

(5) *Manufacturer or sponsor.* A manufacturer or sponsor is the person who:

(i) Meets the definition of “sponsor” in § 312.3 of this chapter for the eligible investigational drug;

(ii) Has submitted an application for the eligible investigational drug under section 505(b) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act; or

(iii) Is other than a contract manufacturer acting on behalf of a manufacturer or sponsor, producing the eligible investigational drug provided to an eligible patient on behalf of the persons described in paragraph (a)(5)(i) or (ii) of this section.

(b)(1) Except as described in paragraph (b)(2) of this section, a manufacturer or sponsor of an eligible investigational drug shall submit to the Food and Drug Administration (FDA), no later than March 31 of each year, an annual summary of any use of eligible investigational drugs supplied to any eligible patient under section 561B of the Federal Food, Drug, and Cosmetic Act for the period of January 1 through December 31 of the preceding year.

(2) For a manufacturer or sponsor of an eligible investigational drug that has supplied an eligible patient with an eligible investigational drug under section 561B of the Federal Food, Drug, and Cosmetic Act between the period from enactment of section 561B (May 30, 2018) and December 31, 2022, the manufacturer or sponsor shall submit to FDA a first annual summary covering that period no later than March 31, 2023.

(c) For each eligible investigational drug, the annual summary must include:

(1) *The name of the eligible investigational drug and applicable IND number.* The name and IND number of the eligible investigational drug supplied by the manufacturer or sponsor for use under section 561B of the Federal Food, Drug, and Cosmetic Act.

(2) *Number of doses supplied.* The total number of doses supplied by the manufacturer or sponsor to eligible patients for use under section 561B of the Federal Food, Drug, and Cosmetic Act. Each dose of an eligible investigational drug supplied for an eligible patient shall be counted as a dose supplied.

(3) *Number of patients treated.* The total number of eligible patients for whom the manufacturer or sponsor provided the eligible investigational drug for use under section 561B of the Federal Food, Drug, and Cosmetic Act.

An eligible patient treated more than one time or with multiple doses of an eligible investigational drug shall be counted as a single patient.

(4) *Use for which the eligible investigational drug was made available.* A tabular summary identifying the diseases or conditions for which the eligible investigational drug was made available for use under section 561B of the Federal Food, Drug, and Cosmetic Act.

(5) *Any known serious adverse events and outcomes.* A tabular summary of any known serious adverse events, including resulting outcomes, experienced by patients treated with the eligible investigational drug under section 561B of the Federal Food, Drug, and Cosmetic Act.

(d) Annual summaries submitted pursuant to this section shall be submitted in an electronic format that FDA can process, review, and archive, and shall be sent directly to a designated point of contact for submissions made under section 561B of the Federal Food, Drug, and Cosmetic Act. The annual summaries must be submitted to the designated point of contact and shall not be submitted to a particular investigational new drug application. FDA will specify the designated point of contact for submission of the annual summary on FDA’s website, as described at <https://www.fda.gov>.

Dated: August 31, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2022–19737 Filed 9–13–22; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 55

[EPA–R02–OAR–2022–0400; FRL 9785–02–R2]

Outer Continental Shelf Air Regulations; Consistency Update for New York

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing an update to a portion of the Outer Continental Shelf (OCS) Air Regulations. Requirements applying to OCS sources located within 25 miles of states’ seaward boundaries must be updated periodically to remain consistent with the requirements of the corresponding onshore area (COA), as

mandated by the Clean Air Act (CAA). The portion of the OCS air regulations that is being updated here pertains to the requirements for OCS sources for which the State of New York is the COA. The intended effect of updating the OCS requirements for the State of New York is to regulate emissions from OCS sources in accordance with the requirements onshore. The requirements discussed in this rule are being incorporated by reference into the OCS air regulations.

DATES: This final rule is effective on October 14, 2022. The incorporation by reference of a certain publication listed in this rule is approved by the Director of the Federal Register as of October 14, 2022.

ADDRESSES: The EPA has established a docket for this action under Docket ID Number EPA–R02–OAR–2022–0400. All documents in the docket are available at www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Viorica Petriman, Air Programs Branch, Permitting Section, U.S. Environmental Protection Agency, Region 2, 290 Broadway, New York, New York 10007, (212) 637–4021, petriman.viorica@epa.gov.

SUPPLEMENTARY INFORMATION:

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I. What is the background for this action?

