

paragraphs (a)(2), (a)(3), (b)(1), and (b)(2) of this section;

(2) A petitioner bears the burden of persuasion to show, by a preponderance of the evidence, that any proposed substitute claims are unpatentable; and

(3) Irrespective of paragraphs (d)(1) and (2) of this section, the Board may, in the interests of justice, exercise its discretion to grant or deny a motion to amend only for reasons supported by readily identifiable and persuasive evidence of record. In doing so, the Board may make of record only readily identifiable and persuasive evidence in a related proceeding before the Office or evidence that a district court can judicially notice. Where the Board exercises its discretion under this paragraph, the parties will have an opportunity to respond.

Andrei Iancu,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

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BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[EPA–HQ–OW–2015–0804; FRL–10017–97–OW]

RIN 2040–AG00

Withdrawal of Certain Federal Water Quality Criteria Applicable to Maine

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The United States Environmental Protection Agency (EPA or Agency) is taking final action to amend the Federal regulations to withdraw human health criteria (HHC) for toxic pollutants applicable to waters in the State of Maine. EPA is taking this action because Maine adopted, and EPA approved, HHC that the Agency determined are protective of the designated uses for these waters. This final rule amends the Federal regulations to withdraw certain HHC applicable to Maine that the Agency had promulgated, as described in the September 3, 2020 proposed rule. The withdrawal of these certain federally promulgated HHC will enable Maine to implement its EPA-approved HHC, submitted on April 24, 2020, and approved on June 23, 2020, as applicable criteria for Clean Water Act (CWA or the Act) purposes.

DATES: This final rule is effective December 21, 2020.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2015–0804. All documents in the docket are listed on the <http://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., CBI or other information for which 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 <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Jennifer Brundage, Office of Water, Standards and Health Protection Division (4305T), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 566–1265; email address: brundage.jennifer@epa.gov or visit <https://www.epa.gov/wqs-tech/federal-water-quality-standards-applicable-maine>.

SUPPLEMENTARY INFORMATION: This final rule is organized as follows:

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- H. Executive Order 13045 (Protection of Children From Environmental Health and Safety Risks)
- I. Executive Order 13211 (Actions That Significantly Affect Energy Supply, Distribution, or Use)
- J. National Technology Transfer and Advancement Act of 1995
- K. Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations)
- L. Congressional Review Act

I. General Information

A. Does this action apply to me?

The State of Maine, as well as entities that discharge pollutants to waters of the United States under the State of Maine’s jurisdiction, such as industrial facilities, stormwater and combined sewer overflow (CSO) management districts, or publicly owned treatment works (POTWs), may be interested in this final rule because it withdraws Federal water quality standards (WQS) promulgated by EPA to allow the State of Maine’s WQS to become the applicable WQS for CWA purposes. Entities discharging in Maine’s waters and citizens concerned with water quality in Maine, including members of the federally recognized Indian tribes, may be interested in this final rule. If you have questions regarding the applicability of this action to a particular entity, consult the person identified in the preceding **FOR FURTHER INFORMATION CONTACT** section.

II. Background

A. What are the applicable Federal statutory and regulatory requirements?

Consistent with the CWA, EPA’s WQS program assigns to states and authorized tribes the primary authority for adopting WQS.¹ After states adopt WQS, they must be submitted to EPA for review and action in accordance with the CWA. The Act authorizes EPA to promulgate Federal WQS following EPA’s disapproval of state WQS or an Administrator’s determination that new or revised WQS are “necessary to meet the requirements of the Act.”²

B. What are the applicable Federal water quality criteria that EPA is withdrawing?

On December 19, 2016, EPA promulgated Federal HHC for 96 toxic pollutants for waters in Indian lands in Maine based on the Agency’s 2015 disapproval of corresponding State-established HHC and an Administrator’s determination that new or revised WQS were necessary to meet the requirements of the Act. 81 FR 92466 (December 19, 2016). EPA also promulgated a phenol criterion to protect human health from consumption of water plus organisms for waters outside of Indian lands in Maine after disapproving the State’s phenol criterion in 2015 because it contained a mathematical error.

