EPA Response to Public Comments on the 2015 Draft Selenium Aquatic Life Ambient Water Quality Criterion

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EPA provided opportunities for the public to provide comments on the 2014 and 2015 drafts of EPA's recommended criterion. EPA carefully considered the comments submitted and made revisions to the final recommended criterion document in response to those comments. In addition, EPA prepared this document which includes EPA's responses to public comments submitted on the 2015 Draft Selenium Aquatic Life Ambient Water Quality Criterion document. This response document is organized in the following manner: Public comments are arranged into major categories; this was done to facilitate considering and responding to public comments overall. For each comment category a summary of overarching public comments is provided, followed by EPA responses to major subthemes for each category of comment. Following these EPA responses, specific public comments are provided. Not all, full text public comments are included here, such as those of a general nature, or those captured under specific subcategories; comments from individual commenters were divided across identified categories as noted above. For the full individual public comments, the reader is directed to the public docket. However, EPA has provided below comprehensive responses to public comments, with reference to relevant locations in the 2016 Selenium Aquatic Life Ambient Water Quality Criterion document where public comments have been addressed.

Comment Category 1.1 – Comments on Sources of Selenium

1.1 Summary

Several commenters provided specific examples of natural selenium sources that contribute to elevated ambient concentrations. Several commenters described activities, such as mining and irrigation that contribute to elevated concentrations of selenium in receiving waters. One commenter asked for an update of the selenium occurrence geographic map.

1.1 Response to comments

1.1 Response to comment on selenium occurrence maps

EPA has replaced the two selenium occurrence geologic maps with one updated figure from the USGS, (Figure 2.1. Selenium in Surficial Soils and Aquatic Sediments in counties of the Conterminous United States).

1.1 Response to the comment on natural sources of selenium

EPA referred to this issue in the 2015 draft document in section 2.1: "Selenium is a naturally occurring element present in sedimentary rocks and soils. Where deposits of Cretaceous marine shales occur, they can weather to produce high selenium soils; such soils are present in many areas of the western U.S. (Lemly 1993c). Selenium is abundant in the alkaline soils of the Great Plains, and some ground waters in California, Colorado, Kansas, Oklahoma, South Dakota and Wyoming contain elevated concentrations of selenium due to weathering of and leaching from rocks and soils." EPA has added additional text to the document, prior to the description of anthropogenic-related increases in selenium stating that "Natural weathering of selenium-bearing geologic strata containing selenium can lead to selenium leaching into groundwater and surface water."

Regarding the comment regarding inclusion of information from the GEI 2014 review on selenium occurrence, EPA did not use this information in the document as presented in that review. The review's figure (map with surface water Se concentrations) provided by GEI in their comment which shows the 2014 lentic value (1.3) exceeded at 64% of sites and lotic value (4.8) exceeded at 24% of sites used the highest selenium value measured at the sites, rather than a concentration that would better reflect the use of the entire data set, such as a central tendency estimate. EPA discussed potential approaches to assessing sites with elevated selenium background in Appendix K of the criterion document.

1.1 Response to comments on site-specific criteria and high natural background selenium

The national 304(a) chronic selenium criterion was developed based on both laboratory and environmentally-exposed organisms and was derived to protect ecosystems and organisms, most notably oviparous fish, from the adverse effects of selenium, regardless of source. The criterion is based on a 10 percent reproductive effect level in fish intended to be protective of 95% of organisms in ecosystems.

States and tribes can develop site-specific criteria, where appropriate. There may be reproducing populations of some species of resistant fish in some selenium polluted ecosystems. In developing a site-specific criterion, it will be important to ascertain if these organisms reflect an ecosystem with a healthy structure and function, prior to concluding that the designated use(s) are being met.

In Appendix K of the criterion document provides recommendations regarding site-specific selenium criteria development.

1.1 Response to comment suggesting additional references

EPA has reviewed citations recommended by commenters and included new citations as appropriate. Examples of citations and information added to the 2016 final selenium criterion document include the Petrov et al. (2012) publication regarding separate forms of selenium in wastewater samples andEPA's added text regarding selenium in shale deposits in the sources and occurrence section (Section 2.1),

which addresses inclusion of the Burau 1985 citation. EPA thanks the commenters for the citations, and Bennett and Janz 2007.

1.1 Specific comments

EPA-HQ-OW-2004-0019-0415-A1; Idaho Department of Environmental Quality (DEQ); Posted 10/28/2015

Given how much attention phosphate mining and selenium contamination have generated in Idaho it seems odd to us that Idaho's Phosphate Patch (southeastern Idaho) does not show up on the "Map indicating deposits of selenium in mining regions" (Figure 2.1, page 6). Also in the caption for this figure, the units of mg/L do not make intuitive sense to characterize "underlying geology." Perhaps what is being addressed here are measures of selenium concentrations in ground water influenced by geology? If so that should be explicitly stated.

EPA-HQ-OW-2004-0019-0401-A1; Colorado Wastewater Utility Council; Posted 10/15/2015

1.1 Background Selenium Sources and Occurrences

EPA provides some discussion of Se sources in Section 3.1 of the 2014 draft selenium criteria document. EPA discusses natural Se deposits and highlights areas where Se deposits have been brought to the surface through mining activities and where irrigation in the western United States may cause leaching from high Se soils. However, in addition to human-induced/ irreversible activities that may contribute to elevated Se in surface waters, there are also natural processes that may leach Se into groundwater, and consequently into surface waters, that were not discussed in the draft criteria document. We provided more in depth information on this topic in our previous review (GEI 2014a).

3.4.2 Appropriateness of Water Column Criteria on a National Basis

In addition, in our previous review (GEI 2014b) we raised concerns regarding naturally occurring Se deposits that may leach Se into groundwater, and consequently into surface waters (also discussed in Section 4.1.1). Previous publications and reports have presented the potential for underlying geology, rich in Se, to contribute to naturally elevated surface water Se concentrations which can be significantly greater than the default water column values recommended in the 2015 draft Se criteria document (GEI 2013a, b, Herring and Walton-Day 2007, and Burau 1985). Burau (1985) states that of general parent-rock types, shales have the highest Se content (500-28,000 µg/kg). Due the large areas of Se rich geology throughout certain regions of the U.S., a water column criteria developed on a regional basis might be more appropriate.

We conducted a review of surface water data provided through the Water Quality Portal (WQP; National Water Quality Monitoring Council), accessed May 27, 2014). The information in this database is composed of data from the USGS National Water Information System and from the USEPA STOrage and RETrieval Data Warehouse. The complete dataset was filtered for dissolved Se in surface water sampled from lotic waterbodies (e.g., rivers and streams) in Colorado.

Using the data extracted from the WQP database as described above, Se concentrations were compared to the draft lotic water quality criterion (3.1 µg/L) as plotted in Figure 1. The samples indicated by red dots indicate those samples that are in exceedance of the draft lotic criterion. Dissolved Se concentrations in lotic systems in Colorado exceed the proposed criterion of 3.1 µg/L in 30% of samples. The majority of these exceedances occur in regions that overly selenium rich geology, or on streams that have headwaters in regions with shales. Although we do not know the specific circumstances for each waterbody, it is unlikely that mining or irrigation are causing all of these exceedences.

Original letter contains Figure 1 – Shale-containing geologic formations and dissolved selenium concentrations in lotic systems across Colorado. See original letter.

In fact, GEI (2013a, b and 2014a) present information on selected stream segments in Colorado that have approved site-specific Se standards based on elevated ambient concentrations due, in large part, to the surrounding geology. These ambient site-specific standards were developed after use attainability analyses were conducted in regions with shale-containing formations and demonstrated that elevated Se concentrations were present in waterbodies with no (or limited) human influence, and that fish populations in these regions were reproducing successfully despite elevated Se in both water and their tissues, or that fish populations were limited due to other factors such as limited flow or habitat. These ambient standards have been approved by both the Colorado Water Quality Control Division and EPA Region 8.

If the EPA dataset and methods used for back calculation of water quality criteria (with the updated GEI data) is narrowed down to just samples collected in CO the resulting lotic water column concentration would be 5.8 µg/L based on 29 samples. This value is almost two times the proposed nationwide value, again demonstrating that inclusion or exclusion of only a few data points can cause a significant change in the calculated criterion, as well as highlighting the importance of consideration of regional and site-specific water quality characteristics.

EPA-HQ-OW-2004-0019-0400-A1; The National Mining Association (NMA); Posted 10/15/2015

1.1 Background Selenium Sources and Occurrences

EPA provides some discussion of Se sources in Section 3.1 of the 2014 draft selenium criteria document. EPA discusses natural Se deposits and highlights areas where Se deposits have been brought to the surface through mining activities and where irrigation in the western United States may cause leaching from high Se soils. However, in addition to human-induced/ irreversible activities that may contribute to elevated Se in surface waters, there are also natural processes that may leach Se into groundwater, and consequently into surface waters, that were not discussed in the draft criteria document. We provided more in depth information on this topic in our previous review (GEI 2014a).

EPA-HQ-OW-2004-0019-0411-A2; American Petroleum Institute (API); Posted 10/28/2015

3.1 Background Selenium

EPA provides discussion of Se sources in Section 2.1 of the 2015 draft Se criteria document. EPA discusses natural Se deposits and highlights areas where Se deposits have been brought to the surface through mining activities and where irrigation in the western United States may cause leaching from high Se soils. However, in addition to human-induced/irreversible activities that may contribute to elevated Se in surface waters, there are also natural processes that may leach Se into groundwater, and consequently into surface waters, that were not discussed in the draft criteria document.

Previous publications and reports have presented the potential for underlying geology, rich in Se, to contribute to naturally-elevated surface water Se concentrations which can be significantly greater than the default water-column values recommended in the 2015 draft Se criteria document (GEI 2013; Herring and Walton-Day 2007; Burau 1985). Burau (1985) states that of general parent-rock types, shales have the highest Se content (*i.e.*, 500-28,000 µg/kg).

3.1.1 Incorporation of Background Conditions into Site-specific Criteria

Appendix K of the 2015 draft Se criteria document, which describes methods for deriving site-specific criteria, does not discuss inclusion/consideration of data from reference or background sites. This is especially critical at sites with background levels of Se that would be considered elevated, comparatively speaking. In Appendix A, Examples 1-6 include calculation of site-specific criteria that include background Se concentrations of 5.0 µg/L. Working through the calculation results in site-specific water-column criteria that are always lower than the original background concentration. It is unclear how these calculations could be applied to sites with naturally-elevated background Se and result in a Se criterion that would be appropriate for that site.

Ambient site-specific criteria may be appropriate in many parts of the country containing underlying geology with elevated Se levels. This naturally-elevated Se may lead not only to elevated water concentrations, but also to naturally-elevated fish tissue concentrations, resulting in the need for not only site-specific water column criteria, but also a need for an approach that acknowledges there could be site-specific tissue criteria.

One example of this is a study conducted on the St. Charles River near Pueblo, CO in 2011 and 2012 with the objective of determining the appropriate water-based site-specific Se standard in a short reach of stream influenced by underlying geology rich in Se. Data were collected seasonally from 2011 — 2012 and included the collection of: water and sediment samples, fish tissue, periphyton tissue, benthic invertebrate tissue, fish and benthic invertebrate populations, and habitat evaluations. Young-of-year fish populations of several species were abundant at sites with ambient Se concentrations averaging 121 µg/L, with populations remarkably similar to those observed at sites with very low Se concentrations, indicating no effect on juvenile recruitment in these reaches with elevated Se (EPA 2015 Table E-18; GEI 2007). Fish also appeared unaffected by the Se concentrations throughout the study reach with WB Se concentrations ranging from 6.88 mg/kg dw to 105.88 mg/kg dw. A number of reasons have been postulated for the persistence of fish communities in locations with elevated Se (Canton 2010), which EPA should consider in the criteria document.

EPA-HQ-OW-2004-0019-0409-A2; OC Public Works; Posted 10/20/2015

10. Natural Background of Selenium

The natural background of selenium is not discussed in the Draft Se Criterion. A large number of waters across the nation are impacted by naturally-occurring selenium with no or insignificant anthropogenic influence. Treating natural selenium to perpetuity is clearly not reasonable and not a good use of public resources.

EPA-HQ-OW-2004-0019-0412-A2; Utility Water Act Group (UWAG); Posted 10/28/2015

2.1 Overview of Selenium Sources and Occurrence

EPA states that: "For example, in scrubbers with forced oxidation systems that produce strong oxidizing conditions and high temperatures, the majority of discharged selenium is in the form of selenate (Maher et al. 2010)." Draft Criterion at 8. While this statement is true, UWAG notes that not all flue gas desulfurization (FGD) scrubbers in operation are the forced oxidation-type. For FGD systems that are the inhibited oxidation-type, the selenium chemistry is complex and selenate may not be primary form. Petrov et al. (2012) identified a total of 13 separate forms of selenium in wastewater samples from these facilities, with selenite, selenate, and selenosulfate being the dominant species in most samples. We recommend that this citation be included in the final criterion document.

EPA-HQ-OW-2004-0019-0398-A1; Kansas Department of Health and Environmental Watershed Planning, Monitoring & Assessment Section; Posted 10/15/15

Certain Kansas streams are subject to selenium inputs from underlying marine shales from the Cretaceous Period, particularly the Pierre Shale and Niobrara Chalk, that manifests as naturally ambient concentrations that are above our current criterion of 5 µg/l, let alone the proposed 3.1 µg/l criterion. For example, numerous tributaries to the North and South Forks of the Solomon River flowing into Waconda Lake in north-central Kansas have selenium concentrations from 6.6 – 16 µg/L. The main natural source of selenium in the Waconda Lake drainage is from the weathering of upper Cretaceous bedrock that underlies the drainage basin. The upper Cretaceous bedrock, primarily the Niobrara Chalk, contains relatively high concentrations of selenium in comparison with other bedrock in Kansas. The bentonite beds and shales in the Chalk can be especially high in selenium. Soils weathered from the bedrock can have relatively high selenium content. Rainfall infiltrating through the high selenium soils and weathered bedrock leaches selenium. Water discharging from the soil and weathered bedrock transports dissolved selenium into streams. Evapotranspiration consumption of surface and ground water in the drainage basin then further increases the selenium concentration of the stream water.

Discounting the consumptive use, which concentrates selenium in those streams, we find that our background levels are persistently over the current and proposed selenium criterion, without an anthropogenic influence. The proposed use of an intermittent exposure calculation does not provide any relief because our background concentrations are often far above the 3.1 µg/l value and because experience has shown that those elevated levels are near constant. Thus the fraction of the 30-day

period used in the calculation will always be at or near 1, rendering the calculated value to be indistinguishable from the proposed criterion. We urge EPA to work with us and other Midwest and Western States to develop appropriate assessments and standards that reflect the dominant influence of geology on selenium levels seen in our streams.

EPA-HQ-OW-2004-0019-0414-A2; Colorado Mining Association (CMA); Posted 10/28/2015

CMA requests consideration of background conditions when calculating site-specific criteria

EPA does not discuss consideration of naturally-elevated background selenium when determining site-specific criteria. There are areas of Colorado that contain elevated selenium concentrations due to the geologic conditions (e.g. marine shales, seleniferous soils, etc.). There needs to be a method to derive criteria for areas that are naturally elevated in selenium. Development of criterion in these areas should still allow a discharger to operate without imposing overly restrictive limits in the NPDES permit.

EPA-HQ-OW-2004-0019-0371-A2; Wyoming Department of Environmental Quality (WDEQ); Posted 09/15/2015

The Wyoming Department of Environmental Quality, Water Quality Division (WDEQ/WQD) administers the Clean Water Act in the State of Wyoming. As such, WDEQ/WQD develops, recommends and facilitates the adoption of surface water quality standards in the State. WDEO/WQD routinely adopts EPA's recommended 304(a) criteria to protect human health and aquatic life designated uses of surface waters in the state. WDEO/WQD is particularly interested in EPA's draft aquatic life criteria for selenium due to the abundant seleniferous geologic formations in Wyoming that result in naturally high selenium concentrations in many water bodies.

WDEQ/WQD appreciates the tiered approach outlined by EPA in the draft criteria document; it is evident that criteria were developed with considerable thought toward implementation and the difficulties in applying a fish tissue based criteria into discharge permits and TMDLs. Further, WDEQ/WQD is pleased to see EPA's efforts to include recommendations on how states would adopt site-specific, fish tissue based criteria (e.g., mechanistic modeling, bioaccumulation factor approaches). However, WDEQ/WQD is concerned that the criteria may be difficult to adopt and implement in the majority of the State's waters and that EPA has not provided sufficient guidance and/or flexibility on specific issues associated with the criteria.

Naturally Occurring Selenium

As outlined in the draft criteria document, selenium is a naturally occurring element present in sedimentary rocks and soils; weathering of and leaching from these formations and soils can lead to naturally elevated concentrations of selenium in ground and surface waters. Although EPA describes these conditions in the draft criteria document, EPA doesn't go any further in describing flexibilities or recommended approaches for criteria development for states that have naturally elevated selenium. Therefore, WDEQ/WQD requests that EPA include recommendations on approaches and considerations for developing site-specific criteria for states that have seleniferous geologic formations.

2. Background Levels of Selenium

One critical issue with selenium is the presence of high background levels in many areas of the country. The presence of selenium in bedrock, and its subsequent concentration in ground and surface waters, varies across U.S. geographic regions, due to geology, climate and topography. Upper Cretaceous to Oligocene marine sedimentary rocks are variably seleniferous, whereas Pliocene and younger nonmarine sedimentary rocks are generally nonseleniferous. This is observed in the continental edges of the Western US, where bedrock geology is primarily from the Tertiary marine sedimentary deposits. As a result, adjacent surface waters and groundwaters may contain greater residuals of elemental selenium, particularly if these waters are downstream of irrigated lands.

It is also the case that the magnitude of selenium levels in drainage-affected aquatic ecosystems is strongly related to the aridity of the area and the presence of terminal lakes and ponds. These selenium concentrations can be worsened in areas where the evaporation rates are at least 2.5 times that of precipitation4. Further, erosion aids selenium transport from upland mountains from either irrigation or natural rainfall. When the runoff meets a terminal stream, pond, or other isolated body of water, evaporative enrichment of selenium occurs.4 (Two examples of these settings are Kesterson Reservoir and the Salton Sea.) The concentration may elevate even further if the area or region is arid. Because, in many cases, elevated concentrations of selenium in surface waters are due to natural conditions, aquatic organisms in these regions may not be as sensitive to the possible effects of elevated selenium concentrations as are organisms in other areas of the country. For all of these reasons, EPA should make it clear that in developing water quality standards for selenium, States should carefully consider factors such as geology, climate, topography, and the selenium sensitivity of receiving stream biota. Without consideration of these contributing factors, the water quality standards that are developed will likely be unrealistic and unattainable.

Comment Category 2.1 – Comments of a General Nature Concerning National Criterion and Primacy Structure

2.1 Summary

The majority of commenters supported the development of the criteria and hierarchy of the criterion elements. A large number of commenters supported the fish tissue primacy and criterion structure. A few commenters expressed general non-support. Many commenters were opposed to the national water column element but recommended its use as a trigger for fish tissue monitoring, implementation tool, or use in site-specific criteria. Several commenters had questions about implementation of the criterion.

2.1 Response to comments

2.1 Response to comments supporting EPAs scientific approach

EPA appreciates the many comments supporting the development and overall structure of the criterion, including those supporting EPA's:

- focus on the chronic criterion,
- focus on reproductive effects, which provide a more reliable basis for the criteria than non-reproductive effects such as survivorship and growth endpoints,
- development of tissue-based elements for this bioaccumulative compound,
- the tiered hierarchy of the criteria elements (fish-tissue as the superseding criterion element),
- use of EC_{10}s,
- data quality decisions, such as juvenile survival data including overwinter survival, and
- discussion on development of site-specific criteria.

2.1 Responses to general comments on data quality and the soundness of EPA's methodology for deriving criterion elements.

The EPA used the best available peer-reviewed science in its development of the selenium water quality criterion. The Agency reviewed all data to ensure it met the quality standards established in the 1985 Guidelines for derivation of water quality criteria for the protection of aquatic life.

In developing the 2016 final selenium criterion, EPA collected and reviewed a large quantity of peer-reviewed scientific reports. EPA evaluated 81 studies on selenium toxicity to aquatic organisms, identified in appendices C, D, and E; and in Section 3 of the criterion document. The 9 fish Genus Mean Chronic Values (GMCVs) were calculated from 12 Species Mean Chronic Values (SMCVs), which were calculated from 13 chronic values obtained from 24 studies. An additional 21 non-reproductive toxicity values were obtained from 20 studies for 10 species, including 5 species that were not used in the SD. Fish reproductive and non-reproductive toxicity test summaries are included in Appendix C and D of the 2016 criterion document, respectively. An additional 21 toxicity values from 22 studies encompassing 18

species, seven of which were not included among the reproductive or non-reproductive studies listed above, were evaluated and are included in Appendix E (other data). Three field studies with multiple species were also evaluated qualitatively to assess the relative sensitivity of Cyprinidae to selenium, and are included in Appendix E. Over one hundred studies were considered for the determination of fish tissue conversion factors (CFs). Of these, 21 studies had paired fish tissue Se measurements from two or more tissues that were used to calculate CFs. Over three hundred studies were considered that had possible paired selenium measurements in one or more ecosystem compartments (water, algae, sediment, detritus, invertebrates, and fish). Of these, 19 studies had paired invertebrate and particulate Se measurements that were used to calculate invertebrate trophic transfer factors (TTFs), 30 studies had paired fish and invertebrate measurements that were used to calculate fish TTFs, and 21 had paired water and particulate measurements that were used to calculate enrichment factors (EFs). Over 50 studies were considered that had potential information for the calculation of a trophic transfer factor based on physiological parameters. Of these, data from nine studies were used to calculate physiologically-derived TTFs.

The resulting criterion reflects a comprehensive use of the best available science that is both technically defensible and reflects a level of protection consistent with the protection goals behind other aquatic life criteria developed by the Agency. The 2016 final selenium criterion database is substantially expanded and improved over the information used to develop the prior final selenium 1999 criteria, particularly regarding the number species for which data are available and the spatial representation of the data.

Specific comments on conclusions regarding inclusion or exclusion of different studies (e.g., brown trout) from the criterion are discussed in separate responses to Specific comments.

2.1 Responses to general comments on the hierarchy or tiering of the criterion elements

EPA has developed a tiered national 304(a) criterion, and is recommending that States and Tribes adopt all four recommended elements and tiers. Tiering enhances both the scientific strength and the usability of the selenium criterion. EPA clearly articulated the application of the tiered criterion in section 4 of the 2015 draft document, and also in the final 2016 document and this is supported by independent expert peer reviewer comments.

Because the egg/ovary concentrations are the most closely associated and proximate to the adverse effects, the egg/ovary criterion element is identified as the measurement that has primacy over the other measurements, where adequate data are available. In the 2016 final criterion document EPA identified two exceptions to this tiering, 1) for new input conditions when the fish tissue concentrations may not yet reflect the “steady state” accumulation of selenium in fish tissue because of a lag time for selenium moving from the water column through the food web into fish, and, 2) for conditions where fish are absent in the aquatic ecosystem. Where fish tissue data are not available, water column elements of the criterion remain applicable to protect aquatic life.

The EPA has made some changes to the footnotes associated with the criteria table in the Executive Summary and Section 4 of the criterion document to clarify the hierarchal relationship among the tissue

elements, and between the tissue water elements, as well as assertion of primacy of water over tissue in fishless waters, and for new discharges until determination of steady state.

EPA paired data water column, detritus/plankton, and fish tissue samples collected within one-year due to availability of data, and based on statistical analyses that this approach was appropriate for national criterion development purposes. However, EPA recommends the collection of samples within appropriately proximate temporal and spatial resolution to ensure the samples represent site conditions during the collection of data for site-specific criteria development. Technical support documents, under development, will contain more information on spatial and temporal resolution of samples for site-specific criteria. Additional information on implementation of the criterion to ensure spatial and temporal representativeness of samples will be available in technical support documents. These documents will be made available for public comment after the publication of the final criteria document.

2.1 Responses to comments on the scientific defensibility of water column criterion elements

The water column criterion element values were derived taking into account accumulation of selenium in fish tissue, and are therefore intrinsically linked to the toxicity data underlying the egg-ovary criterion element. EPA used a peer-reviewed scientifically robust model developed by Luoma and Presser (2010) and worked closely with these developers to ensure that the model was appropriately applied in the development of the national water quality criterion elements for selenium. EPA also conducted additional independent external peer review to evaluate the use of the model in the derivation of the water column criterion elements for selenium.

The water column elements are critical to the construct of the selenium criterion. Because there is greater variability in the elements for water column than fish tissue, the water column elements are ranked lower in the tiering hierarchy than those based on fish tissue (see above). It is necessary to employ certain simplifications when deriving a national default water quality element, since the goal of 304(a) national criteria is to be protective of the designated uses of most waterbodies, most of the time. EPA has taken the relative variability of the water column into account in deriving the national water column criterion elements. EPA concluded it is appropriate to include both fish tissue and water column elements in the criterion to ensure that the criterion as a whole is applicable to the diversity of waterbodies in the US. In circumstances where water is the only media for which data are available (i.e., streams where fish are absent) or where selenium has not reached steady state in the ecosystem, for example, for a new discharge, the water column element of the criterion provides a scientifically-defensible translation of the fish tissue national criterion elements.

A few commenters have suggested that EPA conduct additional uncertainty analyses for the water column criterion elements. Most of the studies that provide the data used to derive the water column criterion elements do not provide enough information to conduct the analyses recommended. It would not be possible to develop a national rate-based dynamic model using speciated selenium data because sufficient data do not exist. One commenter requests an explanation of each parameter in the equation that describes the kinetics of selenium bioaccumulation. Most of these parameters are measured in

laboratory kinetic studies. All EFs and the majority of the TTFs are field-derived and because steady-state conditions are assumed kinetic parameters are not relevant. One commenter noted the discussion of growth rate in App J and requested EPA provide more detail.

- For more information on water column criterion elements, refer to responses to Comment Category 2.4. For information on translation equation (Equation 18), refer to responses to Comment Category 4.1.
- For information on deriving water column criterion element concentration value, refer to responses to Comment Category 4.7.
- For information on modification of water criterion using Equation 18, refer to responses to Comment Category 5.2.

Topic	Location in 2016 Criterion Document	Location in Appendices
Information on water column criterion elements	Section 3	
information on translation equation	Section 3	
information on deriving water column criterion element concentration values	Section 3	Appendices B, H, J, and K
For information on modification of water criterion using Equation 18		Appendix K

For information concerning over-protection or under-protection of aquatic life, refer to responses to Comment Category 2.2.

EPA has provided an expanded, overarching discussion of uncertainty in Section 6 of the criterion document. Additionally, a comparison of the calculation of a site-specific water criterion using the mechanistic model approach and the bioaccumulation factor (BAF) approach is included in Appendix K. Only one study in the water column translation dataset (Saiki et al. 1993) had sufficient data to provide a side-by-side comparison of the use of the mechanistic model and the bioaccumulation factor (BAF) approach, which was conducted for four sites. It should be noted, however, that these data are sparse, with only two selenium measurements per compartment (e.g., algae, detritus, fish species) per site. The comparison is included in Appendix K to illustrate and compare the two translation methods

2.1 Response to Request for EPA to describe parameters used in the criterion derivation

Some commenters noted that EPA should provide an explanation of parameters used in calculating the proposed water quality standard. EPA has provided parameter documentation Section 3.2.2.3 to section 3.2.6 of the 2016 criterion document. EPA also discussed the parameters and provides the data for all parameters in Appendices A, B, H, I, and J of the 2016 selenium criterion document.

2.1 Responses to general comments on the site specific selenium criterion elements.

All 304(a) national criteria are national; however, site-specific criteria can be developed if adequate data are available. Several commenters provided examples of sites where site-specific criteria were developed. For example, if a waterbody meets the fish tissue criterion element but not a water column element, the waterbody may be a candidate for a site-specific water value.

Appendix K of the 2016 selenium criterion document provides information on how a site-specific criterion elements could be developed.

Additional information on the development and implementation of site-specific criteria will be available in a WQS Flexibilities Technical Support Document to be published after the publication of the final selenium criterion.

2.1 Response to comments on effect of timing on spawning strategy and egg-ovary equivalence.

EPA notes that the text in the criterion document actually states: "In this document, concentrations of selenium in ovaries are considered equivalent to concentrations of selenium in eggs because most studies measured selenium in the ovaries prior to spawning." Section 6.1 of the 2016 selenium criterion document notes that researchers who report concentrations of selenium in fish eggs or ovaries, Osmundson et al. (2007), often found reduced levels of selenium in ovaries after spawning, presumably due to the loss of selenium through spawning and release of eggs with relatively high concentrations of selenium. Of the 14 chronic values determined from the maternal transfer reproductive studies, 11 values represent selenium measured in eggs. Three values represent selenium measured in the ovaries: Schultz and Hermanutz (1990), Hermanutz et al. (1992, 1996) and Carolina Power & Light (1997). However, information in two of these studies indicates that the concentrations of selenium in the ovaries were similar to concentrations in eggs. Schultz and Hermanutz (1990) measured selenium in fathead minnow ovaries at the end of the study from fish that presumably had spawned. The authors found the concentrations of selenium in the ovaries and embryos of the fathead minnows exposed to the same treatments to be similar. Hermanutz et al. (1992, 1996) sampled adult female bluegill just prior to spawning and at the end of the test (post spawning) and found no decreases in the concentration of selenium in the post-spawned fish. In the Carolina Power & Light (1997) study, the third study, selenium in ovaries of largemouth bass (Carolina Power & Light 1997) was measured from fish sampled just after spawning. No comparison to pre-spawning fish or selenium in eggs can be made for the largemouth bass study, however, the EC_{10} of 26.3 mg Se/kg ovary dw was mid-range of sensitivity indicating this test was not overly conservative due to lower selenium measurements in post spawning ovaries. Based on the indications that the selenium concentrations in the ovaries were similar to that in eggs in the Schultz and Hermanutz (1990) and Hermanutz et al (1992, 1996) study observations stated above, egg selenium and ovary selenium were considered equal for the toxicity data set. Any potential error resulting from this assumption would be conservative since the effect of spawning only lowers the selenium concentration in the ovary. EPA recognizes selenium ovary concentrations may vary in field collected samples due to fish reproductive cycles and will address such concerns in the implementation information.

The Conley (2014) reference has been reviewed and considered. The agency is aware that spawning strategy likely plays a role in maternal transfer and deposition of selenium into the eggs. The issue raised in Conley 2014 will be addressed in the technical support materials under development regarding the timing and type of sampling (egg-ovary vs whole body vs muscle tissue) based on species spawning strategy (single batch versus multiple smaller batches) and seasonality (spring [e.g., sunfish, some salmonids] or fall [e.g. brown trout] versus sporadic spring/summer [e.g., cyprinids]), while also providing flexibility to states to adapt their monitoring programs to address the additional requirements for fish tissue monitoring for selenium.

Thank you for your comments. EPA considered all available data for use in the derivation of the water column criterion elements. EPA applied the QA procedures described in the 2016 criterion document for the translation effort:

2.1 Specific comments

EPA-HQ-OW-2004-0019-0403-A2; Iowa Department of Natural Resources; Posted 10/15/15

EPA recommends that states adopt all elements of the proposed criteria. However, only fish tissue (egg ovary) criteria were derived based on toxicity data. All other elements of the proposed criteria were estimated to protect the fish tissue (egg ovary) criteria using models. For example, EPA derived the 30-day chronic water column element from the egg-ovary element by modeling selenium bioaccumulation in food webs of lotic and lentic aquatic systems. The modeling approach is subject to a greater degree of uncertainty than the toxicity based approach used in the derivation of fish tissue (egg ovary) criterion. As a result, the four elements of the criteria are not scientifically equivalent and thus should not be applied independently for impairment purposes.

EPA should consider removing the egg/ovary criterion from the options of media/criteria combinations available to states. As noted in Iowa Comment No.1, the egg/ovary criterion is the only criterion that is based on toxicity testing.

The remainder of the recommendations for fish tissue (whole body and muscle) and water (30-day averages and intermittent) are all modeled derivations based on the egg/ovary data. In order to standardize EPA's criteria recommendations for selenium (i.e., all modeled derivations), the egg/ovary criterion should be kept separate from the other recommendation. In addition, while there is a long history of state fish tissue monitoring programs, states do not typically analyze fish eggs or fish ovaries. EPA's tissue-based criteria recommendations for whole-fish and muscle appear to be sufficient for assessing potential aquatic life impacts due to selenium.

EPA recommends that states adopt all elements of the proposed criteria with the implication that all criteria elements be applied to all Clean Water Act programs. Such an approach, however, is scientifically and technically questionable in that not all four criteria elements are appropriate for meeting all Clean Water Act requirements. At a minimum, the criteria document should be specific as to whether EPA expects that all media/criteria combinations be applied to all CWA programs or whether states can select the most appropriate media/criteria combination to meet its varying CWA responsibilities. For example, the draft criteria document says that tissue-based criteria for selenium are

given precedence over water-based criteria. EPA should clarify the relationship between tissue-based and water-based criteria for purposes of identifying Section 303(d) impairments. Iowa's presumption is that the precedence of tissue-based criteria allows states to identify "full support" of aquatic life use in a given waterbody if levels of selenium in tissue are below the criteria even if levels of selenium in water exceed the water-based criteria.

Ambiguity on these issues in the criteria document will likely result in inconsistent application of the media/criteria combinations between EPA regions and may result in unnecessary negotiations regarding selenium criteria between EPA regions and their respective states.

EPA needs to provide implementation methodologies and examples on how to translate the fish tissue criteria to a wasteload allocation and NPDES permit limits. EPA should clarify if States can use only water column criteria to derive wasteload allocations and NPDES permit limits. In addition, EPA needs to describe how the intermittent exposure criteria should be implemented, since it is not an acute criterion.

EPA-HQ-OW-2004-0019-0398-A1; Kansas Department of Health and Environmental Watershed Planning, Monitoring & Assessment Section; Posted 10/15/15

KDHE supports EPA developing criteria using whole-body fish tissue to conduct impairment assessments for selenium. The criteria using whole-body fish tissue more closely links the pollutant to the aquatic life designated use we are trying to protect and because the predominant pathway for harmful selenium accumulations is through the food chain rather than exposure in the ambient water column. We also appreciate the elimination of the acute criterion, which the current value for Kansas is 20 µg/l. We rarely see those levels in our monitoring network and, when we have, there has been no incident of mortality of aquatic life under those elevated concentrations.

For previous TMDL and NPDES purposes, KDHE has contracted the Kansas Biological Survey to conduct a few assessments of site specific selenium data collected from the water column, sediment and fish tissue at monitoring stations on the Arkansas, Pawnee and Solomon Rivers. In doing so we found weak or non-existent linkages between ambient water concentrations and corresponding selenium accumulations in fish tissue. Some instances of elevated fish tissue concentrations above the proposed criterion of 8.0 or 11.3 mg/kg were observed, but not at a frequency one would expect to occur with consistent water column concentrations well over our current chronic criterion of 5 µg/l.

This causes us to worry that adoption of the proposed water column criterion will present an overly conservative prospectus of impairment that corresponding fish tissue levels contradict. Our preference would be to use the water column values as a non-regulatory trigger threshold to conduct more direct assessment of fish tissue accumulations to ascertain if an impaired condition is present. Alternatively, as more fish tissue data become available, we may suggest a Kansas-specific relationship between observed water column concentrations and corresponding fish tissue levels as the basis for deriving appropriate NPDES permit limits and Section 303(d) listing thresholds for selenium in the future.

EPA-HQ-OW-2004-0019-0397-A1; Peabody Energy; Posted 10/15/15

Peabody disagrees with a single water column concentration applied across the nation. EPA used site specific data to derive the proposed water column concentration. Using the same method site specific data from other areas would generate a different limit. It would provide increased accuracy to allow site specific generation of water column concentrations.

Peabody supports the use of fish tissue based standards as a method of determining appropriate Se standards. Concentrations of Se in the water column are often not predictive of concentrations of Se in fish tissue. Directly testing fish tissue appears to be the most practical approach at this time. Fish tissue limits and egg tissue limits should be included directly in NPDES permits using water column concentrations as a trigger only.

EPA-HQ-OW-2004-0019-0395-A1; CONSOL Energy; Posted 10/15/15

CONSOL is in support of EPA's decision to develop aquatic life water quality criterion for selenium, including the tissue-based criteria approach, and feels this is an improvement over the 2004 draft criteria document. These criteria are more consistent with the latest science regarding selenium toxicity. Upon reviewing the Draft document, we would like to submit the following General Comments:

- We would like to acknowledge the extensive effort that EPA and others put into development of these updated chronic selenium criteria and realize the efforts made to create a scientifically sound criteria document.
- We support the use of a fish-tissue based chronic criterion as the superseding criterion, as this is the more ecologically relevant measure of toxicity for selenium.
- We are generally in support of the following sections of the 2015 draft criteria document:
    - Tissue-based standards
    - Use of EC_{10}s
    - Timing of tissue data collection
- Exclusion of juvenile survival data

CONSOL does not agree with the approach used to develop national water-column criteria. A single nationwide standard is not appropriate. The use of site-specific water-column standards, calculated using EPA''s Equation 18 from the criteria document, would be the more scientifically justifiable approach.

EPA-HQ-OW-2004-0019-0390-A1; West Virginia Coal Association (WVCA); Posted 10/14/15

As set forth above, WVCA is pleased that the Draft Selenium Criterion are based upon fish tissue concentrations of selenium, with water column numbers considered secondary for determining the health of the aquatic system. As EPA has acknowledged, certain selenium species are more bioaccumulative than others, and site-specific factors may affect selenium toxicity. Therefore the hierarchy set for the application of selenium criteria, where egg-ovary numbers are considered over

whole body numbers, which in turn are considered over water column numbers, is appropriate and meaningful.

WVCA has concerns with a number of components of the Draft Selenium Criterion. While WVCA believes that the document contains far more political rhetoric than appropriate for a scientific criterion, we will not belabor our comments with this matter and instead will focus on the technical components of the Draft Selenium Criterion. Specifically, the methodology utilized in calculating the Draft Selenium Criterion is substantially different than typically utilized in preparing aquatic life water quality criteria. While WVCA agrees that the selenium criteria should be based upon selenium body burdens for fish, we do not agree with EPA's data decisions for inclusion and interpretation of certain studies which are critical to the calculated criteria. WVCA is also concerned with EPA's water column elements of the chronic criterion, which are back-calculated from the body burden elements using an unconventional methodology that is at odds with the procedure for preparing water quality criteria set forth in EPA's *1985 Guidelines for Deriving Numeric National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses* (1985 Guidelines). Finally, EPA places illogical conditions on the applicability of the selenium criterion, particularly regarding "fishless waters."

EPA-HQ-OW-2004-0019-0393; North Dakota Department of Health; Posted 10/14/2015

The NDDoH does not support a chronic water column criterion. The NDDoH believes that the assumptions linking levels of selenium in fish tissue to water column concentrations do not account for the numerous naturally occurring uncertainties.

The principle avenue for selenium exposure by fish and other aquatic organisms is through ingestions and not through the water column. Since selenium concentrations in North Dakota are predominately natural and increases in water column concentrations are usually linked to precipitation and runoff events, the NDDoH does not believe that a chronic water column criterion (unless triggered by a known tissue concentration) is defensible. To assign a chronic water column criterion to waterbody without adequate science is disingenuous to the state's citizens.

In summary, NDDoH's view is that the draft selenium chronic water column criteria are premature. The linkage between the tissue concentrations and the water column tenuous, and that the process for implementing the intermittent criterion impractical due to naturally occurring background concentrations. North Dakota also supports the comments provided by the state of Kentucky's Division of water.

Although NDDoH recognizes that the criterion are not self implementing, and that each state may adopt, revise or disregard these recommended criterion based on the applicable science for their waters, setting a water quality criterion well below naturally occurring background levels places an undo burden on the states to address that value during their triennial standards review. It would be better for EPA to remain silent, until the sound scientific basis is established, and let those states that desire to be more stringent proceed on their own. Also, it should be noted specifically that states may adopt criteria less stringent than the promulgated value if the science specific to their aquatic ecosystems supports it.

EPA-HQ-OW-2004-0019-0406-A2; Kentucky Chamber of Commerce; Posted 10/15/2015

While the Chamber supports U.S. EPA's efforts to update the recommended aquatic life chronic criterion for selenium to recognize the preference of using fish tissue over a water-column derived standard, the Chamber is concerned about aspects of the proposed criterion related to circumstances where water column concentration criteria would be deemed controlling. The preference for a fish tissue criterion over a water column criterion is a strength of the proposal because as noted in relevant scientific research, the toxic effects of selenium in fish are due to the bioaccumulation of selenium through diet and not the water column concentration level.

The Chamber appreciates the opportunity to provide these comments and urges U.S. EPA to narrow the recommended criterion to fish tissue criteria, which are deemed to take precedence of any water column indicators.

The two qualifiers used in footnote 3 of Table 1 of the draft criterion would trigger the controlling applicability of a water column concentration criterion and create implementation concerns due to a lack of adequate definition. First, the condition for "primacy" of a water column concentration criterion for "new or increased inputs of selenium until equilibrium is reached" is not defined by specific factors regarding the nature of the discharge, including the duration, magnitude, or frequency of such inputs. Therefore any new inputs could potentially trigger the use of the water column criterion instead of the fish tissue criterion. Second, the condition does not differentiate discharge scenarios where similar discharges of selenium have been occurring to the water body, which is frequently the case in coal mining regions of Kentucky. Third, the term "equilibrium" is especially troubling and is also not adequately defined. The lack of clarity from a technical standpoint would create much uncertainty with respect to how equilibrium conditions would be written into permits.

More fundamentally, the record does not provide a scientific basis to support the need for a stringent water column criterion to supplement the fish tissue standard with respect to all new "inputs" of selenium. Specifically, the fish tissue and egg/ovary criteria would still adequately define whether the aquatic life use is protected, and NPDES permits could be written with monitoring conditions for the water column and fish flesh to ensure the aquatic life use is protected. Therefore, the Chamber recommends deleting the conditions in footnote 3 that remove the preference for fish tissue values over water column values for new or expanded discharges of selenium.

EPA-HQ-OW-2004-0019-0379-A1; Pennsylvania Department of Environmental Protection; Posted 09/30/2015

Pennsylvania's current chronic selenium water quality criterion is 4.6 ug/L for the protection of aquatic life. EPA's proposed selenium criterion for lotic waters is 3.1 ug/L. Industries that may be affected by the adoption of this lower proposed selenium criterion could include mining activities, coal mining and processing facilities, coal-fired power plants, and coal refuse facilities. As a result, this criterion must be carefully evaluated and considered before final adoption.

EPA-HQ-OW-2004-0019-0380-A1; California Association of Sanitation Agencies (CASA); Posted 10/01/2015

Over the years, CASA members have worked with other stakeholder groups to provide comments on previous versions of the proposed selenium criteria. As such, we are very supportive of the approach taken in this most recent revision. This approach incorporates multiple tiers of criteria to establish selenium thresholds protective of aquatic life uses. As such, use of fish organ (ovary/eggs) and tissue selenium data are used exclusively when such data are available. In the absence of these direct measurements, water column selenium criteria are being proposed. By incorporating overall fish organ or fish tissue thresholds, the proposed criteria is directly assessing the aquatic life beneficial use and only relies on the less direct and less reliable water column criteria when direct organism measurements are unavailable or the water body does not currently support fish populations. Use of this approach will allow for a more direct assessment of the beneficial use impacts associated with selenium exposure and should significantly minimize unnecessary and costly selenium treatment controls in systems currently achieving these direct beneficial uses. In addition to commending the EPA on this proposed approach, CASA strongly encourages EPA to utilize such a multiple tiered approach in future criteria development and/or reevaluation whenever appropriate.

EPA-HQ-OW-2004-0019-0416-A1; Wyoming Mining Association (WMA); Posted 11/02/2015

In conclusion, WMA supports EPAs efforts to develop selenium standards that protect aquatic life. However, the final standards must be derived and applied in an appropriate, site specific and attainable manner tailored to the aquatic life being protected. WMA additionally supports the selenium comments from the National Mining Association and their consultant, GEI.

WMA can support the use of fish tissue standards as a method of determining appropriate selenium standards. Because concentrations of selenium in the water column are not always predictive of concentrations of selenium in fish tissue, directly testing fish tissue appears to be the most practical approach at this time. Fish tissue limits should be included directly in National Pollutant Discharge Elimination System (NPDES) permits using water column concentrations as a trigger only where fish are present on the specific site.

Need for Site Specific Standards and Guidance for Areas with Naturally Elevated Selenium: WMA believes it is inappropriate to specify national water column-based standards. The great variety of geologic environments, climates, and landscapes lead to tremendous variability in the aquatic life that is potentially affected. National standards cannot address this level of variability.

As the Environmental Protection Agency (EPA) acknowledges in the draft criteria document, weathering and leaching of seleniferous rocks and soils can lead to naturally elevated concentrations of selenium in ground and surface waters. Many healthy streams, ponds, and wetlands exist in Wyoming with waters that may periodically or permanently exceed the published water column standards. Often these waters provide the only source of water for wildlife and waterfowl in the local environment. For these reasons a standard, and especially a national standard, is unacceptable.

EPA needs to develop and explain clear and practical procedures and approaches for states to use in developing achievable site specific criteria for sites with naturally elevated selenium. The general and vague descriptions presented thus far do not provide adequate guidance and in fact, provide the EPA with ample opportunity to simply deny state efforts without explanation or justification.

EPA-HQ-OW-2004-0019-0384-A2; Cameco Resources; Posted 10/13/2015

Finally, we fully support the comments of the North American Metal Council-Selenium Working Group (NAMC-SWG) on both the 2014 and 2015 draft selenium criterion documents. Cameco encourages the US EPA to work with the NAMC-SWG given this group's sound, science-based perspective on issues pertaining to selenium and many years of expertise.

EPA-HQ-OW-2004-0019-0409-A2; OC Public Works; Posted 10/20/2015

The effort to update the Criterion is appropriate given that the science has progressed so much in recent years and a significant update of the California Toxics Rule may be warranted as a follow-up action. USEPA's effort to use tissue-based criteria that directly link to the true protection of designated uses is also appropriate and a significant advance over traditional water column-based criteria.

We have reviewed the comment letter from Gel Consultants, Inc. and support their recommendations, especially those on the chronic tissue criterion concentrations based on revisions to the treatment of three species. Our general comments below are primarily focused on the water column portion of the Criterion.

For the comment 1 above, USEPA should either delay the finalization of this Draft Se Criterion or incorporate the latest scientific consensus on the development of aquatic life criterion to ensure that the Draft Se Criterion is forward-looking and consistent with the latest science.

The pioneering work by Samual Luoma and Teresa Presser (extensively cited by the Draft Se Criterion), including work in the Newport Bay Watershed, recognizes the data gaps, uncertainties and the inappropriateness of the 'one size fits all' approach for water column criterion and proposed water column guideline for the watershed. In fact, due to heterogeneity, more than one water column guideline was proposed for different subareas of the Newport Bay watershed. This is a more appropriate approach.

While the tissue-based criteria appear to be based on sound and best available science, the water column portions of the Criterion have significant issues. The Draft Se Criterion includes 4 numerical criteria, all based on fish egg/ovary numbers, so egg/ovary, and to some extent whole fish, should be the primary numbers and all others secondary. Water column numbers, due to significant uncertainties and large variability in different waterbodies and environments (as elaborated below), are not equivalent with the tissue criteria and should not be treated thus.

In the past, the water column-based water quality criteria have traditionally been derived from toxicity tests directly. In fact, the 1985 Guidelines were specifically prepared for this purpose. Without a peer-

reviewed guideline that specifies a standard method to derive the water column-based criterion indirectly, as being proposed by the Draft Se Criterion, the water-column portion of the Criterion is highly questionable. Instead of being an enforceable criterion, water column numbers should be used as part of the implementation measures to gauge the progress toward attainment of tissue (including egg/ovary) criteria.

Large Uncertainties in Dataset Underlying Water Column Criteria: The water-column criteria, as derived by the bioaccumulation model, failed to acknowledge the excessively large uncertainties associated with a wide range of parameters that the model uses to translate tissue criteria to water column criteria. The trophic transfer factors (TTFs) can often vary 50% or more (Table B8), with many data unusable due to poor or even inverse correlations between the concentrations in the pray and predator (e.g. graphs on B6, B18, B63, and B67). Enrichment factors (Efs), more commonly called particle-water partitioning coefficients (Kd), can often vary by an order of magnitude or more (Appendix H, where EF varies from less than 0.1 to more than 10). With Kds and each of several TTFs bringing considerable uncertainties, the derived water column criteria suffer from exorbitant errors and uncertainties that render their correlation with tissue-based criteria extremely tenuous.

EPA-HQ-OW-2004-0019-0378; Public comment submitted by C. Lish; Posted 09/25/2015

I am pleased to see that the EPA has made improvements in the 2015 draft, compared to what was present in the 2014 draft. I approve of the EPA for lowering the criterion for lotic (flowing) water systems from 4.8 g/L to 3.1 g/L. I also approve of the clarification that water column values have primacy over fish tissue values under two circumstances: 1) “Fishless water” (waters where fish have been extirpated or where physical habitat and/or flow regime cannot sustain fish populations); and 2) New or increased inputs of selenium from a specific source until equilibrium is reached.

I strongly encourage the Environmental Protection Agency (EPA) to strengthen the chronic selenium criterion. While I understand that measuring the level of selenium in fish tissue is a scientifically defensible method for determining the current impacts of selenium in a waterway, it is wholly inadequate for enforcement of permit limits for selenium released from industry point source discharges.

EPA-HQ-OW-2004-0019-0405-A2; Virginia Coal & Energy Alliance (VCEA); Posted 10/15/2015

We support EPA’s decision to base its recommended criteria on fish tissue concentrations of selenium, and to provide a hierarchy where egg-ovary numbers are considered over whole body numbers, and both, in turn, are considered over water column numbers. This approach is appropriate, given the fact that certain selenium species are more bioaccumulative than others, and site-specific factors may affect selenium toxicity.

The Virginia Coal and Energy Alliance1 (“VCEA”) writes to comment on EPA’s Draft Aquatic Life Ambient Water Quality Criterion for Selenium-Freshwater 2015, which was published in the Federal Register on July 27, 2015. We support the use of a fish-tissue based chronic criteria as the overriding criteria, as this

is the most ecologically relevant measure of selenium toxicity. However, as noted below, we have concerns about the manner in which the criteria were derived and will be implemented.

In offering these comments, we endorse and incorporate the questions and concerns raised by West Virginia Coal Association ("WVCA") and National Mining Association ("NMA") in their written submittals. In particular, we question EPA's justification and rationale for deviating from its long-standing procedures and practices for developing water quality criteria, as set forth in the agency's 1985 Guidelines for Deriving Numeric National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses ("1985 Guidelines"). Although we generally agree that selenium criteria should be based upon selenium body burdens for fish, we do not agree with EPA's data decisions for inclusion and interpretation of certain studies that are critical to EPA's proposed criteria. We also share WVCA's concern with EPA's water column elements of the chronic criterion, which are back-calculated from the body burden elements using an unconventional methodology that is at odds with EPA's normal procedure.

Anticipating that EPA's national recommendations may one day be considered for adoption in Virginia, we are deeply concerned that many of the fish species evaluated by EPA are simply not present in our state waters. In other words, the "representative aquatic systems" considered by EPA are not, in fact, representative of Virginia. In particular, of the ten species evaluated by EPA, seven are not present or widely occurring in the state (Dolly Varden, Northern Pike, Desert Pupfish, Cutthroat Trout, Rainbow Trout, Brown Trout and White Sturgeon). We respectfully submit that before Virginia proceeds to adopt any of EPA's final criteria recommendations, the underlying analysis would have to be redone in a manner consistent with the actual "representative aquatic systems" in Virginia.

EPA-HQ-OW-2004-0019-0394-A2; Appalachian Mountain Advocates and Sierra Club Environmental Law Program; Posted 10/14/2015

Commenters are greatly concerned about EPA's Draft Recommended Aquatic Life Ambient Water Quality Chronic Criterion for Selenium, notice of which was provided in the Federal Register on July 27, 2015. These groups are very familiar with the dangers posed by selenium pollution, specifically selenium pollution from coal mines and related facilities in the central Appalachian region. Our organizations have been the primary drivers of enforcement of the existing selenium standards in the region, repeatedly overcoming efforts by industry and compliant state regulators to avoid and delay addressing the problem of selenium pollution. If EPA's Draft Criterion—which gives primacy to fish-tissue concentrations[1] in determining compliance—is finalized and adopted by states in the region, we believe that citizen enforcement will be significantly undermined and that selenium pollution in the region will not be adequately addressed by the underfunded and industry-friendly state regulators.

Commenters are concerned not only that the Criterion is effectively unenforceable, but also that it contains serious scientific flaws that render it unprotective of sensitive aquatic life, aquatic-dependent wildlife, and endangered species. In order to develop criteria that are both practically applicable and fully protective of sensitive species, EPA must revise its fish tissue elements downward before translating them to enforceable water column criteria.

The Criterion Should Be Expressed As Practically Enforceable Water Column Elements

In passing the CWA, Congress recognized the fact that water quality standards – which existed prior to 1972 – would not, of themselves, protect and improve water quality. Accordingly, Congress established the National Pollutant Discharge Elimination System (NPDES), providing a mechanism for clear application and enforcement of water quality standards. Further frustrated with a lack of progress in realizing the promise of narrative water quality goals, Congress again amended the Act in 1987, at that time requiring the development and application of numeric criteria for waterways affected by toxic pollutants. These revisions clearly illustrate Congress' intent to assure that water quality standards and goals are specific and translated into enforceable limitations on pollution sources.

Water quality criteria thus not only measure whether water bodies are meeting the uses mandated by the CWA, but also form the basis for establishing effective controls on water pollution to further the CWA's goal of "restor[ing] and maintain[ing] the chemical, physical and biological integrity of the nation's waters." See 33 U.S.C. § 1251(a). As EPA has recognized, water quality criteria must "serve the dual function of establishing water quality goals for a specific waterbody and providing the basis for regulatory controls." EPA Water Quality Standards Handbook at 4.6 (emphasis added). See also 40 C.F.R. § 130.3 (noting that water quality standards "serve the dual purposes of establishing the water quality goals for a specific water body and serving as the regulatory basis for establishment of water quality-based treatment controls and strategies"). Although a fish tissue-based criterion may be an accurate way to measure the threat posed by selenium in a waterbody (if the criterion is set at the appropriate level), it fails to provide the basis for effective regulatory action.

Based on the Commenters' extensive experience, the adoption by any central Appalachian state of a criterion that gives precedence to fish tissue elements will present obstacles to enforcement that undermine the dual function of water quality standards and will result in a lack of protection of the aquatic life in Appalachian streams, rivers, lakes and reservoirs. Because of a history of lax or non-existent enforcement by regulatory agencies in central Appalachia—particularly with regard to selenium pollution from coal mining operations—we strongly oppose the adoption of fish tissue criteria that are not translated to independently enforceable water column criteria. Indeed, the only reason that the serious problem of selenium pollution from coal mines is being addressed in the region at all is that citizens have been able to compel compliance with the existing water column criteria in permitting and enforcement actions. The state agencies have opposed and undermined those efforts at every step, consistently choosing delay and appeasement over meaningful regulation. Our experience enforcing the selenium standard in central Appalachia has taught us that the only way that coal operators and others in the region will be compelled to comply with selenium standards is if there is an enforceable water column number. We expect that this is true in many other areas of the country as well.

Indeed, in 2005, the USEPA/U.S. Department of Interior Tissue-based Criteria Subcommittee issued a draft report summarizing its opinions on aquatic life water quality standard guidelines. The report cautioned that fish tissue criteria alone would be insufficient to address "both scientific and regulatory needs concerning the relationship between chemical loadings and accumulated chemical residues in the tissues (i.e. bioaccumulation)." Science Advisory Board Consultation Document, Proposed Revisions to Aquatic Life Guidelines, Tissue-Based Criteria for "Bioaccumulative" Chemicals at 10. In the

Subcommittee's opinion, there was a "need to develop guidelines for translating tissue-based aquatic life…criteria into corresponding concentrations in environmental media (e.g. water)…" Id. At 13. The Subcommittee subsequently listed "implementability" as a reason to develop fish-tissue-to-water-column translations, noting that "monitoring and enforcing pollutant discharge limits on the basis of measured chemical concentrations in tissues of organisms may not be practical or desirable…" Id. The central Appalachian states' inability or unwillingness to enforce the existing, simple selenium water column criteria demonstrates the imprudence of adopting fish-tissue criteria that are significantly more difficult and costly to implement.

[1] For ease of use, these comments refer to the whole body, muscle, and egg/ovary elements of EPA's Draft Criterion as "fish tissue" elements.

EPA-HQ-OW-2004-0019-0414-A2; Colorado Mining Association (CMA); Posted 10/28/2015

CMA supports with the fish tissue based standard approach

CMA agrees that fish tissue standards are an appropriate method for determining selenium standards. Water column concentrations are not always predictive of concentrations in fish tissue due to many site-specific factors. Therefore, the water column concentrations should be used as a trigger only. In the event a water column concentration is exceeded, fish tissue testing should be used to determine compliance.

In conclusion, CMA supports EPA's efforts to derive selenium standards protective of aquatic life. However, such standards should be applied practically in order to prevent undue cost and burden on industry. CMA also supports comments from the National Mining Association and Gel Consultants.

CMA believes the water column concentrations are overprotective

The water column concentrations for lentic and lotic environments were derived using conservative assumptions that result in water column concentrations that are overly protective for many locations in the country. It appears that the water column concentrations were derived using the 20th percentile of the distribution of water column concentrations from selected sites. However, each of the water column concentrations shown in the distribution was based on site-specific parameters and is actually protective of location from which it was derived. The distribution shows that the appropriate criterion actually ranges from 0.23 µg/L to 50.4 µg/L for lentic sites and 1.2 µg/L to 40.6 µg/L for lotic sites. Arbitrarily using a metric such as the 20th percentile is not a valid method for determining a nationwide criterion.

Using these overly-restrictive water column concentrations as a trigger for fish tissue sampling will result in widespread fish tissue sampling that is extremely costly and difficult to measure and may not be necessary at a number of locations. Nationwide criteria may not be appropriate considering the large range in water column concentrations that is seen. Instead, it may be appropriate to address the water column concentrations regionally.

EPA-HQ-OW-2004-0019-0404-A2; Kentucky Coal Association (KCA); Posted 10/15/2015

As you are aware, Kentucky was the first state to include selenium criteria based on fish tissue levels in its Water Quality Standards (WQSs). KCA firmly believes water quality standards must be based on sound scientific rationale and appreciates EPA's recognition of this important tenet of water quality standards.

KCA conditionally supports EPA's approach to developing the chronic criterion for selenium. KCA supports EPA's draft criterion to the extent it establishes a preference for the use of a fish tissue criterion over a water column criterion. Existing science strongly supports a fish-tissue approach, and KCA appreciates that EPA is taking steps to update its criterion to reflect the scientific consensus on the use of a fish tissue based standard. KCA is concerned, however, that EPA has inadvertently developed a standard that invalidates this fish tissue preference for new or expanded discharges and in fishless waters, two scenarios of particular importance to KCA's membership.

The Water Column Values Derived by EPA are Overly Conservative and Inappropriate.

The purpose of the selenium criterion is the protection of aquatic life. In the context of selenium, the most scientifically appropriate method of determining whether aquatic life is impacted by any particular discharge is fish tissue sampling because numerous factors beyond the mere concentration of selenium in the water column influence selenium's impact on aquatic life in each stream. Without measuring and studying, redox potential, adsorption of iron and manganese, and the oxidation state of selenate or selenite in each and every water column, it is impossible to determine whether or not selenium will have unacceptable impacts on aquatic life in each and every water column. Simply put, different amounts of selenium have different effects on aquatic life in different waters. As such, a uniform nationwide water column value for selenium is not useful to the ultimate determination of whether the use of a given water will be protected, and therefore, adoption of a uniform numeric water column standard runs contrary to the intent of the rule. By contrast, a fish tissue standard provides a clear and concise standard resulting in a value with excellent repeatability nationwide.

The draft criterion includes qualifiers in footnote 3 of Table 1 that are not based on appropriate scientifically derived numeric values, and conditions for implementation that are not appropriate in a water quality standard. As currently drafted, the criterion would present significant challenges to states that would adopt and implement the criterion.

EPA-HQ-OW-2004-0019-0385-A2; Kentucky Division of Water (KDOW); Posted 10/13/2015

Deference to Tissue Based Criterion.

The toxic effects of selenium in fish are not a response to water column concentrations, but result from accumulation of selenium in fish tissue from dietary uptake (USEPA 1998). The base of the food web (plants, bacteria and invertebrates) is relatively insensitive to selenium; however, fish are exposed to potentially chronically toxic concentrations through dietary uptake (Chapman *et al.* 2010). KDOW believes a water-column threshold which prompts a collection of fish tissue is an appropriate and

protective action with regard to aquatic life. However, KDOW does not believe it is necessary to use a water column number independent of available fish tissue data unless fish tissue data are unavailable.

KDOW conditionally supports EPA's approach to developing the chronic criterion for selenium with respect to establishing a preference to the use of a fish tissue criterion over a water column criterion. The science is clearly leading in this direction. However, KDOW is concerned that EPA has not followed its own guidance (Stephan, et al. 1985) in the development of the criterion, because EPA has relied on at least one study (Linville, 2006) that does not meet the appropriate standard of rigor. KDOW is also concerned that EPA's methodology for calculating the water column criterion from fish tissue is subject to significant uncertainties and is unprecedented. In addition, the criterion includes qualifiers in footnote 3 that are not based on scientifically derived numeric values, include conditions for implementation that are not appropriate to a water quality standard, and present significant challenges to states that would adopt and implement the criterion.

EPA proposes egg/ovary data take precedence over whole-body, muscle or water column data when available. KDOW believes this is an appropriate application of the criterion since selenium toxicity is particularly manifested in fish reproduction and embryo development. However, the reliance on whole-body or muscle tissue residue concentration is equally sound and provides a protective, real-time implementation of a reliable tissue-based alternative when egg/ovary tissue data are unavailable. This approach parallels that of Kentucky's in recognizing that tissue bioaccumulation is an indicator of potential toxicity in the aquatic environment and provides the most reliable medium for monitoring selenium and protecting aquatic habitat.

1. Adopt the statement that fish tissue data should take precedence over water column data in assessing selenium levels (July 27, 20I5 80 FR No. I43 at 44352).
2. Delete the following phrase from footnotes I and 2 (July 27, 20I5 80 FR No. I43 at 44352): "except in certain situations. See footnote 3."
3. Delete the following phrase from footnote 3 (July 27, 20I5 80 FR No. I43 at 44352): "Water column values have primacy over fish tissue values under two circumstances: I) "Fishless Waters" (waters where fish have been extirpated, or where physical habitat or flow regime cannot sustain fish); and 2) New or increased inputs of selenium until equilibrium is reached."

EPA-HQ-OW-2004-0019-0415-A1; Idaho Department of Environmental Quality (DEQ); Posted 10/28/2015

DEQ appreciates the updates and revisions in the most recent draft version of the criteria and urges EPA to consider expounding on the document in consideration of DEQ comments. Attached please find our general and specific comments for EPA's consideration in finalizing this document and promulgating a new national recommendation for selenium criteria to protect aquatic life.

The document remains impressive in its depth and complexity. We commend EPA in their efforts to pull together the extensive scientific information regarding selenium toxicity to aquatic life in the updated draft selenium criteria.

Specific Questions & Comments

Footnote 3 in the table on page XIV summarizing EPA's 4 part criterion says "Water column values are based on ***dissolved*** total selenium in water" ***[Emphasis added],*** while the final statement on page 3 says "These water quality criterion elements apply to the total of all oxidation states (selenite, selenate, organic selenium, **and** ***any other forms)." [Emphasis added].*** The latter is vaguer, possibly read to be inclusive of particulate matter. Please resolve this apparent difference, be absolutely clear and consistent on this matter.

EPA-HQ-OW-2004-0019-0412-A2; Utility Water Act Group (UWAG); Posted 10/28/2015

The agency has proposed a criterion that has four elements, two fish tissue-based and two water column-based. EPA recommends that fish tissue elements be given precedence over the water column elements when both types of data are available, based on an understanding of the latest science that indicates fish tissue selenium concentrations are a more direct measure of potential selenium toxicity to aquatic life than water column concentrations. The Draft Criterion contains a recommendation that states and tribes adopt a similar approach into their water quality standards.

Many UWAG members own and operate coal-fired electric generating facilities. As selenium is a natural trace element in coal, the management of selenium streams originating from coal combustion residues is necessary for the operation of these facilities. Therefore, any proposed changes to the national recommended water quality criterion intended to influence regulatory requirements associated with selenium is of interest to UWAG. While the final revised aquatic life criterion for selenium should be adequately protective, it should not be overly conservative such that unnecessary regulatory burdens are imposed on economic activities important to the states and the nation.

UWAG commends the agency for its long-term commitment to ensuring the revised criterion is based on a strong, updated scientific foundation. We support EPA's conclusion that, based on the latest scientific information, "selenium toxicity to aquatic life is primarily driven by organisms consuming selenium-contaminated food rather than by being directly exposed to selenium dissolved in water." 80 Fed. Reg. at 44,351. UWAG also supports the agency's effort to provide detailed site-specific criteria methodologies. We have serious concerns, however, with the science underlying the draft chronic water column values and believe these issues must be addressed before EPA releases any final criterion.

UWAG appreciates the opportunity to submit comments and requests the agency to consider these comments based on relevance and merit.

Alternatively, UWAG believes EPA's existing nationally-recommended chronic aquatic life criterion (5 µg/L) is protective of all waterbody types. The implementation of this criterion in National Pollutant Discharge Elimination System (NPDES) permits has resulted in the restoration of selenium-sensitive species at many locations. EPA has provided no evidence to suggest that the current water column criterion is not protective for waters where the fish tissue criteria are not applicable (e.g., no fish tissue data are available).

UWAG appreciates the opportunity to provide these comments. We believe that the agency has correctly prioritized the proposed fish tissue criterion over the water column criterion.

UWAG's primary concern with the translation methods is that EPA does not adequately address the inherent variability in the underlying data used to back calculate a water column concentration despite acknowledging it. The methods result in a single concentration derived using average or median values for factors that can be highly variable. There are potentially serious consequences if the derived water-column concentration has considerable uncertainty, which is likely if the inherent variability of the factors from which it is derived is not considered. Applying that single concentration to a waterbody without taking into account that variability could lead to erroneous impairment or non-compliance determinations or overly stringent NPDES limits resulting in significant costs to both states and dischargers with little to no discernable environmental benefit. It also could result in criterion that is under protective of aquatic life. To address sites where one or more of the factors is highly variable, EPA should revise the Draft Criterion to allow the use of a range of site-specific water-column criteria for that particular site. The bottom line is that any translated water-column concentration must reflect the minimization (or elimination) of all possible sources of error.

Additionally, while information on the advantages and disadvantages of the two translation methods is provided, EPA does not provide any information comparing the variability of the results from the two methods. A side-by-side comparison of the variability of water-column concentrations derived with the two methods for the same waterbody would be useful to stakeholders in determining the translation method to use for a specific waterbody. UWAG requests that EPA perform the analysis and include the results, including relevant statistical parameters (*e.g.*, range, average, coefficient of variation), in the final criterion.

EPA-HQ-OW-2004-0019-0411-A2; American Petroleum Institute (API); Posted 10/28/2015

First and foremost, we strongly support EPA's decision to develop Se criteria that are both toxicologically- and ecologically-relevant.

The document is clearly laid out, the derivation method for fish tissue-based criteria follows standard protocols for water quality criteria development, and thorough descriptions of the steps used in the development of the criteria are provided. We are in support of the following core components of the 2015 draft criteria document (see Sections 1.1.1 through 1.1.4 below):

- Tissue-based (vs. water concentration-based) criteria;
- Use of EC_{10}s (*i.e.,* 10% effect concentrations);
- Timing of tissue data collection; and,
- Exclusion of juvenile survival data.

1.1.1 Tissue-based Criteria

We strongly support the approach of employing a fish tissue-based Se chronic criterion approach (*i.e.*, egg/ovary and whole-body) in the final document as the primary criterion. Fish tissue-based Se criteria

are consistent with the latest scientific information regarding the toxicology of Se to aquatic life. Tissue-based criteria are the most ecologically-relevant for Se, as they are based on the chronic toxicity pathway, which includes the bioaccumulation of Se through dietary exposure and incorporates such variables as chemical reaction rates and exchange rates between sediment, water, and organisms (Brix and DeForest 2008, Chapman *et al.* 2010). Further, the critical exposure route for fish is dietary organic selenium, which is the basis for all egg and ovary studies linked to toxicity in offspring (Janz *et al.* 2010).

EPA will need to consider very carefully how to implement tissue-based selenium criteria in determining water quality impairments and in setting technically sound water-quality-based permit limits. Permit limits must account for site-specific conditions. Quantitative links between effluent concentrations/loadings and fish tissue concentrations must account for bioavailability and chemical speciation, and not be speculative but supported by the preponderance of measured, site-specific data. We recommend EPA prepare and release for public comment a comprehensive selenium criteria implementation guide.

EPA-HQ-OW-2004-0019-0391-A1; North American Metals Council (NAMC); Posted 10/14/2015

FISH TISSUE CRITERIA areas of Agreement: NAMC agrees that the focus on chronic effects, as opposed to acute effects, is appropriate, technically defensible, and that it is supported by extensive scientific evidence. Similarly, we agree fully with EPA that reproductive effects, linked to the magnitude of fish egg/ovary selenium concentrations, are of greater ecological concern and provide a more reliable basis for the criterion than non-reproductive endpoints (*e.g.,* survivorship, growth).

The tissue criteria concentrations are not technically defensible and are demonstrably overly conservative. These inappropriately low tissue criteria concentrations and those for lentic waters will result in a very high incidence of false alarms and thus a serious misallocation of resources, thereby reducing rather than enhancing the nation's ability to address environmental problems. They will also unduly penalize industry with consequent negative economic ramifications, without an increased level of environmental protection.

Finally, we support fully the option for the development of site-specific criteria based on appropriate scientific studies. Cases of naturally elevated selenium concentrations in water have been documented, as have elevated selenium concentrations in fish above the proposed criteria, without adverse effects (Chapman *et al*., 2010; 2015 EPA Selenium Draft). In these cases, ambient-based tissue standards may be appropriate.

EPA-HQ-OW-2004-0019-0401-A1; Colorado Wastewater Utility Council; Posted 10/15/2015

As stated in our prior review of the 2014 draft document, we commend EPA's effort in developing Se criteria that are consistent with the latest science regarding Se toxicity. We support the use of a fish-tissue based chronic criterion as the overriding criterion, as this is the most ecologically relevant measure of toxicity for Se. We also agree with the use of EC_{10}s rather than some other endpoint, as this

is the more conservative approach. We also support EPA's conclusions regarding the timing of tissue data collection that samples collected within one year of each other are reasonable for acceptability.

The EPA approach in the 2015 draft Se criteria document is more in line with standard water quality criteria development methodology (Stephan et al. 1985) than previous attempts at revising and updating the Se criteria, and includes a critical evaluation of 16 studies on various fish species and results in Se tissue thresholds for twelve fish species in ten genera. Criteria calculations follow recommendations by Stephan et al. (1985) and use the 5th percentile calculation accounting for the relative sensitivities of all species in the data set. This approach results in more scientifically defensible criteria than the previous draft tissue criterion based on a single study.

As we stated in our review of the 2014 draft document, this document and the tissue-based criteria approach is a significant improvement over the 2004 draft criteria document (EPA 2004). We strongly support EPA's decision to develop Se criteria that are toxicologically and ecologically relevant.

The document is clearly laid out, follows standard protocols for water quality criteria development, and includes thorough descriptions of the steps used in development of the criteria. We are in support of the following core components of the 2015 draft criteria document (see Sections 2.1 through 2.4 below):

- Tissue-based standards,
- Use of EC10s, and
- Timing of tissue data collection
- Reliance on maternal-transfer related data over juvenile survival data

In addition, in Sections 3 and 4 of this review, we have provided several recommended revisions and considerations that we believe will make the 2015 draft criteria document even more scientifically sound.

We do not agree with the approach used to develop national water-column criteria. Our review provides discussion on why single nationwide standards are not appropriate and why site-specific water-column standards, calculated using EPA's Equation 18 from the criteria document, are a more scientifically justifiable approach. In addition, we provide an example of how limited the data set used by EPA to develop the national water-column criteria is, and how inclusion of additional data can make a substantial difference in the calculated water column criteria. Lastly, we would strongly recommend EPA consider changing the paradigm for National Pollutant Discharge Elimination System permitting such that direct use of tissue criteria would be possible. To our understanding, there is nothing in the Clean Water Act that would preclude this. By writing permits to the most defensible endpoint of tissues, EPA would eliminate the need for backing into water concentrations by methods that invariably add significant error and uncertainty.

1.1 Tissue-based Standards

As stated in our previous review, we strongly support the approach of a fish tissue-based Se chronic criterion approach (egg/ovary and whole-body) in the final document as the primary criterion. Fish tissue-based Se criteria are consistent with the latest scientific information regarding the toxicology of Se to aquatic life. Tissue-based criteria are the most ecologically relevant for Se, as they are based on

the chronic toxicity pathway which includes bioaccumulation of Se through dietary exposure and incorporates such variables as chemical reaction rates and exchange rates between sediment, water, and organism (Brix and DeForest 2008, Chapman et al. 2009). In addition, we strongly urge EPA to consider how such tissue-based criteria can be directly incorporated into National Pollutant Discharge Elimination System (NPDES) permitting, as discussed further later in this review.

Based on the results of our analysis, we recommend updating the proposed egg/ovary, whole-body, and muscle chronic criteria to include our suggested changes (Table 8). In addition, because nationwide water column-based criteria should not be derived, we advise EPA to only recommend site-specific water column-based criteria on a site-by-site basis (Table 9).

EPA-HQ-OW-2004-0019-0400-A1; The National Mining Association (NMA); Posted 10/15/2015

As stated in our prior review of the 2014 draft document, we commend EPA's effort in developing Se criteria that are generally consistent with the latest science regarding Se toxicity. We support the use of a fish-tissue based chronic criterion as the overriding criterion, as this is the most ecologically relevant measure of toxicity for Se. We also agree with the use of EC_{10}s rather than some other endpoint, as this is the more conservative approach. We also support EPA's conclusions regarding the timing of tissue data collection that samples collected within one year of each other are reasonable for acceptability.

The EPA approach in the 2015 draft Se criteria document is more in line with standard water quality criteria development methodology (Stephan et al. 1985) than previous attempts at revising and updating the Se criteria, and includes a critical evaluation of 16 studies on various fish species and results in Se tissue thresholds for twelve fish species in ten genera. Criteria calculations follow recommendations by Stephan et al. (1985) and use the 5th percentile calculation accounting for the relative sensitivities of all species in the data set. This approach results in more scientifically defensible criteria than the previous draft tissue criterion based on a single study.

As we stated in our review of the 2014 draft document, this document and the tissue-based criteria approach is a significant improvement over the 2004 draft criteria document (EPA 2004). We strongly support EPA's decision to develop Se criteria that are toxicologically and ecologically relevant.

The document is clearly laid out, follows standard protocols for water quality criteria development, and includes thorough descriptions of the steps used in development of the criteria. We are in support of the following core components of the 2015 draft criteria document (see Sections 2.1 through 2.4 below):

- Tissue-based standards,
- Use of EC10s, and
- Timing of tissue data collection
- Exclusion of juvenile survival data

In addition, in Sections 3 and 4 of this review, we have provided several recommended revisions and considerations that we believe will make the 2015 draft criteria document even more scientifically sound.

Our comments on the 2015 EPA Selenium Draft focus primarily on the fish tissue criteria derivations. While we agree that criteria derived from fish will protect the aquatic community, the criteria must be technically defensible and not overly conservative. Neither is now the case. The present proposed criteria are based on technically flawed data and incorrect assumptions. We provide evidence for higher but still environmentally protective concentrations (i.e., at least 20 mg/kg egg/ovary selenium), which was also noted in our comments to the 2014 EPA draft. We are concerned that the present overly conservative fish tissue criteria, in addition to the overly conservative lentic water criterion and other inappropriate, unrealistic components of the 2015 document, will result in a high rate of false alarms that will further result in a serious misallocation of resources, thereby reducing rather than enhancing the nation's ability to address environmental problems and unnecessarily penalizing industrial activities with concomitant economic costs but without concomitant environmental benefits.

We do not agree with the approach used to develop national water-column criteria. Our review provides discussion on why single nationwide standards are not appropriate and why site-specific water-column standards, calculated using EPA's Equation 18 from the criteria document, are a more scientifically justifiable approach. In addition, we provide an example of how limited the data set is, and how inclusion of additional data can make a substantial difference in the calculated water column criteria. Lastly, we would strongly recommend EPA consider changing the paradigm for National Pollution Discharge Elimination System (NPDES) permitting such that direct use of tissue criteria would be possible. To our understanding, there is nothing in the Clean Water Act that would preclude this. By writing permits to the most defensible endpoint of tissues, EPA would eliminate the need for backing into water concentrations by methods that invariably add significant error and uncertainty.

1.1 Tissue-based Standards

As stated in our previous review, we strongly support the approach of a fish tissue-based Se chronic criterion approach (egg/ovary and whole-body) in the final document as the primary criterion. Fish tissue-based Se criteria are consistent with the latest scientific information regarding the toxicology of Se to aquatic life. Tissue-based criteria are the most ecologically relevant for Se, as they are based on the chronic toxicity pathway which includes bioaccumulation of Se through dietary exposure and incorporates such variables as chemical reaction rates and exchange rates between sediment, water, and organism (Brix and DeForest 2008, Chapman et al. 2009). In addition, we strongly urge EPA to consider how such tissue-based criteria can be directly incorporated into NPDES permitting, as discussed further later in this review.

EPA-HQ-OW-2004-0019-0388-A2; J. R. Simplot Company; Posted 10/14/2015

The J.R. Simplot Company (Simplot) has the following comments on the 2015 Draft Criterion for consideration to aid in developing a protective criterion that is not unduly conservative.

The 2015 Draft Criterion, overall, is based on a scientifically defensible approach and rationale. Simplot supports the choice of a fish egg/over tissue value as the criterion. There are though, several aspects of the document where EPA chose to be overly conservative. In the comments that follow, Simplot identifies several issues where conservatism unnecessarily increases uncertainty in the approach taken

and the resulting criterion value derived. In particular, our comments focus on the brown trout study (Formation Environmental 2011). The unnecessary conservatism is also evident in the selection of the final values derived to makeup the various elements for the National Criterion, particularly the derivation of the final lotic and lentic values for water. Simplot also notes that EPA failed to address issues identified in the review of the 2014 Draft Criterion in respect to the field data associated with the brown trout data.

A.3. Derivation of Water Column Values and Uncertainty in Enrichment Factors

[Pages 90-92, Section 4]

This four part criterion advocates the primacy of the egg/ovary element over other elements of the criterion except under the conditions listed in Table 4.1, footnote 3 (page 91). But the statement, " ... and inclusion of the water column elements into the selenium criterion ensures protection when neither fish egg-ovary nor fish whole-body or muscle tissue measurements are available, and provides consistent coverage for all waters" appears to provide for an optional use of a water criterion when fish tissue data are not available instead of generating the necessary data. In other words, States may simply default to the water criterion if no fish tissue data were available. In fact this appears to be amplified by the following, "Where states use the selenium water column concentration criterion element values only (as opposed to using both the water column and fish tissue elements) for conducting reasonable potential (RP) determinations and establishing water quality-based effluent limitations (WQBELS) per 40 CFR 122.44(d), existing implementation procedures used for other acute and chronic aquatic life protection criteria would be appropriate."

The language above imp lies that only the water criterion element maybe used as opposed to using the fish tissue element for deriving WQBELs for NPDES permits which is likely to result in unnecessarily low permit limits.

Allowing a water concentration to take precedence in any circumstance, where it is not specifically derived from bioaccumulation information available for a state or region, is not consistent with the recommendations in Appendix K, nor the scientific information available indicating that numerous factors that can affect selenium bioaccumulation.

Simplot understands EPA's desire to ease the burden for State's and regulated entities to assess compliance relative to a tissue standard by deriving an aqueous criterion equivalent. However, selection of a single value for a selenium water criterion on a national scale when the prevailing information indicates site or regional specificity in the bioaccumulation of selenium simply is not consistent with the science nor adequately representative of all sites. Multiple factors affect development of a water value from a tissue threshold that creates uncertainty. That uncertainty is multiplied by developing and applying a single water criterion across the entire US with the only distinction being lotic or lentic habitats. This compounding of uncertainty stems not only from species specific bioaccumulation and effect for fish, but also from site specificity in the uptake of selenium into the base layer of the food chain (i.e., enrichment factors) and the high level of uncertainty associated with enrichment factors (EFs). Reviewers of the 2014 Draft Criterion (i.e., Deforest and Cutter, ERG 21 04) have pointed out that the variability in derivation of the EF (i.e., algae, algae and sediment, sediment alone as the particulate fraction) and subsequent use in the Presser and Luoma (2006) model (i.e., kinetic/rate approach, and

not an equilibrium thermodynamic) which pose additional uncertainties that are not accounted for in the model.

Furthermore, because the difference in EFs is wide ranging, based on the type of system being evaluated (low selenium background or reference sites vs high selenium impact sites); the selection of streams that are used to derive a single composite national criterion for water is critical if not impossible to be representative. There is typically an inverse relationship between the exposure concentration and the EF such that low aqueous selenium will result in relatively high EFs and high aqueous selenium will result in low EFs.

Much like the existing revised national copper criterion has been developed to take into account site specific modifying factors that affect toxicity using the Biotic Ligand Model, the selenium criterion should similarly also provide a similar path. That framework is already present in the existing document.

Because EPA has derived a national aqueous criterion value, many states may simply opt to use that value rather than develop the necessary information to provide a state or regional specific criterion for selenium. As noted in Simplot's prior comments on the 2014 Draft Criterion, a reasonable approach is that the aqueous value should ideally serve as a "trigger or screening value" to set in motion the potential need for additional monitoring and data collection rather than it being a set criterion value. For fishless waters, monitoring would entail collecting the necessary information to conduct trophic modeling and with the assumption that the species to be protected is the fish species downstream of the fish less water as described in Appendix K of the 2015 Draft Criterion.

EPA-HQ-OW-2004-0019-0374; Anonymous public comment; Posted 09/23/2015

The 2015 draft Se fish tissue duration and frequency are incompatible with EPA's 2000 fish tissue monitoring guidance, which specifically names selenium as one of the pollutants it applies to:

Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories Volume 1 Fish Sampling and Analysis Third Edition.

The fish tissue monitoring guidance offers far greater scientific rigor than EPA presented in its 2015 draft fish tissue criterion duration and frequency discussion. For the sake of consistency of state approaches for assessing fish tissue, please either incorporate the concepts of that guidance, or explain why you believe that the protection of human individuals allows a far more lenient approach than the protection of aquatic populations.

The relevant part of the fish tissue monitoring guidance, cited by the mercury implementation guidance, is presented below:

6.1.2.7.2 Comparison of Target Analyte Concentrations with Screening Values for Issuing Fish Advisories – Using the statistical model described in Section 6.1.2.7.1, target analyte concentrations from replicate composite samples at a particular site can be compared to screening values using a t-test. Assume that zi is the contaminant concentration of the ith replicate composite sample at the site of interest where i=1,2,3,...,n and, furthermore, that each replicate composite sample comprises m individual fish fillets of equal mass. To test the null hypothesis that the mean target analyte

concentration across the n replicate composite samples is equal to the SV versus the alternative hypothesis that the mean target analyte concentration is greater than the SV, perform the following steps:

1. Calculate ~z, the mean target analyte concentration of observed replicate composite samples at a site: ~z = [Summation] zi / n

where the summation occurs over the n composite samples.

Calculate the estimate of the Var(~z), s^2 :

s^2 = [[Summation](zi - ~z^2] / [n(n – 1)]

where the summation occurs over the n composite samples.

Calculate the test statistic: tc = (~z – SV) / s

The null hypothesis of no difference is rejected in favor of the alternative hypothesis of exceedance if tc > t alpha, n-1

where t alpha, n-1 is the tabulated value of the Student-t distribution corresponding to level of significance and n-1 degrees of freedom. Note that the inequality is in one direction (>) since it is exceedance of the SV that is of interest. When several sites are sampled and/or fish of different size ranges are collected, it is important to conduct the test separately at each site and for each size range. Combining sites or size ranges introduces variance components that are not accounted for in this procedure. The variance estimate may be larger with the additional sources of variability, and more replicate samples may be needed to detect a significant overall exceedance of the SV.

EPA-HQ-OW-2004-0019-0371-A2; Wyoming Department of Environmental Quality (WDEQ); Posted 09/15/2015

Sample Representativeness and Requirements

WDEQ/WQD requests that EPA include a discussion on the variability in fish tissue concentrations, including the intra-fish, intra-species and inter-species variability within the revised criteria document. WDEQ/WQD is concerned that fish tissue variability may cause fish samples to fluctuate between attainment and non-attainment of standards for each successive assessment cycle. Further, the criteria document does not include recommendations on a sufficient sample size that can account for this fish tissue variability. Accordingly, WDEQ/WQD requests EPA to include recommendations on sample sizes for the various fish tissue elements to minimize mischaracterization of a waterbody.

Water Column Data

EPA's draft selenium criteria includes four elements: a fish egg and/or ovary concentration, a fish whole-body or muscle concentration, a 30-day average concentration for lotic and lentic systems, and an intermittent exposure water column concentration. The draft criteria document recommends that states adopt all four elements of the draft criterion into water quality standards as a single criterion

composed of multiple parts. Under "steady state" conditions (i.e., food-web equilibrium), EPA explicitly affirms the primacy of the whole-body or muscle elements over the water column element, and the egg-ovary element over any other element. The draft criteria document also states that freshwater aquatic life would be protected from toxic effects of selenium by applying *all four elements* of the criteria.

Though the draft criteria provides adequate protection from selenium toxicity through all four elements, WDEO/WQD is concerned that only water column measurements will be available for the majority of Wyoming waters. The use of water column elements may not accurately reflect concentrations that are protective of aquatic life, especially since toxicity to aquatic life is primarily driven by dietary exposure (i.e., consumption of selenium-contaminated prey) rather than direct exposure to dissolved selenium in water. Further, water column elements are derived from fish tissue concentrations by way of food-web modeling, hence water column elements are the least accurate of the criteria elements. WDEQ/WQD requests that the criteria document outline that states have flexibility to not identify waters as impaired if data show an exceedance of the water column value and no fish tissue are available. The criteria document could recommend that states conduct tissue monitoring in these instances to confirm impairment. These provisions may prevent states from placing waters on the 303(d) List when aquatic uses are actually being supported.

EPA-HQ-OW-2004-0019-0376-A2 [Comment 0381-A3 is a duplicate of 0376-A2]; Texas Commission on Environmental Quality (TCEQ); Posted 09/24/2015

Comments on Proposed Draft Criterion

EPA's statement that the criterion is comprised of four elements is misleading. The draft criterion document states "the draft criterion has four elements" (Table 1), consisting of two fish tissue-based and two water column-based elements." However, EPA is requesting states and authorized tribes to protect for a total of six different numeric aspects, as identified above. EPA should clearly state the various components of the criterion and provide sufficient guidance to incorporate these components into water quality management programs.

EPA-HQ-OW-2004-0019-0413-A2; Federal Water Quality Coalition (FWQC); Posted 10/28/2015

We commend the Agency for revisiting the selenium criteria, and for developing new criteria that better reflect the state of the science than do the current criteria. In particular, these are aspects of the Criteria Document that we support:

- The Draft Criteria Document appropriately focuses on chronic effects, and does not recommend an acute criterion.
- In assessing chronic issues, the Draft Criteria Document appropriately focuses on reproductive effects, which provide a more reliable basis for the criteria than non-reproductive effects such as survivorship and growth endpoints.

• Studies concerning reproductive effects are used appropriately. Studies on juvenile survival, including overwinter survival, are not used directly.
• The Draft Criteria Document clearly states as a general matter (with exceptions discussed below) that fish tissue data should take primacy over water column data in assessing whether the criteria are met.
• The Draft Criteria Document allows for development of site-specific criteria where that is appropriate for particular situations.

While we support those aspects of the Draft Criteria Document, there are a number of specific issues on which we have concerns about the scientific basis for the recommended criteria. Also, there are several issues on which we think that the EPA approach needs to be clarified. These issues are discussed in detail below.

Converting Data to Fish Tissue Levels: As noted above, the FWQC supports the use of fish tissue levels in whole body, muscle, or egg-ovary concentrations as the primary form for selenium criteria to be expressed. However, prior to establishment of final fish-tissue and organ concentrations, several issues need to be addressed with respect to uncertainties involved in converting data to fish tissue levels in whole body, muscle or organ. Methods to address uncertainty, such as log/log plot regression, linear plot regression, and central tendency of the ratios need to be considered. Further, sound scientific methods exist to control for natural variability through sampling design, ecoregion classification, and regression model application.

II. PRIMACY OF FISH TISSUE DATA

As noted above, the FWQC supports EPA's structuring of the new criterion so that fish tissue data has "primacy" over water column data. The peer reviewers generally supported that approach as well. In fact, some of the reviewers recommended that the water column levels be considered only as "triggers," instead of as part of the criterion. In those comments, the reviewers indicated that the Agency should clarify exactly what "primacy" means – in other words, how fish tissue and water column data should be considered in determining whether the criterion has been attained. However, despite these recommendations, the Agency has not provided that clarity, making several statements about the primacy issue that are not consistent with each other. EPA should state clearly that the fish tissue elements of the criterion do have primacy – in other words, if the fish tissue data show that the fish tissue level in the criterion is being met, then the waterbody is meeting standards. The Agency should also consider making the water column levels into "triggers" rather than elements of the criterion.