On May 20, 2022 (87 FR 30849), EPA proposed to incorporate by reference into the OCS Air regulations at 40 CFR part 55¹ updated requirements pertaining to New York. See 87 FR 30849. The action that EPA is taking in this rule is to finalize those proposed updates. Section 328(a) of the CAA requires that for OCS sources located within 25 miles of a State’s seaward boundary, the requirements shall be the same as would be applicable if the sources were located in the corresponding onshore area (COA). Because the OCS requirements are based on onshore requirements, and onshore requirements may change, CAA section 328(a)(1) requires that the EPA update

¹ EPA promulgated 40 CFR part 55 on September 4, 1992. The reader may refer to the proposed rulemaking to promulgate part 55 from 56 FR 63774 (December 5, 1991) and the preamble to the final rule promulgated 57 FR 40792 (September 4, 1992) for further background and information on the OCS regulations.

the OCS requirements as necessary to maintain consistency with onshore requirements.

To comply with this statutory mandate, the EPA must incorporate by reference into part 55 all relevant State rules in effect for onshore sources, so they can be applied to OCS sources located offshore. This limits EPA's flexibility in deciding which requirements will be incorporated into 40 CFR part 55 and prevents EPA from making substantive changes to the requirements it incorporates. As a result, EPA may be incorporating rules into 40 CFR part 55 that do not conform to all of EPA's state implementation plan (SIP) guidance or certain requirements of the CAA. Inclusion in the OCS rules does not imply that a rule meets the requirements of the CAA for SIP approval, nor does it imply that the rule will be approved by EPA for inclusion in the SIP.

40 CFR 55.12 specifies certain times at which part 55's incorporation by reference of a State's rules must be updated. One time such a "consistency update" must occur is when any OCS source applicant submits a Notice of Intent (NOI) under 40 CFR 55.4 for a new or a modified OCS source. 40 CFR 55.4(a) requires that any OCS source applicant must submit to EPA a NOI before performing any physical change or change in method of operation that results in an increase in emissions. EPA must conduct any necessary consistency update when it receives a NOI, and prior to receiving any application for a preconstruction permit from the OCS source applicant. 40 CFR 55.6(b)(2) and 55.12(f).

On March 14, 2022, the EPA received a NOI from Empire Offshore Wind LLC to submit an OCS air permit application for the construction and operation of a new OCS source (a wind energy project) about 14 miles offshore New York.

The EPA reviewed the New York State Department of Environmental Conservation ("NYSDEC") air rules currently in effect, to ensure that they are rationally related to the attainment or maintenance of Federal and State Ambient Air Quality Standards (AAQS) or part C of title I of the CAA, that they are not designed expressly to prevent exploration and development of the OCS, and that they are applicable to OCS sources. See 40 CFR 55.1. The EPA has also evaluated the rules to ensure they are not arbitrary and capricious. See 40 CFR 55.12(e). The EPA has excluded New York's administrative or procedural rules,² and requirements that

regulate toxics which are not related to the attainment and maintenance of Federal and State AAQS.

II. What comments were received in response to the EPA's proposed action?

The EPA did not receive any comments on the proposal to update a portion of the OCS Air Regulations to incorporate updated requirements into 40 CFR part 55 pertaining to the State of New York.

III. What action is the EPA taking?

The EPA is taking final action to incorporate by reference relevant New York air pollution control rules into § 55.14 and to update the "New York" section of appendix A to 40 CFR part 55, which lists those rules. The EPA is approving this action under section 328(a) of the CAA, 42 U.S.C. 7627(a). Section 328(a) of the CAA requires that EPA establish requirements to control air pollution from OCS sources located within 25 miles of States' seaward boundaries that are the same as onshore requirements. To comply with this statutory mandate, the EPA must incorporate applicable onshore rules into 40 CFR part 55 as they exist onshore.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference as described in sections I. and II. of this preamble. In accordance with the requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of "State of New York Requirements Applicable to OCS Sources," dated March 10, 2022, which provides the text of the NYSDEC air rules in effect as of March 10, 2022 that would apply to OCS sources. The EPA has made, and will continue to make, this material available through www.regulations.gov and at the EPA Region 2 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to establish requirements to control air pollution from OCS sources located within 25 miles of states' seaward boundaries that are the same as onshore air control

use its administrative and procedural rules as onshore. However, in those instances where EPA has not delegated authority to implement and enforce part 55, as in New York, EPA will use its own administrative and procedural requirements to implement the substantive requirements. See 40 CFR 55.14(c)(4).

