6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[EPA-HQ-OW-2016-0694; FRL-10019-00-OW]

RIN 2040-AF70

Federal Aluminum Aquatic Life Criteria Applicable to Oregon

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is promulgating federal criteria for fresh waters in the State of Oregon that are jurisdictional under the Clean Water Act (CWA) to protect aquatic life from the effects of exposure to harmful levels of aluminum. EPA disapproved of Oregon's freshwater acute and chronic aluminum criteria in 2013. The CWA directs EPA to promptly propose water quality standards (WQS) addressing the Agency's disapproval and to promulgate those WQS unless, prior to such promulgation, the state adopts WQS addressing EPA's disapproval that the Agency determines meet the requirements of the

CWA and EPA approves. Since Oregon has not adopted and submitted revised freshwater acute and chronic aluminum criteria to address EPA's 2013 disapproval, EPA is promulgating federal freshwater acute and chronic aluminum criteria to protect aquatic life uses in Oregon as the applicable WQS under the CWA. If, at some point in the future, Oregon submits and EPA approves revised freshwater acute and chronic aluminum criteria to address EPA's 2013 disapproval, EPA would withdraw this regulation.

DATES: This rule is effective on **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: EPA has established a docket for this action under Docket ID No. **EPA-HQ-OW-2016-0694**. All documents in the docket are listed on the *http://www.regulations.gov* web site. Although listed in the index, some information is not publicly available, *e.g.*, confidential business information (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 *http://www.regulations.gov*.

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SUPPLEMENTARY INFORMATION: This final rule is organized as follows:

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

I. General Information

A. Does This Action Apply to Me?

Entities such as industrial facilities, stormwater management districts, or publicly owned treatment works (POTWs) that discharge pollutants to fresh waters of the United States under the State of Oregon's jurisdiction could be affected by this rule because federal WQS promulgated by EPA in this rule will be the applicable WQS for fresh waters in Oregon for CWA purposes after the effective date of this rule. These WQS are the minimum standards which must be used in such CWA regulatory programs as National Pollutant Discharge Elimination System

(NPDES) permitting[1] and identifying impaired waters under CWA Section 303(d). Categories and entities that could potentially be affected by this rule include the following:

Category	Examples of potentially affected entities
Industry	Industrial point sources discharging pollutants to fresh waters of the United States in Oregon.
Municipalities	Publicly owned treatment works or similar facilities discharging pollutants to fresh waters of the United States in Oregon.
Stormwater Management Districts	Entities responsible for managing stormwater in the State of Oregon.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities that could ultimately be affected by this action. Any parties or entities who depend upon or contribute to the water quality of Oregon's fresh waters could be affected by this rule. To determine whether your facility or activities could be affected by this action, you should carefully examine this rule. 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.

B. How Did EPA Develop this Final Rule?

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[1] Before any water quality based effluent limit is included in an NPDES permit, the permitting authority (here, the State of Oregon), will first determine whether a discharge "will cause or has the reasonable potential to cause, or contribute to an excursion above any WQS." 40 CFR 122.44 (d)(1)(i) and (ii).

EPA carefully considered the public comments and feedback received from interested parties on the proposal published in the Federal Register at 84 FR 18454 on May 1, 2019. EPA provided a 45-day public comment period and held two public hearings on June 11 and June 12, 2019, to provide clarification on the contents of the proposed rulemaking and to accept verbal public comments.

A total of eight organizations and individuals submitted comments either to the docket or during the public hearings on a range of issues prior to the close of the public comment period on June 17, 2019. Some comments addressed issues beyond the scope of this rule. Brief summaries of specific comments and EPA's responses are provided in this action. For a full accounting of the comments and the Agency's responses, see EPA's Response to Comments document in the official public docket for this rule.

II. Background

A. Statutory and Regulatory Authority

CWA Section 303(c) (33 U.S.C. 1313(c)) directs states to adopt WQS for state waters subject to CWA jurisdiction. CWA Section 303(c)(2)(A) provides that WQS shall consist of designated uses of the waters and water quality criteria based on those uses. EPA's implementing regulations at 40 CFR 131.11(a)(1) provide that "[s]uch criteria must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use [and] [f]or waters with multiple use designations, the criteria shall support the most sensitive use.” In addition, 40 CFR 131.10(b) provides that “[i]n designating uses of a water body and the appropriate criteria for those uses, the [s]tate shall take into consideration the water quality standards of downstream waters and shall ensure that its water quality standards provide for the attainment and maintenance of the water quality standards of downstream waters.”

States review applicable WQS at least once every three years and, if appropriate, revise or adopt new WQS (CWA Section 303(c)(1); 40 CFR 131.20). Any new or revised WQS must be submitted to EPA for review and approval or disapproval (CWA Sections 303(c)(2)(A) and (c)(3); 40 CFR 131.20 and 131.21). If EPA disapproves a state’s new or revised WQS as not consistent with CWA requirements, the state has 90 days to adopt a revised WQS that adopts the changes specified by EPA to meet CWA requirements. If the state fails to do so, EPA must promptly propose and then, within 90 days, promulgate such WQS unless the state has adopted a revised or new WQS that EPA determines to be consistent with CWA requirements (CWA Sections 303(c)(3) and (c)(4)).

Under CWA Section 304(a), EPA periodically publishes national criteria recommendations for states to consider when adopting water quality criteria for particular pollutants to meet the CWA Section 101(a)(2) goal. When EPA has published recommended criteria, states should establish numeric water quality criteria based on the Agency's CWA Section 304(a) recommended criteria, CWA Section 304(a) recommended criteria modified to reflect site-specific conditions, or other scientifically defensible methods (40 CFR 131.11(b)(1)). Water quality criteria must protect the designated use and be based on sound scientific rationale. For waters with multiple use designations, the criteria shall support the most sensitive use (40 CFR 131.11(a)(1)).

B. EPA's Disapproval of Oregon's Freshwater Aluminum Criteria

As explained in the preamble of the proposed rulemaking, EPA disapproved the State's freshwater aluminum criteria in 2013 because the State had not supplied a scientific rationale for the pH range under which the State's criteria would apply, which differed from the applicable pH range specified in EPA's 1998 national CWA Section 304(a) recommended criteria for aluminum (84 FR 18456-57, May 1, 2019) that existed at that time but have since been updated.

Under the terms of a consent decree (as amended) to resolve litigation in *Northwest Environmental Advocates v. U.S. EPA*, 3:15-cv-00663-BR (D. Or. 2015), EPA is required, no later than six months after the date on which the National Marine Fisheries Service (also known as National Oceanic and Atmospheric Administration (NOAA) Fisheries) issues its Biological Opinion on the aluminum criteria previously proposed by EPA, to either approve aluminum criteria to protect aquatic life in fresh waters submitted by Oregon or sign a notice for publication in the Federal Register to finalize the aluminum criteria EPA proposed for Oregon. NOAA Fisheries transmitted its Biological Opinion to EPA on July 1, 2020. Since Oregon has not yet adopted freshwater aluminum criteria to meet CWA requirements, EPA is promulgating freshwater aluminum criteria for Oregon waters in accordance with CWA Sections 303(c)(3) and (c)(4).

C. General Recommended Approach for Deriving Aquatic Life Criteria

Under the Agency's CWA Section 304(a) authority, EPA develops national recommended criteria and methodologies to protect aquatic life and human health for specific pollutants and pollutant parameters. EPA invites public comment on draft recommended criteria and methodologies and seeks scientific expert review before EPA finalizes them as formal national water quality criteria recommendations for states to consider when developing and adopting applicable water quality criteria. EPA's *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses* (referred to as the "Aquatic Life Guidelines")[2] describe the systematic way in which EPA establishes concentrations for a pollutant in water that will support the aquatic life designated use.

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[2] USEPA. 1985. *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses*. U.S. Environmental Protection Agency, Office of Research and Development, Duluth,

Numeric criteria derived using EPA's Aquatic Life Guidelines are expressed as acute and chronic values representing short-term and long-term exposures, respectively. The combination of a criterion maximum concentration (CMC), typically expressed as a one-hour average value, and a criterion continuous concentration (CCC), typically specified as a four-day average value, protects aquatic life from acute and chronic toxicity, respectively. Neither value is to be exceeded more than once in three years. An exceedance occurs when the average concentration over the duration of the averaging period is above the CMC or the CCC. EPA based its maximum exceedance frequency recommendation of once every three years on the ability of aquatic ecosystems to recover from the exceedances.

