 50 hours per year; \$3,758 per year.	Year 1: 18,750 hours; \$1,409,363. Subsequent Years: 6,250 hours per year; \$469,788 per year.
Revise the regional transmission planning process to enhance transparency of local transmission planning and identifying potential opportunities to right-size replacement transmission facilities.	125 (TSPs and TOs)	125	Year 1: 20 hours; \$1,208 Subsequent Years: 50 hours per year; \$3,758 per year.	Year 1: 2,500 hours; \$151,038. Subsequent Years: 6,250 hours per year; \$469,788 per year.
Seek agreement from the states to establish a Long-Term Regional Transmission Cost Allocation Method and/or a State Agreement Process.	125 (TSPs and TOs)	125	Year 1: 150 hours; \$11,275 Subsequent Years: 50 hours per year; \$3,758 per year.	Year 1: 18,750 hours; \$1,409,363. Subsequent Years: 6,250 hours per year; \$469,788 per year.
Consider in the regional transmission planning processes regional transmission facilities that address certain interconnection-related needs.	125 (TSPs and TOs)	125	Year 1: 50 hours; \$3,758 Subsequent Years: 0 hours per year; \$0 per year.	Year 1: 6,250 hours; \$469,750. Subsequent Years: 0 hours per year; \$0 per year.
Revise interregional transmission coordination procedures to reflect Long-Term Regional Transmission Planning.	125 (TSPs and TOs)	125	Year 1: 50 hours; \$3,758 Subsequent Years: 25 hours per year; \$1,715 per year.	Year 1: 6,250 hours; \$469,750. Subsequent Years: 3,125 hours per year; \$214,375 per year.
FERC-516, Electric Rate Schedules and Tariff Filings (OMB Control No. 1902-0096)				
Revise LGIP to indicate the consideration in the regional transmission planning processes of regional transmission facilities that address certain interconnection-related needs.	125 (TSPs and TOs)	125	Year 1: 30 hours; \$2,058 Subsequent Years: 0 hours per year; \$0 per year.	Year 1: 3,750 hours; \$257,288. Subsequent Years: 0 hours per year; \$0 per year.

450. Our estimates conservatively assume the maximum number of respondents and burdens. We acknowledge that the actual burdens for some respondents may be lower than estimated, and that other respondents may incur the maximum burdens. We seek comment on the estimates in the burden table and on the assumptions described here.

XII. Environmental Analysis

451. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a

⁶⁸³ In the table, Year 1 figures are one-time implementation hours and cost. "Subsequent years" show ongoing burdens and costs starting in Year 2.

⁶⁸⁴ The hourly cost (for salary plus benefits) uses the figures from the Bureau of Labor Statistics (BLS) for three positions involved in the reporting and recordkeeping requirements. These figures include salary (based on BLS data for May 2020, https://bls.gov/oes/current/naics2_22.htm) and benefits (based on BLS data for December 2020; issued March 18, 2021, <https://www.bls.gov/news.release/ecec.nr0.htm>) and are Manager (Occupation Code 11-0000, \$97.89/hour), Electrical Engineer (Occupation Code 17-2071, \$72.15/hour), and File Clerk (Occupation Code 43-4071, \$35.83/hour). The hourly cost for the reporting requirements (\$85.00) is an average of the hourly cost (wages plus benefits) of a manager and engineer. The hourly cost for recordkeeping requirements uses the cost of a file clerk.

significant adverse effect on the human environment.⁶⁸⁵ We conclude that neither an Environmental Assessment nor an Environmental Impact Statement is required for this Proposed Rule under section 380.4(a)(15) of the Commission's regulations, which provides a categorical exemption for approval of actions under sections 205 and 206 of the FPA relating to the filing of schedules containing all rates and charges for the transmission or sale of electric energy subject to the Commission's jurisdiction, plus the classification, practices, contracts and regulations that affect rates, charges, classifications, and services.⁶⁸⁶

XIII. Regulatory Flexibility Act [Analysis or Certification]

452. The Regulatory Flexibility Act of 1980 (RFA)⁶⁸⁷ generally requires a description and analysis of proposed rules that will have significant economic impact on a substantial number of small entities. The Small Business Administration (SBA) sets the

⁶⁸⁵ *Reguls. Implementing the Nat'l Env'tl Pol'y Act*, Ord. No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs. 30.783 (1987) (cross-referenced at 41 FERC ¶ 61,284).

⁶⁸⁶ 18 CFR 380.4(a)(15).

⁶⁸⁷ 5 U.S.C. 601-612.

threshold for what constitutes a small business. Under SBA's size standards,⁶⁸⁸ RTOs/ISOs, planning regions, and transmission owners all fall under the category of Electric Bulk Power Transmission and Control (NAICS code 221121), with a size threshold of 500 employees (including the entity and its associates).⁶⁸⁹

453. The six RTOs/ISOs (SPP, MISO, PJM, ISO-NE, NYISO, and CAISO) each employ more than 500 employees and are not considered small.

454. We estimate that 119 additional transmission providers and transmission owners are affected by the NOPR. Using the list of transmission service providers and transmission owners from the NERC Registry (dated March 3, 2022), we estimate that approximately 68% of those entities are small entities.

⁶⁸⁸ 13 CFR 121.201.

⁶⁸⁹ The RFA definition of "small entity" refers to the definition provided in the Small Business Act, which defines a "small business concern" as a business that is independently owned and operated and that is not dominant in its field of operation. The Small Business Administrations' regulations at 13 CFR 121.201 define the threshold for a small Electric Bulk Power Transmission and Control entity (NAICS code 221121) to be 500 employees. See 5 U.S.C. 601(3), citing to section 3 of the Small Business Act, 15 U.S.C. 632.

455. We estimate additional one-time costs associated with the NOPR (as shown in the table above) of:

- \$31,274 for each transmission provider and transmission owner (FERC-917)
- \$2,058 for each transmission provider and transmission owner (FERC-516)

456. Therefore, the estimated additional one-time implementation cost in Year 1 per entity is \$33,332.

457. We estimate additional recurring costs in subsequent years (starting in Year 2) associated with the NOPR (as shown in the table above) of:

- \$12,989 for each transmission provider and transmission owner (FERC-917)
- \$0 for each transmission provider and transmission owner (FERC-516)

458. Therefore, the estimated recurring costs per entity in subsequent years are \$12,989 per year.

459. According to SBA guidance, the determination of significance of impact “should be seen as relative to the size of the business, the size of the competitor’s business, and the impact the regulation has on larger competitors.”⁶⁹⁰ We do not consider the estimated cost to be a significant economic impact. As a result, we certify that the proposals in this NOPR will not have a significant economic impact on a substantial number of small entities.

XIV. Comment Procedures

460. The Commission invites interested persons to submit comments on the matters and issues proposed in this notice to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due July 18, 2022 and Reply Comments are due August 17,

2022. Comments must refer to Docket No. RM21-17-000, and must include the commenter’s name, the organization they represent, if applicable, and their address in their comments. All comments will be placed in the Commission’s public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

461. The Commission encourages comments to be filed electronically via the eFiling link on the Commission’s website at <https://www.ferc.gov>. The Commission accepts most standard word processing formats. Documents created electronically using word processing software must be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

462. Commenters that are not able to file comments electronically may file an original of their comment by USPS mail or by courier-or other delivery services. For submission sent via USPS only, filings should be mailed to: Federal Energy Regulatory Commission, Office of the Secretary, 888 First Street NE, Washington, DC 20426. Submission of filings other than by USPS should be delivered to: Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852.

XV. Document Availability

463. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this

document via the internet through the Commission’s Home Page (<https://www.ferc.gov>). At this time, the Commission has suspended access to the Commission’s Public Reference Room due to the President’s March 13, 2020 proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID-19).

464. From the Commission’s Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

465. User assistance is available for eLibrary and the Commission’s website during normal business hours from the Commission’s Online Support at 202-502-6652 (toll free at 1-866-208-3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502-8371, TTY (202) 502-8659. Email the Public Reference Room at public.referenceroom@ferc.gov.

By direction of the Commission. Commissioner Danly is dissenting with a separate statement attached. Commissioner Christie is concurring with a separate statement attached. Commissioner Phillips is concurring with a separate statement attached.

Issued: April 21, 2022.
Debbie-Anne A. Reese,
Deputy Secretary.

Note: The following appendices will not be published in the Code of Federal Regulations.

Appendix A: Abbreviated Names of Commenters

Abbreviation	Commenter
Aaron Litz	Aaron Litz.
ACEG	Americans for a Clean Energy Grid.
ACORE	American Council on Renewable Energy.
ACPA and ESA	American Clean Power Association and the U.S. Energy Storage Association.
AEE	Advanced Energy Economy.
Advanced Power	Advanced Power Alliance.
AEP	American Electric Power Service Corporation.
AES Ohio	Dayton Power and Light.
Alabama Commission	Alabama Public Service Commission.
Amazon	Amazon Energy LLC.
Ameren	Ameren Services Company.
American Farmland Trust	American Farmland Trust.
American Municipal Power	American Municipal Power, Inc.
Ample	Ample, Inc.
Anbaric	Anbaric Development Partners, LLC.
APPA	American Public Power Association.
Arizona Commission	Arizona Corporation Commission.
Arizona Public Service	Arizona Public Service Company.
Avangrid	Avangrid.
Berkshire	Berkshire Hathaway Energy Company.

⁶⁹⁰ U.S. Small Business Administration, *A Guide for Government Agencies How to Comply with the*

Regulatory Flexibility Act, at 18 (May 2012), https://www.sba.gov/sites/default/files/advocacy/rfaguide_0512_0.pdf.

www.sba.gov/sites/default/files/advocacy/rfaguide_0512_0.pdf.

Abbreviation	Commenter
BP	BP America Inc.
Bridgeline	Bridgeline Investments, LLC.
Business Council for Sustainable Energy ...	Business Council for Sustainable Energy.
CAISO	California Independent System Operator Corporation.
California Commission	California Public Utilities Commission.
California Municipal Utilities	California Municipal Utilities Association.
California Water	California Department of Water Resources State Water Project.
CBD	The Center for Biological Diversity.
Center for Sustainable Energy	Center for Sustainable Energy.
Certain TDUs	Alliant Energy Corporate Services, Inc. Consumers Energy Company, DTE Electric Company.
Competitive Energy	Competitive Energy Services, LLC.
Citizens Energy	Citizens Energy Corporation.
City of New York	City of New York.
Competition Coalition	Electricity Transmission Competition Coalition.
Competitive Power	Competitive Power Ventures, Inc.
Consumers	Consumer Organizations.
Electricity Consumers Resource Council ...	Electricity Consumers Resource Council.
CTC Global	CTC Global Corporation.
District of Columbia's Office of the People's Counsel.	Office of the People's Counsel for the District of Columbia.
Dominion	Dominion Energy Services, Inc.
Duke	Duke Energy Corporation.
Duquesne Light	Duquesne Light Company.
East Kentucky	East Kentucky Power Cooperative, Inc.
EDF	EDF Renewables, Inc.
EDP Renewables	EDP Renewables North America LLC.
EEL	Edison Electric Institute.
El Paso Electric	El Paso Electric Company.
Enel	Enel North America, Inc.
Entergy	Entergy Services, LLC.
Environmental Advocates	Center for Renewables Integration, Defenders of Wildlife, Environmental Law & Policy Center, National Audubon Society, National Wildlife Federation, and Vote Solar.
EPSC	Electric Power Supply Association.
Eversource	Eversource Energy Service Company.
Exelon	Exelon Corporation.
Grid United	Grid United LLC.
Handy Law	Set Handy, Handy Law.
Harvard ELI	Harvard Electricity Law Initiative.
Idaho Power	Idaho Power Company.
Indiana Commission	Indiana Utility Regulatory Commission.
Indicated PJM TOs	PJM Transmission Owners.
Industrial Customers	Industrial Customer Organizations.
Iowa Consumer Advocate	Iowa Office of Consumer Advocate.
ISO-NE	ISO New England Inc.
ITC	International Transmission Company.
Kansas Commission	Kansas Corporation Commission.
Land Trust	Land Trust Alliance.
LPPC	Large Public Power Council.
Law Students	Students of Law at the University of Minnesota Law School.
LG&E/KU	Louisville Gas and Electric Company and Kentucky Utilities Company.
Louisiana Commission	Louisiana Public Service Commission.
LS Power	LS Power Grid, LLC.
Macro Grid	Macro Grid Initiative.
Massachusetts Attorney General	Massachusetts Attorney General Maura Healey.
Massachusetts DOER	Massachusetts Department of Energy Resources.
Maryland Commission	Maryland Public Service Commission.
Maryland Energy Admin	Maryland Energy Administration.
Michigan Commission	Michigan Public Service Commission.
Minnesota Commerce	Minnesota Department of Commerce.
MISO	Midcontinent Independent System Operator, Inc.
MISO TOs	MISO Transmission Owners.
Mississippi Commission	Mississippi Public Service Commission and the Mississippi Public Utilities Staff.
Missouri Farm Bureau	Missouri Farm Bureau Federation.
Montana QF Developers	Clenera, LLC and Greenfields Irrigation District.
NARUC	National Association of Regulatory Utility Commissioners.
NASEO	National Association of State Energy Officials.
NASUCA	National Association of State Utility Consumer Advocates.
National Grid	National Grid Plc.
Nature Conservancy	The Nature Conservancy.
New England for Offshore Wind	New England for Offshore Wind.
Nebraska Commission	Nebraska Power Review Board.
NEPOOL	New England Power Pool Participants Committee.
NERC	North American Electric Reliability Corporation.
NESCOE	New England States Committee on Electricity.

Abbreviation	Commenter
New England Systems	New England Consumer-Owned Systems.
New Jersey Commission	New Jersey Board of Public Utilities.
NewSun	NewSun Energy LLC.
NextEra	NextEra Energy, Inc.
Niskanen	Niskanen Center.
North Carolina Commission	North Carolina Utilities Commission.
North Carolina Commission Staff	North Carolina Utilities Commission Public Staff.
North Dakota Commission	North Dakota Public Service Commission.
Northern VA Coop	Northern Virginia Electric Cooperative.
Northwest and Intermountain	Northwest & Intermountain Power Producers Coalition.
NRECA	National Rural Electric Cooperative Association.
NY Commission and NYSERDA	New York Public Service Commission and New York State Energy Research and Development Authority.
NY TOs	New York Transmission Owners.
NYISO	New York Independent System Operator, Inc.
Ohio Commission	Public Utilities Commission of Ohio's Office of the Federal Energy Advocate.
Ohio Consumers	Ohio Consumers' Counsel.
Oklahoma Commission	Oklahoma Corporation Commission.
Oklahoma Gas and Electric	Oklahoma Gas and Electric Company.
Omaha Public Power	Omaha Public Power District.
OMS	Organization of MISO States.
Oregon Commission	Public Utility Commission of Oregon.
Orsted	Orsted North America.
Pennsylvania Commission	Pennsylvania Public Utility Commission.
PG&E	Pacific Gas and Electric.
Pine Gate	Pine Gate Renewables, LLC.
PIOs	Public Interest Organizations.
PJM	PJM Interconnection, L.L.C.
PJM Market Monitor	Monitoring Analytics, LLC, acting in its capacity as the Independent Market Monitor of PJM Interconnection, L.L.C.
Indicated PJM TOs	PJM Transmission Owners.
Policy Integrity	Institute for Policy Integrity.
Potomac Economics	Potomac Economics, Ltd.
PPL	PPL Electric Utilities Corporation.
PSEG	PSEG Companies.
Public Citizen	Public Citizen, Inc.
Public Systems	Massachusetts Municipal Wholesale Electric Company, New Hampshire Electric Cooperative, Inc., Connecticut Municipal Electric Energy Cooperative, and Vermont Public Power Supply Authority.
QCo	Q Coefficient, Inc.
R Street	R Street Institute.
Rail Electrification	Rail Electrification Council.
REBA	Renewable Energy Buyers Alliance.
Resale Iowa	Resale Power Group of Iowa.
Resilient Societies	Foundation for Resilient Societies.
RMI	RMI.
Ron Belval	Ron Belval.
SAFE	SAFE.
SoCal Edison	Southern California Edison Company.
SDG&E	San Diego Gas & Electric Company.
SEIA	Solar Energy Industries Association.
SERTP	Sponsors of the Southeastern Regional Transmission Planning Process.
Shell	Shell Energy North America.
Six Cities	Cities of Anaheim, Azusa, Banning, Colton, Pasadena, and Riverside, California.
Sorgo	Sorgo Fuels & Chemicals, Inc.
Southern	Southern Company Services, Inc.
SPP	Southwest Power Pool, Inc.
SPP Market Monitor	Southwest Power Pool Market Monitoring Unit.
SPP RSC	Southwest Power Pool Regional State Committee.
State Agencies	State Agencies (CT, DE, MD, DC, IL, MN, MI, MA, NJ, OR, PA, RI, VT).
State Legislatures	National Conference of State Legislatures.
State of Idaho	Idaho Governor's Office of Energy & Mineral Resources.
State of Massachusetts	Commonwealth of Massachusetts Department of Energy Resources.
State of New York	New York State Department of State Utility Intervention Unit.
State of Tennessee	State of Tennessee.
State of Washington	Jay Inslee, Governor, State of Washington.
State Wildlife Agencies	Association of Fish & Wildlife Agencies.
TANC	Transmission Agency of Northern California.
TAPS	Transmission Access Policy Study Group.
Tenaska	Tenaska, Inc.
Tom Pike	Tom R Pike.
Transmission Dependent Utilities	Transmission Dependent Utility Systems.
Union of Concerned Scientists	Union of Concerned Scientists.
US Chamber of Commerce	US Chamber of Commerce.
U.S. DOE	United States Department of Energy.

Abbreviation	Commenter
US DOI	US Department of Interior.
Utah Commission	Utah Public Service Commission.
VEIR	VEIR Inc.
Vermont Electric	Vermont Electric Power Company.
Vistra	Vistra Corp.
WATT Coalition	WATT Coalition.
WIRES	WIRES.
Xcel	Xcel Energy Services Inc.

Appendix B: Pro Forma Open Access Transmission Tariff Attachment K

Note: Proposed deletions are in brackets and proposed additions are in italics.

Attachment K

Transmission Planning Process

Local Transmission Planning

The Transmission Provider shall establish a coordinated, open, and transparent *local transmission* planning process with its Network and Firm Point-to-Point Transmission Customers and other interested parties to ensure that the Transmission System is planned to meet the needs of both the Transmission Provider and its Network and Firm Point-to-Point Transmission Customers on a comparable and not unduly discriminatory basis. The Transmission Provider's coordinated, open, and transparent *local transmission* planning process shall be provided as an attachment to the Transmission Provider's Tariff. The Transmission Provider's *local transmission* planning process shall satisfy the following nine principles, as defined in Order No. 890: Coordination, openness, transparency, information exchange, comparability, dispute resolution, regional participation, economic planning studies, and cost allocation for new *transmission* projects. The *local transmission* planning process also shall include the procedures and mechanisms for considering transmission needs driven by Public Policy Requirements consistent with Order No. 1000. The *local transmission* planning process also shall provide a mechanism for the recovery and allocation of *transmission* planning costs consistent with Order No. 890. The description of the Transmission Provider's *local transmission* planning process must include sufficient detail to enable Transmission Customers to understand:

- (i) The process for consulting with customers;
- (ii) The notice procedures and anticipated frequency of meetings;
- (iii) The methodology, criteria, and processes used to develop a transmission plan;
- (iv) The method of disclosure of criteria, assumptions, and data underlying a transmission plan;
- (v) The obligations of and methods for Transmission Customers to submit data to the Transmission Provider;
- (vi) The dispute resolution process;
- (vii) The Transmission Provider's study procedures for economic upgrades to address congestion or the integration of new resources;

(viii) The Transmission Provider's procedures and mechanisms for considering transmission needs driven by Public Policy Requirements, consistent with Order No. 1000; and

(ix) The relevant cost allocation method or methods.

Regional Transmission Planning

The Transmission Provider shall participate in a regional transmission planning process through which transmission facilities and non-transmission alternatives may be proposed and evaluated. The regional transmission planning process also shall develop a regional transmission plan that identifies the transmission facilities necessary to meet the needs of transmission providers and transmission customers in the transmission planning region. The regional transmission planning process must be consistent with the provision of Commission-jurisdictional services at rates, terms, and conditions that are just and reasonable and not unduly discriminatory or preferential, as described in Order No. 1000 and Order No. [final rule]. The regional transmission planning process shall be described in an attachment to the Transmission Provider's Tariff.

The Transmission Provider's regional transmission planning process shall satisfy the following seven principles, as set out and explained in Order Nos. 890 and 1000: Coordination, openness, transparency, information exchange, comparability, dispute resolution, and economic planning studies. The regional transmission planning process also shall include the procedures and mechanisms for considering transmission needs driven by Public Policy Requirements, consistent with Order No. 1000. The regional transmission planning process shall provide a mechanism for the recovery and allocation of "*transmission* planning costs" consistent with Order No. 890 and Order No. 1000.

The regional transmission planning process shall include a clear enrollment process for public and non-public utility transmission providers that make the choice to become part of a transmission planning region. The regional transmission planning process shall be clear that enrollment will subject enrollees to cost allocation if they are found to be beneficiaries of new transmission facilities selected in the regional transmission plan for purposes of cost allocation. Each Transmission Provider shall maintain a list of enrolled entities in the Transmission Provider's Tariff.

As part of the regional transmission planning process, the Transmission Providers in each transmission planning region will conduct Long-Term Regional Transmission

Planning, meaning regional transmission planning on a sufficiently long-term, forward-looking basis to identify transmission needs driven by changes in the resource mix and demand, evaluate transmission facilities to meet such needs, and identify and evaluate transmission facilities for potential selection in the regional transmission plan for purposes of cost allocation as the more efficient or cost-effective transmission facilities to meet such needs. As part of this Long-Term Regional Transmission Planning, the Transmission Providers in each transmission planning region will: (1) Identify transmission needs driven by changes in the resource mix and demand through the development of Long-Term Scenarios that satisfy the requirements set forth in Order No. [final rule]; (2) evaluate the benefits of regional transmission facilities to meet transmission needs driven by changes in the resource mix and demand over a time horizon that covers, at a minimum, 20 years starting from the estimated in-service date of the transmission facilities; and (3) establish transparent and not unduly discriminatory criteria to select transmission facilities in the regional transmission plan for purposes of cost allocation that more efficiently or cost-effectively address transmission needs driven by changes in the resource mix and demand in collaboration with states and other stakeholders.

When developing Long-Term Scenarios, the Transmission Providers in each transmission planning region must: (1) Use a transmission planning horizon no less than 20 years into the future; (2) reassess and revise Long-Term Scenarios including to reassess whether the data inputs and factors incorporated in their previously developed Long-Term Scenarios need to be updated and then revise their Long-Term Scenarios as needed to reflect updated data inputs and factors at least every three years, and complete the development of Long-Term Scenarios within three years, before the next three-year assessment commences; (3) incorporate, at a minimum, the seven categories of factors identified in Order No. [final rule] that may drive transmission needs driven by changes in the resource mix and demand; (4) develop a plausible and diverse set of at least four Long-Term Scenarios; (5) use "best available data" (as defined in Order No. [final rule]) in developing Long-Term Scenarios; and (6) consider whether to identify geographic zones with the potential for development of large amounts of new generation. The process through which the Transmission Providers develop Long-Term Scenarios also must comply with the

following six transmission planning principles established in Order No. 890: Coordination; openness; transparency; information exchange; comparability; and dispute resolution.

The Transmission Providers in each transmission planning region must identify the benefits they will use in Long-Term Regional Transmission Planning, how they will calculate those benefits, and how the benefits will reasonably reflect the benefits of regional transmission facilities to meet identified transmission needs driven by

changes in the resource mix and demand. The following set of Long-Term Regional Transmission Benefits may be useful for Transmission Providers in each transmission planning region in evaluating transmission facilities for selection in the regional transmission plan for purposes of cost allocation as the more efficient or cost-effective solutions to meet transmission needs driven by changes in the resource mix and demand: (1) Avoided or deferred reliability transmission projects and aging infrastructure replacement; (2) either reduced

loss of load probability or reduced planning reserve margin; (3) production cost savings; (4) reduced transmission energy losses; (5) reduced congestion due to transmission outages; (6) mitigation of extreme events and system contingencies; (7) mitigation of weather and load uncertainty; (8) capacity cost benefits from reduced peak energy losses; (9) deferred generation capacity investments; (10) access to lower-cost generation; (11) increased competition; and (12) increased market liquidity.

Table 1—Long-Term Regional Transmission Benefits

Benefit	Description
Avoided or deferred reliability transmission facilities and aging transmission infrastructure replacement.	Reduced costs of avoided or delayed transmission investment otherwise required to address reliability needs or replace aging transmission facilities.
Reduced loss of load probability [OR next benefit]	Reduced frequency of loss of load events by providing additional pathways for connecting generation resources with load (if planning reserve margin is constant), resulting in benefit of reduced expected unserved energy by customer value of lost load.
Reduced planning reserve margin [OR prior benefit]	While holding loss of load probabilities constant, system operators can reduce their resource adequacy requirements (i.e., planning reserve margins), resulting in a benefit of reduced capital cost of generation needed to meet resource adequacy requirements.
Production cost savings	Reduction in production costs, including savings in fuel and other variable operating costs of power generation, that are realized when transmission facilities allow for the increased dispatch of suppliers that have lower incremental costs of production, displacing higher-cost supplies; also reduction in market prices as lower-cost suppliers set market clearing prices; when adjusted to account for purchases and sales outside the region, called adjusted production cost savings.
Reduced transmission energy losses	Reduced energy losses incurred in transmittal of power from generation to loads, thereby reducing total energy necessary to meet demand.
Reduced congestion due to transmission outages	Reduced production costs during transmission outages that significantly increase transmission congestion.
Mitigation of extreme events and system contingencies	Reduced production costs during extreme events, such as unusual weather conditions, fuel shortages, and multiple or sustained generation and transmission outages, through more robust transmission system reducing high-cost generation and emergency procurements necessary to support the system.
Mitigation of weather and load uncertainty	Reduced production costs during higher than normal load conditions or significant shifts in regional weather patterns.
Capacity cost benefits from reduced peak energy losses	Reduced energy losses during peak load reduces generation capacity investment needed to meet the peak load and transmission losses.
Deferred generation capacity investments	Reduced costs of needed generation capacity investments through expanded import capability into resource-constrained areas.
Access to lower-cost generation	Reduced total cost of generation due to ability to locate units in a more economically efficient location (e.g., low permitting costs, low-cost sites on which plants can be built, access to existing infrastructure, low labor costs, low fuel costs, access to valuable natural resources, locations with high-quality renewable energy resources).
Increased competition	Reduced bid prices in wholesale electricity markets due to increased competition among generators and reduced overall market concentration/market power.
Increased market liquidity	Reduced transaction costs (e.g., bid-ask spreads) of bilateral transactions, increased price transparency, increased efficiency of risk management, improved contracting, and better clarity for long-term transmission planning and investment decisions through increased number of buyers and sellers able to transact with each other as a result of transmission expansion.

As part of Long-Term Regional Transmission Planning, the Transmission Providers in each transmission planning region must include (1) transparent and not unduly discriminatory criteria, which seek to maximize benefits to consumers over time

without over-building transmission facilities, to identify and evaluate transmission facilities for potential selection in the regional transmission plan for purposes of cost allocation that address transmission needs driven by changes in the resource mix

and demand; and (2) a process to coordinate with relevant state entities in developing such criteria.

If the Transmission Providers include a portfolio approach in selecting transmission facilities in the regional transmission plan for

purposes of cost allocation that address transmission needs driven by changes in the resource mix and demand, then the Transmission Providers must include provisions describing whether the selection criteria would be used for Long-Term Regional Transmission Planning universally to address transmission needs driven by changes in the resource mix and demand or would be used only in certain specified instances.

The Transmission Providers in each transmission planning region shall include in their tariffs either (1) a Long-Term Regional Transmission Cost Allocation Method to allocate the costs of Long-Term Regional Transmission Facilities, or (2) a State Agreement Process by which one or more relevant state entities may voluntarily agree to a cost allocation method, or (3) a combination thereof. A Long-Term Regional Transmission Cost Allocation Method is an ex ante regional cost allocation method that applies to a transmission facility identified as part of Long-Term Regional Transmission Planning and selected in the regional transmission plan for purposes of cost allocation to address transmission needs driven by changes in the resource mix and demand (Long-Term Regional Transmission Facility). The developer of a Long-Term Regional Transmission Facility would be entitled to use the Long-Term Regional Transmission Cost Allocation Method if it is the applicable cost allocation method. A State Agreement Process is an ex post cost allocation process, which may apply to an individual Long-Term Regional Transmission Facility or a portfolio of such Facilities grouped together for purposes of cost allocation. After a Long-Term Regional Transmission Facility is selected in the regional transmission plan for purposes of cost allocation, the State Agreement Process would be followed to establish a cost allocation method for that facility (if agreement can be reached). If the Commission subsequently approves the cost allocation method that results from the State Agreement Process, the developer of the Long-Term Regional Transmission Facility would be entitled to use that cost allocation method if it is the applicable method. The Long-Term Regional Transmission Cost Allocation Method and any cost allocation method resulting from the State Agreement Process for Long-Term Regional Transmission Facilities must comply with the existing six Order No. 1000 regional cost allocation principles.

Transmission Providers in each transmission planning region must seek the agreement of relevant state entities within the transmission planning region regarding the Long-Term Regional Transmission Cost Allocation Method, State Agreement Process.

The regional transmission planning processes must give a state or states a period of time to negotiate a cost allocation method for a transmission facility that is selected in the Long Term Regional Transmission Plan for purposes of cost allocation to address transmission needs driven by changes in the resource mix and demand that is different than the regional cost allocation method (alternate cost allocation method related to

transmission needs driven by changes in the resource mix and demand).

The Transmission Providers in each transmission planning region shall consider in regional transmission planning and cost allocation processes whether selecting transmission facilities in the regional transmission plan for purposes of cost allocation that incorporate dynamic line ratings, as defined in 18 CFR 35.28(b)(14), or advanced power flow control devices would be more efficient or cost-effective than regional transmission facilities that do not incorporate these technologies. Specifically, such consideration must include both: (1) First, whether incorporating dynamic line ratings or advanced power flow control devices into existing transmission facilities could meet the same regional transmission need more efficiently or cost-effectively than other potential transmission facilities; and (2) second, when evaluating transmission facilities for potential selection in the regional transmission plan for purposes of cost allocation, the Transmission Providers in each transmission planning region must also consider whether incorporating dynamic line ratings and advanced power flow control devices as part of any potential regional transmission facility would be more efficient or cost-effective.

This requirement applies in all of the Transmission Provider's regional transmission planning processes, including the regional transmission planning processes for near-term regional transmission needs and Long-Term Regional Transmission Planning required in Order No. [final rule]. The costs of transmission facilities that incorporate dynamic line ratings or advanced power flow control devices that are selected in the regional transmission plan for purposes of cost allocation will be allocated using the applicable regional cost allocation method. The Transmission Provider's evaluation process must culminate in a determination that is sufficiently detailed for stakeholders to understand why a particular transmission facility was selected or not selected in the regional transmission plan for purposes of cost allocation. This process must include the consideration of dynamic line ratings and advanced power flow control devices and why they were not incorporated into selected regional transmission facilities.

The description of the regional transmission planning process must include sufficient detail to enable Transmission Customers to understand:

- (i) The process for enrollment in the regional transmission planning process;
- (ii) The process for consulting with customers;
- (iii) The notice procedures and anticipated frequency of meetings;
- (iv) The methodology, criteria, and processes used to develop a transmission plan;
- (v) The method of disclosure of criteria, assumptions, and data underlying a transmission plan;
- (vi) The obligations of and methods for transmission customers to submit data;
- (vii) The process for submission of data by nonincumbent developers of transmission projects that wish to participate in the

regional transmission planning process and seek regional cost allocation;

(viii) The process for submission of data by merchant transmission developers that wish to participate in the regional transmission planning process;

(ix) The dispute resolution process;

(x) The study procedures for economic upgrades to address congestion or the integration of new resources; and

[The procedures and mechanisms for considering transmission needs driven by Public Policy Requirements, consistent with Order No. 1000; and]

(xi) The relevant cost allocation method or methods.

The regional transmission planning process must include a cost allocation method or methods that satisfy the six regional cost allocation principles set forth in Order No. 1000.

Enhanced Transparency of Local Transmission Planning Inputs in the Regional Transmission Planning Process

The regional transmission planning process must include at least three stakeholder meetings concerning the local transmission planning process of each Transmission Provider that is a member of the transmission planning region before each Transmission Provider's local transmission planning information can be incorporated into the transmission planning region's planning models:

(1) A stakeholder meeting to review the criteria, assumptions, and models related to each Transmission Provider's local transmission planning (Assumptions Meeting);

(2) No fewer than 25 calendar days after the Assumptions Meeting, a stakeholder meeting to review identified reliability criteria violations and other transmission needs that drive the need for local transmission facilities (Needs Meeting); and

(3) No fewer than 25 calendar days after the Needs Meeting, a stakeholder meeting to review potential solutions to those reliability criteria violations and other transmission needs (Solutions Meeting).

Identifying Potential Opportunities to Right-Size Replacement Transmission Facilities

As part of each Long-Term Regional Transmission Planning cycle, Transmission Providers in each transmission planning region shall evaluate whether transmission facilities operating at or above 230 kV that an individual Transmission Provider that owns the transmission facility anticipates replacing in-kind with a new transmission facility during the next 10 years can be "right-sized" to more efficiently or cost-effectively address regional transmission needs identified in Long-Term Regional Transmission Planning. "Right-sizing" means the process of modifying a Transmission Provider's in-kind replacement of an existing transmission facility to increase that facility's transfer capability. The process to identify potential opportunities to right-size replacement transmission facilities must follow the process outlined in Order No. [final rule].

Interregional Transmission Coordination

The Transmission Provider, through its regional transmission planning process, must coordinate with the public utility transmission providers in each neighboring transmission planning region within its interconnection to address transmission planning coordination issues related to interregional transmission facilities. The interregional transmission coordination procedures must include a detailed description of the process for coordination between public utility transmission providers in neighboring transmission planning regions (i) with respect to each interregional transmission facility that is proposed to be located in both transmission planning regions and (ii) to identify possible interregional transmission facilities that could address transmission needs more efficiently or cost-effectively than separate regional transmission facilities. The interregional transmission coordination procedures shall be described in an attachment to the Transmission Provider's Tariff.

The Transmission Provider must ensure that the following requirements are included in any applicable interregional transmission coordination procedures:

(1) A commitment to coordinate and share the results of each transmission planning region's regional transmission plans (*including information regarding the respective transmission needs identified in Long-Term Regional Transmission Planning and potential transmission facilities to meet those needs*) to identify possible interregional transmission facilities that could address transmission needs more efficiently or cost-effectively than separate regional transmission facilities, as well as a procedure for doing so;

(2) A formal procedure to identify and jointly evaluate transmission facilities that are proposed to be located in both transmission planning regions, *including those that may be more efficient or cost-effective transmission solutions to transmission needs identified through Long-Term Regional Transmission Planning*;

(3) An agreement to exchange, at least annually, planning data and information; and

(4) A commitment to maintain a website or email list for the communication of information related to the coordinated planning process.

The Transmission Provider must work with transmission providers located in neighboring transmission planning regions to develop a mutually agreeable method or methods for allocating between the two transmission planning regions the costs of a new interregional transmission facility that is located within both transmission planning regions. Such cost allocation method or methods must satisfy the six interregional cost allocation principles set forth in Order No. 1000 and must be included in the Transmission Provider's Tariff.

Appendix C: Pro Forma LGIP

Note: Proposed deletions are in brackets and proposed additions are in italics.

Standard Large Generator Interconnection Procedures (LGIP) Including Standard Large Generator Interconnection Agreement (LGIA); Standard Large Generator Interconnection Procedures (LGIP) (Applicable to Generating Facilities That Exceed 20 MW)

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Section 1. Definitions

Adverse System Impact shall mean the negative effects due to technical or operational limits on conductors or equipment being exceeded that may compromise the safety and reliability of the electric system.

Affected System shall mean an electric system other than the Transmission Provider's Transmission System that may be affected by the proposed interconnection.

Affected System Operator shall mean the entity that operates an Affected System.

Affiliate shall mean, with respect to a corporation, partnership or other entity, each such other corporation, partnership or other entity that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such corporation, partnership or other entity.

Ancillary Services shall mean those services that are necessary to support the transmission of capacity and energy from resources to loads while maintaining reliable operation of the Transmission Provider's Transmission System in accordance with Good Utility Practice.

Applicable Laws and Regulations shall mean all duly promulgated applicable federal, state and local laws, regulations, rules, ordinances, codes, decrees, judgments, directives, or judicial or administrative orders, permits and other duly authorized actions of any Governmental Authority.

Applicable Reliability Council shall mean the reliability council applicable to the Transmission System to which the Generating Facility is directly interconnected.

Applicable Reliability Standards shall mean the requirements and guidelines of NERC, the Applicable Reliability Council, and the Control Area of the Transmission System to which the Generating Facility is directly interconnected.

Base Case shall mean the base case power flow, short circuit, and stability data bases used for the Interconnection Studies by the Transmission Provider or Interconnection Customer.

Breach shall mean the failure of a Party to perform or observe any material term or condition of the Standard Large Generator Interconnection Agreement.

Breaching Party shall mean a Party that is in Breach of the Standard Large Generator Interconnection Agreement.

Business Day shall mean Monday through Friday, excluding Federal Holidays.

Calendar Day shall mean any day including Saturday, Sunday or a Federal Holiday.

Clustering shall mean the process whereby a group of Interconnection Requests is studied together, instead of serially, for the purpose of conducting the Interconnection System Impact Study.

Commercial Operation shall mean the status of a Generating Facility that has commenced generating electricity for sale, excluding electricity generated during Trial Operation.

Commercial Operation Date of a unit shall mean the date on which the Generating Facility commences Commercial Operation as agreed to by the Parties pursuant to Appendix E to the Standard Large Generator Interconnection Agreement.

Confidential Information shall mean any confidential, proprietary or trade secret information of a plan, specification, pattern, procedure, design, device, list, concept, policy or compilation relating to the present or planned business of a Party, which is designated as confidential by the Party supplying the information, whether conveyed orally, electronically, in writing, through inspection, or otherwise.

Contingent Facilities shall mean those unbuilt Interconnection Facilities and Network Upgrades upon which the Interconnection Request's costs, timing, and study findings are dependent, and if delayed or not built, could cause a need for Re-Studies of the Interconnection Request or a reassessment of the Interconnection Facilities and/or Network Upgrades and/or costs and timing.

Control Area shall mean an electrical system or systems bounded by interconnection metering and telemetry, capable of controlling generation to maintain its interchange schedule with other Control Areas and contributing to frequency regulation of the interconnection. A Control Area must be certified by an Applicable Reliability Council.

Default shall mean the failure of a Breaching Party to cure its Breach in accordance with Article 17 of the Standard Large Generator Interconnection Agreement.

Dispute Resolution shall mean the procedure for resolution of a dispute between the Parties in which they will first attempt to resolve the dispute on an informal basis.

Distribution System shall mean the Transmission Provider's facilities and equipment used to transmit electricity to ultimate usage points such as homes and industries directly from nearby generators or from interchanges with higher voltage transmission networks which transport bulk power over longer distances. The voltage levels at which distribution systems operate differ among areas.

Distribution Upgrades shall mean the additions, modifications, and upgrades to the Transmission Provider's Distribution System at or beyond the Point of Interconnection to facilitate interconnection of the Generating

Facility and render the transmission service necessary to effect Interconnection Customer's wholesale sale of electricity in interstate commerce. Distribution Upgrades do not include Interconnection Facilities.

Effective Date shall mean the date on which the Standard Large Generator Interconnection Agreement becomes effective upon execution by the Parties subject to acceptance by FERC, or if filed unexecuted, upon the date specified by FERC.

Emergency Condition shall mean a condition or situation: (1) That in the judgment of the Party making the claim is imminently likely to endanger life or property; or (2) that, in the case of a Transmission Provider, is imminently likely (as determined in a non-discriminatory manner) to cause a material adverse effect on the security of, or damage to Transmission Provider's Transmission System, Transmission Provider's Interconnection Facilities or the electric systems of others to which the Transmission Provider's Transmission System is directly connected; or (3) that, in the case of Interconnection Customer, is imminently likely (as determined in a non-discriminatory manner) to cause a material adverse effect on the security of, or damage to, the Generating Facility or Interconnection Customer's Interconnection Facilities. System restoration and black start shall be considered Emergency Conditions; provided that Interconnection Customer is not obligated by the Standard Large Generator Interconnection Agreement to possess black start capability.

Energy Resource Interconnection Service shall mean an Interconnection Service that allows the Interconnection Customer to connect its Generating Facility to the Transmission Provider's Transmission System to be eligible to deliver the Generating Facility's electric output using the existing firm or nonfirm capacity of the Transmission Provider's Transmission System on an as available basis. Energy Resource Interconnection Service in and of itself does not convey transmission service.

Engineering & Procurement (E&P) Agreement shall mean an agreement that authorizes the Transmission Provider to begin engineering and procurement of long lead-time items necessary for the establishment of the interconnection in order to advance the implementation of the Interconnection Request.

Environmental Law shall mean Applicable Laws or Regulations relating to pollution or protection of the environment or natural resources.

Federal Power Act shall mean the Federal Power Act, as amended, 16 U.S.C. 791a *et seq.*

FERC shall mean the Federal Energy Regulatory Commission (Commission) or its successor.

Force Majeure shall mean any act of God, labor disturbance, act of the public enemy, war, insurrection, riot, fire, storm or flood, explosion, breakage or accident to machinery or equipment, any order, regulation or restriction imposed by governmental, military or lawfully established civilian authorities, or any other cause beyond a Party's control. A Force Majeure event does

not include acts of negligence or intentional wrongdoing by the Party claiming Force Majeure.

Generating Facility shall mean Interconnection Customer's device for the production and/or storage for later injection of electricity identified in the Interconnection Request, but shall not include the Interconnection Customer's Interconnection Facilities.

Generating Facility Capacity shall mean the net capacity of the Generating Facility and the aggregate net capacity of the Generating Facility where it includes multiple energy production devices.

Good Utility Practice shall mean any of the practices, methods and acts engaged in or approved by a significant portion of the electric industry during the relevant time period, or any of the practices, methods and acts which, in the exercise of reasonable judgment in light of the facts known at the time the decision was made, could have been expected to accomplish the desired result at a reasonable cost consistent with good business practices, reliability, safety and expedition. Good Utility Practice is not intended to be limited to the optimum practice, method, or act to the exclusion of all others, but rather to be acceptable practices, methods, or acts generally accepted in the region.

Governmental Authority shall mean any federal, state, local or other governmental regulatory or administrative agency, court, commission, department, board, or other governmental subdivision, legislature, rulemaking board, tribunal, or other governmental authority having jurisdiction over the Parties, their respective facilities, or the respective services they provide, and exercising or entitled to exercise any administrative, executive, police, or taxing authority or power; provided, however, that such term does not include Interconnection Customer, Transmission Provider, or any Affiliate thereof.

Hazardous Substances shall mean any chemicals, materials or substances defined as or included in the definition of "hazardous substances," "hazardous wastes," "hazardous materials," "hazardous constituents," "restricted hazardous materials," "extremely hazardous substances," "toxic substances," "radioactive substances," "contaminants," "pollutants," "toxic pollutants" or words of similar meaning and regulatory effect under any applicable Environmental Law, or any other chemical, material or substance, exposure to which is prohibited, limited or regulated by any applicable Environmental Law.

Initial Synchronization Date shall mean the date upon which the Generating Facility is initially synchronized and upon which Trial Operation begins.

In-Service Date shall mean the date upon which the Interconnection Customer reasonably expects it will be ready to begin use of the Transmission Provider's Interconnection Facilities to obtain back feed power.

Interconnection Customer shall mean any entity, including the Transmission Provider, Transmission Owner or any of the Affiliates or subsidiaries of either, that proposes to

interconnect its Generating Facility with the Transmission Provider's Transmission System.

Interconnection Customer's Interconnection Facilities shall mean all facilities and equipment, as identified in Appendix A of the Standard Large Generator Interconnection Agreement, that are located between the Generating Facility and the Point of Change of Ownership, including any modification, addition, or upgrades to such facilities and equipment necessary to physically and electrically interconnect the Generating Facility to the Transmission Provider's Transmission System. Interconnection Customer's Interconnection Facilities are sole use facilities.

Interconnection Facilities shall mean the Transmission Provider's Interconnection Facilities and the Interconnection Customer's Interconnection Facilities. Collectively, Interconnection Facilities include all facilities and equipment between the Generating Facility and the Point of Interconnection, including any modification, additions or upgrades that are necessary to physically and electrically interconnect the Generating Facility to the Transmission Provider's Transmission System. Interconnection Facilities are sole use facilities and shall not include Distribution Upgrades, Stand Alone Network Upgrades or Network Upgrades.

Interconnection Facilities Study shall mean a study conducted by the Transmission Provider or a third party consultant for the Interconnection Customer to determine a list of facilities (including Transmission Provider's Interconnection Facilities and Network Upgrades as identified in the Interconnection System Impact Study), the cost of those facilities, and the time required to interconnect the Generating Facility with the Transmission Provider's Transmission System. The scope of the study is defined in Section 8 of the Standard Large Generator Interconnection Procedures.

Interconnection Facilities Study Agreement shall mean the form of agreement contained in Appendix 4 of the Standard Large Generator Interconnection Procedures for conducting the Interconnection Facilities Study.

Interconnection Feasibility Study shall mean a preliminary evaluation of the system impact and cost of interconnecting the Generating Facility to the Transmission Provider's Transmission System, the scope of which is described in Section 6 of the Standard Large Generator Interconnection Procedures.

Interconnection Feasibility Study Agreement shall mean the form of agreement contained in Appendix 2 of the Standard Large Generator Interconnection Procedures for conducting the Interconnection Feasibility Study.

Interconnection Request shall mean an Interconnection Customer's request, in the form of Appendix 1 to the Standard Large Generator Interconnection Procedures, in accordance with the Tariff, to interconnect a new Generating Facility, or to increase the capacity of, or make a Material Modification to the operating characteristics of, an existing Generating Facility that is interconnected

with the Transmission Provider's Transmission System.

Interconnection Service shall mean the service provided by the Transmission Provider associated with interconnecting the Interconnection Customer's Generating Facility to the Transmission Provider's Transmission System and enabling it to receive electric energy and capacity from the Generating Facility at the Point of Interconnection, pursuant to the terms of the Standard Large Generator Interconnection Agreement and, if applicable, the Transmission Provider's Tariff.

Interconnection Study shall mean any of the following studies: The Interconnection Feasibility Study, the Interconnection System Impact Study, and the Interconnection Facilities Study described in the Standard Large Generator Interconnection Procedures.

Interconnection System Impact Study shall mean an engineering study that evaluates the impact of the proposed interconnection on the safety and reliability of Transmission Provider's Transmission System and, if applicable, an Affected System. The study shall identify and detail the system impacts that would result if the Generating Facility were interconnected without project modifications or system modifications, focusing on the Adverse System Impacts identified in the Interconnection Feasibility Study, or to study potential impacts, including but not limited to those identified in the Scoping Meeting as described in the Standard Large Generator Interconnection Procedures.

Interconnection System Impact Study Agreement shall mean the form of agreement contained in Appendix 3 of the Standard Large Generator Interconnection Procedures for conducting the Interconnection System Impact Study.

IRS shall mean the Internal Revenue Service.

Joint Operating Committee shall be a group made up of representatives from Interconnection Customers and the Transmission Provider to coordinate operating and technical considerations of Interconnection Service.

Large Generating Facility shall mean a Generating Facility having a Generating Facility Capacity of more than 20 MW.

Loss shall mean any and all losses relating to injury to or death of any person or damage to property, demand, suits, recoveries, costs and expenses, court costs, attorney fees, and all other obligations by or to third parties, arising out of or resulting from the other Party's performance, or non-performance of its obligations under the Standard Large Generator Interconnection Agreement on behalf of the indemnifying Party, except in cases of gross negligence or intentional wrongdoing by the indemnifying Party.

Material Modification shall mean those modifications that have a material impact on the cost or timing of any Interconnection Request with a later queue priority date.

Metering Equipment shall mean all metering equipment installed or to be installed at the Generating Facility pursuant to the Standard Large Generator Interconnection Agreement at the metering points, including but not limited to

instrument transformers, MWh-meters, data acquisition equipment, transducers, remote terminal unit, communications equipment, phone lines, and fiber optics.

NERC shall mean the North American Electric Reliability Council or its successor organization.

Network Resource shall mean any designated generating resource owned, purchased, or leased by a Network Customer under the Network Integration Transmission Service Tariff. Network Resources do not include any resource, or any portion thereof, that is committed for sale to third parties or otherwise cannot be called upon to meet the Network Customer's Network Load on a non-interruptible basis.

Network Resource Interconnection Service shall mean an Interconnection Service that allows the Interconnection Customer to integrate its Large Generating Facility with the Transmission Provider's Transmission System (1) in a manner comparable to that in which the Transmission Provider integrates its generating facilities to serve native load customers; or (2) in an RTO or ISO with market based congestion management, in the same manner as Network Resources. Network Resource Interconnection Service in and of itself does not convey transmission service.

Network Upgrades shall mean the additions, modifications, and upgrades to the Transmission Provider's Transmission System required at or beyond the point at which the Interconnection Facilities connect to the Transmission Provider's Transmission System to accommodate the interconnection of the Large Generating Facility to the Transmission Provider's Transmission System.

Notice of Dispute shall mean a written notice of a dispute or claim that arises out of or in connection with the Standard Large Generator Interconnection Agreement or its performance.

Optional Interconnection Study shall mean a sensitivity analysis based on assumptions specified by the Interconnection Customer in the Optional Interconnection Study Agreement.

Optional Interconnection Study Agreement shall mean the form of agreement contained in Appendix 5 of the Standard Large Generator Interconnection Procedures for conducting the Optional Interconnection Study.

Party or Parties shall mean Transmission Provider, Transmission Owner, Interconnection Customer or any combination of the above.

Permissible Technological Advancement [Transmission Provider inserts definition here].

Point of Change of Ownership shall mean the point, as set forth in Appendix A to the Standard Large Generator Interconnection Agreement, where the Interconnection Customer's Interconnection Facilities connect to the Transmission Provider's Interconnection Facilities.

Point of Interconnection shall mean the point, as set forth in Appendix A to the Standard Large Generator Interconnection Agreement, where the Interconnection Facilities connect to the Transmission Provider's Transmission System.

Provisional Interconnection Service shall mean Interconnection Service provided by an Interconnection Provider associated with interconnecting the Interconnection Customer's Generating Facility to Transmission Provider's Transmission System and enabling that Transmission System to receive electric energy and capacity from the Generating Facility at the Point of Interconnection, pursuant to the terms of the Provisional Large Generator Interconnection Agreement and, if applicable, the Tariff.

Provisional Large Generator Interconnection Agreement shall mean the interconnection agreement for Provisional Interconnection Service established between Transmission Provider and/or the Transmission Owner and the Interconnection Customer. This agreement shall take the form of the Large Generator Interconnection Agreement, modified for provisional purposes.

Queue Position shall mean the order of a valid Interconnection Request, relative to all other pending valid Interconnection Requests, that is established based upon the date and time of receipt of the valid Interconnection Request by the Transmission Provider.

Reasonable Efforts shall mean, with respect to an action required to be attempted or taken by a Party under the Standard Large Generator Interconnection Agreement, efforts that are timely and consistent with Good Utility Practice and are otherwise substantially equivalent to those a Party would use to protect its own interests.

Scoping Meeting shall mean the meeting between representatives of the Interconnection Customer and Transmission Provider conducted for the purpose of discussing alternative interconnection options, to exchange information including any transmission data and earlier study evaluations that would be reasonably expected to impact such interconnection options, to analyze such information, and to determine the potential feasible Points of Interconnection.

Site Control shall mean documentation reasonably demonstrating: (1) Ownership of, a leasehold interest in, or a right to develop a site for the purpose of constructing the Generating Facility; (2) an option to purchase or acquire a leasehold site for such purpose; or (3) an exclusivity or other business relationship between Interconnection Customer and the entity having the right to sell, lease or grant Interconnection Customer the right to possess or occupy a site for such purpose.

Small Generating Facility shall mean a Generating Facility that has a Generating Facility Capacity of no more than 20 MW.

Stand Alone Network Upgrades shall mean Network Upgrades that are not part of an Affected System that an Interconnection Customer may construct without affecting day-to-day operations of the Transmission System during their construction. Both the Transmission Provider and the Interconnection Customer must agree as to what constitutes Stand Alone Network Upgrades and identify them in Appendix A to the Standard Large Generator

Interconnection Agreement. If the Transmission Provider and Interconnection Customer disagree about whether a particular Network Upgrade is a Stand Alone Network Upgrade, the Transmission Provider must provide the Interconnection Customer a written technical explanation outlining why the Transmission Provider does not consider the Network Upgrade to be a Stand Alone Network Upgrade within 15 days of its determination.

