

(D) Negative test results do not exclude the possibility of exposure to, or infection with, *Mycobacterium tuberculosis*. A negative result must be considered with the individual's medical and historical data relevant to probability of *Mycobacterium tuberculosis* infection and potential risk of progression to tuberculosis disease, particularly for individuals with impaired immune function. Negative predictive values may be low for individuals suspected to have *Mycobacterium tuberculosis* disease.

(E) Positive results do not confirm the diagnosis of active tuberculosis disease.

(F) Assay results are qualitative and the magnitude of the measured assay numeric values cannot be correlated to stage or degree of infection, level of immune responsiveness, or likelihood for progression to active disease.

(G) Heterophilic antibodies, circulating interferon gamma, and other circulating factors may cause inaccurate results.

(H) Patient populations in which test performance characteristics have not been established, or patient populations where test performance may be affected.

(2) Design verification and validation must include the following:

(i) A detailed device description, including the computational path from collected raw data to reported result (e.g., how collected raw signals are converted into a reported result), and rationale used to select stimulation antigens.

(ii) Documentation and characterization of all critical reagents (e.g., determination of the identity, supplier, purity, and stability) and protocols for maintaining product integrity.

(iii) Final lot release criteria to be used for manufactured assay lots with appropriate evidence that lots released at the extremes of the specifications will meet the identified analytical and clinical performance characteristics as well as stability.

(iv) Risk analysis and documentation demonstrating how risk control measures are implemented to address device hazards, such as Failure Modes Effects Analysis and/or Hazard Analysis.

(v) Detailed documentation of analytical studies, including reproducibility, precision (including lot-to-lot precision studies, as appropriate), interference, cross reactivity, carryover, hook effect, sample and reagent stability, and other studies relevant to the technology and intended use (e.g., linearity), as applicable.

(vi) Detailed documentation of device performance data from a multisite

clinical study in geographically diverse areas with a design and performance that is appropriate for the intended use of the device. The study must be performed on populations consistent with the intended use population and compare the device performance to results obtained from a reference or comparator method that FDA has determined is appropriate. The clinical study must include testing of unique prospective (sequentially collected) samples and may, when determined to be acceptable by FDA, include additional characterized clinical samples. The clinical study must include a cohort of subjects with culture-confirmed or FDA-cleared or approved nucleic acid amplification test confirmed active tuberculosis infection, a cohort of subjects with no known risk factors for tuberculosis infection, and a mixed risk cohort of subjects with at least one known risk factor for tuberculosis and/or risk for latent tuberculosis infection. Enrolled subjects must include individuals who are immunosuppressed, individuals who have received the bacille Calmette-Guérin vaccine, or individuals with nontuberculous mycobacterial infections, as applicable. Documentation from the study must include a detailed study report that contains a study description, a summary of testing results, and results of all statistical analyses.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-06064 Filed 3-27-26; 8:45 am]

BILLING CODE 4164-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 716

[EPA-HQ-OPPT-2023-0360; FRL-13162-01-OCSPP]

RIN 2070-AL43

Reporting Deadline Extension for the Health and Safety Data Reporting Rule Under Toxic Substance Control Act (TSCA) Section 8(d)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency is proposing to extend the reporting deadline for the Health and Safety Data Reporting Rule under the Toxic Substance Control Act (TSCA) by one year to May 21, 2027. EPA is seeking public comment on this

proposed action, including any considerations or concerns that stakeholders may have regarding the proposed extension of the reporting deadline. The proposed extension is intended to delay compliance with this one-time reporting rule during EPA's ongoing reconsideration of the rule.

DATES: Comments must be received on or before April 29, 2026.

ADDRESSES: Submit your comments for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2023-0360, online at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional information on how to comment, along with instructions for visiting the docket in-person, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

Lameka Smith, Chemical Information, Prioritization, and Toxics Release Inventory Division (7406M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-1629; email address: smith.lameka@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill of the Finger Lakes, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (including import) any of the chemical substances listed in 40 CFR 716.120(d) of the regulatory text of this document. The following list of North American Industrial Classification System (NAICS) codes affected by this rule are those that align with these activities:

- Chemical manufacturers (including importers), (NAICS code 325); and
- Petroleum refineries (NAICS code 324110).

