EPA Response to Public Comments

on the

2014 External Peer Review Draft

Aquatic Life Ambient Water Quality Chronic Criterion for

Selenium-Freshwater

EPA Response to Public Comments on the 2014 External Peer Review Draft Aquatic Life Ambient Water Quality Chronic Criterion for Selenium-Freshwater

In May 2014, EPA released an External Peer Review Draft national recommended aquatic life criterion for the pollutant selenium in freshwater and provided in total a 75-day public comment period on the draft document (ending July 28, 2014). The 2014 draft document was then subjected to an independent, contractor-led, external expert peer review, and peer reviewers were provided the 2014 public comments for their information.

In July 2015, EPA released a revised draft selenium criterion document that reflected consideration of: a) the external expert peer review feedback on the 2014 draft criterion, b) the external expert peer reviewers' feedback on the 2014 public comments provided to the peer reviewers, and; c) EPA's own consideration of comments from the 2014 public comments on the draft criterion.

The following is a summary of public comments received on the 2014 External Peer Review Draft Aquatic Life Ambient Water Quality Chronic Criterion for Selenium - Freshwater and EPA responses reflecting the science as presented in the 2016 final document. The 2014 public comments listed in this document were arranged into major categories. For each comment category a summary of overarching public comments is provided and comments from individual commenters were divided across identified categories. For the full individual public comments, the reader is directed to the public docket at regulations.gov (Docket ID: EPA-HQ-OW-2004-0019) https://www.regulations.gov/docket?D=EPA-HQ-OW-2004-0019. EPA responses are given below in the right-hand column under each category of comment.

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Comment Category 1.1 – Comments on Sources of Selenium Summary: Many 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.		
165	EPA-HQ-OW-2004-0019-0266-A2; Transportation and Storm Water Department, City of San Diego, California; Posted 6/16/2014 Selenium is an issue for many municipalities within southern California due to local geology rather than runoff from the urban landscape. The local geology is a known source of selenium in California and although surface water concentrations can be higher based on natural soils, bioaccumulation and the resulting impacts to beneficial uses varies significantly. Numerous efforts throughout California 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	**Response to the comment on natural sources of selenium:** EPA referred to this issue raised in 2014 in the 2015 draft document in section 2.1 noting: "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

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	areas, such as Orange County, local agencies have worked for over a decade with the 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 appropriate objectives for selenium. Therefore, the implications of the proposed revisions to the freshwater selenium criterion are an important issue in southern California.	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." Subsequently, EPA added additional text to the 2016 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. Response to comment 163 Regarding comment 163, which notes that EPA discusses natural sources of selenium but "EPA doesn't go any further in describing flexibilities or recommended approaches for criteria development for states that have naturally elevated selenium." Site –specific criteria development is discussed in Appendix K of the 2016 criterion document. Implementation issues such as flexibilities are beyond the scope of a criteria document. Technical support materials are being developed by EPA separately and will be released following the issuance of the final selenium criterion. Response to comment 120: Regarding comment 120 from the Southern Nevada Water Authority, requesting that "river systems and impoundments on river
172	EPA-HQ-OW-2004-0019-0271-A2; Coordinator, Barnes & Thornburg LLP on behalf of the Federal Water Quality Coalition; Posted 6/17/2014 EPA should also consider that natural selenium levels are high in some regions of the country. As a result, selenium concentrations in public water supply systems, provided from groundwater wells, can in some cases be higher than surface water quality standards, so that effluents from facilities using that water supply will also be higher than standards, even if the facilities themselves contribute no significant selenium loadings. This issue should be addressed in the development of water quality standards, as well as in implementation procedures.	
173	EPA-HQ-OW-2004-0019-0272-A2; Clark County Water Reclamation District; Posted 6/17/2014 The Clark County Water Reclamation District (District) appreciates the opportunity to comment on the "External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium – Freshwater 2014." The District collects and treats wastewater at seven plants in Clark County, Nevada. We return much of our highly treated effluent to the Colorado River (River) system via the Las Vegas Wash and Boulder Basin of Lake Mead. The comments below are substantively similar to those submitted by the Southern Nevada Water Authority (Authority), of which we are a member. Selenium is a naturally occurring mineral in certain rocks and soils. Weathering rocks, including volcanic and sedimentary rocks, are the major sources of environmental selenium. These types of rocks and soils are common in the desert southwest, along the Colorado River, and in the Las Vegas Valley. Some waterbodies in the Las Vegas Valley are currently classified as impaired for selenium on Nevada's Water Quality Integrated Report. These listings may affect future discharge permits. Our treatment and return of River water results in the Authority receiving return flow credits. Therefore, our ability to return flows of highly treated wastewater is an essential component in the community's limited water resources.	
163	EPA-HQ-OW-2004-0019-0257-A2; Wyoming Department of Environmental Quality (WDEQ); Posted 6/16/2014 *Naturally Occurring Selenium* As outlined in pages 9 and 10 of 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	

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<tr><th>Comment tracking number</th><th>Docket ID, Attribution, Comment</th><th>Response</th></tr>
<tr><td></td><td>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. WDEQ/WQD, therefore, requests that EPA include recommendations on approaches and considerations for developing site-specific criteria for states that have seleniferous geologic formations.</td><td rowspan="3">systems, like the Colorado River and the reservoirs on the river, be considered "lotic" and be defined as such in the Environmental Protection Agency's (EPA) regulation", EPA notes that the selenium criterion is NOT a regulation. The selenium aquatic life criterion is a recommendation describing concentrations of selenium protective of aquatic life. EPA's recommended criteria do not impose legally binding requirements. States and authorized Tribes have the discretion to adopt, where appropriate, other scientifically defensible water quality criteria that differ from these recommendations.
The Southern Nevada Water Authority may also want to consider that in their effort to develop an average selenium concentration estimate for the Colorado River, after excluding samples below the limit of detection, their calculations will be skewed to higher concentrations, biasing calculations and overestimating the average selenium concentration in the Colorado River entering Lake Mead.

Response to Comment 161, suggesting a need for a nationwide selenium assessment:
As noted in the 2016 final selenium criterion document, EPA's Office of Water and Office of Research and Development conducted the first statistically based survey of contaminants in fish fillets from U.S. rivers from 2008 through 2009. This national fish survey was conducted under the framework of EPA's National Rivers and Streams Assessment (NRSA), a probability-based survey designed to assess the condition of the Nation's streams and rivers (Lazorchak et al. 2014). During June through October of 2008 and 2009, field teams applied consistent methods nationwide to collect samples of fish species commonly consumed by humans at 541 randomly selected river locations (≥ 5th order based on 1:100,000-scale Strahler order) in the lower 48 states. They collected one composite fish sample at every sampling location, with each composite consisting of five similarly sized adult fish of the same species from a list of target species. Largemouth and smallmouth bass were the primary species collected for the study, accounting for 34% and 24% of all fish composites, respectively. Samples were collected from both non-urban (379 sites) and urban</td></tr>
<tr><td>201</td><td>EPA-HQ-OW-2004-0019-0352-A1; Western Coalition of Arid States (WESTCAS) [Comments 0319-A2 and 0321-A1 are duplicates of 0352-A1]; Posted 8/7/2014
In the West, where water is extremely limited, we have a large number of ephemeral or intermittent streams. In many of these streams fish populations are not necessarily limited by water quality but by water quantity and habitat. Water column concentrations in much of the arid West are highly impacted by significant deposits of selenium-rich materials that naturally elevate selenium concentrations in aquatic ecosystems. Consequently, although anthropogenic activities (e.g., irrigation) may facilitate mobilization of selenium from these materials, native fish species undoubtedly have a different exposure and evolutionary history with regard to selenium. As such, BAFs likely vary considerably in this region as BAFs are known to decrease when high concentrations of naturally occurring selenium are present. EPA should provide guidance on how to incorporate naturally elevated background concentrations of selenium into site or region specific criteria.
Site-specific criteria should be an integral component for the implementation of a tissue based chronic selenium criterion and should be clearly defined in the Draft Criterion Document, especially for use in the arid West where naturally high background concentrations and limited water quantity is common.</td></tr>
<tr><td>120</td><td>EPA-HQ-OW-2004-0019-0347-A2; Southern Nevada Water Authority; Posted 8/5/2014
Selenium is a naturally occurring mineral in rock and soils. Weathering rocks, including volcanic and sedimentary rocks, are the major sources of environmental selenium. High selenium concentrations are generally associated with Late Cretaceous sedimentary rocks and soils of marine origin. These types of rocks and soils are common in the desert southwest, along the Colorado Rover, and in the Las Vegas valley. Waterbodies in the Las Vegas valley have currently been classifies as impairment for selenium on Nevada's Water Quality Integrated Report. The listing of waterbodies in southern Nevada may affect discharge permits in the Las Vegas valley. By treating Colorado River water after it is used and returning the water to Lake Mead, the authority receives return flow credits. These credits allow the Authority to divert an equivalent amount of water to the amount of water returned and therefore dischargers play an important role in the water supply for the Las Vegas valley.
The Authority requests that river systems and impoundments on river systems, like the Colorado River and the reservoirs on the river, be considered "lotic" and be defined as such in the</td></tr>
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	Environmental Protection Agency's (EPA) regulation. Currently there are four categories in the regulation: 1) lakes and reservoirs; 2) ponds and marshes; 3) rivers; and 4) streams, drains, washes and creeks. In the case of reservoirs on the Colorado River, such as Lake Powell, Lake Mead, Lake Mohave, and Lake Havasu, there is a large flow between the reservoirs every year and they are an integral part of the river system. In normal years Lake Powell delivers 8.23 million acre feet (MAF) of water to Lake Mead and Lake Mead, Lake Mohave, and Lake Havasu deliver 9.76 MAF to downstream users. Currently the flow of the Colorado River through each of the lakes is controlled by the Bureau of Reclamation and all the reservoirs and the intervening river work together. Based on the amount of water moving through these bodies of water they should be considered lotic. This determination is very important because the background concentration of selenium in the Colorado River system, due to the naturally occurring selenium in rock and soils, varies from 1.6 µg/L to 2.9 µg/L from the entrance to Lake Mead to Morelos Dam, located near the Mexican border. The Authority has developed a database that houses approximately 4 million water quality records for samples taken along the Colorado River from Lake Powell to the international border with Mexico. Sixteen hundred selenium samples have been collected by various agencies at different locations and the results have been uploaded into the database. These data were searched and samples below the limit of detection were discarded. The remaining 1,364 results were analyzed and averaged (Figure 1).The background Colorado River selenium concentrations of water entering Lake Mead average (2.9 µg/L (n=39). Based on the data, it appears that the flowing portions of the river (Grand Canyon, stretch of river between Laughlin, NV and Needles, CA, etc.) will meet the lotic standard but the lakes in between will not meet the lentic standard. *Original letter contains Figure 1 – Average Selenium Concentrations in Colorado River from Lake Mead to Morelos Dam. See original letter.*	locations (162 sites). Each fillet composite sample was homogenized and analyzed using an ICP-MS (Inductively Coupled Plasma- Mass Spectrometry) method for total selenium, and results were reported as wet weight. Three of the 541 samples (approximately 0.6%) exceeded the 2016 criterion for muscle tissue, 11.3 mg/kg dw. The maximum value detected was 17.75 mg Se/kg dw muscle, the median was 1.90 mg Se/kg dw, and the minimum 0.41 mg Se/kg dw. Although this survey was conducted to assess species commonly consumed by humans, the data do indicate exceedance of the fish muscle criterion was to be an infrequent event based on the national survey of these fish species. Response to comment 464: EPA has deleted the maps from the previous 2014 (and 2015) draft. The new map in the 2016 document is based on USGS datasets for the conterminous US; the data consists of surficial soils and aquatic sediments and the concentrations are scaled to the county level using kriging techniques. The data used by EPA to re-create the USGS map can be found at: http://mrdata.usgs.gov/geochem/doc/averages/se/usa.html
121	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 4.1 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	

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	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 2014 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). Consequently, we conducted a review of the native geologic layers (Schweitzer 2011), specifically those containing shale as a primary or secondary rock, throughout the country. The results indicate that shale-containing formations are distributed throughout a large portion of the country; correlations between elevated dissolved Se surface water concentrations and these formations is discussed below (Figure 3). *4.1.1 Background Se Concentrations in Lentic Systems* The proposed water column criterion for lentic systems is substantially lower than that for lotic systems, and significantly lower than previous criteria. Therefore, we conducted a review of surface water data provided through the Water Quality Portal (WQP; National Water Quality Monitoring Council [NWQMC], accessed May 27, 2014). The information in this database is composed of data from the USGS National Water Information System (NWIS) and from the USEPA STOrage and RETrieval (STORET) Data Warehouse. The complete dataset was filtered for dissolved Se in surface water sampled from lentic waterbodies (e.g., lakes and reservoirs). Additional database filtering steps and database use disclaimer language are provided in the footnote below the figure caption. Using the data extracted from the WQP database as described above, Se concentrations were compared to the following threshold concentrations: the proposed lentic Se criterion (1.3 µg/L), the 25th percentile lentic water Se concentration from a recent NAMC-SWG report, which was recommended as a lentic criterion concentration (2.3 µg/L; DeForest et al. 2014), and the proposed lotic criterion, for comparison (4.8 µg/L) as plotted in Figure 3. The text box in the left-hand corner of Figure 3 presents the percentages of samples from lentic systems that would be in exceedance of these three Se concentration thresholds. Dissolved Se concentrations in lentic systems from across the country exceed the proposed criterion of 1.3 µg/L in 64% of samples. Although we do not know the specific circumstances for each waterbody, it is unlikely that mining or irrigation are causing such widespread exceedences. While the results do indicate that there are some instances of correlations between high dissolved Se surface water concentrations and the shale-containing formations, a more detailed analysis should be conducted on a state-by-state basis to more clearly understand the individual formations that are included in Figure 3 and the expected background concentrations in these regions. GEI (2013a, b and	

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	2014) present information on selected stream segments in Colorado that have site-specific Se standards because of elevated ambient concentrations due, in large part, to the surrounding geology. These ambient site-specific standards were developed after use attainability analyses (UAAs) 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 successful despite elevated Se or fish populations were limited due to other factors such as limited flow or habitat.	
164	EPA-HQ-OW-2004-0019-0258-A2; National Association of Clean Water Agencies (NACWA); Posted 6/16/2014 Site-Specific Criteria Critical to Address Unique Aspects of Selenium, Natural Background Levels NACWA appreciates that the draft criterion document allows for the development of site-specific criteria where appropriate. Site-specific fish tissue and toxicity information is preferable to the use of generic toxicity relationships that were developed using data from a broad range of sites, and the Draft Criterion Document should make that preference clear. Factors unique to selenium, including its presence at naturally high background concentrations in some areas, weigh heavily on implementation of the criteria and will necessitate use of site-specific information. In its 2005 comments NACWA provided some detailed technical analysis on a number of compounding factors related to geographic differences in surface water concentration and fish tissue concentration that are sure to complicate implementation of a national criterion. NACWA provided some specific examples from Colorado, where background concentrations are elevated in certain areas: • Like many regions in the western U.S., many areas in Colorado have significant deposits of selenium rich surface materials (e.g., marine shales) that naturally elevate selenium concentrations in aquatic ecosystems; • Despite elevated background levels, studies (see GEI Consultants, Inc. June 2014 review) have found abundant aquatic systems with fish populations similar to sites with low selenium concentration;	
196	EPA-HQ-OW-2004-0019-0349-A1; Colorado Wastewater Utility Council (CWWUC); Posted 8/5/2014 One topic that needs further consideration, and is of particular importance in Colorado, is providing guidance for situations where there are naturally elevated background Se concentrations, such as the ability to develop ambient based site-specific criteria where those elevated concentrations are	

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	unrelated to human-induced sources. Colorado has extensive areas with underlying geology contributing to elevated Se concentrations in ground and surface waters (Figure 4 of the GEI review). GEI has provided a discussion of a case-study in Colorado, in which these elevated natural Se concentrations resulted in ambient-based criteria approved by both the state and EPA (Section 4.1.2). We recommend this type of ambient-based criteria be considered on a case-by-case basis nationwide. EPA's discussion of site-specific standard development is lacking and needs further clarification.	
456	EPA-HQ-OW-2004-0019-0356-A1; Idaho Department of Environmental Quality (DEQ); Posted 09/30/2014 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 have water bodies with naturally elevated selenium levels.	
442	EPA-HQ-OW-2004-0019-0337-A2; Pennsylvania Coal Alliance; Posted 07/28/2014 *Comment* Selenium in Pennsylvania surface waters and in discharges from Pennsylvania mining operations has not received the same level of concern as it has in other coal producing regions of the country. Nevertheless, selenium has the potential to become an issue of concern to Pennsylvania producers as water quality criteria for this metal are developed and/or revised and may subsequently be included in producers' NPDES permits. It is critically important that the science underlying proposed aquatic life water quality criteria be fully developed and accurate. PCA supports and endorses the comments submitted to EPA by NMA and its technical consultant, GEI Consultants, Inc., on this matter. PCA would like to especially underscore two of NMA's comments. First, EPA did not provide any recommendations on how to determine attainment with selenium criteria in ephemeral, intermittent streams and small headwater streams that do not hold fish. There are many such streams in the coal regions of Pennsylvania where available water quantity rather than water quality limits fish populations. NMA's comments recommend methods EPA should consider to evaluate the need for, and to develop, site-specific standards. PCA supports these comments. Second, guidance is needed for streams that have naturally elevated background concentrations of selenium that are unrelated to anthropomorphic activity. Pennsylvania ranks near the top of all states	

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	in the number of miles of rivers and streams, and there is a wide variation in background water quality in these waters. Guidance on when and how to develop site-specific criteria in streams with naturally elevated background concentrations of selenium is vital to ensure that NPDES permits are not written with conditions that are more stringent than necessary to protect fish and aquatic life.	
177	EPA-HQ-OW-2004-0019-0274-A2; National Mining Association (NMA); Posted 6/17/2014 EPA should also provide guidance for situations where there are naturally elevated background Se concentrations, including guidance on developing ambient based site-specific criteria where those elevated concentrations are unrelated to human-induced sources. GEI has provided a discussion of how this has been successfully done in Colorado (Section 4.1.2), and how it could be considered on a case-by-case basis nationwide. Importantly, EPA's discussion of site-specific standard development is lacking and needs further clarification.	
161	EPA-HQ-OW-2004-0019-0256-A1 [Comment 0346-A2 is a duplicate of 0256-A1]; Peabody Energy Corporation; Posted 6/16/2014 Need for Nationwide Assessment The drastic nature of this criterion change has the potential to cause a large increase in the number of lakes and streams that are considered impaired in the United States. As was stated, many areas of the U.S. have naturally elevated selenium concentrations. Two of the most prominent sources of the ambient selenium include marine shales and seleniferous soils. The proposed criterion has potential to cause attainment and subsequent permitting issues in these types of environments. In the case of lentic environments, the water column concentration is being substantially lowered. The EPA should undertake an analysis of the number of lentic systems that would be considered impaired based on 1) the water column criteria and 2) the fish tissue criterion where available. Furthermore, because the majority of water quality sampling to-date has focused solely on water column concentrations, there is some concern that a fish-tissue criterion could potentially impact a large number of streams. Because of these factors it is recommended that the EPA also perform an assessment of the number of streams nationwide that would be considered impaired with respect to each criterion.	
464	EPA-HQ-OW-2004-0019-0356-A1; Idaho Department of Environmental Quality (DEQ); Posted 09/30/2014 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 1, page 11). 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.	

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Comment Category 1.2 – Comments on Selenium Speciation Summary: A commenter noted that dissolved speciation of selenium is critical to the extent of enrichment into primary producers, and that selenite is more readily bioconcentrated than selenate. The commenter further noted that if there would be specific criteria only for lotic versus lentic sites, with no correction for the speciation of selenium, the lotic value is too high given that some sites might be exclusively contaminated with one species of selenium. Another commenter noted that the assumption that "macrophytes and other plants can readily take up selenite and selenate and incorporate selenium in the tissue as selenomethionine" presented in the USEPA 2014 draft document had not been supported in scientific studies and that other classes of selenium compounds are present in aquatic biota. The commenter further noted that only mesocosm studies in which selenium is added to the mesocosm should be used to evaluate the effects presented in the draft criterion. Another commenter noted that potentially a single waterbody could consist of both lentic and lotic sections, and that regulating both using different criterion will not be practical.		
153	EPA-HQ-OW-2004-0019-0353-A1; Mark C. Rigby, Parsons and University of California at Santa Barbara; Posted 8/7/2014 On page 14, the USEPA draft document states "In water, macrophytes and other plants (algae, phytoplankton) can readily take up selenite and selenate and incorporate selenium in the tissue as selenomethionine." As explained by Rigby et al. (2014), the statement made by USEPA is an unsupported assumption based on the analytical chemistry limitations of the late 1990s and early 2000s. This assumption has been maintained in recent selenium speciation studies using XANES and XAS. However, XANES/XAS cannot differentiate among species of C-Se-C and most recent XANES/XAS speciation studies have merely assumed that all C-Se-C is selenomethionine. Many XANES/XAS speciation studies also cannot distinguish between C-Se-C species and C-Se-H species. Where more detailed speciation has been attempted in plants, algae, and bacteria, the situation has proved to be much more complicated with many other organoselenium species present. To my knowledge, only one study to date has speciated the selenium in aquatic biota using modern advanced techniques. That study (Schmidt et al. 2013) showed the following selenium speciation: *Original letter contains Table – not numbered. Selenium species (%) in aquatic biota. See original letter.* As shown in the table above, for fish that consume bacteria, diatoms, or algae (at least for the one ecosystem studied), selenomethionine is not the dominant dietary species. Even in brine flies and brine shrimp, other organoselenium species are present, which may affect the toxicity of selenium. Further, as summarized by Rigby et al. (2014), XANES/XAS speciation of aquatic biota show that there are several other classes of compounds present in aquatic biota including Se0, SeO3 2-/SeO4 2-, Fe-Se-X, CSe- C / C-Se-H, C−Se(O)−C, C-Se-Se-C, C3-Se+, although C-Se-C / C-Se-H is usually the dominant form. Modern selenium speciation techniques have been most rigorously applied to terrestrial plants, which show a dizzying array of organoselenium classes and compounds (e.g., Bierla et al. 2012, Gammelgaard et al. 2011, Ouerdane et al. 2013). While these techniques have not been applied to the vast majority of food items consumed by freshwater fish (or even the speciation of	**Response to comments on selenium speciation:** Selenium speciation is discussed in Section 2 of the criterion document. Regarding the role of speciation, the data available in the peer- reviewed literature to EPA for modeling are typically non-speciated and expressed as "total" selenium. Because of this the selenium criterion is expressed as total dissolved selenium in water (e.g., the total of all oxidation states; selenite, selenate, organic selenium, and any other forms), realizing that multiple forms of inorganic and organic selenium species may be present in any one sample. EPA derived selenium criterion elements for fish tissue based on the relationship between total selenium and the effect observed in fish tissue, which integrates the effect of all selenium species to which the organism has been exposed over time. Regarding the basis of the water column concentrations as "dissolved total selenium in water," EPA recognizes that clarification of the definition of selenium was needed and has included a better definition and discussion of selenium speciation in the water column in the final document. 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 include trophic transfer factors (TTFs) from the multiple Conley et al. publications based on the life-cycle exposure of selenium to mayflies via a complex periphyton diet. There are concerns regarding the Conley mayfly TTFs when insufficient food resulted in different TTF (and toxicity) measurements, which illustrate the potential bias with laboratory

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	selenium in fish eggs), there is no reason to suspect that selenium speciation in aquatic biota should not be as rich. As stated in the draft USEPA document on page 33 "the form or speciation of selenium differs among exposure routes (diet, water), and that the different forms have differing toxicities." Therefore, laboratory studies in which fish are exposed only to selenomethionine may not reflect the toxicity of selenium as encountered by fishes in the wild. Further, field studies have usually be conducted to evaluate the toxicity of selenium to fishes where there is a substantial and sustained release of contaminants that include selenium; e.g., uranium mine effluent, coal mine effluent, phosphate mine effluent, agricultural pesticides, and increased salinity. Unfortunately, field studies conducted in these areas may be biased due to the effects of the other contaminants released. Therefore, the only studies that are likely to evaluate the real-world effects of selenium on fishes (in the absence of effects from other contaminants) are mesocosm studies in which selenium (and only selenium) is added to the mesocosm (e.g., Hermanutz et al. 1996). USEPA should perform mesocosm studies on additional fishes to evaluate the effects presented in the draft criterion.	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.
555	EPA-HQ-OW-2004-0019-0335-A2; County of Orange, OC Pubic Works; Posted 7/30/2014 • While the text acknowledges selenium speciation issues, the water column criterion does not address it. The considerable difference between water column criterion for lentic and lotic waters is apparently due to selenium speciation, which is rather complex and site-specific. Potentially, a single waterbody could consist of both lentic and lotic sections. Regulating both using different criterion will cause confusion and may not be practicable.	
91	EPA-HQ-OW-2004-0019-0260-A2 [Comment 0314-A2 is a duplicate of 0260-A2]; Conley and Buchwalter; Posted 6/16/2014 The following comments are focused on the biodynamics and toxicity of selenium at the base of aquatic foodwebs, namely from the dissolved phase (and associated speciation) to primary producers (i.e., enrichment) and primary consumers (i.e., trophic transfer to aquatic macroinvertebrates). We believe the following weaknesses in the draft document should be addressed: 1. Providing separate dissolved criteria for lotic and lentic sites is an improvement from the previous selenium criterion, however there are two problems with this approach: a. Dissolved selenium speciation is equally as, or more, critical for aquatic foodweb incorporation than site type. The draft document recognizes the importance of dissolved selenium speciation (pages 12 - 16) however directly states that the dissolved criterion values "apply to the total of all oxidation states…"(page 8). Based on our research examining the bioconcentration of dissolved selenium into the base of aquatic foodwebs, the dissolved speciation is critical to the extent of enrichment into	

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	primary producers, particularly in terms of timing of exposure (see Conley et al. (2013) Environmental Science & Technology 47: 7965-7973). In our studies, selenite was much more readily bioconcentrated than selenate. The draft document recognizes that source material dictates the speciation of selenium released into a contaminated site (table on page 13). As such, a lotic site that is impacted by oil refinery effluent or coal fly ash, which predominantly leach selenite, would be at much greater risk of selenium bioaccumulation and toxicity than a similar lotic site with copper mining discharge, which predominantly leaches selenate. If there is only going to be specific criteria for lotic versus lentic sites, with no correction for the speciation of selenium, we believe the lotic value is too high given that some sites may be exclusively contaminated with selenite.	
463	EPA-HQ-OW-2004-0019-0356-A1; Idaho Department of Environmental Quality (DEQ); Posted 09/30/2014 Specific Questions & Comments Footnote 3 in the table on page 4 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 8 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. Calculation of WQC_{int} is unclear. For example, imagine a stream with a high background of selenium of 5 µg/L. So $WQC_{30\text{-}day}$= 4.8 µg/L and C_{bkgrnd} = 5.0 µg/L Let us say this occurs 29 out of 30 days (the apparent max allowed) so f_{int} = 0.967. This appears to give a criterion of 4.8 - 5.0 (0.033) / 0.967 = 4.79 which is less than the 30-day average and not an elevated concentration for the stream in question. This does not seem to allow for a background greater than the $WQC_{30\text{-}day}$. It also appears this criterion is intended to deal with a waterbody that varies in concentration over time; it is not so clear whether EPA envisions application as well to variation in exposure as fish move among waters of varying selenium concentrations.	
Comment Category 1.3 – Comments on Organism Dietary Requirements Summary: Commenters emphasized the selenium dietary requirements of aquatic organisms. One commenter noted that experimental evaluation of the concentrations of selenium in fish eggs at recommended dietary selenium concentrations are needed.		
70	EPA-HQ-OW-2004-0019-0353-A1; Mark C. Rigby, Parsons and University of California at Santa Barbara; Posted 8/7/2014 On page 20, the USEPA draft document states "Dietary requirements in fish have been reported to range from 0.05 to 1.0 mg Se/kg dw (Watanabe et al. 1997). Selenium requirements for optimum	Response to comments on organism dietary requirements: EPA recognizes the duality of selenium as a nutrient at low does and a toxicant at higher doses, as discussed in Section 2 of the 2016 final criterion document. EPA developed the selenium criterion

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	growth and liver glutathione peroxidase activity in channel catfish were reported as 0.25 mg Se/kg dw (Gatlin and Wilson 1984). Estimated selenium dietary requirements in hybrids of striped bass, based on selenium retention, were reported as 0.1 mg Se/kg dw (Jaramillo 2006)." There are multiple additional studies on selenium requirements of fishes. Since the draft criterion is based on a concentration in fish eggs/ovaries, the additional information is unlikely to affect the criterion without further experimental evaluation (i.e., additional experiments to determine concentrations in fish eggs at recommended/optimal dietary selenium concentrations). These experiments should also be performed to bound the tissue criteria developed by USEPA. Hao et al. (2014) summarized the results of their experiments and others as follows (see Hao et al. (2014) for references): "It can be concluded that a diet containing 0.48–0.50 mg Se kg-1 is optimum in loach, when considering liver bioaccumulation, haematological and biochemical blood serum parameters and oxidative stress in loach. The Se requirement in loach (0.48–0.50 mg Se kg-1) determined in this study is higher than that reported for rainbow trout (0.38 mg Se kg-1, Hilton et al. 1980), channel catfish (0.25 mg Se kg-1, Gatlin and Wilson 1984) and Japanese sea bass (0.40 mg Se kg-1, Liang et al. 2006); lower than that reported for grouper (0.77 mg Se kg-1, Lin and Shiau 2005) and gibel carp (Carassius auratus gibelio) (1.18 mg Se kg-1, Han et al. 2011)." Also see NRC (2011) for additional review.	based on high quality toxicity tests based on results of maternal transfer of selenium via diet, and subsequent overt larval toxicity. A summary of several studies that evaluated the deficiency and/or the sufficiency of selenium in the diet of fish is provided in Appendix E of the 2016 final selenium criterion document.
530	EPA-HQ-OW-2004-0019-0293-A2; Pennsylvania Department of Environmental Protection; Posted 6/26/2014 Selenium is an essential micronutrient for most aquatic organisms but in excess it is detrimental. Scientists determined that selenium bioaccumulates in fish via ingestion and accumulates in the eggs and ovaries of adult females causing deformities and reduced survival of offspring. In addition, they found that the toxic effects from selenium exposure occur at different concentrations in lentic aquatic systems (lakes and impoundments, etc.) than in lotic aquatic systems (flowing waters, rivers, streams, etc.).	
Comment Category 2.1 – Comments of a General Nature Concerning National Criterion and Primacy Structure Summary: There were a range of general opinions concerning overall and conditional support of the draft criterion and primacy structure. Some commenters expressed general non-support. Many commenters supported the fish tissue elements of the criterion but were opposed to the national water column element arguing that there is too much site-specific variability across water bodies to make a national criterion appropriate. Several felt the water column criterion element would be useful as a trigger for fish tissue monitoring.		
61, 62, 64, 65, 204	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 8/7/2014 Specific Technical Issues: Very Limited Availability of Reproductive Toxicity Data for Fish Exposures to Selenium The core component of EPA's technical package is the proposed 15.2 mg Se/kg criterion for fish egg	Response to general comments on the criterion and the primary structure: EPA appreciates the many comments supporting the development and overall structure of the criterion, including those supporting EPA's:

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	and/or ovary tissue (E/O tissue); all other components of the proposed chronic criteria are tiered, in one way or another, off of the proposed E/O tissue criterion. One of the Service's foremost scientific concerns regarding this core component of the DSP is the paucity of data available for quantifying the E/O tissue core component with an appropriate degree of confidence. Any proposed toxicological criterion is as certain or uncertain as the extent of toxicity data that the criterion is built upon. In the DSP, EPA is attempting to estimate the true E/O tissue concentration of selenium that would result in 5% or fewer fish taxa experiencing 10 percent or greater selenium-induced reproductive impairment. All uncertainty about the true numeric value of this desired E/O tissue criterion would be removed if reproductive toxicity data were available for all 891 native species of freshwater fish in the United States (species count compiled from American Fisheries Society 2013 and list of Freshwater Fishes for Hawaii accessed at: http://fish.mongabay.com/data/Hawaii.htm). At the other extreme, greatest uncertainty occurs when the desired tissue criterion is estimated from toxicity data for only one species. Between those extremes is a gradient. The DSP's estimate of the desired E/O tissue criterion is based primarily on toxicity data for 11 species of fish, providing nine estimates of Genus Mean Chronic Values (GMCVs; Table 6a). That's equivalent to toxicity data for 1.2% of all native freshwater fish species in the United States. Lacking toxicity data for 98.8% of fish species, the present state of science is clearly still on the very high uncertainty end of the gradient for estimating the desired E/O tissue criterion and should be accounted for in the DSP. A cautionary example from the avian toxicity literature seems very relevant here. For decades, guidelines for protecting birds from reproductive toxicity associated with exposure to mercury were derived from toxicity data from just three reference species of birds: chickens, mallards, and pheasants. Toxicity data for these three species was hypothesized to be sufficiently protective of the 772 species of native seasonally resident avian species found within the United States to serve as a basis for environmental risk assessments (Heinz et al. 2009; http://en.wikipedia.org/wiki/List_of_birds_of_the_United_States). Heinz (2003) tested this hypothesis. Egg injection studies were conducted on field-collected eggs for an additional 23 species of birds spanning a broad range of taxa. Suitable exposure-response curves from egg injection trials were obtained for 20 of the 23 newly tested bird species and 10 of those 20 species (50%) were found to have greater relative sensitivity than any of the three reference species used for decades for environmental risk assessment (Heinz et al. 2009). It now appears that mallards are a fairly tolerant species and chickens and pheasants are near the median sensitivity value for birds. Another way using statistics to account for the uncertainty of limited toxicity data is as follows, knowing the number of fish species to be protected (891) and the number of fish species being utilized for toxicity data (11), the random probability of at least one 10% sensitive-tail species having	• 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. Regarding the fish tissue criterion, the species sensitivity distribution is populated with taxonomic surrogates representing listed species over the known experimental range of selenium. They are (Acipenseridae) white sturgeon (1 endangered population), salmonids (brown trout, cutthroat trout, rainbow trout, and Dolly Varden), the desert pupfish (Cyprinodontidae). In addition, there are centrarchids and esocids represented in the SSD, and other data regarding fish populations in Se-exposed waters indicate that Cyprinids would generally be protected by the 2016 final fish tissue criterion. 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. 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 sensitivity distribution. 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