Standard Large Generator Interconnection Agreement (LGIA) shall mean the form of interconnection agreement applicable to an Interconnection Request pertaining to a Large Generating Facility that is included in the Transmission Provider's Tariff.

Standard Large Generator Interconnection Procedures (LGIP) shall mean the interconnection procedures applicable to an Interconnection Request pertaining to a Large Generating Facility that are included in the Transmission Provider's Tariff.

Surplus Interconnection Service shall mean any unneeded portion of Interconnection Service established in a Large Generator Interconnection Agreement, such that if Surplus Interconnection Service is utilized, the total amount of Interconnection Service at the Point of Interconnection would remain the same.

System Protection Facilities shall mean the equipment, including necessary protection signal communications equipment, required to protect (1) the Transmission Provider's Transmission System from faults or other electrical disturbances occurring at the Generating Facility and (2) the Generating Facility from faults or other electrical system disturbances occurring on the Transmission Provider's Transmission System or on other delivery systems or other generating systems to which the Transmission Provider's Transmission System is directly connected.

Tariff shall mean the Transmission Provider's Tariff through which open access transmission service and Interconnection Service are offered, as filed with FERC, and as amended or supplemented from time to time, or any successor tariff.

Transmission Owner shall mean an entity that owns, leases or otherwise possesses an interest in the portion of the Transmission System at the Point of Interconnection and may be a Party to the Standard Large Generator Interconnection Agreement to the extent necessary.

Transmission Provider shall mean the public utility (or its designated agent) that owns, controls, or operates transmission or distribution facilities used for the transmission of electricity in interstate commerce and provides transmission service under the Tariff. The term Transmission Provider should be read to include the Transmission Owner when the Transmission Owner is separate from the Transmission Provider.

Transmission Provider's Interconnection Facilities shall mean all facilities and equipment owned, controlled, or operated by the Transmission Provider from the Point of Change of Ownership to the Point of Interconnection as identified in Appendix A to the Standard Large Generator Interconnection Agreement, including any

modifications, additions or upgrades to such facilities and equipment. Transmission Provider's Interconnection Facilities are sole use facilities and shall not include Distribution Upgrades, Stand Alone Network Upgrades or Network Upgrades.

Transmission System shall mean the facilities owned, controlled or operated by the Transmission Provider or Transmission Owner that are used to provide transmission service under the Tariff.

Trial Operation shall mean the period during which Interconnection Customer is engaged in on-site test operations and commissioning of the Generating Facility prior to Commercial Operation.

Section 2. Scope and Application

2.1 Application of Standard Large Generator Interconnection Procedures

Sections 2 through 13 apply to processing an Interconnection Request pertaining to a Large Generating Facility.

2.2 Comparability

Transmission Provider shall receive, process and analyze all Interconnection Requests in a timely manner as set forth in this LGIP. Transmission Provider will use the same Reasonable Efforts in processing and analyzing Interconnection Requests from all Interconnection Customers, whether the Generating Facilities are owned by Transmission Provider, its subsidiaries or Affiliates or others.

2.3 Base Case Data

Transmission Provider shall maintain base power flow, short circuit and stability databases, including all underlying assumptions, and contingency list on either its OASIS site or a password-protected website, subject to confidentiality provisions in LGIP Section 13.1. In addition, Transmission Provider shall maintain network models and underlying assumptions on either its OASIS site or a password-protected website. Such network models and underlying assumptions should reasonably represent those used during the most recent interconnection study and be representative of current system conditions. If Transmission Provider posts this information on a password-protected website, a link to the information must be provided on Transmission Provider's OASIS site. Transmission Provider is permitted to require that Interconnection Customers, OASIS site users and password-protected website users sign a confidentiality agreement before the release of commercially sensitive information or Critical Energy Infrastructure Information in the Base Case data. Such databases and lists, hereinafter referred to as Base Cases, shall include all (1) generation projects and (2) transmission projects, including merchant transmission projects that are proposed for the Transmission System for which a transmission expansion plan has been submitted and approved by the applicable authority.

2.4 No Applicability to Transmission Service

Nothing in this LGIP shall constitute a request for transmission service or confer

upon an Interconnection Customer any right to receive transmission service.

Section 3. Interconnection Requests

3.1 General

An Interconnection Customer shall submit to Transmission Provider an Interconnection Request in the form of Appendix 1 to this LGIP and a refundable deposit of \$10,000. Transmission Provider shall apply the deposit toward the cost of an Interconnection Feasibility Study. Interconnection Customer shall submit a separate Interconnection Request for each site and may submit multiple Interconnection Requests for a single site. Interconnection Customer must submit a deposit with each Interconnection Request even when more than one request is submitted for a single site. An Interconnection Request to evaluate one site at two different voltage levels shall be treated as two Interconnection Requests.

At Interconnection Customer's option, Transmission Provider and Interconnection Customer will identify alternative Point(s) of Interconnection and configurations at the Scoping Meeting to evaluate in this process and attempt to eliminate alternatives in a reasonable fashion given resources and information available. Interconnection Customer will select the definitive Point(s) of Interconnection to be studied no later than the execution of the Interconnection Feasibility Study Agreement.

Transmission Provider shall have a process in place to consider requests for Interconnection Service below the Generating Facility Capacity. These requests for Interconnection Service shall be studied at the level of Interconnection Service requested for purposes of Interconnection Facilities, Network Upgrades, and associated costs, but may be subject to other studies at the full Generating Facility Capacity to ensure safety and reliability of the system, with the study costs borne by the Interconnection Customer. If after the additional studies are complete, Transmission Provider determines that additional Network Upgrades are necessary, then Transmission Provider must: (1) Specify which additional Network Upgrade costs are based on which studies; and (2) provide a detailed explanation of why the additional Network Upgrades are necessary. Any Interconnection Facility and/or Network Upgrade costs required for safety and reliability also would be borne by the Interconnection Customer. Interconnection Customers may be subject to additional control technologies as well as testing and validation of those technologies consistent with Article 6 of the LGIA. The necessary control technologies and protection systems shall be established in Appendix C of that executed, or requested to be filed unexecuted, LGIA.

3.2 Identification of Types of Interconnection Services

At the time the Interconnection Request is submitted, Interconnection Customer must request either Energy Resource Interconnection Service or Network Resource Interconnection Service, as described; provided, however, any Interconnection

Customer requesting Network Resource Interconnection Service may also request that it be concurrently studied for Energy Resource Interconnection Service, up to the point when an Interconnection Facility Study Agreement is executed. Interconnection Customer may then elect to proceed with Network Resource Interconnection Service or to proceed under a lower level of interconnection service to the extent that only certain upgrades will be completed.

3.2.1 Energy Resource Interconnection Service

3.2.1.1 The Product

Energy Resource Interconnection Service allows Interconnection Customer to connect the Large Generating Facility to the Transmission System and be eligible to deliver the Large Generating Facility's output using the existing firm or non-firm capacity of the Transmission System on an "as available" basis. Energy Resource Interconnection Service does not in and of itself convey any right to deliver electricity to any specific customer or Point of Delivery.

3.2.1.2 The Study

The study consists of short circuit/fault duty, steady state (thermal and voltage) and stability analyses. The short circuit/fault duty analysis would identify direct Interconnection Facilities required and the Network Upgrades necessary to address short circuit issues associated with the Interconnection Facilities. The stability and steady state studies would identify necessary upgrades to allow full output of the proposed Large Generating Facility and would also identify the maximum allowed output, at the time the study is performed, of the interconnecting Large Generating Facility without requiring additional Network Upgrades.

3.2.2 Network Resource Interconnection Service

3.2.2.1 The Product

Transmission Provider must conduct the necessary studies and construct the Network Upgrades needed to integrate the Large Generating Facility (1) in a manner comparable to that in which Transmission Provider integrates its generating facilities to serve native load customers; or (2) in an ISO or RTO with market based congestion management, in the same manner as Network Resources. Network Resource Interconnection Service Allows Interconnection Customer's Large Generating Facility to be designated as a Network Resource, up to the Large Generating Facility's full output, on the same basis as existing Network Resources interconnected to Transmission Provider's Transmission System, and to be studied as a Network Resource on the assumption that such a designation will occur.

3.2.2.2 The Study

The Interconnection Study for Network Resource Interconnection Service shall assure that Interconnection Customer's Large Generating Facility meets the requirements for Network Resource Interconnection Service and as a general matter, that such

Large Generating Facility's interconnection is also studied with Transmission Provider's Transmission System at peak load, under a variety of severely stressed conditions, to determine whether, with the Large Generating Facility at full output, the aggregate of generation in the local area can be delivered to the aggregate of load on Transmission Provider's Transmission System, consistent with Transmission Provider's reliability criteria and procedures. This approach assumes that some portion of existing Network Resources are displaced by the output of Interconnection Customer's Large Generating Facility. Network Resource Interconnection Service in and of itself does not convey any right to deliver electricity to any specific customer or Point of Delivery. The Transmission Provider may also study the Transmission System under non-peak load conditions. However, upon request by the Interconnection Customer, the Transmission Provider must explain in writing to the Interconnection Customer why the study of non-peak load conditions is required for reliability purposes.

3.3 Utilization of Surplus Interconnection Service

Transmission Provider must provide a process that allows an Interconnection Customer to utilize or transfer Surplus Interconnection Service at an existing Point of Interconnection. The original Interconnection Customer or one of its affiliates shall have priority to utilize Surplus Interconnection Service. If the existing Interconnection Customer or one of its affiliates does not exercise its priority, then that service may be made available to other potential Interconnection Customers.

3.3.1 Surplus Interconnection Service Requests

Surplus Interconnection Service requests may be made by the existing Interconnection Customer whose Generating Facility is already interconnected or one of its affiliates. Surplus Interconnection Service requests also may be made by another Interconnection Customer. Transmission Provider shall provide a process for evaluating Interconnection Requests for Surplus Interconnection Service. Studies for Surplus Interconnection Service shall consist of reactive power, short circuit/fault duty, stability analyses, and any other appropriate studies. Steady-state (thermal/voltage) analyses may be performed as necessary to ensure that all required reliability conditions are studied. If the Surplus Interconnection Service was not studied under off-peak conditions, off-peak steady state analyses shall be performed to the required level necessary to demonstrate reliable operation of the Surplus Interconnection Service. If the original System Impact Study is not available for the Surplus Interconnection Service, both off-peak and peak analysis may need to be performed for the existing Generating Facility associated with the request for Surplus Interconnection Service. The reactive power, short circuit/fault duty, stability, and steady-state analyses for Surplus Interconnection Service will identify any additional Interconnection Facilities and/or Network Upgrades necessary.

3.4 Valid Interconnection Request

3.4.1 Initiating an Interconnection Request

To initiate an Interconnection Request, Interconnection Customer must submit all of the following: (i) A \$10,000 deposit, (ii) a completed application in the form of Appendix 1, and (iii) demonstration of Site Control or a posting of an additional deposit of \$10,000. Such deposits shall be applied toward any Interconnection Studies pursuant to the Interconnection Request. If Interconnection Customer demonstrates Site Control within the cure period specified in Section 3.4.3 after submitting its Interconnection Request, the additional deposit shall be refundable; otherwise, all such deposit(s), additional and initial, become non-refundable.

The expected In-Service Date of the new Large Generating Facility or increase in capacity of the existing Generating Facility shall be no more than the process window for the regional expansion planning period (or in the absence of a regional planning process, the process window for Transmission Provider's expansion planning period) not to exceed seven years from the date the Interconnection Request is received by Transmission Provider, unless Interconnection Customer demonstrates that engineering, permitting and construction of the new Large Generating Facility or increase in capacity of the existing Generating Facility will take longer than the regional expansion planning period. The In-Service Date may succeed the date the Interconnection Request is received by Transmission Provider by a period up to ten years, or longer where Interconnection Customer and Transmission Provider agree, such agreement not to be unreasonably withheld.

3.4.2 Acknowledgment of Interconnection Request

Transmission Provider shall acknowledge receipt of the Interconnection Request within five (5) Business Days of receipt of the request and attach a copy of the received Interconnection Request to the acknowledgement.

3.4.3 Deficiencies in Interconnection Request

An Interconnection Request will not be considered to be a valid request until all items in Section 3.4.1 have been received by Transmission Provider. If an Interconnection Request fails to meet the requirements set forth in Section 3.4.1, Transmission Provider shall notify Interconnection Customer within five (5) Business Days of receipt of the initial Interconnection Request of the reasons for such failure and that the Interconnection Request does not constitute a valid request. Interconnection Customer shall provide Transmission Provider the additional requested information needed to constitute a valid request within ten (10) Business Days after receipt of such notice. Failure by Interconnection Customer to comply with this Section 3.4.3 shall be treated in accordance with Section 3.7.

3.4.4 Scoping Meeting

Within ten (10) Business Days after receipt of a valid Interconnection Request, Transmission Provider shall establish a date

agreeable to Interconnection Customer for the Scoping Meeting, and such date shall be no later than thirty (30) Calendar Days from receipt of the valid Interconnection Request, unless otherwise mutually agreed upon by the Parties.

The purpose of the Scoping Meeting shall be to discuss alternative interconnection options, to exchange information including any transmission data that would reasonably be expected to impact such interconnection options, to analyze such information and to determine the potential feasible Points of Interconnection. Transmission Provider and Interconnection Customer will bring to the meeting such technical data, including, but not limited to: (i) General facility loadings, (ii) general instability issues, (iii) general short circuit issues, (iv) general voltage issues, and (v) general reliability issues as may be reasonably required to accomplish the purpose of the meeting. Transmission Provider and Interconnection Customer will also bring to the meeting personnel and other resources as may be reasonably required to accomplish the purpose of the meeting in the time allocated for the meeting. On the basis of the meeting, Interconnection Customer shall designate its Point of Interconnection, pursuant to Section 6.1, and one or more available alternative Point(s) of Interconnection. The duration of the meeting shall be sufficient to accomplish its purpose.

3.5 OASIS Posting

3.5.1

Transmission Provider will maintain on its OASIS a list of all Interconnection Requests. The list will identify, for each Interconnection Request: (i) The maximum summer and winter megawatt electrical output; (ii) the location by county and state; (iii) the station or transmission line or lines where the interconnection will be made; (iv) the projected In-Service Date; (v) the status of the Interconnection Request, including Queue Position; (vi) the type of Interconnection Service being requested; and (vii) the availability of any studies related to the Interconnection Request; (viii) the date of the Interconnection Request; (ix) the type of Generating Facility to be constructed (combined cycle, base load or combustion turbine and fuel type); and (x) for Interconnection Requests that have not resulted in a completed interconnection, an explanation as to why it was not completed. Except in the case of an Affiliate, the list will not disclose the identity of Interconnection Customer until Interconnection Customer executes an LGIA or requests that Transmission Provider file an unexecuted LGIA with FERC. Before holding a Scoping Meeting with its Affiliate, Transmission Provider shall post on OASIS an advance notice of its intent to do so. Transmission Provider shall post to its OASIS site any deviations from the study timelines set forth herein. Interconnection Study reports and Optional Interconnection Study reports shall be posted to Transmission Provider's OASIS site subsequent to the meeting between Interconnection Customer and Transmission Provider to discuss the applicable study results. Transmission Provider shall also post any known deviations in the Large Generating Facility's In-Service Date.

3.5.2 Requirement To Post Interconnection Study Metrics

Transmission Provider will maintain on its OASIS or its website summary statistics related to processing Interconnection Studies pursuant to Interconnection Requests, updated quarterly. If Transmission Provider posts this information on its website, a link to the information must be provided on Transmission Provider's OASIS site. For each calendar quarter, Transmission Providers must calculate and post the information detailed in sections 3.5.2.1 through 3.5.2.4.

3.5.2.1 Interconnection Feasibility Studies Processing Time

(A) Number of Interconnection Requests that had Interconnection Feasibility Studies completed within Transmission Provider's coordinated region during the reporting quarter,

(B) Number of Interconnection Requests that had Interconnection Feasibility Studies completed within Transmission Provider's coordinated region during the reporting quarter that were completed more than [timeline as listed in Transmission Provider's LGIP] after receipt by Transmission Provider of the Interconnection Customer's executed Interconnection Feasibility Study Agreement,

(C) At the end of the reporting quarter, the number of active valid Interconnection Requests with ongoing incomplete Interconnection Feasibility Studies where such Interconnection Requests had executed Interconnection Feasibility Study Agreements received by Transmission Provider more than [timeline as listed in Transmission Provider's LGIP] before the reporting quarter end,

(D) Mean time (in days), Interconnection Feasibility Studies completed within Transmission Provider's coordinated region during the reporting quarter, from the date when Transmission Provider received the executed Interconnection Feasibility Study Agreement to the date when Transmission Provider provided the completed Interconnection Feasibility Study to the Interconnection Customer,

(E) Percentage of Interconnection Feasibility Studies exceeding [timeline as listed in Transmission Provider's LGIP] to complete this reporting quarter, calculated as the sum of 3.5.2.1(B) plus 3.5.2.1(C) divided by the sum of 3.5.2.1(A) plus 3.5.2.1(C)).

3.5.2.2 Interconnection System Impact Studies Processing Time

(A) Number of Interconnection Requests that had Interconnection System Impact Studies completed within Transmission Provider's coordinated region during the reporting quarter,

(B) Number of Interconnection Requests that had Interconnection System Impact Studies completed within Transmission Provider's coordinated region during the reporting quarter that were completed more than [timeline as listed in Transmission Provider's LGIP] after receipt by Transmission Provider of the Interconnection Customer's executed Interconnection System Impact Study Agreement,

(C) At the end of the reporting quarter, the number of active valid Interconnection Requests with ongoing incomplete System

Impact Studies where such Interconnection Requests had executed Interconnection System Impact Study Agreements received by Transmission Provider more than [timeline as listed in Transmission Provider's LGIP] before the reporting quarter end,

(D) Mean time (in days), Interconnection System Impact Studies completed within Transmission Provider's coordinated region during the reporting quarter, from the date when Transmission Provider received the executed Interconnection System Impact Study Agreement to the date when Transmission Provider provided the completed Interconnection System Impact Study to the Interconnection Customer,

(E) Percentage of Interconnection System Impact Studies exceeding [timeline as listed in Transmission Provider's LGIP] to complete this reporting quarter, calculated as the sum of 3.5.2.2(B) plus 3.5.2.2(C) divided by the sum of 3.5.2.2(A) plus 3.5.2.2(C)).

3.5.2.3 Interconnection Facilities Studies Processing Time

(A) Number of Interconnection Requests that had Interconnection Facilities Studies that are completed within Transmission Provider's coordinated region during the reporting quarter,

(B) Number of Interconnection Requests that had Interconnection Facilities Studies that are completed within Transmission Provider's coordinated region during the reporting quarter that were completed more than [timeline as listed in Transmission Provider's LGIP] after receipt by Transmission Provider of the Interconnection Customer's executed Interconnection Facilities Study Agreement,

(C) At the end of the reporting quarter, the number of active valid Interconnection Service requests with ongoing incomplete Interconnection Facilities Studies where such Interconnection Requests had executed Interconnection Facilities Studies Agreement received by Transmission Provider more than [timeline as listed in Transmission Provider's LGIP] before the reporting quarter end,

(D) Mean time (in days), for Interconnection Facilities Studies completed within Transmission Provider's coordinated region during the reporting quarter, calculated from the date when Transmission Provider received the executed Interconnection Facilities Study Agreement to the date when Transmission Provider provided the completed Interconnection Facilities Study to the Interconnection Customer,

(E) Percentage of delayed Interconnection Facilities Studies this reporting quarter, calculated as the sum of 3.5.2.3(B) plus 3.5.2.3(C) divided by the sum of 3.5.2.3(A) plus 3.5.2.3(C)).

3.5.2.4 Interconnection Service Requests Withdrawn From Interconnection Queue

(A) Number of Interconnection Requests withdrawn from Transmission Provider's interconnection queue during the reporting quarter,

(B) Number of Interconnection Requests withdrawn from Transmission Provider's interconnection queue during the reporting quarter before completion of any interconnection studies or execution of any interconnection study agreements,

(C) Number of Interconnection Requests withdrawn from Transmission Provider's interconnection queue during the reporting quarter before completion of an Interconnection System Impact Study,

(D) Number of Interconnection Requests withdrawn from Transmission Provider's interconnection queue during the reporting quarter before completion of an Interconnection Facilities Study,

(E) Number of Interconnection Requests withdrawn from Transmission Provider's interconnection queue after execution of a generator interconnection agreement or Interconnection Customer requests the filing of an unexecuted, new interconnection agreement,

(F) Mean time (in days), for all withdrawn Interconnection Requests, from the date when the request was determined to be valid to when Transmission Provider received the request to withdraw from the queue.

3.5.3

Transmission Provider is required to post on OASIS or its website the measures in paragraph 3.5.2.1(A) through paragraph 3.5.2.4(F) for each calendar quarter within 30 days of the end of the calendar quarter. Transmission Provider will keep the quarterly measures posted on OASIS or its website for three calendar years with the first required report to be in the first quarter of 2020. If Transmission Provider retains this information on its website, a link to the information must be provided on Transmission Provider's OASIS site.

3.5.4

In the event that any of the values calculated in paragraphs 3.5.2.1(E), 3.5.2.2(E) or 3.5.2.3(E) exceeds 25 percent for two consecutive calendar quarters, Transmission Provider will have to comply with the measures below for the next four consecutive calendar quarters and must continue reporting this information until Transmission Provider reports four consecutive calendar quarters without the values calculated in 3.5.2.1(E), 3.5.2.2(E) or 3.5.2.3(E) exceeding 25 percent for two consecutive calendar quarters:

(i) Transmission Provider must submit a report to the Commission describing the reason for each study or group of clustered studies pursuant to an Interconnection Request that exceeded its deadline (*i.e.*, 45, 90 or 180 days) for completion (excluding any allowance for Reasonable Efforts). Transmission Provider must describe the reasons for each study delay and any steps taken to remedy these specific issues and, if applicable, prevent such delays in the future. The report must be filed at the Commission within 45 days of the end of the calendar quarter.

(ii) Transmission Provider shall aggregate the total number of employee-hours and third party consultant hours expended towards interconnection studies within its coordinated region that quarter and post on OASIS or its website. If Transmission Provider posts this information on its website, a link to the information must be provided on Transmission Provider's OASIS site. This information is to be posted within 30 days of the end of the calendar quarter.

3.6 Coordination With Affected Systems

Transmission Provider will coordinate the conduct of any studies required to determine the impact of the Interconnection Request on Affected Systems with Affected System Operators and, if possible, include those results (if available) in its applicable Interconnection Study within the time frame specified in this LGIP. Transmission Provider will include such Affected System Operators in all meetings held with Interconnection Customer as required by this LGIP. Interconnection Customer will cooperate with Transmission Provider in all matters related to the conduct of studies and the determination of modifications to Affected Systems. A Transmission Provider which may be an Affected System shall cooperate with Transmission Provider with whom interconnection has been requested in all matters related to the conduct of studies and the determination of modifications to Affected Systems.

3.7 Withdrawal

Interconnection Customer may withdraw its Interconnection Request at any time by written notice of such withdrawal to Transmission Provider. In addition, if Interconnection Customer fails to adhere to all requirements of this LGIP, except as provided in Section 13.5 (Disputes), Transmission Provider shall deem the Interconnection Request to be withdrawn and shall provide written notice to Interconnection Customer of the deemed withdrawal and an explanation of the reasons for such deemed withdrawal. Upon receipt of such written notice, Interconnection Customer shall have fifteen (15) Business Days in which to either respond with information or actions that cures the deficiency or to notify Transmission Provider of its intent to pursue Dispute Resolution.

Withdrawal shall result in the loss of Interconnection Customer's Queue Position. If an Interconnection Customer disputes the withdrawal and loss of its Queue Position, then during Dispute Resolution, Interconnection Customer's Interconnection Request is eliminated from the queue until such time that the outcome of Dispute Resolution would restore its Queue Position. An Interconnection Customer that withdraws or is deemed to have withdrawn its Interconnection Request shall pay to Transmission Provider all costs that Transmission Provider prudently incurs with respect to that Interconnection Request prior to Transmission Provider's receipt of notice described above. Interconnection Customer must pay all monies due to Transmission Provider before it is allowed to obtain any Interconnection Study data or results.

Transmission Provider shall (i) update the OASIS Queue Position posting and (ii) refund to Interconnection Customer any portion of Interconnection Customer's deposit or study payments that exceeds the costs that Transmission Provider has incurred, including interest calculated in accordance with section 35.19a(a)(2) of FERC's regulations. In the event of such withdrawal, Transmission Provider, subject to the confidentiality provisions of Section 13.1, shall provide, at Interconnection

Customer's request, all information that Transmission Provider developed for any completed study conducted up to the date of withdrawal of the Interconnection Request.

3.8 Identification of Contingent Facilities

Transmission Provider shall post in this section a method for identifying the Contingent Facilities to be provided to Interconnection Customer at the conclusion of the System Impact Study and included in Interconnection Customer's Large Generator Interconnection Agreement. The method shall be sufficiently transparent to determine why a specific Contingent Facility was identified and how it relates to the Interconnection Request. Transmission Provider shall also provide, upon request of the Interconnection Customer, the estimated Interconnection Facility and/or Network Upgrade costs and estimated in-service completion time of each identified Contingent Facility when this information is readily available and not commercially sensitive.

3.10 Repeat Network Upgrades for Consideration in the Regional Transmission Planning Process

If Transmission Provider: (1) Identifies a Network Upgrade with an interconnection study estimated cost of at least \$30 million or with a voltage of at least 200 kV as necessary to accomplish an interconnection and the underlying interconnection request related to such Network Upgrade is withdrawn; (2) if, within five years of that withdrawal, Transmission Provider identifies a Network Upgrade with an interconnection study estimated cost of at least \$30 million or with a voltage of at least 200 kV to address a similar interconnection-related need as specified in (1) and the underlying interconnection request with cost responsibility for the second identified Network Upgrade is withdrawn; and (3) a similar interconnection-related need is not addressed by any Network Upgrade described in Appendix A of any executed Large Generator Interconnection Agreement or any Large Generator Interconnection Agreement that an Interconnection Customer has requested that Transmission Provider file with the Commission unexecuted, then Transmission Provider shall consider the interconnection-related need addressed by the Network Upgrade(s) that Transmission Provider identified in the interconnection queue cycles specified in (1) and (2) in Long-Term Regional Transmission Planning.

Section 4. Queue Position

4.1 General

Transmission Provider shall assign a Queue Position based upon the date and time of receipt of the valid Interconnection Request; provided that, if the sole reason an Interconnection Request is not valid is the lack of required information on the application form, and Interconnection Customer provides such information in accordance with Section 3.4.3, then Transmission Provider shall assign Interconnection Customer a Queue Position based on the date the application form was originally filed. Moving a Point of

Interconnection shall result in a lowering of Queue Position if it is deemed a Material Modification under Section 4.4.3.

The Queue Position of each Interconnection Request will be used to determine the order of performing the Interconnection Studies and determination of cost responsibility for the facilities necessary to accommodate the Interconnection Request. A higher queued Interconnection Request is one that has been placed "earlier" in the queue in relation to another Interconnection Request that is lower queued.

Transmission Provider may allocate the cost of the common upgrades for clustered Interconnection Requests without regard to Queue Position.

4.2 Clustering

At Transmission Provider's option, Interconnection Requests may be studied serially or in clusters for the purpose of the Interconnection System Impact Study.

Clustering shall be implemented on the basis of Queue Position. If Transmission Provider elects to study Interconnection Requests using Clustering, all Interconnection Requests received within a period not to exceed one hundred and eighty (180) Calendar Days, hereinafter referred to as the "Queue Cluster Window" shall be studied together without regard to the nature of the underlying Interconnection Service, whether Energy Resource Interconnection Service or Network Resource Interconnection Service. The deadline for completing all Interconnection System Impact Studies for which an Interconnection System Impact Study Agreement has been executed during a Queue Cluster Window shall be in accordance with Section 7.4, for all Interconnection Requests assigned to the same Queue Cluster Window. Transmission Provider may study an Interconnection Request separately to the extent warranted by Good Utility Practice based upon the electrical remoteness of the proposed Large Generating Facility.

Clustering Interconnection System Impact Studies shall be conducted in such a manner to ensure the efficient implementation of the applicable regional transmission expansion plan in light of the Transmission System's capabilities at the time of each study.

The Queue Cluster Window shall have a fixed time interval based on fixed annual opening and closing dates. Any changes to the established Queue Cluster Window interval and opening or closing dates shall be announced with a posting on Transmission Provider's OASIS beginning at least one hundred and eighty (180) Calendar Days in advance of the change and continuing thereafter through the end date of the first Queue Cluster Window that is to be modified.

4.3 Transferability of Queue Position

An Interconnection Customer may transfer its Queue Position to another entity only if such entity acquires the specific Generating Facility identified in the Interconnection Request and the Point of Interconnection does not change.

4.4 Modifications

Interconnection Customer shall submit to Transmission Provider, in writing, modifications to any information provided in the Interconnection Request. Interconnection Customer shall retain its Queue Position if the modifications are in accordance with Sections 4.4.1, 4.4.2 or 4.4.5, or are determined not to be Material Modifications pursuant to Section 4.4.3.

Notwithstanding the above, during the course of the Interconnection Studies, either Interconnection Customer or Transmission Provider may identify changes to the planned interconnection that may improve the costs and benefits (including reliability) of the interconnection, and the ability of the proposed change to accommodate the Interconnection Request. To the extent the identified changes are acceptable to Transmission Provider and Interconnection Customer, such acceptance not to be unreasonably withheld, Transmission Provider shall modify the Point of Interconnection and/or configuration in accordance with such changes and proceed with any re-studies necessary to do so in accordance with Section 6.4, Section 7.6 and Section 8.5 as applicable and Interconnection Customer shall retain its Queue Position.

4.4.1

Prior to the return of the executed Interconnection System Impact Study Agreement to Transmission Provider, modifications permitted under this Section shall include specifically: (a) A decrease of up to 60 percent of electrical output (MW) of the proposed project, through either (1) a decrease in plant size or (2) a decrease in Interconnection Service level (consistent with the process described in Section 3.1) accomplished by applying Transmission Provider-approved injection-limiting equipment; (b) modifying the technical parameters associated with the Large Generating Facility technology or the Large Generating Facility step-up transformer impedance characteristics; and (c) modifying the interconnection configuration. For plant increases, the incremental increase in plant output will go to the end of the queue for the purposes of cost allocation and study analysis.

4.4.2

Prior to the return of the executed Interconnection Facility Study Agreement to Transmission Provider, the modifications permitted under this Section shall include specifically: (a) Additional 15 percent decrease of electrical output of the proposed project through either (1) a decrease in plant size (MW) or (2) a decrease in Interconnection Service level (consistent with the process described in Section 3.1) accomplished by applying Transmission Provider-approved injection-limiting equipment; (b) Large Generating Facility technical parameters associated with modifications to Large Generating Facility technology and transformer impedances; provided, however, the incremental costs associated with those modifications are the responsibility of the requesting Interconnection Customer; and (c) a Permissible Technological Advancement for

the Large Generating Facility after the submission of the Interconnection Request. Section 4.4.6 specifies a separate technological change procedure including the requisite information and process that will be followed to assess whether the Interconnection Customer's proposed technological advancement under Section 4.4.2(c) is a Material Modification. Section 1 contains a definition of Permissible Technological Advancement.

4.4.3

Prior to making any modification other than those specifically permitted by Sections 4.4.1, 4.4.2, and 4.4.5, Interconnection Customer may first request that Transmission Provider evaluate whether such modification is a Material Modification. In response to Interconnection Customer's request, Transmission Provider shall evaluate the proposed modifications prior to making them and inform Interconnection Customer in writing of whether the modifications would constitute a Material Modification. Any change to the Point of Interconnection, except those deemed acceptable under Sections 4.4.1, 6.1, 7.2 or so allowed elsewhere, shall constitute a Material Modification. Interconnection Customer may then withdraw the proposed modification or proceed with a new Interconnection Request for such modification.

4.4.4

Upon receipt of Interconnection Customer's request for modification permitted under this Section 4.4, Transmission Provider shall commence and perform any necessary additional studies as soon as practicable, but in no event shall Transmission Provider commence such studies later than thirty (30) Calendar Days after receiving notice of Interconnection Customer's request. Any additional studies resulting from such modification shall be done at Interconnection Customer's cost.

4.4.5

Extensions of less than three (3) cumulative years in the Commercial Operation Date of the Large Generating Facility to which the Interconnection Request relates are not material and should be handled through construction sequencing.

4.4.6 Technological Change Procedures

[Insert technological change procedure here]

Section 5. Procedures for Interconnection Requests Submitted Prior to Effective Date of Standard Large Generator Interconnection Procedures

5.1 Queue Position for Pending Requests

5.1.1

Any Interconnection Customer assigned a Queue Position prior to the effective date of this LGIP shall retain that Queue Position.

5.1.1.1

If an Interconnection Study Agreement has not been executed as of the effective date of this LGIP, then such Interconnection Study, and any subsequent Interconnection Studies, shall be processed in accordance with this LGIP.

5.1.1.2

If an Interconnection Study Agreement has been executed prior to the effective date of this LGIP, such Interconnection Study shall be completed in accordance with the terms of such agreement. With respect to any remaining studies for which an Interconnection Customer has not signed an Interconnection Study Agreement prior to the effective date of the LGIP, Transmission Provider must offer Interconnection Customer the option of either continuing under Transmission Provider's existing interconnection study process or going forward with the completion of the necessary Interconnection Studies (for which it does not have a signed Interconnection Studies Agreement) in accordance with this LGIP.

5.1.1.3

If an LGIA has been submitted to FERC for approval before the effective date of the LGIP, then the LGIA would be grandfathered.

5.1.2 Transition Period

To the extent necessary, Transmission Provider and Interconnection Customers with an outstanding request (*i.e.*, an Interconnection Request for which an LGIA has not been submitted to FERC for approval as of the effective date of this LGIP) shall transition to this LGIP within a reasonable period of time not to exceed sixty (60) Calendar Days. The use of the term "outstanding request" herein shall mean any Interconnection Request, on the effective date of this LGIP: (i) That has been submitted but not yet accepted by Transmission Provider; (ii) where the related interconnection agreement has not yet been submitted to FERC for approval in executed or unexecuted form, (iii) where the relevant Interconnection Study Agreements have not yet been executed, or (iv) where any of the relevant Interconnection Studies are in process but not yet completed. Any Interconnection Customer with an outstanding request as of the effective date of this LGIP may request a reasonable extension of any deadline, otherwise applicable, if necessary to avoid undue hardship or prejudice to its Interconnection Request. A reasonable extension shall be granted by Transmission Provider to the extent consistent with the intent and process provided for under this LGIP.

5.2 New Transmission Provider

If Transmission Provider transfers control of its Transmission System to a successor Transmission Provider during the period when an Interconnection Request is pending, the original Transmission Provider shall transfer to the successor Transmission Provider any amount of the deposit or payment with interest thereon that exceeds the cost that it incurred to evaluate the request for interconnection. Any difference between such net amount and the deposit or payment required by this LGIP shall be paid by or refunded to the Interconnection Customer, as appropriate. The original Transmission Provider shall coordinate with the successor Transmission Provider to complete any Interconnection Study, as appropriate, that the original Transmission Provider has begun but has not completed. If

Transmission Provider has tendered a draft LGIA to Interconnection Customer but Interconnection Customer has not either executed the LGIA or requested the filing of an unexecuted LGIA with FERC, unless otherwise provided, Interconnection Customer must complete negotiations with the successor Transmission Provider.

Section 6. Interconnection Feasibility Study

6.1 Interconnection Feasibility Study Agreement

Simultaneously with the acknowledgement of a valid Interconnection Request Transmission Provider shall provide to Interconnection Customer an Interconnection Feasibility Study Agreement in the form of Appendix 2. The Interconnection Feasibility Study Agreement shall specify that Interconnection Customer is responsible for the actual cost of the Interconnection Feasibility Study. Within five (5) Business Days following the Scoping Meeting Interconnection Customer shall specify for inclusion in the attachment to the Interconnection Feasibility Study Agreement the Point(s) of Interconnection and any reasonable alternative Point(s) of Interconnection. Within five (5) Business Days following Transmission Provider's receipt of such designation, Transmission Provider shall tender to Interconnection Customer the Interconnection Feasibility Study Agreement signed by Transmission Provider, which includes a good faith estimate of the cost for completing the Interconnection Feasibility Study. Interconnection Customer shall execute and deliver to Transmission Provider the Interconnection Feasibility Study Agreement along with a \$10,000 deposit no later than thirty (30) Calendar Days after its receipt.

On or before the return of the executed Interconnection Feasibility Study Agreement to Transmission Provider, Interconnection Customer shall provide the technical data called for in Appendix 1, Attachment A.

If the Interconnection Feasibility Study uncovers any unexpected result(s) not contemplated during the Scoping Meeting, a substitute Point of Interconnection identified by either Interconnection Customer or Transmission Provider, and acceptable to the other, such acceptance not to be unreasonably withheld, will be substituted for the designated Point of Interconnection specified above without loss of Queue Position, and Re-studies shall be completed pursuant to Section 6.4 as applicable. For the purpose of this Section 6.1, if Transmission Provider and Interconnection Customer cannot agree on the substituted Point of Interconnection, then Interconnection Customer may direct that one of the alternatives as specified in the Interconnection Feasibility Study Agreement, as specified pursuant to Section 3.4.4, shall be the substitute.

If Interconnection Customer and Transmission Provider agree to forgo the Interconnection Feasibility Study, Transmission Provider will initiate an Interconnection System Impact Study under Section 7 of this LGIP and apply the \$10,000 deposit towards the Interconnection System Impact Study.

6.2 Scope of Interconnection Feasibility Study

The Interconnection Feasibility Study shall preliminarily evaluate the feasibility of the proposed interconnection to the Transmission System.

The Interconnection Feasibility Study will consider the Base Case as well as all generating facilities (and with respect to (iii), any identified Network Upgrades) that, on the date the Interconnection Feasibility Study is commenced: (i) Are directly interconnected to the Transmission System; (ii) are interconnected to Affected Systems and may have an impact on the Interconnection Request; (iii) have a pending higher queued Interconnection Request to interconnect to the Transmission System; and (iv) have no Queue Position but have executed an LGIA or requested that an unexecuted LGIA be filed with FERC. The Interconnection Feasibility Study will consist of a power flow and short circuit analysis. The Interconnection Feasibility Study will provide a list of facilities and a non-binding good faith estimate of cost responsibility and a non-binding good faith estimated time to construct.

6.3 Interconnection Feasibility Study Procedures

Transmission Provider shall utilize existing studies to the extent practicable when it performs the study. Transmission Provider shall use Reasonable Efforts to complete the Interconnection Feasibility Study no later than forty-five (45) Calendar Days after Transmission Provider receives the fully executed Interconnection Feasibility Study Agreement. At the request of Interconnection Customer or at any time Transmission Provider determines that it will not meet the required time frame for completing the Interconnection Feasibility Study, Transmission Provider shall notify Interconnection Customer as to the schedule status of the Interconnection Feasibility Study. If Transmission Provider is unable to complete the Interconnection Feasibility Study within that time period, it shall notify Interconnection Customer and provide an estimated completion date with an explanation of the reasons why additional time is required. Upon request, Transmission Provider shall provide Interconnection Customer supporting documentation, workpapers and relevant power flow, short circuit and stability databases for the Interconnection Feasibility Study, subject to confidentiality arrangements consistent with Section 13.1.

Transmission Provider shall study the Interconnection Request at the level of service requested by the Interconnection Customer, unless otherwise required to study the full Generating Facility Capacity due to safety or reliability concerns.

6.3.1 Meeting With Transmission Provider

Within ten (10) Business Days of providing an Interconnection Feasibility Study report to Interconnection Customer, Transmission Provider and Interconnection Customer shall meet to discuss the results of the Interconnection Feasibility Study.

6.4 Re-Study

If Re-Study of the Interconnection Feasibility Study is required due to a higher queued project dropping out of the queue, or a modification of a higher queued project subject to Section 4.4, or re-designation of the Point of Interconnection pursuant to Section 6.1 Transmission Provider shall notify Interconnection Customer in writing. Such Re-Study shall take not longer than forty-five (45) Calendar Days from the date of the notice. Any cost of Re-Study shall be borne by the Interconnection Customer being re-studied.

Section 7. Interconnection System Impact Study

7.1 Interconnection System Impact Study Agreement

Unless otherwise agreed, pursuant to the Scoping Meeting provided in Section 3.4.4, simultaneously with the delivery of the Interconnection Feasibility Study to Interconnection Customer, Transmission Provider shall provide to Interconnection Customer an Interconnection System Impact Study Agreement in the form of Appendix 3 to this LGIP. The Interconnection System Impact Study Agreement shall provide that Interconnection Customer shall compensate Transmission Provider for the actual cost of the Interconnection System Impact Study. Within three (3) Business Days following the Interconnection Feasibility Study results meeting, Transmission Provider shall provide to Interconnection Customer a non-binding good faith estimate of the cost and timeframe for completing the Interconnection System Impact Study.

7.2 Execution of Interconnection System Impact Study Agreement

Interconnection Customer shall execute the Interconnection System Impact Study Agreement and deliver the executed Interconnection System Impact Study Agreement to Transmission Provider no later than thirty (30) Calendar Days after its receipt along with demonstration of Site Control, and a \$50,000 deposit.

If Interconnection Customer does not provide all such technical data when it delivers the Interconnection System Impact Study Agreement, Transmission Provider shall notify Interconnection Customer of the deficiency within five (5) Business Days of the receipt of the executed Interconnection System Impact Study Agreement and Interconnection Customer shall cure the deficiency within ten (10) Business Days of receipt of the notice, provided, however, such deficiency does not include failure to deliver the executed Interconnection System Impact Study Agreement or deposit.

If the Interconnection System Impact Study uncovers any unexpected result(s) not contemplated during the Scoping Meeting and the Interconnection Feasibility Study, a substitute Point of Interconnection identified by either Interconnection Customer or Transmission Provider, and acceptable to the other, such acceptance not to be unreasonably withheld, will be substituted for the designated Point of Interconnection specified above without loss of Queue Position, and restudies shall be completed

pursuant to Section 7.6 as applicable. For the purpose of this Section 7.2, if Transmission Provider and Interconnection Customer cannot agree on the substituted Point of Interconnection, then Interconnection Customer may direct that one of the alternatives as specified in the Interconnection Feasibility Study Agreement, as specified pursuant to Section 3.4.4, shall be the substitute.

7.3 *Scope of Interconnection System Impact Study*

The Interconnection System Impact Study shall evaluate the impact of the proposed interconnection on the reliability of the Transmission System. The Interconnection System Impact Study will consider the Base Case as well as all generating facilities (and with respect to (iii) below, any identified Network Upgrades associated with such higher queued interconnection) that, on the date the Interconnection System Impact Study is commenced: (i) Are directly interconnected to the Transmission System; (ii) are interconnected to Affected Systems and may have an impact on the Interconnection Request; (iii) have a pending higher queued Interconnection Request to interconnect to the Transmission System; and (iv) have no Queue Position but have executed an LGIA or requested that an unexecuted LGIA be filed with FERC.

The Interconnection System Impact Study will consist of a short circuit analysis, a stability analysis, and a power flow analysis. The Interconnection System Impact Study will state the assumptions upon which it is based; state the results of the analyses; and provide the requirements or potential impediments to providing the requested interconnection service, including a preliminary indication of the cost and length of time that would be necessary to correct any problems identified in those analyses and implement the interconnection. For purposes of determining necessary Interconnection Facilities and Network Upgrades, the System Impact Study shall consider the level of Interconnection Service requested by the Interconnection Customer, unless otherwise required to study the full Generating Facility Capacity due to safety or reliability concerns. The Interconnection System Impact Study will provide a list of facilities that are required as a result of the Interconnection Request and a non-binding good faith estimate of cost responsibility and a non-binding good faith estimated time to construct.

7.4 *Interconnection System Impact Study Procedures*

Impact Study with any Affected System that is affected by the Interconnection Request pursuant to Section 3.6 above. Transmission Provider shall utilize existing studies to the extent practicable when it performs the study. Transmission Provider shall use Reasonable Efforts to complete the Interconnection System Impact Study within ninety (90) Calendar Days after the receipt of the Interconnection System Impact Study Agreement or notification to proceed, study payment, and technical data. If Transmission Provider uses Clustering, Transmission

Provider shall use Reasonable Efforts to deliver a completed Interconnection System Impact Study within ninety (90) Calendar Days after the close of the Queue Cluster Window.

At the request of Interconnection Customer or at any time Transmission Provider determines that it will not meet the required time frame for completing the Interconnection System Impact Study, Transmission Provider shall notify Interconnection Customer as to the schedule status of the Interconnection System Impact Study. If Transmission Provider is unable to complete the Interconnection System Impact Study within the time period, it shall notify Interconnection Customer and provide an estimated completion date with an explanation of the reasons why additional time is required. Upon request, Transmission Provider shall provide Interconnection Customer all supporting documentation, workpapers and relevant pre-Interconnection Request and post-Interconnection Request power flow, short circuit and stability databases for the Interconnection System Impact Study, subject to confidentiality arrangements consistent with Section 13.1.

7.5 *Meeting With Transmission Provider*

Within ten (10) Business Days of providing an Interconnection System Impact Study report to Interconnection Customer, Transmission Provider and Interconnection Customer shall meet to discuss the results of the Interconnection System Impact Study.

7.6 *Re-Study*

If Re-Study of the Interconnection System Impact Study is required due to a higher queued project dropping out of the queue, or a modification of a higher queued project subject to 4.4, or re-designation of the Point of Interconnection pursuant to Section 7.2 Transmission Provider shall notify Interconnection Customer in writing. Such Re-Study shall take no longer than sixty (60) Calendar Days from the date of notice. Any cost of Re-Study shall be borne by the Interconnection Customer being re-studied.

Section 8. Interconnection Facilities Study

8.1 *Interconnection Facilities Study Agreement*

Simultaneously with the delivery of the Interconnection System Impact Study to Interconnection Customer, Transmission Provider shall provide to Interconnection Customer an Interconnection Facilities Study Agreement in the form of Appendix 4 to this LGIP. The Interconnection Facilities Study Agreement shall provide that Interconnection Customer shall compensate Transmission Provider for the actual cost of the Interconnection Facilities Study. Within three (3) Business Days following the Interconnection System Impact Study results meeting, Transmission Provider shall provide to Interconnection Customer a non-binding good faith estimate of the cost and timeframe for completing the Interconnection Facilities Study. Interconnection Customer shall execute the Interconnection Facilities Study Agreement and deliver the executed Interconnection Facilities Study Agreement to Transmission Provider within thirty (30)

Calendar Days after its receipt, together with the required technical data and the greater of \$100,000 or Interconnection Customer's portion of the estimated monthly cost of conducting the Interconnection Facilities Study.

8.1.1

Transmission Provider shall invoice Interconnection Customer on a monthly basis for the work to be conducted on the Interconnection Facilities Study each month. Interconnection Customer shall pay invoiced amounts within thirty (30) Calendar Days of receipt of invoice. Transmission Provider shall continue to hold the amounts on deposit until settlement of the final invoice.

8.2 *Scope of Interconnection Facilities Study*

The Interconnection Facilities Study shall specify and estimate the cost of the equipment, engineering, procurement and construction work needed to implement the conclusions of the Interconnection System Impact Study in accordance with Good Utility Practice to physically and electrically connect the Interconnection Facility to the Transmission System. The Interconnection Facilities Study shall also identify the electrical switching configuration of the connection equipment, including, without limitation: The transformer, switchgear, meters, and other station equipment; the nature and estimated cost of any Transmission Provider's Interconnection Facilities and Network Upgrades necessary to accomplish the interconnection; and an estimate of the time required to complete the construction and installation of such facilities. The Facilities Study will also identify any potential control equipment for requests for Interconnection Service that are lower than the Generating Facility Capacity.

8.3 *Interconnection Facilities Study Procedures*

Transmission Provider shall coordinate the Interconnection Facilities Study with any Affected System pursuant to Section 3.6 above. Transmission Provider shall utilize existing studies to the extent practicable in performing the Interconnection Facilities Study. Transmission Provider shall use Reasonable Efforts to complete the study and issue a draft Interconnection Facilities Study report to Interconnection Customer within the following number of days after receipt of an executed Interconnection Facilities Study Agreement: Ninety (90) Calendar Days, with no more than a ± 20 percent cost estimate contained in the report; or one hundred eighty (180) Calendar Days, if Interconnection Customer requests a ± 10 percent cost estimate.

At the request of Interconnection Customer or at any time Transmission Provider determines that it will not meet the required time frame for completing the Interconnection Facilities Study, Transmission Provider shall notify Interconnection Customer as to the schedule status of the Interconnection Facilities Study. If Transmission Provider is unable to complete the Interconnection Facilities Study and issue a draft Interconnection Facilities Study report within the time required, it

shall notify Interconnection Customer and provide an estimated completion date and an explanation of the reasons why additional time is required.

Interconnection Customer may, within thirty (30) Calendar Days after receipt of the draft report, provide written comments to Transmission Provider, which Transmission Provider shall include in the final report. Transmission Provider shall issue the final Interconnection Facilities Study report within fifteen (15) Business Days of receiving Interconnection Customer's comments or promptly upon receiving Interconnection Customer's statement that it will not provide comments. Transmission Provider may reasonably extend such fifteen-day period upon notice to Interconnection Customer if Interconnection Customer's comments require Transmission Provider to perform additional analyses or make other significant modifications prior to the issuance of the final Interconnection Facilities Report. Upon request, Transmission Provider shall provide Interconnection Customer supporting documentation, workpapers, and databases or data developed in the preparation of the Interconnection Facilities Study, subject to confidentiality arrangements consistent with Section 13.1.

8.4 Meeting With Transmission Provider

Within ten (10) Business Days of providing a draft Interconnection Facilities Study report to Interconnection Customer, Transmission Provider and Interconnection Customer shall meet to discuss the results of the Interconnection Facilities Study.

8.5 Re-Study

If Re-Study of the Interconnection Facilities Study is required due to a higher queued project dropping out of the queue or a modification of a higher queued project pursuant to Section 4.4, Transmission Provider shall so notify Interconnection Customer in writing. Such Re-Study shall take no longer than sixty (60) Calendar Days from the date of notice. Any cost of Re-Study shall be borne by the Interconnection Customer being re-studied.

Section 9. Engineering & Procurement ('E&P') Agreement

Prior to executing an LGIA, an Interconnection Customer may, in order to advance the implementation of its interconnection, request and Transmission Provider shall offer the Interconnection Customer, an E&P Agreement that authorizes Transmission Provider to begin engineering and procurement of long lead-time items necessary for the establishment of the interconnection. However, Transmission Provider shall not be obligated to offer an E&P Agreement if Interconnection Customer is in Dispute Resolution as a result of an allegation that Interconnection Customer has failed to meet any milestones or comply with any prerequisites specified in other parts of the LGIP. The E&P Agreement is an optional procedure and it will not alter the Interconnection Customer's Queue Position or In-Service Date. The E&P Agreement shall provide for Interconnection Customer to pay the cost of all activities authorized by Interconnection Customer and to make

advance payments or provide other satisfactory security for such costs.

Interconnection Customer shall pay the cost of such authorized activities and any cancellation costs for equipment that is already ordered for its interconnection, which cannot be mitigated as hereafter described, whether or not such items or equipment later become unnecessary. If Interconnection Customer withdraws its application for interconnection or either Party terminates the E&P Agreement, to the extent the equipment ordered can be canceled under reasonable terms, Interconnection Customer shall be obligated to pay the associated cancellation costs. To the extent that the equipment cannot be reasonably canceled, Transmission Provider may elect: (i) To take title to the equipment, in which event Transmission Provider shall refund Interconnection Customer any amounts paid by Interconnection Customer for such equipment and shall pay the cost of delivery of such equipment, or (ii) to transfer title to and deliver such equipment to Interconnection Customer, in which event Interconnection Customer shall pay any unpaid balance and cost of delivery of such equipment.

Section 10. Optional Interconnection Study

10.1 Optional Interconnection Study Agreement

On or after the date when Interconnection Customer receives Interconnection System Impact Study results, Interconnection Customer may request, and Transmission Provider shall perform a reasonable number of Optional Studies. The request shall describe the assumptions that Interconnection Customer wishes Transmission Provider to study within the scope described in Section 10.2. Within five (5) Business Days after receipt of a request for an Optional Interconnection Study, Transmission Provider shall provide to Interconnection Customer an Optional Interconnection Study Agreement in the form of Appendix 5.