The Aquatic Life Guidelines recommend reliance on toxicity test data from a minimum of eight taxa of aquatic organisms in order to derive criteria. These taxa are intended to be representative of a wide spectrum of aquatic life, such that the representative taxa serve as surrogates for untested species. Therefore, the representative test organism species do not need to be present in the water(s) where the criteria will apply. A state is not precluded from relying on toxicity data using resident species to develop site-specific criteria to apply at a localized site. In developing site-specific criteria, EPA recommends that the state maintain similar broad

MN, Narragansett, RI, Corvallis, OR. PB85-227049. https://www.epa.gov/sites/production/files/2016-02/documents/guidelines-water-quality-criteria.pdf taxonomic representation in calculating the site-specific criteria to ensure protection of the most sensitive species at the site. If a state chooses to carry out the "deletion of data" portion of the species re-calculation process, the state should consider how to demonstrate that the species included in the derivation of EPA's national recommended criteria are not present and would not serve as surrogates for other species that occur at the site.[3]

III. Freshwater Aluminum Aquatic Life Criteria

A. EPA's National CWA Section 304(a) Recommended Freshwater Aluminum Criteria

EPA's 2018 national CWA Section 304(a) recommended freshwater aquatic life criteria for aluminum (Final Aquatic Life Ambient Water Quality Criteria for Aluminum 2018, EPA 822-R-18-001, as cited in the Federal Register at 83 FR 65663, December 21, 2018), referred to in this action as the "2018 national recommended criteria," were developed following the Aquatic Life Guidelines. These recommended criteria update and replace EPA's 1988 national CWA Section 304(a) recommended freshwater aquatic life criteria for aluminum. The 2018 national recommended criteria apply to fresh waters and include a calculator that takes into account three water chemistry characteristics that affect aluminum toxicity. The 2018 national

[3] USEPA. 2013. *Revised Deletion Process for the Site-Specific Recalculation Procedure for Aquatic Life Criteria*. U.S. Environmental Protection Agency, Office of Water, Washington, DC. EPA-823-R-13-001. https://www.epa.gov/sites/production/files/2015-08/documents/revised_deletion_process_for_the_site-specific_recalculation_procedure_for_aquatic_life_criteria.pdf.

recommended criteria reflect the latest scientific knowledge and understanding of the interaction between water chemistry and aluminum toxicity, and represent a scientifically defensible method upon which EPA is basing this CWA action to establish WQS for fresh waters in Oregon (83 FR 65663, December 21, 2018).

The 2018 national recommended criteria are based upon Multiple Linear Regression (MLR) models for fish and invertebrate species that use site-specific pH, dissolved organic carbon (DOC), and total hardness inputs to quantify the effects of these water chemistry parameters on the toxicity of aluminum to aquatic organisms. The MLR models normalize the available toxicity data to accurately reflect the effects of the site-specific water chemistry (pH, DOC, total hardness) on the toxicity of aluminum to tested species. The normalized toxicity test data are then used in a criteria calculator to generate criteria for specific ambient water chemistry conditions. The numeric outputs of the 2018 national recommended criteria calculator for a given set of conditions vary depending on the site-specific pH, DOC, and total hardness entered into the calculator. The calculator outputs (CMC and CCC) for a given set of input conditions are numeric values that would be protective for that set of input conditions (i.e., water-chemistry-condition-specific CMC and CCC outputs).

Users of the 2018 national recommended criteria can generate criteria magnitude values in two ways: 1) use the lookup tables provided in the criteria document to find the numeric aluminum CMC and CCC most closely corresponding to the local conditions for pH, DOC, and total hardness; or 2) use the provided Aluminum Criteria Calculator V2.0 Excel spreadsheet to enter the pH, DOC, and total hardness conditions at a specific site to calculate the numeric aluminum CMC and CCC corresponding to the local input conditions.

In its 2018 national recommended criteria, EPA expressed the aluminum criteria as "total recoverable" metal concentrations. The primary reason for the expression of the criteria as total recoverable aluminum concentrations is because the laboratory toxicity tests used in the effects assessment in the development of the aluminum criteria reported the aluminum concentrations as total recoverable aluminum. The use of total aluminum concentrations is justified for laboratory toxicity test data where the total aluminum concentration is in either a dissolved monomeric form or precipitated forms (e.g., aluminum hydroxides) of aluminum. The laboratory dilution waters in tests used for EPA's criteria development did not contain suspended solids, clays, or particulate matter where aluminum could be bound. However, total recoverable aluminum concentrations measured in natural waters may overestimate the potential risks of toxicity to aquatic organisms if suspended solids, clays, or particulate matter to which aluminum may be bound are present, because total recoverable methods measure bioavailable and non-bioavailable forms of aluminum.

As discussed in Section 2.6.2 of EPA's 2018 national recommended criteria document, the different forms of aluminum vary in toxicity. The criteria document discusses differences between aluminum toxicity in a controlled laboratory setting and the toxicity of aluminum in natural waters that contain suspended particles, clays, and aluminosilicate minerals not present in lab waters. Dissolved and particulate (e.g., aluminum hydroxides) aluminum, as well as small sized colloids containing aluminum, exhibit toxic effects on aquatic life depending on the pH, DOC, and total hardness of the waters. Total recoverable aluminum methods determine the total concentration of monomeric (both organic and inorganic) forms of aluminum, polymeric and colloidal forms, as well as particulate forms and aluminum sorbed to clays present in a sample. Total recoverable methods use a strong acid (pH <2) digestion step to prepare the sample for measurement. In contrast, methods to determine dissolved concentrations of aluminum involve filtering test samples prior to digestion, which excludes particulate forms of aluminum from the test sample. Methods to determine dissolved concentrations of aluminum, therefore, may underestimate the toxicity of the aluminum in a sample if the particulate forms including aluminum hydroxide precipitates that contribute to toxicity are not measured. In conclusion, dissolved aluminum measurements are not appropriate for comparison to the aluminum criteria that EPA is promulgating for Oregon. EPA acknowledges, as several commenters noted during the comment periods for both EPA's 2017 draft national CWA Section 304(a) recommended criteria for aluminum and EPA's proposed criteria for Oregon, that not all forms of aluminum that may be present in ambient waters are biologically available or "bioavailable" to aquatic species. Bioavailable aluminum (or the bioavailable fraction of aluminum) is defined as the amount of aluminum that is available to cause a biological response in an aquatic organism. The best measures of bioavailability involve interactions of aluminum with a membrane (e.g., aluminum binding to proteins of gill membranes), diffusion through the cell membrane, and flocculation of precipitated aluminum on the gill. Bioavailable aluminum is the toxicologically relevant fraction of aluminum which results from a combination of dissolved and precipitated aluminum, in contrast to mineralized (non-toxic) forms of aluminum.[4] The non-bioavailable fraction of aluminum includes large suspended particles, clays, and aluminosilicate minerals.

EPA's 2018 national recommended criteria document (Section 2.6.2 from pp. 22-25) explains the science behind this understanding of aluminum chemistry and toxicity in more detail. There is also relevant discussion of aluminum chemistry (Section 2.2 from pp. 7-10) and

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[4] Per Rodriguez et al. 2019: "To properly characterize the Al concentrations in the toxicity studies, a method was needed that could discriminate bioavailable Al from mineral forms of Al. An extraction method at pH 4 for bioavailable Al was developed and evaluated using *C. dubia* chronic toxicity studies in the presence of TSS. It is concluded that the proposed method is better able to discriminate chronic toxicity effects attributable to bioavailable Al from mineralized nontoxic forms of Al compared with existing methods using total or total recoverable Al (i.e., extraction at pH $\leq$ 1.5)."

mode of action and toxicity (Section 2.3 from pp. 10-16) that help explain the factors affecting bioavailability and toxicity.

