PROPOSED UPDATES TO AQUATIC LIFE TOXICS CRITERIA, WAC 173-201A-240 TECHNICAL SUPPORT DOCUMENT

Comments of

NiPERA
NICKEL HEALTH AND ENVIRONMENTAL SCIENCES

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1. EXECUTIVE SUMMARY

The following comments are being submitted on behalf of NiPERA Inc in response to the proposed updates to Aquatic Life Toxic Criteria (WAC 173-201A-240) Technical Support Document.

As the science branch of the Nickel Institute, NiPERA Inc. recognizes that aquatic life criteria for nickel within both the state of Washington as well as within the greater United States at the federal level do not reflect recent significant ecotoxicological developments on nickel. NiPERA acknowledges the Washington Department of Ecology's effort to utilize "new science" in the development of updated criteria. Within the current proposal, such new science is reflected as utilizing bioavailability models for copper and aluminum; however, this methodology does not extend to nickel, zinc, or lead, even though the same principles are applicable and have been well-established within scientific literature. Furthermore, the proposed hardness-based approach is not consistent with best-available science nor the updated methodologies under development by USEPA Office of Water's Cooperative Research and Development Agreement (CRADA, https://www.epa.gov/wqc/metals-crada-phase-1-report). Additionally, we have identified nearly one hundred peer-review manuscripts containing ecotoxicity data that were not considered within the criteria development. These citations are listed within this document, as well as references to publicly available databases containing the relevant ecotoxicity parameters.

NiPERA Inc. is a signatory to the USEPA's CRADA workplan. Additionally, we have engaged with other international jurisdictions including Canada, Europe, and Australia/New Zealand in the development and implementation of bioavailability-based criteriaWe would welcome the opportunity to share our extensive experience with the Washington Department of Ecology in a collaborative manner to assist in developing protective and scientifically robust criteria for metal substances in surface waters.

2. INTRODUCTION

NiPERA Inc. is the independently incorporated science branch of the Nickel Institute, specializing in environmental and human health issues surrounding nickel and nickel compounds. In the United States, the aquatic water quality criteria for nickel were last updated at the federal level in 1995 and in 1997 for the state of Washington. Since the end of the twentieth century, an abundance of ecotoxicity data has been generated for nickel and significant advancements have been made to develop more robust and accurate models for predicting toxicity in the environment.

Due to these advances, NiPERA Inc. recognizes that aquatic life criteria for nickel within both the state of Washington as well as within the greater United States at the federal level do not reflect the state of the science for metals ecotoxicology. However, we believe the update proposed by Washington Department of Ecology can be substantially improved by incorporating the use of bioavailability models for nickel and considering a greater quantity of the scientific literature to result in a more appropriate and relevant evaluation of environmental risks.

This document outlines our concerns surrounding the Proposed WAC 173-201A-240 Technical Support Document and provides justifications for alternative, or additional, methodology that is scientifically credible and is aligned with current criteria development processes around the world. Specific areas of discussion include:

- The importance of considering bioavailability in criteria development
- Bioavailability models available for nickel,
- Data selection process and omitted references, and
- Application of an acute-chronic ratio for nickel criteria.

3. DISCUSSION

3.1 Importance of considering bioavailability within regulatory frameworks

Since the 1985 USEPA WQC derivation methods (Stephen et al., 1985) were published, extensive work has gone into establishing a better understanding of metal toxicity and its effects on the environment (Adams et al., 2020). These efforts have led to approaches in quantifying the relationship between multiple environmental physicochemical parameters (e.g., pH, hardness, dissolved organic carbon) and the toxic effects observed in the presence of a metal substance (Mebane et al., 2020). In order to use the concept of bioavailability to predict the toxicity of an environment, models such as the Biotic Ligand Models (BLMs) and Multiple Linear Regressions (MLRs) have been developed (Brix et al., 2020; Di Toro et al., 2001). The principle behind these models differs in that BLMs follow a mechanistic approach to describe ionic binding at a site associated with the biota while MLRs are mathematical distillations of empirical toxicity observations. Despite these differences, the models developed for nickel have been extensively validated for applicability to a wide-range of waters throughout the U.S. and globally (Besser et al., 2021; Croteau et al., 2021; Stauber et al., 2021). Furthermore, the bioavailability models have been illustrated to perform markedly better than hardness-based equations that have been employed in the U.S. for nearly four decades (Smith et al., 2015).