The Optional Interconnection Study Agreement shall: (i) Specify the technical data that Interconnection Customer must provide for each phase of the Optional Interconnection Study, (ii) specify Interconnection Customer's assumptions as to which Interconnection Requests with earlier queue priority dates will be excluded from the Optional Interconnection Study case and assumptions as to the type of interconnection service for Interconnection Requests remaining in the Optional Interconnection Study case, and (iii) Transmission Provider's estimate of the cost of the Optional Interconnection Study. To the extent known by Transmission Provider, such estimate shall include any costs expected to be incurred by any Affected System whose participation is necessary to complete the Optional Interconnection Study. Notwithstanding the above, Transmission Provider shall not be required as a result of an Optional Interconnection Study request to conduct any additional Interconnection Studies with respect to any other Interconnection Request.

Interconnection Customer shall execute the Optional Interconnection Study Agreement within ten (10) Business Days of receipt and deliver the Optional Interconnection Study Agreement, the technical data and a \$10,000 deposit to Transmission Provider.

10.2 Scope of Optional Interconnection Study

The Optional Interconnection Study will consist of a sensitivity analysis based on the assumptions specified by Interconnection Customer in the Optional Interconnection Study Agreement. The Optional Interconnection Study will also identify Transmission Provider's Interconnection Facilities and the Network Upgrades, and the estimated cost thereof, that may be required to provide transmission service or Interconnection Service based upon the results of the Optional Interconnection Study. The Optional Interconnection Study shall be performed solely for informational purposes. Transmission Provider shall use Reasonable Efforts to coordinate the study with any Affected Systems that may be affected by the types of Interconnection Services that are being studied. Transmission Provider shall utilize existing studies to the extent practicable in conducting the Optional Interconnection Study.

10.3 Optional Interconnection Study Procedures

The executed Optional Interconnection Study Agreement, the prepayment, and technical and other data called for therein must be provided to Transmission Provider within ten (10) Business Days of Interconnection Customer receipt of the Optional Interconnection Study Agreement. Transmission Provider shall use Reasonable Efforts to complete the Optional Interconnection Study within a mutually agreed upon time period specified within the Optional Interconnection Study Agreement. If Transmission Provider is unable to complete the Optional Interconnection Study within such time period, it shall notify Interconnection Customer and provide an estimated completion date and an explanation of the reasons why additional time is required. Any difference between the study payment and the actual cost of the study shall be paid to Transmission Provider or refunded to Interconnection Customer, as appropriate. Upon request, Transmission Provider shall provide Interconnection Customer supporting documentation and workpapers and databases or data developed in the preparation of the Optional Interconnection Study, subject to confidentiality arrangements consistent with Section 13.1.

Section 11. Standard Large Generator Interconnection Agreement (LGIA)

11.1 Tender

Interconnection Customer shall tender comments on the draft Interconnection Facilities Study Report within thirty (30) Calendar Days of receipt of the report. Within thirty (30) Calendar Days after the comments are submitted, Transmission Provider shall tender a draft LGIA, together with draft appendices. The draft LGIA shall be in the

form of Transmission Provider's FERC-approved standard form LGIA, which is in Appendix 6. Interconnection Customer shall execute and return the completed draft appendices within thirty (30) Calendar Days.

11.2 Negotiation

Notwithstanding Section 11.1, at the request of Interconnection Customer Transmission Provider shall begin negotiations with Interconnection Customer concerning the appendices to the LGIA at any time after Interconnection Customer executes the Interconnection Facilities Study Agreement. Transmission Provider and Interconnection Customer shall negotiate concerning any disputed provisions of the appendices to the draft LGIA for not more than sixty (60) Calendar Days after tender of the final Interconnection Facilities Study Report. If Interconnection Customer determines that negotiations are at an impasse, it may request termination of the negotiations at any time after tender of the draft LGIA pursuant to Section 11.1 and request submission of the unexecuted LGIA with FERC or initiate Dispute Resolution procedures pursuant to Section 13.5. If Interconnection Customer requests termination of the negotiations, but within sixty (60) Calendar Days thereafter fails to request either the filing of the unexecuted LGIA or initiate Dispute Resolution, it shall be deemed to have withdrawn its Interconnection Request. Unless otherwise agreed by the Parties, if Interconnection Customer has not executed the LGIA, requested filing of an unexecuted LGIA, or initiated Dispute Resolution procedures pursuant to Section 13.5 within sixty (60) Calendar Days of tender of draft LGIA, it shall be deemed to have withdrawn its Interconnection Request. Transmission Provider shall provide to Interconnection Customer a final LGIA within fifteen (15) Business Days after the completion of the negotiation process.

11.3 Execution and Filing

Within fifteen (15) Business Days after receipt of the final LGIA, Interconnection Customer shall provide Transmission Provider (A) reasonable evidence that continued Site Control or (B) posting of \$250,000, non-refundable additional security, which shall be applied toward future construction costs. At the same time, Interconnection Customer also shall provide reasonable evidence that one or more of the following milestones in the development of the Large Generating Facility, at Interconnection Customer election, has been achieved: (i) The execution of a contract for the supply or transportation of fuel to the Large Generating Facility; (ii) the execution of a contract for the supply of cooling water to the Large Generating Facility; (iii) execution of a contract for the engineering for, procurement of major equipment for, or construction of, the Large Generating Facility; (iv) execution of a contract for the sale of electric energy or capacity from the Large Generating Facility; or (v) application for an air, water, or land use permit.

Interconnection Customer shall either: (i) Execute two originals of the tendered LGIA

and return them to Transmission Provider; or (ii) request in writing that Transmission Provider file with FERC an LGIA in unexecuted form. As soon as practicable, but not later than ten (10) Business Days after receiving either the two executed originals of the tendered LGIA (if it does not conform with a FERC-approved standard form of interconnection agreement) or the request to file an unexecuted LGIA, Transmission Provider shall file the LGIA with FERC, together with its explanation of any matters as to which Interconnection Customer and Transmission Provider disagree and support for the costs that Transmission Provider proposes to charge to Interconnection Customer under the LGIA. An unexecuted LGIA should contain terms and conditions deemed appropriate by Transmission Provider for the Interconnection Request. If the Parties agree to proceed with design, procurement, and construction of facilities and upgrades under the agreed-upon terms of the unexecuted LGIA, they may proceed pending FERC action.

11.4 Commencement of Interconnection Activities

If Interconnection Customer executes the final LGIA, Transmission Provider and Interconnection Customer shall perform their respective obligations in accordance with the terms of the LGIA, subject to modification by FERC. Upon submission of an unexecuted LGIA, Interconnection Customer and Transmission Provider shall promptly comply with the unexecuted LGIA, subject to modification by FERC.

Section 12. Construction of Transmission Provider's Interconnection Facilities and Network Upgrades

12.1 Schedule

Transmission Provider and Interconnection Customer shall negotiate in good faith concerning a schedule for the construction of Transmission Provider's Interconnection Facilities and the Network Upgrades.

12.2 Construction Sequencing

12.2.1 General

In general, the In-Service Date of an Interconnection Customers seeking interconnection to the Transmission System will determine the sequence of construction of Network Upgrades.

12.2.2 Advance Construction of Network Upgrades That Are an Obligation of an Entity Other Than Interconnection Customer

An Interconnection Customer with an LGIA, in order to maintain its In-Service Date, may request that Transmission Provider advance to the extent necessary the completion of Network Upgrades that: (i) Were assumed in the Interconnection Studies for such Interconnection Customer, (ii) are necessary to support such In-Service Date, and (iii) would otherwise not be completed, pursuant to a contractual obligation of an entity other than Interconnection Customer that is seeking interconnection to the Transmission System, in time to support such In-Service Date. Upon such request, Transmission Provider will use Reasonable Efforts to advance the construction of such

Network Upgrades to accommodate such request; provided that Interconnection Customer commits to pay Transmission Provider: (i) Any associated expediting costs and (ii) the cost of such Network Upgrades.

Transmission Provider will refund to Interconnection Customer both the expediting costs and the cost of Network Upgrades, in accordance with Article 11.4 of the LGIA. Consequently, the entity with a contractual obligation to construct such Network Upgrades shall be obligated to pay only that portion of the costs of the Network Upgrades that Transmission Provider has not refunded to Interconnection Customer. Payment by that entity shall be due on the date that it would have been due had there been no request for advance construction. Transmission Provider shall forward to Interconnection Customer the amount paid by the entity with a contractual obligation to construct the Network Upgrades as payment in full for the outstanding balance owed to Interconnection Customer. Transmission Provider then shall refund to that entity the amount that it paid for the Network Upgrades, in accordance with Article 11.4 of the LGIA.

12.2.3 Advancing Construction of Network Upgrades That Are Part of an Expansion Plan of the Transmission Provider

An Interconnection Customer with an LGIA, in order to maintain its In-Service Date, may request that Transmission Provider advance to the extent necessary the completion of Network Upgrades that: (i) Are necessary to support such In-Service Date and (ii) would otherwise not be completed, pursuant to an expansion plan of Transmission Provider, in time to support such In-Service Date. Upon such request, Transmission Provider will use Reasonable Efforts to advance the construction of such Network Upgrades to accommodate such request; provided that Interconnection Customer commits to pay Transmission Provider any associated expediting costs. Interconnection Customer shall be entitled to transmission credits, if any, for any expediting costs paid.

12.2.4 Amended Interconnection System Impact Study

An Interconnection System Impact Study will be amended to determine the facilities necessary to support the requested In-Service Date. This amended study will include those transmission and Large Generating Facilities that are expected to be in service on or before the requested In-Service Date.

Section 13. Miscellaneous

13.1 Confidentiality

Confidential Information shall include, without limitation, all information relating to a Party's technology, research and development, business affairs, and pricing, and any information supplied by either of the Parties to the other prior to the execution of an LGIA.

Information is Confidential Information only if it is clearly designated or marked in writing as confidential on the face of the document, or, if the information is conveyed orally or by inspection, if the Party providing

the information orally informs the Party receiving the information that the information is confidential.

If requested by either Party, the other Party shall provide in writing, the basis for asserting that the information referred to in this Article warrants confidential treatment, and the requesting Party may disclose such writing to the appropriate Governmental Authority. Each Party shall be responsible for the costs associated with affording confidential treatment to its information.

13.1.1 Scope

Confidential Information shall not include information that the receiving Party can demonstrate: (1) Is generally available to the public other than as a result of a disclosure by the receiving Party; (2) was in the lawful possession of the receiving Party on a non-confidential basis before receiving it from the disclosing Party; (3) was supplied to the receiving Party without restriction by a third party, who, to the knowledge of the receiving Party after due inquiry, was under no obligation to the disclosing Party to keep such information confidential; (4) was independently developed by the receiving Party without reference to Confidential Information of the disclosing Party; (5) is, or becomes, publicly known, through no wrongful act or omission of the receiving Party or Breach of the LGIA; or (6) is required, in accordance with Section 13.1.6, Order of Disclosure, to be disclosed by any Governmental Authority or is otherwise required to be disclosed by law or subpoena, or is necessary in any legal proceeding establishing rights and obligations under the LGIA. Information designated as Confidential Information will no longer be deemed confidential if the Party that designated the information as confidential notifies the other Party that it no longer is confidential.

13.1.2 Release of Confidential Information

Neither Party shall release or disclose Confidential Information to any other person, except to its Affiliates (limited by the Standards of Conduct requirements), employees, consultants, or to parties who may be or considering providing financing to or equity participation with Interconnection Customer, or to potential purchasers or assignees of Interconnection Customer, on a need-to-know basis in connection with these procedures, unless such person has first been advised of the confidentiality provisions of this Section 13.1 and has agreed to comply with such provisions. Notwithstanding the foregoing, a Party providing Confidential Information to any person shall remain primarily responsible for any release of Confidential Information in contravention of this Section 13.1.

13.1.3 Rights

Each Party retains all rights, title, and interest in the Confidential Information that each Party discloses to the other Party. The disclosure by each Party to the other Party of Confidential Information shall not be deemed a waiver by either Party or any other person or entity of the right to protect the Confidential Information from public disclosure.

13.1.4 No Warranties

By providing Confidential Information, neither Party makes any warranties or representations as to its accuracy or completeness. In addition, by supplying Confidential Information, neither Party obligates itself to provide any particular information or Confidential Information to the other Party nor to enter into any further agreements or proceed with any other relationship or joint venture.

13.1.5 Standard of Care

Each Party shall use at least the same standard of care to protect Confidential Information it receives as it uses to protect its own Confidential Information from unauthorized disclosure, publication or dissemination. Each Party may use Confidential Information solely to fulfill its obligations to the other Party under these procedures or its regulatory requirements.

13.1.6 Order of Disclosure

If a court or a Government Authority or entity with the right, power, and apparent authority to do so requests or requires either Party, by subpoena, oral deposition, interrogatories, requests for production of documents, administrative order, or otherwise, to disclose Confidential Information, that Party shall provide the other Party with prompt notice of such request(s) or requirement(s) so that the other Party may seek an appropriate protective order or waive compliance with the terms of the LGIA. Notwithstanding the absence of a protective order or waiver, the Party may disclose such Confidential Information which, in the opinion of its counsel, the Party is legally compelled to disclose. Each Party will use Reasonable Efforts to obtain reliable assurance that confidential treatment will be accorded any Confidential Information so furnished.

13.1.7 Remedies

The Parties agree that monetary damages would be inadequate to compensate a Party for the other Party's Breach of its obligations under this Section 13.1. Each Party accordingly agrees that the other Party shall be entitled to equitable relief, by way of injunction or otherwise, if the first Party Breaches or threatens to Breach its obligations under this Section 13.1, which equitable relief shall be granted without bond or proof of damages, and the receiving Party shall not plead in defense that there would be an adequate remedy at law. Such remedy shall not be deemed an exclusive remedy for the Breach of this Section 13.1, but shall be in addition to all other remedies available at law or in equity. The Parties further acknowledge and agree that the covenants contained herein are necessary for the protection of legitimate business interests and are reasonable in scope. No Party, however, shall be liable for indirect, incidental, or consequential or punitive damages of any nature or kind resulting from or arising in connection with this Section 13.1.

13.1.8 Disclosure to FERC, Its Staff, or a State

Notwithstanding anything in this Section 13.1 to the contrary, and pursuant to 18 CFR

1b.20, if FERC or its staff, during the course of an investigation or otherwise, requests information from one of the Parties that is otherwise required to be maintained in confidence pursuant to the LGIP, the Party shall provide the requested information to FERC or its staff, within the time provided for in the request for information. In providing the information to FERC or its staff, the Party must, consistent with 18 CFR 388.112, request that the information be treated as confidential and non-public by FERC and its staff and that the information be withheld from public disclosure. Parties are prohibited from notifying the other Party prior to the release of the Confidential Information to FERC or its staff. The Party shall notify the other Party to the LGIA when it is notified by FERC or its staff that a request to release Confidential Information has been received by FERC, at which time either of the Parties may respond before such information would be made public, pursuant to 18 CFR 388.112. Requests from a state regulatory body conducting a confidential investigation shall be treated in a similar manner, consistent with applicable state rules and regulations.

13.1.9

Subject to the exception in Section 13.1.8, any information that a Party claims is competitively sensitive, commercial or financial information ("Confidential Information") shall not be disclosed by the other Party to any person not employed or retained by the other Party, except to the extent disclosure is (i) required by law; (ii) reasonably deemed by the disclosing Party to be required to be disclosed in connection with a dispute between or among the Parties, or the defense of litigation or dispute; (iii) otherwise permitted by consent of the other Party, such consent not to be unreasonably withheld; or (iv) necessary to fulfill its obligations under this LGIP or as a transmission service provider or a Control Area operator including disclosing the Confidential Information to an RTO or ISO or to a subregional, regional or national reliability organization or planning group. The Party asserting confidentiality shall notify the other Party in writing of the information it claims is confidential. Prior to any disclosures of the other Party's Confidential Information under this subparagraph, or if any third party or Governmental Authority makes any request or demand for any of the information described in this subparagraph, the disclosing Party agrees to promptly notify the other Party in writing and agrees to assert confidentiality and cooperate with the other Party in seeking to protect the Confidential Information from public disclosure by confidentiality agreement, protective order or other reasonable measures.

13.1.10

This provision shall not apply to any information that was or is hereafter in the public domain (except as a result of a Breach of this provision).

13.1.11

Transmission Provider shall, at Interconnection Customer's election, destroy,

in a confidential manner, or return the Confidential Information provided at the time of Confidential Information is no longer needed.

13.2 Delegation of Responsibility

Transmission Provider may use the services of subcontractors as it deems appropriate to perform its obligations under this LGIP. Transmission Provider shall remain primarily liable to Interconnection Customer for the performance of such subcontractors and compliance with its obligations of this LGIP. The subcontractor shall keep all information provided confidential and shall use such information solely for the performance of such obligation for which it was provided and no other purpose.

13.3 Obligation for Study Costs

Transmission Provider shall charge and Interconnection Customer shall pay the actual costs of the Interconnection Studies. Any difference between the study deposit and the actual cost of the applicable Interconnection Study shall be paid by or refunded, except as otherwise provided herein, to Interconnection Customer or offset against the cost of any future Interconnection Studies associated with the applicable Interconnection Request prior to beginning of any such future Interconnection Studies. Any invoices for Interconnection Studies shall include a detailed and itemized accounting of the cost of each Interconnection Study. Interconnection Customer shall pay any such undisputed costs within thirty (30) Calendar Days of receipt of an invoice therefor. Transmission Provider shall not be obligated to perform or continue to perform any studies unless Interconnection Customer has paid all undisputed amounts in compliance herewith.

13.4 Third Parties Conducting Studies

If (i) at the time of the signing of an Interconnection Study Agreement there is disagreement as to the estimated time to complete an Interconnection Study, (ii) Interconnection Customer receives notice pursuant to Sections 6.3, 7.4 or 8.3 that Transmission Provider will not complete an Interconnection Study within the applicable timeframe for such Interconnection Study, or (iii) Interconnection Customer receives neither the Interconnection Study nor a notice under Sections 6.3, 7.4 or 8.3 within the applicable timeframe for such Interconnection Study, then Interconnection Customer may require Transmission Provider to utilize a third party consultant reasonably acceptable to Interconnection Customer and Transmission Provider to perform such Interconnection Study under the direction of Transmission Provider. At other times, Transmission Provider may also utilize a third party consultant to perform such Interconnection Study, either in response to a general request of Interconnection Customer, or on its own volition.

In all cases, use of a third party consultant shall be in accord with Article 26 of the LGIA (Subcontractors) and limited to situations where Transmission Provider determines that doing so will help maintain or accelerate the study process for Interconnection Customer's pending Interconnection Request and not

interfere with Transmission Provider's progress on Interconnection Studies for other pending Interconnection Requests. In cases where Interconnection Customer requests use of a third party consultant to perform such Interconnection Study, Interconnection Customer and Transmission Provider shall negotiate all of the pertinent terms and conditions, including reimbursement arrangements and the estimated study completion date and study review deadline. Transmission Provider shall convey all workpapers, data bases, study results and all other supporting documentation prepared to date with respect to the Interconnection Request as soon as practicable upon Interconnection Customer's request subject to the confidentiality provision in Section 13.1. In any case, such third party contract may be entered into with either Interconnection Customer or Transmission Provider at Transmission Provider's discretion. In the case of (iii) Interconnection Customer maintains its right to submit a claim to Dispute Resolution to recover the costs of such third party study. Such third party consultant shall be required to comply with this LGIP, Article 26 of the LGIA (Subcontractors), and the relevant Tariff procedures and protocols as would apply if Transmission Provider were to conduct the Interconnection Study and shall use the information provided to it solely for purposes of performing such services and for no other purposes. Transmission Provider shall cooperate with such third party consultant and Interconnection Customer to complete and issue the Interconnection Study in the shortest reasonable time.

13.5 Disputes

13.5.1 Submission

In the event either Party has a dispute, or asserts a claim, that arises out of or in connection with the LGIA, the LGIP, or their performance, such Party (the "disputing Party") shall provide the other Party with written notice of the dispute or claim ("Notice of Dispute"). Such dispute or claim shall be referred to a designated senior representative of each Party for resolution on an informal basis as promptly as practicable after receipt of the Notice of Dispute by the other Party. In the event the designated representatives are unable to resolve the claim or dispute through unassisted or assisted negotiations within thirty (30) Calendar Days of the other Party's receipt of the Notice of Dispute, such claim or dispute may, upon mutual agreement of the Parties, be submitted to arbitration and resolved in accordance with the arbitration procedures set forth below. In the event the Parties do not agree to submit such claim or dispute to arbitration, each Party may exercise whatever rights and remedies it may have in equity or at law consistent with the terms of this LGIA.

13.5.2 External Arbitration Procedures

Any arbitration initiated under these procedures shall be conducted before a single neutral arbitrator appointed by the Parties. If the Parties fail to agree upon a single arbitrator within ten (10) Calendar Days of the submission of the dispute to arbitration, each Party shall choose one arbitrator who

shall sit on a three-member arbitration panel. The two arbitrators so chosen shall within twenty (20) Calendar Days select a third arbitrator to chair the arbitration panel. In either case, the arbitrators shall be knowledgeable in electric utility matters, including electric transmission and bulk power issues, and shall not have any current or past substantial business or financial relationships with any party to the arbitration (except prior arbitration). The arbitrator(s) shall provide each of the Parties an opportunity to be heard and, except as otherwise provided herein, shall conduct the arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("Arbitration Rules") and any applicable FERC regulations or RTO rules; provided, however, in the event of a conflict between the Arbitration Rules and the terms of this Section 13, the terms of this Section 13 shall prevail.

13.5.3 Arbitration Decisions

Unless otherwise agreed by the Parties, the arbitrator(s) shall render a decision within ninety (90) Calendar Days of appointment and shall notify the Parties in writing of such decision and the reasons therefor. The arbitrator(s) shall be authorized only to interpret and apply the provisions of the LGIA and LGIP and shall have no power to modify or change any provision of the LGIA and LGIP in any manner. The decision of the arbitrator(s) shall be final and binding upon the Parties, and judgment on the award may be entered in any court having jurisdiction. The decision of the arbitrator(s) may be appealed solely on the grounds that the conduct of the arbitrator(s), or the decision itself, violated the standards set forth in the Federal Arbitration Act or the Administrative Dispute Resolution Act. The final decision of the arbitrator must also be filed with FERC if it affects jurisdictional rates, terms and conditions of service, Interconnection Facilities, or Network Upgrades.

13.5.4 Costs

Each Party shall be responsible for its own costs incurred during the arbitration process and for the following costs, if applicable: (1) The cost of the arbitrator chosen by the Party to sit on the three member panel and one half of the cost of the third arbitrator chosen; or (2) one half the cost of the single arbitrator jointly chosen by the Parties.

13.5.5 Non-Binding Dispute Resolution Procedures

If a Party has submitted a Notice of Dispute pursuant to section 13.5.1, and the Parties are unable to resolve the claim or dispute through unassisted or assisted negotiations within the thirty (30) Calendar Days provided in that section, and the Parties cannot reach mutual agreement to pursue the section 13.5 arbitration process, a Party may request that Transmission Provider engage in Non-binding Dispute Resolution pursuant to this section by providing written notice to Transmission Provider ("Request for Non-binding Dispute Resolution"). Conversely, either Party may file a Request for Non-binding Dispute Resolution pursuant to this section without first seeking mutual

agreement to pursue the section 13.5 arbitration process. The process in section 13.5.5 shall serve as an alternative to, and not a replacement of, the section 13.5 arbitration process. Pursuant to this process, a Transmission Provider must within 30 days of receipt of the Request for Non-binding Dispute Resolution appoint a neutral decision-maker that is an independent subcontractor that shall not have any current or past substantial business or financial relationships with either Party. Unless otherwise agreed by the Parties, the decision-maker shall render a decision within sixty (60) Calendar Days of appointment and shall notify the Parties in writing of such decision and reasons therefore. This decision-maker shall be authorized only to interpret and apply the provisions of the LGIP and LGIA and shall have no power to modify or change any provision of the LGIP and LGIA in any manner. The result reached in this process is not binding, but, unless otherwise agreed, the Parties may cite the record and decision in the non-binding dispute resolution process in future dispute resolution processes, including in a section 13.5 arbitration, or in a Federal Power Act section 206 complaint. Each Party shall be responsible for its own costs incurred during the process and the cost of the decision-maker shall be divided equally among each Party to the dispute.

13.6 Local Furnishing Bonds

13.6.1 Transmission Providers That Own Facilities Financed by Local Furnishing Bonds

This provision is applicable only to a Transmission Provider that has financed facilities for the local furnishing of electric energy with tax-exempt bonds, as described in Section 142(f) of the Internal Revenue Code ("local furnishing bonds"). Notwithstanding any other provision of this LGIA and LGIP, Transmission Provider shall not be required to provide Interconnection Service to Interconnection Customer pursuant to this LGIA and LGIP if the provision of such Transmission Service would jeopardize the tax-exempt status of any local furnishing bond(s) used to finance Transmission Provider's facilities that would be used in providing such Interconnection Service.

13.6.2 Alternative Procedures for Requesting Interconnection Service

If Transmission Provider determines that the provision of Interconnection Service

requested by Interconnection Customer would jeopardize the tax-exempt status of any local furnishing bond(s) used to finance its facilities that would be used in providing such Interconnection Service, it shall advise the Interconnection Customer within thirty (30) Calendar Days of receipt of the Interconnection Request.

Interconnection Customer thereafter may renew its request for interconnection using the process specified in Article 5.2(ii) of the Transmission Provider's Tariff.

Appendix 1 to LGIP—Interconnection Request for a Large Generating Facility

1. The undersigned Interconnection Customer submits this request to interconnect its Large Generating Facility with Transmission Provider's Transmission System pursuant to a Tariff.

2. This Interconnection Request is for (check one):

- A proposed new Large Generating Facility.
- An increase in the generating capacity or a Material Modification of an existing Generating Facility.

3. The type of interconnection service requested (check one):

- Energy Resource Interconnection Service
- Network Resource Interconnection Service

4. Check here only if Interconnection Customer requesting Network Resource Interconnection Service also seeks to have its Generating Facility studied for Energy Resource Interconnection Service

5. Interconnection Customer provides the following information:

- a. Address or location or the proposed new Large Generating Facility site (to the extent known) or, in the case of an existing Generating Facility, the name and specific location of the existing Generating Facility;
- b. Maximum summer at ___ degrees C and winter at ___ degrees C megawatt electrical output of the proposed new Large Generating Facility or the amount of megawatt increase in the generating capacity of an existing Generating Facility;
- c. General description of the equipment configuration;
- d. Commercial Operation Date (Day, Month, and Year);
- e. Name, address, telephone number, and email address of Interconnection Customer's contact person;

- f. Approximate location of the proposed Point of Interconnection (optional);
- g. Interconnection Customer Data (set forth in Attachment A) and
- h. Primary frequency response operating range for electric storage resources.
- i. Requested capacity (in MW) of Interconnection Service (if lower than the Generating Facility Capacity).

6. Applicable deposit amount as specified in the LGIP.

7. Evidence of Site Control as specified in the LGIP (check one)

Is attached to this Interconnection Request
 Will be provided at a later date in accordance with this LGIP

8. This Interconnection Request shall be submitted to the representative indicated below: [To be completed by Transmission Provider]

9. Representative of Interconnection Customer to contact: [To be completed by Interconnection Customer]

10. This Interconnection Request is submitted by:

Name of Interconnection Customer: _____
 By (signature): _____
 Name (type or print): _____
 Title: _____
 Date: _____

Attachment A to Appendix 1 Interconnection Request

Large Generating Facility Data Unit Ratings

kVA _____ °F _____ Voltage _____
 Power Factor _____
 Speed (RPM) _____ Connection (e.g., Wye) _____
 Short Circuit Ratio _____ Frequency, Hertz _____
 Stator Amperes at Rated kVA _____ Field Volts _____
 Max Turbine MW _____ °F _____

Primary frequency response operating range for electric storage resources:
 Minimum State of Charge: _____
 Maximum State of Charge: _____

Combined Turbine-Generator-Exciter Inertia Data

Inertia Constant, H = _____ kW sec/kVA
 Moment-of-Inertia, WR² = _____ lb. ft.²

Reactance Data (Per Unit-Rated KVA)

	Direct axis	Quadrature axis
Synchronous—saturated	X _{dv} _____	X _{qv} _____
Synchronous—unsaturated	X _{di} _____	X _{qi} _____
Transient—saturated	X' _{dv} _____	X' _{qv} _____
Transient—unsaturated	X' _{di} _____	X' _{qi} _____
Subtransient—saturated	X'' _{dv} _____	X'' _{qv} _____
Subtransient—unsaturated	X'' _{di} _____	X'' _{qi} _____
Negative Sequence—saturated	X _{2v} _____	
Negative Sequence—unsaturated	X _{2i} _____	
Zero Sequence—saturated	X _{0v} _____	
Zero Sequence—unsaturated	X _{0i} _____	
Leakage Reactance	X _{lm} _____	

Field Time Constant Data (SEC)

Table with 3 columns: Field Time Constant Data (SEC), T'do, T'qo. Rows include Open Circuit, Three-Phase Short Circuit Transient, Line to Line Short Circuit Transient, Line to Neutral Short Circuit Transient, Short Circuit Subtransient, Open Circuit Subtransient.

Armature Time Constant Data (SEC)

Three Phase Short Circuit—T'a3
Line to Line Short Circuit—T'a2
Line to Neutral Short Circuit—T'a1

Note: If requested information is not applicable, indicate by marking "N/A."

MW Capability and Plant Configuration Large Generating Facility Data

Armature Winding Resistance Data (Per Unit)

Positive—R1
Negative—R2
Zero—R0
Rotor Short Time Thermal Capacity I2^2t =

Field Current at Rated kVA, Armature Voltage and PF = amps
Field Current at Rated kVA and Armature Voltage, 0 PF = amps
Three Phase Armature Winding Capacitance = microfarad
Field Winding Resistance = ohms C
Armature Winding Resistance (Per Phase) = ohms C

Curves

Provide Saturation, Vee, Reactive Capability, Capacity Temperature Correction curves. Designate normal and emergency Hydrogen Pressure operating range for multiple curves.

Generator Step-Up Transformer Data Ratings

Capacity; Self-cooled/Maximum Nameplate / kVA
Voltage Ratio (Generator Side/System side/Tertiary) / kV
Winding Connections (Low V/High V/Tertiary V (Delta or Wye)) /
Fixed Taps Available
Present Tap Setting

Impedance

Positive; Z1 (on self-cooled kVA rating) % X/R
Zero; Z0 (on self-cooled kVA rating) % X/R

Excitation System Data

Identify appropriate IEEE model block diagram of excitation system and power system stabilizer (PSS) for computer representation in power system stability simulations and the corresponding excitation system and PSS constants for use in the model.

Governor System Data

Identify appropriate IEEE model block diagram of governor system for computer

representation in power system stability simulations and the corresponding governor system constants for use in the model.

Wind Generators

Number of generators to be interconnected pursuant to this Interconnection Request:

Elevation: _____

Single Phase _____

Three Phase _____

Inverter manufacturer, model name, number, and version: _____

List of adjustable setpoints for the protective equipment or software: _____

Note: A completed General Electric Company Power Systems Load Flow (PSLF) data sheet or other compatible formats, such as IEEE and PTI power flow models, must be supplied with the Interconnection Request. If other data sheets are more appropriate to the proposed device, then they shall be provided and discussed at Scoping Meeting.

Induction Generators

- (* Field Volts:
(* Field Amperes:
(* Motoring Power (kW):
(* Neutral Grounding Resistor (If Applicable):
(* I2^2t or K (Heating Time Constant):
(* Rotor Resistance:
(* Stator Resistance:
(* Stator Reactance:
(* Rotor Reactance:
(* Magnetizing Reactance:
(* Short Circuit Reactance:
(* Exciting Current:
(* Temperature Rise:
(* Frame Size:
(* Design Letter:
(* Reactive Power Required In Vars (No Load):
(* Reactive Power Required In Vars (Full Load):
(* Total Rotating Inertia, H: Per Unit on KVA Base

Note: Please consult Transmission Provider prior to submitting the Interconnection Request to determine if the information designated by (*) is required.

Appendix 2 to LGIP—Interconnection Feasibility Study Agreement

This agreement is made and entered into this ___ day of ___, 20__ by and between ___, a ___ organized and existing under the laws of the State of ___, ("Interconnection Customer,") and ___ a ___

existing under the laws of the State of ___, ("Transmission Provider "). Interconnection Customer and Transmission Provider each may be referred to as a "Party," or collectively as the "Parties."

Recitals

Whereas, Interconnection Customer is proposing to develop a Large Generating Facility or generating capacity addition to an existing Generating Facility consistent with the Interconnection Request submitted by Interconnection Customer dated _____; and

Whereas, Interconnection Customer desires to interconnect the Large Generating Facility with the Transmission System; and

Whereas, Interconnection Customer has requested Transmission Provider to perform an Interconnection Feasibility Study to assess the feasibility of interconnecting the proposed Large Generating Facility to the Transmission System, and of any Affected Systems;

Now, therefore, in consideration of and subject to the mutual covenants contained herein the Parties agreed as follows:

1.0 When used in this Agreement, with initial capitalization, the terms specified shall have the meanings indicated in Transmission Provider's FERC-approved LGIP.

2.0 Interconnection Customer elects and Transmission Provider shall cause to be performed an Interconnection Feasibility Study consistent with Section 6.0 of this LGIP in accordance with the Tariff.

3.0 The scope of the Interconnection Feasibility Study shall be subject to the assumptions set forth in Attachment A to this Agreement.

4.0 The Interconnection Feasibility Study shall be based on the technical information provided by Interconnection Customer in the Interconnection Request, as may be modified as the result of the Scoping Meeting.

Transmission Provider reserves the right to request additional technical information from Interconnection Customer as may reasonably become necessary consistent with Good Utility Practice during the course of the Interconnection Feasibility Study and as designated in accordance with Section 3.4.4 of the LGIP. If, after the designation of the Point of Interconnection pursuant to Section 3.4.4 of the LGIP, Interconnection Customer modifies its Interconnection Request pursuant to Section 4.4, the time to complete the Interconnection Feasibility Study may be extended.

5.0 The Interconnection Feasibility Study report shall provide the following information:

- Preliminary identification of any circuit breaker short circuit capability limits exceeded as a result of the interconnection;
- preliminary identification of any thermal overload or voltage limit violations resulting from the interconnection; and
- preliminary description and non-bonding estimated cost of facilities required to interconnect the Large Generating Facility to the Transmission System and to address the identified short circuit and power flow issues.

6.0 Interconnection Customer shall provide a deposit of \$10,000 for the performance of the Interconnection Feasibility Study.

Upon receipt of the Interconnection Feasibility Study Transmission Provider shall charge and Interconnection Customer shall pay the actual costs of the Interconnection Feasibility Study.

Any difference between the deposit and the actual cost of the study shall be paid by or refunded to Interconnection Customer, as appropriate.

7.0 Miscellaneous. The Interconnection Feasibility Study Agreement shall include standard miscellaneous terms including, but not limited to, indemnities, representations, disclaimers, warranties, governing law, amendment, execution, waiver, enforceability and assignment, that reflect best practices in the electric industry, and that are consistent with regional practices, Applicable Laws and Regulations, and the organizational nature of each Party. All of these provisions, to the extent practicable, shall be consistent with the provisions of the LGIP and the LGIA.

In witness whereof, the Parties have caused this Agreement to be duly executed by their duly authorized officers or agents on the day and year first above written.

[Insert name of Transmission Provider or Transmission Owner, if applicable]

By: _____

Title: _____

Date: _____

By: _____

Title: _____

Date: _____

[Insert name of Interconnection Customer]

By: _____

Title: _____

Date: _____

**Attachment A to Appendix 2—
Interconnection Feasibility Study
Agreement**

**Assumptions Used in Conducting the
Interconnection Feasibility Study**

The Interconnection Feasibility Study will be based upon the information set forth in the Interconnection Request and agreed upon in the Scoping Meeting held on _____:

Designation of Point of Interconnection and configuration to be studied.

Designation of alternative Point(s) of Interconnection and configuration.

[Above assumptions to be completed by Interconnection Customer and other assumptions to be provided by Interconnection Customer and Transmission Provider]

**Appendix 3 to LGIP—Interconnection
System Impact Study Agreement**

This Agreement is made and entered into this ____ day of _____, 20__ by and between _____, a _____ organized and existing under the laws of the State of _____, (“Interconnection Customer,”) and _____ a _____ existing under the laws of the State of _____, (“Transmission Provider”). Interconnection Customer and Transmission Provider each may be referred to as a “Party,,” or collectively as the “Parties.”

Recitals

Whereas, Interconnection Customer is proposing to develop a Large Generating Facility or generating capacity addition to an existing Generating Facility consistent with the Interconnection Request submitted by Interconnection Customer dated _____; and

Whereas, Interconnection Customer desires to interconnect the Large Generating Facility with the Transmission System;

Whereas, Transmission Provider has completed an Interconnection Feasibility Study (the “Feasibility Study”) and provided the results of said study to Interconnection Customer (This recital to be omitted if Transmission Provider does not require the Interconnection Feasibility Study.); and

Whereas, Interconnection Customer has requested Transmission Provider to perform an Interconnection System Impact Study to assess the impact of interconnecting the Large Generating Facility to the Transmission System, and of any Affected Systems;

Now, therefore, in consideration of and subject to the mutual covenants contained herein the Parties agreed as follows:

1.0 When used in this Agreement, with initial capitalization, the terms specified shall have the meanings indicated in Transmission Provider’s FERC-approved LGIP.

2.0 Interconnection Customer elects and Transmission Provider shall cause to be performed an Interconnection System Impact Study consistent with Section 7.0 of this LGIP in accordance with the Tariff.

3.0 The scope of the Interconnection System Impact Study shall be subject to the assumptions set forth in Attachment A to this Agreement.

4.0 The Interconnection System Impact Study will be based upon the results of the Interconnection Feasibility Study and the technical information provided by Interconnection Customer in the Interconnection Request, subject to any modifications in accordance with Section 4.4 of the LGIP. Transmission Provider reserves the right to request additional technical information from Interconnection Customer as may reasonably become necessary consistent with Good Utility Practice during the course of the Interconnection Customer System Impact Study. If Interconnection Customer modifies its designated Point of Interconnection, Interconnection Request, or the technical information provided therein is modified, the time to complete the Interconnection System Impact Study may be extended.

5.0 The Interconnection System Impact Study report shall provide the following information:

- identification of any circuit breaker short circuit capability limits exceeded as a result of the interconnection;
- identification of any thermal overload or voltage limit violations resulting from the interconnection;
- identification of any instability or inadequately damped response to system disturbances resulting from the interconnection and
- description and non-binding, good faith estimated cost of facilities required to interconnect the Large Generating Facility to the Transmission System and to address the identified short circuit, instability, and power flow issues.

6.0 Interconnection Customer shall provide a deposit of \$50,000 for the performance of the Interconnection System Impact Study. Transmission Provider’s good faith estimate for the time of completion of the Interconnection System Impact Study is [insert date].

Upon receipt of the Interconnection System Impact Study, Transmission Provider shall charge and Interconnection Customer shall pay the actual costs of the Interconnection System Impact Study.

Any difference between the deposit and the actual cost of the study shall be paid by or refunded to Interconnection Customer, as appropriate.

7.0 Miscellaneous. The Interconnection System Impact Study Agreement shall include standard miscellaneous terms including, but not limited to, indemnities, representations, disclaimers, warranties, governing law, amendment, execution, waiver, enforceability and assignment, that reflect best practices in the electric industry, that are consistent with regional practices, Applicable Laws and Regulations and the organizational nature of each Party. All of these provisions, to the extent practicable, shall be consistent with the provisions of the LGIP and the LGIA.]

In witness thereof, the Parties have caused this Agreement to be duly executed by their duly authorized officers or agents on the day and year first above written.

[Insert name of Transmission Provider or Transmission Owner, if applicable]

By: _____

Title: _____

Date: _____

By: _____

Title: _____

Date: _____

[Insert name of Interconnection Customer]

By: _____

Title: _____

Date: _____

**Attachment A To Appendix 3—
Interconnection System Impact Study
Agreement**

**Assumptions Used in Conducting the
Interconnection System Impact Study**

The Interconnection System Impact Study will be based upon the results of the Interconnection Feasibility Study, subject to any modifications in accordance with

Section 4.4 of the LGIP, and the following assumptions:

Designation of Point of Interconnection and configuration to be studied.

Designation of alternative Point(s) of Interconnection and configuration.

[Above assumptions to be completed by Interconnection Customer and other assumptions to be provided by Interconnection Customer and Transmission Provider]

Appendix 4 to LGIP—Interconnection Facilities Study Agreement

THIS AGREEMENT is made and entered into this day ___ of ___, 20__ by and between ___, a ___ organized and existing under the laws of the State of ___, (“Interconnection Customer,”) and ___ a ___ existing under the laws of the State of ___, (“Transmission Provider”). Interconnection Customer and Transmission Provider each may be referred to as a “Party,” or collectively as the “Parties.”

Recitals

Whereas, Interconnection Customer is proposing to develop a Large Generating Facility or generating capacity addition to an existing Generating Facility consistent with the Interconnection Request submitted by Interconnection Customer dated ___; and

Whereas, Interconnection Customer desires to interconnect the Large Generating Facility with the Transmission System;

Whereas, Transmission Provider has completed an Interconnection System Impact Study (the “System Impact Study”) and provided the results of said study to Interconnection Customer; and

Whereas, Interconnection Customer has requested Transmission Provider to perform an Interconnection Facilities Study to specify and estimate the cost of the equipment, engineering, procurement and construction work needed to implement the conclusions of the Interconnection System Impact Study in accordance with Good Utility Practice to physically and electrically connect the Large Generating Facility to the Transmission System.

Now, therefore, in consideration of and subject to the mutual covenants contained herein the Parties agreed as follows:

1.0 When used in this Agreement, with initial capitalization, the terms specified shall have the meanings indicated in Transmission Provider’s FERC-approved LGIP.

2.0 Interconnection Customer elects and Transmission Provider shall cause an Interconnection Facilities Study consistent with Section 8.0 of this LGIP to be performed in accordance with the Tariff.

3.0 The scope of the Interconnection Facilities Study shall be subject to the assumptions set forth in Attachment A and the data provided in Attachment B to this Agreement.

4.0 The Interconnection Facilities Study report (i) shall provide a description, estimated cost of (consistent with Attachment A), schedule for required facilities to interconnect the Large Generating

Facility to the Transmission System and (ii) shall address the short circuit, instability, and power flow issues identified in the Interconnection System Impact Study.

5.0 Interconnection Customer shall provide a deposit of \$100,000 for the performance of the Interconnection Facilities Study. The time for completion of the Interconnection Facilities Study is specified in Attachment A.

Transmission Provider shall invoice Interconnection Customer on a monthly basis for the work to be conducted on the Interconnection Facilities Study each month. Interconnection Customer shall pay invoiced amounts within thirty (30) Calendar Days of receipt of invoice. Transmission Provider shall continue to hold the amounts on deposit until settlement of the final invoice.

6.0 Miscellaneous. The Interconnection Facility Study Agreement shall include standard miscellaneous terms including, but not limited to, indemnities, representations, disclaimers, warranties, governing law, amendment, execution, waiver, enforceability and assignment, that reflect best practices in the electric industry, and that are consistent with regional practices, Applicable Laws and Regulations, and the organizational nature of each Party. All of these provisions, to the extent practicable, shall be consistent with the provisions of the LGIP and the LGIA.

In witness whereof, the Parties have caused this Agreement to be duly executed by their duly authorized officers or agents on the day and year first above written.

[Insert name of Transmission Provider or Transmission Owner, if applicable]

By: _____

Title: _____

Date: _____

By: _____

Title: _____

Date: _____

[Insert name of Interconnection Customer]

By: _____

Title: _____

Date: _____

Attachment A To Appendix 4—Interconnection Facilities Study Agreement

Interconnection Customer Schedule Election for Conducting the Interconnection Facilities Study

Transmission Provider shall use Reasonable Efforts to complete the study and issue a draft Interconnection Facilities Study report to Interconnection Customer within the following number of days after of receipt of an executed copy of this Interconnection Facilities Study Agreement:

—Ninety (90) Calendar Days with no more than a ±20 percent cost estimate contained in the report, or

—one hundred eighty (180) Calendar Days with no more than a ±10 percent cost estimate contained in the report.

Attachment B to Appendix 4—Interconnection Facilities Study Agreement

Data Form To Be Provided by Interconnection Customer With the Interconnection Facilities Study Agreement

Provide location plan and simplified one-line diagram of the plant and station facilities. For staged projects, please indicate future generation, transmission circuits, etc.

One set of metering is required for each generation connection to the new ring bus or existing Transmission Provider station. Number of generation connections:

On the one line diagram indicate the generation capacity attached at each metering location. (Maximum load on CT/PT)

On the one line diagram indicate the location of auxiliary power. (Minimum load on CT/PT) Amps

Will an alternate source of auxiliary power be available during CT/PT maintenance?

Yes ___ No ___

Will a transfer bus on the generation side of the metering require that each meter set be designed for the total plant generation?

Yes ___ No ___ (Please indicate on one line diagram).

What type of control system or PLC will be located at Interconnection Customer’s Large Generating Facility?

What protocol does the control system or PLC use?

Please provide a 7.5-minute quadrangle of the site. Sketch the plant, station, transmission line, and property line.

Physical dimensions of the proposed interconnection station:

Bus length from generation to interconnection station:

Line length from interconnection station to Transmission Provider’s transmission line.

Tower number observed in the field. (Painted on tower leg) *

Number of third party easements required for transmission lines *:

* To be completed in coordination with Transmission Provider.

Is the Large Generating Facility in the Transmission Provider’s service area?

Yes ___ No ___

Local provider:

Please provide proposed schedule dates: Begin Construction:

Date: _____

Generator step-up transformer receives back feed power

Generation Testing _____

Date: _____

Commercial Operation

Date: _____

Appendix 5 to LGIP—Optional Interconnection Study Agreement

This Agreement is made and entered into this ___ day of _____, 20___ by and between _____, a _____ organized and existing under the laws of the State of _____, (“Interconnection Customer;”) and _____ a _____ existing under the laws of the State of _____, (“Transmission Provider”). Interconnection Customer and Transmission Provider each may be referred to as a “Party,” or collectively as the “Parties.”

Recitals

Whereas, Interconnection Customer is proposing to develop a Large Generating Facility or generating capacity addition to an existing Generating Facility consistent with the Interconnection Request submitted by Interconnection Customer dated _____;

Whereas, Interconnection Customer is proposing to establish an interconnection with the Transmission System; and

Whereas, Interconnection Customer has submitted to Transmission Provider an Interconnection Request; and

Whereas, on or after the date when Interconnection Customer receives the Interconnection System Impact Study results, Interconnection Customer has further requested that Transmission Provider prepare an Optional Interconnection Study;

Now, therefore, in consideration of and subject to the mutual covenants contained herein the Parties agree as follows:

1.0 When used in this Agreement, with initial capitalization, the terms specified shall have the meanings indicated in Transmission Provider’s FERC-approved LGIP.

2.0 Interconnection Customer elects and Transmission Provider shall cause an Optional Interconnection Study consistent with Section 10.0 of this LGIP to be performed in accordance with the Tariff.

3.0 The scope of the Optional Interconnection Study shall be subject to the assumptions set forth in Attachment A to this Agreement.

4.0 The Optional Interconnection Study shall be performed solely for informational purposes.

5.0 The Optional Interconnection Study report shall provide a sensitivity analysis based on the assumptions specified by Interconnection Customer in Attachment A to this Agreement. The Optional Interconnection Study will identify Transmission Provider’s Interconnection Facilities and the Network Upgrades, and the estimated cost thereof, that may be required to provide transmission service or interconnection service based upon the assumptions specified by Interconnection Customer in Attachment A.

6.0 Interconnection Customer shall provide a deposit of \$10,000 for the performance of the Optional Interconnection Study. Transmission Provider’s good faith estimate for the time of completion of the Optional Interconnection Study is [insert date].

Upon receipt of the Optional Interconnection Study, Transmission

Provider shall charge and Interconnection Customer shall pay the actual costs of the Optional Study.

Any difference between the initial payment and the actual cost of the study shall be paid by or refunded to Interconnection Customer, as appropriate.

7.0 Miscellaneous. The Optional Interconnection Study Agreement shall include standard miscellaneous terms including, but not limited to, indemnities, representations, disclaimers, warranties, governing law, amendment, execution, waiver, enforceability and assignment, that reflect best practices in the electric industry, and that are consistent with regional practices, Applicable Laws and Regulations, and the organizational nature of each Party. All of these provisions, to the extent practicable, shall be consistent with the provisions of the LGIP and the LGIA.

In witness whereof, the Parties have caused this Agreement to be duly executed by their duly authorized officers or agents on the day and year first above written.

[Insert name of Transmission Provider or Transmission Owner, if applicable]

By: _____

Title: _____

Date: _____

By: _____

Title: _____

Date: _____

[Insert name of Interconnection Customer]

By: _____

Title: _____

Date: _____

Appendix 6 to LGIP—Large Generator Interconnection Agreement (See LGIA)

Appendix 7—Interconnection Procedures for a Wind Generating Plant

Appendix 7 sets forth procedures specific to a wind generating plant. All other requirements of this LGIP continue to apply to wind generating plant interconnections.

A. Special Procedures Applicable to Wind Generators

The wind plant Interconnection Customer, in completing the Interconnection Request required by section 3.3 of this LGIP, may provide to the Transmission Provider a set of preliminary electrical design specifications depicting the wind plant as a single equivalent generator. Upon satisfying these and other applicable Interconnection Request conditions, the wind plant may enter the queue and receive the base case data as provided for in this LGIP.

No later than six months after submitting an Interconnection Request completed in this manner, the wind plant Interconnection Customer must submit completed detailed electrical design specifications and other data (including collector system layout data) needed to allow the Transmission Provider to complete the System Impact Study.

United States of America—Federal Energy Regulatory Commission

Building for the Future Through Electric Regional Transmission Planning and Cost Allocation and Generator Interconnection

Docket No. RM21–17–000

(Issued April 21, 2022)

DANLY, Commissioner, *dissenting*:

1. I welcome long term transmission planning reform. I would prefer that Regional Transmission Organizations (RTOs) and other interested public utilities simply file their own proposals under section 205 of the Federal Power Act (FPA). They are fully capable of proposing rate changes and reforms on their own.¹

2. This Notice of Proposed Rulemaking (NOPR) goes far beyond that. It contemplates a Federal Power Act section 206 finding that existing transmission planning across the nation—in every region, for every utility and market—is so unjust and unreasonable that it must be replaced with mandatory, pervasive, and invasive “reforms.”² But let us be clear. The NOPR’s primary purpose is to achieve narrow environmental policy objectives, not to address legitimate requirements under the Federal Power Act like ensuring just and reasonable rates or reliability. After all, as the NOPR itself repeatedly admits, it is “driven by changes in resource mix and demand,”³ notwithstanding its references to genuine problems with existing transmission planning.⁴

3. The majority seeks to establish policies designed to encourage the massive transmission build-out that will doubtless be required to transition to an aspirational renewable future. To do so, they need to socialize the costs of this transmission across as broad a population of ratepayers as possible. Thus, they seek to use the FPA, a statute that sounds in rate regulation and reliability, as a tool to achieve a particular (and inapposite) policy goal. In this regard, it is much like the majority’s recent foray into transforming our pipeline certification process into a comprehensive environmental review.⁵ Accordingly, I must dissent.

¹ See, e.g., New England Power Pool Participants Committee October 12, 2021 Comments at 4–8 (detailing past and current transmission planning activities).

² *Building for the Future Through Elec. Reg’l Transmission Planning & Cost Allocation & Generator Interconnection*, 179 FERC ¶ 61,028 (2022) (“NOPR”); see also *Building for the Future Through Elec. Reg’l Transmission Planning & Cost Allocation & Generator Interconnection*, 176 FERC ¶ 61,024 (2021) (“ANOPR”).

³ The NOPR uses the phrase “driven by changes in the resource mix and demand” 116 times. These are code words for “renewables.” See NOPR, 179 FERC ¶ 61,028 at P 45 (detailing “[t]hese changes in the resource mix and demand,” almost all of which involve the transition to renewable resources).

⁴ See *id.* PP 37–41, 48–49. Nearly every other preliminary finding related to current transmission planning is tied to “changes in the resource mix and demand.”

⁵ See *Certification of New Interstate Nat. Gas Facilities*, 178 FERC ¶ 61,107, *order dismissing reh’g requests, Certification of New Interstate Nat.*

4. I normally would not oppose a NOPR. What is wrong with asking questions and seeking a record to consider reforms? But this NOPR is a boondoggle. It seeks to change virtually all aspects of transmission planning, including in non-RTO regions and it does so for the specific, though unstated, purpose of suborning the transmission planning process so it can be wielded as a tool to support the development of a specific set of favored generation resources. How does it do this? The NOPR proposes to require regions to factor in any state or even “local” (!) public policy (read, renewable) goals, no matter how far-fetched.⁶ If San Francisco, for example, passes an ordinance that all its energy must be solar no matter the cost, CAISO and perhaps all western regional planning now must take that into account in their transmission plans. And what if the local policy is unreasonable? Or what if a state has far more aggressive goals than another state? No matter: All must plan for the dreams of others.