B. Final Acute and Chronic Aluminum Criteria for Oregon's Fresh Waters

EPA is promulgating aluminum criteria for Oregon that incorporate by reference the calculation of CMC and CCC freshwater aluminum criteria values for a site using the 2018 national recommended criteria.[5] Doing so means that the CMC and CCC freshwater aluminum criteria values for a site shall be calculated using the 2018 Aluminum Criteria Calculator V.2.0 (*Aluminum Criteria Calculator V.2.0.xlsx*) or a calculator in R or other software package using the same 1985 Guidelines calculation procedure and underlying model equations as in the Aluminum Criteria Calculator V.2.0 Excel spreadsheet, as established in the 2018 national recommended criteria. Consistent with the 2018 national recommended criteria, the final water quality criteria for aluminum in Oregon fresh waters are expressed as the CMC as a one-hour average total recoverable aluminum concentration (in µg/L) and the CCC as a four-day average

[5] USEPA. 2018. *Final Aquatic Life Ambient Water Quality Criteria for Aluminum.* U.S. Environmental Protection Agency, Office of Water, Washington, DC. EPA-822-R-18-001. https://www.epa.gov/sites/production/files/2018-12/documents/aluminum-final-national-recommended-awqc.pdf.

total recoverable aluminum concentration (in µg/L). The CMC and CCC are not to be exceeded more than once every three years.

EPA is promulgating multiple footnotes to the criteria statement to provide clarification on the criteria's intended application, and highlights two in this paragraph. The first footnote specifies that to apply the aluminum criteria for CWA purposes, criteria values based on ambient water chemistry conditions must protect the water body over the full range of water chemistry conditions, including during conditions when aluminum is most toxic. The second footnote states that (1) these criteria are based on aluminum toxicity studies where aluminum was analyzed using total recoverable analytical methods; (2) Oregon may utilize total recoverable analytical methods to implement the criteria; (3) for characterizing ambient waters, Oregon may also utilize, as scientifically appropriate and as allowable by State and federal regulations, analytical methods that measure the bioavailable fraction of aluminum, as described above, (e.g., utilizing a less aggressive initial acid digestion, such as to a pH of approximately 4 or lower, that includes the measurement of amorphous aluminum hydroxide yet minimizes the measurement of mineralized forms of aluminum such as aluminum silicates associated with suspended sediment particles or clays); and (4) Oregon shall use measurements of total recoverable aluminum where required by federal regulations.

Commenters were generally supportive of EPA's proposal to base its promulgation for Oregon on EPA's 2018 national recommended criteria for aluminum. EPA acknowledged in the preamble to the proposal that the Agency may consider future modifications to the criteria if warranted based on, among other things, further public input, tribal consultation, new data, or evaluations of listed species completed during Endangered Species Act (ESA) consultation, or the results of ESA consultation. On February 13, 2020 and July 1, 2020, EPA completed consultation with the U.S. Fish and Wildlife Service (USFWS) and NOAA Fisheries, respectively. After evaluating potential effects of the Agency's action on federally-listed species during ESA Section 7(a)(2) consultation with USFWS and NOAA Fisheries, in addition to consideration of comments received during the public comment period associated with the proposed rulemaking, EPA is promulgating aluminum criteria consistent with the 2018 national recommended criteria.

The 2018 national recommended criteria represent the latest scientific knowledge on aluminum speciation, bioavailability, and toxicity, and provide predictable and repeatable outcomes. Consistent with the Aquatic Life Guidelines, the 2018 national recommended criteria protect aquatic life for acute effects (survival and immobility), as well as chronic effects (survival, growth, and reproduction) at a level of 20% chronic Effects Concentration (EC20) for the 95th percentile of sensitive genera. The docket for the 2018 national recommended criteria document contains detailed information on the science underlying that recommendation (Docket ID: EPA-HQ-OW-2017-0260).

Comments regarding total recoverable aluminum and use of an emerging analytical method

As mentioned above, commenters pointed out that, as EPA had acknowledged in its 2018 national recommended criteria document, the current test methods for total recoverable aluminum may, in some waters, overestimate the amount of aluminum that will be toxic to aquatic life in ambient waters in Oregon. Commenters suggested that in order to better approximate the toxic fraction of aluminum, EPA should allow use of an emerging analytical method that measures bioavailable aluminum by using an initial digestion at pH 4. Commenters urged use of such an analytical method to characterize aluminum concentrations in ambient waters, particularly in waters with high levels of total suspended solids suggesting the presence of colloidal, particulate, and clay-bound aluminum. Some commenters requested that the final criteria for Oregon be expressed as “bioavailable or total recoverable” aluminum to confirm availability for use of an alternative analytical method.

EPA acknowledges in the final rule that the promulgated criteria are based on aluminum toxicity laboratory studies where aluminum was analyzed using total recoverable analytical methods. However, EPA also acknowledges that under natural conditions not all of these forms of aluminum would be biologically available to aquatic species. All of the approved total recoverable methods require that samples be preserved in the field by acidifying to pH<2 and digested in the laboratory with strong acid solution that dissolves the monomeric and polymeric forms of aluminum, in addition to colloidal, particulate, and clay-bound aluminum. Over the last three decades, the scientific consensus has been that the total recoverable method for aluminum potentially overestimates the biologically available fraction and that a method that better addresses concerns with including aluminum bound to particulate matter would be useful (e.g., He and Ziemkiewics 2016; Ryan *et al*. 2019).[6]

In an attempt to address concerns with measuring total recoverable aluminum concentrations, researchers recently investigated new analytical methods to measure biologically available forms of aluminum (Rodriguez *et al.* 2019).[7] This approach does not digest the sample at pH of -0.05 to +0.7 but rather to pH 4 to better measure only the bioavailable fraction of aluminum. Rodriguez *et al.* reported that sodium acetate buffer is added to the sample to reach

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[6] He YT, Ziemkiewicz PF. 2016. Bias in determining aluminum concentrations: Comparison of digestion methods and implications on Al management. Chemosphere 159:570–576; Ryan AC, Santore RC, Tobiason S, WoldeGabriel G, and Groffman AR. 2019. Total recoverable aluminum: not totally relevant for water quality standards. *Integrated Environmental Assessment and Management*. 15(6): 974–987.

[7] Rodriguez PH, Arbildua JJ, Villavicencio G, Urrestarazu P, Opazo M, Cardwell AS, Stubblefield W, Nordheim E, Adams W. 2019. Determination of bioavailable aluminum in natural waters in the presence of suspended solids. *Environmental Toxicology and Chemistry*. 38(8):1668-1681.

the desired pH, followed by sample agitation for a specified period of time, and finally 0.45-µm sample filtration. The sample is then acidified with nitric acid before inductively coupled plasma-optical emission spectrometry analysis. These authors provided data that led them to conclude that their proposed method is better able to discriminate chronic toxicity effects attributable to bioavailable aluminum from mineralized nontoxic forms of aluminum compared with existing methods using total or total recoverable aluminum.

EPA expects that an analytical method that uses a less aggressive initial acid digestion that liberates bioavailable forms of aluminum (including amorphous aluminum hydroxide), yet minimizes dissolution of mineralized forms of aluminum such as aluminosilicates associated with suspended sediment particles and clays (referred to as a bioavailable analytical method), will better estimate the bioavailable fraction of aluminum in ambient waters. EPA is not prescribing use of any specific method and looks to further research and method standardization efforts to identify best practices.

For the reasons articulated above, EPA is including the option for Oregon to use a bioavailable analytical method for characterizing aluminum concentrations in ambient waters, except where measurements of total recoverable aluminum are required by federal regulations (e.g., NPDES permit limits for aluminum and compliance reports, by regulation at 40 CFR 122.45, 40 CFR 122.44, and 40 CFR 122.48, must be expressed as "total recoverable aluminum" and measured using analytical methods approved at 40 CFR part 136). Doing so, particularly when testing ambient samples expected to contain significant amounts of colloidal, particulate, and clay-bound aluminum, will better approximate the fraction of aluminum that is "available" to aquatic life in Oregon waters. The footnote in the criteria statement that speaks to Oregon's use of a bioavailable analytical method specifies that such a method may utilize "a less aggressive initial acid digestion, such as to a pH of approximately 4 or lower, that includes the measurement of amorphous aluminum hydroxide yet minimizes the measurement of mineralized forms of aluminum such as aluminum silicates associated with suspended sediment particles or clays." Oregon may use such methods "as scientifically appropriate and as allowable by State and federal regulations." For more discussion on analytical methods considerations, refer to Section *C. Implementation of Final Freshwater Acute and Chronic Aluminum Criteria in Oregon* of this preamble.