Here are some examples of what the peer reviewers had to say about primacy:

"Although I agree that the primacy of each criterion element is logical, it is not clearly stated whether a water Se criterion could be adopted into a permit limit. For example, if compliance with the lotic or lentic Se criterion is demonstrated, is measurement of fish tissue Se concentrations necessary? If a water body meets a fish tissue-based Se criterion, but not a surface water criterion, would the water body be considered in compliance? I believe the answer to the latter is "yes", but this does not seem to be clearly stated in the draft AWQC document." (p. 18)

"The use of water column concentrations of selenium as environmental assessment tools or as triggers for additional assessment is fraught with uncertainty from several sources, which are discussed in subsequent sections of this review." (p. 25)

"However, to use water column [Se] as a criterion in of itself in the absence of tissue [Se] data is a recipe for inappropriate conclusions, which may penalize industry (i.e., false positives) or cause harm to certain fish populations (i.e., false negatives). I strongly believe that water column [Se] should be used more as a "trigger" to initiate further monitoring that includes collection of fish for tissue [Se] determinations." (pp. 30-31)

"However, based on comments provided above (in 1 and especially 2a(iii)), relying on water column dissolved [Se] has a high likelihood of generating both false positive and false negative results with respect to regulatory action. I think the proposed water column criteria (a) should be used as triggers to initiate further monitoring of fish tissue [Se], (b) should be made more conservative (reduced) by application of a safety factor to avoid false negatives, and (c) that the simple classification of a water body as lentic or lotic should be modified to include more quantitative measures of flow such as water residence time and/or mean annual water velocity. Given that many impounded riverine systems in the USA are essentially lentic systems for much of their river-miles, perhaps a water column trigger [Se] could be set at 1 ug/L (same as the current Canadian [CCME] water quality guideline for Se). If exceeded, this trigger value would result in further action in terms of fish collections for tissue [Se]." (pp. 97-98)

In responding to these concerns, EPA could have made a simple statement that if the fish tissue level in the criterion is met, then the criterion has been attained, regardless of the water column level. At one point (cited below), the Agency does say that tissue data "will always supersede" water column data. However, at other points (also cited below), EPA indicates that if the fish tissue levels are being attained but the water column levels are not, then more inquiry is called for. We believe that such an "inquiry" is simply inconsistent with the concept that the fish tissue data have "primacy." To ensure that the fish tissue data are treated as the primary element of the criterion, we believe that EPA should consider treating the water column levels as "triggers" for further assessment, rather than as components of the criterion.

Here are some of the EPA statements on "primacy" that give rise to confusion:

> "Regarding the purpose of the water criterion elements, one of the purposes of the water-based criterion element(s) was to facilitate having an easily implemented value in permits. If a waterbody meets the fish tissue limits yet not a surface water criterion, for an existing input source, it is likely that the site specific dynamics of selenium bioaccumulation may be different than the basis of the national criterion, and this waterbody may be a candidate for a site-specific water value." (p. 15)
>
> "The hierarchy of the criteria is such that, for an existing input, a tissue sample will always supersede the result of the water element, because the tissue sample(s) are most closely associated with the endpoint of concern: reproductive impacts on aquatic species. In the situation the peer reviewer presented, tissue sample(s) could be collected to confirm or refute the result of the water sample(s)." (p. 21)

"Regarding uncertainty associated with the water column criterion elements, EPA recognizes this uncertainty, but notes that the water column element is useful for implementing in permits, and in certain situations water will be the preferred sample in the case of water bodies with new discharges of selenium or where adequate fish samples are not available. In situations where both fish tissue and water samples are available, the water column values are backstopped by the fish tissue criteria elements in the hierarchal construction of the criterion and thus provide a means for reducing the uncertainty." (p. 25)

"Regarding the tiered approach, the water column criteria is backstopped with the hierarchal construction of the tissue criteria; exceedance of a water column value, can be confirmed via sampling of fish tissue." (p. 30)

"The water column criterion element values were derived using the egg-ovary criterion element as the basis of the calculation. EPA developed water column criterion values because routine water concentration monitoring of selenium is more practically feasible than routine tissue monitoring, and used a hierarchal (tiered) approach to insure that water column values indicating a selenium problem could be vetted using a fish tissue sample, because the fish tissue selenium concentrations are indicative of potential effects. Water column values are necessary because they may be the only media data available – i.e. streams where fish are absent, or temporally necessary due to a new discharge where selenium has not accumulated in the system, and so there is uncertainty in the relationship between the discharge and the potential for bioaccumulation in fish at the site." (pp. 97-98)

Each of those EPA statements gives a different rationale for including water column levels in the criterion, and each expresses the relationship between the fish tissue levels and the water column levels in a different way – from fish tissue "superseding" water column, to fish tissue "backstopping" water column. The Agency needs to provide a clear, consistent explanation of how the criterion will work

EPA-HQ-OW-2004-0019-0389-A1; Thunder Basin Coal Company, LLC (TBCC); Posted 10/14/15

Thunder Basin Coal Company, LLC (TBCC) operates surface coal mines located in the Wyoming Powder River Basin and holds valid permits to mine, which include provisions to protect water quality and compliance with all applicable water quality regulations. We support National Mining Association's (NMA) comments and Wyoming Mining Association's (WMA) comments as provided and emphasize the following major points:

Incorporation of Background Conditions into Site-specific Criteria: It is inappropriate to specify national water column-based standards for selenium or any other criterion. The great variety of geologic environments, climates, and landscapes lead to tremendous variability in the aquatic life that is potentially affected. National standards cannot address this level of variability. As EPA acknowledges in the draft criteria document, weathering and leaching of seleniferous rocks and soils can lead to naturally elevated concentrations of selenium in ground and surface waters. Many healthy streams, ponds, and wetlands exist in Wyoming with waters that may periodically or permanently exceed the published water column standards in a natural environment. Often, these waters provide the only source of water for wildlife and waterfowl in the local environment. EPA should develop methods to use natural

background Se concentrations to develop ambient based site-specific criteria (either tissue or water-based) where elevated concentrations are present unrelated to human-induced sources. EPA's discussion of site-specific standard development includes nothing on this issue and needs further clarification. For these reasons, a standard, and especially a national standard, is unacceptable.

EPA needs to develop and explain clear and practical procedures and approaches for states to use in developing achievable criteria for their respective states with consideration of the items mentioned above. The general and vague descriptions presented thus far do not provide adequate guidance and in fact, provide the EPA with ample opportunity to simply deny state efforts without explanation or justification.

Fish Tissue Based Standards: We support the use of fish tissue standards as a method of determining appropriate selenium standards. However, each state must take on this responsibility and develop state-specific standards that apply to their regions. Because concentrations of selenium in the water column are not always predictive of concentrations of selenium in fish tissue, directly testing fish tissue appears to be the most practical approach at this time. Fish tissue limits should be included directly in NPDES permits using water column concentrations as a trigger only where fish are present on the specific site.

EPA-HQ-OW-2004-0019-0402-A2; The Stakeholders Implementing TMDLs in the Calleguas Creek Watershed; Posted 10/15/2015

1. A Universal, Nationally Applicable Water Column Number Is Inappropriate Due to the Site-Specific, Bioaccumulative Nature of Selenium. As such, the 2015 Draft Selenium Criterion Should Only Be Based on Fish Tissue Elements, with Water Column Concentrations Used as a Tool for Implementation of the Criterion.

As stated in Comment #4, the Stakeholders strongly support the approach recommended by USEPA in the 2015 Draft Selenium Criterion pertaining to the tissue-based elements as it provides for the direct assessment and protection of beneficial uses. Notwithstanding this support, the inclusion of water column elements within the 2015 Draft Selenium Criterion is inappropriate as these elements will be either over- or under-protective of the aquatic life present in most water bodies. The type of aquatic environment (e.g. lotic/lentic, marsh/riparian, etc.) and food webs present in a waterbody effect selenium bioavailability and toxicity.[10, 11, 12, 13] In addition, the species of selenium, particulate selenium concentrations, and the resultant biogeochemical transformations and accumulation in the food web can differ substantially even at similar dissolved concentrations.

For instance, in the Calleguas Creek watershed, located in Ventura County in Southern California, co-located fish tissue and water column selenium concentration data were collected from 2008 to 2013 in Revolon Slough, a freshwater tributary to Calleguas Creek. In this lotic system, the water column concentrations are significantly greater than the water column element of the 2015 Draft Selenium Criterion (3.1 µg/L) for over 84% of results and by as much as a factor of eleven (Figure 1). Despite the water column concentrations, which would indicate an impairment to aquatic life according to the 2015 Draft Selenium Criterion, the muscle tissue concentrations are almost all below (with two exceptions) the muscle tissue element of the 2015 Draft Selenium Criterion (11.3 mg/kg). As such, if the water

column element of the 2015 Draft Selenium Criterion were applied in this water body, unnecessary management actions would need to be taken to meet a concentration in the water column that clearly has no relation to the water column concentration necessary to protect aquatic life.

Further, in the Newport Bay watershed, a relatively small watershed located in Southern California, initial model runs of the Luoma Presser model for two tributaries, Peters Canyon Wash and Big Canyon Wash, demonstrate a wide range of water column concentrations needed to protect fish: approximately 16 – 27 µg/L in Peters Canyon Wash and 2 – 3 µg/L in Big Canyon Wash. The difference in the predicted water column concentrations is due to the relatively high proportions of selenite and the high median K_d values (i.e. EF) present in Big Canyon Wash. Even within this small watershed, the use of a universally applicable water column concentration of 3.1 µg/L may be both significantly over-protective and under-protective.

Table 3.13 and Figure 3.9 of the 2015 Draft Selenium Criterion also clearly demonstrate why the water column elements will be either over- or under-protective of the aquatic life present in most water bodies. The data in the table and figure show that for 53 various lentic and lotic systems, the calculated range of protective water column concentrations varies by orders of magnitude (0.23 – 50.44 µg/L for lentic systems and 1.19 – 40.60 µg/L for lotic systems). Given the wide range of values calculated to be protective, it is clearly inappropriate to establish water column elements outside of a site-specific setting. Further, the significant variability demonstrates that water column concentrations are an unreliable measure for the protection for beneficial uses.

Given the site-specific nature of the water column concentrations that protect aquatic life, a more appropriate alternative would be to utilize water column concentrations as an implementation tool for the criterion, rather than as part of the criterion itself. For example, the criterion could require that where tissue values are exceeded, the water column elements would be used for implementation purposes to help determine the extent of BMPs necessary to attain a water column concentration that would attain the fish-tissue values.

Precedent for utilizing very specific implementation tools as part of an objective has been established in the State of California's *Water Quality Control Plan for Enclosed Bays and Estuaries – Part 1 Sediment Quality*[16] (Phase I SQOs), approved by USEPA on August 25, 2009. For example, if the template set by the Phase I SQOs is followed, each of the 69 aquatic sites evaluated in Section 3.2.5 of the 2015 Draft Selenium Criterion would use the model to calculate the water column concentration appropriate for each individual site. As a result, all 69 aquatic sites would target a water column concentration that would most appropriately result in protection of beneficial uses (e.g., neither under- nor over-protective). This evaluation would guide implementation of the tissue-based criterion, rather than establishing separate water column concentrations as part of the criterion itself. Under the current proposed approach in the 2015 Draft Selenium Criterion, only two (2) of the 69 sites (one lentic and one lotic) are assigned water column concentrations which are appropriate (neither over- nor under-protective).

Given the lack of readily available treatment technologies for selenium, and the additional difficulties for urban environments in Southern California (land availability, space requirements, etc.), there is significant impact from establishing water column concentrations that are not directly linked to site-

specific conditions. In addition to not being directly linked to beneficial use protection, utilizing water column concentrations may unnecessarily require implementation of significant and costly BMPs with no net environmental benefit. Based upon evaluations conducted over the last 10 years in Southern California, these additional unnecessary costs can range in the hundreds of millions of dollars.

In addition, utilizing water column elements outside of a site-specific setting may cause the unintended consequence of establishing effluent limits in National Pollutant Discharge Elimination System (NPDES) permits which are inappropriately low, but may not be able to be raised to the appropriate value once an SSO has been adopted due to anti-backsliding concerns (Section 402(o) of the Clean Water Act). As such, dischargers may be put into a position where Minimum Mandatory Penalties are levied against the discharger, even though the discharger is discharging at a concentration that would meet an effluent limit which is fully protective of aquatic life. Utilizing the water column concentrations elements of the criterion as an implementation tool would avoid this unnecessary outcome.

Requested Actions:
Remove the water column elements from the 2015 Draft Selenium Criterion as elements of the criterion and instead utilize water column concentrations as an implementation tool (similar to the approach utilized by the State of California in the Phase I SQOs).

States Should Clearly Be Allowed to Adopt SSOs that not Only Modify Each of the Four Elements of the Criterion, But that Also Allows States to Opt to Eliminate Aspects of the Criterion (e.g., Water Column Concentrations)

The Stakeholders strongly support the approach in the 2015 Draft Selenium Criterion that states "all four elements of the selenium criterion can be modified to reflect site-specific conditions." This approach explicitly provides States the opportunity to account for site-specific factors that are fundamental to developing and adopting appropriate regulations for selenium. As noted in Comments #4 and #5, site-specific factors can vary even within a small watershed, let alone when extrapolated to the national scale.

However, to develop fully appropriate objectives at the State or local level, States also need the flexibility to not only modify the elements, but also to eliminate certain elements of the 2015 Draft Selenium Criterion. The need for this flexibility applies mostly to the water column elements, though certain States in the arid West may also wish to focus on only whole-body fish tissue due to the practical limitations of obtaining egg/ovary samples. As noted in Comment #5, the water column elements could be moved from the criterion to an implementation tool. If USEPA determines that approach is unworkable at the national level, States could implement such an approach if the criterion specifically allows for the elimination of the water column elements via SSOs.

Page K-2 of Appendix K of the 2015 Draft Selenium Criterion cites the following rationale for recommending the water column elements of the 2015 Draft Selenium Criterion:

"Although the selenium concentration in eggs or ovaries is the most sensitive and reliable basis for a criterion, implementation can be challenging because most state and tribal Clean Water Act programs require the expression of water quality criteria as an ambient concentration in the water-column. "

However, not all States require the expression of water quality criteria as an ambient concentration in the water-column. For example, the State of California has been developing SSOs that do not include water column concentrations as part of the objective, but rather uses water column concentrations as an implementation aspect of the objective to guide management actions and permit development. Providing the flexibility to the States to opt to eliminate aspects of the criterion is critical and must be maintained and explicitly provided for in the 2015 Draft Selenium Criterion.

Further, in Southern California, it is not practical to rely on the collection of eggs and/or ovaries because fish eggs and ovaries may be insufficiently present or too unreliable to obtain. In this instance, utilizing an SSO which utilizes whole-body fish and/or muscle tissue is significantly more practical. Therefore, States should also retain the flexibility to focus on whole-body fish and/or muscle tissue and not be required to include egg/ovary elements in SSOs.

Requested Actions:

Revise the language on Page 95, Section 5 of the 2015 Draft Selenium Criterion to read as follows:

"All four elements of the selenium criterion can be modified to reflect site-specific conditions where the scientific evidence indicates that different values will be protective of aquatic life and provide for the attainment of designated uses. Furthermore, the egg/ovary element and the water column elements can be eliminated through site-specific objectives, consistent with Appendix K."

Revise Table 4.1 on Page 91 of the 2015 Draft Selenium Criterion to read as follows:

> Add footnote 618 (place after "Fish Tissue" and "Water Column"): Each of the four elements can be modified through site-specific objectives, consistent with Section 5 and Appendix K.
>
> Add footnote 718 (place after "Egg/Ovary," "Monthly Average Exposure," and "Intermittent Exposure"): Through site-specific objectives, consistent with Section 5 and Appendix K, these elements can be eliminated as part of the criterion.

Revise Appendix K to provide guidance on the rationale, procedures, and pathways to eliminate certain elements of the 2015 Draft Selenium Criterion through SSOs.

Draft Selenium Criterion, Page 100, Section 6. Note that prior comments request additional footnotes to this table. The actual numbering depends upon the approach (es) selected by USEPA in subsequently revised criterion. Numbering is provided for illustrative purposes to note that the requested footnotes are additions to the proposed criterion.

COMMENTS PREVIOUSLY MADE ON 2014 EXTERNAL PEER REVIEW DRAFT CRITERION AND NOT ADDRESSED IN 2015 DRAFT SELENIUM CRITERION

The Stakeholders strongly request the incorporation of the following previously submitted comments on the 2014 External Peer Review Draft Criterion. The comments provided below will support effective implementation of the criteria under the wide range of conditions present in waterbodies in California. Clarification Is Needed Regarding the Applicability of the Four Elements of the Criterion to Ensure that Fish-Tissue Elements Supersede the Water Column Elements.

The Stakeholders strongly support the approach recommended by USEPA on Page 91 of the 2015 Draft Selenium Criterion of establishing "the primacy of the whole-body or muscle elements over the water column element, and the egg-ovary element over any other element." As selenium is primarily accumulated in organisms through diet, water column concentration-based criteria are viewed by many as inappropriate, especially for predicting chronic effects.[5, 6] Tissue-based approaches ensure a direct assessment of the beneficial uses that are being protected. The benefit of fish-tissue assessment is reflected on Page 2, Section 1 of the 2015 Draft Selenium Criterion:

"... fish-tissue values more directly represent chronic adverse effects of selenium than the conventional water concentration approach ... because chronic selenium toxicity is primarily based on the food-chain bioaccumulation route, not a water route of exposure."

Selenium bioaccumulation and toxicity cannot be predicted based solely on selenium concentrations in water.[7] Ecological risks from selenium are governed by uptake that occurs at the base of the food web (primarily via primary producers and microorganisms), dietary exposure and toxicity, the timing of exposure (e.g., during gestation in fish and birds), and transfer through the food web. Selenium uptake within a food web is both species- and environment-specific.[8] Assimilation and retention of selenium in organisms differs between species and environments at all levels of the food web, making it difficult to predict concentrations and toxic exposure at different trophic levels. The poor linkage between dissolved selenium and selenium exposure and toxicity in the food web makes it particularly difficult to determine impairment in a watershed based on water concentrations alone.

It appears that the 2015 Draft Selenium Criterion intends to capture this critical aspect of selenium risk and exposure by structuring the criterion such that the fish-tissue elements supersede the water-column elements. However, this critical aspect of the criterion lacks clarity throughout the document. One example is on Page 90 where the four-part criterion is identified, but language is absent to note that the fish tissue elements supersede the water column elements. It appears as if footnotes which refer to the table footnotes on the following page intend to establish the supremacy of the tissue-based elements, but it is unclear if that is the intent of the 2015 Draft Selenium Criterion. The supremacy of the tissue-based elements of the criterion is so fundamental that it needs to be abundantly clear and explicitly included in all aspects of the criterion, including the Fact Sheet, Executive Summary, and in all instances where elements of the criterion are discussed or described.

In addition, the language currently used in the 2015 Draft Selenium Criterion to describe the relationship between fish tissue and water column elements is "primacy" or "precedence." This language leaves room for interpretation and discretion whereby the water column elements may still be applied even

where fish tissue data are available. As noted above and as supported by the 2015 Draft Selenium Criterion, tissue-based approaches are superior to water column approaches for the protection of beneficial uses. A more direct and clear term would be to state that fish tissue elements supersede water column elements and/or attainment of fish-tissue elements is deemed equivalent to attaining any water column elements. This approach is being employed in site-specific objectives currently under development in certain areas in California.

Lastly, the current language provides for fish tissue elements to have "primacy" where tissue data are available. Page 92 of the 2015 Draft Selenium Criterion states (emphasis added):

"Inclusion of the fish whole-body or fish muscle element into the selenium criterion ensures the protection of aquatic life when fish egg or ovary tissue measurements are not available, and inclusion of the water column elements into the selenium criterion ensures protections when nether fish egg-ovary nor fish whole-body or muscle tissue measurement are available, and provides consistent coverage for all waters ".

And, footnote 1 and 2, respectively, in Table 4.1 on Page 91 of the 2015 Draft Selenium Criterion state (emphasis added):

"Overrides any whole-body, muscle, or water column elements when fish egg/ovary concentrations are measured except in certain situations."

"Overrides any water column elements when both fish tissue and water concentrations are measured except in certain situations."

However, further clarity is necessary regarding data availability and applicability of the four elements of the criterion. For example, in many monitoring programs in California, water bodies are monitored more frequently for water column than for tissue as tissue samples for both fish and birds are collected during the nesting season (typically, late spring). This approach ensures that the most critical condition, the breeding season, is captured in the monitoring data (as fish are also a dietary item for shorebirds, both fish and birds are collected concurrently). Throughout the rest of the year, water column samples are obtained and the data are used to gauge implementation actions. However, the language in the current 2015 Draft Selenium Criterion could imply that even in a monitoring program that is specifically designed on tissue-based approaches, such as the one described here, the water column elements of the criterion would apply throughout the year when tissue samples are not being collected concurrently. If the 2015 Draft Selenium Criterion is interpreted in this way, water bodies could be identified as not meeting the Criterion based upon water column concentrations, despite tissue data demonstrating that the water body meets the Criterion. Therefore, clarifying and explanatory language needs to be included to ensure that the water column elements are not inappropriately applied over tissue-based elements. One potential approach is to limit the applicability of water concentration elements to instances where tissue is not collected within the same calendar year.

Requested Actions:

Revise the 2015 Draft Selenium Criterion to clearly establish that the fish tissue elements supersede the water column elements:

Modify the terminology throughout the document from "primary" and “precedence" to "supersedes"

Modify Table 4.19 as follows:

Modify Footnote 1: "Overrides any Supersedes all whole-body, muscle, or water column elements when fish egg/ovary concentrations are measured except in certain situations. See footnote 3."

Modify Footnote 2: "'Overrides any Supersedes all water column elements when both fish tissue and water concentrations are measured except in certain situations. See footnote 3."

Add Footnote 6 (place after “Fish Tissue”): Fish Tissue elements supersede all water column elements when tissue data are available within the same calendar year.

Add Footnote 7 (place after “Water Column”): Water column elements (both the Monthly Average Exposure and Intermittent Exposure) only apply where fish tissue data are not available within the same calendar year.

Provide more direct and explanatory language throughout the document that clearly limits the applicability and use of water column elements, including but not limited to Page 90 of Section 4 (National Criterion for Selenium in Fresh Waters). Example modified language for Page 92, first paragraph:

“Inclusion of the fish whole-body or fish muscle element into the selenium criterion ensures the protection of aquatic life when fish egg or ovary tissue measurements are not available, and inclusion of the water column elements into the selenium criterion ensures protections when neither fish egg-ovary, nor fish whole-body or muscle tissue measurement are available, and provides consistent coverage for all waters. Therefore, when fish egg or ovary tissue measurements are available, the fish egg or ovary tissue measurements should be the sole measurements used to determine whether or not the selenium criterion is being attained, regardless of the presence or absence of any other measurements. Similarly, when fish egg or ovary measurements are not available, but fish whole-body or fish muscle tissue measurements are available, the fish whole-body or fish muscle tissue measurements should be the sole measurements used to determine whether or not the selenium criterion is being met regardless of the presence or absence of water column measurements. Water column measurements should only be used to determine whether or not the selenium criterion is being met if fish egg, fish ovary, fish whole-body, and fish muscle tissue measurements are all not available. Further, as water column data may be collected more frequently than tissue data, the water column elements do not apply unless tissue data has not been collected within the same calendar year."

Corresponding changes would need to be made throughout the documentation, including but not limited to the table on Page 4 of the Fact Sheet.

EPA-HQ-OW-2004-0019-0419-A2; Lima Refining Company; Posted 11/03/2015

COMMENT #1

The modeling approach used to translate from an egg – ovary tissue based criterion to a water column concentration subsumes within it a number of factors that are poorly quantified and which introduce uncertainty into the results. As such, the accuracy of the water column criteria values and the level of protection they provide are uncertain and potentially problematic for dischargers.

The strength of the approach that serves as the basis for the Se criterion proposed by EPA is that it is based on accumulation of tissue Se at the proximate site of action of toxicity (for reproductive effects), the egg or ovary, or in the associated whole body or muscle tissues. The available data to support the reproductive effect levels of Se in tissues are reasonably strong. From a practical perspective, the need to prescribe water column concentrations of Se for use in permitting is also recognized. However, the approach used for this purpose introduces considerable uncertainty into the process. The model that is applied was originally proposed more than 30 years ago (Thomann et al., 1981) and has been widely applied since that time. The fact that it represents many of the features that are important determinants of the level of selenium accumulation by aquatic organisms is important, but it does not ensure the accuracy of the results produced by its use.

EPA employs several simplifications to the time variable version of the bioaccumulation model to make the translation from the egg — ovary tissue criterion concentration to a water column concentration, one that should result in a tissue Se concentration that equals the egg — ovary benchmark. First, it does not consider (i.e., it neglects) the time variable nature of Se accumulation and effects. That is, the steady state ("SS") form of the solution is used to interpret the inherently time-variable process of Se accumulation. Although this SS solution (Equation 1 from USEPA, 2015, page 55) includes the kinetic coefficients that control a time variable response to changing environmental exposure levels, it fails to represent what is inherently a time variable response in the presence of typically non-constant environmental exposure levels. Second, EPA also assumes, on the basis of a questionable and qualitative rationale, that several of the important terms in this equation (terms related to selenium uptake from water and biomass dilution due to growth) can be neglected. As a result, the calculation used to derive EPA's proposed water quality criterion of 3.1 µg/I does not accurately reflect all relevant scientific data, and should be reconsidered in the Final Rule.

COMMENT #1A. Effect of Growth Rate

EPA, in keeping with the kinetic modeling approach used by Luoma and Rainbow (2005), assumed that for selenium, the growth rate is a relatively inconsequential parameter under most circumstances. Although the publication does make the simplifying assumption that g can be neglected, it is not the case that this assumption was made specifically in regard to selenium. Luoma and Rainbow note that "Growth was not included in most model forecasts reported here, and did not seem necessary. That does not mean that growth considerations are never important."

Part of EPA's rationale for neglecting the growth rate coefficient was that "high consumption rates of selenium-contaminated food may counteract selenium dilution that occurs with the addition of body tissue during periods of fast growth". This statement should only be considered in a qualitative sense.

Further quantitative justification is needed to demonstrate the appropriateness of this approximation in the course of making such an important simplification to a quantitative modeling framework.

While Luoma and Rainbow (2005) do include some steady state results for Se, the predicted and measured values were limited in several respects. Specifically, the results for Se were limited to marine organisms (mussels, clams and zooplankton) from saltwater settings (all of the data were from San Francisco Bay, other than one data point from the Mediterranean Sea). The comparisons were also limited to median concentrations for both modeled and measured results. Importantly, there were no results for fish.

EPA also completed a sensitivity analysis (Appendix J, USEPA, 2015) related to the importance of growth rate. However, this analysis does not provide enough detail to assess the validity of what was done. Based on the description provided, the analysis was based upon Equation 1 from USEPA, 2015, page 55, as a SS evaluation. Equation 1 from USEPA, 2015, page 55, includes the sum of elimination and growth rate coefficients (Ke + g) in the denominator. However, the value of Ke that was used for the comparison is not mentioned. Thus, the degree that this parameter value may have influenced the results of their sensitivity analysis cannot be assessed from the description provided. At the very least, EPA must provide the values used for these coefficients before finalizing this review, so that states and stakeholders can provide meaningful input on this modeling.

The sensitivity analysis completed by EPA was limited in that it was not performed for all trophic levels. Appendix J in USEPA, 2015, states that the sensitivity analysis for growth was only performed for trophic levels 2 and 3 (TL2 and TL3). Thus, it would appear that the analysis did not consider the influence of g on Se accumulation by trophic level 1 (TL1, consisting of algae, periphyton, detritus), where most Se enters the food chain (USEPA, 2015, page 12) and where uptake is entirely from water. This is a potentially significant oversight, because the same rationale for the effect of growth rate can be applied to both algae and periphyton. In this case, it cannot be argued that food consumption [by plants] is high when growth rates are high, yet changes in growth rate may have a direct influence on the concentrations that result. Thus, “biomass dilution” may be important to consider at TL1.

There is relevant scientific data that supports EPA following such an approach. The effect of growth rate on metal accumulation by plants was clearly demonstrated in a study by Hill and Larsen (2005). The authors measured metal concentrations in periphyton grown on tiles placed in a shallow creek for four weeks. The periphyton that grew on shaded tiles had a relatively low g (0.078/day) in comparison to unshaded tiles (g = 0.189/day) and UV-shaded tiles (g = 0.204/day). The ratios of the higher metal concentrations in the low growth rate biofilm to the lower metal concentrations in the high growth biofilms are summarized on Figure 1 (below) for each of the metals considered. As indicated by these ratios, the low growth rate biofilm typically had about 3 to 4.5 times higher metal concentrations than either of the two high growth rate biofilms. While metal uptake rates were found to be relatively independent of growth rate, the higher growth rate coefficient apparently resulted in biomass dilution of accumulated metal. Such results highlight why it may be important to consider (rather than neglect) growth rate in data and modeling analyses. Although the study by Hill and Larsen did not include results for selenium, it is reasonable to expect that a similar finding would apply to selenium as well.

Considering that this process occurs at the base of the food web, where most of the transfer of Se to the food web occurs, this is an important factor that should not be ignored.

Therefore, EPA should provide an explanation of each parameter that is used in calculating the proposed water quality standard.

COMMENT #2. Uncertain water column criteria cause undue burden on dischargers.

The modeling approach used to translate from an egg - ovary tissue-based criterion to a water column concentration subsumes several, poorly quantified factors. In doing so, it introduces uncertainty into the results. As such, the accuracy of the water column criteria values and the actual level of protection they provide are uncertain. This may be problematic for dischargers who must achieve water quality based permit limits. As a result, the discharger may have an unduly burdensome need to implement treatment that may not be required to protect the resident biota.

Given the potential uncertainties discussed above, we respectfully submit that it is not appropriate at this time and until the above uncertainties are addressed, to recommend to the states the use of the water quality criterion **of 1.2 µg/L for lentic systems and 3.1 µg/L for lotic systems. Given the complex** nature of the tiered selenium criterion, and that typical monitoring tends to be at the water column level, states may opt to use the water column criterion to set permit limits. The above discussion indicates that the water column criteria are set at conservative concentrations as they are derived from a series of factors to translate from measured egg ovary effects levels to estimated water column effects concentrations. While egg-ovary and fish tissue criteria are based directly on actual effects data, water column criteria are not (they are calculated based on the egg — ovary criterion). The outcome of having to meet the water column criterion would be permit limits that are unduly burdensome on dischargers.

The preceding point is demonstrated by the large range in water borne concentrations levels that are shown in Figure 3.9 (USEPA, 2015, page 84). The graph shows that environmental protection is still in place for most of the sites (likely including LRC) at water borne concentration levels well beyond the conservative 3.1 ug/liter (20% probability) value. For LRC, imposing the uncertain proposed 2015 USEPA selenium criterion would cause an unnecessary reduction to the plants SeT effluent limit that the plant could not meet without incurring financial hardship, if it could be met at all.

EPA-HQ-OW-2004-0019-0387-A1; Colorado Department of Public Health & Environment; Posted 10/14/2015

The WQCD has concerns with EPA's proposed lentic and lotic water column elements. While the WQCD understands the need for a water column element to simplify implementation of the proposed selenium criterion, the approach taken seems inappropriate.

Our first concern relates to the overall concept of recommending a single water column number for all waters nationwide. While EPA cited a few of the key points from the Pellston Workshop on "Ecological Assessment of Selenium in the Aquatic Environment" (a 2009 gathering of 46 selenium scientists) in the 2015 draft criteria document, the following was not included:

“A single, universal, dissolved water quality value is inappropriate for predicting toxicity. The dissolved Se concentration benchmark that is necessary to protect one site may be either insufficiently protective or unnecessarily protective at another site.” (Chapman et al., 2009)

This is an important consideration, especially considering how low the proposed water column elements are compared to most states’ current criteria. The variability in protective water column values for individual sites is evident in the data used by EPA to develop the water column element (Figure 3. 9, pasted below). Every single water concentration shown in Figure 3. 9 is protective at a particular site.

Original letter contains Figure 3.9 – Probability distribution of the water column concentrations translated from the egg-ovary criterion element at 20 lentic and 22 lotic aquatic sites. See original letter.

In addition, the proposed water column elements are not actual toxicity thresholds like the other elements of the criterion or criteria in general. The 20th percentile of water column concentrations back-calculated from the egg-ovary criterion at 20 lentic and 33 lotic sites has no actual toxicological relevance as an effect level. Use of the 20th percentile of site-specific data only means that 20% of the sites in the distribution are “underprotected” and 80% are “overprotected”. Only at sites with the exact food web/bioaccumulation conditions as those sites falling on the 20th percentile line will the aquatic community appropriately protected.

The WQCD would appreciate EPA’s continued evaluation of options for the water column element. While we understand site-specific standards could be developed where necessary and appropriate, we have serious concerns about the blanket application of such a stringent criterion with potentially little ecological relevance.

EPA-HQ-OW-2004-0019-0410-A2; West Virginia Department of Environmental Protection (DEP); Posted 10/28/2015

EPA’s 2015 Draft proposes two water column elements of 1.2 µg/L for lentic waters, and 3.1 µg/L for lotic waters. EPA's current national recommended chronic criterion for selenium is 5 µg/L, which was developed by EPA to protect bluegills, a recreationally important species. The chronic water column elements in EPA's proposed criteria are not developed based on the current EPA guidelines for developing water quality criteria, but instead are back-calculated from the body burden criteria using trophic transfer functions. EPA's new approach in the 2015 Draft constitutes a full departure from EPA's approach in its 2014 pre-draft selenium criteria. Furthermore, DEP is finishing up a two-year reproductive success study in waters with elevated selenium compared to control water. Preliminary results of this study show the 5 ug/L water column concentration is protective of West Virginia aquatic life. Based on these concerns, West Virginia believes the appropriate approach is to retain the nationally recommended water quality criterion of 5 µg/L for water column concentrations.

Comment Category 2.2 – Comments of General Nature Concerning Over-Protection or Under-Protection of Aquatic Life

2.2 Summary

Many commenters opined that the draft criterion over-protects aquatic life. Often this conclusion appeared in context of commenter evaluations of how EC_{10} values were derived. A few commenters noted that the criterion under-protected aquatic life.

2.2 Response to comments

2.2 Responses concerning over/under protection of aquatic life

In response to comments, EPA performed an additional re-evaluation of the statistical fits of the toxicity studies that were used to derive the egg-ovary criterion. This re-evaluation resulted in several re-analyses of studies resulting in statistically superior fits when compared with the previous TRAP analysis. Based on this re-evaluation, there were minor changes to the final chronic values (FCVs) for several studies. Changes were made to the EC_{10}s for the following genera: Acipenser, Lepomis, Micropterus, Oncorhynchus, Pimephales, and Salmo. The discussion of the re-analyses is provided in detail in the 2016 selenium criterion document in Section 3 as well as Appendix C. Importantly, the lowest genus mean chronic value (GMCV) continues to be from the white sturgeon (*Acipenser transmontanus),* with a new EC_{10} of 15.6 mg/kg dw (the previous EC_{10} was 16.3 mg/kg dw). The result was a change in the 2015 FCV from 15.8 mg/kg dw, to 15.1 mg/kg dw.

The EPA's statistical re-evaluation of the brown trout (*Salmo trutta*) data (Formation Environmental 2011) was confined to observations and data from the exposure period prior to the lab overflow accident. In Simplot's June 24, 2014 comments to EPA docket Simplot states (page 6, number 2) clearly that the contractor doing the experiment preferentially selected non-deformed fish:

"2. Visually deformed fish were culled prior to the start of the 15 day feeding trial and preserved. If deformities existed for those fry that escaped they were not visually apparent."

Formation's preferential selection of non-deformed fish for the post swim up trial introduced uncertainty versus random selection of individuals for inclusion in the post swim up trial. This uncertainty irreparably confounds the data from this portion of the test, therefore, it is only defensible to use to use the study data up to the time of the lab overflow accident in the calculation of the EC_{10}. As a result of the statistical re-evaluation, the new EC_{10} increased from 18.5 mg/kg dw to 21.0 mg/kg dw. For more detail please see Section 3, pg 40-42 of the selenium criterion document,

The white sturgeon (*Acipenser transmontanus*) data (Linville 2006) reanalysis resulted in a statistically superior fit compared to the previous TRAP-derived EC_{10}. The new value uses data for both larval survival and deformities; data solely on deformities were used in the 2015 draft. As a result, the GMCV decrease from 16.27 mg/kg dw to 15.6 mg/kg EO dw. This value is similar to that reported by the author previously 15.3 mg/kg dw, derived using logit regression, based on combined skeletal and edema data,

when comparing deformities from control and Se-diets. Linville (2006) also found that effects at Stage 45 for control and selenium-spiked diets were significantly different using Tukey's Honest Difference Test for the maternal transfer study. For more detail please see Section 3, pg 37 of the selenium criterion document, and Appendix C.

The bluegill (*Lepomis macrochirus*) data (Hermanutz 1992, 1996, as corrected by Tao, 1999) reanalysis resulted in a statistically superior fit to the previous TRAP-derived EC_{10}. As a result, the new EC_{10} increased from 11.36 mg/kg dw to 14.7 mg/kg EO dw. For more detail please see Section 3, pg 41 of the selenium criterion document.

2.2 Responses concerning averaging period for the water column criterion element

EPA has described the selection of the 30-day averaging period in detail in the final 2016 selenium criterion document.

2.2 Responses concerning selection of measure of effect

Many commenters supported the measure of effect (EC_{10}) used by EPA for this bioaccumulative pollutant; a few commenters disagreed. Typically EPA's national 304(a) criteria have been based on an EC_{20} for pollutants whose toxicity is dominantly expressed through water exposure. Because selenium is bioaccumulative in biota and is persistent in the ecosystem, EPA selected the EC_{10} to protect populations of all sensitive (fish) species. In addition, a protective measure of effect is critical for selenium due to the steepness of the dose-response curve, compared to other toxicants. Effects of selenium exposure move from beneficial, to low adverse effects, to major adverse reproductive effects over a very narrow dose range (e.g., 2 mg/Kg bw dw). The selection of the EC_{10} as the measure of reproductive effect for this chemical was identified in the problem formulation for the selenium criterion in the 2014 draft criteria document, and did not change in the problem formulation for the 2015 draft criterion document, or in the 2016 final criterion document. Further, EPA does not agree with the comment that an effects endpoint of 25% (EC_{25}) is negligible, particularly for a bioaccumulative pollutant.

2.2 Responses to general comments

The nature of selenium bioaccumulation may vary on a site-by-site basis in a manner sufficient to justify development of site-specific criteria. Reviewers identified several important issues that will be addressed in the technical information to be developed to guide the implementation of the criteria.

2.2 Responses to comments on the sensitivity of bluegill and catfish

EPA analyzed all available, reliable data for bluegill and catfish and included these data in distributions used to derive the chronic selenium criterion. EPA identified three studies available for these species: Coyle (1993), Doroshov et al., 1992, and Hermanutz et al., 1992. The Doroshov et al. catfish study was

not used by EPA, because fish were exposed via injection, not maternal transfer, which was the route of exposure in the other studies used in the derivation of the criterion. These data were not included in derivation of the criterion because the injection route of exposure is not an acceptable experimental protocol for studies used in criterion derivation due to its difference from exposure routes in the environment (for selenium, diet). While EPA's analysis indicated that the Hermanutz EC_{10} was the lowest of the 3 bluegill studies (Hermanutz, Coyle, and Doroshov) at 14.7 mg/kg dw (vs 9.0 mg/kg dw from Lemly's analysis), the geometric mean of the studies (bluegill SMCV) was 20.6 mg/kg dw. Based on the available data and application of our Guidelines Methodology, we conclude that the criterion is protective of bluegill.

One comment cited field data from Belews Lake and concluded that catfish are "very sensitive" to selenium poisoning and that the final chronic value needs to be lower than 10 mg/kg dw to be protective of bluegill and catfish. In the effects characterization, EPA describes field evidence from Hyco Reservoir that found catfish representing multiple year classes present even after most other fish species were reproductively extirpated from the lake. This indicates that, at a minimum, catfish are no more sensitive than other species for which we have reliable egg-ovary data for (i.e., centrarchids like bass and bluegill), and that they are likely less sensitive, due to their presence in these studies after other species disappeared. Thus, EPA concluded that the egg-ovary criterion is expected to be protective for catfish (i.e., ictalurids), despite the absence of valid egg-ovary test data.

2.2 Response to comments on the phenomenon of "winter stress syndrome"

Due to the lack of demonstration of effects due to winter stress in the field, (e.g., Hermanutz et al., 1992, and others), there is great uncertainty as to the actual field occurrence of these effects observed in the lab studies (Lemly 1993, McIntyre, 2010). In addition to Hermanutz et al., 1992, investigation of the potential for winter stress effect (or winter stress syndrome) has been done in field studies of many types of juvenile fish species (northern pike, fathead minnows, creek chubs, white suckers, and slimy sculpin) inhabiting areas receiving complex metal mine effluents containing elevated selenium concentrations. None of these studies found evidence of winter stress, thus casting doubt on the actual occurrence of this effect in natural aquatic ecosystems. Therefore, the EPA no longer considers "winter stress syndrome" as a viable effect that should be assessed separately for selenium. Furthermore, the effect concentration and proposed whole body tissue criterion based on observations in the Lemly and McIntyre lab studies is similar to the final whole body criterion value of 8.5 mg/kg dw, therefore the level of protection afforded by the whole body criterion should be protective for winter stress syndrome, should it occur, despite the lack of a separate assessment.

2.2 Responses to comments on translation of fish tissue to water

EPA was made aware of an overweighting of certain waters in the 2014 comments provided by the public. The issue stemmed from EPA's use of all fish species monitored at a site. Because the number of fish species were not equal at all sites, this led to the possibility that those sites with several species (up to 6) were more heavily represented in the database than those sites with a single fish species. In lentic

waters, this occurred at several sites with low selenium in the water column (leading to a high EF, and fish tissue values that were protective and low). The opposite scenario occurred in lotic waters, where waters with higher selenium (and lower EFs) had a larger number of fish species available. This led to those waters providing several fish tissue values that were protective at higher selenium concentrations. Because the goal is to provide a national criterion protective of aquatic life designated uses in all lotic or lentic waters, a decision was made to use the most bioaccumulative fish species available at a site. This insured that protection would be provided to those fish that may be sensitive to selenium and have a diet that reflects a bioaccumulative food web. The resulting water column criterion elements ensure that aquatic life uses for selenium-sensitive fish species are protected on a national basis for an estimated approximately 80% of waterbodies.

If the characteristics of a site are such that data demonstrate that a different, perhaps higher, water column criterion element would be equally protective, EPA notes that site specific criteria can be developed. EPA has provided information on how a site-specific selenium criterion could be developed in Appendix K.

An alternative approach for deriving protective national criteria was provided in a 2014 report by DeForest et al. 2014, provided to EPA in 2015 comments by NAMC-SWG. EPA has reviewed the detailed and comprehensive information and analyses that the report presents. This report used many of the same studies that EPA used in the derivation of the national chronic criterion, but excluded a key study, conducted on white sturgeon. EPA notes the recommendation in the report that the egg/ovary criterion be set at 20 mg/kg (higher than EPA's recommendation of 15.1 mg/kg) is primarily due to the exclusion of the white sturgeon study. When adjusted to include this study, the DeForest water column recommendations become 4 µg/L and 1.5 µg/L for lotic and lentic systems respectively. This Deforest-approach based analysis and resultant water column values would represent protection of 75% of waterbodies, while EPA has made a policy decision to select the 80 centile of water values in derivation with the national water column value (slightly more protective). The water column values calculated using this are strikingly similar to EPA's water column recommendations of 3.1 µg/L and 1.5 µg/L for lotic and lentic systems. This result further substantiates and supports EPA's water column values, despite the use of different analytic methods in the two approaches.

2.2 Specific comments

EPA-HQ-OW-2004-0019-0384-A2; Cameco Resources; Posted 10/13/2015

Based on our review, we were disappointed to see that there appears to be no substantive changes to the 2015 draft despite the comments we submitted on the previous published External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium- Freshwater 2014 (EPA 822-P-14-001; 2014 draft) on June 13, 2014 (J. Leftwich, Cameco, to K. Gallagher, US EPA). As an example, the egg/ovary selenium criterion (15.8 mg/kg) is only slightly changed from the 2014 draft criterion (15.2 mg/kg) and is still overly conservative because, as previously detailed there is scientific evidence to suggest an environmentally protective criterion of at least 20 mg/kg egg/ovary selenium.

EPA-HQ-OW-2004-0019-0394-A2; Appalachian Mountain Advocates and Sierra Club Environmental Law Program; Posted 10/14/2015

IV. The Concentrations of the Fish Tissue Elements Are Too High to Protect Sensitive Species

EPA's Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses (1985) explain that water quality criteria should fully protect sensitive species that are "commercially or recreationally important." EPA derived its egg/ovary element, which forms the basis for its other fish tissue elements, by averaging the genus mean chronic values for what it claims are the four most sensitive genera for which adequate data exist. Draft Criterion at 27. The resulting fish tissue elements are not adequate to protect certain sensitive species that are commercially and recreationally important, such as species of bluegill and catfish.

In a letter to EPA expressing concern over the egg/ovary criterion in EPA's 2010 draft proposal, selenium expert Dr. Dennis Lemly of the USDA Forest Service concluded that EPA's inclusion of more tolerant species in the criterion evaluation and development resulted in a proposed criterion that would have allowed mortality to exceed allowable limits in more sensitive species. Dr. Lemly stated that scientific studies show quite clearly that a criterion of 17.07 mg/kg for fish eggs/ovaries will jeopardize two of the most important freshwater fish families in North America: Centrarchidae and Ictaluridae. For example, (1) An EPA field study published in the peer reviewed journal Environmental Toxicology and Chemistry (Hermanutz et al 1992) found that ovary selenium concentrations of 9 mg/kg dw or greater resulted in 40% higher mortality and 80% more edema in larval bluegill sunfish that controls for an EC40-80 (converted from wet weight using 80% moisture, based on mean wet weight +- one standard deviation). The results of this study are not included in EPA's draft criterion calculation, and (2) A laboratory study at the University of California (Doroshov et al. 1992) found that the EC50 for larval mortality of channel catfish and bluegill sunfish occurred at egg selenium concentrations of 7.2 and 15.0 mg/kg dw respectively (lower limit of 95% confidence intervals). These mortality data were not included in the data used to derive the FCV.

Extensive field data from the Belews Lake case example, which includes reproductive analysis from young-of-the-year stock assessment, clearly show that catfish are very sensitive to selenium poisoning in a real-world setting. . .equal to or greater than sunfish (Cumbie 1978, Cumbie and Van Haron 1978, Holland 1979, Garrett and Inman 1984, Lemly 1985). . . .

The FCV needs to be lower than 10 mg/kg dw in order to protect sunfish and catfish at an EC10 level, which is the level of protection afforded to trout by the 17.07 draft criterion value.

Letter to Mr. Joseph Beaman, Chief, USEPA, Office of Water, Ecological Risk Assessment Branch, Washington, DC from A. Dennis Lemly, Ph.D., Research Fish Biologist, USDA Forest Service, Southern Research Station, Piedmont Aquatic Research Laboratory, July 6, 2010 at 1-3 (emphasis added). Clearly, EPA's proposed egg/ovary element of 15.8 mg/kg would not protect those species at the EC10 level that EPA has used to derive its current proposed criterion.

In addition to improperly averaging values across genera, EPA failed to adequately account for "winter stress" in sensitive bluegill species. As EPA recognized in its Draft Criterion document, a study by Dr. Lemly found the protective chronic selenium whole body concentration for juvenile bluegill to be 5.85

mg/kg prior to winter stress. Instead of using this protective value for the bluegill's genus mean chronic value, EPA averaged it with the values from McIntyre et al.'s 2008 study, which also purported to account for winter stress, but arrived at a much less protective concentration of over 9 mg/kg. Draft Criterion at 122–23. Reliance on the McIntyre study to account for selenium is misplaced, however, because that study failed to actually induce winter stress, in part, because it did not control photoperiod or discuss the impacts that the lack of photoperiod controls may have on the interpretation of study results. Indeed, EPA explicitly acknowledges that the "effects of photoperiod on fish and other ectotherms are well-documented." Draft Criterion at C-158. EPA must fully account for winter stress, using studies that actually induce such stress by recreating realistic winter conditions including reduced photoperiod, when revising its fish tissue concentrations to ensure protection of sensitive aquatic species.

For the foregoing reasons, EPA must significantly reduce the concentrations allowed under its fish tissue elements to ensure they are protective of sensitive species, aquatic-dependent wildlife, and threatened and endangered species. EPA must then translate those revised tissue concentrations to enforceable water column criteria that can be practically implemented to achieve the regulatory requirements of the Clean Water Act.

EPA-HQ-OW-2004-0019-0386-A2; Asarco LLC; Posted 10/13/2015

Asarco supports the comments submitted on the draft criteria revision by the North American Metals Counsel ("NAMC"), particularly those portions of the NAMC comments arguing that: (1) the tissue criteria are skewed downwards by reliance on some flawed studies and higher criteria would in fact be protective; (2) "never to be exceeded" tissue criteria are unduly restrictive and should be replaced by seasonal averages; (3) the methodology for translating tissue criteria to water quality criteria is flawed and will result in overly low water quality criteria.

EPA-HQ-OW-2004-0019-0371-A2; Wyoming Department of Environmental Quality (WDEQ); Posted 09/15/2015

Limitations of Fish Reproductive Tissue Endpoint

From 1971 to 2000, Wyoming was the third driest state in the country; only Nevada and Utah were drier. Mean annual precipitation was 13 inches; 30% of the state received less than 12 inches of precipitation per year and 67% of the state received less than 16 inches of precipitation per year[1]. As such, between 70 and 80% of Wyoming's 11 Streams" are ephemeral and/or intermittent without the natural hydrologic potential to support fish populations[2].

WDEQ/WQD understands that EPA developed the draft selenium criteria to protect the most sensitive species and life stages, but the resulting criteria are likely over-protective for most of Wyoming's streams that lack any fish species. WDEO/WQD appreciates EPA's discussion that states should adopt criteria to protect downstream fish species for waters that lack fish. Unfortunately, due to limited staff and resources, it is not practical for Wyoming to develop and adopt water quality standards for

approximately 70% of our streams based on downstream fish assemblages. Further, many of these streams have no hydrologic connectivity or are distant from fish -bearing streams. It is also unrealistic for the State to apply overly stringent criteria to most of our waters since this may result in unnecessary impairment decisions and treatment for point source dischargers.

WDEQ/WQD requests that EPA develop a recalculated criteria without fish reproductive endpoints for waters that lack fish. Currently, EPA has derived the draft selenium criteria as a function of fish egg-ovary values; this approach precludes the use of the recalculation procedure for waters that lack fish since recalculations will be inherently fish -based. Development of a recalculated criteria without fish endpoints would require more toxicological data on additional taxa (e.g., invertebrates including crustaceans) in order to accurately protect aquatic life that may reside in fish less waters. EPA should make it clear within the draft criteria document that there is no expectation for the recommended selenium criteria to be applied to waters without fish.

EPA-HQ-OW-2004-0019-0399; Clean Water Team; Posted 10/15/15

Thank you for the opportunity to comment. The selenium criterion proposed is overprotective for the desert southwest ecoregion. The proposed regulation:

does not recognize that that over millennia, naturally-occurring levels of selenium has resulted in ecoregion-wide biologic adaptation; does not recognize that the predominant form of selenium in the Las Vegas Wash, selenate, is a micronutrient required by endemic life forms ranging from bacteria to mammals. This form of selenium demonstrates the least toxicity in aquatic environments, and widespread selenium toxicity has not been noted in birds or fish in the Las Vegas Wash or Lake Mead; proposes that one tissue test result above the limit stated for ovary or muscle tissue indicates non-compliance. This requirement is unique to this regulation and does not allow for error. No other regulation imposes such a rigorous requirement. For lotic environments, cannot be met in most of the Colorado River system due to naturally-occurring selenium.

EPA-HQ-OW-2004-0019-0391-A1; North American Metals Council (NAMC); Posted 10/14/2015

2.2 Improving the Scientific Foundation for the Fish Selenium Criterion

The proposed tissue criterion in the 2015 EPA Selenium Draft is overly conservative and not technically defensible. A higher criterion would provide environmental protection without unduly penalizing human industrial or other activities with concomitant negative economic impacts, and without unnecessarily expending limited regulatory resources to the detriment of genuine environmental issues. Our comments below focus on three studies that have been misrepresented and thus inappropriately lower the egg/ovary selenium criterion. We also comment on the misuse of technically indefensible overwinter survival data to limit inappropriately the reproduction-based whole body criterion, which impacts the egg/ovary selenium criterion. Finally, we provide evidence that egg/ovary selenium concentrations above the proposed criterion occur in fish from reference areas and provide additional

data supporting a higher fish tissue selenium criterion than provided in the 2015 EPA Selenium Draft, specifically at least 20 mg/kg dw for egg/ovary.

2.2.1 Brown Trout EC10

The EPA brown trout egg/ovary EC10 of 18.09 mg/kg dw was derived only considering survival, not deformities, and without considering the data from full hatch through 15 days post swim-up test. EPA should have used the combined endpoint, which integrates lethal and sublethal endpoints. The uncertainties identified by EPA as justification for selective data exclusion are not technically defensible. Examination of the hatchery data from the Yellowstone cutthroat trout studies (e.g., the wild run of fish from Henry's Lake) clearly indicates that slight abnormalities are consistent with a natural rate of deformities6 and better explains the observed higher incidences of slight deformities for hatchery brown trout. Accordingly, the combined data should have been used, combining fish ranked as 0 (no deformities) and 1 (slight deformities).

As noted in the NAMC comments on the 2014 EPA draft (Attachment 1), there is no sound basis for using either the survival endpoint alone or the deformities endpoint alone when the combined survival and deformities endpoint is available. EPA's first application of regression analysis for estimating ECx values was in the 1999 ammonia criteria document. Whenever possible, that document used the combined survival and growth endpoint, which it termed "biomass." Given EPA's past preference for combining the important endpoints, it is unclear why, in this case, EPA did not combine the survival and deformity endpoints for the brown trout study. There is no technical justification for this unusual and arbitrary decision.

The Toxicity Relationship Analysis Program (TRAP) calculation for the combined endpoint grouping the 0 and 1 deformity data, including the hatchery data, results in an EC10 of 20.5 mg/kg dw as derived by the authors of the brown trout study. (See Figure 1, below, as presented to EPA as part of Simplot's comments on the 2014 EPA draft.) The EPA-proposed EC10 of 18.09 mg/kg dw for brown trout based only on the partial data set should be replaced by the conservative EC10 of 20.5 mg/kg dw, which considers the full data set. As noted in the NAMC 2014 comments (Attachment 1), there is no evidence that selenium is having effects on the combined survival and deformities endpoint at concentrations below 20.5 mg/kg dw. There is less than a 10% effect (relative to the background response) below this concentration. The EPA's TRAP calculation undershoots this data point, thus yielding an overly conservative EC10.

Original letter contains Figure 1 – TRAP tolerance distribution graphical output for the model fit yielding an EC10 of 20.5 mg/kg dw for the combined survival and deformities endpoint. See original letter.

2.2.2 Bluegill EC10

As noted in the NAMC 2014 comments (Attachment 1), EPA obtained its bluegill reproductive genus mean chronic value (GMCV) as the geometric mean of EC10s from three studies: 20.75 mg/kg dw egg from Doroshov et al. (1992),7 24.55 mg/kg dw egg from Coyle et al. (1993),8 and 12.68 mg/kg dw ovary from the combined Hermanutz et al. (1992, 1996)9, 10 studies.

The EC10 obtained from the two Hermanutz et al. studies is an outlier (about half the EC10 of the other two studies) and does not reflect the fact that the correct endpoint reported by Hermanutz et al. (1992) was 30 mg/kg. As detailed in the NAMC comments on the 2014 EPA draft (Attachment 1), use of these two studies is not scientifically defensible. They were not designed to obtain an egg/ovary selenium benchmark11 and there is a clear disconnect in these studies between the well-characterized water selenium concentrations and the supplementary information on selenium in the fish.

Accordingly, the two Hermanutz et al. studies should not be used to determine the combined species mean chronic values (SMCV) and GMCV. Instead, these values should be derived solely from the other two studies -- Doroshov et al. (1992) and Coyle et al. (1993). DeForest et al. (2012) reported a species mean of 21.5 mg/kg dw for these two studies in their derivation of a selenium benchmark.12

2.2.3 White Sturgeon EC10

The 2015 EPA Selenium Draft references the Linville 2006 white sturgeon study, which was not included in the 2014 EPA draft. That study reported the lowest EC10 and thus the lowest GMCV, which drives the current egg/ovary criterion. NAMC notes that this study is very weak, with relatively little effect determined at the highest tested concentration. Effects were noted for both edema and weight of larvae, but not for survival, length, or weight. The combined effects of edema and deformities were 27.8% at 20.5 mg/kg dw egg selenium and 13.3% at 11 mg/kg dw egg selenium.

The Linville study data do not allow calculation of a technically defensible EC10 because a concentration-response curve was not established. There simply are not sufficient data spanning a no effect to effect range to derive a reasonable dose-response curve. Thus, there were insufficient data points to provide an unambiguous EC10, as required by EPA's computer program, TRAP.14, 15 EPA, however, ignored the TRAP requirements for a technically defensible EC10 and calculated a highly uncertain EC10 based on a partial response at the highest selenium concentration. As the 2015 EPA Selenium Draft states, "[a]n EC10 based on only one partial response would not ordinarily be included in the chronic data set…."16

Problems with determining any EC10 from Linville are apparent upon review of Appendix C of the 2015 EPA Selenium Draft. The EPA EC10 is not the only value that could have been derived and was determined subjectively as the most conservative value. The EC10, therefore, is highly uncertain and most likely overly conservative as the slope was determined based on the single highest effect value.

The technically indefensible partial response used to derive a white sturgeon EC10 was explicitly included for two technically inappropriate reasons -- (1) because sturgeon are a threatened or endangered species and (2) because of a non-reproductive study. The non-reproductive study resulted in a whole body EC10 for green sturgeon of 16.36 mg/kg dw and for white sturgeon of 23.94 mg/kg dw. Both EC10s were based on percent body weight increase. There were no mortalities of white sturgeon during the study, while for green sturgeon survival data resulted in a whole body EC10 of 28.93 mg/kg dw. De Riu et al. (2014) noted that the lower body weight increase could have been due to insufficient food and thus "low energy reserves in the green sturgeon."

As previously noted, NAMC agrees fully with EPA that, based on extensive scientific evidence, reproductive effects in conjunction with the magnitude of fish egg/ovary selenium concentrations are of greater ecological concern and provide a more reliable basis for the criterion than non-reproductive

endpoints (e.g., survivorship, growth). Accordingly, EPA's reliance on a non-reproductive endpoint to support a highly questionable reproductive endpoint is not technically defensible.

EPA is proposing a national selenium fish egg/ovary criterion driven by two studies with sturgeon: a partial response for white sturgeon that is only slightly above a negligible effects endpoint of 25% and a slight reduction in body weight for green sturgeon, which are typically found in marine or estuarine waters, not freshwaters. Neither of these responses could reasonably be related to effects that might threaten populations. NAMC reminds EPA that its national water quality criteria do not attempt to protect all species at all times, "[b]ecause aquatic ecosystems can tolerate some stress and occasional adverse effects, protection of all species at all times and places is not deemed necessary."

NAMC notes the coincidence resulting from the use of the Linville study in that it limits the fish tissue criterion relative to the Lemly flawed winter stress syndrome without creating a problem of defending the criterion's protectiveness for juvenile overwinter survival.

2.2.4 Overwinter Survival

The Lemly bluegill overwinter survival value,when averaged with the McIntyre et al. overwinter value,25 appears to limit how high the reproduction-based whole-body criterion can be without creating a problem of defending the criterion's protectiveness for juvenile overwinter survival.26 As highlighted in the NAMC comments on the 2014 EPA draft (Attachment 1), juvenile overwinter survival is not a technically defensible issue based on the Lemly (1993) study.

The juvenile bluegill overwinter survival testing conducted by Lemly (1993) to demonstrate increased overwinter mortality due to selenium is technically flawed. There was only one treatment, and thus no dose-response relationship was established. The relatively high selenium toxicity in Lemly's (1993) study was not found by McIntyre et al. Although the McIntyre et al. study has been criticized for a possible difference in light-dark test conditions, this relatively minor difference from the Lemly (1993) study should not have obviated replicating that Lemly findings of relatively high selenium toxicity if, in fact, the Lemly study results were robust and repeatable. The McIntyre et al. study should be viewed as the more reliable result because it has the greater number of concentrations tested; the more realistic exposure pathway (i.e., yeast to oligochaetes to fish), and the initial exposure period at a warm temperature.

Lemly's winter stress syndrome is based on the hypothesis that fish rely on stored energy to survive winter months due to low food availability that results in increased metabolism and energy deficiency. In fact, fish do not generally rely on stored energy over the winter months as active feeding occurs.

NAMC notes that the seven studies on active feeding referenced in the previous sentence above were provided in the NAMC comments on the 2014 EPA draft (Attachment 1) and, thus, were known to and available to EPA for its consideration. Five of the seven references, however, were neither cited nor considered in the 2015 EPA Selenium Draft. Two of the references (Bennett and Janz, 2007(a) and Bennet Janz, 2007(b)) were cited but not considered in the context of active winter feeding. It is unclear why EPA ignored these technically valid comments on the previous draft document, which calls into question the integrity of the public review process and the technical validity of this revised draft document.

Field studies have provided no support for Lemly's hypothesis of a winter stress syndrome related to selenium exposures. Hermanutz et al. exposed bluegills to selenium in outdoor experimental streams over winter but did not report increased overwinter mortality. Aspects of the winter stress syndrome hypothesis have been investigated in field studies of juvenile fish inhabiting areas receiving complex metal mine effluents containing elevated selenium concentrations. Support for the winter stress syndrome hypothesis would have come from decreased growth and energy storage over winter, more so with elevated selenium concentrations than in reference areas. The opposite was found to occur in juvenile northern pike (Esox lucius), burbot (Lota lota), fathead minnows (Pimephales promelas), creek chubs (Semotilus atromaculatus), and white suckers (Catostomus commersoni). Slimy sculpins (Cottus cognatus) exhibited changes in whole body triglycerides consistent with the winter stress syndrome hypothesis, but this occurred at both sites with elevated selenium and reference sites, thus also providing no support for the winter stress hypothesis related to elevated selenium concentrations.

It is misleading for the draft criteria document to average together the Lemly (1993) and McIntyre et al. (2008) results to create a Lepomis non-reproductive, cold season GMCV, against which the document compares its reproduction-based criterion.A Lepomis non-reproductive, cold season GMCV should not be provided; rather, it should be acknowledged that uncertainty remains regarding juvenile overwinter sensitivity while noting that the weight of field and laboratory evidence indicates that the reproductive endpoint is the critical endpoint. The NAMC notes that EPA states "The observations of Lemly (1993b) are evidence that larval deformity, not juvenile mortality, is the most sensitive endpoint."

2.3.3 Translation from Tissue to Water and High Incidence of False Alarms

The 2015 EPA Selenium Draft method to translate tissue selenium concentrations to water involves using data from the fish that accumulated the highest concentration at each site that had an EF (enrichment factor) rather than the geometric mean. This approach results in an inappropriately low water selenium criteria that will inevitably generate false alarms.

We note that the 2015 EPA Selenium Draft no longer contains the binary statistical analysis that was present in the 2014 document. That analysis used a much larger data set that was not confined to sites where algae/detritus/sediment were all measured. It used all available measurements of water and whole body fish selenium (i.e., fish bioaccumulation factors). The water concentrations in the 2014 binary statistical analysis were adjusted to estimate a site's 95th percentile high concentration based on previous estimates, which were based on time series simulations, of what a 30-day once-in-three year concentration represented. As detailed in the NAMC comments on the 2014 draft, this information provided the basis to demonstrate the expected high incidence of false alarms. EPA should explain why it opted to remove that data set from consideration.

NAMC does not support the 30-day averaging period and continues to believe (Attachment 1) that a 60-day averaging period would be highly protective.

In its comments on the 2014 draft (Attachment 1), NAMC urged EPA to consider a report that had been recently completed by the NAMC-SWG, Selenium Partitioning between Water and Fish Tissue in Freshwater Systems: Development of Water-based Selenium Screening Guidelines. That report, the result of a three-year research effort, contained new information that filled existing data gaps on the

translation of tissue-based criteria to water-based selenium screening levels. Specifically, the report derived and recommended technically- and statistically-defensible lentic and lotic water selenium thresholds, based on regression relationships using tissue thresholds previously determined using a species sensitivity distribution (SSD) from literature values for reproductive effects on fish, due to dietary exposure to selenium. That report is neither cited nor considered in the 2015 EPA Selenium Draft and no rationale is given for this surprising omission of relevant, technically defensible, useful information.

Comment Category 2.3 – Comments Concerning Fish Tissue Criterion Elements

2.3 Summary

Comments concerning the fish tissue criterion element as it appears in Table 1 of the July 2015 draft are included in this section. Some commenters felt that that the fish tissue egg ovary criterion was not legitimate claiming that it was based on the worst case assumption of the most sensitive species. Others commented that the egg-ovary criterion was derived using too few data. The "never to be exceeded" frequency generated much comment. Many interpreted the phrase to mean that a single fish tissue sample measurement above the criterion value would result in non-attainment.

2.3 Response to comments

2.3 Response to comments on the methodology for deriving fish tissue criteria values

While the Guidelines EPA uses to derive aquatic life criteria do not specifically address bioaccumulative pollutants like selenium, EPA followed the Guidelines and used the conceptual approach from EPA's Ecological Risk Assessment Paradigm in deriving the selenium criterion.

1. First EPA gathered all data on the toxic effects of selenium on aquatic organisms, as criteria are meant to protect the entire aquatic community.
2. Second, EPA recognized that the mode of action of selenium and its duality as a nutrient and a toxicant would require special consideration in the criteria derivation process. Given the available data, and deliberations from the 2009 Pellston Conference on selenium, EPA focused on toxicity tests that used maternal transfer of selenium via diet, and subsequent larval toxicity.
3. Using the sensitivity distribution (SD) methodology of the Guidelines, EPA assembled a fish egg-ovary species sensitivity distribution (SSD) based on EC_{10}s for all available reliable studies. We evaluated the available invertebrate tests, and considered them for meeting the 1985 Guidelines requirements for meeting the 8 minimum data requirements, but we did not use them quantitatively in the calculation of the egg-ovary criteria, since the available toxicity tests for invertebrates only use whole body selenium residues. The available tests also indicate that invertebrates are not as sensitive as fish. Amphibian data was also evaluated, but the data quality of the available studies was not sufficient for quantitative inclusion in the analysis. These studies are discussed in sections 3 and 6 in the criteria derivation.
4. We also used principles developed in an EPA White Paper reviewed by the SAB that provided for considering mode of action and other characteristics of pollutants like Contaminants of Emerging Concern (CECs) (and to some extent selenium). (U.S. EPA 2008). We were able to apply these principles because we have specific information about the mode of action and critical effect of selenium in aquatic ecosystems established via peer-reviewed publications in the open scientific literature and reviewed at a SETAC Pellston Workshop (Chapman et al. 2009), specifically, that egg-laying vertebrates are the most sensitive to selenium, and that reproductive effects are the most sensitive measurement endpoint.

Regarding comments on the tissue derivation procedures, EPA first incorporated the commenters' suggestion to use empirical data on muscle or whole body concentrations where such data were available, rather than an estimate derived using a median Conversion Factor (CF), into the criterion element derivation. For the remainder of tissue values that had to be estimated using a CF, EPA evaluated the approaches proposed by commenters. EPA concluded that using the median or using total least squares (TLS) regression are appropriate ways of setting CFs, while using ordinary least squares (OLS) is not supportable for this purpose. The proposed OLS method suffers from added uncertainty since it only considers vertical error (y-axis). However, the TLS method evaluated by EPA considers both horizontal and vertical error, and therefore does not have the uncertainty associated with OLS predicted CFs that depend on which tissue is assigned to which axis. The similarity in CF outcomes between TLS and the use of medians (original EPA method) provided support to retain the simpler median-based method, particularly since the TLS method is not amenable to calculation using readily available spreadsheet software. A more comprehensive description of the evaluation and method used in the 2016 final criterion document is located in Appendix N.

2.3 Response to comments on the normalization of data to dry weight

Regarding the wet weight to dry weight conversion factors, this is a very common conversion when assessing toxicity or concentrations in tissues; data are available in the open literature on wet weight to dry weight ratios. For the purposes of EPA's analyses, the wet to dry weight conversion factors used in the Agency's analysis for 38 fish species are documented in Appendix B, pages B2- B-4.

2.3 Response to comments on the duration of the fish tissue criterion element

Many commenters did not understand the specification of instantaneous duration (*not* instantaneous frequency, as some commenters misunderstood). As noted in the 2015 draft table footnotes, instantaneous refers to the fact that collecting multiple rounds of samples over a long period of time (duration) is not considered essential when proper sample collection is planned and conducted, and when the selenium source is relatively stable. Fish in an ecosystem integrate selenium exposure occurring through the food web/diet over time, and only change gradually. EPA recognizes that there could be some variability in concentrations in fish tissue, due to residence time of the pollutant in the fish habitat or depuration of selenium in females via reproductive loss of selenium to eggs. There are some data comparing eggs and ovary concentrations post spawn to suggest that body burdens may be lower in females for a period of time post spawn based on lower concentrations in the ovaries. There are no data for comparisons in whole body or muscle.

EPA is developing technical support materials regarding how to sample for fish tissue, and is not recommending that a single fish having selenium concentrations above the criterion be considered an exceedance of the criterion. These materials will be made available for public comment prior to finalization.

2.3 Response to comments on the frequency of the fish tissue criterion element

The "never to exceed" frequency was developed to reflect the fact that selenium, as a bioaccumulative pollutant and persistent, stable element, will accumulate and remain in a food web over a long period of time. EPA's aquatic life criteria are traditionally based on aqueous concentrations as toxicity for the chemicals for which criteria have been developed is generally due to aqueous exposure. These concentrations can vary significantly both short-term and long term, allowing organisms in the aquatic community to recover. In contrast, selenium is a bioaccumulative pollutant, and fish tissue concentrations have been directly correlated with the adverse effect. Observed reductions in fish tissue concentrations occur slowly, even after removal of a selenium source. Data from Belew's Lake, NC, indicate that once selenium releases into the lake were terminated, it took fish populations 5-10 years to recover. Thus, because selenium is bioaccumulative and persistent, clearly an exceedance frequency of once-in-3-years would not be protective of the aquatic life use as it would permit selenium to accumulate in a system above the criterion where it would remain in the food web and fish tissues for an extended period of time. Therefore, EPA determined that the fish tissue element of the criterion cannot be exceeded in order to be protective of the aquatic community. EPA is developing technical support materials regarding how to sample for fish tissue, and is not recommending that a single fish having selenium concentrations above the criterion be considered an exceedance of the criterion. These materials will be made available for public comment prior to finalization. EPA has clarified that the selenium criterion is focused on the protection of populations, not individuals. For example, from the criterion table, Footnote 6 states that "Fish tissue data provide instantaneous point measurements that reflect integrative accumulation of selenium over time and space in fish **population(s)** at a given site."

However the criterion document does note, "the assessment endpoint for selenium is the protection of fish populations. In some waters where ESA-listed fish species occur, a protection goal oriented to protection of individuals may be more appropriate. This should be reflected using site-specific data to derive an SSC for the site."

Regarding comments that EPA has deviated from its 1985 Guidelines in using a "never to exceeded" frequency, the 1985 Guidelines also encourage the use of "good science" and best professional judgement to develop protective criteria for the pollutant at hand. EPA notes that for the most part the 1985 Guidelines reflect practices and assumptions that the major exposure to the chemical under analysis is through the water column. This is not the case for selenium, a bioaccumulative pollutant that is persistent in ecosystems. Recommending frequent excursions above the criterion concentration would not be protective of aquatic life.

2.3 Response to comments on definition of fishless waters and new and increased discharges

The 2016 criterion now clarifies that water column values are derived from fish tissue via bioaccumulation modeling under the assumption of steady state conditions. EPA agrees with the commenter regarding increased inputs, as it is possible for a discharger to calculate a new limit based on the existing water and fish tissue (assuming steady state) to insure the increase would not cause an exceedance to the fish tissue criterion. Since there is uncertainty in the relationship between water and

fish tissue under a new discharge scenario, use of the water column value will insure that the fish in the system is protected until steady state is achieved in the fish.

2.3 Responses to footnote 5 of the 2015 criterion table, regarding changes in selenium concentration in fish tissue related to new discharges

Regarding the KDOW comment referring to footnote 5 of the 2015 draft document, this footnote has been edited.

Section 6.1 of the 2016 selenium criterion document notes that researchers often report concentrations of selenium in fish eggs or ovaries Osmundson et al. (2007) found reduced levels of selenium in ovaries after spawning, presumably due to the loss of selenium through spawning and release of eggs with relatively high concentrations of selenium. Of the 14 chronic values determined from the maternal transfer reproductive studies, 11 values represent selenium measured in eggs. Three values represent selenium measured in the ovaries: Schultz and Hermanutz (1990), Hermanutz et al. (1992, 1996) and Carolina Power & Light (1997). However, information in two of these studies indicates that the concentrations of selenium in the ovaries were similar to concentrations in eggs. Schultz and Hermanutz (1990) measured selenium in fathead minnow ovaries at the end of the study from fish that presumably had spawned. The authors found the concentrations of selenium in the ovaries and embryos of the fathead minnows exposed to the same treatments to be similar. Hermanutz et al. (1992, 1996) sampled adult female bluegill just prior to spawning and at the end of the test (post spawning) and found no decreases in the concentration of selenium in the post-spawned fish. In the Carolina Power & Light (1997) study, the third study, selenium in ovaries of largemouth bass (Carolina Power & Light 1997) was measured from fish sampled just after spawning. No comparison to pre-spawning fish or selenium in eggs can be made for the largemouth bass study, however, the EC_{10} of 26.3 mg Se/kg ovary dw was mid-range of sensitivity indicating this test was not overly conservative due to lower selenium measurements in post spawning ovaries. Based on the indications that the selenium concentrations in the ovaries were similar to that in eggs in the Schultz and Hermanutz (1990) and Hermanutz et al (1992, 1996) study observations stated above, egg selenium and ovary selenium were considered equal for the toxicity data set. Any potential error resulting from this assumption would be conservative since the effect of spawning only lowers the selenium concentration in the ovary. EPA recognizes selenium ovary concentrations may vary in field collected samples due to fish reproductive cycles and will address such concerns in the implementation information.

The Conley (2014) reference has been reviewed and considered. The agency is aware that spawning strategy likely plays a role in maternal transfer and deposition of selenium into the eggs. The issue raised in Conley 2014 will be addressed in the technical support materials under development regarding the timing and type of sampling (egg-ovary vs whole body vs muscle tissue) based on species spawning strategy (single batch versus multiple smaller batches) and seasonality (spring [e.g., sunfish, some salmonids] or fall [e.g. brown trout] versus sporadic spring/summer [e.g., cyprinids]), while also providing flexibility to states to adapt their monitoring programs to address the additional requirements for fish tissue monitoring for selenium.

2.3 Specific comments

EPA-HQ-OW-2004-0019-0403-A2; Iowa Department of Natural Resources; Posted 10/15/15

EPA states that all the criteria elements except for the 30-day average should be implemented as never to exceed values: only one exceedance will impair the waterbody. The basis for this approach is not well-justified, deviates from all previous criteria recommendations, and is not well-suited to the implementation of a tissue-based criterion. For example, due to between-year variability in levels of toxic contaminants in fish, the fish consumption advisory protocol used by Iowa DNR specifies that two consecutive samplings are needed that show contaminant levels above the advisory threshold before a fish consumption advisory is issued. This confirmation-type approach is used to ensure, to a reasonable degree, that levels of a toxic contaminant are, in fact, above the consumption advisory threshold. Without such an approach, advisories could easily be based on sampling error associated with year-to-year variability in fish tissue contaminant concentrations. EPA should consider allowing states to adopt a similar approach for implementing tissue-based aquatic life criteria for selenium where impairment would be identified if the tissue-based criteria were exceeded more than once in three years.

Iowa DNR questions the expression of the tissue-based criteria elements as mg/kg *dry* weight. Historically and currently, all of Iowa's fish tissue data have been reported from laboratories as mg/kg *wet* weight. Most of Iowa's historical fish tissue data came from the U.S. EPA Region 7 lab and were reported as wet weight values. If EPA plans to recommend adoption of dry weight concentrations of selenium, then EPA should provide a cross-walk of dry-weight to wet-weight tissue concentrations of selenium.

EPA-HQ-OW-2004-0019-0397-A1; Peabody Energy; Posted 10/15/15

Due to natural variability fish tissue samples should be averaged as opposed to being limited by individual samples

EPA studies and other research indicate that there will be natural variability in tissue samples. Single samples will not represent the environmental condition with precision. Using the "seasonal average" instead of "instantaneous" limits will provide a more accurate tissue criterion requirement.

Peabody disagrees with applying only the proposed water column concentration where a new source exists

Applying the water column concentration only until a new source has been active for several months may result in unwarranted violations. For NPDES applications, a report only requirement along with a reasonable potential analysis would be appropriate for a limited period of time after discharge is initiated. Once equalization is determined to have occurred the fish tissue and egg tissue should apply if the water column limit is exceeded. In fact, EPA leadership recently stated in a stakeholder meeting that the fish tissue standard should be applied as opposed to the guidance language.

Peabody disagrees with applying only the proposed water column concentration to fishless streams

It is unreasonable to apply a water column concentration designed to protect fish in streams that do not have fish. We suggest that a better approach is to test fish tissue downstream, where fish are first present, to determine if a stream segment is in attainment. Macroinvertebrates are less sensitive to Se as compared to fish. If there is a concern for macroinvertebrates, site specific limits should be developed based on the aquatic life that is present. Recent statements by EPA leadership in a stakeholder meeting indicate that states will be given the necessary latitude to test fish tissue downstream or to develop standards based on protecting macroinvertebrates. These options should be clearly reflected in the guidance document.

EPA-HQ-OW-2004-0019-0395-A1; CONSOL Energy; Posted 10/15/15

For tissue criteria frequency, the use of term "never to be exceeded" is neither appropriate nor in-line with standard criteria attainment requirements. Clarification of tissue sampling requirements and use of an alternative approach such as the geometric mean of samples collected, with an allowable exceedance frequency of no more than once every three years on average is needed. This would be in-line with other criteria.

CONSOL believes that the establishment of criteria for streams with no existing fish populations needs to be clarified. We disagree with the default approach to use water-column criteria. A more scientifically rigorous alternative would be the use of the chronic invertebrate data provided by EPA to develop invertebrate tissue-based site-specific criterion and associated protective water-column criteria.

EPA contends that the water column elements should have primacy in "fishless waters" and in waters with new or increased selenium inputs until equilibrium is reached. These decisions should be handled on a case by case basis with final authority given to the individual state authority.

EPA-HQ-OW-2004-0019-0390-A1; West Virginia Coal Association (WVCA); Posted 10/14/15

The expression of the fish tissue numbers in the Draft Selenium Criterion as concentrations that are "never to be exceeded" is not plausible for implementation. This implies that a single fish with a concentration above the criteria would require 303(d) listing of the receiving stream. The criteria should be revised to include better language to clarify EPA's intent for the frequency.

WVCA does not agree with EPA's footnotes setting primacy of the water column elements in certain circumstances. EPA contends that the water column elements should have primacy in "fishless waters" (waters where fish have been extirpated, or where physical habitat and/or flow regime cannot sustain fish populations), and in waters with new or increased selenium inputs until equilibrium is reached. First and foremost, these are not actual elements of the criteria, but instead are efforts to incorporate implementation determinations directly into the chronic criterion. These decisions cannot be made holistically and must be evaluated on a case by case basis. States are given the authority to make permitting and stream listing decisions, which consider the specific facts of each circumstance to make the best decisions for the waters of the State. EPA cannot circumvent this authority and rational decision-making with footnotes to a recommended criterion.

For fishless waters, particularly those where the flow or other elements of the physical habitat is insufficient for fish populations, EPA's recommended approach is nonsensical. Certainly, fish are protected where selenium concentrations in the headwaters do not exceed the concentrations required in the segments where fish are present. An assumption that segments without fish must have selenium concentrations lower than segments with fish defies logic.

EPA attempts to reach too far with its "guidance" on implementation of the selenium criteria. These decisions must be made based on each specific circumstance. If EPA disagrees with a permitting or stream listing decision, we have no doubt that EPA will exercise its authority to express its concerns to the State.

EPA-HQ-OW-2004-0019-0414-A2; Colorado Mining Association (CMA); Posted 10/28/2015

CMA disagrees with the use of the instantaneous measurement for fish tissue compliance

Fish tissue concentrations show variability due to a number of factors including, but not limited to, analytic methods, laboratory procedures, sampling procedures, fish species, seasonal variability, and other environmental characteristics. Because of this variability, CMA believes a more appropriate comparison to the fish tissue criteria would use the average of the fish tissue measurements, or some other statistically derived value, rather than the instantaneous measurement.

CMA disagrees with EPA's application of water column concentrations

EPA proposes to apply the water columns concentrations under two scenarios: 1) fishless streams, and 2) new discharges. On fishless streams, it would be inappropriate to apply the water column concentrations. The water column concentrations were derived to protect fish from reproductive effects of selenium. If there are no fish in the stream, the water column concentrations are overprotective for the resident aquatic life which likely consists predominantly of macroinvertebrates. Rather, EPA should allow the option of 1) fish tissue testing at a point further downstream where fish can be found, or 2) development of site-specific criteria protective of macroinvertebrates, to determine compliance.

For new discharges, applying the water column concentrations for an initial period of time while the stream biota assimilates to the new source discharge can result in needless violations. Instead, the EPA should allow application of report only limits to the new discharge until a reasonable potential assessment can be completed. If selenium limits are determined to be appropriate, then a water column concentration trigger and fish tissue based limit can be applied.

EPA-HQ-OW-2004-0019-0385-A2; Kentucky Division of Water (KDOW); Posted 10/13/2015

KDOW believes that footnote 5 is not entirely accurate and this issue warrants more thorough explanation in the document. The statement: "selenium concentrations in fish tissue are expected to change only gradually over time in response to environmental fluctuations" does not reflect the variations of selenium concentrations in fish tissue resulting from reproduction and depuration.

Delete footnote 5 (July 27, 20I5 80 FR No. I43 at 44352) as this is not entirely accurate and should otherwise be addressed more appropriately elsewhere in the document.

Exceptions to Tissue-Based Criterion

KDOW has several serious concerns regarding footnote 3 in Table 1. EPA does not define, by magnitude of concentration, frequency, or by duration, the discharges that should be considered "new or increased inputs of selenium." There are countless scenarios that create implementation challenges for states. EPA also does not define, by aquatic conditions or by duration, the term "equilibrium." Attempting to define and defend when a stream is in equilibrium or steady-state in order to determine when and what criterion should apply creates a legally and technically unworkable, and unnecessary, requirement for states. Without such terms being clearly defined, states cannot determine in a scientifically defensible manner when such "new or increased inputs" should cause water column values to have primacy over fish tissue values. A water quality standard, or a permit condition based on a water quality standard, that relied upon such "new or increased inputs" and "equilibrium" in order to determine when water column values would have primacy over fish tissue values would create legal jeopardy for states implement this requirement. As such, a standard or permit relying on this approach as proposed would routinely be found as arbitrary and capricious and thus would likely be invalidated.

Essentially these same site-specific concerns were identified during external peer review of the draft criterion. Dr. Kevin V. Brix commented: "[t]he issue of generating pulse loads of [selenium] that may ultimately result in [selenium] accumulation in sensitive downstream systems *(e.g.,* pulse loads in a river that discharges to a wetland) is a legitimate concern. However, in my opinion, this is a site-specific issue and it is not reasonable to establish national WQC that ensure protection of these sites... "

KDOW believes that the "Fishless Waters" language in footnote 3 is unnecessary given that footnotes 1 and 2 address the order of criterion element primacy. Furthermore, use of "(waters where fish have been extirpated, or where physical habitat and/or flow regime cannot sustain fish)" is unnecessary and inadvisably seems to establish and thereby limit the conditions by which there would be a lack of available fish tissue, which KDOW does not believe is EPA's intention.

EPA-HQ-OW-2004-0019-0413-A2; Federal Water Quality Coalition (FWQC); Posted 10/28/2015

I. NEW ISSUES IN 2015 NOTICE

In the Selenium Notice, there are two issues, not raised by the 2014 draft document, on which EPA seeks comment. Since those issues are new, we will address them first, before proceeding to other substantive issues.

As noted above, EPA has applied a general principle, in the Draft Criteria Document, that fish tissue levels of selenium take precedence over water column levels in determining whether the new criteria (and, by extension, the aquatic life designated use) are being attained. We agree strongly with that principle.[1] For that reason, we are concerned with the new exception to that principle that EPA suggests in the Notice. The Agency indicates that in situations where there are "new or increased selenium inputs," EPA recommends that fish tissue levels should not take precedence over water column levels, until "sufficient time has passed" to allow equilibrium to be attained in the food web. We disagree with

the broad adoption of this new policy, for several reasons. First, there is already a regulatory/permitting mechanism to address potential effects of new and increased discharges: the antidegradation program. Second, some new or increased inputs could be very small (i.e., *de minimis),* giving rise to no concern over potential effects on the aquatic system. Moreover, as a scientific matter, while there are some situations in which there may be lag time between new discharges and their effects, there are also situations in which fish tissue levels have been seen to respond rapidly to increases (or decreases) in selenium loadings. If there is a concern in a particular situation, which cannot be addressed through antidegradation review, then development of a site-specific criterion could be considered. But that is not a reason to apply a broad principle to all cases where there are new or increased inputs.[2] EPA's "new or increased" exception to "fish tissue precedence" should not be adopted.

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[1] As discussed below, we believe that EPA needs to explain, in more detail, what it means when it states that the fish tissue levels "take precedence" over water column levels.

[2] Also, EPA's suggested policy, in which water column levels would take precedence for "a few years," until equilibrium is reached, creates substantial permitting problems. A scenario could readily occur in which initial permit limits are imposed back on a "lack of equilibrium." Then, several years later, when equilibrium has been established, the discharger would be entitled to ask that the limits be revised, to reflect precedence of fish tissue data over the water column levels. However, if any compliance schedule that was included in the permit has, by then, expired, then anti-backsliding restrictions could apply, and the permittee could be unable to obtain the revised permit limits that would be justified by the updated scientific evidence. That result should be avoided.

1. Format of Fish Tissue Criteria as "Never to be Exceeded" Numbers

As part of the criteria process, EPA has defined the frequency element by stating that the new fish tissue criteria are "never to be exceeded." We believe that this frequency specification is fundamentally inconsistent with the nature of the effects being addressed, as well as EPA precedents in similar situations. In the Draft Criteria Document, EPA recognizes that uptake and depuration of selenium are usually gradual. But that would justify a long-term average form for the criteria, so EPA's use of an instantaneous form ("never to be exceeded") contradicts the Agency's own scientific conclusions. It also does not consider basic facts about fish: the pollutant content in individual fish, whether for selenium, mercury or another parameter, can vary enormously. Therefore, it is critical that fish tissue data be looked at across a set of fish, representative of the species collected in a waterbody. To apply a "never to be exceeded" test to a single fish, collected at one site, and to extrapolate that data to make attainment decisions as to a water body, would be arbitrary and capricious in the extreme. It would also be inconsistent with the Agency's own guidance for other fish tissue criteria- specifically, for mercury. There, EPA guidance makes clear that review of average tissue levels, looked at across several species representing at least two trophic levels, is the appropriate method of determining whether the criteria are met in the waterbody. A similar policy should be followed for the new selenium criteria.

V. USE OF A "NEVER TO BE EXCEEDED" FISH TISSUE VALUE

While there is general agreement among the peer reviewers that EPA acted properly in establishing fish tissue data as the primary element of the new criterion, there were concerns voiced over the Agency's statement of that element as a "never to be exceeded" value. EPA provides no clear explanation of the

rationale for that decision; while EPA then states that it will provide further detail in guidance, this is an important issue that needs to be addressed now, before the criterion is issued in final form.

Here are the issues with the "never to be exceeded" value that the peer reviewers expressed:

"It is unclear however, how the USEPA will interpret the "never to be exceeded" criteria.

Biological variability, coupled with uncertainty regarding the residence of mobile fish species, will make it likely that some fish in a given collection may exceed the guidelines. It is unclear if a result from one fish (i.e. a single exceedance) will render a given management area in non-compliance, or if some average value is intended as the trigger." (p. 19)

"Although the EPA's AWQC, including the draft water Se criteria, are not to be exceeded more than once in three years, the fish tissue-based Se criteria are "never to be exceeded." To my knowledge, the "frequency" component of AWQC is rarely incorporated into permit limitations, so the implications of fish tissue-based Se criteria "never to be exceeded" are not entirely clear to me. The "frequency" component was initially incorporated into AWQC based on the premise that ecosystems will not be harmed if the number of criterion excursions is limited and/or there are compensating periods of time below the criterion over which the ecosystem can recover. As far as I can tell, the draft AWQC document for Se does not explain the basis for the "never to be exceeded" frequency decision for fish tissue. It seems that there should be some level of consistency between the allowable "frequency" for fish tissue-based and water-based Se criteria." (p. 44)

EPA addresses these concerns in two ways. First, it indicates that guidance will be issued:

"Regarding the interpretation of the "never to be exceeded" criteria, this is an issue that will be addressed in the technical support documents." (p. 18)

On a more substantive level, here is EPA's response:

"Regarding the criterion frequency, selenium is persistent, however, it may be sequestered in an environmental compartment that precludes it from uptake in biota (e.g., burial in sediment). EPA's AWQC are traditionally based on aqueous concentrations since toxicity for the chemicals for which criteria have been developed is generally due to aqueous exposure. These concentrations can vary significantly both short-term and long term, allowing organisms in the aquatic community to recover. In contrast, selenium is a bioaccumulative pollutant, and fish tissue concentrations have been directly correlated with the adverse effect. Also reductions in fish tissue concentrations occur slowly, even after removal of a selenium source. Since exceedance of these concentrations is correlated with adverse effect occurs EPA determined that these levels cannot be exceeded in order to be protective of the aquatic community. Technical support information regarding fish tissue sampling issue is being developed by EPA."

Unfortunately, this response does not answer the question at issue. Exceedance of the concentration specified in a criterion is always connected with an adverse effect – that says nothing about what frequency should be specified in the criterion. Is EPA saying that if one fish from one site is found to possess a tissue level of selenium higher than the criterion, the entire waterbody must be classified as in nonattainment? And if that is so, does that mean that if, on the next sampling event, a fish is found that

has less than the criterion value of selenium, the waterbody is no longer in nonattainment? Surely that is not what EPA means – but by specifying that the criterion is "never to be exceeded," that is a reading of the EPA decision that some will take. And even guidance can only have a limited scope in this circumstance – the guidance will have to explain what "never" means. If the Agency truly wants to examine these issues in a fuller way, and to do so through issuance of guidance, then it should eliminate the "never to be exceeded" language from the criterion structure, and leave the frequency issue to be worked out in the technical guidance to come.

