The EPA shall use the Process for Deriving Criteria, specified below, to derive a chronic criterion for the State of Oregon for freshwater aluminum at pH 6.5-9.0. The EPA shall recommend that the State of Oregon adopt, and EPA will promulgate if necessary, the derived chronic aluminum criteria. The EPA will ensure that the derived chronic aluminum criteria will be effective within 24 months after EPA's final action to approve or disapprove Oregon's proposed water quality criteria under the CWA.

Process for Deriving Criteria

The EPA shall utilize analytical methods that meet specified requirements to derive numeric criteria for aquatic life, taking into account the same factors that NMFS did in completing its analysis for the other criteria in this opinion. The EPA will then evaluate the analytical results with a population model that meets the requirements set out below, and thus is equivalent to that used by NMFS in this opinion, to confirm that the derived criteria will not jeopardize listed fish or adversely modify their critical habitat.

In particular, the EPA shall derive criteria for acute ammonia, acute cadmium, and acute and chronic aluminum in compliance with the following five requirements:

1) Only use toxicity data for ammonia, cadmium, and aluminum that is specific to salmonid fishes (if new information becomes available for these compounds for green sturgeon and eulachon, then EPA shall include this data in its analysis);
2) All toxicity data used to derive the numeric criteria must be curve-fitted, where the literature provides the necessary data to perform this step;
3) When available, the curve-fitted toxicity data must be used to extrapolate threshold acute and chronic toxic effect concentrations;
4) Derived criteria must be model-adjusted to account for chemical mixtures; and,
5) An appropriate population model must be applied to the derived criteria, and must predict no negative change in the intrinsic population growth rate (*e.g.*, lambda, λ).

More specifically, EPA shall ensure that the derived criteria are developed in compliance with the following mandatory sideboards:

- The EPA shall use toxicity data specific to salmonid fishes. The EPA shall use the acute and chronic toxicity data in this opinion as a minimum data set. For green sturgeon and eulachon, EPA shall use the salmonid fishes toxicity data for this analysis, as described in section 2.6.2 in this opinion, in addition to any new data that becomes available for green sturgeon and eulachon.
- The EPA shall use toxicity data based on exposure-response curves and fixed durations toxicity tests to estimate acute and chronic toxic effect thresholds to assess effects on multiple life stages and multiple endpoints, to include at a minimum: mortality, latent mortality, reproduction, growth, physiological, cellular, behavioral, and biochemical effects, where the data exists. The EPA may use existing toxicity data for ammonia, cadmium, and aluminum or generate new data, but the data shall be curve-fitted (see Figure 2.6.1.1) to determine the minimum effect thresholds (*e.g.*, 5%) at which acute and chronic toxic effects are predicted. The minimum effects thresholds shall be used to

derive the criteria instead of using the EPA acute adjustment factor or the acute-to-chronic ratio to derive criteria.

- The EPA shall ensure that each derived criterion for ammonia, cadmium, and aluminum is adjusted to account for chemical mixtures using a concentration–addition model or response-addition model to determine whether or not exposure to multiple compounds will result in additive effects to the listed species considered in this opinion. The concentration–addition model or response-addition model shall include all compounds listed in Table 1.1. If the mixture effects prediction is greater than one, EPA shall adjust the concentrations for ammonia, cadmium, and aluminum until the mixture effects prediction is less than one.
- The EPA shall ensure that the derived criteria for ammonia, cadmium, and aluminum do not result in a negative change in the intrinsic population growth rate based on the geometric mean abundance data for each life history type, *i.e.*, coho salmon (*O. kisutch*), sockeye salmon (*O. nerka*) and ocean-type and stream-type Chinook salmon (*O. tshawytscha*), of salmonid fish considered in this opinion, at the population scale. The EPA shall use stream-type Chinook salmon as a surrogate for steelhead, and ocean-type Chinook salmon as a surrogate for chum salmon in the population model, as described in section 2.6.5.1 of this opinion. Pacific salmon and steelhead abundance data is available from the Northwest Fisheries Science Center Salmon Population Summary Database[12] or from the Columbia Basin Fish and Wildlife Authority Status of the Fish and Wildlife Resources Database[13]. The abundance data used for the population growth rate analysis shall include data from all years with available abundance data. For green sturgeon and eulachon, EPA shall use the salmonid fishes toxicity data and modeling results as surrogate data and outputs for this analysis.
- To ensure that the derived numeric criteria for ammonia, cadmium, and aluminum meet the population growth rate condition of the RPA, EPA shall run the criteria for ammonia, cadmium, and aluminum through a population model (*e.g.*, Leslie Matrix), parameterized for Pacific salmonid fishes. Model requirements include: (1) scenarios based on change in first year survival; (2) an assumption that the populations are density-independent, to reduce the probability of Type II errors; (3) sigmoid slopes are generated from the data used to derive the numeric criteria, and if a slope cannot be generated from the data, EPA shall use the default sigmoid slope of 3.6 used in this opinion; and (4) exposure-response scenarios using the geometric mean of the curve-fitted data, and the minimum species mean value of the curve-fitted data, from the toxicity data used to derive the numeric criteria.