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	already been tested can be directly calculated as 1 minus the product of the probabilities of failing to sample one in 11 consecutive tries without replacement. This calculation is as follows: [1-[[(891- (0.10 X 891))/891) X [((891- (0.10 X 891))-1)/(891-1)) X [((891- (0 . 10 X 891))-2)/(891-2)) X [((891- (0.10 X 891))-3)/(891-3}) X [((891- (0.10 X 891))-4)/(891-4)) X [((891- (0.10 X 891))- 5)/(891-5)) X [((891- (0.10 X 891))-6)/(891-6)) X [((891- (0 .10 X 891))-7)/(891-7)) X [((891- (0.10 X 891))-8)/(891-8)) X [((891- (0.10 X 891))-9)/(891-9)) X [((891- (0.10 X 891))-10)/(891-10)))) = (1- 0.3116) = 0.6884 For water bodies that are substantively over the water-based chronic criteria, how would we know that results of tissue sampling weren't biased low due to the susceptibility of nearly all fish sampling techniques to survivor bias? The changes in fish assemblages following selenium pollution from mountaintop removal-valley fill mining in Appalachia reported by Hitt and Chambers (In Press), and the differential extirpations of select species of fish at Belews Lake, in the San Luis Drain, California, and in the Swedish Lakes study (all these examples summarized in Skorupa 1998) suggest that implementation of tissue-based criteria for fish could face impediments related to sampling designs that don't have a means for detecting and protecting against the invalidating effects of survivor bias	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 selenium 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 selenium 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 criteria, particularly regarding the number species for which data are available and the spatial representation of the data. 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
76	EPA-HQ-OW-2004-0019-0327-A2; Colorado Wastewater Utility Council (CWWUC); Posted 7/30/2014 First, we would like to commend EPA's effort in developing fish tissue-based Se criteria that are consistent with the latest science regarding Se toxicity. We support the use of a fish-tissue based chronic Se criterion as the overriding criterion.	
77, 78	EPA-HQ-OW-2004-0019-0340-A1; CONSOL Energy Inc.; Posted 8/5/2014 CONSOL is in support of EPA's intent to determine appropriate aquatic life water quality criterion for selenium, and upon reviewing the External Peer Review Draft would like to submit the following comments: CONSOL supports the EPA's approach in adopting the use of fish and invertebrate tissue based standards as the primary criterion used in determining selenium impacts. We believe this is a scientifically relevant method to determine and manage the ecological impacts associated with selenium exposure, and agree with its adoption as a replacement for water column assessments. However, we believe that the dataset used by EPA to develop the invertebrate criteria is flawed and further work is necessary to develop a sufficiently robust data set capable of evaluating both the impacts on benthic organisms and provide accurate trophic transfer functions. We also believe that, given the wide variation in estimated trophic transfer functions, that these be used only in cases where a direct site specific correlation between water column selenium	

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	concentrations and fish tissue selenium levels cannot be determined. The limited availability of data relating to the effects of selenium toxicity as a result of bioaccumulation creates the need for continued evaluation. CONSOL is in support of evaluating the most relevant and up to date information provided by the completion of additional selenium studies. We recognize that early test results, like those determined in the Lemly bluegill study, were important to the understanding of chronic selenium toxicity in fish; however, this study was too limited in scope to establish nationwide criterion.	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 observed, the egg/ovary criterion element is identified as the measurement that supersedes 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 are applicable. The EPA has made some changes to the footnotes associated with the criterion table in the Executive Summary and Section 4 of the 2016 criterion document to clarify the hierarchal relationship among the tissue elements, and between the tissue water elements, as well assertion of primacy of water over tissue in fishless waters, and for new discharges until determination of steady state. Regarding risk to aquatic dependent wildlife, EPA understands the potential for risk to birds from selenium exposure and has begun to investigate the potential for a national criteria that would protect aquatic-dependent wildlife. Regarding comment on the uncertainty in selenium's mode of action, EPA reviewed Kupsco and Schlenk 2014. This was an acute (12 hr exposure) at a high water concentration, and the mechanisms of action under these conditions are not likely to be identical to those experienced in a long term, chronic dietary exposure. While the authors hypothesized "SeMet would induce oxidative stress, the UPR and apoptosis in Japanese medaka
81	EPA-HQ-OW-2004-0019-0345-A2; Ohio EPA; Posted 8/5/2014 In regards to the document External Peer Review Draft Aquatic Life Ambient Water Quality Criterion For Selenium—Freshwater 2014 (EPA-820-F-14-005), Ohio EPA appreciates the opportunity to comment on this important issue. We feel that it is important to consider all of the available pertinent data on the subject, and we agree that it is appropriate to consider an update to the existing criterion at this time. Ohio EPA reserves final judgement on the proposed criterion until the final document is released, but our initial review of the draft criterion suggests that it is probably protective of aquatic life in most situations. The proposed criterion accounts for selenium's unique toxicological risk factors and the aquatic food web impacts. The sensitive end point selected for adverse ecological impact is the risk of skeletal deformities and reproductive failure in fish populations. Lemley (published literature 1999, 2001, 2002, and 2004) documented adverse impacts on fish communities at slightly lower levels (2 µg/L for inorganic selenium in filtered water samples and <1 µg/L for organic selenium in filtered water samples) compared to the proposed water column criteria values of 4.8 µg/L and 1.3 µg/L.	
82	EPA-HQ-OW-2004-0019-0349-A1; Colorado Wastewater Utility Council (CWWUC); Posted 8/5/2014 We appreciate the opportunity to provide comments on the draft selenium criteria as any changes to the federal water quality standards will impact the operation, and management of wastewater treatment facilities. Our comments are supported by the attached document, Review of EPA 2014 draft Se criteria document, EPA 822-P-14-001, prepared by GEI Consultants, Inc. First, we would like to commend EPA's effort in developing fish-tissue based Se criteria that are consistent with the latest science regarding Se toxicity. We support the use of a fish-tissue based chronic Se criterion as the overriding criterion.	
86, 507,	EPA-HQ-OW-2004-0019-0353-A1; Mark C. Rigby, Parsons and University of California at Santa	

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508, 511	Barbara; Posted 8/7/2014 On May 14 2014, USEPA proposed draft water quality criteria for selenium. The draft criteria document reviews and summarizes numerous scientific studies and experiments and attempts to use that information to derive scientifically-defensible criteria "to protect against adverse effects of selenium on aquatic life" that "reflect the latest scientific consensus." For selenium, the scope of such an endeavor is quite dauntingly large. The document does a very good job summarizing the available scientific information and presenting it in a format that is not overly technical. The document is necessarily the product of multiple specialists and requires review by multiple specialists. My comments below are restricted to fish toxicity and how to evaluate it. Please also note that I do not have an academic position and, therefore, the amount of time I have available to review this document is extremely limited. EPA-HQ-OW-2004-0019-0278-A1; Mark C. Rigby, Parsons and University of California at Santa Barbara; Posted 06/24/2014 On May 14 2014, USEPA proposed draft water quality criteria for selenium. The draft criteria review and summarize numerous scientific studies and experiments and attempt to use that information to derive scientifically-defensible criteria "to protect against adverse effects of selenium on aquatic life" that "reflect the latest scientific consensus." Overall, the document does a very good job summarizing the available scientific information and presenting it in a format that is not overly technical. The draft document is 637 pages long and contains a very large amount of information. Unfortunately, however, USEPA only provided a 30 day comment period, which is too short a time to permit an in-depth review. Therefore, the comments I present below are necessarily abbreviated. On page 18, the USEPA draft document states "Recent research, however, suggests that selenium's role in oxidative stress plays a role in embryo toxicity, whereas selenium substitution for sulfur does not." As pointed out by Kupsco and Schlenk (2014), the "mechanisms behind Se induced teratogenesis and mortality remain unclear. Several studies point to oxidative stress as one mode of action for Se toxicity. However, oxidative stress is most likely only one factor influencing SeMet toxicity. The unfolded protein response (UPR) is a cellular and molecular response to perturbations in endoplasmic reticulum (ER) homeostasis… If the response is unable to attenuate the stress, the UPR will initiate cell death, often in the form of programmed cell death (apoptosis)." They concluded that "multiple adverse outcome pathways [i.e., oxidative stress, UPR, and apoptosis] may be responsible for the developmental toxicity of Se… and these pathways may be time dependent." Thus, the mechanisms behind the developmental toxicity of selenium appear to be far more nuanced that	embryos," significant effects of SeMet on hatch were not observed in the freshwater treatments. Further, no significant effects of oxidative stress, UPR, or apoptosis were observed in the freshwater SeMet treatment. The authors discuss the potential importance of these mechanisms, but note that "While the UPR may have played a role, oxidative stress and apoptosis measured in the whole embryo were not associated with SeMet induced mortality and teratogenesis at this early stage." Regarding the Muscatello, Nautilus, and Rudolph studies, EPA examined the three studies carefully in terms of data quality prior to use in the criteria derivation process. Muscatello reported an EC24 at 34 mg/kg; as such, it was outside the range of sensitivity of the lowest 4 GMCVs, but counted towards the "N", with regards to the criterion value. Not including Muscatello would have reduced the 2016 egg ovary criterion slightly (from 15.1 to 14.9 mg/kg dw) due to a lower "N". Rudolph 2008 and Formation 2011 were integrated into the analysis following data quality review and comprised two of three studies making up the GMCV for Oncorhynchus (24.7 and 27.7 for Westslope Cutthroat Trout), along with 24.5 for Rainbow trout. Currently the GMCV is 25.3; removal of the two aforementioned studies would lower the GMCV to 24.5 mg/kg, resulting in a slight increase to the FCV (15.1 to 15.2 mg/kg dw). Regarding the need to sample continuously across the 30 day averaging period: EPA does not require continuous daily sampling in order to make a determination of attainment or compliance. Regarding the issue of juvenile mortality in bluegill, and as described in a comment, selenium-induced cold temperature loss of lipid and body condition, a non-reproductive sublethal effect that Lemly (1993a) observed to accompany juvenile mortality in the laboratory (but which McIntyre et al. (2008) did not observe in a similar study) has not generally been corroborated by field evidence

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<tr><td></td><td>recognized in USEPA's draft document.

Table 5 includes several field studies (i.e., Muscatello et al. 2006, Nautilus Environmental 2011, and Rudolph et al. 2008) in which the fishes evaluated were (or may have been) exposed to elevated levels of other contaminants, in addition to selenium. The use of such studies in the derivation of a water quality criterion should be considered very carefully, as it may bias the results. At the very least, USEPA should show the effect of including and excluding these studies on the criterion derived.

Please note that these comments do not necessarily reflect the opinion of either Parsons Corporation or the University of California at Santa Barbara and were submitted by Mark Rigby as an individual.</td><td rowspan="3">(Janz 2008). Given the uncertainty in the occurrence of winter stress, the results of all four cold and cool-temperature (4°C and 9°C) juvenile-survival lab studies were combined per the standard procedure described in the U.S.EPA Ambient Water Quality Criteria Guidelines, to determine the non-reproductive SMCV for bluegill. The SMCV for the combined 4ºC and 9°C tests is 9.33 mg Se/kg dw whole body, based on the four chronic values: (a) the Lemly (1993a) concentration prior to winter stress (5.85 mg Se/kg dw whole body), (b) the McIntyre et al. (2008) ES1 EC10 (9.27 mg Se/kg dw whole body), (c) the McIntyre et al. (2008) ES2 NOEC (>9.992 mg Se/kg dw whole body), and the McIntyre et al. (2008) ES3 EC10 of 14.00 mg Se/kg dw whole body. This value is greater than the reproductive endpoint-based whole-body criterion concentration of 8.5 mg Se/kg dw. The studies of Bryson et al (1985b) and Cleveland et al. (1993) were not conducted at cold or cool temperatures and were thus not used for these SMCV calculations. More detailed discussion on the bluegill non-reproductive tests can be found in Appendices C and D of the 2016 final selenium document.

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 EC10s 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.

Regarding the re-evaluation of acceptable studies, the fathead minnow study (Schultz and Hermanutz 1990) was re-evaluated based on a visual inspection of the TRAP curve that revealed potential inconsistencies that required inquiry. The analysis</td></tr>
<tr><td>167</td><td>EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014

Multiple lines of evidence, including fish health and population studies and food chain modelling, should be considered in addition to water and fish concentrations to assess whether elevated egg/ovary concentrations are actually linked to adverse effects, particularly in recovering systems.

Approach for Deriving Site-Specific Water Concentrations from the Whole Body/Muscle Criterion Element

Whole body/muscle and water-based criterion elements of the draft selenium WQC were derived from the egg/ovary element. As stated previously, the US EPA converted the egg/ovary concentrations to whole body/ muscle tissue concentrations using species-specific conversion factors. The corresponding selenium concentrations were then predicted at each trophic level and at the base of the food web using trophic transfer factors between trophic levels and enrichment factors to estimate transfer from the water column to algae, detritus and sediment.

This model is conceptually similar to the model of bioaccumulation using a bioaccumulation factor (BAF), in which the 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. The U.S. EPA preferred the trophic transfer model to the BAF model in the derivation of a WQC for selenium because the BAF is empirically derived from site-specific measurements and was not deemed appropriate for a criterion for nation-wide application.

Where relatively a large database is available to support BAF derivations for different fish species, the BAF approach should be considered as an alternative to the one presented in the draft selenium criterion document.</td></tr>
<tr><td>183</td><td>EPA-HQ-OW-2004-0019-0313-A2; Wisconsin Department of Natural Resources (WDNR); Posted</td></tr>
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	6/27/2014 However, the WDNR does have some comments and questions with regards to the proposed criterion: Minimum Data Requirements (MDR) The WDNR has not waived any of the MDR for any of the criteria currently in state code (NR105). The procedures for deriving criteria listed in NR105 are those described in EPA's Guidelines for Deriving Numerical National Water Quality Criteria for the Protection Of Aquatic Organisms and Their Uses (July 1985). Therefore, it appears that WI would have an additional challenge in making an exception from NR 105 via rule-making process to promulgate this criterion. Minimum Data Requirements (MDR) Table 3 should include the genera/species considered for each MDR as some genera/species may not be residents in all states. This would be helpful for determining if the criterion needs to be altered to be applicable to WI.	revealed that there was heavy mortality/loss of embryo/larvae during monitoring and an erratic occurrence of the abnormalities (e.g., significant incidence of edema in only 3 of 10 replicates for the Se treatment). Although a case can be made that the selenium treatment had a higher rate of edema and lordosis, there are some issues that add uncertainty to the estimation of an accurate effect concentration. This led to the conclusion that the study results should not be used for criterion derivation. The data from this study still support the range of reproductive effect levels determined in other fish studies, and so the study was retained and is reflected in the number ("N") of studies in the 2016 final document. Additional information is located in Appendix C. An additional study, GEI (2008) estimated EC10s for larval survival and deformities that ranged from 35 – 65 mg Se/kg dw expressed as maternal whole body, was also not used quantitatively in the derivation of the criterion. This information is presented in Appendix E, Figures E-2 and E-3. Regarding bluegill, the Hermanutz study was subsequently re-evaluated pursuant to comments in 2014, and again in 2015. The re-evaluation based on 2015 comments led to EPA using all 3 studies (I, II, and III, the recovery study where tissue concentrations were still elevated). This led to an EC10 of 14.7 mg/kg dw presented in the 2016 final criterion document. Re-evaluation of Coyle (1993) and Doroshov (1992), which led to statistically superior fits, resulted in revised EC10s of 26.3 and 22.6 mg/kg, respectively. The GMCV bluegill is 20.6 mg/kg dw for egg ovary in the 2016 final criteria document. Additional information on these studies is presented in Section 3 and Appendix C of the 2016 final selenium document. 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
195	EPA-HQ-OW-2004-0019-0348-A1; Gopher Resource LLC; Posted 8/5/2014 Gopher Resource is concerned that EPA's proposed use of a water column translator is not suited to establishing a water quality-based effluent limitation (WQBEL) for selenium. Establishing the typical WQBEL involves analyzing s substance's toxic effects on biota in the receiving water. Under such circumstances, a water column value with national application may be warranted. Selenium, however, is different. Its toxicity arises from bioaccumulation, which varies from location to location based upon the type of selenium, the fish species in the receiving water, water chemistry, and other factors. EPA's External Peer Review Draft recognizes the unique and variable nature of selenium bioaccumulation, which may necessitate a site-specific water quality criterion. According to the Peer Review Draft, "[b]ecause the factors that control the bioaccumulation of selenium vary from location to location, a site-specific criterion for the protection of aquatic life can be developed as needed (Appendix I), when establishing allowable concentrations in water or resident fish."[1] However, the Peer Review Draft inexplicably goes on to suggest that States may use selenium water quality concentration values to set WQBELs using the "existing implementation procedures...for other acute and chronic aquatic life."[2] ——— [1] U.S. EPA External Peer Review Draft Aquatic Life Ambient Water Quality Criteria for Selenium-Freshwater 2014 at 1. [2] *Id.* At 98	

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208	EPA-HQ-OW-2004-0019-0258-A2; National Association of Clean Water Agencies (NACWA); Posted 6/16/2014 The National Association of Clean Water Agencies (NACWA) appreciates the opportunity to comment on the U.S. Environmental Protection Agency's (EPA) *Notice of Availability: External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium – Freshwater 2014* (Selenium Notice) (May 14, 2014; 79 *Fed. Reg*. 27601) and EPA's ongoing efforts to revise the selenium criterion. NACWA provided comments in 2005 on the Agency's 2004 draft revisions to the criterion and is pleased that the overall approach EPA has taken with the 2014 draft revision is consistent with NACWA's recommendations. The EPA approach in the 2014 Draft Criterion Document is more in line with standard water quality criteria development and results in a more scientifically defensible criterion than the 2004 draft criterion, which was based on a single study. In the Association's 2005 comments, NACWA stressed that the "selenium content of the eggs or ovaries may better reflect the potential chronic effects to fish." In assessing chronic impacts, the 2014 Draft Criterion Document appropriately focuses on reproductive effects, with criteria values provided for selenium in fish eggs or ovaries. The Draft Criterion Document also clearly states that fish tissue data should take precedence over water column data in assessing whether the criteria are met when both types of data are available. NACWA continues to believe that a tissue-based criterion is the most direct way to quantify the chronic toxicity of a bioaccumulative contaminant such as selenium. While NACWA supports the general approach EPA has taken with the revision – focusing on chronic reproductive effects – the Association does have some concerns with the Draft Criterion Document as outlined below. NACWA also commends to your attention the review of the Draft Criterion Document prepared by GEI Consultants, Inc. (June 13, 2014) and submitted separately to the docket.	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." 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 EC10. As a result of the statistical re-evaluation, the new EC10 increased from 18.5 mg/kg dw to 21.0 mg/kg dw. For more detail please see Section 3 of the 2016 final selenium criterion document EPA re-evaluated the CF derivation methodology, based on comments received in 2014 and 2015. First, EPA modified the approach to provide for the use of empirically derived whole body or muscle tissue value preferentially to a CF-estimated value. Second, EPA modified the relational qualifications for derivation of CFs. Previously, in the 2014 external peer review draft, CFs were derived based on medians of the "average fish" meaning all species were taken together. In the 2015 draft, this was revised to reflect a method using taxonomic proximity, starting with species level data, and working to less related levels of classification (genus, family, then order) as necessary. Finally, EPA compared the CF results using the conventional ordinary least squares (OLS) method, as recommended by commenters to the median ratio method. In doing so, EPA found that because there is no dependency between the selenium concentrations in one tissue type to another tissue type, that CFs derived using OLS resulting in concentrations in both tissue types that are equally uncertain. Because of this, we could assign either tissue type to either axis, and the resulting CF would be slightly different. To address this problem, EPA also evaluated the total least squares (TLS) method. TLS regression is preferable
214, 216	EPA-HQ-OW-2004-0019-0323-A1; California State Water Resources Control Board; Posted 7/30/2014 The California State Water Resources Control Board (Water Board) staff appreciates the opportunity to provide comments on the United States Environmental Protection Agency's (U.S. EPA) External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium — Freshwater 2014 (2014 Draft Selenium Criterion). The revised criterion for selenium has been much anticipated, and will likely impact site-specific selenium criteria that are being developed in California (e.g., the Newport Bay Watershed in Orange County, the Calleguas Creek Watershed in Los Angeles County, and North San Francisco Bay). As a result, we have a number of concerns regarding the 2014 Draft Selenium Criterion. We understand that U.S. EPA is recommending a freshwater chronic criterion for selenium composed of four parts, or elements. The recommended elements are: (1), a fish egg/ovary element; (2), a fish	

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	whole-body and/or muscle element; (3), a water column chronic element for lentic or lotic water body types; and (4), a water column intermittent element for lentic or lotic water body types to account for potential chronic effects from repeated, short-term exposures to this bioaccumulative pollutant. First, we note that U.S. EPA's recommendation that States adopt all four of the proposed elements of the criterion as a single tiered criterion would also include adoption of the proposed water column elements. At various times in the document the terms "override", or "primacy", or "precedence" are applied to the fish tissue elements over the water column concentrations. While it appears that U.S. EPA intends for the proposed fish tissue elements (egg/ovary, whole body, or muscle tissue) to supersede the water column elements, the relevant language is not clear and may lead to misinterpretation. The document appears to leave open the possibility that even in areas where fish tissue concentrations are available, the water concentration may still apply. We strongly believe that this would be inappropriate. In the highly urbanized and arid climate of much of Southern California, water column concentrations of selenium and its subsequent bioaccumulation and effects can vary greatly even within small watersheds, such as the Newport Bay Watershed. For example, two of our freshwater tributaries that are impaired for selenium (San Diego Creek and Big Canyon Wash) differ greatly in their degree of bioaccumulation and ecological risk, even though existing water column concentrations are similar (see Attachment 1). This is because the different hydrologic conditions of these water bodies, and therefore, different proportions of selenium species, result in a much higher rate of bioaccumulation in one tributary compared to another. In the case of the Newport Bay Watershed, modeling using United States Geological Survey's biodynamic model, which is the same model used in the draft criterion, indicates that U.S. EPA's proposed water column element for lotic systems would likely be over-protective of the San Diego Creek subwatershed, but under-protective of the Big Canyon Was subwatershed even though both systems are classified as "lotic" systems. In fact, application of the lentic criterion element to Big Canyon would still be under-protective; under current conditions, the biodynamic model predicts that water column concentrations will need to be reduced to less than 1 µg Se/L unless management actions can be taken to reduce Se cycling and bioaccumulation in this small watershed. 1. Water column concentrations should be used as triggers, not as elements of the criterion, to indicate the need to collect biological data to ascertain whether or not aquatic food webs in a water body are impaired by selenium.	to OLS regression in cases where there is error associated with each of the variables, and there is no dependency of one variable on the other. This eliminates uncertainty based on assigning tissue values to each axis differently (X-Y vs Y-X). TLS based regression is not amenable to a template based construct in common software, so they are more difficult to use than OLS. Given the similarity in CF results using the median and regression methods, and that median values are not subject to influence by data that diverges from the 1:1 regression lines at the tails, the EPA decided to retain the use of the median. While EPA recommends the use of the median, regression based methods (particularly TLS) may be appropriate for robust site-specific data sets, and may provide a more precise CF than the median ratio method in these situations. EPA provides a comparison of the methods in Appendix N of the 2016 criteria document. The EPA has derived both whole body and muscle criterion elements, from the egg-ovary, and has compared those values to non-reproductive toxic effects (e.g., growth, juvenile mortality), and have found the whole-body and muscle translated criteria elements to be protective of non-reproductive effects. This analysis is in Section 6.1.9 of the 2016 final selenium criterion document. Regarding comments on the tissue derivation procedures, EPA first incorporated commenters' suggestions 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 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
219	EPA-HQ-OW-2004-0019-0326-A1; Utility Water Act Group (UWAG); Posted 7/30/2014 GENERAL COMMENTS EPA is recommending national chronic selenium criteria that are based on fish tissue concentrations	

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	in egg/ovary and whole-body or muscle tissue. UWAG supports the Agency's extensive effort to understand and reflect the latest science that concludes diet is the primary pathway of selenium exposure and reproductive effects are of greater significance and concern than non-reproductive effects. We also support EPA's strong acknowledgment that selenium toxicity is highly site-specific and appreciate inclusion of the option for developing site-specific criteria in derivation of the criterion methodology. Overall, we believe EPA's recommended approach is a distinct improvement over selenium criteria proposed in 2004 that were based on juvenile and overwinter survival. As described below, we have certain concerns and questions about specific aspects of EPA's approach, however. <u>Four-Part Criterion for Chronic Effect is Generally Workable</u> EPA has determined that freshwater aquatic life would be protected from toxic effects of selenium by attaining any element of the following four-part criterion (tissue thresholds in dry weight): (i) concentration in eggs/ovary (15.2 mg/kg); (ii) concentration in whole-body (8.1 mg/kg) and muscle (11.8 mg/kg); (iii) 30-day average concentration in water both lotic (4.8 µg/L) and lentic (1.3 µg/L); and (iv) an intermittent concentration (not to exceed an intermittent exposure calculation) in either lentic or lotic water. Among these four elements, EPA has created a preference for focusing on tissue concentrations, as opposed to a measurement in the water column. We believe the science supports EPA's conclusion that water-column concentrations are less precise for predicting and preventing reproductive effects. The consensus of the science supports that selenium toxicity occurs (i) through bioaccumulation, (ii) slowly over time, (iii) primarily through ingestion of food, and (iv) most importantly at the base of the food web where algae and other microorganisms accumulate selenium from water. As an exposure route, water concentrations contribute little to selenium toxicity and are less precise as a surrogate for measuring selenium toxicity in aquatic life. The science also concludes that the most serious effects are reproductive, i.e., resulting from maternal transfer to eggs, making egg/ovary the preferred end point. We agree with EPA's conclusion that focusing on reproductive effects will result in chronic criteria expected to be protective of non-reproductive endpoints such as juvenile survival and growth. Draft Report, pp. 130-33.	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.
220	EPA-HQ-OW-2004-0019-0331-A1; The Fertilizer Institute; Posted 07/29/2014 III. A Tiered Approach is Needed for Application of Criterion EPA's criterion has four-parts:[2] 1. The concentration of selenium in the eggs or ovaries of fish does not exceed 15.2 mg/kg, dry weight; 2. The concentration of selenium (a) in whole-body of fish does not exceed 8.1 mg/kg dry	

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	weight, or (b) in muscle tissue of fish (skinless, boneless fillet) does not exceed 11.8 mg/kg dry weight; 3. The 30-day average concentration of selenium in water does not exceed 4.8 µg/L in lotic (flowing) waters and 1.3 µg/L in lentic (standing) waters more than once in three years on average; and, 4. The intermittent concentration of selenium in either a lentic or lotic water, as appropriate, does not exceed an intermittent exposure calculated value: $\frac{WQCint = WQC30\text{-}day - Cbkground\ (1 - fint)}{fint}$ The Draft Criterion correctly provides that "(egg/ovary) overrides any whole-body, muscle, or water column elements when fish egg/ovary concentrations are measured." However, the four-part criterion as proposed may cause confusion and complexity in regards to implementation and required monitoring. TFI recommends the EPA clarify that the criterion is the egg/ovary value and then use the following multi-step process for application of the criterion: • Initial monitoring should be of the water column selenium concentration. The water selenium concentration threshold (lentic or lotic) should be used as an initial screening value. • Exceedance of the initial screening value triggers the collection and testing of fish to determine status in regards to the criterion (egg/ovary value). • Depending on specific circumstances at the site of interest, a site-specific criterion (Appendix I of Proposed Criterion) may be warranted. EPA has approved a similar approach for the State of Kentucky (EPA 2013). Such an approach minimizes the need for sampling and analyzing fish tissues and provides a more cost-effective method for monitoring. [2] EPA 2014. External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium – Freshwater. p. 96-97.	
221, 222, 262	EPA-HQ-OW-2004-0019-0332-A2; J.R. Simplot Company; Posted 7/30/2014 A Tiered Approach is Needed for Implementation. EPA should make it clear that the egg or ovary tissue value is the criterion. A water column value should be used as a screening threshold for regular monitoring. Specific examples are provided in the detailed comments for monitoring methods. IV. The Criterion Should be Applied in a Tiered Approach Section 5 of the Draft Criterion document presents the recommended criterion and states, "EPA	

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	recommends that states and tribes adopt into their water quality standards a selenium criterion that includes all four elements, expressing the four elements as a single criterion composed of multiple parts, in a manner that 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." We commend EPA for identifying the egg/ovary as the primary criterion taking precedent over all other media; however, we find no mention of which media is the preferred media for regular monitoring. EPA needs to clarify that the egg/ovary value is the criterion. Regular monitoring should be conducted in aqueous media such that there is no implied need for tissue monitoring should a water body have lower selenium concentrations than the recommended national criterion. This is necessary to avoid unnecessary expenditure of resources on tissue monitoring when in fact none is needed. In the event a water body does exceed the national criterion based on the thirty day average, a tiered approach would recommend that trophic transfer and enrichment factors in the document be used to back calculate an egg/ovary tissue concentration (should site specific trophic transfer and enrichment factors not be available). If the aqueous value back calculated to an egg/ovary value does exceed the criterion, then those should be verified through whole body/muscle or egg/ovary tissues collected in the field to assess if the tissue criteria are indeed exceeded. In other words, the aqueous value should serve as a trigger for more in-depth monitoring of tissues rather than serve as an absolute criterion value. As Section 5 is currently written, while the primacy of the criterion elements are established, the bulk of the regulated community who only regularly monitors water quality may find themselves exceeding the criteria when in fact they have not (i.e., false positive). Based on this extensive experience examining the toxicity of selenium, Simplot's comments address the following topics: An Egg/Ovary Tissue Criterion is the Correct Approach. Research has shown for quite some time that chronic toxicity from selenium cannot be determined solely by exposure to selenium in the water column. For a number of years, various studies have proposed the use of tissue residues to establish a site specific water quality standard for selenium. Further studies have shown that selenium concentrations in egg tissues were predictive of early life stage effects. The establishment of an egg or ovary tissue value as the criterion is the right approach for the protection of sensitive species.	

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225	EPA-HQ-OW-2004-0019-0335-A2; County of Orange, OC Pubic Works; Posted 7/30/2014 2. 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. As stated in Comment #1, the County strongly supports the approach recommended by USEPA in the 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 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.[6, 7, 8, 9] 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 Newport Bay watershed, a relatively small watershed located in Southern California, initial model runs[10] of the Presser Luoma model[11] for two tributaries, San Diego Creek and Big Canyon Wash, demonstrate a wide range of water column concentrations needed to protect fish: approximately 10- 19.3 µg/L in San Diego Creek and 0.5 - 1.1 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 Ko values (i.e. EF) present in Big Canyon Wash. Even within this small watershed, the use of a universally applicable water column concentration of 4.8 µg/L would be both significantly over- and under-protective. Table 12 and Figure 11 of the 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 these figures show that for 132 various lentic and lotic systems, the calculated range of protective water column concentrations varies by two orders of magnitude (0.38 - 55.63 µg/L for lentic systems and 1.37 - 98.08 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	

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	purposes to help determine the extent of BMPs necessary to attain a water column concentration that would attain the fish-tissue values. 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 Action: • Remove the water column elements from the 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). --- [6] Lemly, A.D. 1998. A position paper on selenium in ecotoxicology: A procedure for deriving site-specific water quality criteria. *Ecotoxicology and Environmental Safety*. Volume 39, pp. 1-9. [7] Luoma, S.N. and T.S. Presser. 2000. Forecasting Selenium Discharges to the San Francisco Bay-Delta Estuary: Ecological Effects of a Proposed San Luis Drain Extension. U.S. Geological Survey Open-File Report 00-416. [8] 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. US Geological Survey Professional Paper 1646. [9] Skorupa, J.P. 1998. Selenium Poisoning of Fish and Wildlife in Nature: Lessons from Twelve Real World Examples. *In* W. Frankenberger and R.A. Engberg, eds. Environmental Chemistry of Selenium.	

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	Marcel Dekker Inc., New York., p. 315-354. [10] Model runs based upon the Draft Selenium Criterion value of 8.1 mg/kg dw in whole-body fish tissue. [11] This model has been adapted by Luoma and Presser for the Newport Bay watershed. It is the same mechanistic model used in the Draft Selenium Criterion.	
226, 227	EPA-HQ-OW-2004-0019-0343-A2; Kentucky Division of Water; Posted 8/5/2014 The Kentucky Division of Water (KDOW) is pleased to provide the U.S. Environmental Protection Agency (EPA) with comments in support of the External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium — Freshwater 2014 (EPA-822-P-14-001). As you are aware, Kentucky is the first state to include selenium criteria based on fish tissue levels in its Water Quality Standards (WQSs). KDOW firmly believes water quality standards must be based on sound scientific rationale and appreciates the EPA's recognition of this important tenant of water quality standards. The EPA draft selenium criteria and elements incorporate a broad diversity of fishes which protects aquatic habitat against toxicity effects of selenium. 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 chronic toxic concentrations through dietary uptake (Chapman et al. 2010). Kentucky believes a water column threshold which prompts a collection of fish tissue is an appropriate and protective action with regard to aquatic life. Of the four elements of the criterion that EPA proposes, the egg/ovary criterion results take precedence when available, regardless of the results of the remaining three elements. Kentucky believes this is an appropriate application of the criterion since selenium toxicity is particularly manifested in fish reproduction and embryo development. Whole-body or muscle tissue analysis is a sound alternative when egg/ovary tissue is unavailable. This approach parallels that of Kentucky in recognizing that tissue bioaccumulation indicates toxicity in the aquatic environment and provides the most reliable medium for monitoring selenium and protecting aquatic habitat. The proposed nation criterion and its elements appropriately do not include a criterion for acute toxicity because water column concentration exposure is not indicative of toxicity. Kentucky 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. Each water column element is	

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	derived by translating egg/ovary criterion which accounts for ingestion rate, assimilation efficiency, elimination, and concentration in food. The model indicated that growth rate is offset by ingestion rate at different points in the life cycle, and water column intake is inconsequential. Ultimately, the growth and ingestion rates are used to calculate a Trophic Transfer Function for each trophic level. These findings parallel the biogeochemistry and are recognized in various studies (Chapman, et al. 2009, 2010; Presser and Luoma 201a, 2010b, 2013). Datasets from the EPA database were used to derive the lotic and lentic water column concentrations, setting the criterion at the 20th percentile to ensure adequate protection of the aquatic habitat. This calculation affirms the data analysis review from the Kingston, Tennessee coal-ash spill. A similar approach led Kentucky to conclude a 30-day average of 5.0 µg/L water column threshold for total selenium is protective of aquatic life in lotic waterbodies.	
229	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 2.1 Tissue-based Standards We strongly support the approach of a fish tissue-based Se chronic 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 support the use of the tissue-based criterion as the primary overriding criterion (versus water), as it is more representative of potential ecological effects of elevated Se concentrations on aquatic systems. The analysis presented by EPA in their review of safe water column concentrations (based on the observed variability in food-chain components) provides solid evidence that tissues represent the best measure of potential toxicity. As we note later in our review, water concentrations are reliant on and vary considerably depending on site-specific conditions. We emphatically support retention of the fish tissue-based criterion approach (egg/ovary and whole-body) in the final document as the primary criterion.	
230	EPA-HQ-OW-2004-0019-0352-A1; Western Coalition of Arid States (WESTCAS) [Comments 0319-A2 and 0321-A1 are duplicates of 0352-A1]; Posted 8/7/2014 Selenium is a bioaccumulative contaminant with a dietary exposure route for chronic toxicity. Given that water column selenium is not an accurate measurement of chronic selenium toxicity, and because bioaccumulation factors (BAFs) vary by site, WESTCAS is pleased that EPA is recommending that the tissue-based chronic criterion should take primacy over water column data.	