5. The Federal Power Act requires just and reasonable rates. That prohibits the Commission from charging ratepayers for unneeded transmission projects to accommodate someone else’s view of what types of generation might be preferable. And we are not talking about economic or reliability projects. The transmission at issue here is that required to accommodate state and local laws establishing the composition of their generation fleets. Choosing their own generation mix is undoubtedly their right, since such choices are unambiguously reserved to the states under the FPA, but the FPA does not require the Commission to accommodate these policies under either of its core statutory obligations: To ensure just and reasonable rates and to ensure reliability. In fact, it is quite the opposite, the NOPR risks further undue discrimination. Nevertheless, the NOPR starts from the premise that such projects must be considered in regional planning.

6. Even if no transmission projects are ever selected under the new regional planning regime, the process imposed by the NOPR itself will substantially increase customer costs. As Arizona’s largest utility commented in the record, “[w]hile [Arizona Public Service Company] acknowledges the Commission’s desire to construct transmission for a quicker transition to a clean energy mix, unbound[ed] study work would lengthen timelines, thereby increasing the associated costs, for both the transmission planning process and the generator interconnection process.”⁷

7. The NOPR not only is too expansive, it also is too specific. It proposes scores of detailed mandates. One such mandate, for example, is that four is the minimum number of planning scenarios a public utility must study, and that if one of the scenarios is a “base case,” that one must be “most likely.”⁸ “[A]t least one of the four distinct” scenarios

“must account for uncertain operational outcomes . . . during high-impact, low-frequency events” but we do “allow” utilities “to determine *which* . . . high-impact, low-frequency event should be modeled.”⁹ Woe unto the utility that conducts long term planning by considering a fewer number of scenarios, but you do get to pick your favorite high-impact, low-frequency event.

8. Entire sections of the NOPR read like a think tank’s wish list rather than a rigorous analysis of whether such Nice-to-Have ideas are required for just and reasonable, non-discriminatory ratemaking. For some reason, the NOPR proposes that dynamic line ratings and advanced power flow control devices must be the default when studying any new transmission or generation solution “in all aspects of the regional transmission planning processes, including the existing regional transmission planning processes for near-term regional transmission needs.”¹⁰ Never mind that we already have a Notice of Inquiry on dynamic line ratings.¹¹ And I thought this proceeding was about long-term planning? For some other reason, the NOPR has a section on “Specificity of Data Inputs”¹² which defines the “best available data” everyone in the industry must use in their planning, particularly endorsing “the most recent data on renewable energy potential and distributed energy resources developed by national labs.”¹³ The NOPR also considers a mandate to establish a “periodic forum” to study best practices and additional reforms.¹⁴ Why would this need to be mandated? Must the Commission control everything? Is no one in the industry capable of such foresight absent our intervention? And, by the way, the NOPR also proposes (in the name of “transparency”) to require new levels of “enhancements” and oversight for local transmission planning, by requiring utilities to incorporate detailed tariff amendments to describe their local planning processes.¹⁵ It also obligates them to consider, among other things, requirements for how utilities should be “right-sizing” transmission facilities, and whether we should mandate information requirements on “estimated in-kind replacements of . . . existing transmission.”¹⁶ Does this not seem like overly prescriptive regulatory meddling?

9. And yet—notwithstanding its bulk and granularity—the NOPR fails to clarify the single most critical question confronting individual states and consumers: Will unwilling states’ ratepayers be required to pay for their neighboring state’s new transmission project which is being built solely for the purpose of achieving that neighboring state’s (or locality’s) public policy goals? The NOPR leaves open what happens if states cannot voluntarily agree on

such issues,¹⁷ but many will seek to have the RTO allocate costs as it sees fit, including to unwilling states. I oppose forcing the ratepayers in states with different public policy goals to pay for another state’s plans.

10. According to a 2018 summary by the National Conference of State Legislatures, 24 states either did not have any renewable portfolio standard or it had expired or was set to expire: Alabama, Alaska, Arkansas, Florida, Georgia, Idaho, Iowa (expired), Kansas (expired), Kentucky, Louisiana, Michigan (expired in 2021), Mississippi, Missouri (expired in 2021), Montana (expired), Nebraska, North Carolina (expired in 2021), North Dakota (expired), Oklahoma (expired), Pennsylvania (expired in 2021), South Dakota (expired), Tennessee, West Virginia, Wisconsin (expired), and Wyoming.¹⁸ Renewable standards in an additional 3 states were voluntary: Indiana, South Carolina, and Utah.¹⁹ That 27 states lack mandatory renewable portfolio standards rather suggests that the country is divided on this issue.

11. Not surprisingly, states are among the primary opponents of the reforms contemplated in the ANOPR, many of which have survived through to the issuance of today’s NOPR. The Utah Public Service Commission correctly commented “that FERC seeks to reshape transmission planning and cost allocation for the purpose of expanding the transmission system ‘in areas with high degrees of renewable resources’ that require ‘extensive’ and ‘more expensive’ new transmission facilities.”²⁰ The Utah Public Service Commission explained that: [I]ncreased development and integration of renewable generation is a highly charged political question and a matter of significant political interest. Different states’ legislatures have made different policy choices. Some states, like California, have enacted very ambitious laws that require revolutionary changes to their generation mixes. As the [ANOPR] makes clear, these changes require significant investment in, among other things, new transmission infrastructure to wheel renewable generation.

* * * * *

The [Utah Public Service Commission] is deeply concerned the [ANOPR] advertises an interest in rewriting the rules governing transmission planning and cost allocation to better facilitate policy choices, not of Congress, but of particular state legislatures. More specifically, the [Utah Public Service Commission] is opposed to any rule change that would allow such preferences to impose costs on ratepayers in other states.²¹

12. Different policy goals are a critical reason for state opposition to a federal transmission planning regime, but certainly not the only one. The Louisiana Public Service Commission explained:

¹⁷ *Id.* P 310.

¹⁸ See *State Renewable Portfolio Standards & Goals*, National Conference of State Legislatures (Aug. 13, 2021), <https://www.ncsl.org/research/energy/renewable-portfolio-standards.aspx>.

¹⁹ See *id.*

²⁰ Utah Public Service Commission October 8, 2021 Comments at 2 (citing ANOPR, 176 FERC ¶ 61,024 at P 40).

²¹ *Id.* at 2–3.

⁹ *Id.* P 124 (emphasis added).

¹⁰ *Id.* P 274.

¹¹ *Implementation of Dynamic Line Ratings*, 178 FERC ¶ 61,110 (2022).

¹² NOPR, 179 FERC ¶ 61,028 at PP 91, 127–134.

¹³ *Id.* P 131 & n.247 (citing National Renewable Energy Laboratory’s Renewable Energy Potential model and Distributed Generation Market Demand model).

¹⁴ *Id.* P 255.

¹⁵ *Id.* PP 7, 400–415.

¹⁶ *Id.* PP 414–415.

Gas Facilities, 179 FERC ¶ 61,012 (2022); see also *Certification of New Interstate Nat. Gas Facilities*, 178 FERC ¶ 61,197 (2022).

⁶ NOPR, 179 FERC ¶ 61,028 at PP 104, 106.

⁷ Arizona Public Service Company October 12, 2021 Comments at 4.

⁸ NOPR, 179 FERC ¶ 61,028 at P 123.

the Commission proposes to change transmission planning and cost allocation to support a new fleet of renewable generating resources in preference to other types of generation. But it is not within the Commission's FPA authority, or within the ambit of sound transmission planning, to dictate the choice of generating resources and then determine what planning and cost allocation metrics will lead to the appearance of an economic transmission build-out to support those resources. This approach interferes with the jurisdiction and authority of the states, fails to recognize regional differences, and could stifle innovation and the development of the most reliable and beneficial solutions at the least delivered energy and capacity cost.

Many of the ANOPR's proposals would not achieve just and reasonable rates, and, in fact, could lead in the opposite direction. They would dramatically increase costs imposed on consumers while potentially jeopardizing the reliability of the grid. Renewable resources are inherently intermittent and not dispatchable. They do not and will not have the same reliability benefits as thermal generation without significant technological investment and/or duplicative back-up power costs. Consumer costs should not increase without a corresponding benefit, and certainly not in the face of diminished reliability, one of the bedrock principles of electric rate regulation.²²

13. I also attended the meetings of the joint federal-state task force on electric transmission in which numerous state commissioners voiced their concern that federal transmission planning regimes would be imposed upon the states, that the Commission would insist on uniformity throughout the country, and most importantly, that the Commission might require their state's ratepayers to shoulder the costs of another state's transmission projects.²³ It should go without saying that the Commission would be wise to proceed with caution before acting in the face of state opposition.

14. The NOPR raises another serious issue: I do not know how most of these proposals are supposed to work in non-RTO regions. Nor, apparently, does anyone else. This may explain the repeated entreaties for the Commission to allow regional variation in transmission planning. For example: the [Sponsors of the Southeastern Regional Transmission Planning Process (SERTP Sponsors)] are concerned that a one-size-fits-all adoption of some of the items contemplated in the ANOPR could prove counter-productive or unworkable in the SERTP's expansive, twelve-state, non-RTO footprint. The SERTP Sponsors respectfully submit that the Commission's rules concerning regional transmission planning should continue to accommodate varying

approaches to transmission and system planning in recognition of the inherent variability of existing market structures, state policies and requirements, locally available resources, and customer needs that prevail throughout the country.²⁴

15. It likewise is doubtful that many of the problems highlighted in the NOPR apply to the entire country or even extend beyond certain RTOs. In the southeast, at least, where there is no RTO, public utilities added 3,158 miles of new transmission and 6,989 miles of uprates between 2015–2020, representing 12% of all transmission in the region.²⁵ This non-RTO region provided detailed record evidence that strongly suggests it is managing transmission expansion and renewable integration as well as or better than any RTO.²⁶ Somehow this evidence evaded discussion in the NOPR and the Commission, regardless of the record evidence, seems intent on subjecting all public utilities, even those outside of the RTOs, to the same planning requirements.²⁷

16. Even RTOs are calling for the Commission to recognize regional differences and not to impose uniform federal mandates. The New England Power Pool, for example, tells us in its ANOPR comments that “[t]he Commission should allow ISO-NE, NEPOOL, the [transmission owners in New England] and the New England States to continue to have the flexibility to develop solutions in planning, cost allocation and generator interconnection that work best for New England”²⁸

17. I recognize that there are at least some stakeholders, particularly in RTOs, that want guidance or direction from the Commission to address the current or potential lack of stakeholder consensus for transmission planning reforms. But replacing the stakeholder process with FERC-driven mandates only pleases the subset of stakeholders who agree with the mandates. It is another way to overrule voices in opposition.

18. The numerous comments in response to the ANOPR requesting the continued recognition of regional differences underscore one of my primary concerns. I simply disagree that the record before us supports the scope and profundity of change the Commission seeks to impose. Other broad Commission rulemakings have had sufficient record support to satisfy our statutory obligations. Here, I am doubtful. I agree with the comments of the U.S. Chamber of Commerce which stated that:

the Commission should seriously consider the gravity of this undertaking and its potential significant impacts on both the reliability and the cost of electricity for

²⁴ Sponsors of the Southeastern Regional Transmission Planning Process October 12, 2021 Comments at 2.

²⁵ See *id.* at 11.

²⁶ See *id.* at 12–14 (detailing renewable integration in the southeast on a state-by-state basis).

²⁷ See, e.g., NOPR, 179 FERC ¶ 61,028 at P 3 (“the reforms proposed in this NOPR would require public utility transmission providers” to amend their tariffs) (emphasis added).

²⁸ New England Power Pool Participants Committee October 12, 2021 Comments at 8.

businesses and consumers across the country. Many of the policies and procedures subject to reevaluation in this docket have served their intended purposes. They should not be abruptly jettisoned without a thorough evaluation of the costs and benefits resulting from any significant transmission planning and interconnection policy changes.²⁹

19. In the same vein, the Large Public Power Council “asks the Commission to be careful not to disrupt planning and cost allocation principles within and outside ISOs/RTO structures *that are currently working, and pursuant to which transmission is being planned and developed.*”³⁰ Again, there is no mention of this argument or the supporting evidence in the NOPR.

20. The NOPR solicits further comment, but it also plainly anticipates rule changes for which my own review of the record indicates only partial, or lukewarm, or minimal support. The most common comment I have seen in the record, and at the task force meetings, as I have already highlighted above, is some variation of “regional planning is a good idea, and reform is needed, but please do not tell us what to do.” Well, here are 450 pages of the Commission proposing to tell you what to do.

21. I freely acknowledge that the NOPR includes several potentially reasonable ideas for reform. But that is not the test under section 206 of the FPA. We are not the Good Ideas Commission. We must have substantial record evidence that the existing rate is unjust and unreasonable. We must find that the current planning processes are so unacceptable that the existing system essentially must be scrapped. We must also have record evidence that the replacement rate—the final rule to follow the NOPR—is just and reasonable. We owe it to the jurisdictional entities and the ratepayers to assure ourselves that each of the prescriptive requirements we seek to impose are actually necessary to ensure a just and reasonable, non-discriminatory replacement rate. I certainly do not see the required evidentiary support in the record we have compiled to date and I am skeptical that I will ever see it.

22. Every single party with an interest should file in this docket. And many parties will. The sheer scope of the NOPR means that there is likely to be at least some support in the record for just about anything. I must therefore underscore that it is critical for parties filing comments in response to the NOPR to be *direct and clear*. This can be as simple as styling comments as “Comments in Opposition” when the filing party opposes any significant part of the NOPR. For example, if you are one of the numerous parties that filed comments in the ANOPR proceeding requesting that “[i]n any final rule that comes out of this rulemaking proceeding the Commission should allow for regional variations and flexibility in compliance for RTO/ISO regions,”³¹ or for

²⁹ Chamber of Commerce of the United States of America October 12, 2021 Comments at 1.

³⁰ Large Public Power Council October 12, 2021 Comments at 5 (emphasis added).

³¹ New England Power Pool Participants Committee October 12, 2021 Comments at 7.

²² Louisiana Public Service Commission October 12, 2021 Comments at 2–3.

²³ See, e.g., *Joint Fed.-State Task Force on Elec. Transmission*, 175 FERC ¶ 61,224 (2021) (establishing task force); see *Joint Fed.-State Task Force on Elec. Transmission*, FERC (last updated Apr. 4, 2022), <https://www.ferc.gov/TFSOET>.

non-RTO regions, then I strongly suggest that you file “Comments in Opposition” to the NOPR. The NOPR appears to anticipate only limited regional flexibility.³²

23. I further specifically request itemized lists from each commenting party indicating whether it supports, opposes, or abstains as to each of the NOPR’s preliminary findings and proposed reforms. The Commission’s ultimate findings cannot rest merely on a tally of votes, but the scope of this proceeding would make such basic summaries of the comments immensely helpful and will aid the Commission in its review of the (already) voluminous record.

24. To the extent possible, every part of a comment should directly respond to a particular preliminary finding or proposal in the NOPR. The ANOPR comments have been filed and reviewed. The time for generic comments, “principles” of planning, the voicing of general support and the like is over and such comments will be nearly without value in the face of page after page of detailed, specific preliminary findings and proposed requirements. Do you support the finding or not? Do you support the proposal or not?

25. And in voicing your support or opposition, I also remind commenting parties to submit hard data whenever possible, including in affidavits, to help the Commission meet—or not—both of the required legal showings for this section 206 proposal (that existing rates are unjust and unreasonable, and that the proposed replacement rate is just and reasonable). I am fully aware that parties have limited resources to comment on the Commission’s generic proceedings. And while the scope of this NOPR will inevitably make this an expensive and burdensome endeavor for commenters, I urge you not to rest solely on your ANOPR comments. Support or opposition to the specific proposals in the NOPR is necessary. It will be worth the effort. After all, the only thing at stake in this proceeding is nearly everything connected with transmission planning.

26. Parties should remember that this is not the final rule. The Commission can issue a final rule that contains any provision based on substantial evidence and that is a “logical outgrowth”³³ of the provisions in today’s proposed rule. That gives wide berth for any number of ultimate outcomes. In other words, this rule, when finalized, could be substantially different. Given what is at stake, be certain to inform the Commission of your positions on every element of the NOPR that could possibly be of concern to you.

27. In this regard, I strongly object to our 75- and 30-day comment and reply periods. Commenting parties presumably do not have hundreds of hours to wade through 450 pages of detailed proposals and to marshal evidence and legal argument for or against every potential change. I am not sure how the same Commission that just set up an Office of Public Participation thinks anyone can reasonably comment on every detail in this tome in 6 months, let alone 75 days. In

another proceeding today, we provide RTOs with 6 months to file reports on potential “modernizing” reforms to electricity markets, yet here, where no less than the entirety of transmission planning is at stake, we suddenly are in a rush.³⁴

28. Do not forget that we are also actively considering interconnection queue reforms, albeit separately, which might be an even greater priority. If we are going to propose comprehensive transmission planning changes in a rulemaking, regional planning and transmission interconnection queue reform should not be considered in silos.

29. While I think this NOPR is a mistake, I am happy to be convinced that particular reforms are justified by sound legal argument and solid record evidence. Where reform is needed to ensure just and reasonable rates and reliable service, and the reform itself is just and reasonable, I can be persuaded that it is worthy of support. I nevertheless reiterate my strong preference that we allow public utilities to file their own transmission planning solutions under FPA section 205. The Commission does not need to issue rules to change everything. Sometimes it is better to build incrementally to improve the current system, rather than to scrap everything and start from scratch. In my view, if an RTO or public utility wants to “enhance” its regional planning, it can figure out how to do so. And if the Commission really believes that we cannot rely on public utilities to seek more efficient transmission planning of their own volition, my second option would be to issue section 206 orders requiring the RTOs to show cause why their existing transmission planning processes are just and reasonable. Whether you agree or disagree with these alternative procedural vehicles for change, please say so in your comments.

30. I conclude with a note of caution. A transmission planning revolution opposed by half of the country risks becoming a transmission planning civil war. The Commission should not cram “reforms” down the throats of opponents on issues of such deep division, such as whether we can force utilities in unwilling states to consider the transmission needs of other states’ policy aspirations. The result will be protracted proceedings, litigation, and risk. Who is going to fund a transmission project in such an environment, in the face of the perpetual risk that it might have its costs “reallocated”?

For these reasons, I respectfully dissent.

James P. Danly,

Commissioner.

United States of America Federal Energy Regulatory Commission

Building for the Future Through Electric Regional Transmission Planning and Cost Allocation and Generator Interconnection

Docket No. RM21–17–000

(Issued April 21, 2022)

CHRISTIE, Commissioner, *concurring*:

1. The broad purpose of this Commission’s oversight of transmission planning under the

Federal Power Act (FPA) is to provide consumers with reliable power at just and reasonable rates. I am voting for this Notice of Proposed Rulemaking (NOPR) because I believe it contains some very good proposals that could protect consumers from paying unjust and unreasonable rates for transmission service while also supporting the delivery of reliable power to those consumers. I also believe it comports with our legal authority under the FPA.

2. First, the legal framework: While the FPA gives this Commission authority over “the transmission of electric energy in interstate commerce,”¹ the Commission has no authority to encroach on matters regulated by the states.² The planning, approval and siting of the *generation* resources necessary to meet the needs of customers in a state are under the regulatory authority of the states, not the Commission.³ States can prefer, mandate or subsidize specific types of generation resources, but the Commission cannot use its authority over transmission to pressure, steer or require regional planning entities to act as the Commission’s agents and do indirectly what the Commission cannot do directly. The Commission is not a national integrated resource planner. Order No. 1000, to its credit, recognized this clear delineation between federal and state authority.⁴

3. Further, under the FPA our authority over transmission planning and cost allocation must ensure that wholesale transmission rates are not unjust and unreasonable.⁵ We also have the authority to promote the reliability of the bulk power grid.⁶ Those are *consumer protection* functions, not a license to promote the policy goals of any presidential administration or of any corporate or special-interest group that have not been enacted into law in the FPA or any other federal statute.

4. With that legal framework in mind, I am voting in favor of issuing this NOPR at this time and in this form because, on the whole, I find the current draft is consistent with our authority under the FPA and contains some important and constructive proposals that will serve the consumer protection goals of just and reasonable rates and reliability.

5. For example, and as described more fully below, this NOPR will *formally* put the states—for the first time—at the center of regional transmission planning and cost allocation decision-making for policy-driven projects in *all* regional transmission entities,

¹ 16 U.S.C. 824(b)(1).

² *Id.* § 824(a).

³ *Id.* § 824(b)(1).

⁴ *Transmission Planning and Cost Allocation by Transmission Owning and Operating Public Utilities*, Order No. 1000, 136 FERC ¶ 61,051, at P 154 (2011), *order on reh’g*, Order No. 1000–A, 139 FERC ¶ 61,132, *order on reh’g and clarification*, Order No. 1000–B, 141 FERC ¶ 61,044 (2012), *aff’d sub nom. S.C. Pub. Serv. Auth. v. FERC*, 762 F.3d 41 (DC Cir. 2014) (“[T]he regional transmission planning process is not the vehicle by which integrated resource planning is conducted; that may be a separate obligation imposed on many public utility transmission providers and under the purview of the states.”) (emphases added); *see also id.* PP 107, 156.

⁵ 16 U.S.C. 824e(a).

⁶ *Id.* § 824o.

³² *See* NOPR, 179 FERC ¶ 61,028 at PP 183, 355.

³³ *See, e.g., Sierra Club v. Costle*, 657 F.2d 298, 352 (D.C. Cir. 1981).

³⁴ *See Modernizing Wholesale Elec. Mkt. Design*, 179 FERC ¶ 61,029 at P 1 (2022).

if the states choose.⁷ As another valuable example, also described below, the NOPR will shift the risk of financing policy-driven projects from consumers back to developers, where it should be.

6. Let me also emphasize that this is a NOPR—the “P” stands for “Proposed”—it is not a final rule. This is only another step in a long process. I look forward to reviewing the comments reacting to it, which I suspect will come in significant quantities. My vote on any final rule will, of course, be based on the text of that final rule. I will not support any final rule that exceeds our FPA authority and/or threatens to cause unjust and unreasonable rates to consumers.

7. When we issued the ANOPR last summer,⁸ I said:

This ANOPR contains a number of good proposals, some *potentially* good proposals (depending on how they are fleshed out), and frankly, some proposals that are not—and may never be—ready for prime time, or could potentially cause massive increases in consumers’ bills for little to no commensurate benefit or inappropriately expand the role of federal regulation over local utility regulation.

Fortunately, this NOPR contains some very good proposals and leaves out the worst of the “not ready for prime time” ideas of the ANOPR. While it still contains some features I would not choose,⁹ on balance I am comfortable in voting for it in this form and putting it out for additional comment. Here are some of the best features of this NOPR:

8. First, it leaves unchanged the planning criteria and cost allocation frameworks for

⁷ States have long played an informal advisory and advocacy role through organizations such as the Organization of PJM States, Inc. (my alma mater) and the Organization of MISO States. In Southwest Power Pool, Inc. (SPP) and ISO New England Inc. states have played what could be perhaps described as a more formal role in the decision-making processes of the regional entity, through the SPP Regional State Committee and the New England States Committee on Electricity, respectively. In single-state RTOs/ISOs such as New York Independent System Operator, Inc. (NYISO) and California Independent System Operator Corporation, state policies and policy-makers already heavily influence transmission planning and cost allocation. *See, e.g., N.Y. Indep. Sys. Operator, Inc.*, 178 FERC ¶ 61,179 (2022) (Christie, Comm’r, concurring) (“The specific [transmission] projects at issue in this proceeding are designed to implement the public policies of the State of New York, which are ultimately the responsibility of New York’s elected legislators. . . . NYISO is a single-state ISO that is attempting to act in accordance with the public policies of the state.”). The states, as sovereign entities, must choose to embrace the heightened role offered by this NOPR; no state can be compelled to do so, as the NOPR makes clear. *Building for the Future Through Electric Regional Transmission Planning and Cost Allocation and Generator Interconnection*, 179 FERC ¶ 61,028, at P 308 (2022) (NOPR).

⁸ *Building for the Future Through Electric Regional Transmission Planning and Cost Allocation and Generator Interconnection*, 176 FERC ¶ 61,024 (2021) (Christie, Comm’r, concurring, at P 5).

⁹ For example, I agree with Commissioner Danly’s dissent that many of the specific long-term planning directives proposed in the NOPR may be far too prescriptive and may need to be revised in any final rule to permit more regional variation and flexibility.

Reliability and Economic projects.¹⁰ Reliability and Economic projects are the meat and potatoes of regional transmission planning. These categories of projects are, by definition, integral to the primary duty of utilities *to serve retail customers (load)*. Reliability projects are essential to keep the lights on. Economic projects are constructed to reduce quantifiable and definable congestion costs. When these projects are needed, they should be expeditiously built.¹¹ The NOPR wisely does not disturb existing criteria for timely planning, constructing and paying for these two categories of projects.

9. Second, the NOPR proposes to create a separate category of projects, which we can label “Long-Term Regional Transmission Facilities,”¹² or “LTRT projects.” This new category replaces Order No. 1000’s “public policy projects.”¹³ As with these public policy projects, the new category of LTRT projects are mostly driven, in whole or in part, directly or indirectly, by public policies, such as projects that would accommodate a state’s legislated preferences for certain resources, or projects that could accommodate generation growth and retirements resulting from states’ implementation of their own integrated resource plans (IRP), or corporate goals recognized in state utility regulation.

10. For this new category of LTRT projects, the NOPR proposes to require a planning *process* extending out 20 years, based on the premise that a 20-year projection of the expected generation mix, costs of generation, and/or load has validity. Based on my experience as a state regulator with IRPs and computer models purporting to predict the future two or more decades down the road, I regard 20-year projections of this sort as, at best, occasionally interesting, but they certainly provide no basis whatsoever for saddling consumers with the costs of a billion-dollar transmission line. However, while this NOPR does propose to require a 20-year planning *process* for LTRT projects, it does *not* propose to require that any individual LTRT project or group of projects must be approved for inclusion in any regional transmission expansion plan. Indeed, there are *no* mandated LTRT projects in this NOPR, nor any planning-cycle quotas that regional entities must meet for including these types of projects in regional plans.

11. Even more importantly though, for these LTRT projects, the NOPR proposes to require the regional planning entities to consult with *and seek the agreement of* the relevant states to *both* the selection criteria for these projects *and* to the regional cost allocation arrangements. State approval is especially important in a multi-state region, where different states have different policies. The NOPR proposes to provide the maximum opportunity for creativity and flexibility to

¹⁰ NOPR, 179 FERC ¶ 61,028 at PP 3, 89, 314.

¹¹ I recognize that, with regard to projects to relieve congestion costs, in some circumstances there may be cheaper solutions available through new builds of generation.

¹² NOPR, 179 FERC ¶ 61,028 at P 4 & n.6; *see also id.* n.507.

¹³ Order No. 1000 described these types of projects as those that address “transmission needs driven by Public Policy Requirements.”

the states and regional entities in developing the process for designing and approving regional selection criteria and cost allocation arrangements. States can agree to an *ex ante* formula for regional cost allocation of these types of projects—such as, for example, the “highway-byway” formula approved by the SPP Regional State Committee—or states can agree to a process for a project-by-project agreement on cost allocation among one or several states—such as, for example, the State Agreement Approach in PJM—or states may choose some combination of both.¹⁴ States in a multi-state RTO or ISO can even agree to defer the decision on cost allocation to the governing board of the RTO/ISO.¹⁵ The result is, while we are proposing to require regional planning entities to study and evaluate a broad, forward-looking array of information—including information addressing states’ individual energy policies and goals—any projects identified through this new process will not be built, or more importantly, paid for by consumers, until the states representing such consumers have agreed that such projects are indeed needed and wanted by those same consumers.

12. And let me emphasize two points: First, as stated above, the Commission cannot *impose* a preference for certain types of generation *nor require* regional entities to plan transmission designed to prefer or facilitate one type of generation over another. Second, regardless of any ultimate cost allocation arrangement agreed to in a regional entity, no individual state’s consumers can be forced to bear the costs of another state’s policy-driven project or element of a project against its consent.¹⁶ That would be inconsistent with the cost-allocation principles of Order No. 1000, which this NOPR explicitly proposes to preserve.¹⁷

13. States did not join RTOs¹⁸ to pay for other states’ public policies or to pay for the public policy goals of huge multinational corporations or asset managers.¹⁹ States joined to provide their retail consumers with the promised benefits of lower transmission costs and strengthened reliability through regional planning of core Reliability projects. Some may say that state regulators should have no more special right to consent to planning criteria and cost allocation for these projects than other stakeholders in the RTO/ISO. But states are not just “stakeholders.” State regulators have the duty to act in the *public interest* and states alone are sovereign authorities with inherent police powers to regulate utilities through their designated state officers. The FPA itself explicitly recognizes state authority. So it is perfectly fitting for state regulators to have the

¹⁴ NOPR, 179 FERC ¶ 61,028 at PP 302–303, 305.

¹⁵ *Id.* PP 305, 307.

¹⁶ *See, e.g., id.* PP 302, 312.

¹⁷ *Id.*

¹⁸ I am aware that states *qua* states do not join RTOs/ISOs. Rather, they use their regulatory power to allow or require their regulated transmission-owning utilities to join.

¹⁹ *See, e.g., Google, A Policy Roadmap for 24/7 Carbon-Free Energy* (Apr. 14, 2022), <https://cloud.google.com/blog/topics/sustainability/a-policy-roadmap-for-achieving-247-carbon-free-energy>; *see also BlackRock, Inc.*, 179 FERC ¶ 61,049 (2022) (Christie, Comm’r, concurring).

important roles proposed in this NOPR, without preempting the regional planning entities from seeking additional input through their existing stakeholder processes.

14. The bottom line for me is this: I believe that elevating the role in planning and cost allocation of state regulators—who are, as a group, deeply concerned about the monthly bills paid by consumers, of which transmission is a rapidly growing component—will make it *more likely, not less*, that necessary transmission can get built while ensuring that rates resulting from these types of policy-driven projects will not be unjust and unreasonable, which they clearly have the potential to be.

15. There is a third feature of this NOPR I also find very important. For LTRT projects the NOPR proposes to end the Commission's long practice of awarding, as an incentive, cost recovery for Construction Work in Process (CWIP); instead it will propose to require the booking of these pre-service costs as Allowance for Funds Used During Construction (AFUDC).²⁰ CWIP is the award of cost recovery of construction costs during the pre-construction and construction phases to the developer. CWIP is, of course, passed through as a cost to consumers, making consumers effectively an involuntary lender to the developer. By contrast, AFUDC is booked during the pre-service phases, but *cannot* be recovered from customers until the project is completed and actually serving customers, *i.e.*, "used and useful." The NOPR proposal is simply in keeping with traditional good utility ratemaking principles. Booking these costs as AFUDC also recognizes the reality that just because an LTRT project is selected for a regional plan, it still has to obtain all state siting, certificate of public convenience and necessity and other, including environmental, approvals, and survive what may be the subsequent litigation, before it is actually built.²¹ Consumers should be protected from paying CWIP costs during this potentially long period before a project actually enters service, if it ever does. This NOPR proposal represents a major step forward in consumer protection and is a big reason I am voting for it.

16. Finally, let me note again that this is a NOPR—a continuing work in progress with more work ahead. For example, the section on planning of local projects²² seeks to address a concern expressed by many commenters, that local projects may not be getting sufficiently vetted by regional planning entities. In response, the NOPR

essentially proposes PJM's procedures for vetting and transparency of local projects, but I welcome additional comment from other regional entities as to whether there are more conducive measures for such vetting that may fit their own regions better. Most importantly, on the broader issue of whether local projects are being properly scrutinized, as a former state regulator who sat on scores of local-project cases, I would point out that no local project is going to be built unless a state agency approves a certificate or its equivalent. While the commenters note that procedures differ greatly from state to state, and some state utility commissions have more authority than others,²³ there is no question that states have within their inherent police powers the authority to regulate utilities and that includes the power to vet local projects both as to need and cost before approving them, just as states have the siting authority. If states are not using these powers to vet fully such local projects, they should review their own state laws and procedures. And if states believe they need more information from the RTOs/ISOs to make more informed decisions in their vetting processes, please comment on what additional information would be helpful for the RTOs and ISOs to provide. States should be a full partner in the process for vetting and approving local projects and I invite comment on how to strengthen state oversight of these projects to get the best deal for the consumer.

For these reasons cited above, I concur in the issuance of the NOPR.

Mark C. Christie,
Commissioner.

United States of America Federal Energy Regulatory Commission

Building for the Future Through Electric Regional Transmission Planning and Cost Allocation and Generator Interconnection
Docket No. RM21–17–000

(Issued April 21, 2022)

PHILLIPS, Commissioner, *concurring*:

1. I concur in today's Notice of Proposed Rulemaking (NOPR) to emphasize the importance of our action today and to call attention to the work that remains. I believe today's NOPR represents a critical first step toward ensuring a 21st century electric grid that is capable of reliably and affordably accommodating new generation.

2. Most commenters urge the Commission to reexamine the transmission planning and cost allocation policies adopted in Order No. 1000 over a decade ago.¹ While Order No.

1000 was well intentioned, commentators argue that it fell short of its goal to spur competitive transmission buildout. Under section 206 of the Federal Power Act,² the Commission must ensure that transmission rates are just and reasonable. If there are deficiencies in the Commission's existing regional transmission planning and cost allocation requirements, we must endeavor to remedy those deficiencies. For this reason, I support the NOPR's proposal to revisit our existing policies.

3. This NOPR acknowledges the facts on the ground. It is an inescapable fact that our resource mix is changing, which is a key factor leading to a greater need for transmission. Due in large part to economies of scale, the cost of renewable energy has fallen rapidly over the last decade while the demand for those resources has increased.³ As of the end of 2020, there were over 800 GW of wind, solar, and energy storage capacity seeking interconnection in the United States.⁴ That figure has now risen to 1,300 gigawatts of wind, solar and storage capacity proposed for interconnection as of the end of 2021.⁵ At the same time as the resource mix is changing, severe weather events and wildfires are becoming more frequent and extreme.⁶ These are just a few of the factors contributing to a greater need for expansion of our nation's grid.⁷

4. The record here appears to show that transmission expansion is increasingly occurring in a piecemeal and inefficient fashion outside of the regional transmission

Utilities, Order No. 1000, 136 FERC ¶ 61,051 (2011), *order on reh'g*, Order No. 1000–A, 139 FERC ¶ 61,132, *order on reh'g and clarification*, Order No. 1000–B, 141 FERC ¶ 61,044 (2012), *aff'd sub nom. S.C. Pub. Serv. Auth. v. FERC*, 762 F.3d 41 (D.C. Cir. 2014).

² 16 U.S.C. 824e.

³ For instance, after an 85% cost decline over the past decade, solar photovoltaic systems are among the most cost-competitive energy resources in the market. See Deloitte, 2022 Renewable Energy Outlook, <https://www2.deloitte.com/us/en/pages/energy-and-resources/articles/renewable-energy-outlook.html>.

⁴ *Queued Up: Characteristics of Power Plants Seeking Transmission Interconnection As of the End of 2020*, Lawrence Berkeley National Laboratory, at 22 (May 2021).

⁵ *Queued Up: Characteristics of Power Plants Seeking Transmission Interconnection As of the End of 2021*, Lawrence Berkeley National Laboratory, at 3 (April 2022).

⁶ As outlined in the November 2021 FERC–NERC–Regional Entity Staff Report on Winter Storm Uri, interregional transfers played a critical role in helping MISO and SPP compensate for generation outages during the event. *The February 2021 Cold Weather Outages in Texas and the South Central United States*, FERC, NERC and Regional Entity Staff Report, at 98 (November 2021).

⁷ See National Association of Regulatory Utility Commissioners (NARUC) Comments at 17 ("Because certain clean energy resources are diffuse by nature, meaning the resources exist at disparate locations and cannot simply be placed near existing load centers, new transmission facilities may need to be developed to gather and transport energy from generation rich areas to load."); Harvard Electricity Law Initiative Comments at 17 ("Transmission is needed to connect these location-constrained resources and to ensure that the system remains reliable with a larger share of intermittent generation.").

²⁰ NOPR, 179 FERC ¶ 61,028 at P 333 & n.530.

²¹ See *e.g.*, *Nat'l Wildlife Refuge Ass'n v. Rural Utils. Serv.*, Nos. 21–cv–096–wmc & 21–cv–306, 2021 WL 5050073 (W.D. Wis. Nov. 1, 2021) (enjoining on environmental grounds construction of a segment of a transmission project intended to bring wind-generated power from generators in Iowa to Wisconsin); see also Clark Mindock, *Wis. Judge Blocks \$500M Power Line From Wildlife Refuge*, LAW360 (Mar. 2, 2022), <https://www.law360.com/articles/1469697> ("The CHC Project is a proposed 102-mile high-voltage transmission line in the Midwest that was proposed as a way of connecting parts of Milwaukee and Chicago to cheap wind power by connecting Dubuque, Iowa, to southwestern Wisconsin.").

²² NOPR, 179 FERC ¶ 61,028 at PP 383–415.

²³ See, *e.g.*, Ohio Consumers' Counsel Comments at 13 (explaining that the Ohio Power Siting Board (OPSB) does not review local projects "for need, prudence, or cost efficiency"); Ohio Consumers' Counsel Reply Comments at 8 ("the OPSB rejected [Ohio Consumers' Counsel's] recommendation that the OPSB report to the General Assembly that the state legislature should pass new statutory authority for OPSB that would require the agency to regulate the siting, need for and cost-effectiveness of any proposed new transmission facilities in Ohio rated at 69 kV and above.").

¹ *Transmission Planning and Cost Allocation by Transmission Owning and Operating Public*

planning process, which may not be cost-effective for consumers in the long run.⁸ While commenters' views vary on how best to address this problem, nearly all commenters endorse some form of proactive planning for the future resource mix and demand.⁹ I believe the NOPR proposal to require long-term scenario planning, including accounting for extreme weather events, is necessary to maintain the reliability of the grid and to ensure that transmission costs are just and reasonable. I also note that while this NOPR proposes to require the evaluation of benefits of long-term regional transmission facilities over a 20-year time horizon, it does not propose to prescribe any particular definition of "benefits" or "beneficiaries," nor require use of any specific benefits.¹⁰ Instead, we continue to acknowledge the benefits of regional flexibility. Nor does it propose to require that transmission providers select any particular transmission projects, instead proposing to provide transmission providers the flexibility to propose the selection criteria that they, in consultation with their stakeholders and states, believe will ensure that more efficient or cost-effective long-term regional transmission facilities ultimately are selected.¹¹ And I support the proposal to require transmission providers to consult with and incorporate states' views in project selection and cost allocation. I invite comment on the value of such state involvement for increasing the likelihood that those facilities are sited and ultimately developed with fewer costly delays.

5. I also strongly support the NOPR proposal for greater consideration of dynamic line ratings and advanced power flow control devices in regional transmission planning processes. Grid-enhancing technologies (GETs) can optimize our existing transmission infrastructure and provide cost-effective solutions for consumers. For example, by allowing the measurement of transmission capacity in real-time, dynamic line ratings can provide net benefits to customers by allowing increased power flow and reducing congestion costs, as well as by detecting when power flows should be

reduced to avoid unnecessary wear on transmission equipment. The role that these and other GETs could play in delaying or eliminating the need for new transmission facilities cannot be ignored. I urge the Commission to consider further reforms to incentivize the adoption and deployment of GETs.

6. Many commenters raise concerns about delays and significant backlogs in interconnection queues across the country.¹² Currently, less than a quarter of generator interconnection applications actually result in an interconnection.¹³ Interconnection applicants submitting speculative interconnection requests can linger in the queue, only to withdraw at late stages, often necessitating the study of non-viable projects as well as restudies due to withdrawals. These often result in delays and cost risks for commercially viable projects that are otherwise ready to interconnect. Although the reforms we propose in this NOPR may help mitigate these issues in the long term, they are not enough to alleviate existing backlogs in the near term. While I recognize and commend the ongoing efforts in some regions to address the large volume of interconnection requests,¹⁴ I encourage my colleagues to consider whether it is necessary to require certain best practices, such as first-ready, first-served cluster study approaches, to process interconnection requests more efficiently.

7. Similarly, many commenters have highlighted the importance of adopting interregional coordination and planning reforms, particularly for reliability.¹⁵ Today's

NOPR does not, at this time, propose changes to the existing interregional transmission coordination and cost allocation requirements of Order No. 1000. As we continue to examine those issues, I urge the Commission to act expeditiously to propose interregional reliability planning reforms. Looking beyond regional boundaries is important so that cost-efficient regional and interregional projects can be considered and studied together. We should consider whether neighboring regions should adopt common planning assumptions and methods that allow for region-specific inputs. Additionally, I believe we must consider whether to adopt a requirement for a minimum amount of interregional transfer capacity to protect against generation shortfalls, especially during extreme weather events.

8. Finally, I note that this NOPR is merely a proposal and I am looking forward to reviewing the comments in response. In addition, I emphasize that the reforms in this NOPR are not intended to be one-size-fits-all, nor would I support such an approach. Recognizing the unique needs and characteristics of individual markets and regions, I am particularly interested in comments on whether the reforms proposed in this NOPR allow for a sufficient level of regional flexibility.

For these reasons, I respectfully concur.
Willie L. Phillips,
Commissioner.

[FR Doc. 2022-08973 Filed 5-3-22; 8:45 am]

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planning should strive to quantify benefits associated with enhancing interregional import and export capabilities, given the likelihood of future extreme weather events and related energy shortages. Further analysis and process improvements in interregional transmission development and imports and exports capability will be necessary, not only to accommodate demand for a clean energy transition, but also for reliability and defined resiliency benefits."); PJM Interconnection, L.L.C. Comments at 72-73 (stating that greater interregional transfer capability has a significant reliability benefit as demonstrated by the February 2021 Cold Snap and the 2014 Polar Vortex, and the Commission should approach the issue of strengthening interregional ties as a broad reliability-based benefit); New York Independent System Operator, Inc. Comments at 55 ("Interconnections with neighboring systems are important tools to support grid reliability, resiliency, and market efficiency by providing opportunities for the exchange of capacity and energy.").

⁸ See *Building for the Future Through Electric Regional Transmission Planning and Cost Allocation and Generator Interconnection*, 179 FERC ¶ 61,028, at P 38 (2022) (NOPR) (discussing the dramatic increase in cost, size, and scope of interconnection-related network upgrades).

⁹ See *Americans for a Clean Energy Grid Reply Comments*, Appendix A (listing 174 commenters).

¹⁰ See NOPR, 179 FERC ¶ 61,028 at P 183.

¹¹ *Id.* P 242.

¹² See, e.g., *Advanced Energy Economy Reply Comments* at 17-23; *American Electric Power Service Corporation Comments* at 36-38; *American Public Power Association Comments* at 27; *Edison Electric Institute Reply Comments* at 27-30; *NextEra Energy, Inc. Comments* at 12.

¹³ See *Queued Up . . . But in Need of Transmission Unleashing the Benefits of Clean Power with Grid Infrastructure*, U.S. Department of Energy, at 2 (April 2022).

¹⁴ See, e.g., *California Public Utilities Commission Comments* at 70 (noting that California Independent System Operator Corporation is undertaking a stakeholder process focused on increasing efficiency of the interconnection study process); *PJM Interconnection, L.L.C. Comments* at 47-49.

¹⁵ See, e.g., *NARUC Comments* at 8 ("The planning process should share system planning information on an interregional level whenever appropriate."); *id.* at 19 (describing how during Winter Storm Uri, "usually a net exporter of energy, SPP relied significantly on imported energy to serve load during the winter event" and that "effective



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Part V

Department of Homeland Security

8 CFR Part 274a

Temporary Increase of the Automatic Extension Period of Employment Authorization and Documentation for Certain Renewal Applicants;
Temporary Rule

DEPARTMENT OF HOMELAND SECURITY

8 CFR Part 274a

[CIS No. 2714–22; DHS Docket No. USCIS–2022–0002]

RIN 1615–AC78

Temporary Increase of the Automatic Extension Period of Employment Authorization and Documentation for Certain Renewal Applicants

AGENCY: U.S. Citizenship and Immigration Services, DHS.

ACTION: Temporary final rule with request for comments.

SUMMARY: This rule temporarily amends existing Department of Homeland Security (DHS) regulations to provide that the automatic extension period applicable to expiring Employment Authorization Documents (Forms I–766 or EADs) for certain renewal applicants who have filed Form I–765, Application for Employment Authorization, will be increased from up to 180 days to up to 540 days from the expiration date stated on their EADs. This increase will be available to eligible renewal applicants with pending Forms I–765 as of May 4, 2022, including those applicants whose employment authorization may have lapsed following the initial 180-day extension period, and any eligible applicant who files a renewal Form I–765 during the 540-day period beginning on or after May 4, 2022, and ending October 26, 2023. In light of current processing times for Forms I–765, DHS is taking these steps to help prevent renewal applicants from experiencing a lapse in employment authorization and/or documentation while their applications remain pending and solutions are implemented to return processing times to normal levels.

DATES:

Effective date: This temporary final rule is effective May 4, 2022, through October 15, 2025.

Submission of public comments: Written comments must be submitted on or before July 5, 2022. The electronic Federal Docket Management System will accept comments prior to midnight eastern time at the end of that day.

ADDRESSES: You may submit comments on the entirety of this temporary final rule package, identified by DHS Docket No. USCIS–2022–0002, through the Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the website instructions for submitting comments.

Comments submitted in a manner other than the one listed above,

including emails or letters sent to USCIS or DHS officials, will not be considered comments on the temporary final rule and may not receive a response. Please note that USCIS cannot accept any comments that are hand-delivered or couriered. In addition, USCIS cannot accept comments contained on any form of digital media storage devices, such as CDs/DVDs and USB drives. USCIS is not accepting mailed comments at this time. If you cannot submit your comment by using <https://www.regulations.gov>, please contact Samantha Deshommes, Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, by telephone at 240–721–3000 (not a toll-free call) for alternate instructions.

FOR FURTHER INFORMATION CONTACT:

Melissa Lin, Branch Chief, Policy Development and Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, 5900 Capital Gateway Drive, Camp Springs, MD 20746; telephone 240–721–3000 (not a toll-free call).

Individuals with hearing or speech impairments may access the telephone numbers above via TTY by calling the toll-free Federal Information Relay Service at 1–877–889–5627 (TTY/TDD).

SUPPLEMENTARY INFORMATION:

I. Public Participation

DHS invites you to participate in this rulemaking by submitting written data, views, or arguments on all aspects of this temporary final rule. Comments providing the most assistance to DHS will reference a specific provision of the temporary final rule, explain the reason for any recommended change, and include data, information, or authority that supports the recommended change. Comments submitted in a manner other than explicitly provided above, including emails or letters sent to USCIS or DHS officials, will not be considered comments on the temporary final rule and may not receive a response.

Instructions: All submissions should include the agency name and DHS Docket No. USCIS–2022–0002 for this rulemaking. Providing comments is entirely voluntary. DHS will post all submissions, without change, to the Federal eRulemaking Portal at <https://www.regulations.gov> and will include any personal information you provide. Because the information you submit will be publicly available, you should consider limiting the amount of personal information in your submission. DHS may withhold

information provided in comments from public viewing if it determines that such information is offensive or may affect the privacy of an individual. For additional information, please read the Privacy Act notice available through the link in the footer of <https://www.regulations.gov>.

Docket: For access to the docket and to read comments received, go to <https://www.regulations.gov>, referencing DHS Docket No. USCIS–2022–0002. You may also sign up for email alerts on the online docket to be notified when comments are posted or subsequent rulemaking is published.

II. Background

Operational challenges, exacerbated by the emergency measures USCIS employed to maintain its operations through the height of the COVID–19 pandemic in 2020, which greatly affected operations and staffing, combined with a sudden increase in Form I–765 filings, have resulted in processing times for Form I–765 increasing to such a level that the 180-day automatic extension period for Form I–765 renewal applicants' employment authorization and/or EADs is temporarily insufficient. For some applicants, the extension has already expired, while for many others, it is in imminent danger of expiring. As a result, renewal applicants are losing their jobs and employers suddenly are faced with finding replacement workers during a time when the U.S. economy is experiencing more job openings than available workers.¹ DHS has determined that it is imperative to immediately increase the automatic extension period of employment authorization and/or EADs for eligible Form I–765 renewal applicants for a temporary period. This temporary increase to the automatic extension period will avoid the immediate harm that otherwise would affect tens of thousands of EAD renewal applicants and their U.S. employers in those cases where USCIS is unable to process applicants' EAD renewal applications before the end of the current 180-day automatic extension period. USCIS is already taking steps to more permanently address its backlogs for EAD applications and other form types, and this temporary increase will provide a temporary extension while

¹ Bureau of Labor Statistics data show that, as of December 2021, there were 0.6 unemployed persons per job opening. U.S. Department of Labor, U.S. Bureau of Labor Statistics, *Number of unemployed persons per job opening, seasonally adjusted* (Jan. 2007 through Jan. 2022), <https://www.bls.gov/charts/job-openings-and-labor-turnover/unemp-per-job-opening.htm> (last visited Mar. 14, 2022).

USCIS works to return to pre-pandemic processing times.

A. Legal Authority

The Secretary of Homeland Security's (Secretary) authority for the regulatory amendments made in this TFR are found in: section 274A(h)(3)(B) of the Immigration and Nationality Act (INA), 8 U.S.C. 1324a(h)(3)(B), which recognizes the Secretary's authority to extend employment authorization to noncitizens in the United States; and section 101(b)(1)(F) of the Homeland Security Act, 6 U.S.C. 111(b)(1)(F), which establishes as a primary mission of DHS the duty to "ensure that the overall economic security of the United States is not diminished by efforts, activities, and programs aimed at securing the homeland." In addition, section 103(a)(3) of the INA, 8 U.S.C. 1103(a)(3), authorizes the Secretary to establish such regulations as the Secretary deems necessary for carrying out the Secretary's authority under the INA, and section 214 of the INA, 8 U.S.C. 1184, including section 214(a)(1), 8 U.S.C. 1184(a)(1), authorizes the Secretary to prescribe, by regulation, the terms and conditions of the admission of nonimmigrants.

B. Legal Framework for Employment Authorization

1. Types of Employment Authorization: 8 CFR 274a.12(a), (b), and (c)

Whether or not a noncitizen is authorized to work in the United States depends on the noncitizen's immigration status or other conditions that may permit employment authorization (for example, having a pending application for asylum or a grant of deferred action). DHS regulations outline three classes of noncitizens who may be eligible for employment in the United States, as follows:²

- Noncitizens in the first class, described at 8 CFR 274a.12(a), are authorized to work "incident to status" for any employer, as well as to engage in self-employment, as a condition of their immigration status or circumstances. Although authorized to work as a condition of their status or circumstances, certain classes of noncitizens must apply to USCIS in order to receive a Form I-766 EAD as

² There are several employment-eligible categories that are not included in DHS regulations but instead are described in the form instructions to Form I-765, Application for Employment Authorization. Employment-authorized L nonimmigrant spouses are an example. See INA sec. 214(c)(2)(E), 8 U.S.C. 1184(c)(2)(E).

evidence of that employment authorization;³

- Noncitizens in the second class, described at 8 CFR 274a.12(b), also are authorized to work "incident to status" as a condition of their immigration status or circumstances, but generally the authorization is valid only for a "specific employer;"⁴ and

- Noncitizens in the third class, described at 8 CFR 247a.12(c), are required to apply for employment authorization and may work only if USCIS approves their application. Therefore, they are authorized to work for any employer, as well as to engage in self-employment, upon approval, in the discretion of USCIS, of Form I-765, Application for Employment Authorization, so long as their EAD remains valid.⁵

2. The Application Process for Obtaining Employment Authorization and EADs: 8 CFR 274a.13(a)

For certain eligibility categories listed in 8 CFR 274a.12(a) (the first class) and all eligibility categories listed in 8 CFR 274a.12(c) (the third class), as well as additional categories specified in form instructions, an Application for Employment Authorization (Form I-765) must be properly filed with USCIS (with fee or fee waiver as applicable) to receive employment authorization and/or the Form I-766 EAD.⁶ If granted, such employment authorization and EADs allow noncitizens to work for any U.S. employer or engage in self-employment, as applicable. Certain noncitizens may file Form I-765 concurrently with a related benefit request if permitted by the form instructions or as announced by USCIS.⁷ In some instances, the underlying benefit request, if granted, would form the basis for eligibility for employment authorization.

For eligibility categories listed in 8 CFR 274a.12(a) and (c), USCIS has the

³ See 8 CFR 274a.12(a).

⁴ See 8 CFR 274a.12(b). These noncitizens are issued an Arrival-Departure Record (Form I-94) indicating their employment-authorized status in the United States and do not file separate requests for evidence of employment authorization.