requirements. To comply with this statutory mandate, the EPA must incorporate applicable onshore rules into part 55 as they exist onshore. 42 U.S.C. 7627(a)(1); 40 CFR 55.12. Thus, in promulgating OCS consistency updates, the EPA's role is to maintain consistency between OCS regulations and the regulations of onshore areas, provided that they meet the criteria of the Clean Air Act. Accordingly, this action simply updates the existing OCS requirements to make them consistent with requirements onshore, without the exercise of any policy discretion by the EPA.

a. Executive Order 12866, Regulatory Planning and Review

This action is not a "significant regulatory action" under the terms of Executive Orders (E.O.) 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011) and is therefore not subject to review under the E.O.

b. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under PRA because this action only updates the State rules that are incorporated by reference into 40 CFR part 55. OMB has previously approved the information collection activities contained in the existing regulations at 40 CFR part 55 and, by extension, this update to part 55, and has assigned OMB control number 2060-0249. This action does not impose a new information burden under PRA because this action only updates the state rules that are incorporated by reference into 40 CFR part 55.

c. Regulatory Flexibility Act (RFA)

I certify that this action does not have a significant impact on a substantial number of small entities under the RFA. This final rule does not impose any requirements or create impacts on small entities. This consistency update under CAA section 328 does not create any new requirements but simply updates the State requirements incorporated by reference into 40 CFR part 55 to match the current State requirements.

d. Unfunded Mandates Reform Act (UMRA)

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

² Each COA which has been delegated the authority to implement and enforce part 55, will

e. Executive Order 13132, Federalism

This action does not have federalism implications. It 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.

f. Executive Order 13175, Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), 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, nor does it impose substantial direct costs on tribal governments, nor preempt tribal law. It merely updates the State requirements incorporated by reference into 40 CFR part 55 to match current State requirements.

g. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 and simply updates the State requirements incorporated by reference into 40 CFR part 55 to match the current State requirements.

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

This final rule 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 rulemaking is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements is inconsistent with the Clean Air Act.

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

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health, or environmental effects, using practicable and legally permissible methods.

k. Congressional Review Act (CRA)

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

VI. Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 14, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* CAA section 307(b)(2).

List of Subjects in 40 CFR Part 55

Environmental protection, Administrative practice and procedures, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Nitrogen oxides, Outer Continental Shelf, Ozone, Particulate matter, Permits, Reporting and

recordkeeping requirements, Sulfur oxides.

Lisa Garcia,
Regional Administrator, Region 2.

For the reasons set out in the preamble, 40 CFR part 55, is amended as follows.

PART 55—OUTER CONTINENTAL SHELF AIR REGULATIONS

■ 1. The authority citation for part 55 continues to read as follows:

Authority: Section 328 of the Clean Air Act (42 U.S.C. 7401, *et seq.*) as amended by Pub. L. 101–549.

■ 2. Section 55.14 is amended by revising the paragraph (e)(16)(i)(A) to read as follows:

§ 55.14 Requirements that apply to OCS sources located within 25 miles of States’ seaward boundaries, by State.

* * * * *
(e) * * *
(16) * * *
(i) * * *

(A) State of New York Requirements Applicable to OCS Sources, March 10, 2022.

* * * * *

■ 3. Appendix A to 40 CFR part 55 is amended by revising the entry for “New York” to read as follows:

Appendix A to Part 55—Listing of State and Local Requirements Incorporated by Reference Into Part 55, by State

* * * * *

New York

(a) State requirements.
(1) The following State of New York requirements are applicable to OCS Sources, as of March 10, 2022. New York Environmental Conservation Law—Department of Environmental Conservation. The following sections of Title 6, Chapter III:

Subchapter A. Prevention and Control of Air Contamination and Air Pollution

- Part 200. General Provisions
- 6 NYCRR 200.1. Definitions (effective 4/2/2020)
- 6 NYCRR 200.3. False Statement (effective 6/16/1972)
- 6 NYCRR 200.4. Severability (effective 8/9/1984)
- 6 NYCRR 200.6. Acceptable Ambient Air Quality (effective 4/6/1983)
- 6 NYCRR 200.7. Maintenance of Equipment (effective 2/22/1979)
- 6 NYCRR 200.9. Referenced Material (effective 2/11/2021)
- Part 201. Permits and Certificates
- 6 NYCRR 201–1.1. Purpose and applicability (effective 2/22/2013)
- 6 NYCRR 201–1.4. Malfunctions and start-up/shutdown activities (effective 2/25/2021)