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234	EPA-HQ-OW-2004-0019-0266-A2; Transportation and Storm Water Department, City of San Diego, California; Posted 6/17/2014 Requested Actions: • Remove the water column elements from the Draft Selenium Criterion as elements of the criterion and instead utilize as an implementation tool (similar to the approach utilized by the State of California in the Phase I SQOs).	
271	EPA-HQ-OW-2004-0019-0274-A2; National Mining Association (NMA); Posted 6/17/2014 NMA also recommends that EPA reconsider the methodology used to derive protective water column concentrations. As described in Section 3.3 of the GEI review, calculating single nationwide standards for only two water body types using a probability distribution of protective water column concentrations is not appropriate. As parameters used to determine protective concentrations are highly variable depending on site conditions, there is no defensible national water column number, as shown by EPA's own analysis. Section 4.5 of the GEI review discusses the elements of the equation used to translate fish-tissue to water column concentrations, and some of the inherent uncertainty in the approach EPA has taken.	
277	EPA-HQ-OW-2004-0019-0327-A2; Colorado Wastewater Utility Council (CWWUC); Posted 7/30/2014 We also recommend EPA reconsider the methodology used to derive protective water column concentrations. Calculating single nationwide standards for only two water body types using a probability distribution of protective water column concentrations is not appropriate. As parameters used to determine protective concentrations are highly variable depending on site conditions, EPA should only develop water column criteria on a site-specific basis - there is no defensible national water column number, as shown by EPA's own analysis. Section 4.5 of the GEI review discusses the elements of the equation used to translate fish-tissue to water column concentrations in more detail, and some of the inherent uncertainty in the approach EPA has taken. Overall, this document is a substantial improvement over previous Se criteria documents, and we thank EPA for the opportunity to provide feedback and comments on this draft of the document.	
278	EPA-HQ-OW-2004-0019-0339-A2; West Virginia Department of Environmental Protection (DEP); Posted 7/30/2014 Lentic water column criteria - In terms of realized impacts, if a lentic water column exposure of <1.3 ppb selenate-Se is necessary to protect resident aquatic life from detrimental impacts, culminating in reproductive failures and population collapses (among fishes), how have lentic waters that have been exposed to >1.3 ppb Se +6 and often much higher concentrations persisted and, in most instances,	

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	flourished in these environs? More simply, in these waters exposed to concentrations in excess of 1.3 ppb Se 16 for decades (e.g. 4 ppb Se +6), not a single example of species extirpation due to selenium-induced effects has been documented. This evidence clearly demonstrates that the lentic criterion, as well as the lotic criterion, are not indicative of actual toxicological thresholds and exposure-effect scenarios and are incorrectly based on modeled predictions.	
283	EPA-HQ-OW-2004-0019-0315-A1; USGS - Comment submitted by Theresa S. Presser and Samuel N. Luoma, National Research Program, U.S. Geological Survey, Western Branch, Menlo Park, CA; Posted 7/15/2014 The following are the U.S. Geological Survey (USGS) comments on the U.S. Environmental Protection Agency (USEPA) Draft Aquatic Life Ambient Water Quality Criterion for Selenium (Se)—Freshwater. The Draft Criterion Document (DCD) consists of proposed fish-tissue and water-column based Se criteria and an implementation methodology. In general, tissue Se criteria would help to directly connect the toxicological effects of Se in fish to the primary Se exposure pathway of diet in aquatic systems. Implementation of a fish-tissue criterion, however, would also require derivation of a traditional water-column Se concentration to satisfy other regulatory requirements, such as permit and load limits.	
302	EPA-HQ-OW-2004-0019-0318-A2; Appalachian Voices; Posted 7/29/2014 The EPA Should Strengthen the Proposed Criteria In order to create a standard that is both scientifically valid and enforceable, the EPA should adopt a standard that is based solely on water column criteria that are translated from fish tissue concentrations. When developing standards, the EPA needs to consider the feasibility of their implementation. A tissue based standard will be extremely difficult to enforce. The currently proposed standard demonstrates that water column criteria can be derived from fish tissue concentrations. First, the EPA should consider the issues mentioned above and those raised in response to previous proposed standards and determine a fish tissue concentration that will be protective of all species. This includes selenium sensitive fish species as well as aquatic dependent wildlife like birds. This fish tissue concentration should then be translated into a water column-only standard in order to avoid implementation issues.	
394	EPA-HQ-OW-2004-0019-0254-A1; Gary. L. Persinger; Posted 06/05/2014 My concern with the proposed draft of new national water quality standards for selenium in which junk science now wants fish tissue tested is extreme since there has been no proof that selenium even causes any harm to aquatic life. There is more than enough research about selenium not being harmful to the stream conditions than the made up junk science that is only trying to destroy our	

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	environmental essence in the U.S. of America. The greatest environmentalist today are the industry people who is not only keeping this country moving with the GOD given resources to do such, but having to fight against the ever present regulations that are destroying the lives of our people. Regulations has proven; not only harmful to the people, but are eliminating certain species into extinction. One example is the Indiana bat being eliminating by the white nose symptom caused by regulators, and protestors entering caves with contamination. Industry has increased the bat numbers by the reclamation techniques used in mining by providing corridors into design roads, and feeding areas. Industry should be given less regulation to save this environment than more regulation to destroy it. In the beginning industry; like all phases of life, need a certain amount of regulation to control, and make things better, but up to a certain point, and over the last many years regulators has went way beyond extreme. It's more of a control mechanism against all forms of success; against society, than just providing regulation. In the end; too much weight will soon break all of our backs.	
402	EPA-HQ-OW-2004-0019-0267-A2; Water Quality Division, District Department of the Environment (DDOE), Government of the District of Columbia; Posted 06/17/2014 Comment 3. DDOE is concerned whether EPA is considering the recommended human health criterion for fish consumption coordinates with the recommended fish tissue level, to result in realistic fish consumption advisory.	
412	EPA-HQ-OW-2004-0019-0286-A1; W. Vinett; Posted 06/26/2014 Given that so much enforcement of selenium pollution comes from citizen collection of polluted water samples, the "fish tissue" standards raise a bar that will be most difficult for most citizens to hurtle, resulting in far fewer investigations and far less enforcement. This would appear to be at cross purposes with the mandate of the EPA. Please develop and implement a water sample-based standard for selenium pollution of waterways. Thank you for your work,	
420	EPA-HQ-OW-2004-0019-0295-A1; Anonymous public comment; Posted 06/26/2014 PLEASE PROTECT OUR WATER NOW! THANK YOU.	

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481	EPA-HQ-OW-2004-0019-0274-A2; National Mining Association (NMA); Posted 6/17/2014 NMA notes that, while we appreciate EPA's consideration of the information and analysis contained in the attached review, overall, this document represents a significant improvement over previous Se criteria documents, and we thank EPA for this opportunity to provide feedback and comments.	
485	EPA-HQ-OW-2004-0019-0313-A2; Wisconsin Department of Natural Resources (WDNR); Posted 6/27/2014 The WDNR agrees that Aquatic Life Criterion (ALC) for Selenium needs to be revised. The WDNR had several concerns with the <u>current criterion</u>: • Since the current criterion for selenium was generated from data obtained in the field and only one field location was used, it is possible that other factors (e.g., water characteristics, other toxicants) may have been responsible for the toxicity observed. • Since only one field location was used to generate the current criterion for selenium, it is unclear whether this criterion is applicable to the nation as a whole. • The current criterion for selenium was generated using the procedures described in EPA's <u>Guidelines for Deriving Numerical National Water Quality Criteria for the Protection Of Aquatic Organisms and Their Uses</u> (July 1985). As such, this method was inconsistent with the approach adopted in both the Great Lakes Water Quality Initiative (March, 1995) and Wisconsin's NR105 (Wisconsin Administrative Code). These previous concerns have been addressed by the proposed criterion for selenium.	
490	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 Cameco Resources (Cameco) appreciates the opportunity to provide comments on the Draft Aquatic Ambient Water Quality Criterion for Selenium (draft criterion document) released by the United States Environmental Protection Agency (U.S. EPA). We recognize that the U.S. EPA has presented an approach which incorporates both tissue-based and water quality criterion for lentic and lotic environments, as this aligns with the current understanding of selenium and its interactions within food webs. As well, providing the option to derive a site-specific selenium criterion based on site-specific factors is a valuable and scientifically defensible approach. While we appreciate the approach that has been put forward, we feel there are a number of considerations that should be incorporated prior to finalizing the draft criterion document. A summary of the key points that should be considered in the next version of the draft criterion document are provided below. We have also provided more detailed comments in the attached document, Appendix "A".	

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522	EPA-HQ-OW-2004-0019-0316-A1; Alaska Department of Environmental Conservation (ADEC); Posted 7/25/2014 The Alaska Department of Environmental Conservation (ADEC) has reviewed the U.S. Environmental Protection Agency's (EPA) External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium- Freshwater published in the *Federal Register* on May 14, 2013 (Federal Register, Vol. 79, No. 93, pp. 27601-27604). Under Clean Water Act (CWA) section 303(c), EPA requires states to regularly review and update CWA 304(a) criteria based on EPA recommendations. While this is a good goal and has the potential to help maintain strong state and national water quality standards programs, ADEC believes it is premature to require states to adopt further revisions to criteria until EPA acts on the tremendous backlog of revised water quality standards already adopted by states. ADEC believes that flexibility through extended review periods is required where adoption of revised 304(a) criteria will require modification of state specific criteria or poses significant implementation challenges. Allowing states to determine the water quality issues most pertinent to its residents and stakeholders is a practical approach as well as in line with the original goals of the Clean Water Act. ADEC appreciates EPA's efforts to compile and review the data quantifying the toxicity of selenium to aquatic organisms while assessing the basis for a criterion that will protect population assemblages of fish, amphibians, aquatic invertebrates and plants. ADEC has the following detailed comments related to the proposed *External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium — Freshwater*.	
525	EPA-HQ-OW-2004-0019-0339-A2; West Virginia Department of Environmental Protection (DEP); Posted 7/30/2014 The West Virginia Department of Environmental Protection (DEP) appreciates this opportunity to provide the U.S. Environmental Protection Agency (EPA) with comments on the *External Peer Review Draft Aquatic Life Ambient Water Quality Criterion or Selenium--Freshwater 2014* released for review and comment on May 14, 2014. We greatly appreciate the opportunity to comment on this critical criteria update. As a state that has continuously requested EPA to update the current outdated 304(a) recommended selenium criteria, we are pleased to see the update effort initiated. We also appreciate EPA recognizing the importance of adopting a tissue-based approach and acknowledging the wealth of scientific information supporting the use of a tissue-based criteria for selenium. After a review of the draft materials, we have developed the following comments for consideration in moving forward with the development of the draft criteria:	

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538	EPA-HQ-OW-2004-0019-0323-A1; California State Water Resources Control Board; Posted 7/30/2014 While we appreciate U.S. EPA's effort to adopt a selenium criterion that takes a flexible, tiered approach, we believe that the criterion as presented is not clear in its intent, and does not address aquatic-dependent species of concern such as shorebirds, which are known to be sensitive to selenium. We understand that U.S. EPA will provide another 30 day comment period once peer review is completed and we look forward to seeing the results of the revisions that come out of that review.	
539	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014 NAMC commends EPA on key technical improvements to the proposed document, including: the focus on chronic not acute effects; the recognition that reproductive effects are of greater ecological concern and significance than non-reproductive effects; the reliance on diet as the primary pathway of selenium exposure for both invertebrates and vertebrates; the decision, supported by the fact that the winter stress syndrome has not been shown to occur in field studies and not to include overwinter survival or juvenile survival in the development of the proposed criterion; and, the provision of the option for development of site specific criteria based on the principle that toxicity of selenium in aquatic systems is highly dependent upon site-specific factors, including food web structure and hydrology. We are highly supportive of the tissue-based approach and believe this is the most credible and scientific approach to assessing potential environmental effects from selenium and protecting aquatic resources in the future.	
554	EPA-HQ-OW-2004-0019-0335-A2; County of Orange, OC Pubic Works; Posted 7/30/2014 The criterion does not provide protection to aquatic-dependent wildlife (e.g. birds).	
564	EPA-HQ-OW-2004-0019-0332-A2; J.R. Simplot Company; Posted 7/30/2014 Page 140, Section 7.4: We agree with EPA for stating that effects to wildlife are beyond the scope of the 2014 National Criterion.	
580, 581	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 1. Introduction The first national ambient water quality criteria (AWQC) for selenium (Se) for the protection of aquatic life were published in 1976 (EPA 1976), updated in 1980 (EPA 1980), and then partially updated in 1987, 1995, and 1996 (EPA 1987, 1995, and 1996). These criteria were recommendations of water column limits for Se for the protection of aquatic life as required in the Clean Water Act (CWA). Under	

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	Section 304(a) of the CWA, the United States Environmental Protection Agency (EPA) must also periodically revise AWQC to incorporate the latest scientific knowledge on the kind and extent of all identifiable effects of pollutants on aquatic communities and human health. National AWQC are recommendations to states that must adopt water quality standards. Respective criteria can be modified to best reflect each state's unique aquatic communities and environmental conditions. In 2002 and later in 2004, the EPA published draft Se criteria documents that recognized the differential acute toxicity of selenite and selenate, the relationship between selenate toxicity and ambient sulfate concentration, and the dietary pathway for chronic toxicity of Se (Canton 1999, Brix et al. 2001a,b, EPA 2002 and 2004). Chronic Se toxicity is a result of dietary exposure and bioaccumulative properties of Se in aquatic biota rather than exposure to water column concentrations. Therefore, the 2004 draft criteria document proposed a national tissue-based chronic criterion. Due to the bioaccumulative properties of Se, exposure routes in embryonic and larval fish can be from maternally-derived yolk absorption or directly from the environment. Selective early life stage sensitivities in fish can create a scenario where significant population mortality occurs in Se-affected waters, despite the presence of seemingly healthy adult populations (Lemly 2002). The number and scope of available toxicity studies addressing tissue-based effects of chronic Se exposure remain limited. Twenty-four studies were evaluated in the 2004 Se draft document (EPA 2004) resulting in Se tissue thresholds for nine species in seven genera and one general family tissue threshold. After their evaluation of all acceptable studies, the EPA proposed the chronic criterion of 7.9 milligrams per kilogram (mg/kg) Se whole-body (wb) dry weight (dw), which was derived from a single study that investigated juvenile bluegill mortality during winter months (Lemly 1993). Although it is acceptable to default to a particularly important test result (Stephan et al. 1985), criteria are more commonly derived from a 5th percentile calculation that takes into account the relative sensitivity of all species represented in a dataset containing a minimum of eight specific families. Alternatively, a criterion may be set to the most sensitive species or genus mean value, both of which are mean values derived from multiple studies. The latter may be appropriate for a fish-tissue-based criterion because it is a fish-specific value and other nominally less sensitive aquatic life (e.g., invertebrates) are not taken into consideration. The EPA approach in the 2014 draft Se criteria document is more in line with standard water quality criteria development methodology (Stephan et al. 1985) and includes a critical evaluation of 37 studies on various fish species and results in Se tissue thresholds for eleven fish species in nine 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.	

<table>
<tr><th>Comment tracking number</th><th>Docket ID, Attribution, Comment</th><th>Response</th></tr>
<tr><td></td><td>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. 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 on the 2014 draft Se criteria document.

2. Positives

Overall, this document and the tissue-based criteria approach is a significant improvement over the 2004 draft criteria document. We realize EPA may face some opposition to tissue-based criteria rather than water column-based criteria; however, 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 2014 draft criteria document:
• Tissue-based standards
• Use of EC10s, and
• Timing of tissue data collection (see Sections 2.1 through 2.3 below).

In addition, in Sections 3 through 5 of this review, we have provided several recommended revisions and considerations that we believe will make the 2014 draft criteria document even better.</td><td></td></tr>
<tr><td>588</td><td>EPA-HQ-OW-2004-0019-0256-A1 [Comment 0346-A2 is a duplicate of 0256-A1]; Peabody Energy Corporation; Posted 06/16/2014
Conclusion

We believe that EPA is on the right track, however, there are many important unanswered questions that should be addressed before this criterion is finalized.</td><td></td></tr>
<tr><td>594</td><td>EPA-HQ-OW-2004-0019-0266-A2; Transportation and Storm Water Department, City of San Diego, California; Posted 06/17/2014
The City of San Diego, Transportation & Storm Water Department (City) appreciates the opportunity to provide comments on the United States Environmental Protection Agency's (USEPA) External Peer Review Draft Aquatic Life Ambient Water Quality Criterion/or Selenium - Freshwater 2014 (Draft Selenium Criterion). The City's primary comments are limited to the information that is presented within the Draft Selenium Criterion. Our primary comments are presented in the body of this letter,</td><td></td></tr>
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	and additional comments on specific language and provisions of the Draft Selenium Criteria are provided in the attached table. As noted in the technical comments in the attachment, additional review of key elements is necessary once supporting information and documentation is provided by USEPA.	
601	EPA-HQ-OW-2004-0019-0352-A1; Western Coalition of Arid States (WESTCAS) [Comments 0319-A2 and 0321-A1 are duplicates of 0352-A1]; Posted 8/7/2014 WESTCAS supports the comments provided by the Colorado Wastewater Utility Council, as provided in their attached document, Review of EPA 2014 draft Se criteria document, EPA 822-P-14-001, prepared by GEI Consultants, Inc.	
479	EPA-HQ-OW-2004-0019-0271-A2; Coordinator, Barnes & Thornburg LLP on behalf of the Federal Water Quality Coalition; Posted 06/17/2014 In the Selenium Notice and the draft criteria document that is referred to in the Notice (the "Draft Criteria Document"), EPA has summarized scientific studies relating to aquatic toxicity of selenium, and has recommended water quality criteria to protect against those effects. As an initial matter, 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 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 as follows:	

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390	EPA-HQ-OW-2004-0019-0250; Anonymous public comment; Posted 05/30/2014 I still cannot believe that the extremely low limits for Selenium discharges are still in place and based on what I consider a flawed study on the Mud River that says these low limits deform some fish embryos. Did EPA ever look into those results? Just another knee jerk reaction to the "tree hugger" crowd that wants to ban coal mining coming up with some preposterous way to stop mining. Thank goodness that a study to sample fish tissues is in the works. Hopefully the study will at least raise the limits to human health standards. How many millions of dollars have been already wasted in WV to treat for a metal that appears to have caused no harm even as selenium discharges have most likely been present since mining started in the 1800s.	
406	EPA-HQ-OW-2004-0019-0279; Anonymous public comment; Posted 06/24/2014 I am writing to encourage strong, water-based standards for selenium that will protect all aquatic life. The recent spills in West Virginia and North Carolina show us that we must be vigilant with water quality standards.	
408	EPA-HQ-OW-2004-0019-0282-A1; V. Gilbert; Posted 06/26/2014 We NEED strong water based standards for selenium that will protect all aquatic life! All life is connected. We are All One.	
411	EPA-HQ-OW-2004-0019-0285-A1; W. Fast; Posted 06/26/2014 You are not protecting the environment when you make it MORE difficult to enforce selenium pollution limits. Making the standards overly complex and less stringent is protecting the coal companies, not the communities, not the water, nor the already impacted aquatic flora and fauna. Please come up with some real selenium protection.	
413	EPA-HQ-OW-2004-0019-0287-A1; Anonymous public comment; Posted 06/26/2014 America needs strong water based standards for selenium that will protect all aquatic life!!!	
419	EPA-HQ-OW-2004-0019-0294-A1; A. Artzt; Posted 06/26/2014 We need strong water based standards for selenium that will protect all aquatic life. Please stop the pollution and start saving the environment instead of despoiling it.	
421	EPA-HQ-OW-2004-0019-0296-A1; A. Montapert; Posted 06/26/2014 There needs to be strong water based standards for selenium that will protect aquatic life.	

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425	EPA-HQ-OW-2004-0019-0300-A1; D. Selquist; Posted 06/26/2014 We need strong water based standards for selenium that will protect all aquatic life. There are no shortcuts on the way to healthy ecosystems.	
426	EPA-HQ-OW-2004-0019-0301-A1; Dr. and Mrs. M. Justice; Posted 06/26/2014 We need stronger, less complicated measurements and rules for selenium in our waters.	
428	EPA-HQ-OW-2004-0019-0303-A1; J. J. Smith; Posted 06/26/2014 We need strong water-based standards for selenium that will protect all aquatic life!	
434	EPA-HQ-OW-2004-0019-0309-A1; N. Beavers; Posted 06/26/2014 We need strong water based standards for selenium that will protect ALL aquatic life.	
436	EPA-HQ-OW-2004-0019-0311-A1; S. Wittmann; Posted 06/26/2014 We need strong water based standards for selenium that will protect all aquatic life.	
415	EPA-HQ-OW-2004-0019-0289-A1; E. Butler; Posted 06/26/2014 We need strong water based standards for selenium that will protect all aquatic life. The EPA's proposed standards are too weak to be protective of aquatic life. Studies have shown negative effects of selenium at levels half as high as the fish tissue standards proposed by the agency. These standards are even weaker than those proposed by the EPA in 2004, which were withdrawn after public comments from agencies and scientists demonstrated that they would not protect aquatic life. By partially basing the standards on fish tissue sampling, the EPA has created a significant burden for citizens and agencies trying to enforce the limits on selenium pollution. Fish tissue sampling will be more expensive and time consuming, and it will require special permits for collecting fish. This is especially problematic in Appalachia, where selenium standards have primarily been enforced through citizen actions. These standards will be more difficult to enforce, and will just lead to more streams being degraded.	
417	EPA-HQ-OW-2004-0019-0291-A1; L. Manzione; Posted 06/26/2014 We need strong water based standards for selenium that will protect all aquatic life! By partially basing the standards on fish tissue sampling, the EPA has created a significant burden for citizens and agencies trying to enforce the limits on selenium pollution. Fish tissue sampling will be more expensive and time consuming, and it will require special permits for collecting fish.	

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	This is especially problematic in Appalachia, where selenium standards have primarily been enforced through citizen actions. These standards will be more difficult to enforce, and will just lead to more streams being DEGARDED.	
418	EPA-HQ-OW-2004-0019-0292-A1; S. Iverson; Posted 06/26/2014 *Americans deserve strong water based standards for selenium that will protect all aquatic life.* By partially basing the standards on fish tissue sampling, the EPA has created a significant burden for citizens and agencies trying to enforce the limits on selenium pollution. Fish tissue sampling will be more expensive and time consuming, and it will require special permits for collecting fish. This is especially problematic in Appalachia, where selenium standards have primarily been enforced through citizen actions. These standards will be more difficult to enforce, and will just lead to more streams being degraded.	
424	EPA-HQ-OW-2004-0019-0299-A1; C. Sword; Posted 06/26/2014 It is difficult for me to understand from a rational point of view why you would propose new standards for selenium in rivers that are weaker and harder to enforce than the current standards. The levels now in many places are already toxic. Is this some deal with the coal companies that regular citizens don't know about? Please take another look at this and think about the aquatic life and the humans that are affected by selenium poisoning.	
432	EPA-HQ-OW-2004-0019-0307-A1; L. H. Garber; Posted 06/26/2014 We need strong water based standards for selenium that will protect all aquatic life. As Eric Chance says in *Appalachian Voices* , the EPA's newly proposed standards are too weak to do so. "By partially basing the standards on fish tissue sampling, the EPA has created a significant burden for citizens and agencies trying to enforce the limits on selenium pollution. Fish tissue sampling will be more expensive and time consuming, and it will require special permits for collecting fish. This is especially problematic in Appalachia, where selenium standards have primarily been enforced through citizen actions. These standards will be more difficult to enforce, and will just lead to more streams being degraded." Please help to clean up our water. The EPA and every citizen on the planet is responsible for it and must be held accountable to do so.	
437	EPA-HQ-OW-2004-0019-0312-A1; T. David; Posted 06/27/2014 We need strong water based standards for selenium that will protect all aquatic life. By using standards based on fish tissue sampling, the EPA has made it extremely difficult for citizens and	

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	agencies to help enforce selenium pollution limits. Permits to collect fish will be needed and the process will be more expensive and time consuming. It will be harder to enforce selenium standards, especially where it is citizens who drive the enforcement. This will lead to more streams being degraded.	
439	EPA-HQ-OW-2004-0019-0330-A1; A. Hayes; Posted 07/30/2014 The U.S. Environmental Protection Agency recently proposed new national recommended water quality criteria for selenium. Because these new standards are weaker and more complex than the current standards, they pose a major threat to the health of streams in coal-impacted communities. The EPA's proposed standards are too weak to be protective of aquatic life. Studies have shown negative effects of selenium at levels half as high as the fish tissue standards proposed by the agency. These standards are even weaker than those proposed by the EPA in 2004, which were withdrawn after public comments from agencies and scientists demonstrated that they would not protect aquatic life. By partially basing the standards on fish tissue sampling, the EPA has created a significant burden for citizens and agencies trying to enforce the limits on selenium pollution. Fish tissue sampling will be more expensive and time consuming, and it will require special permits for collecting fish. This is especially problematic in Appalachia, where selenium standards have primarily been enforced through citizen actions. These standards will be more difficult to enforce, and will just lead to more streams being degraded. We need strong water based standards for selenium, that will protect all aquatic life. Please make this happen.	
570	EPA-HQ-OW-2004-0019-0344-A1; Sanitation District No. 1 of Northern Kentucky (SD1); Posted 8/5/2014 The U.S. Environmental Protection Agency (EPA) recently published the *"External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium - Freshwater 2014"* and is requesting public comment by June 13, 2014. This document proposes a set of selenium (Se) tissue and water concentration based criterion for the protection of aquatic life in the freshwaters of the United States (U.S. EPA. 2014a,b,c). Sanitation District No. 1 of Northern Kentucky (SD1) recognizes the significant amount of time and effort that this draft document represents and welcomes the opportunity to provide comments with the intent and goal of assisting the achievement of the important goals represented by this criterion. In general, we are supportive of the approach EPA used to establish the fish tissue criterion. We are, however, concerned that EPA's use of the current proposed water concentration criterion and request that EPA take the proposed actions identified at the end of our	

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	comments. We believe the current proposal is unnecessarily overly protective and burdensome to the regulated community and state regulatory agencies. The proposal, if not revised, will result in increased costs to comply with the Clean Water Act while providing no additional environmental benefit.	
440	EPA-HQ-OW-2004-0019-0333-A2; Alpha Natural Resources Services, LLC; Posted 07/28/2014 On behalf of Alpha Natural Resources Services, LLC (Alpha) and its affiliate companies please accept the following comments regarding the United States Environmental Protection Agency's ("USEPA") draft aquatic life criterion for selenium published on May 14, 2014. Alpha's family of companies constitutes a major US coal producer with operations in areas that are associated with detectable levels of selenium in the rock adjacent to the coal seams being mined. Alpha and its affiliated operations have been involved with implementation of the existing selenium water quality standard as a regulated entity and have collected site-specific information that indicates the current standard, which is based on outdated science, is vastly overprotective. Alpha supports efforts to adopt a selenium criterion that reflects current science and is based upon fish tissue. Alpha does have concerns that modeling and questionable studies that have been used to derive the current draft criterion are overly conservative. Alpha looks forward to a thorough scientific review and an opportunity to comment on the final version of the criterion before it becomes effective. Additionally, Alpha specifically supports the opportunity for States and Tribes to collect state-specific data and develop state-specific fish tissue based standards. Alpha supports and joins in the comments filed by the National Mining Association, the North American Metals Council – Selenium Working Group, and the West Virginia Coal Association and urges USEPA to adopt the changes recommended by these groups.	
103	EPA-HQ-OW-2004-0019-0343-A2; Kentucky Division of Water; Posted 8/5/2014 The element of the criterion which address intermittent exposure in the water column is meant 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. This criterion component is appropriately determined site-specifically and depends on the frequency and magnitude of selenium "spike" 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 element would be applied to the mathematical average of the spike concentrations. The 30-day average concentration element is the appropriate element to utilize. Kentucky's criterion require tissue sampling in the event the water column concentration exceeds the threshold of 5.0 µg/L, which protects the critical aquatic endpoint, the fish, which are monitored to detect any potential toxicity concerns.	

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	For the above reasons, Kentucky supports EPA's approach to developing selenium criteria and encourage the EPA in the formal selenium criteria proposal to: 1) Adopt the statement that fish tissue data should take precedence over water column data in assessing selenium levels (May 14, 2014 79 FR at 27602), and 2) Establish that the chronic selenium criteria is sufficient to protect streams and aquatic habitats, and forego any recommendation for state adoption of an acute criteria.	
410	EPA-HQ-OW-2004-0019-0284-A1; W. Balder; Posted 06/26/2014 By partially basing the standards on fish tissue sampling, the EPA has created a significant burden for citizens and agencies trying to enforce the limits on selenium pollution. Fish tissue sampling will be more expensive and time consuming, and it will require special permits for collecting fish. This is especially problematic in Appalachia, where selenium standards have primarily been enforced through citizen actions. These standards will be more difficult to enforce, and will just lead to more streams being degraded. We need strong water based standards for selenium that will protect all aquatic life.	
414	EPA-HQ-OW-2004-0019-0288-A1; M. A. Murphy; Posted 06/26/2014 TWIMC: We need strong water based standards for selenium that will protect all aquatic life. By partially basing the standards on fish tissue sampling, the EPA has created a significant burden for citizens and agencies trying to enforce the limits on selenium pollution. Fish tissue sampling will be more expensive and time consuming, and it will require special permits for collecting fish. This is especially problematic in Appalachia, where selenium standards have primarily been enforced through citizen actions. These standards will be more difficult to enforce, and will just lead to more streams being degraded.	
427	EPA-HQ-OW-2004-0019-0302-A1; J. Hodie; Posted 06/26/2014 Clean water is a right, not a want. Clean water is a necessity, not a luxury. Clean water is life, dirty water is....... Every living thing on Earth depends on clean water to thrive and survive. And clean water is a necessity so that our environment and lands thrive and survive too. The EPA can and must be allowed to protect all of us. Our lives depend on it! By partially basing the standards on fish tissue sampling, the EPA has created a significant burden for	

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	citizens and agencies trying to enforce the limits on selenium pollution. Fish tissue sampling will be more expensive and time consuming, and it will require special permits for collecting fish. This is especially problematic in Appalachia, where selenium standards have primarily been enforced through citizen actions. These standards will be more difficult to enforce, and will just lead to more streams being degraded. PLEASE protect our water!	
438	EPA-HQ-OW-2004-0019-0329-A1; J. Jones; Posted 07/30/2014 I appreciate this opportunity to comment on EPA's External Peer Review Draft Aquatic Life Ambient Water Quality Criteria for Selenium– Freshwater, EPA 822-P-14-001 (May 2014) ("Peer Review Draft"). Selenium is a key issue, particularly in the face of new, unfounded lawsuits by third party activists alleging unpermitted selenium discharges from mining operations and previously mined lands. The existing criteria – which many states, including Virginia, have adopted as their applicable state water quality criteria –are over 25 years old and do not reflect the latest scientific information, including chemical speciation of selenium, exposure and uptake. The existing criteria are unnecessarily stringent to protect aquatic life. I believe that both EPA should move toward tissue-based chronic criteria because the tissue-based approach is better suited to incorporating site-specific factors such as chemical speciation and rates of transformation, variations in temporal concentrations in water, types of organisms constituting the food chain, and variable rates of exchange between water, sediment and organisms. With respect to the Peer Review Draft, in particular, I commend EPA for moving toward a tissue-based approach to address chronic selenium toxicity. I generally support this as the overriding criterion. As EPA has acknowledged, certain selenium species are more bioaccumulative than others, and a range of different site-specific factors may affect selenium toxicity. As a result, we support EPA's proposed hierarchy for applying the revised draft criteria, where egg/ovary numbers are considered over whole body numbers, which in turn are considered over water column numbers. However, several key technical issues require further review and analysis, I urge EPA to address them before finalizing its revised national recommended selenium criteria.	
443	EPA-HQ-OW-2004-0019-0338-A2; Virginia Mining Issues Group (VMIG) and Virginia Coal and Energy Alliance (VCEA); Posted 07/28/2014 The Virginia Mining Issues Group and Virginia Coal and Energy Alliance appreciate this opportunity to comment on EPA's External Peer Review Draft Aquatic Life Ambient Water Quality Criteria for	

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	Selenium-Freshwater, EPA 822-P-14-001 (May 2014) ("Peer Review Draft"). Selenium is a key issue to our members, particularly in the face of new, unfounded lawsuits by third party activists alleging unpermitted selenium discharges from mining operations and previously mined lands. Revisions to EPA's national recommended selenium criteria are long overdue. The existing criteria - which many states, including Virginia, have adopted as their applicable state water quality criteria - are over 25 years old and do not reflect the latest scientific information, including chemical speciation of selenium, exposure and uptake. Not only are they outdated, we are gravely concerned that the existing criteria are unnecessarily stringent to protect aquatic life. As long as these obsolete criteria remain on the books, we are concerned that dischargers will be placed in peril of unreasonable compliance obligations, misguided enforcement actions and unfounded lawsuits. We have already seen these perils come to pass in Virginia through a wave of recent lawsuits, threatened lawsuits and end-of-pipe permit limits that are based on the old, outdated water column criteria. During the last legislative session, our Virginia General Assembly adopted two resolutions to address selenium: House Joint Resolution 57 and Senate Joint Resolution 35. These resolutions direct the Virginia Department of Environmental Quality to conduct a review of the latest science and studies on selenium, including recent groundbreaking work in Kentucky that resulted in revisions to the state's criteria. The primary purpose of this review is to lay the technical groundwork for state-based criteria revisions, particularly with respect to the chronic criteria. We believe that both EPA and Virginia should move toward tissue-based chronic criteria because the tissue-based approach is better suited to incorporating site-specific factors such as chemical speciation and rates of transformation, variations in temporal concentrations in water, types of organisms constituting the food chain, and variable rates of exchange between water, sediment and organisms. We strongly support the kind of tissue-based screening approach taken by Kentucky in the state's EPA-approved chronic criteria revisions. With respect to the Peer Review Draft, in particular, we commend EPA for moving toward a tissue-based approach to address chronic selenium toxicity. We generally support this as the overriding criterion. As EPA has acknowledged, certain selenium species are more bioaccumulative than others, and a range of different site-specific factors may affect selenium toxicity. As a result, we support EPA's proposed hierarchy for applying the revised draft criteria, where egg/ovary numbers are considered over whole body numbers, which in turn are considered over water column numbers. However, several key technical issues require further review and analysis, as described in more detail in the National Mining Association's comments on the Peer Review Report and supporting technical review by GEI Consultants, Inc. (initially submitted on June 13 and supplemented on July 23). We hereby adopt and incorporate those documents herein, and we urge EPA to address them before	

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	finalizing its revised national recommended selenium criteria.	
454	EPA-HQ-OW-2004-0019-0356-A1; Idaho Department of Environmental Quality (DEQ); Posted 09/30/2014 General Comments The document is 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. On the other hand EPA's attention to implementation of this new criterion is lacking. While dearly 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, creating a 4-layered criterion hierarchy that in the end is very complex. Although the hierarchy allows traditional water testing, this hierarchy is 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 offish 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.	
556	EPA-HQ-OW-2004-0019-0335-A2; County of Orange, OC Pubic Works; Posted 7/30/2014 • A universal, nationally applicable water column number is inappropriate due to the site specific, bioaccumulative nature of selenium. In the Newport Bay watershed, for example, the 'safe' water column numbers corresponding to the same fish tissue concentration could vary by more than an order of magnitude depending on structures and complexities of different food webs. As such, the criterion should only be based on fish tissue elements, with water column concentrations used as a tool for implementation of the criterion.	
568	EPA-HQ-OW-2004-0019-0331-A1; The Fertilizer Institute; Posted 07/29/2014 On behalf of its member companies, The Fertilizer Institute ("TFI") submits these comments in response to the U.S. Environmental Protection Agency ("EPA") *External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium – Freshwater 2014*, 79 Fed. Reg. 27,601 (May 14, 2014) ("Draft Criterion"). In addition to its own comments, TFI is a member of the North American Metals Council ("NAMC") and incorporates NAMC's comments by reference. Further, TFI supports and incorporates by reference the comments submitted by the National Mining Association.	