EPA-HQ-OW-2004-0019-0415-A1; Idaho Department of Environmental Quality (DEQ); Posted 10/28/2015

Does "never to be exceeded in fish tissue" really mean not even in one fish sample, ever? Or is some averaging allowed, intended, possible? Could there be compositing of samples for a species from a site for example, as a way to reduce costs as well as smooth out some variability? If just one sample exceedance will bust the criterion, then how are analytical outliers, or a wandering individual to be taken into account? A better discussion on the relation of individual effect thresholds to population effects, including statistical foundation, is needed to understand the monitoring and assessment implications of the "never to be exceeded in fish tissue" statement. EPA should address directly and clearly in revisions to this criterion proposal issues of measurement variability as well as environmental variability, to arrive at an allowable frequency of exceedance; the never to be exceeded requirement should be dropped.

EPA-HQ-OW-2004-0019-0401-A1; Colorado Wastewater Utility Council; Posted 10/15/2015

3.5 Recommendations for "Never to be Exceeded" Frequency

Although it is inherent in the way this document was written that the burden to determine how a tissue-based standard will be implemented will be left to the States, we would like to comment on the "instantaneous" and "never to be exceeded" language that is presented in relation to the proposed tissue standard.

Generally, the term "never to be exceeded" requires substantive clarification to make clear what is expected – an issue that cannot wait for some future undetermined "implementation guidance" document. The way the language is written currently suggests that a single fish tissue sample with a concentration above the criteria (egg/ovary, whole-body, or muscle) would result in non-attainment – a result that is directly contradictory to the data used to develop the criterion. However, other alternatives could be employed (as discussed in our previous review) to ensure that a single fish would not be used to determine attainment. We also support the very detailed analysis of this issue contained in last year's comments by NAMC-SWG (2014).

3.6 Recommendation for Fishless Waters

In cases where fish populations are not present due to flow limitations the aquatic life to be protected are the macrobenthos. In EPA's analysis of invertebrate data, the mayfly, *Centroptilum triangulifer*, was found to be the most sensitive, with a GMCV of 24.2 mg Se/kg dw wb. Effect concentrations for the other invertebrates for which chronic data were available were substantially higher than 24.2 mg/kg. Therefore, based on these data, an invertebrate Se tissue concentration of 24.2 mg/kg dw would be protective of the attainable uses of those fishless waters, i.e., invertebrates.

The key issue is to ensure protection of downstream waters through evaluation of fish tissue attainment measurements. If downstream receiving waters are in attainment with water quality standards (based on tissue-based criteria) it is not necessary to protect non-existent fish in the upstream waters. However, it may be appropriate to develop site-specific standards to protect other aquatic life in these fishless streams.

5.1 Other Considerations

As stated in our review of the 2014 criteria document (GEI 2014b), we agree that any fish tissue collected is representative of accumulation over time and could be considered an "instantaneous" measurement of the current conditions. However, we believe the use of the term "instantaneous" leads to substantial confusion regarding the tissue sampling requirements. We support the thorough discussion of this topic in the NAMC-SWG 2014 review and agree that there will be natural variability in the tissue samples collected, and a single sample may be over- or under-representative of site conditions. The best way to represent environmental conditions is to average the tissue samples in some manner. We recommend replacing "instantaneous" with "seasonal average" in the tissue criterion requirements.

Regarding implementation of the tissue-based criteria, the use of "never to be exceeded" frequency is inappropriate and not in line with standard criteria attainment requirements. We recommend clarification of tissue sampling requirements and use of an alternative approach such as the geometric mean of samples collected, with an allowable exceedance frequency of no more than once every 3 years on average.

There are several other components of the criteria that should be reevaluated by the EPA. The use of "never to be exceeded" frequency for the tissue criteria is inappropriate and not in line with standard criteria attainment requirements. We recommend clarification of tissue sampling requirements and use of an alternative approach such as the geometric mean of samples collected, with an allowable exceedance frequency of no more than once every 3 years on average – consistent with other criteria. Another issue that requires reevaluation is how to establish criteria for streams with no existing fish populations. The default by EPA is to use water-column criteria; however, we provide discussion of an alternative involving use of the chronic invertebrate data provided in the EPA document.

Overall, this document is a substantial improvement over pre-2014 Se criteria documents, and we look forward to the final draft document, with the hope our recommendations are taken into consideration.

We also have general concerns with the language in Footnote 3 of the criteria table. This footnote states:

> Water column values are based on dissolved total selenium (includes all oxidation states, i.e., selenite, selenite, organic selenium and any other forms) in water. Water column values have primacy over fish tissue values under two circumstances: (1) "Fishless waters" (waters where fish have been extirpated, or where physical habitat and/or flow regime cannot sustain fish); and (2) New or increased inputs of selenium until equilibrium is reached.

Our concerns are how this language will potentially be used by state agencies and their (NPDES permit writers. In the case of new or expanded discharges, the permit writer would be required to put a water quality-based effluent limit (WQBEL) in the permit based on the proposed water quality criterion during the time period it takes for the stream to reach "equilibrium", which may take months or even years. When equilibrium is reached, and a fish tissue concentration is deemed appropriate, the limit derived from the fish tissue concentration-based effluent limit may likely be higher than the existing limit based on the water column value. As a result of EPA's anti-backsliding and antidegradation provisions, state agencies and permit writers generally do not incorporate WQBELs in permit renewals that are less stringent that those that were previously issued. Therefore, it is likely that the fish tissue-based effluent limit will not be permissible after a water column limit is already in place.

This same concern could also apply to existing dischargers, which currently have water column criteria in place with limited or no existing fish tissue data. During the permit renewal process implementation of fish tissue-based limits could be complicated due to the anti-backsliding antidegradation provisions unless an exception in included in any selenium implementation guidance that EPA issues. Another approach to eliminating this issue would be to implement a tiered approach such as that approved in Kentucky, in which the water column values are considered "thresholds" rather than "criteria".

Another issue that requires reevaluation and clarification is how to establish criteria for streams with no existing fish populations. The default approach from EPA is to use water-column criteria; however, an alternative would be the use of the chronic invertebrate data provided by EPA to develop invertebrate tissue-based site-specific criterion.

Another topic that needs further consideration is the use of natural background Se concentrations to develop ambient based site-specific criteria. We have provided discussion of how this has been successfully done in Colorado in our previous review (GEI 2014a), and how it should be considered on a case-by-case basis nationwide. EPA's discussion of site-specific standard development is lacking any discussion of naturally elevated selenium in water and fish tissues and needs further clarification.

EPA-HQ-OW-2004-0019-0400-A1; The National Mining Association (NMA); Posted 10/15/2015

2.3.2 Protection Goal and High Incidence of False Alarms

The duration and frequency for the tissue criteria could be interpreted to mean that no individual fish in a water body is ever allowed to exceed the tissue criterion. Given that the goal is to protect populations of fish, not individual fish, we request that EPA clarify that the protection goal is, in fact, fish populations, not individual fish. Therefore, the criteria should be applied as geometric means for a sampled population, not individual fish.

We are also concerned that the tissue criterion, inappropriately expressed as "never to be exceeded" on an instantaneous basis, will result in a high incidence of false alarms that will lower national and state abilities to address genuine environmental problems. Such a specification is unprecedented for EPA aquatic life criteria and EPA has presented no rationale for this recommendation. Nor has EPA explained how it should be interpreted or implemented. Because EPA's permit program incorporates assumptions of lognormal concentration distributions in its permit derivations, we are unable to understand how either the permit writer or the discharger can design for a criterion that is "never to be exceeded," since lognormal distributions have no concentration that is never exceeded.

We point out that an EPA requirement to "never exceed a tissue criterion" has significant implications in implementation and engineering design of water treatment facilities. A "never to exceed" criterion means that industrial and municipal water treatment facilities must over-design either in treatment capability or water holding capacity to avoid never having a tissue exceedance. This effectively lowers the selenium tissue criterion to a much lower concentration than proposed in the current document to ensure there is never an exceedance. We do not have the data at present to estimate the impact, but it would be significant. A "never to exceed" is unrealistic, technically indefensible, and unworkable.

Accordingly, we recommend that, in accord with EPA Guidelines, "instantaneous" be replaced with "seasonal average," and "never to be exceeded" be replaced with "not to be exceeded more than once in three years on average" applicable to the seasonal average concentration.

As noted, NAMC is extremely concerned by an expected high rate of false alarms. State pollution control agency budgets are fixed. Each time there is a false alarm, state government resources that had been allocated to solving genuine environmental problems must be reallocated to resolve the false alarm, even if that only means overseeing a tissue monitoring study performed by the discharger and arriving at a conclusion after examining the results. Because we are supportive of the mission of the state pollution control agencies and of EPA, we are concerned by the fact that setting the criteria inappropriately low will result in a serious misallocation of resources, thereby reducing rather than enhancing the nation's ability to address environmental problems.

3.5 Recommendations for "Never to be Exceeded" Frequency

Although it is inherent in the way this document was written that the burden to determine how a tissue-based standard will be implemented will be left to the States, we would like to comment on the "instantaneous" and "never to be exceeded" language that is presented in relation to the proposed tissue standard.

Generally, the term "never to be exceeded" requires substantive clarification to make clear what is expected – an issue that cannot wait for some future undetermined "implementation guidance" document. The way the language is written currently suggests that a single fish tissue sample with a concentration above the criteria (egg/ovary, whole-body, or muscle) would result in non-attainment – a result that is in direct contradiction to the data used to develop the criterion, which are based on EC_{10}s calculated from means of treatments. However, other alternatives could be employed (as discussed in our previous review) to ensure that a single fish would not be used to determine attainment. We also support the very detailed analysis of this issue contained in last year's comments by NAMC-SWG (2014).

3.6 Concerns with Primacy of Water Column Values

We also have serious concerns with Footnote 3 of the proposed criterion. Footnote 3 outlines two scenarios in which water column values have primacy over fish tissue values – "fishless waters" and waters with "new or increased inputs of selenium until equilibrium is reached." Specifically, Footnote 3 states:

> Water column values are based on dissolved total selenium (includes all oxidation states, i.e., selenite, selenate, organic selenium and any other forms) in water. Water column values have primacy over fish tissue values under two circumstances: (1) "Fishless waters" (waters where fish have been extirpated, or where physical habitat and/or flow regime cannot sustain fish); and (2) New or increased inputs of selenium until equilibrium is reached.

While we understand the concerns EPA is seeking to address with respect to these two scenarios, we think that the proposed language, when taken in conjunction with the anti-backsliding provisions of the CWA, the requirements of the National Pollutant Discharge Elimination System (NPDES) permitting process for establishing water quality-based effluent limits (WQBELs), and state antidegradation regulations could in some instances effectively nullify the fish tissue approach all together. While EPA considers this an "implementation" issue, it is in fact the language of the criterion itself that will cause the issue and it cannot be rectified with implementation guidance. However, we think that there are ways to address EPA's intent in the criterion document that will allow state programs to maintain the primacy of the fish tissue values in permits without compromising the quality of downstream waters or waters with new or expanded selenium discharges.

The CWA's anti-backsliding provision provides that "a permit may not be renewed, reissued, or modified…to contain effluent limitations which are less stringent than the comparable effluent limitations in the previous permit." CWA Sec. 402(o). While there are listed exceptions to the anti-backsliding requirements, many state agencies and their NPDES permit writers construe these exceptions narrowly and generally interpret anti-backsliding to mean that permits cannot be modified or renewed with less stringent WQBELs than those contained in the previous version. Additionally, certain anti-backsliding exceptions for WQBELs are tied to both attainment and antidegradation regulations, which may cause additional issues with their application in some state programs.

As written, with respect to new or expanded discharges, the criterion would require a permit writer to put WQBELs based on the proposed water column criteria into NPDES permits during the months or even years that it takes for the receiving water to reach "equilibrium."[1]

Due to the conservative estimates used to derive the water column concentrations, it is possible that in many instances a post-equilibrium discharge limit derived from a fish tissue concentration-based effluent limit will be higher than one based on the water column value. However, because a discharger's permit will already contain the more stringent limitation, even after equilibrium is reached a discharger may only be allowed to have a limitation based on a fish tissue concentration put into their permit if that limitation would be more stringent than the one based on the water column value. In other words, there will likely be instances in which a fish tissue-based effluent limitation will not be permissible if states adopt the criterion as proposed despite the fact that such a limitation would represent the best available science and reflect the EPA's intent as we understand it. This same analysis applies to existing discharges where states may choose to first apply a WQBEL based on the proposed water column

criterion where data regarding fish tissue and fish egg ovary selenium concentrations may be scarce, not collected during permit renewal, or otherwise unavailable at the time of permit renewal.

While for some states programs this may not pose an issue (and we support such states' interpretation of anti-backsliding), and for others implementation guidance *may* be able to address this issue by fitting the criterion into one of the anti-backsliding exceptions, it is unclear if that will be legally possible, and regardless it would not matter because as a practical matter dischargers would have already had to install control technologies to treat to the more stringent water column-based limit despite the fact that such controls are not necessary to protect aquatic life. In more extreme cases, dischargers may not be able to get a permit at all based on Footnote 3 due to elevated natural background levels of selenium, despite the fact that certain levels of selenium could be discharged safely as demonstrated by the fish tissue concentrations, because permit writers would be inappropriately basing their calculations on the water column number. Because of this, we make two recommendations. The first is deleting Footnote 3 as written, and instead including a provision for new or expanded discharges whereby limitations are derived from fish tissue concentrations but compliance cannot be tested until the appropriate amount of time has elapsed for the receiving water to reach equilibrium (i.e., a bioaccumulation study special condition requirement). The second is renaming the water column "criteria" as water column "thresholds," as was done in Kentucky's recently approved selenium water quality criteria revision. This would clarify EPA's intent to allow fish tissue concentrations to have primacy over the water column values.

With respect to "fishless waters," Footnote 3 will likewise lead to situations in which dischargers must install expensive control technologies or not be able to discharge selenium at all despite the fact that such requirements are not necessary to protect aquatic life. We understand that EPA is required under the CWA to protect downstream waters when deriving water quality criteria. However, a scientifically defensible approach to "fishless waters" that EPA should provide to states as an option in the criterion is the derivation of a site-specific criterion that takes into account the sensitivity of the macrobenthos in the receiving water to protect the receiving water's attainable uses (i.e., to protect the receiving water's macrobenthic communities), while protecting downstream waters through determination of the flow rate of the receiving water into the nearest fish-containing water and ensuring that the fish tissue standard is being met in the downstream fish populations. Such a criterion would ensure that both in-stream and downstream aquatic life are protected without arbitrarily assigning overly-protective water column-based limitations to permittees. We therefore again recommend deleting Footnote 3 as written, and instead including a provision for "fishless waters" that allows for the development of site-specific criteria that protect the attainable use of in-stream macrobenthos as well as downstream fish populations through application of the tissue-based criterion (see additional discussion in Section 3.6.1).

Concerning a related issue, we also note that EPA guidance limits the terms of compliance schedules to five years, as do many state permitting programs based on EPA's guidance. Because in some situations where selenium levels are being decreased based on the new criterion it may take longer than 5 years for corresponding fish tissue concentrations to decrease, NMA recommends including a provision in the criterion stating that longer compliance schedules may be needed with respect to bioaccumulants. Although again this could be considered an "implementation" issue, because it is a facet of the criterion that could directly conflict with existing state water quality programs – thereby limiting states' ability to adopt it – it is necessary to adopt language in the criterion itself that addresses this concern.

5.1 Other Considerations

As stated in our review of the 2014 criteria document (GEI 2014b), we agree that any fish tissue collected is representative of accumulation over time and could be considered an “instantaneous” measurement of the current conditions. However, we believe the use of the term “instantaneous” leads to some confusion regarding the tissue sampling requirements. We support the thorough discussion of this topic in the NAMC-SWG 2014 review and agree that there will be natural variability in the tissue samples collected, and a single sample may be over- or under-representative of site conditions. The best way to represent environmental conditions is to average the tissue samples in some manner. We recommend replacing “instantaneous” with “seasonal average” in the tissue criterion requirements.

Regarding implementation of the tissue-based criteria, the use of “never to be exceeded” frequency is inappropriate and not in line with standard criteria attainment requirements. We recommend clarification of tissue sampling requirements and use of an alternative approach such as the geometric mean of samples collected, with an allowable exceedance frequency of no more than once every 3 years on average.

Based on the results of our analysis, we recommend updating the proposed egg/ovary, whole-body, and muscle chronic criteria to include our suggested changes (Table 8). In addition, because nationwide water column-based criteria cannot not be derived reliably, we advise EPA to only recommend water column-based criteria be developed on a site/state/region-specific basis (Table 8).

There are several other components of the criteria that should be reevaluated by the EPA. The use of “never to be exceeded” frequency for the tissue criteria is inappropriate and not in line with standard criteria attainment requirements. We recommend clarification of tissue sampling requirements and use of an alternative approach such as the geometric mean of samples collected, with an allowable exceedance frequency of no more than once every three years on average – consistent with other criteria. Another issue that requires reevaluation is how to establish criteria for streams with no existing fish populations. The default by EPA is to use water-column criteria; however, we provide discussion of an alternative involving use of the chronic invertebrate data provided in the EPA document.

EPA-HQ-OW-2004-0019-0389-A1; Thunder Basin Coal Company, LLC (TBCC); Posted 10/14/15

Frequencies of Exceedance

The "Never to be Exceeded" and "Not more than Once (Exceedance) in Three Years on Average" could prove very difficult for regulators and permittees to work with. EPA needs to explain how single sample exceedances, outliers, and false positives will be taken into account given the great variety of species and environments in which the new standards will be applied. In addition, if averaging is allowed, then EPA needs to better explain their rationale and procedures.

EPA-HQ-OW-2004-0019-0372; Anonymous public comment; Posted 09/23/2015

Please provide scientific evidence that justifies not following the 1985 Guidelines in setting the 2015 draft Se tissue criterion duration at "instantaneous" and its frequency at "never".

The 1985 Guidelines assert: "A statement of a criterion as a number that is not to be exceeded any time or place is not acceptable". In addition, "rather than try to reinterpret a [never-to-exceed] criterion that is neither useful nor valid, it is better to develop a more appropriate way of stating criteria."

The Guidelines also say, "the concentrations of a pollutant in a body of water can be above the CCC without causing an unacceptable affect if (a) the magnitudes and durations of the excursions above the CCC are appropriately limited and (b) there are compensating periods of time during which the concentration is below the CCC."

EPA's 2015 draft selenium document rationalizes its choice of instantaneous on the grounds that "fish tissue data provide point, or instantaneous, measurements". It is not apparent that EPA understands that tissue concentrations vary from fish to fish, and that a fish tissue sample collected at one instant would be expected to differ from a nearby fish tissue sample collected at a different instant.

Given that the criterion statement implies that the occurrence of a single fish with tissue concentration marginally above the criterion at any time, no matter how infrequent, can prevent the water body from attaining its designated use as a fishery, please provide scientific evidence to support your duration and frequency statements.

The "never" frequency implies that a system experiencing even a marginal exceedance can never recover. In fact, the scientific evidence in Chapman 2010 (cited in the EPA's draft) indicates that systems that once experienced long periods of exceedances several fold above the criterion have all since recovered.

Furthermore, while it is understandable that there is a range of scientifically defensible approaches, there appears to be an extreme difference between the 2015 draft fish tissue duration (instantaneous) and frequency (never) versus the Utah selenium bird egg criterion, which EPA approved as the geometric mean of samples, thus to be exceeded around 50% of the time. Please explain how this great difference in acceptable approaches is rationalized.

Standards for Fishless Waters and Use of Nationwide Water Column Based Standards

Approximately 70 to 80 percent of Wyoming streams are ephemeral or intermittent without the natural hydrologic potential to support fish populations (National Hydrologic Database). It is unreasonable to apply a water column concentration designed to protect fish in streams that do not have fish. It is also unreasonable to develop national standards to protect downstream fish species for all fishless waters; many Wyoming streams lack hydrologic connection or are very distant from streams with fish. For waters such as these, it is unnecessarily overprotective to apply such a national standard.

Waters with New or Increased Selenium Inputs

Applying the water column concentration only until a new source has been active for several months may result in unwarranted violations. For NPDES applications, we recommend reporting and a

reasonable site specific potential analysis for impacts on local aquatic life for a specified period of time after discharge has begun.

EPA-HQ-OW-2004-0019-0416-A1; Wyoming Mining Association (WMA); Posted 11/02/2015

Frequencies of Exceedance

The “Never to be Exceeded” and “Not more than Once (Exceedance) in Three Years on Average” could prove very difficult for regulators and permittees to work with. EPA needs to explain how single sample exceedances, outliers, and false positives will be taken into account given the great variety of species and environments in which the new standards will be applied. In addition, if averaging is allowed, then EPA needs to better explain their rationale and procedures.

Standards for Fishless Waters and Use of Nationwide Water Column Based Standards

Approximately 70 to 80 percent of Wyoming streams are ephemeral or intermittent without the natural hydrologic potential to support fish populations (National Hydrologic Database). It is unreasonable to apply a water column concentration designed to protect fish in streams that do not have fish. It is also unreasonable to develop national standards to protect downstream fish species for all fishless waters because many Wyoming streams lack hydrologic connection or are very distant from streams with fish. For waters such as these, it is unnecessarily overprotective to apply such a national standard. National standards could result in costly and unnecessary water quality exceedances and require treatment as well as unnecessary reductions in discharges if standards are not or cannot be met.

WMA believes that an acceptable option for some fishless waters would be to test macroinvertebrates to develop site specific limits. Macroinvertebrates are less sensitive to selenium compared to fish, but as other reviewers have commented, more data should be gathered for these species prior to implementation of the standards.

Waters with New or Increased Selenium Inputs

Applying the water column concentration only until a new source has been active for several months may result in unwarranted violations. For NPDES applications, a better approach would be to require reporting and a reasonable site specific potential analysis for impacts on local aquatic life for a specified period of time after discharge has begun.

EPA-HQ-OW-2004-0019-0402-A2; The Stakeholders Implementing TMDLs in the Calleguas Creek Watershed; Posted 10/15/2015

1. Justification and Explanation for the Selection of Execeedance Frequencies is Absent and Must be Provided in Order to Comment on the Appropriateness of Such Frequencies. However, Even Without Any Provided Explanation or Justification, the Exceedance Frequency for the Fish Tissue Elements of the Criterion of "Never to Be Exceeded" is Inappropriate, Impractical and Contrary to USEPA Guidance.

As previously noted in the Stakeholder's comments on the 2014 External Peer Review Draft Criterion, an exceedance frequency of "not more than once in three years on average" is identified for the water-

column elements of the criterion, yet no explanation or justification is provided to support this proposed frequency. Therefore, it is not possible to comment on the appropriateness of this selection. Given that this is such an important aspect of the criterion, it is unclear why the 2015 Draft Selenium Criterion was not updated to provide the requested justification. Additional supporting documentation needs to be provided with an additional opportunity to comment on this issue.

However, even without additional supporting explanation or justification, the exceedance frequency for the fish tissue elements of the criterion of "never to be exceeded" is impractical, inappropriate, and contrary to the guidance provided by the USEPA in the *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses*[19] (1985 Guidance Document) and the *Technical Support Document for Water Quality-based Taxies Control*[20] (1991 TSD). In the 1991 TSD, USEPA explicitly states (emphasis added):

> *"To predict or ascertain the attainment of criteria it is necessary to specify the allowable frequency for exceeding the criteria. This is because* ***it is statistically impossible to project that criteria will never be exceeded.*** *As ecological communities are naturally subjected to a series of stresses, the allowable frequency of pollutant stress may be set at a value that does not significantly increase the frequency or severity of all stress combined.* "

An exceedance frequency of "never to be exceeded" cannot reasonably or foreseeably be implemented in the impairment assessment of waterbodies required under Section 303(d) of the Clean Water Act. By the definition of "never to be exceeded," once a fish tissue exceedance is documented, there is no way to make a valid statistical determination that the waterbody has improved or meets the criterion. The 2015 Draft Selenium Criterion creates an unreasonable and unnecessary requirement that can be avoided by applying existing federal technical criteria guidance.

To address the shortcomings of the exceedance frequency of "never to be exceeded," one potential alternative is the development of a statistical threshold value (STV), a concept described in USEPA's nationally recommended *Recreational Water Quality Criteria*[21] (RWQC) released by USEPA in 2012. The STV approximates the 90th percentile of the water quality distribution and is intended to be a value that should not be exceeded by more than 10 percent of the samples taken. This concept can be applied as a frequency by stating that there should not be greater than a ten percent excursion frequency of the selected STV magnitude.

Requested Actions:

- ***Revise the frequency for the fish tissue elements of the criterion from "never to be exceeded" to an alternative frequency that allows a certain percentage of exceedances over a unit of time.***
- ***Provide the rationale for the exceedance frequency of "not more than once in three years on average" for the water column elements and any other exceedance frequencies included in a revised criterion (e.g., frequencies for the tissue-based elements).***

SUMMARY OF KEY TECHNICAL ISSUES

New Comments on the 2015 Draft Selenium (Addressing Modifications to the 2014 External Peer Review Draft Criterion)

- For evaluating "fishless waters," surrogate biological parameters should be used in place of water column values.
- Considerations for new or increased inputs should be included as implementation guidance and not included directly as part of the criterion.

The Stakeholders have the following specific technical comments related to the summary of key issues above:

NEW COMMENTS ON THE 2015 DRAFT SELENIUM (ADDRESSING MODIFICATIONS TO THE 2014 EXTERNAL PEER REVIEW DRAFT CRITERION)

1. Clarifying Language Added to Footnote 3 of Table 4.1 Is Appreciated.

Notwithstanding Comment # 1 0 the Stakeholders appreciate the USEPA's effort to clarify the basis for water column values in footnote 3 of Table 4.1 of the 2015 Draft Selenium Criterion by adding "(includes all oxidation states, i.e., selenite, selenate, organic selenium and any other forms)."

2. Considerations for New or Increased Inputs Should Be Included as Implementation Guidance and Not Included Directly as Part of the Criterion

As noted in Comment #2, the 2015 Draft Selenium Criterion includes two circumstances where water column values have primacy over fish tissue values:

> "1) 'Fishless waters' (waters where fish have been extirpated or where physical habitat and/or flow regime cannot sustain fish populations); and 2) New (see glossary) or increased inputs of selenium from a specific source, until equilibrium is reached."

The Stakeholders reaffirm that water column values should not have primacy over fish tissue values under any circumstance, including both of these circumstances. This comment addresses the aspect of establishing primacy of water column values over fish tissue values for new or increased inputs of selenium from a specific source.

USEPA's intent behind including a mechanism to prevent new or increased inputs of selenium from a specific source from causing increased bioaccumulation in fish over a period of time is understood. However, this aspect addresses implementation of the criterion itself, and not whether or not designated uses are being protected.

Therefore, it is not appropriate to include this mechanism as part of the criterion as it is more directly related to implementation of the criterion (e.g., NPDES permits). Given that addressing these site-specific situations seems to be more appropriately done through the NPDES permitting process for individual dischargers, it seems that this mechanism would be much more appropriately incorporated as an implementation tool for the criterion. Precedent for utilizing very specific implementation tools as part of an objective has been established in the State of California's *Water Quality Control Plan for Enclosed Bays and Estuaries- Part 1 Sediment Quality*[4] (Phase I SQOs), approved by USEPA on August 25, 2009. Incorporating this mechanism, as well as the edits to the water column element as a whole as described in Comment #5, as an implementation tool would give permit writers more flexibility to address new or increased inputs and identify the water column concentration that is most appropriate for a dischargers given situation. Reserving the water column concentrations as an implementation tool

for the criterion would allow NPDES permits to individualize the water column concentrations needed to protect or obtain the specific tissue concentrations, negating the need to attempt to incorporate such implementation concerns in the criterion itself. By continuing to include the water column concentration directly into the criterion itself, EPA is limiting the ability for States to address these site-specific issues (such as an increased input or a new discharge).

Further, the concept of "increased inputs" is very vague and broad. While at the national level broad can have benefits in providing flexibility to States for implementation, the term should be limited to instances where such inputs have the expectation to negatively impact tissue concentrations such that the designated use would not be protected.

Requested Actions:

- *Revise the language in Table 4.1 of the 2015 Draft Selenium Criterion to read as follows:*

    - *Modify Footnote 3: "Water column values are based on dissolved total selenium (includes all oxidation states, i.e., selenite, selenate, organic selenium and any other forms) in water. ~~Water column values have primacy ever fish tissue values under two circumstances: 1) "Fishless waters" (waters where fish have been extirpated or where physical habitat and/or flow regime cannot sustain fish populations); and 2)~~ New (see glossary) or increased inputs of selenium from a specific source~~,~~ should not cause or have the reasonable potential to cause the fish tissue elements to be exceeded in any downstream waterbody ~~until~~ when equilibrium is reached. This aspect shall be implemented as described in [Insert Reference to section titled 'Implementation for Assessing Protection of Fish Tissue When New or Increased Inputs of Selenium (rom a Specific Source Are Present']."*

- *Add a section to the 2015 Draft Selenium Criterion titled "Implementation for Assessing Protection of Fish Tissue When New or Increased Inputs of Selenium from a Specific Source Are Present". Move the following language from Page 93, Section 4 into this section with the underlined modification:*

New inputs are defined as new activities (see glossary) resulting in selenium being released into a lentic or lotic waterbody. Increased input is defined as an increased discharge of selenium from a current activity released into a lentic or lotic waterbody that has the potential or reasonable potential to result in exceedances of fish tissue concentrations in any downstream waterbody. New or increased inputs ~~will likely~~ have the potential to result in increased selenium in the food web, ~~likely~~ potentially resulting in increased bioaccumulation of selenium in fish over a period of time until the new or increased selenium release achieves a quasi-"steady state" balance within the food web. EPA estimates that concentrations of selenium fish tissue will not represent a "steady state" for several months in lotic systems, and longer time periods (e.g., 2 to 3 years) in lentic systems, dependent upon the hydrodynamics of a given system; the location of the Se input related to the shape and internal circulation of the waterbody, particularly in reservoirs with multiple riverine inputs; and the particular food web. Estimates of steady state under new or increased selenium input situations are expected to be site dependent, so local information should be used to better refine these estimates for a particular waterbody. Thus, EPA recommends that ~~fish tissue~~

~~*concentration not override water column concentration until these periods of time have passed in lotic and lentic systems, respectively*~~ *when incorporating the criterion from a specific source into appropriate regulatory mechanisms (e.g., NPDES permits), new or increased inputs that have the potential or reasonable potential to cause exceedances offish tissue concentrations in any downstream water body, water column concentrations that will result in attainment of the fish tissue concentrations should be developed (or the site-specific situation and included in the applicable regulatory mechanism.*

1. For Evaluating "Fishless Waters," Surrogate Biological Parameters Should Be Used In Place of Water Column Values.

The 2015 Draft Selenium Criterion includes two circumstances where water column values have primacy over fish tissue values:

> "1) 'Fishless waters' (waters where fish have been extirpated or where physical habitat and/or flow regime cannot sustain fish populations); and 2) New (see glossary) or increased inputs of selenium from a specific source, until equilibrium is reached."

However, water column values should not have primacy over fish tissue values under any circumstance, including both of these circumstances. This comment addresses the aspect of establishing primacy of water column values over fish tissue values for "fishless waters."

Page 92, Section 4 of the 2015 Draft Selenium Criterion states (emphasis added):

> *"The magnitudes of the water column elements are derived* ***from the egg-ovary element coupled with bioaccumulation consideration.***"

As shown in Figure 2.4 of the 2015 Draft Selenium Criterion (presented on the following page for ease of reference), the pathway for translating the concentration of selenium in eggs and ovaries to a concentration of selenium in the water-column involves a number of steps. To proceed from one step along the pathway to another, relational parameters (i.e., a species-specific Trophic Transfer Function *[TTF],* an egg-ovary to whole-body conversion factor [*CF*], or a site-specific enrichment factor *[EF])* must be used. Given that these parameters are species-specific or site-specific, there are a range of values which may be appropriate for each parameter. As a result, with each step that is taken from the egg-ovary element to the water-column element, a greater degree of uncertainty is introduced. For this reason, it is much more accurate to use a surrogate parameter, which represents a step along the pathway closer to the egg-ovary element upon which all other elements are derived, as opposed to the water column-element, which represents the end of the pathway, when trying to determine the health of "fishless waters". Additionally, as stated on Page K-13, Appendix K, it is appropriate to use surrogate parameters when evaluating the health of a waterbody (emphasis added):

> "In addition, states and tribes may evaluate upstream waters without fish by measuring the selenium concentration in water, **biotic and/or abiotic particulate material, and/or the tissues of invertebrate aquatic organisms** that reside there."

USEPA's peer reviewer, Dr. Gregory A. Cutter, reminded USEPA of the Chapman et al (2009 and 2010) recommendations from the SETAC Pellston workshop which specifically states, "Understanding Se speciation is critical to understanding its mobility, transformation, partitioning in the environment, and potential risk to aquatic ecosystems".[2] The Stakeholders agree with Dr. Cutter's critique of USEPA's translation from fish tissue to water column. Incorporating the very straightforward suggestions below

to enable use of biological surrogates would go a long way towards addressing the Stakeholder's concerns in this matter.

Original letter contains Figure 2.4 – Conceptual model for translating the selenium egg-ovary concentration to a water column concentration. See original letter.

As a result, rather than defaulting to the water column element derived to protect fish when evaluating "fishless waters", a surrogate parameter (e.g., tissue of invertebrate aquatic organisms, particulate material) should be used when evaluating "fishless waters".

Requested Actions:

- *Revise the 2015 Draft Selenium Criterion as follows to clearly establish that, if the water column element continues to be a part of the 2015 Draft Selenium Criterion as more than an implementation tool, surrogate parameters should be used in place of the water column element when evaluating "fishless waters":*
    - *Modify Table 4.1[3] as follows:*
        - *Modify Footnote 1: "Overrides any whole-body, muscle, or water column elements-when fish egg/ovary concentrations are measured except in certain in situations. See footnote 3. <u>For evaluating "fishless waters" (waters where fish have been extirpated or where physical habitat and/or flow regime cannot sustain fish populations), a surrogate parameter (e.g., tissue of invertebrate aquatic organisms, particulate material) derived from the egg-ovary element using a species-specific Trophic Transfer Factor [TTF] or a site-specific enrichment factor [EF] should be used."</u>*
        - *Modify Footnote 2: "Overrides any water column elements when both fish tissue and water concentrations are measured except in certain in situations. See footnote 3. <u>For evaluating "fishless waters" (waters where fish have been extirpated or where physical habitat and/or flow regime cannot sustain fish populations), a surrogate parameter (e.g., tissue o(invertebrate aquatic organisms, particulate material) derived from the egg-ovary element using a species-specific Trophic Transfer Factor [TTF] or a site-specific enrichment factor [EF] should be used."</u>*

Modify Footnote 3: "Water column values are based on dissolved total selenium (includes all oxidation states, i.e., selenite, selenate, organic selenium and any other forms) in water. Water column values have primacy over fish tissue values under ~~two~~ <u>the following</u> circumstances: ~~1) "Fishless waters" (waters where fish have been extirpated or where physical habitat and/or flow regime cannel sustain fish populations); and 2)~~ ... "

EPA-HQ-OW-2004-0019-0388-A2; J. R. Simplot Company; Posted 10/14/2015

A. Implementation Processes

A.1. Fishless Waters and "Increased" Inputs

[Page xiv , Executive Summary, Table 1]

EPA implements the tissue criterion as an instantaneous measurement never to be exceeded. Maintaining the fish tissue criterion as an instantaneous measurement implies that a single fish with a concentration of selenium in its t issue exceeding the tissue threshold would be a violation of the criterion. Much of the field data collected by numerous investigators has indicated that individual fish will have varying levels of selenium as part of their body burden. While fish tissue may represent an integrated exposure, each fish may integrate that exposure differently depending upon its history at a site. While the criterion as it is written may imply the instantaneous measurement is meant to be temporally instantaneous as alluded to in the footnote,[1] it should be more specific about how tissue selenium is measured, including the number of fish needed for a representative sample for a site. In the ecological risk assessment process (EPA 1997, 1998) EPA expects that exposure point concentrations are based on the average of multiple samples, represented by the 95th upper confidence limit (UCL) of the arithmetic mean as a "high end" estimate of the average. It would seem practical that decisions about criterion exceedance not rely on a single measurement, but on a representative exposure estimate.

There are two characteristics of the criterion that will have far reaching and likely unintended conservative consequences. As noted in Table 1 of the 2015 Draft Criterion (page xiv), tissue data take precedence over water concentrations, except when the following conditions are present:

1. "Fishless waters" (waters where fish have been extirpated or where physical habitat and/or flow regime cannot sustain fish populations); and/or
2. New or increased inputs of selenium from a specific source until equilibrium is reached.

The 2015 EPA Selenium Draft defines fishless waters as waters with insufficient instream habitat and/or flow to support a population of any fish species on a continuing basis, or waters that once supported populations of one or more fish species but no longer support fish (i.e., extirpation) due to temporary or permanent changes in water quality (i.e., due to selenium contamination), flow, or instream habitat. Because of the inability to collect sufficient fish tissue to measure selenium concentrations in fish in such waters, water column concentrations are prescribed as best representing selenium levels required to protect aquatic communities and downstream waters in such areas.[2]

The above definition of the "process" for fishless waters is inconsistent with Appendix K of the External Peer Review Draft (Section 1.2.1.2), where EPA states that "when fish are naturally absent from a waterbody, states and tribes should target the most sensitive fish species inhabiting downstream waters."[3] Recommendations from Appendix K are consistent with current risk assessment methods in that consideration of exposure is taken into account. Default application of an aqueous criterion based on fish tissue to "fishless waters" will result in values at or below background for many stream systems, and thus will certainly result in a large number of false positives with consequent dilution of efforts to address real environmental problems.

The 2015 EPA Selenium Draft defines new inputs or increasing inputs as: "new activities resulting in selenium being released into a lentic or lotic waterbody. Increased input is defined as an increased discharge of selenium from a current activity released into a lentic or lotic waterbody. New or increased inputs will result in increased selenium in the food web, likely resulting in increased bioaccumulation of selenium in fish over a period of time until the new or increased selenium release achieves a quasi "steady state" balance within the food web. EPA estimates that the concentration of selenium in fish

tissue will not represent a "steady state" for several months in lotic systems ... EPA recommends that fish tissue concentration not override water column concentration until these periods of time have passed in lotic and lentic systems, respectively."[4]

This issue has a number of nuances and complications, such as establishing an initial permit limit for selenium. Most likely, this initial permit limit will be "conservative" (i.e., more stringent than might be using a fish tissue measurements to compare to the criterion). Once fish tissue monitoring and comparison to the criterion can occur, an increase in the selenium limit may not be possible due to the "antibacksliding" provision in the Clean Water Act. Also, the frequency of monitoring that a discharger will have to perform will be higher than otherwise would be required.[5] Finally, the discharger will have had to invest in the control equipment necessary to meet the initial permit limit. Thus, considerable resources will likely have been expended that were not necessary to protect aquatic life.

This new addition to the selenium criterion will be problematic for many regulated entities. By using the language "new or increased" rather than "new and increased" EPA has automatically assumed that any new inputs into a system will automatically increase selenium concentrations. How then does this affect for example a treatment plant designed to reduce selenium? By the definition above, it is a new input. Specific language needs to be included that excludes capture and reintroduction discharges that treat and reduce selenium concentrations.

As defined above, increased input is an increased discharge of selenium from a current activity released into a lentic or lotic waterbody. What is the time frame for "current activity"? More importantly, what is the definition of "activity"? Would a spring discharge that is increasing be considered a current activity, even if it has been present and discharging for hundreds of years? What is the time frame for "increasing" for the determination of whether or not the "activity" is increasing or simply fluctuating naturally?

As noted in comments below, EPA's action to implement a traditional aqueous criterion for selenium will create unnecessary burdens on regulated entities due to an overly conservative "National Criterion" in water that is inherently uncertain. Much like the methyl mercury criterion, the selenium criterion document needs to identify a tissue threshold that is the basis for the criterion and provide methods for regional application and derivation of an aqueous value.

We recommend that existing Footnote 3 in Table 1 be deleted and replaced with the following: "Limitations are derived from fish tissue concentrations, but compliance cannot be fully tested until the appropriate amount of time has elapsed for equilibrium in the receiving water for new and increased inputs of selenium.[6] In the interim, both tissue and water column concentrations in the receiving water can be monitored. For fishless waters, the most sensitive fish species inhabiting downstream waters should be monitored."

Implementation Approach Needs Changes to Address Fishless and Increased Inputs Waters

The summary of the draft criterion (Table 1, page xiv) presents a number of issues associated with implementation of the criterion. Specifically, for certain situations the deviations from the use of the fish tissue value result in a very conservative water column value being the criterion. Such an approach defeats the rationale for establishment a criterion based on fish tissue and will likely result in significant

negative consequences for dischargers. Simplot recommends several changes to Table 1 to address these consequences including the use of a tiered and combined monitoring approach to specific situations.

Regarding the draft proposal, the TCEQ would like to emphasize the need for the development of implementation guidance due to the complexity of the various aspects incorporated in the draft criterion.

EPA-HQ-OW-2004-0019-0412-A2; Utility Water Act Group (UWAG); Posted 10/28/2015

In addition, UWAG has the following concerns with the technical basis and implementation of the "never to be exceeded" averaging period:

- EPA's assumption that tissue selenium concentrations change only gradually over time (and thus a measured concentration in the tissue represents a relatively unvarying level for at least a portion of the fish's longevity) is not universally accurate. In some cases the selenium content in fish tissue changes relatively rapidly. Figures 1 to 5 of these comments indicate the concentration of selenium measured in otolith (ear bone) cross sections for four fish species (channel catfish, sauger, flathead catfish, bluegill) collected in the Ohio River (reference site) or in the mixing zone of an FGD and/or fly ash wastewater discharge during October 2013. Selenium was measured in the otoliths using laser ablation mass spectrometry inductively coupled plasma. Otoliths are ideal structures for reconstructing the exposure history of a given fish to trace elements. Unlike tissue samples, which reflect contaminant concentrations only in the recent past of fish, otoliths illustrate a lifetime exposure. In each graph the black line represents a running average concentration value and the word "distance" is the radius distance of the otolith, from fish hatching (centrum) to the time of fish collection (right outer edge). As "distance" increases, fish age increases. Fish length, age, and measured selenium concentration in fillet (muscle) samples are also indicated.
  The figures, collectively, indicate varying exposure to selenium for each fish. In other words, the exposure to selenium can be gradual (resulting in a shallow slope of the mean otolith selenium concentration) during some periods, but temporally variable (resulting in a steep slope of selenium concentrations) during other periods. Most studies report a significant positive correlation between tissue selenium and otolith selenium content within the past 6 to 12 months of the fish's life. Depending on when the fish are collected and analyzed for selenium tissue content, compliance with regulatory tissue criterion could either be verified, or not verified. ***Thus, to assess compliance with tissue criterion several individuals of a given species need to be analyzed because the variability of selenium content in individual fish may be marked***.

- EPA provides no clarification on whether the proposed averaging period applies to a single fish (of several analyzed from various species) whose tissue concentration exceeds the tissue criterion, or whether it applies to an average (or geometric mean) value for: 1) a particular selenium-sensitive species; or 2) for all species evaluated at a site (i.e., a grand average value for

all species pooled). ***The exact manner in how fish tissue data are evaluated for criterion compliance at a given site is extremely important***. ***Clarification on this issue is needed in the final criterion documents.***

- Assuming EPA intends that ***no single fish sample*** exceed a tissue criterion, then this policy is unprecedented. In 2001, EPA issued an ambient water quality criterion recommendation for methylmercury for the protection of people who eat fish (66 Fed. Reg. 1,344). EPA later issued implementation guidance in response to stakeholder requests. (US EPA, 2010a). In the guidance, EPA states clearly that – for assessment of criterion compliance – stakeholders are to evaluate levels of methylmercury in several species of fish (representing at least two trophic levels), and that ***average*** methylmercury tissue concentrations are to be calculated:

> *Statistical tests for comparing the average concentration from multiple replicate composite samples to the criterion may be conducted where a sufficient number of replicates have been collected. [EPA] recommends using the t-test to determine whether the mean concentration of mercury in composite fish tissue samples exceeds the screening value. This test involves a statistical comparison of the mean of all fish tissue data to the criterion.*

US EPA, 2010a at 59.

- Establishing that the proposed tissue criterion should be attained at all times is erroneous because all of the toxicity (and other underlying) data have, themselves, variability. A particular chronic toxicity test uses *average values* of parameters: 1) toxicant concentrations in control and treatment groups (e.g., all water quality variables); and 2) fish testing endpoints (e.g., tissue concentration, survival, growth). Indeed, the reason for the testing of replicates ***is to understand the magnitude of variability***. EPA's 1985 Guidelines support that a criterion should be implemented consistent with how it was developed. 1985 Guidelines at 4.

- Setting a water quality criterion that is "never to be exceeded" is very problematic from a permitting standpoint. Regarding the proposed revised chronic selenium fish tissue criterion, a permitting authority may need to derive a numeric effluent limitation to ensure that tissue levels outside of the mixing zone do not exceed – *at any time* – the tissue criterion. Calculating an effluent limitation that *never* causes, or contributes to, an exceedance of an applicable water quality criterion will be extremely stringent because the factor of effluent variability is removed. The concentration (or loading) of all pollutants regulated by the CWA exhibit some level of variability. A permitting authority *must* consider effluent variability when determining the need for a water quality-based effluent limit (WQBEL):

> *When determining whether a discharge causes, has the reasonable potential to cause, or contributes to an in-stream excursion above a narrative or numeric criteria within a State water quality standard, the permitting authority shall use procedures which account for existing controls on point and nonpoint sources of pollution, the variability of*

the pollutant or pollutant parameters in the effluent, the sensitivity of the species to toxicity testing (when evaluating whole effluent toxicity), and where appropriate, the dilution of the effluent in the receiving water.

(40 CFR 122.44(d)(1)(ii))

When determining the need for a WQBEL, a permitting authority also must consider the dilution and fate of a particular pollutant in the receiving water:

[E]ffluent data alone, showing toxicity at the RWC [receiving water concentration], may be adequate to demonstrate the need for a limit for toxicity or for individual toxicants…The regulatory authority will need to prioritize, on a case-by-case basis, the importance of all data and information used in making a determination.

(US EPA, 1991. p. 49)

- Federal regulations require that permit writers calculate two types of effluent limitations: an average monthly limitation and a maximum daily limitation. EPA's "NPDES Permit Writers Manual" (US EPA, 2010b) clarifies this requirement:

The NPDES regulations at § 122.45(d) require that all effluent limitations be expressed, unless impracticable, as both AMLs [average monthly limitation] and MDLs [maximum daily limitation] for all discharges other than POTWs and as both AMLs and average weekly limitations (AWLs) for POTWs. The AML is the highest allowable value for the average of daily discharges over a calendar month. The MDL is the highest allowable daily discharge measured during a calendar day or 24-hour period representing a calendar day.

(p. 6-34)

Even when a daily maximum WQBEL is established by a permitting authority, multiple samples may be collected within a 24-hour period as there is variability in the effluent concentration during this period.

In summary, there will be pragmatic problems with how a criterion that is expressed as "never to be exceeded" is implemented in wastewater permits. It does not appear EPA has considered any of these real-world consequences that will be imposed on states to decide during implementation.

Exceedance frequency of tissue criterion "never to be exceeded" must be clarified.

EPA must clarify that it is the protection of fish ***populations*** and not ***individual*** fish that is intended by the term "never to be exceeded." As written, the language suggests that a single fish tissue sample with a concentration that exceeds the proposed tissue criterion would result in non-attainment. UWAG does

not believe that is EPA's intent. We agree with the comments of expert peer reviewer Vince Palace, Ph.D.:

> Biological variability, coupled with uncertainty regarding the residence of mobile fish species, will make it likely that some fish in a given collection may exceed the guidelines. It is unclear if a result from one fish (i.e. a single exceedance) will render a given management area in non-compliance, or if some average value is intended as the trigger.

2014 Peer Review at 86.

Assuming EPA intends such a literal reading, however, UWAG finds several flaws with the proposed exceedance frequency. First, EPA's Derivation Guidelines very clearly oppose adoption of a "never to be exceeded" approach. 1985 Guidelines at 4. ("A statement of a criterion as a number that is not to be exceeded any time or place is not acceptable because few, if any, people who use criteria would take it literally and few, if any, toxicologists would defend a literal interpretation."). Second, even if EPA made a policy decision to depart from the 1985 Guidelines prohibition on a never to be exceeded frequency, the agency provides no technical justification to support such a drastic departure. EPA has not even provided a sound policy rational for adopting such a conservative approach. Finally, the following statements in the Draft Criterion appear in conflict with EPA's proposed exceedance frequency:

- In Appendix J, Section 3.0 at J-12, EPA states:

  > *It can be concluded that the kinetics of selenium accumulation and depuration are sufficiently slow that applying a 30-day averaging period to the water criterion concentration affords protection even under unrealistic worst case conditions*.

- In Table 4.1, footnote 5, EPA references the "never to be exceeded" exceedance frequency with the following:

  > *Instantaneous measurement. Fish tissue data provide point measurements that reflect integrative accumulation of selenium over time and space in the fish at a given site. Selenium concentrations in fish tissue are expected to change only gradually over time in response to environmental fluctuations*.

- In Appendix J, Section 3.0, EPA presents the results of modeling analyses which illustrate the uptake and depuration rates of selenium in various aquatic biota, under varying exposure regimes (steady, uniform spikes, and smooth variable). Regarding the relationship between averaging period and kinetics speed (rate of uptake or depuration), EPA states at J-5:

  > *Because short averaging periods are more environmentally conservative than long averaging periods, selecting parameter values for fast kinetics is more environmentally conservative. Figure J1 reflects environmentally conservative choices for k values.*

Thus, it appears that EPA chose to ignore its own conclusions that the kinetics of selenium uptake are gradual. UWAG finds these positions contradictory and, like EPA, we believe the "never to be exceeded" averaging period is overly conservative. EPA should abandon or clarify that implementation of a literal

reading of the proposed "never to be exceeded" is inconsistent with the science on selenium kinetics and depuration and in violation of the agency's 1985 Guidelines.

Primacy of Water Column Criterion

Footnote 3 of Table 4.1 indicates that the proposed numeric lentic and lotic water column elements have primacy over the proposed fish tissue elements in two circumstances: 1) waterbodies with no sustaining fish populations due to extirpation or habitat limitations; and 2) new or increased inputs of selenium until equilibrium is reached. UWAG recommends that footnote 3 be revised to delete the second sentence or to indicate that a state ***may*** determine that the water column values have primacy in those two circumstances. We believe that states should have flexibility to decide whether implementation of EPA's policy decisions as set forth in the footnotes to Table 4.1 is appropriate. Moreover, deleting this language from footnote 3 is consistent with EPA's statement that the timing for when a waterbody will reach "steady state" or equilibrium is dependent on site specific conditions and local information. Draft Criterion at 93.

EPA's rationale for this policy is as follows:

> *New inputs are defined as new activities resulting in selenium being released into a lentic or lotic waterbody. Increased input is defined as an increased discharge of selenium from a current activity released into a lentic or lotic waterbody. New or increased inputs will likely result in increased selenium in the food web, likely resulting in increased bioaccumulation of selenium in fish over a period of time until the new or increased selenium release achieves a quasi-"steady state" balance with the food web. EPA estimates that the concentration of selenium in fish tissue will not represent a "steady state" for several months in lotic systems, and longer time periods (e.g., 2 to 3 years) in lentic systems, dependent upon the hydrodynamics of a given system;…Estimates of time to achieve steady state under new or increased selenium input situations are expected to be site dependent, so local information should be used to better refine these estimates for a particular waterbody.*

(Draft Criterion at xv)

UWAG agrees that site-specific attributes should be recognized and assessed to determine when the new or increased loading of selenium becomes fully assimilated in the water and biota of the receiving stream. We believe, however, that the technical basis of the proposed policy is speculative. And, the policy could result in the unnecessary and costly treatment of selenium at facilities.

While UWAG understands the agency's position that a tissue criterion should not apply in settings where compliance with a tissue criterion cannot be assessed, UWAG disagrees with the agency's position that the proposed water column criterion should always take precedence over tissue criterion when a new or expanded discharge of selenium occurs. The latter is unnecessary because other requirements, such as anti-degradation, may apply to such discharges ensuring adequate water quality protection. For example, states typically address new (and some address expanded) discharges as part of their anti-degradation review, which will afford them the opportunity to determine the appropriate criterion for the discharge. UWAG believes EPA has not provided evidence to suggest the agency has fully assessed the implications of footnote 3 in the context of existing regulatory programs.

EPA's assumption that there will be some period during which a waterbody will assimilate new or expanded discharges before reaching "steady state" or equilibrium (e.g., between months to possibly three years) is reasonable. There are clearly some settings, however, where the response of tissue selenium to either new inputs, or to eliminated inputs, is relatively rapid. The kinetics of selenium biomagnification is highly site-specific as the efficiency of the transfer of dissolved selenium to water column particulate matter is variable across locations. This is observed in Figure 6, which shows average muscle selenium concentrations in bluegill collected from Hyco Reservoir during 1987 - 2014.

Original letter contains Figure 6 – Graph of average selenium concentrations in bluegill muscle samples collected in Hyco Reservoir, North Carolina, 1987 – 2014. See original letter.

- In 1989, Roxboro Steam Electric Station completed the installation of a dry fly ash disposal system. Reductions of fly-ash derived selenium loading to the lake first began in July 1985. The concentration of selenium in bluegill tissue samples collected just after the dry handling system was installed (1990) was markedly lowered. Though selenium levels in tissue samples collected in 1991 increased somewhat, steadily decreasing concentrations in following years (up until about 1995) were observed.
- In 2008, Roxboro Steam Electric Station began operation of a flue gas desulfurization. A new source of selenium, present in FGD wastewater, was introduced to the lake. Annual fish tissue monitoring continued following this operational change. During 2011 to mid-2012 selenium levels in bluegill muscle tissue samples began to increase, though the concentrations never approached the markedly high tissue concentrations observed during 1976 – 1987. The relatively rapid response in bluegill tissue samples to the (initial) elimination of selenium, and the (subsequent) addition of selenium after FGD operation, is somewhat unexpected due to the long hydraulic residence time of the reservoir (4.6 years). One possible explanation for this rapid tissue response is the accelerated and efficient transfer of aqueous selenium to suspended particulate matter (which may include plankton and zooplankton) in the lake.
- Reash et al. (2006) reported concentrations of selenium and other trace elements in bluegill gonad samples collected just before and just after the installation of an FGD system at American Electric Power's James M. Gavin Plant. The FGD system became operational in December 1994. Bluegills were collected in October 1994 and May 1995. The following table indicates the mean concentration of selenium in ovary and teste tissue samples during the two periods.

Original letter contains Table 2 – Mean Selenium Concentration in Bluegill Gonad Tissue Samples. See original letter.

The reductions in tissue selenium concentration mirrored the change in water selenium levels; the mean selenium concentration in October 1994 was 15 µg/L whereas the mean concentration in May 1995 was 2 – 3 µg/L.

If, after considering these comments, EPA does not decide to remove the "new or expanded discharge" footnote from Table 4.1, we request that the agency limit the applicability of the policy. UWAG recommends that EPA, in its final guidance, allow states the flexibility of determining whether primacy of the water column elements of the criterion is absolutely needed for maintenance of applicable water quality standards. There are certainly some settings in which a new or expanded discharge will clearly not result in tissue selenium levels in excess of the criterion values. These include large impounded rivers and lakes with relatively short hydraulic retention times. UWAG recommends that EPA consider a

threshold attribute that, if met, may justify primacy of the water column criterion. For example, if the calculated instream waste concentration (IWC) of selenium – accounting for the new or expanded discharge – meets or exceeds 50% using effluent design flow and a receiving stream flow equal to the 7Q10 value, the applicability of the water column criterion may take primacy. Low risk settings should be identified by EPA and the agency should allow states to use all reliable, relevant data for a specific location.

EPA-HQ-OW-2004-0019-0419-A2; Lima Refining Company; Posted 11/03/2015

COMMENT #4. The document does not provide guidance as to when a waterbody is impaired.

EPA's proposal sets the fish-tissue concentration limit as a "never to be exceeded" limit, however, there is no discussion in the proposed criterion about the practicality of enforcing such a limit. States must use the criteria published by EPA to create or revise water quality standards for each state's waters. See, 33 U.S.C. § 1313(c)(2)(B). Following implementation of those water quality standards, states must provide a list of those waters in their state where effluent limitations are not sufficient to meet the applicable water quality standard. See, 33. U.S.C. § 1313(d). In this proposed criterion, EPA does not acknowledge the practical impact of setting a water quality standard at a "never to be exceeded" limit. Is a water body impaired at the water column, fish tissue or egg ovary level? What happens if one fish out of 10 exceeds the FCV (based on tissue), which typically is based on an EC10? If its reproductive success is reduced by 10%, it could be reasoned that this equates to a 1% impact on the reproductive success of the population (a 10% decrease for 10% of the fish). Is the tissue level in a sensitive species, or an insensitive species? The implication of the "never to be exceeded" fish tissue limit is discussed further.

There is a subtle difference with respect to implications of exposure when the "never to be exceeded" fish tissue limit is applied. A water quality criterion (WQC) based on a measured water concentration is relevant to all of the aquatic organisms that are present and exposed to selenium in the water. In the case of a fish tissue concentration, which may vary from one individual to the next, at any point in time, an exceedance by a single fish defines the exposure of that individual to Se, not all of the individuals present at the site. Therefore the application of a "never to be exceeded" fish tissue limit does not correlate to broad spectrum impact, as does a WQC based on measured water concentrations.

LRC believes that the "never to exceed" limit is overly burdensome to states and dischargers and creates a situation where a single fish tissue sample could lead to an impairment listing under CWA § 303(d). We believe the states would look to USEPA to provide guidance as to how to apply the proposed AWQC. The 2015 USEPA Se Draft AWQC does not provide such guidance

COMMENT #5. EPA's proposal to implement an interim Water Column Criteria for the time period before steady state is achieved is unduly burdensome, and not based upon the best available scientific data.

As noted above, LRC acknowledges that the strength of EPA's proposal is the use of fish tissue data to establish the applicable standard that is protective of aquatic life, but that the calculation used to derive a water quality standard from that fish tissue criterion is flawed. LRC believes that this flawed calculation will result in water quality criteria that are overly restrictive and unduly burdensome to

dischargers. Furthermore, while EPA states that fish tissue concentrations can override water column concentrations, EPA is recommending to states that in implementing a selenium water quality standard to protect aquatic life, "fish tissue concentrations should not override water column concentrations until sufficient time has passed to allow equilibrium to be attained in the food web of lentic and lotic systems" See, Notice of Availability for Request for Scientific Views, 80 FR 44350, at 44353 (July 27, 2015). This approach will result in the application of the most inaccurate and restrictive portions of EPA's proposal to become effective immediately, with no relief for dischargers in the interim period. Therefore, LRC requests that EPA include in their fish tissue to water column translation calculation various measures (i.e., growth considerations) that will provide dischargers with a more accurate representation of the fish tissue concentration baselines, until those baselines can be confirmed at steady state. In the alternative, LRC requests that EPA include in the final criterion a recommendation that the current State selenium standard, which, in Ohio, is 5.0 ug/L for total recoverable selenium, be maintained as an interim water column standard to meet until steady state conditions are achieved.

EPA-HQ-OW-2004-0019-0406-A2; Kentucky Chamber of Commerce; Posted 10/15/2015

In addition, the "fishless" waters language in footnote 3 of Table 1 could also be interpreted in an overly restrictive manner. Many discharges are to "fishless" ephemeral streams that lead to and merge into larger water bodies that support fish within a short distance. The footnote and supporting language in the draft criterion document could be construed to always require a water column standard to be imposed in such cases even though fish tissue is readily available in relatively close proximity to the outfall at a downstream perennial water body. This concern is heightened due to adoption of the Clean Water Rule, which further expands the number of fishless waters that are deemed a water of the United States and thus a receiving water under Section 402 of the Act.

Indeed, the water column concentration criteria were developed using a complex formula designed to model trophic transfer of selenium through the food chain "resulting in the fish tissue concentration that yields the chronic reproductive effects of concern." *Draft Aquatic Life Ambient Water Quality Criterion for Selenium - Freshwater* (2015) (hereinafter Criterion Document), p. 23. The proposed water column concentrations of selenium in ephemeral "fishless" streams cannot, by definition, cause any such impacts in those waters, and the potential for such impacts in downstream perennial waters supporting fish can still be monitored by fish tissue. At most, the determination of when fish are not available for testing to determine any potential impact of a discharge to an aquatic life use should be made by the permit issuing authority on a case-by-case basis and should take into account the proximity of fish in downstream waters that would reflect any impacts from the discharge. Where fish are available for testing downstream, they can be used to determine the aquatic life use is fully protected in receiving streams and fish tissue should still be given precedence. Therefore, the fishless stream restriction on the precedence of fish tissue data should be removed or, at a minimum, fishless streams should not be defined in the criterion document and U.S. EPA should recognize that the issue should be determined by the NPDES permitting authority.

EPA-HQ-OW-2004-0019-0378; Public comment submitted by C. Lish; Posted 09/25/2015

The language for new or increased inputs of selenium should be modified so as to lengthen the time period where the fish tissue standard does not override the water column standard. Currently, the language states a period of "several months," but surface mines in particular change regularly over the lifespan of the mine, so the characteristics of wastewater outflows also change. Because mine discharge will often not allow a stream to reach a state of equilibrium, the selenium water quality standard should retain primacy until the mine permit has been fully bond released.

Enforcement of a selenium standard based on fish tissue for point source discharges will be difficult, especially in watersheds with multiple selenium discharges. In Central Appalachia, many rivers and streams have multiple wastewater discharges from multiple coal mines. Because fish move within the stream, it may be impossible to prove which mine is responsible for the fish tissue selenium exceedance. Additionally, enforcement of water quality standards in Central Appalachia is often dependent on citizen enforcement. Testing for selenium in fish tissue will make citizen enforcement much more cumbersome and less likely to occur.

For these reasons, the EPA needs to implement a protective, enforceable, water column-based selenium standard that is enforceable by citizens.

EPA-HQ-OW-2004-0019-0405-A2; Virginia Coal & Energy Alliance (VCEA); Posted 10/15/2015

That said, we are deeply troubled by EPA's suggestion that in "fishless waters" (e.g., those where flow or other aspects of the physical habitat are insufficient to sustain fish), EPA's water column criteria must be applied. This is fundamentally inconsistent with the federal and state water quality standards program. Criteria must be protective of uses. Where a use does not exist, the criteria simply do not apply (since there is nothing to protect). EPA's proposal would make the criteria independent of the use, which is both illogical and inappropriate. In any event, where and how the criteria are applied are decisions relegated to the states with primary authority for implementation of the Clean Water Act. These kinds of implementation details do not belong in EPA's national recommended criteria document.

EPA-HQ-OW-2004-0019-0404-A2; Kentucky Coal Association (KCA); Posted 10/15/2015

Footnote 3 of Table 1 Creates Unnecessary Implementation Problems and Undercuts EPA's Stated Preference for a Fish-Tissue Based Standard. KCA has serious concerns with Footnote 3 of Table 1 of the proposed criterion. Footnote 3 outlines two scenarios in which water column values have primacy over fish tissue values - specifically, in "fishless waters" and waters with "new or increased inputs of selenium until equilibrium is reached." While we understand that EPA is seeking to address with respect to these two scenarios, we think that the proposed language, when taken in conjunction with the anti-backsliding provisions of the Clean Water Act (CWA) and the requirements of the National Pollutant Discharge Elimination System (NPDES) permitting process for establishing Water Quality-Based Effluent limits (WQBELs), effectively nullifies the fish tissue approach all together. While EPA considers this an "implementation" issue, it is not clear that the implementation difficulties posed by the language of the criterion can, in fact, be rectified through implementation guidance. EPA's intent in the criterion

document to avoid compromising downstream waters or waters with new or expanded discharges can be accomplished under a standard that does not create unnecessary confusion in future implementation and maintains the primacy of the fish tissue values in permits.

The "New or Expanded Discharges" Qualifier Will Lead to Unnecessarily Stringent Permit Terms and Preclude Future Permit Limits Based on Fish Tissue. By requiring a water column based WQBEL for expanded discharges, the criterion effectively vitiates the ability of permit writers to incorporate more scientifically justifiable fish-tissue based limits into permits. The CWA's anti-backsliding provision provides that "a permit may not be renewed, reissued, or modified ... to contain effluent limitations which are less stringent than the comparable effluent limitations in the previous permit." CWA Sec. 402(o). While there are listed exceptions, the general interpretation of state agencies and their NPDES permit writers is that permits cannot be modified or renewed with less stringent WQBELs than those contained in the previous version.

As written, with respect to NPDES permits for new or expanded discharges, the criterion would require a permit writer to establish WQBELs based on the proposed water column criteria, and that water column-based WQBEL would apply during the months or even years that it takes for the receiving water to reach "equilibrium." Due to the overly conservative estimates used to derive the water column concentrations, it is anticipated that in many instances a post-equilibrium discharge limit derived from a fish tissue concentration-based effluent limit will be higher than any initial limit based on the water column value. Because a discharger's permit will already contain the more stringent limitation, even after equilibrium is reached a discharger will only be able to obtain a more appropriate permit limitation based on a fish tissue concentration if that limitation would be more stringent than the one based on the water column value. In other words, under the criterion as it is currently written, there will likely be many instances in which a fish tissue-based effluent limitation will not be permissible in actual permits, despite the fact that such a limitation would represent the best available science and reflect the EPNs intent as we understand it. This same analysis could also potentially be applied by permit writers even to existing discharges, because states may choose to first apply a WQBEL based on the proposed water column criterion in cases where data regarding fish tissue and fish egg ovary selenium concentrations is scarce, was not collected during permit renewal, or is otherwise unavailable at the time of permit renewal. In essence, the criterion as drafted establishes a sound rule- that fish tissue is the best indicator of protection of the designated use - then establishes an ambiguous and potentially vast exception that threatens to swallow the rule whole. Water quality standards must be drafted not only in a manner that is sufficiently protective of designated uses, but also in a manner that provides clear guidance to permit writers who must implement the standards.

While implementation guidance may be able to address this issue in some cases where the criterion fits into one of the anti-backsliding exceptions, it is unclear if that will be legally possible, and regardless it would provide no relief as a practical matter to dischargers who are forced to install control technologies to meet the more stringent water column-based limit, despite the fact that such controls are not necessary to protect aquatic life. In more extreme cases, footnote 3 may prevent dischargers from obtaining any permit at all, even when their discharges present no risk to aquatic life, due to elevated natural background levels of selenium in the receiving water, because permit writers would be inappropriately basing their calculations on the water column number.

Because of this significant and likely unintended consequence posed by Footnote 3 to Table 1, KCA makes two recommendations. First, EPA could delete Footnote 3 as written, and instead include a provision for new or expanded discharges whereby limitations are derived from fish tissue concentrations but compliance cannot be tested until the appropriate amount of time has elapsed for the receiving water to reach equilibrium (i.e., a compliance schedule). The second is renaming the water column "criteria" as water column "thresholds," as was done in Kentucky's recently approved selenium water quality criteria revision. *See* 401 KAR 10:031 Section 6(1). This would clarify EPA's intent to allow fish tissue concentrations to have primacy over the water column values.

Concerning a related issue, we also note that EPA guidance limits the terms of compliance schedules to five years, as do many state permitting programs based on EPA's guidance. Because in some situations where selenium levels are being decreased based on the new criterion it may take longer than five years for corresponding fish tissue concentrations to decrease, KCA recommends including a provision in the criterion stating that longer compliance schedules may be needed with respect to bioaccumulants. Although again this could be considered an "implementation" issue, because it is a facet of the criterion that could directly conflict with existing state water quality programs- thereby limiting *states'* ability to adopt it- it is necessary to adopt language in the criterion itself that addresses this concern.

The qualifier related to "new or expanded discharges" is also problematic because it is ambiguous. The criterion does not define, by magnitude of concentration, frequency, or by duration, the discharges that should be considered "new or increased inputs of selenium." Similarly, the criterion does not define, by aquatic conditions or by duration, the term "equilibrium." Attempting to define and defend whether and when a stream is in "equilibrium" or "steady-state" in order to determine when and what criterion should apply creates a legally and technically unworkable, and unnecessary, requirement for states. Without such terms being clearly defined, permittees cannot determine in a scientifically defensible manner when such "new or increased inputs" should cause water column values to have primacy over fish tissue values.

The "Fishless Waters" Qualifier Also Creates Unnecessary Implementation Problems. With respect to "fish less waters," footnote 3 will likewise lead to situations in which dischargers must install expensive control technologies or not be able to discharge selenium at *all,* despite the fact that such requirements are not necessary to protect aquatic life. The concept of a "fishless" stream could be used to impose overly restrictive limits in many cases where discharges occur to "fishless" ephemeral streams, even where those streams ultimately flow into and merge with larger bodies of water that contain fish only a short distance away. This is of particular concern to KCA, because mining discharges frequently occur to these smaller streams, where selenium poses no risk to aquatic life at the outfall or downstream. The recent adoption of the Clean Water Rule, which significantly expands the number of so-called "fishless" streams subject to classification as receiving water, only heightens this concern.

We understand that EPA is required under the CWA to protect downstream waters when deriving water quality criteria. But KCA does not believe that the water column number proposed for "fishless waters" is necessary to protect downstream waters. KCA believes that more scientifically defensible approaches to addressing the issue of "fishless waters" may exist. However, it does not appear based on the current record for development of the criterion that these potential alternative approaches have been adequately investigated and analyzed.

EPA-HQ-OW-2004-0019-0410-A2; West Virginia Department of Environmental Protection (DEP); Posted 10/28/2015

Bioaccumulation modeling shows that selenium accumulates in fish tissue based on dietary exposure, and toxicity occurs primarily through maternal-egg transfer. This research indicates that an appropriate approach to a selenium criterion is to use fish tissue and/or egg/ovary concentration to determine selenium toxicity in water. With EPA's proposed criterion, when the chronic water column limit is exceeded, fish tissue and/or egg/ovary tissue concentrations may be assessed to make a final determination of exceedance. While DEP agrees with much of the data interpretations that EPA has provided in this revised draft, DEP believes some changes should be made to preliminary implementation strategies put forth in the EPA 2015 Draft.

Regarding EPA 2015 Draft consideration of chronic selenium criteria to address waters with new or increased selenium inputs, while DEP agrees with EPA's approach to new discharges of selenium in waters previously unimpacted by selenium (new inputs), DEP believes additional inputs of selenium on already impacted waters (increased inputs) should be handled differently. Specifically, when additional inputs are proposed on previously selenium-impacted waters, fish tissue concentrations should continue to take precedence over water column concentrations, as they reflect the bioaccumulation of selenium in those waters.

In regards to the EPA 2015 Draft descriptive element for fishless waters, EPA defines fishless waters as:

> Waters with insufficient instream habitat and/or flow to support a population of any fish species on a continuing basis, or waters that once supported populations of one or more fish species but no longer support fish (i.e., extirpation) due to temporary or permanent changes in water quality (e.g., due to selenium pollution), flow or instream habitat
>
> (EPA 2015 Draft pg. xv).

EPA 2015 Draft recommends that a water column concentration take precedence over fish tissue concentrations in fishless waters, but this approach is unreasonable for waters which are fishless due to insufficient flow, or which have been extirpated for reasons unrelated to selenium. In these examples of fishless waters, basing selenium outputs on receiving water column selenium concentration could not result in the re-establishment of fish, because the cause of fishless water would not have been resolved. Rather, in the situations of insufficient flow or fish extirpation due to non-selenium related pollution, precedence should remain with fish tissue analysis downstream, where conditions do allow for fish populations. Because the "fishless waters" element better relates to implementation of the selenium criteria, DEP believes these decisions are best made on a case-by-case basis in National Pollution Discharge Elimination System (NPDES) permitting, rather than attempting to prescribe implementation aspects of the criterion in water quality standards.

DEP understands EPA's goal of ensuring that fish tissue concentrations do not increase above the chronic selenium criteria. However, a more detailed approach is appropriate in considering protective effluent limits for increased discharges and for fishless waters. The amount of water discharged, the location with respect to the nearest fish population, and the existing tissue and water column concentrations in the watershed may all influence the decisions made with regard to effluent limits for

new or expanded selenium discharges. The goal is to ensure that water column concentrations do not increase above the level required to protect the segments where fish are or could be located.

EPA-HQ-OW-2004-0019-0391-A1; North American Metals Council (NAMC); Posted 10/14/2015

2.3.5 Implementation: Fishless Waters and Increasing Inputs

There are two aspects of the proposed criteria that will have far reaching and unintended, inappropriate consequences. As noted in the 2015 EPA Selenium Draft,[53] tissue data take precedence over water concentrations, except when the following conditions are present:

1. "Fishless waters" (waters where fish have been extirpated or where physical habitat and/or flow regime cannot sustain fish populations); and/or,
2. New or increased inputs of selenium from a specific source until equilibrium is reached.

The 2015 EPA Selenium Draft defines fishless waters[54] as waters with insufficient instream habitat and/or flow to support a population of any fish species on a continuing basis, or waters that once supported populations of one or more fish species but no longer support fish (*i.e.*, extirpation) due to temporary or permanent changes in water quality (*e.g.*, due to selenium contamination), flow, or instream habitat. Because of the inability to collect sufficient fish tissue to measure selenium concentrations in fish in such waters, water column concentrations are prescribed as best representing selenium levels required to protect aquatic communities and downstream waters in such areas.

The above definition of the "process" for fishless waters is inconsistent with Appendix K of the External Peer Review Draft (Section 1.2.1.2), where EPA states that "[w]hen fish are naturally absent from a waterbody, states and tribes should target the most sensitive fish species inhabiting downstream waters."[55] Recommendations from Appendix K are consistent with current risk assessment methods in that consideration of exposure is taken into account. Default application of an aqueous criterion based on fish tissue to "fishless waters" will result in values at or below background for many stream systems, and thus will certainly result in a large number of false positives with consequent dilution of efforts to address real environmental problems.

The 2015 EPA Selenium Draft defines new inputs or increasing inputs as:[56] "new activities . . . resulting in selenium being released into a lentic or lotic waterbody. Increased input is defined as an increased discharge of selenium from a current activity released into a lentic or lotic waterbody. New or increased inputs will result in increased selenium in the food web, likely resulting in increased bioaccumulation of selenium in fish over a period of time until the new or increased selenium release achieves a 'steady state' balance within the food web. EPA estimates that the concentration of selenium in fish tissue will not represent a 'steady state' for several months in lotic systems... EPA recommends that fish tissue concentration not override water column concentration until these periods of time have passed in lotic and lentic systems, respectively."[57]

This issue has a number of nuances and complications, such as establishing an initial permit limit for selenium. Most likely, this initial permit limit will be "conservative" (i.e., more stringent than using a fish

tissue measurements to compare to the criterion). Once fish tissue monitoring and comparison to the criterion can occur, an increase in the selenium limit may not be possible due to the "antibacksliding" provision in the Clean Water Act. Also, the frequency of monitoring that a discharger will have to do may be larger.[58] And, finally, the discharger will have had to invest in the control equipment necessary to meet the initial permit limit. Thus, considerable resources will likely have been expended that were not necessary to protect aquatic life.

We recommend that existing Footnote 3 in Table 1[59] be deleted and replaced with the following: "Limitations are derived from fish tissue concentrations, but compliance cannot be fully tested until the appropriate amount of time has elapsed for equilibrium in the receiving water for new and increased inputs of selenium. In the interim, both tissue and water column concentrations in the receiving water should be monitored. For fishless waters, the most sensitive fish species inhabiting downstream waters should be monitored."

EPA-HQ-OW-2004-0019-0387-A1; Colorado Department of Public Health & Environment; Posted 10/14/2015

- The proposed criterion also applies to fishless waters, with the goal of protecting downstream waters. However, because the water column element is derived from the fish egg/ovary element, application of the water column element to fishless waters may not always be appropriate.
  Many waters in the west have naturally very low flows or are headwater streams, and therefore only support invertebrates. Water chemistry conditions in such waters can be quite different from those further downstream. For instance, in areas where fish are absent due to low flow, it is likely that water inputs further downstream would affect water chemistry (increasing or decreasing selenium concentrations). Where fish are not part of the expected aquatic community, and there is evidence of downstream protection, an alternative criterion may be more appropriate. For example, it may be possible to derive a criterion protective of invertebrates and/ or amphibians.

  Additionally, while states and authorized tribes are required to consider and ensure the protection of downstream water quality, they are allowed to choose their own preferred approach in their standards. EPA has provided guidance and suggestions on how states can include narrative downstream protection criteria in their standards (EPA Publication No. 820-F-14-002), and provided several different template options for the states to work from and use based on their individual circumstances. There are many different ways (e.g., permit limits based on downstream waters) to ensure the protection of downstream water quality, and not all of them require assigning the most stringent standards to all waters.

For these reasons, the WQCD recommends EPA acknowledge the potential need for and appropriateness of alternative approaches for selenium criteria in fishless waters.

EPA-HQ-OW-2004-0019-0411-A2; American Petroleum Institute (API); Posted 10/28/2015

2.3.4 Back-calculated Particulate Se "Thresholds" Relative to Background

A key implementation issue is how to address background Se concentrations. As discussed in Section 2.3.2, particulate Se concentrations of 2.3 to 4.6 mg/kg-dw, based on the food web models compiled by the EPA, are predicted to result in the draft fish egg Se criterion of 15.8 mg/kg-dw. For comparison, Skorupa (1998) noted that background Se concentrations in sediment, freshwater algae, and freshwater macrophytes range up to 2.0, 1.5, and 2.0 mg/kg-dw, respectively. This means that the most conservative "safe" particulate Se concentration of 2.3 mg/kg-dw approaches these values. As also discussed above, there are also two clearly identified reference lakes in the EPA (2015) dataset that have particulate Se concentrations within the 2.3 to 4.6 mg/kg-dw range. These are particulate Se concentrations of 3.34 and 3.99 mg/kg-dw for High Rock Lake and Badin Lake, respectively, which were reported as reference lakes in Lemly (1985). This suggests that the $TTF^{composite}$ values and/or CFs are conservative for at least some sites. Consideration of regression-based TTFs could reduce the likelihood of back-calculating "safe" particulate Se concentrations that fall with the range of reference area concentrations.

EPA-HQ-OW-2004-0019-0409-A2; OC Public Works; Posted 10/20/2015

'New or Increased Selenium Inputs'

The Draft Se Criterion allows water column portion of the criterion to be the primary one when there are 'new or increased selenium inputs' to a water body. The scientific basis of this provision appears tenuous. In addition to the issues presented in the comments 2-6 above, new or increased input to a waterbody is clearly a site-specific issue and should be treated as such. Since the bioaccumulation model for any given site is essentially a linear regression model, for any given site where both fish tissue and water column concentrations have been established, the upper end of water column concentration where fish species could potentially be impacted can be established through a simple calculation, and that calculation should be the basis for the limit of new or increased input. If the 'new' input does not increase the existing water column selenium concentration, or is well below the calculated water column concentration that could cause fish impairment this provision will impose an overly stringent and unnecessary requirement.

To justify this 'new or increased input' provision, USEPA states that these inputs will cause excursion of 'steady state' or 'equilibrium' thus their impacts on fish species cannot manifest themselves in time to be captured by monitoring. This is reasonable but it should only apply when a short term, new or increased, and high concentration input cause an excursion above the water column concentration that could potentially cause fish impairment under equilibrium condition. If the new or increased input is below this concentration, it would be scientifically impossible that fish t issue can be impacted when steady state is reached.

The 'equilibrium' and 'steady state' language in the Draft Se Criterion overlooked the fact that these terms are relative and represent an ideal condition. In nature, few water bodies are in steady state and many exhibit considerable excursions. The language does not acknowledge the considerable natural variations (seasonal, interannual, or even dry/wet weather) in most waters.

'Fishless Water' Paradox

For water bodies with fish, the issues associated with water column portion of the Criterion (discussed in comments 2-6 above) will not pose a problem due to the primacy of fish tissue numbers. This is reasonable because fish tissue level is directly linked to designated uses. If fish are absent, however, and the primary criterion becomes water column based, a paradox is created. A water body with aqueous selenium concentrations exceeding the Draft Se Criterion could be fish less due to one of three reasons: 1) selenium is naturally-occurring but other natural factors preclude fish from establishment, such as limitations of habitat, including intermittent flows; physical and chemical constraints, predatory pressure, lack of food items, etc. Fish would have been extirpated even if selenium levels were reduced to levels below the Draft Se Criterion; 2) anthropogenic factors that, by altering physical, chemical (other than selenium), biological factors and flow regime, result in the extirpation of resident fish species even if selenium levels were reduced to a level below the Draft Se Criterion; 3) anthropogenic input of selenium that result, entirely or in combination with other factors, in the extirpation of resident fish species. The intention of the Draft Se Criterion is clearly to protect the third scenario, but the 'fishless waters' issue will likely result in expenditure of considerable resources to manage scenarios 1 and 2, which is essentially protecting designated uses that do not exist or protecting designated uses that are not impacted by selenium. This issue becomes even more acute considering the significant issues with the development of water column portion of the Draft Se Criterion discussed above.

For comment 8, a fish habitat survey should be conducted, either independently or as part of a use attainability analysis, to determine the existence of designated use and viability of fish species in the subject waters before selenium water column guidelines are applied. Water column guidelines or screening levels can be used as part of the habitat and use assessment. If water column selenium concentration is determined not to be a contributing factor to fish extirpation, no selenium reduction effort should be implemented or prioritized. If the monitoring suggests that selenium is causing or contributing to cause fish extirpation, an adaptive approach should be designed to improve all of the factors to help fish population to be reestablished. With fish tissue concentration to determine attainment, water column guidelines can be used to assess the progress of selenium reduction efforts.

Comment Category 2.4 – Comments Concerning Water Column Criterion Elements

2.4 Summary

Comments concerning the water column criterion element as it appears in Table 1 of the July 2015 draft are included in this section. Several commenters provided comments on magnitude, duration, and frequency. However, the bulk of the comments were focused on the intermittent equation and how it should be implemented. Some commenters noted that the criterion values should include uncertainty data.

2.4 Response to comments

2.4 Responses concerning the intermittent water column criteria element

Regarding the intermittent exposure criterion element, EPA recognizes that not all exposures are continuous and developed the intermittent criterion element due to concern that intermittent discharge sources may not be accounted for with the national 30-day average chronic water column criterion element, yet intermittent discharges of sufficient magnitude and frequency could accumulate through the food web and ultimately result in chronic impacts on aquatic life.

EPA believes, and many comments support EPA's conclusion, that it is unnecessary to have an additional acute criterion element which addresses acute, water column-only events, because selenium is bioaccumulative and toxicity primarily occurs through dietary exposure. Although selenium may cause acute toxicity at high concentrations (which would be captured by the intermittent criterion element) the most deleterious effect on aquatic organisms is due to selenium's bioaccumulative properties; these effects occur at lower concentrations than acute effects. Chapman et al. (2009) noted that selenium acute toxicity has rarely been reported in the aquatic environment and that traditional methods for predicting effects based on direct exposure to dissolved concentrations do not work well for selenium.

Regarding the intermittent criterion element, as described in Section 2.7.9 of the 2015 draft, this criterion element fills a need to account for intermittent discharges that may be elevated but infrequent, and to account for associated potential loadings and resulting chronic risk (not risk from intermittent or variable exposures per se) to downstream waters. Modifications of the criterion can be made on a site-specific basis, with data from the site. Biokinetic modeling, if used, should be adapted to a site using appropriate data – the values EPA presented represent default values that will be generally protective.

FWPC commented that they "agree with the concept that intermittent exposure to selenium, as with other pollutants, is less toxic than continual exposure." EPA is not articulating such a concept in the document. Repeated exposures of selenium are expected to result in accumulation through an ecosystem's food web leading to sustained exposure. Because the effect related to the intermittent criterion element is the chronic effect not effects due to variable exposure, additional toxicity testing is not needed, as suggested in some comments.

The citation (Hoang and Klaine 2008)[1] provided by FWPC, as evidence to support FWPC's assertion that "intermittent exposure to selenium, as with other pollutants, is less toxic than continual exposure" is for a study on an invertebrate species with a water column only exposure, which is not representative of the dietary exposure considered important for selenium and discussed in the criterion document. Further the study authors, Hoang and Klaine 2008, specifically identify an important issue not described in the public comment: because of latent mortality observed in their study they indicate that "standard toxicity tests using continuous exposures would underestimate Se toxicity." This comports with EPA's practice of developing criteria durations typically less than the toxicity test experimental duration. These authors did find recovery of the aquatic invertebrate tested after water column only exposures, most likely because the pulsed selenium diminished in water column, unlike dietary exposures where selenium bioaccumulates. Further, all exposures in this study were for 12 hours of water column exposure, less than typical acute test exposure durations. Dietary exposures in an ecosystem are unlikely to be of such short exposure durations.

The intermittent criterion element is meant to protect receiving and downstream waters from bioaccumulative impacts by limiting the amount of selenium that is available to be taken up by biota and bioaccumulated to levels of concern in sensitive species. Because (a) the derivation of the 30-day averaging period, and the subsequent derivation of the intermittent criterion element, and (b) the considerations upon which EPA based its decision to use the EC_{10} both involve the kinetics of bioaccumulation, EPA understands the connection the comment is making between the two. However, EPA does not agree that it is addressing the same issue twice. Rather EPA is addressing two distinct issues that are both affected by bioaccumulation and kinetics.

EPA notes that several reviewers viewed the intermittent criterion element as a reasonable surrogate for an acute criterion for protecting aquatic ecosystems, particularly downstream lentic waterbodies, from the effects of intermittent discharges of selenium. EPA has also further examined the lentic/lotic classification issue, and has evaluated each site used in the criterion development individually to ensure it was not mischaracterized.

[1] Hoang, T.C., Klaine, S.J. 2008. Characterizing the toxicity of pulsed exposure to Daphina magna. *Chemosphere* 71(2008) 429-438.

2.4 Specific comments

EPA-HQ-OW-2004-0019-0403-A2; Iowa Department of Natural Resources; Posted 10/15/15

(4) EPA states that the "Water Intermittent" criterion is not an acute criterion. Also, it is not an independent criterion but a re-expression of the 30-day criterion. States should not be required to adopt both the 30-day average criterion and the intermittent criterion because the chronic effect through dietary consumption of selenium (not short-term) is the cause for selenium toxicity to aquatic life based on the available toxicity data. Meeting the 30-day chronic criterion will ensure that acute toxicity can be prevented.

(5) States should have the option to use "water intermittent" criterion as an alternative to the 30-day average criterion for intermittent discharges of selenium, but the intermittent and 30-day average criteria should not be applied together in the implementation of Clean Water Act programs.

EPA-HQ-OW-2004-0019-0389-A1; Thunder Basin Coal Company, LLC (TBCC); Posted 10/14/15

Intermittent Water Column Exposure Criteria

Due to the wide variation in site specific selenium concentrations even in small areas and since selenium concentrations can change rapidly due to flow and geochemical conditions, the intermittent exposure criteria will be very difficult and costly to correctly determine for regulators and permittees alike. The proposed criteria and procedures should be better explained by EPA or dropped from the proposed standards and replaced by a simpler chronic standard.

EPA-HQ-OW-2004-0019-0393; North Dakota Department of Health; Posted 10/14/2015

Additionally while EPA's attempt to address the intermittent nature of the selenium concentrations in the water column is commendable, the implementation process is not practical, and again places an unsupported burden on the state. The translation between intermittent high concentrations and tissue concentration does not withstand scientific rigor. Until a broader dataset is established, a link between intermittent concentrations and tissue concentrations should not be established.

EPA-HQ-OW-2004-0019-0416-A1; Wyoming Mining Association (WMA); Posted 11/02/2015

Intermittent Water Column Exposure Criteria

Due to the wide variation in site specific selenium concentrations even in small areas and since selenium concentrations can change rapidly due to flow and geochemical conditions, the intermittent exposure criteria will be very difficult and costly to correctly determine for regulators and permittees alike. The proposed criteria and procedures should be better explained by EPA or dropped from the proposed standards and replaced by a simpler chronic standard.

EPA-HQ-OW-2004-0019-0394-A2; Appalachian Mountain Advocates and Sierra Club Environmental Law Program; Posted 10/14/2015

II. The Chronic Water Column Element Should Be Expressed as a Four-Day Average

As explained above, an inviolable water column criterion is necessary to achieve the dual purposes of setting water quality goals and providing the basis for effective regulatory controls. While we believe that EPA must give precedence to the water column elements of its Draft Criterion, those elements must be revised to ensure that they can be practically enforced and implemented. The Draft Criterion includes, as one of its four elements, a "Monthly Average" water column element that is based on the "30-day average water concentration." Draft Criterion at xiv, 22. This 30-day average replaces the existing criterion for chronic exposure, which is expressed as a "four-day average." *See* 64 Fed. Reg 61,182 at 61,194-61,195. By shifting from a four-day to a 30-day average, EPA has removed important protections for aquatic life. EPA has not explained the basis for its shift from a four-day to a 30-day average. This shift and the lack of explanation are particularly problematic because multiple EPA guidance documents explicitly state that four-day averaging periods are preferred while 30-day averaging periods should be discouraged. The documents that support a four-day averaging period include EPA's "*Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses* (1985)"[8] and "*Technical Support Document For Water Quality-based Toxics Control* (1991)."[9] In its final selenium criterion, EPA should return to the use of a four-day average.

A. EPA's Use of a 30-day Average is Inconsistent with EPA Guidance

One of the documents that supports a four-day average over a 30-day average was directly relied on by EPA in preparing the proposed selenium criterion. EPA's public notice states that the proposed selenium criterion is "based on the latest scientific information and current EPA policies and methods, including EPA's *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses* (1985) (EPA/ R–85–100)." 80 Fed. Reg at 44,351. Despite this apparent reliance, EPA has ignored the *Guidelines'* express statement that a four-day average is more protective than, and therefore preferable to, a thirty-day average.

The *Guidelines* first observes that the averaging period should be shorter than the test used to derive the criteria, stating that "Life-cycle tests with species such as mysids and daphnids and early life-stage tests with warmwater fishes usually last for 20 to 30 days. An averaging period that is equal to the length of the test will obviously allow the worst possible fluctuations and would very likely allow increased adverse effects." *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses* (1985) at 5.