Comments regarding language included in the aluminum criteria table

In addition to addressing comments pertaining to the use of analytical methods described above, EPA also addressed separate and unrelated comments regarding language included in the proposed criteria table. In the proposed rulemaking, the proposed criteria table included the following text: "Calculator outputs shall be used to calculate criteria values for a site that protect aquatic life throughout the site under the full range of ambient conditions, including when aluminum is most toxic given the spatial and temporal variability of the water chemistry at the site." Commenters requested that the text be moved out of the criteria table because they suggested that it referred to implementation of the criteria and that the criteria regulation should only contain a reference to the 2018 national recommended criteria for aluminum. In response, the final rule removes the proposed text from the criteria table and instead includes a modification of EPA's statement as a footnote to the criteria table. The Agency is using Oregon's adopted water quality criteria for the copper Biotic Ligand Model (BLM) as its guide, specifically Endnote N, Subpart 3(a), which states that Oregon "will apply the BLM criteria for Clean Water Act purposes to protect the water body during the most bioavailable or toxic conditions."[8]

Commenters also requested that EPA edit the above-referenced statement to avoid the implication that a static set of criteria values must be calculated for each site for CWA implementation purposes. EPA affirms that the State need not calculate static criteria values for each site and has revised the statement to provide that for CWA purposes, criteria values based on ambient water chemistry conditions must protect the water body over the full range of water chemistry conditions, including during conditions when aluminum is most toxic. The intention of the statement is to reflect that site-specific pH, DOC, and total hardness conditions vary both

[8] See Endnote "N," https://www.oregon.gov/deq/Rulemaking Docs/tables303140.pdf.

spatially and temporally and that the State must apply the criteria in a manner that ensures protection over the full range of variability.

The State may ensure protection over the full range of water chemistry conditions in different ways for different CWA implementation purposes. For example, for NPDES permitting, the permit protects the water body during critical conditions and therefore under other foreseeable conditions. The State could use multiple outputs of the calculator to generate a static set of criteria values that would be protective for the range of ambient conditions at a site, and use these to calculate a water quality-based effluent limit (WQBEL) for an NPDES permit for a water body. For assessment, the State could concurrently measure the aluminum concentration and the input parameters at the site. The calculator would generate instantaneous criteria values against which the concurrently collected aluminum monitoring data would be compared.

Comments regarding default criteria values

Regarding the topic of default criteria values, Oregon will need to use ambient water chemistry data (i.e., paired pH, DOC, total hardness) as inputs to the calculator in order to determine protective aluminum criteria values when implementing the criteria, unless the State provides protective default values. To ensure that all subject waters will be protected by the aluminum criteria, EPA recommends the State have either protective default input values for

DOC, default criteria magnitude values, or procedures for how to calculate criteria values for waters for which there are insufficient data to adequately characterize site-specific conditions in the water body. EPA recommends that pH values be directly measured rather than estimated, given the variability of pH in the environment and the sensitivity of criteria calculations to differences in pH. EPA solicited comment in the preamble to the proposed rulemaking on whether it should promulgate default criteria values for aluminum to ensure protection of the aquatic life designated use when available data are insufficient to characterize a site. EPA agrees with comments that while default values may be needed in some situations, it is preferable to collect the needed ambient data and use the calculator to calculate criteria values. Commenters supported the use of default ecoregional criteria values for situations when data for more than one input parameter are unavailable, but requested that the final rule not include promulgation of default criteria values. In consideration of these comments, EPA has elected not to finalize default criteria procedures or values in this rule.

Although Oregon is not required to identify default input parameters or default criteria values for aluminum, the State is required to protect the designated uses of the waterbodies within its jurisdiction. As described in more detail below, EPA has elected to provide the procedures for developing default criteria values and default DOC inputs in the docket to this rulemaking. These procedures are available to Oregon to use at the State's discretion, in the event the State does not yet have sufficient site-specific ambient data upon which to rely for a particular location. EPA expects that the State will provide publicly available default procedures or values so that the public and implementing entities will be aware of how all of the State's fresh waters subject to the rule will be protected by the criteria when available data are insufficient to characterize a site.

Per commenters' suggestions, this final preamble briefly describes a suggested procedure for calculating default ecoregional criteria, but does not include a table of pre-calculated values. Comments supported the option of "ecoregional criteria default values" based on the 10th percentile of the distribution of calculator outputs calculated within an ecoregion, which is similar to the approach that EPA suggested in the preamble to the proposal and described in a technical analysis included in the docket ("Analysis of the Protectiveness of Default Ecoregional Al Criteria Values" Docket ID: EPA-HQ-OW-2016-0694-0114). In this procedure, EPA calculated ecoregional default aluminum criteria values based on publicly available data from each of Oregon's Level III Ecoregions.[9] To calculate ecoregional default criteria values, (1) EPA identified paired measurements of the three calculator input parameters

[9] USEPA. 2013. U.S. Environmental Protection Agency, 2013, Level III ecoregions of the continental United States: Corvallis, Oregon, U.S. EPA - National Health and Environmental Effects Research Laboratory, map scale 1:7,500,000, http://www.epa.gov/wed/pages/ecoregions/level_iii_iv.h. Omernik, J.M. 1987. Ecoregions of the conterminous United States. *Annals of the Association of American Geographers.* 77:118-125.

where available, and (2) where paired measurements of the three calculator input parameters were unavailable, EPA identified paired ambient data measurements for available input parameters along with estimated DOC and/or total hardness estimated from measured Total Organic Carbon (TOC) and specific conductivity, respectively as needed. EPA then calculated the 10th percentile CMC and CCC (and other percentiles) for each ecoregion from the distributions of calculator outputs. Finally, depending on the ecoregion and data censoring method, EPA selected the 5th or 10th percentile as a statistic that represents a lower bound of spatially and temporally variable conditions that will be protective in the majority (>90%) of cases. This procedure is available for the State to use to generate default criteria values for areas for which the Aluminum Criteria Calculator v.2.0 will be used and there are insufficient site-specific ambient data. The State may also use another scientifically defensible procedure to generate default criteria values.

In addition to soliciting comment on including default ecoregional criteria, EPA also solicited comment on whether the final rule should include default DOC input values. Among the input parameters, ambient DOC data are the least likely to be available out of the three input parameters. DOC influences aluminum toxicity unidirectionally. Higher levels of DOC provide more mitigation of aluminum toxicity. For water bodies for which sufficient pH and total hardness data are available, but sufficient DOC data are not available, Oregon may develop default DOC input values to use with ambient pH and total hardness data, as an alternative to using default criteria values. Comments supported the use of default DOC inputs when DOC input parameter data are unavailable. Commenters requested the final rule afford the State the discretion to develop its own DOC defaults, including a comment requesting that the State be able to use its own DOC default inputs from its copper BLM criteria rule.[10] EPA has elected not to finalize default DOC inputs for this aluminum rule so that the State may use its discretion to develop or apply its own.

Per commenters' suggestions, EPA briefly describes a possible procedure for calculating default DOC input values. One such approach would be to mirror the approach EPA described in the preamble to the proposed rulemaking, which also is described in technical support materials associated with EPA's proposed rulemaking and included in the docket to this rulemaking ("Analysis of the Protectiveness of Default DOC Options" Docket ID: EPA-HQ-OW-2016-0694-0116). In that analysis, EPA analyzed the State's DOC default procedures for its copper water quality standard and found that in most of the ecoregions, the default values those procedures would generate would be protective as default inputs for aluminum as well, with some exceptions and considerations. EPA derived its suggested default DOC input values as the

[10] Oregon Administrative Rules, Copper Standard Implementatoin (Chapter 340, Division 041, Section 0033), https://www.oregon.gov/deq/wq/Pages/WQ-Standards-Copper.aspx.

15th or 20th percentile of the distribution of data from a compilation of high quality data available for Oregon's georegions (aggregated ecoregions with similar water quality characteristics). Depending on the ecoregion and the data censoring method, EPA selected the 5th, 15th, or 20th percentiles as low-end percentiles of georegional DOC concentrations that represent a lower bound of spatially and temporally variable conditions that will be protective in the majority of cases. EPA encourages the State to continue refining its DOC default input procedures to ensure the calculated aluminum criteria values will be protective for all of Oregon's fresh waters subject to this rule.