⁵ See 8 CFR 274a.12(c); *Matter of Tong*, 16 I&N Dec. 593, 595 (BIA 1978) (holding that the term "employment" is a common one, generally used with relation to the most common pursuits, and includes "the act of being employed for one's self").

⁶ See 8 CFR 103.2(a) and 8 CFR 274a.13(a). Applicants who are employment authorized incident to status (e.g., asylees, refugees, TPS beneficiaries) will file Form I-765 to request a Form I-766 EAD. Applicants who are filing within an eligibility category listed in 8 CFR 274a.12(c) must use Form I-765 to request both employment authorization and an EAD.

⁷ See 8 CFR 274a.13(a).

discretion to establish a specific validity period for the EAD.⁸

3. Automatic Extensions of EADs for Renewal Applicants: 8 CFR 274a.13(d)

a. Renewing Employment Authorization and/or EADs

EADs are not valid indefinitely, but instead expire after a specified period of time.⁹ Noncitizens within eligibility categories listed in 8 CFR 274a.12(c) must obtain a renewal of employment authorization and their EAD before the expiration date stated on the current EAD, or the noncitizen will lose the eligibility to work in the United States unless the noncitizen has obtained an immigration status or belongs to a class of individuals with employment authorization incident to that status (or class) since obtaining a current EAD. The same holds true for some classes of noncitizens authorized to work incident to status whose EADs' expiration dates coincide with the termination or expiration of their underlying immigration status. Other noncitizens authorized to work incident to status, such as asylees, refugees, and Temporary Protected Status (TPS) beneficiaries, may have immigration status that confers employment authorization that continues past the expiration date stated on their EADs. Nevertheless, such individuals may wish to renew their EAD in order to have valid evidence of their continuous employment authorization for various purposes, such as presenting evidence of employment authorization and identity to their employers for completion of the Employment Eligibility Verification (Form I-9), or to obtain benefits such as a driver's license from a State motor vehicle agency.¹⁰ Failure to renew their EADs prior to the expiration date may result in job loss if such individuals do not have or cannot present alternate evidence of employment authorization, as employers who continue to employ individuals without employment

⁸ See 8 CFR 274.12(a) and (c).

⁹ See 8 CFR 274a.13(b) and 274a.14(a).

¹⁰ For example, the status of asylees generally continues unless and until it is adjusted to lawful permanent resident status, and asylees are employment authorized incident to status. Therefore, asylees' employment authorization typically will continue beyond the expiration date on the EAD, which is issued in 2-year increments. On the other hand, a K-1 fiancée, while also employment authorized incident to status, will receive only a 90-day period in K-1 nonimmigrant status upon admission to the United States. The expiration date of EADs issued to K-1 fiancées will coincide with the 90-day admission period.

authorization may be subject to civil money penalties.¹¹

Those seeking to renew previously granted employment authorization and/or EADs must file the renewal request on Form I-765 with USCIS in accordance with the form instructions.¹²

Module A. b. Minimizing the Risk of Gaps in Employment Authorization and/or EAD Validity Through Automatic Extensions

If an eligible noncitizen is not able to renew their employment authorization and/or EAD before it expires, the noncitizen and the employer may experience adverse consequences. For the noncitizen, the lack of renewal could cause job loss, gaps in employment authorization, and loss of income to the noncitizen and their family member(s). For the noncitizen's employer, the disruption may cause instability with business continuity or other financial harm. Beyond the financial and economic impact that gaps in employment create for the employer and the noncitizen, if the noncitizen engages in unauthorized employment, such activity may render a noncitizen removable,¹³ render a noncitizen ineligible for future benefits such as adjustment of status,¹⁴ and/or may subject the employer to civil and criminal penalties.¹⁵

Before 2016, USCIS regulations indicated that USCIS would "adjudicate an application [for an EAD] within 90 days" from the date USCIS received the application.¹⁶ If USCIS did not adjudicate the application within that timeframe, the applicant was eligible to be issued an interim document evidencing employment authorization with a validity period not to exceed 240 days. On November 18, 2016, as part of

¹¹ For an initial hire, the employee must present the employer with acceptable documents evidencing identity and employment authorization. The lists of acceptable documents can be found on the last page of the Form I-9. See <https://www.uscis.gov/sites/default/files/document/forms/i-9.pdf> (last updated Oct. 21, 2019). An employer that does not properly complete Form I-9, which includes reverifying continued employment authorization, or continues to employ an individual with knowledge that the individual is not authorized to work may be subject to civil money penalties. See <https://www.uscis.gov/i-9-central/handbook-for-employers-m-274/100-unlawful-discrimination-and-penalties-for-prohibited-practices/108-penalties-for-prohibited-practices> (last updated Apr. 27, 2020).

¹² See <https://www.uscis.gov/sites/default/files/document/forms/i-765instr.pdf> (08/25/20 edition). In reviewing the Form I-765, USCIS ensures that the fee was paid, a fee waiver was granted, or a fee exemption applies.

¹³ See, e.g., INA sec. 237(a)(1)(C), 8 U.S.C. 1227(a)(1)(C).

¹⁴ See INA sec. 245(c), 8 U.S.C. 1255(c).

¹⁵ See INA sec. 274A, 8 U.S.C. 1324a.

¹⁶ See 8 CFR 274a.13(d) (2016).

DHS's efforts to implement the flexibilities provided to noncitizens and employers by the American Competitiveness in the Twenty-first Century Act of 2000 (AC21), as amended, and the American Competitiveness and Workforce Improvement Act of 1998, DHS published a final regulation¹⁷ removing the provision and replacing it with the current 8 CFR 274a.13(d).

Under the current provision, certain employment eligibility categories receive an automatic extension of employment authorization and EAD for up to 180 days if certain conditions (outlined below) are met.¹⁸ DHS created the provision to prevent gaps in employment authorization and related consequences for certain renewal applicants,¹⁹ and in light of processing times and possible filing surges.²⁰ To significantly mitigate the risks of and consequences related to gaps in employment authorization for renewal applicants, DHS changed its regulations at 8 CFR 274a.13(d) to provide certain categories of renewal applicants with an automatic extension of their EADs and, if applicable, related employment authorization, for up to 180 days from the expiration date on the EAD if:

- The renewal applicants timely file an application to renew their employment authorization and/or EAD on Form I-765 before the EAD expires;²¹

¹⁷ See Final Rule, *Retention of EB-1, EB-2, and EB-3 Immigrant Workers and Program Improvements Affecting High-Skilled Nonimmigrant Workers*, 81 FR 82398 (Nov. 18, 2016) ("AC21 Final Rule"). The final rule was issued after a proposed rule was published in the **Federal Register**. See Notice of Proposed Rulemaking, *Retention of EB-1, EB-2, and EB-3 Immigrant Workers and Program Improvements Affecting High-Skilled Nonimmigrant Workers*, 80 FR 81899 (Dec. 31, 2015) ("AC21 NPRM").

¹⁸ See 81 FR at 82455-82463 (AC21 Final Rule).

¹⁹ See 80 FR at 81927 ("DHS proposes to amend its regulations to help prevent gaps in employment authorization for certain employment-authorized individuals who are seeking to renew expiring EADs. . . . These provisions would significantly mitigate the risk of gaps in employment authorization and required documentation for eligible individuals, thereby benefitting them and their employers.")

²⁰ See 80 FR at 81927 ("DHS believes that this time period [of up to 180 days] is reasonable and provides more than ample time for USCIS to complete the adjudication process based on USCIS's current 3-month average processing time for Applications for Employment Authorization."); *id.* at 81927 n.77 ("Depending on any significant surges in filings, however, there may be periods in which USCIS takes longer than 2 weeks to issue Notices of Action (Forms I-797C).")

²¹ 8 CFR 274a.13(d)(1)(i). TPS beneficiaries must file during the designated period in the applicable **Federal Register** notice. In addition, the TPS and TPS-related documentation, including EADs, of certain TPS beneficiaries under the TPS designations for Haiti, El Salvador, Sudan, Nicaragua, Honduras, and Nepal are continued

• The renewal Form I-765 is based on the same employment authorization category on the front of the expiring EAD or is for an individual approved for TPS whose EAD was issued pursuant to 8 CFR 274a.12(c)(19);²² and

• The noncitizen's eligibility to apply for employment authorization continues notwithstanding the expiration of the EAD and is based on an employment authorization category that does not require the adjudication of an underlying application or petition before the adjudication of the renewal application, as announced on the USCIS website.²³

The following classes of noncitizens filing to renew an EAD may be eligible to receive an automatic extension of their employment authorization and/or EAD for up to 180 days, which USCIS discusses in detail at <https://www.uscis.gov/eadautoextend>:²⁴

- Noncitizens admitted as refugees (A03).²⁵
- Noncitizens granted asylum (A05).²⁶
- Noncitizens admitted as parents or dependent children of noncitizens granted permanent residence under section 101(a)(27)(I) of the INA, 8 U.S.C. 1101(a)(27)(I) (A07).²⁷
- Noncitizens admitted to the United States as citizens of the Federated States

subject to current court orders and litigation compliance **Federal Register** notices. See 86 FR 50725 (Sept. 10, 2021) (continuing TPS and TPS-related documentation for eligible beneficiaries of the TPS designations for the noted six countries through December 31, 2022, and further noting that DHS will issue future such notices as necessary to comply with court orders in *Ramos, et al. v. Nielsen, et al.*, No. 18-cv-01554 (N.D. Cal. Oct. 3, 2018) ("*Ramos*"); *Saget, et al. v. Trump, et al.*, No. 18-cv-1599 (E.D.N.Y. Apr. 11, 2019) ("*Saget*"); and *Bhattarai v. Nielsen*, No. 19-cv-00731 (N.D. Cal. Mar. 12, 2019) ("*Bhattarai*"). DHS also will comply with any superseding court orders in these lawsuits. This TFR will be construed in harmony, to the extent possible, with the existing and any future court orders in this referenced litigation.

²² See 8 CFR 274a.13(d)(1)(ii) (exempting individuals approved for TPS with EADs issued pursuant to 8 CFR 274a.12(c)(19) from the requirement that the employment authorization category on the face of the expiring EAD be the same as on the request for renewal (Form I-765)). See also DHS, USCIS, *Employment Authorization for Certain H-4, E, and L Nonimmigrant Dependent Spouses*, PA-2021-25 (Nov. 12, 2021), <https://www.uscis.gov/sites/default/files/document/policy-manual-updates/20211112-Employment-Authorization.pdf> (explaining that certain H-4, E, or L dependent spouses may submit a document combination including an unexpired Form I-94 indicating H-4, E, or L-2 nonimmigrant status alongside Form I-797C).

²³ See 8 CFR 274a.13(d)(iii).

²⁴ See DHS, USCIS, *Automatic Employment Authorization Document (EAD) Extension*, <https://www.uscis.gov/eadautoextend> (last updated Nov. 12, 2021).

²⁵ See 8 CFR 274a.12(a)(3).

²⁶ See 8 CFR 274a.12(a)(5).

²⁷ See 8 CFR 274a.12(a)(7).

of Micronesia or the Marshall Islands pursuant to agreements between the United States and the former trust territories (A08).²⁸

- Noncitizens granted withholding of deportation or removal (A10).²⁹

- Noncitizens granted TPS, regardless of the employment authorization category on their current EADs (A12 or C19).³⁰

- Noncitizen spouses of E–1/2/3 nonimmigrants (Treaty Trader/Investor/Australian Specialty Worker) (A17).³¹

- Noncitizen spouses of L–1 nonimmigrants (Intracompany Transferees) (A18).³²

- Noncitizens who have properly filed applications for TPS and who have been deemed *prima facie* eligible for TPS under 8 CFR 244.10(a) and have received an EAD as a “temporary treatment benefit” under 8 CFR 244.10(e) and 274a.12(c)(19) (C19).³³

- Noncitizens who have properly filed applications for asylum and withholding of deportation or removal (C08).³⁴

- Noncitizens who have filed applications for adjustment of status to lawful permanent resident under section 245 of the INA, 8 U.S.C. 1255 (C09).³⁵

- Noncitizens who have filed applications for suspension of deportation under section 244 of the INA (as it existed prior to April 1, 1997), cancellation of removal pursuant to section 240A of the INA, or special rule cancellation of removal under section 309(f)(1) of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (C10).³⁶

- Noncitizens who have filed applications for creation of record of lawful admission for permanent residence (C16).³⁷

- Noncitizens who have properly filed legalization applications pursuant to section 210 of the INA, 8 U.S.C. 1160 (C20).³⁸

- Noncitizens who have properly filed legalization applications pursuant to section 245A of the INA, 8 U.S.C. 1255a (C22).³⁹

- Noncitizens who have filed applications for adjustment of status

pursuant to section 1104 of the Legal Immigration Family Equity Act (C24).⁴⁰

- Noncitizen spouses (H–4) of H–1B nonimmigrants with an unexpired Form I–94 showing H–4 nonimmigrant status (C26).⁴¹

- Noncitizens who are the principal beneficiaries or qualified children of approved VAWA self-petitioners, under the employment authorization category “(c)(31)” in the form instructions to Form I–765 (C31).

Currently, the extension automatically terminates the earlier of up to 180 days after the expiration date of the EAD, or upon issuance of notification of a decision denying the renewal request.⁴² An EAD that has expired on its face is considered unexpired when combined with a Form I–797C indicating a timely filing of the application to renew the EAD.⁴³ Therefore, when the expiration date on the front of the EAD is reached, a noncitizen who is continuing in their employment with the same employer and relying on their extended EAD to show their employment authorization must present to the employer the Form I–797C to show continued employment authorization, and the employer must update the previously completed Form I–9 to reflect the extended expiration date based on the automatic extension while the renewal is pending. For new employment, the automatic extension date is recorded on the Form I–9 by the employee (if applicable) and employer in the first instance. In either case, the reverification of employment authorization or the EAD occurs when the automatic extension period terminates.⁴⁴

USCIS policy generally permits the filing of a Form I–765 renewal application up to 180 days before the current EAD expires.⁴⁵ If the renewal application is granted, the employment authorization and/or EAD generally will be valid as of the date of approval of the application. If the application is denied, the employment authorization and/or EAD generally is terminated on the day of the denial.⁴⁶ If the renewal application was timely and properly filed but remains pending beyond the

180-day automatic extension period and the employee cannot provide other evidence of current employment authorization, the employee must stop working on the beginning of the 181st day after the expiration of the EAD, and the employer must remove the employee from the payroll.⁴⁷ As a result, both the employee and the employer will experience the negative consequences of gaps in employment authorization and/or EAD validity. Since its promulgation in 2016, the automatic extension provision at 8 CFR 274a.13(d) has helped to minimize the risk of these negative consequences for applicants who are otherwise eligible for the automatic extension and their employers.

Recently, however, it has become apparent that the 180-day automatic extension is not enough for a growing number of renewal applicants. Thousands of renewal applications remain pending beyond the 180-day automatic extension period resulting in applicants losing employment authorization and/or EAD validity. The grave situation that applicants and, in turn, their employers are facing generally is not the result of the applicant’s actions, but instead the result of several converging factors affecting USCIS operations that have been compounded by the COVID–19 public health emergency. These factors resulted in a significant increase in USCIS processing times for several categories of Form I–765 renewal applications, as described in detail below. DHS has determined that the 180-day automatic extension provision is currently insufficient to protect applicants as was originally intended.

III. Purpose of This Temporary Final Rule

A. Overview of Issues Negatively Impacting Form I–765 Processing Times

Prior to 2019, USCIS generally kept pace with the steady flow of Form I–765 filings and met its 3-month internal processing goal. However, in the years leading up to 2019, USCIS began accruing backlogs in adjudications across various other form types owing to shifting priorities, increased form lengths, expanded interview requirements, increased Request for Evidence issuance, and insufficient staffing levels due to a hiring freeze within the Field Operations Directorate beginning December 2019 and one in the Service Center Operations

²⁸ See 8 CFR 274a.12(a)(8).

²⁹ See 8 CFR 274a.12(a)(10).

³⁰ See 8 CFR 274a.12(a)(12) or (c)(19).

³¹ See INA sec. 214(e)(2), 8 U.S.C. 1184(e)(2).

³² See INA sec. 214(c)(2)(E), 8 U.S.C.

1184(c)(2)(E).

³³ See 8 CFR 274a.12(c)(19).

³⁴ See 8 CFR 274a.12(c)(8).

³⁵ See 8 CFR 274a.12(c)(9).

³⁶ See 8 CFR 274a.12(c)(10).

³⁷ See 8 CFR 274a.12(c)(16).

³⁸ See 8 CFR 274a.12(c)(20).

³⁹ See 8 CFR 274a.12(c)(22).

⁴⁰ See 8 CFR 274a.12(c)(24).

⁴¹ See 8 CFR 274a.12(c)(26).

⁴² See 8 CFR 274a.13(d)(3).

⁴³ See 8 CFR 274a.13(d)(4).

⁴⁴ See DHS, USCIS, *Completing Section 3, Reverification and Rehires*, <https://www.uscis.gov/i-9-central/complete-correct-form-i-9/completing-section-3-reverification-and-rehires> (last updated July 10, 2020).

⁴⁵ See USCIS’ web page at <https://www.uscis.gov/green-card/green-card-processes-and-procedures/employment-authorization-document> (last updated Feb. 11, 2022); see also 81 FR at 82456 (AC21 Final Rule).

⁴⁶ See 8 CFR 274a.13(d)(3).

⁴⁷ See 8 CFR 274a.2(b)(vii) (reverification provision).

Directorate beginning February 2020.⁴⁸ Those backlogs in other program areas strained USCIS resources, which, when coupled with USCIS' worsening fiscal situation beginning in late 2019 and continuing into 2020 and part of 2021, hindered USCIS' ability to allocate resources to respond to the increase in Form I-765 filings in a manner that would allow USCIS to continue to meet its 3-month internal processing goal as it historically had. Additionally, strain on USCIS' financial resources, which was due in part to USCIS' inability to update its fee structure since 2016, negatively affected staffing levels and hampered the ability to quickly respond to shifting workload demands. The COVID-19 pandemic exacerbated USCIS' precarious fiscal situation, deepening its fiscal emergency. The pandemic also led to new and significant operational disruptions, reversing any gains the agency had made on existing backlogs;⁴⁹ these pandemic-related disruptions impacted adjudications of immigration benefit requests as well as the pipeline of work for which all required pre-adjudicative processing was completed (making forms "adjudication-ready"), including for Form I-765 adjudications.⁵⁰ In 2021, before USCIS could recover from these fiscal and operational impacts, USCIS experienced a sudden and dramatic increase in Form I-765 filings due to:

Increased filings in the C09 (pending adjustment) category generally caused by changes in employment-based visa availability, new Temporary Protective Status (TPS) designations and redesignations, and the cyclical nature of the C08 (pending asylum) and C33 (DACA) categories. USCIS has experienced significant Form I-765 backlogs since then.

Presently, Form I-765 processing times vary, with many categories' processing times extending far beyond USCIS' 3-month processing goal for the form type. By December 2021, the median⁵¹ processing time for all initial and renewal Form I-765 applications was 6.5 months, and the median processing time for all Form I-765 renewal applications was 5.4 months. For those renewal applicants within employment authorization categories eligible for the up to 180-day automatic extension of employment authorization provided by 8 CFR 274a.13(d), as of December 2021, USCIS' median processing time was 8.0 months.⁵² Given these processing times, DHS recognizes that approximately 87,000 renewal applicants eligible for an automatic extension under 8 CFR 274a.13(d)(1) are, or soon will be, past the 180-day automatic extension period of their employment authorization and/or EAD validity.

The vast majority of applicants filing renewal Form I-765 applications and who are eligible for the automatic extension of EADs under 8 CFR 274a.13(d) fall under three filing categories: (1) Noncitizens who have properly filed applications for asylum and withholding of deportation or removal (C08); (2) noncitizens who have properly filed applications for adjustment of status to lawful permanent resident under section 245 of the INA, 8 U.S.C. 1255 (C09);⁵³ and (3) noncitizens who have properly filed applications for suspension of deportation under section 244 of the INA (as it existed prior to April 1, 1997), cancellation of removal pursuant to section 240A of the INA, or special rule cancellation of removal under section 309(f)(1) of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (C10).⁵⁴ As of December 2021, the processing time range (between median and 93rd percentile) for Form I-765 renewal applications filed based on the C08 category was 10.1 to 11.5 months; for the C09 category, 7.7 to 11.6 months; and for the C10 category, 6.1 to 8.6 months. By comparison, this processing time range as of December 2020, for the C08 category, was 5.0 to 6.9 months; for the C09 category, 2.5 to 5.6 months; and for the C10 category, 3.2 to 4.2 months.

TABLE 1—RECENT DRAMATIC GROWTH IN 50TH AND 93RD PERCENTILE PROCESSING TIMES FOR FORM I-765 RENEWAL APPLICATIONS FILED BY TOP THREE FILING CATEGORIES

Fiscal year ⁵⁵	Pending asylum applicants (C08)	Adjustment of status applicants (C09)	Suspension/cancellation applicants (C10)
2017	6.5 to 7.1 months	4.6 to 6.5 months	6.3 to 8.4 months.
2018	2.8 to 4.4 months	4.7 to 8.1 months	7.0 to 9.5 months.

⁴⁸ A U.S. Government Accountability Office report observed that despite receipts remaining steady (between 8 million and 10 million) from fiscal year (FY) 2015 through FY 2019, USCIS' processing times increased through FY 2020, and the overall pending caseload grew an estimated 85 percent, with USCIS having received more than 4 million applications and petitions in the first two quarters of FY 2020, owing to the factors listed above. Factors that affected Form I-765, specifically, will be discussed in further detail below. See GAO-21-529, U.S. Citizenship and Immigration Services: Actions Needed to Address Pending Caseload (Aug. 2021), pp. 9, 12, 14, and 20, <https://www.gao.gov/assets/gao-21-529.pdf>. The hiring freezes that began in the Field Operations and Service Center Operations Directorates were eventually subsumed by an agency-wide hiring freeze beginning May 1, 2020, which is discussed in further detail below. USCIS lifted the agency-wide hiring freeze in March 2021.

⁴⁹ USCIS had made some progress in addressing these backlogs before the COVID-19 pandemic. In FY 2019, USCIS observed a backlog growth rate of less than 1 percent—the smallest growth in backlogs since 2012. This was due to a 4-percent decrease in receipts, increases in completions (naturalizations, adjustments of status, and nonimmigrant and immigrant worker petitions),

and additional staffing. However, the COVID-19 pandemic reversed any gains USCIS had made.

⁵⁰ Other contributing factors include competing priorities, such as litigation obligations and administration priorities, that shifted resources away from Form I-765 adjudications or caused the agency to focus resources on certain categories or subcategories of Form I-765; and policy changes (such as expanding biometrics requirements to certain applicants filing Form I-539, Application to Extend/Change Nonimmigrant Status), which delayed USCIS' ability to approve any Form I-765 relying on an underlying Form I-539 decision. See GAO-21-529, U.S. Citizenship and Immigration Services: Actions Needed to Address Pending Caseload (Aug. 2021), pp. 15–20. However, these factors, while relevant, have been mitigated through recent policy changes and, therefore, are no longer a significant cause of gaps in employment authorization for applicants. For example, on May 17, 2021, USCIS temporarily suspended the biometrics requirement for certain Form I-539 applicants to address the processing delays exacerbated by limited Application Support Center (ASC) capacity due to COVID-19. See USCIS News Alert, USCIS Temporarily Suspends Biometrics Requirement for Certain Form I-539 Applicants, <https://www.uscis.gov/news/alerts/uscis-temporarily-suspends-biometrics-requirement-for->

[certain-form-i-539-applicants](https://www.uscis.gov/news/alerts/uscis-temporarily-suspends-biometrics-requirement-for-certain-form-i-539-applicants) (last updated May 13, 2021).

⁵¹ The median processing time represents the time it took to complete 50 percent of the cases completed in a given time period.

⁵² The time it took USCIS to complete 93 percent of these cases was 11.4 months. For more information on how USCIS calculates its processing times, see USCIS' web page at <https://egov.uscis.gov/processing-times/more-info> (last visited Feb. 9, 2022).

⁵³ Applicants filing a Form I-765 based on a pending LRIF-based adjustment application also use "(c)(9)" as their eligibility category on Form I-765.

⁵⁴ In December 2021, these three filing categories made up nearly 95 percent of the renewal EAD receipts filed in categories eligible for the automatic extension of employment authorization. Broken down further among these three categories: The C08 category comprised approximately 58 percent of the renewal EAD receipts filed in categories eligible for the automatic extension, while the C09 category comprised approximately 19 percent and the C10 comprised approximately 18 percent.

⁵⁵ In some cases, USCIS' data is based on its fiscal year, beginning on October 1 and ending on September 30 of the reporting period.

TABLE 1—RECENT DRAMATIC GROWTH IN 50TH AND 93RD PERCENTILE PROCESSING TIMES FOR FORM I–765 RENEWAL APPLICATIONS FILED BY TOP THREE FILING CATEGORIES—Continued

Fiscal year ⁵⁵	Pending asylum applicants (C08)	Adjustment of status applicants (C09)	Suspension/cancellation applicants (C10)
2019	4.1 to 5.2 months	5.2 to 7.8 months	2.7 to 4.6 months.
2020	5.0 to 6.9 months	2.5 to 5.6 months	3.2 to 4.2 months.
2021	10.1 to 11.5 months	7.7 to 11.6 months	6.1 to 8.6 months.

With current processing times far exceeding USCIS' normal 3-month goal, the 180 days of additional employment authorization/EAD validity provided for these renewal (and some additional) categories by 8 CFR 274a.13(d) is insufficient.⁵⁶ After the additional 180 days is exhausted, many applicants are still waiting for their Form I–765 renewal applications to be approved. Such applicants therefore lose employment authorization and/or their EADs become invalid while the decision on their renewal applications remains outstanding. By December 31, 2021, approximately 66,000 renewal EAD applicants were in this situation. By comparison, in December 2020, approximately 3,300 applicants⁵⁷ had Form I–765 renewal applications pending beyond the 180-day automatic extension.⁵⁸

⁵⁶ Other renewal categories that fall within 8 CFR 274a.13(d) experiencing processing times in December 2021 that exceed the 3-month goal include EAD applicants filing under 8 CFR 274a.12(a)(5) for individuals granted asylum (6.1 to 10.2 months), (a)(10) for individuals granted withholding of deportation or removal (7.2 to 10.3 months), and (c)(31) for VAWA self-petitioners (6.3 to 13.1 months).

⁵⁷ Reasons for delays in case completions for these approximately 3,300 applicants included competing priorities, Requests for Evidence, staffing, and the COVID–19 pandemic.

⁵⁸ The 66,000 and approximately 3,300 figures reflect all EAD categories eligible for automatic extension of employment eligibility and/or EAD validity. Therefore, some applicants within this population, namely applicants filing under 8 CFR 274a.12(a) (employment authorized incident to status or circumstance), do not necessarily lose their employment authorization after the 180-day automatic extension period is exhausted. Because their employment authorization is incident to their immigration status or circumstance, these renewal EAD applicants' primary consequence is that their EADs become invalid. Considering that the vast majority (approximately 95 percent as of December 2021) of renewal EAD applicants are those filing under 8 CFR 274a.12(c)(8), (9), and (10), however, the 66,000 and 3,300 figures are presumed to represent largely applicants whose primary consequence is a loss of employment authorization itself. Even so, DHS recognizes harm may be experienced by applicants filing under 8 CFR 274a.12(a) categories as well. While these applicants may have available alternative evidentiary options other than an EAD that they can use to show proof of employment authorization to their employers for Form I–9 completion or for purposes of receiving State or local public benefits (e.g., driver's licenses), DHS recognizes that having no valid EAD may nevertheless cause harm, including job loss.

Without immediate intervention, DHS estimates that the situation will only worsen over time, as each month, thousands of additional EAD renewal applicants are at risk of losing their employment authorization and/or EAD validity despite the 180-day automatic extension period currently provided by regulation. Beginning in calendar year (CY) 2022, DHS estimates that approximately 14,500 or more renewal applicants, the majority of whom are in the C08 pending asylum applicant category, lost or could lose their employment authorization and/or EAD validity *each month* unless immediate action is taken to remedy the situation.

The situation for asylum applicants is especially dire because of the significant time that asylum applicants must wait to become employment-authorized in the first place. Under regulations that were in effect from August 2020 through February 2022, most members of this vulnerable population were not permitted to apply for employment authorization until 365 calendar days had elapsed since the filing of their asylum application.⁵⁹ Although this regulation was vacated⁶⁰ in February of 2022, by statute, asylum applicants still cannot be approved for initial EADs until their asylum applications have been pending for 180 days.⁶¹ This initial wait time exacerbates the often-precarious economic situations asylum seekers may be in as a result of fleeing persecution in their home countries. Many lacked substantial resources to support themselves before they fled, or spent much of what they had to escape their country and travel to the United States. Those with resources may have been forced to leave what they had behind because they lacked the time to sell property or otherwise gather what they owned. When whole families are threatened, the primary earner may be

the first to travel to the United States to establish a new home before bringing the rest of the family. The cost to travel to the United States is high, as is the relative cost of living. In these circumstances, if the asylum seeker is unable to seek employment for extended periods of time, it can not only negatively impact that individual, but the whole family as well.

For those who have already found jobs to support their needs, the potential for their initial EADs to expire prior to the approval and issuance of a renewed EAD may force them back into instability caused by a gap in the ability to legally work. Some employers, notwithstanding possible violation of INA section 274B governing unfair immigration-related employment practices (8 U.S.C. 1324b), or other laws, may also be hesitant to accept EADs as proof of employment authorization or hire employees who present EADs in the first place if it appears maintaining their employment will be difficult due to potential lapses in employment authorization. Continuous employment authorization during the pendency of an asylum application is vital for asylum seekers in the United States in order to access housing, food, and other necessities. In addition, asylum seekers may need income or employment to access medical care, mental health services, and other resources, as well as to access legal counsel in order to pursue their claims before USCIS or the Executive Office for Immigration Review (EOIR). Access to mental health services is particularly crucial for asylum seekers due to the prevalence of trauma-induced mental health concerns, including depression and post-traumatic stress disorder (PTSD). The physical harm experienced by many asylum seekers necessitates continuous medical care for extended periods of time. Finally, the purpose for which asylum seekers came to the U.S. is to seek long-term protection by receiving asylum. Legal assistance may be key for an asylum seeker to successfully claim asylum,⁶² but it is also often expensive.

⁵⁹ See Employment Authorization Applications Rule and the Asylum Application, Interview, and Employment Authorization for Applicants Rule ("Broader Asylum EAD Rule"), 85 FR 38532 (June 26, 2020), and preliminary injunction in *Casa de Maryland Inc. et al. v. Chad Wolf et al.*, 8:20–cv–02118–PX (D. Md. Sept. 11, 2020).

⁶⁰ See *Asylumworks, et al. v. Alejandro N. Mayorkas, et al.*, No 20–CV–3815 BAH, 2022 WL 355213 (D.D.C. Feb 7, 2022).

⁶¹ See INA 208(d)(2), 8 U.S.C. 1158(d)(2).

⁶² See Transactional Records Access Clearinghouse, *Asylum Grant Rates Climb Under*

B. Effect of Operational Challenges on Form I-765 Adjudications

1. Precarious Fiscal Status in 2020 and Part of 2021

USCIS is a fee-based agency that relies on predictable fee revenue and its carryover from the previous year. USCIS began experiencing fiscal troubles as early as December 2019, when at least one USCIS directorate initiated a hiring freeze.⁶³ These fiscal troubles were due in part to the fact that USCIS has not been able to update its fee structure since the 2016 Fee Rule⁶⁴ (including fees for Form I-765), which does not fully cover the costs of administering current and projected volumes of immigration benefit requests.

USCIS promulgated a new Fee Rule in August 2020 to address this fee/cost disparity.⁶⁵ In September 2020, however, the 2020 Fee Rule was enjoined before it took effect and remains under a preliminary injunction.⁶⁶ As such, the current fee for Form I-765 remains at \$410, the fee set by the earlier 2016 Fee Rule.⁶⁷ The 2016 Fee Rule also exempts applicants from paying a fee if filing a Form I-765 to request renewal or replacement under 8 CFR 274a.12(c)(9) (pending adjustment of status application), as well as some additional categories.⁶⁸

The 2020 Fee Rule would have made various changes to USCIS filing fees to help cover the increased cost of adjudicating benefit requests, including a 34 percent increase for the Form I-765

filing fee to \$550, and removing fee exemptions for Form I-765 renewals or replacements for applicants filing under 8 CFR 274a.12(c)(9), among other categories.⁶⁹ USCIS continues to rely on the fee schedule established in the 2016 Fee Rule, which does not fully account for current costs associated with adjudicating benefit requests. This unsustainable fiscal situation has, among other things, resulted in the inability to fund sufficient new officer positions to handle the heavy adjudication workload,⁷⁰ meaning that USCIS was already in a precarious financial position with regard to staffing when the COVID-19 pandemic began.

2. Public Health Emergency

On January 31, 2020, the Secretary of Health and Human Services (HHS) declared a public health emergency under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19, which is caused by the SARS-CoV-2 virus.⁷¹ On February 24, 2021, the President issued a continuation of the national emergency concerning the COVID-19 pandemic.⁷² Effective October 15, 2021, HHS renewed the determination that “a public health emergency exists and has existed since January 27, 2020 nationwide.”⁷³ On January 14, 2022, and as a result of the continued consequences of the COVID-19 pandemic, HHS renewed yet again the determination that a public health emergency exists.⁷⁴

As noted above, USCIS was already in a precarious financial situation in 2019. This was severely exacerbated by a significant drop in receipts across many of the most common benefit types at the beginning of the COVID-19 pandemic in spring 2020.⁷⁵ The significant drop in revenue USCIS experienced early in the pandemic led the agency to plan for a sweeping furlough of approximately 70 percent of its workforce to avoid financial collapse, including furloughing immigration services officers who adjudicate the Form I-765.⁷⁶ To avoid the drastic furlough measures, USCIS employed every available means to preserve sufficient funds to meet payroll and carryover obligations. These measures included drastic cuts for supplies, facilities, overtime, and contractor support services, as well as an agency-wide hiring freeze lasting from May 1, 2020, through March 31, 2021. The loss of overtime funds hindered USCIS’ ability to address and mitigate backlogs through use of existing staff, which has been a strategy used successfully in the past to ensure processing times remain within goals. For example, in FY 2019, USCIS used \$5.52 million of overtime funds for assigned staff to conduct border case⁷⁷ processing after working business hours and on the weekends, instead of assigning more staff to those caseloads during regular work hours, which would have pulled them away from affirmative asylum processing. Through the use of overtime, USCIS was able to continue to maintain its assigned staffing levels to affirmative asylum processing, but this option was not available in 2020, due to USCIS’ worsening fiscal situation beginning in late 2019 and continuing into 2020 and part of 2021. USCIS took action to avert a fiscal crisis, including limiting

Biden (2021), <https://trac.syr.edu/immigration/reports/667/> (last updated Nov. 10, 2021) (“Asylum seekers who are represented by an attorney have greatly increased odds of winning asylum or other forms of relief from deportation.”).

⁶³ USCIS’ Field Operations Directorate (FOD) initiated a hiring freeze in December 2019; USCIS’ Service Center Operations Directorate (SCOPS) did the same starting in February 2020. While both FOD and SCOPS adjudicate Forms I-765, SCOPS adjudicates the vast majority, including all those filed by pending asylum applicants (CO8 category).

⁶⁴ See 81 FR 73292 (Oct. 24, 2016).

⁶⁵ See *U.S. Citizenship and Immigration Services Fee Schedule and Changes to Certain Other Immigration Benefit Request Requirements*, 85 FR 46788 (Aug. 3, 2020) (“2020 Fee Rule”). The 2020 Fee Rule, among other things, adjusted certain immigration and naturalization benefit request fees charged by USCIS, removed certain fee exemptions, and changed the fee waiver requirement.

⁶⁶ On September 29, 2020, the U.S. District Court for the Northern District of California in *Immigration Legal Resource Center, et al. v. Wolf, et al.*, 20-cv-05883-JWS, preliminarily enjoined DHS from implementing or enforcing any part of the 2020 Fee Rule.

⁶⁷ See 81 FR 73292 (Oct. 24, 2016).

⁶⁸ See 85 FR 46788 (Aug. 3, 2020). Additional categories exempt from the filing fee include 8 CFR 274a.12(a)(8) and (10) and (c)(1), (4), (7), and (16). The category at 8 CFR 274a.12(c)(9) is one of the top categories experiencing unusually long processing times and, therefore, is one of the main focuses of this rule.

⁶⁹ See 85 FR 46788 (Oct. 2, 2020). As noted above, DHS is preliminarily enjoined from implementing or enforcing any part of this rule.

⁷⁰ From FY 2015 through FY 2020, USCIS received a range of approximately 2.0 to 2.3 million Form I-765 filings (seeking both initial EADs and renewal of initial EADs) each fiscal year. In FY 2021, this figure increased to approximately 2.6 million. This increase in Form I-765 filings, which was largely observed in the volume of Form I-765 renewal applications sought in categories eligible for automatic extension of EADs, contributed to the formation of backlogs, as discussed further in Section II.C below.

⁷¹ See HHS, *Determination that a Public Health Emergency Exists* (Jan. 31, 2020), <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

⁷² *Notice on the Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID-19) Pandemic*, 86 FR 11599 (Feb. 26, 2021); *Proclamation 9994 of March 13, 2020, Declaring a National Emergency Concerning the Coronavirus Disease (COVID-19) Outbreak*, 85 FR 15337 (Mar. 18, 2020).

⁷³ HHS, *Renewal of Determination that a Public Health Emergency Exists* (Oct. 15, 2021), <https://www.phe.gov/emergency/news/healthactions/phe/Pages/COVID15Oct21.aspx>.

⁷⁴ See HHS, Office of the Assistant Secretary for Preparedness and Response, *Renewal of Determination that a Public Health Emergency Exists* (Jan. 14, 2022), <https://aspr.hhs.gov/legal/PHE/Pages/COVID19-14Jan2022.aspx>.

⁷⁵ See 2020 USCIS Statistical Annual Report, p. 4: “[During the onset of the COVID-19 pandemic], incoming receipts were 32 percent lower compared to the same time period in FY 2019. By the end of FY 2020, USCIS received about 5% fewer receipts than in FY 2019. Although receipts decreased in some of the most frequently submitted form types, others such as the N-400 (Application for Naturalization) and I-129 (Petition for Nonimmigrant Worker) increased slightly from FY 2019.” In addition to the lowest number of receipts in the past 5 years, USCIS also completed the lowest number of benefit requests in the past 5 years. The worst rates of completion were observed during the beginning of the pandemic when USCIS field offices and ASCs were closed to the public. While USCIS attempted to recover by shifting adjudications to form types not requiring in-person appearances, USCIS still completed fewer benefit requests than it received in FY 2020. See 2020 USCIS Statistical Annual Report, p. 4.

⁷⁶ During this time period, USCIS had an estimated \$1.2-billion budget shortfall.

⁷⁷ A border case included credible and reasonable fear interviews, as well as Migrant Protection Protocols (MPP) non-refoulement interviews.

spending to salaries and mission-critical activities; making drastic cuts to spending on supplies, facilities, and contractor support services; and eliminating overtime. The loss of contractor support services also hindered USCIS' ability to intake filings efficiently and prepare cases for adjudication by officers. The agency-wide hiring freeze expanded upon individual USCIS components' hiring freezes already in place.

These fiscal issues had a direct impact on staffing, and insufficient staffing levels directly impacted the processing times for Form I-765. In addition to a direct shortage of staff due to hiring freezes, USCIS experienced a noticeable increase in attrition following announcement of a potential furlough that could have impacted nearly 70 percent of employees.⁷⁸ Although DHS cannot quantify employees' reasons for leaving, it is likely that the threatened furlough and uncertain fiscal status of the agency played a role. The hiring freeze also meant that the higher-than-normal number of vacancies could not be filled. Additionally, a number of initiatives have taken staff away from their normal duties such as important temporary assignments to the southern border, efforts relating to unaccompanied children, and processing petitions and applications by or on behalf of Afghan evacuees. All these factors contributed to a decrease in Form I-765 completions. For example, in FY 2019, the Service Center Operations Directorate (SCOPS)

allocated 343,399 officer hours to its Form I-765 workload⁷⁹ and completed 1,443,235 adjudications (mostly Form I-765 applications filed under 8 CFR 274a.12(c)(8), followed by (c)(33) (granted DACA) and (c)(3)(B) (student post-completion optional practical training (OPT)). By comparison, in FY 2020, SCOPS allocated 327,947 (or approximately 4.5 percent fewer) officer hours to the same workload and subsequently was only able to complete 1,379,745 (or approximately 4.4 percent fewer) adjudications. These reductions were partly attributable to the overall decrease in staff, as well as competing priorities which factor into how existing resources are allocated. At the start of FY 2020, SCOPS had 5,102 employees on board. This diminished to 4,886 at the start of FY 2021 and 4,731 at the start of FY 2022 as the effects of attrition and the hiring freeze continued. This overall decrease of approximately 7.3 percent does not include the additional loss of I-765 adjudication hours that stemmed from SCOPS supporting several programs requesting detailees.⁸⁰ The number of detailees temporarily missing from the SCOPS workforce has not been static, but exceeded 200 employees at points during FY 2021, leaving SCOPS staffed at levels less than 89 percent of what existed going into FY 2020. This data does not include contractor hours, which also were severely impacted by USCIS' fiscal situation as USCIS was forced to reduce

the number of contractors available to assist with case processing.

Nonetheless, despite the reduction in officer hours, USCIS was able to maintain its 3-month processing goal up until December 2020, due to a corresponding reduction in Form I-765 receipts. This changed in CY 2021, when USCIS experienced an extraordinary, 2-month surge of Form I-765 filings in spring 2021 and a sustained increase of filings thereafter, which is discussed further in Section C below. Despite the surge of Form I-765 filings, SCOPS was able to allocate only 314,924 officer hours (or approximately 4.0 percent fewer than FY 2020 and approximately 8.3 percent fewer than FY 2019) to its Form I-765 workload and completed only 1,249,548 adjudications (or approximately 9.4 percent fewer than FY 2020 and approximately 13.4 percent fewer than FY 2019) due to insufficient staffing and competing priorities. USCIS was unable to surge additional resources to increase officer hours adjudicating Form I-765 applications because of USCIS' limited resources and the need to manage other competing priorities in FY 2021. For example, USCIS surged officers to adjudicate employment-based Form I-485 applications to minimize the number of employment-based immigrant visas that would go unused at the end of FY 2021, after an extraordinary number of such unused family-preference visa numbers from FY 2020 "fell across" to the employment-based visa allocation for FY 2021, *see generally* INA 201(d)(2)(C), 8 U.S.C. 1151(d)(2)(C), due primarily to Department of State consular closures caused by the COVID-19 pandemic.

⁷⁸ See DHS, USCIS, News Release, *Deputy Director for Policy Statement of USCIS' Fiscal Outlook* (June 25, 2020), <https://www.uscis.gov/news/news-releases/deputy-director-for-policy-statement-on-uscis-fiscal-outlook>.

⁷⁹ Form I-765 workload includes requests for initial, renewal, and replacement employment authorization and/or EADs.

⁸⁰ A detail is a temporary assignment of an employee to a different position for a specified period, with the employee returning to his or her regular duties at the end of the detail.

TABLE 2—IMPACT OF STEADILY DECREASING STAFFING LEVELS ON SCOPS’ FORM I–765 COMPLETIONS
[initial and renewal applications]

Fiscal year	Officer hours allocated	Form I–765 completions
2019	343,399	1,443,235.
2020	327,947 (approximately 4.5 percent fewer than 2019)	1,379,745 (approximately 4.4 percent fewer than 2019).
2021	314,924 (approximately 8.3 percent fewer than 2019 and 4.0 percent fewer than 2020).	1,249,548 (approximately 13.4 percent fewer than 2019 and 9.4 percent fewer than 2020).

Note: This data does not include contractor hours, which also were severely impacted by USCIS’ fiscal situation as USCIS was forced to reduce the number of contractors available to assist with case processing. SCOPS’ contractor staff has been reduced by approximately 8.2% since October 1, 2020.

The Field Office Directorate’s National Benefit Center (NBC), which also adjudicates a number of Form I–765

applications⁸¹ observed a similar reduction in staff and completions.

TABLE 3—IMPACT OF STEADILY DECREASING STAFFING LEVELS ON NBC’S FORM I–765 COMPLETIONS
[initial and renewal applications]

Fiscal year	Officer hours allocated	Form I–765 completions
2019	115,510	612,464.
2020	112,266 (approximately 2.8 percent fewer than 2019)	605,105 (approximately 1.2 percent fewer than 2019).
2021	102,099 (approximately 11.6 percent fewer than 2019 and 9.1 percent fewer than 2020).	509,973 (approximately 16.7 percent fewer than 2019 and 15.7 percent fewer than 2020).

Note: This data does not include contractor hours, which also were severely impacted by USCIS’ fiscal situation as USCIS was forced to reduce the number of contractors available to assist with case processing.

3. Other Impacts to Operations

In response to the declaration of a public health emergency, USCIS instituted a number of changes to protect USCIS employees and immigration benefit applicants. From March 18 through June 3, 2020, USCIS closed all field offices and asylum offices to the public, nearly halting all in-person services.⁸² At USCIS field offices, officers conduct in-person interviews related to Form I–485, Application to Register Permanent Residence or Adjust Status, as well as Form N–400, Application for Naturalization, to become a U.S. citizen, among other work. At USCIS asylum offices, officers conduct in-person interviews of asylum applicants (using Form I–589, Application for Asylum and Withholding of Removal). Upon reopening to the public, many asylum offices operated at lower capacity than

before the halt in in-person services. Interviewing rooms that previously accommodated asylum officers, asylum applicants, interpreters (if present), and attorneys (if present) all in one room, now would accommodate just the asylum officer, with applicants and any other participants each sitting in separate interview rooms and connecting electronically. This setup substantially decreased daily interview capacity.⁸³

SCOPS’ service centers and the NBC, which are not open to the public, never closed, but all Federal functions that could be accomplished at an alternate location were designated for telework to minimize in-person contact and allow proper social distancing for Federal and contract staff whose work required on-site presence. In the early weeks of COVID–19 restrictions, assignments were adjusted to provide telework-

suitable work as logistics relating to industrial hygiene were put in place to expand capacity for on-site functions while providing appropriate protections for on-site workers. Service centers and the NBC continued operations by expanding telework capabilities; however, logistics associated with completing work that could not be conducted at home, such as accepting filings, mailroom activities, and file movement, remained a challenge. There was high absenteeism due to COVID–19 quarantine rules among contractors engaged in receipt and file movement activities, which created “frontlogs” in receipts—delays in entering receipt data into USCIS systems—as well as delays in other areas requiring physical handling of files and mail. Furthermore, Form I–765 generally is adjudicated on

⁸¹ Such as initial and renewal Forms I–765 filed under 8 CFR 274a.12(c)(9) and (10), which experienced a dramatic growth in processing times in 2021, as detailed in this rule.

⁸² See, e.g., News Alert, USCIS Temporarily Closing Offices to the Public March 18–April 1 (Mar. 17, 2020), <https://www.uscis.gov/news/alerts/uscis-temporarily-closing-offices-to-the-public-march-18-april-1>. Some limited emergency in-person services were available upon request during this time.

⁸³ USCIS has issued a series of temporary final rules that allow asylum offices to increase the use of telephonic interpreters, in order to minimize the impact of this safety measure on the agency’s ability to adjudicate asylum applications in a timely manner. See *Asylum Interview Interpreter*

Requirement Modification Due to COVID–19, 85 FR 59655 (Sept. 23, 2020) (TFR); *Asylum Interview Interpreter Requirement Modification Due to COVID–19*, 86 FR 15072 (Mar. 22, 2021); and *Asylum Interview Interpreter Requirement Modification Due to COVID–19*, 86 FR 51781 (Sept. 17, 2021). As described in Section D.1. below, asylum application processing times impact Form I–765 renewal processing because the longer an asylum application is pending, the more times an applicant may need to file Form I–765 to renew employment authorization. If an individual’s asylum application is approved, they no longer need to file Form I–765 to obtain employment authorization because asylees are employment authorized incident to status. See 8 CFR 274a.12(a)(5). While some asylees may choose to file Form I–765 using the (a)(5) category to receive

EADs as evidence of their employment authorization, asylum applicants under the (c)(8) category make up approximately 10 times more Form I–765s than asylees under the (a)(5) category. See DHS, USCIS, *Form I 765 Application for Employment Authorization All Receipts, Approvals, Denials Grouped by Eligibility Category and Filing Type* (FY 2019–21), https://www.uscis.gov/sites/default/files/document/data/I-765_Application_for_Employment_FY03-21.pdf (last updated Oct 2021). Therefore, USCIS’ efforts to minimize the impact of safety measures on the agency’s ability to adjudicate asylum applications is helping to reduce the number of asylum applicants making up the pending Form I–765 applicant pool, which is helping to reduce the overall Form I–765 adjudication backlog.

a paper receipt file,⁸⁴ and up until 2020, application intake and initial processing generally was handled by Federal contractors, many of whom were terminated due to USCIS' fiscal troubles as detailed above. Proactive adjustments to workspaces, schedules, and file movement practices restored these functions despite a contractor workforce shortfall, but adjustments took approximately 3–5 months to develop and take effect.

USCIS Application Support Centers (ASC), which primarily collect biometrics such as photographs and fingerprints in relation to immigration benefit requests, were similarly impacted by the COVID–19 public health emergency. ASCs were temporarily closed from March 18 through July 12, 2020, and began a phased reopening with limited capacity on July 13, 2020. Under normal circumstances, individuals who must appear at an ASC are scheduled to do so within 3–4 weeks of USCIS receiving the underlying application; however, the lengthy closures created massive appointment backlogs. The ASC appointment backlog reached its peak of 1.4 million in January 2021. Although this backlog has been largely addressed, the downstream effects linger in many work streams.⁸⁵ Historically, there have been limited Form I–765 categories that require biometrics submission;⁸⁶ however, the Employment Authorization Applications Rule and the Asylum Application, Interview, and Employment Authorization for Applicants Rule (“Broader Asylum EAD Rule”), 85 FR 38532 (June 26, 2020), imposed a biometrics collection

⁸⁴ Although some Form I–765 applications for certain eligibility categories (e.g., (c)(3)(A), F–1 Pre-completion OPT; (c)(3)(B), F–1 Post-completion OPT; and (c)(3)(C), F–1 STEM OPT extension) now can be received and adjudicated in an electronic system, in early 2020, all Form I–765 applications were adjudicated on paper.

⁸⁵ USCIS sought to mitigate the impact of this biometrics capture delay by reusing biometrics where possible. See, e.g., USCIS News Alert, USCIS to Continue Processing Applications for Employment Authorization Requests Despite Application Support Center Closures (Mar. 30, 2020), <https://www.uscis.gov/news/alerts/uscis-to-continue-processing-applications-for-employment-authorization-extension-requests-despite>.

⁸⁶ For example, in general, applicants must pay an \$85 biometric collection services fee if filing with one of the following eligibility categories: (c)(8) An applicant with a pending asylum application requesting an initial or renewal EAD; (c)(33) Requesting consideration of Deferred Action for Childhood Arrivals (DACA); (c)(35) A principal beneficiary of an approved employment-based immigrant petition who is facing compelling circumstances; (c)(36) A spouse or unmarried dependent child of a principal beneficiary of an employment-based immigrant petition who is facing compelling circumstances; or (c)(37) An applicant for Commonwealth of the Northern Mariana Islands long-term resident status.

requirement for initial and renewal Forms I–765 in the C08 asylum applicant category—which represents approximately 58 percent of the renewal EAD receipts filed that are eligible for the automatic extension. Consequently, when ASCs were closed, most Form I–765 renewal applications in the C08 category could not be processed.⁸⁷ Furthermore, once ASCs reopened, a large number of applications of varying types needed to be rescheduled, yet there were a limited number of ASC appointments available. This led to delays in applicants receiving ASC appointments, which further delayed the processing of their applications, including Form I–765 renewal applications in the C08 category. The delay in biometrics capture created an interruption to adjudications by preventing applications from getting to the “adjudication-ready” stage. Many categories of I–765s are dependent on their own biometrics requirement or a biometrics requirement associated with an underlying benefit, resulting in bottlenecks that slowed overall adjudications and increased processing times. The new biometrics collection requirement for Form I–765 renewal applications in the C08 category thus played a significant role in the downstream effects of ASCs' temporary closures.