The Guidance then expands on the benefits of a four-day averaging period:

An averaging period of four days seems appropriate for use with the CCC [criterion continuous concentration] for two reasons. First, it is substantially shorter than the 20 to 30 days that is obviously unacceptable. Second, for some species it appears that the results of chronic tests are due to the existence of a sensitive life stage at some time during the test, rather than being caused by either long-term stress or long-term accumulation of the test material in the organism. The existence of a sensitive

life stage is probably the cause of acute-chronic ratios that are not much greater than 1, and is also possible when the ratio is substantially greater than 1. In addition, some experimentally determined acute-chronic ratios are somewhat less than 1, possibly because prior exposure during the chronic test increased the resistance of the sensitive life stage. A four-day averaging period will probably prevent increased adverse effects on sensitive life stages by limiting the durations and magnitudes of exceedences of the CCC.

Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses (1985) at 5.

The *Guidance* upon which the proposed selenium criterion is supposedly "based on" thus recognizes that an averaging period of 30-days "is obviously unacceptable" and recommends instead an averaging period of four-days.

Other EPA publications also recommend the use of a four-day average. The "*Technical Support Document For Water Quality-based Toxics Control* (1991)" states that "a 4-day averaging period is recommended for application of the CCC in aquatic-life criteria for both individual pollutants and Whole Effluents." *Technical Support Document* at Appendix D-2. Just as the *Guidelines* did, the *Technical Support Document* makes clear that the "averaging period should be substantially less than the lengths of the tests" on which it is based. *Id.* at Appendix D-3. The chronic exposure tests cited by EPA in its Draft Criterion document include studies of 30 or fewer days. *See e.g.* Draft Criterion at 102 (describing a 28-day study of "fry surviving at swim-up"); 36 ("the 30-day larval survival test"). Because these tests were as little as 30 days, the averaging period should be substantially shorter.

The *Technical Support Document* provides several additional reasons why a four-day averaging period is recommended:

- It is substantially shorter than the 20- to 30-day duration of most chronic tests and is somewhat shorter than the 7-day duration of the *Ceriodaphnia* life-cycle test.
- For both endrin and fenvalerate, Jarvinen et al. found that a 72-hour exposure caused about the same amount of effect on the growth of fathead minnows in early life-stage tests as did a 30-day exposure to the same concentration.
- In some life-cycle tests on effluents with Ceriodaphnids, concentrations of effluents that were a factor of 1.8 greater than the CCC caused unacceptable effects in 4 or 5 days.
- It is not so short as to effectively defeat the purpose of the concept of the averaging period.

Id. at Appendix D-2 (internal citations omitted).

B. EPA's Use of a 30-day Average Will Render the Water-Column Element Unenforceable

Of equal or greater importance is the fact that the use of a 30-day average will render the water-column based chronic element unenforceable. As EPA has provided no explanation as to how the 30-day average is to be implemented, courts and state regulators are free to interpret the element as they see fit. At least one federal judge has interpreted a four-day average as requiring four consecutive days of sampling. Such an interpretation applied to a 30-day standard would make it impossible for citizen

groups to monitor compliance with a selenium water quality standard and would greatly increase the cost to states of determining compliance with the standard.

In a Clean Water Act citizen suit enforcing a permit condition that forbade violations of water quality standards, a West Virginia federal district court acknowledged that the citizen plaintiffs had presented selenium monitoring data in which "some months have two days of measurements per location, [and] other months have only one day." *Ohio Valley Environmental Coalition, Inc. v. Consol of Kentucky, Inc*., 2014 WL 1761938 at *16 (S.D.W.Va., 2014). Although the court acknowledged that "every measurement reported exceeds [the existing chronic criterion of] 5 ug/l," it concluded that "it is not clear that any of these measurements are actually *chronic* measurements, that is, four-day average concentrations." *Id*. The implication of the district court's decision is that four consecutive days of sampling data are required to prove a violation of a standard expressed as a four-day average. The further implication is that a thirty-day average would require thirty consecutive days of sampling data. Such a requirement would be logistically complicated to the point of impracticality, and would be prohibitively expensive given the costs of the sampler's time and the laboratory fees for each sample. This would thwart enforcement in the not-uncommon situation where regulators have not imposed end of pipe numerical effluent limitations but rather rely on general permit conditions that prohibit violation of water quality standards.

C. EPA Must At Least Clarify How the 30-day Average is to be Implemented and Enforced

As explained in the *Guidelines* and *Technical Support Document*, the water-column based element should be expressed as a four-day average. If EPA does not intend to utilize a four-day average, but does intend to allow the 30-day average to be implemented and enforced based on less than 30 days of data, EPA must at least clarify that. For example, if EPA intended that the 30-day average be implemented as a monthly average, EPA should state that directly, and should reference 40 C.F.R. § 122.2, which defines "average monthly discharge limitation" as "the highest allowable average of 'daily discharges' over a calendar month, calculated as the sum of all 'daily discharges' measured during a calendar month divided by the number of 'daily discharges' measured during that month." In other words, EPA should clarify that compliance can be determined based on less than 30 samples taken within a given month.

III. The Intermittent Exposure Water Column Element Needs Clarification

In order to address the cumulative, chronic effects of shorter-term pulses of selenium pollution, EPA included an intermittent exposure water concentration element in its Draft Criterion. Draft Criterion at 86. Compliance with this element is determined using an equation that involves the concentration of selenium during pulse events as well as the "average background selenium concentration" during the rest of the 30-day measurement period. Although the Commenters generally agree with such an approach at this time, the element as proposed suffers from similar implementation problems as the monthly average element. In particular, the data necessary to determine the "background concentration" term of the intermittent exposure element equation will be lacking in most circumstances. As explained above, thirty consecutive days of water column data are rarely available to either citizens or regulators, such that, even where data exists to show high pulses of selenium, compliance with the intermittent exposure element cannot be easily determined. EPA should make clear

that citizens and regulators may extrapolate from more limited data to determine the “background exposure” occurring during the non-pulse days of the 30-day period.

EPA-HQ-OW-2004-0019-0385-A2; Kentucky Division of Water (KDOW); Posted 10/13/2015

Intermittent Exposure

The element of the criterion which addresses intermittent exposure in the water column is presumably intended to mitigate exposure to high concentration pulses or "spikes" in selenium entering a waterbody and accumulating in food particles at a concentration that may cause chronic toxicity to the aquatic habitat. The calculated intermittent criterion is to be determined site-specifically and depends on the frequency and magnitude of selenium "spikes" over a 30-day period. To account for variability in the selenium concentrations, the mathematical average is used as the input data. The calculated intermittent criterion would be applied to the mathematical average of the spike concentrations. While the formula EPA provided for "Intermittent Exposure" is sufficiently understandable, the implementation of this criterion is not practical.

On its face, the Intermittent Exposure criterion element appears to have been developed and is intended to apply to a narrow range of discharge scenarios or types. In so doing the criterion unnecessarily complicates implementation as a "national" criterion. There are a wide variety of discharge in which the intermittent exposure criterion could otherwise potentially be interpreted to be applied if adopted and implemented by states. Consequently, this proposed EPA approach is cumbersome and impractical to implement. EPA's contract peer review also concludes that "the intermittent approach proposed is unnecessarily complicated if the simpler approach continues to achieve the same objective."

KDOW requests that EPA defer to its contractor peer review which indicates that while the proposed method for addressing intermittent and time-varying discharges may be reasonable if adequate data are available, given that limited bio-kinetic data are available, it is premature to implement such as approach for setting water quality criteria. As such, KDOW urges EPA to reconsider this approach and to rely on what KDOW and EPA agree is the appropriate endpoint: fish tissue data. As with Kentucky's chronic criterion, requiring tissue sampling in the event the water column concentration exceeds a given threshold *(i.e.* 5.0 µg/L) protects the critical aquatic endpoint, which are monitored to detect any potential toxicity concerns. EPA has clearly articulated and developed tissue based chronic criteria for the purpose of protecting against chronic endpoints that the Intermittent Exposure criterion is also intended to protect. EPA must ultimately succinctly and definitively answer the question: Are technically sound tissue-based criterion protective or not, to which the science supports an affirmation in response.

Delete footnote 4 (July 27, 20I5 80 FR No. I43 at 44352) and the "Intermittent Exposure" criterion as this criterion is scientifically premature and is impractical to implement.

EPA-HQ-OW-2004-0019-0387-A1; Colorado Department of Public Health & Environment; Posted 10/14/2015

The Intermittent Exposure criterion element seems complicated to implement. Would calculation of this element require daily water collection to determine when and how long elevated selenium concentrations are observed? If selenium concentrations are constant, can this element of the criterion be disregarded? Does EPA expect that intermittent pulses of selenium occur in all types of waters, or are there particular situations EPA has in mind where an intermittent criterion would be most applicable?

EPA-HQ-OW-2004-0019-0413-A2; Federal Water Quality Coalition (FWQC); Posted 10/28/2015

1. Adjustment for Intermittent Exposures

In the Criteria Document, EPA has included a provision for adjusting the applicable water column criteria to less stringent levels where the discharge of selenium is "intermittent." We agree with the concept that intermittent exposure to selenium, as with other pollutants, is less toxic than continual exposure, and we support the Agency's incorporation of this concept into the criteria. However, we have several questions and concerns about the new "intermittent" criteria. For one thing, it is not clear when the adjusted criteria would apply; EPA indicates that they are triggered when selenium is present at an "elevated concentration." But that term is never defined. In addition, it is not clear how the criterion is applied when the background level is high. It appears that the equation would lead to a zero limit in that circumstance, which would obviously not be attainable.

EPA should also clarify the scope of the "intermittent" process - in particular, as to what types of discharges it is meant to cover. EPA indicates that it would apply to "short-term exposures that contribute to chronic effects through selenium bioaccumulation (e.g., stormwater overflows from storage ponds or other intermittent releases." However, that discussion conflates two very different types of releases: intermittent discharges of process wastewater, and releases of stormwater during and after wet-weather events. In contrast to process discharges, stormwater discharges tend to peak quickly (in terms of concentration of pollutants) and then decline rapidly as well. In these circumstances, bioaccumulation is less likely, and there is also evidence that aquatic toxicity effects are reduced as compared to constant-discharge situations. Until EPA has reviewed this issue, and determined the nature of the selenium toxicity effects caused by stormwater discharges, it should not apply the selenium criteria to those discharges.

I. INTERMITTENT CRITERION

One of the aspects of the criterion that most troubled the peer reviewers was the new criterion level for intermittent exposures. They raised a number of serious concerns with that aspect of the criterion, and suggested other options for EPA to consider. We believe that those concerns are well-founded, and that the Agency should seriously consider adopting an alternative approach to intermittent exposures.

Here are some of the statements by the peer reviewers on the intermittent exposure issue:

"I also do not agree with the intermittent exposure criterion; it is unclear why it was developed, how it could be implemented consistently and reliably, and in general I think it just adds too much complexity to an already complex (indeed perhaps the most complex) water quality criterion." (p. 10)

"[t]he discussion of background science, data and methods used in the intermittent exposure tier of the present criterion needs significant improvement" (p. 12)

"The draft intermittent exposure Se criteria represent a mathematical manipulation of the monthly average criteria in order to derive values that would still result in 30-day average concentrations of 4.8 and 1.3 µg/L for lotic and lentic waters, even if those were exceeded for x number of days. A limitation of this approach is that it does not consider the uptake and elimination kinetics of Se in aquatic food chains and the influence of exposure duration and magnitude on these biokinetic parameters. In my opinion, a biokinetic modeling-based approach would be more appropriate for deriving intermittent, or acute, criteria that are protective against exceeding fish tissue-based Se criteria." (p. 43)

"I am not sure that the criterion equation for intermittent dischargers is meaningful, as it is basically a mathematical manipulation and does not in any way account for selenium uptake and elimination kinetics. An alternative approach that the EPA may want to consider is based on biokinetic modeling, such as that described in Brix and DeForest (2008). The method they described was based on modeling of a food chain comprised of periphyton, an invertebrate (mayfly), and a fish (fathead minnow). Inputs to the model include the background water Se concentration, the magnitude of an intermittent Se pulse, and the duration of the Se pulse. This provides a tool for evaluating whether a Se pulse of a given magnitude and duration could result in exceedance of a whole-body fish Se criterion, or short-term Se criteria could be derived for given short-term durations.

For a comparison of the biokinetic-based approach to the intermittent criterion equation in the draft AWQC document, I assumed that the background water Se concentration is 1 µg/L, the lotic criterion is 4.8 µg/L, and the number of days elevated is 4. The intermittent criterion would be 29.5 µg/L. Just as an example, if a lotic food chain consisting of periphyton→mayflies→fathead minnows were assumed, a 4-d pulse of 29.5 µg Se/L would not be nearly sufficient to reach a whole body Se concentration of 8.1 mg/kg dw (Fig. 2). There is a rapid increase in predicted Se concentrations in periphyton and mayflies and then a rapid elimination, but uptake is slower in fathead minnows.

In my opinion, a biokinetic-based modeling approach would be more appropriate for deriving acute or intermittent water Se criteria." (p. 120)

"It is not clear how the intermittent criterion outlined in the Draft Document will be applied. The mathematical expression of the criteria on page 93 is clear but the terms surrounding the application of the criterion are not. For example, the criterion is not intended to apply to "ordinary smoothly varying concentrations" (Page 94). However, what specifically will constitute a discharge curve that is not "smooth" has not been defined. It is also not clear what magnitude of selenium concentration spikes would designate a discharge as having to be regulated as an intermittent discharge. Finally, designation of an intermittent criterion appears to contradict the data in Appendix G and the statement on page 94 that "kinetics of selenium accumulation and depuration are sufficiently slow that attainment of the water criterion concentration element by ambient 30 day averages will protect sensitive aquatic life

species even where concentrations exhibit a high degree of variability. While outside the area of our expertise it is noted that several comments in the public registry suggest that a biokinetic model may be more appropriate than the application of an expansion of the 30-day average calculation for determining intermittent criterion." (pp. 123-124)

In response to these concerns, here is EPA's primary response:

"EPA notes that several reviewers viewed the intermittent criterion element as a reasonable surrogate for an acute criterion for protecting aquatic ecosystems, particularly downstream lentic waterbodies, from the effects of intermittent discharges of selenium."

We believe that this summary response is not adequate to address the significant problems with the intermittent exposure element of the criterion that were raised by the peer reviewers. Before finalizing the criterion, EPA needs to consider each of these issues and assess whether changes can be made in the new criterion, or alternative approaches can be adopted, that would address these problems.

EPA-HQ-OW-2004-0019-0415-A1; Idaho Department of Environmental Quality (DEQ); Posted 10/28/2015

The intermittent water column exposure criterion does not appear to be very practicable. It is highly unlikely Idaho, or any regulatory entity, will have sufficient daily selenium data to make use of it. EPA should better explain the utility and application of the intermittent exposure criteria, or better yet, simplify their proposal by dropping the intermittent criteria as impractical and unneeded.

The intermittent water column criterion is an interesting way to deal with variable exposure. It appears this criterion is intended to deal with a waterbody that varies in concentration over time. It is not clear whether EPA envisions or would allow application as well to variation in exposure as fish move among waters of varying selenium concentrations.

EPA-HQ-OW-2004-0019-0412-A2; Utility Water Act Group (UWAG); Posted 10/28/2015

3.3 Intermittent-Exposure Water Criterion Element: Derivation From the Chronic Water Criterion Element

EPA has proposed a criterion equation that would adjust the applicable lotic and lentic water criterion to a less stringent criterion in settings where the discharge of selenium is intermittent. UWAG agrees with the agency that the proposed fish tissue criterion would override the water-based intermittent criterion in instances where fish tissue data are available. We also agree that there is merit to the proposed intermittent exposure value based on the understanding that intermittent exposures to trace elements and other pollutants is generally less toxic to aquatic life relative to continual exposure. However, UWAG strongly disagrees with the suggestion that the intermittent value should be applied to stormwater overflows as suggested by EPA in the Executive Summary of the Draft Criterion (at xiii):

EPA is recommending the intermittent value to address short-term exposures that contribute to chronic effects through selenium bioaccumulation (e.g., stormwater overflows from storage ponds or other intermittent releases).

Stormwater discharges are chemically and physically distinct from traditional process waste-stream discharges. During storm events, concentrations of pollutants increase drastically in a short period of time, a peak concentration is observed, and then the concentration of pollutants decreases rapidly. For example, Riscassi et al. (2010) reported that, during a storm event, the cycle of increasing total mercury concentration, peak concentration, and declining concentration lasted no more than 12 hours. The rapid peak and declining concentration of pollutants during a storm event is fundamentally distinct relative to batch or intermittent discharges of process waste-streams. Thus, the potential for bioaccumulation of selenium in the proximal food web is significantly reduced during storm events. Lastly, EPA does not require states to implement numeric water quality-based effluent limitations for stormwater discharges (memo from Andrew Sawyers and Benita Best-Wong, US EPA Office of Wastewater Management, to US EPA Region Water Directors dated November 26, 2014). UWAG requests EPA delete language from the final criterion that suggests the intermittent criterion should apply to stormwater discharges.

Additionally, UWAG believes the agency should have made an effort to gather information on the kinetics of intermittent selenium exposure, although UWAG acknowledges that there are likely few published papers on chronic tests of aquatic life exposed to intermittent pulses of selenium. In one such study, Hoang and Klaine (2008) reported results of a 21-day chronic test using *Daphnia magna* exposed to intermittent pulses of selenium. The study indicated that:

- Survival of *D. magna* was higher following a second pulsed exposure compared to the first, suggesting some kind of tolerance induction following the first pulse.
- Growth of *D. magna* was not affected by the duration or magnitude of the pulses. Likewise, reproduction was not affected by pulse duration or magnitude, indicating that *D. magna* fully recovered (or tolerance was induced) after the pulses.

It is certainly possible that intermittent chronic exposure to selenium could induce tolerance in aquatic organisms other than *D. magna*. As such, UWAG requests that EPA evaluate this issue prior to finalizing the freshwater selenium chronic criterion. Because the most sensitive endpoint to assess selenium toxicity is survival and deformity incidence in fish, EPA should seek to conduct studies to evaluate whether intermittent exposure causes the same magnitude of reproductive effects that continual exposure induces.

EPA-HQ-OW-2004-0019-0406-A2; Kentucky Chamber of Commerce; Posted 10/15/2015

The Chamber also questions the need for an intermittent water column exposure criterion. U.S. EPA's intent is to mitigate exposure to occasional high concentration spikes in selenium in a discharge. Because the proposed formula is highly reliant on the availability of adequate data on individual streams, it would create significant implementation concerns. Additionally, since only chronic impacts are at issue and the fish tissue standard adequately and directly determines the existence of any "chronic" impact endpoint, an intermittent standard (even if it were shown to be a reliable indirect

indictor of a chronic endpoint) is not necessary. Finally, the intermittent standard is based upon "further modeling" beyond that used for determining the water column concentration criteria for lotic and lentic aquatic systems, and therefore it is also unreliable and unproven. (Criterion Document at p. 26). The Chamber requests that it not be included in the final recommended criterion.

EPA-HQ-OW-2004-0019-0391-A1; North American Metals Council (NAMC); Posted 10/14/2015

The key problem with the manner in which EPA has approached the development of waterborne selenium concentrations is that the criteria derived from medians do not apply to medians but rather to the 30-day once-in-three years, upper-tail of the distribution value. There is a clear disconnect between criteria development and application that will provide ample work and fees for consultants, will have negative economic consequences, and will not notably advance environmental protection.

Comment Category 2.5 – Comments Concerning Items Considered out of Scope

2.5 Summary

This section includes comments that EPA considered "out-of-scope" given the purpose and objectives of EPA's 2016 Selenium Aquatic Life Water Quality Criteria recommendations. A range of topics are commented on such as acute toxicity of selenium, selenium impacts on aquatic-dependent wildlife, the role sulfate might play in toxicity to aquatic organisms, the applicability of the criterion to marine environments, economic impacts associated with criterion implementation, and questions about previous (2002 and 2004) selenium criteria drafts.

2.5 Response to comments

2.5 Response to comments that are out of scope

As shown in Table 2.2 of the 2015 draft, EPA has indicated that acute toxicity is not included in the assessment. EPA notes that several peer reviewers viewed the intermittent criterion element as a reasonable surrogate for an acute criterion for protecting aquatic ecosystems, particularly downstream lentic waterbodies, from the effects of intermittent discharges of selenium. Many public comments support the development of intermittent criterion element in lieu of an acute criterion.

Regarding risk to aquatic dependent wildlife, EPA understands the potential for risk to birds from selenium exposure and has begun work on a national criteria for selenium that would protect aquatic-dependent wildlife.

EPA decided not to include a sulfate correction factor in the 2016 selenium criterion due to uncertainties in the science. The Deforest et al 2014 report referred to in the NAMC and API 2015 public comments notes that a sulfate-dependent selenium criteria would apply only to selenate-dominated, well-oxygenated streams, which is a small subclass of waters in the US. The publication discussed experiments to assess influence of sulfate on selenate uptake on only one species of macrophyte (Lemna minor) and one algal species (Pseudokirchnella subcapitata), a very limited data set of primary producers. The authors themselves note that "*It does need to be emphasized here, however, the analysis currently does not include Se data for periphyton and benthic diatoms, as these data are not available*." The authors also note that "*due to methodological challenges and high costs, it is difficult to comprehensively evaluate the influence of sulfate on bioconcentration and transfer up the food chain*." Similarly, EPA describes effects of mercury on aquatic life, but did not adjust the chronic criterion.

Regarding the need to clarify that the criterion applies to freshwater, the criterion document cover page indicates this is a freshwater criterion. EPA has added additional text in the body of the criterion document to ensure that this is clear. It is important to note, however, that the approach used in the development of the Freshwater Selenium criterion could clearly be applied to other systems, if data for those systems (e.g., estuarine/ marine food web data, surrogates) were available.

Finally, EPA has reviewed all available reliable data and used that as a basis for deriving the 2016 chronic selenium criterion. This criterion document replaces the 2002 and 2004 draft criteria documents, and EPA is not responding to comments on those older documents at this time.

2.5 Specific comments

EPA-HQ-OW-2004-0019-0399; Clean Water Team; Posted 10/15/15

The economic burden arid western states will incur complying with the proposed regulation is enormous and essentially an unfunded mandate to the local community's ratepayers. The proposal for site specific criteria can help address ecoregion concerns; however, this is an additional cost. We urge EPA to revise the regulation to include ecoregion specific stipulations especially for criteria that can never be exceeded in the present draft.

EPA-HQ-OW-2004-0019-0385-A2; Kentucky Division of Water (KDOW); Posted 10/13/2015

The proposed national criterion and its elements appropriately do not include a criterion for acute toxicity since the mode of action for toxicity in the aquatic habitat is dietary driven; the pronounced toxic effects of concern are lethality and embryonic teratogenicity driven by the cellular incorporation of seleno-amino acids. Thus, the mode of toxicity is unlike oral ingestion or dermal sorption that may lead to system lethality in developed organisms. Therefore, short-lived, high water-column concentration exposure is not indicative of a toxicity problem.

Establish that the chronic selenium criterion is sufficient to protect streams and aquatic habitats, and forego any recommendation for state adoption of an acute criterion.

EPA-HQ-OW-2004-0019-0390-A1; West Virginia Coal Association (WVCA); Posted 10/14/15

The Draft Selenium Criterion do not offer adequate detail regarding site-specific factors that inhibit or enhance selenium toxicity, such as sulfate, and how these factors should be incorporated into implementation of the criteria.

EPA-HQ-OW-2004-0019-0410-A2; West Virginia Department of Environmental Protection (DEP); Posted 10/28/2015

EPA’s 2015 Draft, like the 2014 Peer Review Draft, removes the acute water quality criterion of 20 µg/L. DEP agrees with EPA that acute toxicity to selenium occurs at higher concentrations than chronic effect concentrations, negating the need for an acute selenium criterion in the presence of a protective chronic criterion.

EPA-HQ-OW-2004-0019-0387-A1; Colorado Department of Public Health & Environment; Posted 10/14/2015

In Appendix A, page A-2, EPA discusses evidence of the relationship between selenate and sulfate (i.e., sulfate can reduce the accumulation of selenate). Specifically, EPA stated "A significant inverse relationship was shown to exist between acute selenate toxicity to aquatic organisms and ambient sulfate concentrations (Brix et al. 2001 a). Competition with selenate has also been observed for phosphate in green algae (Riedel and Sanders 1996), and with chromate and tungstate in anaerobic bacteria (Oremland et al. 1989)". However, it does not appear that the effects of sulfate were considered in development of the draft criterion. If it is possible for sulfate to affect bioaccumulation of selenium in the food chain, thus resulting in less selenium in fish tissues than would be predicted by food web modeling, it seems this would be an important consideration. The WQCD requests that EPA consider adding more information about why sulfate was not considered in the current draft criterion, especially considering its importance in previous selenium criteria documents. A section similar to the "Interactions with Mercury" section would be useful.

EPA-HQ-OW-2004-0019-0411-A2; American Petroleum Institute (API); Posted 10/28/2015

2.3.5 Alternative Sulfate-dependent Selenium Guideline Approach

Sulfate (SO_4) competes with selenate for uptake by algae and macrophytes (Williams *et al.* 1994; Lo *et al.* 2015) and, therefore, can influence the magnitude of EFs in selenate-dominated systems and the amount of Se that is ultimately bioavailable to fish. Most recently, Lo *et al.* (2015) provided a comprehensive study on how sulfate concentrations influenced the uptake of selenate by an alga and a macrophyte. DeForest *et al.* (2014; in revision) provide an example of how these data could be used to develop sulfate-dependent Se guidelines for selenate-dominated waters. This included the following steps:

- Compiled paired water selenate, water sulfate, and particulate Se concentrations from laboratory studies (namely the data recently published in Lo *et al.* [2015]);
- Applied particulate-to-invertebrate and invertebrate-to-fish eggs regression models to particulate Se concentrations;
- Conducted multiple quantile regression to predict fish egg Se concentrations (dependent variable) as a function of water selenate and water sulfate concentrations (independent variables); and,
- Potential SO_4-dependent water Se screening guidelines were then validated against colocated water Se, water sulfate, and fish tissue data from lotic field sites presumed to be dominated by selenite.

Using the multiple quantile regression analysis of fish egg Se concentrations predicted as a function of waterborne selenate and sulfate concentrations to which particulates were exposed, the following 75th quantile regression equation was derived:

Original letter contains Equation – not numbered. See original letter.

This equation can be rearranged to solve for the waterborne Se concentration which predicts a given fish egg Se concentration at a given waterborne sulfate concentration:

Original letter contains Equation – not numbered. See original letter.

Assuming the 75th quantile and an egg Se guideline of 20 mg/kg-dw (DeForest *et al.*, 2012), water Se guidelines were calculated at a large number of lotic field sites from which co-located water Se, water SO_4, and fish egg Se data were available. The fish Se ratios (ratio of fish egg Se concentration to the guideline of 20 mg/kg-dw) corroborated the waterborne Se ratios (ratio of waterborne Se concentration to the sulfate-dependent guideline) 73% of the time, with 28% of the cases resulting in false positives and 5% of the cases in false negatives (Figure 5). Therefore, the waterborne Se ratio based on the sulfate-dependent guideline was protective in 95% of the samples.

Original letter contains Figure 5 – Relationship between mean fish egg Se and waterborne Se ratios based on the sulfate-dependent screening guideline. See original letter.

Using this equation with the egg/ovary value of 15.8 mg/kg and sulfate concentrations ranging from 50 mg/L to 300 mg/L would result in protective water column criteria ranging from 8.1 µg/L to 97.0 µg/L, respectively (Table 4).

Original letter contains Table 4 – Protective water column Se concentrations at various sulfate concentrations. See original letter.

2.4 Applicability to Estuarine Waters

The 2015 draft AWQC are explicitly identified as freshwater criteria. However, it is not clear from the current draft, whether the EPA would ever intend for the freshwater criteria to be applicable, without modification, to estuarine or other saltwater environments. This seems counter-intuitive. We recommend that the EPA explicitly address this issue in the final version of the AWQC document.

EPA-HQ-OW-2004-0019-0391-A1; North American Metals Council (NAMC); Posted 10/14/2015

2.3.4 Selenium and Mercury

The 2015 EPA Selenium Draft does not fully evaluate the interactions of mercury with selenium, which can reduce selenium toxicity. Although already noted in our comments on the 2014 EPA draft (Attachment 1), NAMC again recommends that EPA fully evaluate the extensive evidence for modification of selenium toxicity by mercury relative to the potential for these interactions to comprise exposure and toxicity modifying factors that should be considered when applying the proposed criteria.

EPA-HQ-OW-2004-0019-0402-A2; The Stakeholders Implementing TMDLs in the Calleguas Creek Watershed; Posted 10/15/2015

As described in the Stakeholder's comment letter on the 2014 External Peer Review Draft Criterion, selenium is an issue for many municipalities within Southern California due to the natural geology of the

Monterey Formation. This formation is a known source of selenium in California and surface water concentrations tend to be higher where the geologic formation is present; however, bioaccumulation and the resulting impacts to beneficial uses varies significantly. Many efforts throughout the State have focused on tissue-based approaches to more appropriately manage and regulate selenium, with an emphasis on protection of aquatic life (fish) and aquatic-dependent wildlife (birds).

In certain areas, such as Orange County, local agencies have worked for over a decade with the United States Environmental Protection Agency (USEPA), United States Fish and Wildlife Service (USFWS), United States Geological Survey (USGS), the State Water Resources Control Board, and the Santa Ana Regional Water Quality Control Board, to develop revised objectives for selenium.

In the Calleguas Creek Watershed, Stakeholders have been implementing a Total Maximum Daily Load (TMDL) for selenium[1] since 2006. Implementation efforts have resulted in a greater understanding of the relationship between water column concentrations and tissue concentrations (birds and fish) in the watershed. As a result, stakeholders are considering the development of a site-specific objective.

Additionally, there are potentially significant cost implications and the potential need to address natural sources in the Calleguas Creek Watershed that could be avoided by implementing the changes requested in the summary of key issues and specific technical comments contained herein. Not implementing the changes requested in the summary of key issues and specific technical comments contained herein may unnecessarily require implementation of significant and costly BMPs (predominately to address natural sources) with no net environmental benefit. Based upon evaluations conducted over the last 10 years in Southern California, these additional unnecessary costs can range in the hundreds of millions of dollars. Therefore, the implications of the proposed revisions to the freshwater selenium criterion are an important issue in Southern California.

EPA-HQ-OW-2004-0019-0409-A2; OC Public Works; Posted 10/20/2015

OC Public Works is concerned that the Draft Se Criterion, in the face of this newly available science, will rapidly become obsolete and inappropriate. This may have a significant impact on on-going selenium-related actions in Orange County. For example, a tissue-based site-specific selenium water quality objective (SSO) is currently under development for the Newport Bay watershed, that will consider protection of not only aquatic species (mainly fish), but also aquatic dependent wildlife (mainly birds, including several T&E species). Since selenium is such a unique contaminant, most, if not all, of the new issues raised at the meeting are relevant to how the aquatic life selenium criterion is derived. Therefore, EPA should carefully review the information from the Invited Expert Meeting and ensure that the most up-to-date science is incorporated in the derivation of the Draft Se Criterion.

9. Aquatic-Dependent Wildlife Protection

Protection of wildlife-dependent species is not part of the Draft Se Criterion. Not only will this pose an issue for the Endangered Species Act Section 7 review process that could complicate the adoption of the Criterion, future reconsideration of the aquatic-dependent wildlife would require a completely new analysis of the same dataset and could takes years to complete. This may not be an efficient approach.

EPA-HQ-OW-2004-0019-0394-A2; Appalachian Mountain Advocates and Sierra Club Environmental Law Program; Posted 10/14/2015

V. The Criterion Must Protect Aquatic-Dependent Wildlife

The Clean Water Act mandates that water quality standards protect not only fish, but all aquatic organisms and other wildlife that depend on healthy streams. Section 303(c) requires that such standards "shall be established taking into consideration their use and value for . . . propagation of fish and wildlife," among other things. 33 U.S.C. § 1313(c)(2)(A) (emphasis added); see also 33 U.S.C. § 1252(a) (directing states to develop comprehensive programs for controlling water pollution giving due regard to improvements necessary to "conserve such waters for the protection and propagation of fish and aquatic life and wildlife"). EPA's regulations require states to develop standards that will "[s]erve the purposes of the Act," meaning that they will "provide water quality for the protection and propagation of fish, shellfish and wildlife," among other things. 40 C.F.R. § 130.3 (emphasis added). Commenters are not aware of any states that have adopted selenium water quality standards specifically for the protection of aquatic-dependent wildlife and EPA does not have a Recommended Criteria for selenium to protect aquatic-dependent wildlife. In the absence of any standards that address wildlife, an approach that focusses solely on aquatic life does not satisfy the requirements of the CWA because it leaves such wildlife without any protection under the Act from selenium pollution.

Although EPA did not analyze the impacts of its criterion on aquatic-dependent wildlife, existing evidence makes clear that the concentrations of the proposed fish tissue elements are not protective of aquatic dependent wildlife. In 2004, EPA proposed but did not adopt recommended criteria that included a whole-body fish tissue criterion of 7.91 µg/l, which is more protective than EPA's current proposal. See Notice of Draft Aquatic Life Criteria for Selenium and Request for Scientific Information, Data, and Views, 69 Fed. Reg. 75, 541 (December 17, 2004). A group of the nation's leading selenium scientists wrote a white paper vigorously criticizing that criterion as not protective and too high. The authors explained the history of the EPA's flawed number:

> During the past 17 years numerous researchers including those funded by EPA have estimated that the toxicity threshold for selenium lies below the current chronic aquatic life criterion of 5 µg/L. Recently, corporate interests have claimed that 5 µg/L is overly restrictive. Because of an endangered species issue in California, EPA agreed to re-evaluate their CWA criteria guidance for selenium by 2002. This was problematic because:
>
> - EPA's normal procedure for setting Aquatic Life Criteria does not directly consider toxicity data for aquatic-dependent wildlife
> - EPA has promulgated no separate wildlife criteria for selenium.
> - EPA's normal procedure for setting criteria is better suited to non-bioaccumulative pollutants – selenium is bioaccumulative.
> - ESA-listed species every individual of a population "counts" and therefore criteria guidance would need to be fully protective at an individual-effects level.

> EPA contracted with the Great Lakes Environmental Center (GLEC) to derive the new selenium criteria. GLEC was instructed to derive the chronic criterion on a fish-tissue basis rather than on a water concentration basis. The GLEC derived criterion was released in March 2002. The draft tissue-based chronic criterion, of 7.9 µg/g, dry weight basis, assumed 20% of the target population would die. The USFWS asked EPA to not promulgate the criterion because it wasn't protective of endangered species.

Joseph P. Skorupa, USFWS, Theresa S. Presser, USGS, Steven J. Hamilton, USGS, A. Dennis Lemly, USFS, Brad E. Sample, CH2M HILL, EPA's Draft Tissue-Based Selenium Criterion: A Technical Review. Spring 2004 at 2-3.

The authors noted significant additional flaws in EPA's proposed criterion that would lead to harm to wildlife, including threatened and endangered species:

> GLEC's assessment of risk to aquatic-dependent wildlife was based on an erroneous draft wildlife toxicology report. The draft tissue-based chronic criterion for selenium of 7.9 µg/g would leave a substantive proportion of aquatic- dependent wildlife species unprotected; on the order of half the species. Aquatic life criteria are considered by EPA to be separate and distinct from wildlife criteria. Nonetheless, in the absence of promulgated wildlife criteria (as is the case for selenium), if the aquatic life criteria do not protect wildlife the purposes of the CWA are not being met. More critically, for waters of the United States supporting ESA-listed aquatic-dependent wildlife, the criteria would not be approvable for incorporation into state or tribal water quality standards.

Id. Those experts estimated that EPA's previously proposed criterion would have caused reproductive impairment in, conservatively, 40% and possibly as high as 95% of exposed mallard ducks. See Lemly, A. Dennis, Assessing the toxic threat of selenium to fish and aquatic birds, Environmental Monitoring and Assessment 43: 19-35 (1996). Reproductive impairment occurs if ducks are exposed through a contaminated diet during the development of their chicks. Mallard ducks are ubiquitous, breeding near and relying on aquatic resources throughout the US. They are primarily vegetarians eating seeds of grasses and sedges and the leaves, stems and seeds of aquatic plants. They occasionally eat insects, crustaceans and mollusks, especially when they are young. See http://www.nhptv.org/natureworks/mallard.htm. While the ducks do not eat fish, "allowing fish tissue to reach 7.9 ug/g would allow a level of contamination in the other parts of the aquatic ecosystem sufficient to cause nearly total reproductive failure among mallard ducks." Skorupa et al. at 22. Indeed, EPA explicitly recognizes that its proposed Criterion may not be protective of certain wildlife species, particularly those that regularly feed on mollusks. Draft Criterion at 131. The USFWS previously stated that a protective fish tissue standard for water birds would be 5 µg/g selenium, much lower than EPA's proposed whole body element of 8.0 mg/kg. See, e.g., Letter from Virgil Lee Andrews, USFWS Kentucky Field Office Supervisor to Annie Godfrey, Chief of USEPA Water Quality Standards Section, December 27, 2013. More recently, USFWS stated that a whole body criterion of about 4 mg Se/kg would be necessary to protect mallards. July 28, 2014 Comments at 18. EPA thus must either revise its fish tissue elements to ensure that they protect aquatic-dependent wildlife or else issue a concurrent wildlife criterion that must be adopted along with EPA's recommended aquatic life criterion.

Comment Category 2.6 – Comments on Various Implementation Topics

2.6 Summary

The purpose of the selenium criterion document is to set forth EPA's basis for and derivation of the water quality criterion recommendations for protecting aquatic life from the harmful effects of selenium. Many commenters expressed the need for EPA to develop implementation materials, provided feedback on how the criterion should be implemented, and some identified specific topics that EPA should address in upcoming implementation materials. There were a wide range of these types of comments including: how to measure attainment in monitoring, how to distinguish between lotic and lentic systems, and how to establish NPDES permit limits and thresholds for 303(d) listings and TMDLs.

2.6 Response to comments

2.6 Response to comments concerning implementation

EPA's criterion provides recommendations for states and authorized tribes to consider in their adoption of water quality standards under CWA section 303(c). The implementation documents that EPA is developing are intended to provide assistance to states and authorized tribes that adopt into the water quality standards a criterion based on or similar to EPA's recommended criterion. The implementation documents are also intended to provide assistance to other stakeholders and the public. If EPA refers to implementing the 304(a) criterion, it means implementing a state- or tribally-adopted criterion based on, or similar to, EPA's recommended criterion EPA is currently working on developing technical information that will help in the implementation of a selenium criterion in the many areas identified in Specific comments. EPA recognizes that there are numerous aspects of the recommended criterion that will benefit from technical support documents to enhance implementation of state and tribal criteria, and is planning to develop such documents and make them available for public comment. Note, background selenium is addressed in section 1.1 of the response to comments.

2.6 Responses to comments on implementation materials addressing the hierarchy of elements

The design of the tiered criterion is such that the hierarchy allows for the assessment of samples that are available (i.e., egg-ovary, muscle, whole body, and water). There are practical and scientific considerations for the collection and assessment of specific types of samples which EPA plans to address in a detailed technical support document. For example, whole body or muscle tissue from fish may provide the best estimate of critical body burdens of selenium in fish (male or female) that are not in the process of spawning. This and other issues will be discussed in the technical support document on fish tissue monitoring which is under development by EPA at this time.

2.6 Responses to comments on implementation materials addressing collection of fish tissue

Regarding collecting fish tissue samples, EPA agrees that technical support information is needed on sampling approaches for each element of the tissue criterion, since there are various situations where one tissue type may be favored over another, or the sample logistics (e.g., fish size) may limit the sample to a certain type of tissue sample. EPA is developing information for states, tribes and stakeholders to

consider when sampling fish tissue for the purposes of implementing the freshwater selenium criterion. In addition EPA has derived and is recommending that states adopt all of the fish tissue elements to provide maximum flexibility for a states monitoring and assessment program. Adopting all elements covers all potential logistical, spatial, temporal, and species- and life history-specific considerations.

2.6 Responses to comments on implementation of fish tissue in the GLI

EPA thanks MDEQ for the comment identifying implementation issues for selenium fish tissue elements in the GLI methods. EPA intends to work with MDEQ and the environmental agencies in the Great Lakes states to address those concerns.

2.6 Response to comments on Analytical Methods

Several commenters requested more information on analytical methods for selenium, especially for fish tissue. Such methods will be described in implementation materials.

2.6 Response to comments on use of methyl mercury guidance for implementation of the selenium criterion.

A few comments suggested EPA utilize an existing guidance on fish tissue monitoring issued in 2001 for methylmercury in implementing the selenium criterion. One key difference between these two documents is that they were developed for different purposes. The 2001 guidance was developed to support monitoring for the purposes of developing fish consumption advisories to protect human health from potential effects of methylmercury based on human diets from a variety of sources. The selenium fish tissue criterion element was developed to support the protection of aquatic life with fish diets based on a single ecosystem (with areal extent dependent on species being assessed). There are a number of issues relevant for aquatic life that must be considered that are not addressed in the 2001 methylmercury guidance to protect human health.

2.6 Response to comments on sampling window recommendations

Several commenters provided comments supporting a 1-year sampling window recommendation attributed to EPA. EPA has not made such recommendations in the selenium criterion document. Discussions of appropriate sampling windows will be addressed in implementation materials currently under development.

2.6 Specific comments

EPA-HQ-OW-2004-0019-0398-A1; Kansas Department of Health and Environmental Watershed Planning, Monitoring & Assessment Section; Posted 10/15/15

Our monitoring protocols do not accommodate calculation of a 30-day average of selenium concentrations to assess against the proposed 3.1 µg/l water column criterion. We would appreciate

guidance on how to use sample values collected typically once per calendar quarter to assess against the proposed criterion. We would also like some clarification on how selenium is intended to be analyzed. The proposal frames selenium as “dissolved total selenium”, whereas our laboratories analyze for “total recoverable selenium”. We are unsure if our analyses produce values that may be directly comparable to how selenium is expressed in the EPA proposal.

Reliance on the newly proposed ambient water column criterion of 3.1 µg/l for lotic waters will surely increase the number of streams listed under Section 303(d) for impairment by selenium, given current monitoring protocols are hampered by a preponderance of instantaneous grab samples that weakly represent 30-day averages as well as limited availability of laboratory resources to conduct fish tissue analyses.

KDHE appreciates this opportunity to comment and looks forward to working with EPA to properly assess impairments to aquatic life in Kansas streams caused by natural and anthropogenic-influenced selenium.

EPA-HQ-OW-2004-0019-0379-A1; Pennsylvania Department of Environmental Protection; Posted 09/30/2015

- The concepts and methodologies used by EPA to develop this criterion, as well as the recommendations on how this multi-medium based criterion is to be implemented, are relatively new. Therefore, we recommend that the Technical Guidance Document precede the final aquatic life criterion for Selenium.
- EPA wants states to adopt a criterion that includes two media, fish tissue and water-based. The Clean Water Act program requires the expression of water quality criteria as ambient concentrations in water. Other fish tissue criteria developed by EPA, such as the methyl mercury fish tissue based water quality criterion, have been difficult to implement. We see no evidence that this criterion will be any different.
- The proposed criterion states, "New or increased inputs will likely result in increased selenium in the food web, likely resulting in increased bioaccumulation of selenium in fish over a period of time until the new or increased selenium release achieves a quasi-"steady state" balance within the food web. Estimates of time to achieve steady state under new or increased selenium input situations are expected to be site dependent, so local information should be used to better refine these estimates for a particular waterbody. Thus, EPA recommends that fish tissue concentration not override water column concentration until these periods of time have passed in lotic and lentic systems, respectively." It is not clear how to implement this recommendation. EPA needs to clarify how EPA expects the "steady state" of a waterbody should be determined. What types of "local information" does EPA consider applicable?
- States may be reluctant to adopt this criterion because its conversion from a fish tissue concentration to a water concentration is extremely difficult to achieve. The proposed fish tissue criterion would require states to develop site specific water concentration values based on one of two models; a mechanistic modeling approach or using a field derived bioaccumulation factor. Both of these conversion techniques require more than one analytical determination to calculate a protective limit.
- We recommend EPA obtain early approval on the selenium aquatic life criterion from the U.S. Fish and Wildlife Service (USFWS). Comments received by EPA from USFWS on the pre-draft

selenium document contained a number of concerns relating to incomplete data used in the criterion determination. USFWS recently blocked EPA approval of the nationally recommended aquatic life criterion for Nonylphenol because they believed the national recommended criterion is not protective of endangered mussels. We had adopted this criterion for Nonylphenol in our most recent triennial review of water quality standards. We would like to avoid being in the same situation relative to selenium.

EPA-HQ-OW-2004-0019-0407-A2; Michigan Department of Environmental Quality (MDEQ); Posted 10/15/2015

Thank you for the opportunity to provide comments on the *Draft Aquatic Life Ambient Water Quality Criterion for Selenium - Freshwater 2015.* The aquatic life criterion for selenium is of interest to the Michigan Department of Environmental Quality (MDEQ), Water Resources Division (WRD), since there are some surface waters in Michigan with elevated selenium levels. We appreciate the United States Environmental Protection Agency's (USEPA) efforts to develop a scientifically defensible surface water criterion for selenium. We have the following comments on the draft document:

The Methodology Conflicts with the Great Lakes Initiative (GLI)

Michigan promulgated into state rules the selenium Criterion Continuous Concentration of 5 micrograms per liter derived by the USEPA as part of Title 40 of the Code of Federal

Regulations, Part 132, Water Quality Guidance for the Great Lakes System, commonly known as the GLI. Michigan also promulgated the methodology that the USEPA developed for deriving surface water values protective of aquatic life into our state rules. As you know, a methodology for developing a fish tissue level-based water quality standard (WQS) was not included as part of the GU. It is our opinion that we are required to retain our current selenium WQS until the USEPA revises the numerical WQS in the GLI. The USEPA should rescind the current selenium criterion and modify the methodology provided in the GLI to allow the Great Lakes states to use a fish tissue criterion to protect aquatic life from the effects of selenium.

Additional Guidance is Needed

The document developed by the USEPA provides much detail on how the criterion was derived. However, it does not provide adequate guidance on how to apply the criterion. For example, additional guidance for the following is needed:

1. Species selection for tissue-based criteria attainment measurement is critical. It is also inherently more complicated than water column-based criteria attainment measurement because many different fish species might be considered for attainment sampling. Because of this complexity, the US EPA should provide fish species selection guidance for tissue-based criteria attainment measurement.
2. Footnote No. 3 in Table 1 states that the surface water criterion for selenium will take precedence over the fish tissue criterion when there are "new or increased inputs of selenium until equilibrium is reached." Guidance needs to be provided on how states should define a new or increased input of selenium and how the state can determine that selenium is at equilibrium in the receiving water.

3. The USEPA derived a criterion for total selenium as part of the GLI. The proposed criterion for selenium is based on dissolved selenium. Since many states develop wasteload allocations based on total selenium, the USEPA should develop a translator to convert dissolved selenium to total selenium.

EPA-HQ-OW-2004-0019-0413-A2; Federal Water Quality Coalition (FWQC); Posted 10/28/2015

I. IMPLEMENTATION ISSUES FOR NEW CRITERIA

Beyond the derivation of the numeric levels in the Criteria Document, there are a number of other issues with the application of the new criteria that EPA should consider, which are set forth below. Further, as a general matter, it is important for the Agency to recognize that due to the format of the new criteria (which we believe is scientifically appropriate), implementation issues will be somewhat different than for other criteria that the Agency has developed in the past. Therefore, EPA should develop draft implementation guidance, and should make that guidance available for public comment before it issues the new criteria in final form.

1. Fish Tissue Data Taking Precedence

EPA has stated that while the new draft criteria have four parts (two based on fish tissue levels and two based on water column levels), the fish tissue elements "take precedence" over the water column elements. We believe that this precedence policy is fully consistent with, and even mandated by, the scientific information available, which shows that effects on aquatic life from selenium are indicated most directly through analysis of fish tissue selenium levels, rather than review of selenium levels present in waterways. However the EPA criteria document does not make entirely clear what the "take precedence" policy will mean in practice. For example, in a situation where fish tissue levels in a water body are below EPA's specified criteria, but the water column levels are above the EPA criteria, we believe that the scientific conclusion to draw is that the selenium levels are acceptable, and that the waterbody is not impaired. Since the new criteria will be used (after adoption by States) to make attainment decisions, EPA should make it clear that in making those decisions, available fish tissue should dictate the result.

VI. COMMITMENTS TO ISSUE GUIDANCE

Throughout the Response to Peer Review Comments, EPA frequently responds to questions and concerns raised by the peer reviewers by indicating that it will address those issues in implementation guidance. As a general matter, EPA states as follows:

“EPA recognizes that there are numerous aspects of the criteria that will benefit from technical support documents to enhance its application, and is planning to develop such documents.” (p. 11)

The Agency also states that:

“EPA, in a parallel process to the criterion development, is working to develop technical information that will assist in the implementation of the selenium criteria.”

We support these commitments by the Agency. It will be critical, as the guidance is developed, for EPA to issue draft documents for public review and comment. It will also be important for the guidance to cover the gamut of issues that will arise as the new criterion is implemented. To assist in compiling that

list of issues, we have reviewed the Response to Peer Review Comments to cull out the specific commitments that EPA has made in that document to develop guidance on particular issues. Here they are:

> "Regarding the interpretation of the "never to be exceeded" criteria, this is an issue that will be addressed in the technical support documents." (p. 18)
>
> "The design of the tiered criterion is such that the hierarchy allows for the assessment of samples that are available (i.e., muscle, egg ovary, or whole body). There are practical and scientific considerations for the collection and assessment of specific types of samples which EPA plans to address in a detailed technical support document. For example, whole body or muscle tissue from fish may provide the best estimate of critical body burdens of selenium in fish (male or female) that are not in the process of spawning. This and other issues will be discussed in the technical support document on fish tissue monitoring which is under development by EPA at this time." (p. 20)
>
> "EPA also thanks you for the important information on seasonal considerations of collection of egg-ovary versus whole body or muscle tissue and will consider this information in the technical support document on fish tissue sampling for selenium." (p. 22)
>
> "The issue of temporal considerations on collection of a specific tissue type (egg ripeness) for selected species is relevant and will be discussed (to the extent information is available) in the information developed for states to aid in the implementation of the criterion." (p. 23)
>
> "However, the agency is aware that spawning strategy likely plays a role in accumulation, and maternal transfer and deposition of selenium into the eggs. This issue will be addressed in the technical support materials under development regarding the timing and type of sampling based on species spawning strategy (single batch versus multiple smaller batches) and seasonality (spring or fall [some salmonids] versus sporadic spring/summer [e.g., cyprinids]), while also providing flexibility to states to adapt their monitoring programs to address the additional requirements for fish tissue monitoring for selenium." (p. 32)
>
> "Technical support information regarding fish tissue sampling issue is being developed by EPA." (p. 40)
>
> "EPA realizes that the nature of selenium bioaccumulation may be effectively reflected through the development of site-specific criteria. Other public comments that reflect implementation issues are beyond the scope of the scientific criterion document and will be addressed in technical support documents under development by EPA." (p. 127)
>
> "The nature of selenium bioaccumulation may vary on a site-by-site basis in a manner sufficient to justify development of site-specific criteria. The reviewer identifies several important issues that will be addressed in the technical information to be developed to guide the implementation of the criteria." (p. 129)

In addition to those specific statements by EPA, the Agency also makes general commitments to develop guidance on the following additional issues raised by reviewers, including concerns that were initially raised by public comments and then assessed (at EPA request) by the peer reviewers:

"The EPA must provide guidance on several aspects related to implementation of the tiered criteria approach, at the very least including (a) when to sample fish so that females are in vitellogenic or pre-ovulatory stages of oogenesis, (b) what sample size of fish to collect for tissue [Se] determinations (I suggest a minimum of n=10 female fish per site), (c) recommended analytical procedures for quantification of Se, (d) guidelines for implementation of the 30-day average water column criterion element (how, when, where), and (e) guidelines for implementation of the intermittent water column criterion, if the EPA chooses to keep it in the tiered criterion." (pp. 130-131)

"Averaging period: Comment reasonably addresses the need for clearer implementation guidance of the intermittent water column criterion. (p. 132)"

"Implementation: The public comments express thoughtful concerns and practical implementation questions that can serve as prompts to draft additional guidance." (p. 135)

"Intermittent criterion: Several good points are raised in the public comments. Suggestions to abandon one model for another do not provide adequate support for the suggestion. Practical implementation concerns are valid and should be addressed." (p. 135)

"Natural background: The public comments correctly identify concerns of naturally occurring selenium contamination of waters and impacted aquatic life. The draft criterion should explicitly address these concerns in regards to implementation of the draft criterion." (p. 136)

"Site-specific criteria: There are numerous public comments that should be addressed in guidance for implementation. (p. 138)

"Tiered criteria: There are numerous public comments that should be addressed in guidance for implementation." (p. 138)

"Tissue criterion: There are numerous public comments that should be addressed in guidance for implementation." (p. 138)

EPA-HQ-OW-2004-0019-0376-A2 [Comment 0381-A3 is a duplicate of 0376-A2]; Texas Commission on Environmental Quality (TCEQ); Posted 09/24/2015

Background

The EPA published the current nationally-recommended chronic selenium water quality criterion in 1987, which is expressed solely as a water column concentration. Since then, there has been considerable scientific review on the exposure pathways and effects of selenium on aquatic life. EPA published initial proposed revisions to the criterion in 2004, which were based upon whole-body fish tissue concentrations. In 2014, EPA developed the 2014 External Peer Review draft, which expanded the criterion to include four elements, including concentrations of selenium in fish tissue and the water column. The latest draft proposal includes four elements comprising six aspects of the criterion: (1) fish tissue concentration in egg-ovaries, (2) fish tissue concentration in muscle, (3) fish tissue concentration in the whole-body, (4) monthly water column concentration for lentic (non-flowing) systems such as reservoirs, (5) monthly water column concentration for lotic (flowing) systems such as streams and

rivers, and (6) intermittent concentrations for lotic and lentic aquatic systems to account for pulses of elevated selenium concentrations. EPA's draft proposed criterion incorporates all six of these targets, and EPA recommends all aspects to be adopted into state water quality standards. When available, fish-tissue based aspects would override water column concentrations, since selenium is bioaccumulative. Considerable uncertainty exists regarding how these elements would be implemented in regulatory programs under the CWA, particularly due to the complex nature of the criterion and lack of implementation guidance. The TCEQ offers the comments provided below.

C. EPA is requested to develop suggested monitoring guidance for sample protocols, including target fish species and fish eggs.

Guidance is needed standardizing the various aspects of fish tissue sample collection with respect to selenium evaluation. Clarifications for the target fish species or trophic levels, time of year of sampling and harvesting of eggs, as well as general considerations such as sample collection and handling are needed. Current research has determined that the bioaccumulation of selenium through aquatic food webs is the primary mechanism of exposure for aquatic life. However, EPA suggests that exposure and accumulation occurs significantly at base levels of the food chain, and site-specific factors such as dietary preferences of consumers can play a large role in determining exposure. Guidance is needed to specify what trophic levels should be sampled for evaluation and compliance with the criteria. Additionally, the monitoring of fish eggs is not practical for the state or permittees. The harvesting of eggs may require additional considerations such as spawning periods, special sample collection or analysis protocols. As a result, it is anticipated that this particular sample effort may be much more complex than the simple collection of fish for whole-body or tissue analysis. Without guidance and standard protocols, states and tribes may develop inconsistent methods for sampling and monitoring.

The TCEQ is concerned that the proposed changes could interfere with the effectiveness of the existing TCEQ water quality management processes. In particular, the comments address the need for implementation guidance for incorporation of the criterion in wastewater permitting, Total Maximum Daily Loads, and water quality assessment activities. The major TCEQ concerns included in the comments are as follows:

- the misleading nature in which EPA describes the criterion as having "four elements" when in fact there are six numeric components to the complex criterion;
- the lack of implementation guidance accompanying the criterion. Guidance for implementation of the criterion in permitting, monitoring and assessment programs is needed;
- EPA's expectations for consideration and adoption of the criterion as part of triennial reviews of water quality standards, particularly in light of the complexity of the criterion and lack of implementation procedures;
- lack of guidance for the sampling of target fish species, including the harvesting of fish eggs; and,
- lack of guidance regarding the development of site-specific criteria to account for regional differences in naturally-occurring selenium.

II. Lack of Implementation Guidance for Incorporation of the Criterion into Water Quality Management Programs of the Clean Water Act.

A. The proposed criterion lacks guidance for implementation. EPA is requested to coordinate with the states and tribes to provide guidance for implementation of the draft criterion in permitting, Total Maximum Daily Loads (TMDL) and water quality assessment. EPA should postpone the adoption of the criteria until all the necessary information, including the guidance, is available for public review and comment.

Current implementation procedures to establish effluent limits for National Pollution Discharge Elimination System permits are based upon water column concentrations. Guidance is needed to address various aspects of the six-part criterion, particularly since EPA is recommending that fish tissue elements be given precedence over water column components. The following key areas need to be addressed in the guidance:

- The development of water quality based effluent limits necessary to ensure attainment of the fish tissue criterion from whole-body, muscle, eggs or ovaries. Since permit limits are not written directly from tissue-based criteria, guidance is needed to assist states and tribes with the translation of fish tissue to water-column concentrations for use in site-specific wastewater permitting and TMDLs.
- The characterization of intermittent exposure scenarios (including determination of background concentrations), to account for pulses of selenium occurring during single day, high exposure events.
- Procedures for determining a "steady-state equilibrium" has been achieved in lentic and lotic environments as a result of increased inputs of selenium.
- Recommendations for determining attainment of criteria during assessment scenarios, particularly when data to evaluate all aspects of the criterion are not available. It is unclear whether all six numeric components must be considered or whether a combination of less than the six components can be used.

It is requested EPA seek input from the states and tribes to develop adequate guidance for the implementation of the criterion prior to final publication.

B. The proposal lacks clarity regarding the expectations for inclusion of the draft criterion in water quality standards. EPA should postpone adoption of this document and develop guidance through coordination with the states and tribes.

Due to the lack of guidance provided by EPA, additional uncertainties for entities with adopted acute and chronic selenium criteria remain:

- EPA has provided insufficient discussion regarding expectations of the timeframe for inclusion of this criterion in the triennial reviews of water quality standards. It is unclear whether states and tribes are expected to immediately adopt this complex criterion with no considerations to implementation or existing criteria.
- EPA is requested to provide information regarding acute effects. The draft criterion document states that these endpoints are of minor concern when compared to chronic exposure and maternal transfer, but the document does not expressly continue to endorse the current nationally recommended acute criterion. If an acute criterion is no longer needed, please directly state this in the final document.

The Federal Register notice states that EPA is developing information material to aid state and tribal adoption and that these materials will be released when the final criterion is published. Given the

complex nature of this criterion and the significant change to the approach, EPA should postpone adoption of the proposed criterion and coordinate with states and tribes regarding the expectations for inclusion of this criterion in triennial reviews. EPA is requested to develop guidance documents and propose them together with the final criterion document. Informational material should be provided for review prior to finalization of the criterion. Without this additional information, stakeholders cannot completely evaluate the proposal and will miss the opportunity to provide proper feedback on the proposal.

EPA-HQ-OW-2004-0019-0387-A1; Colorado Department of Public Health & Environment; Posted 10/14/2015

General Implementation

- While we appreciate EPA's consideration of the difficulties in collecting tissue data (especially egg/ovary), suggesting that all four elements should be adopted as the criterion seems complicated and potentially excessive, especially if data for one tissue type will override all other elements. Including all four elements suggests that, when all four types of data are available, they should all be collected (even though egg/ovary would be the only data 'used'). Is this what EPA intends? Perhaps there is a way to present the criterion in a different way so it recommends only collection of the highest 'tier' component possible (e.g., egg/ovary) and the lesser-tiered elements (e.g., whole-body/ muscle, water) can be disregarded.

Implementation in Discharge Permits

- Page xvi states "... states should establish additional procedures to facilitate translation of the fish tissue criterion concentration elements into water concentration permit limits". This suggests that the water column element of the criterion would not be used in the permit. Is this the intent? If so, why can't the water column element (i.e., 1.2 or 3.1 µg/L) be used to determine the permit limit?

- How will the four-part criterion be applied to short-term discharges (e.g., construction dewatering), since the water column element is based on long-term bioaccumulation?

How will the four-part criterion be implemented in storm water permits, which often have practice-based, rather than numeric-based, permits?

- The proposed multi-part criterion is based on 'tiered' values, where egg/ovary data have precedence over whole-body/muscle and water data, and whole-body/muscle has precedence over water. If a site exceeds the water column value but attains the egg/ovary value, does this mean the site is in attainment of the chronic selenium criterion?
  Many waters do not currently have tissue data available, but do have water column data. If a waterbody does not attain the proposed water column element, it is expected that tissues would be collected as soon as possible, if feasible. These kinds of situations may result in many new (and potentially only temporary, if tissues are in attainment) impairment listings for waterbodies that do not yet have tissue data.

Does EPA plan to include guidance for handling selenium in the 303(d) listing context to minimize inappropriate impairment listings? For instance, perhaps streams with water column exceedances should only be placed in 303(d) Category 3 (insufficient data to make a use support determination) until tissue data are collected.

- Does EPA still recommend a zero exceedance frequency for the fish tissue element of the criterion? Colorado's data indicate that there is wide variability among individual fish collected from the same waterbody at the same time. When a single fish may be used as the basis for impairment, it discourages collection of larger sample sizes, which may provide more insight into the actual distribution of concentrations. It is also possible that this approach will result in a finding of impairment when the vast majority of the fish population is well below the standard.

- The draft criterion document focuses on selenium sources related to anthropogenic activities and does not discuss how to handle the natural processes that can be sources of selenium. As mentioned above, Colorado has high amounts of selenium-laden shale in much of its geology. EPA should add a discussion of natural selenium sources in the draft criteria document and consider including additional alternatives or considerations for site-specific standards in these situations. Would EPA consider site-specific tissue-based standards in these cases? Or could site-specific water column-based standards over-ride the national tissue-based criterion elements?

EPA-HQ-OW-2004-0019-0370-A2; USGS Leetown Science Center; Posted 09/08/2015

We evaluated the sample sizes necessary to assess whole-body fish tissue Se concentrations to detect mean Se concentrations above candidate water quality standards (Hitt and Smith 2014). We used data from our collections (as published in Presser 2013) as well as data from the West Virginia Department of Environmental Protection. We found that natural variation in Se concentrations within samples (i.e., among individuals sampled from a given location) increases with increasing mean Se values, and this will affect the sample sizes needed to assess compliance with the proposed standard. The underlying mean-variance relationship was expected (for reasons provided in the paper) and was observed for several taxa: Green Sunfish (*Lepomis cyanellus*), Creek Chub (*Semotilus atromaculatus*), and Central Stoneroller (*Campostoma anomalum*) (see Figure 2 in Hitt and Smith 2014).

Our power analysis can inform sample designs based on the proposed whole-body criterion of 8.0 mg Se/kg (Figure 1). For example, given a type-I error rate of 0.10 (i.e., bottom-center panel in Figure 1), a sample of 2 fish would be unable to detect true-mean Se concentrations below 11.0 mg Se/kg with 80% power. In contrast, samples of 16 fish would be expected to detect true mean concentrations of 9.0 mg Se/kg (i.e., 1 mg Se/kg above the criterion) with 80% power. If higher type-I error rates are allowed (i.e., alpha = 0.20) then lower sample sizes may be necessary to achieve 80% power. However, even with relaxed alpha levels, samples of 4 or fewer fish would be unlikely to detect an increase of 2 mg Se/kg above the criterion with 80% power. Given the rapid transition from essentiality to toxicity for Se, sampling designs capable of detecting near-threshold concentrations may be warranted.

Original letter contains Figure 1 – Power analysis results for Se assessment in whole-body samples of stream fish (Figure 3 in Hitt and Smith 2014). See original letter.

EPA-HQ-OW-2004-0019-0419-A2; Lima Refining Company; Posted 11/03/2015

COMMENT #3. There is insufficient guidance for State implementation that may lead to application of the least certain criterion (water column).

The 2015 USEPA Se Draft AWQC does not provide sufficient guidance to the states on implementing the tiered criteria. The Peer Review Team (External Peer Review of the Draft Aquatic Life Ambient Water Quality Criterion for Selenium — Freshwater 2014) has noted that implementation is a major concern from the public and that more guidance is needed in order to implement this very complex water criteria guidance which ideally should include a continuous program to measure egg ovary, fish tissue and water column selenium levels. Each of these parameters would require individual programs. It does not appear that the 2015 USEPA Se Draft AWQC has addressed the public's concerns. The provisions of the 2015 USEPA Se Draft AWQC gives the states great latitude in how the guidelines are used; or not even used at all. States can use in increasing order of preference:

a) Water
b) Fish tissue (whole body or muscle) — overrides water when measured
c) Egg ovary — overrides whole body, muscle or water column when measured

This tiered approach presents increased levels of complexity that may discourage the states from using the best and more reliable criteria, which are for fish tissue and/or egg ovary. The water column criterion, which is the least certain criterion, may be used by the states simply because water column measurements are the most straight forward and is what typically has been part of state monitoring programs. In fact, the 2015 USEPA Se Draft AWQC in Section 2.7 Measures of Effect, Subsection 2.7.2 Water on Page 22 states the "While state monitoring programs may sample ambient waters for selenium, widespread measurements of selenium in fish tissue are relatively rare." The document as written offers no protection to the discharger.

EPA-HQ-OW-2004-0019-0415-A1; Idaho Department of Environmental Quality (DEQ); Posted 10/28/2015

The attention to implementation of this new criterion is still lacking and should be detailed furthered. While clearly representing the state of the science, an egg-ovary criterion is also clearly impracticable for routine criteria compliance monitoring and assessment. EPA has attempted to address this through translation to other criteria bases, e.g. whole body and muscle tissues, as well as translation to water. In the end this creates a 4- layered criterion hierarchy that is very complex.

Although this hierarchy allows traditional water testing, this hierarchy is also likely to create pressure for acquiring "acid test" egg-ovary data that is the most difficult and expensive to obtain. Furthermore, some fish species are highly mobile which leaves the door open to raise a number of biological and life history questions that call into question association of fish selenium concentrations to site water quality that are not simply answered or addressed in routine monitoring programs. This complexity is likely to further strain already reduced state monitoring budgets.

It is not clear how high natural selenium is to be handled, that is, selenium levels that would exceed the criterion in the absence of human cause. While there are general schemes in water quality standards that can address this they are under attack. It would be helpful for a modern criterion document to address the issue of naturally occurring selenium up-front with clear direction to the states. This is especially important in Idaho where we likely have water bodies with naturally elevated selenium levels.

What about methods of analysis? Currently there is no EPA approved method for analysis of selenium in fish tissue. While states/dischargers are clearly given analytical flexibility under the NPDES regulations where no EPA approved method exists, this situation does invite debate, and places an extra burden as well on states and dischargers. It should be EPA practice to promulgate an approved analytical method(s) in advance or at the same time it proposes a criterion that calls for new analytical methods. In general, EPA needs to do a better job describing how a fish tissue criterion is to be implemented in NPDES permits and TMDLs.

The document leaves it unclear how depth profiles or area-volume relationships fit into evaluation of the lentic water criterion. Is there to be area or volume weighted averaging? Or is it intended that one sample, no matter how little time or space it represents, be sufficient to show violation of the criterion? If the latter, this is does not seem to be reasonable or statistically justified.

While researchers often report selenium concentrations in eggs or ovaries (bottom page 26), such sampling is not trivial and is far from routine in environmental monitoring by environmental agencies or regulated entities. Although we end up with perhaps a better criterion from a science standpoint, we get a practical nightmare from an implementation and measuring compliance standpoint. We believe EPA needs to pay even more attention to the implementation and monitoring implications of this new criterion.

EPA-HQ-OW-2004-0019-0411-A2; American Petroleum Institute (API); Posted 10/28/2015

- EPA should prepare, accept public comment on, and release a comprehensive implementation guide to accompany the final selenium criteria. EPA will need to consider very carefully how to implement tissue-based selenium criteria in determining water quality impairments and in setting technically sound water-quality-based permit limits. API recommends the guidance afford flexibility, not prescription, in translating between tissue and water column selenium concentrations.

Although EPA clearly notes that fish tissue-based selenium criteria override water column-based criteria (with the exception of "fishless" waters and for new discharges), EPA needs to more explicitly define how the water column criteria could be considered "trigger" values for collection of fish tissue data.

We support EPA's conclusions that Se measurements from water and tissue samples collected at the same site within one year can, for the purpose of developing a database designed to capture a broad range of conditions, serve as "matched pairs" of measurements, provided the limitations and constraints of this assumption are fully understood for the specific site. In local evaluations implementing tissue-based criteria into NPDES permits and general 303(d) assessments, however, the timing of co-located water and tissue data collection must consider myriad important site-specific factors and non-steady-state conditions, including the migration of local fish populations, and seasonal and/or storm-related Se pulses. Allowance of appropriate sampling windows provides time for the analysis of effluent data and

potential follow-up tissue sampling. In addition, this large sampling window could be very important in ephemeral and intermittent aquatic systems where flowing surface water may only be present during certain times of the year, resulting in limited time periods to conduct fish sampling.

Criteria Implementation

EPA will need to consider very carefully how to implement tissue-based selenium criteria in determining water quality impairments and in setting technically sound water-quality-based permit limits. Permit limits must account for site-specific conditions. Quantitative links between effluent concentrations/loadings and fish tissue concentrations must account for bioavailability and chemical speciation, and not be speculative but supported by the preponderance of measured, site-specific data. We recommend EPA prepare and release for public comment a comprehensive selenium criteria implementation guide.

Fish and Water Se Criteria Hierarchy

Although EPA (2015) clearly notes that the fish tissue-based Se criteria override the water column-based Se criteria (with the exception of "fishless" waters and for new discharges), we recommend that the EPA more explicitly define how the water Se criteria could be considered "trigger" values that identify the need to collect data on Se concentrations in fish tissue. In our experience, this is an issue of on-going concern within both the regulatory and the regulated community.

EPA-HQ-OW-2004-0019-0417-A1; Utility Water Act Group (UWAG); Posted 11/02/2015

1. Implementation guidance is needed for the selenium criterion.

EPA has indicated that it will provide guidance on implementing the selenium criterion. UWAG agrees that guidance is necessary, indeed imperative, for the criterion to be used in any meaningful way. We recommend that the following be addressed in the implementation guidance in addition to the topics EPA has self-identified:

- Clarification of when fish should be collected that addresses the importance of the egg or ovary maturity level.
- Selection of fish species to base determination of impairment status of a waterbody.

EPA-HQ-OW-2004-0019-0401-A1; Colorado Wastewater Utility Council; Posted 10/15/2015

1.2 Timing of Tissue Data Collection

We support EPA's conclusions that selenium measurements from samples collected at the same site within one year can serve as matched pairs of measurements, and feel the timing of tissue data collection will be an important component of implementing tissue-based criteria into NPDES permits and general 303(d) assessments. Allowance of appropriate sampling windows provides time for analysis of effluent data and potential follow-up tissue sampling. In addition, this large sampling window could be very important in ephemeral and intermittent aquatic systems where water may only be present during certain times of the year, resulting in limited time periods to conduct fish sampling.

EPA-HQ-OW-2004-0019-0400-A1; The National Mining Association (NMA); Posted 10/15/2015

1.2 Timing of Tissue Data Collection

We support EPA's conclusions that selenium measurements from samples collected at the same site within 1 year can serve as matched pairs of measurements, and feel the timing of tissue data collection will be an important component of implementing tissue-based criteria into NPDES permits and general 303(d) assessments. Allowance of appropriate sampling windows provides time for analysis of effluent data and potential follow-up tissue sampling. In addition, this large sampling window could be very important in ephemeral and intermittent aquatic systems where water may only be present during certain times of the year, resulting in limited time periods to conduct fish sampling.

Another issue that requires reevaluation and clarification is how to establish criteria for streams with no existing fish populations. The default approach is to use water-column criteria; however, an alternative states could be provided is the use of the chronic invertebrate data provided by EPA to develop invertebrate tissue-based site-specific criterion and associated protective water-column criteria.

Another topic that needs further consideration is the use of natural background Se concentrations to develop ambient based site-specific criteria. We have provided discussion of how this has been successfully done in Colorado in our previous review (GEI 2014a), and how it should be considered on a case-by-case basis nationwide. EPA's discussion of site-specific standard development is lacking and needs further clarification.

EPA-HQ-OW-2004-0019-0394-A2; Appalachian Mountain Advocates and Sierra Club Environmental Law Program; Posted 10/14/2015

EPA has not explained how it and authorized state agencies would incorporate the proposed fish-tissue elements into enforceable measures needed for NPDES permit limits, TMDLs, and other pollution control decisions required by the Clean Water Act. Indeed, EPA explicitly recognizes that, if states choose to use the tissue criterion elements for NPDES permitting purposes, "additional state WQS implementation procedures (IPs) will be needed to determine the need for and development of WQBELs necessary to ensure attainment of the fish tissue criterion element(s)." Draft Criterion at 92. EPA entirely fails, however, to provide any meaningful guidance on what those procedures should entail. EPA's proposal thus leaves unanswered fundamental questions about how the fish-tissue elements are to be used when issuing NPDES permits. For instance, how are regulators to determine the "reasonable potential" for a proposed new discharge to cause or contribute to violations of the fish tissue elements? How will appropriate "end of pipe" effluent limits be determined? If there is a "reasonable potential," when must treatment start? Without clear guidance from EPA, we fear that states will adopt and EPA will be forced to approve standards that cannot practically be used to set necessary water quality-based permit limits.[2] Our experience has shown that underfunded and/or industry-friendly state regulators will only impose enforceable permit limits when they are forced to do so by clear standards and incontrovertible evidence of reasonable potential. A recommended criterion that does not explicitly establish when permit limits must be imposed but instead injects considerable uncertainty into the

reasonable potential analysis invites regulators to acquiesce to industry pressure to impose no limits or limits that are effectively meaningless.

Likewise, EPA's proposal lacks necessary information regarding how compliance with the fish-tissue elements should be determined for the purpose of enforcing NPDES permit limits, evaluating waters for impairment, and developing and enforcing TMDLs. For instance, if a permittee receives a fish tissue-based NPDES permit limit, where must sampling of fish occur in relation to the discharge? How many fish must be collected to provide a representative sample?[3] How often and at what stages of life must sampling take place? What fish taxa will be used to determine compliance? How will regulators account for variation and individual differences and toxicity within taxa depending on, among other things, age, individual diet, areas of forage, and duration of stay in polluted waters?[4] If adequate numbers of fish are indeed collected, what impact will this have on fish populations that may already be pressured by selenium and other pollution? How will regulators ensure that endangered species are protected by sampling protocols such that illegal "take" is avoided? How will impairment be detected in waters where sensitive species that rapidly accumulate selenium have already been extirpated?[5]

EPA has not shown that compliance with the fish tissue elements can accurately be determined in most circumstances. This is particularly problematic in small headwater streams that directly receive much of the selenium pollution from coal mines in Appalachia. These streams often lack sufficient fish populations for a truly representative sample to be collected, and downstream reaches with larger fish populations often receive discharges from many different sources such that responsibility for violations of the standard will be extremely difficult to assign. See Hitt and Smith (2014). Moreover, if a "species-composite" method is used to determine compliance with a fish-tissue element, wherein the tissue of all fish collected is combined for analysis, it is likely to miss impairment of sensitive species that accumulate selenium more rapidly. USFWS, July 28, 2014 Comments. In sum, regulators who are under heavy pressure from industry and whose resources are already stretched far too thin are unlikely to develop and implement the complex, expensive fish sampling and testing protocols necessary to obtain representative samples to determine a waterbody's compliance with the fish-tissue elements, to the extent that such protocols are even possible to develop.

Instead of relying on fish tissue standards that present critical implementation problems, EPA should adopt clearly enforceable water column criteria. EPA's Draft Criterion document recognizes that the dietary pathway of selenium accumulation can still be accounted for in water column criteria. Using the methods developed by the EPA and the United States Geological Survey, protective fish tissue concentrations can be translated to practically enforceable water column criteria. Draft Criterion at 28. The model developed by USGS and modified by EPA recognizes that diet is the primary pathway of exposure for selenium and creates a simple, direct linkage between dissolved selenium in the water column and selenium toxicity to aquatic life. As EPA explains, its approach "explicitly recognizes the sequential transfer of selenium between environmental compartments (water, particulate material, invertebrate tissue, fish tissue, and eggs and/or ovary tissue) by incorporating quantitative expressions of selenium transfer from one compartment to the other." Draft Criterion at 63. Indeed, EPA's analysis found that that the expected and measured relationships between egg-ovary concentrations and water column concentrations are "highly correlated."[6] Draft Criterion at 125. An inviolable water column criterion that is based on fish tissue concentrations is therefore scientifically defensible because it recognizes and accounts for the fact that diet is the primary pathway for selenium uptake.

The Draft Criterion's inclusion of water column based elements in no way corrects this fundamental flaw. EPA has explicitly stated that the fish tissue elements should be given primacy over the water column elements. Draft Criterion at xiv. That statement essentially eliminates any practical benefits from including water column elements. This is true despite EPA's qualification of the primacy of fish tissue elements in "fishless waters." See Draft Criterion at xiv. Although the inclusion of that qualification improves the Draft Criterion, it does not go nearly far enough. For example, "fishless waters" should not be limited to "waters where fish have been extirpated or where physical habitat and/or flow regime cannot sustain fish populations." As explained above, accurately determining compliance with fish tissue elements requires significant sample sizes, regular collection of which is likely to have a severe impact on fish populations, particularly in smaller headwater streams. See supra footnote 3. In order to be practically protective, the water column elements would need to be given primacy in all waters that lack adequate numbers of fish to regularly collect large tissue samples without adversely affecting resident populations, not just in waters that completely lack fish. Moreover, in order to combat the survivor bias inherent in tissue sampling and be truly protective of aquatic life, see supra footnote 5, the water column elements would need to be given primacy in all waters where sensitive species could be supported but have been extirpated. See Hitt and Chambers, Temporal changes in taxonomic and functional diversity of fish assemblages downstream from mountaintop mining, Freshwater Science 33:915-926 (2014) (finding that sensitive species have been largely extirpated from sites downstream of mountaintop removal mining operations as a result of changes to water quality, including increased selenium pollution).

Likewise, giving water column elements primacy in waters with new or increased selenium inputs prior to reaching ecological equilibrium will not adequately protect aquatic life. As EPA acknowledges, the time needed for waters with new or increased inputs to reach such an equilibrium varies greatly from site to site depending on "the hydrodynamics of a given system; the location of the selenium input related to the shape and internal circulation of the waterbody, particularly in reservoirs with multiple riverine inputs; and the particular food web." Draft Criterion at 93. State agencies that are subject to extreme resource limitations and industry pressures are unlikely to ensure that the elements are properly implemented. Indeed, the complexity and uncertainty involved in determining when water column elements should take primacy over fish tissue elements demonstrates the impracticality of EPA's multi-element Draft Criterion. The better approach that would be both scientifically defensible and practically implementable would be to adopt a criterion consisting only of translated water column elements.

Not only is a translated water column criterion scientifically defensible, it is vastly more useful as a regulatory tool that places minimal burden on states to implement without significant delay or expense. Most states have specific, federally-approved procedures for how to convert water column criteria to enforceable restrictions on wastewater discharges, in addition to the technical guidance, training and other materials on scientifically valid models, necessary background data, sampling protocols, and acceptable laboratory techniques for the implementation of traditional water column criteria that EPA has provided. See Draft Criterion at 92 (explaining that existing state procedures will be adequate for implementing the water column elements of the criteria, but that new procedures will be needed to implement the tissue-based elements). Water column criteria also can be more easily enforced by citizens with limited resources when state regulators fail to uphold their duties. Enforcing the proposed fish-tissue elements, in contrast, will require a case-by-case analysis of the local ecosystem, including

collection, processing, and testing of fish tissue, all of which will require significant resources and inject considerable uncertainty. Thus, in order to achieve the dual purposes of water quality criteria, EPA should adopt as its Recommended Criteria a set of water column criteria that are translated from protective fish-tissue concentrations.

EPA-HQ-OW-2004-0019-0373; Anonymous public comment; Posted 09/23/2015

Certain issues considered in EPA's mercury implementation guidance seem highly relevant to establishing a selenium tissue criterion duration and frequency. Because the draft Se tissue duration and frequency recommendations are incompatible with EPA's mercury implementation guidance, please explain why you are not using the concepts from that guidance:

Guidance for Implementing the January 2001 Methylmercury Water Quality Criterion, Final, EPA-823-R-10-001.

The relevant portion of the mercury implementation guidance is shown below:

4.3 How should waterbody impairment be assessed for listing decisions?

Section 303(d)(1) of the CWA and EPA's implementing regulations require states and authorized tribes to identify and establish priority ranking for waters that do not, or are not expected to, achieve or maintain water quality standards. In accordance with this ranking, a TMDL for such waters must then be established. For purposes of determining impairment of a waterbody and whether to include it on section 303(d) lists, or in category 5 of the Integrated Report under sections 303(d) and 305(b)15, states and authorized tribes must consider all existing and readily available data and information (see 40 CFR 130.7).

States and authorized tribes determine attainment of water quality standards by comparing ambient concentrations to the numeric and narrative AWQC (40 CFR 130.7 (b)(3)). Where a fish tissue criterion has been adopted, states and tribes should consider observed concentrations in fish tissue in comparison to the criterion. Where a water column translation of the fish tissue criterion has been developed and is adopted as part of the state's or tribe's water quality standards, states and tribes should consider ambient water concentrations in comparison to the translation.

For assessment of concentrations in fish tissue, resources may typically be unavailable to collect an adequate number of replicate composite samples to support rigorous statistical testing, especially where it is desirable to evaluate each individual target species separately. In these situations, states should make direct comparisons between composite sample concentrations and the criterion, as each composite effectively represents the average concentration observed in several fish.

Statistical tests for comparing the average concentration from multiple replicate composite samples to the criterion may be conducted where a sufficient number of replicates have been collected. EPA's Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories, volume 1 (USEPA 2000c), at section 6.1.2.7.2, recommends using the t-test to determine whether the mean concentration of mercury in composite fish tissue samples exceeds the screening value. This test involves a statistical comparison of the mean of all fish tissue data to the criterion. States and authorized tribes can evaluate whether the t-test statistic of the mean exceeds the water quality standards. This procedure could also

be used to determine impairment, provided it is consistent with a state's water quality standards. States and authorized tribes might also want to consider the guidance in appendixes C and D of the Consolidated Assessment and Listing Methodology: Toward a Compendium of Best Practices (USEPA 2002e). Ultimately, the method that states and authorized tribes choose depends on how they express their water quality standards and apply their water quality assessment methodology.

Comment Category 2.8 – Comments Concerning the Protection of Threatened or Endangered Species

2.8 Summary

Some commenters were concerned that the criterion would not protect some ESA-listed species and urged coordination with U.S. Fish and Wildlife Services and other relevant agencies.

2.8 Response to comments

2.8 Responses concerning threatened and endangered species

Regarding consideration of endangered species, EPA has provided a summary of available data on the adverse effects of selenium to endangered species, and taxonomically related surrogates. EPA identified data for white sturgeon (a species with one population listed as endangered, and a closely related taxonomic surrogate for other endangered sturgeon), several species in the family Salmonidae, Cyprinidae as well as a pupfish in the Cyprinodontidae, and several less closely related species with tests in the order Perciformes (sunfish and bass) as surrogates for endangered darters.

Regarding endangered species, EPA recognizes the concern regarding protection of listed species. EPA has considered and described available data on impacts of selenium on endangered species in the criterion document as well as impacts on species that are close phylogenetic surrogates of listed species dataset. EPA notes that site-specific criteria can be developed if sensitive endangered species not represented by surrogates in the dataset used in the criterion are present at a specific site.

EPA had significant data quality concerns with the Hamilton et.al. 1990 data, most significantly that the 90-day control survival (67%) was below toxicity test acceptability thresholds, such that we could not use those effects data. We did consider and use the 60-day time point for this study, and concluded that the egg-ovary transformed whole body criteria of 8 mg/kg dw would protect against growth effects in juvenile salmonids. Compromising data analysis to include very high control mortality data despite the availability of other more acceptable data within the same test does not meet EPA's data quality expectations. Further, use of poor quality data is not an improvement to or modernization of methods for criteria development.

Published data indicates that endangered fish species have not been found to be more sensitive to toxicants than common species (Sappington et al 2001, and other). EPA acknowledges that there may be locations where a lower criterion could be applicable on a site specific basis due to the site-specific presence of a particularly sensitive species.

EPA disagrees that before making general recommendations to states regarding future state actions to adopt selenium criteria, it is helpful or legally necessary to first engage in consultation under the ESA to ensure that any possible subsequent federal action to approve new or revised state selenium criteria consistent with the national recommendations would necessarily be protective of listed species. The issuance of national criterion recommendations for selenium does not impose any legally binding requirements on states. Nor does it authorize any state or federal action that would otherwise be

inconsistent with the ESA, simply on the grounds that such action is consistent with EPA's national recommendations under the Clean Water Act. Since the distribution of listed species which might affect the appropriate water quality criteria is location-specific, and the national recommendations for selenium are intended to be generally informative, allowing the most sensitive location-specific potential concerns to drive national recommendations would tend to inappropriately distort those recommendations. This approach would tend to produce national criteria recommendations for selenium that states would need to modify to make less stringent before incorporating into their own standards, based on the absence of species-specific concerns. And national consultation on general recommendations for selenium criteria would still be unlikely to obviate the need for step-down consultations on subsequent federal actions to approve particular new or revised state water quality criteria for selenium. Therefore, EPA believes that it is more efficient for states to modify national criteria recommendations for selenium to make them more stringent, as needed based on the presence of localized species-specific concerns. EPA intends to engage in ESA consultation about a proposed approval of a state water quality standard under Clean Water Act Section 303(c) to the extent that it determines that such approval may affect listed species and to the extent that it has relevant discretion to consider those effects.

2.8 Specific comments

EPA-HQ-OW-2004-0019-0396-A1; National Marine Fisheries Service Office of Protected Resources Interagency Cooperation Division; Posted 10/15/15

The National Marine Fisheries Service (NMFS), Office of Protected Resources appreciates the opportunity to provide input on the Environmental Protection Agency's (EPA) external peer review Draft Aquatic Life Criteria Document for Selenium. We understand that EPA has been developing this criterion for several years and we appreciate the hard work that has gone into this effort. Our comments focus on implications of the selenium guideline for NMFS ESA-listed species and age classes foraging in freshwater. With the exception of shortnose sturgeon, adult NMFS ESA-listed species feed little or not at all in freshwater. However, there are some reports of freshwater feeding by adults of other sturgeon species, particularly in females after spawning. The guideline also has implications for NMFS ESA-listed juvenile salmonids and sturgeon rearing in freshwater.

Conclusion: We conclude that the guideline document needs to convey an understanding that, due to the vulnerability of ESA-listed species populations, an ESA-listed species need not be toxicologically more sensitive to a stressor, selenium in this instance, to require site-specific protective criteria. We encourage EPA to work with us to determine the impact of an EC10 larval deformity response threshold to the continued existence of populations of ESA-listed species such as shortnose sturgeon and determine if location specific criteria are necessary for rivers where susceptible populations occur. The guideline document should clearly indicate that the presence of ESA-listed species can trigger development of site specific criteria and reevaluation of existing data. In such cases, derivation of site specific criteria for waters containing shortnose sturgeon would need to incorporate relevant exposure parameters. In addition, the evaluation and analysis of dietary data in the guideline document should be updated. For example Hamilton et al. 1990 data set should be reevaluated in an effort to extract additional information from the 90 day exposure data.

EPA-HQ-OW-2004-0019-0415-A1; Idaho Department of Environmental Quality (DEQ); Posted 10/28/2015

We also believe it is EPA's responsibility to conduct Endangered Species Act consultation with the services nationally on its national criteria recommendations, and not shift this burden to state adoption of nationally recommended criteria.

EPA-HQ-OW-2004-0019-0394-A2; Appalachian Mountain Advocates and Sierra Club Environmental Law Program; Posted 10/14/2015

VI. The Criterion Must Protect All Threatened or Endangered Species

Water quality standards must protect all existing uses in a waterbody, which uses often include supporting species that are listed as threatened or endangered pursuant to the Endangered Species Act. See 33 U.S.C. § 1313. Additionally, Section 7 of the Endangered Species Act and its implementing regulations require each federal agency, in consultation with the appropriate wildlife agency, to insure that any action authorized, funded, or carried out by the agency is not likely to (1) jeopardize the continued existence of any threatened or endangered species or (2) result in the destruction or adverse modification of the critical habitat of such species. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14(a). EPA thus must ensure that any criteria that it recommends states to adopt will be fully protective of listed species.

EPA's Draft Criterion document concludes that it will protect threatened and endangered species based off analysis of only two listed species and two additional species that are closely related to listed species. USFWS records show that there are currently 163 fish species in the US that are listed as threatened or endangered pursuant to the Endangered Species Act. See USFWS, Environmental Conservation Online System, Summary of Listed Species.[10] EPA cannot safely assume that the two listed species and two closely related species are good proxies for every single endangered species in the country that could be exposed to selenium pollution. Indeed, EPA recognizes that "because other threatened or endangered species might be more sensitive, if relevant new information becomes available in the future, it should be considered in state- or site-specific criteria calculations." Draft Criterion at 127. Instead of putting off protection of sensitive endangered species to later state or site-specific standard setting, EPA must revise its criterion to ensure protection of all endangered species. It is not sufficient to say that the agency lacks information. Rather, in the absence of additional data regarding selenium-sensitive listed species, EPA must apply a substantial safety factor to its criterion to ensure protection of such species.

EPA-HQ-OW-2004-0019-0409-A2; OC Public Works; Posted 10/20/2015

For comment 9 USEPA should coordinate the United States Fish and Wildlife Service to reach consensus on the approach to the protection of aquatic-dependent wildlife.

Comment Category 3.1 – Comments on Use and Calculation of EC_{10}

3.1 Summary

This section focuses on the use and calculation of EC_{10}. Comments in section include those on EPA's use of the TRAP software, and the selection of EC_{10} as the most appropriate endpoint.

Commenters suggested:

- Use of EC_{10} is not well justified by EPA and should be better explained
- Commenters agree that EC_{10} is appropriate, as compared to EC_{20}, but EPA's methodology using TRAP, which is consistent yet yields values for EC_{10}s that are different than those estimated by study authors; these commenters suggested using the EC_{20} values as an estimate for the EC_{10}s
- Use of EC_{10} is not protective of listed species

One commenters agreed with EPA's use of EC_{10}.