C. Implementation of Final Freshwater Acute and Chronic Aluminum Criteria in Oregon

EPA understands that states have certain flexibilities under 40 CFR part 131 regarding how each implements water quality standards, such as today's freshwater aluminum criteria for Oregon. To support the State, the proposed rulemaking identified a range of acceptable approaches for the State and the commenting public to consider. The State may elect to utilize one or more of the approaches or to implement the final aluminum criteria in other ways that are consistent with 40 CFR part 131.

For CWA implementation purposes, the State will need to identify one or more outputs from the calculator or a value derived from a scientifically defensible percentile of the distribution of the output values as the magnitude(s) of the criteria, to be applied together with duration and frequency, to protect the water body under the range of water chemistry conditions at a site. In practice, EPA expects the State to collect sufficient data to characterize the most toxic conditions at a site. The State could collect samples for the input parameters concurrently or as close to the same time as possible while representing the same environmental condition, and could use default values if appropriate where data are unavailable or insufficient to capture the variability in conditions. The ways by which the State may evaluate sufficiency are described in more detail below.

The proposal preamble described three example approaches that the State could use to calculate criteria values when multiple calculator outputs, representing different ambient conditions over time, are available (i.e., how to reconcile multiple calculator outputs). EPA agrees with commenters' suggestions that further development and implementation of these approaches should be left to the State's discretion, and that the term used to identify one or more protective values, "reconcile," was not appropriate to describe how the State should manage multiple calculator outputs. The appropriate approach for each circumstance will depend primarily on data availability and on the programmatic purposes for which criteria values are being calculated. For purposes which require forecasting a protective loading allocation under varying ambient conditions, for example, the State could calculate a single set of numeric criteria values (CMC and CCC) by choosing the lowest output or a low percentile of the outputs of multiple calculator runs, or use conservative default values.

Oregon should ensure that sufficiently representative data are collected for the calculator’s input parameters (pH, DOC, and total hardness) to have confidence that the most toxic conditions are adequately characterized. To accomplish this, Oregon may evaluate the input parameter data and resultant criteria values that are calculated over time for different flows and seasons through the use of appropriate statistical methods, such as Monte Carlo[11] simulation. One consideration when defining a site to which to apply criteria for aluminum is whether the concentration of metals are generally consistent throughout the area. As the size of a site increases, the spatial and temporal variability is likely to increase; thus, more water samples may be required to adequately characterize the entire site. Implementation materials that outline the State’s approaches will help provide transparency for the public and predictable, repeatable outcomes. Additional transparency and public accountability will be achieved if Oregon makes publicly available each site’s ambient water chemistry data, including the inputs used in the aluminum criteria value calculations, resultant criteria values, and the geographic extent of the site.

[11] Given sufficient data, Monte Carlo simulation or equivalent analysis can be used to determine the probability of identifying the most toxic time period for a series of monitoring scenarios. From such an analysis, the State can select an appropriate monitoring regime.

Similarly, NPDES permit effluent limits that are derived from the aluminum criteria calculator should be sufficiently explained in Fact Sheets or Statements of Basis. This includes providing an explanation of how the aluminum criteria values were calculated; the input data or summary of input data and source of data; and how criteria values were used to determine whether the discharge would cause or have the reasonable potential to cause or contribute to an excursion above the aluminum criteria, and if so, how the values were used to derive WQBELs for aluminum. The State's assessment methodology and any TMDLs developed for waters impaired for aluminum criteria developed using the calculator should also be adequately explained for transparency and public accountability in TMDL documents and Integrated Reports, as appropriate.

Substantial changes in a water body's ambient input parameter concentrations will likely affect aluminum toxicity at that site. In addition, as a robust, site-specific dataset is developed with regular monitoring, criteria values previously calculated by the State can be updated to more accurately reflect site conditions. The State may wish to revisit calculated aluminum criteria values periodically (for example, with each CWA Section 303(d) listing cycle or WQS triennial review) or when changes in water chemistry are evident or suspected at a site and as additional monitoring data become available. This will ensure that the criteria values used for implementing CWA programs accurately reflect the toxicity of aluminum and remain protective of the aquatic life designated uses including when aluminum is most toxic.

Analytical methods considerations

As discussed earlier, the forms of aluminum introduced into the laboratory toxicity tests upon which EPA relied for criteria development do not include suspended solids or clays where aluminum may be bound. Aluminum bound in suspended solids or clays would be extracted when using total recoverable methods that have a strong acid (pH <2) digestion step, but these forms of aluminum would not be biologically available to aquatic species in ambient waters. Empirical laboratory chronic (7-day) testing with *Ceriodaphnia dubia* investigating survival and reproduction endpoints indicates that total recoverable (pH -0.05 to +0.7 digestion) and bioavailable measurements of aluminum in lab waters are essentially equal up to approximately 1 mg/L of aluminum.[12] Studies are currently being conducted at Oregon State University with test solutions with greater than 1 mg/L of aluminum to better understand the relationship between the total recoverable and bioavailable analytical methods at concentrations above 1 mg/L. Initial studies indicate there is little variability between total recoverable and bioavailable

[12] Rodriguez PH, Arbildua JJ, Villavicencio G, Urrestarazu P, Opazo M, Cardwell AS, Stubblefield W, Nordheim E, Adams W. 2019. Determination of bioavailable aluminum in natural waters in the presence of suspended solids. *Environmental Toxicology and Chemistry*. 38(8):1668-1681.

aluminum above 1 mg/L in lab waters because the laboratory waters do not include clays or suspended solids.

It is not necessary to apply a conversion or translation factor to compare field measurements using a bioavailable method against the promulgated aluminum total recoverable criteria. This is because both bioavailable and total recoverable analytical methods quantify the toxic fraction of aluminum equivalently in laboratory test waters given that standard toxicity test waters do not include suspended solids or clays per test protocols. For NPDES compliance monitoring and reporting, total recoverable measurements for metals are required. By comparison, for ambient water measurements, analytical methods that measure bioavailable aluminum should provide more accurate quantification of the toxic fraction of aluminum. EPA has included a footnote to the final criteria statement specifically noting that for characterizing ambient waters, Oregon may utilize, as scientifically appropriate and as allowable by State and federal regulations, analytical methods that measure the bioavailable fraction of aluminum. The State's use of such a method would need to comply with other requirements in the State's own program, for example, any applicable Quality Assurance/Quality Control requirements. For assessment and listing purposes, ambient field measurements analyzed using a bioavailable analytical method may be compared directly to the criteria because both represent the toxic fraction of aluminum.

EPA recognizes that in some circumstances, assessing waters using the total recoverable analytical method could result in the listing of some waters (i.e., those with high amounts of total suspended solids) as impaired even though the elevated aluminum measurements could be largely attributed to non-bioavailable forms of aluminum. EPA's existing regulations do not require use of analytical test methods promulgated at 40 CFR part 136 in the implementation of CWA Section 303 programs, including assessment and listing of waters, nor in the determination of the need for a WQBEL. However, EPA's regulations require that states assemble and evaluate all existing and readily available water quality-related data and information for use in developing their CWA Section 303(d) lists. 40 CFR 130.7(b)(5). The requirement to assemble and evaluate all data and information for assessment and listing purposes includes situations where only total recoverable aluminum data and information are available. However, in those circumstances, the State is not required to rely on that data for listing purposes as long as it provides a technical, science-based rationale for not using the data and information. 40 CFR 130.7(b)(6)(iii). This technical, science-based rationale documenting the State's consideration of existing and readily available data and information is referenced in the additional footnote language to the criteria statement, which speaks to Oregon's ability to use analytical methods that measure the bioavailable fraction of aluminum for characterizing ambient waters “as scientifically appropriate.” For example, the State may be able to demonstrate that total recoverable aluminum samples are not representative of water quality conditions because non-toxic, non-bioavailable forms of aluminum are leading to an exceedance above the criterion. When data and information are available for both total recoverable and bioavailable aluminum, the State must evaluate all of it, but need not rely on all of it for assessment and listing purposes. Applicable regulations do not prohibit the State from assigning more weight to data and information about bioavailable aluminum than total recoverable aluminum for assessment and listing purposes.