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447	EPA-HQ-OW-2004-0019-0351-A2; Stakeholders Implementing TMDLs in the Calleguas Creek Watershed, California; Posted 08/05/2014 2. 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. As stated in Comment #1, the Stakeholders strongly support the approach recommended by USEPA in the 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 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.[7, 8, 9, 10] 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 Draft Selenium Criterion (4.8 µg/L) for over 84% of results and by as much as a factor of seven (Figure 1). Despite the water column concentrations, which would indicate an impairment to aquatic life according to the Draft Selenium Criterion, the muscle tissue concentrations are almost all below (with one exception) the muscle tissue element of the Draft Selenium Criterion (11.8 mg/kg). As such, if the water column element of the 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[11] of the Luoma Presser model[12] for two tributaries, San Diego Creek and Big Canyon Wash, demonstrate a wide range of water column concentrations needed to protect fish: approximately 10 - 19.3 µg/L in San Diego Creek and 0.5 - 1.1 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 4.8 µg/L would be both significantly over- and under-protective.	

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	Table 12 and Figure 11 of the 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 these figures show that for 132 various lentic and lotic systems, the calculated range of protective water column concentrations varies by two orders of magnitude (0.38 - 55.63 pg/L for lentic systems and 1.37 - 98.08 pg/L for lotic systems). Given the wide range of values calculated to be protective, it is clearly Page 9 of 15 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*[13] (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 4.2.5 of the 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 overprotective). 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 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	

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	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 antibacksliding 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 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). [7] Lemly, A.D. 1998. A position paper on selenium in ecotoxicology: A procedure for deriving site-specific water quality criteria. Ecotoxicology and Environmental Safety. Volume 39, pp. 1-9. [8] Luoma, S.N. and T.S. Presser. 2000. Forecasting Selenium Discharges to the San Francisco Bay-Delta Estuary: Ecological Effects of a Proposed San Luis Drain Extension. U.S. Geological Survey Open-File Report 00-416. [9] 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. US Geological Survey Professional Paper 1646. [10] Skorupa, J.P. 1998. Selenium Poisoning of Fish and Wildlife in Nature: Lessons from Twelve Real World Examples. In W. Frankenberger and R.A. Engberg, eds. Environmental Chemistry of Selenium. Marcel Dekker Inc., New York., p. 315-354. [11] Model runs based upon the Draft Selenium Criterion value of 8.1 mg/kg dw in whole-body fish tissue. See Comment Letter on the Draft Selenium Criterion submitted by the County of Orange. [12] This model has been adapted by Luoma and Presser for the Newport Bay watershed. It is the same mechanistic model used in the Draft Selenium Criterion. [13] California State Water Resources Control Board. 2009. Water Quality Control Plan for Enclosed Bays and Estuaries — Part I Sediment Quality. California Environmental Protection Agency. Effective August 25, 2009.	
379	EPA-HQ-OW-2004-0019-0318-A2; Appalachian Voices; Posted 7/29/2014 Citizen Enforcement Will be Difficult or Impossible	

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	One of Appalachian Voices' major initiatives is a citizen-science water quality monitoring program called the Appalachian Community Enforcement (ACE) Project. The ACE project is a joint effort between 16 groups across the coal-impacted region of Central Appalachia. In order to engage community members in the health of the streams they care about, the ACE project equips local people with the knowledge, instruments and professional support to monitor their local waterways. To date the ACE Project has trained over 170 volunteers in water monitoring. Those who care about their local waterways generally want do what they can to change it for the better. Unfortunately, these new standards will further tie the hands of citizens hoping to improve water quality in Appalachia. Citizen monitors are often the first, and at times only, way a water quality issue comes to light. Through citizen monitoring and citizen water pollution reporting, Appalachian Voices and other organizations throughout Central Appalachia have identified acid mine drainage, unpermitted mine discharge, permit limit exceedances and other water quality violations. Selenium pollution has been established as one of the major causes of decreased quality and quantity of aquatic communities below mountaintop removal coal mines[i], yet in many cases regulatory authorities have been reluctant to address it. As a result, citizen enforcement has been the main driving force for the enforcement of selenium water quality standards at coal mines in Central Appalachia. Unfortunately, citizens' suits were necessary to achieve the addition of selenium limits on national pollutant discharge elimination system (NPDES) permits in West Virginia, and further litigation was needed for enforcement of those limits. Similar cases have also been filed in Kentucky and Virginia. Currently there are no active NPDES permits for coal mines with selenium limits in Kentucky[ii]. In Virginia there is only one permit (VA/NPDES permit number 0082052) that has been required to address selenium, but that was a result of a court order, based on a citizen suit[iii]. Litigation is both costly and time-consuming for citizens' groups, but is unfortunately often necessary to ensure adequate protection of public waters. Currently, in order to pursue excessive selenium discharges, citizens' organizations undertake water column grab sampling in public waterways downstream of NPDES discharge points. Some courts have required at least four consecutive days of grab sampling in order to establish violations of the current, four day chronic selenium criterion. The proposed changes to the selenium criteria will make citizens' pursuit of selenium enforcement much more difficult. Potential foreseeable problems include: • The need to sample for more than 4 days, possibly up to 30 or more days. This issue would increase both the time and cost necessary to confirm a violation. • The standard for intermittent exposure is likely to be misapplied to situations where less than 30 days of data is available or where the duration of a discharge is unknown. In these cases, the proposed standard will be significantly weaker than either the current standard or the proposed	

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	30 day standard, allowing a four day average concentration of 36 µg/L (lentic, assuming a background concentration of 0 µg/L). Application of this standard will be further complicated by the fact that in many cases the background selenium concentration is unknown. • The need to collect fish tissue samples to confirm a violation. Several issues arise when considering this possibility. In some cases, all fish may have already been extirpated from the stream. In other cases, sensitive species may have been extirpated, leaving only more tolerant species that may accumulate selenium at a slower rate. Time, cost and logistics all become more problematic as individuals will likely need state permits to collect fish samples, and laboratory fees will likely be higher. Additionally, training citizens to collect fish tissue samples is more difficult than training for water column grab samples. This standard will be more difficult and costly to enforce, both for state agencies with limited resources and for individual citizens. Enforcing a standard based on four elements - fish egg/ovary, fish whole-body, chronic water-column and intermittent water-column - will likely increase the extent to which resolution of violations is held up in lengthy and costly litigation. Overall, we anticipate the new standard leading to decreased compliance from industries that discharge selenium. ——— [i] U.S. EPA (Environmental Protection Agency). 2011. The Effects of Mountaintop Mines and Valley Fills on Aquatic Ecosystems of the Central Appalachian Coalfields. Office of Research and Development, National Center for Environmental Assessment, Washington, DC. EPA/600/R-09/138F. [ii] Based on Appalachian Voices Review of Kentucky Energy and Environment Cabinet, Division of Water, response to Open Records Act request for "A copy of a list of current Individual KPDES permits, identified by Permittee and Permit Number, for which either an acute or chronic water-quality based effluent limit for selenium has been imposed." submitted by Kentucky Resources Council, Inc. April 18, 2013. None of the facilities with selenium limitations in their KPDES permits were coal mines. However, recently KY DEP has issued a single draft individual KPDES permit for coal mining containing limitations on selenium. To the best of our knowledge a final permit has not yet been issued. Despite being issued a permit from the Kentucky Division of Natural Resources in January of 2011, it appears that mining at this facility has yet to begin. See the draft KPDES permit for Nally & Hamilton Enterprises Inc. DNR permit number 848-0292, KPDES Permit KY0108227 (June 19, 2014), AI No. 101089, available at: http://dep.gateway.ky.gov/eSearch/search_ai_detail.aspx?AgencyID=101089. [iii] Southern Appalachian Mountain Stewards et al. v. A&G Coal Corp., case number 13-2050, currently under appeal in the U.S. Court of Appeals for the Fourth Circuit.	

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259	EPA-HQ-OW-2004-0019-0341-A1; West Virginia Coal Association (WVCA); Posted 8/5/2014 Development of Fish Tissue Concentrations As set forth above, WVCA is pleased that the Draft Selenium Criteria 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. We appreciate EPA's recognition of the need to translate body concentrations of selenium into water column criteria and ultimately into effluent limits. WVCA agrees with the overall methodology employed by EPA in preparing the egg/ovary, whole body, and muscle fish tissue concentrations. We agree that the GMCV approach is appropriate, and that EC10 is the appropriate endpoint for the toxicity studies included in the calculation of the tissue criteria. However, WVCA does not agree with EPA's decisions on the inclusion or exclusion of certain studies into the criteria calculations. We are also concerned with EPA's use of TRAP, the Toxicity Relationship Analysis Program, allegedly to standardize the results of the studies included in the criteria calculations. In this regard, WVCA adopts and incorporates Sections 3.1 and 3.2 of the comments of GEI Consultants, Inc., prepared on behalf of the National Mining Association, as if fully set forth herein.	
333	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014 2.0 KEY TECHNICAL IMPROVEMENTS IN THE PROPOSED CRITERION DOCUMENT We are pleased to highlight key technical improvements in the current proposed criteria in comparison with previous criteria. The focus on chronic as opposed to acute effects is appropriate and technically defensible, and is supported by extensive scientific evidence, as provided in the Draft Selenium Criterion Document. Similarly, we fully agree 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). Again, this is supported by extensive scientific evidence, as provided in the Draft Selenium Criterion Document. We strongly support EPA's decision to not use juvenile survival, in particular juvenile overwinter survival, as an endpoint in developing the proposed criterion; again, the scientific evidence strongly supports this decision. The juvenile bluegill overwinter survival testing conducted by Lemly (1993) to demonstrate increased overwinter mortality due to selenium (the “winter stress syndrome” -- Lemly	

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	1996) is technically questionable. With only one treatment, there is no supporting information regarding a dose-response relationship and a partial response with only one treatment, although possible, is surprising. More importantly, the relatively high selenium toxicity in Lemly's (1993) study was not found by McIntyre et al. (2008). Although the McIntyre et al. (2008) study has been criticized for a possible slight difference in light-dark test conditions, this relatively minor difference from Lemly's (1993) study should not have obviated replicating that study's findings of relatively high selenium toxicity if, in fact, the Lemly (1993) study results were robust and repeatable. The McIntyre et al. (2008) study should be viewed as the more reliable result because of: the greater number of concentrations tested; the more realistic exposure pathway (yeast to oligochaetes to fish); and the initial exposure period at a warm temperature. The latter two improvements over the Lemly (1993) experimental design were recommended by John Besser of the U.S. Geological Survey. The critical aspect of Lemly's (1993, 1996) winter stress syndrome hypothesis is increased metabolism resulting in an energy deficit as fish rely on stored energy to survive winter months due to low food availability. In fact, fish do not generally rely on stored energy over the winter months; active feeding occurs (Sogard and Olla, 2000; McCollum et al., 2003; Biro et al., 2004; Parrish et al., 2004; Eckmann, 2004; Bennett and Janz, 2007a,b). Field studies have provided no support for Lemly's (1993, 1996) hypothesis of a winter stress syndrome related to selenium exposures. Hermanutz et al. (1992, 1996) 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 (Bennett and Janz, 2007a,b; Kelly and Janz, 2008; Drieger et al., 2009). 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 genus mean chronic value (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	

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	laboratory evidence indicates that the reproductive endpoint is the critical endpoint. Finally, we fully support the option for the development of site-specific criteria based on appropriate scientific studies, where appropriate and practical. As noted in the Draft Selenium Criterion Document and in the extensive references provided with that document, the fate and effects of selenium introduced to aquatic environments is complex and there will certainly be cases where the generic national criteria are unnecessarily overprotective. Cases of naturally elevated selenium concentrations in water have been documented, as have elevated selenium concentrations in fish without adverse effects (Chapman et al., 2010).	
574	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 Executive Summary 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 EC10s rather than some other endpoint, as this is the more conservative approach.	
334	EPA-HQ-OW-2004-0019-0343-A2; Kentucky Division of Water; Posted 8/5/2014 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. EPA properly excluded bioassay studies using only water column exposure. 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. Kentucky agrees with the EPA's selection of the EC10 (Effect Concentration) is preference of the EC20 (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 toxic criteria were derived using the EC20. This approach mirrors that taken by Kentucky 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 EC10. Acceptable study data representing 12 fish species were available to calculate the SMCV (Species Mean Chronic Value) and nine fish genera to calculate the GMCV (Genus Mean Chronic Value). The EPA considered 14 genera to calculate the GMCV, but because the data indicate invertebrates are	

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	tolerant of high selenium concentrations, the invertebrate values were not included in deriving the FCV (Final Chronic Value) which is determined from the four most sensitive GMCVs. The EPA also incorporated the 1985 Guidance (Stephen, 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. A review of the literature and scientific findings leads to the conclusion that toxicity through contaminated food consumption is of paramount concern and that the proposed criteria protect the most sensitive aspect of the fish life cycle. Of note, Crutchfield (2000) found a positive correlation between selenium-effects Centrarchidae (sunfish population decrease as selenium concentration increased) and a negative correlation to Ictaluridae (catfish population decreased as selenium concentrations decreased). These correlative relationships were illustrated after selenium contamination in Belews Lake, North Carolina, in which only three of the 29 inhabiting species remained, including catfish (Young et al. 2010). This result contradicted the Doroshov (1992) study. Also of note, a Lemly (1993) study indicated that cold-stress increases selenium toxicity, and that a fish population should be monitored in the winter if selenium residue exceeded a screening value in fish tissue. Subsequent studies could not produce those same results (Hermanutz, et al. 1996; McIntyre et al. 2008). Regardless, a thermal regime of 4C for 120 days does not exist in Kentucky waters nor for most of the waters of the United States. Given that EPA followed the recommendations in Stephan et al. (1985), the EPA-proposed tissue-based criterion presumptively protects all aquatic species, including those on the Threatened and Endangered Species lists. The four most sensitive aquatic taxa were used to calculate the GMCV, and that GMCV was used to calculate the FCV.	
84	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 6. Conclusions Overall, the 2014 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 2014 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.	

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	6.1 Reevaluation of Acceptable Studies We reviewed all of the reproductive toxicity study data deemed acceptable by EPA in the 2014 draft Se criteria document. Data were presented for nine 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 fathead minnow, bluegill, and brown trout data, and use of invertebrate data in the criteria calculations. • Fathead minnow – We recommend updating the fathead minnow GMCV to include data from GEI Consultants, Inc. (2008) and using the new CF of 1.4 (see Section 4.4.1, Table 11) to translate between egg/ovary and whole-body. The updated fathead minnow egg/ovary GMCV is 37.48 mg/kg, with an accompanying whole-body value of 26.77 mg/kg. • Bluegill – We have concerns about the data used from the Hermanutz et al. (1992, 1996) studies. We recommend rejecting data from Study I of Hermanutz et al. (1992) and using only Study II data (Hermanutz et al. 1996) data to derive an updated EC10 for this study. The updated bluegill egg/ovary GMCV is 22.50 mg/kg, with an accompanying whole-body value of 10.78 mg/kg using regression-based CF. • Brown trout – We recommend using the brown trout EC10 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 EC10 value, which is equivalent to the SMCV, is 18.36 mg/kg, with an accompanying whole-body value of 12.66 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. • Invertebrates – We do not agree with using the invertebrate data and nonexistent crustacean values in the criteria calculations (i.e., it is more appropriate to use N=9 based on the nine fish genera in the database). However, we believe the invertebrate data are useful for evaluation of safe Se concentrations in streams unable to support fish. 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).	
63	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and	

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	Wildlife Service, Paul Souza; Posted 8/7/2014 The British Columbia Ministry of Environment (BCMoE 2014) accounted for the paucity of fish toxicity data (and other potential uncertainties) by applying an uncertainty/safety factor of 2 to the E/O tissue selenium guideline derived from limited available data. In the DSP, EPA does not apply an uncertainty/safety factor. EPA appears to assume that the 11 species tested for reproductive sensitivity to selenium exposure include one or more species representative of the sensitive tail of the species sensitivity distribution (SSD). However, the relatively few species tested so far were selected because they are easy to culture in laboratories (Newman et al. 2000); they are commercially (Salmonids) or recreationally (Centrarchids) important (Stephan et al. 1985); or because they were the species for which sufficient sample sizes could most readily be obtained from field studies. For example, in the uranium milling contaminated aquatic system that produced the toxicity data for northern pike, two other species of fish had already become locally extirpated including yellow perch (Wismer and McKee 2006), a species in the Swedish Lakes study that appeared to be much more sensitive to selenium than the "selected" for study species of northern pike (see review of the Swedish Lakes Study presented in Skorupa (1998)).	
215	EPA-HQ-OW-2004-0019-0323-A1; California State Water Resources Control Board; Posted 7/30/2014 In addition, although the criterion document acknowledges that the binary classification scheme used by U.S. EPA to validate the water column criterion elements does not consider the degree to which measurements are above or below the criteria, it concludes that the method confirms the environmental "protectiveness" of the water column criterion elements. However, as is apparent in Tables 18 and 19, there is a significant percentage of sites where the selenium water column criterion elements and/or egg/ovary criterion element would be either under- or over-protective. This is especially the case for lotic systems, where only 36% (248 samples) of the water column or fish egg/ovary selenium concentrations correlated well with their corresponding criterion. Thirty percent (206) of the samples however, were cases where the water concentrations were below the proposed fish egg/ovary criterion. In California, this has been observed in several areas (e.g., Calleguas Creek, Muddy Slough in the Central Valley). For lentic systems, while 69% of the paired data used showed a good correlation between both tissue and water concentrations exceeding their respective proposed criteria; more than 30% of the time, the binary relationship between water and tissue concentrations was either over or under their respective criteria, with 11% (16 samples) falling into the over-protective category. This is especially important as the water column criterion elements would likely be used to develop states' CWA Section 303(d) lists since collection of fish tissue data is time consuming and expensive, and for some water bodies, may not even be possible (e.g. "fishless" waters). Use of the water	

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	column elements to assess impairment under CWA Section 303(d) could be substantially increase the number of listings of impairment for selenium, requiring additional diversion of State resources to address those listings via Total Maximum Daily Loads (TMDLs) or other alternative regulatory actions, even though the listings may not be necessary. The data required to delist a water body is usually greater than that required to list a water body as impaired. We therefore recommend that the water column elements not be included as part of the criterion, but instead be utilized as triggers for additional investigations of a water body or as guidance during implementation. Application of generic water column criteria for selenium for the entire United States ignores the differences in hydrology, geology, and climate that influence aquatic environments and the bioaccumulation and effects of selenium in those environments. It may also cause an unnecessary increase in the findings of impairment due to selenium under CWA Section 303(d) and the subsequent diversion of limited resources to address those findings.	
520	EPA-HQ-OW-2004-0019-0315-A1; USGS - Comment submitted by Theresa S. Presser and Samuel N. Luoma, National Research Program, U.S. Geological Survey, Western Branch, Menlo Park, CA; Posted 7/15/2014 The DCD proposes a new approach to regulating. Its credibility rests with transparency in documentation of the choices and a clear basis as to how it should be implemented. While the regulation is appropriate in using a tissue guideline to address Se bioaccumulation as the basis of toxicity, it falls short with regard to site-specific application of the approach. Details follow on the short-comings listed above.	
550	EPA-HQ-OW-2004-0019-0326-A1; Utility Water Act Group (UWAG); Posted 7/30/2014 CONCLUSION UWAG strongly supports EPA's decision to develop tissue-based selenium criteria that reflect the latest science that concludes diet is the primary pathway of selenium exposure and reproductive effects are of greater significance and concern than non-reproductive effects. We also support EPA's strong acknowledgment that selenium toxicity is highly site-specific and appreciate inclusion of the option for developing site-specific criteria in derivation of the criterion methodology. Overall, we believe EPA's recommended approach is a distinct improvement over selenium criteria proposed in 2004 that were based on juvenile and overwinter survival. We look forward to EPA's response to our questions and requests for clarifications, and welcome an opportunity to discuss technical aspects of these comments with the agency.	
218	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014	

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	3.0 CONSTRUCTIVE CRITICISMS 3.1 Need for Tiered Approach The national criterion proposed for selenium in fresh waters has four-parts:[2] 1. The concentration of selenium in the eggs or ovaries of fish does not exceed 15.2 mg/kg, dry weight; 2. The concentration of selenium (a) in whole-body of fish does not exceed 8.1 mg/kg dry weight, or (b) in muscle tissue of fish (skinless, boneless fillet) does not exceed 11.8 mg/kg dry weight; 3. The 30-day average concentration of selenium in water does not exceed 4.8 µg/L in lotic (flowing) waters and 1.3 µg/L in lentic (standing) waters more than once in three years on average; and, 4. The intermittent concentration of selenium in either a lentic or lotic water, as appropriate, does not exceed an intermittent exposure calculated value: $WQC_{int} = \frac{WQC_{30\text{-}day} - C_{bkground}(1 - f_{int})}{f_{int}}$ Research has shown for quite some time that chronic toxicity from selenium cannot be determined solely by exposure to selenium in the water column (Canton and Van Derveer, 1997). Toll et al. (2005) and Brix et al. (2005) proposed the use of tissue residues to establish a site-specific water quality standard for selenium. NAMC supports the use of an egg or ovary tissue value as the criterion. As described above, EPA has proposed a four-part criterion for selenium. The proposal does provide that "(egg/ovary) overrides any whole-body, muscle, or water column elements when fish egg/ovary concentrations are measured." The four-part criterion as proposed, however, add complexity and potential confusion in regard to implementation. NAMC recommends that EPA make it clear that the official criterion is the egg-ovary value. It is appropriate and, in fact, necessary for EPA to specify a tiered (step-wise) approach to applying selenium criteria in aquatic systems. Thus, NAMC further recommends that EPA use a tiered approach in which the water column selenium lentic or lotic value is a screening value. Exceedance of the screening value would trigger monitoring of the fish community to determine status in relation to the criterion, possibly followed by development of a site-specific tissue benchmark. In this regard, we recommend the use of the following conceptual tiered (step-wise) system: • The water selenium concentration threshold (lotic or lentic as appropriate, see Section 3.3) should be used as an initial screening value (Tier 1); • Exceedance of Tier 1 would indicate a potential risk, triggering a more robust line of evidence,	

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	specifically the generic fish egg-ovary selenium concentration to further evaluate potential risk (Tier 2); and, • Where appropriate, in particular due to confounding or modifying site conditions and/or limited or seasonal species distribution, it may also be necessary for a site-specific fish egg-ovary to be derived and applied at a site in question to provide a final evaluation of potential risk (Tier 3). The tiered approach described above applies step-wise lines of evidence (tiers) with increasing certainty, when thresholds are exceeded. EPA has approved such an approach for the State of Kentucky (USEPA, 2013a). Moreover, this approach provides users with an opportunity to develop practical, cost-effective, and minimally invasive monitoring programs (i.e., reduce the need to sample and analyze fish tissue, if water can be monitored), while also ensuring environmental protection. [2] Draft Selenium Criterion Document at 96-97.	
224	EPA-HQ-OW-2004-0019-0335-A2; County of Orange, OC Pubic Works; Posted 7/30/2014 1. 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 County strongly supports the approach recommended by USEP A on Page 97 of the 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.[1,2] 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 7, Section 2 of the Draft Selenium Criterion: " ... fish-tissue ·values better 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 direct waterborne route. " Selenium bioaccumulation and toxicity cannot be predicted based solely on selenium concentrations in water.[3] 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 envirorunent-specific.[4] 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.	

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	It appears that the 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 of many is the figure on Page 3 of the Executive Summary. The figure summarizes the structure of the criterion, but the tiered or prioritized structure is absent. Another example is on Page 96 where the four-part criterion is identified. Again, language is absent to note that the fish tissue elements supercede the water column elements. 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 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 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 SSOs 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 98 of the 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 <u>are not available</u>, 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 <u>are available</u>". And, footnote 1 and 2, respectively, in Table 15 on Page 97 of the Draft Selenium Criterion state (emphasis added): "Overrides any whole-body, muscle, or water column elements <u>when fish egg/ovary concentrations are measured</u>." "Overrides any water column elements <u>when both fish tissue and water concentrations are measured</u>." 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,	

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	water column samples are obtained and the data are used to gauge implementation actions. However, the language in the 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 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 Draft Selenium Criterion to clearly establish that the fish tissue elements supersede the water column elements: o Modify the terminology throughout the document from "primary" and "precedence" to "supersedes" o Modify Table 15[5] as follows: ▪ Modify Footnote 1: "~~Overrides any~~ Supersedes all whole-body, muscle, or water column elements ~~when fish egg/ovary concentrations are measurred~~." ▪ Modify Footnote 2: "~~Overrides any~~ Supersedes all water column elements ~~when both fish tissue and water concentrations are meaured~~." ▪ 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. o Provide more direct and explanatory language throughout the Draft Selenium Criterion that clearly limits the applicability and use of water column elements, including but limited to the figure on Page 3 of the Executive Summary and Page 96 of Section 5 (National Criterion for Selenium). Example modified language for Page 98, 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	

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	criterion ensures protections when neither fish egg-ovary nor fish whole-body or muscle tissue measurement are available. 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." [1] Hamilton, S.J. 2003. Review of residue-based selenium toxicity thresholds for freshwater fish. Ecotoxicology and Environmental Safety, Volume 56, pp. 201-210. [2] 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 SET AC Pellston Workshop, 22-28 February 2009, Pensacola, Florida. [3] Stewart R, Grosell M, Buchwalter D, Fisher N, Luoma S, Mathews T, Orr P, Wang W-X. 2010. Bioaccumulation and Trophic Transfer of Selenium. 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. Chapter 5. Society of Environmental Toxicology and Chemistry (SET A C) Publications. CRC Press, Boca Raton FL (USA). pp. 93-139. [4] Ibid. [5] Corresponding changes would need to be made throughout the documentation, including but not limited to the table on Page 4 of the Fact Sheet.	
231	EPA-HQ-OW-2004-0019-0266-A2; Transportation and Storm Water Department, City of San Diego, California; Posted 6/17/2014 Requested Action: • Revise the Draft Selenium Criterion to clearly establish that the fish tissue elements supersede	

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	the water column elements: o Modify the terminology throughout the document from "primary" and "precedence" to "supersedes" o Modify Table 15[5] as follows: ▪ Modify Footnote 1: "~~Overrides any~~ Supersedes all whole-body, muscle, or water column elements ~~when fish egg/ovary concentrations are measured~~." ▪ Modify Footnote 2: "~~Overrides any~~ Supersedes all water column elements ~~when both fish tissue and water concentration are measured~~." ▪ 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 in the same calendar year. [5] Corresponding changes would need to be made throughout the documentation, including but not limited to the table on Page 4 of the Fact Sheet.	
321	EPA-HQ-OW-2004-0019-0270-A2; Central Contra Costa Sanitary District (CCCSD); Posted 8/5/2014 New data on selenium is continually being published. Prior to the next public consultation period on this criterion, a full assessment of available peer-reviewed publications should be completed along with other available reports and publications.	
261	EPA-HQ-OW-2004-0019-0331-A1; The Fertilizer Institute; Posted 07/29/2014 DISCUSSION TFI supports EPA's use of an egg or ovary tissue value as the selenium criterion. This approach, though different than most criteria, is scientifically sound. Numerous studies have shown that a tissue-based criterion is appropriate for selenium due to the widely varying bioaccumulation rates and manifestation of effects in developing young fish from freshwater systems. However, the chronic value calculated by EPA hinges on a conservative use of data from several studies. The result is a proposed chronic value that is not technically defensible and is overly conservative. Adjustments are needed by EPA in the use of data from several key studies. A fish tissue criterion requires a change in the standard monitoring approach used to implement a standard; a tiered implementation method is recommended. Finally, because of the widely differing effects of selenium in aquatic systems, site	

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	specific standard development is important. TFI offers specific comments on the Draft Criterion in the sections below. I. Fish Egg/Ovary Concentration Criterion is the Correct Approach TFI supports the use of an egg or ovary tissue value as the criterion. Research has shown for quite some time that chronic toxicity from selenium cannot be determined solely by exposure to selenium in the water column (Canton and Van Derveer, 1997). Toll et al. (2005) and Brix et al. (2005) proposed the use of tissue residues to establish a site-specific water quality standard for selenium and deBruyn et al. (2008) recommended that egg selenium concentration would be the most useful basis for a selenium tissue criterion. A review of four studies showed that selenium concentrations in egg tissues were predictive of early life stage effects. The establishment of an egg or ovary tissue value as the criterion is the right approach for the protection of sensitive species.	
491	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 In general, Cameco would suggest the following: A tiered approach is necessary in order to direct the need for the sampling of fish. A water screening level should be used to indicate if the analysis of fish tissue is required. The intended application of the fish tissue criterion (for egg-ovary, whole body and muscle) in assessing population effects is not clear.	
499	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 Incorporating a tiered approach is to direct the need for the sampling of fish. Similar to what has been established in Kentucky, a water screening level should be used to indicate if the analysis of fish tissue is required.	
531	EPA-HQ-OW-2004-0019-0293-A2; Pennsylvania Department of Environmental Protection; Posted 6/26/2014 EPA is recommending that states and tribes adopt a four part selenium criterion in a manner that allows for primacy of the whole-body or muscle element over the water-column elements, and the egg-ovary element over any other elements. The adoption of the fish whole-body or muscle element is to ensure the protection of aquatic life when fish egg or ovary tissue measurements are not available, and the adoption of the water-column elements are to ensure the protection when neither fish egg-ovary nor fish whole-body of muscle tissue measurements are available. The EPA pre-proposed draft aquatic life criterion for selenium:	

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	1. The concentration of selenium in the eggs or ovaries of fish does not exceed 15.2 mg/kg, dry weight; 2. The concentration of selenium (a) in whole-body of fish does not exceed 8.1 mg/kg dry weight, or (b) in muscle tissue of fish (skinless, boneless fillet) does not exceed 11.8 mg/kg dry weight; 3. The 30-day average concentration of selenium in water does not exceed 4.8 µg/L in lotic (flowing) waters and 1.3 µg/L in lentic (standing) waters more than once in three years on average; 4. The intermittent concentration of selenium in either a lentic or lotic water, as appropriate, does not exceed more than once in three years on average. Industry that may be affected by the adoption of the pre-proposed selenium criterion could include at least mining activities, coal mining and processing facilities, coal-fired power plants, and coal refuse facilities.	
444	EPA-HQ-OW-2004-0019-0351-A2; Stakeholders Implementing TMDLs in the Calleguas Creek Watershed, California; Posted 08/05/2014 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 to better reflect the observed conditions in the watershed. As will be discussed in more detail in this letter, the Stakeholders support the use of tissue-based criteria for selenium, but feel the relationship between water quality criteria and the tissue values can vary significantly between watersheds. As a result, our primary request is that the Draft Selenium Criterion clarify the applicability of the four elements of the criterion and clearly establish that the fish	

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	tissue elements have precedence over the water column elements. Clarification of this key element along with the additional technical elements presented in this letter will support cost-effective implementation of the Metals and Selenium TMDL in the Calleguas Creek Watershed while ensuring beneficial use protection. [1] TMDL for Metals and Selenium in the Calleguas Creek, Its Tributaries, and Mugu Lagoon, Resolution No. R4-2006-012	
480	EPA-HQ-OW-2004-0019-0274-A2; National Mining Association (NMA); Posted 6/17/2014 As an initial matter, NMA would like to commend EPA's effort to develop fish tissue based Se criteria that are consistent with the latest science regarding Se toxicity. NMA generally supports the use of a fish-tissue based chronic Se criterion as the overriding criterion. However, there are several key issues we would like to bring to EPA's attention for further review.	
597	EPA-HQ-OW-2004-0019-0266-A2; Transportation and Storm Water Department, City of San Diego, California; Posted 06/17/2014 The City strongly supports the approach recommended by USEPA on Page 97 of the 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 clement." 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. [1, 2] 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 7, Section 2 of the Draft Selenium Criterion: *"..fish-tissue values better 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 direct waterborne route.* " Selenium bioaccumulation and toxicity cannot be predicted based solely on selenium concentrations in water.[3] 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.[4] 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	

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	based on water concentrations alone. It appears that the 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 the figure on Page 3 of the Executive Summary. The figure summarizes the structure of the criterion, but the tiered or prioritized structure is absent. Another example is on Page 96 where the four-part criterion is identified, but language is absent to note that the fish tissue elements supersede the water column elements. 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 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 and the criterion attained. As noted above and as supported by the 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 of the water column elements. [1] Hamilton, S.J. 2003. Review of residue-based selenium toxicity thresholds for freshwater fish. Ecotoxicology and Environmental Safety, Volume 56, pp. 201-210. [2] 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, 22-28 February 2009, Pensacola, Florida. [3] Stewart R, Grosell M, Buchwalter D, Fisher N, Luoma S, Mathews T, Orr P, Wang W-X. 2010. Bioaccumulation and Trophic Transfer of Selenium. 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. Chapter 5. Society of Environmental Toxicology and Chemistry (SETAC) Publications. CRC Press, Boca Raton FL (USA). pp. 93-139. [4] *Ibid.*	
209	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 A tiered approach is necessary in order to direct the need for the sampling of fish. A water screening level should be used to indicate if the analysis of fish tissue is required.	