Within a regulatory context, the importance of considering bioavailability has been recognized since 2007 by the USEPA and Canada (Canadian Council of Ministers of the Environment, 2007; USEPA, 2007) and in Europe since 2008 (European Commission, 2008). The guidance and implementation methods surrounding the use of these tools has varied by jurisdictions in which Europe and Canada utilize BLMs and Australia has recently elected to move forward with MLR methodology for nickel. In 2017, the USEPA initiated a Cooperative Research and Development Agreement (CRADA) with eight metals associations, including NiPERA Inc., as signatories. The objective of this ongoing agreement is to support the development of bioavailability-based aquatic life criteria (USEPA, 2023).

Since 2018, and in support of criteria development under the CRADA, NiPERA has developed expanded nickel ecotoxicity databases and bioavailability models, generated model comparison documents, and produced several peer-reviewed publications supporting the continued use of bioavailability concepts in regulatory settings (Besser et al., 2021; Croteau et al., 2021; Peters et al., 2023; Santore et al., 2021). These peer-reviewed resources should be considered for use in the derivation of statewide guidance.

3.2 Bioavailability models for nickel

3.2.1 Nickel Biotic Ligand Models (BLMs)

Several manuscripts have been published in recent years detailing updates to the nickel ecotoxicity database as well as updated bioavailability models. In 2021, Santore et al. (2021) reviewed the water quality parameters that affected nickel toxicity in aquatic systems and concluded that, along with

hardness, the concentration of dissolved organic carbon (DOC) was also a significant factor in accurately quantifying nickel effects. The impact of pH on nickel toxicity has been observed to be inconsistent but, for most organisms, there was little pH effect or a reduction in nickel toxicity observed at low pHs. This manuscript used these observations to refine the previous nickel BLM and to validate the model in both synthetic and natural waters. In a step further, Besser et al. (2021) examined the performance of the updated nickel BLM in the waters of the U.S. Midwest. These waters are considered unique as compared to the majority of freshwaters, having combinations of low pH, low hardness, and high DOC (Minnesota) or high pH, high hardness, and low DOC (Illinois). The prediction performance of BLMs was evaluated to determine the reliability and ultimately the BLM framework successfully modeled variation in toxicity for nickel across the wide ranges of chemistries.

Besser JM, Ivey CD, Steevens JA, Cleveland D, Soucek D, Dickinson A, Van Genderen EJ, Ryan AC, Schlekat CE, Garman E, Middleton E. Modeling the bioavailability of nickel and zinc to *Ceriodaphnia dubia* and *Neocloeon triangulifer* in toxicity tests with natural waters. Environmental Toxicology and Chemistry. 2021 Nov;40(11):3049-62.

Santore RC, Croteau K, Ryan AC, Schlekat C, Middleton E, Garman E, Hoang T. A review of water quality factors that affect nickel bioavailability to aquatic organisms: Refinement of the biotic ligand model for nickel in acute and chronic exposures. Environmental Toxicology and Chemistry. 2021 Aug;40(8):2121-34.

3.2.2 Nickel Multiple Linear Regression (MLR) Models

Multiple linear regression models are developed using mathematical regressions to quantify relationships in observed toxicity data, thus making them an empirical counter-part to BLMs (Brix et al., 2020). MLRs are often calibrated by accounting for the interactions of only major toxicity modifying factors (TMFs) such as pH, hardness, and dissolved organic carbon rather than a 'full suite' of water chemistry parameters. In early 2023, the USEPA published the CRADA Phase 1 Report (USEPA, 2023) which provides a review of models available to predict the toxicity of metals to aquatic life by considering toxicity modifying factors. The conclusion of this report identified that:

> *"Given the similarities in performance between the BLM and MLR approaches for several metals, EPA intends to use MLR models as the bioavailability-modelling approaching in AWQC development because of the robustness, relative simplicity, transparency, decreased number of input data needed, and ease of use of the MLR approach compared to the BLM approach."*

(Note: Despite this endorsement by USEPA, updated nickel criteria following this approach has yet to be released from the Office of Water and certain regions/states may find the BLM usage more aligned with their specific needs.)