This action applies to manufacturers in these NAICS codes who are currently manufacturing (including importing) a listed chemical substance (or will do so during the chemical's reporting period) or who have manufactured (including imported) or proposed to manufacture (including import) a listed chemical substance within the last 10 years.

B. What action is the Agency taking?

EPA is proposing to extend the reporting deadline for the data submission period for the TSCA section 8(d) Health and Safety Data Reporting Rule.

C. What is the Agency's authority for taking this action?

The Health and Safety Data Reporting rule for the 16 chemical substances is promulgated under TSCA section 8(d) (15 U.S.C. 2607(d)) and codified at 40 CFR part 716. EPA's statutory authority to modify the deadline for the final TSCA section 8(d) rule is the same statutory authority relied upon to promulgate the underlying rule.

The statutory provision, along with administrative agencies' authority to reconsider prior regulations, provides EPA's authority for the targeted amendment to the compliance deadline finalized in this action. Unless provided otherwise by statute, an agency may change existing positions (e.g., reconsider, revise, or rescind prior rules) provided they acknowledge the change in position, offer a reasonable explanation for the change, and take any serious reliance interests into account. See, e.g., *FDA v. Wages & White Lion Invs., L.L.C.*, 145 S. Ct. 898, 917 (2025); *Encino Motorcars v. Navarro*, 579 U.S. 211, 221 (2016); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983).

D. Why is the Agency taking this action?

EPA promulgated a final rule on December 13, 2024 (89 FR 100756 (FRL-11164-02-OCSP)), to require manufacturers (including importers) of 16 specific chemical substances to submit copies and lists of certain unpublished health and safety studies to the EPA. The 16 chemical substances were added to 40 CFR 716.120 to support ongoing and upcoming activities under TSCA section 6. On March 13, 2025, EPA extended the submission deadlines from March 13, 2025, to June 11, 2025, for vinyl chloride (CASRN 75-01-4) and from March 13, 2025, to September 9, 2025, for the remaining 15 chemical substances. See (90 FR 11899 (FRL-11164.-02-OCSP)). On June 9, 2025, EPA amended the submission deadlines for all 16 chemical substances subject to the rule to May 22, 2026. EPA now recognizes a need to further extend these reporting deadlines as noted below.

EPA is considering a proposal to modify the scope of the TSCA section 8(d) Health and Safety Data Reporting

Rule. Such a rulemaking would make infeasible the current reporting deadline of May 22, 2026, (90 FR 24228 June 9, 2025 (FRL-11164.2-02-OCSP)). EPA is proposing to extend the reporting deadline by one year to May 21, 2027. Should EPA finalize modifications to the TSCA section 8(d) Health and Safety Data Reporting Rule, the Agency's final action on the rule would update the deadline, as appropriate.

EPA is taking this action because it has determined additional time is necessary to alleviate the compliance burdens associated with this one-time reporting rule while EPA considers potential modifications to the regulations, including aligning the rule with Executive Order 14219 "Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' Deregulatory Initiative" (90 FR 10583, February 19, 2025) and EPA's Powering the Great American Comeback Initiative Pillar I: Clean Air, Land, and Water for Every American. Rather than requiring businesses to prepare submissions under a rule that is in the process of being revised, this action provides regulatory certainty and prevents duplicative or potentially inconsistent reporting. Once the updated rule is finalized, reporting requirements and timelines will be clearly communicated to ensure a smooth and efficient compliance process. EPA is not reopening or reconsidering provisions of the underlying regulations other than the submission deadline in this rule.

II. Request for Comment

EPA invites comments on all aspects of this proposed action to extend the reporting deadline for the TSCA section 8(d) Health and Safety Data Reporting Rule. Specifically, EPA requests comment on the proposed reporting timeline and is soliciting comments on the nature and extent of any reliance interests that may have arisen from the rule.

III. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulations 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 under Executive Order 12866 (58 FR 51735,

October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Executive Order 14192: Unleashing Prosperity Through Deregulation

This action is an Executive Order 14192 deregulatory action. This proposed rule provides burden reduction by providing relief against existing compliance deadlines.

C. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA, 44 U.S.C. 3501 *et seq.* OMB has previously approved the information collection activity contained in the existing regulation and has assigned OMB control number 2070-0224 (EPA ICR No. 2703.02). This action does not create any new reporting or recordkeeping obligations and does not otherwise change the burden estimates that were approved.

D. 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, 5 U.S.C. 601 *et seq.* In making this determination, the 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 because the rule relieves regulatory burden on the small entities subject to the rule. This proposed action would extend compliance dates of one data reporting rule and alleviate compliance burden on small entities subject to those actions. We have therefore concluded that this action will relieve regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate of \$100 million (adjusted annually for inflation) or more (in 1995 dollars) 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.

F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because 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.

G. Executive Orders 13175: Consultation and 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 will not have substantial direct effects on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. This action does not impose substantial direct compliance costs on federally recognized Indian tribal governments. Thus, Executive Order 13175 does not apply to this action.

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

Although this action does not concern an environmental health or safety risk, the information obtained from the reporting required by this rule will be used to inform the Agency's decision-making process regarding chemical substances to which children may be exposed. This information will also assist the Agency and others in determining whether the chemical substances included in this proposed rule present potential risks, allowing the Agency and others to take appropriate

action to investigate and mitigate those risks.

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to regulatory actions considered significant under section 3(f)(1) of Executive Order 12866 and that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2–202 of Executive Order 13045.

Since this is not a "covered regulatory action," E.O. 13045 does not apply. However, the Policy on Children's Health does apply.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve technical standards under the NTTAA section 12(d), 15 U.S.C. 272.

List of Subjects in 40 CFR Part 716

Environmental protection, Chemicals, Hazardous substances, Health and

safety, Reporting and recordkeeping requirements.

Lee Zeldin,
Administrator.

Therefore, for the reasons stated in the preamble, EPA proposes to amend 40 CFR 716 as follows:

PART 716—HEALTH AND SAFETY DATA REPORTING

■ 1. The authority citation for part 716 continues to read as follows:

Authority: 15 U.S.C. 2607(d).

■ 2. Amend § 716.120 in table 3 to paragraph (d), under the heading "OPPT 2024 Chemicals", by revising the entries for "Acetaldehyde", "Acrylonitrile", "2-anilino-5-[(4-methylpentan-2-yl)amino]cyclohexa-2,5-diene-1,4-dione (6PPD-quinone)", "Benzenamine", "Benzene", "Bisphenol A", "Ethylbenzene", "Hydrogen fluoride", "4,4-Methylene bis(2-chloraniline)", "N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD)", "Naphthalene", "Styrene", "4-tert-octylphenol(4-(1,1,3,3-Tetramethylbutyl)-phenol)", "Tribromomethane (Bromofom)", "Triglycidyl isocyanurate"; and "Vinyl Chloride."

The revisions read as follows:

§ 716.120 Substances and listed mixtures to which this subpart applies.

* * * * *
(d) * * *

TABLE 3 TO PARAGRAPH (d)

Category	CASRN	Special exemptions	Effective date	Sunset date
* * * * *				
OPPT 2024 Chemicals				
Acetaldehyde	75–07–0	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	May 21, 2027.
Acrylonitrile	107–13–1	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	May 21, 2027.
2-anilino-5-[(4-methylpentan-2-yl) amino]cyclohexa-2,5-diene-1,4-dione (6PPD-quinone)	2754428–18–5	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	May 21, 2027.
Benzenamine	62–53–3	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply applies; § 716.20(a)(9) does not apply.	January 13, 2025	May 21, 2027.
Benzene	71–43–2	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	May 21, 2027.
Bisphenol A	80–05–7	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	May 21, 2027.
Ethylbenzene	100–41–4	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	May 21, 2027.
Hydrogen fluoride	7664–39–3	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	May 21, 2027.
4,4-Methylene bis(2-chloraniline)	101–14–4	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	May 21, 2027.
N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediamine (6PPD)	793–24–8	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	May 21, 2027.