EPA’s 2015 disapproval of the State’s HHC for waters in Indian lands was based on its decision that they were inadequate to protect the sustenance

¹ 33 U.S.C. 1313(a), (c).

² 33 U.S.C. 1313(c)(4).

fishing designated uses that EPA interpreted and approved for waters in Indian lands in the same 2015 action. On May 27, 2020, after a thorough review of the applicable provisions of the CWA, implementing regulations and longstanding EPA guidance, EPA withdrew its 2015 interpretation and improper approvals of the alleged sustenance fishing designated uses and corresponding disapprovals of Maine's HHC that flowed from the flawed designated use determinations.³ Also on that date, EPA approved Maine's general fishing designated use for waters in Indian lands without the interpretation that it means "sustenance fishing."⁴

On April 24, 2020, the Maine Department of Environmental Protection submitted new and revised WQS in accordance with CWA Section 303(c). The new and revised provisions included HHC. On June 23, 2020, EPA approved the State's new and revised HHC as consistent with the requirements of the CWA and applicable Federal regulations.⁵ There are two sets of HHC in the State's newly approved criteria. One set protects the statewide general "fishing" designated use, and the other set protects the State's new "sustenance fishing" designated use subcategory that applies to specifically identified waters where sustenance fishing is or may be occurring. Between these two sets of HHC, all the waters covered by EPA's promulgated Federal HHC for toxic pollutants in 2016 are addressed. The new and revised HHC also address all the toxic pollutants for which EPA promulgated Federal HHC in 2016. All of EPA's prior decisions and action letters related to these Agency actions are available in docket ID EPA-HQ-OW-2015-0804 at <https://www.regulations.gov>.

As provided in 40 CFR 131.21(c), federally promulgated WQS that are more stringent than EPA-approved state WQS remain applicable for purposes of the CWA until EPA withdraws the Federal WQS. EPA's 2016 federally

promulgated HHC are as stringent or more stringent than the State's newly approved HHC. Accordingly, EPA is amending the Federal regulations to withdraw those federally promulgated HHC for which the Agency has approved Maine's corresponding HHC.

EPA's withdrawal of federally promulgated HHC following approval of corresponding state HHC is consistent with the Federal and state roles contemplated by the CWA. Consistent with the cooperative federalism structure of the CWA, once EPA approves state WQS addressing the same pollutants for which EPA has promulgated Federal WQS, it is incumbent on EPA to withdraw the Federal WQS to enable EPA-approved state WQS to become the applicable WQS for CWA purposes. This final rule will allow Maine to implement its EPA-approved WQS. This final rule is consistent with EPA's withdrawal of other federally promulgated WQS following the Agency's approval of state-adopted WQS.⁶

This final rule amends Federal regulations to withdraw all Federal HHC for waters in Indian lands and the phenol criterion for waters outside of Indian lands promulgated for Maine in December 2016 at 40 CFR 131.43. All other federally promulgated criteria at 40 CFR 131.43 remain in effect.

EPA did not make any changes in response to the comments received on the proposed rulemaking. EPA received eight unique comments on the proposed rulemaking. EPA also held two public, online hearings on the proposed rulemaking (September 30, 2020, and October 1, 2020). EPA received no comments during these hearings. Brief summaries of the comments and EPA's responses are provided in the next section. As noted previously, a full accounting of the comments and the Agency's responses can be found in the docket for this rulemaking.

C. Comments on the Proposed Rulemaking

i. Comments in Support of EPA's Proposal To Withdraw the Federal HHC

EPA received several comments in support of the proposal to withdraw the Federal HHC. EPA appreciates the comments in support of this action.

⁶ See e.g., *Withdrawal of Certain Federal Water Quality Criteria Applicable to California: Lead, Chlorodibromomethane, and Dichlorobromomethane*, 83 FR 52163 (October 16, 2018); *Water Quality Standards for the State of Florida's Lakes and Flowing Waters; Withdrawal*, 79 FR 57447 (September 25, 2014); *Withdrawal of Certain Federal Water Quality Criteria Applicable to California, New Jersey and Puerto Rico*, 78 FR 20252 (April 4, 2013).