For developing TMDLs and load allocations, field measurements analyzed using a bioavailable method also may be used as the basis for identifying allocations for TMDLs, both wasteload allocations (WLA) for point sources and load allocations (LA) for nonpoint sources. For implementing a WLA, the associated WQBEL must be assessed for NPDES compliance purposes using total recoverable methods just as would be the case for other NPDES applications consistent with permitting regulations (NPDES permit limits for aluminum and compliance reports, by regulation at 40 CFR 122.44, 40 CFR 122.45, and 40 CFR 122.48, must be expressed as “total recoverable aluminum” and measured using analytical methods approved at 40 CFR part 136). For implementing a LA, a bioavailable analytical method could be used to measure nonpoint source contributions because significant solids with colloid and clay-bound aluminum could be present (He and Ziemkiewics 2016; Ryan *et al*. 2019),[13] and should not contribute to the measured aluminum for comparison to a LA.

The contexts where use of an EPA approved method is required are: (1) applications for NPDES permits, specifically, measurements of effluents, (2) reports required from dischargers, and (3) certifications issued by states under CWA Section 401. 40 CFR 136.1(a). NPDES permit limits for metals must be expressed as "total recoverable" metals with the exception of circumstances that would not apply for the aluminum criteria in this rule. 40 CFR 122.45(c).

D. Incorporation by Reference

The regulatory text incorporates an EPA document by reference, specifically, EPA's Final Aquatic Life Ambient Water Quality Criteria for Aluminum – 2018, December 2018 (EPA-822-R-18-001). The 2018 national recommended criteria document is an update to the 1988 recommended aluminum aquatic life ambient water quality criteria, in accordance with the provisions of CWA Section 304(a) directing EPA to revise criteria from time to time to reflect the latest scientific knowledge. The criteria for aluminum that protect aquatic life in fresh water depend on a site's water chemistry parameters. Using those inputs, users can enter a site's pH,

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[13] He YT, Ziemkiewicz PF. 2016. Bias in determining aluminum concentrations: Comparison of digestion methods and implications on Al management. Chemosphere 159:570–576; Ryan AC, Santore RC, Tobiason S, WoldeGabriel G, and Groffman AR. 2019. Total recoverable aluminum: not totally relevant for water quality standards. *Integrated Environmental Assessment and Management*. 15(6): 974–987.

DOC, and total hardness into the aluminum criteria calculator or use the lookup tables in the criteria document's appendix. Incorporating this document by reference will allow the State to access all of the underlying information and data EPA used to develop the 2018 national recommended criteria for aluminum. With access to this information, the State will have the flexibility to create its own version of the calculator built upon the underlying peer-reviewed models. EPA has made, and will continue to make, this document publicly available electronically through www.regulations.gov at the docket associated with this rulemaking and at www.epa.gov/wqc/aquatic-life-criteria-aluminum.

IV. Critical Low Flows and Mixing Zones

To ensure that the final criteria for aluminum are applied appropriately to protect Oregon's aquatic life uses, EPA recommends Oregon use critical low flow values consistent with longstanding EPA guidance[14] when calculating the available dilution for the purposes of determining the need for and establishing WQBELs in NPDES permits. Dilution is one of the primary mechanisms by which the concentrations of contaminants in effluent discharges are reduced following their introduction into a receiving water. During a low flow event, there is less water available for dilution, resulting in higher instream pollutant concentrations. If criteria are

[14] USEPA. 1991. *Technical Support Document For Water Quality-based Toxics Control*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA/505/2-90-001. http://www3.epa.gov/npdes/pubs/owm0264.pdf.

implemented using inappropriate critical low flow values (i.e., flow values that are too high), the resulting ambient concentrations could exceed criteria values when low flows occur.[15]

EPA notes that in ambient settings, critical low flow conditions used for NPDES permit limit derivation purposes may not always correspond with conditions of highest aluminum bioavailability and toxicity. EPA's *NPDES Permit Writers' Manual* describes the importance of characterizing effluent and receiving water critical conditions, because if a discharge is controlled so that it does not cause water quality criteria to be exceeded in the receiving water under critical conditions, then water quality criteria should be attained under all other conditions.[16]

EPA's March 1991 *Technical Support Document for Water Quality-based Toxics Control* recommends two methods for calculating acceptable critical low flow values: the traditional hydrologically-based method developed by the USGS and a biologically based method developed by EPA.[17] The hydrologically-based critical low flow value is determined statistically, using probability and extreme values, while the biologically-based critical low flow is

[15] USEPA. 2014. *Water Quality Standards Handbook-Chapter 5: General Policies*. U.S. Environmental Protection Agency, Office of Water. Washington, D.C. EPA-820-B-14-004. http://www.epa.gov/sites/production/files/2014-09/documents/handbook-chapter5.pdf.
[16] The same principle holds for developing a TMDL target, the total load.
[17] USEPA. 1991. *Technical Support Document For Water Quality-based Toxics Control*. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA/505/2-90-001. http://www3.epa.gov/npdes/pubs/owm0264.pdf.

determined empirically using the specific duration and frequency associated with the criterion. For the acute and chronic aluminum criteria, EPA recommends the following critical low flow values, except where modeling demonstrates that the most significant critical conditions occur at other than low flow:

Acute Aquatic Life (CMC): 1Q10 or 1B3

Chronic Aquatic Life (CCC): 7Q10 or 4B3

Using the hydrologically-based method, the 1Q10 represents the lowest one-day average flow event expected to occur once every ten years, on average, and the 7Q10 represents the lowest seven-consecutive-day average flow event expected to occur once every ten years, on average. Using the biologically-based method, 1B3 represents the lowest one-day average flow event expected to occur once every three years, on average, and 4B3 represents the lowest four-consecutive-day average flow event expected to occur once every three years, on average.[18]

The final criteria must be attained at the point of discharge unless Oregon authorizes a mixing zone. Where Oregon authorizes a mixing zone, the criteria would apply at the locations

[18] *See* USEPA, 2014.

allowed by the mixing zone (i.e., the CMC would apply at the defined boundary of the acute mixing zone and the CCC would apply at the defined boundary of the chronic mixing zone).[19,20]

V. Endangered Species Act

Section 7(a)(2) of the ESA requires that each federal agency ensure that any action authorized, funded, or carried out by such Agency is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of critical habitat. For this rule, EPA transmitted a Biological Evaluation to NOAA Fisheries Service and USFWS on September 20, 2019. NOAA Fisheries responded on October 18, 2019, that EPA's Biological Evaluation was insufficient to initiate formal consultation. EPA submitted a revised Biological Evaluation to NOAA Fisheries on January 2, 2020. On February 13, 2020, EPA received a final Biological Opinion from USFWS that determined that EPA's proposed action is likely to adversely affect, but will not jeopardize the continued existence of bull trout and will not destroy or adversely modify its designated critical habitat. USFWS also concluded that the proposed action may affect, but is not likely to adversely affect, eight other federally-listed species and is not likely to destroy or adversely modify the critical habitat for the other species that were included in the consultation. On July 1, 2020, EPA received a final

[19] *See* USEPA, 1991.
[20] Oregon Administrative Rules, Mixing Zones (Chapter 340, Division 41, Section 0053), https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=68770.

Biological Opinion from NOAA Fisheries that determined that EPA's proposed action is likely to adversely affect, but will not jeopardize the continued existence of 18 listed species and will not destroy or adversely modify designated critical habitat for the species that were included in the consultation. The receipt of the NOAA Biological Opinion concludes the consultation for this rule under ESA Section 7(a)(2). Documents associated with ESA consultation are available in the docket associated with this rule (Docket ID: EPA-HQ-OW-2016-0694).