TABLE 3 TO PARAGRAPH (d)—Continued

Category	CASRN	Special exemptions	Effective date	Sunset date
Naphthalene	91–20–3	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	May 21, 2027.
Styrene	100–42–5	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	May 21, 2027.
4-tert-octylphenol(4-(1,1,3,3-Tetramethylbutyl)-phenol).	140–66–9	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	May 21, 2027.
Tribromomethane (Bromoform)	75–25–2	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	May 21, 2027.
Triglycidyl isocyanurate	2451–62–9	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	May 21, 2027.
Vinyl chloride	75–01–4	§ 716.21(a)(11) applies; § 716.20(a)(9) does not apply.	January 13, 2025	May 21, 2027.
*	*	*	*	*

[FR Doc. 2026–06066 Filed 3–27–26; 8:45 am]
 BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 260325–0090; RTID 0648–XF172]

Fisheries of the Northeastern United States; Mid-Atlantic Blueline Tilefish and Golden Tilefish Fisheries; 2026 Specifications

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

ACTION: Proposed rule; request for comments.

SUMMARY: In this action, NMFS proposes specifications for the 2026 fishing year for the golden tilefish and blueline tilefish fisheries north of the North Carolina/Virginia border. The proposed action is necessary to establish allowable harvest levels and other management measures to prevent overfishing while allowing optimum yield, consistent with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) and the Tilefish Fishery Management Plan (FMP).

DATES: Comments must be received by April 14, 2026.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2026–0430, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to <https://www.regulations.gov> and enter NOAA–NMFS–2026–0430 in the Search

box. Click on the “Comment” icon, complete the required fields, and enter or attach your comments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on <https://www.regulations.gov> without change. All personal identifying information (e.g., name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter “N/A” in the required fields if you wish to remain anonymous).

Copies of the supporting documents for these proposed specifications are available from Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, 800 North State Street, Suite 201, Dover, DE 19901. These documents are also accessible via the internet at: <https://www.mafmc.org>.

FOR FURTHER INFORMATION CONTACT: Matthew Rigdon, matthew.rigdon@noaa.gov, 978–281–9336.

SUPPLEMENTARY INFORMATION:

Background

The golden tilefish and blueline tilefish fisheries north of the North Carolina/Virginia border are managed under the Tilefish FMP, which outlines the process for establishing annual specifications. The Tilefish FMP requires the Mid-Atlantic Fishery Management Council (Mid-Atlantic Council) to recommend acceptable biological catch (ABC), annual catch limit (ACL), annual catch target (ACT), total allowable landings (TAL), and other management measures for the commercial and recreational sectors of the fisheries. The Mid-Atlantic Council’s Scientific and Statistical

Committee (SSC) provides ABC recommendations for both species to the Council to derive these catch limits. The Mid-Atlantic Council makes recommendations to NMFS that may not exceed the SSC’s ABC recommendation. The Mid-Atlantic Council’s recommendations must include supporting documentation concerning the environmental, economic, and social impacts of the recommendations. NMFS reviews these recommendations, proposes them for public comment, and, if approved, publishes the final specifications in the **Federal Register**.

Proposed Specifications

Blueline Tilefish

Consistent with recommendations made by the Mid-Atlantic Council, this action proposes specifications for blueline tilefish for fishing year 2026 that would increase the commercial TAL by 426 percent and the recreational TAL by 350 percent. The increased catch limits are primarily due to updated data analyses of fishing effort but may represent some increased fishing opportunity for both the commercial and recreational fisheries. Mid-Atlantic recreational fisheries are valued at approximately \$439 million as of 2021. The blueline tilefish recreational fishery represents one component of this value, and the increased recreational TAL for fishing year 2026 could contribute additional value to Mid-Atlantic recreational fisheries. The blueline tilefish commercial fishery was valued at approximately \$67,000 in fishing year 2024 based on recent ex-vessel value data. This action would authorize approximately \$454,000 in commercial blueline tilefish value due to the increased commercial TAL for fishing year 2026.

The proposed specifications are consistent with recommendations of the