Several of these commenters also urged EPA to withdraw other federally promulgated WQS, specifically relating to mixing zones and aquatic life criteria for certain waters, which are not related to the HHC for toxic pollutants that are the subject of this rulemaking. EPA's proposal solicited comments only on withdrawing the Federal HHC for toxic pollutants and these comments are outside the scope of this proceeding.

ii. Comments in Opposition to EPA's Proposal To Withdraw the Federal HHC

EPA received two comments in opposition to EPA's proposal to withdraw the Federal HHC. Both comments object to the proposal based on the stringency, scope, and enforceability of the HHC that would remain in place after the withdrawal, i.e., the State of Maine's federally approved HHC. The protectiveness of the State's federally approved HHC, however, is outside the scope of this rulemaking. EPA's June 23, 2020, approval of the State's HHC was a separate, final agency action. EPA's rationale for this approval is provided in detail in the attachment to the approval letter. More information on EPA's action to approve Maine's HHC can be accessed at https://www.epa.gov/sites/production/files/2020-06/documents/hhc_approval_decision_final.pdf.

Given that EPA approved state HHC that correspond to the federally approved HHC, the Agency is thus withdrawing its Federal criteria so that the state criteria are the applicable WQS for CWA purposes. See 40 CFR 131.21(c).

D. Effective Date of Withdrawal

Section 553(d)(3) of the Administrative Procedure Act (APA), 5 U.S.C. 553(d), provides that final rules shall not become effective until 30 days after publication in the **Federal Register** "except . . . as otherwise provided by the agency for good cause." The purpose of this provision is to "give affected parties a reasonable time to adjust their behavior before the final rule takes effect." *Omnipoint Corp. v. Fed. Comm'n Comm'n*, 78 F.3d 620, 630 (D.C. Cir. 1996); see also *United States v. Gavrilovic*, 551 F.2d 1099, 1104 (8th Cir. 1977) (quoting legislative history). Thus, in determining whether good cause exists to waive the 30-day delay, an agency should "balance the necessity for immediate implementation against principles of fundamental fairness which require that all affected persons be afforded a reasonable amount of time to prepare for the effective date of its ruling." *Gavrilovic*, 551 F.2d at 1105. In this case, EPA has determined that there

³ Letter from Dennis Deziel, Regional Administrator, EPA Region 1, to Gerald D. Reid, Commissioner, Maine Department of Environmental Protection, "Re: Withdrawal of Certain of EPA's February 2, 2015 Decisions Concerning Water Quality Standards for Waters in Indian Lands" (May 27, 2020).

⁴ In 2019, Maine adopted, and EPA approved, a sustenance fishing designated use (SFDU) subcategory of its general fishing designated use for certain identified waters where sustenance fishing or increased fish consumption is or may be occurring.

⁵ Letter from Ken Moraff, Water Division Director, EPA Region 1, to Gerald D. Reid, Commissioner, Maine Department of Environmental Protection, "Re: Review and Action on Maine Water Quality Standards, 06-096 Chapter 584" (June 23, 2020).

is good cause for waiving the 30-day delayed effective date because the final rule does not impose any new requirement on any affected entity, rather it withdraws Federal WQS applicable to waters in the State of Maine, thus allowing Maine's WQS to take effect for CWA purposes. Because by itself this final rule does not impose new requirements on affected entities, it is not necessary to provide affected entities time to adjust to this final rule. Having this withdrawal take effect upon publication in the **Federal Register** will help provide immediate clarity for the State of Maine as it proceeds with creating its latest list of impaired of waters under CWA Section 303(d), as well as in issuing NPDES permits, developing TMDLs, and issuing water quality certifications under CWA Section 401. For these reasons, the Agency finds that good cause exists under APA Section 553(d)(3) to make this rule withdrawing Federal WQS in Maine effective immediately upon publication.

III. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

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. Executive Order 13771 (Reducing Regulations and Controlling Regulatory Costs)

This action is a deregulatory action under Executive Order 13771.