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	The intended application of the fish tissue criterion (for egg-ovary, whole body and muscle) in assessing population effects is not clear. Specifically, the duration and frequency of the fish tissue elements needs to be revised. The water quality criterion (WQC) should be a conservative screening tool that identifies the need for further investigation. Merely because a no effect level may be exceeded; an exceedance of the WQC does not necessarily indicate that adverse effects are occurring, particularly in recovering systems.	
210	EPA-HQ-OW-2004-0019-0273-A2; Gopher Resource LLC; Posted 6/17/2014 EPA's suggestion that States may use water quality concentration values alone to set selenium WQBELs ignores selenium's site-specific bioaccumulative effects and is inconsistent with the Peer Review Draft's emphasis on the "primacy" of fish tissue data. The entire rationale for EPA's ten-year review of the fresh water selenium water quality criterion is selenium's status as a bioaccumulative pollutant. Selenium is a naturally occurring chemical element that is nutritionally essential in small amounts but toxic at higher concentrations.[3] In addition, selenium's bioaccumulative effects vary markedly based on location.[4] As a result, the Peer Review Draft sets forth a selenium water quality criterion with four elements, including a water quality concentration value and fish tissue concentrations. The Peer Review Draft acknowledges, however, that fish tissue-based concentration is a more direct measure of selenium toxicity to aquatic life than water column concentrations, and specifically states that the fish tissue elements should supersede water column elements when both types of data are available.[5] In addition, the Peer Review Draft recommends that States and Tribes incorporate in their water quality standards "a selenium criterion that includes all four elements [set forth in the Draft], expressing the four elements as a single criterion composed of multiple parts, in a manner that explicitly affirms the primacy of the whole-body or muscle element over the water-column elements, and the egg-ovary element over any other element."[6] [3] Notice of Availability of 2014 USEPA External Peer Review Draft Aquatic Life Water Quality Criterion for Selenium-Freshwater, 79 Fed. Reg. 27601, 27602 (May 14, 2014). [4] U.S. EPA External Peer Review Draft Aquatic Life Ambient Water Quality Criteria for Selenium-Freshwater 2014 at 1. [5] *Id. at 4* [6] *Id.*	
217	EPA-HQ-OW-2004-0019-0323-A1; California State Water Resources Control Board; Posted 7/30/2014 2. The criterion should clarify that fish egg/ovary, whole body, or muscle tissue supersedes the water column criterion elements in all classes. The criterion should also make it clear that States can	

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	choose to adopt only those elements of the criterion that in the State's professional judgement are scientifically appropriate, supported by the data, and relevant to the State's beneficial uses.	
238	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 For the proposed criterion to be more scientifically defensible, the chronic EC 10 values used to derive the criterion must be substantiated to ensure that they are distinguishable from background concentrations or control/reference concentrations. The egg-ovary element in the draft criterion document is suspect due to the issues with the brown study used to develop it and it is unclear if the range of EC10 values for brown trout reflect this underlying uncertainty.	
577	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 We do not agree with the approach used to develop national water-column criteria. Our review provides discussion on why single nationwide standards for only two water body types (lentic or lotic) are not appropriate and why site-specific water-column standards, calculated using EPA's Equation 18 from the criteria document, are more scientifically justifiable approach. In addition, the intermittent-exposure criteria element of the water-column criteria seems oversimplified, and we feel a better developed approach, such as use of a biokinetic model, would be more appropriate.	
188	EPA-HQ-OW-2004-0019-0326-A1; Utility Water Act Group (UWAG); Posted 7/30/2014 <u>National Criteria For Selenium Challenging</u> UWAG believes that site-specific variables influence selenium bioavailability and bioaccumulation and make deriving national criteria challenging. The science suggests that the EF and TTF variables are affected by site-specific parameters and not constant across a range of exposure concentrations, making a high level of accuracy in empirical sampling unlikely. We also agree that there are situations where nationally derived criteria are simply not appropriate and will lead to over-protective or under-protective results. Understanding the composition of resident fish communities – particularly in areas that are naturally enriched with selenium (seleniferous soils in some western U.S. states) – is critically important. Some fish may contain selenium tissue levels that exceed the Agency's national chronic criterion, yet biosurveys indicate that seemingly sensitive populations remain stable and have sustainable reproduction. There are a number of studies in many different field settings that find feral populations with far higher selenium tissue residues with no adverse effects. As discussed by Hodson et al. (2010), seemingly healthy fish populations with elevated concentrations of selenium in one or more	

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	tissue types may be due to long-term genetic or physiological acclimation or tolerance. Obviously, the exposure history of wild fish is considerably different than fish used in laboratory studies where no previous exposure to selenium has occurred. These cases present challenges to adoption of a nationally applicable fish tissue criterion and create a preference for tailoring the model with site-specific data where such data are available. EPA should provide flexibility and guidance in the final proposal on how these realities should be addressed in implementation. For example, does EPA believe that there may be instances where the chronic water column criteria are being attained but the egg/ovary tissue criterion (and/or the whole-body or muscle criterion) is exceeded in representative sensitive fish? If this circumstance were to occur, would the particular water body be considered in nonattainment for the selenium criterion? UWAG suggests that EPA should allow states to consider available data on feral population health (when adequate comprehensive information is available) in instances where the applicable tissue criterion is being exceeded. This approach would likely pertain to lotic settings, as the sensitivity of fish reproduction impairment in running water bodies is less than for lakes and reservoirs.	
590	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 08/07/2014 The U.S. Fish and Wildlife Service (Service) thanks the U.S. Environmental Protection Agency (EPA) for the opportunity to submit the following technical comments in response to EPA's request for public comment and scientific views pertaining to the "External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium- Freshwater 2014" (Federal Register 79(93):27601-27604; May 14, 2014) . Selenium is a potent environmental stressor for fish and wildlife, and the Service's scientists (often in collaboration with the U.S. Geological Survey (USGS), EPA, and academia) have produced a substantial portion of the scientific record documenting the ecotoxicology of selenium through a combination of field and laboratory research. The Service is aware of the exceptional complexity of selenium's aquatic biogeochemistry; its environmental dynamics and partitioning; and its toxic effects. We therefore appreciate the technical challenges associated with deriving Ambient Water Quality Criteria for selenium. The Service commends EPA's substantial allocation of expertise and other resources to produce the Draft Selenium Proposal (DSP). EPA has invested nearly ten years consolidating an enormous and diverse base of scientific information into a single document that deserves thoughtful review by the wider scientific community.	
400	EPA-HQ-OW-2004-0019-0267-A2; Water Quality Division, District Department of the Environment (DDOE), Government of the District of Columbia; Posted 06/17/2014	

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	Comment 1. EPA is updating its national recommended chronic aquatic life criteria for Selenium in freshwater and fish tissue concentration to reflect the latest scientific information. DDOE believes that the federal Clean Water Act (CWA) requires states to adopt specific numeric criteria for the protection of aquatic life designated use for pollutants. DDOE is concerned about EPA not providing an acute 1-Hr Average aquatic life water quality criteria for Selenium at this time.	
396	EPA-HQ-OW-2004-0019-0259-A2; Idaho Mining Association (IMA); Posted 06/16/2014 Several of IMA's members have participated in the development of comments submitted to this docket by the National Mining Association and by the North American Metals Council – Selenium Work Group. Rather than repeat the substance of the comments submitted by those organizations, IMA fully supports those comments and requests that those comments be incorporated into this letter by reference.	
552	EPA-HQ-OW-2004-0019-0335-A2; County of Orange, OC Pubic Works; Posted 7/30/2014 Selenium is an issue for many municipalities within southern California due to the natural geology of the Monterey Formation. Selenium concentrations in Formation areas may be more than two orders of magnitude higher than the average background. Bioaccumulation and the resulting impacts to beneficial uses, however, vary significantly. Many efforts in California 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 Orange County, a collaborative stakeholder group, called the Nitrogen and Selenium Management Program (NSMP) was formed in 2004 to deal with selenium-related issues in the Newport Bay watershed. The NSMP consists of State, County, and city agencies, water districts, private entities, and environmental groups. The NSMP has worked for over a decade with USEPA, United States Fish and Wildlife Service, United States Geological Survey, the State Water Resources Control Board, and the Santa Ana Regional Water Quality Control Board, to develop revised objectives for selenium. Therefore, the proposed revisions to the freshwater selenium criterion are an important issue for the Newport Bay watershed and more broadly throughout southern California. In addition to the comments provided herein, the County has also reviewed and supports the comment letter submitted by the State of California, State Water Resources Control Board. We also recognize that other states in the western United States have similar issues, and we support the comment letter submitted by the Colorado Wastewater Utilities Council.	

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486	EPA-HQ-OW-2004-0019-0317-A1; Intermountain Region, Forest Service, United States Department of Agriculture (USDA); Posted 7/29/2014 The Intermountain Region has a specific interest in this new draft criterion since the EPA relied on data produced by the J.R. Simplot Company (Simplot) in their pursuit of a site-specific selenium criterion for surface waters in the vicinity of Smoky Canyon Mine. Smoky Canyon Mine is a phosphate mine, located primarily' on National Forest System lands. Simplot is currently conducting a remedial investigation under the Comprehensive Environmental · Response, Compensation, and Liability Act with Forest Service oversight.	
595	EPA-HQ-OW-2004-0019-0266-A2; Transportation and Storm Water Department, City of San Diego, California; Posted 06/17/2014 SUMMARY OF KEY TECHNICAL ISSUES • Clarification is needed throughout the Draft Selenium Criterion regarding the applicability of the four elements of the criterion, to ensure that fish tissue elements supersede the water column elements.	
541	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014 We also highlight the need for a tiered approach beginning with screening based on water selenium concentrations then proceeding, if necessary, to generic tissue concentrations and to site-specific tissue concentrations. We also note the need for a clear definition of lentic and lotic waters.	
Comment Category 2.2 – Comments of General Nature Concerning Over-Protection or Under-Protection of Aquatic Life Summary: Many commenters opined that the draft criterion over-protects aquatic life. Several commenters noted that the criterion under-protected aquatic life.		
49, 237, 498	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 General Comments The draft selenium criterion for water and tissue concentrations seem overly conservative with no appreciable benefit to the environment. We believe that there is scientific evidence that higher criterions would still be environmentally protective without creating an unnecessary burden on activities. We believe the slow recovery of tissues in fish previously exposed to selenium is not adequately captured in criterion or the draft criterion document.	Responses concerning over/under protection of aquatic life: As described in Section 2.6 of the 2015 draft, Aquatic life criteria are designed to be protective of approximately 95% of aquatic genera present in ecosystems. 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

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	Summary Overall, there a few key points that could be addressed that would strengthen the criterion and provide additional clarity about the application and use of the criterion. In general, Cameco Corporation would suggest the following: • Based on other water and tissue criteria that have been published in peer review literature or by government agencies (e.g., the state of Kentucky), the draft selenium criterion for water and tissue concentrations seem overly conservative with no appreciable benefit to the environment. We believe that there is scientific evidence that higher criterions would still be environmentally protective without creating an unnecessary burden on activities. The occurrence of false-positives seems highly likely due the very low water quality criterion element for lent environments and that the criterion does not consider background or reference area concentrations.	source. Since exceedance of these concentrations is correlated with adverse effects 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. Regarding the sensitivity of catfish to selenium, 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 ictalurids, despite the absence of valid egg-ovary test data. The EPA uses the best available science in its development of Water Quality Criteria (WQC); the Agency also follows rigorous data quality guidelines developed under the Data Quality Act. The EPA has Guidelines for the use of toxicity data in its derivation of WQC for the protection of aquatic life and its uses, and has followed those guidelines in the derivation of the selenium criterion. 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 EPA has derived both whole body and muscle criterion elements, from the egg-ovary, and has compared those values to non-reproductive toxic effects (e.g. growth, juvenile mortality), and have found the whole body and muscle translated criteria elements to be protective of non-reproductive effects. This analysis is in Section 6.1.9 of the 2016 final criterion document. With regard to put and take fisheries, there may be one or more non-fisheries related species that may also be sensitive to selenium and have reproducing populations in the waterbody. These species
50	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 The occurrence of false-positives seems highly likely. For example, the water quality element of the criterion for lentic environments is very low and is likely to result in exceedences that would require investigation when there may be no elevation of selenium concentrations in fish tissues. Additionally, there may be instances where water concentrations of selenium in background or reference areas may exceed the water quality element of the criterion for lentic environments because these concentrations are not considered within the water quality element of the criterion.	
51	EPA-HQ-OW-2004-0019-0275-A1; Institute for Fisheries Resources; Posted 6/18/2014 Thank you for the opportunity to comment on the "Draft Aquatic Life Ambient Water Quality Criterion for Selenium - Freshwater". The undersigned groups representing fishing, tribes, low-income communities and communities of color, business and conservation organizations agree with the scientific view supported by federal government scientists that "Few environmental contaminants have the potential to impact aquatic resources on such a broad scale, and even fewer exhibit the complex aquatic cycling pathways and range of toxic effects that are characteristic of selenium (Lemly and Smith 1987; Lemly 2004)." Thus, adopting a protective water quality standard is essential not only for various aquatic species, through various lifecycles, during various seasons, but also for the protection of terrestrial wildlife that feed on these aquatic resources. Unfortunately the proposed criterion for selenium is not protective of aquatic resources or the food chain that depends upon this habitat.	
162	EPA-HQ-OW-2004-0019-0257-A2; Wyoming Department of Environmental Quality (WDEQ);	

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	Posted 6/16/2014 In addition to sites without fish, WDEQ/WQD is concerned that the criteria are not easily adapted to situations where a water body may not need to be protected for reproductive endpoints, such as put and take fisheries. While applying the criteria as drafted would be protective, it would also be overly-protective for put and take fisheries since there is no expectation that the fish in those waters will reproduce. In these cases, criteria derived to protect for non-reproductive effects would be most appropriate. WDEQ/WQD therefore requests that EPA include a recalculation of the criteria based on non-reproductive effects so that these modified criteria can be adopted on waters where it is appropriate.	should be considered in developing site specific criteria (and in assessment) . when evaluating potential effects to aquatic species. Regarding the commenters concern about the whole body tissue element, the available high quality data do not support the commenters contention that the EPA WQC element for whole body needs to be in the range of 4-6 mg/kg dw. As indicated in the 2016 final selenium criterion document, with 15 GMCVs included, the 5th percentile analysis yields a whole body criterion element concentration of 8.5 mg Se/kg dw whole-body criterion element, based on reproductive effects. This value is slightly lower than the most sensitive fish species tested, white sturgeon (*Acipenser transmontanus*). Regarding water values that are "too high", EPA's final 2016 water quality criterion elements concentrations are 3.1 µg/L for lotic systems, and 1.5 µg/L for lentic systems. These values bracket a Lemly and Skorupa 2007 recommended screening value of 2 µg/L for all waters. The EPA lentic value provides more protection then the FWS-recommended screening value. Regarding the protectiveness of the lotic water value, the EPA 2016 final values are lower than the 2014 value of 4.8 µg/L highlighted by the Services and therefore provide more protection for endangered species than the previous draft value for lotic waters. The comment is somewhat misleading, as it does not include an assessment of the lentic values, (1.3 µg/L in the 2014 draft, 1.5 µg/L in the final 2016 criterion), which are lower than the 2 µg/L value previously stated (Lemly and Skorupa 2007) as being protective. Regarding the protection of aquatic –dependent wildlife, the 2016 final aquatic life selenium criterion covers only aquatic species such as fish and invertebrates, not aquatic-dependent wildlife. EPA has initiated development of an aquatic-dependent wildlife criterion, intended to protect species such as aquatic dependent birds. Regarding the commenters concern that the selenium criterion is
212	EPA-HQ-OW-2004-0019-0293-A2; Pennsylvania Department of Environmental Protection; Posted 6/26/2014 Selenium Criteria Comments The Pennsylvania Department of Environmental Protection (DEP) currently has a chronic selenium water quality criterion of 4.6 µg/L for the protection of aquatic life. This criterion is more protective than the proposed EPA water quality criterion for the water column in lotic systems (number 3 above).	
289	EPA-HQ-OW-2004-0019-0315-A1; USGS - Comment submitted by Theresa S. Presser and Samuel N. Luoma, National Research Program, U.S. Geological Survey, Western Branch, Menlo Park, CA; Posted 7/15/2014 4. A downward bias in overall model predictions is also evidenced by the relationship shown in Figure 16 of the DCD. If a local entity employed the model parameters in the DCD, then the calculated water-column guideline is likely to be under-protective.	
309	EPA-HQ-OW-2004-0019-0332-A2; J.R. Simplot Company; Posted 7/30/2014 Proposed Lentic and Lotic Aqueous Values are too Conservative for Variable Conditions. EPA has calculated nationwide criteria for only two water body types, using a probability distribution of individual site-derived chronic criteria protective of the water concentrations at each site. This process is inherently conservative by EPA's use of the 201 h percentile of the distribution of chronic criteria values for water. This conservatism is compounded by using a dataset that was disproportionately weighted to what may have been background or reference sites (i.e., EF values >1 for the lentic data), the analysis biased resulting water quality concentrations for lentic sites low. Further, parameters used to determine protective concentrations can be highly variable depending on site conditions, and such a calculation has the potential for a high degree of uncertainty.	
323, 324,	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014	

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542	3.4.1 Influence of Sampling Error on EPA's Calculated Sensitivity of the Water Criterion We have examined the Draft Selenium Criterion Document's novel application of the type of statistics that are often applied to medical diagnostic tests. We find its explanation in Appendix H and its application in Section 7.2.2 to be interesting and believe the concepts might have other useful applications in environmental analysis. Although we endorse the concept that the measurement of water concentrations can be viewed as a diagnostic test for the possibility that tissue concentrations are elevated, we point out one significant problem -- as few as two water samples were often coupled with a tissue concentration measurement to ascertain whether exceedance of the tissue criterion was accompanied by an exceedance of the water criterion (thereby determining diagnostic test sensitivity). We recognize the limitations in the data available for this analysis of binary statistics, and we recognize that EPA has incorporated adjustments into the analysis in an attempt to estimate from as few as two samples whether the 30-day, once-in-three-year concentration would exceed the water criterion if more samples had been taken. Nevertheless, the problem remains that the use of two samples involves a great deal of sampling error. In real-world site decision-making, two samples do not generally serve as the basis for an assessment. Relative to how site monitoring is actually done, using only two samples might be viewed as a rather haphazard application of the water-measurement diagnostic test. As with any diagnostic test, haphazard application increases random noise, and the influence of random noise on sensitivity is not unbiased. As is apparent, random noise depresses sensitivity, increases uncertainty, and results in more conservatism since randomness is not predictive of anything. As a consequence of the resulting depression in sensitivity caused by the high level of sampling error in EPA's analysis, we believe EPA has mistakenly set the water concentrations unnecessarily low in order to achieve high sensitivity. 3.4.2 Concerns Regarding "False Alarms" Caused by Setting the Criteria Too Low Beyond the above problem, we are concerned about the high number of false positives that are likely to result from setting the lentic water criteria concentrations as low as EPA has proposed. In particular, we are concerned about the poor Positive Predictive Values (PPV) of the water criteria. As EPA notes in Appendix H of the Draft Selenium Criterion Document, given that the water criterion is exceeded, PPV represents the probability that the tissue criterion is exceeded. On page H-4, EPA correctly presents the standard equation for adjusting PPV for the difference in prevalence of tissue criteria exceedances in (a) the high-risk site population represented by Tables 18 and 19, and (b) the waters of the U.S. as a whole, as intended to be represented by EPA's National Rivers and Streams Assessment (NRSA; USEPA, 2013b):	too weak, EPA has based the final 2016 criterion, as well as previous drafts, on the best available science EPA previously submitted the 2014 draft to an external expert peer review, and has modified the document considering to the reviews received. The external peer review, and EPA responses are available online at https://www.epa.gov/wqc/aquatic-life-criterion-selenium-documents. EPA then produced a revised draft, and released it for public comment in 2015. The 2016 final criteria document was developed considering all of those aspects (both original and revised) of the science commented on by experts and the public. Regarding data quality, EPA must follow data quality guidelines set forth by the Data Quality Act (2001), ensuring and maximizing the quality, objectivity, utility, and integrity of information (disseminated by EPA and other federal agencies. EPA also follows test acceptability and data quality guidelines set forth in our "1985 Guidelines" (Stephan et.al., 1985) Regarding the Kentucky WQS approval, EPA disapproved the Kentucky egg-ovary criterion of 19.3 mg/kg (vs 15.1 mg/kg for 2016 EPA egg-ovary criterion), as it would be unprotective of sturgeon, and possibly other selenium-sensitive species in Kentucky. EPA approved Kentucky's whole body criterion of 8.6 mg/kg bw dw (vs. EPA 2016 value of 8.5 mg/kg bw dw. Section 7 consultation with the Kentucky field office of the USFWS resulted in a non-jeopardy conclusion by USFWS.

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	PPV = Sens · P / ((Sens · P) + (1 – Spec)(1 – P)) where Sens is sensitivity, Spec is specificity, and P is the nationwide prevalence of waters with fish-tissue criteria exceedances. The Draft Selenium Criterion Document does not show an application of the above equation. Nor does it present the NRSA results in terms of the prevalence of fish muscle selenium concentrations above the muscle criterion. Nevertheless, we estimate that less than 1% of U.S. waters have fish muscle selenium concentrations exceeding EPA's muscle criterion. In such case, applying the above EPA equation using EPA's tabulated sensitivity and specificity for lentic and lotic waters, we calculate PPV to be less than 2% when applying the water criteria to all waters of the U.S. This means that more than 98% of water criteria exceedances would be false alarms. That is, they would not be accompanied by tissue criterion exceedances. This calculation can be checked against the online calculator at http://vassarstats.net/clin2.html. We are extremely concerned by this apparent 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. Since we are supportive of the mission of the state pollution control agencies and of EPA, we are concerned that setting the water criteria too low will result in a serious misallocation of resources, thereby reducing rather than enhancing the nation's ability to address environmental problems. NAMC is concerned that the lentic water criteria concentrations and the tissue criteria concentrations in the Draft Selenium Criterion Document are not technically defensible and are demonstrably overly conservative. We provide evidence for higher but still environmentally protective concentrations that would not unnecessarily expend limited regulatory resources to the detriment of genuine environmental issues, nor unduly penalize human industrial or other activities. We are concerned that the low lentic criteria concentrations will result in a serious misallocation of resources, thereby reducing rather than enhancing the nation's ability to address environmental problems.	

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457	EPA-HQ-OW-2004-0019-0356-A1; Idaho Department of Environmental Quality (DEQ); Posted 09/30/2014 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 outliers 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.	
79	EPA-HQ-OW-2004-0019-0332-A2; J.R. Simplot Company; Posted 7/30/2014 In May 2014, EPA released its External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium - Freshwater (2014) (hereafter referred to as the 2014 Draft Criterion). In this initial peer review draft, EPA chose to focus on a chronic criterion based on selenium concentrations in egg/ovary tissue because selenium effects in fish are manifested in the egg/ovary resulting in reproductive impairment (mortality and deformities in developing fry). Through compilation of the available studies where selenium was evaluated relative to reproductive impairment, twelve studies representing nine species ultimately make up the database of effects for selenium. The resulting egg/ovary criterion is based on the 5th percentile of the different species sensitivity distribution (N = 14 EC10 genus mean chronic values), with the most sensitive species being brown trout. As part of the public review process, EPA has provided 60 days for entities to submit comments on the 2014 Draft Criterion. The J.R. Simplot Company has the following comments on the 2014 Draft Criterion for consideration. Simplot commends EPA for its forward thinking based on the state of the science, to advocate a criterion based on effects due to selenium concentrations in egg/ovary tissues in the 2014 Draft Criterion. As well, Simplot is pleased to see that the 2014 Draft Criterion provides for alternative means of computing or back calculating from egg/ovary tissue concentrations to whole body/muscle tissue and/or aqueous selenium concentrations, all the while establishing that the primary criterion is the egg/ovary tissue concentration. The 2014 Draft Criterion acknowledges that there were potentially several avenues of data analysis, resulting in a range of possible EC10 values for the most sensitive species, which also included a novel combined endpoint for survival and deformities. EPA chose to build upon the science suggesting separate criteria for lentic and lotic environments as well. Simplot believes these elements of the 2014 Draft Criterion can be propagated into a protective criterion that is not overly conservative. While there were several key aspects in the 2014 Draft Criterion where EPA provided a sound scientifically defensible approach and rationale, there were also key aspects of the document where	

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	EPA chose an ultra-conservative approach. The primary issue Simplot has identified in the 2014 Draft Criterion is that the final egg/ovary criterion value is based on the worst case assumptions of the most sensitive species. There is a layering of conservatism built on assumptions, which ultimately reduce the criterion value to an effect level that when back calculated to aqueous concentrations yields a value in lotic systems lower than the current existing selenium criterion and a lentic criterion which is below background.[1] In the comments that follow, Simplot identifies several issues where conservatism increases uncertainty in the approach taken and the resulting criterion value derived. In particular, our comments focus on the brown trout study. The conservatism is also evident in the lotic and lentic water quality values calculated by EPA. Also, comments are provided on several additional topics. Simplot recommends utilization of a tiered approach for implementing the criterion, and an example for monitoring and sampling procedures for fish is provided. This discussion also includes addressing EPA's proposal to apply the tissue criterion as instantaneous measurement. Finally, Simplot recommends that data from an additional study on cutthroat trout should be considered by EPA. [1] 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 (VanderHoeven et al. 1997; Warne and van Dam 2008).	
205	EPA-HQ-OW-2004-0019-0257-A2; Wyoming Department of Environmental Quality (WDEQ); Posted 6/16/2014 EPA's draft criteria document highlights the natural variability in selenium accumulation in aquatic systems as well as the natural variability in bioaccumulation of selenium in fish, independent of the water column concentrations. The draft criteria document also articulates that selenium toxicity to aquatic life is primarily driven by organisms consuming selenium-contaminated food rather than being directly exposed to selenium dissolved in water. Furthermore, since the water column values were derived from fish tissue concentrations by modeling selenium transfer through the food web, the water column elements are the least accurate of the criteria elements. EPA's discussion of sensitivity, specificity, positive predictive value, and negative predictive values within Appendix H highlights the inaccuracy of the water column criteria further, particularly of the lotic water column criteria. Using the formula and data provided in Appendix H, the positive predictive value (PPV) for lotic waters is very low, 55%. If a state only has water column data and uses the water column concentration to assess designated use support for lotic systems, the state may incorrectly assess waters as not meeting their aquatic life uses half of the time. Likewise, while applying the lotic water column value would be protective of aquatic life uses, in many instances the criteria will be overly stringent.	

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407	EPA-HQ-OW-2004-0019-0281-A1; T. Mattiello; Posted 06/26/2014 The recently proposed U.S. Environmental Protection Agency new standards for water quality criteria for selenium are weaker and more complex than the current standards, and they pose a major threat to the health of streams in coal-impacted communities. Selenium is a pollutant released from many mountaintop removal coal mines in Appalachia that is extremely toxic to fish at very low levels. Over time, it builds up in fish and other aquatic organisms leading to reproductive failure, deformities and death. The EPA's proposed standards are too weak to be protective of aquatic life. Studies have shown negative effects of selenium at levels half as high as the fish tissue standards proposed by the agency. These standards are even weaker than those proposed by the EPA in 2004, which were withdrawn after public comments from agencies and scientists demonstrated that they would not protect aquatic life. We need strong water based standards for selenium that will protect all aquatic life.	
409	EPA-HQ-OW-2004-0019-0283-A1; V. Brandt; Posted 06/26/2014 The U.S. Environmental Protection Agency recently proposed new national recommended water quality criteria for selenium. These new standards are weaker and more complex than the current standards, and therefore pose a major threat to the health of streams in coal-impacted communities. Selenium is released from many mountaintop removal coal mines in Appalachia and is extremely toxic to fish, even at very low levels. Over time, it builds up in fish and other aquatic organisms leading to reproductive failure, deformities and death. The EPA's proposed standards are too weak to be protective of aquatic life. Studies have shown negative effects of selenium at levels only HALF as high as the fish tissue standards proposed by the agency. These standards are even weaker than those proposed by the EPA in 2004, which were withdrawn after public comments from agencies and scientists demonstrated that they would not protect aquatic life. At a time when water is becoming an ever-more precious resource, we need STRONGER standards than ever, not weaker ones, to protect it.	
416	EPA-HQ-OW-2004-0019-0290-A1; E. Willey; Posted 06/26/2014 I am writing to request that strong water based standards for selenium is what is needed to protect all aquatic life. Your proposed standards are too weak to protect aquatic life and are weaker than the unacceptable standards proposed and later withdrawn in 2004 and weaker than current standards. Why would you weaken your standards when we have scientific evidence to show that higher	

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	standards are actually needed. It is your job to protect our water quality for all living things.	
441	EPA-HQ-OW-2004-0019-0336-A2; Patriot Coal Corporation; Posted 07/28/2014 Patriot Coal Corporation ("Patriot") on behalf of itself and its subsidiaries and affiliates submits the following comments regarding the United States Environmental Protection Agency's ("USEPA") draft aquatic life criterion for selenium published on May 14, 2014. Patriot mines coal in Kentucky and West Virginia and employees nearly 4,000 people. Some of our mines are in certain areas that are associated with elevated levels of selenium in the rock adjacent to the coal seams being mined. As a result, Patriot has had significant experience both with the existing standard, which we believe to be based on outdated science, and the actual effects, or lack thereof, of selenium on fish populations. We are also acutely aware of the difficulty of installing treatment to meet the existing, but outdated, standard. Providing such treatment comes at a cost and all of the treatment options that Patriot has studied throughout the years have consequences or byproducts. It is imperative that the nationally recommended water quality criterion be set at an appropriate level to protect aquatic life, but not to force unnecessary treatment. Accordingly, Patriot supports USEPA's efforts to adopt a selenium criterion that reflects current science and is based upon fish tissue. This approach is much better suited for protecting the aquatic life in the streams downstream from our discharges. We are concerned, however, that some of the assumptions and calculations used to derive the current draft criterion are overly conservative. Accordingly, Patriot joins in the comments filed by the National Mining Association, the West Virginia Coal Association, and the North American Metals Council Selenium Working Group and urges USEPA to adopt the changes recommended by these groups.	
487	EPA-HQ-OW-2004-0019-0318-A2; Appalachian Voices; Posted 7/29/2014 We would like to thank you for the opportunity to comment on the EPA's proposed External Peer Review Draft Aquatic Life Criterion for Selenium in Freshwater. These comments are intended to supplement those submitted by Benjamin Luckett of Appalachian Mountain Advocates, on behalf of Appalachian Voices, and a number of other organizations. Appalachian Voices is a North Carolina based nonprofit working to protect and improve water quality across Appalachia. Selenium is a major source of pollution from coal mines across Appalachia, and we have particular concerns about this standard and its implications in our region. Primarily, we do not believe that this standard will be adequate to protect aquatic life. Also, we have significant concerns about the implementation of a fish tissue based standard, especially with regards to citizen enforcement actions.	
52	EPA-HQ-OW-2004-0019-0275-A1; Institute for Fisheries Resources; Posted 6/18/2014 As briefly summarized below, the Draft Criterion does not address previous concerns and required	

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	corrections outlined by other federal agencies—U.S. Fish and Wildlife Service, U.S. Forest Service, and U.S. Geological Survey—and, therefore, is not adequately protective of either aquatic life or the birds and other animals that feed on aquatic life. Previous comments by scientists from other agencies are summarized in two documents, which are attached: EPA's Draft Tissue-Based Selenium Criterion: A Technical Review (Presented to U.S. Environmental Protection Agency, June 16, 2004) Joseph P. Skorupa, USFWS, Theresa S. Presser, USGS; Steven J. Hamilton, USGS; A. Dennis Lemly, USFS; Brad E. Sample, CH2M HILL Technical Issues Affecting the Implementation of US Environmental Protection Agency's Proposed Fish Tissue-Based Aquatic Criterion for Selenium A Dennis Lemly and Joseph P Skorupa: Integrated Environmental Assessment and Management — Volume 3, Number 4—pp. 552-558 (552 _ 2007 SETAC) These documents make many key points about errors and needed changes that have not been properly addressed in the updated Draft Criterion, but among the most critical and fundamental flaws are: 1. The central component of the Draft Criterion is a whole-body fish tissue concentration of 8.1 mg/kg. This value is not adequately protective of aquatic resources. As documented in detail in Reference 1, "The public-service scientific community has identified 4-6 µg/g whole-body selenium in fish as the appropriately protective guidance for more than a decade (1, 4, 21, 39, 49)." 2. The inappropriately high tissue criterion leads to water criteria that are also too high and will not adequately protect aquatic resources. The proposed water criterion of 4.8 µg/L as a monthly average in lotic systems is much more permissive than the 5 µg/L as a 4-day average. 3. The Draft Criterion is not protective of Endangered Species. In previous review, USFWS and NMFS determined that the existing 5 µg/L chronic criterion for selenium would likely jeopardize 15 ESA-listed species. To avoid a final ''Jeopardy Opinion'' from the Services, and the associated legal ramifications, the USEPA agreed to reevaluate their CWA criteria guidance for selenium (FWS and NMFS 2000). Clearly, the new draft criterion of 4.8 µg/L over a much longer averaging period (30 days instead of 4 days) does not address these concerns. We urge USEPA to work directly with the scientific experts from their sister Federal agencies in order to develop selenium criteria that will protect our public resources. Our plea is that the scientists from USFWS, NMFS, USFS, and USGS be brought directly into the Criterion setting process with EPA	

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	scientists to ensure a consensus-based criterion that all federal resource agencies will support. USEPA needs to ensure that the selenium criteria adopted will in fact comply with the Endangered Species Act, Migratory Bird Treaty Act and any peer review has the benefit of all sister federal agencies' thorough review.	
56	EPA-HQ-OW-2004-0019-0318-A2; Appalachian Voices; Posted 7/29/2014 The Standard is Too Weak to be Protective of Aquatic Life The currently proposed standards are too weak to be protective of aquatic life. The Water Quality Standards Regulation states "water quality standards should, wherever attainable, provide water quality for the protection and propagation of fish, shellfish and wildlife."[iv] A water quality standard should be protective of aquatic life, but in its current form, this standard is too weak to perform its intended purpose. The newly proposed tissue based standards are too weak, and contradict well established science. Studies have shown negative effects of selenium at levels that are only half as high as the fish tissue standards proposed by the EPA. A recent study published in the journal Aquatic Toxicology found that compared to the control group, the reproductive success of zebrafish was reduced by half with average selenium concentrations of 4.3 ppm (whole body, dry weight) and 7.2 ppm (eggs, dry weight)[v]. These concentrations are significantly lower than the EPA's proposed standards, and indicate that those standards will not be protective of aquatic life. A toxicity threshold that is well below the EPA's proposed standards is not a new development in the scientific literature. In 2003 a review of existing literature by US Geological Survey researcher Steven Hamilton states, "The majority of the selenium literature supports a whole-body threshold of 4 mg/g in fish and 3 mg/g in diet." The review goes on to state that there are issues with the studies proposing higher toxicity thresholds, and states, "The proposed high-selenium thresholds by DeForest et al. (1999) and Brix et al. (2000) does not stand on equal footing with reviews of more extensive datasets by USDOI (1998), Lemly (1996), Maier and Knight (1994), and Hamilton (2002). Recent studies continue to support the dietary selenium threshold of 3 mg/g and the whole-body selenium threshold of 4 mg/g for fish."[vi] The newly proposed standard for whole body selenium is slightly less protective than the draft proposed by the EPA in 2004. The EPA subsequently withdrew that draft, based in part on public comments from scientists and other agencies showing that the proposed criterion was too high and would not be protective of sensitive species. Because this current draft standard is even weaker, comments from the previous draft are still applicable and should be considered by the EPA when evaluating this current draft. In reference to the previously proposed standards, the US Fish and Wildlife Service stated, "The draft criteria document proposes an acute aquatic life criterion of 185	

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	µg/L in the water column and a chronic aquatic life criterion of 7.9 µg/g (dry weight in fish tissue). Based on a large body of scientific evidence the Service believes these criterion values will not protect federally listed fish and wildlife species. Furthermore, the service believes these values are not even sufficient to protect the aquatic life for which the criteria were developed."[vii] These newly proposed draft standards are also substantially similar to those approved by the EPA adopted by Kentucky in late 2013. In response to the EPA's biological evaluation for those new standards, the US Fish and Wildlife service stated, "the Service believes the described standards may result in negative impacts to federally-listed species. Potential negative impacts to threatened and/or endangered species include...significant food chain-based effects to federally-listed, egg-laying vertebrates associated with the selenium criterion. Consequently, the Service is unable to concur with EPA's determinations."[viii] Fish and Wildlife has repeatedly told the EPA that several substantially similar selenium standards would result in impacts to federally listed species. This set of draft standards is no different, they are too weak to protect aquatic life and are thus likely to result in the "take" of federally listed threatened and endangered species. [iv] 40 CFR 131.2 [v] S. Penglase. Selenium and Mercury have a Synergistic Negative Effect on Fish Reproduction. Aquatic Toxicology 149 pages 16–24 (See section 4.3 paragraph 2). 2014. [vi] Hamilton, S.J., 2003. Review of residue-based selenium toxicity thresholds for fresh-water fish. Ecotoxicology and Environmental Safety56, 201–210. [vii] Letter to Geoffrey H. Grubbs, Director, USEPA/OST, from Wayne White, Manager, U.S. Department of the Interior, Fish and Wildlife Service, California/Nevada Operations Office, re: the USEPA Draft Aquatic Life Criteria Document for Selenium. May 15, 2002. http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OW-2004- 0019-0009 [viii] Virgil Lee Andrews, Jr.. FWS #2014-B-0086; Biological Evaluation for the EPA's approval of new and revised water quality standards for Kentucky. December 27, 2013.	
57, 58, 59	EPA-HQ-OW-2004-0019-0334-A2; Appalachian Mountain Advocates et al.; Posted 7/30/2014 Commenters are greatly concerned about EPA's Draft Aquatic Life Ambient Water Quality Criterion for Selenium, notice of which was provided in the Federal Register on May 14, 2014. 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	