3.1 Response to comments

3.1 Response to concerns with the use and calculation of EC_{10}

When considering the use of the EC_{10} versus the EC_{20}, an EC_{10} was determined to be a more appropriate endpoint for tissue-based criteria given the nature of exposure and effects for this bioaccumulative chemical. EC_{20}s have historically been used in the derivation of EPA criteria applicable to the water medium. While water concentrations may vary rapidly over time, tissue concentrations of bioaccumulative chemicals are expected to vary gradually. Thus, where concentrations of selenium in fish tissue are used as an effect threshold, there is potential for sustained impacts on aquatic systems, relative to chemicals that are not as bioaccumulative. This calls for use of a lower level of effect to attain sufficient protection.

Also, detection in fish tissue above these levels can potentially have longer-term impacts due to the bioaccumulative nature of selenium. This is further demonstrated by field observations that reproductive effects in fish can take on the order of a decade for a selenium contaminated ecosystem to recover from (e.g., Belews Lake, NC). Further, and most importantly, the steepness of the dose-response curve for selenium argues for a more protective value, not less, because small increases in concentrations of selenium can have larger impacts than for toxicants with shallower dose-response curves.

The EC_{10} was also preferred for selenium over the NOEC or LOEC as these measures of effect are influenced by study design, specifically the concentrations tested, the number of concentrations tested, the number of replicates for each concentration, and the number of organisms in each replicate. As noted by Campbell (2011), EC_{10}s and NOECs are generally of similar magnitude, but EC_{10}s have the advantage of being more reproducible than NOECs (Van der Hoeven et al. 1997; Warne and van Dam 2008).

Regarding the comment that it is possible that the EC_{10} might not be sufficiently protective of a particular endangered aquatic species, the commenter did not recommend any specific studies, regarding any particular endangered species that provides additional evidence for EPA to consider, to be addressed more thoroughly. Further, published data indicates that endangered fish species have not

been found to be more sensitive to toxicants than common non-endangered species (Sappington et al 2001). EPA acknowledges that there may be locations where a lower criterion could be applicable on a site specific basis due to the site-specific presence of a particularly sensitive species (including those that are endangered). However, as discussed in section 2.8 above, EPA disagrees that before making general recommendations to states regarding future state actions to adopt selenium criteria, it is helpful or legally necessary to first engage in consultation under the ESA to ensure that any possible subsequent federal action to approve new or revised state selenium criteria consistent with the national recommendations would necessarily be protective of listed species.

Regarding the comment that **"**the degree of variability in measured concentrations would seem to provide rationale in the choice of statistic to best characterize exposure… rather than in the choice of an ecologically meaningful effects level," the goal of aquatic life criteria is, roughly speaking, to protect aquatic life from ecologically meaningful and adverse effects. Thus, EPA selected such a level for the criteria basis, and does not find the rationale that the criteria should be based on statistical utility compelling.

Following issuance of the 2015 draft, EPA has reviewed the statistical fits of the using the computer program TRAP (version 1.30a), Toxicity Relationship Analysis Program (U.S. EPA 2013) for all fish species that have a numeric impact on the criterion, as suggested by a number of commenters. A full discussion of the refined statistical approach is provided in the 2016 criterion document, with details provided for each species analyzed.

3.1 Specific comments

EPA-HQ-OW-2004-0019-0403-A2; Iowa Department of Natural Resources; Posted 10/15/15

(6) The use of EC10 as the chronic toxicity end point to derive the criteria is inconsistent with the EPA's current procedure, which recommends the use of EC20. The use of the end point EC10 as the end point is not well-justified.

EPA-HQ-OW-2004-0019-0385-A2; Kentucky Division of Water (KDOW); Posted 10/13/2015

Appropriate Endpoint and Criterion Calculations

KDOW agrees with the EPA's selection of the EC_{10} (Effective Concentration) in preference of the EC_{20} (the observed or measured effect concentration at 10 or 20 percent, respectively) to measure a chronic end-point *(e.g.,* growth, development effects or reproduction). Previous national toxicity criteria were derived using the EC_{20}. This approach mirrors that taken by KDOW when developing its chronic criterion for selenium. Calculations were also made from appropriate studies for the NOEC (No Observed Effect Concentration) and LOEC (Lowest Observed Effect Concentration) with preference given to the EC_{10}.

EPA-HQ-OW-2004-0019-0415-A1; Idaho Department of Environmental Quality (DEQ); Posted 10/28/2015

The rationale provided on page 20-21 for favoring an EC_{10} over an EC_{20} for assessing selenium toxicity, i.e. stability of tissue concentrations of selenium relative to aqueous concentrations leads to greater potential for sustained impacts, should be more fully developed. This appears to us to be more of a policy decision by EPA, than something that is needed to deal with lower environmental variability. In our view the degree of variability in measured concentrations would seem to provide rationale in the choice of statistic to best characterize exposure, e.g. choice of a mean or median of observed environmental concentrations versus an upper percentile, rather than in the choice of an ecologically meaningful effects level. Variability in exposure among individuals in a population versus variability in exposure over time in relation to expected population level effects deserves greater discussion.

EPA-HQ-OW-2004-0019-0411-A2; American Petroleum Institute (API); Posted 10/28/2015

1.1.1 Use of EC10s

We support the use of EC_{10} values to develop the tissue-based Se criteria, as data allow. Use of EC_{10}s is more conservative and is consistent with other recent approaches (e.g., DeForest and Adams 2011). However, we note that for some studies it may not be possible to calculate technically defensible EC10 values and note that EC_{20} (20% effect concentrations) can realistically be used where EC_{10}, values cannot be calculated (Chapman 2015). In general, we support the data decisions used by EPA for those studies where EC_{10} values could not be calculated, with the exception of the suggested modifications for specific studies and their data noted below.

2.1 Review of Toxicity Studies Used for Criteria Development

The 2015 draft Se criteria document includes reproductive toxicity study data for nine fish genera (see Table 3.1, page 40). As noted previously, we concur with most of the EPA's decisions regarding which data to use. However, we would like to provide comments and suggestions on the data used to develop the chronic egg/ovary criterion (and subsequently, the whole-body and muscle criteria). We believe that incorporation of these suggested changes would result in a more scientifically-defensible egg/ovary criterion, which would have greater consistency with EPA's other data-usage decisions used elsewhere in the document.

2.1.1 General

We examined each of the data points deemed to be acceptable by EPA for use in the calculation of the egg/ovary criterion (see Table 3.1, page 40); the intention was to determine if we saw any potential issues with EPA's use of the data.

We have some concerns with the EPA's exclusive use of the Toxicity Relationship Analysis Program (TRAP) for all data analyses conducted, although we understand the value of standardizing the calculation of chronic values from each study by using one statistical approach. However, many of the values calculated by TRAP differ considerably from those calculated by the study authors. We would again recommend that EPA consider comparing effects calculations using other standard toxicological statistical programs to better understand the variability among programs used by researchers in this field, and any implications of their choice to use TRAP for the resulting criteria.

EPA-HQ-OW-2004-0019-0401-A1; Colorado Wastewater Utility Council; Posted 10/15/2015

1.3 Use of EC10s

We agree with the use of EC_{10} values to develop the tissue-based Se criteria, as data allow. Use of EC_{10}s is more conservative and consistent with other recent approaches (e.g., DeForest and Adams 2011). In addition, for many of the studies, other endpoints (e.g., EC_{20}) may not be able to be determined based on the response curves observed in the data.

We also understand that not all available studies provide sufficient data to reliably calculate EC_{10} values. In general, we support the data decisions used by EPA for those studies, with the exception of the suggested modifications for specific studies and their data noted later in our review (Section 3.1).

1.4 Review of Toxicity Studies Used for Criteria Development

The 2015 draft Se criteria document includes reproductive toxicity study data for nine fish genera (Table 3.1, page 40). As noted previously, overall, we concur with most of the data usage decisions made by EPA. However, we would like to reiterate some of our comments and suggestions on the data that were used to develop the egg/ovary chronic criterion (and subsequently, the whole-body and muscle criteria), as well as provide new comments and suggestions. We believe incorporation of these suggested changes would result in an egg/ovary chronic criterion that is even more scientifically defensible and have greater consistency with EPA's other data-usage decisions used elsewhere in their document.

1.4.1 General

As with the 2014 review, we examined each of the data points deemed acceptable by EPA for use in the egg/ovary criterion calculation (Table 3.1, page 40) to determine if we saw any potential issues with EPA's use of the data.

We continue to have some concerns with the use of TRAP for all data analysis (described in Section 4.2), although we do understand the value in standardizing the calculation of chronic values from each study by using one statistical approach. However, many of the values calculated by TRAP differ considerably from those calculated by the study authors. We would recommend EPA consider comparing effects calculations using other standard toxicological statistical programs to better understand the variability among programs and any implications of their choice to use TRAP for the resulting criteria.

1.5 Use of TRAP versus Other Statistical Methods

As mentioned previously, we continue to have some concern with the exclusive use of TRAP for determination of all EC_{10} values used in criteria development. TRAP may work well with certain data sets, but may pose problems for analysis of others. We provided additional discussion of the potential issues in our previous review (GEI 2014a).

In many of the studies provided in the 2015 draft Se criteria document, the EC_{10} values calculated by EPA differed from the original values determined by the study authors and those calculated by DeForest and Adams (2011). EPA should provide a list of all parameters and "Initial Guesses" on slopes used for analyses.

EPA-HQ-OW-2004-0019-0400-A1; The National Mining Association (NMA); Posted 10/15/2015

1.3 Use of EC10s

We agree with the use of EC_{10} values to develop the tissue-based Se criteria, as data allow. Use of EC_{10}s is more conservative and consistent with other recent approaches (e.g., DeForest and Adams 2011). In addition, for many of the studies, other endpoints (e.g., EC_{20}) may not be able to be determined based on the response curves observed in the data.

We also understand that not all available studies provide sufficient data to reliably calculate EC_{10} values. In general, we support the data decisions used by EPA for those studies, with the exception of the suggested modifications for specific studies and their data noted later in our review (Section 3.1).

1.4 Review of Toxicity Studies Used for Criteria Development

The 2015 draft Se criteria document includes reproductive toxicity study data for nine fish genera (Table 3.1, page 40). As noted previously, overall, we concur with most of the data usage decisions made by EPA. However, we would like to reiterate some of our comments and suggestions on the data that were used to develop the egg/ovary chronic criterion (and subsequently, the whole-body and muscle criteria), as well as provide new comments and suggestions. We believe incorporation of these suggested changes would result in an egg/ovary chronic criterion that is even more scientifically defensible and have greater consistency with EPA's other data-usage decisions used elsewhere in their document.

1.4.1 General

As with the 2014 review, we examined each of the data points deemed acceptable by EPA for use in the egg/ovary criterion calculation (Table 3.1, page 40) to determine if we saw any potential issues with EPA's use of the data.

We continue to have some concerns with the use of TRAP for all data analysis (described in Section 4.2), although we do understand the value in standardizing the calculation of chronic values from each study by using one statistical approach. However, many of the values calculated by TRAP differ considerably from those calculated by the study authors. We would recommend EPA consider comparing effects calculations using other standard toxicological statistical programs to better understand the variability among programs and any implications of their choice to use TRAP for the resulting criteria.

We have some concern with the EC_{10} calculations used in the document such as the use of TRAP for all statistical analyses and we recommend EPA consider other options as well. We have also provided additional information regarding calculation of egg/ovary to whole-body conversion factors (CFs), which we used to revise the GMCVs and SMCVs discussed previously.

Overall, this document is a substantial improvement over pre-2014 Se criteria documents, and we look forward to the final draft document, with the hope our recommendations are taken into consideration.

1.5 Use of TRAP versus Other Statistical Methods

As mentioned previously, we continue to have some concern with the exclusive use of TRAP for determination of all EC_{10} values used in criteria development. TRAP may work well with certain data sets, but may pose problems for analysis of others. We provided additional discussion of the potential issues in our previous review (GEI 2014a).

In many of the studies provided in the 2015 draft Se criteria document, the EC_{10} values calculated by EPA differed from the original values determined by the study authors and those calculated by DeForest and Adams (2011). EPA should provide a list of all parameters and "Initial Guesses" on slopes used for analyses.

EPA-HQ-OW-2004-0019-0394-A2; Appalachian Mountain Advocates and Sierra Club Environmental Law Program; Posted 10/14/2015

Moreover, as USFWS has noted to EPA, use of the EC10 effect level that EPA has employed here, see Draft Criterion at 21–22, is inappropriate for water quality criteria that apply to listed species. When dealing with listed species, every individual is important. An EC10 effects level assumes that one out of every ten individuals will suffer adverse effects. That is unacceptable for listed species. As the Us Fish and Wildlife Service explained in their comments on the 2014 Draft Criterion,

> it is still unclear how an EC-10 standard for fish-tissue criteria relates to threatened and endangered species conservation. A large majority (>90%) of all species of freshwater fish listed under the Endangered Species Act (ESA) have not been tested for sensitivity to selenium toxicity. Assuming that ESA-listed species exhibit a distribution of sensitivities comparable to non-listed species (as several EPA-funded studies have indicated), it can be expected that in waters achieving EPA's newly proposed fish-tissue criteria about 5% of ESA-listed species would experience a 10% or greater level of reproductive toxicity. Also, it can be expected that some unknown additional percentage of ESA-listed species would experience a level of reproductive toxicity greater than 0% but less than 10%. It's possible that a toxic standard more protective than an EC-10, such as EPA's (2012) benchmark dose approach, might be required for waters that host untested ESA-listed species of fish.

July 28, 2014 Comments at 1. In order to ensure that endangered species are protected, EPA must initiate and complete consultation with the USFWS pursuant to Section 7 of the ESA prior to finalizing any recommended aquatic life criteria for selenium.

Comment Category 3.2 – Comments on Studies of Fish Reproductive Effects Used in Numeric Criterion Derivation

3.2 Summary

This section includes comments concerning studies of the reproductive effects of selenium on fish. The majority of the comments focus on specific studies of three of the four most egg ovary sensitive genera (i.e., white sturgeon, bluegill, and brown trout). In general, commenters questioned the validity and applicability of specific studies. Additionally, one commenter questions the overall methodology used by EPA and suggests that EPA change to consider the unique dietary toxicant nature of selenium, in particular with respect to threatened and endangered species.

3.2 Response to comments

3.2 Responses concerning studies on fish reproduction effects

EPA had significant concerns with the 90-day endpoint in Hamilton et.al. 1990, most significantly that the 90-day control survival (67%) was below toxicity test acceptability thresholds, such that we could not use those effects data. We did consider and use the 60-day time point for this study, and concluded that the egg-ovary transformed whole body criteria of 8 mg/kg dw would protect against growth effects in juvenile salmonids.

Updated descriptions of the key toxicity tests and the statistical analyses used to calculate the EC_{10} are provided in toxicity Section 3 of the 2016 Criterion document, and are summarized below for reference.

Whenever possible, estimates of selenium concentrations associated with a low level of effect (i.e., EC_{10}) were calculated for each study using the computer program TRAP (version 1.30a), Toxicity Relationship Analysis Program (U.S. EPA 2013). The program is based on a regression approach that models the level of adverse effects as a function of increasing concentrations of the toxic substance. With the fitted model it is possible to estimate the contaminant concentration associated with a small effect. TRAP is used when there are sufficient data for EC_{10} estimation. For studies with binary data, the analysis proceeds by tolerance distribution analyses using the log-triangular distribution, unless there is substantial extrabinomial variability, in which case regression analysis was used. For regression analysis, the threshold sigmoidal model is used, exposure variables are log-transformed, and effects variables are weighted appropriately to address their relative uncertainties.

When there are insufficient data for TRAP to fit an effects/exposure curve (no treatments with clear effects near the EC_{10} and/or significant background variability), the EC_{10} is based on interpolation. To ensure that the interpolations were comparable to the TRAP analyses, threshold sigmoidal equation was used. This equation is fitted to two points, and constrained so that 3 equation parameters can be set. The first set-point is treated as the EC_0 with a second associated set-point being the threshold for background effects values, based on the highest NOEC (HNOEC) datum and other NOEC data. The final set-point is the LOEC. If the LOEC is a partial effect, then this point was used to estimate the equation slope. If the LOEC is a 100% effect, it is specified as the EC_{100}; with the EC_0 specified, then this relationship dictates the equation slope. It should be noted that despite the superficial resemblance of

these analyses to TRAP they are also subject to the uncertainties associated with the interpolation method.

It should be noted that TRAP involves the assumption that (a) there is a single underlying relationship of the effects variable to the exposure variable which follows the specified equation and (b) the exposure variable is known with negligible error, with uncertainty being predominantly in the effects variable. Some of the reproductive data involved multiple sources of variability that lead to both multiple relationships across different cohorts of offspring and uncertainty in the exposure variable, so that the resulting TRAP curves were more approximate, and TRAP error estimates are generally not useful. These issues can also affect the interpolation protocol. It should also be noted that estimating a concentration associated with a low effects level, such as an EC_{10}, is especially uncertain when treatments yielding partial effects values are lacking in the concentration response data produced by a study. These two issues prevented the use of TRAP for some datasets. When the data are insufficient to provide any meaningful EC_{10} by the first two approaches, the study should either not be used for criteria development or a chronic value should be set by other means than an estimated EC_{10} if possible.

Brown Trout (*Salmo trutta*)

For the (brown trout) Formation Environmental study (2011), EPA continues to use the 2015 draft report analysis approach, with a refinement of the statistical fit. Thus, EPA recalculated the EC_{10} for larval survival for the hatch through swim-up portion of the test based on the same data as in the 2015 draft, but using an improved statistical analysis and fit of the data. The study had two phases, hatch-to-swim up, and swim up-to-15 days post swim-up. There are two experimental complications that affected the interpretation of these data: (a) elevated deformity rates among the offspring that were to serve as hatchery-originated method controls (very low selenium exposure) and among some of the low exposure field-collected organisms, and (b) the accidental loss of a number of individuals from several treatments during the 15-day post swim up portion of the test due to overflow of the tank water. Because of uncertainties as to how to best address the loss of fish during the overflow event during the second phase of the test, and also because of the preferential selection of healthy fish introduced during the thinning process prior to the post-swim up potion of the test by the experimenters, where only those individuals presumed to be healthy were retained, survival during only the first portion of the test (hatch to swim up) was used because it provides a more reliable chronic value.

The dataset of percent survival from hatch to swim up versus the selenium concentration in the eggs was an excellent dataset and provided a good foundation for setting benchmark concentrations for selenium. There is a narrow range between the NOEC (20.5 mg/kg) and an LOEC with severe effects (26.8 mg/kg, 61% mortality) that leaves little uncertainty in what an appropriate low effects concentration should be. There were sufficient data for TRAP to estimate a curve, using weighted least-squares nonlinear regression with the threshold sigmoidal model generating an EC_{10} of 21.0 mg/kg.

Bluegill (*Lepomis machrochirus*)

In the 2016 selenium criterion document, EPA used three Bluegill studies in the derivation of the tissue-based criteria: Doroshov *et al.* (1992), Coyle *et al.* (1993), and Hermanutz *et al.* (1992, 1996). The text below describes an overview of EPA's re-examination of the Hermanutz blueguill data, which EPA retained 2016 criterion document, and described in full in the 2016 selenium criterion document in section 3.

Hermanutz et al. (1992), and Hermanutz et al. (1996) exposed bluegill sunfish to sodium selenite spiked into artificial streams which entered the food web, thus providing a simulated field exposure (waterborne and dietary selenium exposure. These data come from a series of three studies lasting from 8 to 11 months, conducted over a 3-year period. All three studies began with exposure of adult bluegill sunfish in the fall, and with respective studies ending in the summer of the following year. Temperatures averaged 4.6, 4.1 and 4.5^{o}C during the winter months and averaged 26.4, 23.9 and 22.4^{o}C during the spawning months (June-July) for Studies I, II and III, respectively.

The egg-cup data for all streams of Studies I, II, and III of this experiment were combined and analyzed in response to measured selenium concentration in the maternal ovaries (mg/kg dw) using TRAP; i.e., all 3 experiments were used in the 2016 selenium criterion analysis for this study. Data for streams receiving water-borne selenium were combined with data for streams recovering from the previous year's contamination. The absence of effects at high tissue levels (55 mg Se/kg ovary dw) in the recovering stream of Study II did not affect the EC_{10} estimate because it was outweighed by three other points showing severe effects at concentrations as low as 16.7 mg Se/kg ovary dw. Several egg-cup endpoints were analyzed by TRAP independently (% edema, % lordosis, and % hemorrhage) and in combination (% normal and surviving).

The best fit and most sensitive was the combined percent normal and surviving larvae. Due to inadequate partial effects for the ovary analysis, a threshold sigmoidal model was used to interpolate an EC_{10} estimate between the first interpolation point set to the highest no observed effect concentration (HNOEC) of 14.0 mg/kg and the average background survival/normal of 69.1% and the second point set to the LOEC of 16.7 mg/kg and a survival/normal of 5.76%. The resulting EC_{10} is 14.7 mg/kg ovary dw.

The SMCV for bluegill reproductive endpoints based on EC_{10} values is 20.6 mg Se/kg dw in egg/ovary, based on the EC_{10} values of Doroshov et al. (1992), Coyle et al. (1993), and Hermanutz et al. (1992, and 1996 as corrected by Tao et al. 1999).

White sturgeon (*Acipenser transmontanus*)

The discussion below provides an overview of EPA's statistical re-analysis of the Linville (2006) data for the dietary/reproduction part of the experiment.

EPA agrees with the comment regarding the egg injection aspect of the Linville 2006 sturgeon study: "results obtained through short-term exposure of seleno-L-methionine via injection into larval fish yolk sacs are not environmentally relevant and do not correlate to environmental dietary exposure during the period of embryonic development."

EPA notes it did not, in any draft nor in the final criterion, use the Linville egg injection data from the study in the criterion calculation, as clearly explained in the criterion document. There are dietary, maternal transfer aspects in the Linville study, and these are the data that were used by EPA. Linville (2006) data EPA considered regarded the effect of elevated dietary selenium on the health and reproduction of white sturgeon. Adult female white sturgeon (approximately 5 years old) were fed either a control diet or a diet spiked with selenized yeast for six months in a freshwater flow through system. At the end of the dietary exposure, females were induced to spawn and fertilized with non-exposed male milt. Large cohorts of fertilized eggs from individual females were collected and

separately hatched and progeny from two control females and three treatment females were examined for length, weight, edema and deformities. The test fulfilled Guidelines requirements for larval control survival and the highest test concentration indicated evidence of reproductive effects.

No selenium effects were observed for length or weight of larvae but effects were observed for both edema and skeletal deformities. EPA evaluated larval survival and abnormality frequency at stage 45. Because the mortalities for each cohort were recorded up to the sample collection time for abnormalities, a combined effects variable was derived based on the total proportion of hatched larvae which were both alive and without any abnormalities at stage 45.

Estimation of the EC_{10} was conducted using weighted nonlinear regression analysis with the threshold sigmoidal model equation (TRAP version 1.30a).

Since the study yielded only one definite partial effect, TRAP cannot be used to estimate a concentration-response curve. Instead, TRAP was used to interpolate between the last two points to estimate the EC_{10} (see Appendix C for detail). The resultant TRAP slope is 2.96 and the interpolated EC_{10} is 15.6 mg/kg.

The white sturgeon EC_{10} of 15.6 mg/kg egg dw is important because this species is a commercially and recreationally important fish species in the Pacific Northwest, and also serves as a surrogate for other sturgeon species in the United States (see Section 6.3, Protection of Threatened and Endangered Species), and has a population listed as endangered in the Kootenai River in Idaho and Montana.

Other Fish Species

Regarding the use of the Esox data, EPA exhaustively examined the data. EPA does not believe that the authors' EC_{10} calculation is scientifically defensible. The spacing between exposures is too large to estimate the EC_{10} either by the authors' linear regression approach, or by EPA's nonlinear regression approach. But based on its cluster of three values with concentrations near 34 mg/kg dw, and having a 24% effect, EPA estimates that Esox is somewhat sensitive, but not among the four most sensitive species.

3.2 Specific comments

EPA-HQ-OW-2004-0019-0395-A1; CONSOL Energy; Posted 10/15/15

CONSOL is concerned about the decisions EPA made in calculating the chronic tissue criterion concentrations. We ask that the EPA adopt the recommendations provided by the National Mining Association (NMA) on revisions to the bluegill and brown trout Genus Mean Chronic Values (GMCVs) or Species Mean Chronic Values (SMCVs).

Fish Body Burden Recommendations

CONSOL has concerns with the usage of specific bluegill, brown trout, and white sturgeon data in the criteria calculations.

- Bluegill – We have major concerns about the data used from the Hermanutz et al. (1992, 1996) studies. These concerns were previously submitted to the EPA by commenters in response to

EPA's 2014 draft criteria. EPAs decision to exclude Study Ill and several streams from Study II because they were considered to be "recovering" streams and were no longer receiving aqueous selenium calls into question the validity of its use. These fish were exposed to selenium and EPA has not properly explained why these studies were not included in the criteria development. Also, the use of results from Study I and selected results from Study II over two different years is not common practice in the development of criteria. We recommend excluding all of the data from the Hermanutz studies. Hermanutz et al. (1992) had a chronic value of 11.36 mg/kg while the more reliable studies by Doroshov (1992) and Coyle (1993) had chronic values of 20.05 mg/kg and 24.55 mg/kg respectively. The impacts of the use of this invalid study are significant.

- Brown trout − During the Formation Environmental (2011) study a tank overflowed resulting in the loss of many study fish. In the 2014 draft, EPA presented two approaches for dealing with this loss of these study fish:
    1. Assume that all fry lost were dead or deformed ("worst case" assumption), or
    2. Assume that fry lost had the same rates of mortality and deformities as those not lost ("optimistic" assumption).

  In the 2015 draft EPA acknowledged the uncertainty with how to best address the loss of fish, and decided to calculate an EC_{10} for survival only during the first portion of the test, prior to the accident. This resulted in calculation of an EC_{10} of 18.09 mg/kg egg dw for larval survival. We recommend using the brown trout EC_{10} calculated under the "optimistic" /realistic assumption for dealing with the lab accident that resulted in loss of the study fish. This data would represent what was observed in the remaining fish population that was not lost to overflow. An assumption that the fish lost from the study have the same rate of deformity and mortality as the other fish in the study is much more scientifically defensible.
- White sturgeon − CONSOL believes that the Linville (2006) white sturgeon data should be excluded from the 2015 draft criteria calculations. We recommend these data be excluded from the calculations due to lack of sufficient response and a scientifically defensible EC_{10} calculation. These data were not included in the 2014 draft. White sturgeon is now the most sensitive species in the database. The EPA calculated EC_{10} for total deformities (edema+ skeletal) of 16.3 mg/kg was calculated based on a partial dose response. Use of an EC_{10} based on a partial response is not appropriate for national criteria development, especially when it results in a value becoming the "most sensitive" and thereby driving the final criterion. In fact, on page 33 of the 2015 draft criteria document, EPA states that "an EC_{10} based on only one partial response would not ordinarily be included in the data set".

EPA-HQ-OW-2004-0019-0390-A1; West Virginia Coal Association (WVCA); Posted 10/14/15

In this case, the four lowest GMCVs are for white sturgeon, bluegill, brown trout, and largemouth bass. EPA's data decisions for the lowest three species -- white sturgeon, bluegill, and brown trout − depart significantly from acceptable scientific procedure and from the requirements of the 1985 Guidelines. The following data decisions resulted in body burden elements that are overly stringent and inaccurate.

(1) EPA should have excluded Linville (2006) for white sturgeon. EPA correctly determined that this study was not appropriate for use in criterion calculation in its 2014 peer review draft criterion. However, due to pressure from US Fish and Wildlife Service, EPA included this inappropriate study in the 2015 Draft Selenium Criterion. EPA explicitly acknowledges that Linville (2006) does not qualify for inclusion: "An EC_{10} based only on only one partial response [27.8% effect at the highest egg selenium concentration] would not ordinarily be included in the chronic data set." (Draft Selenium Criterion, p. 33). Clearly, EPA seems to believe that the use of bad science is appropriate when no valid data exists. This is disturbing on the most basic level.
(2) EPA should have excluded Hermanutz (1992) for bluegills due to serious issues with the scientific validity of the test. Multiple commenters raised these concerns with EPA in response to EPA's 2014 draft criteria. The difference caused by this invalid study is substantial. Whereas Hermanutz (1992) had a chronic value of 11.36 mg/kg, the more reliable bluegill studies had chronic values of 20.75 mg/kg (Doroshov, 1992) and 24.55 mg/kg (Coyle, 1993). The Hermanutz study should be excluded and the criteria recalculated.
(3) For brown trout, EPA mishandled the interpretation of data where fish that accidentally were lost due to a laboratory accident causing overflow from the test chambers (Formation, 2011). EPA calculated an EC_{10} for survival during only the first portion of the test, resulting in an EC_{10} of 18.09 mg/kg. The more defensible approach is to excluded these fish (324 lost of 11,130 fish) from the results of the toxicity testing, resulting in an assumption that the fish accidentally lost from the testing had the same rate of deformity and mortality as the other fish in the study.

These adjustments to the database should be made, and the criteria calculations revised accordingly.

EPA-HQ-OW-2004-0019-0396-A1; National Marine Fisheries Service Office of Protected Resources Interagency Cooperation Division; Posted 10/15/15

The selenium guidelines are unique because selenium is a *dietary toxicant* and an appropriate methodology needed to be developed. Likewise, when evaluating dietary data, EPA needs to include dietary considerations in its discussion. NMFS agrees that control survival rate is an important component of study quality, but control survival alone should not be a basis for evaluating such data. For example, dietary studies, particularly those measuring growth, need to account for any influence of dietary content in addition to the stressor being evaluated. Specifically proximate analysis (lipid, carbohydrate, protein, fiber, moisture, and ash) of the diets need to be comparable. Hamilton et al. (1990) did not report proximate analysis, but the diet composed of reference site mosquitofish spiked with selenomethionine could be considered a dosed reference diet that would account for any effects of nutritional quality or other toxicants in the diet made using mosquitofish from the selenium-contaminated San Luis Drain. The two diets provided similar results indicating a selenium dose response decline in mass and length throughout the study. All treatments experienced high mortality at 90 days, negating the possibility that control mortality would be due to deficiency in selenium in the uncontaminated control diet. The 90 day data were also marked by a slight decline in growth rates. Mortality and growth rate decline at 90 days was greatest in the higher selenium exposures.

At 90 days a confounding stressor (e.g., disease, parasitism) likely influenced results, but the effect of that stressor was most severe in treatments that were already compromised by selenium toxicity. Given EPA's interest in updating the methodology, exploration of ways to extract useful information from

datasets such as the 90 day exposures in Hamilton et al 1990 offers an opportunity to expand the dataset.

Inclusion of larval deformity data for white sturgeon: The only sturgeon data considered in the original 2014 draft selenium guideline were for growth decline in white sturgeon. NMFS appreciates EPA's consideration of De Riu's 2014 data on the sensitivity of green sturgeon to selenium in deciding whether to incorporate Linville's 2006 larval deformity data for white sturgeon. EPA's calculated larval deformity EC_{10} of 16.3 mg/kg egg dw is close to the selenium egg-ovary guideline of 15.8 mg/kg dw (<5% higher) and EPA concluded that the guideline is protective because it falls below the white sturgeon larval skeletal deformity EC_{10}. However, confidence interval for the EC_{10} of 16.3 mg/kg egg dw likely overlaps the guideline and Linville also reported an EC_{10} for either larval edema or skeletal effects that was below the guideline, at 15.01 mg/kg dry weight. In stating that the guideline is protective when it is roughly equivalent to an EC10 for larval deformity, EPA needs to take into consideration whether an effect level of 10% represents an impact that can contribute to the decline in recruitment and may adversely affect threatened and endangered fish species under the jurisdiction of NOAA Fisheries.

Addressing potential for greater selenium sensitivity in ESA-listed species: While EPA acknowledges De Riu's data suggests that green sturgeon are more sensitive to selenium than white sturgeon, EPA concludes *"inclusion of the white sturgeon's EC10 in the dataset provides surrogacy for the threatened and endangered species from this group"*. Further, EPA recommends that, since ESA listed species may be more sensitive to selenium, relevant new information should be considered in state- or site-specific criteria calculations (page 127). This does not convey the greater importance of toxicity to individuals of ESA-listed species, regardless of whether the species EC10 is similar to or lower than that of non-ESA listed species. Populations of a listed species may not be able to sustain a 10% decline in reproduction, while stable populations of non-ESA listed species may not be affected. Further, EPA does not suggest that *existing* data should be reassessed for waters where selenium-susceptible ESA-listed species occur and does not specifically indicate the presence of ESA-listed species among reasons for deriving site-specific criteria (Section 5). New data should not be the only consideration for state- or site-specific criteria calculations that are protective of ESA-listed species. Reassessing existing data is the most logical approach to deriving such criteria. For example, if the generic guideline is based on the geometric mean of observed EC10s for a particular response, a site-specific criterion intended to be protective of ESA-listed species may be a lower ECxx calculated from existing data or, if an EC10 is determined to be an appropriate threshold, the appropriate criterion may be the lower bound or some lower quantile within the credible interval around the geometric mean of observed EC10s.

Extrapolating to water column and whole body concentrations and calculation of site-specific criteria: White sturgeon parameters used in the derivation of whole body tissue and water column guidelines and site specific guidelines do not reflect the environmental conditions under which shortnose sturgeon would accumulate selenium. Shortnose sturgeon ingest much sediment when foraging, and they consume mainly mollusks from bottom sediments. Stomach contents of juvenile shortnose sturgeon have been reported to contain 85-95% non-food matter, mostly mud (Curran and Ries, 1937; Dadswell, 1979). EPA's model does not account for species that consume large amounts of sediment/particulate bound selenium. In addition, the trophic transfer factor for white sturgeon used in EPA's model indicates a diet composed predominantly of fish, insects, and benthic crustaceans, with a dietary mollusk composition of only 9%. Mollusks tend to accumulate selenium at higher concentrations than other trophic level 2 organisms so fish that consume a large portion of their diet as freshwater mollusks, such

as shortnose sturgeon, will exhibit greater selenium bioaccumulation than fish in the same waters that consume primarily insects or crustaceans.

EPA-HQ-OW-2004-0019-0385-A2; Kentucky Division of Water (KDOW); Posted 10/13/2015

Use of Appropriate and Peer Reviewed Science

The EPA appropriately reviewed the body of available scientific literature when it developed its database for criterion formulation, which resulted in a pertinent subset of studies based on the understanding of the mode of selenium toxicity. However, the final chronic value of this draft criterion is based in-part on reliance on a study that was not peer reviewed and for which the results obtained were driven only partly by dietary uptake. EPA's reliance on the bioassay results from the Linville (2006) study is concerning from the standpoint of the use of this data in the development of the tissue-based Final Chronic Value (FCV) from which to recommend 304(a) Se criteria.

The Linville (2006) study results were based in-part on data gleaned from test offspring where the larval uptake (exposure) of selenium was not solely through dietary uptake; rather, the larval yolk sacs were injected with seleno-L-methionine directly. This is not the pathway in the aquatic habitat by which fish are exposed to selenium, but more importantly the study does not account for complex processes in dietary exposure and subsequent cellular incorporation, including ratios and forms of other chemical compounds and elements in the natural environment that may affect the incidence of teratogenicity; therefore this exposure is not considered empirical.

EPA has rejected the use of studies based on this method of exposure *(i.e.* direct injection); in prior drafts of selenium criteria documents (e.g. see page 6, Appendix G, EPA 2004 draft selenium criteria *[e.g.* Doroshov, 1992]) as a matter of misapplication of procedures to derive water quality criteria (Stephan, *et al.* 1985). KDOW recognizes that the long ovarian cycle may make it difficult and/or expensive to study teratogenicity effects in white sturgeon, however that is not a scientifically valid reason to go forward with the a study utilizing inappropriate methodology. Therefore, results obtained through short-term exposure of seleno-L-methionine via injection into larval fish yolk sacs are not environmentally relevant and do not correlate to environmental dietary exposure during the period of embryonic development. To adequately control the experiment and shadow exposure to selenium in the natural habitat, parental female exposure to selenium through dietary uptake followed by contaminant transfer from the parental female to the eggs is required.

Furthermore, the stress of handling and injecting the selenium on the test fishes was not thoroughly accounted, and the sample size was inadequate to allow for statistical comparability. Additionally, the high mortality rate (45 to 70 percent) of the larvae that underwent injection does not meet the rigor and test acceptability standards outlined in guidance (Stephan, *et al.* 1985). Therefore, this study should also be rejected due to insufficient control performance.

Summary

For the reasons provided above, KDOW supports EPA's taking the following approach to developing selenium criteria and encourages EPA in the formal selenium criteria proposal to:

1. Exclude the Linville (2006) study from the EPA selenium criterion calculations for similar reasons that EPA has excluded other studies.

EPA-HQ-OW-2004-0019-0388-A2; J. R. Simplot Company; Posted 10/14/2015

An Egg/Ovary Tissue Criterion is the Correct Approach, but the Effects Values Need to be Recalculated

The establishment of an egg or ovary fish tissue value as the criterion is the right approach for the protection of sensitive species. A review of the studies used (Table 3-1, page 40) show that two of the studies (white sturgeon and brown trout) warrant a reevaluation of the EC_{10} calculated by EPA. For example, use of all the data from the white sturgeon study would result in an EC_{10} of 19 mg/kg (dw) instead of the 16.27 mg/kg (dw) value chosen by EPA.

Brown Trout Study Endpoint should be no lower than 20.5 mg/kg (dw)

Formation Environmental has conducted for Simplot a series of studies for over the past decade examining the toxicity of selenium on brown and cutthroat trout in eastern Idaho. These studies have included both field and laboratory work. The brown trout study in particular, has been extensively reviewed, including an external peer review panel assembled by EPA. One of the reviewers, in response to one of the "charge questions" posed by EPA, stated the following:

> "The final point in Note B to Charge Question #5 is *"EPA's belief that given its effort to understand how the study uncertainties affect the resulting EC_{10}, the study contains valuable information that should not be discarded. EPA does not believe the uncertainties in the brown trout EC_{10} are much greater than, and may in fact be less than, those for other studies used in criteria derivation. "* ***I concur with this view, and note that this study has been vetted to a degree that I have never before encountered."*** *(ERG 2012- emphasis added)*

Simplot commented extensively in 2014 that EPA had evaluated the brown trout study in an excessively conservative method. EPA has revised the calculation of an endpoint from the brown trout study, however EPA has not fully followed the recommendations of the peer reviewers. Simplot recommends the use of the study data to calculate a combined endpoint (survival and deformity) EC_{10} value of 20.5 mg/kg (dw) or higher as compared to EPA's calculated value of 18.09 mg/kg (dw).

B. Effects Data

B.1. White Sturgeon Study

(Page 33, Section 3.1.1.1)

EPA included the white sturgeon study from Linville (2006) and derived an EC_{10} of 16.3 mg/kg dw using only partial response data from the final stage of a multi-staged reproduction test. In doing so, EPA lost some of the variability that would occur in the dose response estimate simply due to ignoring those earlier stages. Below is a dose response curve utilizing all three stages of the original data using the TRAP model for the same combined endpoint EPA used (edema and skeletal deformities).[7] The EC_{10} for this dose response curve is 19 mg/kg dw. As illustrated in the figure below, the TRAP model attempts to fit the data, but the dose response is incomplete. However, by including all effects data from the final

stages of the test as the original study authors did, the TRAP model is not trying to fit a dose response curve to a single data point as its basis for the slope of the curve. It is not clear why EPA chose to not use the earlier stages in their analysis, but if the original author was able to identify edema and skeletal deformities in these earlier stages, then those data would be applicable for use in defining the dose response just as the final stage was applicable. EPA should provide a transparent justification for not including all of the data for the three final stages of the test or include all three stages and adjust the white sturgeon EC_{10} to 19 mg/kg dw.

Original letter contains Figure 1 – TRAP Model output for the Linville (2006) study using the final three stages from the study. See original letter.

B.2. Brown Trout Study

(Page 34, Section 3.1 .1.2.1, Section 6.1.6, and Appendix C summary for brown trout)

Endpoint Selection and the Overflowing Test Chamber

In the 2014 Draft Criterion, of the six different types of endpoints evaluated for the brown trout study, and EPA selected the most conservative endpoint. One key aspect to EPA's endpoint selection revolved around how to handle the loss of fish from a test chamber due to overflow from an overflow pipe getting clogged (due to uneaten food). Simplot (and others) submitted extensive comments on how to handle the loss of fish due to the test chamber overflow and other aspects of the different endpoint evaluations.

For the 2015 Draft Criterion, EPA has decided to use the larval survival endpoint from the first portion of the test rather than other endpoints they derived. EPA cites the rationale for using this endpoint by stating, "Because of uncertainties as to how to best address the loss of fish during the overflow event during the second phase of the test, an EC_{10} for survival during only the first portion of the test was calculated."[8] The EC_{10} for this endpoint was 18.09 mg/kg egg dw for larval survival during the first portion of the test, hatch to swim up.

EPA has once again selected the most conservative endpoint, "Larval survival was the most sensitive endpoint, followed by the combined survival and deformities endpoint, with deformities being the least sensitive. For each of the three endpoints, the EC_{10} for the worst case scenario was lower than the EC_{10} for the optimistic scenario"[9]

EPA states the following, "In contrast to other EC_{10} calculations, this approach is free from all assumptions, and even with respect to larvae that fail to reach swim up, the EC_{10} calculation is based on measured, rather than assumed, values."[10] For this conclusion, EPA set non-swim ups to their actual value rather than assuming them to be dead as they had done previously per comments from USFWS.[11] When the non-swim-ups were set to zero for survival, the EC_{10} was 20.62 mg/kg dw, which is very close to and within the range of the three optimistic scenario EC_{10s} is defined.

The Formation Environmental brown trout study has been extensively studied by EPA and various experts retained by EPA. EPA put together an external peer review (Eastern Research Group 2012) to review the Formation Environmental 2011 study and EPA's analysis of the Formation Environmental 2001 study. One such reviewer commented:

> "The final point in Note B to Charge Question #5 is *"EPA's belief that given its effort to understand how the study uncertainties affect the resulting EC_{10}, the study contains valuable information that should not be discarded. EPA does not believe the uncertainties in the brown trout EC_{10} are much greater than, and may in fact be less than, those for other studies used in criteria derivation." I concur with this view, and note* ***that this study has been vetted to a degree that I have never before encountered****."* [Emphasis added.]

Thus, the Formation Environmental brown trout study has been extensively and comprehensively reviewed. This decision to use the most conservative endpoint is not consistent with the peer-review comments and document. Throughout the discussions of the brown trout data and analyses conducted, EPA overall concludes that the worst case assumption was not a technically sound analysis approach.[12]

"In summary, the positive correlation between survival during the hatch to swim up portion of the test and survival during the 15 day post swim up portion of the test, combined with the lack of correlation between mortality during the hatch to swim up portion of the test and overflow loss during the second stage of the test, suggests that the overflow loss may represent a random technical error not related to the health of the individuals lost. The relationship between selenium egg concentrations and overflow loss was lower for the larvae hatched from hatchery fish compared to the larvae hatched from field collected fish; however, among field treatments ranging from 6.0-20.5 mg/kg there was no correlations, **further supporting the hypothesis that the overflow event was a random occurrence unrelated to the health of larval fish."** [Emphasis added]

However, it is unclear why EPA would go through the effort to document and illustrate that the overflow loss was not related to the health of the organisms and then disregard any of these endpoints from the optimistic scenario.

By a process of elimination, only the optimistic scenario is a logical choice, and the endpoints remaining for developing viable EC_{10}s would then include the following:

- survival- hatch through 15 day post swim up (optimistic);
- deformities - hatch through 15 day post swim up (optimistic);
- combined endpoint - hatch through 15 day post swim up (optimistic);
- survival - hatch through swim up

For each of these endpoints, EPA derived EC10s (with the lowest sum of squares) which are as follows:

- EC_{10} survival- hatch through 15 day post swim up (optimistic)= 20.4 mg/kg dw
- EC_{10} deformities- hatch through 15 day post swim up (optimistic) = 21.95 mg/kg dw
- EC_{10} combined endpoint- hatch through 15 day post swim up (optimistic)= 21.16 mg/kg dw
- EC_{10} survival- hatch through swim up= 18 .09 mg/kg dw

The three different endpoints converge on such a narrow range (20.4 to 21.95) which is a difference of only 1.5 mg/kg dw, but EPA then used a value of 18.09 mg/kg dw as the brown trout EC_{10} which is separated by a wider margin from the lowest of the other endpoints . It may be the most conservative value, but it is not the most representative value*. Based on these data, the correct value for the brown trout EC_{10} is best represented by the combined endpoint of 21.16 mg/kg dw*.

Deformity Endpoint

EPA also stated that a complicating factor for use of the deformity data and the combined endpoint data was the presence of multiple minima and high variability among low selenium and hatchery treatments. Simplot commented on these concepts in the 2014 Draft Criterion and provided a revised summary and derived EC_{10} to provide evidence that the high variability in low and hatchery endpoints is a function of the ranking system for deformities.

For its deformity assessment and combined endpoint, EPA only used fish that were ranked as "0" (i.e., no deformities present). However, a less conservative approach, and likely a more realistic approach, would be to include fry ranked as 0 or 1 (slight deformities) as insignificant deformities and to include fry ranked as 2 or 3 as significant deformities. Simplot (Simplot 2013) presented these data to EPA and Idaho Department of Environmental Quality (IDEQ) in response to the US Fish and Wildlife Service (USFWS) comments.

The rationale for the approach described above stems from the MacDonald and Chapman (2009) QA review on a number of larval deformity assessment studies for selenium where they provided some guidelines to reduce uncertainty in the results of those assessments. In particular, they examined the frequency of overlap or non-overlap between two observers rating of deformity rankings for larval fish. They found a lower average difference in observed ranking by two individuals for those fry ranked as 2 and 3 versus those ranked as 0 and 1. In other words, significant deformities were more consistently identified similarly by two different individuals, whereas insignificant or low levels of deformities were more often scored differently. The biggest differences occurred for edema for fish ranked in the zero and one category, but differences were also noted for skeletal and craniofacial deformities in these same categories. Fewer differences (i.e., more agreement) were found between the two observers for fish ranked as 2 and 3 level deformities. The findings of this evaluation suggest that enough uncertainty is present in the identification of no and low levels of deformities that overly conservative estimates of deformities may be made by only considering fry ranked as zero deformities. From this, the biological relevance and association of actual effects must be considered for fish that are considered to be only slightly deformed versus those that have more severe deformities.

When considering deformities based on these two categories for the **wild** brown trout, the mean proportion for insignificant deformities (i.e., ranked as 0 or 1) was 92.3 percent (range: 67 to 99%) at an egg selenium concentration of 20.5 mg/kg dw[13] or less. There is a stark contrast to the mean proportion normal (i.e., ranked as 0) used in the EPA analysis which was 61 percent (range: 31 to 88.7%) at an egg selenium concentration of 20 .5 mg/kg dw or less. Similarly, the mean proportion for insignificant deformities (i.e., ranked as 0 or 1) was 17.5 percent (range: 4 to 28%) versus a mean proportion normal of 5.9 percent (range: 2 to 11.3%) at an egg Se concentration of greater than 20.5 mg/kg/ dw. For the hatchery fish, the mean proportion normal (i.e., ranked as 0) was 64.4 percent (range: 32.8 to 85.4%). For that same group of fish, the mean proportion of insignificant deformities (i.e., ranked as 0 or 1) was 88 percent (range: 57.8 to 100%). If only the fish from background areas are considered, (i.e., those fish from up gradient of Sage Creek including the CC-150 and CC-350 locations), the mean proportion normal (ranked as 0) is 55 percent (range: 31 to 81 percent). Using these same locations, the mean proportion of insignificant deformities is 90 percent (range: 67 to 98%).

Evidence Supporting a Combined Endpoint

Based on the evaluation of these data, it is apparent that the uncertainty questions EPA raises in the 2014 and 2015 Draft Criterion concerning the deformity rate can be significantly reduced by separating the data into two categories, insignificant (rank 0 and 1) and significant (rank 2 and 3) deformities. The organization of these data is such that the analysis can be easily done and there is evidence that suggests (i.e., the hatchery fish data), an insignificant level of deformities can and does occur even at low levels of selenium exposure. Consider for example the Yellowstone cutthroat trout (YCT) studies where "wild fish" treatments were tested simultaneously with Henry's Lake "hatchery" fish. A similar level of variability is observed with the YCT "hatchery" fish as that found with the brown trout hatchery fish. However, Henry's Lake "hatchery" fish were not hatchery fish at all, but a wild run of fish from Henry's Lake where the Idaho Department of Fish and Game (IDFG) has set up a station to retrieve ripe and running YCT to extract eggs for propagation in other systems through Idaho. These wild fish, assessed for deformities using the ranking system similar to that used for brown trout (i.e. 0, 1, 2, and 3) had a similarly variable range of deformities despite low selenium exposure.

For two species, tested in similar manners, low selenium exposures result in a variable range of deformities (if only fish ranked as zero are considered). For both species, that variability is significantly reduced by simply using the fish ranked as zero and one and dividing the data into groups of insignificant and significant deformities. The result of analyses using these data as described above is increased certainty in the EC_{10} values derived from data with this level of detail.

Using EPA's approach to derive a combined endpoint, Simplot derived an endpoint for surviving fish with in significant deformities (i.e., 0 and 1 rankings) (see Figure 2). The EC_{10} for this approach is 20.5 (LCL = 19.81, UCL=21.24) mg/kg dw egg selenium.[14] It is not surprising that when the data are grouped in a logical manner, the combined endpoint reflects nearly the exact EC_{10} as the EC_{10} for survival for all of the data, and the EC_{10} for the survival data from hatch to swim up when the non-swim ups were set to zero.

By including fry ranked as 0 and 1, the analysis appears to be more robust (though no statistical analysis has been done to confirm this). This illustrates that two different populations of data for brown trout (i.e., low selenium exposure hatchery fish and higher exposure wild fish) demonstrate a very similar range of insignificant deformities, similar to observations made in the Yellowstone cutthroat trout studies that used a wild run of "hatchery fish" and wild fish from the sites adjacent to the Smoky Canyon Mine. When selenium exceeded 20.5 mg/kg dw in eggs for brown trout as shown, then the response is immediate.

Original letter contains Figure 2 – Brown trout combined endpoint (deformities ranked as 0 and 1) used. See original letter.

B.3. Cutthroat Trout Whole Body Conversion Factor

[Page 73, Table 3.12, footnote b]

The footnote states "The reason for the higher variability in the cutthroat trout *CF* values is due to the relatively higher *CF* values in the hatchery fish from the Formation study." It is important to note that the "hatchery" here is a natural run of Yellowstone cutthroat trout from Henry's Lake and it is not a hatchery at all, but is a station set up by the IDFG to collect ripe and running males and females for the

purpose of collecting eggs and milt. The higher CFs for these fish is simply a function of fish from a different natural environment.

C. 2. Citation Clarification

[Page 73, Table 3.12, footnote b]

Any references to Newfields should be deleted and replaced with Formation (2011) if specifically referencing the brown trout study.

EPA-HQ-OW-2004-0019-0387-A1; Colorado Department of Public Health & Environment; Posted 10/14/2015

The WQCD has concerns about the use of the Hermanutz et al. (1992 and 1996) data for bluegill (pages 37-39). First, the EC_{10} from these studies (11.36 mg/kg) is approximately half the EC_{10}s from the two other bluegill studies (20.75 and 24.55 mg/kg) in EPA's database. This discrepancy warrants additional review of all bluegill studies being considered, and such a review has been conducted by EPA and many reviewers. As a result of these reviews, several concerns have been raised regarding the Hermanutz et al. (1992 and 1996) studies. For instance, in Study I, the 10 µg/L treatment resulted in an ovary concentration of 17.71 mg/kg, while the 30 µg/L treatment resulted in an ovary concentration of only 15.46 mg/kg; these results are not what would be expected under typical dosing conditions, suggesting there may be issues in the study design or methods. Because there are other bluegill data with consistent results, the WQCD recommends rejecting this questionable study and using only the Doroshov et al. (1992) and Coyle et al. (1993) study results for bluegill.

EPA-HQ-OW-2004-0019-0413-A2; Federal Water Quality Coalition (FWQC); Posted 10/28/2015

I. SCIENTIFIC CONCERNS ABOUT STUDIES AND VALUES

In evaluating the data that were used to derive the criteria, the FWQC carne to the conclusion that several of the Agency's conclusions are problematic and should be reevaluated. One example is the derivation of a very low EC10 value for white sturgeon, based on incidence of larval edema and deformities. There were not a clear dose-response relationship for those effects across treatment levels. Use of the data was justified by EPA based on reported adverse effects of selenium exposure for a different, federally threatened species (green sturgeon). However, that is not an adequate reason to apply a value that is not scientifically supported. EPA should reconsider the EC10 value of 16.27 mg/kg dw, and should apply a higher value based on the white sturgeon data that are available.

Flaws are also evident in how the Agency used studies of selenium effects on bluegill sunfish. Two studies by Hermanutz et al. (one from 1992 and one from 1996) played critical roles in the Agency's derivation of a Species Mean Chronic Value (SMCV) of 17.95 mg/kg for bluegill. This value is much lower than the SMCV's reported in other bluegill studies. The problems in using the low value become evident when one considers that incorporation of that value results in bluegills appearing to be much more sensitive to selenium than are largemouth bass. Given that studies looking at both of those species

simultaneously showed effects on largemouth bass much earlier than effects on bluegill, it is highly unlikely that the bluegill are more sensitive than the largemouth bass. Therefore, EPA should remove the Hermanutz studies from the bluegill database before calculating the final criteria.

EPA-HQ-OW-2004-0019-0410-A2; West Virginia Department of Environmental Protection (DEP); Posted 10/28/2015

EPA 2015 Draft has improved upon their External peer review draft aquatic life ambient water quality criterion for selenium—freshwater 2014 (2014 Peer Review Draft) in several ways. Among these, EPA changed its interpretation of a Formation Environmental brown trout study involving a tank overflow which killed a portion of study fish. Previously, EPA's interpretation assumed 100% of overflowed fish were deformed/dead. This new draft interprets the Formation Environmental 2011 study overflow event closer to DEP's interpretation, changing the GMCV for brown trout from 15.91 mg Se/kg dry weight Egg-Ovary to 18.09; therefore, DEP supports this change.

EPA-HQ-OW-2004-0019-0415-A1; Idaho Department of Environmental Quality (DEQ); Posted 10/28/2015

The Linville (2006) study on white sturgeon departs from norms for acceptable toxicity studies in its atypical method of exposure — direct injection of larval yolk sacs — and in its high control mortality. This study was also not subject to peer review. This is all the more concerning as these questionable results provide the most sensitive genus mean chronic value. As EPA has done in prior drafts, we recommend EPA not use this study for criteria derivation due to its departure from EPA's guidelines (Stephan and others, 1985).

EPA-HQ-OW-2004-0019-0412-A2; Utility Water Act Group (UWAG); Posted 10/28/2015

1.1.1 Acceptable Studies of Fish Reproductive Effects of Four Most Sensitive Genera

White sturgeon

EPA should exclude data from the white sturgeon study from calculations used for setting national criteria. EPA derived an estimated EC_{10} value of 16.27 mg/kg dw based only on a partial response (27.8% effect larval edema and deformities) at the highest egg selenium concentration (20.5 mg/kg Se egg) using the most conservative model across a range of slopes. Although UWAG acknowledges that the incidence of edema and deformities was elevated at the highest dietary exposure treatment, a clear dose-response relationship considering all treatment levels was not evident. We believe that this reason alone should be sufficient to exclude the estimated effect level for this study. But additionally, there was no observed elevated incidence of edema and deformities in the two lowest treatment levels (2.68 and 7.61 mg/kg, respectively). Moreover, EPA acknowledged that adoption of an EC_{10} based on a partial response would not normally be included in a data set. Draft Criterion at 33. It is inappropriate to include a partial response study in the dataset, particularly where, as in this case, use of the study

resulted in the white sturgeon being the most sensitive species in the dataset and the cause for lowering the value significantly.

EPA's basis for including the data is that effects due to selenium exposure have been reported for green sturgeon (a federally threatened species), and that protection of the white sturgeon provides surrogacy for other threatened or endangered sturgeon species. Draft Criterion at 126-128. We find this justification weak. Protection of a specific ESA species is not an appropriate justification for developing a nationally applicable criterion, especially when the chronic toxicity study is speculative in terms of what the effect level is. Additionally, a white sturgeon chronic toxicity study conducted by Tashjian et al. (2006) found no effects on juvenile sturgeon survival within a selenium dietary exposure range of 0.4 - 191.1 mg/kg. Growth rate and swimming ability of sturgeon, however, were significantly affected at dietary exposure concentrations at or above 41.7 mg/kg.

While there have been numerous studies reporting measured levels of pollutants (organic and inorganic) in white sturgeon (collected mostly from the Columbia River), to date no specific pollutant has been unequivocally linked to the species' long-term population stability/decline. Changes in Columbia River substrate composition, however, have been strongly linked to poor recruitment of the species in some stretches (Steven and McAdam, 2015). This demonstrates that ecological factors are, at least, just as important as contaminant levels regarding the long-term sustainability of white sturgeon. If EPA had compelling evidence that levels of selenium in water or food prey organisms was limiting the persistence and abundance of white sturgeon, then the relevance of the chronic toxicity study suggesting an EC_{10} value of 16.27 mg/kg would be acknowledged. Instead, the agency has not made this demonstration.

Bluegill

EPA should not use the unrealistic, conservative reproductive chronic value of 11.36 mg/kg for bluegill based on Hermanutz et al. (1992, 1996) in deriving the Species Mean Chronic Value (SMCV). EPA relied on laboratory studies by Doroshov et al. (1992) and Coyle et al. (1993) along with Hermanutz et al. (1992, 1996) to derive a SMCV of 17.95 mg/kg for bluegill sunfish. See Table 3.1 (maternal transfer reproductive studies). Draft Criterion at 40. This SMCV is much lower than would be expected and results in bluegills appearing to be much more sensitive to selenium toxicity than largemouth bass. This conclusion is inconsistent with field studies (with both species present) that indicate the exact opposite, i.e., largemouth bass are more sensitive to chronic selenium exposure than bluegill.

EPA's SMCV calculation was influenced by chronic values reported by Hermanutz et al. (1992) and Hermanutz et al. (1996). In analyzing the results of these two studies, EPA derived a chronic value of 11.36 mg/kg. UWAG questions the validity of this value as it is markedly lower than the chronic values reported for the two other bluegill studies: Doroshov et al. (1992) and Coyle et al. (1992). Moreover, the agency acknowledges the conservatism of the chronic value of 11.36 mg/kg:

> *The EC_{10} value of 11.36 mg/kg Se dw (combined larval survival and edema in response to Se concentration in the parental ovaries) is considered an environmentally conservative chronic value for this bluegill study*.

Draft Criterion at 38. UWAG's technical experts believe this chronic value should have been discarded as an outlier. Failing to discard the extremely low reproductive effects-based value of 11.36 mg/kg for this

species results in the bluegill being the second lowest GMCV value for the 11 species tested for reproductive effects. A related species, the largemouth bass, however, is the fourth most sensitive species for reproductive effects. This conclusion conflicts with the totality of the science as it relates to these two species.

The following table indicates chronic values for bluegill and largemouth bass, and the ratios of these values:

Original letter contains Table 1 – Comparison of Reproductive Chronic Value and Whole Body Converted Chronic Values for Bluegill and Largemouth Bass. See original letter.

One would ***not*** expect bluegill to be 1.7 times more sensitive to chronic selenium exposure relative to largemouth bass in terms of a whole body effect level, and the science does not support such a conclusion. In field studies where both species were adversely affected by selenium-laden wastewaters, UWAG finds no evidence that bluegills were more sensitive (i.e., suffered significant population declines at an earlier time than largemouth bass). The studies at Belews Lake and Hyco Reservoir clearly showed that largemouth bass suffered selenium-induced population declines ***before*** effects on bluegill. Cumbie and Van Horn (1980) reported that in Belews Lake the standing crop and density of largemouth bass was virtually zero during rotenone cove surveys conducted during 1976. During this same year, the standing crop and density of bluegill were somewhat reduced but a viable population was still maintained. Crutchfield (2000) reported that in Hyco Reservoir the density of largemouth bass was reduced significantly starting in 1982, while marked reductions in bluegill density were not observed until 1986.

Studies also show that bluegill are able to accumulate very high tissue levels of selenium without seemingly adverse population-level effects. In a fly ash-impacted receiving stream (Stingy Run, Ohio) average whole body and ovary selenium concentrations in bluegill were 17.26 mg/kg and 32.48 mg/kg, respectively (Reash et al., 2006). These values are significantly higher as compared with EPA's calculated species mean chronic values for bluegill: 8.41 mg/kg (whole body) and 17.95 mg/kg (egg/ovary).

In summary, UWAG urges EPA to not use the unrealistically conservative reproductive chronic value of 11.36 mg/kg. The effect of using this value is to calculate SMCVs for bluegill that are considerably lower than those for largemouth bass, which, as discussed above, is not supported by field studies.

Hermanutz Bluegill Study:

"In my opinion, the uncertainty in the moisture content of the bluegill ovaries in the Hermanutz et al. (1992, 1996) [studies], along with the uncertainties in the ovary Se concentrations in Study I, are sufficiently great that this study should not be included in the SMCV for bluegill, as there are other studies (Doroshov et al. [1992] and Coyle et al. [1993]) for which dry weight ovary Se concentrations were reported and the EC10s from those two studies were very comparable." (2014 Peer Review at 28).

4.0 National Criterion for Selenium in Fresh Waters

Table 4.1 lists the proposed revised fish tissue and water column chronic aquatic life criterion. UWAG offers comments on the following: (1) the numeric fish tissue criterion values, (2) the fish tissue exceedance frequency of "never to be exceeded," and (3) the requirement that the lotic or lentic water column criterion have primacy for new or expanded discharges of selenium.

Numeric fish tissue criterion values must be recalculated.

UWAG believes EPA must recalculate the egg/ovary, muscle, and whole-body numeric criterion based on our comments above that: 1) EPA inappropriately relied on an insufficient, "partial" treatment response in the white sturgeon study to calculate the SMCV value of 16.27 mg/kg, and thus, this value should not be used as it is not scientifically sound; and 2) EPA should remove the anomalous, obviously conservative chronic value of 11.36 mg/kg for bluegill calculated based on the Hermanutz et al. (1992, 1996) studies. With these changes, a more scientifically defensible egg/ovary criterion (about 20 mg/kg) based on sound data would result.

EPA-HQ-OW-2004-0019-0411-A2; American Petroleum Institute (API); Posted 10/28/2015

- Given the very large uncertainties in the concentration-response data for White Sturgeon, the EPA should not use these data.

- EPA should exclude from its analysis the technically flawed Bluegill EC_{10} of 11.36 mg/kg-dw.

- EPA should reconsider for Brown Trout an EC_{10} of21.16 mg/kg-dw, based on larval mortality and deformities.

2.1.2 White Sturgeon (Acipenser transmontanus)

In the 2015 draft criteria document, EPA included data from the Linville (2006) White Sturgeon study. These data were not included in the 2014 draft, and inclusion of this study now results in White Sturgeon being the most sensitive species in the database used to derive the criteria. Linville (2006) fed adult female sturgeon a control diet (*i.e.*, 1.4 mg Se/kg-dw) or Se-enriched diets (*i.e.*, 34 mg Se/kg-dw), with Se provided as selenized yeast for six months. Females were induced to spawn, and eggs were fertilized with milt from non-Se-exposed males. Eggs were hatched and larvae reared in the laboratory, with edema and skeletal deformities observed at different stages of development. Eggs (and hatched larvae) from each female were kept separate. Only a single dietary Se treatment was tested (vs. a concentration gradient, as is usually tested in these types of studies). Mean egg Se concentrations from the different females provided three different egg and muscle Se exposure concentrations (due to between-individual variability in the internal transfer of Se to different tissues).

The levels of effect cited in Linville (2006) were relatively low, with the highest Se tissue concentration associated with an effect level of 28%. The lack of a complete concentration-response relationship imparts uncertainty in the concentration-response models. For example, the EPA derived an egg Se EC_{10} of 16.27 mg/kg-dw using TRAP, but noted that "the modeled EC_{10} was sensitive to the slope of the model, and the EC_{10} of 16.3 mg/kg was the most conservative model across a range of slopes with identical goodness of fit" (EPA 2015). In fact, by varying the initial slope estimate in the model, EPA could also derive egg Se EC_{10}s ranging from 17.5 to 19.1 mg/kg-dw (each with an equivalent goodness-of-fit). The geometric mean of four different EC_{10} estimates derived by EPA is 17.8 mg/kg-dw. In addition to varying initial slope estimates, the choice of concentration-response model also influences the EC_{10}. The EC_{10} of 16.3 mg/kg-dw was based on the threshold sigmoid model, while EC_{10}s of 17.9 and 18.9 mg/kg-dw are estimated from the piecewise linear and logistic models, respectively (both are valid options in TRAP) (Fig. 1). The geometric mean of these possible EC_{10}s is 17.7 mg/kg-dw, which is

comparable to the geometric mean EC_{10} of 17.8 mg/kg-dw, based on the different initial slope estimates. Note in Figure 1, however, that the uncertainty in all concentration-response slopes is high; of 4 data points only one provides a measurable effect. A slope effectively based on a single measurable effect data point is not technically defensible. Thus the Linville (2006) study is inappropriate and should not have been used to develop a national criterion.

Original letter contains Figure 1 – Fit of different concentration-response models to the White Sturgeon maternal transfer effects data from Linville (2006). See original letter.

The use of an EC_{10} based on a partial response is not appropriate for national criteria development, especially when it results in a value becoming the "most sensitive" and thereby driving final criteria values. In fact, on page 33 of the 2015 draft criteria document EPA states that "an EC_{10} based on only one partial response would not ordinarily be included in the data set." A similar partial response was observed in the Fathead Minnow data from the GEI (2008) study; EPA excluded these data from the chronic dataset because of an "insufficient response". EPA's rationale for using the White Sturgeon data that also had only a partial response is that there are data suggesting that the federally-listed Green Sturgeon is also sensitive to Se. The Green Sturgeon study (De Riu *et al.* 2014), however, consisted of effects on survival and percent body weight in juvenile sturgeon and is not comparable to the reproductive endpoints in all other studies used for criteria development. Although we realize that EPA is concerned with protecting threatened or endangered species such as sturgeon, technically indefensible data sets cannot be used for this purpose.

2.1.3 Bluegill (Lepomis macrochirus)

In the 2015 draft Se criteria document, EPA utilized three Bluegill studies in the derivation of the tissue-based criteria: Doroshov *et al.* (1992), Coyle *et al.* (1993), and Hermanutz *et al.* (1992, 1996). While we agree with the use of the Doroshov *et al.* (1992) and Coyle *et al.* (1993) studies, we have concerns regarding the use of the Hermanutz *et al.* (1992, 1996) data.

EPA reported an egg/ovary EC_{10} of 12.68 mg/kg for the Hermanutz *et al.* (1992, 1996) studies. This value was derived through a re-analysis of the data using TRAP and combining results from the two separate studies, Studies I and II (Hermanutz *et al.* 1992, 1996) — in other words, data were combined from studies conducted over two different years, a practice rarely employed in criteria development. EPA elected to exclude Study III and several streams from Study II because they were considered to be "recovering" streams and were no longer receiving aqueous Se dosing. However, fish in these streams were exposed to dietary Se throughout the study, which is the same exposure route used in other studies considered as acceptable by EPA, such as the Linville (2006) White Sturgeon study, the Doroshov *et al.* (1992) Bluegill study, and the CP&L (1997) Largemouth Bass study. It is unclear why these dietary studies were included in the criteria development and the "recovering" streams from Studies II and III, in which no effects were observed, were not.

In addition, we previously expressed concerns regarding the results of Studies I and II and the resulting analysis for the following reasons:

- The two studies were not conducted concurrently, resulting in significant variation in all of the measured water quality parameters between the two studies (e.g., Study I waters were 5 degrees warmer in summer; Study I had higher hardness, alkalinity, turbidity, and conductivity;

and, dissolved oxygen varied differently between seasons and studies; Hermanutz *et al.* 1992, 1996).

- There were differences in how EPA analyzed and used the data from the two studies in Appendix C of the draft document (EPA 2015). For Study I, EPA calculated geometric means of two replicate Se concentrations (and used these geometric means to calculate the EC_{10}), whereas for Study II, EPA calculated geometric mean concentrations but used individual replicates to calculate EC_{10}s.
- There were differences in egg and larval survival between Studies I and II (EPA 2015). In the egg cup observations, egg percent survival to day 3 or 4 in the 10 µg/L exposure was much lower in Study I (*i.e.*, 28.8%) than in Study II (*i.e.*, 57.1 — 57.7%). In the nest observations, the percent dead larvae in the 10 µg/L exposure was much higher in Study I (*i.e.*, 17%) than in Study II (*i.e.*, 0.4 — 0.5%).
- The ovary Se concentrations resulting from the same water exposures were different. In Study I, the control exposure resulted in ovary Se concentrations ranging from 0.29 — 2.21 mg/kg, whereas the control exposure in Study II resulted in ovary Se concentrations ranging from 3.72 — 3.79 mg/kg. In Study I, the 10 µg/L exposure resulted in ovary Se concentrations ranging from 13.73 — 22.85 mg/kg, whereas the 10 µg/L exposure in Study II resulted in ovary Se concentrations ranging from 33.75 — 39.02 mg/kg. This variability between studies raises concerns that differences in Se uptake, bioaccumulation, exposure, or other factors could have been occurring between Studies I and II.
- In Study I, the geometric mean ovary Se concentrations were higher in the 10 µg/L exposure (*i.e.*, 17.71 mg/kg) than in the 30 µg/L exposure (*i.e.*, 15.46 mg/kg). Related to the concerns discussed above, this unexpected result indicates that there may have been an issue with study conditions that resulted in inconsistencies with Se uptake, bioaccumulation, or exposure. Interestingly, invertebrate Se concentrations in Study I were as expected (*i.e.*, they increased with increasing Se exposure), so it is odd that the fish did not show the same result.

Based on the above-mentioned concerns, as well as the omission of any data from Study III, we recommend that the Hermanutz *et al.* (1992, 1996) data be completely removed from the database used for criteria derivation. If only the other two chronic values for bluegill (*i.e.*, 20.75 mg/kg [Doroshov *et al.* 1992] and 24.55 mg/kg [Coyle *et al.* 1993]) are used, a Bluegill egg/ovary GMCV of 22.57 mg/kg would be appropriate, and indicates that the EC_{10} EPA derived from the Hermanutz *et al.* (1992, 1996) studies would be an outlier.

The much lower EC_{10} mentioned above is also inconsistent with field data for Bluegill reported in Finley and Garret (2007). Fish populations in Hyco Reservoir (North Carolina) were decimated following high Se inputs in the early 1980s. After Se inputs were curtailed, Bluegill populations recovered, and by 2003-2005 the mean whole-body (WB) Se concentration was approximately 8 mg/kg-dw, respectively. Assuming the EPA's WB-to-egg conversion factor (CF) of 2.13 for Bluegill results in a predicted egg Se concentration of 17 mg/kg-dw, which falls above the Bluegill EC_{10} of 11.36 mg/kg-dw derived from Hermanutz *et al.* (1992, 1996), but below the EC_{10} values of 20.75 and 24.55 mg/kg-dw derived from Doroshov *et al.* (1992) and Coyle *et al.* (1993). This lends further support to use of only the latter EC_{10} values in calculating the SMCV for Bluegill.

2.1.4 Brown Trout (Salmo trutta)

In the 2015 draft Se criteria document, EPA (2015) utilized Brown Trout data from Formation Environmental (2011). During this study, a tank overflow accident occurred, resulting in the loss of several study fish. In the 2014 draft, EPA presented two approaches for dealing with the loss of these study organisms: (1) assume that all fry lost were dead or deformed (*i.e.*, worst case assumption); and, (2) assume that fry lost had the same rates of mortality and deformities as those not lost. In the 2014 draft, EPA (2014) chose to assume the worst case scenario and derived an egg/ovary EC_{10} of 15.91 mg/kg, using the results from that scenario and the deformity-alone endpoint.

In the 2015 draft, EPA (2015) acknowledged the uncertainty with how to best address the loss of fish, and decided to calculate an EC_{10} for survival only during the first portion of the test, prior to the accident. This resulted in the calculation of an EC_{10}, of 18.09 mg/kg egg dw for larval survival.

We still believe that all appropriate data from this study should be used and that the realistic scenario should be assumed, namely, that the lost fry had the same rates of mortality and deformity as the fry not lost. EPA did not provide any justification for using the worst case assumption rather than the realistic scenario. In the course of conducting standard toxicity tests in the laboratory, based on the expertise of those who conduct them, it has been observed that dead fish actually collect at the bottom of the aquarium not at the top, where fish would be more likely to be lost in an overflow event. Therefore, based on what has been observed in standard toxicity tests, EPA should use the realistic assumption, and continue to use the entire data set that provides both survival and deformity information, rather than just using survival data from only one portion of the test.

We also believe there is no valid reason to use the deformity-alone endpoint when the combined survival and deformities endpoint is available. In fact, this is consistent with the EPA's previous approach in the 2013 ammonia criteria document, in which they used the combined survival and growth endpoints, termed "biomass" (EPA 2013). Additionally, there were no difficulties in using TRAP to fit the combined data, and these data and resulting graphs are provided in Appendix C, Figure 1 of the EPA 2015 draft Se criteria document.

In summary, we believe that: (1) data for the overflow aquaria should not be excluded; (2) there is no reason to assume that the fish lost to the overflow were dead or deformed (similar mortality and deformity rates would have been expected in the no-overflow aquaria which had similar egg Se concentrations); and, (3) the most comprehensive endpoint is a combination of larval mortality and deformities, not the truncated study data used by EPA. Following these considerations, the EC_{10} for the realistic scenario, as derived by the EPA, is 21.16 mg/kg for egg/ovary. We recommend this EC_{10} as an appropriate and protective Brown Trout chronic value.

2.1.5 Toxicity Data for Less Sensitive Species

The draft fish egg Se criterion is based on toxicity data for 10 species and 9 genera. Most of the toxicity data are expressed as EC_{10}s, but due to the nature of the toxicity data, an EC_{24} was used for northern pike and an LOEC was used for fathead minnow (with a footnote for the latter, noting that additional data suggest that the LOEC is conservative). There are laboratory and field data for other fish species that are not sufficiently robust for calculation of a threshold (*e.g.*, EC_{10}), but adequate for demonstrating that these species are not among the four most sensitive, and therefore could be included to increase "n". This is not inconsistent with the EPA's current guidelines for ambient water quality criteria (AWQC) development (Stephan *et al.* 1985), which states that "*If the tests were conducted properly, acute values*

reported as "greater than" values and those which are above the solubility of the test material should be used, because rejection of such acute values would unnecessarily lower the Final Acute Value by eliminating acute values for resistant species."

As the EPA discusses in Appendix E of EPA (2015), there are several cyprinid species with sustainable reproducing populations that have WB Se concentrations greater than the draft WB Se criterion of 8.0 mg/kg-dw. The information (included in Appendix E) could be used to increase the number of genera in the species sensitivity distribution, including Central Stonerollers (*Campostoma anomalum*), Red Shiner (*Cyprinella lutrensis*), and Sand Shiner (*Notropis stramineus*). These species were able to maintain successfully-reproducing populations (similar to their populations at low Se locations) with WB tissue concentrations over 40 mg/kg dw in a study conducted near Pueblo, Colorado (EPA 2015; Table E-18 and GEI 2007). Because these species are insensitive to elevated Se, they would not be in the top four most sensitive genera; however, they can be included in the total number of species. Inclusion of these fish species would increase the "n" from 15 to 18 (implications of changing "n" on the criterion is provided in Section 2.2).

2.2 Derivation of Tissue Criterion Elements

2.2.1 Updates to the Egg/Ovary Criterion

Implementing the data usage modifications discussed above (*i.e.*, Section 2.1) results in changes to the criteria calculations. The following is a summary of our recommended modifications:

- Eliminate the White Sturgeon data. Although a SMCV of 17.8 mg/kg can be calculated as the geometric mean of the four EC_{10}s calculated by EPA, any such calculation is not technically defensible given the few data points and only one partial response.
- Update the Bluegill GMCV to 22.57 mg/kg
    - Result of excluding the data from the two Hermanutz *et al.* (1992, 1996) studies
- Update the Brown Trout SMCV to 21.16 mg/kg
    - Result of using all data (*i.e.*, both survival and deformity) with the realistic assumption for addressing the issue of the fry lost during the accident that occurred during the study
- Include three additional fish species to increase "n" based on observed insensitivity to Se, similar to inclusion by EPA of crustacean "placeholder taxa" to fulfill the 8-family rule and increase "n".

The order and chronic values for the top four most sensitive species change as a result of the above (Table 1). We recommend that the EPA consider these scientifically-defensible data for relevant species.

Fish Tissue-based Toxicity Data

- Given the very large uncertainties in the concentration-response data for White Sturgeon, the EPA should not use these data.
- We also strongly recommend that the EPA exclude the Bluegill EC_{10} of 11.36 mg/kg-dw derived from the data presented in Hermanutz *et al.* (1992, 1996), which is technically flawed, inconsistent with the laboratory results of Doroshov *et al.* (1992) and Coyle *et al.* (1993), and inconsistent with the field data presented in Finley and Garrett (2007).

- Finally, we recommend that the EPA reconsider the EC_{10} for Brown Trout, given that the most comprehensive endpoint is combined larval mortality and deformities, which results in an EC_{10} of 21.16 mg/kg-dw based on the realistic assumption for addressing fry lost during the study.

Original letter contains Table 1 – Modified version of Table 3.2 of EPA (2015) following adjustments to chronic values based on review and analysis of study data. See original letter.

EPA-HQ-OW-2004-0019-0391-A1; North American Metals Council (NAMC); Posted 10/14/2015

The available, technically defensible data clearly indicate that the egg/ovary criterion should be at least 20 mg/kg dw and the whole body/muscle criterion should be proportional. The 2015 EPA Selenium Draft is proposing a national selenium fish egg/ovary criterion driven by two studies with sturgeon: a partial response that is only slightly above a negligible effects endpoint, and a slight reduction in body weight. Neither of these responses could reasonably be related to effects that might threaten populations.

EPA-HQ-OW-2004-0019-0401-A1; Colorado Wastewater Utility Council; Posted 10/15/2015

We do have some concern with several of the data decisions made by EPA in calculating the chronic tissue criterion concentrations. We have provided recommendations on revisions to the White Sturgeon, Bluegill and Brown Trout genus mean chronic values (GMCVs) or species mean chronic values (SMCVs). Should our recommendations be accepted, the result would be minor, but significant, changes, with an egg/ovary criterion to 17.9 mg/kg, the whole-body criterion to 9.5 mg/kg, and the muscle criterion to 12.0 mg/kg. These revisions are based on our reanalysis of the studies, recalculation of tissue-to-tissue conversion factors, or both.

1.3 Reliance on Maternal-Transfer Related Data over Juvenile Survival

We would like to point out one additional point which we strongly agree with. We support EPA's decision to rely primarily on data from maternal-transfer studies and measures of larval survival and deformities, rather than relying on juvenile survival data, including overwinter survival, in developing the Se criteria. Although winter-stress may be a valid hypothesis, there are no data supporting its occurrence in the field (Janz 2008). Additionally, if other commenters have concerns with the exclusion of winter-stress data, we would recommend directing them to the Bluegill studies by Hermanutz et al. (1992, 1996), which included Bluegill exposed to year-round seasonal conditions in an outdoor test system, and thus include "winter stress" under natural conditions.

1.3.1 Bluegill

In the 2015 draft Se criteria document, EPA utilized three Bluegill studies in the derivation of the tissue-based criteria: Doroshov et al. (1992), Coyle et al. (1993), and Hermanutz et al. (1992, 1996). While we agree with the use of the Doroshov et al. (1992) and Coyle et al. (1993) studies, we have several concerns regarding the use of the Hermanutz et al. (1992, 1996) data.

EPA reported an egg/ovary EC_{10} of 12.68 mg/kg for the Hermanutz et al. (1992, 1996) studies. This value was derived through a reanalysis of the data using TRAP and combining results from Studies I and II (Hermanutz et al. 1992, 1996) – in other words, they actually combined data from studies conducted

over 2 different years, a data usage practice rarely used in criteria development. EPA elected to exclude Study III and several streams from Study II because they were considered to be "recovering" streams and were no longer receiving aqueous Se dosing. However, fish in these streams were obviously exposed to dietary Se throughout the study, which is the same exposure route that was used in other studies considered acceptable by EPA, such as the Linville (2006) White Sturgeon study, the Doroshev et al. (1992) Bluegill study, and the CP&L (1997) Largemouth Bass study. It is unclear why these dietary studies were included in the criteria development and the "recovering" streams from Studies II and III, which showed no effects, were not.

In addition, we previously expressed several concerns about the results of Studies I and II and the resulting analysis:

- The studies were conducted one year apart, which resulted in significant variation in all of the measured water quality parameters between the two studies.
- There were differences in how EPA analyzed and used the data from the two studies in Appendix C (see pages C-107 and C-108 of the 2014 draft Se criteria document).
- There were differences in egg and larvae survival between Studies I and II (see pages C-107 and C-108 of the 2014 draft Se criteria document).
- The ovary Se concentrations resulting from the same water exposures were quite different. These variations raise concerns that differences in Se uptake, bioaccumulation, exposure, or other factors could have been occurring between Studies I and II.
- In Study I, geometric mean ovary Se concentrations were higher in the 10 µg/L exposure (17.71 mg/kg) than the 30 µg/L exposure (15.46 mg/kg). Related to the concerns discussed above, this unexpected result indicates there may have been an issue with study conditions that caused inconsistencies with Se uptake, bioaccumulation, or exposure.

Based on these concerns, as well as the omission of any data from Study III, we recommend the Hermanutz et al. (1992, 1996) data could be completely removed from the database used for criteria derivation altogether. If only the other two chronic values for Bluegill (20.75 mg/kg [Doroshov et al. 1992] and 24.55 mg/kg [Coyle et al. 1993]) are used, a Bluegill egg/ovary GMCV of 22.57 mg/kg would be appropriate, and show that the value EPA derived from the Hermanutz et al. studies would be an outlier.

1.3.1.1 Use of Only Egg Data from Bluegill Studies with Egg and Ovary Data Available

Both Doroshov et al. (1992) and Coyle et al. (1993) present tissue data for both ovaries and eggs. It is unclear why EPA only used egg data from these studies and did not include both egg and ovary tissues as an average value. On page 78 of the 2014 draft Se criteria document, EPA suggests that it is appropriate to use the average of egg and ovary concentrations when both tissues are reported when deriving conversion factors (CFs). We recommend EPA include data for both ovaries and eggs, or at the very least provide details about its preference for egg versus ovary tissues, as this information will be important to make sure future toxicity testing and criteria implementation include measurement of Se in appropriate tissues.

1.3.2 Brown Trout

In the 2015 draft Se criteria document, EPA utilized Brown Trout data from Formation Environmental (2011). During this study, a tank overflow accident occurred which resulted in the loss of several study fish. In the 2014 draft, EPA presented two approaches for dealing with this loss of these study

organisms: 1) assume that all fry lost were dead or deformed ("worst case" assumption) and 2) assume that fry lost had the same rates of mortality and deformities as those not lost ("optimistic" assumption). In the 2014 draft, EPA chose to assume the "worst case" scenario and derived an egg/ovary EC_{10} of 15.91 mg/kg using the results from that scenario and the deformity alone endpoint. In the 2015 draft EPA acknowledged the uncertainty with how to best address the loss of fish, and decided to calculate an EC_{10} for survival only during the first portion of the test, prior to the accident. This resulted in calculation of an EC_{10} of 18.09 mg/kg egg dw for larval survival.

We still believe that all appropriate data from this study should be used and that the "optimistic" scenario should be considered, as it reflects what was observed in the remaining population (i.e., the fish not lost to overflow). EPA did not provide any reasons for why use of all data with the "optimistic" assumption is not a valid approach. As stated previously, throughout GEI's 25 years of conducting toxicity tests in our laboratory, we have observed that dead fish actually collect at the bottom of the aquarium not at the top, where fish would be more likely to be lost in an overflow event. Therefore, based on what has been observed in standard toxicity tests EPA should use their "optimistic" (i.e., what we consider to be realistic) assumption, and continue to use the entire data set that provides both survival and deformity information, rather than just using survival data from one portion of the test.

We also believe there is no valid reason to use the deformities endpoint alone when the combined survival and deformities endpoint is available. In fact, this is more in line with the EPA's previous approach in the 1999 ammonia criteria document where they used the combined survival and growth endpoint, termed "biomass". Additionally, there were no difficulties in using TRAP to fit the combined data, and these data and resulting graphs are provided in Appendix C, Figure 1 of the EPA 2015 draft Se criteria document. When these combined data are used, the EC_{10} for the "optimistic" assumption is 21.16 mg/kg for egg/ovary, which we recommend as an appropriate and protective Brown Trout chronic value.

1.3.3 White Sturgeon

In the 2015 draft criteria document EPA included data from the Linville (2006) White Sturgeon study. These data were not included in the 2014 draft, but White Sturgeon is now the most sensitive species in the database. This study was a dietary exposure in which adult female sturgeon were fed a Se spiked diet, and effects on larvae were measured. Larval effects were observed for edema and deformities.

EPA calculated an EC_{10} for total deformities (edema + skeletal) of 16.3 mg/kg using TRAP. This value was calculated based on a partial dose response. When data from this study are analyzed, TRAP warns that data should only be used for "exploratory purposes." Due to the partial response in the data, the calculation is highly dependent on the initial guess used for the slope in TRAP. In fact, in Appendix C (EPA 2015), EPA shows how choice of initial slope can affect these calculations, with EC_{10} values ranging from 16.3 mg/kg to 19.1 mg/kg when using different slopes. EPA selected the most conservative value for use in criteria development, even while acknowledging there was no scientific reason one value was more valid than another (and, in fact, all calculated values were statistically identical).

Generally, use of an EC_{10} based on a partial response is not appropriate for national criteria development, especially when it results in a value becoming the "most sensitive" and thereby driving the final criterion. In fact, on page 33 of the 2015 draft criteria document EPA states that "an EC_{10} based on only one partial response would not ordinarily be included in the data set". A similar partial response was observed in the Fathead Minnow data from the GEI 2008 study; EPA excluded these Fathead

Minnow data from the chronic dataset because of an "insufficient response". EPAs reasoning for using the White Sturgeon data that also had only a partial response is because there are data that suggest that the federally-listed Green Sturgeon is also sensitive to selenium. The Green Sturgeon study consisted of effects on survival and percent body weight in juvenile sturgeon and is not comparable to the reproductive endpoints in all other studies used for criteria development. However, we realize that EPA is concerned with protecting any threatened or endangered species, and the criteria document states that the White Sturgeon serves as a surrogate for other sturgeon as well.

Although the White Sturgeon data are somewhat questionable, they are important data due to the threatened or endangered listings of other species of sturgeon. However, we do recommend revisions to the EC_{10} value used for criteria calculations. As stated previously, the EC_{10} is based on only a partial response, therefore when the threshold sigmoid nonlinear regression model in TRAP is used, several curves may be fit by varying the slope used in the calculation. In Appendix C of the 2015 EPA criteria document, four EC_{10} values have been calculated, all with the same goodness of fit. While EPA chose the most conservative value for use in criteria calculations, we recommend use of the geometric mean of the four EC_{10}s, as they are all equally valid. This results in an egg/ovary EC_{10} of 17.8 mg/kg dw for White Sturgeon (Table 2).

4. Conclusions

Overall, the 2015 draft Se criteria document, including the tissue-based criteria approach, is a significant improvement over the 2004 draft criteria document. We strongly support EPA's decision to develop tissue-based Se criteria that are toxicologically and ecologically relevant. While we support the overall approach and core of the 2015 draft Se criteria document, we have several recommended revisions and considerations that, if considered by EPA, could significantly improve the document and resulting Se criteria.

5.1 Reevaluation of Acceptable Studies

We reviewed all of the reproductive toxicity study data deemed acceptable by EPA in the 2015 draft Se criteria document. Data were presented for ten fish genera. Overall, we concur with most of the data usage decisions made by EPA, but have comments and suggestions on some of the data that were used to develop the egg/ovary chronic criterion (and subsequently, the whole-body and muscle criteria).

Specifically, we had comments on usage of specific White Sturgeon, Bluegill and Brown Trout data in the criteria calculations.

- White Sturgeon – We recommend using the geometric mean of all the EC_{10}s calculated by EPA, as the goodness-of-fit is equal for all curves, therefore all EC_{10}s are equally appropriate. The recommended egg/ovary EC_{10} value, which is equivalent to the SMCV, is 17.8 mg/kg.
- Bluegill – We have concerns about the data used from the Hermanutz et al. (1992, 1996) studies. We recommend rejecting data from all Hermanutz studies. Using only data from the other two studies, the updated Bluegill egg/ovary GMCV is 22.57 mg/kg, with an accompanying whole-body value of 10.58 mg/kg using regression-based CF.
- Brown Trout – We recommend using the Brown Trout EC_{10} calculated under the "optimistic"/realistic assumption for dealing with the lab accident that resulted in loss of study organisms in the Formation Environmental (2011) study. The recommended EC_{10} value, which is

equivalent to the SMCV, is 21.16 mg/kg, with an accompanying whole-body value of 14.59 mg/kg based on updated CFs.

- We developed regression-based CFs for translating between egg/ovary and whole-body. When the regression relationship is strong, we recommend using regression-based CFs instead of median ratio-based CFs. Incorporation of these suggested changes results in updated egg/ovary, whole-body, and muscle chronic criteria that are even more scientifically defensible and consistent with EPA's other data-usage decisions (Table 13).

EPA-HQ-OW-2004-0019-0400-A1; The National Mining Association (NMA); Posted 10/15/2015

We do have some concerns with several of the data decisions made by EPA in calculating the chronic tissue criterion concentrations. We have provided recommendations on revisions to the White Sturgeon, Bluegill and Brown Trout genus mean chronic values (GMCVs) or species mean chronic values (SMCVs). Should our recommendations be accepted, the result would be small, but significant, changes, with an egg/ovary criterion to 17.9 mg/kg, the whole-body criterion to 9.5 mg/kg, and the muscle criterion to 12.0 mg/kg. These revisions are based on our reanalysis of the studies, recalculation of conversion factors, or both.