VI. Under What Conditions Would Federal Standards Be Withdrawn?

Under the CWA, Congress gave states and authorized tribes primary responsibility for developing and adopting WQS for their navigable waters (CWA Sections 303(a) through (c)). Although EPA is finalizing aluminum aquatic life criteria for Oregon's fresh waters subject to this rule on the basis of having disapproved Oregon's 2004 criteria in February 2013, Oregon retains the option to adopt and submit to the Agency acute and chronic aluminum criteria for the State's fresh waters consistent with CWA Section 303(c) and the Agency's implementing regulation at 40 CFR part 131. Indeed, EPA encourages Oregon to do so expeditiously. The Agency would approve the State's criteria if the criteria meet the requirements of CWA Section 303(c) and implementing regulation at 40 CFR part 131. If EPA's federally promulgated criteria are more stringent or prescriptive than the State's criteria, EPA's federally promulgated criteria are and will be the applicable water quality standard for purposes of the CWA until the Agency withdraws those federally promulgated standards (40 CFR 131.21(c)). EPA would expeditiously undertake such a rulemaking to withdraw the federal criteria if and when Oregon adopts, and the Agency approves, corresponding criteria that meet the requirements of CWA Section 303(c) and implementing regulation at 40 CFR part 131. After such a withdrawal of EPA's federally promulgated criteria, the State's EPA-approved criteria would become the applicable criteria for CWA purposes (40 CFR 131.21(c)).

VII. Alternative Regulatory Approaches and Implementation Mechanisms

The federal WQS regulation at 40 CFR part 131 provides several tools that Oregon has available to use at its discretion when implementing or deciding how to implement these aquatic life criteria, once effective. Among other things, EPA's WQS regulation: (1) specifies how states and authorized tribes establish, modify, or remove designated uses (40 CFR 131.10); (2) specifies the requirements for establishing criteria to protect designated uses, including criteria modified to reflect site-specific conditions (40 CFR 131.11); (3) authorizes and provides regulatory guidelines for states and authorized tribes to adopt WQS variances that provide time to achieve the applicable WQS (40 CFR 131.14); and (4) allows states and authorized tribes to authorize the use of compliance schedules in NPDES permits to meet WQBELs derived from the applicable WQS (40 CFR 131.15). Each of these approaches is discussed in more detail in the next sections. Whichever approach a state pursues, however, all NPDES permits would need to comply with EPA's regulations at 40 CFR 122.44(d)(1)(i).

A. Designating Uses

EPA's final aluminum criteria apply to fresh waters in Oregon where the protection of fish and aquatic life is a designated use (see Oregon Administrative Rules at Chapter 340 Division 41). The federal regulation at 40 CFR 131.10(g) provides requirements for establishing, modifying, and removing designated uses when attaining the use is not feasible for one of the six factors in the regulation. If Oregon removes designated uses such that no fish or aquatic life uses apply to any particular water body affected by this rule and adopts the highest attainable use,[21] the State must also adopt criteria to protect the newly designated highest attainable use consistent with 40 CFR 131.11. It is possible that criteria other than the federally promulgated criteria would protect the highest attainable use. If EPA finds removal or modification of the designated use and the adoption of the highest attainable use and criteria to protect that use to be consistent with CWA Section 303(c) and the implementing regulation at 40 CFR part 131, the Agency

[21] If a state or authorized tribe adopts a new or revised WQS based on a required use attainability analysis, then it must also adopt the highest attainable use (40 CFR 131.10(g)). The highest attainable use is the modified aquatic life, wildlife, or recreation use that is both closest to the uses specified in section 101(a)(2) of the CWA and attainable, based on the evaluation of the factor(s) in 40 CFR 131.10(g) that preclude(s) attainment of the use and any other information or analyses that were used to evaluate attainability. There is no required highest attainable use where the state demonstrates the relevant use specified in section 101(a)(2) of the Act and sub-categories of such a use are not attainable (see 40 CFR 131.3(m)).

would approve the revised WQS. EPA would then undertake a rulemaking to withdraw the corresponding federal WQS for the relevant water(s).

B. WQS Variances

Oregon's WQS provide authority to apply WQS variances when implementing federally promulgated criteria for aluminum, as long as such WQS variances are adopted consistent with 40 CFR 131.14 and submitted to EPA for review under CWA Section 303(c). The federal regulation at 40 CFR 131.3(o) defines a WQS variance as a time-limited designated use and criterion, for a specific pollutant or water quality parameter, that reflects the highest attainable condition during the term of the WQS variance. A WQS variance may be appropriate if attaining the use and criterion would not be feasible during the term of the WQS variance because of one of the seven factors specified in 40 CFR 131.14(b)(2)(i)(A), including if NPDES permit limits more stringent than technology-based controls would result in substantial and widespread economic and social impact. WQS variances adopted in accordance with 40 CFR 131.14 (including a public hearing consistent with 40 CFR 25.5) provide a flexible but defined pathway for states and authorized tribes to issue NPDES permits with limits that are based on the highest attainable condition during the term of the WQS variance thereby allowing dischargers to make water quality improvements when the WQS is not immediately attainable but may be in the future. When adopting a WQS variance, states and authorized tribes specify the interim requirements of the WQS variance by identifying a quantitative expression that reflects the highest attainable condition (HAC) during the term of the WQS variance, establishing the term of the WQS variance, and describing the pollutant control activities expected to occur over the specified term of the WQS variance. WQS variances provide a legal avenue by which NPDES permit limits can be written to comply with the WQS variance rather than the underlying WQS for the term of the WQS variance. If dischargers are still unable to meet the WQBELs derived from the applicable WQS once a WQS variance term is complete, the regulation allows the State to adopt a subsequent WQS variance if it is adopted consistent with 40 CFR 131.14. EPA is promulgating criteria that apply to the use designation that Oregon has already established. Oregon's WQS regulations currently include provisions to use WQS variances when implementing criteria, as long as such WQS variances are adopted consistent with 40 CFR 131.14 and approved by EPA. Oregon may use the State's EPA-approved WQS variance procedures when adopting such WQS variances.

C. NPDES Permit Compliance Schedules

EPA's regulations at 40 CFR 122.47 and 131.15 address how permitting authorities can use schedules for compliance with a limit in the NPDES permit if the discharger needs additional time to undertake actions like facility upgrades or operation changes to meet a WQBEL based on the applicable WQS. EPA's regulation at 40 CFR 122.47 allows a permitting authority to include a compliance schedule in the NPDES permit, when appropriate and where authorized by the state, in order to provide a discharger with additional time to meet a WQBEL implementing applicable WQS. EPA's regulation at 40 CFR 131.15 requires that a state that intends to allow the use of NPDES permit compliance schedules adopt specific provisions authorizing their use and obtain EPA approval under CWA Section 303(c) to ensure that a decision to allow a permit compliance schedule is transparent and allows for public input (80 FR 51022, August 21, 2015). EPA already has approved Oregon's State law provision authorizing the use of permit compliance schedules (see OAR 340-041-0061), consistent with 40 CFR 131.15. Oregon's compliance schedule authorizing provision is not affected by this rule. Oregon is authorized to grant permit compliance schedules, as appropriate, based on the federal water quality criteria for aluminum in Oregon, as long as such permit compliance schedules are consistent with EPA's permitting regulation at 40 CFR 122.47.

VIII. Economic Analysis

To best inform the public of the potential impacts of this rule, EPA evaluated the potential costs associated with State implementation of the Agency's aluminum criteria based on available information. This analysis is documented in *Economic Analysis for the Final Rule: Federal Aluminum Aquatic Life Criteria Applicable to Oregon*, which can be found in the record for this rule. For this analysis, EPA assumed that Oregon fully implements its existing narrative water quality criteria for aluminum (i.e., “baseline criteria”) and estimated the incremental impacts for compliance with the aluminum criteria in this rule. For point source costs, EPA assumed any NPDES-permitted facility that discharges aluminum would have reasonable potential and would be subject to effluent limits and would incur compliance costs if it chose to continue discharging. EPA also evaluated nonpoint sources that contribute aluminum loadings to waters that would be considered impaired for aluminum under the final criteria, which may incur incremental costs for additional best management practices (BMPs). The total cost annualized of this final rule would range from $1.2 million to $8.0 million at a 3% discount rate, and $1.2 million to $8.1 million at a 7% discount rate, for the first 10 years. See *Economic Analysis for the Final Rule: Federal Aluminum Aquatic Life Criteria Applicable to Oregon* for a detailed summary of the information and assumptions EPA relied on to estimate potential costs for the final rule.