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	problem of selenium pollution. If EPA's Draft Criterion—which gives primacy to fish-tissue concentrations[2] 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. CONCLUSION 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. V. The Concentrations of the Fish Tissue Elements Are Too High to Protect Sensitive Species As stated above, the thirty day peer review period did not give Commenters adequate time to solicit and obtain the opinions of academic experts in the field of selenium toxicity on the technical aspects of EPA's Draft Criteria. However, Commenters provide their initial observations of flaws in EPA's criterion development process that render the fish tissue-based elements insufficiently protective of sensitive species.[8] 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. 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	

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	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 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 15.2 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. EPA must fully account for winter stress, using studies that actually	

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	induce such stress by recreating realistic winter conditions including reduced photoperiod, when revising its fish tissue concentrations to ensure protection of sensitive aquatic species. [8] Commenters incorporate by reference into this section the critiques and accompanying authority on pages 3–4 of Appalachian Voices July 22, 2014 comments. [1] These comments also incorporate by reference the separate comments submitted by Appalachian Voices on July 22, 2014. [2] 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.	
55	EPA-HQ-OW-2004-0019-0352-A1; Western Coalition of Arid States (WESTCAS) [Comments 0319-A2 and 0321-A1 are duplicates of 0352-A1]; Posted 8/7/2014 Nationwide water column standards are not appropriate in areas such as the arid West with naturally elevated selenium concentrations. The majority of the data used in the probability distribution of protective water column concentrations are derived from studies in the arid West; however, the criteria developed are based on the 20th percentile, which includes primarily the data from studies conducted in North Carolina. The majority of the arid West data, which were primarily above the 20th percentile, were ignored when EPA chose to base the national criterion on the small east coast data subset. EPA should encourage states (e.g. flexibilities to states document) that want to use water column standards for permitting to use site specific determinations to develop water column standards due to the number of compounding factors related to stream-to-stream, and potentially site-to-site differences in BAFs, resident fish populations, and geology affecting surface water concentrations. Basing a nationwide water column criterion on a percentile of the calculated protective site specific concentrations as determined in the Draft Criterion Document for Selenium creates a situation where the water column criterion is overprotective for much of the arid West.	
246	EPA-HQ-OW-2004-0019-0271-A2; Coordinator, Barnes & Thornburg LLP on behalf of the Federal Water Quality Coalition; Posted 6/17/2014 In addition, the Agency used a bluegill study by Hermanutz et al. that yielded a problematic EC10. There are alternative interpretations, and the raw data need to be examined. Further, the egg target level of 15 mg/kg dry weight is overprotective. The proper level should be 18-20 mg/kg dry weight (with the whole body target of 8.1 mg/kg increasing proportionately).	
561	EPA-HQ-OW-2004-0019-0332-A2; J.R. Simplot Company; Posted 7/30/2014 While there were several key aspects in the 2014 Draft Criterion where EPA provided a sound scientifically defensible approach and rationale, there were also key aspects of the document where EPA chose an ultra-conservative approach. In particular, for the most sensitive species (brown trout),	

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	the decisions made by EPA with the data from Simplot's brown trout result in a layering of conservatism built on assumptions. The result is a proposed criterion that is not consistent with the study results and is scientifically not defensible.	
113	EPA-HQ-OW-2004-0019-0326-A1; Utility Water Act Group (UWAG); Posted 7/30/2014 <u>Lentic and Lotic Criteria Unworkable; Revision and Clarification Needed</u> UWAG finds the proposed lentic water criterion unrealistic and believes that implementation challenges will result. EPA should consider a more reasonable number, such as 5.4 and 2.1 µg/L, as well as more clearly define the difference between lentic and lotic systems. *The Proposed Lentic Criterion Is Overly Stringent* UWAG believes that the proposed lentic water criterion is too stringent and is not environmentally realistic. See DeForest et al. 2014 at 21 (in support of using the 75th percentile as appropriately conservative and that the 90th percentile of 1.3 µg/L for lentic systems would appear to be overly conservative). According to DeForest et al., differences between lotic and lentic sites is one of the primary areas of uncertainty related to the partitioning of selenium between water and fish in freshwater systems. (DeForest et al., Exec. Summ., i.). DeForest also finds, and UWAG concurs, that use of field data is appropriate because these systems are not well-modeled in the laboratory.[3] The DeForest study, compiled by U.S. and Canadian selenium aquatic risk scientists, resulted in selenium screening guidelines of 5.4 and 2.1 µg/L for lotic and lentic water bodies, respectively, while EPA's 1.3 µg/L threshold for lentic systems is only marginally above the upper range of concentrations measured at reference sites. *Implementation Challenges Will Result from the Overly Stringent Threshold* Adopting EPA's overly conservative lentic threshold does not establish a meaningful "trigger" and will cause implementation problems. The purpose of a trigger would be to promote investigation where resident fish tissue may not be available. A trigger that indicates pervasive "trips" could result in wasted or misdirected resources. For example, during July to November 2012, a total of seven water samples analyzed for dissolved selenium exceeded 1.3 µg/L at various Ohio River lock and dam ambient site locations (ORSANCO data; see http://orsanco.org/clean-metals-76/3-mainpages/data/196-clean-metals-data). For regulatory agencies that do not have historical selenium fish tissue data applicable to lakes or other lentic waters, exceedances of the draft lentic water column criterion could compel the agencies to either collect data or list the water body as impaired for selenium and develop a total maximum daily load for selenium; both options are costly and time intensive. This would be especially true in states where many water bodies are naturally (geologically) enriched with selenium. Moreover, while subsequent fish tissue testing may – in some cases –	

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	indicate attainment of one or more tissue thresholds, the very stringent lentic water column criterion will likely result in pervasive findings of reasonable potential for a variety of industrial facilities. And while many facilities will choose to conduct fish tissue studies to ascertain attainment of one or more tissue criteria, the initial finding of reasonable potential (based on water concentration) will put the facility in "compliance limbo." *A More Realistic Lentic Criterion Is Appropriate* A more realistic lentic water criterion, such as the 5.4 and 2.1 µg/L supported by DeForest, will reduce the frequency of such unintended consequences. Due to the effort and cost of collecting and analyzing fish tissue samples for selenium, EPA should closely consider the environmental and compliance costs associated with an overly stringent criterion. We strongly urge EPA to consider the practical real-world effects of "false positives" that would likely occur during water body monitoring studies in states that may adopt the 1. 3 µg/L lentic water quality criterion. *Clear Definition of Lentic and Lotic Systems Distinctions Needed* Furthermore, the difference between lentic and lotic systems is not clearly defined. EPA needs to discuss clearly how differentiations were made between lotic and lentic settings. This clarification is important for implementation of the final revised criteria. Some water bodies have both lotic and lentic attributes, depending on flow rate and regulation (dam) practices. Of all the sites that EPA designated as lentic (Table 12, pp. 85 – 89), was information on hydraulic retention time or other limnological factors available? UWAG requests the external peer reviewers, and the public, be provided with such information to the extent it is available. We recommend that EPA consider a baseline hydraulic retention time of one year for the designation of lentic waters. As an example, for implementation of approved numeric nutrient criteria, the State of Wisconsin defined "lakes" as those water bodies having an average hydraulic retention time of one year or more (Wisconsin Administrative Code, Chapter NR 217). In addition, UWAG suggests the Agency make clear that the criteria should not be applied to marine or estuarine habitats. Table 15, p. 97, clearly indicates numeric criteria are for freshwater applications. [3] Selenium EFs in laboratory studies are often inversely related to the exposure concentration in water. Thus, the highest EFs tend to be associated with relatively low water selenium concentrations, and the lowest EFs tend to be associated with relatively high water selenium concentrations with almost all selenium EFs above the 90th percentile in both lotic and lentic systems associated with water selenium concentrations <1 µg/L. Because water concentrations at reference sites are usually at or near 1 µg/L, these higher EFs appear to be biased high for the purposes of deriving a water selenium screening guideline for toxicity. DeForest 2014 at 10.	

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207	EPA-HQ-OW-2004-0019-0257-A2; Wyoming Department of Environmental Quality (WDEQ); Posted 6/16/2014 *Limits 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 "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 sensitive life stages, but the resulting criteria are likely over-protective for most of Wyoming's streams and do not give enough consideration to the thousands of stream miles that lack any fish species. WDEQ/WDQ appreciates EPA's discussion in Appendix I that describes that for waters that lack fish, states should adopt criteria to protect the downstream fish species. Unfortunately, it is not practical for a state such as Wyoming, with one staff person devoted to development and adoption of water quality standards and 115,000 miles of streams[3], to develop site-specific criteria for approximately 70% of our streams based on downstream fish species. Nor is it realistic for the State of Wyoming to apply an overly stringent criteria to most of our waters that may result in unnecessary impairment decisions and costly treatment for point source discharges. Furthermore, many of these waters are miles and miles from a stream containing resident fish or may have no hydrologic connectivity to waters that contain fish. Moreover, the way that EPA derived the selenium criteria, as an egg-ovary based criteria, precludes the use of the recalculation procedure for waters that lack fish. Since the criteria, as currently drafted, are not applicable to most of Wyoming's waters and cannot be easily adapted to most of Wyoming's waters, WDEQ/WQD requests that EPA develop a recalculated criteria without fish endpoints, similar to the 2013 ammonia criteria that was recalculated for waters that lack unionid mussels. EPA should also make it clear within the criteria document that there is no expectation that the selenium criteria be applied to waters without fish since the criteria were derived as fish-tissue criteria and that the recalculation procedure can only be used to remove various fish species, not all fish species. [1] USDA/NRSC 2006: Precipitation — Annual 1971-2000 for Wyoming at 1:250,000. ERSL Metadata. United States Department of Agriculture/ Natural Resources Conservation Service, National Cartography and Geospatial Center, Fort Worth, Texas. [2] National Hydrography Dataset: 100k NHD identifies ~70% of flowline miles as intermittent or	

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	ditches; 24k NHD identifies ~80% of flowlines as intermittent, ephemeral or canals/ditches. [3] National Hydrography Dataset: 100,000 NHD includes 115,487 miles of flowlines in Wyoming.	
117	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 8/7/2014 Since mercury loading into American waters is becoming nearly ubiquitous as a result of atmospheric transport and deposition from both local industrial activities and industrial activities as far away as China, and since mercury and selenium interact synergistically to increase reproductive toxicity effects on both water birds (Heinz and Hoffman 1998) and fish (Penglase et al. 2014), the Service recommends that EPA offer guidance for more stringent selenium criteria for known mercury-contaminated waters (perhaps via a modest safety factor).	
17	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; U.S. Fish and Wildlife Service, Paul Souza; Posted 8/7/2014 The DSP gives too much weight to these McIntyre et. al (2008) experiments (ES1 and ES2) in finding a Species Mean Chronic Value for bluegill. These experiments were intended to replicate and improve on the experiment of Lemly (1993), in which Lemly showed the importance of winter stress in exacerbating the negative effects of selenium. The experiments of McIntyre et. al (2008) failed to replicate a key component of the winter stress syndrome: the decreased photoperiod that accompanies decreasing temperature with the onset of winter. The importance of photoperiod to the expression of winter stress syndrome is highlighted by the fact that the experiment of McIntyre et. al (2008) that most closely replicated Lemly's work (experiment ES2) except inappropriate photoperiod showed no effect at the exposure treatment at which Lemly found a clear effect. Thus, the McIntyre et. al (2008) experiments are of highly doubtful validity in assessing the interactive effects of winter stress and selenium exposure on bluegill. (Note. The reference cited for this work in the DSP (p. 192) is incomplete, lacking coauthors).	
332	EPA-HQ-OW-2004-0019-0320-**A2**; National Mining Association (NMA) and GEI Consultants, Inc. (GEI); Posted 7/29/2014 Additionally, if other commenters have concerns with the exclusion of winter-stress data, we would recommend directing them to the bluegill studies which were used in the criteria development (Hermanutz et al. 1992 and 1996), which include bluegill exposed to year-round seasonal conditions in an outdoor test system, and thus include "winter stress" under natural conditions.	
240, 503	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 A greater link between tissue concentrations and population level effects should be stated. This is the rationale for some of the conservative assumptions used to support the criterion, but the population	

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	level studies used to support this link does not seem to be thoroughly discussed. For example, there are instances where tissue concentrations are elevated in fish, but deformities are absent, which contradicts the rationale for the selenium criterion and these are not comprehensively captured. The application of the criterion to environmental systems in recovery is unclear. We believe the slow recovery of tissues in fish previously exposed to selenium is not adequately captured in criterion or the draft criterion document. Studies should not be excluded where elevated concentrations do not translate to population level effects.	
422	EPA-HQ-OW-2004-0019-0297-A1; B. Rae; Posted 06/26/2014 We need strong water based standards for selenium that will protect all aquatic life. The EPA's proposed standards are too weak to be protective of aquatic life. Environmental Protection Agency recently proposed new national recommended water quality criteria for selenium. Because these new standards are weaker and more complex than the current standards, they pose a major threat to the health of streams in coal-impacted communities. Please understand and act accordingly: selenium is a toxic pollutant released from many mountaintop removal coal mines in Appalachia: extremely toxic to fish at very low levels. Over time, it builds up in fish and other aquatic organisms leading to reproductive failure, deformities and death. Obviously NOT protecting our water does NOT work and negatively impacts our health. EPA's proposed standards are too weak to be protective of aquatic life. Studies have shown negative effects of selenium at levels half as high as fish tissue standards proposed by the agency. These standards are even weaker than those proposed by the EPA in 2004, which were withdrawn after public comments from agencies and scientists demonstrated that they would not protect aquatic life. This cannot be considered acceptable, by any means. The EPA's purpose is to protect us...please do so.	
423	EPA-HQ-OW-2004-0019-0298-A1; C. Swing; Posted 06/26/2014 The EPA's proposed standards are too weak to be protective of aquatic life. Studies have shown negative effects of selenium at levels half as high as the proposed fish tissue standards. These standards are even weaker than those proposed by the EPA in 2004, which were withdrawn after public comments from agencies and scientists demonstrated that they would not protect aquatic life. We need strong water based standards for selenium that will protect all aquatic life.	
429	EPA-HQ-OW-2004-0019-0304-A1; J. Hassberg; Posted 06/26/2014 Protect Appalachian streams from selenium contamination!	

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	These new water quality criteria are weaker and more complex than the current standards, they pose a major threat to the health of streams in coal-impacted communities. Selenium is a pollutant released from many mountaintop removal coal mines in Appalachia that is extremely toxic to fish at very low levels. Over time, it builds up in fish and other aquatic organisms leading to reproductive failure, deformities and death. The EPA's proposed standards are too weak to be protective of aquatic life, and the other life forms (i.e. humans) that consume them. Studies have shown negative effects of selenium at levels half as high as the fish tissue standards proposed by the agency. These standards are even weaker than those proposed by the EPA in 2004, which were withdrawn after public comments from agencies and scientists demonstrated that they would not protect aquatic life. Please re-think these standards and protect the community and the environment!	
430	EPA-HQ-OW-2004-0019-0305-A1; K. Robertson; Posted 06/26/2014 The EPA's proposed standards are too weak to be protective of aquatic life. Studies have shown negative effects of selenium at levels half as high as the fish tissue standards proposed by the agency. These standards are even weaker than those proposed by the EPA in 2004, which were withdrawn after public comments from agencies and scientists demonstrated that they would not protect aquatic life.	
431	EPA-HQ-OW-2004-0019-0306-A1; K. Pagenkopf; Posted 06/26/2014 The EPA's proposed standards are too weak to be protective of aquatic life. Studies have shown negative effects of selenium at levels half as high as the fish tissue standards proposed by the agency. These standards are even weaker than those proposed by the EPA in 2004, which were withdrawn after public comments from agencies and scientists demonstrated that they would not protect aquatic life. We need strong water based standards for selenium that will protect all aquatic life.	
433	EPA-HQ-OW-2004-0019-0308-A1; M. Brushaber; Posted 06/26/2014 Strong water based standards for selenium protecting all aquatic life are needed in Kentucky. Safe water is a must for all life in the streams and watersheds anywhere. Why does the burden of proof have to rest on the public testing the water supply? Why can't the EPA make sure that the water is clean in a way that is fair to the drinkers/residents? The burden of keeping water clean should rest on	

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	the coal companies not the local residents and wildlife.	
435	EPA-HQ-OW-2004-0019-0310-A1; S. Chapman; Posted 06/26/2014 Selenium water based standards must be strengthened, not weakened. Water quality must be insured via The Clean Water Act and pertinent related law and regulations. Incremental weakening will only result in greater wildlife and human health costs. Please act for the long term health of our water supplies and the humans and wildlife who depend on it.	
Comment Category 2.3 – Comments Concerning Fish Tissue Criterion Elements Summary: Comments concerning the fish tissue criterion element as it appeared in 2014 draft are included in this section. Some commenters felt that that the fish tissue egg ovary criterion was over-protective because it was based on the worst case assumption of the most sensitive species. Others noted 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.		
247	EPA-HQ-OW-2004-0019-0271-A2; Coordinator, Barnes & Thornburg LLP on behalf of the Federal Water Quality Coalition; Posted 6/17/2014 The fish tissue concentrations should not be expressed as "never to be exceeded" levels. Fish tissue concentrations do not change markedly or readily with temporal changes, or even spikes, in water column concentrations. The appropriate way to express fish tissue levels is on an average basis.	Responses concerning fish tissue criterion element frequency: Regarding the comment that EPA has provided no rational for the recommendation for the frequency of the draft tissue criterion element of "never to be exceeded", EPA has clarified this with additional text in the 2015 draft and 2016 final criterion documents. The 2016 fish tissue criterion element frequency has been modified to "not to exceed." EPA is developing technical support materials regarding how to sample for fish tissue, and is not recommending a single fish having selenium concentrations above the criterion be considered an exceedance of the criterion. 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 2016 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." Technical support materials will be made available for public
336	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014 3.7 Inappropriate Expression of Tissue Criterion as "Never to Be Exceeded" on an Instantaneous Basis EPA indicates that its draft tissue criteria are never to be exceeded.[11] 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. Although EPA has provided no scientific support for its "never to be exceeded" recommendation, EPA does present its rationale for the instantaneous duration, labeling it an "Analysis Plan for Derivation of Duration."[12] We find that this section does not describe a plan for derivation from scientific data. Rather, it provides general statements for why EPA is recommending an instantaneous duration. The rationale hinges on two premises: (1) grab sample monitoring represents an instantaneous measurement; and, (2) duration is not important because tissue concentrations change so gradually.	

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	The rationale, based on these two premises, is not scientifically defensible. We find the first premise, that monitoring is generally instantaneous, to be irrelevant. Although ambient monitoring of toxicant concentrations in water is likewise generally done with instantaneous grab samples, EPA has never cited this as being relevant to setting water criteria averaging periods. Take for example EPA's rationale for the 30-day averaging period for the ammonia chronic criterion. Rather than citing how ambient monitoring is usually done, it examines the toxicity tests from which the criterion concentration is derived. The results of those tests determine the averaging period. That is, the nature of toxic action of the pollutant determines the criterion, including its averaging period. The criterion, which includes its averaging period, describes the ambient condition to be attained, which then informs the interpretation of monitoring data. The selenium document's reversal of the process logic, basing its criterion derivation on common monitoring modes of operation, is not scientifically defensible. The second premise, that duration is not important because practical (regulatory) outcomes would not change with different specifications of the averaging duration, is not supported by any information EPA provides in the Draft Selenium Criterion Document. EPA did not compare real-world outcomes stemming from different durations. Rather, EPA has asked the regulated community to accept EPA's worst-case specification of duration on the grounds that EPA is not concerned enough about the difference between worst case and reasonable case to provide an analysis of this difference. Because the sensitivity of real-world regulatory outcomes to EPA's worst-case assumption cannot be foreseen at this time (considering the diversity of situations to which the tissue criteria may apply), we cannot agree that EPA's approach is sound. A particular concern about the instantaneous stipulation is that a single high outlier could completely subvert the weight of evidence from a much larger body of evidence. Although tissue concentrations vary gradually, when assessing monitoring data, there may be a substantial amount of random variability between samples at a site. To get an accurate determination of the risks at a site, these random variations need to be averaged out. Traditionally, EPA has cited concerns about lethal effects from brief concentration spikes to justify short averaging periods. However, because selenium tissue concentrations vary gradually, and because the effect of concern is the reduction in the average reproductive potential, not lethality to the standing crop of juvenile and adult individuals, the situation with selenium cannot be justified as requiring a short averaging period. Rather, because short-term spikes in tissue concentrations are not a concern, the tissue averaging period should be long, thereby allowing optimum consideration of the weight of evidence of all tissue concentrations that may be measured at a site. 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 water treatment facilities (industrial and municipal) have to	comment prior to finalization. As the 2016 criterion document notes, criterion frequency is the number of times an excursion can occur over time without impairing the aquatic community or other use. The current recommendation (1985 Guidelines – EPA PB85-227049) for return frequency of once in 3 years on average is based on the ability of an aquatic ecosystem to recover from a toxic insult <u>when pollutant impacts are associated exclusively with a water column exposure</u>. This recommendation is also based on the variability of water concentrations that aquatic life will be exposed to, and is set at a low level such that the water concentrations would mostly be below the criteria concentration. Selenium, however, is a bioaccumulative pollutant, and elevated levels in various ecological compartments (e.g., biota, surficial sediments) require a long period to decrease once the elevated concentration is reduced, and the associated aquatic community requires a long time to recover following reduction or removal of an elevated selenium exposure to a given system (e.g., Belews Lake, NC, and Hyco Lake, NC). The Belews and Hyco Lake examples indicate that a protracted period of time (in excess of 10 years) would be necessary for fish communities to recover once a selenium in fish tissue reached concentrations associated with reproductive impacts. Since exceedance of these concentrations is correlated with adverse effects 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. Regarding the comment on the imposition of a "never to exceed" wastewater limitation for selenium, the language in the 2016 final criteria document is "not to be exceeded", and only applies to the tissue criterion elements. The chronic water elements include are a 30 day average duration and the standard 1-in-3 year return frequency. Regarding WQC for recovering systems and application of the tiered approach, it is expected that fish communities will gradually

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	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 level 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 unworkable. More details on these concerns are provided below. [11] *Id* at 4 and 97. [12] *Id.* at 34.	recover once selenium reductions have been implemented. In both Belews and Hyco Lakes, it took between 10-20 years for the fish community structure and function to fully recover. Regarding comments that EPA is not following its own 1985 Guidelines methodology, the Guidelines allow for use of flexibility in approach to achieve the desired environmental protection goals, and it must be kept in mind that many of the quotes referred to by commenters pertain to Guidelines discussion of approaches for pollutants acting through direct water column toxicity, not stable, bioaccumulative pollutants such as selenium. Regarding the commenters' reference to 1985 Guidelines language not allowing "not to exceed" recommendations for the fish tissue criterion element's frequency, EPA notes that the 1985 Guidelines state, as quoted in a commenters' submission, *"The Criterion Continuous Concentration (CCC) is intended to be a good estimate of this threshold of unacceptable effect. If maintained continuously, any concentration above the CCC is expected to cause an unacceptable effect."* (emphasis added) Since selenium fish tissue concentration is expected to be maintained in relatively stable/continuous manner in fish once steady state is achieved (unless selenium is depurated to the eggs, passing the immediate risk directly to offspring), any concentration above the CCC is expected to cause an unacceptable effect, as the Guidelines state. This supports EPA's "not to exceed" frequency recommendation for fish tissue criterion elements. Further, the steepness of the dose-response curves for selenium in fish further indicate the importance of ensuring fish tissue concentrations remain below the criterion level, because small increases, a few mg/kg bw dw, in selenium in fish tissue concentrations have been experimentally determined in multiples species to result in unusually large increases in unacceptable adverse effects, relative to other pollutants. The 1985 Guidelines also state, as the commenter noted, *"On the other hand, the concentration of a pollutant in a body of water can*
337	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014 3.7.1 EPA's Own Guidelines Are Violated with Regard to Frequency EPA's criteria derivation Guidelines (Stephan et al., 1985) are unequivocal about the inappropriateness of EPA's draft selenium recommendation: 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. Absent any rationale for "never to be exceeded," this facet of the draft tissue criterion appears to be arbitrary and capricious. We can find no precedent for the "never to be exceeded" stipulation. It is incompatible with EPA's Mercury Implementation Guidance (USEPA, 2010) and EPA's fish tissue monitoring guidance (USEPA, 2000), which addresses issues similar to those faced by the selenium tissue criterion. We also note that many human health criteria, which include bioaccumulative pollutants, are implemented as long-term arithmetic means (implying a harmonic mean flow for permit design conditions), per EPA's California Toxics Rule (40 C.F.R. Section 131.38), EPA's Permit Writers' Manual (USEPA, 1996), and EPA's Water Quality Standards Handbook (USEPA, 2014). Implementation as a long-term arithmetic mean implies a roughly 40% allowable exceedance frequency in a lognormal distribution of typical variability. We thus note that water quality criteria can allow substantial exceedance frequencies while achieving their protectiveness goal. After examining the derivation of the proposed selenium water criteria from the fish tissue criteria, we believe that "never to be exceeded" is incompatible with that derivation. The water criterion derivation appears to treat the tissue criterion as a central tendency value for a site, not as an extreme upper limit. If the Appendix I criteria derivation procedures in the Draft Selenium Criterion Document are followed, we believe that the resulting water criterion would not achieve attainment of the tissue criterion if the tissue criterion were implemented as "never to be exceeded." Rather, the tissue	

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	criterion would need to be implemented as a central tendency value.	*be above the CCC without causing an unacceptable effect **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*.(emphasis added). Regarding the commenter's citation of this part of the 1985 Guidelines, this information clearly refers to water column concentrations of a pollutant, not a body burdens. Further, as noted above, given that concentrations in fish at steady state are relatively stable, the duration of excursion above the CCC will: (a) not be limited, and there will be (b) no compensating period of time during which the concentration is below the CCC. That is, fish tissue concentrations aren't expected to decrease greatly at steady state, except when the selenium burden, and risk, may be passed through depuration to eggs/offspring, also further supporting EPA's recommendation of "not to exceed" for the fish tissue element frequency. Responses concerning fish tissue criterion element duration: Some 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. Response to comment 335 regarding ww vs dw measurements; the final 2016 egg-ovary criterion only uses 1 study that reported selenium concentrations on a wet weight basis. All other studies
338	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014 3.7.2 EPA's Own Guidelines Are Violated with Regard to Duration As with frequency, it appears that EPA once again did not follow its own guidance when it incorporated an instantaneous (zero) duration into its tissue criterion. The 1985 Guidelines (Stephan et al., 1985) state the following: *The Criterion Continuous Concentration (CCC) is intended to be a good estimate of this threshold of unacceptable effect. If maintained continuously, any concentration above the CCC is expected to cause an unacceptable effect. On the other hand, the concentration of a pollutant in a body of water can be above the CCC without causing an unacceptable effect 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.* *[The approach taken by the Guidelines] is to require that the average concentration not exceed the CCC. The average concentration should probably be calculated as the arithmetic average rather than the geometric mean. If a suitable averaging period is selected, the magnitudes and durations of concentrations above the CCC will be appropriately limited.* *…it is the purpose of the averaging period to allow concentrations above the CCC only if the total exposure will not cause any more adverse effect than continuous exposure to the CCC would cause.* We believe that the above material conclusively demonstrates that the instantaneous duration recommended in the Draft Selenium Criterion Document is inconsistent with EPA's own Guidelines. To accord with the Guidelines, it would be necessary to provide a genuine (i.e., non-zero) averaging period. In accord with its past approaches for deriving a pollutant-specific averaging period, we recommend that EPA consider the data used in the derivation of the tissue criterion concentration. They are of two types of data, laboratory studies and field studies. The Besser et al. (2012) study is an example of a comprehensive laboratory study. With eggs collected over a 60-day period, it is apparent that concentrations were measured over a substantial period of time, essentially a reproductive season. Coyle et al. (1993) observed bluegill reproduction over an 80-day period, again essentially equivalent to a reproductive season. Carolina Power and Light (1997) observed 56 successful largemouth bass spawns over a two-year period. In contrast, some of the field studies collected gravid females over a short period of time, for example, the Formation Environmental (2011) brown trout study. This was by (2002) and Holm et al. (2003,	

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<tr><td></td><td>2005) took observations over a multi-year period.

Considering the above, we find no evidence that “instantaneous” can in general be viewed as appropriate for the range of studies on which the criterion is based. On the other hand, we believe that “seasonal average” would likely be the most appropriate designation, while recognizing that, for some species, this is a short period of time, while for others it is substantially longer. We note that the criterion averaging period never establishes a duration over which samples must be taken. It designates the period over which averaging may be done when sufficient samples are available. That is, if tissue samples were collected on a single day during a year, those samples would constitute the seasonal average for assessment purposes. On the other hand, if samples were collected on multiple days, those samples should be averaged when they are part of the same reproductive season.</td><td rowspan="2">that were used quantitatively reported selenium concentration in dry weight.</td></tr>
<tr><td>340</td><td>EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014

3.7.4 Conclusions Regarding Duration and Frequency

Regarding averaging, both within sampling events and across sampling events (over time), we conclude:

• In studies where the concentration-response curve (and hence EC10) was derived from measurements of concentrations in individual fish, the individual concentration deviations from the central tendency curve generated by TRAP have a CV of 0.53. This CV is greater than typical variation within species tissue samples collected in a year.
• Consequently, irrespective of whether a concentration-response curve was generated from treatment average concentrations or from individual fish concentrations, the curve represents an average of variable observations.
• To be consistent with what the concentration-response curve represents, individual sample concentrations for a species should ordinarily be averaged before comparing to a concentration-response curve, and hence to the criterion.
    o If the aggregate effect is calculated using individual sample concentrations (rather than averages) using the approach shown in Campbell (2011), the effect will be overestimated.
    o If only one sample is available, the average used for assessment is the same as the individual sample concentration. The point here is not that multiple samples of a species are required, but rather that, when multiple samples are available, they should generally be averaged.
• For a species having sensitivity equal to the 5th percentile hypothetical genus targeted by the criterion, if the average of the samples of that species does not exceed the tissue criterion, then the level of effect will not exceed 10% (the target level of protection for the criterion,</td></tr>
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	representing insignificant effect), provided that the CV of the samples is equivalent to or less than approximately 0.53. o If the CV is somewhat greater than approximately 0.53, then the effect would be only slightly greater than 10%, as would be surmised from the type of calculations shown in Campbell (2011). • Because the use of averages (comprised of individual samples having CV equivalent to or less than 0.53) will not allow the total exposure to "cause any more adverse effect than continuous exposure to the CCC would cause" (quote from EPA's 1985 Guidelines), it is fully consistent with the language and the intent of the Guidelines. That is, it will provide the level of protection intended by the Guidelines. Regarding frequency, we conclude: • Because the "never to be exceeded" stipulation is without precedent or visible means of support, it is difficult for us to view it as other than arbitrary and capricious. • Given the extreme nature of "never," we do not believe that EPA can develop a convincing rationale for why "never" is essential for attaining biological quality goals. Were EPA to press forward with an argument that it is necessary, we believe that a substantial body of evidence can be brought forth indicating that it is not necessary. • The "never to be exceeded" provision is incompatible with the mathematics used for permit derivation, inconsistent with the selenium water criterion concentration derivation, and inconsistent with past EPA regulations and guidance (including the related Mercury Implementation Guidance). • EPA needs to consider the Guidelines (Stephan et al., 1985). They are unequivocal: "A statement of a criterion as a number that is not to be exceeded any time or place is not acceptable." We recognize that a rigorous derivation of an allowable exceedance frequency is a difficult technical problem. Given that difficulty, we suggest that EPA apply its traditional "once-in-three-years" provision to an appropriate average selenium fish tissue concentration. When applied to a seasonal duration averaging period, as we are recommending here, we believe the once-in-three-year target is appropriately protective and scientifically defensible. To be scientifically defensible, consistent with the 1985 Guidelines, internally consistent with the selenium water criterion derivation, compatible with other approaches EPA is using with bioaccumulative pollutants, and implementable without ambiguity by the state pollution control agencies, we recommend that EPA replace "instantaneous" with "seasonal average," and replace "never to be exceeded" with "not to be exceeded more than once in three years on average"	

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	applicable to the seasonal average concentration. While we commend EPA for the level of effort it has put into deriving its draft recommended criterion concentrations, we believe that the level of rigor we have put into our rationale for duration and frequency far exceeds what EPA described as its basis for a duration and frequency, noting that EPA has supported its "instantaneous" provision with a footnote and one paragraph, and has provided no explanation for its "never to be exceeded" provision. More importantly, we believe that our recommendation provides a high degree of environmental protection and will assure attainment of biological quality goals. We are quite willing to discuss this further with the Agency and other parties.	
341	EPA-HQ-OW-2004-0019-0326-A1; Utility Water Act Group (UWAG); Posted 7/30/2014 <u>"Never to Be Exceeded" Approach Unworkable</u> For the following reasons, UWAG does not support the Agency's decision that it is appropriate to express fish tissue threshold concentrations as levels that are "never to be exceeded." Draft Report at 34. First, the Agency's criteria development guidelines expressly state that establishing a criterion as a number that is not to be exceeded is not acceptable (Stephan et al., 1985). EPA has provided no explanation for the need to depart from its own criterion development guideline. Next, the tissue thresholds (egg/ovary and muscle/whole-body), are derived using the geometric mean of replicate tissue concentration measurements; therefore, it would be inappropriate to express fish tissue levels using anything but an average basis. In addition, tissue thresholds represent the myriad biotic and abiotic factors that affect bioaccumulation; bioaccumulation is dependent on many temporal and spatial factors and cannot be adequately represented through one sample. Even during the laboratory chronic toxicity tests that the agency relied on to derive the final tissue thresholds, average concentrations of replicate tissue measurements were used. And, aquatic life in the field are not exposed to a non-varying "maximum" selenium concentration. Figure 1 of these comments indicates the lifetime concentrations of selenium measured in the otolith of a freshwater drum collected from the Ohio River in 2010. Clearly, the fish was exposed to highly varying selenium levels (whether in food items or water, or both) during its lifetime. This would be the expected pattern of exposure in wild fish. Lastly, the imposition of a "never to exceed" wastewater limitation for selenium would be unnecessarily expensive to implement. Industrial and public facilities would be required to design treatment works that would "guarantee" that any collected sample would be equal to or less than the tissue-derived wastewater limitation 100% of the time. The installation and operation of such a design would incur significant costs that are unnecessary from an environmental protection standpoint. The	

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	Draft Report does not provide any scientific explanation or rationale for EPA's decision to adopt a "never to be exceeded" limit for compliance while using an average of the tissue data approach for establishing the criteria. We recommend the basis for the approach be closely reexamined and revised consistent with what we know about selenium bioaccumulation in fish tissue and the agency's own guidelines for deriving aquatic life criteria	
342	EPA-HQ-OW-2004-0019-0332-A2; J.R. Simplot Company; Posted 7/30/2014 III. Application of a Tissue Criterion as Instantaneous is Inappropriate "Instantaneous" application of the egg/ovary or whole body/muscle criterion (Page 97, table 15) implies that a single fish tissue measurement could be used to show exceedence of the criterion. While fish tissue may represent an integrated exposure, each fish may integrate that exposure differently depending upon its history at a site. Furthermore, when dealing with migratory species such as trout, multiple samples of tissue are necessary to derive a representative sample for a site as fish may have moved in and out of a site for spawning. The most representative assessment of fish tissues from a site relies on having good site history for tissue data and has multiple samples from a site to ensure that the egg/ovary or whole body/muscle samples collected from a site are consistent with the history of that site. In its proposal for a site-specific selenium criterion to Idaho Department of Environmental Quality (IDEQ) (Formation 2012), Simplot presented an implementation process for monitoring to gauge compliance. When or if tissue data were needed, a minimum of 10 fish were recommended for tissue analyses. The lower 95th percentile of the mean data distribution was selected as a conservative endpoint, but a geometric mean of those tissue measurements could also be used as a compliance measurement. To gauge compliance with a fish tissue criterion, the data must be representative of the site and a single tissue measurement has the potential to over or under representative site conditions, particularly if migratory fish are being evaluated.	
343	EPA-HQ-OW-2004-0019-0335-A2; County of Orange, OC Pubic Works; Posted 7/30/2014 5. 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. 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	