1.6 Reliance on Maternal Transfer Rather Than Juvenile Survival Data

We would like to point out one additional point which we strongly agree with. We support EPA's decision to not rely on juvenile survival data, including overwinter survival, in developing the Se criteria. Although winter-stress may be a valid hypothesis, there are no data supporting its occurrence in the field (Janz 2008). Additionally, if other commenters have concerns with the exclusion of winter-stress data, we would recommend directing them to the Bluegill studies by Hermanutz et al. (1992, 1996), which included Bluegill exposed to year-round seasonal conditions in an outdoor test system, and thus include "winter stress" under natural conditions.

1.6.1 Bluegill

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EPA reported an egg/ovary EC_{10} of 12.68 mg/kg for the Hermanutz et al. (1992, 1996) studies. This value was derived through a reanalysis of the data using TRAP and combining results from Studies I and II (Hermanutz et al. 1992, 1996) – in other words, they actually combined data from studies conducted over two different years, a data usage practice rarely used in criteria development. EPA elected to exclude Study III and several streams from Study II because they were considered to be "recovering" streams and were no longer receiving aqueous Se dosing. However, fish in these streams were obviously exposed to dietary Se throughout the study, which is the same exposure route that was used in other studies considered acceptable by EPA, such as the Linville (2006) White Sturgeon study, the Doroshev et al. (1992) Bluegill study, and the CP&L (1997) Largemouth Bass study. It is unclear why these dietary studies were included in the criteria development and the "recovering" streams from Studies II and III, which showed no effects, were not.

In addition, we previously expressed several concerns about the results of Studies I and II and the resulting analysis:

- The studies were conducted 1 year apart, which resulted in significant variation in all of the measured water quality parameters between the two studies.
- There were differences in how EPA analyzed and used the data from the two studies in Appendix C (see pages C-107 and C-108 of the 2014 draft Se criteria document).
- There were differences in egg and larvae survival between Studies I and II (see pages C-107 and C-108 of the 2014 draft Se criteria document).
- The ovary Se concentrations resulting from the same water exposures were quite different. These variations raise concerns that differences in Se uptake, bioaccumulation, exposure, or other factors could have been occurring between Studies I and II.
- In Study I, geometric mean ovary Se concentrations were higher in the 10 µg/L exposure (17.71 mg/kg) than the 30 µg/L exposure (15.46 mg/kg). Related to the concerns discussed above, this unexpected result indicates there may have been an issue with study conditions that caused inconsistencies with Se uptake, bioaccumulation, or exposure.

Based on these concerns, as well as the omission of any data from Study III, we recommend the Hermanutz et al. (1992, 1996) data could be completely removed from the database used for criteria derivation altogether. If only the other two chronic values for Bluegill (20.75 mg/kg [Doroshov et al. 1992] and 24.55 mg/kg [Coyle et al. 1993]) are used, a Bluegill egg/ovary GMCV of 22.57 mg/kg would be appropriate, and show that the value EPA derived from the Hermanutz et al. studies would be an outlier.

1.6.1.1 Use of Only Egg Data from Bluegill Studies with Egg and Ovary Data Available

Both Doroshov et al. (1992) and Coyle et al. (1993) present tissue data for both ovaries and eggs. It is unclear why EPA only used egg data from these studies and did not include both egg and ovary tissues as an average value. On page 78 of the 2014 draft Se criteria document, EPA suggests that it is appropriate to use the average of egg and ovary concentrations when both tissues are reported when deriving CFs. We recommend EPA include data for both ovaries and eggs, or at the very least provide details about its preference for egg versus ovary tissues, as this information will be important to make sure future toxicity testing and criteria implementation include measurement of Se in appropriate tissues.

1.6.2 Brown Trout

In the 2015 draft Se criteria document, EPA utilized Brown Trout data from Formation Environmental (2011). During this study, a tank overflow accident occurred which resulted in the loss of several study fish. In the 2014 draft, EPA presented two approaches for dealing with this loss of these study organisms: 1) assume that all fry lost were dead or deformed ("worst case" assumption) and 2) assume that fry lost had the same rates of mortality and deformities as those not lost ("optimistic" assumption). In the 2014 draft, EPA chose to assume the "worst case" scenario and derived an egg/ovary EC_{10} of 15.91 mg/kg using the results from that scenario and the deformity alone endpoint. In the 2015 draft EPA acknowledged the uncertainty with how to best address the loss of fish, and decided to calculate an EC_{10} for survival only during the first portion of the test, prior to the accident. This resulted in calculation of an EC_{10} of 18.09 mg/kg egg dw for larval survival.

We still believe that all appropriate data from this study should be used and that the "optimistic" scenario should be considered, as it reflects what was observed in the remaining population (i.e., the fish not lost to overflow). EPA did not provide any reasons for why use of all data with the "optimistic" assumption is not a valid approach. As stated previously, throughout GEI's 25 years of conducting toxicity tests in our laboratory, we have observed that dead fish actually collect at the bottom of the aquarium not at the top, where fish would be more likely to be lost in an overflow event. Therefore, based on what has been observed in standard toxicity tests EPA should use their "optimistic" (i.e., what we consider to be realistic) assumption, and continue to use the entire data set that provides both survival and deformity information, rather than just using survival data from one portion of the test.

We also believe there is no valid reason to use the deformities endpoint alone when the combined survival and deformities endpoint is available. In fact, this is more in line with the EPA's previous approach in the 1999 ammonia criteria document where they used the combined survival and growth endpoint, termed "biomass." Additionally, there were no difficulties in using TRAP to fit the combined data, and these data and resulting graphs are provided in Appendix C, Figure 1 of the EPA 2015 draft Se criteria document. When these combined data are used, the EC_{10} for the "optimistic" assumption is 21.16 mg/kg for egg/ovary, which we recommend as an appropriate and protective Brown Trout chronic value.

1.6.3 White Sturgeon

In the 2015 draft criteria document EPA included data from the Linville (2006) White Sturgeon study. These data were not included in the 2014 draft, but White Sturgeon is now the most sensitive species in the database. This study was a dietary exposure in which adult female sturgeon were fed a Se spiked diet, and effects on larvae were measured. Larval effects were observed for edema and deformities.

EPA calculated an EC_{10} for total deformities (edema + skeletal) of 16.3 mg/kg using TRAP. This value was calculated based on a partial dose response. When data from this study are analyzed, TRAP warns that data should only be used for "exploratory purposes." Due to the partial response in the data, the calculation is highly dependent on the initial guess used for the slope in TRAP. In fact, in Appendix C (EPA 2015), EPA shows how choice of initial slope can affect these calculations, with EC_{10} values ranging from 16.3 mg/kg to 19.1 mg/kg when using different slopes. EPA selected the most conservative value for use in criteria development, even while acknowledging there was no scientific reason one value was more valid than another (and, in fact, all calculated values were statistically identical).

Generally, use of an EC_{10} based on a partial response is not appropriate for national criteria development, especially when it results in a value becoming the "most sensitive" and thereby driving the final criterion. In fact, on page 33 of the 2015 draft criteria document EPA states that "an EC_{10} based on only one partial response would not ordinarily be included in the data set." A similar partial response was observed in the Fathead Minnow data from the GEI 2008 study; EPA excluded these Fathead Minnow data from the chronic dataset because of an "insufficient response." EPA's reasoning for using the White Sturgeon data that had only a partial response is that there are data that suggest that the federally-listed Green Sturgeon is also sensitive to selenium. The Green Sturgeon study consisted of effects on survival and percent body weight in juvenile sturgeon and is not comparable to the reproductive endpoints in all other studies used for criteria development. However, we realize that EPA is concerned with protecting any threatened or endangered species, and the criteria document states that the White Sturgeon serves as a surrogate for other sturgeon as well.

Although the White Sturgeon data are somewhat questionable, they are important data due to the threatened or endangered listings of other species of sturgeon. However, we do recommend revisions to the EC_{10} value used for criteria calculations. As stated previously, the EC_{10} is based on only a partial response, therefore when the threshold sigmoid nonlinear regression model in TRAP is used, several curves may be fit by varying the slope used in the calculation. In Appendix C of the 2015 EPA criteria document, four EC_{10} values have been calculated, all with the same goodness of fit. While EPA chose the most conservative value for use in criteria calculations, we recommend use of the geometric mean of the four EC_{10}s, as they are all equally valid. This results in an egg/ovary EC_{10} of 17.8 mg/kg dw for White Sturgeon (Table 2).

3.3 Derivation of Tissue Criterion Elements

3.3.1 Updates to Egg/Ovary Criterion

Implementing the data usage modifications discussed above (Section 3.1.1) results in changes to the criteria calculations. The following is a summary of our recommended modifications:

- Update the White Sturgeon SMCV to 17.8 mg/kg
- Result of calculating the geometric mean of the four EC10s calculated by EPA
- Update the Bluegill GMCV to 22.57 mg/kg
- Result of excluding the Hermanutz et al. (1992, 1996) studies
- Update the Brown Trout SMCV to 21.16 mg/kg
- Result of using all data (survival and deformity) with the "optimistic"/realistic assumption for addressing the issue of the fry lost during the study
- Include three additional fish species to increase N based on observed insensitivity to Se

The order and chronic values for the top four most sensitive species change as a result of the modifications to the White Sturgeon, Bluegill and Brown Trout GMCVs (Table 1). In addition, the sample size increases from N=15 to N=18. Using the data presented in Table 3, an updated egg/ovary criterion of 17.9 mg/kg can be derived using EPA criteria calculation methodology (Stephan et al. 1985; Table 2). We recommend EPA considers this recalculated criterion, as it is based on sound data for relevant species.

Original letter contains Table 1 – Modified version of Table 3.2 of the 2015 draft Se criteria document following adjustments to chronic values for White Sturgeon, Bluegill, and Brown Trout based on review and analysis of study data. See original letter.

Original letter contains Table 2 – Updated calculation of egg/ovary fish tissue-based Se criterion based on modifications in Table 2 (N= 14 genera, R = sensitivity rank in database). See original letter.

4. Conclusions

Overall, the 2015 draft Se criteria document, including the tissue-based criteria approach, is a significant improvement over the 2004 draft criteria document. We strongly support EPA's decision to develop tissue-based Se criteria that are toxicologically and ecologically relevant. While we support the overall approach and core of the 2015 draft Se criteria document, we have several recommended revisions and considerations that, if considered by EPA, could significantly improve the scientific validity of the document and resulting Se criteria.

5.1 Reevaluation of Acceptable Studies

We reviewed all of the reproductive toxicity study data deemed acceptable by EPA in the 2015 draft Se criteria document. Data were presented for ten fish genera. Overall, we concur with most of the data usage decisions made by EPA, but have comments and suggestions on some of the data that were used to develop the egg/ovary chronic criterion (and subsequently, the whole-body and muscle criteria).

Specifically, we had comments on usage of specific White Sturgeon, Bluegill and Brown Trout data in the criteria calculations.

- White Sturgeon – We recommend using the geometric mean of all the EC_{10}s calculated by EPA, as the goodness-of-fit is equal for all curves, therefore all EC_{10}s are equally appropriate. The recommended egg/ovary EC_{10} value, which is equivalent to the SMCV, is 17.8 mg/kg.
- Bluegill – We have concerns about the data used from the Hermanutz et al. (1992, 1996) studies. We recommend rejecting data from all Hermanutz studies. Using only data from the other two studies, the updated Bluegill egg/ovary GMCV is 22.57 mg/kg, with an accompanying whole-body value of 10.58 mg/kg using regression-based CF.
- Brown Trout – We recommend using the Brown Trout EC_{10} calculated under the "optimistic"/realistic assumption for dealing with the lab accident that resulted in loss of study organisms in the Formation Environmental (2011) study. The recommended EC_{10} value, which is equivalent to the SMCV, is 21.16 mg/kg, with an accompanying whole-body value of 14.59 mg/kg based on updated CFs.
- We developed regression-based CFs for translating between egg/ovary and whole-body. When the regression relationship is strong, we recommend using regression-based CFs instead of median ratio-based CFs.

Incorporation of these suggested changes results in updated egg/ovary, whole-body, and muscle chronic criteria that are even more scientifically defensible and consistent with EPA's other data-usage decisions (Table 13).

Comment Category 3.3 – Comments on Deriving Egg-Ovary Criterion Element Value

3.3 Summary

This section contains comments about EPA's method of deriving the egg-ovary criterion element. Specifically, the derivation of Species Mean Egg-Ovary Chronic Values (SMCVs), Genus Mean Egg-Ovary Chronic Values (GMCVs) and the Final Egg-Ovary Chronic Value (FCV). Included are comments concerning the identification of the four most sensitive Egg-Ovary GMCVs and the use of 5th percentile projection to select the FCV. Some commenters requested clarification on how the FCV was calculated using the GMCVs.

3.3 Response to comments

3.3 Responses concerning the derivation of the egg ovary criterion element value

Egg-ovary Equivalence

Regarding the comment on egg-ovary equivalence, EPA notes that the text in the criterion document actually states: "In this document, concentrations of selenium in ovaries are considered equivalent to concentrations of selenium in eggs because most studies measured selenium in the ovaries prior to spawning." The last part of the sentence is the relevant part as to why EPA considers theses tissues equivalent in the document.

From Section 6.1.8. Researchers often report concentrations of selenium in fish eggs or ovaries (e.g., Formation Environmental 2011; Formation Environmental 2012; Holm et al. 2005; Osmundson et al. 2007). Osmundson et al. (2007) found reduced levels of selenium in ovaries after spawning, presumably due to the loss of selenium through spawning and release of eggs with relatively high concentrations of selenium. Of the 14 chronic values determined from the maternal transfer reproductive studies, 11 values represent selenium measured in eggs. Three values represent selenium measured in the ovaries: Schultz and Hermanutz (1990), Hermanutz et al. (1992, 1996) and Carolina Power & Light (1997). However, information in two of these studies indicates that the concentrations of selenium in the ovaries were similar to concentrations in eggs. Schultz and Hermanutz (1990) measured selenium in fathead minnow ovaries at the end of the study from fish that presumably had spawned. The authors found the concentrations of selenium in the ovaries and embryos of the fathead minnows exposed to the same treatments to be similar. Hermanutz et al. (1992, 1996) sampled adult female bluegill just prior to spawning and at the end of the test (post spawning) and found no decreases in the concentration of selenium in the post-spawned fish. In the Carolina Power & Light (1997) study, the third study, selenium in ovaries of largemouth bass (Carolina Power & Light 1997) was measured from fish sampled just after spawning. No comparison to prespawning fish or selenium in eggs can be made for the largemouth bass study, however, the EC10 of 26.3 mg Se/kg ovary dw was mid-range in the SSD indicating this test was not overly conservative due to lower selenium measurements in post spawning ovaries. Based on the indications that the selenium concentrations in the ovaries were similar to that in eggs in the Schultz and Hermanutz (1990) and Hermanutz et al (1992, 1996) study observations stated above, egg selenium and ovary selenium were considered equal for the toxicity data set. Any potential error resulting from this

assumption would be conservative since the effect of spawning only lowers the selenium concentration in the ovary. EPA recognizes selenium ovary concentrations may vary in field collected samples due to fish reproductive cycles and will address such concerns in the implementation information. Although there is a strong correlation between predicted and observed egg-ovary concentration values, Figure 16 does show more data points above the y = x (observed egg-ovary concentration vs predicted egg- ovary concentration) line at low selenium concentrations. This result suggests the model underestimates bioaccumulation at low selenium concentrations. However, within the range of concentrations near the egg-ovary criterion element value, the relationship between predicted and observed selenium concentrations are evenly dispersed around the y = x line. Thus the model is unlikely to result in biased estimates near the egg-ovary criterion concentration, the focus of the criteria development.

GMCVs

Regarding the comment on the logic for setting the number of GMCVs to 14, the goal of aquatic life criteria is to ensure protection of populations of species representing the entire aquatic community, and not just fish, as described in the methodology for criteria development (Stephan et al. 1985). Estimated egg-ovary concentrations were originally calculated in 2014 for invertebrates as a point of reference to show that they were typically less sensitive then the fish represented in the SSD, and would therefore be protected by a tissue criterion based on fish. In the 2015 draft and 2016 final document, fish and invertebrate SMCVs and GMCVs are listed in separate tables, and whole body and estimated egg- ovary values for invertebrates have been removed from the two tables showing the distribution of GMCVs used in the Sensitivity Distribution for egg-ovary and whole body criteria, respectively.

A separate Table (5b) was added showing the measured whole body SMCVs and GMCVs for the three invertebrate taxa with relevant test data, as well as what the predicted whole body fish tissue concentrations would be after multiplying the measured invertebrate SMCV and GMCV by the median tropic level 2 to trophic level 3 trophic transfer function of 1.27. The results described in sections 3.1 demonstrate that invertebrates are less sensitive to selenium in fish, and while they are used implicitly in the SSD to fulfill taxonomic minimum data requirements, they are not included with fish values. These studies are taken into account as part of the total “N” in the criterion calculations, in accordance with the standard methodology for criteria development (EPA 2008).

Criteria are developed to protect the entire aquatic community, such that the available data should reflect the sensitivity range for various components (e.g., fish, invertebrates) of the aquatic system. Towards this end, invertebrate sensitivity to selenium was evaluated in terms of both measured whole body concentrations as well as in terms of what the whole body tissue concentration of a representative fish would be were it to consume each invertebrate with a whole body concentration at the SMCV and GMCV, by multiplying each invertebrate GMCV by 1.27, the median TTF for all fish species. When evaluated with or without the trophic level biomagnification, the available data demonstrate that compared to fish, invertebrates are not as sensitive to selenium, and do not comprise any of the four lowest GMCVs. They are used to fulfill the taxonomic minimum data requirements, and are counted in the total number of genera (“N”) in the calculations. We note the numeric impact of increasing “N” though inclusion of the invertebrate data in the “N” for the criterion calculation is minimal, reflecting an approximately 3% change in the egg-ovary criterion element value.

Regarding the comment on the number of GMCVs, EPA agrees that the invertebrate and the Gambusia data should not be represented in the egg-ovary sensitivity distribution, and they have been removed from that distribution.

3.3 Specific comments

EPA-HQ-OW-2004-0019-0390-A1; West Virginia Coal Association (WVCA); Posted 10/14/15

Calculation of Fish Body Burden Elements

The 1985 Guidelines provide two options for preparation of a numeric water quality criterion. Both processes begin with the compilation of a database of all available, qualifying aquatic life toxicity studies meeting the requirements of the 1985 Guidelines. In its 2014 peer review draft selenium criteria, EPA published an updated selenium database and received extensive comments regarding its data decisions. While EPA made some adjustments based on the comments received, EPA's database utilized for calculation of the body burden elements remains crippled by improper data decisions.

The draft body burden numbers are based on Genus Mean Chronic Values (GMCVs) calculated from the database, and the inclusion or exclusion of a specific study can materially affect the calculated selenium criteria. The egg-ovary element is calculated directly from available toxicity studies, whereas the whole body number is calculated from conversion of the egg-ovary concentrations for each genus to whole-body concentrations. The chronic criterion is calculated through a multi-step process following a statistical methodology based on qualifying toxicity tests for all available aquatic life species. However, the four lowest egg-ovary GMCVs largely determine the resultant numeric chronic criterion elements for fish tissue.

EPA-HQ-OW-2004-0019-0391-A1; North American Metals Council (NAMC); Posted 10/14/2015

2.2.6 Egg/Ovary Selenium Criterion Should Be at Least 20 mg/kg dw

As outlined above, the three studies that drive the egg/ovary selenium criterion below 20 mg/kg are technically flawed as is the historic winter stress syndrome that also limits the whole body criterion to 8.0 mg/kg whole body or 11.3 mg/kg muscle.

Eight of the ten fish species for which the EPA developed SMCVs/GMCVs are the same fish species for which DeForest *et al.* determined predicted no effect concentrations (PNEC).[47] The values are all >20 mg/kg dw other than the EPA's brown trout and bluegill data (Table 1). As previously noted, those data should also be >20 mg/kg dw.

Original letter contains Table 1 – Comparison of EPA SMCVs/GMCVs with DeForest et al. (2012) PNECs. See original letter. Table 1 contains footnote 48 in reference to "cutthroat trout."

The egg/ovary PNEC developed by DeForest *et al.* of 20 mg/kg dw is above the highest documented reference concentration of 19 mg/kg dw.[49] It was based on a species sensitivity distribution (SSD), was

published in an international peer-reviewed journal, and as the authors note, “should be considered a conservative, broadly applicable guideline.”

The 2015 EPA Selenium Draft considered two fish species not considered by DeForest *et al.*, the desert pupfish, at 27 mg/kg dw; and, the white sturgeon at 16.27 mg/kg dw. As detailed in Section 2.2.3, the white sturgeon study is flawed and should not have been included in the criterion derivation. Accordingly, the available, technically defensible data clearly indicate that the egg/ovary criterion should be at least 20 mg/kg dw and the whole body/muscle criterion should be proportional.

Field evidence also supports an egg/ovary criterion ≥20 mg/kg dw. For example, pages E31 to E36 in the 2015 EPA Selenium Draft document present a study of a contaminated creek (Denver, CO) that clearly demonstrates that fathead minnows have a relatively high tolerance to selenium based on the deformity data, which provide a fingerprint of selenium effects. That study’s findings relative to selenium, in which acute effects occurred related to other stressors, mirror data from Belews Lake, where fathead minnow were relatively insensitive to selenium as they were one of the few fish species left after other fish species had been lost from the lake.[50] Thus, the Schultz and Hermanutz study used by EPA to establish the proposed egg/ovary criterion was likely overly conservative because that study did not provide a clear endpoint as it was unbounded for fathead minnows.[51]

EPA-HQ-OW-2004-0019-0385-A2; Kentucky Division of Water (KDOW); Posted 10/13/2015

Acceptable study data representing twelve fish species were available to calculate the SMCV (Species Mean Chronic Value) and nine fish genera to calculate the Genus Mean Chronic Value (GMCV). The EPA considered fourteen genera to calculate the GMCV, but because the data indicate invertebrates are tolerant of high selenium concentrations, the invertebrate values were not included in deriving the FCV which is determined from the four most sensitive GMCVs.

The EPA also incorporated the 1985 Guidance (Stephan, *et al.* 1985) recommendations which include consideration of a commercially or recreationally important warm water species when determining appropriate data to calculate the GMCVs. This important consideration was also essential in developing Kentucky's selenium criteria. Like Kentucky, the EPA concluded that the Doroshov, *et al.* (1992) catfish (Ictaluridae) study contained unusable data because the mode of exposure was injection of the test fishes, rather than through diet *(cf.* the inclusion of Linville, 2006)

Comment Category 3.4 – Comments Deriving Whole Body and Muscle Criterion Element Values

3.4 Summary

This section focuses on comments about EPA's method of deriving the whole body criterion and muscle element. It includes comments concerning using egg-ovary and the measured egg-ovary/whole body or measured egg-ovary/ muscle ratios for calculating the whole body and muscle chronic values, the derivation of a generic muscle/whole body ratio, and the use of a taxonomic classification method to estimate conversion factors. Also presented are comments concerning derivation of a final whole body and muscle chronic values, including the identification of the four most sensitive whole body and muscle GMCVs and the use of the 5th percentile projection to select the final whole body and muscle criterion values. Some commenters recommended that regression-based conversion factors should be used instead of the median ratio-based approach. Also some commenters did not agree with the concept of generic muscle/whole body information, citing studies that illustrate variability associated with the spawning cycle, seasonal dietary changes, etc.

3.4 Response to comments

The majority of the data for the egg-ovary to whole body selenium relationship analysis came from Osmundson et al (2007) who did have egg data and whole body selenium concentration data from the same fish. The whole body selenium concentration was calculated by adding back the egg selenium that was removed for analysis. Osmundson et al (2007) had 9 of the 10 species in EPA's data set for this analysis. Coyle et al (1993) also added back egg selenium for the whole body same fish comparison. Formation (2011) and Doroshov et al. did not specify how the whole body selenium concentration was determined. Hermanutz (1996) and Hardy (2005) apparently measured whole body and egg selenium concentrations in different fish with the same exposure. EPA has added clarifying discussion to the section discussing fish tissue relationships.

Regarding the definition of a whole body tissue sample, the entire fish (carcass and visceral tissue) is homogenized, and then a sample of the homogenized tissue is collected and analyzed for selenium

3.4 Description of refined approach to deriving Conversion Factors (CFs), for conversions to whole body or muscle selenium concentrations

In the 2016 final document, EPA retained the methodology incorporated into the 2015 draft using species-specific data or most-taxonomically-proximate muscle to whole body, and egg-ovary to muscle, conversion factors to calculate CF values when matched pairs of selenium measurements in eggs and/or ovaries and whole body tissue or muscle were not available.

Species-specific data were used preferentially over other available data. When species-specific data were not available, EPA estimated CFs using sequentially higher taxonomic classifications (i.e., species, genus, family, order, then class) until one or more taxa for which a calculated CF value was available matched the taxon being considered. If the lowest matching taxon was common to more than one species with CF value available, EPA used the median CF from the matching species. EPA has decided to

retain the use of the median rather than a higher percentile as the general range of CFs is relatively narrow with the exception of the mountain whitefish, so use of a higher percentile threshold would allow the CF to be unduly influenced by this species. (See response below, and 2016 final document, Section 3)

3.4 EPAs Response to Conversion Factor Comments

EPA noted that both GEI and NAMC commented that conversion factors (CFs) derived using a median were inappropriate; GEI comments did not provide specific reasons for why medians were inappropriate, but rather, that regressions would be more appropriate, whereas NAMC noted that "in many cases, assumptions of linear regression were violated, and thus the results were unreliable." No specific details were provided by the commenters to describe how this conclusion was reached.

Given the commenters concern over the statistical basis of the derivation of the CFs, EPA examined the issue thoroughly.

First, EPA incorporated comments regarding the use of directly calculated muscle or whole body tissue selenium concentrations rather than an estimated value using conversion factors. For whole body, this resulted in the use of empirically-derived chronic toxicity values for bluegill, and brown trout. For muscle this resulted in the use of empirically derived chronic values for bluegill, cutthroat trout, white sturgeon and northern pike. These empirically derived whole body or muscle toxicity values were used preferentially over CF-derived chronic values.

Second, EPA evaluated an approach using ordinary least squares (OLS) regression. For each species 2 regressions were performed: standard OLS regression (xy OLS), and then a second regression with the axes switched (yx OLS). EPA noted that OLS regression only considers vertical fitting error resulting in uncertainties in predictions depend on which tissue is assigned to which axis. Given the uncertainty associated with OLS, EPA then used total least squares regression (TLS) in the derivation of CFs. Unlike OLS, which only considers vertical fitting error, TLS considers both vertical and horizontal fitting error. CFs derived using TLS typically fell between the values derived using xy OLS or yxOLS.

In general, the median and the TLS predicted CFs will be similar under either of the following conditions: (a) log-log slope near 1.0, or (b) criterion near the middle of the observed data range of tissue concentrations for the species, irrespective of slope or R-square. They will be distant from each other when both of the following conditions simultaneously occur: (c) log-log slope distant from 1.0, and (d) criterion distant from the center of the data range, again irrespective of R-squared.

Regarding the median, EPA applied statistical criteria to the available data plots to determine whether the relationship is strong enough to obtain a median. The commenter's statement that a ratio is analogous to a constrained regression is incorrect. This is because a median is a non-parametric measure of central tendency, and is not subject to assumptions of linearity. It is in not analogous to a constrained regression, except for the fact that it is a single parameter, and does not have a y-intercept term.

Based on EPA's in-depth analyses as a result of public comments, it was determined that all 4 approaches yielded CFs that were similar. EPA decided to retain the use of the median to derive CFs in

the criteria document for several reasons: because it is a non-parametric measure of central tendency that does not required an assumption of linearity; it is direct and simple analysis that can easily be verified and replicated with simple spreadsheet tools, and the more complex analyses such as TLS did not yield results that were different or superior. A chart comparing the CFs derived by each method is shown in Appendix N.

Regarding variability in egg-ovary to whole body CFs, in the EPA dataset, variability in egg-ovary to whole body CFs was relatively low for the majority of species, ranging from 1.38-2.44 for 16 of 17 species. The inter-species range of CFs for egg-ovary to muscle was comparable.

Regarding inter-species variability in conversion factors, while not all fish taxa have been studied, major freshwater fish families that are phylogenetically distinct and diverse are represented, and yet there is only roughly a two-fold variability between them. Given the inherent variability in sensitivity observed even among species with repeated toxicity tests, 2-fold variability in CFs is a small level of uncertainty compared to uncertainty associated with other pollutants. EPA agrees that more data for the tissue conversion factors are always desirable. EPA is moving forward with the current database to ensure protection of aquatic life based on the current state-of-the- science.

For those species of fish with neither sufficient data to directly calculate an egg-ovary to whole body CF, nor data to calculate a conversion factor for egg-ovary to muscle or whole body to muscle, EPA estimated CF following the approach described for the estimation of TTF values in the 2016 Selenium Criterion document. In this approach, EPA sequentially considered higher taxonomic classifications until one or more taxa for which a calculated CF value was available matched the taxon being considered, and if the lowest matching taxon was common to more than one species with a CF value available, EPA used the median CF from the matching species. For fish species without sufficient data to directly calculate an egg-ovary to whole body CF but which had sufficient data to calculate a conversion factor for either egg-ovary to muscle or whole body to muscle, EPA followed a two-stage approach based on taxonomic similarity. If a fish species had a species- specific egg-ovary to muscle conversion factor, but no whole-body data with which to calculate an egg to whole body CF, then available data for other species were used to estimate a muscle- to-whole-body conversion factor for that species based on taxonomic relatedness. The estimated muscle-to-whole-body factor would be multiplied by the directly measured egg-ovary- to-muscle factor to estimate an egg-ovary-to-whole-body CF for that species.

Typographical errors in CF values were corrected based on comments.

3.4 Specific comments

EPA-HQ-OW-2004-0019-0387-A1; Colorado Department of Public Health & Environment; Posted 10/14/2015

EPA used conversion factors to derive whole-body and muscle concentrations from egg/ ovary values. Were there any studies that provided egg/ ovary data in addition to whole-body or muscle data? If so, it seems appropriate to use actual measured values instead of translated values, which have an added element of uncertainty.

3.3.2 Updates to Whole-body Criterion

In Section 3.1.5.2 of the 2015 draft Se criteria document, EPA presents its approach for deriving a whole-body-based criterion. To develop whole-body chronic values, EPA translated the egg/ovary chronic values used to develop the egg/ovary criterion using egg/ovary to whole-body CFs (Table 3.5 of the 2015 draft Se criteria document). These converted values were then used to calculate a whole-body criterion of 8.0 mg/kg. EPA again used a sample size of 15, which included the three invertebrate-based values, the two assumed crustaceans, and Gambusia.

As we previously commented, in the past, EPA has used regression-based CFs (e.g., Bluegill CF from EPA's 2004 draft Se criteria document). However, in the 2015 draft Se criteria document, EPA developed CFs based on the median of available matched egg/ovary and whole-body Se data. We believe a more appropriate method would be to use regression-based egg/ovary to whole-body translators when appropriate (i.e., when the regression relationship had an R2 value >0.70). We translated the egg/ovary database to whole-body and derived an updated whole-body criterion (Table 3 and Table 4). For Oncorhynchus, individual CFs were used to translate each species individually (O. mykiss and O. clarkii), but an overall regression using data for both species was used to convert the Oncorhynchus egg/ovary GMCV to a whole-body GMCV of 14.99 mg/kg (Table 6). In addition, as discussed in Section 4.3.1, we corrected and updated the median-based CFs based on our review of EPA's data and addition of our data; these updates were incorporated here. Many of these recommendations, which are based on data EPA had in 2014 or provided in our earlier review, were not used, and with no reasons provided.

The whole-body criterion should also be adjusted as a result of our updates to the White Sturgeon, Bluegill, and Brown Trout egg/ovary chronic values.

Incorporating our modifications to the egg/ovary to whole-body translators, updated toxicity values for White Sturgeon, Bluegill, and Brown Trout, and increasing the sample size from 15 to 18 results in an updated whole-body criterion of 9.55 mg/kg which can be derived using EPA criteria calculation methodology (Stephan et al. 1985; Table 7). We recommend EPA considers this recalculated criterion with regression-based CFs in place of median-based conversion factors when possible, as it is based on sound data for relevant species.

Original letter contains Table 3 – Modified version of Table 3.5 of the 2015 draft Se criteria document following adjustments to conversion factors and chronic values for White Sturgeon, Bluegill, and Brown Trout. See original letter.

Original letter contains Table 4 – Updated calculation of whole-body fish tissue-based Se criterion based on modifications, including use of EO/WB regressions (N = 18 genera, R = sensitivity rank in database). See original letter.

3.3.3 Updates to Muscle Criterion

In Section 3.1.5.3 of the 2015 draft Se criteria document, after presenting its approach for developing the egg/ovary criterion, EPA presents its approach for deriving a muscle-based criterion. To develop muscle chronic values, EPA translated the egg/ovary chronic values used to develop the egg/ovary criterion using egg/ovary to muscle CFs (Table 3.7 of the 2015 draft Se criteria document). These

converted values were then used to calculate a muscle-based criterion of 11.3 mg/kg. EPA again used a sample size of 15, which included the three invertebrate-based values, the two crustaceans and Gambusia.

As a result of our recommended updates to the White Sturgeon, Bluegill, and Brown Trout egg/ovary chronic values, the muscle criterion will also need to be adjusted.

Incorporating our suggested modifications results in several changes in the top four most sensitive species of the muscle-based toxicity database (Table 5). In addition, the sample size increases from N=15 to N=18 as a result of the additional fish species discussed previously. Using the data presented in Table 6 an updated muscle criterion of 11.96 mg/kg can be derived using EPA criteria calculation methodology (Stephan et al. 1985). We recommend EPA considers this recalculated criterion, as it is based on sound data for relevant species.

Original letter contains Table 5 – Modified version of Table 3.7 of the 2015 draft Se criteria document following adjustments to chronic values for White Sturgeon, Fathead Minnow, Bluegill, and Brown Trout based on review and analysis of study data. See original letter.

Original letter contains Table 6 – Updated calculation of muscle fish tissue-based Se criterion based on modifications to Table 8 (N = 18 genera, R = sensitivity rank in database). See original letter.

4.3 Additional Discussion of Tissue Criterion Elements

4.3.1 Conversion Factors

As part of our previous review, we conducted an evaluation of the CFs developed by EPA in the 2014 draft Se criteria document, we reviewed all of the data used and corrected values where mistakes were found. A detailed evaluation of this issue is also presented by NAMC-SWG (2014).

In addition to reviewing EPA's data and calculations, we also compiled matched tissue data from studies conducted by GEI to supplement the CF database (GEI Appendix A, 2014). We also used the matched egg/ovary, whole-body, and muscle Se data provided in the 2014 draft Se criteria document, which was further updated by GEI as described above, and developed regression-based CFs (Table 9; Appendix A). When the regression has a relatively high goodness of fit (i.e., when R2 is at least 0.70), we recommend using the regression equation in place of the median (or geometric mean) ratios, as the regression better predicts tissue concentrations, particularly at the high and low ends of the spectrum. Where the strength of the regression is not as high (e.g., creek chub, Fathead Minnow, mountain whitefish), it may be more appropriate to use the median or geometric mean CF to represent the central tendency of the relationship. As shown in Section 3.2.2, we used the regression-based CFs where appropriate to translate the updated egg/ovary criterion database for these species to whole-body for the purposes of deriving the updated whole-body criterion. For the remaining species, we used the updated and new median ratio-based CFs.

EPA-HQ-OW-2004-0019-0400-A1; The National Mining Association (NMA); Posted 10/15/2015

3.3.2 Updates to Whole-body Criterion

In Section 3.1.5.2 of the 2015 draft Se criteria document, EPA presents its approach for deriving a whole-body-based criterion. To develop whole-body chronic values, EPA translated the egg/ovary chronic values used to develop the egg/ovary criterion using egg/ovary to whole-body CFs (Table 3.5 of the 2015 draft Se criteria document). These converted values were then used to calculate a whole-body criterion of 8.0 mg/kg. EPA again used a sample size of 15, which included the three invertebrate-based values, the two assumed crustaceans, and Gambusia.

As we previously commented, in the past EPA has used regression-based CFs (e.g., Bluegill CF from EPA's 2004 draft Se criteria document). However, in the 2015 draft Se criteria document, EPA developed CFs based on the median of available matched egg/ovary and whole-body Se data. We believe a more appropriate method would be to use regression-based egg/ovary to whole-body translators when appropriate (i.e., when the regression relationship had an R2 value >0.70). We translated the egg/ovary database to whole-body and derived an updated whole-body criterion (Table 3 and Table 4). For Oncorhynchus, individual CFs were used to translate each species individually (O. mykiss and O. clarkii), but an overall regression using data for both species was used to convert the Oncorhynchus egg/ovary GMCV to a whole-body GMCV of 14.99 mg/kg (Table 6). In addition, as discussed in Section 4.3.1, we corrected and updated the median-based CFs based on our review of EPA's data and addition of our data; these updates were incorporated here. Many of these recommendations, which are based on data EPA had in 2014 or were provided in our earlier review in 2014, were not used, with no reasons provided.

The whole-body criterion should also be adjusted as a result of our updates to the White Sturgeon, Bluegill, and Brown Trout egg/ovary chronic values.

Incorporating our modifications to the egg/ovary to whole-body translators, updated toxicity values for White Sturgeon, Bluegill, and Brown Trout, and increasing the sample size from 15 to 18 results in an updated whole-body criterion of 9.55 mg/kg which can be derived using EPA criteria calculation methodology (Stephan et al. 1985; Table 7). We recommend EPA considers this recalculated criterion with regression-based CFs in place of median-based conversion factors when possible, as it is based on sound data for relevant species.

Original letter contains Table 3 – Modified version of Table 3.5 of the 2015 draft Se criteria document following adjustments to conversion factors and chronic values for White Sturgeon, Bluegill, and Brown Trout recommended by GEI Consultants, Inc. See original letter.

Original letter contains Table 4 – Updated calculation of whole-body fish tissue-based Se criterion based on modifications recommended by GEI Consultants, Inc., including use of EO/WB regressions (N= 14 genera, R = sensitivity rank in database). See original letter.

3.3.3 Updates to Muscle Criterion

In Section 3.1.5.3 of the 2015 draft Se criteria document, after presenting its approach for developing the egg/ovary criterion, EPA presents its approach for deriving a muscle-based criterion. To develop muscle chronic values, EPA translated the egg/ovary chronic values used to develop the egg/ovary criterion using egg/ovary to muscle CFs (Table 3.7 of the 2015 draft Se criteria document). These converted values were then used to calculate a muscle-based criterion of 11.3 mg/kg. EPA again used a

sample size of 15, which included the three invertebrate-based values, the two crustaceans and Gambusia.

As a result of our recommended updates to the White Sturgeon, Bluegill, and Brown Trout egg/ovary chronic values, the muscle criterion will also need to be adjusted.

Incorporating our suggested modifications results in several changes in the top four most sensitive species of the muscle-based toxicity database (Table 5). In addition, the sample size increases from N=15 to N=18 as a result of the additional fish species discussed previously. Using the data presented in Table 6 an updated muscle criterion of 11.96 mg/kg can be derived using EPA criteria calculation methodology (Stephan et al. 1985). We recommend EPA considers this recalculated criterion, as it is based on sound data for relevant species.

Original letter contains Table 5 – Modified version of Table 3.7 of the 2015 draft Se criteria document following adjustments to chronic values for White Sturgeon, Fathead Minnow, Bluegill, and Brown Trout based on review and analysis of study data. See original letter.

Original letter contains Table 6 – Updated calculation of muscle fish tissue-based Se criterion based on modifications to Table 8 (N= 14 genera, R = sensitivity rank in database). See original letter.

4.3 Additional Discussion of Tissue Criterion Elements

4.3.1 Conversion Factors

As part of our previous review, we conducted an evaluation of the conversion factors (CFs) developed by EPA in the 2014 draft Se criteria document wherein we reviewed all of the data used and corrected values where mistakes were found. A detailed evaluation of this issue is also presented by NAMC-SWG (2014).

In addition to reviewing EPA's data and calculations, we also compiled matched tissue data from studies conducted by GEI to supplement the CF database (GEI Appendix A, 2014). We also used the matched egg/ovary, whole-body, and muscle Se data provided in the 2014 draft Se criteria document, which was further updated by GEI as described above, and developed regression-based CFs (Table 9; GEI Appendix A). When the regression has a relatively high goodness of fit (i.e., when R2 is at least 0.70), we recommend using the regression equation in place of the median (or geometric mean) ratios, as the regression better predicts tissue concentrations, particularly at the high and low ends of the spectrum. Where the strength of the regression is not as high (e.g., creek chub, Fathead Minnow, mountain whitefish), it may be more appropriate to use the median or geometric mean CF to represent the central tendency of the relationship. As shown in Section 3.3.2, we used the regression-based CFs where appropriate to translate the updated egg/ovary criterion database for these species to whole-body for the purposes of deriving the updated whole-body criterion. For the remaining species, we used the updated and new median ratio-based CFs.

EPA-HQ-OW-2004-0019-0411-A2; American Petroleum Institute (API); Posted 10/28/2015

2.2.2 Updates to the Whole-Body Criterion

In Section 3.1.5.2 of the 2015 draft Se criteria document, EPA (2015) presents its approach for deriving a WB-based criterion. To develop WB chronic values, EPA translated the egg/ovary chronic values used to develop the egg/ovary criterion using egg/ovary to WB CFs (i.e., Table 3.5 of EPA (2015)). These converted values were then used to calculate a WB criterion of 8.0 mg/kg. EPA again used a sample size of 15, which included the three invertebrate-based values, the two 'assumed' crustaceans, and the genus, Gambusia.

In the past, EPA has used regression-based CFs (e.g., Bluegill CF from EPA's 2004 draft Se criteria document). However, in the 2015 draft Se criteria document, EPA developed CFs based on the median of available matched egg/ovary and WB Se data. As noted in comments on the 2014 draft (GEI 2014a, b), we believe that a more appropriate method would be to use regression-based egg/ovary to WB translators when the regression relationship has an R2 value >0.70. We translated the egg/ovary database to WB and derived an updated WB criterion. For the genus Oncorhynchus, individual CFs were used to translate each species individually (i.e., O. mykiss and O. clarkii), but an overall regression using data for both species was used to convert the Oncorhynchus egg/ovary GMCV to a WB GMCV of 14.99 mg/kg

In addition, we updated the median-based CFs based on our review of EPA's data and the addition of our data; these updates were incorporated here. Many of these recommendations are based on data that EPA had included in the 2014 draft (EPA 2014) or were provided in an earlier review of the criteria document (including tissue-to-tissue data for fathead minnows in the GEI (2008) study cited by EPA), and were not used; no reasons for this were provided.

The WB criterion should also be adjusted as a result of our updates to the egg/ovary chronic values (Table 2). We recommend that EPA consider a recalculated criterion with regression-based CFs in place of median-based CFs when possible, as it is based on scientifically-defensible data for relevant species.

Original letter contains Table 2 – Modified version of Table 3.5 of (EPA 2015) following adjustments to conversion factors and chronic values recommended herein. See original letter.

2.2.3 Updates to Muscle Criterion

In Section 3.1.5.3 of EPA (2015), after presenting its approach for developing the egg/ovary criterion, EPA presents its approach for deriving a muscle-based criterion. To develop muscle-based chronic values, EPA translated the egg/ovary chronic values used to develop the egg/ovary criterion using egg/ovary to muscle CFs (Table 3.7 of EPA (2015)). These converted values were then used to calculate a muscle-based criterion of 11.3 mg/kg. EPA again used a sample size of 15, which included the three invertebrate-based values, the two 'assumed' crustaceans and the genus, Gambusia.

As a result of our recommended updates to the egg/ovary chronic values, the muscle-based criterion will also need to be adjusted (Table 3). We recommend that EPA consider this recalculated criterion, as it is based on scientifically-defensible data for relevant species.

Original letter contains Table 3 – Modified version of Table 3.7 of EPA (2015) following adjustments to chronic values based on review and analysis of study data recommended herein. See original letter.

Comment Category 3.6 – Comments Concerning Other Toxicity Data Fulfilling Minimum Data Needs (N=15)

3.6 Summary

This section contains comments about chronic effects studies of non-fish organisms, including invertebrates, crustaceans and amphibians, and their use in the minimum data requirements to fulfill EPA's guideline recommendations for calculating the criterion. Some commenters questioned the decision and method used to translate invertebrate chronic concentrations to a predicted fish tissue concentration. Some commenters noted that invertebrate data would be useful in establishing site specific criteria for streams that do not support fish populations.

3.6 Response to comments

3.6 Responses regarding use of other toxicity data

EPA agreed that the estimated egg-ovary concentrations for invertebrates should be deleted and did so in the 2015 draft and also in the 2016 final selenium Criterion document. The data available do indicate that the invertebrates are somewhat less sensitive to fish on a whole-body basis and thus invertebrates are included in the "N" for the criterion derivation. Invertebrates are portrayed explicitly in the whole body Sensitivity Distribution (SD) with the converted whole-body fish tissue concentrations for comparative purposes.

The selenium fish tissue criterion is expected to be protective of invertebrates, based on limited data available. EPA further agrees that additional data on invertebrate sensitivity to selenium would be useful to further support this conclusion. EPA is aware of the available invertebrate data that reported selenium impacts at low concentrations, however our review of these data uncovered data quality flaws that limit the quantitative use of these studies for criteria derivation.

In the criterion document, fish and invertebrate SMCVs and GMCVs are no longer presented on the same tables and invertebrate SMCVs and GMCVs are presented as whole body concentrations. However, criteria are developed to protect the entire aquatic community, such that the available data should reflect the sensitivity range for various components (e.g., fish, invertebrates) of the aquatic system. Towards this end, invertebrate sensitivity to selenium was evaluated in terms of both measured whole body concentrations as well as in terms of what the whole body tissue concentration of a representative fish would be were it to consume each invertebrate with a whole body concentration at the SMCV and GMCV, by multiplying each invertebrate GMCV by 1.27, the median TTF for all fish species. When evaluated with or without the trophic level biomagnification, the available data demonstrate that compared to fish, invertebrates are not as sensitive to selenium, and do not comprise any of the four lowest GMCVs. They are used to fulfill the taxonomic minimum data requirements, and are counted in the total number of genera ("N") in the calculations. We note the numeric impact of increasing "N" though inclusion of the invertebrate data in the "N" for the criterion calculation is minimal, reflecting an approximately 3% change in the egg-ovary criterion element value.

Regarding the comment on the number of GMCVs, EPA agreed that the invertebrate and the Gambusia data should not be represented in the egg-ovary sensitivity distribution, and they have been removed

from that distribution. EPA 304(a) criteria are developed to protect the aquatic community, and so the "N" should consider the other less sensitive taxa data implicitly; even though they are not represented in the SD, they are still protected by the criterion. We also evaluated new studies, and so the "N" reflects the number of studies that are used quantitatively, and represented explicitly in the SD; as well as those less sensitive taxa that cannot be represented in the SD, but are part of the total number of taxa where data are available that show that the criterion is protective.

EPA identified limited data on amphibians and characterized effects in comparison to fish in the 2015 draft. Data indicate that the selenium fish tissue criterion is expected to be protective of the aquatic community including invertebrates and amphibians.

3.6 Specific comments

EPA-HQ-OW-2004-0019-0387-A1; Colorado Department of Public Health & Environment; Posted 10/14/2015

- In Table 3.9 (page 53), it would be helpful to list the species or genera used for each category, rather than just counts.
- Should Xenopus be included in the total number of GMCVs? While not a native species, it is a surrogate for amphibians in general. In addition, including Xenopus would be consistent with EPA's approach of including "waived" genera in the "N" used derive the criterion.

EPA-HQ-OW-2004-0019-0412-A2; Utility Water Act Group (UWAG); Posted 10/28/2015

3.1.4 Summary of Relevant Invertebrate Tests

UWAG agrees with EPA's conclusion that there is implicit protection for invertebrates if the fish-based chronic tissue criteria are attained. EPA reviewed all of the available literature concerning chronic toxicity effects to invertebrates and found that:

The relative insensitivity of invertebrates when compared with the fish whole-body concentrations demonstrates that invertebrates are generally protected by selenium criterion values derived from fish. Therefore, the invertebrates are considered implicitly in the species sensitivity distribution, and are counted toward the number of values available to calculate the fish tissue criterion elements…

Draft Criterion at 45.

Considering acute water column exposure only, invertebrates (notably amphipods and planktonic crustaceans) are more sensitive than fish when exposed to either selenite or selenate (US EPA 1995). However, when invertebrate species are exposed to selenium via the diet during chronic tests, the resulting chronic values are higher than the four most sensitive fish species GMCVs based on reproductive effects (Draft Criterion Tables 3.3 and 3.4 at 46-47). Additional studies support that invertebrates can accumulate selenium to very high levels in field settings, with seemingly no population-level effects. For example, in a fly ash-impacted receiving stream in West Virginia (Little Scary Creek), Hydropsychid caddis flies and the hellgrammite Corydalus had mean whole-body selenium concentrations of 31 mg/kg and 25 mg/kg, respectively, without any apparent population-level adverse

effects (Reash et al. 1999). These studies lend additional support to EPA's decision to assume the criterion is protective of invertebrates at the proposed levels.

3.1.6 Selenium Fish Tissue Toxicity Data Fulfilling Minimum Data Needs

EPA's "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses" ("1985 Guidelines")(US EPA, 1985) specify certain data that should be available if a numerical criterion is to be derived. If all the required data are not available, then "usually a criterion should not be derived." 1985 Guidelines at 3. In developing the selenium criterion, EPA found there were no available data on the chronic toxicity to two invertebrate groups, planktonic crustaceans and benthic crustaceans. EPA's Guidelines specifically require toxicity data representing these two faunal groups. EPA made a policy decision to waive this requirement. While UWAG normally would not support derivation of aquatic life criteria in the absence of the minimum data specified in the 1985 Guidelines, in this case UWAG agrees with EPA's policy decision.

EPA used available toxicity data for organisms from the phylum Arthropoda (which includes insects) as a surrogate for the two missing faunal groups. Those data indicate that invertebrates are less sensitive than the aquatic species having the four lowest Genus Mean Acute Values. Because crustaceans are arthropods, the agency concluded that there are no data that might indicate that planktonic and benthic crustaceans are more sensitive to selenium than insects. The agency also relied on field studies and consensus of the experts that it is the egg-laying (oviparous) vertebrates that are most at risk. UWAG agrees with this conclusion. Since crustaceans are less likely to transfer selenium via the egg, EPA determined the data requirements to be adequately met. EPA's conclusion is consistent with results from field studies that suggest amphipods are tolerant to chronic selenium exposure. For example, in Connor Run, a fly-ash pond receiving stream with average water concentrations of 73 µg/L, composite samples of Hyallela azteca had a mean concentration of 25.4 mg/kg (American Electric Power unpublished data).

EPA-HQ-OW-2004-0019-0400-A1; The National Mining Association (NMA); Posted 10/15/2015

3.6.1 Recommendation for Invertebrate Tissue Criterion

In cases where fish populations are not present due to flow limitations the aquatic life to be protected are the macrobenthos. In EPA's analysis of invertebrate data, the most sensitive species had a GMCV of 24.2 mg Se/kg dw wb. All other effect concentrations for invertebrates for which chronic data were available were substantially higher than 24.2 mg/kg. Therefore, based on these data, an invertebrate Se tissue concentration of 24.2 mg/kg dw would be protective of these invertebrates and an appropriate tissue-based criterion for fishless waters.

Comment Category 3.7 – Comments on Studies Not Used in Derivation of Fish Tissue Criterion Elements

3.7 Summary

This section contains comments on reproductive and non-reproductive studies that were not used in numeric criterion derivation. Included are comments concerning juvenile salmonids studies.

3.7 Response to comments

3.7 Responses concerning studies not used by EPA

EPA did not use Gambusia data directly to derive the selenium egg-ovary criterion, given they are a viviparous fish. EPA did use these data to calculate the whole body criterion, as well as counted in the "N" for derivation of the egg-ovary criterion. The available data indicates that Gambusia is insensitive compared to other species in the database.

EPA examined Buchwalter's (Conley et al. 2013) recent study. There were 2 studies with the same exposures but different food rations (1x and 2x). There were major differences in the effects levels observed, which seemed to be a diet effect, rather than a selenium toxicity effect. These data are discussed in the selenium criterion document. EPA has also examined the Conley data and have included the data that has met the data quality requirements for quantitative consideration in the criteria derivation process.

Regarding consideration of new data, EPA has acquired new data through the peer review and public process and has included these data, as appropriate, in the derivation of the criterion.

EPA has not previously accepted injection studies as a valid exposure method for aquatic life criteria development, and this exposure route is considered particularly critically regarding selenium for several reasons.

1. A 100% selenomethionine exposure does not reflect natural dietary sources.
2. Microinjection does not include the natural metabolic detoxification and storage processes occurring in the female over time in the diet, as opposed to a bolus dose of a single form of selenium which likely overwhelms the body's metabolic processes.

We note that most of the peer-reviewers of the 2014 criterion agreed with the exclusion of the injection route of exposure, and several provided additional lines of reasoning for excluding injection studies from consideration. EPA has reexamined the Doroshov et al. (1992) study data and determined that it will not accept this injection study as a valid exposure method for selenium aquatic life criterion development. The majority of the peer reviewers' comments on the 2014 criterion support this decision.

Regarding the exclusion of the 90-day endpoint in Hamilton et.al. 1990, EPA had significant data quality concerns with this data, most significantly that the 90-day control survival (67%) was below toxicity test acceptability thresholds, such that we could not use those effects data. We did consider and use the 60-day time point for this study, and concluded that the egg-ovary transformed whole body criteria of 8 mg/kg dw would protect against growth effects in juvenile salmonids. Compromising data analysis to

include very high control mortality data despite the availability of other more acceptable data within the same test does not meet EPA's data quality expectations, and would not constitute modernizing methods.

Regarding the relative sensitivity of reproductive and non- reproductive (e.g., larval growth) effects, EPA completed a new analysis and found that the reproductive endpoint is protective of juvenile survival and growth (see pages 134 and 135 in the revised 2015 document, and Section 6 of the final 2016 Selenium Criterion document). EPA however has noted in the criterion document that the whole body tissue is the sample of choice to assess selenium exposure in freshwater environments in juvenile anadromous salmonids (i.e., Pacific Northwest species) from the larval swim up to the smolt stage prior to outmigration to the marine environment.

We have added a figure to Section 6 where the reproductive effects and non-reproductive effects are compared, demonstrating that the whole body criterion element translated from egg-ovary criterion threshold is expected to be protective against non-reproductive effects.

Regarding the comment on the inclusion of additional genera, the Catostomus and Xyrauchen studies, presented in Appendix D of the 2014 draft, EPA determined these studies are not of sufficient quality for quantitative use, therefore they have not been included in setting N. During development of the document, EPA considered increasing the N used in the criterion calculation to reflect inclusion of Catostomus, based on the suggestive evidence from the de Rosemond et al. study, but decided that it would be more prudent not to, given that Crutchfield (2000) states that "By the early 1980s, the fish community had collapsed in the Hyco Reservoir and species such as [names of several taxa]… and suckers (Catostomidae) became much reduced throughout the reservoir." Regarding the Hamilton et al. study, EPA does not believe it can come to any reliable conclusion about the relative sensitivity of razorback suckers.

Regarding the comment on adding new studies, the authors of the mountain whitefish study were contacted by EPA; however, the authors declined to provide these data to EPA at this time. The Formation Environmental Yellowstone cutthroat trout study has been analyzed and added to the database.

Regarding the zebrafish studies, EPA has evaluated the available zebrafish data and identified several important issues with the quantitative use of those data. This information is included and fully discussed in the revised 2015 draft criterion document and the 2016 Final Selenium Criterion document. This issue was also highlighted in the FR Notice in July 2015 with a request for additional data on zebrafish and other cyprinids. A major problem is that the concentration-response curve was so unusually shallow that zebrafish could be interpreted to be among the most or least sensitive species depending on the level of effect considered. Further, high control mortality (47%) at the end of the study raised concerns about the health of the fish at the time of testing. In addition, since the zebrafish is a non-native cyprinid species, EPA assessed the information available on zebrafish sensitivity to selenium compared to the sensitivity of native cyprinid (minnow) species across the United States (Appendix D in the criteria document), including several studies where native cyprinids were investigated in selenium-impacted waters. Data from these studies suggest that native cyprinids are likely less sensitive to selenium than the currently available non-native zebrafish data suggest. The results of these analyses, particularly a comparison of the concentration response relationships of zebrafish versus all of the other fish species

for which we have similar data, raises a concern. Given these concerns, EPA has not used the zebrafish data quantitatively in the derivation of the 2016 criterion.

3.7 Specific comments

EPA-HQ-OW-2004-0019-0385-A2; Kentucky Division of Water (KDOW); Posted 10/13/2015

The exclusion of bioassay studies using only water-column exposure is appropriate. Chapman, et al. (2010) found the measurement of selenium in fish tissue appropriate given its close ties to chronic toxicity, namely embryo mortality and teratogenic effects.

EPA-HQ-OW-2004-0019-0387-A1; Colorado Department of Public Health & Environment; Posted 10/14/2015

In Section 3 of the criteria document, the Gambusia data are only mentioned in footnotes to Tables 3.2 and 3.5 and shown in figures. It would be helpful to have more information in the text about its status and use in the criteria. It appears to have been included in the "N" used to derive the different elements of the criterion, as it is included in the genera list on page 54, but its use should be explained in the main text.

EPA-HQ-OW-2004-0019-0413-A2; Federal Water Quality Coalition (FWQC); Posted 10/28/2015

In its Notice, EPA also asks for comment on its decision not to use studies of zebrafish (a non-native minnow species) in developing the draft criteria. While these studies were submitted to EPA for consideration in developing the criteria, the Agency identified a number of concerns, with the studies, including issues regarding the concentration response curve and a high control mortality rate. EPA also concluded that native minnow species are probably less sensitive to selenium than the zebrafish data suggest. We agree that these reasons are well-founded. Therefore, we support EPA's decision not to use the zebrafish data in deriving the new criteria.

EPA-HQ-OW-2004-0019-0411-A2; American Petroleum Institute (API); Posted 10/28/2015

1.1.4 Exclusion of Juvenile Survival

We support EPA's decision to focus on studies using dietary uptake and maternal transfer to young, rather than juvenile survival data.

EPA-HQ-OW-2004-0019-0391-A1; North American Metals Council (NAMC); Posted 10/14/2015

We support strongly EPA's decision to not use juvenile survival, in particular juvenile overwinter survival, as an endpoint in developing the proposed criterion. We note, however, that the reproductive criterion is inappropriately compared to endpoints from juvenile overwintering survival in Section 2.2.4 of the 2015 EPA Selenium Draft.

NAMC supports EPA's decision not to include data on zebrafish for the reasons outlined in the Federal Register. The data in question are from an academic study on a non-native fish with a very strange dose-response curve that is not typical of the selenium dose-response curve.

EPA-HQ-OW-2004-0019-0396-A1; National Marine Fisheries Service Office of Protected Resources Interagency Cooperation Division; Posted 10/15/15

Special Considerations for Pacific Salmonid Juveniles: While NMFS appreciates EPA's consideration of the effects of selenium on Pacific salmonid juvenile growth rates in both the 2014 and 2015 drafts, the handling of the 90 day exposure data from Hamilton et al. 1990 should reflect a more up to date perspective. EPA states that these data were excluded based on control survival requirements for ambient aquatic toxicity data established in the 1985 Aquatic Life Guidelines (USEPA, 1985) and the Manual of Instructions for Preparing Aquatic Life Water Quality Criteria Documents (Stephan, 1987). The guidance documents EPA referenced were developed at a time when approaches to tease out interacting factors or incorporate complex aspects of exposure were not readily performed due to limitations in computational technology. EPA has already circumnavigated these limitations in its development of the copper guidelines based on biotic ligand binding and the dietary exposure based selenium guideline currently under review. EPA also recently hosted an "Invited Expert Meeting on Revising U.S. EPA's Guidelines for Deriving Aquatic Life Criteria" to collect information on alternative approaches to selecting and analyzing data, with a view to expanding the data used in guideline development. This selenium guideline should reflect EPA's intent to modernize its assessment approaches in arriving at water quality guidelines. Eliminating data based on these valuable, but outdated guidances, is not consistent with EPA's current vision for guideline development.

EPA-HQ-OW-2004-0019-0412-A2; Utility Water Act Group (UWAG); Posted 10/28/2015

6.1.5 Reproductive studies not used in the numeric criterion derivation

EPA considered two studies conducted using zebrafish (a non-native minnow species) but found a number of anomalies with each. The study by Penglase et al. (2014) was not used for criterion calculation purposes due to only one treatment level causing reproductive effects. The study by Thomas and Janz (2014) was considered but not used by EPA due to the extremely low reproductive-based EC10 value (7.0 mg/kg). The agency then evaluated the relative sensitivity of native minnow species based on laboratory and field studies (analysis found in Appendix E). UWAG agrees with EPA's decision not to use the zebrafish data and offers the following comments on native minnow selenium sensitivity.

In a field study, Reash et al. (2006) reported an average selenium whole-body concentration for bullhead minnows (Pimephales vigilax) in a fly-ash pond receiving stream of 44.55 mg/kg. For comparison, bluegill collected in the same stream had an average whole body concentration of 17.26

mg/kg. The bullhead minnow population in the stream was considerable, and the species fed largely on filamentous algae. Creek chub (Semotilus atromaculatus) and blacknose dace (Rhinichthys atratulus) collected from a different fly ash pond receiving stream also accumulated high levels of selenium (Reash, 2012). The findings in these studies suggest that some minnow species are relatively tolerant to long-term selenium exposure.

EPRI (2001) reported results of a selenium uptake and depuration study using fathead minnows. This study is attached as Appendix 1 and UWAG requests that this study be added to the Draft Criterion section "Studies of Non-Reproductive Effects" in Appendix D. Juvenile fathead minnows were exposed to selenium via water (sodium selenite), diet (fish chow spiked with selenomethionine), or both water and diet. Fish were exposed to selenium in flow-through tanks for 144 days; one group of fish were then analyzed for selenium content in muscle, carcass, liver, and gonad tissue, while another group were provided a depuration period of approximately 60 days after which tissue samples were analyzed. In a parallel study, minnows were exposed to selenium at four discrete temperatures: 10, 15, 20, and 25° C. The principal results of the study were:

- Original letter contains additional information in the form of an attached appendix, EPRI (2001) report: Selenium Cycling and Impact in Aquatic Ecosystems: Defining Trophic Transfer and Water-Borne Exposure Pathways. See original letter 0412-A3.
- Fish exposed via the diet accumulated significantly higher levels of selenium compared to fish exposed via water. This finding is consistent with several other studies referenced by EPA. Tissue selenium concentrations were highest in fish exposed to selenium via both water and diet. Selenium concentrations in the various tissues were liver > muscle > gonads.
- Depuration of tissue selenium was observed starting four days after the exposures were discontinued. Within 30 days post-exposure, the reduction in tissue selenium was 73% in ovary samples, 49% in liver samples, and 19% in muscle samples.
- The effect of temperature on fish growth and selenium accumulation was not consistent. As expected, growth was lowest at the coldest temperature (10° C). The selenium content in muscle and liver samples was highest at 20°C, however the lowest level of selenium in these tissues occurred at different temperatures.
- Fish survival and weight was not different between control fish and fish exposed to 30 mg/kg Se in their diet. And the concentration of selenium in the various tissues was not elevated (relative to control fish) at a dietary concentration of 13 mg/kg Se; markedly higher tissue levels were evident in fish exposed to a diet concentration of 30 mg/kg. The mean concentration of selenium in ovary and muscle tissues, at this dietary exposure concentration, was 36.9 and 28.5 mg/kg, respectively. Though the sample sizes of fish in the various tests were not substantial, the results of this study suggest a non-reproductive effect level for this species as > 30 mg/kg (expressed as selenium in the diet) for fish growth and survival and an ovary concentration effect level of 25.7 mg/kg (the mean ovary concentration in fish exposed to 30 mg/kg in their diet).
- Whatever the exact effect levels are based on this study, there is strong evidence that fathead minnows are more tolerant to selenium compared to largemouth bass (the species having the 4th lowest reproductive effect Species Mean Chronic Level).
- UWAG agrees with EPA's assessment that the zebrafish reproductive effect EC10 value of 7.0 mg/kg Se should not be used to derive a reproductive effect-based chronic value. The

information provided above, and in Appendix E of the Draft Criterion, clearly indicates a reasonable weight-of-evidence conclusion that native minnow species are considerably more tolerant to chronic selenium exposure relative to zebrafish.

Comment Category 4.1 – Comments on Translation Equation (Eq. 18)

4.1 Summary

This section contains comments about EPA's equation that translates tissue concentration to an equivalent water concentration. It includes comments on the USGS bioaccumulation model (Equation 1), EPA's decision to simplify Equation 1 by not including growth and selenium uptake, and the method for deriving of single-species TTF and $TTF^{composite}$. Comments on structure and applicability of Equation 18 are also included here. Many commenters agree that the translation equation was a valid approach.

4.1 Response to comments

4.1 Responses to comments on translation equation

Regarding the translation of the tissue criterion to water, EPA re-evaluated conversion factors used and refined the approach to reflect the most taxonomically proximate data in its criterion calculations in 2015, strengthening its previous draft analyses as noted above. EPA also re-evaluated the lentic and lotic water column values, and developed values that are based on the best available, scientifically defensible science to yield water column values that are protective of aquatic life based on available data.

The water-column element is a translation of the egg-ovary element and thus is intended to provide the same level of protection as the egg-ovary element. However, some level of uncertainty in translating the egg-ovary element to the water-column element is unavoidable. To address this uncertainty, EPA chose the 20th percentile of translated water-column values using the most bioaccumulative food web present at each site to select a protective national water column criterion element. Limitations of available data allowed translation of the egg-ovary criterion element at 69 unique aquatic sites. The 20th percentile was selected because it results in a low probability of false negatives even for the most bioaccumulative species in ecosystems, (i.e., low probability of failure to indicate exceedance of the egg-ovary criterion element via use of the water column element).

It would be impossible to complete a national-level kinetic analysis because sufficient data do not exist to allow for a rate-based dynamic model using speciated selenium data. Thus, EPA uses total dissolved selenium to reflect the selenium concentration in water that is available for uptake and assimilation at TL1. The 2014 document's narrative on the uptake and transformation of selenium has been rewritten to reflect the actual processes in nature.

EPA has followed up on the recommendation from a peer reviewer of the 2014 draft that:

> "all that is needed is a model that covers dissolved to first trophic level interactions, and from there the existing biodynamic part of the Presser and Luoma (2006; 2010) could be employed. In this case, using Equations 4-6, and 7, in the Meseck and Cutter (2006) paper (and related equations in the Appendices) could suffice."

EPA coupled the above with consideration of the reviewer's recommendation to:

> "Use … simple first order rate equations (and values) described in the literature."

Based on input from the peer review of the 2014 criterion, with first-order kinetics and steady-state assumptions, particulate organic selenium, PSe(-II), in the primary producers is proportional to dissolved organic selenium, DSe(-II), which in turn is proportional to dissolved Se(IV), which in turn is proportional to dissolved Se(VI). Consequently, under these model assumptions, selenium in the primary producers is proportional to total dissolved selenium in the water column. The recommended approach from a peer reviewer of the 2014 criterion thus appeared to be a more detailed articulation of the approach EPA applied, provided that the first-order kinetic assumption is taken to be one of the acceptable approaches, as the reviewer seemed to suggest, and if the commonly used steady-state modeling assumption is applied, as was done for all other trophic levels.

In site-specific situations where ample measurements are available for all forms of selenium, EPA recognizes the value of a detailed articulation of the organic-inorganic selenium processes. However, because such data are rarely available, the detailed approach is not feasible to capture the wide diversity of sites represented via the derivation of the national criterion. EPA believes that confining its assessment to a very small number of well-studied sites where such measurements are available would reduce rather than increase confidence in the appropriateness of the national criterion. Likewise, an analysis based on a few site- or lab-specific measurements would also decrease rather than increase confidence, when compared to an approach that homogenizes the rate coefficients but uses the end-resulting ratios of concentrations observed in water and primary producers at a wide diversity of sites.

The model prediction itself is correct with respect to the translation calculations. In applying the translation model, the egg-ovary criterion element concentration is used to translate that value to a water concentration by dividing that egg-ovary criterion element by the product of a species-specific composite TTF, a species specific egg-ovary to whole body to CF, and a site specific EF). The model values in Table 12 of the 2015 draft, as well as in the final 2016 Criterion, are correct calculations that have been verified through a data quality analysis.

EPA disagrees that the previously peer-reviewed and published methodology (Presser and Luoma, 2010) applied by EPA to derive the criteria needs to be reformulated. EPA worked with the scientists who published the methodology in applying their model in the context of a national criterion development to ensure appropriate application of their model. Further, none of the other six peer reviewers recommended or indicated that EPA needs to reformulate the methodology used for setting water column criteria.

Notably, an entirely independent analysis (DeForest et al 2014, as provided as an appendix to the NAMC 2015 public comments) based on a regression approach directly comparing empirical water column data to empirical egg/ovary data, resulted in a water column criterion magnitudes for lotic and lentic systems that were less than 1 µg/L different than EPA's bioaccumulation modeling approach, when the same toxicity data used by EPA were applied (15.1 mg/kg). This further substantiates the rigor and outcome of EPA's approach.

Regarding the inclusion of sulfate interactions in the criterion derivation, the Deforest et al 2014 report indicated that a sulfate-dependent selenium criteria would apply only to selenate dominated, well-oxygenated streams, which is a small subclass of waters in the US. The publication also noted that "due to methodological challenges and high costs, it is difficult to comprehensively evaluate the influence of

sulphate on bioconcentration and transfer up the food chain." For reasons including these uncertainties, EPA has decided not to include a sulfate correction factor in the 2016 selenium criterion.

EPA has noted previously in its response to Peer Review Comments document (https://www.epa.gov/sites/production/files/2015-10/documents/epa-response-external-peer-review-comments-selenium.pdf) and in its 2015 draft criterion document that a "trophic transfer model that is dynamic and rate/kinetically based" is not feasible due to lack of availability of kinetic data. The kinetic analyses recommended in the comment would be impossible to complete nationally because sufficient data do not exist to allow for of a rate-based dynamic model using speciated selenium data. Thus, EPA uses total dissolved selenium to reflect the selenium concentration in water that is available for uptake and assimilation at trophic level 1.

As noted in the criterion document, states can develop their own site-specific criterion. EPA has provided substantial assistance for state interested in developing site-specific criteria, including descriptions of two different approaches to developing SSCs, with example calculations, and several appendices contain data with geographical specification that could be applied to develop SSC's.

4.1 Specific comments

EPA-HQ-OW-2004-0019-0392; Anonymous Commenter; Posted 10/14/15

First, although the mathematical structure presented in the document appears to be sound, there is no way to know whether the computations were set up correctly in the spreadsheet or whatever computational tool EPA used. Consequently, EPA needs to release that computational tool (such as a spreadsheet) to the public for inspection, in order to assure that the equations, as described in the document, were incorporated correctly into the computational tool used for the criterion derivation. Because of the complexity of the water criterion derivation from its database, this is not a trivial matter. In general, QA/QC checking of computational tools is not a trivial matter.

EPA-HQ-OW-2004-0019-0390-A1; West Virginia Coal Association (WVCA); Posted 10/14/15

Development of Water Column Concentrations

WVCA is most concerned with the methodology utilized by EPA to convert the egg-ovary criteria into water column criteria for lentic and lotic waters. As described more fully below, we believe the USGS methodology described in Section 3.2 of the Draft Selenium Criterion and most recently published by Presser (2013) is fatally flawed and cannot be utilized for this purpose. We will focus our comments on EPA's use of this troubling publication.

The water column criteria are based largely upon the model presented in the recent USGS publication Selenium in Ecosystems within the Mountaintop Coal Mining and Valley-Fill Region of Southern West Virginia-Assessment and Ecosystem-Scale Modeling (Presser 2013) and previous publications supporting the same concepts regarding selenium uptake in the food web. WVCA has grave concern with EPA's use of this publication and the validity of the base assumptions in the USGS ecosystem-scale model.

The USGS model claims to integrate a predator's dietary exposure pathway to develop a link to selenium toxicity and, thus, to species vulnerability. West Virginia has conducted extensive water column monitoring, fish tissue analysis, and deformity analysis for State waters. The field evidence and laboratory data entirely contradict the USGS model. The route of selenium uptake into aquatic species in West Virginia waters cannot be accounted for by the USGS model.

EPA entirely departs from the 1985 Guidelines in preparing the water column elements in the Draft Selenium Criterion. Instead, EPA develops tropic transfer function (TTF) values for a number of freshwater fish and attempts to use these numbers to back-calculate conversion factors (CF) to prepare water column criteria. This procedure is complex and is fraught with inconsistent internal assumptions and cross-species extrapolation to yield the calculated water column elements of the chronic criterion.

The derived water column numbers are entirely at odds with the criteria that would be calculated based upon the methodology set forth in the 1985 Guidelines and empirical data. EPA's novel approach has not received public input separate and apart from its use for selenium, requiring the public to challenge both the TTF methodology as well as the data decisions by EPA that are specific to selenium.

WVCA urges EPA to reconsider the draft water column elements of the selenium criterion. This effort is too broad, which leads to numbers that are likely inaccurate all of the time. While WVCA understands and appreciates EPA's effort to create a shortcut for States who do not want to develop water column numbers, the development of generic numbers based on inaccurate assumptions that contradicts empirical data is not an acceptable approach.

EPA-HQ-OW-2004-0019-0404-A2; Kentucky Coal Association (KCA); Posted 10/15/2015

KCA is also concerned that EPA's methodology for calculating the water column criterion from fish tissue is unprecedented, not properly supported by sound science, and subject to significant uncertainties.

Although KCA strongly supports the fish tissue approach and urges EPA to reconsider the concept of alternative water column concentrations proposed in the criterion, if a water column number is included in the criterion in any form, it must be based on scientifically defensible methods. Here, KCA does not believe the record adequately demonstrates that EPA has used reliable science to derive water column values. The criterion states that EPA derived the water column values through use of a complex formula that estimates bioaccumulation and trophic transfer by relying on many variables that will differ widely in the field based on site-specific conditions. There is no clear indication that EPA's methods have been tested or proven to be reliable. And aside from the apparent unreliability of its approach, by layering conservative assumption upon conservative assumption in the models, EPA's final derived water column criteria is necessarily overly conservative and fails to accurately reflect actual conditions in real-life receiving streams. Given these concerns, the water column values should, at most, be used as a "trigger" as in the case of Kentucky's 5 ug/l standard, particularly given that the Kentucky experience demonstrates that such a water column trigger has been sufficiently protective of aquatic life.

EPA-HQ-OW-2004-0019-0412-A2; Utility Water Act Group (UWAG); Posted 10/28/2015

1. EPA Should Recalculate the Draft Water Column Criterion Using Appropriate Data and Good Science.

UWAG has serious concerns with the science underlying the draft chronic water column values. While the bioaccumulation model that EPA selected to back-calculate site-specific water quality criteria from egg/ovary thresholds and site-specific factors is a scientifically valid approach when used on a site-specific basis, application of the model to derive nationally recommended criteria for lotic and lentic settings has significant uncertainty in terms of all input variables being available for all sites. EPA's reliance on a limited data set and selection of a conservative 20th percentile protection value resulted in water column criterion that is overly conservative for most sites and will compel many permittees to conduct needless fish tissue studies. UWAG recommends that EPA withdraw and recalculate the proposed water column criterion considering the additional data made available through comments submitted by GEI Consultants in comments on the 2014 Draft. This approach was strongly recommended by several of the external expert peer reviewers and should not be ignored by EPA. See, e.g., 2014 Peer Review at 21-22. Failure to recalculate the water column values will result in unnecessarily over-conservative criterion while achieving no environmental benefit.

Water Column Translation:

- "I am very concerned that EPA is placing too much value on extrapolated and modeled values. The translation approach [calculating site water criteria based on a bioaccumulation model] involves building food models for 69 sites that in many cases have significant data gaps (e.g., dietary composition, extrapolated TTFs, extrapolated CFs, etc.)." (2014 Peer Review at 7).
- "Related to this was the "translation" of the tissues (all)-based criteria to the water column (14% of comments), and most of these comments were directed to the inappropriate use of the Presser and Luoma model. Considering my review above and the community response, it would seem that the EPA needs to reformulate their methodology for setting water column criteria." (2014 Peer Review at 21-22).

EPA-HQ-OW-2004-0019-0406-A2; Kentucky Chamber of Commerce; Posted 10/15/2015

With respect to the derivation of the proposed water column concentration criteria for lotic and lentic waters, the Chamber also believes U.S. EPA has not adequately demonstrated the reliability of the science that was used to derive those values. As stated above, EPA derived the water column values using a complex model that attempts to estimate bioaccumulation and trophic transfer through aquatic system food-webs. There are many variables, which largely depend on site-specific conditions. (Criterion Document at Section 3.2.1). The model appears to be untested and is not proven to be reliable. By definition, water column values cannot be as reliable an indicator of the threshold for impact as the fish tissue concentrations from which they were derived. The derived water column values are more stringent than the 5 µg/l total selenium value previously adopted by many states, including Kentucky, based upon U.S. EPA's prior recommended criterion. Based upon available (albeit limited) fish flesh test

data, it appears that the 5 mg/l value has been protective of aquatic life in Kentucky. Given the documented superiority of fish tissue as a more reliable indicator of protection of the aquatic life use, there is no justification or record support to require states to adopt the unproven proposed lotic and lentic water concentration criteria particularly where existing state water column selenium standards have been shown to be protective of aquatic life. At most, any such water column concentrations should only apply as a "reasonable potential" trigger for conducting fish tissue testing. The record does not support the establishment of those concentration values as reliable independent criteria.

EPA-HQ-OW-2004-0019-0385-A2; Kentucky Division of Water (KDOW); Posted 10/13/2015

Water Column Criterion

KDOW believes that EPA's approach to deriving water column elements, considering lotic and lentic waters separately, appropriately considers how aquatic habitat affects selenium speciation, water residence time, and selenium accumulation in the food chain. However, EPA has not adequately explained its approach to deriving the water column criteria for lentic and lotic waters from the fish-tissue values. As much as any aspect of this proposed criterion the method for deriving the water-column values should be transparent and fairly scrutinized. Using the (extremely low) water-column values as proposed by EPA, many waters currently meeting their intended uses and that do not have selenium concentrations in fish tissue at a level of concern would otherwise be deemed as not meeting designated uses, if based solely on water chemistry. That empirical disconnect may be the result, in part, of the inappropriate inclusion of the Linville (2006) study. However, as the methodology for deriving water column values has not been adequately explained any conclusion is speculative.

EPA-HQ-OW-2004-0019-0388-A2; J. R. Simplot Company; Posted 10/14/2015

C. Miscellaneous Comments

C.1. Simplifying the Bioaccumulation Model

[Page 55, Section 3 .2.1.1]

In ERG's (2014) External Peer Review of the 2014 Draft Criterion, Dr. Gregory Cutter noted the following with respect to the first step of trophic transfer:

> "The overall approach of considering selenium's pathway from the water column , dissolved state, through trophic levels, and into tissues such as reproductive organs is well justified , particularly the trophic transfer model that is dynamic and rate/kinetically based (uptake rate * assimilation efficiency/elimination rate); the trophic transfer approach largely developed by Nick Fisher and collaborators. However, the water to first trophic level approach is completely unacceptable in that it is not dynamic or rate-based (actually assumes equilibrium) and completely ignores the effects of speciation. The latter is curious in that they seem to be relying on the Chapman et al (2009 and 2010) recommendations from the SETAC Pellston workshop which specifically states, "Understanding Se speciation is critical to understanding its mobility,

> transformation, partitioning in the environment, and potential risk to aquatic ecosystems ." and 'The single largest step in the bioaccumulation of Se occurs at the base of food webs, characterized by an "enrichment function"; thermodynamic or equilibrium-based principles are not appropriate for predicting Se bioaccumulation at the base of food webs." The choice of the Presser and Luoma model used in this EPA document is completely contrary to these recommendations since the water/particle ratio called the Enrichment Factor (EF) is only a renamed equilibrium distribution coefficient (Kd) that was used long ago for metal cations."

He goes on to state,

> "The use of the Presser and Luoma (2006, 201 0) model for any aquatic ecosystem to predict dissolved or particulate concentrations is questionable for the simple reason that while it acknowledges the importance of chemical speciation , and the rates of processes (kinetics as opposed to equilibrium thermodynamics) , it largely ignores them in application."

Dr. Cutter recommends, at least for the first step in the trophic transfer modeling approach for selenium, that "biological uptake of dissolved nutrients such as nitrogen, and metals, is best (most accurately) modeled using Michaelis-Menten kinetics, or at least pseudo-first order rate expressions." He suggests that simple Michealis-Menten equations and values in the literature (i.e., Riedel et al., 1991), and simple first order rate equations (and values) described in the literature (i.e., Cutter, 1982; Cutter and Bruland, 1984; Reinfelder et al., 1993) would suffice for the EF stage of the Presser Luoma Model. He concludes by stating,

> "After the dissolved to first trophic level particulate selenium part of the model that I am criticizing above, the rest of the Presser and Luoma (2006) model (including the derivation of TTFs) is excellent and accurately predicts bioaccumulation through the various parts of the food web (and earlier documented in the Luoma and Rainbow (2005) peer-reviewed paper). The reason here is that once into the first trophic level, the primary speciation of particulate selenium is organic selenide, and the concepts of assimilation efficiency, trophic transfer factors, ingestion and depuration (egestion) work well for selenium (and any other metal or nutrient)."

This concept is empirically demonstrated by using much of the field data generated for selenium to derive an aqueous concentration. Very low selenium concentrations in water result in high EF values, that drive the ultimate aqueous value derivation to a value as low or lower than the original field measured value. Conversely, high aqueous selenium values in water often times result in low uptake in algae and thus low EF values. Resulting aqueous values using EFs from these types of scenarios will result in higher concentrations due to the low EFs. It is clear that the EFs drive the Presser Luoma model and more than one investigator has suggested that the uncertainty in this single (large) step results in an uncertain aqueous value (Deforest and Cutter, in ERG 2014).

EPA-HQ-OW-2004-0019-0395-A1; CONSOL Energy; Posted 10/15/15

Water Column Concentration Recommendations

CONSOL recommends that EPA reconsider the draft water column elements of the selenium criterion. The methodology utilized by EPA to convert the egg-ovary criteria into water column criteria for lentic and lotic waters is too broad, and could lead to inaccuracies. These nationwide lentic and lotic water column-based criteria were derived to supplement the tissue-based criteria. However, it is not appropriate to derive a single nationwide standard for water column based criteria for only two water body types (lentic or lotic); and, such an effort is not supported by EPA's own analysis. The water column criterion from the egg/ovary criterion is a valid approach, but should be used on a site-specific basis. In addition, we recommend that EPA evaluate direct use of tissue-based criteria in NPDES permitting, which would eliminate the need for the back-calculation to a water value.

EPA-HQ-OW-2004-0019-0401-A1; Colorado Wastewater Utility Council; Posted 10/15/2015

3.4.3 Alternative Approach to Chronic Water Column Standard

An alternative to the EPA approach for the water column criterion, would be to use an alternative chronic water column criterion, developed using the approach described in DeForest et al. 2014. The authors derived an equation for developing protective water concentrations that, like EPA's water column criteria, are based on attaining a tissue-based criterion, but are also dependent on sulfate (SO4) concentrations. In addition to sulfate limiting the acute effects of Se exposure, it has been shown that increasing sulfate concentrations reduce the bioavailability of Se to organisms at the base of the food web, which in turn reduces dietary concentrations for higher trophic level organisms (DeForest et al. 2014). This protective effect of sulfate occurs in selenate-dominated lotic systems. The equation used to calculate the water column value is:

[Original letter contains Equation – not numbered. See original letter.]

Where 'Water Se concentration' is in µg/L, 'fish Se conc' is the egg/ovary criterion in mg/kg, and SO4 is in mg/L.

Using this equation with the egg/ovary value of 17.9 mg/kg and sulfate concentrations ranging from 50 mg/L to 250 mg/L would result in protective water column criteria ranging from 5.7 µg/L to 40.0 µg/L, respectively (Table 7). These values fall within the range of protective lotic water column concentrations of 1.2 µg/L to 40.6 µg/L calculated by EPA, and well within the protective concentrations calculated by GEI of 1.2 to 81.0 µg/L.

[Original letter contains Table 7 – Protective water column Se concentrations at various sulfate concentrations using the equation from DeForest et al. 2014. See original letter.]

EPA-HQ-OW-2004-0019-0411-A2; American Petroleum Institute (API); Posted 10/28/2015

2.3.6 Overall Comment on Water Column Criteria Elements

The previous sections highlight our concerns with the methodology for back-calculating the water column criterion element, discuss the resulting conservatism in the draft criteria for lentic and lotic waters, and identify alternative methodologies for deriving water column criteria that we believe to be more robust. Several concerns with the methodology were also raised by the external peer reviewers of the EPA's 2014 draft AWQC for Se (Eastern Research Group Inc. 2014), but negligible revisions were considered in the revised draft. The most substantive change from 2014 to 2015 in this regard was that the number of data points included in the evaluation was reduced, which had the subsequent effect of lowering the draft lentic and lotic Se criteria further. At a minimum, we request that the EPA clarify that states may derive water Se criteria based on alternative methods and using site-specific data for state water bodies.

Water Column Criterion Element

- We advocate for flexibility in translating between tissue and water: guidance, not prescription.
- We believe that the model used to derive lentic and lotic water column Se criteria is technically flawed. The unusual use of site-specific EFs, along with various amounts of site-specific food web information and TTFs compiled from a variety of non-site-specific sources, results in translated water Se concentrations that have no ecological relevance in actual systems. The fact that the model predicts that the water column concentration at a reference lake would need to be lowered from 0.32 µg/L to 0.23 µg/L to meet the draft fish egg Se criterion of 15.8 mg/kg-dw, despite fish tissue Se concentrations being nowhere near levels of concern in the lake, highlights the fundamental flaw in the model and its lack of ecological relevance.
- Five of seven external peer reviewers of the 2014 draft AWQC document (EPA 2014) identified concerns in the EPA's approach for deriving lentic and lotic water column Se criteria; yet, no effort was made to reconsider the methodology. We do not suggest that the EPA abandon the food web modeling approach, but highly recommend that the EPA reconsider how the EFs and TTFs are compiled and applied. Use of regression relationships, rather than constant EF and TTF assumptions when translating between different Se concentration magnitudes, would remove a lot of the concerns with the current approach.
- EPA should adopt an alternative model to derive lentic and lotic water column selenium criteria. The model EPA used to derive the proposed criteria is technically flawed.

Comment Category 4.2 – Comments on Derivation of Trophic Transfer Function (TTF) Values

4.2 Summary

This section contains comments on deriving trophic transfer function (TTF) values using physiological coefficients found in literature and the empirical relationship of matched pairs, including EPA's hybrid approach using selenium tissue concentration to food concentration ratios, and ordinary least squares for statistical verification.

4.2 Response to comments

4.2 Responses concerning derivation of TTF values

In effect, EPA is positing that although partitioning from water to particulate matter is highly variable and can best be evaluated using data gathered from the specific site under consideration (if available), selenium partitioning among tissues (CF), and from particulate matter to fish through the food chain (TTF) is relatively similar for a given species regardless of site. Although this introduces some uncertainty to the translated values, CFs and TTFs are less variable across sites than EFs based on available data. EPA also notes that site-specific data necessary to evaluate the partitioning of selenium from water to particulate matter is often not available.

EPA used TTFs derived from both lab and field data, but field data were considered superior to lab data for several reasons, such as: having representative diets, reflecting assumed steady-state conditions and an absence of artifacts that can be observed in laboratory exposures (e.g., poor nutrition, selenium speciation issues). TTFs derived from field data are expected to be sufficiently protective of aquatic life in the field since they are estimates based on real- world conditions.

The dynamic nature of selenium transfer from one trophic level to another is better represented in field data than in laboratory or mesocosm data. EPA did however include TTFs from the multiple Conley et al. publications based on the life-cycle exposure of selenium to mayflies via a complex periphyton diet. There were some concerns regarding the Conley mayfly TTFs when insufficient food resulted in different TTF (and toxicity) measurements, which illustrate the potential bias with laboratory studies. The decision to include the Conley studies was based on the weight of evidence of similar TTFs for most of the exposures and the need to fill a data gap for a TTF of an important fish prey item.

Regarding regression versus median approaches, ultimately, a hybrid approach (median ratios with regression statistics used to screen data quality) was selected by EPA because the use of ratios was less sensitive to outliers or from regressions where the y-intercept was notably different from zero, and the slope of a constrained regression (following the approach used by Presser and Luoma) had a poor fit. Every approach (median ratios, constrained regression, and conventional ordinary least squares (OLS) regression) has inherent strengths and weaknesses, and ultimately, the hybrid approach was determined to be the most robust.

EPA has carefully considered its assumption that EFs and TTFs do not vary with concentration. One advantage of total least squares (TLS) is that the regression relationship is unaffected by which variable is assigned to the x and y axes. Another advantage is that introducing sampling noise into an underlying relationship does not consistently flatten the TLS slope (in contrast to its flattening of the OLS slope). Because concentrations in both media have essentially equal uncertainty, total least squares might be the preferred approach.

EPA used a median of concentrations of lower trophic organisms since most predators are opportunistic, preying on the organism that they encounter at random. Site-specific studies would reveal predator prey preference or prey abundance relationships that may warrant consideration of a different approach.

EPA used a time limit threshold of 1 year to characterize samples as "matched" to maximize the available data that are likely to be temporally similar. This approach was deemed necessary in order to obtain sufficient data from sufficient sites in order to develop water column criteria. It is more appropriate to collect site-specific data for a known impacted site at more proximate time intervals to insure that both temporal and spatial considerations at the site are accounted for. This will be addressed in implementation materials.

Again, EPA supports the development of site-specific values to reflect bioaccumulation of selenium in specific ecosystems when data are available, and EPA has provided supporting information for SSC development in appendices to the 2016 criterion document.

4.2 Specific comments

EPA-HQ-OW-2004-0019-0411-A2; American Petroleum Institute (API); Posted 10/28/2015

2.3.3 Constant TTFs Used in the EPA's Food Web Models

The EPA's food web model assumes that TTFs are constant over a range of dietary Se exposure concentrations. However, as for EFs, there is typically an inverse relationship between TTF and exposure concentration, which the EPA acknowledges in the draft document (EPA 2015). The EPA suggests that use of median TTF data helps to account for this issue: "EPA evaluated the effect of very high and very low selenium concentrations on the calculation of TTF values using the hybrid approach described above by excluding selenium measurements above various minimum and/or below various maximum selenium concentrations. EPA found that using the median ratio effectively attenuates any effects of selenium concentration on the calculation of TTF values using the hybrid approach described above without the need to introduce additional arbitrary exclusion criteria."