In addition, while adjudication of Form I–765 does not generally include an in-person interview, some Forms I–765 are based on pending applications that do involve in-person interviews. With the fiscal and operational constraints outlined above, USCIS had processing delays in adjustment of status applications and asylum applications; applicants seeking employment authorization based on a pending adjustment of status application or asylum application comprise the great majority of the filing population seeking renewal EADs and

⁸⁷ However, the U.S. District Court for the District of Maryland's Sept. 11, 2020, preliminary injunction in *Casa de Maryland Inc. et al. v. Chad Wolf et al.*, 8:20-cv-02118-PX (D. Md. Sept. 11, 2020), provided limited injunctive relief to members of two organizations, CASA de Maryland (CASA) and the Asylum Seeker Advocacy Project (ASAP), who file Form I–589 or Form I–765 as asylum applicants. Specifically, the court preliminarily enjoined enforcement of several regulatory changes in the Removal of 30-Day Processing Provision for Asylum Applicant-Related Form I–765 Employment Authorization Applications Rule, 85 FR 37502 (June 22, 2020), and the Broader Asylum EAD Rule for CASA and ASAP members, including the requirement to submit biometric information as part of the filing of a Form I–765 based on an asylum application. On February 7, 2022, the U.S. District Court for the District of Columbia in *Asylumworks, et al. v. Alejandro N. Mayorkas, et al.* vacated these two rules entirely.

eligible for an automatic extension of their EADs under 8 CFR 274a.13(d).⁸⁸ Owing to USCIS' inability to adjudicate interview-dependent adjustment of status and asylum applications while its offices were closed, those cases were pending longer than usual, in addition to an influx of new applications. With those underlying applications taking longer to process, the population of applicants who needed to request EAD renewals during the pendency of their primary applications increased.⁸⁹

Even though USCIS reopened its ASCs, field offices, and asylum offices in mid-2020, USCIS still is working to return to pre-pandemic levels of operation, with varying progress across programs. For example, social distancing guidelines result in reduced interview capacity and productivity for some interview-dependent benefit requests, including some adjustment of status and asylum applications. USCIS implemented measures to recapture productivity under social distancing protocols, including video-assisted interviewing, increased use of telephonic interpreters,⁹⁰ expanded

⁸⁸ See above section entitled “Overview of Issues Negatively Impacting Form I–765 Processing Times.”

⁸⁹ For example, in 2020, an applicant seeking employment authorization based on a pending adjustment of status application would have obtained an EAD valid for 1 year, if eligible. With processing times for adjustment of status applications extending beyond 1 year, the applicant would have to apply to renew the EAD to obtain employment authorization while their adjustment of status application remains pending. Where adjustment of status applications with an immediately available immigrant visa are processed within the 6-month processing goal, such applicants generally should not have to renew their EAD as they would receive employment authorization incident to their lawful permanent resident status upon approval of their adjustment of status application. In recognition of prolonged processing times for adjustment of status applications, USCIS updated its policy guidance to provide a 2-year validity period for initial and renewal EADs issued based on pending adjustment of status applications. See USCIS Policy Manual, Policy Alert (PA–2021–10), Employment Authorization for Certain Adjustment Applicants (Jun. 9, 2021), <https://www.uscis.gov/sites/default/files/document/policy-manual-updates/20210609-EmploymentAuthorization.pdf>. In doing so, USCIS attempted to alleviate the burden on adjustment of status applicants seeking EADs. Unfortunately, USCIS was unable to take similar steps for the asylum applicant population, as it was already providing 2-year validity periods for employment authorization and EADs, the maximum allowed by the Broader Asylum EAD Rule. As of December 2021, the median processing time for affirmative asylum applications (Form I–589) is 55.4 months. As of December 2021, the median processing time for adjustment of status applications (Form I–485) is 13.2 months, however some adjustment applications remain pending much longer because of regression in the cutoff dates used to determine when an immigrant visa is immediately available.

⁹⁰ See *Asylum Interview Interpreter Requirement Modification Due to COVID–19*, 85 FR 59655 (Sept.

work flexibilities for USCIS employees,⁹¹ and remote applicant-centric services such as a pilot remote-attorney participation program.⁹² However, the impacts of the operational disruptions in 2020 are still evident in USCIS' prolonged processing times, illustrating USCIS' continued struggle to address the pending cases that accrued when offices were closed while attempting to keep pace with new filings (which, in the case of Form I-765 renewals, unexpectedly surged in 2021, as described below).⁹³

Additionally, USCIS continues to provide flexibilities in recognition of the pandemic's ongoing impacts on benefit requestors, which in some cases negatively impact the efficiency of USCIS operations.⁹⁴ For example, USCIS continues to provide rescheduling flexibilities for interviews and ASC appointments, limit the number of staff and members of the public that may appear in person at a USCIS office, and provide flexibilities pertaining to responses to Requests for

23, 2020) (TFR); *Asylum Interview Interpreter Requirement Modification Due to COVID-19*, 86 FR 15072 (Mar. 22, 2021); and *Asylum Interview Interpreter Requirement Modification Due to COVID-19*, 86 FR 51781 (Sept. 17, 2021).

⁹¹ As an example, USCIS expanded telework flexibility arrangements under which an employee could perform the duties and responsibilities of such employee's position, and other authorized activities, from an approved worksite other than the location from which the employee would normally work. In addition, certain telework restrictions were lifted (e.g., allowing split shifts, non-standard work hours, and mixing telework and leave) so that caregivers and parents could meet personal and work obligations while working from home.

⁹² See *Impact of Pandemic Response Measures*, p. 6, in *Backlog Reduction of Pending Affirmative Asylum Cases: Fiscal Year 2021 Report to Congress* (Oct. 20, 2021), <https://www.dhs.gov/sites/default/files/2021-12/USCIS%20-%20Backlog%20Reduction%20of%20Pending%20Affirmative%20Asylum%20Cases.pdf>.

⁹³ In the last three fiscal years, the median processing time across all form types was 8.7 months in FY 2021, 8.3 months in FY 2020, and 6.5 months in FY 2019.

⁹⁴ For a detailed description of the many flexibilities and precautionary measures USCIS provides to combat COVID-19, see USCIS's website at <https://www.uscis.gov/about-us/uscis-response-to-covid-19> (last updated Mar 30, 2022).

Evidence (RFEs) and Notices of Intent to Deny (NOIDs) by considering a response received within 60 calendar days after the response due date set in the request or notice before taking any action.⁹⁵

While USCIS believes these steps have been critical to address the impacts of the COVID-19 pandemic, these measures have not been implemented without costs. Limiting the number of in-person staff at any given time may reduce the number of interviews USCIS can conduct in any given day, although USCIS is exploring additional alternatives to in-person interviewing that may mitigate this impact. Providing rescheduling flexibilities for interviews and time for responses for RFEs or NOIDs also prolong the officer's adjudication times. The downstream effect of delays in initial file processing, delays at the ASC and field offices, and insufficient staffing levels due to USCIS' fiscal situation in calendar years 2019 and 2020, as well as delays caused in certain workloads due to workforce shifts to ensure timely adjudication of other benefits, contributed to USCIS accruing an overall net backlog⁹⁶ of approximately 5.1 million cases as of the end of December 2021, of which 930,000 (approximately 18%) were pending Form I-765 applications.

⁹⁵ See *Deadlines for Certain Requests, Notices, and Appeals in the USCIS Response to COVID-19* web page at <https://www.uscis.gov/about-us/uscis-response-to-covid-19> (last updated Mar. 30, 2022).

⁹⁶ Backlog is defined as the volume of pending applications that exceed the level of acceptable pending cases. Whether a pending case load is acceptable is pegged to the volume of applications receipted during the target cycle time period (e.g., 5 months). The target cycle time refers to the processing time goal for a given application type. Net backlog is defined similarly to backlog, except that the number of pending applications is reduced to account for cases in active suspense categories (i.e., cases that are deducted from the gross backlog, such as cases with a pending Request for Evidence, cases awaiting visa availability from the Department of State, or cases pending re-examination for an N-400, Application for Naturalization).

C. Sudden Increase in Form I-765 Filings in 2021

1. Comparing FY 2021 Receipts to Prior Years' Receipts

The most recent contributing factor to the severe backlog and increased processing times for Forms I-765 is a substantial and unprecedented 2-month increase of Form I-765 renewal filings in March and April 2021, and a sustained increase in filings thereafter. In CY 2019, the average number of monthly renewal applications filed for the C08, C09, and C10 categories combined was 46,715. In CY 2020, the average number of monthly renewal applications filed for these three categories was 43,232. In March 2021, the renewal receipt numbers for these three categories spiked 56 percent over the previous month and 76.4 percent over the monthly average total for 2020. In April 2021, the renewal receipt numbers for these three categories remained elevated such that they were 25.6 percent higher than February 2021, and 53.6 percent over the monthly average total for 2020. The March and April 2021 increase in Form I-765 renewal applications was unexpected based on historical filing patterns and appears to be related to litigation.⁹⁷

⁹⁷ This increase in Form I-765 filings may have been driven primarily by litigation and the "frontlog" of applications at the three USCIS lockbox facilities, which receive and process applications and payments in Chicago, Illinois; Phoenix, Arizona; and Lewisville, Texas. On July 20, 2020, Casa de Maryland, Inc. filed suit against then-Acting DHS Secretary Chad Wolf and DHS to enjoin changes to EAD rules for asylum seekers. On September 11, 2021, the U.S. District Court of Maryland issued a preliminary injunction of the new EAD rules. See *Casa de Maryland v. Wolf*, 486 F.Supp.3d 928 (D. Md. Sept. 11, 2020). Consequently, approximately 23,000 applications pending at the USCIS lockbox were rejected in late October 2020 for a failure to pay the required biometrics fee or a failure to provide proof that the applicant was a member of the litigation class. These applications were refiled and, coupled with the prioritization of initial Form I-765 applications under category C08 due to the litigation, led to a redirection of resources away from Form I-765 renewal applications. In addition, as noted above, the lockbox was experiencing a "frontlog" of applications, which led to a processing delay.

TABLE 4—SURGE IN RENEWAL FORM I-765 FILINGS

Month	C08 category	C09 category	C10 category	Average total
February 2021	30,857	14,661	8,367	52,885
March 2021	52,007	19,589	10,840	82,436
April 2021	42,101	15,189	9,134	66,424
May 2021	32,751	13,332	7,887	53,960

In the eight months following April 2021, the receipt numbers for these categories fell to an average of 52,400 receipts per month, but that was still 21 percent above the average monthly total for CY 2020. The increase in the number and duration of pendency of asylum and adjustment of status applications, which form the basis for the two most populous EAD filing categories eligible

for the automatic extension under 8 CFR 274a.13(d)(1), may have led to this sustained increase in applications for initial and renewal employment authorization (in the C08 and C09 categories, respectively), which further compounded the Form I-765 adjudication backlog.⁹⁸

Specifically, in the years leading up to FY 2022, asylum application receipts

outpaced available resources leading to an increase in pending asylum cases, both in affirmative and defensive filings, as shown in Table 5.⁹⁹ The increase in pending asylum cases contributed to the increase in C08 renewal filings in FY 2021, which further impacted the Form I-765 renewal backlog.

TABLE 5—TOTAL ASYLUM CASES PENDING

	DOJ ¹⁰⁰	USCIS ¹⁰¹	Total
Total Asylum Cases Pending in:			
FY 2017 (Sep 2017)	377,140	289,835	666,975
FY 2018 (Sep 2018)	473,510	319,202	792,712
FY 2019 (Sep 2019)	608,976	339,836	948,812
FY 2020 (Sep 2020)	647,923	386,014	1,033,937
FY 2022 (Dec 2021)	628,551	432,341	1,060,892

The number of employment-based adjustment of status applications increased significantly in FY 2021, as well, due to the inordinate number of employment-based visas that became available as a result of unusually low visa usage in other categories in FY 2020 due to the COVID-19 pandemic. At the start of FY 2021, there were approximately 126,000 employment-based adjustment of status applications pending with USCIS. Approximately 313,000 employment-based adjustment of status applications were received during FY 2021, which likely contributed to the increase in C09 initial filings in FY 2021, consequently further taxing USCIS' resources to timely process renewal applications. USCIS also saw significant increases in filings across other benefit request types during CY 2021.¹⁰²

This surge and sustained increase in Form I-765 receipts over the course of

CY 2021 as compared to the previous calendar year compounded what otherwise might have been a moderate Form I-765 backlog and created a substantial spike in processing times. In CY 2021, USCIS received approximately 2,550,000 initial and renewal Forms I-765, which was 22 percent higher than the volume received in CY 2020 (approximately 2,090,000) and 15 percent higher than the volume received in CY 2019 (approximately 2,210,000). Similarly, in CY 2021, USCIS received approximately 1,260,000 Form I-765 renewal applications, which was 21 percent higher than the volume received in CY 2020 (approximately 1,040,000) and 13 percent higher than the volume received in CY 2019 (approximately 1,120,000).

TABLE 5A—INITIAL AND RENEWAL FORM I-765 FILINGS

Calendar year	Form I-765 filings	Surge or difference
2019	2,210,000	
2020	2,090,000	5 percent lower than 2019.
2021	2,550,000	15 percent higher than 2019. 22 percent higher than 2020.

TABLE 5B—RENEWAL FORM I-765 FILINGS

Calendar year	Form I-765 filings	Surge or difference
2019	1,120,000	
2020	1,040,000	7 percent lower than 2019.
2021	1,260,000	13 percent higher than 2019. 21 percent higher than 2020.

As demonstrated above, calendar years 2020 and 2021 were difficult years for USCIS because unprecedented

⁹⁸ USCIS is actively working to address prolonged processing times affecting applications and petitions that form the basis of a Form I-765 filing. These measures are described in further detail in Section D.1 below.

⁹⁹ See Background, p. 2, in Backlog Reduction of Pending Affirmative Asylum Cases: Fiscal Year 2021 Report to Congress (Oct. 20, 2021), <https://www.dhs.gov/sites/default/files/2021-12/USCIS%20-%20Backlog%20Reduction%20of%20Pending%20Affirmative%20Asylum%20Cases.pdf> (“The affirmative asylum backlog is the result of a prolonged, significant increase in affirmative asylum application filings and credible fear screenings,

which are processed by the U.S. Citizenship and Immigration Services (USCIS) asylum offices. Between FY 2013 and FY 2017, despite significant staffing increases, receipt growth in asylum office workloads outpaced the expansion of asylum office staffing and the establishment of new or expanded facilities needed to support additional staffing growth.”).

¹⁰⁰ See Executive Office of Immigration Review Adjudication Statistics, Total Asylum Applications (Jan 19, 2022), <https://www.justice.gov/eoir/page/file/1106366/download>.

¹⁰¹ Data reflects affirmatively filed I-589 asylum applications and do not include defensive asylum claims before a DOJ EOIR immigration court. See

USCIS, Number of Service Wide Forms, October 1, 2021–December 31, 2021, https://www.uscis.gov/sites/default/files/document/reports/Quarterly_All_Forms_FY2022_Q1.pdf (last updated Feb. 2022).

¹⁰² For example, USCIS also encountered large increases of filings of Form I-131, Application for Travel Document, possibly related to the increase in filings of Form I-485, Application to Register Permanent Residence. From CY 2020 to CY 2021, USCIS observed an overall 25.8 percent increase in receipts across form types. Although this represents a substantial increase, there was a 29 percent increase in Form I-765 renewal applications in the auto extension categories.

financial strains led to staffing issues, resulting in an inability to handle the 2-month spike and monthly increase in filings in CY 2021 over CY 2020. The average monthly receipts in 2021 for the automatic extension categories were 60,300, which was 13,500 per month (or 29 percent) higher than 2020 monthly averages. In addition to this higher overall receipt volume in 2021, there was a surge in receipts in March 2021 (88,500) and April 2021 (71,200) that led to a rapid increase in pending applications. On top of the higher receipt volumes, due to staffing issues, the average number of monthly completions in 2021 was 33,900 per month, which was 10,600 per month (or 24 percent) lower than 2020 monthly averages. The combination of higher receipts and lower completions led to increased processing times, which downstream resulted in higher numbers of renewal applications pending past the 180-day automatic extension period.

2. Workforce Planning Shortfall

USCIS normally uses an annual workforce planning process to assess staffing requirements, known as the Staffing Allocation Model (SAM). The SAM is focused on allocating staff to process the anticipated number of new/incoming receipts for all workloads for the next fiscal year. Workforce planning is based on USCIS estimates for each adjudication workload for the coming year. These workload estimates are established through a cross-disciplinary committee, the Volume Projection Committee, that forecasts receipts on the basis of statistical modeling and any recent policy changes. In 2021, new receipts rose too rapidly to provide new staffing allocations within the SAM for both new receipts and backlog cases. In other words, despite the predictions based on data and historic trends, the Form I-765 filings in FY 2021 were significantly greater than forecasted. USCIS relies on a combination of internal processes and plans to plan for backlog reduction.¹⁰³

D. Emergency Temporary Solution To Address Current Backlog

The sudden 2-month increase in Form I-765 renewal filings in March and April of 2021 and sustained overall increase in Form I-765 renewal receipts thereafter prompted USCIS to directly address the growing backlog of Form I-

765 filings. Historically, USCIS had sufficient resources to address growing backlogs by allocating additional officers to a particular workload. However, USCIS was unable to do so in the summer of 2021 due to understaffing, including reduced contracting resources resulting from the prior years' fiscal situation; the broad scope of backlogs across numerous benefit types; and competing priorities, as discussed above. USCIS was, however, able to apply overtime funds to the renewal Form I-765 workload in an attempt to control the growing backlog during the last quarter of FY 2021.¹⁰⁴ Indeed, USCIS observed an increase in Form I-765 renewal completions, however, it was not enough to match the increased volume of receipts and therefore USCIS' responsive measures mitigated but did not halt the backlog growth.¹⁰⁵ Considering the operational constraints described above, USCIS also explored programmatic improvement initiatives and updates to its policy and operational guidance in the summer of 2021 to attempt to address prolonged Form I-765 processing times and their impact. For example, USCIS launched a backlog reduction effort in September 2021 to assess other options available to the agency to address the severe and growing Form I-765 backlogs.¹⁰⁶ It has become apparent to USCIS, however, that its limited resources are insufficient to appropriately address the growing backlogs, with the incoming volume of Form I-765 renewal filings showing no signs of slowing. Further, USCIS has assessed that the conventional measures USCIS had applied (*e.g.*, overtime) and was continuing to explore (*e.g.*, through the backlog reduction effort) will not be able to timely address the impending

¹⁰⁴ See Section B.2 for more information on USCIS' use of overtime funds as a tool to manage its workload.

¹⁰⁵ For example, USCIS completed 15,904 Form I-765 C08 renewals in July 2021. After applying overtime funds to Form I-765s, USCIS completed 23,987 and 24,267 Form I-765 C08 renewals in August and September 2021, respectively. However, USCIS returned to its prior completion rate in October 2021 (where USCIS completed 13,932 C08 renewals) due to such overtime funds no longer being available in the new fiscal year. USCIS received additional appropriated funding for overtime in FY 2022 to apply toward backlog reduction efforts, but these funds only became available for operational use in early 2022.

¹⁰⁶ See, *e.g.*, USCIS Policy Manual, Policy Alert (PA-2022-07), Updating General Guidelines on Maximum Validity Periods for Employment Authorization Documents based on Certain Filing Categories (Feb. 7, 2022), <https://www.uscis.gov/sites/default/files/document/policy-manual-updates/20220207-EmploymentAuthorizationValidity.pdf>.

loss of employment authorization and EAD validity.

1. Current Measures To Reduce the Backlog and Reduce Processing Times

Addressing Form I-765 processing times is a priority for USCIS. Backlogs in general are a significant concern for the applicants who are applying for benefits with USCIS because, as the backlogs increase, applicants and petitioners experience longer wait times to receive a decision on their benefit requests. This is especially concerning where the backlog involves employment authorization, which is critical to applicants' and their families' livelihoods as well as U.S. employers' continuity of operations. USCIS understands the impact that delays in receiving decisions and documentation have on applicants and petitioners and is striving to address the backlogs and the resulting negative consequences through a number of measures, including but not limited to this TFR.

USCIS continues to recover from the pandemic-related impacts on operations and revenue, leading to a gradually improving fiscal situation, return to stability, and renewed capacity to undertake initiatives to reduce backlogs. USCIS lifted the agency-wide hiring freeze in March 2021. With the hiring freeze lifted, USCIS was able to begin hiring staff in an attempt to return to pre-pandemic staffing levels.¹⁰⁷ Initial hiring was largely internal in order to fill promotional vacancies, with public job announcements to hire from outside USCIS following. This effort's impact is not realized immediately, as it is lengthy, time-consuming, and ongoing.

¹⁰⁷ Such a long pause in hiring from May 1, 2020, to March 2021 resulted in approximately 2,000 unfilled vacancies, out of approximately 20,000 positions across the agency. As of November 6, 2021, USCIS estimates the number of vacancies had risen to approximately 3,000 due to primarily internal selections following the hiring freeze, although USCIS did also add some positions as well. USCIS estimates it will take the agency to the end of CY 2022 to fill the current level of vacancies. While USCIS did receive \$250 million in funding from Congress for application processing, backlog reduction, and the refugee program in late September 2021, it will take time for such funding to translate to a significant increase in additional officers proficient at adjudicating and completing Form I-765 renewal applications. See Extending Government Funding and Delivering Emergency Assistance Act, 2022, Public Law 117-43 (Sept. 30, 2021). USCIS has identified Form I-765 as well as Form I-485 and Form I-589 (which represent two of the three major filing categories seeking renewal EADs and eligible for automatic extension of the prior EAD) for inclusion in backlog reduction efforts funded in part by appropriations. The \$250 million appropriated through Public Law 117-43, however, will only partly fund the 1,316 positions needed for all of USCIS' backlog reduction initiatives; therefore, USCIS continues to seek additional funding as requested in the FY 2022 President's Budget (\$345 million).

¹⁰³ One such process or plan is the Model for Operational Planning, which considers the backlog and the outlook of future backlogs based on current and future staffing. The primary way staffing for backlog reduction has taken place is through improved efficiencies to current processes as well as appropriations from Congress.

The hiring process itself is lengthy as it includes posting the job announcement, reviewing resumes, providing qualified candidates' information to the hiring office, assessments, interviews, selections, and background checks prior to a new employee entering on duty. New hires then go through orientation, basic training, duty-specific training and mentoring. The entire process from posting to a new hire reaching full proficiency takes several months.

USCIS is also in the process of developing a new Fee Rule to recoup adjudicatory costs incurred at current levels, and to support the agency's ability to match staffing levels with its workload in a sustainable way. To effect more immediate change with EAD renewals, USCIS reviewed its policies and procedures to update policy guidance,¹⁰⁸ expanded use of overtime hours as funding permitted, and applied innovative approaches to backlog reduction using technology in strategic ways, which initially is showing promising results.¹⁰⁹ In addition, USCIS is focused on addressing prolonged processing times affecting applications and petitions that form the basis of a Form I-765 filing and, therefore, indirectly impact Form I-765 renewal processing times, such as in the case of asylum or adjustment of status applications where a Form I-765 filing is based on the continued pendency of such application.

For example, an applicant seeking asylum is eligible for employment

¹⁰⁸ See, e.g., USCIS Policy Manual, Policy Alert (PA-2021-25), Employment Authorization for Certain H-4, E, and L Nonimmigrant Dependent Spouses (Nov. 12, 2021), <https://www.uscis.gov/sites/default/files/document/policy-manual-updates/20211112-EmploymentAuthorization.pdf>. See USCIS Policy Manual, Policy Alert (PA-2021-10), Employment Authorization for Certain Adjustment Applicants (June 9, 2021), <https://www.uscis.gov/sites/default/files/document/policy-manual-updates/20210609-EmploymentAuthorization.pdf>. See USCIS Policy Manual, Policy Alert (PA-2022-07), Updating General Guidelines on Maximum Validity Periods for Employment Authorization Documents based on Certain Filing Categories (Feb. 7, 2022), <https://www.uscis.gov/sites/default/files/document/policy-manual-updates/20220207-EmploymentAuthorizationValidity.pdf>.

¹⁰⁹ Efforts to improve timely processing and remove bureaucratic hurdles are underway. One of the first initiatives is to automatically identify pending applications that are no longer needed (for example, a Form I-765 based on a pending adjustment application is moot upon the applicant's adjustment of status to that of a lawful permanent resident) and close them, thus eliminating the need for an officer to review and allowing other applications to proceed to adjudication more quickly. While initial results of such initiatives are promising, it is too early to tell what the long-term, sustained impacts on processing times will be. USCIS continues to look for additional areas where systems can be used to identify and complete simple functions that free up officer resources for adjudicative work.

authorization on the basis of the pendency of the asylum application.¹¹⁰ USCIS currently grants employment authorization based on a pending asylum application in 2-year increments.¹¹¹ If an asylum application is pending for up to 5 years or more, as is currently the case for some applications,¹¹² then an applicant must file to renew employment authorization at least twice. If processing times for asylum applications were reduced to 3 years, the applicant would need only file to renew employment authorization once, saving USCIS adjudicatory resources.

Another area in which USCIS is actively prioritizing its workload is employment-based adjustment of status applications as backlogs in adjudication of these applications also have downstream effects on EAD application adjudications, as described above. While USCIS normally processes approximately 115,000 employment-based adjustment of status applications annually,¹¹³ generally to correspond with the number of available employment-based immigrant visas minus the number typically issued by Department of State annually, USCIS prioritized processing employment-based adjustment applications to maximize available visa usage in FY

¹¹⁰ An asylee cannot apply for initial employment authorization earlier than 150 calendar days after the date USCIS or the immigration court accepts the asylum application.

¹¹¹ This was the maximum time allowed under regulation until February 7, 2022, when the U.S. District Court for the District of Columbia vacated parts of 8 CFR 274a.12(c)(8) ("Employment authorization may be granted according to the provisions of 8 CFR 208.7 of this chapter in increments to be determined by USCIS but not to exceed increments of two years."). See *Asylumworks, et al. v. Alejandro N. Mayorkas, et al.*, No. 20-cv-3815, 2022 WL 355213 (D.D.C. Feb. 7, 2022). USCIS is considering what, if any, steps it may take in light of this ruling.

¹¹² The extended wait time for asylum applications particularly affects many defensive asylum filings in immigration court. (A noncitizen may apply for asylum affirmatively with USCIS or defensively in immigration court.) As of December 31, 2021, there were 628,551 asylum applications pending in immigration courts. See Executive Office for Immigration Review Adjudication Statistics, <https://www.justice.gov/eoir/page/file/1106366/download> (last visited Apr. 14, 2022). This DOJ data also implies that 156,127 and 90,880 cases were completed in FY2020 and 2021, respectively, or an average of 123,504 cases a year. In the first quarter of FY2022, 42,090 cases were completed. If this rate continues, it would take approximately 4.2 years to complete the adjudication of the total 628,551 asylum cases pending in the courts as of December 31, 2021.

¹¹³ See DHS Office of Immigration Statistics, 2019 Yearbook of Immigration Statistics, Table 6, Persons Obtaining Lawful Permanent Resident Status by Type and Major Class of Admission: Fiscal Years 2010 2019 (Sep. 2020), https://www.dhs.gov/sites/default/files/publications/immigration-statistics/yearbook/2019/yearbook_immigration_statistics_2019.pdf.

2021. By the end of FY 2021, USCIS had processed and approved approximately 172,000 employment-based adjustment of status applications, an increase of approximately 50 percent above the typical baseline;¹¹⁴ however, approximately 257,000 remained unadjudicated, including approximately 75,000 impacted by priority date retrogressions that may leave them pending for many years, and thereby eligible for C09 EADs over this extended period.¹¹⁵ To the extent possible, USCIS is committed to prioritizing employment-based adjustment of status applications to utilize the available visa numbers each fiscal year; doing so relieves applicants from filing Forms I-765 to seek renewal EADs while their adjustment of status application remains pending since lawful permanent residents are employment authorized incident to status.¹¹⁶ Therefore, the more adjustment of status applications USCIS is able to process, the fewer Form I-765 renewal applications USCIS will receive (based on pending INA 245 adjustment of status applications).

DHS expects that USCIS' backlog reduction efforts in these areas will positively impact Form I-765 backlogs by reducing the volume of Form I-765 filings. However, we anticipate that the impact of these backlog reduction efforts will not be immediately felt by applicants with expiring or expired employment authorization. Therefore, DHS has determined that in the interim, urgent action is needed to address the

¹¹⁴ See News Release, USCIS Announces FY 2021 Accomplishments, (Dec. 15, 2021), <https://www.uscis.gov/newsroom/news-releases/uscis-announces-fy-2021-accomplishments>.

¹¹⁵ Applicants from China and India seeking adjustment of status based on the employment-based third preference category experienced visa retrogression in their respective filing categories as of October 1, 2021, impacting approximately 75,000 applicants. For more information on visa retrogression, see <https://www.uscis.gov/green-card/green-card-processes-and-procedures/visa-availability-priority-dates/visa-retrogression> (last updated Mar. 8, 2018). Based on a rate of approximately 8,000 visa numbers becoming available for these affected categories per year, as was the case in FY 2019, it may take more than 9 years for visas to become available for these approximately 75,000 applicants. In the interest of reducing the burden on both the agency and the public, on June 9, 2021, USCIS increased the maximum validity period for initial and renewal EADs issued to applicants for adjustment of status under INA 245 from 1 year to 2 years based on average processing times. See USCIS Policy Manual, Policy Alert, Employment Authorization for Certain Adjustment Applicants (Jun 9, 2021), <https://www.uscis.gov/sites/default/files/document/policy-manual-updates/20210609-EmploymentAuthorization.pdf>. USCIS' return to its processing goal of 3 months for Form I-765 renewal applications is critically important for such applicants who may rely on timely renewals multiple times.

¹¹⁶ See 8 CFR 274a.12(a)(1).

plight of a growing number of EAD renewal applicants who have experienced or may in the near future experience a gap in their employment authorization and/or EAD because of USCIS' unprecedented processing times.

2. Existing Automatic Extension Period of Up to 180 Days Temporarily Not Sufficient

DHS is aware of the importance of employment authorization and EADs as evidence of employment authorization for applicants' and their families' livelihoods, as well as their U.S. employers' continuity of operations and financial health. DHS is also aware of the potential detrimental impact that gaps in employment authorization may have on an applicant's eligibility for future immigration benefits, should the applicant engage in unauthorized employment during the gap,¹¹⁷ and on the U.S. employer's responsibilities under the INA. DHS also acknowledges that the substantial increase in backlogs and prolonged processing times across USCIS-administered benefit requests are not the fault of applicants but have had and continue to have significant adverse consequences for applicants and employers awaiting a USCIS decision on pending Form I-765 renewal applications.

As noted, the current 180-day automatic extension under 8 CFR 274a.13(d)(1) for certain applicants who have properly filed Form I-765 for renewal of their employment authorization and/or EADs is an insufficient time period to ensure against lapses in employment authorization and/or EAD validity.¹¹⁸ In December 2020, the median processing time for Form I-765 renewal applications eligible for the automatic extension was 3.6 months (close to USCIS' processing goals), ranging from 2.5 months to 5 months.¹¹⁹ At the end of December 2020, there were approximately 3,300 applicants whose Form I-765 renewal applications were still pending past their 180-day auto-extension period.

However, Form I-765 processing times and Form I-765 renewal applications pending beyond the 180-

day period increased rapidly in the second half of CY 2021 and continue to increase in CY 2022 despite backlog mitigation efforts. As of December 31, 2021, the processing time for EAD renewal applications (all categories) completed by USCIS ranged from 6.1 months (median) to 10.1 months (93rd percentile) and there were approximately 66,000 applicants whose Form I-765 renewal applications were still pending past their 180-day automatic extension period. This means that, as of December 31, 2021, approximately 66,000 applicants—at no fault of their own and because of circumstances currently faced by USCIS—were not authorized to work and/or no longer had a valid EAD to evidence their employment authorization,¹²⁰ potentially jeopardizing their families' livelihoods.

TABLE 6—NUMBER OF FORM I-765 RENEWALS PENDING PAST THEIR 180-DAY AUTO-EXTENSION PERIOD

Date	Median processing time (months)	Renewals pending past 180-day period
December 31, 2020.	3.6	3,300 renewal applications (approx.).
December 31, 2021.	8.0	66,000 renewal applications (approx.).

This also means that a large majority of these workers, and their U.S. employers, would not be able to meet the verification or reverification requirement for completion of Employment Eligibility Verification (Form I-9),¹²¹ resulting in terminations

¹²⁰ Of the 66,000 applicants, 63,000 fall into the C08, C09, and C10 categories and, therefore, are facing a gap of employment authorization. The remaining 3,000 applicants fall into the following EAD categories: Refugees (A03 under 8 CFR 274a.12(a)(3)), asylees (A05 under 8 CFR 274a.12(a)(5)), and withholding of deportation or removal beneficiaries (A10 under 8 CFR 274a.12(a)(10)). Such applicants are still authorized for employment incident to status but would no longer have a valid EAD. For purposes of this rule's analysis, DHS has determined that it is appropriate to include the 3,000 applicants who are employment authorized incident to status given their reasonable reliance on USCIS' timely issuance of their renewal EADs. Also, it is unknown how many applicants in this group have in their possession acceptable alternative documentation they can show their employers in order to maintain their employment (e.g., Form I-94 or an unrestricted Social Security card together with an unexpired State-issued driver's license pursuant to 8 CFR 274a.2(b)(1)(v)). Moreover, through its public outreach efforts, DHS has learned that job loss has affected this group on account of the lack of sufficient documentation to present to employers for Form I-9 completion.

¹²¹ All U.S. employers must properly complete Form I-9 for each individual they hire for employment in the United States. See I-9, Employment Eligibility Verification USCIS web

and incurring the costs of finding replacement workers, if possible. If DHS does not immediately increase the 180-day automatic extension period, the total number of applicants with renewal applications pending past the 180-day auto-extension period is expected to increase by approximately 14,500 per month.¹²² This estimated monthly increase of 14,500 applicants is based on recent trends.

Although USCIS has been diligently trying to reduce the adjudication backlog and EAD processing times, USCIS is unable to quickly return to its processing goals due to the volume of pending cases, new filings that USCIS continues to receive, and time needed to increase staffing needs to meet existing demands. As of December 31, 2021, USCIS had approximately 520,000 pending EAD renewal requests in automatic extension-eligible categories and continues to receive approximately 55,000 additional Form I-765 applications in automatic extension-eligible categories per month. These additional renewal applications are adding to the current backlog, given that USCIS currently completes approximately 33,000–34,000 such requests per month. Further, as of November 6, 2021, 905 out of 8,721 (or, 10% of) officer positions allocated to the Field Office Directorate (FOD) and the Service Center Operations Directorate (SCOPS) were vacant and USCIS estimates it may take at least until the end of CY 2022 for USCIS to fill such vacancies.¹²³

The impact of the prolonged processing times is stark when considering the number of individuals who will lose employment authorization and/or EAD validity each month if immediate action is not taken. As indicated, the total number of renewal applications pending past the 180-day period, which was approximately 66,000 as of December

page, <https://www.uscis.gov/i-9> (last updated Apr 13, 2021).

¹²² As noted elsewhere in this preamble, the number of applicants who face expiration of the up-to-180-day automatic-extension each month is approximately 30,000. However, as some applicants who are already past the 180-day automatic extension period will receive final adjudication of their application each month, the total number of those in the population past the 180-day period is expected to increase by 14,500 each month rather than by 30,000.

¹²³ As mentioned above in section I.LD.1, USCIS had approximately 3,000 vacancies, 905 of which were officer positions in FOD and SCOPS, the two directorates that adjudicate Form I-765 renewal applications filed in categories eligible for automatic extension of EADs. Even after USCIS fills an Immigration Services Officer (ISO) position, there is a delay between the time of hiring and the time the ISO is fully trained and able to complete adjudications to meet productivity targets.

¹¹⁷ With certain exceptions, if a noncitizen continues to engage in or accepts unauthorized employment, the individual may be barred from adjusting status to that of a lawful permanent resident under INA 245. See INA 245(c)(2) and (c)(8), 8 U.S.C. 1255(c)(2) and (c)(8).

¹¹⁸ See section II, Purpose of this Temporary Final Rule.

¹¹⁹ See section II, Purpose of this Temporary Final Rule, Table 1. Recent Dramatic Growth in 50th and 93rd Percentile Processing Times for Form I-765 Renewal Applications Filed by Top Three Filing Categories.

31, 2021, is expected to increase by approximately 14,500 each month; that monthly figure represents approximately 10,500 asylum applicants, 3,000 adjustment of status applicants, and 1,000 suspension/cancellation applicants per month.

DHS therefore has determined that an automatic extension period of up to 180 days at 8 CFR 274a.13(d) is temporarily no longer sufficient to meet its original purpose and goal for which it was implemented: To prevent and/or mitigate the risk of gaps in employment authorization and documentation for a majority of eligible applicants. Due to the presently insufficient staffing levels, which may take USCIS at least until the end of CY2022 to fill and additional time to train, USCIS may be unable to significantly increase its rate of completion in the immediate term, and therefore, currently may be unable to meaningfully reduce the volume of pending cases while also keeping pace with the inflow of Form I-765 filings. While USCIS will continue to explore ways to improve adjudicative efficiencies in the short and long term, USCIS expects Form I-765 backlogs will continue in the immediate future as it works to implement changes to improve Form I-765 processing efficiencies, hire and train new officers, and take additional steps to reduce the backlog and processing times. This temporary and extraordinary circumstance has created an emergent and urgent situation for noncitizens and U.S. employers as gaps in employment authorization and documentation have a highly detrimental impact on noncitizen workers and their U.S. employers. This is taking place at a time when such employers already are facing unprecedented workforce disruptions due to the COVID crisis, which further underscores the importance of immediate action.¹²⁴ While the high

¹²⁴ According to the U.S. Bureau of Labor Statistics (BLS), on the last business day of January 2022, there were 11.3 million job openings and 6.3 million unemployed people. See U.S. Department of Labor, U.S. Bureau of Labor Statistics, *Job Openings and Labor Turnover—January 2022* (Mar. 9, 2022), <https://www.bls.gov/news.release/pdf/jolts.pdf>; U.S. Department of Labor, U.S. Bureau of Labor Statistics, *The Employment Situation—February 2022* (Mar. 4, 2022), <https://www.bls.gov/news.release/pdf/empst.pdf>. From June 2021 through January 2022, the ratio of unemployed persons per job opening was below 1.0, meaning that there were more job openings than individuals seeking work. For context, there were roughly 0.8 unemployed persons per job opening in January and February 2020 before COVID. U.S. Department of Labor, U.S. Bureau of Labor Statistics, *Number of unemployed persons per job opening, seasonally adjusted* (Jan. 2007 through Jan. 2022), <https://www.bls.gov/charts/job-openings-and-labor-turnover/unemp-per-job-opening.htm> (last visited Mar. 14, 2022). See also Christopher Decker,

unemployment rate has declined significantly, the United States is now experiencing high demand for labor as compared to the available supply of workers. As of February 2022, the labor force participation rate was at 62.3 percent, having recovered about 66 percent of what was lost at height of the COVID-19 pandemic compared with the February 2020 rate of 63.4 percent.¹²⁵

3. Temporary 360-Day Increase Beyond 180 Days Needed for 540-Day Period

DHS has determined that providing additional time beyond the current 180 days during which an eligible applicant's employment authorization and/or EAD are automatically extended is necessary to mitigate the risk to applicants of incurring a lapse in employment authorization or documentation while USCIS works toward reducing processing times.¹²⁶ As stated above, USCIS receives approximately 55,000 Form I-765 renewal requests per month and completes approximately 33,000–34,000 requests per month, leading to the growing backlog. Without intervention, this processing rate could result in a median processing time of 14.2 months for all Form I-765 renewals by the end of December 2022. Considering the current range of processing times, a significant number of these renewal applications likely would take longer

Lurking behind lackluster jobs gain are a stagnating labor market and the threat of omicron. The Conversation, Jan. 7, 2022, 12:50 p.m. EST, <https://theconversation.com/lurking-behind-lackluster-jobs-gain-are-a-stagnating-labor-market-and-the-threat-of-omicron-174534>; Ben Casselman, *More quit jobs than ever, but most turnover is in low-wage work.*, N.Y. Times, Jan. 4, 2022, <https://www.nytimes.com/2022/01/04/business/economy/job-openings-coronavirus.html>; Lucia Mutikani, *U.S. labor market recovery gaining steam; unemployment rolls smallest in 52 years*, Reuters, Feb. 24, 2022, 11:48 a.m. EST, <https://www.reuters.com/business/us-labor-market-recovery-gaining-steam-unemployment-rolls-smallest-52-years-2022-02-24/>.

¹²⁵ See U.S. Department of Labor, U.S. Bureau of Labor Statistics, *Civilian labor force participation rate* (Feb. 2002 through Feb. 2022), <https://www.bls.gov/charts/employment-situation/civilian-labor-force-participation-rate.htm> (last visited Mar. 8, 2022).

¹²⁶ DHS is applying this rule to all renewal EAD application categories eligible for automatic extension pursuant to 8 CFR 274a.13(d), even though some of these categories currently experience processing times that do not raise a risk of the applicant experiencing a lapse in employment authorization or documentation. As stated earlier, 95 percent of applications fall within the C08, C09, and C10 categories. DHS has made this decision because it has determined that it would not be operationally practical for USCIS to implement a different approach; making distinctions among categories would cause confusion among employers and employees; and backlogs and processing times may yet increase for these other categories.

than the 14.2-month median time, up to 18 months.¹²⁷

Based on the trend USCIS has observed in the growth of processing times for Form I-765 renewal applications in the past year (see section II.A. Table 1 for more details), and USCIS' projection of similar growth through the end of CY 2022,¹²⁸ DHS calculated that a temporary increase of 360 days (beyond the 180-day period) for a total of 540 days, or approximately 18 months) is an appropriate increase of the automatic extension period. Such period better reflects current and potential processing times for Form I-765 renewals. By extending the automatic extension period, this TFR therefore is intended to reduce the potential for disruptions in employment authorization and EAD validity for those who otherwise qualify for an automatic extension while USCIS continues to work to reduce its processing times to return to its goal of processing Form I-765 within 3 months.

To determine how long DHS should provide this temporary increased automatic extension period, DHS assessed the pending and incoming volume of Form I-765 renewal filings against USCIS' resources. As of December 31, 2021, USCIS had approximately 520,000 pending EAD renewal requests in automatic extension-eligible categories. To achieve USCIS' processing goal of 3 months,¹²⁹ USCIS must keep pace with the incoming volume (in other words, complete approximately 55,000 Form I-765 renewal requests in automatic

¹²⁷ The estimated processing time is calculated using the current number of pending renewal applications as of December 31, 2021 (520,000), adding in the estimated 55,000 new incoming receipts each month, and subtracting the 34,000 estimated completions each month to estimate the pending inventory at the end of December 2022. Next, the USCIS cycle time methodology is applied to calculate the processing time statistic (see "Cycle Time Methodology" on the USCIS processing times website at <https://egov.uscis.gov/processing-times/more-info> (last visited Apr 19, 2022)). The upper range value of 18 months is estimated by multiplying the cycle time by 1.3 based on the cycle time methodology. Note that individual offices may have higher or lower processing times, but the general USCIS-wide processing times likely would fall in the 14- to 18-month range.

¹²⁸ These projections are based on USCIS processes in place as of December 31, 2021, and do not account for other changes USCIS is exploring outside of this TFR and that may be implemented concurrent with this TFR. USCIS is committed to doing everything possible under the law and current resource availability to mitigate the impact of EAD renewal application processing delays on applicants.

¹²⁹ USCIS has determined that a processing time of 3 months for Form I-765 renewals would suffice to prevent lapses in employment authorization for most applicants who are eligible for the up to 180-day automatic extension. See 80 FR at 81911 (AC21 NPRM). See 81 FR at 82398 (AC21 Final Rule).

extension-eligible categories per month) in addition to reducing the pending volume of renewal requests from 520,000 to 150,000–200,000.¹³⁰ USCIS determined that, as of May 4, 2022, the maximum number of officer hours it can devote to Form I–765 renewal requests in the automatic extension-eligible categories is 217,800 per year, based on its resources and capacity. By comparison, USCIS devoted a total of approximately 432,500 officer hours to all Form I–765 adjudications in FY 2021.

USCIS calculated that, if it applied 217,800 officer hours at approximately 15 minutes per Form I–765¹³¹ per month, to keep pace with the incoming flow of 55,000 new renewal requests as well as to reduce the volume of pending requests from 520,000 to 150,000–200,000, it would take USCIS 540 days—or approximately 18 months—to reach its goal of processing Form I–765 renewal applications within 3 months. Therefore, DHS has concluded that the temporary 360-day increase to the automatic extension time period must be in place for 540 days for those with pending renewal applications during this period.

Applicants who file a Form I–765 renewal application after this filing timeframe and who are eligible for an automatic extension of their employment authorization and/or EADs will receive the 180-day automatic extension period currently provided at 8 CFR 274a.13(d)(1). DHS expects that, by the close of the filing timeframe outlined in this temporary final rule, the usual 180-day automatic extension period will be sufficient to prevent applicants filing Forms I–765 renewal applications from incurring a lapse in employment authorization and/or EAD validity, as USCIS expects to have returned to achieving its 3-month processing goal by then.

¹³⁰ USCIS estimates that 150,000–200,000 pending requests translates roughly to a 3-month processing time, as the figure reflects 3 months' worth of Form I–765 renewal receipts.

¹³¹ This figure is based on an analysis of historic rates of completion. Between FY 2019 and FY 2021, the total officer hours for all Form I–765 processing (initials and renewals for all categories, including non-automatic extension categories) ranged from approximately 460,000 (FY 2019) to 420,000 (FY 2021), the equivalent of approximately 38,300 to 35,000 officer hours per month to process approximately 153,200 to 140,000 cases per month. Therefore, each case took an average of 15-minutes to process. Based on the USCIS Volume Projection Committee forecasts, USCIS expects to receive about 2.2 million Form I–765s in FY 2022 and FY 2023. Using the 15-minute per case factor, and based on the 2.2 million projections, USCIS would need to expend approximately 45,800 officer hours a month to meet incoming demand or increase adjudication efficiencies through hiring, resource allocation, and efficiency gains.

This temporary final rule applies to three groups of applicants. First, the rule applies to those renewal applicants eligible for the automatic extension who already have filed their renewal Form I–765 application, which remains pending as of the date this rule goes into effect, May 4, 2022, and whose EAD has not expired or whose current up to 180-day auto-extension has not yet lapsed, since this group is at immediate or near term risk of experiencing a gap in employment authorization and/or documentation. Second, the rule applies to new renewal applicants who file Form I–765 during the 18-month period following the rule's publication to avoid a future gap in employment authorization and/or documentation.¹³² Third, for those renewal applicants who already are experiencing a gap in employment authorization and/or EAD validity, fairness dictates that such renewal applicants also should receive the benefit of the increase in the automatic extension, to enable them to resume an additional period of employment authorization and/or EAD validity, since they were the first group to have been placed in a detrimental position on account of USCIS' long processing times. For these applicants, this TFR provides that employment authorization and/or validity of their EADs will resume beginning on the date the rule is published in the **Federal Register**, May 4, 2022, and continue for a period of up to 540 days from the date their employment authorization and/or EAD expired, as shown on the face of

¹³² While USCIS expects to return to its 3-month processing goal by the end of the 18-month period, DHS will continue to provide eligible renewal applicants up to 540 days of automatic extension as outlined in this rule throughout the entirety of the 18-month period for ease of administrability, to mitigate the potential for confusion among the regulated public, and in recognition of the potential that circumstances outside of USCIS's control may frustrate this expectation. Providing a set amount of additional automatic extension time for a set time period is the least administratively burdensome approach, allowing the agency to focus its limited resources on addressing the lengthy processing times themselves. Additionally, DHS anticipates that this approach is the least burdensome for the public, including employees and employers as well, since the temporary solution remains clear, can be relied upon, and can be planned for, and otherwise operates in the same way as the existing automatic extension described in 8 CFR 274a.13(d)(1). DHS acknowledges that the utility of the additional automatic extension time may diminish toward the end of the 18-month period (or sooner, if USCIS achieves its processing goals earlier than anticipated, due in part to backlog reduction efforts discussed in Section II.D.1. or to other factors yet unknown or a combination of the two). However, DHS believes that such consequence is acceptable and appropriately balances competing policy concerns because shorter processing times ultimately mean applicants will receive a decision on their Form I–765 renewal application sooner and, in that event, will rely less on the automatic extension period.

the EAD. However, in recognition of Congress' clear intent in the INA regarding unauthorized employment, including the accountability of employers that employ noncitizens who are not authorized to work in the United States,¹³³ this TFR does not address periods of unauthorized employment.¹³⁴ In other words, this rule does not cure any unauthorized employment that may have accrued prior to issuance of the rule.¹³⁵

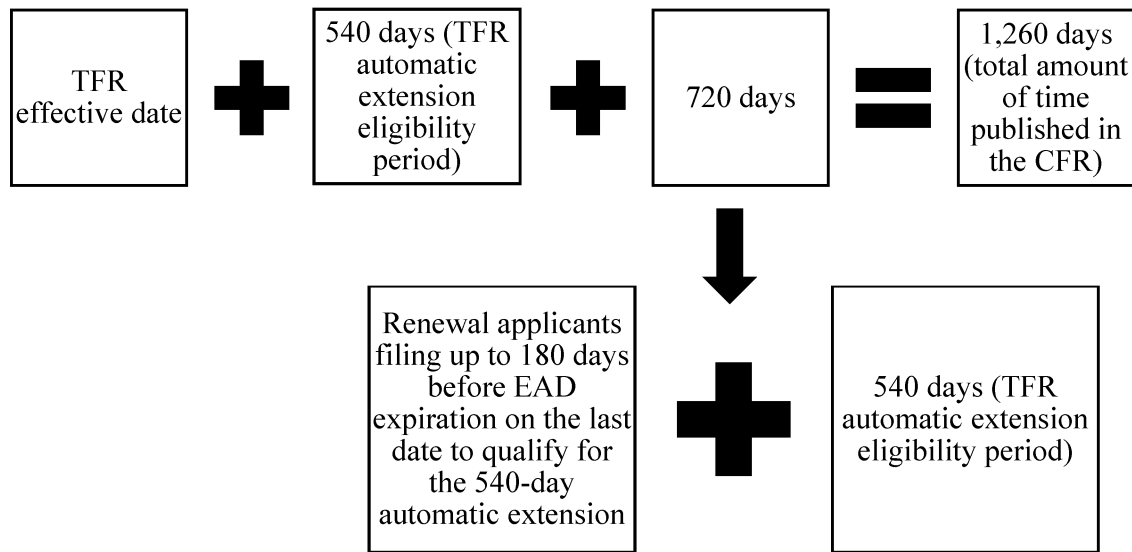
In addition, DHS has determined that the temporary amendment made by this rule should remain in the Code of Federal Regulations (CFR) for an amount of time sufficient to cover the approximately 18-month period during which the up to 540-day automatic extension will be authorized, plus an additional 720 days so that the regulatory provision remains in the CFR for the entire time that applicants may be relying on this temporary increase to the regular automatic extension period.¹³⁶ As such, this TFR will take effect on May 4, 2022, and will be removed from the CFR on October 15, 2025; that is, approximately 3½ years (or 1,260 days) after the rule takes effect, although no new beneficiaries will receive a 540-day automatic extension after October 26, 2023. Further, as is consistent with current guidance, applicants should file a renewal Form I–765 no earlier than 180 days prior to the expiration date of their EAD.

¹³³ See INA sec. 274A, 8 U.S.C. 1324a.

¹³⁴ By way of example, if an applicant timely filed a Form I–765 renewal application that is still pending and the expiration date on the front of the applicant's EAD is June 1, 2021, then the applicant's 180-day automatic extension expired November 28, 2021. If the TFR is published on April 1, 2022, then the applicant's EAD automatically becomes valid from April 1, 2022, up to November 23, 2022, which is 540 days after June 1, 2021, the expiration date on the face of the EAD. If the employee in this example worked without authorization between November 29, 2021, and March 31, 2022, however, the employee and employer may be subject to any consequences outlined in the law.

¹³⁵ For example, if an applicant timely filed a Form I–765 renewal application that is still pending and the expiration date on the front of the applicant's EAD is June 1, 2021, then the applicant's 180-day automatic extension expired November 28, 2021. If the TFR is published and effective on April 1, 2022, then the applicant's EAD automatically becomes valid from April 1, 2022, up to November 23, 2022, which is 540 days after June 1, 2021, the expiration date on the face of the EAD. If the employee in this example worked without authorization between November 29, 2021, and March 31, 2022, however, the employee and employer would be subject to any consequences outlined in the law.

¹³⁶ 720 days is the amount of time needed to cover the up to 540-day automatic extension and to account for the fact that renewal applicants may file their EAD renewal application up to 180 days before their EAD expires.