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	proposed frequency. Therefore, it is not possible to comment on the appropriateness of this selection. 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/or the Protection of Aquatic Organisms and Their Uses[13] (1985 Guidance Document) and the Technical Support Document/or Water Quality-based Taxies Control[14] (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. " Furthermore, "never to be exceeded" implies that where tissue objectives are not currently being attained, or even where one sample exceeds the tissue element out of possibly hundreds of samples, those areas are and will remain out of compliance with the criterion. From a practical implementation perspective, not providing a mechanism by which compliance can be attained demonstrates that an alternative frequency must be developed. 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[15] (RWQC) released by USEPA in 2012. The STV approximates the 90 th percentile of the water quality distribution and is intended to be a value that should not be exceeded by more than I0 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). 13 USEPA. 1985. Guidelines for Deriving Numerical National Water Quality Criteria for the Protection	

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	of Aquatic Organisms and Their Uses. Office of Research and Development. PB85-227049 [14] USEPA. 1991. Technical Support Document for Water Quality-based Toxics Control. Office of Science and Technology, Office of Water. USEPA-505-2-90-001. [15] USEPA. 2012. Recreational Water Quality Criteria. Office of Science and Technology, Office of Water. USEPA820- F-12-058.	
345	EPA-HQ-OW-2004-0019-0266-A2; Transportation and Storm Water Department, City of San Diego, California; Posted 6/17/2014 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. Additionally, 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.	
347	EPA-HQ-OW-2004-0019-0320-A2; National Mining Association (NMA) and GEI Consultants, Inc. (GEI); Posted 7/29/2014 3.0 Additional Comments on Tissue Sampling and Data Usage As stated in our original review, 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, upon further review, we believe the use of the term “instantaneous” leads to some confusion regarding the tissue sampling requirements. As stated in the conclusions of our initial review, we had recommended clarification of tissue sampling requirements and use of an alternative approach such as the geometric mean of samples collected. We support the thorough discussion of this topic in the NAMC-SWG 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.	
348	EPA-HQ-OW-2004-0019-0322-A1; American Petroleum Institute (API); Posted 7/30/2014 Fish tissue criteria are based on bioaccumulation that happens only over time. Fish tissue concentrations do not change markedly with temporal changes or even spikes in water column concentrations. Thus fish tissue criteria should not be expressed as instantaneous not-to-exceed limits but rather as average limits.	
349	EPA-HQ-OW-2004-0019-0339-A2; West Virginia Department of Environmental Protection (DEP); Posted 7/30/2014	

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	Revise criteria to be expressed as "seasonal average" - EPA's tissue-based criteria, expressed in not-to-exceed terms, seems to devalue information that may be available for multiple individuals of a species population or even community-level biological tissue data that indicates average or median tissue concentrations are not exceeding the recommended thresholds. A seasonal average approach would be more statistically relevant since all information is incorporated into a measurement; whereas, the not-to-exceed limits often rely on the validity of a single sample or measurement and ignore voluminous contradictory information. We recommend that EPA utilize seasonal averages as a means of evaluation of tissue matrix information with a criteria expressed in terms of "not to exceed more than X times per Y years."	
350	EPA-HQ-OW-2004-0019-0341-A1; West Virginia Coal Association (WVCA); Posted 8/5/2014 The expression of the fish tissue numbers in the Draft Selenium Criteria 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.	
351	EPA-HQ-OW-2004-0019-0323-A1; California State Water Resources Control Board; Posted 7/30/2014 Third, we are very concerned with U.S. EPA's stance that the proposed fish tissue elements - egg/ovary, whole body, or muscle tissue - are "never to be exceeded." This implies that where tissue objectives are not currently being attained, or even where one sample exceeds the tissue element out of possibly hundreds of samples, those areas are and will remain out of compliance with the criterion. This is not only impractical and inappropriate, but it is also contrary to the guidance provided by the U.S. EPA in their *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses*[1] (1985 Guidance Document) and the *Technical Support Document for Water Quality-based Toxics Control*[2] (1991 TSD). In the 1991 TSD, U.S. EPA 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.*" The State's *Water Quality Control Policy for Developing California's Clean Water Action Section 303(d) List*[3] (California Listing Policy), which was adopted and submitted to U.S. EPA in 2004, provides for an exceedance frequency that is based on a binomial distribution if the number of measure exceedances supports rejection of the null hypothesis as described in Attachment 2 to this	

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	letter. This approach acknowledges and quantifies what is considered as an acceptable or unacceptable exceedance proportion for any given toxic pollutant, including bioaccumualtive contaminants such as selenium. *Original letter contains Attachment 2 entitled TABLE 3.1: MINIMUM NUMBER OF MEASURED EXCEEDANCES NEEDED TO PLACE A WATER SEGMENT ON THE SECTION 303(d) LIST FOR TOXICANTS.[1] See original letter.* [1] U.S. EPA. 1985. Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses. Office of Research and Development. PB85-227049 [2] U.S. EPA. 1991. Technical Support Document for Water Quality-based Toxics Control. Office of Science and Technology, Office of Water. U.S. EPA-505-2-90-001. [3] State Water Resources Control Board. 2004. Water Quality Control Policy [1] SWRCB 2004	
536	EPA-HQ-OW-2004-0019-0320-A2; National Mining Association (NMA) and GEI Consultants, Inc. (GEI); Posted 7/29/2014 EPA should consider replacing the term “instantaneous measurement” with “seasonal average” and provide a more complete discussion of tissue sampling requirements.	
360	EPA-HQ-OW-2004-0019-0266-A2; Transportation and Storm Water Department, City of San Diego, California; Posted 6/17/2014 Additionally, footnote 5 of Table 15 of the Draft Selenium Criterion provides justification for the duration of the fish tissue elements of the 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 15. Requested Action: 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. <u>Fish tissue data are to be collected as composite samples</u>."	
543	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014	

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	We are also concerned, relative to addressing genuine environmental problems nationally, that the tissue criterion is inappropriately expressed as “never to be exceeded” on an instantaneous basis, which is inconsistent with EPA Guidelines. 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.	
558	EPA-HQ-OW-2004-0019-0335-A2; County of Orange, OC Pubic Works; Posted 7/30/2014 • 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.	
450	EPA-HQ-OW-2004-0019-0351-A2; Stakeholders Implementing TMDLs in the Calleguas Creek Watershed, California; Posted 08/05/2014 5. 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. 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. 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*[16] (1985 Guidance Document) and the *Technical Support Document for Water Quality-based Toxics Control*[17] (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	

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	frequency of pollutant stress may be set at a value that does not significantly increase the frequency or severity of all stress combined." Furthermore, "never to be exceeded" implies that where tissue objectives are not currently being attained, or even where one sample exceeds the tissue element out of possibly hundreds of samples, those areas are and will remain out of compliance with the Draft National Criterion. From a practical implementation perspective, not providing a mechanism by which compliance can be attained demonstrates that an alternative frequency must be developed. 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 [18] (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). [16] USEPA. 1985. Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses. Office of Research and Development. PB85-227049 [17] USEPA. 1991. Technical Support Document for Water Quality-based Toxics Control. Office of Science and Technology, Office of Water. USEPA-505-2-90-001. [18] USEPA. 2012. Recreational Water Quality Criteria. Office of Science and Technology, Office of Water. USEPA-820-F-12-058.	
578	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 There are several other components of the criteria that should be reevaluated by the EPA. 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	

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	of no more than once every three years on average. Another issue that requires reevaluation and clarification is how to establish criteria for streams with no existing fish populations. There is some discussion of this in Appendix I, but the recommendations are not appropriate for all stream types. It appears the default would be to use water-column criteria; however, we provide discussion of an alternative involving use of the chronic invertebrate data provided in the EPA document. Another topic that needs further consideration is providing guidance for the use of natural background Se concentrations to develop ambient based site-specific criteria where elevated concentrations are present unrelated to human-induced sources. We have provided discussion of how this has been successfully done in Colorado, 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.	
445	EPA-HQ-OW-2004-0019-0351-A2; Stakeholders Implementing TMDLs in the Calleguas Creek Watershed, California; Posted 08/05/2014 SUMMARY OF KEY TECHNICAL ISSUES • 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 SS0s, 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 15 and need to be added or modified in order to interpret the proposed criterion.	
353	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014	

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	3.4 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. It is indicated in the summary table on page 4 of the 2014 draft Se criteria document that "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." We agree that any tissue collected is representative of accumulation over time and should be considered an "instantaneous" measurement of the current conditions. Generally, the term "never to be exceeded" requires substantive clarification to make clear what is expected. 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. However, other alternatives could be employed (as discussed below) to ensure that a single fish would not be used to determine attainment. In Section 3.6 of the 2014 draft Se criteria document, on pages 21-23, EPA discusses the use of assessment endpoints and how they can be defined "at any level of organization (e.g., individual, population, community)". However, ecological assessment endpoints tend to represent population levels (e.g., maintaining a viable fishery) or community levels (e.g., maintaining adequate species diversity) of biological organization, except when evaluating threatened and endangered species, when individuals need to be protected (USEPA 1998, Suter et al. 2005). Thus, because water quality criteria are designed to protect the most sensitive species, applying endpoints (i.e., in this case, tissue criteria) at population and community levels of organization is most appropriate. That is, it would be overly conservative to suggest that a single fish measurement could render a permittee in non-compliance or waterbody in non-attainment when the underlying criterion is already inherently conservative. An alternative approach to the "never to exceed" language would be use of the geometric or arithmetic mean value of individual fish tissue concentrations for assessment of the fish tissue criteria. The geometric mean is a good measure of central tendency and is consistent with EPA's preference for use of geometric means to calculate SMCVs and GMCVs in criteria development. In addition, the allowable exceedance frequency would be based on exceeding the tissue criteria no more than once every three years on average. This rationale is based on Stephan et al. (1985), which states that exceedances are generally the result of usual variation, therefore most exceedances are small, and	

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	most aquatic ecosystems can recover from these small exceedances in about three years. We also support the very detailed analysis of this issue contained in the review by NAMC-SWG (2014).	
179	EPA-HQ-OW-2004-0019-0327-A2; Colorado Wastewater Utility Council (CWWUC); Posted 7/30/2014 There are several components of the draft Se criteria which will directly impact the regulated community that EPA should expand upon and clarify in the criteria document. EPA did not provide any specific recommendations for determining attainment with Se criteria in streams without fish. In the West, where water is extremely limited, we have a large number of ephemeral or intermittent streams, in many of these streams fish populations are not necessarily limited by water quality but by water quantity. In addition, 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 three years on average.	
168	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 Application of the Tiered Approach Criterion to an Existing Operation The intended application of the fish tissue criteria (for egg-ovary, whole body and muscle) in assessing population effects is not clear. The proposed criterion stipulates that fish tissue elements are "never to be exceeded" in any "instantaneous measurement". While it is agreed that an instantaneous measurement will reflect the integrative accumulation of selenium over time and space in the sampled fish at a given site since selenium concentrations in fish tissue are expected to change only gradually over time in response to environmental fluctuations, one exceedance of the criterion in a single fish tissue sample does not demonstrate effects at the population level. Some consideration should be given in the application of the criterion to take into account an appropriate statistical representation of the population (e.g. 95% upper confidence limit of the mean of at least ten fish tissue measurements). Further guidance would then be needed on the collection of fish tissue samples to ensure that appropriate data for the assessment are collected.). In terms of the water element, it is not clear whether any fish tissue data are required if the selenium water concentration is below the water elements. It would make sense that fish tissue should be collected given the bioaccumulative nature of selenium; however, this does not seem to be the case in the document. In addition, if a discharge is into a lotic system, what is the responsibility towards the downstream lakes? Additional clarity is needed on the application of the various elements of the criterion. The Kentucky standard is a good example of a tiered approach that would result in monitoring of fish tissue when a water concentration is elevated above a threshold (Payne 2013).	

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	As of 2014, Kentucky was the only state to adopt an egg/ovary-based chronic criterion for selenium (Payne, 2013) which has been approved by the U.S. EPA. The adoption of the Kentucky selenium tissue-based criterion preceded the publication of draft criterion document. Virginia has proposed to adopt an egg/ovary-based Se WQS consistent with the Kentucky Se WQS (GEI, 2013). Kentucky calculated site-specific water quality standards for selenium. Whole body and egg/ovary GMCV were calculated using toxicity data for ten fish species found in the state waters. Final chronic values were derived for both whole body and egg/ovary tissues estimated using the GMCVs for the 4 most sensitive genera. The four most sensitive genera used to calculate the FCVs for Kentucky differed from those selected by the U.S. EPA for the draft criterion document. In particular, the most sensitive species used by the U.S. EPA for the draft criterion document, brown trout, was not included in the four most sensitive genera for Kentucky. Not only did Kentucky report a brown trout GMCV of 22 mg/kg dw for egg/ovary compared to the U.S. EPA which reported a brown trout GMCV of 15.91 mg/kg dw for egg/ovary for what appears to be the same study (cited as Newfield, 2009 in Payne, 2013, and as Formation Environment, 2011 in U.S. EPA, 2014). Although a rationale for this decision was not presented, Kentucky reported that the U.S. EPA data were unusable (Payne, 2013). The FCV for whole body fish tissue of 8.6 mg/kg dw and the egg/ovary tissue FCV of 19.3 mg/kg dw derived for Kentucky and proposed for Virginia are higher than the draft 2014 WQC values for whole body fish tissue of 8.1 mg/kg dw and egg/ovary tissue of 15.2 mg/kg dw by 6 and 27%, respectively. The values derived by Kentucky were almost 6 and 30% above the recommended U.S. EPA values, respectively. These values are greater than the draft criterion document and reflect the different species included in the derivation. To implement the selenium WQS, Kentucky has established a tiered monitoring approach to ensure compliance with the chronic water quality standard. If the total selenium concentration in the water column is less than or equal to 5 µg/L, the water body is meeting its aquatic life use. If the total selenium concentration in the water column is more than 5 µg /L, fish tissue sampling is required to compare to the tissue criteria (whole body fish tissue of 8.6 µg/g dw and for egg/ovary tissue of 19.3 µg/g dw). If below the criteria, the water body is meeting the chronic standard for selenium. If above the criteria, the site is considered in non-attainment of the selenium standard. This tiered approach is an example the U.S. EPA could adopt to help guide the measurement and evaluation of the selenium criterion.	
176	EPA-HQ-OW-2004-0019-0274-A2; National Mining Association (NMA); Posted 6/17/2014 Additionally, there are several components of the draft Se criteria that will directly impact the	

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	regulated community which EPA should expand upon and clarify in the criteria document. For example, the use of a "never to be exceeded" frequency is inappropriate, and not in line with standard criteria attainment requirements. NMA therefore recommends clarification of the tissue sampling requirements, as well as the application 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. Furthermore, EPA did not provide any specific recommendations for determining attainment with the Se criteria in streams without fish. In the case of ephemeral or intermittent streams and in small headwater streams, all of which are commonly found in mining regions, fish populations are not necessarily limited by water quality but by water quantity. Section 3.5 of GEI's review provides recommendations for developing site-specific standards in such situations, which EPA should consider adopting.	
244	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 Application for Recovering Systems The draft document considered data for bluegill in continually exposed systems from Hermanutz et al. (1992 and 1996) but excluded the data from recovering stream systems from the same study based on the argument that "they do not reflect the type of system that water quality criteria are most commonly applied to, those receiving existing waterborne pollutant discharges". In the recovering systems, adult bluegill were exposed only to selenium in the foodweb in preexposed systems in which all continued external dosing of selenite was halted. These adult bluegills accumulated selenium in their tissues to levels very near to those accumulated by bluegill that were exposed to selenium through the foodweb and to aqueous selenium. However, no effects (larval survival, deformities, hemorrhaging) were observed in the bluegill progeny in the recovering system experiments. The results from the Hermanultz et al. studies corroborate field observations of biological recovery in Belews Lake and Hyco Reservoir cited in the draft 2014 U.S. EPA document after selenium loads were reduced but while tissue concentrations remained relatively high. The U.S. EPA concluded that "the implication is that for some period of time, recovering systems might possibly exceed tissue criteria concentrations even though the effects of selenium have been mitigated". As selenium concentrations in fish tissue are expected to change only gradually over time in response to environmental fluctuations, it is not clear whether any fish tissue data are required if the selenium water concentration is below the water column-based elements. An approach similar to that used by the State of Kentucky could be adopted where a requirement for fish tissue analysis, to determine whether the chronic criteria for selenium are being met, is triggered when a threshold selenium water concentration is exceeded (5.0 pg/L total selenium) (Payne 2013). Considering that regulated activities may require implementing improvements to existing operations to	

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	achieve compliance with the draft criterion, the U.S. EPA should consider implications of the proposed WQC for recovering systems and how the tiered approach should be applied to these conditions. Since fish tissue concentrations may remain high in recovering systems while water quality monitoring indicates compliance with the water column element of the draft WQC, clarification is needed as to when tissue analysis is no longer required to assess compliance. It is logical, and consistent with the apparent intent of the draft WQC that for recovering systems, once selenium water concentrations in the environment comply with the water column element value, tissue concentrations should not be necessary to assess compliance.	
335	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 8/7/2014 Much of the literature for toxic thresholds of selenium concentrations in fish E/O tissue report results only on a wet-weight basis. We have two concerns regarding the conversion of these results to a dry-weight basis. First, Doroshov et al. (1992) presented data showing that percent moisture in bluegill eggs continuously vary throughout the reproductive cycle, thus assumed percent moistures can be quite inaccurate without measuring it or knowing fairly precisely at what point in the reproductive cycle they were collected. Secondly, categorically the moisture content of fish eggs is substantively different for eggs chemically analyzed prior to water hardening as compared to after water hardening. EPA's estimates of percent moisture for studies reporting results only on a wet-weight basis provide no indication of whether they match typical pre- and post-water hardening percent moisture values to the types of eggs being sampled in particular studies.	
Comment Category 2.4 – Comments Concerning Water Column Criterion Elements Summary: Comments concerning the water column criterion element as it appears in the 2014 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.		
8	EPA-HQ-OW-2004-0019-0256-A1 [Comment 0346-A2 is a duplicate of 0256-A1]; Peabody Energy Corporation; Posted 6/16/2014 Intermittent Concentration: With regard to the intermittent concentration standard, EPA only mentions the fact that this standard is unnecessary for discharges that exhibit relatively smooth concentration curves. This explanation should be expanded upon to show that, because the intermittent concentration is based on a 30-day analysis, discharges that exhibit seasonal variations over multiple months should not be subject to this analysis. Some regions show a strong seasonal relationship in selenium concentrations due to natural conditions including, but not limited to, higher concentrations in spring due to increased baseflow, increased residence time during snowmelt events, geochemical	Responses concerning the water column criteria elements: Regarding the issue of a 30 day vs a 60 day averaging period, EPA has followed the 1985 Guidelines in setting the water criterion averaging period. The 30-day averaging period provides a protective margin given the nature of the effect, reproductive malformation, and the uncertainty in the data, especially in the kinetics associated with uptake from the water to inorganic and

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<tr><td></td><td>changes in alluvial waters during drying and wetting seasons, or higher concentrations in summer and fall due to increased evaporation rates in pooled water.

Sites with seasonal variation in selenium concentrations may show large differences in concentrations across seasons but smooth changes in concentrations within the season. In these situations the day-to-day variation in concentration is relatively small, and is better characterized by applying the chronic water column criteria using the 30-day average. It should be made clear that the intermittent concentration is only meant to be applied to discharges that show rapid fluctuation on the order of a day(s).</td><td rowspan="3">organic particulate, and subsequent trophic transfer to sensitive receptors (fish). Because tests with water-only exposure are not the basis for the selenium criterion, the considerations for deriving the water averaging period are based on rates of bioaccumulation, as described in the Appendix G of the 2016 final criteria document. The analysis of that Appendix indicates that the 30-day averaging period is protective.

Regarding the comment that the chronic Water Column Element Should Be Expressed as a Four-Day Average, EPA has followed the 1985 Guidelines in setting the water criterion averaging period. Because tests with water-only exposure are not the basis for the selenium criterion, the considerations for deriving the water averaging period are based on rates of bioaccumulation, as described in the Appendix G of the 2014 draft (Appendix J in the 2016 document). The analysis in that Appendix indicates that the 30-day averaging period is protective.

Regarding the statement referring to life cycle tests with mysids and daphnids, these are in reference to tests with pollutants that are toxic through the water only exposure scenario. Because selenium results in chronic toxicity through bioaccumulation via the diet, not through direct water column exposure, and because the bioaccumulation rate is related to both dietary exposure and depuration rate, the 30 day averaging period accounts for these variables to ensure that selenium in the water column is controlled to minimize the amount of selenium available for uptake and conversion to organic selenium in the particulate phase, the key step in the bioaccumulation process of selenium in aquatic systems.

The 30-day average is intended to reflect an average of water column samples over any given 30-day rolling time period, and does not imply that 30 days of consecutive water samples need to be collected to determine whether the criterion is met. EPA's ammonia criteria has included a 30-day averaging period for the last 15 years. Thus, problems are not anticipated in applying the same 30-day averaging period for selenium as for ammonia.</td></tr>
<tr><td>10</td><td>EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 8/7/2014

<u>Overarching Comments:</u>

The Service finds the DSP to be substantively improved in several respects compared to the 2004 proposal.

We commend EPA for its innovative approach to resolving the mismatch between traditional methods for deriving an acute criterion and the ecotoxicology of bioaccumulative contaminants such as selenium. Generally, we support EPA's new "Intermittent-Exposure" approach although it is not clear to us whether limiting the monthly mean is the appropriate temporal window to effectively safeguard against hazardous bioaccumulative loading of selenium into aquatic food webs during short-term acute spikes of waterborne selenium concentrations. It would be helpful if EPA could provide the scientific basis for focusing on monthly mean selenium concentrations as opposed to alternative time frames, especially shorter time frames given the known rapid bioaccumulation dynamics of selenium.</td></tr>
<tr><td>12</td><td>EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014

3.4.3 30-Day Duration for Water Concentrations

We commend EPA for evaluating data relevant to setting the appropriate averaging period for the water criterion. With the recent ammonia criteria document also evaluating such data, we are hopeful that EPA is setting a precedent to evaluate the relevant underlying data and derive a pollutant-specific averaging period in every future criterion document.

We find the analysis that EPA has done to be appropriate but question why the averaging period is not 60 days rather than 30 days. EPA has presented a characteristic time of 60 days. USEPA (1995) indicates that the averaging period should equal the characteristic time. We cannot find a reason why the averaging period should be shortened to one-half the characteristic time, or 30 days. Such shortening of the averaging period to 30 days appears to be arbitrary. Because EPA's characteristic</td></tr>
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	time derivation incorporated the environmentally conservative assumption of instantaneous kinetics at the sediment and primary producer level, we believe that a 60-day averaging period would be highly protective.	Regarding the intermittent exposure criterion, EPA recognizes that not all exposures are continuous and developed the intermittent criterion element due to concern that intermittent inputs may not be accounted for with the national 30-day average chronic criterion water column element, yet intermittent discharges of sufficient magnitude and frequency could cause selenium to accumulate through the food web and ultimately result in chronic impacts on aquatic life. EPA believes 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 (rarely observed in natural systems), the most deleterious effect on aquatic organisms is due to its bioaccumulative properties; these effects are found 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 criteria, as described in Section(s) 2.7.10, and 3.3 of the 2016 final criteria document, 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 chronic risk to downstream waters. Modifications of the criterion can be made on a site-specific basis, with data from the site. As mentioned above, biokinetic modeling, if used should be adapted to a site using appropriate data – the values EPA presented represented default values that will be generally protective in these situations. As described in Section 2.7.10 and 3.3 of the 2016 final criterion document, the intermittent criterion was developed to address situations where a system is subject to elevated concentrations for short durations. The kinetic considerations used to set the averaging period for the chronic water criterion, from which the intermittent criterion is calculated, address a different facet of the
13	EPA-HQ-OW-2004-0019-0334-A2; Appalachian Mountain Advocates et al.; Posted 7/30/2014 III. 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 4, 8. 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)"[6] and "Technical Support Document For Water Quality-based Toxics Control (1991)."[7] 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)." 79 Fed. Reg at 27,602. 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	

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	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 44 (describing a 28-day study of "fry surviving at swim-up"); 48 ("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-	time variability problem than do the considerations for using the EC_{10}. The selection for use of the EC_{10} considered the appropriate level of effect for a criterion that fish tissue concentrations may approach for extended periods of time. The environmental concern is thus greater than that involving water criteria that typically are only infrequently approached by rapidly varying concentrations in the water column. It is for this reason that EPA has derived its selenium tissue criteria based on the EC_{10} while it continues to derive water criteria for other pollutants based on the EC_{20}. Further, the steepness of the dose-response curve argues for a more protective value, not less, because small increases in concentrations can have larger impacts than for toxicants with shallower dose-response curves. 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. EPA has since revised the 2014 Appendix G (now Appendix J in the 2016 final document) kinetic model to include a water-TL1 step. The 2016 document's language about the intermittent criterion not being intended to apply to ordinary smoothly varying concentrations has been deleted. The intermittent criterion provides the same protection as the 30-day chronic criterion (from which it is derived). Regarding the comment on the biokinetic approach, EPA's kinetic analysis was presented in Appendix G of the 2014 draft (now Appendix J of the 2016 final document). It was similar to the work of

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	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* The use of a 30-day average will also fail to adequately protect aquatic life because it 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 µg/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. §	Brix and DeForest (2008) and 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 2016 Appendix J are based on the same fathead minnow study by Bertram and Brooks (1986). Regarding the biokinetic model and intermittent criteria, the kinetic analysis in Appendix J of the 2016 final document specifically addresses intermittent exposure. When applied to intermittent exposure, the analysis demonstrates the protectiveness of the 30-day averaging period that EPA recommends. **Responses concerning the derivation of the whole body criterion element:** 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] data from the same fish. The whole body [selenium] 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] was determined. Hermanutz (1996) and Hardy (2005) apparently measured whole body and egg selenium in different fish with the same exposure. EPA has added a clarifying discussion to the section discussing fish tissue relationships. Regarding the concern that intermittent dissolved selenium criteria would allow for dissolved concentrations that would pose high risk to aquatic organisms. The intermittent criterion is simply a rearrangement of the 30 day criterion and so it provides the same level of protection. Regarding the definition of a whole body tissue sample, the entire fish (carcass and visceral tissue) is homogenized, and then a

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	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. [6] Available at: http://water.epa.gov/scitech/swguidance/standards/criteria/aqlife/upload/85guidelines.pdf [7] Available at: http://www.epa.gov/npdes/pubs/owm0264.pdf	sample of the homogenized tissue is collected and analyzed for selenium. The whole body criterion element is ranked as a lower tier than the egg-ovary criterion element because of the additional uncertainty associated with variable selenium concentrations across tissue types. Regarding the suggestion for EPA to consider using empirically measured whole-body selenium (or muscle selenium) data for those species where they are available, the EPA has adopted that approach in the 2016 final criteria document. It has also retained the use of the median CF (for those species without directly calculated empirical values, after a thorough analysis of other methods such as OLS; proposed by commenters), and TLS. The analysis is located in Appendix N of the final 2016 criterion document Regarding the practicality of the intermittent criterion element, EPA envisions the intermittent criterion element being most useful in waters where selenium inputs may be precipitation driven, or in situations where there may be infrequent discharges. Daily monitoring data is not necessary for use of the intermittent criterion element. **Response concerning the intermittent exposure water column criterion element:** Regarding the intermittent exposure criterion, 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
93	EPA-HQ-OW-2004-0019-0260-A2 [Comment 0314-A2 is a duplicate of 0260-A2]; Conley and Buchwalter; Posted 6/16/2014 2. Given the comment above in 1a, we believe the derivation of intermittent dissolved selenium criteria allow for dissolved concentrations that would pose high risk to aquatic organisms. For example, a stream (lotic site) with a background concentration of 0.1 µg L-1 and experiencing contamination from a source that is leaching selenite (e.g., coal fly ash) would be allowed to run at ≤ 15.9 µg L-1 for 9 days to remain in attainment. The speed and extent to which primary producers bioconcentrate selenite could lead to basal foodweb concentrations as high as 37.2 µg g-1 (see Table 1 below for 9 day selenite enrichment factor (2345-fold) from our studies) which would likely lead to dietary selenium concentrations exceeding the threshold for even the most tolerant fish species. We believe that an intermittent criteria calculation that allows for large increases in dissolved selenium concentration, even for short periods, is poses high risk to aquatic organisms given the rapid nature of selenite bioconcentration into primary producers..	
346	EPA-HQ-OW-2004-0019-0266-A2; Transportation and Storm Water Department, City of San Diego, California; Posted 6/17/2014 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. 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[16] (1985 Guidance Document) and the Technical Support Document for Water Quality- based Toxics Control[17] (1991	

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	TSD). In the 1991 TSD, USEPA explicitly states (emphasis added): "To predict or ascertain the attainment of criteria it is necessary to speck 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." 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[18] (RWQC) released by USEPA in 2012. This concept can be applied as a frequency by stating that there should not be greater than a 10 percent excursion frequency of the selected STV magnitude. Requested Actions: • 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). • 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. [16] USEPA. 1985. Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses. Office of Research and Development. PB85-227049 [17] USEPA. 1991. Technical Support Document for Water Quality-based Toxics Control. Office of Science and Technology, Office of Water. USEPA-505-2-90-001. [18] USEPA. 2012. Recreational Water Quality Criteria. Office of Science and Technology, Office of Water. USEPA-820-F-12-058.	exposure. Although selenium may cause acute toxicity at high concentrations the most deleterious effect on aquatic organisms is due to selenium's bioaccumulative properties; these effects occur at lower concentrations than acute effects. Thus, the intermittent criterion element will be protective of these high exposures. 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 criteria, 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. Regarding the intermittent criteria, 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 chronic risk to downstream waters. Modifications of the criterion can be made on a site-specific basis, with data from the site. As mentioned above, biokinetic modeling, if used should be adapted to a site using appropriate data – the values EPA presented represented default values that will be generally protective in these situations. 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. Because (a) the derivation of the 30-day averaging period, and the subsequent derivation of the intermittent criterion, and (b) the
14	EPA-HQ-OW-2004-0019-0277-A1; Arkansas Department of Environmental Quality; Posted 6/24/2014 Executive Summary: 1. Summary table: The frequency for the water column should be better defined for assessment purposes. The frequency is defined as "Not more than once in three years on average" – what extra steps are being proposed by adding "on average" to the frequency of not more than once in three years? The criteria is already a monthly average, therefore, this is suggesting that for assessment one takes the average of an average; but what data are to be averaged the second time?	