The EPA did explore the use of a regression-based approach, but noted disadvantages that included an assumption that the underlying data are normally distributed and that one or a very few high values can have a disproportionate influence on the slope of fitted line. Ultimately, the EPA chose to use median TTFs, by species, if the ordinary least squares (OLS) linear regression of those data resulted in a significant (i.e., $p \leq 0.05$) fit and positive regression coefficient. Ultimately, in developing the water-column criteria elements, the EPA derived TTF composite values that ranged from 1.73 to 3.51, with a

median of 2.75 (Table 3.13; EPA 2015). These magnitudes do not seem unreasonable, but it would be interesting to see a sensitivity analysis of whether the median TTFs tend to be biased high or low relative to the exposure concentrations to which they are being applied.

For example, the first row in Table 3.13 (EPA 2015) is for Iowa Darter in East Allen Reservoir, Wyoming The $TTF_{composite}$ is 3.08, which is based on a median TTF of 1.62 for the darter and an invertebrate TTF of 1.90 [calculated from: (2.14insects X 0.70) + (1.22amphipods X 0.16) + (1.46crayfish X 0.08) + (1.41planktonic_crustaceans X 0.06) = 1.90]. If we accept the WB-to-egg CF of 1.45, the draft egg Se criterion of 15.8 mg/kg-dw translates to a WB Se concentration of 10.9 mg/kg-dw. The median TTF of 1.62 for the darter was based on data for fish in the family Percidae. Based on the relationship between WB Se in fish within this family and co-located invertebrates, the invertebrate Se concentration predicted to result in a WB Se concentration of 10.9 mg/kg-dw is 9.3 mg/kg-dw (Figure 4). This results in a WB TTF of 1.18 and a revised TTFcomposite of 2.24 (for the purposes of this example we are assuming the same invertebrate TTF used by the EPA, but that could be adjusted as well). Use of this revised TTF would result in a translated water Se concentration of 2.11 mg/L (i.e., 15.8 mg/kg-dw / [2.31 L/kg x 1.45 x 2.24]). This translated water Se concentration of 2.11 µg/L is 38% greater than the concentration of 1.53 µg/L reported in Table 3.13 (EPA 2015). Accordingly, selection of the median TTF, rather than a regression-based TTF, can potentially have important implications.

This is just one example, but it raises the question of whether it was premature to abandon a regression-based approach, or at least evaluate the median TTFs relative to the exposure concentrations in the food web models to ensure that they appear to be of an appropriate magnitude.

EPA-HQ-OW-2004-0019-0401-A1; Colorado Wastewater Utility Council; Posted 10/15/2015

4.4 Derivation of Water Column-based Criterion Elements

In Section 3.2 of the 2015 draft Se criteria document, EPA derives an equation to be used to translate the egg/ovary tissue criterion into a water column criterion. The result is Equation 18 on page 63:

[Original letter contains Equation – not numbered. See original letter.]

There are several components of this equation that require further analysis and consideration as discussed below.

4.4.1 Discussion of Trophic Transfer Functions (TTF)

4.4.1.1 Importance of Site-specific TTFs

Ranges of TTFs can vary widely due to site-specific factors. To demonstrate this in our previous review (GEI 2014a), we reviewed data in Appendix B of the 2014 draft Se criteria document and compiled information on the ranges of TTFs for each species with data derived from field studies. We also verified the median TTF values and found several errors in Tables 9 and 10 on pages 76 and 77 of the 2014 draft, these errors still remain in the 2015 draft and should be fixed. Additionally, we recalculated TTF's including additional data that were submitted for addition to the TTF database in our previous review,

but were not incorporated in the 2015 draft. These values are included in Table 8 (below) and the corrections are shown in bold with the incorrect values shown as strikeouts.

[Original letter contains Table 8 – TTF median ratios from Table 3.10 and 3.11 in the 2015 draft Se criteria document and calculated ranges and geomean ratios. See original letter.]

EPA-HQ-OW-2004-0019-0400-A1; The National Mining Association (NMA); Posted 10/15/2015

4.4 Derivation of Water Column-based Criterion Elements

In Section 3.2 of the 2015 draft Se criteria document, EPA derives an equation to be used to translate the egg/ovary tissue criterion into a water column criterion. The result is Equation 18 on page 63:

[Original letter contains Equation – not numbered. See original letter.]

There are several components of this equation that require further analysis and consideration.

4.4.1 Discussion of Trophic Transfer Functions (TTF)

4.4.1.1 Importance of Site-specific TTFs

Ranges of TTFs can vary widely due to site-specific factors. To demonstrate this in our previous review (GEI 2014a), we reviewed data in Appendix B of the 2014 draft Se criteria document and compiled information on the ranges of TTFs for each species with data derived from field studies. We also verified the median TTF values and found several errors in Tables 9 and 10 on pages 76 and 77 of the 2014 draft, these errors still remain in the 2015 draft and should be fixed. Additionally, we recalculated TTF's including additional data that were submitted for addition to the TTF database in our previous review, but were not incorporated in the 2015 draft. These values are included in Table 7 (below) and the corrections are shown in bold with the incorrect values shown as strikeouts.

[Original letter contains Table 7 – TTF median ratios from Table 3.10 and 3.11 in the 2015 draft Se criteria document and calculated ranges and geomean ratios. See original letter.]

EPA-HQ-OW-2004-0019-0390-A1; West Virginia Coal Association (WVCA); Posted 10/14/15

The use of the composite trophic transfer function (TTF) and the calculated enrichment factor (EF) is highly questionable. WVCA believes that site-specific or State-specific studies are necessary to implement the fish tissue criteria as water column concentrations.

EPA-HQ-OW-2004-0019-0391-A1; North American Metals Council (NAMC); Posted 10/14/2015

Further, the method used to apply EFs and TTFs (trophic transfer functions) to back-compute waterborne concentrations used as much of the available data as possible, but ignored important processes such as, for example, time variable accumulation processes (uptake and depuration kinetics) and the effects of site chemistry (e.g., selenium speciation, SO4). Site-specific considerations should

allow for a mechanistically detailed site-specific analysis, which can be compared to the simplified approach used in the subject document.

Comment Category 4.4 – Comments on Derivation of Site-Specific Enrichment Factor (EF) Values

4.4 Summary

This section contains comments on deriving EF values using the empirical relationship of matched pairs. Included are comments on the use of median water and particulate measurements, ratios and rules for inclusion in analysis (≥2 measurements and ≤1 sediment) and the EF calculations for 69 sites.

4.4 Response to comments

4.4 Responses concerning derivation of site-specific enrichment factor values

It is technically incorrect to call EFs an equilibrium concept. EFs, like TTFs and BAFs, are better characterized as steady-state concepts. Steady state does not require equilibrium or process reversibility. For example, irreversible uptake coupled with growth dilution would still yield a steady-state EF.

EPA carefully re-examined the distribution of EFs and corrected the data for overweighting by EFs measured in systems with unusually low or high waterborne selenium. Appendix (H) of the 2016 criterion document lists all of the EF values, by site, and the values used to make the calculations.

To reduce uncertainty in estimating site-specific EF values, EPA limited its analysis to those aquatic sites with at least two particulate selenium measurements with corresponding water column measurements, and only used sediment measurements if there was at least one other measurement from either algae or detritus. That is, EPA would calculate an EF from algae (or detritus) alone; however, in order to qualify, at least 2 algal (or detritus) samples from a site were required. In contrast, sediment data alone were insufficient to calculate an EF. In order for sediment to be included, additional algal or detrital data were also required.

EPA added the data from Bowie et al 1996, Casey 2005, Fan et al 2002, McDonald and Strosher 1998 and Zhang and Moore 1996 to the EF data set. EPA already had Minnow Environmental 2007 in the EF data set which includes the data contained in Orr et al 2006.

Regarding the nonlinear EF comments, some commenters opined that because EFs are not constant over a range of water-column selenium concentrations, EPA developed water column values that are too conservative (in a protective sense) because the analysis resulted in high EFs in low selenium concentration water driving the water column value too low. Others commented, on the other hand, that because there is higher selenium bioaccumulation in low selenium waters, EPA developed water column values that were too high and did not account for this potentially higher relative impact in low selenium waters. EPA used empirical data and a peer-reviewed, published model to generate protective water column values based on the best available data.

Stakeholders desiring to develop site-specific criteria based on local, site relevant data are encouraged to do so. EPA provides information in Appendix K of the 2016 final criterion document, and other appendices also contain data that would support such approaches.

One commenter (NAMC) submitted an analysis by DeForest el al (2014) regarding factors such as the influence of exposure concentration on EF estimation. Following extensive analysis of this and other factors, DeForest et al (2014) derived water column recommendations of 5.4 µg/L for lotic and 2.1 µg/L for lentic systems at an egg-ovary value of 20 mg/kg, based on a regression analyses. The Deforest water column values would equal approximated recommendation of 4 µg/L and 1.5 µg/L for lotic and lentic systems respectively, at the EPA 15 mg/kg egg-ovary recommendation, based on an proportional reduction in egg/ovary and water column values to EPA's values. These DeForest-approach-based calculated water column values are strikingly similar to EPA's 3.1 lotic and 1.5 µg/L lentic recommendations, with the lotic water value being less than 1 µg/L different than EPA's and the lentic value being identical to EPA's value. This result further substantiates and supports EPA's water column values, despite the use of different analytic approaches and slightly different protection levels for water column values (75th percentile versus EPA's 80th percentile).

Regarding the comment on timing of sample collection within a year and that it somehow reflects a **"**weak tie between dietary exposure and related tissue accumulation," there is a well know strong tie between dietary exposure, fish tissue concentrations and adverse effects of selenium, and that selenium, once in an ecosystem, persists in the food web for an extended period of time. Numerous publications noting this relationship are cited in the criterion document.

Regarding the treatment of growth (g) in the bioaccumulation modeling, Luoma and Rainbow (2005) suggest that for selenium, growth rate is a relatively inconsequential parameter under most circumstances. Food consumption is typically high during periods of high growth rate. Because food consumption is the primary route of selenium uptake in aquatic organisms (Ohlendorf et al. 1986a, b; Saiki and Lowe 1987; Presser and Ohlendorf 1987; Lemly 1985a; Luoma et al. 1992; Presser et al. 1994, Chapman et al. 2010), high consumption rates of selenium-contaminated food may counteract the selenium dilution that occurs with the addition of body tissue during periods of fast growth. EPA evaluated the effect of removing the parameter *g* in the by performing a sensitivity analysis. EPA concluded from that analysis that omitting the growth rate parameter *g* is an appropriate simplification of Equation 1. A more detailed description of this sensitivity analysis is provided in Appendix J of the 2016 criterion document.

Regarding requests for more discussion on uncertainty, EPA has conducted additional analyses and has included a more extensive discussion of uncertainty in Section 6.5 of the 2016 final criterion document in Section 6.

4.4 Responses to other issues brought up in these comments

Specifically with regards to EPA-HQ-OW-2004-0019-0400-A1 and additional data for EFs and, EPA contacted data stewards identified by commenters (e.g., DeForest, DeBruyn), and requested data sets from them. EPA then independently evaluated those data sets for quality, and then used those data

that met Agency data quality standards. In some cases, EF data in particular could not be used since there was no paired fish data collected with the water and particulate matter at a site. This is crucial for calculating water values used in the distributional analyses in the derivation of the water column elements. Useable quality data was entered into the models' data sheets for use in deriving EFs. Data used to calculate EFs in DeForest et al. 2014 were received by the author. Studies were examined, and data for EFs that met EPA data requirements, such as the requirement of at least two particulate measurements, one of which must be either algae or detritus, for example, were added to the EPA dataset. A total of 22 EFs were added, increasing the total number of EFs in the EPA dataset to 91. This included the addition of 6 EFs from data separately obtained from Adrian DeBruyn of Golder Associates. Of the additional added EFs, examination of the source material associated with the EF data resulted in the addition of 11 sites for which water could be translated, increasing the total from 53 to 64. Data were added from Orr et al. (2006), Muscatello et al. (2008), Muscatello and Janz (2009), Orr et al. (2012), and Golder (2011); Teck Coal (2013). EPA thanks the data stewards for providing requested data.

GEI Consultants were contacted and paired fish and invertebrate data were obtained for fourteen species, which were added to the EPA dataset and used to update TTF values. Additional TTF data were added from Muscatello and Janz (2009), Muscatello et al. (2008), and Orr et al. (2012) as a result of the inclusion of additional of EF data. In addition to changes in TTFs resulting from additional data, TTFs for some species have changed slightly as a result to changes in conversion factors between tissue types. Finally, discrepancies in TTF values reported by EPA in the 2014 draft criterion document and those calculated by GEI in their review of that draft were examined and updated if needed. In some instances, EPA disagreed with the recommended changes. For example, EPA reported a TTF of 2.88 for damselflies and 1.97 for dragonflies, in contrast to GEIs recalculated TTFs of 0.89 and 1.30. In both cases, TTFs differed by a factor of 2.21. This is because EPA incorporated an additional trophic level accounting for the TTF between the invertebrate prey of damsel and dragonflies and their prey's food, which had a median TTF of 2.21. As a second example, the difference between the striped bass TTF of 1.48 calculated by EPA and 0.62 calculated by GEI was the result in how data across studies were grouped. EPA calculated the median AE, IR, and Kd data across all studies, while it appears GEI calculated TTF separately for each study, and then calculated the median of the two TTFs for the two studies.

Regarding the issue of the "constant EF approach", the relationship between EF and Se in water, that is that EF decreases as Se in water increases, is recognized by EPA and is presented in Section 3.2.4. The effect of this decreasing trend in bioaccumulation (including EF) is discussed on page 145 of the 2016 final document as it pertains to the ability of the model to predict observed concentrations. The model accurately predicts observed values around the criterion concentration (15.1). See Figure 6.4 of the 2016 criterion document. This demonstrates that at the criterion, the model works. At low concentrations, the model underestimates because of the nonlinearity of EF, TTF and CF - due to saturation. EPA discusses the application of the model (which includes EF) on page 145 in that statement. The linear assumption is environmentally protective.

EPA does not believe it has erred in the wet weight/dry weight conversions for the Lemly data. Regarding the role of sediment and its variability, EPA only used sediment when either algae or detritus were also available, to form a geometric mean. Regarding the use of reference sites like Badin Lake, EPA

asserts that the use of this lake is defensible; however, commenters on the previous 2014 draft pointed out the methodology used by EPA to assemble a distribution of lotic and lentic values was flawed. Commenters stated that some waters (including Badin Lake) were over-represented in the distribution due to unequal weighting of water values available based on the number of fish species sampled at a site. For Badin Lake, this was 6 species at 3 sites, so 18 of 44 water measurements were derived from this waterbody, skewing the distribution. EPA corrected this methodological flaw in subsequent analyses by using only the species most sensitive to selenium bioaccumulation when more than 1 fish was sampled, resulting in EPA using only 1 fish per site in the criterion document. Therefore in both the 2015 and 2016 analyses, Badin Lake data consists of only 3 measurements in the database.

Because of its high BAF, EPA examined the Lemley study carefully and found the data acceptable.

As discussed in Appendix I, EPA also considered the influence of the linearity assumption: that is, the assumption, implicit in the derivation, that BAFs remain constant if a site's observed tissue concentrations increased or decreased to the criterion level. The assumption has a protective influence as low concentrations, but has the opposite influence at high concentrations. Overall, because the criterion is set based on the 20th percentile calculated BAF, it has a protective influence.

EPA examined the sensitivity of the criterion to the Badin Lake data point. Even if a reason could be found to reject it, the lentic criterion element would change from 1.53 to only 1.57 µg/L (recognizing an additional significant digit for comparison purposes), indicating the lack of substantial impact of this data on the magnitude of the lentic criterion element, furthering the support for its sustained inclusion in the criterion derivation.

For examining the influence of the potential outliers, it is likely better to consider the effect of simultaneously trimming both ends of the distribution. If one data point was trimmed from each end of the lentic and lotic distributions (while calculating criteria to three significant digits), the lentic criterion would increase by 0.02 µg/L and the lotic criterion by 0.22 µg/L. If two data points were trimmed from each end, the lentic criterion would increase by 0.18 µg/L and the lotic criterion by 0.37 µg/L. This information is intended for understanding the sensitivity of the result to the values at the ends of the site distributions. EPA does not believe it has a sound reason to actually exclude those data points from the calculation, but is simply providing this information as a point of reference.

4.4 Specific comments

EPA-HQ-OW-2004-0019-0409-A2; OC Public Works; Posted 10/20/2015

5. Calculation of Kd and Treatment of Se Speciation

In the bioaccumulation model EFs are not based on real Kds, which by definition are the ratio between selenium concentrations in particulate form (w/w) and dissolved form (w/v) for a single chemical species. Instead, fine sediment or organic-rich debris, or often bedded sediment were used to substitute for particulates in the calculation of EFs. Furthermore, Kds are species-specific (i.e. different selenium species, if measured separately, will have drastically different Kd values) and aggregating together all species in calculating EFs is inappropriate for developing a national Criterion. While this approach is due

to a severe lack of selenium speciation data, the result appears to be a large spread of EF values. Without a good estimate of EFs, which introduce the largest errors, it is impossible to make the bioaccumulation model sufficiently robust.

EPA-HQ-OW-2004-0019-0388-A2; J. R. Simplot Company; Posted 10/14/2015

Simplifying the Bioaccumulation Model

EPA derived a chronic water column selenium criterion element by translating the egg-ovary concentration to an equivalent water concentration through the use of a bioaccumulation model (Presser and Luoma 2010). However, a close examination of the first step (i.e., enrichment factor) of this trophic transfer model shows that there are high uncertainties associated with the calculated water column values. Other approaches may result in a more robust calculated water column value.

EPA-HQ-OW-2004-0019-0419-A2; Lima Refining Company; Posted 11/03/2015

COMMENT #1B. Kinetic Artifacts -The use of a steady state modeling framework for translation of the egg — ovary criterion to a water column criterion introduces poorly quantified kinetic artifacts that further add to the unexplained variability in the results, including field measurements of trophic transfer factors. For example, some sites exhibit well defined patterns that reflect seasonal variations in annual rainfall — runoff processes that tend to repeat from one year to the next (e.g., San Louis Drain; Elk River Valley). During months of the year when instream concentrations are increasing, biota levels should tend to increase, but will lag the increasing water column concentrations (steady state is an elusive condition, a moving target that may never be achieved). During such times the measured tissue Se levels will tend to understate the steady state concentration associated with the current water concentration and/or the Se concentrations in their diet. During other months, the reverse occurs as water column concentrations are decreasing while tissue concentrations continue to lag behind, perhaps even continuing to increase. This is because their body burden reflects the previously higher instream concentrations. At this point, measured tissue concentrations may overstate the steady state residues associated with the current, descending water concentrations. The reverse occurs when water column concentrations are approaching an annual minimum. The EPA simulations of Figure 2 (Figure J5 from Appendix J, inserted below) illustrate trends of this sort quite nicely. For example, note how the maximum fish tissue concentration (brown line) occurs at about day 310, approximately 25 days after the occurrence of the maximum 30-d average water concentration (blue dashed line), and not far in advance of the time when the minimum 30-day average water concentration occurs. Such patterns are relatively easily understood when a kinetic model is applied in time variable mode, but they become subsumed in the data when a steady state analysis is used to interpret the results.

[Original letter contains Figure 2 – Time Variable Simulation of Normalized Selenium in Fish Tissue Relative to Daily Water Column Selenium (Figure J5 of Appendix J in USEPA, 2015). See original letter.]

In regard to a somewhat related matter, EPA presents an analysis used to establish an appropriate time period with which to define matched pairs of Se measurements to use to evaluate trophic transfer

factors (TTFs; Section 3.2.2.1). They conclude from the consistency in correlation coefficients over a wide range of lag-times that timing is "insensitive to relative collection time within a one year time period". Whether this somewhat surprising result is a reflection of the insensitivity of the TTFs to timing of sample collection, or some other possibility (e.g., a mis-match between paired concentrations in the predator and presumed food item(s)) is never addressed. Regardless, it would seem to be the case that this sort of weak tie between dietary exposure and related tissue accumulation introduces considerable uncertainty in the interpretation of results.

As a check on the veracity of the predictions of translated water column Se concentrations EPA uses the same database that was used to derive the translated WQC values in the first place. Although the predicted egg - ovary concentrations are correlated to the observed values, they tend to underestimate observed tissue Se levels at low concentrations. EPA recognizes that this deviation likely reflects the simplifying assumption of "constant bioaccumulation rates regardless of selenium concentration" in spite of the commonly observed inverse relationship between accumulation (e.g., enrichment factor) and water column selenium (Figure 3.7B of USEPA, 2015). Otherwise, the predicted and observed concentrations tend to increase in a qualitatively consistent manner, though the unexplained variation displayed by the overall trend in the data, and about the line of agreement, is considerable. EPA attributed the uncertainty to several sources, including small sample sizes ("two particulate measurements are only marginally sufficient"), temporal and spatial variability in selenium exposure, and local variability in food webs.

Finally, it is important to recognize that g, in combination with Ke, also controls the response time of biota tissue Se to changes in Se concentration in water or food. Thus, it is necessary to consider the magnitude of g relative to Ke before one can neglect g (i.e., Ke » g for the effect of g on response time to be neglected). EPA should also consider the possible effect of g on response times, and hence on the averaging period analysis, as presented in Appendix J. Since a tissue residue-based criterion is being proposed, the response time for tissue Se accumulation is expected to be important (see Paquin & Bubnyte, 2014, a SETAC presentation on averaging period for Se).

EPA-HQ-OW-2004-0019-0411-A2; American Petroleum Institute (API); Posted 10/28/2015

2.3 Derivation of Lentic and Lotic Water Column Criteria Elements

In EPA (2015), lentic and lotic water-column criteria elements were back-calculated from the draft egg/ovary Se criterion of 15.8 mg/kg-dw using the following equation:

[Original letter contains Equation – not numbered. See original letter.]

The EPA's first step was to compile enrichment factors (EFs) from sites for which information was available on the fish species and the food web. For each EF, a composite trophic transfer factor ($TTF^{composite}$,) value was identified for each of the fish species present. This $TTF^{composite}$ considered both the fish species present and the "nature" of the food web. Because the TTF for fish was based on Se concentrations in WB fish, a CF was needed in order to convert the WB Se concentration to an

egg/ovary Se concentration. Below we provide narrative comments on specific components of this approach, followed by comments on the overall approach.

We have concerns with this approach, the most important of which is that the measured EF for each site used in the evaluation is assumed to be constant. However, Se EFs are clearly not constant over a range of water-column Se concentrations (DeForest et al. 2014; in revision). Rather, they tend to be inversely related with higher EFs observed at low water Se concentrations and lower EFs observed at high water Se concentrations. The EPA made this same observation in Fig. 3.7 of EPA (2015), when comparing the magnitudes of EFs for lentic and lotic sites; yet, the implications of this inverse relationship on the translation of the draft fish egg Se criterion of 15.8 mg/kg-dw to water Se concentrations was not accounted for. The end result is that sites with low water Se concentrations, such as reference water bodies, are the drivers for both the draft lentic and lotic criterion elements, as the EFs for these sites are relatively high. The problem is that these relatively high EFs should decrease as the water Se concentration is "translated up."

The following narrative provides two examples of how the "constant EF approach" used by the EPA provides counterintuitive results, followed by an alternative interpretation of the same dataset used in EPA (2015). For the latter, the relationship between particulate Se and water Se concentrations is considered, instead of assuming a constant EF at each site.

2.3.1 Examples of Counterintuitive Results Using "Constant EF Approach" for Translating Water Column Se Concentrations Within a Site

2.3.1.1 Lentic Example

The lowest translated water Se concentration in Table 3.13 (EPA 2015) is 0.23 µg/L in Badin Lake, NC. In other words, a water Se concentration of 0.23 µg/L is predicted to result in the draft fish egg Se criterion of 15.8 mg/kg-dw based on a site-specific EF of 12.48 L/g, a WB-to-egg conversion factor (CF) of 2.00, and a $TTF^{composite}$ of 2.77. The EF of 12.48 L/g is very high because the water Se concentration reported for Badin Lake is very low (i.e., 0.32 µg/L). We can evaluate the accuracy of the EF of 12.48 L/g in translating from a fish egg Se criterion of 15.8 mg/kg-dw by reviewing the co-located measured fish Se concentrations in Badin Lake. Six fish species were identified for this site, and the EPA selected the Fathead Minnow as the most conservative species. Lemly (1985) reported Se concentrations of 0.57 and 1.38 mg/kg-ww, respectively, in Fathead Minnow muscle and viscera (i.e., 2.28 and 5.52 mg/kg-dw; assuming 75% moisture). For the sake of comparison, if it is assumed that the WB Se concentration is near the mean of these two tissue components (i.e., 3.9 mg/kg-dw) and using the WB-to-egg Se concentration factor of 2.00 (Table 3.13), the predicted egg Se concentration would be 7.9 mg/kg-dw — less than one-half the draft egg Se criterion of 15.8 mg/kg-dw.

In other words, the empirical data for Badin Lake indicate that a water Se concentration of 0.32 µg/L is associated with a fish Se concentration that is well below the draft tissue criterion; however, the model applied by the EPA (2015) predicts that a lower water Se concentration of 0.23 µg/L in this lake will result in a fish egg Se concentration of 15.8 mg/kg-dw despite the fact that the measured water Se concentration is higher (0.32 µg/L) and the associated Se concentration in Fathead Minnows is well below the draft fish tissue-based criterion. This erroneous conclusion is strongly driven by the

assumption that the EF of 12.48 L/g is a constant that equally applies to higher Se concentrations in Badin Lake, which is clearly not the case. This highlights the fact that the EPA's overall approach for translating from the egg/ovary-based Se criterion to water column concentrations is flawed and has no bearing on actual ecosystems. This is especially problematic because examples like this one (and similar for the High Rock Lake reference lake) are the drivers for the lentic water column criterion element.

2.3.1.2 Lotic Example

Another counterintuitive example, this time for lotic sites, are the translated water Se concentrations of 1.19 and 8.15 µg/L derived for Deerlick Creek and Luscar Creek, respectively (both in the McLeod River Basin in West-Central Alberta, Canada) (Casey 2005). Deerlick Creek is a reference creek with a water Se concentration of 0.2 µg/L and an EF of 2.24 L/g and Luscar Creek is a Se-exposed creek with a water Se concentration of 10.7 µg/L and an EF of 0.33 L/g (as reported in Appendix H; EPA (2015)). Consistent with the inverse relationship between EF and water Se concentration that is typically observed, the Deerlick Creek EF is relatively high (i.e., about 7-fold greater than the Luscar Creek EF). Use of the relatively high EF for the reference Deerlick Creek results in a relatively low translated water Se concentration of 1.19 µg/L, while use of the relatively low EF for the Se-exposed creek (Luscar Creek) results in a relatively high translated water Se concentration of 8.15 µg/L. In other words, the EPA model predicts that a water Se concentration of 1.19 µg/L in Deerlick Creek would result in the draft fish egg Se criterion of 15.8 mg/kg-dw, while a water Se concentration of 8.15 µg/L would be required in Luscar Creek.

Given the overall similarity of these creeks in terms of location and size, and the fact that both creeks support Rainbow Trout, it is counterintuitive that the reference creek could only tolerate a water Se concentration up to 1.19 µg/L before exceeding the draft fish tissue-based criterion, while the Se-exposed creek could tolerate a water Se concentration up to 8.15 µg/L and not exceed the draft fish tissue-based criterion. Again, as in the above lentic example, the only reason for this difference in translated water column concentrations is the inverse relationship between EF and water Se concentration that is not being accounted for in the EPA model. As also noted above, this becomes especially problematic because this incorrect application of the EF results in a reference site being the lowest translated water column concentration.

2.3.1.3 Overall Relationship Between Empirical and Translated Water Se Concentrations

Sections 2.3.1.1 and 2.3.1.2 provide two specific examples in which the simplified application of uncertain EFs from reference sites results in very low water Se concentrations predicted to result in the draft fish egg Se criterion of 15.8 mg/kg-dw. We also looked at the relationship between the paired empirical and translated water Se concentrations for all 53 sites (i.e., 20 lentic and 33 lotic) used by the EPA (translated water Se concentrations are those back-calculated from the egg Se criterion and reported in Table 3.13). As shown in Figure 2, there is a positive relationship between the empirical and translated water Se concentrations (i.e., translated water Se concentrations increase as empirical water Se concentrations increase). Again, this is reflecting the influence of water Se magnitude on the EF and highlights a deficiency in the "constant EF" approach used in EPA's model.

[Original letter contains Figure 2 – Relationship between translated water Se concentrations at various field sites that are predicted to result in a fish egg Se concentration of 15.8 mg/kg-dw (Table 3.13) vs. measured water Se concentrations at those sites (Appendix H; EPA 2015). See original letter.]

2.3.2 Alternative "Non-constant EF" Evaluation of EPA's Dataset

Given our concerns for the "constant EF" approach used in the EPA model, we provide an alternative evaluation of the EPA's dataset. First, using the CF and $TTF^{composite}$ assumptions in Table 3.13 of EPA (2015), particulate Se concentrations predicted to result in the draft fish egg Se criterion of 15.8 mg/kg-dw could be back-calculated. In the first row of Table 3.13, for example, the particulate Se concentration was calculated as follows:

[Original letter contains Equation – not numbered. See original letter.]

This calculation was applied for all 53 sites in Table 3.13 and the particulate Se concentrations ranged from 2.3 to 4.6 mg/kg-dw. This means that particulate Se concentrations of 2.3 to 4.6 mg/kg-dw, based on the food web models compiled by the EPA, are predicted to result in the draft fish egg Se criterion of 15.8 mg/kg-dw. Then, using the co-located particulate and water column Se concentrations compiled in Appendix H of EPA (2015), we evaluated the water Se concentrations in lentic and lotic water bodies predicted to result in the back-calculated particulate Se concentration range of 2.3 to 4.6 mg/kg-dw. This approach allows for consideration of the relationship between particulate and water Se concentrations without the use of a model that relies on a constant EF assumption. This approach also allows for a direct comparison to the draft water column criterion elements of 1.2 and 3.1 µg/L for lentic and lotic sites (EPA 2015), respectively, based strictly on the data already compiled and used by the EPA.

Using the paired particulate and water Se data compiled by the EPA (2015) in Appendix H, the inflection points where particulate Se concentrations begin to exceed the particulate Se concentration range of 2.3-4.6 mg/kg-dw is at about 3 µg/L for lentic waters and 6 µg/L for lotic waters (Figure 3). For lentic waters, note that there are three data points in the particulate Se range of 2.3 to 4.6 mg/kg-dw that are to the left of the vertical dashed green line (Figure 4a). Two of these are the reference lakes in Lemly (1985), which were discussed above in Section 1.1.1. The other is a pond within the Mancos River Basin, CO (Site MNP3; Butler et al. 1997). The reported water Se concentration in this pond was 1 µg/L and the associated particulate Se concentration was 5.15 mg/kg-dw. In a nearby pond (MNP2), the water Se concentration was 3 µg/L and the associated particulate Se concentration was 6.01 mg/kg-dw. The higher water Se concentration in the nearby pond (MNP2), which had very similar particulate Se concentrations, suggests that the single water Se concentration of 1 µg/L measured in MNP3 may not be reflective of the true Se exposure over time in this pond. This raises the question of whether the particulate Se concentration is linked to the appropriate waterborne Se concentration (or the particulate Se concentration may simply be of a magnitude that is similar to the two reference lakes evaluated in Lemly [1985]).

Interestingly, these lentic and lotic Se concentrations of about 3 and 6 µg/L that begin to exceed the critical particulate Se range, are similar to recommended lentic and lotic guidelines of 3.5 and 6.0 µg/L that have been previously developed (DeForest et al. 2014; in revision). In the latter evaluation, Se EF

and TTF data were compiled from a large number of both field and laboratory studies, and quantile regression methodology was used to relate a fish tissue Se guideline back to water Se guidelines.

The methodology of using site-specific EF data and then often generic TTFs and WB-to-egg Se CFs in order to estimate what the site-specific water Se concentration would need to be to result in a criterion of 15.8 mg/kg-dw is unusual and, as shown above, inappropriate, given the assumptions of constant EFs and TTFs that are required over broad ranges of Se exposure concentrations. Furthermore, several of the TTFs WB-to-egg CFs used in the evaluation are not even species-specific, so it appears that the final number of sites evaluated (53) is artificially limited. If the model is sometimes based on generic fish and food web information anyway, a much larger number of sites could be incorporated into the evaluation. Finally, it seems that it would be better to compile the "universe" of available Se partitioning data between water and particulates and among different trophic levels, and then consider the complete relationships over a range of exposure concentrations, rather using constant EF and TTF ratios. From these partitioning relationships, reasonable and appropriately-conservative estimates of water Se concentrations that may result in the fish egg Se criterion can be derived (e.g., DeForest et al. 2014). This, in our view, would be an improvement over the EPA's current approach in which EFs and TTFs are separately compiled and defined without consideration of how they may or may not relate to one another in actual field scenarios. As indicated in our comments, the EPA model often produces results that are counterintuitive with the site-specific data from which they were partially derived.

[Original letter contains Figure 3 – Relationships between particulate and water Se concentrations for (a) lentic and (b) lotic water bodies. See original letter.]

EPA-HQ-OW-2004-0019-0392; Anonymous Commenter; Posted 10/14/15

Third, most importantly, EPA has relied on a small number of sites (69) where EF values are available. This approach exacerbates the problem that EF values are highly uncertain and highly variable across sites, as discussed on page 74. In EPA's first draft, released in 2014, this small dataset having EF values was supported by a much larger database where fish tissue and water concentrations were measured but algae-detritus-sediment concentrations were not measured. In the 2014 draft this is discussed starting on page 90: 2,588 lotic and 596 lentic sites. Oddly, EPA removed this large database from the 2015 document. The removal of so large a body of highly relevant scientific evidence has the appearance of scientific misconduct. EPA must consider the large database of 2,588 lotic and 596 lentic sites and make that database available to the public.

EPA-HQ-OW-2004-0019-0415-A1; Idaho Department of Environmental Quality (DEQ); Posted 10/28/2015

EPA's derivation of protective water column concentrations from the root egg-ovary criterion is logical. However, the dataset used is skewed toward waters that would likely be judged as impaired. While EPA acknowledges that "selenium accrual in particulate matter is lower at aquatic sites with a higher water concentration of selenium compared to aquatic sites with a lower water concentration of selenium"

they don't appear to have taken this into account. We urge EPA to seek out and incorporate data sets from waters with lower selenium levels to assure the relations relied upon in their criterion derivation hold at lower environmental concentrations as well. As an example we provide the figure below plotting empirical selenium bioaccumulation versus ambient selenium concentrations in water in Idaho's major rivers.

[Original letter contains an unnumbered figure – Se BAFs vs SE in H2O. See original letter.]

While representing a variety of species, these data hint that selenium bioaccumulates more strongly in environments with less selenium in water, as would be expected with bio-regulation of a metabolically important element. These data represents a probabilistic slice of waters across Idaho, thus a more typical range of water quality than EPA examined in their criteria development. The implication is that if a median BAF, or EF, were used it would lead to a translation to a water column criterion that would be under-protective at low environmental selenium concentrations and over-protective at high environmental selenium concentrations.

EPA-HQ-OW-2004-0019-0401-A1; Colorado Wastewater Utility Council; Posted 10/15/2015

4.4.2 Enrichment Factors (EF)

Pages 74 of the 2015 draft Se criteria document state that "The single most influential step in selenium bioaccumulation occurs at the base of the aquatic food webs (Chapman et al. 2010)" and "The availability of selenium measurements from particulate material was limited." Given these statements and how critical it is to generate valid EFs, EPA should consider inclusion of an uncertainty discussion related to the particulate material Se data and how representative the calculated EF values may (or may not) be to all sites. We specifically note that reliance on only suspended particulate Se in the water column (as described in the document) is a poor measure of Se at the base of the food web in flowing waters. EPA should specifically note that inclusion of periphyton, biofilm, or sediment Se can and should also be considered when developing EFs for lotic systems.

Additional data to add to the EF database from GEI studies were included in Appendix A of our previous review. These additional data were not incorporated into the 2015 draft; therefore, calculated EF values for GEI studies are shown in Appendix A.

EPA-HQ-OW-2004-0019-0400-A1; The National Mining Association (NMA); Posted 10/15/2015

4.4.2 Enrichment Factors (EF)

Pages 74 of the 2015 draft Se criteria document state that "The single most influential step in selenium bioaccumulation occurs at the base of the aquatic food webs (Chapman et al. 2010)" and "The availability of selenium measurements from particulate material was limited." Given these statements and how critical it is to generate valid Enrichment Factors (EF), EPA should consider inclusion of an uncertainty discussion related to the particulate material Se data and how representative the calculated EF values may (or may not) be to all sites. Additional data to add to the EF database from GEI studies are

were included in Appendix A of our previous review. These additional data were not incorporated into the 2015 draft; therefore, calculated EF values for GEI studies are shown in Appendix A.

Comment Category 4.5 – Comments on EPA-Developed Food-Web Models and Calculation of Trophic Transfer Function – Composite ($TTF^{Composite}$) Values

4.5 Summary

This section contains comments on the trophic transfer function – composite ($TTF^{composite}$) approach and suggestions for making the analyses more accurate.

4.5 Response to comments

Regarding the comment that "the $TTF^{composite}$ approach would require prey item-specific consumption rate/frequency data (ideally site-specific) to best characterize exposure" EPA did use prey specific consumption rates in developing all food webs, where those data were available.

Equation 9 quantitatively expresses selenium bioaccumulation in fish ($C_{whole\text{-}body}$) as the product of the concentration of selenium at the base of the food web ($C_{particulate}$) and a parameter representing the trophic transfer of selenium through all dietary pathways ($TTF^{composite}$). This model of bioaccumulation is conceptually similar to the model of bioaccumulation utilizing a bioaccumulation factor (BAF). A BAF is the ratio of the concentration of a chemical in the tissue of an aquatic organism to the concentration of the chemical dissolved in ambient water at the site of sampling (U.S. EPA 2001c). Similar to the term $TTF^{composite}$, a BAF quantitatively represents the relationship between the chemical concentrations in multiple environmental compartments. However, a BAF is empirically derived from site-specific measurements, whereas $TTF^{composite}$ is derived from knowledge of the ecological system. Because each *TTF* is associated with a particular taxon, $TTF^{composite}$ can be inferred for an aquatic system using existing knowledge of dietary pathways and reasonable assumptions, without the considerable time and cost of collecting and analyzing tissue and water samples.

The parameter $TTF^{composite}$ quantitatively represents all dietary pathways of selenium exposure for a particular fish species within an aquatic system. The parameter is derived from species-specific *TTF* values representing the food web characteristics of the aquatic system, w_i, the proportion of species consumed.

In the 2016 final document, EPA retained the improved methodology incorporated into the 2015 draft by using species-specific or most- taxonomically-proximate TTFs

Species specific data was used preferentially over other available data. When species-specific data were not available, EPA estimated TTFs using sequentially higher taxonomic classifications (i.e., species, genus, family, order, then class) until one or more taxa for which a calculated TTF value was available matched the taxon being considered. If the lowest matching taxon was common to more than one species with a TTF value available, EPA used the median TTF from the matching species.

As noted in the 2016 criterion document, site-specific criteria can be developed using site-specific data. Appendix K of the 2016 criterion document provides additional information to support such approaches.

4.5 Specific comments

EPA-HQ-OW-2004-0019-0401-A1; Colorado Wastewater Utility Council; Posted 10/15/2015

4.4.1.2 Use of Composite TTFs

The composite TTF is the product of the TTFs that represent dietary pathways of Se exposure for a given species within an aquatic system. As we commented in our previous review, the $TTF^{composite}$ approach would require prey item-specific consumption rate/frequency data (ideally site-specific) to best characterize exposure. Species-and site-specific dietary preference data are likely not available for many combinations of organisms. In those scenarios, assumptions will need to be made for each prey item, introducing additional and potentially unrealistic uncertainty to derive a TTF composite value.

For more accurate analysis of a specific aquatic system, the best approach is to collect and analyze tissue and water samples to measure actual Se concentrations rather than making assumptions and using highly uncertain composite TTFs.

EPA-HQ-OW-2004-0019-0400-A1; The National Mining Association (NMA); Posted 10/15/2015

4.4.1.2 Use of Composite TTFs

The composite TTF is the product of the TTFs that represent dietary pathways of Se exposure for a given species within an aquatic system. As we commented in our previous review, the $TTF^{composite}$ approach would require prey item-specific consumption rate/frequency data (ideally site-specific) to best characterize exposure. Species-and site-specific dietary preference data are likely not available for many combinations of organisms. In those scenarios, assumptions will need to be made for each prey item, introducing additional and potentially unrealistic uncertainty to derive a TTF composite value.

For more accurate analysis of a specific aquatic system, the best approach is to collect and analyze tissue and water samples to measure actual Se concentrations rather than making assumptions and using highly uncertain composite TTFs.

Comment Category 4.6 – Comments on Classifying Categories of Aquatic Systems

4.6 Summary

This section contains comments on the characteristics EPA used to define lotic and lentic systems. Also included are comments on influence of residence time on selenium bioaccumulation and EPA's classification of the 69 EF sites. Comments also request that EPA specify a tissue-only criterion and guidance on fishless waters.

4.6 Response to comments

4.6 Responses on classifying categories of aquatic systems

Based on the comments of peer reviewers as well as stakeholders in the public process, the EPA went through each waterbody used in its analysis to develop lotic and lentic water column values, and determined whether it was lentic or lotic, being careful to note specific issues like run of the river reservoirs which could cause misclassification.

EPA revised the lotic and lentic section to better identify the difference between lotic and lentic in Section 3.2.4. Unfortunately, a parameter like residence time was not available for most of the waters in the dataset, thus EPA cannot provide this information in response to comments.

Regarding the somewhat conflicting comments that "it is **known that bioaccumulation of Se is significantly different in lentic and lotic systems** (Adams et al. 2000)." … and "it would be more appropriate to develop site-specific criteria rather than create **artificial groupings of waterbody types** that mask the site-specific differences so important to ensuring attainment of the tissue criterion" (emphasis added), EPA's goal was to provide national guidance on water column values that reflect the agreed-upon differences in selenium bioaccumulation between lotic and lentic systems. We agree the classification of lotic and lentic waterbodies could be nuanced in some instances, but in many cases such water body classification will be clear and self-evident (i.e., flowing and non-flowing waters, respectively). Residence time information for the waterbodies included in the 2016 criterion document analysis was not available to EPA, so EPA cannot provide specific residence time values associated with the lotic and lentic classifications used in the criterion, or that could be applied more generally, as some commenters are seeking.

We assert that decision to generate 2 sets of values to reflect the "known" fact "that bioaccumulation of Se is significantly different in lotic and lentic systems" to be superior and more appropriate than developing one national water column value which could be overprotective of lotic waters and underprotective of lentic water bodies, in some cases. Interested parties can develop site-specific criteria to reflect their particular water body conditions, as noted in the selenium criterion document. EPA has also provided helpful information regarding the development of site-specific criteria in Appendix K of the 2016 criterion document. Water column criterion element values were developed and are important to support adoption and implementation of the selenium criterion.

4.6 Specific comments

EPA-HQ-OW-2004-0019-0409-A2; OC Public Works; Posted 10/20/2015

6. Unclear Definition of Lentic and Lotic Waters

The water column portion of the Draft Se Criterion has very different concentrations for lotic and lentic waters. This appears reasonable because selenium speciation, thus its transport, fate, and bioaccumulation, are all affected by residence time, reaeration rate, and other biogeochemical characteristics in which lentic and lotic waters are distinct from each other. However, it is not clear how these two water types are defined, how transitional waters (i.e. those with characteristics between lentic and lotic) and seasonally-variable waters (i.e. those switching from lentic to lotic between seasons) and specially-variable waters (i.e. those with lentic and lotic conditions at different sections of the water body) are treated. Without this distinction, the development process as depicted in figures 3.6-3.9 appears arbitrary and significant issues will be raised when the Draft Se Criterion is implemented in these three types of waters.

For comments 2 through 7, USEPA should clarify the definition of lotic and lentic waters and use water column concentrations as a screening tool. For sites where selenium levels in tissue is near or above the Draft Se Criterion, site-specific water column guidelines should be derived by the bioaccumulation model used in this Draft Se Criterion. In this approach, only site-specific data should be used to reduce the uncertainty and improve scientific vigor of the model. With the tissue-based criterion to assess final attainment, the water column guidelines should be used to gauge the progress toward selenium load reduction and attainment of tissue-based criterion. This approach will also solve the 'new or increased inputs' issue (comment 7).

EPA-HQ-OW-2004-0019-0415-A1; Idaho Department of Environmental Quality (DEQ); Posted 10/28/2015

Bifurcating water column criteria into lotic and lentic has merit based on the information presented on differences in selenium speciation, food webs, and residence in these different waterbody types (section 3.2.4). But this also presents implementation challenges EPA should better address. Although EPA speaks of residence time as a defining characteristic, no definitive residence time is offered. EPA does not even provide descriptive information on the residence time of the waters used in their criteria development. A clear definition or method of classifying waterbodies into lentic and lotic is crucial to appropriate application of these separate criteria. Examples of waters that may be hard to classify include so called "run of the river" impoundments and the flooded outlet streams of dammed natural lakes. Furthermore there will always be transition areas, the inflows to lakes and reservoirs that may behave more stream-like. And outlet streams whose water quality, if not ecology, will for some distance be dictated by the water leaving the lake or reservoir. EPA should address how these transition zones are to be handled, especially in the light of their national push for clearer downstream waters protection.

EPA-HQ-OW-2004-0019-0391-A1; North American Metals Council (NAMC); Posted 10/14/2015

2.3 Other Comments

2.3.1 Definition of Lentic and Lotic

NAMC again requests that EPA provide a clear and unambiguous definition of lotic and lentic areas and clearly state that, since the draft criteria are based on freshwater data, they do not apply to estuaries or other transitional waters (e.g., coastal lagoons).

Other issues that will also result in a very high incidence of false alarms include, but are not restricted to: a clear definition of lentic and lotic is notably absent; protection goals are not clearly defined; there are flaws in the translations from tissue to water; a key exposure and toxicity modifying factor is ignored: the inappropriate requirement to "never exceed a tissue criterion"; and the current unrealistic approach to fishless waters and increasing inputs.

EPA-HQ-OW-2004-0019-0401-A1; Colorado Wastewater Utility Council; Posted 10/15/2015

4.4.3 Classification of Aquatic Systems – Lotic vs. Lentic

It is known that bioaccumulation of Se is significantly different in lentic and lotic systems (Adams et al. 2000). EPA attempts to differentiate between system types using EFs and residence time. As discussed in our previous review, this makes sense in theory, however, the resulting data have substantial overlap, indicating the differences are not that clear. It would be more appropriate to develop site-specific criteria rather than create artificial groupings of waterbody types that mask the site-specific differences so important to ensuring attainment of the tissue criterion.

5.1 Discussion of Final Criterion

As stated above, we strongly support EPA's decision to develop tissue-based Se criteria that are toxicologically and ecologically relevant. The tissue-based criteria, including our recommended modifications and updates, reflect the best science and are protective of fish.

EPA also derived nationwide lentic and lotic water column-based criteria to supplement the tissue-based criteria. However, as discussed in Section 3.3 it is not possible or appropriate to derive a single nationwide standard for water column-based criteria for only two water body types (lentic or lotic), and such an effort is not supported by EPA's own analysis. While we agree that use of Equation 18 (or a bioaccumulation factor) to translate a water column criterion from the egg/ovary criterion is a valid approach, it should only be used on a site-specific basis. In addition, as noted earlier, we strongly urge EPA to evaluate direct use of tissue-based criteria in NPDES permitting, which would obviate the need for the back-calculation to a water value, thus eliminating the potential errors and uncertainty that arise in such calculations.

EPA-HQ-OW-2004-0019-0400-A1; The National Mining Association (NMA); Posted 10/15/2015

4.4.3 Classification of Aquatic Systems – Lotic vs. Lentic

It is known that bioaccumulation of Se is significantly different in lentic and lotic systems (Adams et al. 2000). EPA differentiates between system types using EFs and residence time. As discussed in our previous review, this makes sense in theory, however, the resulting data have substantial overlap, indicating the differences are not that clear. It would be more appropriate to develop site-specific criteria rather than create artificial groupings of waterbody types that mask the site-specific differences so important to ensuring attainment of the tissue criterion.

5.1 Discussion of Final Criterion

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EPA also derived nationwide lentic and lotic water column-based criteria to supplement the tissue-based criteria. However, as discussed in Section 3.3 it is not possible or appropriate to derive a single nationwide standard for water column-based criteria for only two water body types (lentic or lotic), and such an effort is not supported by EPA's own analysis. While we agree that use of Equation 18 or other approaches could be used to translate a water column criterion from the egg/ovary criterion, this type of modeling should only be done with the appropriate site-specific data and not rely on default generalized model parameters. In addition, as noted earlier, we strongly urge EPA to evaluate direct use of tissue-based criteria in NPDES permitting, which would obviate the need for the back-calculation to a water value, thus eliminating the potential errors and uncertainty that arise in such calculations.

EPA-HQ-OW-2004-0019-0413-A2; Federal Water Quality Coalition (FWQC); Posted 10/28/2015

1. Classification of Lentic and Lotic Waters

The draft criteria contain different water column levels for the two categories of lentic and lotic waters. However, it is not entirely clear how waters will be classified as either lentic or lotic. The Agency indicates that it has confidence in how it classified various waters that it included in its evaluation for development of the criteria document. However, that does not tell regulated parties and other stakeholders how those waters were classified, or how other waters would be placed into one or the other category. EPA should provide clear definitions of the "lentic" and "lotic" terms that can be readily applied, considering factors such as flow rate, hydraulic residence time, selenium speciation, and (if appropriate) differing biological conditions.

III. CLASSIFYING WATERS AS LOTIC OR LENTIC

In the water column element of the criterion, there are separate values for lotic and for lentic waters. Because those levels differ substantially, it is critical for the criterion structure to clearly differentiate between those two types of waters.1 Unfortunately, EPA has not provided a clear differentiation, and

the peer reviewers raised this as a concern. The Agency's responses to those comments shed no clearer light on the question. If the water column levels are retained as elements of the criterion, then EPA needs to provide a clear, quantitative way to determine whether a waterbody is classified as lotic or lentic.

Here are some of the statements by peer reviewers on the lotic/lentic issue:

> "Presumably the definitions for lotic and lentic systems would be based on residence time of water or some related criteria, but the Draft Document does not contain an explicit definition of either type of system. Back calculating from egg/ovary to muscle/whole body and then down through trophic levels to derive allowable water column criterion for each of these types of aquatic systems is not scientifically valid, because of the use of generic conversion factors and broadly based trophic transfer factors. These generic terms do not incorporate site specific information, including concentration dependent uptake kinetics and consideration for important influencing factors (e.g., sulfate). The water based criterion is therefore, conservative and variable. As evidence for this, the monthly average exposure value for lentic systems is 1.3 ug/L. This value is at the upper end of background values for freshwater and may be exceeded even in the absence of industrial inputs in areas receiving runoff from seleniferous soils. The value is also lower than recently recommended lentic values based on similar analysis (2 and 2.1 ug/L respectively (Deforest et al., 2104, BC MoE 2014). (pp. 51-52)
>
> "Derivation of Enrichment Factors (EF) based on paired concentrations of selenium determined in water and particulate would have been influenced by the practice of allowing data to be paired if they were collected up to a year apart. In terms of application of EF to categories for lentic and lotic systems it is difficult to judge because of the lack of specific criteria to distinguish between the two types of systems in the Draft Document. While the US-EPA acknowledges the importance of residence time for defining aquatic systems as either lentic or lotic, the criterion for their initial assignment to each category is not apparent (Page 82). Despite statistical comparisons that support their aggregation, it is very likely that lakes, reservoirs, ponds and marshes will have vastly different selenium kinetics, and yet they are all designated as lentic systems. Likewise, selenium uptake into aquatic food-webs of creeks, drains, washes, rivers and streams may differ markedly. The wide range of variability in the aggregated categories (Figure 10, page 84) is compelling evidence in support of this point. Additional specific guidance is required to distinguish between the two types of aquatic systems and the applicability of EFs for each." (p. 118)
>
> "I agree with several commenters that EPA must develop rigorous definitions of lentic and lotic as guidance for regulators." (p. 125)
>
> "Again related to implementation, is the question of whether the lotic and lentic water Se criteria can be replaced by a different metric, such as residence time. In my opinion, the latter would be worthy of further consideration by the EPA, although I wonder whether more reliable categories could be developed based on existing datasets." (p. 128)

> "Lentic lotic clarification: The public comments express thoughtful concerns and practical questions that can serve as prompts to draft additional guidance and supporting information. (p. 135)

EPA responded to each of these concerns in the same basic way, expressing this thought:

> "Regarding the lack of clarity in the definitions of lotic and lentic water bodies.

Based on comments received, EPA examined the potential for residence time to classify the water bodies in the database, but available data were extremely limited. EPA also examined each waterbody to ensure that the available characteristics and sample location indicated that it was either a lentic or lotic site. EPA's follow-up analyses ensured that sites such as run-of-the-river-reservoirs, an example discussed in the reviewers comment, were not misclassified as lotic." (pp. 30-31)

In this response, EPA seems to be answering only part of the question. The Agency is explaining how it tried to ensure that among the waterbodies covered in its studies, it did not mischaracterize a waterbody as lentic when it should have been lotic, or vice versa. But the main concern being expressed by the commenters is that guidance is needed to determine whether other waters – ones that are not covered in the studies – are lentic or lotic. It does no good, in addressing that issue, for EPA to say that it did work to ensure that studied waters were properly classified. More is needed.

In addition, the FWQC disagrees with EPA's statement that "sites such as run-of-the-river- reservoirs" would be "misclassified as lotic." To the contrary, we believe that river systems and impoundments on river systems should be clearly classified as "lotic." For many such large river systems, there is a large flow between the related reservoirs each year, and the reservoirs are an integral part of the river systems. Based on the amount of water moving through these river systems and related reservoirs, they should be considered as lotic rather than lentic.

IV. CONCERNS ABOUT LENTIC VALUE

In addition to voicing concern about the Agency's lack of clarity in distinguishing between lotic and lentic waters in the water column element of the criterion, the peer reviewers also identified specific problems with the development of the lentic value, which is 1.3 ug/l. EPA has recognized these issues, but the way in which they have addressed the problems does not adequately respond to the comments.

Here is what the peer reviewers said about the lentic value:

> "The draft water column selenium criteria are 4.8 and 1.3 µg/L for lotic and lentic waters, respectively. In general, I do not agree with the approach used by the EPA in deriving these water column criteria. Although I do not agree with the approach, I do believe that the draft criterion of 4.8 µg/L for lotic waters is reasonable and consistent with our understanding of the range of Se bioaccumulation potential into fish across a wide range of lotic sites. However, for the draft lentic Se criterion of 1.3 µg/L, the approach used by the EPA results in this criterion being almost exclusively driven by data for two reference locations. This in turn is mostly due to what I perceive as a flaw in the approach, where site-specific Se data in invertebrates and fish are ignored and instead non-site-specific TTFs and CFs are applied that are inconsistent with the site-specific data. This resulted in cases where erroneously high modeled Se concentrations in

fish tissue are linked with low water Se concentrations (i.e., reference site concentrations), and then these become the "drivers" for the draft lentic criterion of 1.3 µg/L." (p. 42).

"For the water column based criterion, two separate elements are prescribed in the Draft Document: a monthly average and a separate element for intermittent (discontinuous) exposures. Each of these is further delineated to apply to either lentic or lotic systems. Presumably the definitions for lotic and lentic systems would be based on residence time of water or some related criteria, but the Draft Document does not contain an explicit definition of either type of system. Back calculating from egg/ovary to muscle/whole body and then down through trophic levels to derive allowable water column criterion for each of these types of aquatic systems is not scientifically valid, because of the use of generic conversion factors and broadly based trophic transfer factors. These generic terms do not incorporate site specific information, including concentration dependent uptake kinetics and consideration for important influencing factors (e.g., sulfate). The water based criterion is therefore, conservative and variable. As evidence for this, the monthly average exposure value for lentic systems is 1.3 ug/L. This value is at the upper end of background values for freshwater and may be exceeded even in the absence of industrial inputs in areas receiving runoff from seleniferous soils. The value is also lower than recently recommended lentic values based on similar analysis (2 and 2.1 ug/L respectively (Deforest et al., 2104, BC MoE 2014)." (pp. 51-52)

"A limitation of this modeling approach is that it ignored site-specific information on Se bioaccumulation in fish and their diets. The EFs used were site-specific, but Se modeling up the rest of the food chain and into fish was based on assumed model parameters. This becomes particularly important when considering the data "drivers" for the draft lentic Se criterion of 1.3 µg/L. This value is driven almost exclusively by data for two reference lakes (Badin Lake and High Rock Lake, NC, USA). Badin Lake was reported to have a water Se concentration of 0.32 µg/L and High Rock Lake a water Se concentration of 0.67 µg/L (Lemly 1985). For comparison, the mean water Se concentrations translated from a fish egg/ovary Se criterion of 15.2 mg/kg dw were 0.54 µg/L for Badin Lake and 1.2 µg/L for High Rock Lake. The former falls between the water Se concentrations reported for these two reference lakes and the latter almost equals the draft lentic criterion of 1.3 µg/L. Since six fish species were assumed to represent each of these two sites, these two reference sites are the drivers for the draft lentic Se criterion of 1.3 µg/L.

In addition to two reference sites being the drivers for the draft lentic Se criterion of 1.3 µg/L, the model for translating a fish egg/ovary Se criterion of 15.2 µg/L to a water Se concentration does not appear to be correct for these two sites. Although fish egg/ovary Se concentrations were not reported for Badin Lake and High Rock Lake, muscle Se concentrations were. Those muscle Se concentrations were reported on a wet weight basis and converted to a dry weight basis by assuming a moisture content of 75%. The muscle-to-egg CFs reported in Table 12 of the draft AWQC document were then used to estimate fish egg Se concentrations. These estimated fish egg Se concentrations for the two reference sites were, on average, less than one-half of the draft fish egg/ovary Se criterion of 15.2 mg/kg dw. Further, the muscle Se concentrations at the references sites ranged from 2.3 to 5.8 mg/kg dw, which are well below the draft muscle Se criterion of 11.8 mg/kg dw. The above demonstrates that the food

web model for these two reference sites does not accurately reflect Se bioaccumulation potential at these two sites and in fact greatly overestimates Se bioaccumulation potential."(pp. 93-94)

In response to these serious concerns with the lentic value, EPA says as follows:

> "Regarding the influence of Badin and High Rock Lakes, EPA agrees that they have a strong influence on the derived lentic value. Of the 44 site-species used for the lentic derivation via the 20th percentile value, 12 of the lowest 13 values are for Badin and High Rock. These lakes each have one EF, but each of its EFs is used six times, once for each of six fish species. The particulate concentrations measured in both of these lakes are near the median observed in EPA's lentic database, but their water concentrations are among the lowest. As a result of the peer reviewer's comments, EPA completed a reanalysis of the data to remove any overweighting of a few key high and low end sites in the calculations. To account for overweighting, EPA used one fish species per site – the species most sensitive to selenium bioaccumulation, to yield an appropriately protective water column criterion element." (pp. 93-94)

While it is helpful that EPA took action to address the overweighting problem, that is not a complete response to the concerns being raised. The peer reviewers indicated several problems with the way in which the lentic value was calculated, but the Agency addressed only one small part of the overall problem. Until it has considered and taken action to remedy the issues that have been identified, a lentic value should not be adopted as an element of the selenium criterion.

1. We recognize that this clear differentiation is difficult for some waterbodies. The uncertainty that results is yet another reason why it is important for EPA to clearly state the primacy of the fish tissue elements of the criterion over the water column elements.

Comment Category 4.7 – Comments on Deriving Water Column Criterion Element Concentration Value

4.7 Summary

This section contains comments on EPA's methods for deriving the water criterion element concentration value including filtering for sites having both an EF value and at least one fish species (n=53 in the 2015 draft document). This section also contains comments on using the lowest translated water value when having multiple fish species with translated water concentration values for the 53 sites (Table 3.13 in the 2015 draft document), and the use of the 20th percentile value for lotic and lentic water value distributions.

4.7 Response to comments

4.7 Responses concerning deriving water column criterion element concentration value

EPA notes that the number of sites having both an EF value and at least one fish species increased to 65 sites in the 2016 final criterion document, due to inclusion of new data, mostly obtained through the public comment process.

Regarding the surface water selenium criteria monthly average, EPA reanalyzed the data after considering a peer review comment on the 2014 draft and recalculated the lentic and lotic water column elements of the criterion to reflect appropriate consideration of both high and low exposure sites. In the 2014 External Peer Review Draft, translated lentic and lotic water criteria were calculated from 44 and 88 site-species combinations, respectively. A single site had as many as 8 sampled fish species. For example, of the 44 site-species used for the lentic derivation via the 20th percentile value, 12 of the lowest 13 values are for Badin and High Rock. In the 2014 draft, these lakes each had one EF, but each of its EFs was used six times, once for each of six fish species. The particulate concentrations measured in both of these lakes were near the median observed in EPA's lentic database, but their water concentrations were among the lowest. Conversely, several lotic sites (e.g., McElmo Cr., Spring Creek at LaBoca) had very low EFs (and by extension, high translated water concentrations), but each EF was used several times, once for each fish species. As a result of a peer reviewer's comments on the 2014 criterion, EPA completed a re-analysis of the data to remove any overweighting of a few high and low end sites in the calculations. To account for overweighting, EPA used one fish species per site, the species most sensitive to selenium bioaccumulation, to yield an appropriately protective water column criterion element for both lentic and lotic values. In addition to adjustments to correct for overweighting due to the influence of multiple species at high and low EF sites, EPA model changes to several TTFs and CFs were made reflecting incorporation of new information. Adjustments to correct for overweighting due to the influence of multiple species at high and low EF sites resulted in an increase in the translated lentic water concentration criterion from 0.9 µg/L to 1.5 µg/L, and a decrease in the translated lotic water concentration criterion from 4.2 µg/L to 3.5 µg/L.

EPA has not asserted, as the commenter states, that the "20th percentile cutoff points do NOT protect 80% of the fish species." EPA derived its fish tissue criterion elements to be protective of approximately

95% of aquatic genera, employing fish as the most sensitive taxa. EPA expects the water column values developed through bioaccumulation modeling to be protective against selenium impacts in the most bioaccumulative food web in 80% of lentic and lotic water bodies, respectively.

Regarding the number of studies upon which this approach is ultimately reliant, EPA evaluated 80 studies on selenium toxicity to aquatic organisms, identified in appendices C, D, and E; and in section 3.1.3. The 13 GMCVs (not including the 2 "placeholder" GMCVs used to fulfill missing taxonomic minimum data requirements [MDRs] included in the sensitivity distribution [SD]) were calculated from 15 SMCVs, which were calculated from 19 chronic values obtained from 24 studies. An additional 21 non-reproductive toxicity values were obtained from 20 studies for 10 species, including 5 species that were not used in the SD. Fish reproductive and non-reproductive summaries are included in Appendix C and D, respectively, and were used to demonstrate that the egg-ovary based criterion protects against both reproductive and non-reproductive effects in aquatic organisms. An additional 21 toxicity values from 22 studies encompassing 18 species, seven of which were not included among the reproductive or non-reproductive studies listed above, were evaluated and are included in Appendix E (other data). Three field studies with multiple species were also evaluated qualitatively to assess the relative sensitivity of Cyprinidae to selenium, and are included in Appendix E.

Finally, 11 studies encompassing 11 species were qualitatively evaluated to assess selenium nutritional requirements and are included in Appendix E. While EPA agrees that additional studies are always desirable, the selenium criterion is based upon a substantial dataset.

Regarding the comment that notes that there are a few reproductive studies for which EC_{10}s can be directly calculated as muscle or whole-body concentrations measured during the study, EPA opted to use the egg-ovary EC_{10} from such studies and then convert the SMCV or GMCV from egg-ovary to whole body or muscle using all available whole body/egg-ovary or muscle/egg-ovary ratios. EPA used the current approach because it is also scientifically defensible.

There were over 3000 whole- body fish tissue measurements that could be coupled with water concentrations measured. The 3000 measurements include same- site values of (a) different species measured at the same time, (b) the same species measured at different times, and (c) different species measured at different times.

4.7 Responses to other issues brought up in these comments

Regarding the comment on the biokinetic approach, EPA's kinetic analysis was presented in Appendix G of the 2014 draft. It was similar to the work of Brix and DeForest (2008). It has since been revised to make it even more similar in structure to Brix and DeForest (2008). It continues to have a similar response time as Brix and DeForest because the limiting kinetic rate used in both Brix and DeForest and the 2014 Appendix G is based on the same fathead minnow study by Bertram and Brooks (1986).

Regarding the biokinetic model and intermittent criteria, the kinetic analysis of Appendix G of the 2014 draft specifically addressed intermittent exposure. When applied to intermittent exposure, the analysis demonstrated the protectiveness of the 30- day averaging period that EPA is recommending.

The intermittent criterion is a rearrangement of the water chronic criterion and its kinetic model-based 30-day averaging period. The 2014 intermittent criterion thus hinged on the kinetic model of the 2014 Appendix G. In the final 2016 criterion document Appendix G is now Appendix J. Appendix J uses a single set of kinetic parameters. Its different figures address different assumptions about the time series of water concentrations.

Regarding the comment that "EPA's approach suffers a weakness in relying on model-predicted fish/water concentration ratios," rather than on the measured fish /water ratios, as noted above, such an empirical fish/water ratio approach was used by DeForest et al in 2014. Recalculating the DeForest et al water concentrations based on EPA's 2016 15.1 mg/kg dw bw egg-ovary criterion element value (instead of the authors' proposed 20 mg/kg egg-ovary value), the outcome of the DeForest analysis matched EPA's 2016 lentic water column element criterion value exactly, and was within 1 µg/L of the EPA's 2016 water column element criterion value. This information further corroborates and substantiates the validity of EPA's bioaccumulation modeling approach.

4.7 Specific comments

EPA-HQ-OW-2004-0019-0392; Anonymous Commenter; Posted 10/14/15

Second, irrespective of the soundness of the mathematical structure, EPA's approach suffers a weakness in relying on model-predicted fish/water concentration ratios for the 69 sites in its database, rather than on the actual measured ratios. This seems peculiar. Reliance on model predictions can be appropriate when observations are lacking. But there appears to be no good reason for opting for model-predicted fish/water concentration ratios for sites where the actual fish and water concentrations have been measured.

EPA-HQ-OW-2004-0019-0409-A2; OC Public Works; Posted 10/20/2015

4. Deviation of Established Aquatic Life Criterion Development Process

In Figure 3.9 on page 84, the probability distributions with lentic and lotic conditions no longer correspond to the 20th percentile protection as claimed. Due to the large uncertainties in the calculation of water column numbers, as explained above, the lower end data points simply represent water bodies with the lowest observed water column selenium concentrations, not necessarily fish with the lowest egg/ovary levels. Therefore these 20th percentile cutoff points do NOT protect 80% of the fish species. More importantly, USEPA selected the lowest water column level for each site with more than one fish species, while higher water column numbers at these sites corresponding to other species were not represented at all in Figure 3.9. This is a clear violation of the established protocol and has resulted in artificially lowered water column criteria. This approach is not justified and Figure 3.9 needs to be replotted.

EPA-HQ-OW-2004-0019-0388-A2; J. R. Simplot Company; Posted 10/14/2015

A.2. Conservatism in Calculating Lentic and Lotic Values

[Page 80, Section 3.2.5]

This section presents EPA's approach to deriving protective water column concentrations for lentic and lotic categories. Translated aqueous concentrations are derived for each site evaluated. The resulting water quality lotic and lentic criterion values are derived from the 20th percentile of translated water column values using the egg/ovary criterion as the target criterion. Table 3.13 (pages 82-83) of the document compiles the dataset for lotic and lentic translated chronic criterion values from a number of different field studies. The primary issue that arises in review of this section is that both the lentic and lotic values are very low and may lead to conclusions of impairment when in fact none exists.

As noted in Simplot's previous comments on the 2014 Draft, EPA has continued to use the 20th percentile of a distribution of chronic criterion values for the lentic and lotic systems, which are each individually based on an EC10 response. This is an example of conservatism that is compounding uncertainty by ultimately deriving a value that is too low.

EPA-HQ-OW-2004-0019-0401-A1; Colorado Wastewater Utility Council; Posted 10/15/2015

3.4 Derivation of Protective Water Column Concentrations

3.4.1 Use of Probability Distribution of Water Column Concentrations

As stated previously, we do not agree with the general approach used to derive the two default water column concentrations meant to be protective of fish-tissues. Table 3.13 on page 82 of the 2015 draft Se criteria document presents site-specific data for 20 lentic and 33 lotic species-site combinations and includes site-specific enrichment factors (EF), species-specific whole-body to egg/ovary CF, and composite trophic transfer function (TTFcomposite) values based on expected trophic levels at the site. As will be discussed in Section 4.4 of our review, use of site-specific EFs and TTFs is critical when deriving a translated water quality criterion.

The final water quality criteria selected for lotic and lentic systems were based on Figure 3.96, page 84 of the 2015 draft Se criteria document. This figure is a probability distribution of the water column concentrations for lentic and lotic sites after being translated from the final egg/ovary tissue criterion (data from EPA Table 3.13). As we stated in our previous review, it appears this figure and the choice of a 20th percentile were used as if these represented sensitivity distribution curves, in which protectiveness can be predicted based on selecting a certain percentile value from the curve. However, these are not sensitivity distribution curves – in fact, as we pointed out last year, each value on these curves is a translated water concentration value that was specifically calculated to be protective of the egg/ovary tissue criterion. Therefore, each and every point on this graph (and those values in the far-right column of Table 12) is protective of the egg/ovary criterion based on the site-specific parameters at that site (given site-specific EF, CF, TTF).

Thus, the analysis by EPA actually demonstrates that water concentrations that are protective of the tissue criterion can range from 0.23 µg/L to 50.4 µg/L for lentic sites, and 1.2 µg/L to 40.6 µg/L for lotic sites, depending on the site-specific factors used in Equation 18. By selecting a 20th percentile value to use as the water column criteria, as EPA did, 80% of the sites in Table 3.13 would be overprotected, and 20% of the sites would be underprotected, resulting in a water column criterion that is wrong virtually 100% of the time – with the exception being the particular sites that fell right on the 20th percentile lines.

We agree that use of Equation 18 (or a bioaccumulation factor, as discussed later) to translate a water column criterion from the egg/ovary criterion is one of many valid approaches, but only on a site-specific basis. In addition, the dataset used to derive these water column values is very limited, especially when considering this is supposed to be the basis for a national criterion. Using additional data from several GEI projects (and other GEI updates previously discussed in this document), paired data were available for 47 additional sites, which more than doubles the database used by EPA. Using this expanded dataset, we recalculated the lotic water column value using EPA's method and derived a value of 4.2 µg/L, roughly 35% higher than EPA's default. Protective values for these lotic sites range from 1.18 µg/L to 81.03 µg/L.

While we still believe this method for calculating a nationwide water column value is over-conservative, this recalculation demonstrates how additional data can substantially affect the final value. If EPA intends to use this method to calculate a nationwide water column value, there should be more effort put into collecting site-specific data to include in the database, and not just relying on a few published literature values, most of which were data collected more than 20 years ago.

EPA-HQ-OW-2004-0019-0400-A1; The National Mining Association (NMA); Posted 10/15/2015

3.4 Derivation of Protective Water Column Concentrations

3.4.1 Use of Probability Distribution of Water Column Concentrations

As stated previously, we do not agree with the general approach used to derive the two default water column concentrations meant to be protective of fish-tissues. Table 3.13 on page 82 of the 2015 draft Se criteria document presents site-specific data for 20 lentic and 33 lotic species-site combinations and includes site-specific enrichment factors (EF), species-specific whole-body to egg/ovary conversion factors (CF), and composite trophic transfer function ($TTF^{composite}$) values based on expected trophic levels at the site.

The final water quality criteria selected for lotic and lentic systems were based on Figure 3.96, page 84 of the 2015 draft Se criteria document. This figure is a probability distribution of the water column concentrations for lentic and lotic sites after being translated from the final egg/ovary tissue criterion (data from EPA Table 3.13). As we stated in our previous review, it appears this figure and the choice of a 20th percentile were used as if these represented sensitivity distribution curves, in which protectiveness can be predicted based on selecting a certain percentile value from the curve. However, these are not sensitivity distribution curves – in fact, as we pointed out last year, each value on these

curves is a translated water concentration value that was specifically calculated to be protective of the egg/ovary tissue criterion. Therefore, each and every point on this graph (and those values in the far-right column of Table 12) is protective of the egg/ovary criterion based on the site-specific parameters at that site (given site-specific EF, CF, TTF).

Thus, the analysis by EPA actually demonstrates that water concentrations that are protective of the tissue criterion can range from 0.23 µg/L to 50.4 µg/L for lentic sites, and 1.2 µg/L to 40.6 µg/L for lotic sites, depending on the site-specific factors used in Equation 18. By selecting a 20th percentile value to use as the water column criteria, as EPA did, 80% of the sites in Table 3.13 would be overprotected, and 20% of the sites would be underprotected, resulting in a water column criterion that is wrong virtually 100% of the time – with the exception being the particular sites that fell right on the 20th percentile lines.

We believe there are a number of valid approaches to translate an egg/ovary criterion to a water column value, such as Equation 18 or a bioaccumulation factor (as discussed later), but only if the proper data are used in the equations. The key is to properly characterize the base of the food chain, which for lotic systems includes incorporating sediment and/or periphyton data, rather than relying on suspended particulate Se data. Other modeling approaches that also capture the various aspects of the system could also be used to translate a water column criterion.

In addition, the dataset used to derive EPA's water column values is very limited, especially when considering this is supposed to be the basis for a national criterion. Using additional data from several GEI projects (and other GEI updates previously discussed in this document), we recalculated the lotic water column value using EPA's method and derived a value of 4.2 µg/L. Paired data from GEI projects were available for 47 additional sites, which more than doubles the database used by EPA. Protective values for these lotic sites range from 1.18 µg/L to 81.03 µg/L. While we still believe this method for calculating a nationwide water column value is over-conservative, this recalculation demonstrates how additional data can substantially affect the final value. If EPA intends to use this method to calculate a nationwide water column value, there should be more effort put into collecting site-specific data to include in the database, and not just relying on a few published literature values, most of which were data collected more than 20 years ago.

In addition, we also concur with comments provided by (API 2015) regarding the counterintuitive results calculated when using constant EFs and TTFs. We would agree that the alternative approaches they provide for these calculations would result in more appropriate protective water column criteria.

Comment Category 4.8 – Comments on Deriving Averaging Period and Intermittent Exposure Water Criterion Element

4.8 Summary

This section contains comments on the derivation of the averaging period for the water criterion element, including kinetics for the trophic levels and EPA's analysis resulting in a 30-day averaging period. Also included in this section are comments on the derivation of the intermittent exposure equation. Some commenters proposed that the averaging period should be 60 days and one proposed a four-day average. Several commenters disagree with EPA's derivation of the intermittent exposure equation and recommended the use of a biokinetic model. Some commenters noted that the terms *background concentration* and *elevated concentration* were not well-defined.

4.8 Response to comments

4.8 Responses concerning the averaging period of the intermittent exposure element

The intermittent criterion is meant to protect receiving and downstream waters from bioaccumulative impacts by limiting the amount of selenium that is available to be taken up by biota and bioaccumulated to levels of concern in sensitive species. The derivation of the 30-day averaging period (and the subsequent derivation of the intermittent criterion) and the considerations upon which EPA based its decision to use the EC_{10} involve the kinetics of bioaccumulation. However, EPA is not addressing the same issue twice. Rather EPA is addressing two distinct issues that are both affected by bioaccumulation and kinetics. For these reasons EPA finds it is reasonable and protective to select the EC_{10} as the measurement endpoint for this tissue- based criterion.

The intermittent criterion elements were developed to address intermittent elevated input scenarios that could result in chronic effects via bioaccumulation in an ecosystem, effects that may not be captured through assessing impacts considering only continuous 30-day exposure scenarios. EPA has since revised the 2014 Appendix G (now Appendix J) kinetic model to include a water-TL1 step.

EPA deleted the 2014 document's language about the application of the intermittent criterion to ordinary smoothly varying concentrations. The intermittent criterion provides the same protection as the 30-day chronic criterion (from which it is derived). Whereas the 30-day chronic expresses the criterion in terms of one average of all concentrations occurring within a 30-day period, the intermittent criterion applies to two averages, occurring for two different durations within the 30-day period, one labeled the intermittent and one labeled background. The intermittent criterion will achieve its purpose no matter where the line is drawn between intermittent concentration and background concentration. The intermittent criterion elements were developed to address intermittent elevated input scenarios that could result in chronic effects via bioaccumulation in an ecosystem, effects that may not be captured when considering only continuous 30-day exposure scenarios.

EPA's kinetic analysis was presented in Appendix G of the 2014 draft. It was similar to the work of Brix and DeForest (2008). It was since revised in the 2015 draft to make it even more similar in structure to

Brix and DeForest (2008). It continues to have a similar response time as Brix and DeForest because the limiting kinetic rate used in both Brix and DeForest and the 2014 Appendix G is based on the same fathead minnow study as referred to in the comment: Bertram and Brooks (1986).

Regarding the biokinetic model and intermittent criteria, the kinetic analysis of Appendix G of the 2014 draft specifically addressed intermittent exposure. When applied to intermittent exposure, the analysis demonstrated the protectiveness of the 30- day averaging period that EPA is recommending.

The intermittent criterion is a rearrangement of the water chronic criterion and its kinetic model-based 30-day averaging period. The 2014 intermittent criterion thus hinged on the kinetic model of the 2014 Appendix G. In the revised document Appendix G is now Appendix J.

4.8. Specific comments

EPA-HQ-OW-2004-0019-0392; Anonymous Commenter; Posted 10/14/15

Fourth, EPA has indicated that the water criteria were derived from site median water concentrations. To accord with how EPA derived them, each of the two water criteria must be expressed as a site median water concentration, not as a site 30-day once-in-three-year concentration. If EPA wants a criterion that applies to once-in-three-year concentrations, then EPA's derivation must use water concentrations corresponding to the upper tail of observed concentrations at each site having an EF measurement.

EPA-HQ-OW-2004-0019-0387-A1; Colorado Department of Public Health & Environment; Posted 10/14/2015

While the WQCD appreciates a simplified approach such as that used to develop the intermittent criterion, there are other methods available (e.g., biokinetic-based model [Brix and DeForest 2008]) that may be more relevant and scientifically valid. Did EPA consider use of any other type of model? The draft criteria document would benefit from a detailed discussion on this topic, including an evaluation of the benefits of using one approach over the other. It may be possible to recommend multiple options for acceptable approaches that would answer the same question, as both regulators and the regulated community appreciate knowing criteria are as precise and relevant as possible.

The WQCD looks forward to seeing implementation guidance and additional information from EPA on this element of the criterion.

EPA-HQ-OW-2004-0019-0401-A1; Colorado Wastewater Utility Council; Posted 10/15/2015

3.4.4 Intermittent-exposure Element

The intermittent exposure component of the water column-based criterion attempts to address pulses of elevated Se concentrations that could contribute to chronic effects. The equation to calculate the intermittent exposure criterion seems to be an oversimplification as it is essentially just a rearrangement of the equation to calculate a 30-day average concentration. A more appropriate way to determine limits for short-term elevated pulsed Se exposures would be to use a scientifically-based biokinetic model as discussed in Appendix G of the 2014 draft Se criteria document, and described in more depth in DeForest et al. (in press). We have also provided further recommendations on calculation of this element in our previous review (GEI 2014a).

EPA-HQ-OW-2004-0019-0400-A1; The National Mining Association (NMA); Posted 10/15/2015

3.4.2 Intermittent-exposure Element

The intermittent exposure component of the water column-based criterion attempts to address pulses of elevated Se concentrations that could contribute to chronic effects. The equation to calculate the intermittent exposure criterion seems to be an oversimplification as it is essentially just a rearrangement of the equation to calculate a 30-day average concentration. A more appropriate way to determine limits for short-term elevated pulsed Se exposures would be to use a scientifically-based biokinetic model as discussed in Appendix G of the 2014 draft Se criteria document, and described in more depth in DeForest et al. (in press). We have also provided further recommendations on calculation of this element in our previous review (GEI 2014a).

Comment Category 4.9 – Comments on EPA's Validation of the Translation Equation (Equation 18)

4.9 Summary

This section contains comments on the method EPA used to validate the translation equation.

4.9 Response to comments

4.9 Response concerning the validation of the translation equation

Regarding the translation of the tissue criterion to water, EPA re-evaluated conversion factors used and refined the approach to reflect the most phylogenetically proximate data in its criterion calculations (see section 6.2 of the 2016 final criterion document), strengthening its previous draft analyses. As noted above EPA also re-evaluated the lentic and lotic water column values, and developed values that are based on the best available, scientifically defensible science to yield water column values that are protective of aquatic life based on available data.

The water-column element is a translation of the egg-ovary element and thus is intended to provide the same level of protection as the egg-ovary element. However, some level of uncertainty in translating the egg-ovary element to the water-column element is unavoidable. To address this uncertainty, EPA chose the 20th percentile of translated water-column values using the most bioaccumulative food web present at each site to select a protective national water column criterion element. Limitations of available data only allowed translation of the egg-ovary criterion element at 69 unique aquatic sites. The 20th centile was selected because it results in a low probability of false negatives, (i.e., low probability of failure to indicate exceedance of the egg-ovary criterion element via the water column element).

4.9 Specific comments

EPA-HQ-OW-2004-0019-0418; Anonymous public comment; Posted 11/02/2015

The Selenium aquatic life criterion is proposed to be reduced from the current 5 g/L water to new criteria of 1.2 f g/L in lentic water and 3.1 g/L water in lotic water. These significant reductions of 76% and 38% respectively are based on the correlation in Figure 6.4 on page 125 of the document. That figure shows a chart that has a stated coefficient of correlation (r) of 0.81. This means it has a coefficient of determination (r2) of 0.65. Thus only 65% of the variance of one variable can be explained by the other variable.

This chart with the low 65% factor of predictability is being used to make significant reductions in a criterion that will eventually be applied to direct and indirect dischargers of waste water containing selenium. There is no practical large-scale waste water treatment method to achieve the proposed 1.2 and 3.1 g/L levels if they were ever imposed by permits on direct and indirect waste water discharges.

Additional testing should be conducted in order to increase the model's coefficient of determination (r2) before making such a significant reduction in a criterion that will have real-world impacts on direct and indirect waste water discharges. Thank you for letting me comment.

Comment Category 5.1 – Comments on Site Specific Modification of Fish Tissue Criterion Elements

5.1 Summary

This section contains comments on site-specific modification of fish tissue criterion elements including applying EPA's Recalculation Procedure to edit the species toxicity database and conducting original reproductive effect studies at the site. Commenters expressed a need for more guidance in terms of process and data requirements.

5.1 Response to comments

5.1 Responses concerning the site-specific modification of fish tissue criterion elements

This criterion structure can be applied to site- specific conditions; the variability and uncertainty will likely be lower with a dataset from a specific site.

Regarding those aquatic systems where fish and their prey species can experience significant bioaccumulation of selenium despite low water concentrations, data on fish tissue in waters where available data (e.g., unusually large EFs) suggest the possibility of "toxicologically significant bioaccumulation" despite low selenium water concentrations can support site specific criteria development. Furthermore, the national criterion can easily be adapted to site- specific situations using site-specific data using the modeling information provided in the document, and/or information provided in the 2016 criterion appendices.

EPA is also developing implementation information via separately issued draft technical support documents, including information on conducting fish tissue sampling that could be applied to inform development of site-specific criteria.

5.1 Specific comments

EPA-HQ-OW-2004-0019-0395-A1; CONSOL Energy; Posted 10/15/15

While we appreciate the EPA's development of chronic selenium criteria and acknowledge that this more scientifically justifiable approach, we urge the EPA to allow states to continue to develop and implement their own standards. Given the wide variation in selenium sources, ecosystems, and climate, efforts like those of West Virginia and other state environmental agencies to develop region specific tissue based criteria should be encouraged by EPA. EPA should give significant weight to these and other efforts being conducted by regions of the U.S. in developing scientifically defendable region specific criteria.

EPA-HQ-OW-2004-0019-0386-A2; Asarco LLC; Posted 10/13/2015

Like NAMC, Asarco supports the option for development of site-specific criteria based on appropriate studies, to reflect instances of naturally elevated selenium and/or the presence of less sensitive populations.

EPA-HQ-OW-2004-0019-0413-A2; Federal Water Quality Coalition (FWQC); Posted 10/28/2015

One concern is the use of species sensitive distributions (SSDs) to generate predictions and quantify stressor-response relationships. While we support the use of SSDs when used to generate relative species sensitivities, it is important to recognize that SSDs are predictive toxicological responses of a range of test organisms as well as some surrogate species. Since concern about selenium is not based on its acute or chronic toxicity of its inorganic form in the water column per se, but rather, the accumulation of its organic form via dietary exposure that is subsequently passed to eggs resulting in juvenile deformities and/or embryonic mortality, the automatic incorporation of SSDs as default values, without consideration of other information, is inappropriate. We suggest that one should have the opportunity to collect and apply site-specific fish tissue and toxicity information, which could be used instead of relying entirely on simple SSD toxicity relationships. This approach will address key variables, including, but not limited to: geologic substrate, temporal differences, hydrological and chemical conditions, watershed land-use, geomorphology, and natural vegetation.

EPA-HQ-OW-2004-0019-0401-A1; Colorado Wastewater Utility Council; Posted 10/15/2015

1.1.1 Incorporation of Background Conditions into Site-specific Criteria

Appendix K of the 2015 draft Se criteria document, which describes methods for deriving site-specific criteria, does not discuss inclusion/consideration of data from reference or background sites. This is especially critical at sites with background levels of Se that would be considered elevated, comparatively speaking. In Appendix A, Examples 1-6 include calculation of site-specific criteria that includes background Se concentrations of 5.0 µg/L. Working through the calculation results in a site-specific water column criteria that are always lower than the original background concentration. It is unclear how these calculations could be applied to sites with naturally elevated background Se and result in a Se criterion that would be appropriate for that site.

As discussed in Section 4.1 of this review, ambient site-specific criteria may be appropriate in many parts of the country containing underlying geology with elevated Se levels. This naturally elevated Se may lead not only to elevated water concentrations, but also to naturally elevated fish tissue concentrations, resulting in the need for not only site-specific water column criteria but also a need for an approach that acknowledges there could be site-specific tissue criteria. In our previous review a more in depth discussion of this issue was provided along with specific examples (GEI 2014a).

4.5 Site-specific Criteria

4.5.1 Deriving Site-specific Water Concentration Values from the Egg/Ovary Criterion

Appendix K of the 2015 draft Se criteria document describes a methodology to derive site-specific criteria using a mechanistic modeling approach. However, Appendix K seems to simply be a more detailed presentation of information presented in the main text. It does not describe the process or data requirements that a state or tribe would need to follow/generate in order to have their site-specific criteria considered by EPA. In our previous review we discussed several questions and concerns that should be addressed to enable states and tribes to appropriately develop site-specific criteria (GEI 2014a).

EPA-HQ-OW-2004-0019-0400-A1; The National Mining Association (NMA); Posted 10/15/2015

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Appendix K of the 2015 draft Se criteria document, which describes methods for deriving site-specific criteria, does not discuss inclusion/consideration of data from reference or background sites. This is especially critical at sites with background levels of Se that would be considered elevated, comparatively speaking. In Appendix A, Examples 1-6 include calculation of site-specific criteria that includes background Se concentrations of 5.0 µg/L. Working through the calculation results in a site-specific water column criteria that are always lower than the original background concentration. It is unclear how these calculations could be applied to sites with naturally elevated background Se and result in a Se criterion that would be appropriate for that site.

As discussed in Section 4.1 of this review, ambient site-specific criteria may be appropriate in many parts of the country containing underlying geology with elevated Se levels. This naturally elevated Se may lead not only to elevated water concentrations, but also to naturally elevated fish tissue concentrations, resulting in the need for not only site-specific water column criteria but also a need for an approach that acknowledges there could be site-specific tissue criteria. In our previous review a more in depth discussion of this issue was provided along with specific examples (GEI 2014a).

4.5 Site-specific Criteria

4.5.1 Deriving Site-specific Water Concentration Values from the Egg/Ovary Criterion

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EPA-HQ-OW-2004-0019-0402-A2; The Stakeholders Implementing TMDLs in the Calleguas Creek Watershed; Posted 10/15/2015

For the Development of SSOs, the Methodology to Derive Water Concentrations from Whole-Body Fish or Muscle Tissue Criterion, Rather than Egg/Ovary Criterion, Should Be Clearly Presented.

The Stakeholders strongly support the flexibility provided by the 2015 Draft Selenium Criterion on Page 95, Section 5 to adopt SSOs which use a peer-reviewed model to derive water concentrations from fish whole-body or muscle tissue criterion rather than egg/ovary criterion:

> "Using either the EPA national recommended egg-ovary, whole-body, or muscle criterion concentration element or a site-specific egg-ovary, whole-body, or muscle criterion element, translation of the fish tissue criterion to a water concentration can be performed in a manner that accounts for site-specific conditions."

While the Stakeholders acknowledge that selenium toxicity occurs primarily through transfer to the eggs and subsequent reproductive effects, using a peer-reviewed model to derive water column concentrations from fish whole-body or muscle tissue criterion is necessary during development of SSOs because the site-specific validation of the model may prove to be infeasible if fish eggs and/or ovaries are needed for model validation. In many areas in Southern California, obtaining fish eggs/ovaries is infeasible, whereas collection of whole-body fish tissue can be consistently expected and is therefore significantly more practical.

For these reasons, efforts in Southern California have focused on whole-body fish tissue for regulatory purposes, including development of site-specific objectives. In Southern California (and most likely throughout the arid western United States), all model validation efforts will be based on whole-body fish tissue. As a result, it may be necessary and/or preferable for the model to be validated using fish whole-body or muscle tissue data. Therefore, SSOs should not be limited to relying on calculating water column concentrations from egg/ovary and the 2015 Draft Selenium Criterion should explicitly provide the process for such a translation in Appendix K. Currently, Appendix K only identifies the steps necessary to translate egg/ovary concentrations into water column concentrations (using both the mechanistic model and a field derived bioaccumulation factor (BAF)). While the steps may be very similar, identifying the process specifically for whole-body fish tissue would aid in making the appropriateness of such a translation more explicit, as well as supporting local efforts to implement such a translation.