2.10.2 Compliance with RPA Criteria

A reasonable and prudent alternative to the proposed action is one that avoids jeopardy by ensuring that the action's effects do not appreciably increase the risks to the species' potential for survival or to the species' potential for recovery. It also must avoid destruction or adverse modification of designated critical habitat. A detailed analysis of how the RPA avoids jeopardy

[12]https://www.webapps.nwfsc.noaa.gov/sps
[13]http://sotr.cbfwa.org

selected toxicity data in the core data file with a reported concentration type of total ammonia. For these toxicity studies, temperature and pH were not reported in the core data files; therefore verification regarding normalization was not possible and creates uncertainty. Therefore, as an additional step to address this uncertainty and to assess the potential for chronic toxic effects of ammonia to the listed species considered in this opinion using an additional line of evidence, NMFS used four ACRs described in section 2.6.2.1.7 of this opinion to estimate a NOEC for ammonia. These produced no concentrations less than the chronic criterion concentration, which indicates that listed species exposed to waters equal to chronic criterion concentrations may not suffer chronic toxic effects. To take into account the shortcomings and implications of laboratory-derived toxicity tests and the ecological consequences for field-exposed fishes, we considered factors such as hypothesis tests in our effects analysis to assess the uncertainty of the revised criteria.

- The NMFS also considered non-lethal effects based on best available information and determined that they would be suffered at low-intensity.
- The revised criterion for ammonia will not adversely modify critical habitats for the listed species considered in this opinion as the data suggests that the criteria concentrations are likely to have low-intensity adverse effects on the PCEs substrate, forage. Ammonia does not bioaccumulate or bind to sediments—therefore effects on the PCEs substrate and forage are unlikely to be affected in a manner inconsistent with the recovery requirements of the listed fishes considered in this opinion. Furthermore, based on the ACR analyses, the revised criterion is likely to have low-intensity adverse effects on the PCEs substrate, forage, or water quality at the watershed and designation scales.

2.10.3.3 Derived Criteria

The EPA will derive criteria for acute ammonia, acute cadmium, and acute and chronic aluminum in accordance with the Process for Deriving Criteria set out above to ensure an adequately protective criterion is established.

The NMFS has determined that the derived criteria will satisfy the conservation needs of the species and function of critical habitat PCEs because the RPA relies on a conservative, well-defined methodology and requires EPA to ensure that the acute criterion for ammonia, the acute criterion for cadmium, and the acute and chronic criteria for aluminum do not cause a change in the intrinsic population growth rate (*e.g.*, λ). More specifically, NMFS developed the following requirements to address the uncertainties associated with the toxicity data, sublethal effects, multiple environmental stressors, and biological requirements consistent with the principles of conservation biology.

Toxicity Data

Because EPA is required to use toxicity data specific to salmonid fishes (and green sturgeon and eulachon, if it becomes available), this will minimize the uncertainties regarding the use of surrogate species and methodologies, *e.g.*, interspecies correlation analyses, to derive criteria that are consistent with the biological requirement of the species considered in this opinion.

Curve-fitted Data to Extrapolate Threshold Concentrations

The EPA is required to use toxicity data based on exposure-response curves and fixed durations toxicity tests to estimate acute and chronic toxic effect thresholds to assess effects on multiple life stages and multiple endpoints, to include at a minimum: mortality, latent mortality, reproduction, growth, physiological, cellular, behavioral, and biochemical effects, where the data exists. This requirement operates to ensure the derived criteria account for effects beyond the standard mortality, growth, and reproduction endpoints, but considers effects on a species life cycle and on sublethal endpoint that can affect the fitness and survival of affected species.

Adjust for Chemical Mixtures

The EPA is required to adjust each derived criterion for chemical mixtures using a concentration–addition model or response-addition model to determine whether or not exposure to multiple compounds will result in additive effects to the listed species. This requirement operates to ensure that environmental exposure conditions are considered in the development of the derived criteria. Fish exposed to multiple compounds, versus a single compound exposure, are likely to suffer toxicity greater than the assessment effects such as mortality, reduced growth, impairment of essential behaviors related to successful rearing and migration, cellular trauma, physiological trauma, and reproductive failure. The requirement to adjust the criteria using a concentration–addition model or response-addition model will ensure that the derived criteria have a low probability of causing additive effects to the listed species.

No Negative Change in Intrinsic Population Growth

Important assurances are provided by the requirement that the derived criteria do not result in a negative change in the intrinsic population growth rate based on the geometric mean abundance data for each life history type (as determined by a population model parameterized for Pacific salmonid fishes and otherwise meeting the RPA requirements). The requirement that the derived criteria are run through a population model is a method to assess population-level effects. A change in the intrinsic population growth rate, *e.g.*, λ, is an accepted population parameter often used in evaluating population productivity, status, and viability. The NMFS uses changes in λ when estimating the status of species, conducting risk and viability assessments, developing recovery plans, ESA consultations, and communicating with other federal, state and local agencies (McClure *et al.*, 2003). While values of $\lambda<1.0$ indicate a declining population, in cases when an exposure causes the population growth rate to decrease more than natural variability, a loss of productivity will result even if lambda remains above 1.0. Decreases in response to chemical exposures can be a cause for concern since the impact could make a population more susceptible to declining (lambda dropping below 1.0) due to impacts from other stressors. Therefore, the no change in the intrinsic population growth rate ensures that effects from the derived criteria will not manifest at the population scale, and are consistent with the recovery of the species considered in this opinion.