IX. 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 a significant regulatory action and was submitted to the Office of

Management and Budget (OMB) for review. Any changes made during OMB's review have been documented in the docket. EPA prepared an analysis of the potential costs to NPDES dischargers associated with State implementation of the aluminum criteria in this rule. This analysis, *Economic Analysis for the Final Rule: Federal Aluminum Aquatic Life Criteria Applicable to Oregon*, is summarized in section VIII of the preamble and is available in the docket.

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

This action is considered an Executive Order 13771 regulatory action. Details on the estimated costs of this final rule can be found in EPA's analysis of the potential costs and benefits associated with this action.

C. Paperwork Reduction Act

This action does not impose any new information-collection burden under the Paperwork Reduction Act. This action does not directly contain any information collection, reporting, or record-keeping requirements. 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. The EPA-promulgated WQS are implemented through various water quality control programs including the NPDES program, which limits discharges to navigable waters except in compliance with a NPDES permit. CWA Section 301(b)(1)(C)[22] and EPA's implementing regulations at 40 CFR 122.44(d)(1) and 122.44(d)(1)(vii)(A) provide that all NPDES permits shall include any limits on discharges that are necessary to meet applicable WQS. Thus, under the CWA, EPA's promulgation of WQS establishes WQS that the State implements through the NPDES permit process. While the State has discretion in developing discharge limits, as needed to meet the WQS, those limits, per regulations at 40 CFR 122.44(d)(1)(i), "must control all pollutants or pollutant parameters (either conventional, nonconventional, or toxic pollutants) which the Director determines are or may be discharged at a level that will cause, have the reasonable potential to cause, or contribute to an excursion above any [s]tate water quality standard, including [s]tate narrative criteria for water quality." As a result of this action, the State of Oregon will need to ensure that permits it issues

[22]CWA Section 301(b) TIMETABLE FOR ACHIEVEMENT OF OBJECTIVES In order to carry out the objective of this chapter there shall be achieved—(1)(C): not later than July 1, 1977, any more stringent limitation, including those necessary to meet water quality standards, treatment standards, or schedules of compliance, established pursuant to any State law or regulations (under authority preserved by section 1370 of this title) or any other Federal law or regulation, or required to implement any applicable water quality standard established pursuant to this chapter.

include any limitations on discharges necessary to comply with the WQS established in the final rule. In doing so, the State will have a number of choices associated with permit writing. Oregon's implementation of the rule may ultimately result in new or revised permit conditions for some dischargers. EPA is unaware of any current permit holders or other entities that would be required to obtain new permits or update existing permits as a result of this action, including small entities. EPA's action, by itself, does not impose any requirements on small entities; that is, the requirements are not self-implementing.

E. Unfunded Mandates Reform Act

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 goverments. This 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. EPA believes, however, that this action may be of significant interest to state governments. Consistent with EPA's policy to promote communications between EPA and state and local governemnts, EPA consulted with Oregon early in the process of developing this rulemaking to permit them to have meaningful and timely input into its development. EPA discussed with Oregon the Agency's development of the federal rulemaking and clarified early in the process that if and when the State decided to develop and establish its own aluminum standards, EPA would assist the State in its process. During these discussions, EPA explained the scientific basis for the aluminum criteria to protect aquatic life for fresh waters in Oregon; the Agency's consideration of comments received during the public comment period associated with this rulemaking; and the overall timing of the federal rulemaking effort. EPA took these discussions with the State into account during the drafting of this rule.

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

This action does not have tribal implications as specified in Executive Order 13175. This rule does not impose substantial direct compliance costs on federally recognized tribal governments, nor does it substantially affect the relationship between the federal government and tribes, or the distribution of power and responsibilities between the federal government and tribes. Thus, Executive Order 13175 does not apply to this action.

Consistent with EPA Policy on Consultation and Coordination with Indian Tribes, the Agency offered government to government consultation to potentially affected tribes during the development of this action. EPA sent letters to tribal leaders of potentially affected tribes in the Pacific Northwest offering government-to-government consultation on the proposed aluminum rule for fresh waters in Oregon. EPA held two conference calls (June 4 and June 13, 2019) with the interested tribal water quality staff to explain the Agency's proposed action and timeline. No tribes requested formal government-to-government consultation on this rulemaking. EPA has continued to apprise the tribes of the status of its final action.

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.

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 rule does not involve technical standards.

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

EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

The freshwater criteria for aluminum in Oregon will support the health and abundance of aquatic life in Oregon, and will therefore benefit all communities that rely on Oregon's ecosystems.

L. 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).

List of Subjects in 40 CFR Part 131

Environmental protection, Incorporation by reference, 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

2. Add §131.47 to read as follows:

§131.47 Aquatic life criteria for aluminum in Oregon.

(a) *Scope*. This section promulgates aquatic life criteria for aluminum in fresh waters in Oregon that are jurisdictional under the Clean Water Act.

(b) *Criteria for aluminum in Oregon*. The aquatic life criteria in Table 1 apply to all fresh waters in Oregon that are jurisdictional under the Clean Water Act to protect the fish and aquatic life designated uses.

Table 1- Aluminum Aquatic Life Criteria for Oregon Fresh Waters

Metal	**CAS Number**	**Criterion Maximum Concentration (CMC)[3] (μg/L)**	**Criterion Continuous Concentration (CCC)[4] (μg/L)**
Aluminum[1,2]	7429905	Acute (CMC) and chronic (CCC) freshwater aluminum criteria values for a site shall be calculated using the 2018 Aluminum Criteria Calculator (*Aluminum Criteria Calculator V.2.0.xlsx*), or a calculator in R or other software package using the same 1985 Guidelines calculation approach and underlying model equations as in the Aluminum Criteria Calculator V.2.0.xlsx, as defined in EPA's Final Aquatic Life Ambient Water Quality Criteria for Aluminum.[5]	

[1] To apply the aluminum criteria for Clean Water Act purposes, criteria values based on ambient water chemistry conditions must protect the water body over the full range of water chemistry conditions, including during conditions when aluminum is most toxic.

[2] These criteria are based on aluminum toxicity studies where aluminum was analyzed using total recoverable analytical methods. Oregon may utilize total recoverable analytical methods to implement the criteria. For characterizing ambient waters, Oregon may also utilize, as scientifically appropriate and as allowable by State and federal regulations, analytical methods that measure the bioavailable fraction of aluminum (e.g., utilizing a less aggressive initial acid digestion, such as to a pH of approximately 4 or lower, that includes the measurement of amorphous aluminum hydroxide yet minimizes the measurement of mineralized forms of aluminum such as aluminum silicates associated with suspended sediment particles or clays). Oregon shall use measurements of total recoverable aluminum where required by federal regulations.

[3] The CMC is the highest allowable one-hour average ambient concentration of aluminum. The CMC is not to be exceeded more than once every three years. The CMC is rounded to two significant figures.

[4] The CCC is the highest allowable four-day average ambient concentration of aluminum. The CCC is not to be exceeded more than once every three years. The CCC is rounded to two significant figures.
[5] EPA-822-R-18-001, Final Aquatic Life Ambient Water Quality Criteria for Aluminum – 2018, December 2018, is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available from U.S. Environmental Protection Agency, Office of Water, Health and Ecological Criteria Division (4304T), 1200 Pennsylvania Avenue, N.W., Washington, DC 20460; telephone number: (202) 566-1143, www.epa.gov/wqc/aquatic-life-criteria-aluminum. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov or go to www.archives.gov/federal-register/cfr/ibr-locations.html.

(c) *Applicability*. (1) The criteria in paragraph (b) of this section are the applicable acute and chronic aluminum aquatic life criteria in all fresh waters in Oregon that are jurisdictional under the Clean Water Act to protect the fish and aquatic life designated uses.

(2) The criteria established in this section are subject to Oregon's general rules of applicability in the same way and to the same extent as are other federally promulgated and state-adopted numeric criteria when applied to fresh waters in Oregon that are jurisdictional under the Clean Water Act to protect the fish and aquatic life designated uses.

(3) For all waters with mixing zone regulations or implementation procedures, the criteria apply at the appropriate locations within or at the boundary of the mixing zones and outside of the mixing zones; otherwise the criteria apply throughout the water body including at the end of any discharge pipe, conveyance or other discharge point within the water body.