Requested Actions:

Revise Section 1.1 and 1.2 of Appendix K to include the process for deriving a site-specific water column concentration value from whole-body and/or muscle tissue criterion.

EPA-HQ-OW-2004-0019-0415-A1; Idaho Department of Environmental Quality (DEQ); Posted 10/28/2015

The criterion proposed is fish-centric. While there is good reason for this, i.e. greater sensitivity of fish than other aquatic taxa, this can be problematic for states like Idaho whose fish species diversity is

naturally low. The national criterion is based on a number of fish species that are not native to Idaho, but excluding those non-native species in a criterion recalculation may not leave enough data to do a calculation. A broader species sensitivity distribution, including less sensitive macro-invertebrates might address this but would yield a quite different criterion that could leave the more important and more sensitive fish suffering. How does EPA view this conundrum? What do you recommend for waters with limited fish species diversity? Would EPA accept a criterion be based on a single native 'most-sensitive' fish species?

Tailoring the criterion to site-specific aquatic communities should be built into the criterion. EPA acknowledges different sites will have different communities with different species selenium sensitivities (e.g. lentic and lotic, warm versus coldwater), yet of necessity the national criterion throws all species into one sensitivity distribution. While recalculation of a site-specific criterion is offered as a route to an alternative, selectively dropping species not present at a site, this will require rulemaking and EPA action over and over. We suggest EPA build into the criterion, much like the translation of the root egg-ovary criterion to other bases, a preset recalculation procedure that would not require rulemaking to tailor the criterion to species present at a site. For example, like the lentic-lotic bifurcation of the water criterion, EPA could develop a cold-warm water fisheries bifurcation as well.

We recommend EPA make an explicit statement that implementing the chapter 6 "site-specific criteria" is a translation of the national criteria using site-specific conditions, and as such can be implemented without additional rulemaking. Site-specific translations have been around for decades with the pH and temperature dependent ammonia criteria, hardness-dependent metals criteria, and more recently the BLM-based copper criteria. Such "on-the-spot" calculations of national criteria that are dependent on site-specific data are quite different administratively than are "site-specific criteria," which must be adopted through rulemaking. If the chapter 6 procedures are intended to be "site-specific translation" — an approach we strongly recommend — then consistent use of the term "site-specific translation" and removal of all instances of "site-specific criteria" throughout the document would be helpful.

EPA-HQ-OW-2004-0019-0417-A1; Utility Water Act Group (UWAG); Posted 11/02/2015

a. EPA should clarify what is meant by "ecological significance".

UWAG requests EPA clarify what it means by "ecological significance" and identify the ecological parameters to consider in relation to identifying the appropriate target fish species in aquatic systems with fish of unknown selenium sensitivity and bioaccumulation potential. *See* Draft Criterion at K-10. Ecological significance could refer to a variety of traits, such as trophic level or habitat preferences. Clarity on this is important to ensure appropriate traits are considered. Absent clarity, the default may be to use trophic level as the deciding trait for determining ecological significance, which may be inappropriate because, unlike mercury, selenium levels normally do not increase with fish trophic level.

EPA should include flexibility to use data from species other than the targeted species.

UWAG recommends that EPA include flexibility to collect and use data on more than the targeted fish species to derive a water-column concentration. Such flexibility is necessary because there is likely to be

situations where collecting representative data on the most sensitive species is not possible. For example, a warm water stream may contain three or four species of sunfish (family Centrarchidae), including bluegill. UWAG believes that documenting the selenium tissue level of the related sunfish species should be allowed. Such data would provide useful information on the potential range of selenium concentrations in fish belonging to the genus *Lepomis*, which in turn would improve the validity of the derived water-column concentration.

If EPA revises the Draft Criterion to include the requested flexibility, we recommend that EPA also provided guidance on how the data from multiple species should be evaluated, particularly if used to determine compliance with the criterion. We recommend the following approach, consistent with EPA's recommended approach for the methylmercury human health fish tissue criterion:

- Calculate a sample size-weighted geometric mean selenium concentration for each genus.
- If fish from only one genus are targeted, use the geometric mean concentration to derive a water-column concentration or to compare to the appropriate tissue criterion.
- If fish from two or more genera are targeted, calculate the sample size-weighted geometric mean concentration for all genera combined and use it to derive a water-column concentration or to compare to the appropriate tissue criterion.

The methods for deriving water-column concentrations from fish tissue concentrations must take into consideration the variability of the data.

In Appendix K of the Draft Criterion, EPA discusses two options for translating the egg-ovary final chronic value (FCV) into site-specific water-column concentrations – (1) a mechanistic model of bioaccumulation, and (2) a site-specific, field-derived bioaccumulation factor (BAF). Both are serviceable methods, but they could benefit from additional consideration of the variability in the data as well as clarification and flexibility to ensure derivation of an appropriate water-column concentration.

UWAG's supplemental comments focus on EPA's guidance for developing a site-specific criterion by translating fish tissue concentrations into a water-column concentration as presented in Appendix K of the Draft Criterion.[2] UWAG also identifies topics that are important for EPA to address in the forthcoming implementation guidance. Finally, UWAG is clarifying some information presented in its October 13, 2015 comments.

EPA-HQ-OW-2004-0019-0387-A1; Colorado Department of Public Health & Environment; Posted 10/14/2015

On Pages K-10 and K-12, the concept of "ecological significance" for choosing target species is presented. Does EPA plan to provide guidance for how "ecological significance" might be determined? There are multiple ways this concept could be considered (e.g., endangered species, keystone species, species with economic value) and it would be useful for EPA to present some acceptable options for considering this approach.

Can EPA provide information regarding the use of median, geomean, and average in the analyses? That is, what was the rationale for using one statistic versus another for different components of the criteria

derivation (e.g., ITF, EF, water translations, etc.)? Similarly, what statistics does EPA recommend for site-specific calculations? For instance, on page K-19, EPA suggests "calculating the mean or median of all the ratios." It would be helpful to have guidance on what statistic EPA finds most appropriate for each calculation that would be needed to develop site-specific criteria.

EPA-HQ-OW-2004-0019-0411-A2; American Petroleum Institute (API); Posted 10/28/2015

3.2 Site-specific Criteria

3.2.1 Deriving Site-specific Water Concentration Values from the Egg/Ovary Criterion

Appendix K of the 2015 draft Se criteria document describes a methodology to derive site-specific criteria using a mechanistic modeling approach. However, Appendix K seems to simply be a more detailed presentation of information presented in the main text. It does not describe the process or data requirements that a state or tribe would need to follow/generate in order to have their site-specific criteria considered by EPA. This type of information is very important to those that need to develop site-specific criteria and should be provided in a timely fashion in implementation guidance.

EPA-HQ-OW-2004-0019-0376-A2 [Comment 0381-A3 is a duplicate of 0376-A2]; Texas Commission on Environmental Quality (TCEQ); Posted 09/24/2015

D. EPA is requested to provide guidance on the development of site-specific criteria to account for regional differences in naturally-occurring selenium.

EPA states in the draft criterion that underlying geology may contain deposits of selenium-rich materials, such as organic-enriched, sedimentary shales and petroleum source rocks. In locations where elevated selenium is naturally occurring, native fish species may have lower sensitivities to these naturally occurring concentrations. The draft criterion does not account for variability in selenium levels based on region or aquatic species' sensitivity. Guidance for the development of site-specific bioaccumulation factors for selenium is needed to account for regional differences and elevated background concentrations in lotic and lentic environments. Site-specific studies evaluating bioaccumulation certainly seem possible; however, it is unclear how criterion will affect permit reviews and effluent limits until implementation guidance is provided by EPA.

Comment Category 6.1 – Comments Concerning Corrections and Typos

6.1 Summary

Several typos and corrections were noted by commenters.

6.1 Response to comments

6.1 Response to concerns with typographical corrections

EPA has noted suggested edits and corrected the typographical errors. EPA has clarified phrases and terms to enhance readability.

Regarding the reviewer's recommendation to periodically redefine acronyms in the document, EPA has adopted that practice for those terms that are that are heavily used in the document.

Regarding the missing "dw," it has been added.

6.1 Specific comments

EPA-HQ-OW-2004-0019-0387-A1; Colorado Department of Public Health & Environment; Posted 10/14/2015

Typos

- Page 4, second to last line: Consider replacing "... is the mining of metals, minerals and refinement and use ..." with "...is the mining of metals and minerals, as well as refinement and use... ".
- Page 5, second line: Correct the reference error.
- Page 9, third line in Section 2.2.1: Remove comma before "to transformed inorganic and organic species ... "
- Page 34, third line: The sentence starting with "This species, which is listed as endangered ..." is incomplete.
- Page 41, notes: Add space between "Concentration" and "reported".
- Page 46, third line in Section 3.1.5: Should this be 9 fish genera and 10 fish species?
- Page 50, third line: instead of "egg-ovary concentrations to whole-body concentrations", this should read "egg-ovary concentrations to muscle concentrations".
- Page 53, sixth line: Delete the space between "arthropods" and the comma.
- Page 54, first line of Last paragraph: The number should be 15 instead of 154.
- Page 64, third line in Section 3.2.2: There is a period missing after "literature as described above".
- Page 80, third line: Change "EPA uses" to "EPA used".
- Page 98, last line: "GEI Associates (2008)" is not in the references.
- Page 101, first line in Section 6.1.2.3.2: The Kennedy et al. (2000) study has not been discussed yet. Consider adding something like (see 6.1.5.1.2 below) to help guide the reader.
- Page 110, second to last line: Delete the apostrophe from "EC_{10}'s".
- Page 131, third line from end of the second paragraph: Delete the comma after the period.

- Page 159: There are three "GEl Consultants. 2008" references. Consider using letters (e.g., 2008a, 2008b, and 2008c) to clarify which reference is intended in the text.
- Page D-2: Italicize the scientific names.
- Page K-23, third line from the bottom: The word "alsites" appears to be a typo.
- Pages K-30 and K-31: The allowable water column concentrations (4.2 and 0. 9 µg/L) used in the examples are different from the proposed water column criteria (3.1 and 1.2 µg/L). Is this intentional or a typo? If intentional, how were the values in the examples derived?

EPA-HQ-OW-2004-0019-0412-A2; Utility Water Act Group (UWAG); Posted 10/28/2015

3.1.5.3 Fish Muscle Criterion Element Concentration

On page 50, a correction should be made in the 2nd sentence:

> *Table 3.7 shows the conversion of reproductive-effect egg-ovary concentrations to whole-body concentrations.*

The word “whole-body” should be changed to “muscle”.

EPA-HQ-OW-2004-0019-0417-A1; Utility Water Act Group (UWAG); Posted 11/02/2015

a. EPA should make the following corrections.

On the middle of page K-22 of the Draft Criterion (§ 1.2.5.2), EPA states:

> “Alternatively, a state or tribe could derive a CF value by verifying the statistical relationship between paired ***particulate and water*** concentrations through linear regression, calculating the ratios of paired $C_{egg\text{-}ovary}$ to $C_{whole\text{-}body}$, and then taking the median ratio of the paired values as the CF (see Appendix B).”

UWAG believes that highlighted language is incorrect and should be revised as follows:

> “Alternatively, a state or tribe could derive a CF value by verifying the statistical relationship between paired ***egg or ovary and whole-body*** concentrations through linear regression, calculating the ratios of paired $C_{egg\text{-}ovary}$ to $C_{whole\text{-}body}$, and then taking the median ratio of the paired values as the CF (see Appendix B).”

At the bottom of page K-23 of the Draft Criterion (§ 1.3), there is a typographical error as highlighted which EPA needs to correct:

Though not required, the effectiveness of effluent limits and waste load ***alsites*** of selenium that are based on water concentration values derived from the egg-ovary FCV should be confirmed whenever practical using appropriate fish tissue assessment methods.

Comment Category 6.2 – Comments Requesting Clarification

6.2 Summary

Several commenters requested better definitions of specific terms.

6.2 Response to comments

6.2 Response to requests for clarification

EPA has clarified phrases and terms to enhance readability.

6.2 Specific comments

EPA-HQ-OW-2004-0019-0387-A1; Colorado Department of Public Health & Environment; Posted 10/14/2015

In Appendix C, it would helpful to denote which studies were used to derive the criterion.

EPA-HQ-OW-2004-0019-0417-A1; Utility Water Act Group (UWAG); Posted 11/02/2015

In addition to addressing the variability, UWAG requests that EPA incorporate the following clarifications, flexibility and correction into the final criterion.

a. EPA should clarify what is meant by "steady state".

Several of the factors in the mechanistic model (TTF, EF and CF) are defined as "steady state." UWAG requests that EPA clarify what is meant by "steady state" in relation to the sampling necessary for deriving the factors. In other words, what amount of variability (spatial and temporal) is acceptable in the underlying data for the derived factor still to be considered steady state. This clarification is particularly important for the enrichment factor (EF), which, as EPA acknowledges, is subject to significant variability and has the "greatest potential to introduce uncertainty" in the translation. Draft Criterion at K-18. EPA provides three procedures[3] to determine an appropriate EF but does not address what is meant by steady state.

EPA-HQ-OW-2004-0019-0402-A2; The Stakeholders Implementing TMDLs in the Calleguas Creek Watershed; Posted 10/15/2015

Key Definitions are Absent from Table 4.1 and Need to be Added or Modified in order to Interpret the Proposed Criterion.

The 2015 Draft Selenium Criterion lacks clarity in that many terms are used but not defined until much later in the document. As a result, it is very difficult to interpret, evaluate, or implement (once

promulgated) the criterion without searching through the 740 pages of the 2015 Draft Selenium Criterion to find the definitions and intentions of key terms.

For example, footnote 4 of Table 4.1 of the 2015 Draft Selenium Criterion defines the Cbkgmd variable as the "average background selenium concentration." However, the definition for Cbkgmd is absent from the table. The definition is located on Page 87 of the 2015 Draft Selenium Criterion and identified as "the average daily background concentration occurring during the remaining time" (when elevated selenium concentrations are not occurring). Further, the use of this element is to capture situations whereby the average monthly concentrations attain the criterion, but intermittent excursions of concern may occur. Therefore, it would be helpful to add to the definition or explanation of this element that it only applies when the average monthly concentrations are not attained. As the definition of Cbkgmd is necessary to interpret Table 4.1, a modified and more precise definition needs to be added.

Additionally, footnote 5 of Table 4.1 of the 2015 Draft Selenium Criterion provides justification for the duration of the fish tissue elements of the 2015 Draft Selenium Criterion being expressed as an "instantaneous measurement". However, it is unclear whether this "instantaneous measurement" should consist of either an individual fish sample or a composite sample. Fish tissue samples typically consist of composite samples to provide spatial representation of the conditions at a site. Clarification regarding the type of sample to be collected needs to be added to Table 4.1.

Requested Actions:

- Define each term upon initial use and revise the language in Table 4.1 of the 2015 Draft Selenium Criterion to read as follows:
- Modify footnote 4: "...Cbkgrnd is the average background selenium concentration occurring during the remaining time when elevated selenium concentrations are not occurring..."
- Modify footnote 5: ''Instantaneous measurement. Fish tissue data provide point measurements that reflect integrative accumulation of selenium over time and space in the fish at a given site. Selenium concentrations in fish tissue are expected to change only gradually over time in response to environmental fluctuations. Fish tissue data are to be collected as composite samples.”

The Term "Dissolved Total Selenium" is Ambiguous and Should Be Avoided.

Footnote 3 of Table 4.1 of the 2015 Draft Selenium Criterion states that water column values are based on "dissolved total selenium (includes all oxidation states, i.e., selenite, selenite, organic selenium and any other forms) in water". However, "dissolved total selenium" is an ambiguous term as typically, total recoverable selenium is the terminology employed. The Stakeholders request the term "dissolved total selenium be eliminated from the 2015 Draft Selenium Criterion and that the species and fraction (i.e., dissolved or total) be clearly identified and defined, and consistently applied, throughout the document.

Requested Actions:

Revise the language in Table 4.1 of the 2015 Draft Selenium Criterion to read as follows:

Modify footnote 3: "Water column values are based on dissolved total recoverable selenium (includes all oxidation states, i.e., selenite, selenate, organic selenium, and any other forms) in water."

Comment Category 6.3 – Comments Concerning the Additional Data, Informational Sources, and Alternative Approaches

6.3 Summary

Several commenters recommended EPA incorporate additional studies in their analyses.

6.3 Response to comments

6.3 Response to concerns with additional data

Regarding consideration of new data, EPA has acquired new data through the peer review and public process and has included these data, as appropriate, in the derivation of the criterion.

Comment Category 6.4 – Comments Concerning Failure to Address 2014 Public and/or External Peer Review Comments

6.4 Summary

Several commenters requested that EPA provide responses to specific public and/or external peer review comments provided on the 2014 draft selenium criterion.

6.4 Response to comments

EPA carefully considered the 2014 public and external peer-review comments in revising the 2015 draft document and subsequently the final 2016 document. Additionally EPA had provided the 2014 external peer reviewers with the 2014 public comments and solicited their feedback on the 2014 public comments. The external peer reviewers' feedback on the 2014 public comments was also considered directly in developing the 2015 draft selenium criterion document. The EPA response to external peer review comments was released previously. EPA will provide the Response to 2014 Public Comments on the EPA website.

6.4 Specific comments

EPA-HQ-OW-2004-0019-0384-A2; Cameco Resources; Posted 10/13/2015

The Federal Register (Vol 80, No 143, July 27, 2015) states that US EPA responses to comments on the 2014 draft would be available in the docket with the 2015 draft. However, they are not available and we have not received responses to comments from the US EPA in this regard. Thus, it would appear that our comments on the 2014 draft have not been considered. This raises concern about not only the transparency of the development of the selenium criterion, but also the public review process itself. From our review, it appears that revisions in the 2015 criterion may have been selective in nature rather than based on full consideration of the science-based perspectives submitted.

Furthermore, it is challenging to comment on the 2015 draft because many of the same comments that we made on the 2014 draft would still apply given the lack of change in the draft selenium criterion.

In the result, we want to encourage the US EPA to consider and fully respond to the comments Cameco submitted during the public review period for the 2014 draft document. In addition, a further opportunity to comment on any revisions made to the criterion document prior to finalization would enhance this process.

EPA-HQ-OW-2004-0019-0402-A2; The Stakeholders Implementing TMDLs in the Calleguas Creek Watershed; Posted 10/15/2015

The Stakeholders previously submitted a comment letter on the External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium - Freshwater 2014 (2014 External Peer Review Draft

Criterion); however, many of the Stakeholder's comments included on the 2014 External Peer Review Draft Criterion have not been addressed and are still applicable. In addition to the Stakeholder's comments on the 2014 External Peer Review Draft Criterion which have not been addressed, the 2015 Draft Selenium Criterion contains modification that are also of concern for the Stakeholders.

Comments Previously Submitted on the 2014 External Peer Review Draft Criterion and Not Addressed in 2015 Draft Selenium Criterion

- Clarification is needed regarding the applicability of the four elements of the criterion to ensure that fish-tissue elements supersede the water column elements.
- A universal, nationally applicable water column number is inappropriate due to the site-specific, bioaccumulative nature of selenium. As such, the Draft Selenium Criterion should only be based on fish tissue elements, with water column concentrations used as a tool for implementation of the criterion.
- States should clearly be allowed to adopt Site-Specific Objectives (SSOs) that not only modify each of the four elements of the criterion, but that also allows States to opt to eliminate aspects of the criterion (e.g., water column concentrations).
- For the development of SSOs, the methodology to derive water concentrations from the whole-body fish or muscle tissue criterion, rather than egg/ovary criterion, should be clearly presented.
- Justification and explanation for the selection of exceedance frequencies is absent and must be provided in order to comment on the appropriateness of such frequencies. However, even without any provided explanation or justification, the exceedance frequency for the fish tissue elements of the criterion of "never to be exceeded" is inappropriate, impractical and contrary to USEPA guidance.
- Key definitions are absent from Table 4.1 and need to be added or modified in order to interpret the proposed criterion.
- The term "dissolved total selenium" is ambiguous and should be avoided.

EPA-HQ-OW-2004-0019-0411-A2; American Petroleum Institute (API); Posted 10/28/2015

EPA released a previous draft of the selenium criteria on May 14, 2014 (79 Fed. Reg. 27601, May 14, 2014, hereafter "2014 Notice"), in response to which API submitted detailed comments (API letter, R. Claffto K. Gallagher, July 28, 2014). API is pleased EPA accepted public comment in response to the 2014 Notice, and conducted a contractor-led expert external peer review, leading to the current Notice. API fully supports EPA's efforts to obtain input from the public and from technical experts. But EPA did not respond in full to the comments submitted by API and others. In addition to API's comments in and attached to today's letter and the comments submitted by the NAMC-SWG in response to the current Notice, EPA should review, respond to, and address API's and NAMC-SWG's comments submitted in response to the 2014 Notice.

API's detailed comments and concerns about the present Notice are attached. A summary of API's comments follows.

- EPA should consider and address peer-review comments on the criteria in the 2014 Notice. Not all of the technical comments provided by expert peer reviewers in response to the 2014 Notice were addressed in the current Notice, including comments pertaining to: site-specificity of conversion calculations between tissue and water column selenium concentrations; transparency of uncertainties and the need for less emphasis on modelled data; sensitivity analysis of the EC10 method; conflicting comments on the use of injection studies; and the need for detailed implementation guidance.
- EPA should consider and address public comments on the criteria in the 2014 Notice. Not all of the technical comments provided by the public in response the 2014 Notice were addressed in the current Notice, including concerns over food web models used to convert tissue selenium concentrations to water column concentrations; the designations of water bodies as lotic vs. lentic and the application of freshwater criteria to estuarine environments; the primacy criteria for selenium thresholds, including the determinations of tissue and water thresholds; concern about the flexibility to preferentially choose criteria for site-specific objectives (application of tiered criteria); and concern about the application of various statistical methods such as the percentile model to derive criteria.

1. Introduction

The United States Environmental Protection Agency (EPA) approach in the 2015 draft selenium (Se) criteria document (EPA 2015) is more consistent with standard water quality criteria development methodology (Stephan et al. 1985) than previous attempts at revising and updating the Se criteria (i.e. ., EPA 2004, 2014), and includes a critical evaluation of 16 studies using various fish species and results in Se tissue thresholds for twelve fish species within ten genera. Fish tissue-based criteria calculations follow recommendations by Stephan et al. (1985), including the use of the 5th percentile (HC5) of genus mean chronic values (GMCVs). This approach is more scientifically-defensible than the earlier 2004 draft tissue criterion (EPA 2004), which was based on a single study.

We acknowledge the extensive effort that EPA and others put into development of these updated chronic Se criteria and realize that all attempts were made to develop and establish a scientifically-sound criteria document. However, even though a substantial number of interested parties provided written comments pertaining to the first draft of this criteria document (EPA 2014), the majority of these comments appear to have largely been ignored; as of the preparation of this technical memorandum, there was no response provided as to the reason why particular comments were not considered in the 2015 revision. Having ecologically-relevant water quality criteria based on current science is of great importance to the scientific and regulated community and we appreciate this opportunity to provide our comments and recommendations pertaining to the 2015 draft Se criteria document, with hopes that they will be reviewed and considered in the next draft of the document.

2. Key Concerns and Recommendations

As indicated above, while the 2015 draft Se criteria are a significant improvement over previous criteria (e.g., EPA 2004), there are some key areas of the criteria that we feel still need closer examination and revision. We should also note that many recommendations provided in comments on the 2014 draft (for

instance, GEI 2014a, b), were not incorporated in the latest draft, with no explanation provided as to why.

4. EPA Response to Comments on the 2014 Draft

Subsequent to the publication of the 2014 Draft (EPA 2014), comments and suggestions for improvement were solicited from both peer reviewers (Eastern Research Group Inc. 2014) and multiple public stakeholders (see below) over a period between May 14, 2014 and June 13, 2014 (originally). Due to numerous requests by many stakeholders - based on the volume and complexity of the document - the original 30-day period was extended by a total of an additional 45 days, with final comments being due to EPA by July 28, 2014.

Part of our review of the 2015 draft included the review of the above-mentioned peer review and public comments and comparing it to the modifications made in the 2015 draft; however, this specific information was not provided by EPA (e.g., in a comment/response tracking table).

During the review, we corresponded with EPA staff to inquire about this, and they communicated to us that the current 2015 draft (EPA 2015) reflected a number of modifications, including: improvements in calculations; analyses of additional data based on references obtained from the peer and public reviewers; the inclusion of updated (and higher quality) data, as appropriate; enhanced discussions of uncertainty throughout the document; and, other improvements based on suggestions raised during the peer review and via comments from the public. Finally, it was indicated that the structure of the tiered criterion and the structure of the document had not changed between the two (EPA 2014 and EPA 2015) drafts.

4.1 Peer Review Comments

A total of seven (7) expert reviewers, selected by EPA, were asked to complete a questionnaire provided by the Eastern Research Group Inc. (2014). The result of the peer review process comprised a series of comments and perspectives provided by the reviewers in response to a series of specific questions — in 4 parts — relating to a number of issues about the clarity and scientific defensibility of the [first] draft EPA Se criteria document (EPA 2014). We consolidated the peer review comments, by reviewing all of the responses for questions/concerns raised by each reviewer, with the identified elements of the [first] draft EPA Se criteria document (EPA 2014). These were then categorized by subject, with the intention of determining the level of agreement (consensus)/ disagreement among reviewers.

Not all of the technical comments provided by expert peer reviewers were addressed in the 2015 draft (EPA 2015). The suggested modifications — some of which were addressed and some of which were not - related to the following major themes:

- The conversions (i.e., 'back-calculation') between tissue and water-column Se concentrations do not necessarily take into account differing kinetics of Se uptake and elimination from an aquatic system. Site-specific information and species-specific regressions are needed in order to reduce uncertainty and variability. Some reviewers suggested that biokinetic models would be a better option than the current model.

- Given site-specific differences in Se behavior, it was suggested that uncertainties be made more transparent and that less emphasis should be placed on the modelled data without further exploring the variability and uncertainty inherent in each of the parameters.
- There were mixed feelings among reviewers regarding the use of the EC10 method. It was highlighted by some as arbitrary and by others, as scientifically sound. A sensitivity analysis would be need to be conducted to address this and such an analysis has not been done by EPA, to our knowledge.
- There were conflicting comments from peer reviewers on the use of injection studies. In particular, some reviewers felt that results from these studies should be removed from the guideline derivation, as injection does not represent a realistic environmental route of exposure.
- Reviewers felt that better guidance was needed on the application of the proposed criteria for various purposes: small streams, permitting, implementation, frequency limits, and acute releases. Intermittent discharge was mentioned as being arbitrary.

We are unclear as to why the EPA did not address the concerns of the majority of peer reviewers. As an example, we reviewed the responses relative to the back-calculation of the water Se criteria for lentic and lotic. The following were the general comments from the reviewers (numbers identify reviewer):

1. Concerned with the approach;
2. Questioned the approach;
3. Concerned with the approach;
4. Didn't provide a clear statement of support;
5. Thought the approach was modern and valid, but a safety factor should be applied and call it a trigger;
6. Supports the approach;
7. Concerned with the approach and the conservatism inherent in the values.

Based on this, it would appear that 5 of the 7 peer reviewers were generally not satisfied with the approach, for various reasons and to different degrees. Nevertheless, the EPA moved forward with the approach, with the major change being to actually remove data from their analyses, which in turn resulted in even lower lentic and lotic criteria.

4.2 Public Comments

A substantial number (i.e., > 100) of stakeholders including representatives of: governments (e.g., federal, state, regional, municipal); industry associations; private companies; academics; environmental non-governmental organizations; and private citizens, provided written comments — in some cases, detailed technical comments - pertaining to the first draft of this criteria document (EPA 2014).

Some of the major themes of the comments provided — and it is not clear which of the comments were addressed/incorporated in EPA (2015) - included the following:

- Concerns were raised by a number of stakeholders over the food web models used to back-calculate from tissue Se concentrations to water concentrations. Comments focused on the

nature and magnitude of trophic transfer/conversion factors (e.g., TTFs), selected organisms, and differences in bioaccumulation factors.

- A number of technical comments were made regarding the designation of water bodies as lotic vs. lentic. While several paragraphs were added to the text of the 2015 draft regarding this issue (making it clearer how EPA classified systems as either lotic or lentic), many comments were not addressed. As examples, will estuarine environments be classified as lentic or lotic? Also, how will fish tissue criteria for selenium derived from freshwater species be applied to fish species that live in an estuarine environment?
- Concerns were also expressed regarding the primacy criteria for Se thresholds, including the determinations of tissue and water thresholds. There were many comments relating to variability based on the way in which thresholds were calculated.
- There was concern across different regions in the US regarding how the criteria are meant to be applied, how much flexibility there will be to preferentially choose criteria in order to create site-specific objectives (e.g., ensuring there is a hierarchy/tiering in the application of thresholds for the various media (e.g., water, WB/muscle, egg/ovary); e.g., the state of Kentucky employs a tiered approach to the application of criteria)).
- Concerns were also raised regarding the use and application of various statistical methods in deriving the criteria, including some suggestions that the percentile model used by EPA is out-dated; in addition, there were requests for disclosure of the variability inherent in all parameters used to calculate/derive the various thresholds.

Based on our review of the comments in comparison to the changes between the 2014 and 2015 drafts, it appeared that the majority of these comments were not addressed (i.e., resulting in changes to the criteria document, and in particular to the derivation and establishment of thresholds/criteria for different media (e.g., water, WB/muscle, egg/ovary)).

We corresponded with EPA staff to inquire about this, and they communicated that the case with the review of the Se drafts is an extraordinary situation (i.e., the public having the opportunity to evaluate how the peer review and public comments were addressed prior to final document being released). In other words, there is typically no response to peer review or public comment released until the criteria document is final. Based on this response, we assume that a clearer understanding of the way in which EPA has addressed the various stakeholder comments will not be available until the publication of the final criteria document.

5. Conclusions and Recommendations

We have highlighted several technical concerns with the EPA's draft 2015 AWQC for Se, with key conclusions and recommendations provided below:

Previous Comments

Even though a substantial number of interested parties provided written comments pertaining to the first draft of the selenium criteria document, the majority of these comments appear to have been largely ignored. EPA should consider and respond to all of the substantive comments received, both on the first draft and on the current one.

EPA-HQ-OW-2004-0019-0391-A1; North American Metals Council (NAMC); Posted 10/14/2015

NAMC notes that the Federal Register stated: "EPA will make the external peer review and public comments, as well as Agency responses to these comments on the previously published External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium – Freshwater 2014 (EPA 822-P-14-001) (External Peer Review Draft), available in the docket with the revised draft selenium criteria document at www.regulations.gov." This, however, has not occurred. It is difficult to comment on the 2015 EPA Selenium Draft without knowing how our previous comments on the 2014 EPA draft were addressed, particularly given that there appear to be no substantive changes to the 2015 EPA Selenium Draft based on our previous, extensive technical comments (i.e., the differences between the 2014 and 2015 drafts are relatively minor), and there is clear evidence that some, if not all, of our technical review comments were ignored. For example, one of our major recommendations, to consider new information that fills existing data gaps on the translation of tissue-based criteria to water-based selenium screening levels, appears to have been ignored, as has information related to fish feeding over winter. Thus, as Attachment 1 to the present comments, NAMC resubmits its comments on the previous draft, requesting review and response from EPA on both our 2014 and 2015 comments.

1.0 INTRODUCTION

This document, submitted by the North American Metals Council (NAMC), comprises integrated comments provided by individual Members and Associates of the North American Metals Council-Selenium Work Group (NAMC-SWG). It is provided in response to the U.S. Environmental Protection Agency's (EPA) July 27, 2015, request for public comment on its "External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium – Freshwater 2015" (2015 EPA Selenium Draft).[1]

We note that the Federal Register stated: "EPA will make the external peer review and public comments, as well as Agency responses to these comments on the previously published External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium – Freshwater 2014 (EPA 822-P-14-001) (External Peer Review Draft), available in the docket with the revised draft selenium criteria document at www.regulations.gov."[2] This, however, has not occurred. It is difficult to comment on the 2015 EPA Selenium Draft without knowing how our previous comments on the 2014 EPA draft were addressed, particularly given that there appear to be no substantive changes to the 2015 draft based on our previous, extensive technical comments (i.e., the differences between the 2014 and 2015 drafts are relatively minor). Accordingly, NAMC resubmits its comments on the previous draft as Attachment 1 to the present comments, requesting review and response from EPA on both our 2014 and 2015 comments. We note that, to date, EPA has not denied our technical arguments nor provided evidence that our arguments are not technically defensible. As detailed below, it appears that some, if not all, of our previous 2014 comments (Attachment 1) and supporting evidence were ignored.

We thank EPA for the opportunity to provide these comments that primarily focus on the fish tissue criteria derivations. We trust EPA will seriously consider them as well as our previous comments and look forward to the eventual adoption of a technically defensible selenium aquatic life criterion that is appropriately but not, as is now the case, unnecessarily protective.

3.0 CONCLUSIONS

The primary conclusions from our review of the 2015 EPA Selenium Draft are that:

- Our previous, detailed comments on the 2014 EPA draft do not appear to have been given serious consideration. There is clear evidence that at least some, if not all, of our technically valid review comments were ignored. Accordingly, the previous comments are resubmitted as Attachment 1 for consideration. EPA has neither denied our technical arguments and evidence nor provided evidence that our arguments and evidence are not technically defensible.

EPA-HQ-OW-2004-0019-0401-A1; Colorado Wastewater Utility Council; Posted 10/15/2015

We would like to acknowledge the extensive effort that EPA and others put into development of these updated chronic Se criteria and realize that all attempts were made to create a scientifically sound criteria document. However, it seems that even though a substantial number of interested parties provided written comments to the first draft of this criteria document in 2014, the majority of these comments appear to be largely ignored, with no responses provided as to the reason why particular comments were not considered in the revision beyond responding to those provided by the peer reviewers. Having ecologically relevant water quality criteria based on current science is of great importance to the scientific and regulated community and we appreciate this opportunity to again provide our comments and recommendations on the 2015 draft Se criteria document, and hope they will be reviewed and considered in the next draft of the document.

1. Key Issues and Recommendations

While the 2015 draft Se criteria are an improvement over previous criteria, there are some key areas of the criteria that we feel still need closer examination and revision. We presented many of these recommendations and revisions to these key issues in our review of the 2014 draft, but most appear not to have been addressed. We provide additional comments on these areas below, and a further discussion of new concerns on the 2015 draft.

EPA-HQ-OW-2004-0019-0400-A1; The National Mining Association (NMA); Posted 10/15/2015

We would like to acknowledge the extensive effort that EPA and others put into development of these updated chronic Se criteria and realize that considerable attempts were made to create a scientifically sound criteria document. However, it seems that even though a substantial number of interested parties provided written comments to the first draft of this criteria document in 2014, the majority of these comments do not appear to be addressed in the criteria, with no responses provided as to the reason why particular comments were not considered in the revision beyond responding to those provided by the peer reviewers. Having ecologically relevant water quality criteria based on current science is of great importance to the scientific and regulated community and we appreciate this opportunity to again provide our comments and recommendations on the 2015 draft Se criteria document.

1. Key Issues and Recommendations

While the 2015 draft Se criteria are an improvement over previous criteria, there are some key areas of the criteria that we feel still need closer examination and revision. We presented many of these recommendations and revisions to these key issues in our review of the 2014 draft, but most appear not to have been addressed. We provide additional comments on these areas below, and a further discussion of new concerns on the 2015 draft.

EPA-HQ-OW-2004-0019-0413-A2; Federal Water Quality Coalition (FWQC); Posted 10/28/2015

I. PROCESS PROBLEMS

Many of our concerns regarding the Draft Criteria Document are the same as, or related to, concerns that we raised in 2014 as to the previous version of this document. The fact that these issues do not appear to have been addressed, or have been addressed only partially, touches on a fundamental procedural problem with EPA's Notice and its Draft Criteria Document. The Agency has provided no indication of how it has addressed - if at all- the significant issues that were raised as to the 2014 draft, by the FWQC or other commenters. In addition, while EPA had an independent peer review panel conduct a review of its 2014 draft document, the Agency did not- until just a week ago- give the public any information about how it was addressing (or not addressing) the comments of that panel. The public simply has not been given the information needed in order to perform an adequate review of the new draft and to develop useful, complete comments.

The FWQC, for example, raised a series of specific concerns about particular studies and the manner in which those studies were used in deriving the criterion. It appears that some of those comments were not accepted, since the discussion of these studies in the Draft Criteria Document is the same, or nearly the same, as it was in the 20 14 draft. But nowhere in any of the EPA documents is there a clear, direct explanation of why those comments by the FWQC were not accepted. In some instances, the discussion of studies in the Draft Criteria Document has changed, indicating that comments were considered - but again, there is no explanation of the Agency's thought process in making these changes. As a result, the commenters are left without any ability to comment effectively on the new draft, since the Agency's rationale for the new decisions is entirely opaque. Before moving forward with the new criteria, EPA should make available, for public review, a detailed response to comments on the 2014 draft document, so stakeholders can more fully understand the basis for the 2015 proposal.

This lack of explanation, made available in a timely manner, is particularly troubling as to the comments submitted by the peer review panel. This group of seven non-EPA scientists was convened to review the 2014 draft of the Criteria Document, and they submitted a final report in September 2014- over a year ago. The peer review panel's individual comments, which are included in the final report, raise a number of serious questions as to the scientific basis for the proposed criteria. Yet, until October 6 - one week ago - EPA had not made available any document that reviews the panel's comments and explains how they were addressed, or whether they were not appropriate to address. As a result, commenters could not determine what EPA thought of the peer review panel's comments, and had no ability to assess how those issues have been dealt with by the Agency in the Draft Criteria Document.

Then, on October 6, EPA finally made available its responses to the peer review comments, in the form of a 145-page document. Surely the Agency did not expect that the interested stakeholders would be able, in those seven days, to carefully review all 145 pages, determine how the new document affects the comments that they had already been drafting, and make all necessary modifications and additions to address issues raised in the new 145 pages. That is simply not possible. Therefore, upon learning of the new document, the FWQC submitted a request for an extension of the comment period by 60 days, to give the public enough time to fully absorb the new information and supplement or revise their comments accordingly. As of October 13, we have not received a response from the Agency to that request, despite the impending end of the comment period. Therefore, we are forced to submit these comments without being able to perform a careful review of the new EPA document. The FWQC, and all other commenters, deserve that opportunity. Therefore, before finalizing new criteria, EPA needs to provide a 60-day comment period on the new document, so we can submit a supplemental set of comments that are considered before any final criteria decisions are made.

Comment Category 7.1 – Comments about Inadequate Time for Review and Extension Requests

7.1 Summary

Commenters expressed a concern that a 30-day comment period was not adequate.

7.1 Response to comments

EPA extended public comment periods for both the 2014 and 2015 draft criterion documents, as commenters requested.

For the 2014 external peer review draft criterion, EPA held a 30-day public comment period and extended the public comment period for another 30 days based on public comments. The 2014 public comment period totaled over 60 days due to Federal Register Notice issuance lag time. Thus, the 2014 external peer review criterion document the docket was open from May 14 to July 28, 2014, approximately 2.5 months

For the 2015 criterion document, EPA held a 60-day public comment period, with two 15 -day extensions of the public comment period. Thus, for the 2015 draft selenium criterion document, the docket was open from July 28, 2015 to October 30, 2015, approximately 3 months

In total, EPA provided a total of approximately 5.5 months of public comment on the recommended selenium national criterion draft documents.

EPA carefully considered the 2014 public comments in revising the 2014 document for the 2015 draft criterion document, and additionally provided the 2014 external peer reviewers with the 2014 public comments and solicited their feedback on the public comments. The external peer reviewers' feedback on the 2014 public comments was also considered directly in developing the 2015 draft selenium criterion document. EPA will provide the Response to 2014 Public Comments on the EPA website.

7.1 Specific comments

EPA-HQ-OW-2004-0019-0390-A1; West Virginia Coal Association (WVCA); Posted 10/14/15

Conclusion

WVCA agrees with commenters that have already requested an extension of the comment deadline. The new methodology for calculation of the water column elements deserves a separate comment period apart from consideration of the Draft Selenium Criterion. EPA's attempt to circumvent the approach required by the 1985 Guidelines is not appropriate. While WVCA has not had sufficient time to develop detailed comments regarding all aspects of the Draft Selenium Criterion, we also have general concern regarding the following additional components of the document:

EPA-HQ-OW-2004-0019-0414-A1; Colorado Mining Association (CMA); Posted 10/28/2015

-- I had understood that the comment period for ID: EPA-HQ-OW-2004-0019-0367 would be open through October 13; I attempted to submit comment through Regulations.gov but the website was down much of the day. When it came back on-line, I saw two notices of extension of time in the docket, but one listed "comments closed" as of October 10. The second listing under the "Extension of time - Request for Scientific Views: Draft Recommended Aquatic Life Ambient Water Quality Chronic Criterion for Selenium – Freshwater 2015" describes a completely different regulation on the Safe Drinking Water Act was listed.

I am therefore submitting the Selenium comments made on behalf of the Colorado Mining Association by e-mail in the event the comments are still being received on the selenium criterion.

EPA-HQ-OW-2004-0019-0412-A2; Utility Water Act Group (UWAG); Posted 10/28/2015

On behalf of the Utility Water Act Group (UWAG), we write to request that the public comment period for the U.S. Environmental Protection Agency's (EPA) Draft Aquatic Life Ambient Water Quality Criterion for Selenium - Freshwater 2015 be extended 30 days, from September 25, 2015 to October 26, 2015. The Draft Criterion and External Peer Review Comments documents were published on July 27 providing stakeholders just 60 days to review and develop comments. Our technical experts believe that a minimum of 30 additional days is needed to thoroughly review EPA's revised interpretation of the science and methodologies used to derive the proposed criterion. Sufficient additional time is also needed to review comments of 7 expert external peer reviewers and analyze how EPA considered these comments in developing the revised draft criterion.

Introduction

These are the supplemental comments of the Utility Water Act Group (UWAG)1 on EPA's Request for Scientific Views: Draft Recommended Aquatic Life Ambient Water Quality Criterion for Selenium— Freshwater 2015 ("Draft Criterion"). 80 Fed. Reg. 44,350 (Jul. 27, 2015). Previously, UWAG filed comments on October 13, 2015. EPA subsequently extended the comment period until October 30, 2015. 80 Fed. Reg. 63,552 (Oct. 20, 2015). UWAG appreciates the additional time to file comments on the Draft Criterion and to review EPA's responses to the external peer review comments, which were made available on September 25, 2015.

The importance of science-based water quality criterion development cannot be overstated. For over two decades, the best science and approach for assessing the risks of selenium exposure has been widely debated. The final criterion will have significant regulatory impact as EPA is encouraging states and Tribes to adopt EPA's recommended 304(a) criteria directly into their water quality standards. It is therefore vital that such recommendations be based on sound science and proper data. To help the agency achieve that aim, UW AG respectfully requests an additional 30 days, until October 26, 2015, to review the revised draft criterion so that we and other interested parties may have sufficient time to provide meaningful substantive technical comments.

Attached are the Comments of the Utility Water Act Group (UWAG) in response to the Request for Scientific Views: Draft Recommended Aquatic Life Ambient Water Quality Chronic Criterion for Selenium — Freshwater 2015. 80 Fed. Reg. 44350 (Jul. 27, 2015) (providing notice and request for comments by September 25, 2015). On September 24, 2015, EPA announced that the deadline for comments was extended for an additional 15 days, from September 25, 2015 to October 10, 2015. 80 Fed. Reg. 57065. Subsequently, the agency confirmed, on October 1, 2015, that the agency would accept comments through Tuesday, October 13, 2015, to avoid closing the comment period on Saturday, October 10 or Monday, October 12, a federal holiday. See, email from Betsy Behl, Director, Health and Ecological Division, to UWAG counsel, Karen Bennett, Hunton and Williams, LLP, October 1, 2015 (attached).

1. ***EPA Should Reopen the Public Comment Period to Afford Time to Review and Comment on the Agencies Responses to the 2014 Peer Review.***

During 2014, the agency formed an external peer review group of seven experienced scientists to review EPA's External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium— Freshwater 2014, 79 Fed. Reg. 27,601 (May 14, 2014) ("2014 Draft").2 The final external peer review report, External Peer Review of the Draft Aquatic Life Ambient Water Quality Criterion for Selenium – Freshwater 2014 ("2014 Peer Review"), was issued on September 25, 2014 and made available to the public in July 2015. The 2014 Peer Review is relevant to the agency's development of sound, scientifically-defensible water quality criteria. Equally important is the public's ability to understand how EPA considered the 2014 Peer Review in developing the 2015 Draft Criterion. It is troubling that EPA waited until just days before the close of the comment period to make the agency's response to the peer reviewers' comments available to the public. See EPA's Response to Comment Document for the external peer review of the "External Peer Review Draft for the Chronic Aquatic Life Criterion for Selenium: Freshwater 2014" (September 25, 2015).

In the recent update to the federal water quality standards rule, EPA emphasized how important transparency is in relation to adoption of criteria. See, e.g., 80 Fed. Reg. 51,020, 51,022 (Aug. 21, 2015). Since that new rule requires states to either adopt EPA's Clean Water Act Section 304 (a) criteria or provide an explanation for not doing so, transparency in how EPA adopted the criteria is equally important, if not more so. Yet, for the draft selenium aquatic life criteria, EPA has not been transparent with the scientific community or the public by providing this information so late in the comment period. There simply was not enough time provided for stakeholders to understand and comment on how EPA dealt with important aspects of the science underlying the criteria development.

EPA should re-open the comment period, providing additional time needed to thoroughly review and adjust comments in light of EPA's delay in making the agency's responses to the peer reviewers' comments available to the public. The following are a few examples of relevant external peer review comments that warrant additional time for consideration of EPA's response:

- The agency also solicited public comments on the 2014 Draft with the intent of making those comments available to the expert peer reviewers. UWAG filed comments on the 2014 Draft and those comments are attached to this document and incorporated by reference.

EPA-HQ-OW-2004-0019-0383; Federal Water Quality Coalition (FWQC); Posted 10/13/2015

The Federal Water Quality Coalition (the "FWQC" or the "Coalition") hereby submits the following response to EPA's Reopening of Request for Scientific Views on the Draft Aquatic Life Ambient Water Quality Criterion for Selenium – Freshwater 2015 (80 Fed. Reg. 63552, October 20, 2015), which is referred to in these comments as the "Selenium Notice" or the "Notice").

The Notice reopens the comment period concerning EPA's draft recommended freshwater aquatic life criterion for selenium. The previous deadline for submitting comments on the criterion was October 13, 2015, and the FWQC submitted comments on that date. On that same date, EPA granted the FWQC's earlier-submitted request for an extension of the comment period, setting a new deadline of October 30, 2015.

The primary basis for the FWQC extension request was that EPA had just made available a significant new document that bears directly on the scientific basis for EPA's draft criterion: a detailed, 145-page response to comments submitted by the Agency's peer review panel concerning the draft selenium criterion (referred to here as the "Response to Peer Review Comments"). The FWQC appreciates EPA's attention to, and granting of, its request. We believe that allowing this opportunity for public input regarding new scientific information can only serve to strengthen the technical basis for the decision that is eventually made by the Agency.

On behalf of the Federal Water Quality Coalition (FWQC), I am requesting an extension of time for the comment period on EPA's draft selenium criteria document. We understand that the initial comment deadline has recently been extended by about two weeks, so that comments are due on October 13. However, the Agency has still not made the information available that is needed in order for us to comment effectively. This is so in several respects. First, it is important to recognize that the criteria document is a revised version of the draft that was sent out for comment in 2014. The FWQC and other parties submitted detailed comments on the 2014 document. We think, based on our review of the 2015 document, that EPA has taken action on some of the comments, and has not taken action on others. But there is no explanation, anywhere in the 2015 document or elsewhere in the record, of what changes EPA decided to make - or not make - and why it made or didn't make those changes. We simply cannot tell what the Agency thinks of the issues raised in the 2014 comments. Even a line-by-line comparison of the 2014 and 2015 documents will not tell us what EPA's rationale is for any changes that were made, and it certainly cannot tell us why some of our suggested changes were not made.

In addition to those problems in assessing the Agency's action or inaction on the 2014 public comments, there is another lack of information that hampers our ability to formulate new comments. EPA formed an independent peer review panel to assess the 2014 document. That panel delivered a final report in September 2014, which included numerous specific comments, concerns and recommendations. Yet until yesterday, the Agency had provided no indication at all of how it was addressing - or not addressing - the issues raised by the panel, in developing the 2015 document. Then yesterday (October 6), just seven days before the end of the comment period on the 2015 document, EPA issued a 145-page response to the peer review comments. Apparently EPA expects that commenters will now review the entire 145-page document, assess how the Agency responded to each of the peer review comments, and incorporate our thoughts on those issues into the comments that we have to file in six days. That

expectation by EPA contravenes every principle of adequate public participation, and is simply inconsistent with due process and with the Agency's own public participation regulations.

EPA needs to do two things. First, the Agency needs to extend the comment period by at least 60 days. Second, within 15 days, EPA needs to produce a detailed response to the public comments on the 2014 draft criteria document, so the commenters can understand how their concerns were (or were not) addressed in the 2015 document. Then, the stakeholders can review that response-to-comments document, and the newly available response to peer review comments, and incorporate their remaining concerns into their comments on the 2015 document. This process is necessary in order to ensure that stakeholders will be able to effectively assess the Agency's decision-making process and then submit comments that reflect a full understanding of the science regarding EPA's actions.

Comment Category 7.2 – Comments Requesting Delaying Issuance of Criterion

7.2 Summary

Commenters requested that issuance of the final criterion recommendations should be delayed until comment is received on the informational material being provided to aid state and tribal adoption of the rule as discussed in the Federal Register notice.

7.2 Response to comments

The 2016 final selenium criterion scientific recommendations are being issued, not delayed, to provide states and the public with the benefit of EPA's recommendations, based on the best available science, on the development of water quality standards to protect aquatic life designated uses. The 2016 criterion document contains substantial information in the appendices, including recommended approaches to calculating site-specific criteria and data that could be applied in developing site-specific criteria. EPA intends to issue implementation materials and implementation-related technical support documents for comment following the issuance of the 2016 final.

7.2 Specific comments

EPA-HQ-OW-2004-0019-0389-A1; Thunder Basin Coal Company, LLC (TBCC); Posted 10/14/15

Conclusion

Promulgation of this rule should be delayed until comment is received on the informational material being provided to aid state and tribal adoption of the rule as discussed in the Federal Register notice.

Final standards must be derived and applied in an appropriate, site specific and attainable manner tailored to the aquatic life being protected. TBCC supports the selenium comments from the National Mining Association and their consultant GEl as well as comments from Wyoming Mining Association. Thank you for your consideration of these comments.

EPA-HQ-OW-2004-0019-0416-A1; Wyoming Mining Association (WMA); Posted 11/02/2015

WMA also believes that promulgation of the rule should be delayed until comment is received on the informational material being provided to aid state and tribal adoption of the rule as discussed in the Federal Register notice.

Comment Category 8.1 – References

8.1 Response to comments

EPA reviewed submitted references and data and included them in the 2016 final selenium criterion document as appropriate.

8.1 Specific comments

EPA-HQ-OW-2004-0019-0388-A2; J. R. Simplot Company; Posted 10/14/2015

References

AECOM. 2012. Reproductive success study with brown trout (Salmo trutta). Data quality assurance Report. Final. December 2012.

Chapman P.M. , W.J. Adams, M.L. Brooks, C.G. Delos, S.N. Luoma, W.A Maher, H.M. Ohlendorf, T .S. Presser and D.P. Shaw. 2009. Ecological Assessment of Selenium in the Aquatic Environment: Summary of a SETAC Pellston Workshop. Pensacola FL (USA): Society of Environmental Toxicology and Chemistry (SETAC).

Chapman P.M., W.J. Adams, M.L. Brooks, C.G. Delos, S.N. Luoma, W.A Maher, H.M. Ohlendorf, T.S . Presser and D.P. Shaw (eds). 2010. Ecological Assessment of Selenium in the Aquatic Environment. SETAC Press, Pensacola, FL, USA.

Cutter, G.A. 1982. Selenium in reducing waters. Science 217:829-83 1.

Cutter, G. A. and Bruland, K. W. 1984. The marine biogeochemistry of selenium: a re-evaluation Limnol. Oceanogr. 29: 1179- 1192.

DeForest OK, Brix KV, Elphick JR, Rickwood CJ, DeBruyn AMH, Tear LM, Gilron G, Hughes SA, Adams WJ. 2014. Selenium partitioning between water and fish tissue in freshwater systems: Development of water-based selenium screening guidelines. Prepared for the North American Metals Council - Selenium Working Group, Washington ,D.C. http://www.namc.org/docs/Selenium%201ntegrated%20Report%20-%20Final%20(2014-05-20).pdf

ERG (Eastern Research Group, Inc.) 2012. External Peer Review of the Interpretation of Results of a Study on the Effect of Selenium on the Health of Brown Trout Offspring. EPA Office of Science and Technology. Contract No. EP-C-12-021.

ERG (Eastern Research Group, Inc.). 2014. External Peer Review of the Draft Aquatic Life Ambient Water Quality Criterion for Selenium- Freshwater 2014. EPA Office of Science and Technology. Contract No. EP-C-12-021.

Formation Environmental. 2011. Brown Trout Laboratory Reproduction Studies Conducted in Support of Development of a Site-Specific Selenium Criterion. Prepared for J.R. Simplot Company by Formation Environmental. Revised October 2011.

Formation Environmental. 2012. Technical Support Document: Proposed Site-Specific Selenium Criterion, Sage and Crow C reeks, Idaho.

Great Lakes Environmental Center (GLEC). 2014. External Peer Reviewer Comments on Review of Draft EPA Report, 'Analysis of the Brown Trout Selenium Toxicity Study Presented by Formation Environmental and Reviewed by U.S. Fish and Wildlife Service'. Prepared for the USEPA Office of Water, Washington, D.C.

Linville, R.G. 2006. Effects of Excess Selenium on the Health and Reproduction of White Sturgeon (Acipenser transmontanus): Implications for San Franscisco Bay Delta. Dissertation. University of California at Davis.

Luoma, S.N. and T.S. Presser. 2009. Emerging opportunities in management of selenium contamination: Environmental Science and Technology. 43:8483-8487.

McDonald, B.G. and P .M. Chapman. 2009. The need for adequate quality assurance/quality control measures for selenium larval deformity assessments: Implications for tissue residue guidelines. Integrated Environmental Assessment and Management, Vol. 5, Number 3. Pp. 470-475.

Presser, T.S. and S.N. Luoma. 2006. Forecasting selenium discharges to the San Francisco Bay-Delta estuary: ecological effects of a proposed San Luis drain extension. Professional Paper 1646, U.S. Department of Interior, U.S. Geological Survey, Reston, Virginia.

Presser, T.S. and S.N. Luoma. 2010. A Methodology for Ecosystem-Scale Modeling of Selenium. Integrated Environmental Assessment and Management. Volume 6, Number 4, pp. 685-710.

Reinfelder, J.R., N.S. Fisher, S .W. Fowler and J.L. Teyssie. 1993. Release rates of trace elements and protein from decomposing planktonic debris 2. Copepod carcasses and sediment trap particulate matter. J. Mar. Res. 51 (2): 423-442.

Riedel, G. F., D.P. Ferrier and J.G. Sanders. 1991. Uptake of selenium by freshwater phytoplankton. Water Air Soil Pollut. 57-58: 23-30.

Simplot. 2013. J .R. Simplot Company (Simplot) Responses to US Fish and Wildlife Service (USFWS) Comments on the Draft Interpretive Report, August 2010. March 2013.

USFWS. 2012. Technical Review: Smoky Canyon Mine Site-Specific Selenium Criterion Report. US Department of Interior, Fish and Wildlife Service, Division of Environmental Quality, Environmental Contaminants Program.

USEPA. 1997. Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments. Interim Final. EPA 540- R-97-006. Environmental Response Team, Edison, NJ.

USEPA. 1998. Guidelines for Ecological Risk Assessment. Final. Risk Assessment Forum. EPA/630/R-95/002F.

USEPA. 2014. External Peer Review Draft- Aquatic Life Ambient Water Quality Criterion for Selenium-Freshwater, 2014. Office of Water. USEPA-822- P-14- 001.

USEPA. 2015a. Draft Aquatic Life Ambient Water Quality Criterion for Selenium Freshwater, 2015. Office of Water. USEPA-822-P- 15-001.

USEPA. 2015b. External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium - Freshwater 2015. USEPA-822-P-15-001.

USEPA. 2015c. Toxicity Relationship Analysis Program (TRAP Version 1.20). NHERL. Duluth, MN.

USEPA. 2012. Toxicity Relationship Analysis Program (TRAP Version 1.3A). Mid-Continent Ecology Division. http://www.epa.gov/med/Prods Pubs/trap.html

EPA-HQ-OW-2004-0019-0385-A2; Kentucky Division of Water (KDOW); Posted 10/13/2015

Literature Cited

Chapman, P.M., W.J. Adams, M.L. Brooks, C.G. Delos, S.N. Luoma, W.A. Maher, H.M. Ohlendorf, T.S. Presser and D.P. Shaw (eds). 2010. Ecological assessment of selenium in the aquatic environment. SETAC Press, Pensacola, FL.

Doroshov, S., J. Van Eenennaam, C. Alexander, E. Hallen, H. Bailey, K. Kroll and C. Restrepo. 1992. Development of water quality criteria for resident aquatic species of the San Joaquin River, Part I, bioaccumulation of selenium in broodstock of channel catfish (lctalurus punctatus) and its effects on reproduction. Final report to State Water Resources Control Board, State of California. Contract number 7- 197-250-0.

Linville, R.G. 2006. Effects of excess selenium on the health and reproduction of white sturgeon (Acipenser transmontanus): implication for San Francisco Bay-Delta. PhD dissertation, University of California at Davis.

Stephan, C.E., D.l. Mount, D.J. Hansen, J.H. Gentile, G.A. Chapman and W.A. Brungs. 1985. Guidelines for deriving numerical national water quality criteria for the protection of aquatic organisms and their uses. PB85-227049. National Technical Infonnation Service, Springfield, VA.

U.S. EPA 19978. Report on the peer consultation workshop on selenium aquatic toxicity and bioaccumulation. Office of Water. USEPA, Washington, DC. EPA-822-R-98-007.

EPA-HQ-OW-2004-0019-0387-A1; Colorado Department of Public Health & Environment; Posted 10/14/2015

References

Brix, K.V., and D.K. DeForest. 2008. Selenium. Pages 123-172 in Gensemer RW, Meyerhoff RD, Ramage KJ, Curely EF, eds. Relevance of ambient water quality criteria in ephemeral and effluent-dependent watercourses of the arid western US. SETAC Press, Pensacola, FL, USA.

Chapman, P.M., W.J. Adams, M.L. Brooks, C.G. Delos, S.N. Luoma, W.A. Maher, H.M. Ohlendorf, T.S. Presser, and D.P. Shaw. 2009. Ecological assessment of selenium in the aquatic environment: Summary

of a SETAC Pellston Workshop. Pensacola FL (USA): Society of Environmental Toxicology and Chemistry (SETAC).

EPA-HQ-OW-2004-0019-0370-A2; USGS Leetown Science Center; Posted 09/08/2015

Hitt, N.P. and D.R. Smith. 2014. Threshold-dependent sample sizes for selenium assessment with stream fish tissue. Integrated Environmental Assessment and Management 11:143-149.

Presser, T.S. 2013. Selenium in ecosystems within the mountaintop coal mining and valley-fill region of southern West Virginia – assessment and ecosystem-scale modeling. US Geological Survey Professional Paper 1803. 86 pg. http://pubs.usgs.gov/pp/1803/

EPA-HQ-OW-2004-0019-0419-A2; Lima Refining Company; Posted 11/03/2015

References

CH2M Hill, 2010. Ottawa River Biological and Water Quality Study and Ecological Risk Assessment. Prepared for Lima Refining Company. March 2010.

Hill, W.R., and I.L. Larsen, 2005. "Growth Dilution of Metals in Microalgal Biofilms," Environmental Science and Technology, 39(6): 1513-1518.

HydroQual, 2009. Ottawa River Sampling Program for Water Quality Analyses to Determine the Selenium Load Upstream of the Husky Refinery in Lima, Ohio: Survey results and Waste Load Allocation Analysis. Prepared for the Lima Refining Company.

Luoma, S.N., and P.S. Rainbow, 2005. "Why is metal bioaccumulation so variable? Biodynamics as a unifying concept, a critical review." Environmental Science & Technology, 39: 1921-1931.

Paquin R., and R. Bubnyte, 2014. "Considerations for Evaluating an Averaging Period for Selenium Bioaccumulation," presented at the 2014 SETAC meeting, Vancouver, BC, CA.

Thomann, R.V., 1981. "Equilibrium Model of the Fate of Microcontaminants in Diverse Aquatic Food Chains," Canadian Journal of Fisheries and Aquatic Sciences, 38: 280-296.

USEPA, 2015. Draft Aquatic Life Ambient Water Quality Criterion for Selenium — Freshwater 2015. Office of Water, Office of Science and Technology, Washington, D.C. EPA 822-P-15-001. July 2015.

EPA-HQ-OW-2004-0019-0410-A2; West Virginia Department of Environmental Protection (DEP); Posted 10/28/2015

Formation Environmental. 2011. Brown Trout Laboratory Reproduction Studies Conducted in Support of Development of a Site-Specific Selenium Criterion. Prepared for J.R. Simplot Company by Formation Environmental. Revised October 2011.

USEPA. 2014. External peer review draft aquatic life ambient water quality criterion for selenium—freshwater 2014. Federal Register, Vol. 79, No. 93. pp. 27601-27604. http://www.gpo.gov/fdsys/pkg/FR-2014-05-14/html/2014-11080.htm.

USEPA. 2015. Draft Aquatic Life Ambient Water Quality Criterion for Selenium – Freshwater 2015. http://water.epa.gov/scitech/swguidance/standards/criteria/aqlife/selenium/loader.cfm?csModule=security/getfile&PageID=718002.

EPA-HQ-OW-2004-0019-0412-A2; Utility Water Act Group (UWAG); Posted 10/28/2015

Literature Cited

Coyle, J.J., D.R. Buckler, C.C. Ingersoll, J.F. Fairchild, and T.W. May. 1993. Effect of dietary selenium on the reproductive success of bluegills Lepomis macrochirus. Environmental Toxicology and Chemistry 12: 551 – 565.

Crutchfield, J.U., Jr. 2000. Recovery of a power plant cooling reservoir ecosystem from selenium bioaccumulation. Environmental Science and Policy 3: S145 – S163.

Cumbie, P.M., and S.L. Van Horn. 1980. Selenium accumulation associated with fish mortality and reproductive failure. Proceedings of the Annual Conference of Southeast Association of Fishery and Wildlife Agencies 32: 612 – 624.

Doroshov, S., J. Van Eenennaam, C. Alexander, E. Hallen, H. Bailey, K. Kroll, and C. Restrep. 1992. Development of Water Quality Criteria for Resident Aquatic Species of the San Joaquin River, Part II: Bioaccumulation of Dietary Selenium and its Effects on Growth and Reproduction in Bluegill (Lepomis machrochirus). Final Report to State Water Resources Control Board, State of California.

EPRI. 2001. Selenium cycling and impact in aquatic ecosystems: defining trophic transfer and water-borne exposure pathways. Technical Report 1005217. Electric Power Research Institute, Palo Alto, CA.

Hermanutz, R.O., K.N. Allen, T.H. Roush, and S.F. Hedtke. 1992. Effects of elevated selenium concentrations on bluegills Lepomis macrochirus in outdoor experimental streams. Environmental Toxicology and Chemistry 11: 217 – 224.

Hermanutz, R.O., K.N. Allen, N.E. Detenbeck, and C.F. Stephan. 1996. Exposure to bluegill (Lepomis machrochirus) to selenium in outdoor experimental streams. U.S. EPA Report. Mid- Continent Ecology Division, Duluth, MN.

Hoang, T.C., and S.J. Klaine. 2008. Characterizing the toxicity of pulsed selenium exposure to Daphnia magna. Chemosphere 71: 429 – 438.

Penglase, S., K. Hamre, and S. Ellingson. 2014. Selenium and mercury have a synergistic negative effect on fish reproduction. Aquatic Toxicology 149: 16 – 24.

Petrov, P.K., J.W. Charters, and D. Wallschlager. 2012. Identification and determination of selenosulfate and selenocyanate in flue gas desulfurization waters. Environmental Science & Technology 46: 1716 – 1723.

Reash, R.J., T.W. Lohner, K.V. Wood, and V.E. Willet. 1999. Exotoxicological assessment of bluegill sunfish inhabiting a selenium-enriched fly ash stream. Pp. 423 – 445 in Environmental Toxicology and Risk Assessment: Standardization of Biomarkers for Endocrine Disruption and Environmental

Assessment: Eighth Volume, ASTM STP 1364. American Society for Testing and Materials, West Conshohocken, PA.

Reash, R.J., T.W. Lohner, and K.V. Wood. 2006. Selenium and other trace metals in fish inhabiting a fly ash stream: implications for regulatory tissue thresholds. Environmental Pollution 142: 397 – 408.

Reash, R.J. 2012. Selenium, arsenic, and mercury in fish inhabiting a fly ash exposure gradient: bioaccumulation patterns and elemental associations. Environmental Toxicology and Chemistry 31: 739 – 747.

Riscassi, A.L., A.D. Converse, K.J. Hokanson, and T.M. Scanlon. 2010. Evaluation of automated streamwater sampling during storm events for total mercury analysis. Journal of Environmental Monitoring 12: 1833 – 1839.

Steven, D., and O. McAdam. 2015. Retrospective weight-of-evidence analysis identifies substrate change as the apparent cause of recruitment failure in the upper Columbia River white sturgeon (Acipenser transmontanus). Canadian Journal of Fisheries and Aquatic Sciences 72: 1208 – 1220.

Tashjian, D.H., S.J. The, A. Sogomonyan, and S.S.O. Hung. 2006. Bioaccumulation and chronic toxicity of dietary L-selenomethionine in juvenile white sturgeon (Acipenser transmontanus). Aquatic Toxicology 79: 401 – 409.

Thomas, J.K., and D.M. Janz. 2014. In ovo exposure to selenomethionine via maternal transfer increases developmental toxicities and impairs swim performance in F1 generation zebrafish (Danio rerio). Aquatic Toxicology 152: 20 – 29.

US EPA. 1985. Guidelines for Deriving Numeric National Water Quality Criteria for the Protection of Aquatic Organisms and their Uses. PB85-227049. US EPA Office of Research and Development, Duluth, MN.

US EPA. 1995. Great Lakes Water Quality Initiative Criteria Documents for the Protection of Aquatic Life in Ambient Water. EPA-820-B-95-004. US EPA Office of Water, Washington, DC.

US EPA. 1991. Technical Support Document for Water Quality-based Toxics Control. EPA/505/2- 90-001. US EPA Office of Water, Washington, DC.

US EPA. 2010a. Guidance for Implementing the January 2001 Methylmercury Water Quality Criterion. EPA 823-R-10-001. US EPA Office of Science and Technology, Washington, DC.

US EPA. 2010b. U.S. Environmental Protection Agency NPDES Permit Writer's Manual. EPA-833- K-10-001. US EPA Office of Wastewater Management, Washington, DC.

6. References

Brix KV, DeForest DK. 2008. Selenium. Pages 123-172 in Gensemer RW, Meyerhoff RD, Ramage KJ, Curely EF, editors. Relevance of ambient water quality criteria in ephemeral and effluent-dependent watercourses of the arid western US. SETAC Press, Pensacola, FL, USA.

Burau, R.G. 1985. Environmental Chemistry of Selenium. California Agriculture pp. 16-18.

Butler DL, Osmundson BC, Krueger RP. 1997. Field screening of water, soil, bottom sediment, and biota associated with irrigation drainage in the Dolores Project and the Mancos River Basin, southwestern Colorado, 1994. US Geological Survey, Denver, CO, USA.

Canton S. 2010. Appendix B: Commentary: Persistence of some fish populations in high-Se environments. Pages 293-323 in Chapman PM, Adams WJ, Brooks ML, Delos CG, Luoma SN, Maher WA, Ohlendorf HM, Presser TS, Shaw DP, editors. Ecological assessment of selenium in the aquatic environment. SETAC Press, Pensacola, FL, USA.

Casey R. 2005. Results of aquatic studies in the McLeod and Upper Smoky River systems. Alberta Environment, Edmonton, AB, Canada.

Chapman PM. 2015. Including or excluding toxicity test data for development of a geometric mean. Environ Toxicol Chem 34: 1691-1692.

Chapman PM, Adams WJ, Brooks ML, Delos CG, Luoma SN, Maher WA, Ohlendorf HM, Presser TS, Shaw DP. 2010. Ecological assessment of selenium in the aquatic environment. SETAC Press, Pensacola, FL, USA.

Coyle JJ, Buckler DR, Ingersoll CG, Fairchild JF, May TW. 1993. Effect of dietary selenium on the reproductive success of bluegills (Lepomis macrochirus). Environ Toxicol Chem 12:551-565.

CP&L (Carolina Power & Light). 1997. Largemouth bass selenium bioassay. Environmental Services Section, NC, USA.

DeForest DK, Adams WJ. 2011. Selenium accumulation and toxicity in freshwater fishes. Pages 193-229 in Beyer WN, Meador JP, editors. Environmental contaminants in biota: Interpreting tissue concentrations (Second Edition). CRC Press, Boca Raton, FL, USA.

DeForest DK, Gilron G, Armstrong SA, Robertson EL. 2012. Species sensitivity distribution (SSD) evaluation for selenium in fish eggs: Considerations for development of a Canadian tissue-based guideline. Integr Environ Assess Manag 8:6-12.

DeForest DK, Brix KV, Gilron G, Hughes SA, Tear LM, Elphick JR, Rickwood CJ, DeBruyn AMH, Adams WJ. 2014. Selenium partitioning between water and fish tissue in freshwater systems: Development of water-based selenium screening guidelines. Poster presentation at the Society of Environmental Toxicology and Chemistry 35th Annual Meeting, Vancouver, BC, Canada. November 9-13, 2014.

DeForest DK, Brix KV, Gilron G, Hughes SA, Tear LM, Elphick JR, Rickwood CJ, DeBruyn AMH, Adams WJ. In Revision. Selenium partitioning between water and fish tissue in freshwater systems: Development of water-based selenium screening guidelines. Submitted to Environ Sci Technol.

De Riu, D., L. Jang-Won, Huang, S., Monielloa, G., and Hung, S. 2014. Effect of dietary selenomethionine on growth performance, tissue burden, and histopathology in green and white sturgeon. Aquat. Toxicol. 148:65-73.

Doroshov S, Van Eenennaam J, Alexander C, Hallen E, Bailey H, Kroll K, Restrepo C. 1992. Development of water quality criteria for resident aquatic species of the San Joaquin River. University of California-Davis, CA, USA.

Eastern Research Group. 2014. External Peer Review of the Draft Aquatic Life Ambient Water Quality Criterion for Selenium — Freshwater 2014. Contract No. EP-C-12-021, Work Assignment 1-43. September 25, 2014.

EPA. 2004. Draft aquatic life water quality criteria for selenium - 2004. Office of Water, Washington, D.C. EPA 822-D-04-001.

EPA. 2013. Aquatic life ambient water quality criteria for ammonia — freshwater 2013. Office of Water, Washington, D.C. EPA 822-R-13-001.

EPA. 2014. External peer review draft aquatic life ambient water quality criterion for selenium — freshwater 2014. Office of Water, Washington, D.C. EPA 822-P-14-001.

EPA. 2015. Draft aquatic life ambient water quality criterion for Selenium — freshwater 2015. Office of Water, Washington, D.C. EPA 822-P-15-001.

Finley K, Garrett R. 2007. Recovery at Belews and Hyco Lakes: Implications for fish tissue selenium thresholds. Integr Environ Assess Manag 3:297-299.

Formation Environmental. 2011. Brown trout laboratory reproduction studies conducted in support of development of a site-specific selenium criterion. Prepared for J.R. Simplot Company by Formation Environmental. Revised October 2011.

GEI Consultants, Inc. (GEI). 2007. Aquatic Biological Monitoring and Selenium Investigation of the Arkansas River, Fountain Creek, Wildhorse Creek, and the St. Charles River. Prepared for City of Pueblo WRP.

GEI Consultants. 2008. Maternal transfer of selenium in fathead minnows, with modeling of ovary tissue to whole body concentrations. Project 062790. Chadwick Ecological Division, Littleton, CO.

GEI Consultants, Inc. (GEI). 2013. Use Attainability Analysis for the St. Charles River, Middle Arkansas River Segment 6, Colorado. Prepared for Public Service Company of Colorado.

GEI Consultants, Inc. (GEI). 2014a. Review of EPA 2014 draft Se criteria document EPA 822-P14- 001. Submitted to Docket ID EPA-HQ-OW-2004-0019.

GEI Consultants, Inc. (GEI). 2014b. Supplemental comments on EPA 2014 draft Se criteria document EPA 822-P-14-001. Submitted to Docket ID EPA-HQ-OW-2004-0019.

Hermanutz RO, Allen KN, Roush TH, Hedtke SF. 1992. Effects of elevated selenium concentrations on bluegills (Lepomis macrochirus) in outdoor experimental streams. Environ Toxicol Chem 11:217-224.

Hermanutz RO, Allen KN, Detenbeck NE, Stephan CE. 1996. Exposure of bluegills (Lepomis macrochirus) to selenium in outdoor experimental streams. U.S. Environmental Protection Agency, Duluth, MN, USA.

Herring, J.R., and K. Walton-Day. 2007. Selenium and Other Elements in Water and Adjacent Rock and Sediment of Toll Gate Creek, Aurora, Arapahoe County, Colorado, December 2003 through March 2004, 58 p.

Janz DM, DeForest DK, Brooks ML, Chapman PM, Gilron G, Hoff D, Hopkins WA, McIntyre DO, Mebane CA, Palace VP, Skorupa JP, Wayland M. 2010. Selenium toxicity to aquatic organisms. Pages 141-231 in Chapman PM, Adams WJ, Brooks ML, Delos CG, Luoma SN, Maher WA, Ohlendorf HM, Presser TS, Shaw DP. 2010. Ecological assessment of selenium in the aquatic environment. SETAC Press, Pensacola, FL, USA.

Lemly AD. 1985. Toxicology of selenium in a freshwater reservoir: Implications for environmental hazard evaluation and safety. Ecotoxicol Environ Saf 10:314-338.

Linville RG. 2006. Effects of excess selenium on the health and reproduction of white sturgeon (Acipenser transmontanus): Implications for San Francisco Bay-Delta. Doctoral Dissertation. University of California-Davis, CA, USA.

Lo BP, Elphick JR, Bailey HC, Baker JA, Kennedy CJ. 2015. The effect of sulphate on selenate bioaccumulation in two freshwater primary producers: a duckweed, Lemna minor, and a green alga, Pseudokirchneriella subcapitata. Environ Toxicol Chem DOI: 10.1002/etc.3127.

Skorupa JP. 1998. Selenium. United States Department of the Interior. National Irrigation Water Quality Program Information Report No. 3: Guidelines for interpretation of the biological effects of selected constituents in biota, water, and sediment.

Stephan CE, Mount DI, Hansen DJ, Gentile JH, Chapman GA, Brungs WA. 1985. Guidelines for deriving numerical national water quality criteria for the protection of aquatic organisms and their uses. U.S. Environmental Protection Agency, Washington, D.C. NTIS No. PB85- 227049. 98 pp.

Williams MJ, Ogle RS, Knight AW, Burau RG. 1994. Effects of sulfate on selenate uptake and toxicity in the green alga Selenastrum capricornutum. Arch Environ Contam Toxicol 17:449-453.

EPA-HQ-OW-2004-0019-0401-A1; Colorado Wastewater Utility Council; Posted 10/15/2015

5. References

Adams, W.J., J.E. Toll, K.V. Brix, L.M. Tear and D.K. DeForest. 2000. Site-specific approach for setting water quality criteria for selenium: differences between lotic and lentic systems. Proceedings Mine Reclamation Symposium: Selenium Session; Sponsored by Ministry of Energy and Mines, Williams Lake, British Columbia, Canada, June 21-22, 2000.

Brix, K and D. De Forest. 2008. Selenium. In: Relevance of ambient water quality criteria in ephemeral and effluent-dependent watercourses of the arid western US (Gensemer RW, Meyerhoff RD, Ramage KJ, Curely EF, eds.). Pensacola, FL:SETAC Press, pp. 123-172.

Carolina Power & Light (CP&L). 1997. Largemouth Bass Selenium Bioassay- Report. Carolina Power & Light Company, Environmental Services Section, NC. December 1997.

Chapman P.M., W.J. Adams, M.L. Brooks, C.G. Delos, S.N. Luoma, W.A Maher, H.M. Ohlendorf, T.S. Presser, and D.P. Shaw. 2009. Ecological Assessment of Selenium in the Aquatic Environment: Summary of a SETAC Pellston Workshop. Pensacola, FL (USA): Society of Environmental Toxicology and Chemistry (SETAC).

Chapman P.M., W.J. Adams, M.L. Brooks, C.G. Delos, S.N. Luoma, W.A Maher, H.M. Ohlendorf, T.S. Presser, and D.P. Shaw (eds). 2010. Ecological Assessment of Selenium in the Aquatic Environment. SETAC Press, Pensacola, FL, USA.

Coyle, J.J., D.R. Buckler, C.G. Ingersoll, J.F. Fairchild, and T.W. May. 1993. Effect of dietary selenium on the reproductive success of bluegills Lepomis macrochirus. Environmental Toxicology and Chemistry 12(3):551-565.

DeForest D.K., and W.J. Adams. 2011. Selenium accumulation and toxicity in freshwater fishes. pp. 193-229. In: Beyer, W. N., and J. P. Meador, editors. Environmental contaminants in biota: interpreting tissue concentrations. 2nd edition. Boca Raton (FL, USA): Taylor and Francis.

DeForest, D.K., K.V. Brix, J.R. Elphick, C.J. Rickwood, A.M.H. deBruyn, L.M. Tear, G. Gilron, S.A. Hughes, and W.J. Adams. 2014. Final Report, Selenium Partitioning between Water and Fish Tissue in Freshwater Systems: Development of Water-based Selenium Screening Guidelines. Prepared for: North American Metals Council -Selenium Working Group, Washington, D.C. May 2014.

DeForest, D.K., S. Pargee, C. Claytor, S. Canton and K. Brix. In press. Biokinetic food chain modeling of waterborne selenium pulses into aquatic food chains: implications for water quality criteria. Integrated Environmental Assessment and Management.

Doroshov, S., J.V. Eenennaam, C. Alexander, E. Hallen, H. Bailey, K. Kroll, and C. Restreppo. 1992. Development of water quality criteria for resident aquatic species of the San Joaquin River. Draft final report to the California State Water Resources Control Board for Contract No. 7-197-250-0. Department of Animal Science, University of California, Davis, CA.

Formation Environmental. 2011. Yellowstone cutthroat trout laboratory reproduction studies conducted in support of development of a site-specific selenium criterion. Draft. Prepared for J.R. Simplot Company. Pocatello (ID): Smoky Canyon Mine.

GEI Consultants, Inc. (GEI). 2007. Aquatic Biological Monitoring and Selenium Investigation of the Arkansas River, Fountain Creek, Wildhorse Creek, and the St. Charles River. Prepared for City of Pueblo WRP.

GEI Consultants, Inc. (GEI). 2008. Maternal transfer of selenium in fathead minnows, with modeling of ovary tissue to whole body concentrations. Project 062790. Chadwick Ecological Division, Littleton, CO.

GEI Consultants, Inc. (GEI). 2013a. Use Attainability Analysis for the St. Charles River, Middle Arkansas River Segment 6, Colorado. Prepared for Public Service Company of Colorado. Corporation.

GEI Consultants, Inc. (GEI). 2013b. Bioassessment of the Streams in the Vicinity of the Catenary and Hobet Mine Complexes, West Virginia. Prepared for Patriot Coal

GEI Consultants, Inc. (GEI). 2014a. Review of EPA 2014 draft Se criteria document EPA 822-P-14-001. Submitted to Docket ID EPA-HQ-OW-2004-0019.

GEI Consultants, Inc. (GEI). 2014b. Supplemental comments on EPA 2014 draft Se criteria document EPA 822-P-14-001. Submitted to Docket ID EPA-HQ-OW-2004-0019.

GEI Consultants, Inc. (GEI). 2014c. Use-Attainability Analysis for Selected Tributaries to the Yampa River, Routt County, Colorado. Prepared for Seneca Coal Company, Peabody Sage Creek Mine, LLC and Twentymile Coal, LLC.

Hermanutz, R.O., K.N. Allen, T.H. Roush, and S.F. Hedtke. 1992. Effects of elevated Se concentrations on bluegills (Lepomis macrochirus) in outdoor experimental streams. Environmental Toxicology and Chemistry 11:217-224.

Hermanutz, R.O., K.N. Allen, N.E. Detenbeck, and C.E. Stephan. 1996. Exposure of bluegill (Lepomis macrochirus) to selenium in outdoor experimental streams. U.S. EPA Report. Mid-Continent Ecology Division. Duluth, MN.

Janz, D.M. 2008. A critical evaluation of winter stress syndrome. In Selenium tissue thresholds: Tissue selection criteria, threshold development endpoints, and potential to predict population or community effects in the field. Washington (DC, USA): North America Metals Council – Selenium Working Group.

Linville, R.G. 2006. Effects of Excess Selenium on the Health and Reproduction of White Sturgeon (Acipenser transmontanus): Implications for San Francisco Bay-Delta. Dissertaiton. University of California at Davis.

North American Metals Council-Selenium Working Group (NAMC-SWG). 2014. Comments of the North American Metals Council-Selenium Working Group in Response to EPA's Draft National Recommended Aquatic Life Criterion for the Pollutant Selenium. Submitted to Docket ID EPA-HQ-OW-2004-0019.

Stephan, C.E., D.I. Mount, D.J. Hansen, J.H. Gentile, G.A. Chapman, and W.A. Brungs. 1985. Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses. PB85-227049. National Technical Information Service, Springfield, VA.

U.S. Environmental Protection Agency (EPA). 2004. Draft Aquatic Life Water Quality Criteria for Selenium - 2004. EPA-822-D-04-001. Office of Water, Washington, DC.

U.S. Environmental Protection Agency (EPA). 2014. External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium – Freshwater 2014. EPA 822-P-14-001. Office of Water 4304T, Washington, D.C.

5. References

Adams, W.J., J.E. Toll, K.V. Brix, L.M. Tear and D.K. DeForest. 2000. Site-specific approach for setting water quality criteria for selenium: differences between lotic and lentic systems. Proceedings Mine Reclamation Symposium: Selenium Session; Sponsored by Ministry of Energy and Mines, Williams Lake, British Columbia, Canada, June 21-22, 2000.

Brix, K and D. De Forest. 2008. Selenium. In: Relevance of ambient water quality criteria in ephemeral and effluent-dependent watercourses of the arid western US (Gensemer RW, Meyerhoff RD, Ramage KJ, Curely EF, eds.). Pensacola, FL:SETAC Press, pp. 123-172. Carolina Power & Light (CP&L). 1997. Largemouth Bass Selenium Bioassay- Report.

Carolina Power & Light Company, Environmental Services Section, NC. December 1997.

Chapman P.M., W.J. Adams, M.L. Brooks, C.G. Delos, S.N. Luoma, W.A Maher, H.M. Ohlendorf, T.S. Presser, and D.P. Shaw. 2009. Ecological Assessment of Selenium in the Aquatic Environment: Summary of a SETAC Pellston Workshop. Pensacola FL (USA): Society of Environmental Toxicology and Chemistry (SETAC).

Chapman P.M., W.J. Adams, M.L. Brooks, C.G. Delos, S.N. Luoma, W.A Maher, H.M. Ohlendorf, T.S. Presser, and D.P. Shaw (eds). 2010. Ecological Assessment of Selenium in the Aquatic Environment. SETAC Press, Pensacola, FL, USA.

Coyle, J.J., D.R. Buckler, C.G. Ingersoll, J.F. Fairchild, and T.W. May. 1993. Effect of dietary selenium on the reproductive success of bluegills Lepomis macrochirus. Environmental Toxicology and Chemistry 12(3):551-565.

DeForest D.K., and W.J. Adams. 2011. Selenium accumulation and toxicity in freshwater fishes. pp. 193-229. In: Beyer, W. N., and J. P. Meador, editors. Environmental contaminants in biota: interpreting tissue concentrations. 2nd edition. Boca Raton (FL, USA): Taylor and Francis.

DeForest, D.K., S. Pargee, C. Claytor, S. Canton and K. Brix. In press. Biokinetic food chain modeling of waterborne selenium pulses into aquatic food chains: implications for water quality criteria. Integrated Environmental Assessment and Management.

Doroshov, S., J.V. Eenennaam, C. Alexander, E. Hallen, H. Bailey, K. Kroll, and C. Restreppo. 1992. Development of water quality criteria for resident aquatic species of the San Joaquin River. Draft final report to the California State Water Resources Control Board for Contract No. 7-197-250-0. Department of Animal Science, University of California, Davis, CA.

Formation Environmental. 2011. Yellowstone cutthroat trout laboratory reproduction studies conducted in support of development of a site-specific selenium criterion. Draft. Prepared for J.R. Simplot Company. Pocatello (ID): Smoky Canyon Mine.

GEI Consultants, Inc. (GEI). 2007. Aquatic Biological Monitoring and Selenium Investigation of the Arkansas River, Fountain Creek, Wildhorse Creek, and the St. Charles River. Prepared for City of Pueblo WRP.

GEI Consultants, Inc. (GEI). 2008. Maternal transfer of selenium in fathead minnows, with modeling of ovary tissue to whole body concentrations. Project 062790. Chadwick Ecological Division, Littleton, CO.

GEI Consultants, Inc. (GEI). 2013a. Use Attainability Analysis for the St. Charles River, Middle Arkansas River Segment 6, Colorado. Prepared for Public Service Company of Colorado.

GEI Consultants, Inc. (GEI). 2013b. Bioassessment of the Streams in the Vicinity of the Catenary and Hobet Mine Complexes, West Virginia. Prepared for Patriot Coal Corporation.

GEI Consultants, Inc. (GEI). 2014a. Review of EPA 2014 draft Se criteria document EPA 822-P-14-001. Submitted to Docket ID EPA-HQ-OW-2004-0019.

GEI Consultants, Inc. (GEI). 2014b. Supplemental comments on EPA 2014 draft Se criteria document EPA 822-P-14-001. Submitted to Docket ID EPA-HQ-OW-2004-0019.

GEI Consultants, Inc. (GEI). 2014c. Use-Attainability Analysis for Selected Tributaries to the Yampa River, Routt County, Colorado. Prepared for Seneca Coal Company, Peabody Sage Creek Mine, LLC and Twentymile Coal, LLC.

Hermanutz, R.O., K.N. Allen, T.H. Roush, and S.F. Hedtke. 1992. Effects of elevated Se concentrations on bluegills (Lepomis macrochirus) in outdoor experimental streams. Environmental Toxicology and Chemistry 11:217-224.

Hermanutz, R.O., K.N. Allen, N.E. Detenbeck, and C.E. Stephan. 1996. Exposure of bluegill (Lepomis macrochirus) to selenium in outdoor experimental streams. U.S. EPA Report. Mid-Continent Ecology Division. Duluth, MN.

Janz, D.M. 2008. A critical evaluation of winter stress syndrome. In Selenium tissue thresholds: Tissue selection criteria, threshold development endpoints, and potential to predict population or community effects in the field. Washington (DC, USA): North America Metals Council – Selenium Working Group.

Linville, R.G. 2006. Effects of Excess Selenium on the Health and Reproduction of White Sturgeon (Acipenser transmontanus): Implications for San Francisco Bay-Delta. Dissertaiton. University of California at Davis.

North American Metals Council-Selenium Working Group (NAMC-SWG). 2014. Comments of the North American Metals Council-Selenium Working Group in Response to EPA's Draft National Recommended Aquatic Life Criterion for the Pollutant Selenium. Submitted to Docket ID EPA-HQ-OW-2004-0019.

Stephan, C.E., D.I. Mount, D.J. Hansen, J.H. Gentile, G.A. Chapman, and W.A. Brungs. 1985. Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses. PB85-227049. National Technical Information Service, Springfield, VA.

U.S. Environmental Protection Agency (EPA). 2004. Draft Aquatic Life Water Quality Criteria for Selenium - 2004. EPA-822-D-04-001. Office of Water, Washington, DC.

U.S. Environmental Protection Agency (EPA). 2014. External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium – Freshwater 2014. EPA 822-P-14-001. Office of Water 4304T, Washington, D.C.

Comment Category 8.2 – Additional Data

8.2 Summary

Several commenters provided EPA additional data for consideration in updating selenium criterion documentation.

8.2 Response to comments

EPA has acquired new data through the peer review and public process and has included these data, as appropriate, in the derivation of the criterion.

8.2 Specific comments

EPA-HQ-OW-2004-0019-0413-A2; Federal Water Quality Coalition (FWQC); Posted 10/28/2015

Original letter contains additional information in the form of an attached comment letter submitted by Barnes & Thornburg LLP, on behalf of Federal Water Quality Coalition (FWQC) for the 2014 selenium comment response. See original letter.

EPA-HQ-OW-2004-0019-0412-A3; Utility Water Act Group (UWAG); Posted 10/28/2015

Original letter contains additional information in the form of an appendix, EPRI (2001) report: Selenium Cycling and Impact in Aquatic Ecosystems: Defining Trophic Transfer and Water-Borne Exposure Pathways. See original letter.

EPA-HQ-OW-2004-0019-0391-A1; North American Metals Council (NAMC); Posted 10/14/2015

Original letter contains additional information in the form of an attached comment letter submitted by North American Metals Council (NAMC) for the 2014 selenium comment response. See original letter.

EPA-HQ-OW-2004-0019-0401-A1; Colorado Wastewater Utility Council; Posted 10/15/2015

Original letter contains additional information in the form of supplemental data tables. See original letter.

EPA-HQ-OW-2004-0019-0400-A1; The National Mining Association (NMA); Posted 10/15/2015

Original letter contains additional information in the form of supplemental data tables. See original letter.