- 6 NYCRR 201–1.5. Emergency defense (effective 2/25/2021)
- 6 NYCRR 201–1.7. Recycling and salvage (effective 2/22/2013)
- 6 NYCRR 201–1.8. Prohibition of reintroduction of collected contaminants to the air (effective 2/22/2013)
- 6 NYCRR 201–1.11. Temporary emission sources (effective 2/25/2021)
- 6 NYCRR 201–1.12. Suspension, reopening, reissuance, modification, or revocation of air permits (effective 2/25/2021)
- 6 NYCRR 201–2. Definitions (effective 2/25/2021)
- 6 NYCRR 201–4. Minor Facility Registration (effective 2/25/2021)
- 6 NYCRR 201–5. State Facility Permits (effective 2/25/2021)
- 6 NYCRR 201–6. Title V Facility Permits (effective 2/25/2021)
- 6 NYCRR 201–7. Federally Enforceable Emission Caps (effective 2/25/2021)
- 6 NYCRR 201–8. General Permits (effective 2/22/2013)
- 6 NYCRR 201–9. Tables (effective 2/25/2021)
- Part 202. Emissions Verification
- 6 NYCRR 202–1. Emissions Testing, Sampling and Analytical Determinations (effective 9/30/2010)
- 6 NYCRR 202–2. Emission Statements (effective 12/3/2020)
- Part 207. Control Measures for an Air Pollution Episode (effective 2/22/1979)
- Part 211. General Prohibitions (effective 1/1/2011)
- Part 212. Process Operations (effective 6/13/2015)
- Part 215. Open Fires (effective 10/14/2009)
- Part 219. Incinerators
- 6 NYCRR 219–1. Incineration—General Provisions (effective 3/15/2020)
- 6 NYCRR 219–2. Municipal and Private Solid Waste Incineration Facilities (effective 5/21/2005)
- 6 NYCRR 219–10. Reasonably Available Control Technology (RACT) For Oxides of Nitrogen (NO_x) at Municipal and Private Solid Waste Incineration Units (effective 3/15/2020)
- Part 221. Asbestos-Containing Surface Coating Material (effective 9/29/1972)
- Part 222. Distributed Generation Sources (effective 3/26/2020)
- Part 225. Fuel Consumption and Use
- 6 NYCRR 225–1. Fuel Composition and Use—Sulfur Limitations (effective 2/4/2021)
- 6 NYCRR 225–2. Fuel Composition and Use—Waste Oil as a Fuel (effective 4/2/2020)
- 6 NYCRR 225–3. Fuel Composition and Use—Gasoline (effective 11/4/2001)
- 6 NYCRR 225–4. Motor Vehicle Diesel Fuel (effective 5/8/2005)
- Part 226. Solvent Metal Cleaning Processes and Industrial Cleaning Solvents (effective 11/1/2019)
- Part 227. Stationary Combustion Installations
- 6 NYCRR 227–1. Stationary Combustion Installations (effective 2/25/2000)
- 6 NYCRR 227–2. Reasonably Available Control Technology (RACT) for Major Facilities of Oxides of Nitrogen (NO_x) (effective 12/7/2019)
- 6 NYCRR 227–3. Ozone Season Oxides of Nitrogen (NO_x) Emission Limits for Simple Cycle and Regenerative Combustion Turbines (effective 1/16/2020)
- Part 228. Surface Coating Processes, Commercial and Industrial Adhesives, Sealants and Primers (effective 6/5/2013)
- Part 229. Petroleum and Volatile Organic Liquid Storage and Transfer (effective 4/4/1993)
- Part 230. Gasoline Dispensing Sites and Transport Vehicles (effective 2/11/2021)
- Part 231. New Source Review for New and Modified Facilities
- 6 NYCRR 231–3. General Provisions (effective 2/25/2021)
- 6 NYCRR 231–4. Definitions (effective 2/25/2021)
- 6 NYCRR 231–5. New Major Facilities and Modifications to Existing Non-Major Facilities in Nonattainment Areas, and Attainment Areas of the State Within the Ozone Transport Region (effective 2/25/2021)
- 6 NYCRR 231–6. Modifications to Existing Major Facilities in Nonattainment Areas and Attainment Areas of the State Within the Ozone Transport Region (effective 2/25/2021)