The most recent development of multiple linear regression models has been published by Croteau et al. (2021) pertaining to U.S./North American freshwaters and, by Stauber et al. (2021) applicable to Australian freshwaters. Specifically, Croteau et al. (2021) calibrated eight acute models considering invertebrate and fish species, and eleven chronic models covering invertebrate, fish, algae and plant species. This manuscript also compared the performance of the MLR models to the BLM that was developed in Santore et al. (2021) and concluded that the performance of the two models were largely equal, though more apparent differences were noted when examining specific subsections of data.

Croteau K, Ryan AC, Santore R, DeForest D, Schlekat C, Middleton E, Garman E. Comparison of multiple linear regression and biotic ligand models to predict the toxicity of nickel to aquatic freshwater organisms. Environmental Toxicology and Chemistry. 2021 Aug;40(8):2189-205.

3.3 Data selection

In reviewing the proposed nickel criteria, it is evident that a substantial number of pertinent manuscripts were not considered in the update. Specific citations that have been identified as being omitted are listed in appendices following this document. Detailed databases of nickel ecotoxicity information have been made publicly available in the supplemental material for Croteau et al. (2021) and Peters et al. (2023). Additionally, NiPERA maintains an internal database of catalogued ecotoxicity data from peer-reviewed manuscripts and we would be happy to work with the Department of Ecology to share the applicable data and references in an effort to streamline a revision to this proposal.

For some cases in which a study was reviewed, it was accompanied by a "note" justifying its omission from being included in the criteria derivation. We appreciate and commend the transparency of this process. In reviewing the omitted studies, we note that four references (Klemish et al., 2018; Niyogi et al., 2014; Nys et al., 2016; Nys et al., 2017) accompanied the note: "static-renewal test design, according to EPA 1985 guidance chronic studies should be flow-through". However, the "Final Chronic Value" section VI-B of the 1985 guidance prescribes:

> "*Chronic values should be based on results of flow-through (except renewal is acceptable for daphnids) chronic tests in which the concentrations of test material in the test solutions were properly measured at appropriate times during the test." (Stephan et al., 1985)*

With this exception noted in the guidance, chronic toxicity tests in which daphnids were exposed to nickel in static-renewal exposures should be acceptable for consideration in criteria development.

3.4 Application of an Acute-Chronic Ratio (ACR)

The concept of Acute-Chronic Ratios (ACRs) was developed to support guideline derivations in instances where insufficient data was available, as was generally the case of chronic studies in the 20th century. Today, however, a substantial amount of high-quality ecotoxicity data is available for both acute and chronic endpoints across a wide variety of species, genus, and families. This data has been generated over the past two decades largely to support the development of bioavailability models and hazard regulations within the European jurisdictions (e.g., REACH) but, importantly, toxicity evaluations generally follow standard methodologies and use model organisms, making them applicable on a global level. Furthermore, similar to nickel toxicity, ACRs have been observed to vary depending on the different water chemistry parameters of the exposure. For instance, an ACR determined at high pH, low hardness waters will not be the same ACR observed in low pH, high hardness waters.

Due to the abundance of available data surrounding nickel ecotoxicity for both acute and chronic exposures, and the inherent variability in accurate ACRs, we advocate for the Washington Department of Ecology to consider bioavailability-based criteria for both short-term and long-term exposures, rather than applying an ACR.

4. CONCLUSIONS

This document has identified several areas under which the acute and chronic criteria proposed for nickel by the Washington Department of Ecology should be reevaluated and updated to consider more appropriate science-based methodologies. The lines of evidence presented herein include the importance of applying bioavailability concepts and models, as well as a reconsideration of the data selection, and methodologies, associated with determining the acute and chronic criteria.

5. ABOUT NiPERA & THE NICKEL INSTITUTE

With offices in North America, Europe and Asia, the Nickel Institute is the center of excellence for information on nickel and nickel-containing materials. The NI promotes sound science, risk management, and socio-economic benefit as the basis for public policy and regulation. NiPERA Inc. is the independently incorporated science division of the Nickel Institute in which we undertake leading-edge scientific research relevant to human health and the environment.

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APPENDIX A. ACUTE STUDIES NOT CONSIDERED IN PROPOSAL

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APPENDIX B. CHRONIC STUDIES NOT CONSIDERED IN PROPOSAL

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