Figure 1. TFR Process Map

IV. Temporary Regulatory Change: 8 CFR 274a.13(d)(5)

DHS is amending 8 CFR 274a.13(d) to add a new paragraph (5) that will be in effect temporarily until October 15, 2025.¹³⁷ Under the new paragraph, DHS is increasing the automatic extension period for employment authorization and/or EAD validity of up to 180 days (described in 8 CFR 274a.13(d)(1)) to a period of up to 540 days for renewal applicants eligible to receive an automatic extension who have a timely filed Form I-765 renewal application pending during the 18-month¹³⁸ period beginning May 4, 2022, and ending October 26, 2023. After the 18-month period, automatic extensions of employment authorization and EAD validity will revert to the up to 180-day period for those eligible applicants who timely file renewal Form I-765 applications after October 26, 2023. The increased automatic extension period will apply to eligible renewal applicants who timely file their Forms I-765 on or before the last day of the 18-month period, even if filed prior to May 4, 2022. In addition, for renewal

applicants whose Forms I-765 remain pending but who are no longer within the up to 180-day automatic extension period on or before May 4, 2022, DHS has determined that, in the interest of fairness, such renewal applicants automatically will resume employment authorization and/or the validity of their EADs beginning on the effective date of this TFR, May 4, 2022, and up to 540 days from the expiration of their employment authorization and/or EAD.¹³⁹

Similar to the 180-day automatic extension period provided by 8 CFR 274a.13(d)(1), the increased automatic extension period of up to 540 days established by this TFR generally will automatically terminate the earlier of up to 540 days after the expiration date of the EAD, or upon issuance of notification of a denial on the Form I-765 renewal request even if this date is after October 26, 2023.

Moreover, 8 CFR 274a.13(d)(5) will remain in the CFR for an additional 720 days after this 540-day period, until October 15, 2025, to ensure that renewal applicants who are already within their up to 540-day automatic extension period as of October 26, 2023, will not get cut off from any remaining employment authorization and/or EAD validity that is over 180 days (the

normal automatic extension period under 8 CFR 274a.13(d)(1) but instead will be able to take full advantage of the 540-day period.

Similar to 8 CFR 274a.13(d)(4), this TFR provides that an EAD that appears on its face to be expired is considered unexpired under this rule for up to 540 days from the expiration date on the front of the EAD when combined with a Notice of Action (Form I-797C) indicating timely filing of the EAD renewal application and the same employment eligibility category as stated on the facially expired EAD (or in the case of an EAD and I-797C notice that each contains either an A12 or C19 TPS category code, the category codes need not match). While the current provision at 8 CFR 274a.13(d)(4), and, likewise, the provision in this TFR, do not require that qualifying Notices of Action specify the automatic extension period, in practice, USCIS issues a Form I-797C Notice of Action to all renewal applicants with general information regarding who is eligible for an automatic extension and currently includes an explanation of the up to 180-day automatic extension period. On and after May 4, 2022, USCIS plans to issue Form I-797C Notices of Action with an explanation of the up to 540-day automatic extension period. USCIS does not plan to issue updated Form I-797C notices to eligible applicants who filed their Form I-765 renewal application before May 4, 2022. However, even Form I-797C notices that refer to a 180-day automatic extension still meet the regulatory requirements.

¹³⁷ The rule will be in effect for approximately 3½ years, after which paragraph (d)(5) will terminate automatically. As explained earlier in the preamble, this effective date period, while lengthy, is necessary so that those eligible who file a Form I-765 renewal application on the last available day of the 18-month period during which the increased automatic extension period is available and who qualify for an automatic extension will have the full benefit of the up to 540-day extension period.

¹³⁸ For ease of reference, DHS sometimes refers to the approximate time period of 18 months. However, the precise number of days is 540.

¹³⁹ If a renewal applicant whose employment authorization and/or EAD validity has lapsed on or before the date this rule goes into effect, May 4, 2022, and the lapse is 540 days or more, then such applicant will not receive any additional employment authorization and/or EAD validity under this rule. DHS anticipates that very few applicants will be in this situation.

Therefore, individuals who show Form I-797C notices that refer to a 180-day extension, along with their qualifying EADs, still receive the up to 540-day extension under this rule. USCIS will update the web page on the USCIS website that is referenced in the current Form I-797C notice to reflect the change in the automatic extension period. The public should refer to this web page when determining whether a Form I-797C Notice of Action, if presented with the expired EAD, is acceptable for Form I-9 or other purposes, such as to obtain benefits. Employers should attach a copy of the web page with the employee's Form I-9 to document the extension of employment authorization and/or EAD validity. USCIS will also update I-9 Central on the USCIS website to provide employees and employers with specific guidance on Form I-9 completion, including any required notations indicating the above-described extension of employment authorization and/or EAD validity, in such cases. If a benefit-granting agency accepts EADs, then the agency should accept the EADs that are automatically extended under this rule. The up to 540-day extension under this rule applies even if a Form I-797C notice refers to a 180-day extension.

This rule does not modify the current requirements an employer must follow for Form I-9 at 8 CFR 274a.2(b)(1)(vii) that apply to automatic extensions, except that this rule temporarily replaces "180" with "540" in its reference to the maximum number of days for the automatic extension period. Therefore, when an employee chooses to use an EAD and Form I-797C receipt notice as provided under this rule to complete Form I-9 for new employment, the employee and employer should use the extended expiration date to complete Section 1 (if applicable) and Section 2 of the Form I-9 and reverify no later than the date that the automatic extension period expires.¹⁴⁰ For current employment, the employer should update the previously completed Form I-9 to reflect the extended expiration date based on the automatic EAD extension while the renewal is pending and reverify no later than the date that the automatic extension expires.¹⁴¹ For renewal applicants with pending Forms I-765 who experienced a lapse in employment authorization and/or EAD validity prior

to the effective date of this rule, May 4, 2022, yet resume a period of employment authorization and/or EAD validity under this rule, and are rehired by the same employer, their employers must complete Form I-9 by treating the individual's employment authorization as having previously expired pursuant to 8 CFR 274a.2(c)(1)(ii) but have a choice of either reverifying employment authorization on the employee's Form I-9 or completing a new Form I-9.¹⁴²

Under this Temporary Final Rule, just as under existing 8 CFR 274a.13(d)(3), DHS will retain the ability to otherwise terminate any employment authorization or EAD, or extension period for such employment authorization or document, by written notice to the applicant, by notice to a class of noncitizens published in the **Federal Register**, or as provided by statute or regulation, including 8 CFR 274a.14.¹⁴³

V. Regulatory Requirements

A. Administrative Procedure Act

DHS is issuing this rule without prior notice and an opportunity to comment and with an immediate effective date pursuant to the Administrative Procedure Act's (APA's) "good cause" exception. 5 U.S.C. 553(b)(B) and (d)(3). Agencies may forgo notice-and-comment rulemaking and a delayed effective date when a rulemaking is published in the **Federal Register**, because the APA provides an exception from those requirements when an agency "for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. 553(b)(B); see also 5 U.S.C. 553(d)(3). Additionally, on multiple occasions, agencies have relied on this exception to promulgate both communicable disease-

related¹⁴⁴ and immigration-related¹⁴⁵ interim rules. The good cause exception for forgoing notice-and-comment rulemaking "excuses notice and comment in emergency situations, or where delay could result in serious harm." *Jifty v. FAA*, 370 F.3d 1174, 1179 (D.C. Cir. 2004); *Am. Fed. of Gov't Emps. v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981) ("As the legislative history of the APA makes clear, moreover, the exceptions at issue here are not 'escape clauses' that may be arbitrarily utilized at the agency's whim. Rather, use of these exceptions by administrative agencies should be limited to emergency situations . . ."). Furthermore, notice and comment is impracticable under the APA, when an agency finds that due and timely execution of its functions would be impeded by the notice requirement under the APA, and for example, an investigation into the facts shows that a new rule must be put in place immediately to avert some type of emergency.¹⁴⁶ Courts have held that impracticability "is inevitably fact- or context-dependent."¹⁴⁷ Although the

¹⁴⁴ HHS Control of Communicable Diseases; Foreign Quarantine, 85 FR 7874 (Feb. 12, 2020) (interim final rule to enable the CDC "to require airlines to collect, and provide to CDC, certain data regarding passengers and crew arriving from foreign countries for the purposes of health education, treatment, prophylaxis, or other appropriate public health interventions, including travel restrictions"); Control of Communicable Diseases; Restrictions on African Rodents, Prairie Dogs, and Certain Other Animals, 68 FR 62353 (Nov. 4, 2003) (interim final rule to modify restrictions to "prevent the spread of monkeypox, a communicable disease, in the United States").

¹⁴⁵ See, e.g., Visas: Documentation of Nonimmigrants Under the Immigration and Nationality Act, as Amended, 81 FR 5906, 5907 (Feb. 4, 2016) (interim rule citing good cause to immediately require a passport and visa from certain H-2A Caribbean agricultural workers to avoid "an increase in applications for admission in bad faith by persons who would otherwise have been denied visas and are seeking to avoid the visa requirement and consular screening process during the period between the publication of a proposed and a final rule"); Suspending the 30-Day and Annual Interview Requirements From the Special Registration Process for Certain Nonimmigrants, 68 FR 67578, 67581 (Dec. 2, 2003) (interim rule claiming the good cause exception for suspending certain automatic registration requirements for nonimmigrants because "without [the] regulation approximately 82,532 aliens would be subject to 30-day or annual re-registration interviews" over a 6-month period).

¹⁴⁶ See *Util. Solid Waste Activities Grp. v. E.P.A.*, 236 F.3d 749, 754-55 (D.C. Cir. 2001) (citations omitted) (the Attorney General's Manual explains "that a situation is 'impracticable' when an agency finds that due and timely execution of its functions would be impeded by the notice otherwise required in [§ 553], as when a safety investigation shows that a new safety rule must be put in place immediately.).

¹⁴⁷ *Mid-Tex Electric Coop. v. FERC*, 822 F.2d 1123, 1132 (D.C. Cir. 1987). Examples where courts have found notice-and-comment rulemaking impracticable include: where air travel security

¹⁴² See 8 CFR 274a.2(c).

¹⁴³ Therefore, for example, in situations where the underlying status that provides employment authorization would expire prior to 540 days, USCIS may include specific information on the applicant's Form I-797C receipt notice as to how long the automatic extension of the individual's EAD will last. More specifically, in the case of a TPS beneficiary who files a Form I-765 for a renewal EAD, such TPS beneficiary would not receive the full 540 days of EAD auto-extension where the relevant TPS country designation expires prior to that 540-day point.

¹⁴⁰ See 8 CFR 274a.2(b)(1)(vii). See also <https://www.uscis.gov/i-9-central/form-i-9-resources/handbook-for-employers-m-274/40-completing-section-2-of-form-i-9/44-automatic-extensions-of-employment-authorization-documents-eads-in-certain-circumstances> (last updated Nov. 16, 2021).

¹⁴¹ *Id.*

good cause exception is “narrowly construed and only reluctantly countenanced,” *Tenn. Gas Pipeline Co. v. FERC*, 969 F.2d 1141 (D.C. Cir. 1992), DHS has invoked the exception appropriately in this case given the totality of the circumstances in which this TFR is implemented:¹⁴⁸ Providing advance notice and comment would be impracticable because doing so would result in serious harm, for the reasons set forth below.

As discussed earlier in this preamble, the untenable situation that applicants and their employers are facing is the result of several converging factors affecting USCIS operations that were compounded by the COVID-19 national health emergency. USCIS faced an overall higher level of adjudicatory workload, coupled with insufficient resources to complete the work, which resulted in the significant increase in USCIS processing times for Form I-765 applications (initials and renewals). Staffing shortfalls mean that the workforce cannot keep pace with these operational strains at present, and staffing issues cannot immediately be remedied.¹⁴⁹ While the agency had hoped to overcome the effects of the factors adversely affecting processing times by using operational and other measures, these measures did not produce effects as fast as the agency had hoped, as some of the corrective measures are lengthy, time-consuming, and ongoing. Unfortunately, USCIS’ previous financial strains, including a preliminarily enjoined 2020 Fee Rule, continuing workforce shortfalls due to a previously threatened furlough, attrition, a hiring freeze, and an unusual

agencies would be unable to address threats posing “a possible imminent hazard to aircraft, persons, and property within the United States.” *Jifty v. FAA*, 370 F.3d 1174, 1179 (D.C. Cir. 2004); if “a safety investigation shows that a new safety rule must be put in place immediately.” *Util. Solid Waste Activities Grp. v. EPA*, 236 F.3d, 749, 755 (D.C. Cir. 2001)(ultimately finding that not to be the case and rejecting the agency’s argument); or if a rule was of “life-saving importance” to mine workers in the event of a mine explosion, *Council of the S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 581 (D.C. Cir. 1981) (describing that circumstance as “a special, possibly unique, case”). This prong sets a high bar for the agency to meet.

¹⁴⁸ See *National Women, Infants, & Children Grocers Ass’n v. Food & Nutrition Service*, 416 F. Supp. 2d 92, 108 (D.D.C. 2006) (“[H]aving examined the totality of circumstances in which the interim rule was promulgated, the Court finds that the FNS’ invocation of the good cause exception is justified.”).

¹⁴⁹ As explained in the preamble, increasing staffing levels and the agency’s capacity are closely tied to the agency’s ability to recoup adjudicatory costs through a fee rule, overcoming the effects of the hiring freeze and pandemic related consequences, and backlog reduction efforts. However, none of the efforts undertaken by the agency are realized immediately as these processes are lengthy, time-consuming, and ongoing.

spike and sustained increase in filings at a rate above that which USCIS can match continue to impact processing times for renewal Forms I-765.

USCIS has been diligently taking steps, many of which had generally been effective in the past, to address these factors and improve adjudicative efficiency after the surge in EAD renewal applications in March and April of 2021, while, at the same time also attending to emergent and other critical demanding obligations of the agency. These steps included applying overtime funds to the Form I-765 renewal workload in an attempt to control the growing backlog, and exploring programmatic improvement initiatives for the adjudication of Form I-765 applications overall. However, although these measures initially showed some success, it has become apparent that USCIS’ limited resources are insufficient to address the immediate situation. With the incoming volumes of Form I-765 renewal filings showing no sign of slowing, USCIS assesses that it will not be able to avert the impending crisis of more renewal applicants experiencing gaps in employment authorization and/or documentation, and that such gaps’ length in time are growing. As a result, USCIS has determined that until processing times can be reduced significantly, an increase in the automatic extension period is needed as soon as possible to avert imminent harm. This rule is imperative to provide an interim measure for thousands of renewal applicants who are facing imminent job loss through no fault of their own, and thousands who have already experienced a lapse in employment authorization and/or EAD validity despite USCIS’ best efforts to employ operational measures to avoid this result.

As explained throughout this preamble, and as of December 31, 2021, the impact is significant. USCIS data show that approximately 66,000 renewal applications remained unadjudicated beyond the automatic extension period of 180 days under 8 CFR 274a.13(d)(1). Therefore, the individuals who filed those renewal applications and relied on the automatic extension to maintain employment already would have experienced job loss as a result of the lack of employment authorization and/or EAD validity. Of the approximately 66,000 renewal applicants in this situation, 58 percent are asylum applicants, a particularly vulnerable population. Continuous employment authorization during the pendency of an asylum application is vital for asylum seekers in the United

States, given that they need employment authorization not just to work but also to access services and other resources required to pursue their asylum applications before USCIS or EOIR, which are often costly. Therefore, this entire group of renewal applicants needs immediate help via this rulemaking so these applicants can regain employment authorization and/or EAD validity and rejoin the workforce in order to continue to make a living to sustain their families.

Given that renewal applications continue to be filed—USCIS receives about 55,000 new renewal Forms I-765 in automatic extension-eligible categories per month—the backlog is expected to increase and, with it, the number of renewal applicants who could lose their ability to be employed and to support themselves and their families.¹⁵⁰ DHS estimates that approximately 14,500 renewal applicants per month will join the group of approximately 66,000 renewal applications who faced a lapse in employment authorization and/or EAD validity as of December 2021.¹⁵¹ Furthermore, data estimates show that an estimated 266,841 to 375,545 renewal applicants could lose their employment authorization and/or EAD validity over the next 18 months if this rule is not promulgated immediately.

Considering the total population potentially impacted by this rule, DHS estimates that, with the implementation of this rule, approximately \$3,098 million in labor earnings for renewal applicants would be stabilized and not forgone.¹⁵² In other words, this rule will preserve an estimated total of \$3,098.0 million in labor earnings for the estimated 266,841 to 375,545 affected renewal applicants. Any delay in action such as by providing notice and comment, therefore, would raise the imminent threat and create severe adverse consequences to labor earnings

¹⁵⁰ As explained in the preamble, certain applicants within the affected population, including those who are employment authorized incident to status or non-working adults and children, may not necessarily lose their employment authorization after the 180-day automatic extension period is exhausted, but their EADs become invalid so that they can no longer use them for other purposes, such as an identification document or as proof for receiving State or local public benefits to the extent eligible, in addition to not having proof of employment authorization for Form I-9 purposes.

¹⁵¹ See USCIS’ analysis outlined in the preamble at section IV.B, “Executive Order 12866 (Regulatory Planning and Review) and Executive Order 13563 (Improving Regulation and Regulatory Review),” regarding the affected population.

¹⁵² Labor earnings includes wages and salaries as well as benefits (e.g., paid leave, supplemental pay, insurance). Amount shown as total present value at a 7 percent discount rate.

and the financial well-being of applicants and their families. DHS believes that with the immediate implementation of this rulemaking, the potential for additional gaps in employment authorization and/or EAD validity, job loss, and financial uncertainty will be reduced significantly for Form I-765 renewal applicants and their families while USCIS works toward implementing its backlog reduction plan to return processing times to the pre-emergency 3-month average.

DHS believes that the imminent and continuing impact on employers' business continuity and related effects caused by gaps in employment authorization and/or EAD validity additionally justify that DHS issue this temporary final rule. The imminent or ongoing gaps in employment authorization and/or EAD validity being experienced by renewal applicants through no fault of their own adversely affect not only applicants and their families, but also employers, which experienced difficulties in maintaining their workforce as a result of the pandemic, and continue to face a variety of challenges as the United States progresses on its path to recovery from the pandemic, such as more job openings than available workers.¹⁵³ To ensure continuity of operations, businesses and entities may have made decisions in reliance on the possibility that eligible renewal Form I-765 applicants may receive renewals of employment authorization and documentation (for example, by establishing business contracts, applying for grants, signing leases, and commencing development of product lines). As DHS predicts that it will take approximately 18 months to return to normal processing levels, DHS seeks to mitigate the potential that additional businesses and entities may temporarily be adversely impacted by required terminations as a result of gaps in employment authorization or documentation.

Such adverse impacts on employers and businesses, who have already experienced significant economic harm on account of the pandemic, gives cause to address an emergency situation as quickly as possible to prevent further imminent harm to an increased number of renewal applicants and their employers. While the number of businesses affected is unknown, DHS's analysis suggests that, if this rule were not implemented immediately, businesses that employ affected EAD holders would incur approximately

\$4,037.6 million in labor turnover costs for the separation and replacement these employees.¹⁵⁴ This amount represents significant cost savings to businesses under this rule. The longer this rule is delayed, the greater the costs to business because of applicants' gaps in employment authorization and/or documentation and the resulting disruptions in business continuity that employers will experience, defeating the very purpose 8 CFR 274a.13(d) and this rulemaking, creating 8 CFR 274a.13(d)(5), seek to prevent.¹⁵⁵ That is, because of the serious harm that would be caused to applicants and employers described throughout this rulemaking, providing notice and comment, as well as a 60-day effective date delay,¹⁵⁶ would expose the public to the harm that 8 CFR 274a.13(d) and this rulemaking are trying to prevent, and would thereby defeat the very purpose of rulemaking.

Furthermore, DHS believes that given the imminent and continuing impact of gaps in employment authorization and/or EAD validity on renewal applicants, their families, employers, and employers' business continuity make following ordinary notice and timing impracticable. As a DHS component agency, one of USCIS' primary missions is to administer immigration benefits, including adjudicating requests for and issuing employment authorization and/or

¹⁵⁴ Turnover costs are calculated as a percent of annual salary. Amount shown as total present value, using a 7 percent discount rate.

¹⁵⁵ As explained elsewhere in this preamble, 8 CFR 274.13(d) was proposed in 2016 to mitigate the risk of gaps in employment authorization and required documentation, and its related consequences for eligible renewal applicants and their employers. See AC21 NPRM, 80 FR 81899, 81927. In the AC21 NPRM, DHS explained that it believed the 180-day auto extension to be a reasonable and effective amount of time to mitigate that risk. See 80 FR at 81927 ("DHS believes that this time period [of up to 180 days] is reasonable and provides more than ample time for USCIS to complete the adjudication process based on USCIS's current 3-month average processing time for Applications for Employment Authorization."). After having received and carefully considered public comments, DHS published the final rule. Thus, the concept of the up to 180-day automatic extension has been tested in the public sphere already and gone through proper rulemaking. This TFR is merely a temporary 18-month deviation from the 180-day timeframe, warranted by this untenable situation.

¹⁵⁶ While the effective date for a substantive rule under the APA is not less than 30 days, 5 U.S.C. 553(d), this rule is a major rule subject to the Congressional Review Act, codified at 5 U.S.C. 801 through 808. Under 5 U.S.C. 801, a major rule's effective date generally is delayed for at least 60 days. Under the APA and the Congressional Review Act, however, the agency is exempt from the delayed effective date requirements of both acts if the agency provides good cause. See 5 U.S.C. 553(d) and 808(2).

or EADs.¹⁵⁷ Under the INA, the Secretary is authorized to take necessary regulatory action to carry out this mission effectively. As established above, the current situation is untenable for renewal applicants and their employers. Given the current processing backlogs and delays, USCIS also predicts that it will take approximately 18 months to revert to normal processing timeframes, a significant portion of which would be taken up by notice and comment rulemaking and the 60-day publication requirement. Thus, given the immediate harm that these backlogs create for renewal applicants and employers alike, the notice and comment requirements, and associated time requirements, would not allow USCIS to timely avert the harms discussed in this rule. Providing notice and comment rulemaking and complying with the 60-day publication requirement is therefore simply impracticable as it would impede USCIS functions, and has a significant impact on applicants and employers.

Additionally, DHS believes that issuing this temporary rule is a reasonable approach to implement this temporary measure, which will be effective for only a finite period. Specifically, the up to 360-day increase of the current 180-day automatic extension period via the amendments to DHS regulations made by this rule are limited to individuals who are seeking a Form I-765 renewal application within the next 18 months from the rule's publication, while the amendments to DHS regulations will only remain in place for a total of 1,260 days (*i.e.*, 3½ years). These time periods are suitable to avert imminent harm to a specific class of individuals and their employers.¹⁵⁸ As demonstrated in the

¹⁵⁷ As of March 1, 2003, the former INS ceased to exist as an agency within the United States Department of Justice, and its functions respecting applications for immigration benefits (such as the adjudication of requests for employment authorization and/or EADs) were transferred to United States Citizenship and Immigration Services in the United States Department of Homeland Security. See Homeland Security Act of 2002, Public Law 107-296, sec. 471(a), (Nov. 25, 2002); 68 FR 10922 (Mar. 6, 2003). Additionally, under the Homeland Security Act sec. 101(b)(1)(F), 6 U.S.C. 111(b)(1)(F), USCIS, as a DHS component, should exercise this function in a manner that ensures that the overall economic security of the United States is not diminished by efforts, activities, and programs aimed at securing the homeland.

¹⁵⁸ Courts have been more inclined to finding good cause for issuance of TFRs if the effect is limited in scope and duration. See, e.g., *San Diego Navy Broadway Complex Coalition v. U.S. Coast Guard*, 2011 WL 1212888, *6 (S.D. Cal. 2011) (finding good cause for issuance of a TFR because agency limited its effect for several months and also explicitly indicated its intent to initiate notice-and-comment rulemaking); *Nat'l Fed'n Emps v. Divine*, 671 F.2d 607 (D.C. Cir. 1982) (finding that OPM's

¹⁵³ See FN 124.

preamble, extending the automatic extension provision temporarily by up to an additional 360 days for a period of 540 days (*i.e.*, approximately 18 months) directly corresponds to USCIS' data-driven estimates on how long USCIS will need to reduce the processing times of backlogged Form I-765 renewal applications. In addition, DHS has determined that the rule will need to remain in the Code of Federal Regulations for another 720 days so that eligible prior renewal applicants can take advantage of the full up to 360-day increase if necessary, even after the 18-month window for the increase closes.¹⁵⁹ After this period, the amendments made by this rule will expire automatically. Therefore, this rulemaking is limited in time and scope in order to prevent harm to the public.

Bypassing the ordinary APA procedures will allow USCIS immediately to reduce the dire impact the current circumstances create for affected noncitizens and their employers—circumstances that were and continue to be beyond the control of renewal applicants and their U.S. employers. As described above and throughout this preamble, while USCIS has been taking active measures to reduce the backlog and return to its processing goal of an average of 3 months as soon as possible,¹⁶⁰ backlogs and processing times grew to such an extent due to the COVID-19 pandemic's impacts on agency operations and finances, in combination with other factors such as filing surges, staffing shortages, and a sustained increase in the number of filings in other benefit request types such as adjustment of

emergency action was within the scope of the "good cause" exception as the agency's action of postponing the open benefits season was required by events and circumstances beyond its control and necessary because not delaying would have been not only impracticable but also potentially harmful); *Council of Southern Mountains, Inc. v. Donovan*, 653 F.2d 573 (D.C. Cir. 1981) (upholding Mine Safety and Health Administration rule delaying the effective date without notice and comment).

¹⁵⁹ DHS believes that 720 days is the amount of time needed to cover the up to 540-day automatic extension and to account for the fact that renewal applicants may file their EAD renewal application up to 180 days before their EAD expires.

¹⁶⁰ These measures include staffing increases and reallocations to focus on Form I-765, backlog reduction initiatives that apply technology in strategic ways to more efficiently adjudicate Forms I-765, new monthly completion goals, and policy changes to improve efficiency for the agency and eliminate unnecessary hurdles for applicants. In addition, USCIS is focused on addressing prolonged processing times in other areas impacting Form I-765 overall processing times also, for example, in cases where a Form I-765 filing is based on an underlying benefit request, such as an application for asylum or to adjust to lawful permanent resident status.

status and asylum that impact EAD receipts, that those measures were insufficient to avoid the current circumstances.

USCIS expects that its backlog reduction efforts will allow the agency to return to its 90-day processing goal before this TFR expires. In the meantime, this TFR will mitigate harm to individuals, families, and businesses while USCIS works to rebound from the adverse impacts of COVID-19, staffing shortages, and financial strains. A subsequent, extraordinary surge and sustained increase in Form I-765 submissions further undermined those efforts such that the only practicable solution to avoid placing thousands of renewal applicants in the untenable situation of losing employment authorization and/or EAD validity and experiencing employment termination is this time-limited and narrowly drawn rule. Data show that if this rule is implemented without notice and comment, DHS will have mitigated gaps in employment authorizations for virtually all the affected population.¹⁶¹

This temporary measure is consistent with the intent of current 8 CFR 274a.13(d). In this rule, DHS is simply temporarily increasing the 180-day timeframe for those already eligible for an automatic extension. DHS neither makes additional categories eligible nor alters existing procedures through this TFR. Therefore, the increase in the automatic extension of employment authorization and/or EAD is not just highly effective but also limited in scope and application. For this additional reason, DHS believes that the good cause exception is properly invoked in this rulemaking.

In sum, for the reasons stated, including the need to be responsive to the operational demands and challenges facing USCIS to reduce its processing times, renewal applicants' needs to avoid gaps in employment and/or documentation, and employers' need to maintain their workforce, DHS believes that, based on the totality of the circumstances in which this TFR is issued, it has good cause to bypass ordinary notice-and-comment procedure for this temporary action, and that moving expeditiously to make this change effective immediately upon publication is in the best interest of the public.

DHS has concluded that the good cause exceptions in 5 U.S.C. 553(b)(B) and (d)(3) apply to this TFR. Delaying

¹⁶¹ See USCIS' analysis outlined in the preamble at section IV.B, "Executive Order 12866 (Regulatory Planning and Review) and Executive Order 13563 (Improving Regulation and Regulatory Review)."

implementation of this rule until the conclusion of notice-and-comment procedures of section 553(b) and the delayed effective date provided by section 553(d)(3) would be impracticable due to the need to prevent renewal applicants, otherwise eligible for the up to 180-day automatic extension, from experiencing the immediate harm caused by gaps in employment authorization and/or documentation, which would in turn cause imminent harm to their U.S. employers and their ability to maintain their workforce, while USCIS works to reduce adjudicatory processing times and otherwise address the Form I-765 backlogs through various measures.

B. Executive Order 12866 (Regulatory Planning and Review) and Executive Order 13563 (Improving Regulation and Regulatory Review)

Executive Order (E.O.) 12866 and E.O. 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and to the extent permitted by law, to proceed if the benefits justify the costs. They also direct agencies to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). In particular, E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The Office of Information and Regulatory Affairs (OIRA), within the Office of Management and Budget (OMB), has designated this final rule a significant regulatory action that is economically significant under section 3(f)(1) of E.O. 12866. Accordingly, OIRA has reviewed this regulation.

1. Introduction

As fully detailed in the preamble, this TFR temporarily amends existing DHS regulations to provide that the automatic extension period applicable to expiring employment authorization and/or Employment Authorization Documents (Forms I-766 or "EADs") for certain renewal applicants who have filed Form I-765, Application for Employment Authorization, will be increased from up to 180 days to up to 540 days for a period of 540 days (*i.e.*, approximately 18 months). For those renewal applicants whose 180-day automatic extension of employment authorization and/or EADs (hereinafter may be referred to collectively as "EADs" for ease of reference) have expired by the date this rule goes into effect, this rule provides for an additional period of employment

authorization and EAD validity, beginning on the date the rule goes into effect and up to 540 days from the date their EADs expired as shown on the face of the card. The purpose of this TFR is to reduce the likelihood that certain eligible applicants who qualify for automatic extensions of their expiring EADs will experience gaps in employment authorization and/or EAD validity, and therefore allow earnings stability for individuals and continuity of business operations for their employers.

DHS determines that the population impacted by this TFR consists of three components applicable to the pool of applicants who have renewal Form I-765 applications pending. The first component consists of the pool whose EADs and 180-day auto-extensions have lapsed, and renewal Form I-765 applications still have not been approved as of December 31, 2021—we refer to this group as the “current” population segment. The second component consists of the pool for whom coverage by the current 180-day auto-extension has prevented the lapse of their EADs to date but who would experience a lapse due to expiration of their 180-day auto-extensions in the 120-day period between the date of the

analysis and the TFR taking effect.¹⁶² This second group is referred to as “near-term,” in context. The third group consists of the “future” population that, without this rule, could experience a lapse in employment during the 18-month period in which the TFR is effective. Because we cannot forecast the future population with precision, we present a range. The baseline population comprising the current, near-term, and future components could range from 301,463 to 423,863. After applying several adjustments described in the “Background and Population” section, we arrive at an adjusted population that could range from 266,841 to 375,545.

Our analysis suggests that virtually all eligible applicants with pending Form I-765 renewal applications who are otherwise eligible for the automatic extension would be covered by the TFR, though we cannot rule out the possibility that some automatically extended EADs might still lapse, as our analysis reveals that over recent months a minuscule share had lapsed for more than 540 days. We expect that the monetized estimates will be beneficial to individuals, and that they will also generate beneficial cost-savings to businesses.

DHS has prepared quantified estimates of the impacts that could be

generated by this TFR applicable to the adjusted population. This rule will prevent EAD holders from incurring a loss of earnings (“stabilized earnings”), as under this rule there will be no disruption to their earnings due to a lapsed EAD. Additionally, this rule will generate labor turnover cost savings to businesses that employ the EAD holders, as under this rule there will be no disruption to EAD holders’ employment authorization. However, we are unable to ascertain how many individual businesses could be impacted. Additionally, to the extent this rule prevents affected EAD holders’ jobs from going unfilled, there will be less impacts to tax transfers from businesses and employees to the Federal Government.

Due to substantial variation in the inputs utilized to estimate the impacts, there is a very wide range in which they could fluctuate. These impacts are summarized in Table 7, where the monetized figures represent the forecast expected value (which is the mean of trial-based simulations) discounted at 7 percent rate of discount for a range based on simulations that account for variations in the components of the impacts. The figures represent the total cost over two years.

TABLE 7—SUMMARY OF IMPACTS
[FY 2020 Values]

Module A.

EAD Holder Earnings Preserved (“Stabilized Earnings”):

- *Entities directly affected:* Individual EAD holders.
- *Population:* 266,841 to 375,545 individuals with EAD renewals.
- *Monetized present value estimate (7 percent):* \$3,098.0 million.
- *Type:* Stabilized labor income to affected EAD renewal applications; this labor income is a proxy for either prevented transfers from EAD holders to others in the workforce or cost savings to employers for preserved productivity, depending on if employers would have been able to easily find replacement labor for affected EAD holders without this rule.
- *Summary:* Individuals would benefit from being able to maintain their employment without disruption; DHS estimated these savings based on data from recently lapsed EADs and labor earnings, both of which vary within a range.
- *Potential preserved employment taxes =* \$326.9 million (Present Value, 7 percent discount rate); actual amount will depend on how easily businesses would have been able to find replacement labor for affected EAD holders without this rule.

Module B.

Employer Labor Turnover Cost Savings:

- *Entities directly affected:* businesses that employ the EAD holders.
- *Population:* Unknown number of businesses; impacts based on 265,987 to 374,343 individuals with EAD renewals.
- *Monetized present value estimate (7 percent):* \$4,037.6 million.
- *Type:* Cost-savings.
- *Summary:* There would be cost savings to employers in terms of continuity of business operations due to the worker not being separated; DHS estimated these savings based on information applicable to turnover costs relevant to the annual earnings, both of which vary within a range.

Module C.

Other Impacts Considered:

- Individuals impacted would likely benefit from cost-savings accruing to not having to incur the direct costs associated with searching for and obtaining a new job once their renewal EAD that lapsed is eventually approved.
- The estimates of stabilized earnings understate the true impact because they do not factor in the time it would take affected EAD holders to find employment beyond when the lapsed EAD is finally renewed.
- To the extent that individuals’ earnings will be maintained, burdens to their support network would be prevented.
- DHS does not expect labor market impacts from this TFR, as the total maximum population that could be impacted is a very small share of the national labor force.
- Avoid opportunity costs to businesses for having to choose the next best alternative to employment of the affected EAD renewal applicant. We do not know if the replacement hire in a next best alternative scenario would have been a comparable substitute (i.e., a productivity or profit charge to employers).

¹⁶² The near-term captures the dates of January 1, 2022, to mid-April, 2022, when the TFR is expected to take effect.

Some of the impacts of this rule will depend on whether businesses would have been able to find replacement labor for the positions the affected EAD renewal applicants would have lost if they had experienced a gap in employment without this rule. If businesses would have been able to find replacement labor from the pool of the unemployed, the only monetized cost savings of the rule to society is for preventing costs resulting from labor turnover. If businesses would not have been able to find replacement labor, the monetized cost savings of the rule would also include prevented lost productivity due to a lack of available labor. However, the impacts of this rule to the affected EAD renewal applicants do not depend on whether their employer can find replacement labor. This rule will prevent affected EAD renewal applicants from incurring a loss of earnings.

DHS estimates that stabilized earnings to EAD renewal applicants ranges from \$81.3 million to \$6,388.6 million with a primary estimate of \$1,713.5 million (annualized, 7 percent), depending on the wages the EAD renewal applicants earn, the number of EAD renewal applicants affected, and the duration of the gap in employment authorization that would occur without this rule. DHS uses estimates of the stabilized earnings as a measure of either 1) prevented transfers of these wages from the affected population to others in the labor market, or 2) a proxy for businesses' cost savings from prevented lost productivity, depending on whether businesses would have been able to find replacement labor for affected EAD renewal applicants without this rule.

DHS does not know what the next best labor alternative would have been

for businesses without this rule. Accordingly, DHS does not know the portion of the overall effects of this rule that are transfers or costs savings. To begin, DHS describes the two extreme scenarios, which provide the bounds for the range of effects.

Scenario 1: If, in the absence of this rule, all businesses would have been able to easily find reasonable labor substitutes for the positions the EAD renewal applicants would have lost, businesses would have lost little or no productivity. Accordingly, this rule prevents \$1,713.5 million (primary estimate annualized, 7 percent) from being transferred from affected EAD renewal applicants to workers currently in the labor force (whom are not presently employed full time) or induced back into the labor force and this rule would result in \$0 cost savings to businesses for prevented productivity losses.

Scenario 2: Conversely, if all businesses would have been unable to immediately find reasonable labor substitutes for the position the EAD holder filled, then businesses would have lost productivity. Accordingly, \$1,713.5 million is the estimated monetized cost savings from this rule for prevented productivity losses and this rule will result in preventing \$0 from being transferred from affected EAD renewal applicants to replacement labor. Because under this scenario businesses would not have been able to find replacement labor, the rule may also result in additional cost savings to employers for prevented profit losses; and further, may also prevent a reduction in tax transfer payments from businesses and employees to the government. DHS has not estimated all potential tax effects but notes that

stabilized earnings of \$1,713.5 million would have resulted in employment tax losses to the Federal Government (*i.e.*, Medicare and Social Security) of \$180.8 million (annualized, 7 percent).

In both scenarios, whether without this rule employers would have been able to find replacement labor or not, DHS assumes that businesses would have incurred labor turnover costs for having to replace affected EAD renewal applicants. Accordingly, DHS estimates the rule will also result in additional labor turnover cost savings to businesses ranging from \$232.2 million to \$6,666.8 million, with a primary estimate of \$2,233.1 million (annualized, 7 percent) depending on the wages the EAD renewal applicants earn, the number of EAD renewal applicants affected, and the replacement cost to employers.

Table 8 below summarizes these two scenarios and the primary estimate of this rule (Tables 8A and 8B capture the impacts at 3 and 7 percent rates of discount, respectively). Because DHS does not know the overall proportion of businesses that would have been able to easily find replacement labor in the absence of this rule, for DHS's primary estimate we assume that replacement labor would have been found for half of all EAD renewal applicants and not found for the other half (*i.e.*, an average of the two extreme scenarios described above). However, as noted previously, December 2021 unemployment and job openings data indicate there are more jobs available than people looking for jobs.¹⁶³ Accordingly, we believe the impacts of this rule will most likely skew towards Scenario 2, with the rule resulting in mostly cost savings for employers who would have been unable to fill the jobs of affected EAD renewal applicants without this rule.

TABLE 8A—PRIMARY ESTIMATE—MONETIZED ANNUALIZED IMPACTS AT 3%
[Millions]

Category	Description	Scenario 1: Replacement labor found for ALL affected EAD holders	Scenario 2: No replacement labor found for affected EAD holders	Primary estimate: Replacement labor found for HALF of affected EAD holders
Transfers				
Stabilized Earnings	Prevented compensation transfers from EAD renewal applicants to other workers.	\$1,693.0	\$0	\$846.5
Employment Taxes	Prevented reduction in employment taxes paid to the Federal Government.	0	178.6	89.3

¹⁶³ Bureau of Labor Statistics data show that as of December 2021, there were 0.6 unemployed persons per job opening. U.S. Department of Labor, U.S.

Bureau of Labor Statistics, *Number of Unemployed Persons per Job Opening, Seasonally Adjusted* (Jan. 2007 through Jan. 2022), <https://www.bls.gov/charts/job-openings-and-labor-turnover/unemp-per-job-opening.htm> (last visited Mar. 14, 2022).

TABLE 8A—PRIMARY ESTIMATE—MONETIZED ANNUALIZED IMPACTS AT 3%—Continued
[Millions]

Category	Description	Scenario 1: Replacement labor found for ALL affected EAD holders	Scenario 2: No replacement labor found for affected EAD holders	Primary estimate: Replacement labor found for HALF of affected EAD holders
Cost Savings				
Labor Turnover	Prevented labor turnover costs to businesses	2,206.5	2,206.5	2,206.5
Productivity	Prevented lost productivity to businesses (stabilized earnings used as a proxy).	0	1,693.0	846.5
Total Cost Savings	2,206.5	3,899.5	3,053.0

TABLE 8B—PRIMARY ESTIMATE—MONETIZED ANNUALIZED IMPACTS AT 7%
[Millions]

Category	Description	Scenario 1: Replacement labor found for ALL affected EAD holders	Scenario 2: No replacement labor found for affected EAD holders	Primary estimate: Replacement labor found for HALF of affected EAD holders
Transfers				
Stabilized Earnings	Prevented compensation transfers from EAD renewal applicants to other workers.	\$1,713.5	\$0	\$856.7
Employment Taxes	Prevented reduction in employment taxes paid to the Federal Government.	0	180.8	90.4
Cost Savings				
Labor Turnover	Prevented labor turnover costs to businesses	2,233.1	2,233.1	2,233.1
Productivity	Prevented lost productivity to businesses (stabilized earnings used as a proxy).	0	1,713.5	856.7
Total Cost Savings	2,233.1	3,946.6	3,089.9

There are two important caveats to the monetized estimates. First, as the pending caseload evolves over the course of time that this TFR applies to, the pending count and therefore the total number of EADs and individuals associated with them will change. A resultant effect of the caseload changes is that as USCIS works through this backlog, the number of affected EAD renewal applicants and the durations for which EAD renewal applicants may have experienced a lapse in employment without this rule will likely vary from the durations modeled, which was those experienced in December 2021. As a result, DHS acknowledges the uncertainty in the above monetized impacts.

Second, DHS recognizes that non-work time performed in the absence of employment authorization has a positive value, which is not accounted

for in the above monetized estimates.¹⁶⁴ For example, if someone performs childcare, housework, home improvement, or other productive or non-work activities that do not require employment authorization, that time still has value. In assessing the burden of regulations to unemployed populations, DHS routinely assumes the time of unemployed individuals has some value.¹⁶⁵ The monetized estimates of the wages this rule preserves are measured relative to a baseline in which individuals lose EADs and the associated income as a result of the problem this rule seeks to address. The monetary value of the wages this rule preserves are savings to the individual, but DHS has considered whether net societal savings may be lower than the

¹⁶⁴ Boardman et al., *Cost-Benefit Analysis Concepts and Practice* (2018), p.152

¹⁶⁵ For regulatory analysis purposes, DHS generally assumes the value of time for unemployed individuals is at least the value of the Federal minimum wage.

sum of the preserved wages to the individuals and whether a more accurate estimate of the net impact to society from losing employment authorization in the absence of this rule might take into account the value of individuals' non-work time, even though this population has lost their authorization to sell their time as labor. Due to the variety of values placed on non-work time, and the additional fact that this non-work time is involuntary, it is difficult to estimate the appropriate adjustment that DHS should make to preserved wages in order to account for the social value of non-work time. Accordingly, DHS recognizes that the net societal savings of this rule may be somewhat lower than those reported below, but they are a reasonable estimate of the impacts to avoiding the costs of lapsed EADs.

Pursuant to OMB Circular A-4, DHS has prepared an A-4 Accounting Statement for this rule.

TABLE 9—OMB A-4 ACCOUNTING STATEMENT
 [\$ millions, 2020]
 [Period of analysis: 2022–2023]

Category	Primary estimate		Minimum estimate	Maximum estimate	Source citation (RIA, preamble, etc.)
Benefits:					
Monetized Benefits	7% 3%	N/A N/A	N/A N/A	N/A N/A	RIA.
Annualized quantified, but un-monetized, benefits	N/A		N/A	N/A	RIA.
Unquantified Benefits	Without this rule, affected EAD renewal applicants who remain eligible for employment authorization would encounter delays in EAD renewals and be unauthorized to work for periods of time. This rule will ensure that these EAD renewal applicants do not experience gaps in employment authorization as a result of USCIS processing delays and can continue to make a living to sustain their families. Accordingly, stabilized earnings for these EAD renewal applicants may also prevent any monetary or other support that would have been necessary from the support network of affected EAD holders during such a period of unemployment. It will also ensure other benefits of holding an EAD or job will continue, such as valid identity documents, or health insurance obtained through an employer. Additionally, this rule will prevent adverse impacts on businesses that would result from required terminations for affected EAD renewal applicants.				RIA.
Costs:					
Annualized monetized costs	7% 3%	-\$3,089.9 -3,053.0	-\$232.2 -229.4	-\$13,055.4 -13,131.0	RIA.
Annualized quantified, but un-monetized, costs	N/A		N/A	N/A	RIA.
Qualitative (unquantified) costs	In cases where, in the absence of this rule, companies cannot find reasonable substitutes for the labor the affected EAD renewal applicants have provided, affected businesses would also save profits from the productivity that would have been lost. In all cases, companies would avoid opportunity costs from having to choose the next best alternative to employment of the affected EAD renewal applicant.				RIA.
Transfers:					
Annualized monetized transfers: “on budget”	7% 3%	0 0	0 0	0 0	RIA.
From whom to whom?	N/A	N/A			
Annualized monetized transfers: stabilized earnings	7% 3%	856.7 846.5	0 0	6,388.6 6,312.4	RIA.
From whom to whom?	This rule will prevent compensation from transferring from affected EAD renewal applicants to other workers.				RIA.
Annualized monetized transfers: taxes	7% 3%	90.4 89.3	0 0	674.1 666.1	RIA.
From whom to whom?	This rule will prevent a reduction in employment taxes from companies and employees to the Federal Government (quantified). It would also prevent the transfer of additional Federal, State, and local income tax revenue (unquantified).				RIA.
Category	Effects			Source citation (RIA, preamble, etc.)	
Effects on State, local, and/or tribal governments	This rule will prevent a reduction in State and local tax revenue (unquantified). It will also prevent potential reliance on State or local government-funded support services that may have been necessary with a gap in employment authorization (unquantified).			RIA.	
Effects on small businesses	This rule does not directly regulate small entities but has indirect cost-saving to small entities that may employ affected EAD renewal applicants. Such businesses will avoid the costs for labor turnover and loss of productivity and profits had they not been able to immediately fill the labor performed by the affected EAD renewal applicant.			RIA, RFA.	

TABLE 9—OMB A-4 ACCOUNTING STATEMENT—Continued

[\$ millions, 2020]

[Period of analysis: 2022–2023]

Category		
Effects on wages	Preserve access to wages for EAD renewal applicants.	RIA.
Effects on growth	None.	RIA.

2. Background and Population

Backlogs across USCIS-administered benefit requests, including employment authorization, have been increasing steadily since FY 2010, due to factors discussed in the preamble. Unforeseen obstacles driven by the COVID-19 pandemic that exacerbated existing financial problems within USCIS, staffing issues, and a surge in FY 2021 EAD filings, have aggravated the situation and caused a recent spike in USCIS processing times. This is especially concerning where the backlog involves employment authorization and documentation, which is critical to applicants' livelihoods and the financial well-being of their families, as well as U.S. employers' continuity of operations. USCIS understands the potential impact that delays in receiving final decisions have on applicants and tackling the backlog and reducing processing times is a priority for DHS.

Currently, applicants in specific categories who are seeking to renew their expiring EADs are eligible for an automatic extension of that employment authorization and/or EAD for up to 180 days if they meet certain requirements. Because of the recent spike in processing times, however, DHS has determined that 180 days is no longer sufficient to prevent gaps in employment authorization and documentation for most eligible applicants. Therefore, DHS will provide an additional 360 days of employment authorization to the existing 180 days (for a total of up to 540 days from the EAD expiration date), automatically provided to certain applicants seeking a

renewal of their EADs under 8 CFR 274a.13(d)(1).

In developing the populations examined for this analysis, it is useful to discuss four categories. First, there are applicants whose auto-extended EADs under the relevant categories have lapsed and whose renewal Forms I-765 have since been approved, providing them with a new grant of employment authorization and/or new documentation. Second, there are applicants whose auto-extended EADs have lapsed but renewal Forms I-765 have not yet been approved as of the date of the most recent data applicable to this analysis (December 31, 2021). Third, there are applicants whose EADs are still valid, including being within the 180-day auto-extension period, but whose auto-extension period will expire over the next 120 days, in the timespan leading up to the TFR taking effect (the near-term period captures the date of the analysis, which is January 1, 2022, through mid-April 2022). Fourth are the applicants whose EAD would lapse after the TFR becomes effective if it were not for the TFR. These population components will be considered "past," "current," "near-term," and "future."

In this specific case, we think it is most appropriate to attribute the impacts to the population that is current in terms of being impacted, or that could be impacted in the near-term timespan leading up to the TFR, and the future, when the TFR is in effect. Hence, while we draw on data and information from the pool of applicants whose auto-extended EADs lapsed but whose renewal Forms I-765 applications were

subsequently approved, they are not part of the population affected by the rule.

DHS analyzed pending renewal Form I-765 filing and processing information and determined that the current pool of relevant-category Form I-765 renewals that have expired and are pending in a lapse-state of the current analysis stands at 66,077. Furthermore, the near-term population (120-day period starting on January 1, 2022) is 96,786. For the future population, USCIS estimates with about 30,000 additional EADs per month are at risk of lapse without additional adjudication efforts. For the future, we also relied on certain projections about USCIS's efforts to reduce backlogs to make initial estimates. If current adjudication trends hold steady, about 14,500 EADs (10,500 per month for the C08, 3,000 per month C09, and 1,000 for the rest automatic extension-eligible categories) per month would lapse for the duration of the rule's effective timeframe. Over 18 months, that would be 261,000 new applicants who would lose at least one day of employment authorization without this rule. If, however, we assume a linear decrease in processing times such that by the end of the 18 months they were back to more reasonable levels, then about 138,600 individuals would lose employment authorization during the 18-month time frame (500 per month C08, 300 per month C09, and 100 per month for all others at the end of the period) without this rule. Hence, as depicted in Table 10, a range for the future population would be 138,600 to 261,000.

TABLE 10—TFR FUTURE POPULATION PROJECTIONS

Approx. days	Month	Additional EADs facing lapse each month without additional efforts to reduce lapses (A)	Future low bound		Future upper bound	
			USCIS efforts to reduce lapses, outside of this rule: <i>linear improvement of 800 each month</i> (B)	Sum of lapsed EADs (A – B)	USCIS efforts to reduce lapses, outside of this rule: <i>no improvement over 18 months</i> (C)	Sum of lapsed EADs (A – C)
30	1	30,000	15,500	14,500	15,500	14,500
60	2	30,000	16,300	13,700	15,500	14,500

TABLE 10—TFR FUTURE POPULATION PROJECTIONS—Continued

Approx. days	Month	Additional EADs facing lapse each month without additional efforts to reduce lapses (A)	Future low bound		Future upper bound	
			USCIS efforts to reduce lapses, outside of this rule: <i>linear improvement of 800 each month</i> (B)	Sum of lapsed EADs (A – B)	USCIS efforts to reduce lapses, outside of this rule: <i>no improvement over 18 months</i> (C)	Sum of lapsed EADs (A – C)
90	3	30,000	17,100	12,900	15,500	14,500
120	4	30,000	17,900	12,100	15,500	14,500
150	5	30,000	18,700	11,300	15,500	14,500
180	6	30,000	19,500	10,500	15,500	14,500
210	7	30,000	20,300	9,700	15,500	14,500
240	8	30,000	21,100	8,900	15,500	14,500
270	9	30,000	21,900	8,100	15,500	14,500
300	10	30,000	22,700	7,300	15,500	14,500
330	11	30,000	23,500	6,500	15,500	14,500
360	12	30,000	24,300	5,700	15,500	14,500
390	13	30,000	25,100	4,900	15,500	14,500
420	14	30,000	25,900	4,100	15,500	14,500
450	15	30,000	26,700	3,300	15,500	14,500
480	16	30,000	27,500	2,500	15,500	14,500
510	17	30,000	28,300	1,700	15,500	14,500
540	18	30,000	29,100	900	15,500	14,500
Cumulative Total			138,600		261,000	

Note: A linear reduction in the monthly shortfall of 14,500, over 18 months is 805.6, rounded to 800 in these projections for simplicity.

We stress that these estimates were not made via a formal modelling or time series analysis approach, as variables could affect the population over time via changes in volumes, processing times, and other factors that are not possible to predict. As such, DHS acknowledges the uncertainties in these estimates, but they represent the potential population for the impact estimates using the best available information at the time of this analysis.

We thus define the broad population baseline (denoted generally as “ P_B ”) as the sum of the three components, which, given the range for the future, would lie between 301,463 and 423,863.¹⁶⁶ We next proceed to make a few adjustments to P_B . First, for the current population, we parsed out late filers (who are not eligible for the 180-day automatic extension) and some applications that may have lapsed for other reasons not exclusive to the context of the TFR to obtain a narrower population of 65,000.¹⁶⁷

An assumption that is implicit in the populations developed below is that every individual with a lapsed EAD

would be unauthorized to work. In reality, some of the individuals may be authorized to work—or become authorized to work—incident to status and merely relying upon the EAD to evidence that employment authorization. Others may be relying upon the EAD as a government-issued identity document and not using it to obtain employment. In either instance, USCIS does not know, and is unable to reasonably estimate, how many individuals or what percentages of the populations may be separately employment authorized or otherwise not relying on the EAD to document their employment authorization. It is possible, therefore, that the lower bound estimate of population is overstated.