- 6 NYCRR 231–7. New Major Facilities and Modifications to Existing Non-Major Facilities in Attainment Areas (Prevention of Significant Deterioration) (effective 2/25/2021)
- 6 NYCRR 231–8. Modifications to Existing Major Facilities in Attainment Areas (Prevention of Significant Deterioration) (effective 2/25/2021)
- 6 NYCRR 231–9. Plantwide Applicability Limitation (PAL) (effective 2/25/2021)
- 6 NYCRR 231–10. Emission Reduction Credits (ERCs) (effective 2/25/2021)
- 6 NYCRR 231–11. Permit and Reasonable Possibility Requirements (effective 2/25/2021)
- 6 NYCRR 231–12. Ambient Air Quality Impact Analysis (effective 2/25/2021)
- 6 NYCRR 231–13. Tables and Emission Thresholds (effective 2/25/2021)
- Part 241. Asphalt Pavement and Asphalt Based Surface Coating (effective 1/1/2011)
- Part 242. CO₂ Budget Trading Program
- 6 NYCRR 242–1. CO₂ Budget Trading Program General Provisions (effective 12/31/2020)
- 6 NYCRR 242–2. CO₂ Authorized Account Representative for CO₂ Budget Sources (effective 12/31/2020)
- 6 NYCRR 242–3. Permits (effective 1/1/2014)
- 6 NYCRR 242–4. Compliance Certification (effective 1/1/2014)
- 6 NYCRR 242–5. CO₂ Allowance Allocations (effective 12/31/2020)
- 6 NYCRR 242–6. CO₂ Allowance Tracking System (effective 12/31/2020)
- 6 NYCRR 242–7. CO₂ Allowance Transfers (effective 1/1/2014)
- 6 NYCRR 242–8. Monitoring and Reporting (effective 12/31/2020)
- 6 NYCRR 242–10. CO₂ Emissions Offset Projects (effective 12/31/2020)
- Part 243. CSAPR NO_x Ozone Season Group 2 Trading Program (effective 1/2/2019)
- Part 244. CSAPR NO_x Annual Trading Program (effective 1/2/2019)
- Part 245. CSAPR SO₂ Group 1 Trading Program (effective 1/2/2019)
- Subchapter B. Air Quality Classifications and Standards**
- Part 256. Air Quality Classifications System (effective 5/1/1972)
- Part 257. Air Quality Standards
- 6 NYCRR 257–1. Air Quality Standards-General (effective 12/6/2019)
- 6 NYCRR 257–2. Air Quality Standards-Sulfur Dioxide (SO₂) (effective 3/18/1977)
- 6 NYCRR 257–3. Air Quality Standards-Particulates (effective 12/6/2019)
- 6 NYCRR 257–4. Ambient Air Quality Standards-Fluorides (effective 12/6/2019)
- 6 NYCRR 257–5. Ambient Air Quality Standards-Hydrogen Sulfide (H₂S) (effective 12/6/2019)
- Subchapter C. Air Quality Area Classifications**
- Part 287. Nassau County (effective 5/1/1972)
- Part 288. New York City (effective 5/1/1972)
- Part 307. Suffolk County (effective 5/1/1972)
- Part 315. Westchester County (effective 5/1/1972)
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- [FR Doc. 2022–19782 Filed 9–13–22; 8:45 am]
- BILLING CODE 6560–50–P**
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- ENVIRONMENTAL PROTECTION AGENCY**
- 40 CFR Part 180**
- [EPA–HQ–OPP–2020–0244; FRL–10167–01–OCSPP]**
- Hypochlorous Acid; Exemption From the Requirement of a Tolerance**
- AGENCY:** Environmental Protection Agency (EPA).
- ACTION:** Final rule.
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- SUMMARY:** The Environmental Protection Agency (EPA) is exempting residues of the antimicrobial pesticide ingredient hypochlorous acid from the requirement of a tolerance when used on or applied to food-contact surfaces in public eating places. The EPA is finalizing this rule on its own initiative under the Federal Food, Drug, and Cosmetic Act (FFDCA) to address residues identified as part of the EPA’s registration review program under the Federal Insecticide,