C. Paperwork Reduction Act

This action does not impose any new information-collection burden under the Paperwork Reduction Act because it is administratively withdrawing Federal requirements that are no longer needed in Maine. It does not include any information collection, reporting, or recordkeeping requirements. The OMB has previously approved the information collection requirements contained in the existing regulations 40 CFR part 131 and has assigned OMB control number 2040-0049.

D. Regulatory Flexibility Act

The Agency certifies that this action will not have a significant economic impact on a substantial number of small

entities under the Regulatory Flexibility Act. This action will not impose any requirements on small entities.

E. Unfunded Mandates Reform Act

This action does not contain Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. As this action withdraws certain federally promulgated criteria, 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. 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. This rule imposes no regulatory requirements or costs on any state or local governments. Thus, Executive Order 13132 does not apply to this action.

G. Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)

This action has tribal implications. However, it will neither impose substantial direct compliance costs on federally recognized tribal governments, nor preempt tribal law. In the State of Maine, there are four federally recognized Indian tribes represented by five tribal governments. As a result of the unique jurisdictional provisions of the Maine Indian Claims Settlement Act, the State has jurisdiction for setting WQS for all waters in Indian lands in Maine. This rule will have no effect on that jurisdictional arrangement. This final rule affects federally recognized Indian tribes in Maine because it changes the WQS applicable to all waters in Indian lands.

EPA initiated consultation with federally recognized tribal officials under EPA's Policy on Consultation and Coordination with Indian tribes early in the process of developing this rule to allow meaningful and timely input into its development. A summary of that consultation is provided in "Summary of Tribal Consultations Regarding Water Quality Standards Decisions on Remand Applicable to Waters in Indian Lands within Maine," which is available in the docket for this rulemaking.

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

EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the Agency 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 does not concern an environmental health risk or safety risk that may disproportionately affect children.

I. Executive Order 13211 (Actions That Significantly Affect Energy Supply, Distribution, or Use)

This action is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution or use of energy.

J. National Technology Transfer and Advancement Act of 1995

This final rule does not involve technical standards.

K. Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations)

The human health or environmental risk addressed by this action will not have disproportionately high and adverse human health or environmental effects on minority, low income or indigenous populations. EPA has previously determined that Maine's state-adopted and EPA-approved criteria are protective of human health.

L. Congressional Review Act

This action is subject to the Congressional Review Act 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).

List of Subjects in 40 CFR Part 131

Environmental protection, Indians-lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water pollution control.

Andrew Wheeler,
Administrator.

For the reasons set forth in the preamble, EPA amends 40 CFR part 131 as follows:

PART 131—WATER QUALITY STANDARDS

■ 1. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq.*

Subpart D—Federally Promulgated Water Quality Standards

§ 131.43 [Amended]

■ 2. Amend § 131.43 by removing paragraphs (a) and (j) and redesignating paragraphs (b) through (i) as paragraphs (a) through (h).

[FR Doc. 2020–26998 Filed 12–18–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0233; FRL–10017–30]

2,4-D; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of 2,4-D in or on intermediate wheatgrass bran, forage, grain, and straw and sesame seed. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 21, 2020. Objections and requests for hearings must be received on or before February 19, 2021, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2019–0233, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited

exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: RDPRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2019–0233 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 19, 2021. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2019–0233, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- **Mail:** OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of September 30, 2020 (85 FR 61681) (FRL–10014–74), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (an amended PP 9E8745 and PP 0E8848) by IR–4, IR–4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. This September 30, 2020 Notice supersedes the previous document the Agency published notifying the public of the filing of the IR–4 petition PP9E8745 in the **Federal Register** of August 30, 2019 (84 FR 45702) (FRL–9998–15).

The petitions requested that 40 CFR part 180 be amended by establishing tolerances for residues of 2,4-D in or on the raw agricultural commodities wheatgrass, intermediate, bran at 4 parts per million (ppm); wheatgrass, intermediate, grain at 2 ppm; wheatgrass, intermediate, straw at 50 ppm, and wheatgrass, intermediate, forage at 25 ppm (PP 9E8745) and sesame, seed at 0.05 ppm (PP 0E8848). That document referenced summaries of the petitions prepared by Nufarm and PBI Gordon, the registrants, which are