All the impacts that we estimate quantitatively rely on labor earnings by the relevant individuals with EADs. The assessments of possible impacts rely on the assumption that everyone who was approved for an EAD under the relevant categories entered the labor force. DHS believes this assumption is justifiable because applicants would generally not have expended the direct filing (for the pertinent EAD categories in which there is a filing fee) and time-related opportunity costs associated with applying for an EAD if they did not expect to recoup an economic benefit. Realistically, however, individuals might not be employed for any number of other reasons not specifically relevant

to this action. The national unemployment rate (“ U_R ”) as of November 2021, is 4.2 percent.¹⁶⁸ There is constant and considerable job turnover in the labor market even when the unemployment rate is low. Individuals could be unemployed due to this normal turnover or from any number of case-specific factors and conditions. As such, we believe it is reasonable to scale the population to account for unemployment. In addition, not all Form I-765 renewal applications are approved. DHS calculated the applicable Form I-765 renewal approval rate (“ R_A ”) for FY 2020 through 2021 filings, which was 92.7 percent.¹⁶⁹ To obtain the adjusted population (“ P_A ”) we use the formula: $P_B \times (1 - U_R) \times (R_A)$, which yields a population that could range from 266,841 to 375,545. These population data and associated shares of the totals are presented in Table 11.

¹⁶⁸ Source: BLS, The Employment Situation—November 2021, https://www.bls.gov/news.release/archives/empsit_12032021.pdf (last visited Dec. 10, 2021).

¹⁶⁹ Calculation was made from EAD filing data, Form I-765, Application for Employment Authorization, Eligibility Category and Filing Type FY 2003 through 2021, https://www.uscis.gov/sites/default/files/document/data/I-765_Application_for_Employment_FY03-21.pdf (last updated Oct. 2021). Due to the increase in backlogs, the approval rate was calculated as the number of approvals divided by the sum of approvals and denials, rather than the receipts basis.

¹⁶⁶ 66,077 “current” + 96,786 “near-term” + 138,600 “future” = 301,463 total (low end of the range) 66,077 “current” + 96,786 “near-term” + 261,000 “future” = 423,863 total (high end of the range).

¹⁶⁷ Data provided by DHS, USCIS Office of Performance and Quality (OPQ); Claims 3 and SAS PME; obtained on January 17, 2022.

TABLE 11—ESTIMATED TFR POPULATION

Module A. baseline	Low bound		Upper bound	
Component	Number	Share (percent)	Number	Share (percent)
i. Current	66,077	21.9	66,077	15.6
ii. Near-term	96,786	32.1	96,786	22.8
iii. Future	138,600	46.0	261,000	61.6
Total	301,863	100.0	423,863	100.0
Module B. adjusted	Low bound		Upper bound	
Component	Number	Share (percent)	Number	Share (percent)
i. Current	57,795	21.7	57,795	15.4
ii. Near term	85,956	32.2	85,956	22.9
iii. Future	123,091	46.1	231,794	61.7
Total	266,841	100.0	375,545	100.0

Source: USCIS analysis of EAD renewal filing data, provided by DHS, USCIS Office of Performance and Quality (OPQ); data provided 1–1–2022. Estimate for the future population provided by OPQ on 2–3–2022.

The adjusted population captures the population that will incur impacts applicable to both labor earnings for individuals and labor turnover costs to employers. While some information on employment is available through E-Verify (discussed below) we cannot determine how many individual employers would be impacted. The high population bound would represent the maximum number of businesses impacted under a scenario in which each business hired one and only one individual from the population.

There is an important caveat to the adjusted populations upon which DHS will base our estimated impacts. Over time, the backlog and pending pool will evolve according to multiple factors. While we have attempted to account for future changes in the backlog based on the information we have available to us at this time, it is possible that other factors may change that we have been unable to capture such as future surges in renewal applications. Therefore, DHS acknowledges the uncertainty in the above estimated ranges of affected populations and that the number of individuals impacted over the course of time may differ from our adjusted population.

3. Impact Analysis

This section is organized into modules as follows: In Module A, DHS develops earnings levels for the EAD renewal filers.

Module B focuses on labor earnings impacts and is divided into two sections. First, the analytical procedures and results applicable to durations for auto-extended EADs that lapsed but where renewal Form I–765 applications

were since approved are detailed; as described in the preceding section, this portion is not part of the adjusted population affected by this rule, but metrics and data derived from it are vital to the subsequent estimation procedures. Second, the requisite impact simulations for the impacted populations are calibrated, run, and the results presented.

Module C addresses labor turnover cost savings from the rule. Module D collates the monetized impacts and reports the discounted terms, since the TFR will stretch past one year. Module E discusses the impacts from an economic and business perspective, and Module F concludes with consideration of other possible effects.

Since we are dealing with multiple variables, we use abbreviations where possible, as in the above discussion of the population.

Module A. Earnings of EAD Renewal Applicants

We expect two broad types of impacts from this TFR that are estimated and quantified. First, there will be impacts to eligible individual EAD holders in terms of their ability to maintain labor earnings. Second, impacts will accrue to businesses that employ the EAD holders in maintaining continuity of employment and thus avoiding labor turnover costs. A central component of both impacts is the earnings of the EAD renewal filers, which figure prominently into the monetized estimates. An important factor in the estimation procedure requires establishing a range bounded by a lower and upper level.

The Federal minimum wage is \$7.25 per hour; however, in this rulemaking,

we rely on the national “effective minimum wage” of \$11.80 for the forthcoming estimation procedures, which considers the diverse lower wage bounds practiced across U.S. States.¹⁷⁰

Because the individuals renewing EADs would be relatively new entrants to the labor force, we would not expect most of them to earn high wages. However, it is likely that some earn wages above the minimum. Because the EADs impacted do not include or require, at the initial or renewal stage, any data regarding wages, DHS has no information from the associated forms concerning earnings, occupations, industries, positions, or businesses that may employ such workers. DHS can add some robustness to the estimates by incorporating actual data concerning the employment of the EAD holders to draw inference on their earnings.

DHS obtained FY 2020 E-Verify (“EV”) records for the EAD categories potentially impacted, which yielded 4.71 million records.¹⁷¹ These records neither distinguish between an EV case for an initial EAD, a renewal EAD, or the EV case result, but they do provide information that we can draw from regarding employment. The data record the North American Industry Classification System (NAICS) code,

¹⁷⁰ See Ernie Tedeschi, *Americans Are Seeing Highest Minimum Wage in History (Without Federal Help)*, N. Y. Times (Apr. 24, 2019), <https://www.nytimes.com/2019/04/24/upshot/why-america-may-already-have-its-highest-minimum-wage.html>. We note that with the wage level applies to 2019, but we do not make an inflationary adjustment because not all minimum wage levels are set to adjust with inflation.

¹⁷¹ Data were provided by DHS, USCIS Immigration Records and Identity Services Directorate (IRIS), Verification Division; obtained on December 23, 2021.

which is utilized by Federal statistical agencies in classifying business establishments. The EV data does not provide information on job type or occupation, but it does substantiate the NAICS code pursuant to the 3-digit “subsector” level (with a few exceptions).

Analysis of the EV records shows that they disproportionately accrued to a small subset of subsectors. Of one hundred represented subsectors, only four exhibited shares higher than 10 percent—Professional, Scientific, & Technical Services (22.7 percent), Other Information Services (13.3 percent), Administrative and Support Services (13.0 percent), and internet Service Providers, Web Search Portals, and Data Processing Services (11.6 percent). Moreover, the upper quartile is reached with just eleven subsectors. The average individual share across these eleven subsectors was 6.9 percent, while for the entire remainder the individual average was 0.3 percent. Given this concentration, we will center the analysis on these eleven subsectors.

We rescaled the shares of the subsectors according to the total number of records for these eleven subsectors (3.55 million) and obtained the average hourly wage for all occupations within the relevant NAICS codes from BLS. We then calculated a weighting factor input, which is the product of the wage and the rescaled share, and then summed across all rows to obtain a weighted average of \$36.78.¹⁷² We applied this figure as the upper earnings bound, noting that it is more than one-third (35.9 percent) higher than the current national average wage weighted across all occupations, of \$27.07.¹⁷³

Module B. Impacts That Could Accrue to Labor Earnings

1. Duration Analysis for Previously Lapsed EAD Renewals

To estimate the impacts that could accrue to labor earnings, DHS extracted a filing sample size and adjudication records on 31,676 auto-extended EADs for the relevant categories which had lapsed and where the renewal Form I–765 applications were subsequently approved from June–December 31, 2021.

This time frame was chosen to draw recent data in context of the problem set being addressed. For each record, we calculated the duration in calendar days (“ D_L ”) applicable to the end of the initial EAD validity date and the eventual approval of the renewal Form I–765 application in cases where the auto-extended EAD had lapsed. The analysis of the lapse-data shows that the durations are not normally distributed and in fact display a strong positive skew; this is because the majority of the pending EADs are resolved within the first 50 days after lapsing. Less than 10 percent of the pending EADs take more than 115 days to be approved. Please see Table 12 below for a breakout of the number of days the EADs have lapsed.

We utilized the Oracle Crystal Ball[®] Modelling and Simulation Software (“OCB”) to analyze the data. OCB indicates that the Gamma density function provides the best fit.¹⁷⁴ The Gamma distribution is a member of the exponential distributions and is applicable in situations where the data displays considerable variance, is restricted to positive values, and is skewed to the right (positively skewed). It is frequently utilized in analyses to predict durations and wait times until future events occur. Overall, the range of the lapse-durations is very high. However, values of more than 360 days have a very small probability, 0.32 percent, of being realized.

To illustrate the feature of the lapse-durations, we provide the associated probability plot in the Appendix (Figure A.2). The value bars are overlaid with the gamma curve, which visually displays a very good fit. In addition, we can see that as the values get to about 180 or so, they asymptotically converge to zero. We have also marked the plot with the mode (the most frequently observed value, of 7), the median, (40.0), and the mean (52.5). The larger mean compared to the median confirms the positive skew, as it is generally indicative that unusually high individual values tend to pull the mean above the median, the latter of which is not significantly impacted by the skew. Figure A.2 is trimmed to 540 days, and shows a marker for 360 days, as the

latter is the maximum lapse duration this rule can prevent as it provides a temporary increase of 360 days beyond the existing 180-day auto-extension period (for a total automatic extension period of 540 days). The value of 360 is at the 99.8th percentile. At this level, there is still almost a zero probability of a lapse in an EAD occurring with this rule’s temporary increase to the auto-extension period. The percentiles presented in Table 12 represent the fitted values under the Gamma density curve for D_L up to 360 days.

TABLE 12—PERCENTILES FOR THE NUMBER OF CALENDAR DAYS BETWEEN WHEN AUTO-EXTENDED EADS EXPIRED AND RENEWAL FORMS I–765 WERE SUBSEQUENTLY APPROVED IN RECENT MONTHS

[“Lapse Duration” in calendar days]

Percentile	Gamma distribution (calendar days)
0	1
10	7
20	13
30	19
40	28
50	40
60	53
70	69
80	88
90	114
100	358+

Source: USCIS analysis of EAD data; provided by DHS, USCIS, OPQ, Claims 3 database; obtained on 12–17–2021. Analysis conducted with OCB and SAS VIYA PME.

As the percentiles increase, the durations increase at a consistent rate; however, the upper percentile exhibits a significant jump. This data therefore corresponds to the probability graph in showing that once the 90th percentile is reached, the lapse-durations begin to diverge from the distribution to that point and gravitate to almost zero.

2. Simulation and Impact Estimation

The adjusted population (“ P_A ”) of 266,841 to 375,545 individuals could incur impacts that would result in stabilized earnings, as there would be no disruption to their earnings under the TFR. For the estimation procedure we account for worker benefits by calculating a benefits-to-wage multiplier using the most recent BLS information detailing the average employer costs for employee compensation for all civilian workers in major occupational groups and industries. DHS relies on a benefits-to-wage multiplier (“ B_M ”) of 1.45 and, therefore estimates the full opportunity cost per applicant, including employee

¹⁷² Additional details are available in the Appendix, which is located in the Docket for this rulemaking on www.regulations.gov.

¹⁷³ The earnings information for the NAICS codes are found in the “May 2020 National Industry-Specific Occupational Employment and Wage Estimates” in the BLS Occupational Employment and Wage Statistics (OEWS) portal, <https://www.bls.gov/oes/2020/may/oesnci.htm> (last updated Mar. 31, 2021). The national average wage is also found in the above OEWS suite, https://www.bls.gov/oes/2020/may/oes_nat.htm (last updated Mar. 31, 2021).

¹⁷⁴ OCB ranks density fit according to internal routines that evaluate the appropriateness of several tests according to the sample size/population. In this case, the Gamma density function fits the data best based on all continuous distributions subject to a scoring method applicable to the test statistic of the Anderson-Darling (A–D) test, which in this case is 40.84 (it is not however, based on a test of significance. For sample sizes and populations that are large, exact tests of significance based on p -values are generally unreliable in terms of providing evidence in support of the null hypothesis for any distribution).

wages and salaries and the full cost of benefits such as paid leave, insurance, retirement, and other benefits.¹⁷⁵ The total rate of compensation for the effective minimum hourly wage is \$17.11 (\$11.80 × benefits burden of 1.45), which is 62.8 percent higher than the basic Federal minimum wage of \$7.25. Burdened by benefits, the weighted average hourly wage (derived from the EV analysis) is \$53.33 (\$36.78 × benefits burden of 1.45). An hourly benefits-burdened earnings bound of \$17.11–\$53.33 provides a range that we think is realistic to estimate the impacts for this TFR.

DHS is interested in estimating the mean and a range for the impacts that is likely to be realized. Since the population, earnings, and lapse-

durations all vary within a range, and noting especially high variance of the latter, we employ via OCB a simulation approach. For the earnings and population, we rely on the uniform distribution. This is a discreet distribution which essentially means that any value in the range has the same probability as being selected as any other value. This structure is chosen because we have no evidence or data to suggest that the earnings or population would tend to cluster at either the low or high end of the range. The minimum and maximum level are pursuant to the relative figures in preceding paragraph.

The Gamma distribution is generally continuous in the upper tail. However, because the software is utilized extensively for scenario-specific and

risk management simulations, we can calibrate the forthcoming simulation to exclude choosing values above a certain level, which we tune to the value of 360, as that is the maximum day-lapse duration this rule can prevent.

In addition, we introduce a time scalar (“ T_s ”) to account for a typical 8-hour workday and 5-day workweek; the product of $8 \times (5/7)$ is 5.714.¹⁷⁶ Denoting hourly earnings (“ E_H ”), under the “define forecast” toolkit we entered the program: $P_A \times E_H \times B_M \times T_s \times D_L$ and tuned the Gamma distribution for the produced parameters.¹⁷⁷ The tuning features for the system are listed in Table 13, which includes the three-parameters OCB produced for the distribution:

TABLE 13—CALIBRATION FOR STABILIZED EARNINGS ESTIMATION

	Minimum	Maximum	Distribution
Population (P_A)	266,841	375,545	Uniform.
Fully-loaded Earnings ($E_H \times B_M$)	\$17.33	\$53.33	Uniform.
Durations (D_L)	1	360	Gamma: Location: .0017. Scale: 44.57. Shape: 1.16.

Source: USCIS Analysis.

OCB repeatedly calculates results using a different set of random values from the range of values and probability distributions described in Table 13 above to build a model of possible results. We ran 100,000 randomized seed trials, which is sufficient to generate a 95 percent level of precision in the results. Based on the simulation, the expected value (which is the mean of probabilistic-based forecast values) for stabilized earnings is \$3,354.3 million.¹⁷⁸ We also generated a 95 percent certainty range, which reports \$159.2 million to \$12,506.4 million, noting that the extreme range is due to the high variation in the inputs.¹⁷⁹ A sensitivity analysis that scores the

inputs in terms of how much variation in each contributes to fluctuation in the forecasted values reveals that the vast majority, 90.7 percent, of the variation was driven by variation in the lapse duration-days.

If, without this rule, businesses would not have been able to find replacement labor for the position the affected EAD renewal applicant filled, then the unperformed labor would have resulted in a reduction in taxes from employers and employees to governments. Accordingly, the stabilized earnings derived from this rule, and estimated above, will prevent such a reduction in taxes. It is challenging to quantify Federal and State income tax impacts of

employment in the labor market scenario because individual and household tax situations vary widely as do the various State income tax rates.¹⁸⁰ But DHS is able to estimate the potential contributory effects on employment taxes, namely Medicare and Social Security, which have a combined tax rate of 7.65 percent (6.2 percent and 1.45 percent, respectively).¹⁸¹ With both the employee and employer paying their respective portion of Medicare and Social Security taxes, the total estimated level of tax transfer payments from employees and employers to Medicare and Social Security is 15.3 percent.

We estimate the tax impacts on the unburdened earnings basis. Denoting

¹⁷⁵ The benefits-to-wage multiplier is applicable to civilian workers and is calculated as follows: (\$38.91 Total Employee Compensation per hour)/(\$26.85 Wages and Salaries per hour) = 1.44916 = 1.45 (rounded). See BLS, Economic News Release, *Employer Cost for Employee Compensation (June 2021)*, Table 1, *Employer Costs for Employee Compensation by ownership* (dated September 16, 2021, reissued Dec. 17, 2021), https://www.bls.gov/news.release/archives/cecc_09162021.htm (last visited Feb. 23, 2022).

¹⁷⁶ DHS assumes that all EAD renewal applicants are employed full-time; DHS recognizes that some employees may be employed only part-time. DHS recognizes this may result in an overestimate of the below stabilized earnings estimates.

¹⁷⁷ $P_A \times E_H \times B_M \times T_s \times D_L = 266,841$ to 375,545 Adjusted Population × \$11.80 to \$36.78 Hourly Earnings × 1.45 Benefits Multiplier × 5.714 Time

Scalar × Gamma Distributed Lapse Duration in Calendar Days.

¹⁷⁸ The certainty level is based on the entire range of forecast values, so the 95 percent certainty range is the range between which 95 percent of forecasted values are expected to fall, regardless of proximity to the mean. Roughly speaking, the 95 percent certainty bound would generally capture the distribution-specific forecast values lying between the 2.5th and 97.5th percentiles.

¹⁷⁹ In one sense, the stabilized earnings impacts are overstated a bit. For some portion of the near-term population, the effective date of the TFR would interrupt their EAD lapse such that the lapse would not be as long as it otherwise would. It would be extremely difficult to attempt to estimate this reality quantitatively, as, over the course of the near-term, EADs would lapse at different points in time and some would be approved prior to the TFR

while others would have their lapse interrupted by it.

¹⁸⁰ <https://www.cnn.com/2021/08/18/61percent-of-americans-paid-no-federal-income-taxes-in-2020-tax-policy-center-says.html> (last updated Aug. 20, 2021) and for varying State income tax rates see, <https://www.thebalance.com/state-income-tax-rates-3193320> (last updated Jan. 3, 2022).

¹⁸¹ The various employment taxes are discussed in more detail, see <https://www.irs.gov/businesses/small-businesses-self-employed/understanding-employment-taxes> (last updated Mar. 14, 2022). See IRS Publication 15, Circular E, Employer’s Tax Guide for specific information on employment tax rates (Dec. 16, 2021). <https://www.irs.gov/pub/irs-pdf/p15.pdf>. Relevant calculation: (6.2 percent Social Security + 1.45 percent Medicare) × 2 employee and employer losses = 15.3 percent total estimated public tax impact.

the tax impact “ T_I ” and stabilized earnings “ E_S ,” for the three values reported the tax impact is derived as: $(T_I \times E_S) / B_M$.¹⁸² If, without this rule, all employers would have been unable to find replacement labor for the position the EAD renewal applicant filled, this rule will prevent a reduction in employment taxes from employers and employees to the Federal Government of \$353.9 million, but could range from \$16.8 million to \$1,319.5 million. The actual value of tax impacts will depend on the number of affected EAD holders that businesses would have been able to easily find reasonable labor substitutes for in the absence of this rule.

Module C. Labor Turnover Cost Impacts

This TFR is expected to generate a labor turnover cost savings to employers of affected EAD holders. DHS bases the assessment of these costs on the assumption that every EAD applicable to the adjusted population that would have lapsed without this rule would have generated an involuntary separation from an employer, and that the separation is due to no other factors. While DHS cannot estimate how many actual employers would be impacted because DHS does not have employer information for all affected EAD holders, DHS can make an informed estimate of the aggregate scope of the impact, embodied in a cost-savings to the employers.¹⁸³

Employment separations can generate substantial labor turnover costs to employers that can be divided into several components. First are the direct or “hard” costs that involve separation and replacement costs. The separation costs include exit interviews, severance pay, and costs of temporarily covering the employee’s duties and functions with other employees, which may require overtime or temporary staffing. The replacement costs typically include expenses of advertising positions, search and agency fees, screening applicants, interviews, background verification, employment testing, hiring bonuses, and possible travel and relocation costs. Once hired, employers face additional training, orientation, and assessment costs.

Second, direct costs involve loss of productivity and possibly profitability

¹⁸² We divide by the 1.45 benefits multiplier to account for the fact that employment taxes are calculated based upon wages paid, not including fringe benefits.

¹⁸³ We have no basis to say how many employers will be impacted, because any individual employer could have hired more than one of the EAD holders in the population. Therefore, if each individual was hired by one and only one business, the number of employers impacted would converge to the maximum population.

due to operational and production disruptions, which can include errors from other employees that may temporarily fill the position. Some analysts have identified a third cost segment, which is a type of indirect cost, which encompasses loss of institutional knowledge, networking, and impacts to work-culture, morale, and interpersonal relationships. This last type of cost is almost impossible to measure quantitatively.¹⁸⁴

There are numerous studies and reports concerning labor turnover costs (“LTC”) available from Human Resource entities which are cited across correspondent literature. Some focus on specific occupations, industries, salary levels, and often measure LTC in slightly different ways. LTC is generally reported as a share (percentage, “ L_C ”) of the annual earnings (“ E_A ”) or an actual cost per employee for which a percentage can be calculated. Many reports cite a 2012 report published by the Center for American Progress (CAP) that surveyed more than 30 studies that considered both direct (*e.g.*, separation and replacement) and indirect (*e.g.*, loss of institutional knowledge) costs. In Module B above, DHS captures preserved productivity savings had employers not been able to immediately find replacement labor for EAD renewal applicants without this rule. DHS requests comment on how, or if, that measure of productivity may overlap with the types of productivity covered in the CAP report captured here, such as from the substitutability of replacement labor.

The CAP and other reports that we reviewed confirm three central aspects of LTC: (i) That they vary substantially across industries and jobs; (ii) that they tend to grow (in absolute and percentage terms) according to skill level and earnings; and (iii) that they are higher for salaried workers compared to hourly-wage earners.¹⁸⁵ The reporting notes that specialized technical jobs and highly paid jobs in line with senior or executive levels, which involve high levels of education, credentials, and stringent hiring criteria, can generate disproportionately high LTC that can reach more than 100 percent of the

¹⁸⁴ For additional descriptions of the components of labor turnover costs, see “Employee retention: The Real Cost of Losing an Employee,” by Gabrielle Smith, PeopleKeep (September 17, 2021), <https://www.peoplekeep.com/blog/employee-retention-the-real-cost-of-losing-an-employee>.

¹⁸⁵ See “There Are Significant Business Costs to Replacing Employees,” By Heather Boushey and Sarah Jane Glynn (Nov. 16, 2012), Center for American Progress, <https://www.americanprogress.org/issues/economy/reports/2012/11/16/44464/there-are-significant-business-costs-to-replacing-employees/>.

salary—compared to jobs with low educational and technical requirements.¹⁸⁶ However, the CAP survey found that costs tend to range within a bound of 10 percent to around 40 percent of the salary. For example, CAP found despite wide variation and range, for workers earning \$50,000 or less, and for workers earning \$75,000 or less, which, at the time of the study in 2012 corresponded to, the 75th and 90th percentiles of typical earnings, LTC ranged typically from 10 to 30 percent of the salary, clustering at about 21 percent. More recent reports indicate that the typical cost is about one-third of the salary.¹⁸⁷

DHS could nest the information above into an estimation procedure, but it would be beneficial to examine granular data to hone the estimates for two reasons. First, it would be valuable to quantify the correlation between annual earnings and labor turnover costs and incorporate it in the forecast procedure. Second, it is desirable to obtain a distribution for the data—an average and median could be gathered from the referenced reporting, but there would be a gap in terms of other metrics needed to calibrate a certain distribution. DHS examined a 2020 report by the Washington Center for Equitable Growth, which updated the earlier CAP study results to provide information on about thirty studies on LTC.¹⁸⁸ We selected data points that captured both the annual earnings salary (which the study benchmarked to 2019 levels) and turnover costs. We then culled the data applicable to salary levels more than the maximum in our earnings bound. At 2,080 annual work hours, the unburdened weighted average E_A is \$76,502 (the higher earnings levels also corresponded generally to very high LTC that are outside what we think is

¹⁸⁶ See “This Fixable Problem Costs U.S. Businesses \$1 Trillion,” by Shane Mcfeely and Ben Wigert, Workplace (March 13, 2019), <https://www.gallup.com/workplace/247391/fixable-problem-costs-businesses-trillion.aspx>. See also “Dangers of Turnover: Battling Hidden Costs,” by Kate Heinz (last updated: March 25, 2020), Built in, <https://builtin.com/recruiting/cost-of-turnover>.

¹⁸⁷ See “The Real Cost of Employee Turnover in 2021,” Terra Staffing Group (Nov. 4, 2020), <https://www.terstaffinggroup.com/resources/blog/cost-of-employee-turnover>. See also “112 Employee Turnover Statistics: 2021 Causes, Cost & Prevention Data,” by Louie Andre, Finances Online, <https://financesonline.com/employee-turnover-statistics/#cost>.

¹⁸⁸ See “Improving U.S. Labor Standards and the Quality of Jobs to Reduce the Costs of Employee Turnover to U.S. Companies,” By Kate Bahn and Carmen Sanchez Cumming (December 2020), Washington Center for Equitable Growth, at: <https://equitablegrowth.org/wp-content/uploads/2020/12/122120-turnover-costs-ib.pdf>. The data is found in the methodological appendix, located in the Docket for this rulemaking.

the reasonable range).¹⁸⁹ We note that we are assuming that the individuals are employed full time, as 2,080 annual work hours corresponds to a five-day work week and 8-hour work-day. We welcome public input on this assumption. Twenty-seven resulting data points were employed for the analysis.¹⁹⁰ While this may be relatively few observations, OCB nevertheless was able to fit a Beta density function to the data, and we are confident in relying on the results. Foremost, the mean of 24.3 percent and the median of 19.8 percent are very similar to the information reported in the studies referenced above and fall within a substantial range, from 4.1 percent to 68.7 percent. Second, on qualitative grounds the Beta distribution is well-suited as a setup. The Beta distribution is also a family member of the exponential distributions and closely resembles the gamma function. It is utilized in situations where there is substantial variance and is discrete at the lower end minimum, further restricted to positive values. First, negative values can be ruled out in context—there cannot be zero cost to an employee separation—and thus a lower tail cutoff to bound to the cost percentage is appropriate. Second, we can reasonably conjecture that the costs would tend to cluster near the lower tail of the distribution (as outlined in the

CAP report), which is amenable to the positive skew of the distribution, reinforced by the data resultant mean being larger than the median.¹⁹¹ Additionally, the scatterplot (see Appendix, Table A.3) with the fitted least squares line clearly reveals that L_C is an increasing function of the earnings, with a correlation coefficient of 0.661. The Ordinary Least Squares regression indicates that a \$1,000 increase in annual earnings leads to a .63 percentage point increase in labor turnover costs (L_C).

DHS notes that the studies utilized to develop the turnover cost percentage range are based on diverse studies across a range of industries and that they that measure these costs different ways. DHS welcomes public input concerning the range we rely on as well as the way in which turnover costs are tabulated in terms of direct and indirect costs, including productivity effects.

Based on an average of 2,080 annual work hours, the unburdened effective minimum \$11.80 hourly wage maps to annual earnings (E_A) of \$24,544. We have made an additional adjustment regarding the population. This rule will provide EAD renewal applicants with stabilized earnings for an additional 360 days and will prevent turnover costs for employers of applicants whose EADs will be adjudicated within the 360-day

timeframe of the rule. However, for the 0.32 percent of the population whose EAD renewal application could still be pending after 360 days, this rule will delay the turnover costs, not prevent them. Accordingly, we have scaled the population to exclude 0.32 percent of the population whose EAD could still lapse. DHS also recognizes that a certain number of individuals may have been terminated or chosen to leave irrespective of this rule and, accordingly, this rule won't prevent such turnover. DHS does not have data on the number of EAD renewal applicants that would have been terminated from or left their jobs had they not lost employment authorization. DHS requests comment on data that could be used to make such an adjustment.

We calibrated the Beta distribution for the four parameters produced and under the “define forecast” function, entered the program: $P_A \times E_A \times L_C$ with correlation tuned to 0.661.¹⁹² Nesting the correlation essentially means that if a randomly chosen earnings value is high, there is a higher probability that a high turnover cost percentage will be selected as well and vice versa for lower cost percentages. The tuning features for the system are listed in Table 14, which includes the four parameters for the distribution.

TABLE 14—CALIBRATION FOR TURNOVER COST ESTIMATION

	Minimum	Maximum	Distribution
Population (P_A)	265,987	374,343	Uniform. Uniform. Beta: ¹⁹³ Minimum: .031. Maximum: .987. Alpha: 1.214. Beta: 4.27.
Earnings (annual, E_A)	\$24,544.0	76,502.4	
Turnover cost % (L_C)	4.1%	68.7%	
Correlation: Turnover Cost % and Earnings661		

Source: USCIS Analysis.

We ran 100,000 randomized seed trials, which is sufficient to generate a 95 percent level of precision in the results and tuned the simulation to cutoff trials with an L_C greater than the

maximum in our sample, of 68.7 percent. Based on the simulation, the expected value is \$4,371.6 million, and the 95 percent precision bound results in a range of forecasts from \$454.5.0 million to \$ 13,509.3 million.¹⁹⁴

Module D. Monetized Impacts for the TFR

In Table 15 we collate the undiscounted monetized impacts derived from the above sections.

¹⁸⁹ $\$36.78 \times 2,080 = \$76,502$. DHS assumes that all EAD renewal applicants are employed full-time; DHS recognizes that some employees may work only part-time. However, the \$76,502 represents the maximum of the range and employees who earn less wages, such as those who work part-time, are captured by the lower salaries included in the range for LTC estimates.

¹⁹⁰ For the specific data points used, see the Technical Appendix, located in the Docket for this rulemaking.

¹⁹¹ OCB indicates that the multiple continuous distributions are appropriate for the data but ranks the Beta distribution highest in terms of goodness of fit with an A–D test statistic of 0.1336. The four produced parameters are as follows: minimum=0.0314, maximum = .987, alpha = 1.214, Beta = 4.267.

¹⁹² Adjusted Population $\times (1-0.32\%)$ of the population whose EAD would be adjudicated after the 540-day auto-extension window $\times \$11.80$ to $\$36.78$ Hourly Earnings \times Beta Distributed Labor Turnover Cost.

¹⁹³ The beta distribution includes two parameters, alpha (α) and beta (β), which control the shape of distribution and thus influence the minimum and maximum values.

¹⁹⁴ When there are correlated assumptions, OCB does not provide sensitivity for the uncorrelated input, which, in this case, is the population. As a result, the sensitivity analysis indicates that the variation in the forecasts was contributed somewhat equally by the cost percentage (56.7 percent) and the annual earnings (42.7 percent).

TABLE 15—SUMMARY OF MONETIZED IMPACT ESTIMATES APPLICABLE TO LABOR EARNINGS AND LABOR TURNOVER
[Undiscounted, in millions]

	Labor earnings			Tax impacts*		
	Min	Mean	Max	Min	Mean	Max
Stabilized earnings	\$159.2	\$3,354.3	\$12,506.4	\$16.8	\$353.9	\$1,319.6
Labor turnover	454.5	4,371.6	13,509.3	0.0	0.0	0.0
Total	613.7	7,725.9	26,015.7	16.8	353.9	1,319.6

* If, without this rule, businesses could not find replacement labor for any of the affected EAD holders, the tax impacts shown represent the loss in employment taxes this rule would prevent. The actual amount will depend on how easily businesses would have been able to find replacement labor in the absence of this rule.

Because the TFR will apply to more than one full fiscal year, we also apply a discounting framework to the impacts. Since there is a one-to-one mapping from the population to the impacts, we can derive the yearly allocations

directly from the population figures. The approach, encapsulated in Table 16 in step-by step fashion, builds off the population data in Tables 10 and 11. By grouping the current and near-term populations into year one, and then

calculating the portion of the future population attributable to year one, we can logically calculate the year two allocation.

TABLE 16—WORKSHEET FOR IMPACT ALLOCATION ACROSS TWO YEARS

Population segment	Low population	High population
A. Current	57,795	57,795
B. Near-term	85,956	85,956
C. Year 1 initial (A+B)	143,751	143,751
D. Future	123,091	231,794
E. Total TFR months	18	18
F. Future by month (D/E)	6,838	12,877
G. Year 1 months	12	12
H. Year 2 months (E – G)	6	6
I. Year 1 addition (G*F)	82,060	154,529
J. Year 1 total (C+I)	225,811	298,280
K. Year 2 (H*F)	41,030	77,265
L. Total (check: J+K)	266,841	375,545
M. Year 1 allocation (J/L)	84.6%	79.4%
N. Year 2 allocation (K/L)	15.4%	20.6%
O. Average share: year 1	82.0%	
P. Average share: year 2	18.0%	

As can be gathered from rows M and N, the allocations are different according to the high and low population. However, the impact estimates already have incorporated the population variation, meaning that we need to rely on a single percentage for the share allocations. Since the shares

are close across the population bounds, we average them and apply the resulting figures, of 82.0 percent and 18.0 percent, in order (Rows O and P). Table 17 provides the allocated impacts according to the allocation derived above, incorporating sub-tables A–C, to account for the average, and low and high ends of the certainty bound in

order. Each sub-table is organized into three additional sections, to account for undiscounted terms, and those at 3 percent rate of discount, and a 7 percent rate of discount, in order. We parsed out the stabilized earnings and labor turnover impacts separately, as they will embody different types of impacts.

TABLE 17—MONETIZED EXPECTED VALUE IMPACTS FOR THE TFR
[Millions]

Undiscounted	Stabilized earnings	Labor turnover	Total	Taxes*
A. Average (Expected Value)				
Year 1	\$2,751.4	\$3,585.8	\$6,337.2	\$290.3
Year 2	602.9	785.8	1,388.7	63.6
Total	3,354.3	4,371.6	7,725.9	353.9

TABLE 17—MONETIZED EXPECTED VALUE IMPACTS FOR THE TFR—CONTINUED
[Millions]

3% Discount	Stabilized earnings	Labor turnover	Total	Taxes
Year 1	\$2,671.2	\$3,481.4	\$6,152.6	\$281.9
Year 2	568.3	740.7	1,309.0	60.0
Total	3,239.6	4,222.1	7,461.6	341.8
Annualized	1,693.0	2,206.5	3,899.5	178.64
7% Discount	Stabilized earnings	Labor turnover	Total	Taxes
Year 1	\$2,571.4	\$3,351.2	\$5,922.6	\$271.3
Year 2	526.6	686.3	1,213.0	55.6
Total	3,098.0	4,037.6	7,135.6	326.9
Annualized	1,713.5	2,233.1	3,946.6	180.8
B. Low end of certainty range				
Undiscounted	Stabilized earnings	Labor turnover	Total	Taxes *
Year 1	\$130.6	\$372.8	\$503.4	\$13.8
Year 2	28.6	81.7	110.3	3.0
Total	159.2	454.5	613.7	16.8
Average	79.6	227.3	306.9	8.4
3% Discount	Stabilized earnings	Labor turnover	Total	Taxes
Year 1	\$126.8	\$361.9	\$488.7	\$13.4
Year 2	27.0	77.0	104.0	2.8
Total	153.8	439.0	592.7	16.2
Annualized	80.35	229.4	309.8	8.5
7% Discount	Stabilized earnings	Labor turnover	Total	Taxes
Year 1	\$122.0	\$348.4	\$470.5	\$12.9
Year 2	25.0	71.4	96.4	2.6
Total	147.0	419.8	566.8	15.5
Annualized	81.3	232.2	313.5	8.6
C. High End of Certainty Range				
Undiscounted	Stabilized earnings	Labor turnover	Total	Taxes *
Year 1	\$10,258.4	\$11,081.0	\$21,339.3	\$1,082.4
Year 2	2,248.0	2,428.3	4,676.4	237.2
Total	12,506.4	13,509.3	26,015.7	1,319.6
Average	6,253.2	6,754.7	13,007.9	659.8
3% Discount	Stabilized earnings	Labor turnover	Total	Taxes
Year 1	\$9,959.6	\$10,758.2	\$20,717.8	\$1,050.9
Year 2	2,119.0	2,288.9	4,407.9	223.6
Total	12,078.6	13,047.2	25,125.7	1,274.5
Annualized	6,312.39	6,818.6	13,131.0	666.1

TABLE 17—MONETIZED EXPECTED VALUE IMPACTS FOR THE TFR—CONTINUED
[Millions]

	7% Discount	Stabilized earnings	Labor turnover	Total	Taxes
Year 1		\$9,587.2	\$10,054.4	\$19,943.3	\$1,011.6
Year 2		1,963.5	1,999.2	4,084.5	207.2
Total		11,550.8	12,053.7	24,027.8	1,218.8
Annualized		6,388.6	6,666.8	13,289.6	674.1

* If, without this rule, businesses could not find replacement labor for any of the affected EAD holders, the tax impacts shown represent the loss in employment taxes this rule would prevent. The actual amount will depend on how easily businesses would have been able to find replacement labor in the absence of this rule.

For the discounted figures, the annualized amounts are the average annual equivalence basis. Since the inputs are different for each year, the annualized terms differ across discount rates.

Module E. Economic and Business Impacts

As explained previously, DHS does not know what the next best alternative would have been for businesses without this rule. Accordingly, DHS does not know the proportion of the stabilized labor earnings estimates developed above that would represent cost savings to businesses for prevented lost productivity or are prevented transfer payments from affected EAD holders to replacement labor.¹⁹⁵ These effects are very difficult to quantify and could be influenced by multiple factors, but we will address the possibilities at a conceptual level.

In the cases where, in the absence of this rule, businesses would have been able to easily find reasonable labor substitutes for the EAD renewal applicants, then the impact of this rule is preventing a distributional impact where the earnings of affected EAD holders would be transferred to others, who might fill in for (and presumably replace) the EAD renewal applicants during their earnings lapse. The portion of the total estimate of stabilized income that would represent this prevented transfer payment will depend on the ability of businesses to have found replacement labor in the absence of this rule.

In the cases where, in the absence of this rule, businesses would not have been able to easily find reasonable labor substitutes for the EAD renewal applicants, then the impact of this rule

¹⁹⁵ Transfer payments are monetary payments from one group to another that do not affect total resources available to society. See OMB Circular A-4 pages 14 and 38 for further discussion of transfer payments and distributional effects. Circular A-4 (Sept. 17, 2003), https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf.

is preventing an associated loss of productivity for employers. Therefore, the portion of the total estimate of stabilized income that would represent cost savings to employers for prevented productivity losses will depend on the ability of businesses to have found replacement labor in the absence of this rule. In this case, the rule may also result in additional cost savings to employers for prevented profit losses and having to choose the next best alternative to the EAD holder.

DHS does not know what this next-best alternative may be for those companies. However, if the replacement candidate would have been substitutable for the affected EAD renewal applicant to a high degree, the labor performed by the new candidate would not have resulted in changes to profits or productivity. Accordingly, if the replacement labor is highly substitutable, we wouldn't expect this rule to result in cost savings for productivity loss as a result of employing the next available alternative for labor. If, however, the replacement labor is a poor substitute and would have decreased productivity, then this rule will preserve that lost productivity.

The above discussion involves two important points: If employers replaced individuals who faced a lapse in their EAD after the automatic extension with others in the labor force, then once the EAD was eventually reauthorized the EAD holder would need to conduct a new search for a new job. They would thus incur direct costs associated with seeking new employment. In addition, it can take time to establish new employment. According to the Bureau of Labor Statistics, in November 2021 the average duration of unemployment was 28.9 weeks (about 7 months) and the median duration was 12.7 weeks (about 3 months).¹⁹⁶ This has varied historically, according to factors such as

¹⁹⁶ Bureau of Labor Statistics, Employment Situation News Release (November 2021), Table A-12, https://www.bls.gov/news.release/archives/empst_12032021.htm.

the overall strength of the economy, employment conditions in specific industries, individual search effort, and geographical considerations.¹⁹⁷

Based on this average search time, in cases where affected EAD renewal applicants would not be able to immediately return to their previous jobs once their EAD is approved, the duration of lapsed earnings this TFR is addressing is likely higher than that we have relied on from the analysis of the data. As a result, search costs and the potential for earnings to continue to lapse even when the individuals affected are able to return to work probably makes our estimated impacts of the amount in stabilized earnings to affected EAD holders smaller than the actual impacts. However, we do not have a method to allocate the job search time to a portion that could be conducted while the EAD was in lapse mode and a portion that would need to be held off until the Form I-765 renewal application was approved and a new EAD issued. Therefore, it would be speculative to try to incorporate these additional factors into a cohesive model and thus we have not quantified them.

Module F. Other Impacts

DHS does not expect material impacts to the U.S. labor market from this TFR. According to the most recent data (applicable to November 2021), the U.S. labor force stands at 162,052,000.¹⁹⁸ The maximum population impacted by the TFR is 375,545, which is only 0.23 percent of the national labor force.

Without this rule, EAD holders who remain eligible for employment authorization would encounter delays

¹⁹⁷ Bureau of Labor Statistics, Duration of Unemployment, Seasonally Adjusted, <https://www.bls.gov/charts/employment-situation/duration-of-unemployment.htm> (last visited Mar. 9, 2022).

¹⁹⁸ BLS, Employment Situation, Table A-1. Employment status of the civilian population by sex and age. The figure applies to the civilian labor force, seasonally adjusted, https://www.bls.gov/news.release/archives/empst_12032021.htm (last visited Dec. 14, 2021).

in EAD renewals and either be unauthorized to work for periods of time, or lack documentation reflecting their employment authorization. This rule is not making additional categories eligible for employment authorization; it simply temporarily increases the 180-day timeframe for those already eligible for an automatic extension. It will ensure that these EAD holders do not experience gaps in employment as a result of USCIS processing delays. Accordingly, stabilized earnings for these EAD holders may also relieve the support network of the applicants for any monetary or other support that would have been necessary during such a period of unemployment. This network could include public and private entities, and it may comprise family and personal friends, legal services providers and advisors, religious and charity organizations, State and local public institutions, educational providers, and non-governmental organizations. DHS believes these impacts would accrue as benefits to the noncitizen EAD holders and their families.

Finally, we have already noted that the goal of this TFR is to prevent EADs from lapsing, and that the 540-day benchmark would cover almost every case. For the small portion that lapsed for more than 540 days, we have already noted that these would embody extreme outliers and may be skewed by data errors. Nevertheless, for purposes of transparency we provide Table 18, which shows the share of EADs that would lapse under several alternatives to the 360-day extension to the existing 180-day benchmark.

TABLE 18—PERCENTAGE OF EADS THAT WOULD LAPSE UNDER ALTERNATIVE EXTENSION-DAY SCENARIOS

The number of extension days added to the existing 180	Share that would lapse (percent)
30	57.7
60	35.3
90	19.0
120	8.41
180	1.44
360	0.32
540+	0.10

It is important to note that our analysis was based on data from June through December of 2021. If processing times and resultant backlogs are higher now, than lapse-durations would potentially also be higher, and the shares affected may be larger than those shown in Table 16.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), requires an agency to prepare and make available to the public a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.*, small businesses, small organizations, and small governmental jurisdictions). The RFA’s regulatory flexibility analysis requirements apply only to those rules for which an agency is required to publish a general notice of proposed rulemaking pursuant to 5 U.S.C. 553(b) or any other law. *See* 5 U.S.C. 604(a). As discussed previously, USCIS did not issue a notice of proposed rulemaking for this action. Therefore, a regulatory flexibility analysis is not required for this rule.

D. Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act)

The Congressional Review Act (CRA) was included as part of SBREFA by section 804 of SBREFA, Public Law 104–121, 110 Stat. 847, 868, *et seq.* OIRA has determined that this TFR is a major rule as defined by the CRA because it will result in a major increase in costs or prices.¹⁹⁹ DHS has complied with the CRA’s reporting requirements and has sent this rule to Congress and to the Comptroller General as required by 5 U.S.C. 801(a)(1). As stated in section IV.A of this preamble, DHS has found that there is good cause to conclude that notice, the opportunity for advanced public participation, and a delay in the effective date are impracticable and contrary to the public interest. Accordingly, this rule is effective immediately upon publication.²⁰⁰

E. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (UMRA) is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and Tribal governments. Title II of UMRA requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed rule, or final rule for which the agency published a proposed rule, that includes any Federal mandate that may result in a \$100 million or more expenditure (adjusted annually for inflation) in any one year by State, local, and Tribal governments, in the aggregate, or by the private

sector.²⁰¹ This rule is exempt from the written statement requirement, because DHS did not publish a notice of proposed rulemaking for this rule.

In addition, this rule does not contain a Federal mandate as the term is defined under UMRA.²⁰² The requirements of title II of UMRA, therefore, do not apply, and DHS has not prepared a statement under UMRA.

F. Executive Order 13132 (Federalism)

This rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of E.O. 13132, 64 FR 43255 (Aug. 4, 1999), this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

G. Executive Order 12988 (Civil Justice Reform)

This rule was drafted and reviewed in accordance with E.O. 12988, Civil Justice Reform. This rule was written to provide a clear legal standard for affected conduct and was reviewed carefully to eliminate drafting errors and ambiguities, so as to minimize litigation and undue burden on the Federal court system. DHS has determined that this rule meets the applicable standards provided in section 3 of E.O. 12988.

H. National Environmental Policy Act

DHS Directive 023–01 Rev. 01 and Instruction Manual 023–01–001–01 Rev. 01 (Instruction Manual)²⁰³ establish the policies and procedures that DHS and its components use to comply with the National Environmental Policy Act (NEPA) and the Council on Environmental Quality (CEQ) regulations for implementing NEPA.²⁰⁴

The CEQ regulations allow Federal agencies to establish, with CEQ review and concurrence, categories of actions (“categorical exclusions”) that experience has shown do not have a significant effect on the human environment and, therefore, do not

²⁰¹ *See* 2 U.S.C. 1532(a).

²⁰² The term “Federal mandate” means a Federal intergovernmental mandate or a Federal private sector mandate. *See* 2 U.S.C. 1502(1) and 658(6).

²⁰³ The Instruction Manual contains the Department’s procedures for implementing NEPA and was issued November 6, 2014. Instruction Manual, <https://www.dhs.gov/publication/directive-023-01-rev-01-and-instruction-manual-023-01-001-01-rev-01-and-catex> (last updated Nov. 12, 2021).

²⁰⁴ 40 CFR parts 1500 through 1508.

¹⁹⁹ *See* 5 U.S.C. 804(2).

²⁰⁰ *See* 5 U.S.C. 808(2).

require an environmental assessment or environmental impact statement.²⁰⁵

The Instruction Manual establishes categorical exclusions that DHS has found to have no such effect.²⁰⁶ Under DHS NEPA implementing procedures, for an action to be categorically excluded it must satisfy each of the following three conditions: (1) The entire action clearly fits within one or more of the categorical exclusions; (2) the action is not a piece of a larger action; and (3) no extraordinary circumstances exist that create the potential for a significant environmental effect.²⁰⁷

This rule amends 8 CFR 274a.13(d) to temporarily increase the period of time that the employment authorization and/or EADs of certain eligible Form I-765 renewal applicants are automatically extended while their renewal applications remain pending with USCIS. More specifically, this rule provides that the automatic extension period applicable to expiring EADs for certain renewal applicants who have filed Form I-765 will be increased from up to 180 days to up to 540 days.

Amending the current rule to increase the automatic extension period for employment authorization and/or EADs' validity from 180 days to 540 days will not result in any meaningful, calculable change in environmental effect with respect to the number of individuals affected by current EAD renewal requirements. Furthermore, this rule's amendment will not alter immigration eligibility criteria or result in an increase in the number of individuals who will be eligible for employment authorization and/or EADs. Therefore, DHS has determined that the temporary amendment to 8 CFR 274a.13 clearly fits within Categorical Exclusion A3(d) contained in the Instruction Manual because it amends a regulation without changing its environmental effect. Furthermore, DHS has determined that this rule fits within Categorical Exclusion A3(a) contained in the Instruction Manual because DHS considers temporarily increasing the automatic extension period for employment authorizations and/or EADs for certain renewal applicants to be an action of a strictly administrative or procedural nature.

The temporary amendment to 8 CFR 274a.13 is a standalone action to increase an automatic extension period. It is not part of a larger action. This amendment will not result in any major

Federal action that will significantly impact the human environment. Furthermore, USCIS has determined that no extraordinary circumstances exist that would create the potential for significant environmental effects. Therefore, this rule amendment is categorically excluded from further NEPA review.

I. Family Assessment

DHS has reviewed this rule in line with the requirements of section 654 of the Treasury and General Government Appropriations Act, 1999,²⁰⁸ enacted as part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999.²⁰⁹ DHS has systematically reviewed the criteria specified in section 654(c)(1), by evaluating whether this regulatory action: (1) Impacts the stability or safety of the family, particularly in terms of marital commitment; (2) impacts the authority of parents in the education, nurture, and supervision of their children; (3) helps the family perform its functions; (4) affects disposable income or poverty of families and children; (5) only financially impacts families, if at all, to the extent such impacts are justified; (6) may be carried out by State or local government or by the family; or (7) establishes a policy concerning the relationship between the behavior and personal responsibility of youth and the norms of society. If the agency determines a regulation may negatively affect family well-being, then the agency must provide an adequate rationale for its implementation.

DHS has determined that the implementation of this regulation will not negatively affect family well-being and will not have any impact on the autonomy or integrity of the family as an institution.

J. Paperwork Reduction Act

This rule does not propose new, or revisions to existing, "collection[s] of information" as that term is defined under the Paperwork Reduction Act of 1995, Public Law 104-13, 44 U.S.C. chapter 35, and its implementing regulations, 5 CFR part 1320. As this is a TFR that only will increase the duration of an automatic extension of employment authorization and EAD, USCIS does not anticipate a need to update the Form I-765 or to collect additional information beyond that already collected on Form I-765.

List of Subjects in 8 CFR Part 274a

Administrative practice and procedure, Aliens, Employment, Penalties, Reporting and recordkeeping requirements.

Accordingly, for the reasons set forth in the preamble, the Secretary of Homeland Security amends 8 CFR part 274a as follows:

PART 274a CONTROL OF EMPLOYMENT OF ALIENS

■ 1. The authority citation for part 274a continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1324a; 48 U.S.C. 1806; 8 CFR part 2; Pub. L. 101-410, 104 Stat. 890, as amended by Pub. L. 114-74, 129 Stat. 599.

■ 2. Effective May 4, 2022, through October 15, 2025, amend § 274a.13 by adding paragraph (d)(5) to read as follows:

§ 274a.13 Application for employment authorization.

* * * * *

(d) * * *

(5) *Temporary increase in the automatic extension period.* The authorized extension period stated in paragraph (d)(1) of this section, 8 CFR 274a.2(b)(1)(vii), and referred to in paragraphs (d)(3) and (4) of this section is increased to up to 540 days for all eligible classes of aliens as described in paragraph (d)(1) who properly filed their renewal application on or before October 26, 2023. Such automatic extension period will automatically terminate the earlier of up to 540 days after the expiration date of the Employment Authorization Document (Form I-766, or successor form) or upon issuance of notification of a denial on the renewal request, even if such date is after October 26, 2023. Aliens whose automatic extension under paragraph (d)(1) expired before May 4, 2022, will receive an automatic resumption of employment authorization and the validity of their Employment Authorization Document, as applicable, for an additional period beginning from May 4, 2022, and up to 540 days from the expiration of their employment authorization and/or Employment Authorization Document as shown on the face of such document. An Employment Authorization Document that has expired on its face is considered unexpired when combined with a Notice of Action (Form I-797C), which demonstrates that the requirements of paragraph (d)(1) of this section and this paragraph (d)(5) have been met, notwithstanding any notations on such notice indicating an automatic extension of up to 180 days.

²⁰⁵ 40 CFR 1507.3(e)(2)(ii) and 1501.4.

²⁰⁶ See Appendix A, Table 1.

²⁰⁷ See Instruction Manual section V.B(2)(a) through (c).

²⁰⁸ See 5 U.S.C. 601 note.

²⁰⁹ Public Law 105-277, 112 Stat. 2681 (1998).

Nothing in this paragraph (d)(5) will affect DHS's ability to otherwise terminate any employment authorization or Employment Authorization Document, or extension

period for such employment authorization or document, by written notice to the applicant, by notice to a class of aliens published in the **Federal**

Register, or as provided by statute or regulation, including 8 CFR 274a.14.

Alejandro N. Mayorkas,
Secretary, U.S. Department of Homeland Security.

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