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	5 National Criterion for Selenium in Fresh Waters 1. Where are these footnotes defined? Also define "on average." See Executive Summary comments.	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. Unfortunately, residence time was not a common metric available in the available studies. UWAG commented that "there is adequate evidence that the toxicity of intermittent acute exposure to selenium is less than continuous exposure.". 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 water column exposure, additional toxicity testing is not needed, as suggested in some comments.
95	EPA-HQ-OW-2004-0019-0320-A2; National Mining Association (NMA) and GEI Consultants, Inc. (GEI); Posted 7/29/2014 5.0 Additional Comments on Intermittent Exposure Element As described in our original review (GEI 2014), the intermittent exposure element for water column criteria is an oversimplification of environmental conditions and use of a biokinetic model, such as that being developed by DeForest et al. (in prep), would be more appropriate. The biokinetic model in development includes uptake and elimination coefficients from a variety of studies and test species and can be used to calculate Se concentrations of either selenate or selenite, as uptake of these selenium species can vary considerably, that would be protective of the chronic tissue criterion. For comparison to the protective concentrations calculated using the biokinetic model, Table 7 provides intermittent exposure-based water column criteria calculated using a background Se concentration of 1 µg/L and either 1-day or 4-day pulses. Approximations of protective Se concentrations for 1-day and 4-day pulses calculated using three different versions of the biokinetic model, a periphyton-mayfly-fathead minnow model, phytoplankton-daphnia-bluegill model, and a "combined" model which includes all species (DeForest et al. in prep), are provided in Table 8. Although selenate and selenite are not specific to either lotic or lentic systems and cannot be directly compared to the lotic and lentic criteria, selenate does tend to predominate in well-aerated lotic systems and selenite is more prevalent in slow-moving lentic waters. Therefore, the protective selenate concentrations could be considered representative of a lotic value and selenite could be representative of a lentic value. The protective selenate and selenite concentrations calculated using the most conservative biokinetic "combined" model (Table 8) are approximately three times higher than the lotic criteria calculated using EPA's intermittent exposure equation, and the protective selenite concentrations calculated using the "combined" biokinetic model are a factor of 10 higher than the lentic criteria calculated using EPA's intermittent exposure equation.	
96	EPA-HQ-OW-2004-0019-0320-**A2**; National Mining Association (NMA) and GEI Consultants, Inc. (GEI); Posted 7/25/2014 EPA should use a more robust method of calculating the intermittent exposure, such as use of a biokinetic model.	
99	EPA-HQ-OW-2004-0019-0344-A1; Sanitation District No. 1 of Northern Kentucky (SD1); Posted	

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	8/5/2014 Intermittent-Exposure Water-Based Criterion Element Should be Withdrawn While expressing reservations over the potentially disproportionate influence of varying bioaccumulation rates at low and high exposure concentrations in developing tissue based criterion, U.S. EPA 2014a instead adopts the contradictory approach in the development of the Intermittent-Exposure Water-based Criterion Element that involves no data censoring at all. On pages 93-94 of U.S. EPA 2014a, the draft criterion states that "The reasonable worst-case assumption inherent in this approach is that selenium bioaccumulation is linear over a wide range of concentrations: that is, EFs and TTFs do not decrease significantly as concentrations increase". Further evaluation of the kinetics of uptake and depuration provided in Appendix G (U.S. EPA 2014a) demonstrated that no specific studies were used to determine the influence of rapidly changing exposure concentrations on the resulting uptake rate of selenium in fish dietary items, and that a set of highly conservative assumptions were instead employed in the development of the intermittent-exposure criterion. Without a scientific basis for the potential responses and changes in uptake and depuration (purification) rates to pulses of selenium, the intermittent-exposure water-based criterion is highly speculative, and places a significant unsupported burden on the regulated community that does not achieve any improved protection of the environment over the monthly average exposure. As such, this criterion is not currently warranted by the science or goals of protecting the aquatic life community, and should be withdrawn at this time until additional scientific studies are available to support its development.	
100	EPA-HQ-OW-2004-0019-0326-A1; Utility Water Act Group (UWAG); Posted 7/30/2014 More Information Needed On Novel Intermittent Exposure Approach In an effort to address cumulative effects from intermittent exposures, the agency has constructed a novel, intermittent exposure criterion element, intended to limit cumulative exposure by limiting shorter term or pulsed exposures that could result in bioaccumulation. The guideline methodology is a recalculation of the 30-day average chronic water criterion element to establish a limit on an intermittent elevated concentration that occurs a specified percentage of time. UWAG is interested in EPA's approach but, as discussed more fully below, much more information is needed to assess its appropriateness. The Draft Report fails to explain what EPA is attempting to accomplish or how the new criterion will be implemented. For example, does EPA believe the intermittent exposure criterion element is an alternative to the chronic criteria under specific discharge scenarios and, if so, exactly what discharges does the Agency intend to address with this intermittent exposure approach? UWAG believes there are certain discharge scenarios, "batch" discharges, for example, where an intermittent criterion should be	

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	applicable as an alternative to the chronic criteria element. The Draft Report should include expanded discussion on this subject. Furthermore, there is adequate evidence that the toxicity of intermittent acute exposure to selenium is less than continuous exposure. Based on this, UWAG believes the science would support a decision to withdraw the acute criterion and adopt an intermittent exposure guideline instead. If that is the Agency's intent, then the Draft Report needs to make that clear. UWAG appreciates EPA's attempt to look at pulse exposures, and we point out that there are several examples in the literature where a parameterized kinetic-based (or bioavailability-based) model has been used to predict the toxicity of pulsed and/or intermittent exposures of trace metals to freshwater organisms (e.g., EPRI, 2009; WERF, 2006). For the benefit of states, tribes, and other stakeholders, UWAG recommends that EPA include expanded discussion of how the criterion would be implemented in the final criteria documents. In any case, we agree with EPA that the draft criteria are not meant to protect aquatic dependent wildlife (piscivorous birds and mammals). Any concerns with wildlife exposed to selenium should be addressed at the state or site-specific level.	
102	EPA-HQ-OW-2004-0019-0334-A2; Appalachian Mountain Advocates et al.; Posted 7/30/2014 IV. 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 92. 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.	
104	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 *3.3.2 Discussion of Intermittent-exposure Element*	

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	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 (page 93 of the 2014 draft Se criteria document) 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. Brix and DeForest (2008) developed a Se biokinetic model using a food chain consisting of periphyton, mayflies, and minnows in order to evaluate the concentrations and durations of Se pulses that would be required to potentially achieve whole-body fish Se concentrations of interest (e.g., a tissue-based criterion). Inputs to the model included the background waterborne Se concentration, the Se concentration in the pulse, and the duration of the pulse. This model is currently undergoing revision to include data from Se biokinetic studies published since the earlier effort, as well as develop additional food web models for lotic and lentic systems and a "combined" model which includes parameters for both lotic and lentic organisms (DeForest et al. in prep). These models can be used to predict the fish tissue Se concentrations that could result from Se pulses into a water body and can potentially be used to derive an acute (or "intermittent") water column-based Se criterion that is protective of the chronic fish tissue-based criterion. In addition, these models differentiate between selenate and selenite, which has previously been recommended by the EPA for water column-based Se criteria, and is part of the current Se criteria. There are significant differences between the intermittent or pulse concentrations that would result from use of the EPA equation (page 93 of the 2014 draft Se criteria document) compared to the biokinetic models. If a background concentration of 1 µg/L is assumed, and there are four instances of elevated Se (exceedances of water column Se criterion) in a month, the resulting intermittent water quality criteria (or allowable pulse concentrations) would be 29.5 µg/L for lotic systems and 3.25 µg/L for lentic systems using the EPA equation. Using the biokinetic models with the same background assumption and a 4-day Se pulse, the concentrations predicted to be protective of the whole-body-based fish tissue criterion range from 40 to 350 µg/L for a selenate pulse, and 20 to 180 µg/L for selenite pulse, depending on the model used. The numbers predicted by the biokinetic model are substantially higher than those predicted by the EPA equation, but protective of the chronic tissue standard. EPA should reconsider the intermittent exposure approach and consider a more scientifically-based toxicological approach such as biokinetic modeling.	
455	EPA-HQ-OW-2004-0019-0356-A1; Idaho Department of Environmental Quality (DEQ); Posted 09/30/2014 The intermittent water column exposure criterion does not appear to be very practicable. It is highly	

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	unlikely Idaho 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 simplify their proposal by dropping the intermittent criteria.	
94	EPA-HQ-OW-2004-0019-0271-**A2**; Coordinator, Barnes & Thornburg LLP on behalf of the Federal Water Quality Coalition; Posted 6/17/2014 EPA should clarify the purpose of the "intermittent" criterion, and how that criterion will be implemented. One issue is how the Agency would determine if selenium is at an "elevated concentration." Another issue is how the criterion would be applied if the background concentration is high; it appears that a zero concentration target could be imposed in such circumstances. If so, the Agency needs to explain why that would be appropriate and attainable.	
98	EPA-HQ-OW-2004-0019-0322-A1; American Petroleum Institute (API); Posted 7/30/2014 The criteria document calls for application of intermittent criteria when "elevated concentrations" occur with some frequency. What constitutes "elevated" and what frequency of that concentration calls for these criteria? If a high background concentration occurs, the calculation could yield a very small or even a negative intermittent selenium criterion. Guidance is needed to address these circumstances. API recommends the intermittent criterion be no less than the water column criterion.	
101	EPA-HQ-OW-2004-0019-0326-A1; Utility Water Act Group (UWAG); Posted 7/30/2014 <u>Criteria Development Methodology – Intermittent Criterion; May Be Workable But More Information is Needed</u> As an initial matter, the Agency states that the draft intermittent water criterion was derived "[t]o address intermittent exposures that could contribute to chronic effects of selenium due to its bioaccumulative nature …." Draft Report, p. 92. We note that intermittent exposures of selenium are associated with fewer reproductive effects compared to continual exposure (e.g., Hoang et al., 2007; Hoang and Klaine, 2008), and thus risk evaluations for both exposure scenarios need to be made independently. Based on our initial review of the limited information provided, UWAG commends the agency for recognizing the need to evaluate risks and address "pulse" exposures separate from more typical chronic exposures. It remains unclear to us exactly how the agency intends to implement the criterion in the regulatory program, however. For example, one scenario would be to use the intermittent criterion to derive an in-stream water quality criterion that would be applied as an alternative to the fish tissue criteria under certain exposure scenarios. Or, instead, perhaps the agency intends to apply the criterion methodology to derive permit limits under certain circumstances where doses are	

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	intermittent for a discreet period of time. In addition, we believe the intermittent criterion equation can be improved by modifying the fint variable such that it includes the fraction of a 24-hour day that a discharge occurs. For example, if a controlled discharge is completed within one hour, the potential toxic effect (if there is one) would be considerably reduced relative to a continual 24-hour release. Without more information, it is difficult to provide meaningful comments and recommendations for how to improve implementation of this criterion. We look forward to additional opportunities to expand on our evaluation once the Agency provides necessary clarification.	
92	EPA-HQ-OW-2004-0019-0258-A2; National Association of Clean Water Agencies (NACWA); Posted 6/16/2014 Expression of the Draft Criterion, Intermittent Criterion Need Further Explanation EPA expresses the fish tissue concentrations as “never to be exceeded” levels (criteria frequency component is essentially zero), noting that “fish tissue data provide point measurements that reflect integrative accumulation” and that selenium concentrations “in fish tissue are expected to change only gradually over time”. NACWA requests that EPA provide the data used to document that a selenium criterion with a return frequency of zero is necessary to protect aquatic life populations and communities. The way the language is written 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 more appropriate approach would be the use of the geometric mean value of individual fish tissue concentrations for assessment of the fish tissue criteria. The “never to be exceeded” approach also precludes the consideration of tissue data collected at other times or within the same 303(d) receiving water segment when making a water quality standard attainment decision. EPA should clarify the purpose of the intermittent criterion and how it will be implemented. Several questions arise when considering this element: How will the Agency determine if selenium is at an “elevated concentration”? How will the criterion be applied if the background concentration is high? It appears that a zero concentration target could be imposed in such circumstances, and if so, the Agency needs to explain why that would be appropriate and attainable. The review conducted by GEI Consultants, Inc. provides some insight into the problems with EPA’s methodology and a potential alternative for addressing short-term, elevated selenium exposures.	

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571	EPA-HQ-OW-2004-0019-0344-A1; Sanitation District No. 1 of Northern Kentucky (SD1); Posted 8/5/2014 Overall, SD1 agrees with the general approach taken in setting the initial criteria based on the egg/ovary Se concentrations that represent documented adverse embryological effects on fish species. A recent review by DeForest and Adams 2010 of fish tissue concentrations collected from reference water bodies of the United States and Canada found that whole-body and egg/ovary Se concentrations of *"8.1 and 17 µg/g dw, respectively, nicely distinguish the reference and no-effect sites from the effect sites".* The EPA egg/ovary criterion of 15.2 µg/g dw, while somewhat below the value assessed in DeForest and Adams 2010, is an appropriately data-based criterion to protect aquatic life uses from selenium exposures. However, it is our opinion, based on the available data and scientific literature, that the approaches and information used to translate these tissue based concentrations into equivalently protective water column concentrations require additional effort and review before this criterion should be finalized by EPA and adopted by the states and tribes. Our review also found the Intermittent-Exposure Water Criterion is based on a highly speculative approach that would place an unwarranted burden on the regulated community, and it is our opinion that this part of the Se criterion should be withdrawn at this time. Lastly, we believe that it is critical that EPA provide additional guidance on how to develop sites-specific tissue residue based criterion in addition to the site-specific water quality criterion already provided in Appendix I of the draft peer review document (U.S. EPA 2014a). Our specific comments and proposed actions necessary to finalize this criterion and accompanying guidance are presented below.	
Comment Category 2.5 – Comments Concerning Items Considered out of Scope Summary: This section includes comments that can be considered “out-of-scope” given the purpose and objectives of this document. A range of topics are commented on such as acute criterion, selenium impacts on wildlife and human health, and the role sulfate might play in selenium toxicity to aquatic organisms.		
1	EPA-HQ-OW-2004-0019-0271-A2; Coordinator, Barnes & Thornburg LLP on behalf of the Federal Water Quality Coalition; Posted 6/17/2014 We agree with EPA that acute criteria are not necessary. However, the Agency might want to consider providing guidance for those States that decide to retain an acute criterion. In that circumstance, it would be appropriate to develop a criterion using the current criterion as a starting point, and modifying that level based on analysis of more recent studies.	Response to comments that are out of scope: As shown in Table 2.1 of the 2016 final 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. EPA also notes many public comments support EPA’s conclusion, that it is unnecessary to have an additional acute criterion element which addresses acute, water column-only events, because
2	EPA-HQ-OW-2004-0019-0313-A2; Wisconsin Department of Natural Resources (WDNR); Posted 6/27/2014 Acute criterion • The EPA’s proposal only includes a chronic criterion for selenium, the WDNR recommends that	

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	the EPA also develop an acute criterion for selenium. • An acute criterion may account for differences in sensitivity between organism types (e.g. fish versus invertebrates) due to the differences in the mechanism of toxicity between acute and chronic exposure to selenium. In this regard, there is a large body of data concerning the acute toxicity of selenium to aquatic organisms that was not addressed in this criterion document. • According to 40 CFR 122.45(d), effluent limits must be expressed as daily maximum, weekly average, and monthly averages in NPDES permits. Therefore, including an acute criterion will assist in the calculation of Wisconsin Pollutant Discharge Elimination System (WPDES) permit limits. Without it, the WDNR would have to "back-calculate" a daily maximum limit using the chronic criteria.	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.
3	EPA-HQ-OW-2004-0019-0326-A1; Utility Water Act Group (UWAG); Posted 7/30/2014 <u>Clarity Needed Regarding Existing Acute Criterion</u> EPA also recognizes that selenium acute toxicity is rare and that traditional methods for predicting acute effects, i.e., based on acute water column-only exposure data, do not work well for selenium and have little environmental relevance. It appears EPA does not believe a national acute criterion guideline is necessary or appropriate for selenium, and is recommending a site-specific criterion be developed in those rare instances where selenium sources could cause acute effects without also exceeding the selenium chronic criterion. Draft Report, p. 98. UWAG supports such an approach. We agree instances of acute toxicity are rare where applicable water quality standards are implemented and that very few, if any, situations will arise where acute exposure would not also exceed the chronic criterion. Nonetheless, UWAG recommends the agency clarify in the upcoming proposal whether the existing national acute criterion (based on the relative proportion of selenate and selenite in a receiving stream) is still valid. In any case, recognizing there may be states that continue to implement the acute criteria in need of guidance, EPA should clarify that the Criterion Maximum Concentration ("CMC") values for selenate and selenite expressed in EPA's draft selenium criteria (U.S. EPA, 2004) are appropriate for use. <u>Acute Water Column Criteria Unnecessary</u> EPA has chosen not to use acute toxicity test data in developing the selenium criteria because acute effects are not of concern regarding long-term exposure to selenium. Draft Report, p. 22. This is an improvement over past approaches. EPA has identified other approaches, including the approach discussed in the Draft Report, that recognize short-term, acute toxicity exposures are rare and that it would be highly unlikely that such an exposure would not exceed the chronic criteria. UWAG believes focusing on chronic effects is appropriately protective. However, if the agency determines there is a need to connect tissue-based standards to acute exposure scenarios, then we recommend the	Regarding EPA's approval of Oregon's revised speciation-based CMC equation, EPA had not yet released its 2014 External Peer Review draft for selenium for public comment and external peer review at the time of this approval. Regarding UWAG's comment" : "UWAG recommends the agency clarify in the upcoming proposal whether the existing national acute criterion (based on the relative proportion of selenate and selenite in a receiving stream) is still valid." EPA is clarifying here that the 2016 final selenium criterion supersedes all previous selenium criteria. The 2016 criterion does not include an acute criterion discussing relative proportions of selenate and selenite. Previous draft or final selenium criteria are no longer recommended. Regarding the influence of sulfate on selenium bioaccumulation, sulfate-selenium interactions are addressed in Section 6.2.2 of the 2016 final criteria document. EPA decided not to include a sulfate correction factor in the 2016 final selenium criterion due to uncertainties in the science. The Deforest et al 2014 report referred to 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*

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	Agency should work to develop more reasonable criteria through a model that does this and is still protective of acute exposures. In the meantime, we understand there may be a need for EPA to provide guidance to states that retain an acute water column criterion. In particular, EPA should clarify that the CMC values for selenate and selenite expressed in EPA's draft selenium criteria (U.S. EPA, 2004) are appropriate for use. Recent EPA decision on this topic have been inconsistent. For example, the Kentucky Department of Environmental Protection updated its acute warm water aquatic habitat criteria for selenium in 2013. Kentucky based its proposal on EPA's 2004 draft acute criteria; however, EPA disapproved the revised criteria indicating further research suggests the criterion may change. See Letter to Mr. Bruce Scott, Commissioner, Kentucky Department of Environmental Protection, from Mr. James D. Giattina, Director, U.S. EPA, Region 4, October 25, 2013. Even more recently, EPA Region 10 approved revised acute criterion, applicable to Oregon, consistent with EPA's nationally recommended approach. See Letter from Daniel D. Opalski, Director, Office of Water, Region 10, April 11, 2014. EPA's very recent approval suggests the Agency believes the methodology is both scientifically sound and consistent with the Clean Water Act. UWAG seeks clarification on whether EPA's approval of Oregon's revised criterion indicates the speciation-based CMC equation from the nationally recommended water quality criteria table is still valid, such that states and permittees may utilize the equation for statewide adoption or site-specific applications. Or, whether EPA's disapproval of Kentucky's use of EPA's 2004 approach represents a national policy shift away from the 2004 CMC approach, or perhaps, from inclusion of an acute criterion for selenium as a whole. If the last, then EPA should make the agency's intent clear by withdrawing the acute criterion entirely and focusing on the chronic criterion. If, on the other hand, EPA intends to pursue a more reasonable recommended acute criterion, it would be appropriate for EPA to review the most recent science and issue a revised recommended water-based acute criterion, consistent with our comments above, once the revised chronic criteria are finalized.	*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*." Regarding risk to aquatic dependent wildlife, EPA understands the potential for risk to aquatic-dependent birds from selenium exposure and has begun to investigate the potential for a national criteria that would protect aquatic-dependent wildlife. Regarding the comment that criteria must protect aquatic-dependent wildlife, EPA acknowledges that its national criteria recommendations for selenium are not designed to account for the protection of aquatic-dependent wildlife. However, EPA disagrees with commenters that the Clean Water Act precludes it from issuing water quality criterion recommendations for a pollutant until such time as EPA is prepared to issue recommendations of universal scope (i.e., covering every manner in which that pollutant might interfere with any designated use in any location of any state.) Collectively, a state's water quality standards "shall be established taking into consideration their use and value for public water supplies, propagation of fish and wildlife, recreational purposes, and agricultural, industrial and other purposes." CWA 303(c)(2)(A). But this does not preclude states from developing criteria that are designed to respond to a particular subset of the overall concerns relating to selenium pollution. See NRDC v. EPA, 16 F3d 1404 (4th. Cir 1993). Criteria designed to protect aquatic dependent wildlife have the potential to be more site-specific in their derivation than criteria designed to protect aquatic life, and so it is not unreasonable to anticipate that states may seek to address the protection of aquatic-dependent wildlife by separate standards from those that those that address aquatic life. This practice need not be in conflict with the state's overall obligations under CWA 303(c)(2)(A). EPA, in turn, reviews new and revised state criteria under CWA 303(c)(3), consistent with the scope of protection that
4	EPA-HQ-OW-2004-0019-0332-A2; J.R. Simplot Company; Posted 7/30/2014 VIII. Focus on Chronic Value- Future of Acute Value On page 98, the document states, "EPA is not recommending a separate acute criterion derived from the results of toxicity tests having water-only exposure, because selenium is bioaccumulative and toxicity primarily occurs through dietary exposure." We commend EPA on taking this stance. However, should EPA alter that stance in future revisions of this document, we believe they should carry forward the work from the 2004 Draft National criteria and integrate sulfate into the acute equations.	

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6, 7	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 8/7/2014 (7) Risk to aquatic-dependent wildlife As the ecosystem-scale modelling approach makes clear, when EPA sets its primary criterion, which is the chronic criterion for fish E/O tissue, the effects will cascade throughout the aquatic ecosystem and therefore indirectly set the limits for selenium concentrations that can be expected to be observed in every compartment of the ecosystem. So, for example, if translation of the E/O chronic criterion leads EPA to set a fish whole body criterion of 8.1 mg Se/kg, then using EPA's median TTF of 1.27 for transfer of selenium from aquatic invertebrates to fish (from Table 10, p. 77), we can expect that the median limit for aquatic invertebrates has now been set at about 6.4 mg Se/kg (i.e., 8.1/1.27). Ovulating female water birds rely almost exclusively on an animal diet due to the high protein demands of egg formation, and like the species of fish studied by Conley et al. (2014) and Penglase et al. (2014), water birds move selenium into their eggs directly from their diets, not from internal tissue stores of selenium (Chapman et al. 2010). Thus, using the dietary exposure-response curve developed for mallards and reported in Ohlendorf (2003) we can directly estimate the toxic risk to mallards posed by a whole body fish tissue criterion of 8.1 mg Se/kg. Based on a table of exposure-response values provided by Dr. Ohlendorf for his 2003 publication, a mallard dietary exposure to 6.4 mg Se/kg would correspond to 27% reduction in egg hatchability (EC-27) and the 10th percentile TTF of 0.901 calculated from the data presented in Table 10, p. 77. The corresponding value of 8.99 mg Se/kg in aquatic invertebrates would lead to a 62% reduction in mallard egg hatchability. At the median TTF of 1.27, a whole body fish tissue criterion of about 4 mg Se/kg would be required to have a safe dietary exposure of about 3 mg Se/kg for mallards. The Service notes that this is similar to the conclusion we presented in our comment package on EPA's 2004 proposed selenium criteria (that a fish whole body tissue criterion in the range of 4-5 mg Se/kg would be required to adequately protect both fish and aquatic-dependent wildlife), which we incorporate here by reference and, which is still available for viewing in the current Docket (EPA-HQ-OW-2004-0019). Furthermore, a value of 4 mg Se/kg in whole body fish tissue is the guideline value recently published by the British Columbia Ministry of Environment, in part, explicitly to provide sufficient protection for aquatic-dependent wildlife (BC MoE 2014).	the criteria were designed to afford. Whether a state also needs wildlife criteria is a separate question, which EPA has separate authority to consider under 303(c)(4)(B). Regarding the relationship of the selenium aquatic life criterion to human health, EPA derives recommendation including criteria for the protection of human health in a separate process using a model and assumptions associated with human consumption of fish and human associated metrics (bodyweight, water consumption, lifespan, diet). States adopt criteria for human health and aquatic life separately, and adoption of one criteria does not imply protection of more than use for which it was derived (e.g., aquatic life, or human health.)
80	EPA-HQ-OW-2004-0019-0332-A2; J.R. Simplot Company; Posted 7/30/2014 IX. Miscellaneous General Comments Sulfate Effects on Bioaccumulation The 2014 Draft Criterion is silent on integration of sulfate into the chronic criteria derivation process. Discussions of sulfate and potential competitive effects in organisms for binding sites, and	

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	implications that sulfate may have ameliorating effects on selenium bioaccumulation, appear in the document, but it fails to take this knowledge to the logical next step, perhaps because data were not available to do so. Deforest et al. (2014) produced a white paper for the North American Metals Council that provides the data, technical basis and rationale for inclusion of sulfate into a criterion derivation process. This paper and its resulting finding should be considered by EPA in future revisions of the 2014 Draft National Criterion. Using the equations provided in Deforest et al. (2014) for deriving a sulfate based criterion translated from the egg/ovary criteria into a corresponding water quality value, Figure 5 illustrates the difference in predicted aqueous selenium concentrations over a range of sulfate concentrations at two different egg/ovary selenium criteria. Note that the difference in predicted aqueous selenium concentrations becomes greater as sulfate concentration increase (Figure 5).The criterion derivation from Deforest et al. (2014) includes a sulfate based expression that was developed based on laboratory generated exposure data and a range of selenium and sulfate concentrations. Empirical data from the field may also suggest sulfate affects bioaccumulation into the primary level of the food chain (Figure 6).Selenium concentrations in aqueous media are plotted relative to the corresponding sulfate concentrations from a number of sites. Sulfate increases at corresponding concentrations relative to increased selenium due to the groundwater releases to surface water at some of these sites. Enrichment factors are also plotted to illustrate the subsequent decrease in EFs with increasing selenium. While this is expected, note that as the sulfate concentrations increase to above about 35 mg/L along with corresponding increases in aqueous selenium, EF variability is substantially lower and trending down despite the continued increase in aqueous selenium concentrations.	
325	EPA-HQ-OW-2004-0019-0257-A2; Wyoming Department of Environmental Quality (WDEQ); Posted 6/16/2014 Based on the tolerance of invertebrate species to selenium, but the potential sensitivity of wildlife species to selenium, EPA should also consider delaying the release of the final selenium criteria until a wildlife criterion can be developed that can be applied to waters with wildlife uses, yet may not have fish species present.	
327	EPA-HQ-OW-2004-0019-0323-A1; California State Water Resources Control Board; Posted 7/30/2014 Fifth, we note that while U.S. EPA's 2014 Draft Selenium Criterion clearly states that oviparous vertebrates such as fish and birds are the groups most sensitive to effects from selenium, the document also clearly states that:	

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	"The criterion is not intended to address concerns about selenium toxicity to aquatic-dependent wildlife such as aquatic bird species."[6] As fish are an important dietary component[7] for many species of aquatic-dependent birds, and selenium effects in birds have been widely documented in California and other areas, we believe that in order to protect all beneficial uses, including WILD[8], California could not adopt U.S. EPA's recommended selenium criterion without ensuring that it was also protective of both piscivorous and omnivorous aquatic bird species. In addition, we strongly recommend that U.S. EPA reassess the proposed criterion in view of its potential effects on birds, by either providing a bird egg tissue-based element in addition to the fish tissue and water column elements, or a secondary dietary fish tissue element that would be protective of both the fish and the birds that eat them. It does not make sense for U.S. EPA to promulgate a criterion for selenium that has not been reviewed in light of its potential impacts to all aspects of the aquatic food web, which includes aquatic-dependent birds. [6] Executive summary, page 1, second paragraph, last sentence. [7] Fish tissue selenium concentrations also often are used as surrogate concentrations for invertebrate food items as trophic transfer factors from invertebrates to fish (excluding bivalves) are generally around 1.1 — 1.3. [8] WILD = Wildlife Habitat; waters support wildlife habitats that may include, but are not limited to, the preservation and enhancement of vegetation and prey species used by waterfowl and other wildlife	
329	EPA-HQ-OW-2004-0019-0323-A1; California State Water Resources Control Board; Posted 7/30/2014 5. The criterion does not address aquatic-dependent birds and provides no assessment as to whether the proposed tissue criterion elements would be protective of aquatic bird species.	
600	EPA-HQ-OW-2004-0019-0352-A1; Western Coalition of Arid States (WESTCAS) [Comments 0319-A2 and 0321-A1 are duplicates of 0352-A1]; Posted 8/7/2014 The following comments are submitted on behalf of the Western Coalition of Arid States (WESTCAS). We appreciate the opportunity to provide comments on the draft selenium criteria as any changes to the federal water quality standards will impact the operation, and management of wastewater treatment facilities. WESTCAS is a coalition of approximately 125 water and wastewater districts, cities, towns, and professional organizations focused on water quality and water quantity issues in the States of Arizona, California, Colorado, Nevada, New Mexico, Texas and regional water quality and quantity agencies. Our mission is to encourage the wise use and development of water resources in our member states where there is little rain in many months and frequently less than 12 inches for the	

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	entire year. Considering this reality, our particular focus is working to ensure that Federal water policy and regulations are appropriate and reflect the reality of water resources in the Arid West.	
330	EPA-HQ-OW-2004-0019-0334-A2; Appalachian Mountain Advocates et al.; Posted 7/30/2014 VI. 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	

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	• 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 µg/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. The US Fish and Wildlife Service has stated that a protective fish tissue standard for water birds would be	

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	5 µg/g selenium, much lower than EPA's proposed whole body element of 8.1 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. 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.	
331	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 8/7/2014 Additionally, to the extent that EPA's proposed fish-tissue criteria might result in components of aquatic food webs posing a toxic exposure pathway for aquatic-dependent birds (an assessment of this possibility is presented later), migratory birds may be affected. Additionally, there are many species of ESA-listed aquatic dependent wildlife (in addition to birds) that the DSP has not addressed. In Section 7.4 of the DSP titled, "Aquatic-Dependent Wildlife is (sic) Beyond the Scope of this Aquatic Criteria Derivation," it is stated that "EPA plans, in the future, to consider the effects of selenium on aquatic--dependent wildlife, potentially in the form of criteria expanded to address aquatic-dependent wildlife (p. 140)." That is encouraging news. The Service urges EPA to develop criteria designed to be adequately protective of aquatic-dependent wildlife as soon as possible, preferably as a collaborative effort with the Service as recommended by the United States General Accounting Office (GAO 1987:5): "GAO recommends that the Administrator, EPA, in close coordination with the Secretary of the Interior, develop water quality criteria for protecting wildlife and refuge habitat." This would also meet the Clean Water Act's (CWA) stated goal of water quality which provides for "the protection and propagation of fish, shellfish, and wildlife ..." (Section 101(a)(2)). The Service also notes with interest that the British Columbia Ministry of Environment (BCMoE 2014) recently finalized selenium water quality guidelines explicitly designed to adequately protect aquatic-dependent wildlife and the resulting tissue-based guidance values are viewed by the Service as recommendations that would be fully compatible with both the ESA and the Migratory Bird Treaty Act.	
90	EPA-HQ-OW-2004-0019-0332-A2; J.R. Simplot Company; Posted 7/30/2014 Human Health The 2014 Draft Criteria for egg/ovary selenium concentration is 15.2 mg/kg dw which translates to a whole body value of 8.1 mg/kg dw or filet value of 11.8 mg/kg dw). Some may question whether or not the tissue values associated with the 2014 Draft Criterion or higher values proposed in these comments would be protective of the fish consuming public. A recent Health Consultation was conducted by the Idaho Department of Health and Welfare (IDHW) in cooperation with the Agency for Toxic Substances and Disease Registry (ATSDR) (IDHW 2013) for the Blackfoot River and Salt River Drainages in Southeast Idaho. Exposure scenarios for men and	

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	women were 8 ounces of fish per week while for children it was 4.5 ounces per week.[5] The ATSDR selenium oral minimum risk level (MRL) of 0.005 mg/kg/day was used to calculate the amount of fish that can be safely eaten on a regular basis without any adverse health effects. The highest fish tissue concentration in the Salt River drainage (5.34 mg/kg ww; 21.36 mg/kg dw[6]) did not result in a dose that exceeded the MRL. Assuming an egg/ovary concentration of 15.2 mg/kg dw which translates to 11.8 mg/kg dw in filet, it is clear that 2014 Draft Criterion egg/ovary value would result in a filet tissue concentration much lower than the highest tissue concentration screened in the Salt River Drainage (21.36 mg/kg dw) at an MRL of 0.005 mg/kg/day. For example, if the egg/ovary criterion were increased to, for example, 20.5 mg/kg dw, the dry weight filet/muscle concentration (using EPA's conversion factor for brown trout in Table Sa) is 18.06 mg/kg dw. Assuming this to be a maximum fish tissue concentration for brown trout, an adult could consume up to 68 g/day dw (272 g/day ww) of fish at that concentration with no apparent risk. This estimates is within the mean range of 20-70 grams per day (0.14-0.49 kg/week) from relevant studies on freshwater recreational fish intake in the United States cited in the 2011 EPA exposure factors handbook (US EPA, 2011). Increasing the egg/ovary criterion to a concentration that is consistent with the data for effects in the most sensitive species, brown trout, would not result in a criterion that allows for edible portions of fish to exceed an acceptable risk threshold for the typical recreational fisherman. As noted in IDHW (2013), the use of a 75% moisture content is conservative and may overestimate the selenium content in fish. [5] Exposure frequency is 104 meals, 2 fish meals per week over 365 days for a 70 kg adult over a 30 year period. [6] Consistent with IDHW (2013) the moisture content was assumed to be 75%.	
Comment Category 2.6 – Comments on Various Implementation Topics Summary: The purpose of the criterion document is to set forth EPA's basis for and derivation of the water quality criterion for protecting aquatic life from the harmful effects of selenium. Many commenters, however, provided comments on how the criterion should be implemented. There were a wide range of these types of comments including how to measure attainment, how to distinguish between lotic and lentic systems, how to apply the criterion in waters with naturally elevated selenium levels, how to apply the criterion in fishless waters and/or new inputs (Footnote 3 of Table 1), and how to establish NPDES permit limits and thresholds for 303(d) listings and TMDLs. Many commenters expressed the need for EPA to develop implementation guidance.		
75	EPA-HQ-OW-2004-0019-0257-A2; Wyoming Department of Environmental Quality (WDEQ); Posted 6/16/2014 The Wyoming Department of Environmental Quality, Water Quality Division (WDEQ/WQD)	Responses concerning implementation: EPA received a number of public comments (over 100) concerning implementation issues in t response to the 2014 draft. In response

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	administers the Clean Water Act in the State of Wyoming. This includes developing, recommending and facilitating adoption of surface water quality standards in the State. WDEQ/WQD routinely adopts EPA's recommended 304(a) criteria to protect human health and aquatic life designated uses of surface waters in the state. Moreover, Wyoming contains many selenium-rich geologic formations that result in naturally high selenium concentrations in many water bodies. For these reasons WDEQ/WQD is particularly interested in EPA's external peer review draft aquatic life criteria for selenium. WDEQ/WQD is pleased to see the tiered approach outlined by EPA in the draft criteria document. The criteria appear to have been developed with considerable thought toward implementation and the difficulties in applying a fish tissue based criteria into discharge permits and TMDLs. Moreover, WDEQ appreciates EPA's efforts to include recommendations on how states would adopt site-specific fish tissue based criteria through the mechanistic modeling or bioaccumulation factor approaches. However, WDEQ/WQD is concerned that the criteria, as currently drafted, may be difficult to adopt and implement in most of our waters and that EPA has not provided sufficient guidance and/or flexibility on a number of issues related to the criteria.	to the 2015 draft, the EPA also received a number, of comments (approximately 75, mostly similar or identical to the 2014 submission). 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 and make them available for public comment. The design of the tiered criterion is such that the hierarchy allows for the assessment of samples that are available (e.g.., muscle, egg-ovary, whole body, or water). In the absence of fish tissue values, water column exceedances suffice to show water is not meeting the criterion. As with any WQC, the use is assessed based on the available data. Water column exceedances might be countermanded by fish tissue values if those become available at a later date, but in the absence of fish tissue values, water column exceedances suffice to show water is not meeting criteria. 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 under development by EPA at this time. 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 a range of potential logistical, spatial, temporal, and species- and life history-specific considerations. EPA has developed a tiered national 304(a) criterion, and is recommending that States and Tribes adopt all four recommended
97	EPA-HQ-OW-2004-0019-0322-A1; American Petroleum Institute (API); Posted 7/30/2014 Intermittent criteria appear to be exposure-based and intended to address cumulative, chronic exposure. How does EPA envision such criteria would be implemented? If this will require ambient monitoring for selenium water column concentration to determine "elevated "concentrations, who will do this monitoring and at what frequencies? Against what benchmarks would this be measured presumably, these measurements will be species- and site-specific? If the applicable criteria become a moving target, how and when will compliance be determined? For what duration would an intermittent criterion apply, or once triggered, would these become the de facto applicable criteria for the water body in question? How does this affect questions around anti-degradation and anti-backsliding?	
185	EPA-HQ-OW-2004-0019-0323-A1; California State Water Resources Control Board; Posted 7/30/2014 Seventh, the criterion does not sufficiently address fishless waters; the criterion should provide more detailed guidance as to how states can establish an appropriate surrogate, such as an invertebrate or aquatic bird species, that is applicable to the water body of concern and will protect all aspects of the aquatic food web therein.	
187	EPA-HQ-OW-2004-0019-0323-A1; California State Water Resources Control Board; Posted 7/30/2014 7. The criterion does not sufficiently address fishless waters; the criterion should provide more	

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	detailed guidance to states on how an appropriate surrogate, such as an invertebrate or aquatic bird species, should be established that is applicable to, and protective of, the aquatic uses in the water body of concern.	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 supersedes 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 are applicable. The EPA has made some changes to the footnotes associated with the criteria table in the Executive Summary and Section 4 of the 2016 criterion document to clarify the hierarchal relationship among the tissue elements, and between the tissue water elements, as well assertion of primacy of water over tissue in fishless waters, and for new discharges until determination of steady state. Regarding the intermittent criteria, 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 chronic risk to downstream waters. Modifications of the criterion can be made on a site-specific basis, with data from the site. As mentioned above, biokinetic modeling, if used should be adapted to a site using appropriate data – the values EPA presented represented default values that will be generally protective in these situations.
206	EPA-HQ-OW-2004-0019-0257-A2; Wyoming Department of Environmental Quality (WDEQ); Posted 6/16/2014 The positive predictive value for lentic waters, on the other hand, is 88%, indicating that if a state only used the water column value to assess designated use support for lentic systems, they may be incorrect 12% of the time. WDEQ/WQD appreciates that EPA included the discussion of sensitivity, specificity, positive predictive value, and negative predictive value within Appendix H, but would ask that EPA go one step further and calculate these values so that states can see which aspects of the criteria do the best job of indicating impairment and where potential issues may arise if a state only has water column data. Furthermore, 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 data are available. The criteria document could recommend that states conduct tissue monitoring in these instances to confirm impairment.	
235	EPA-HQ-OW-2004-0019-0275-A1; Institute for Fisheries Resources; Posted 6/18/2014 Low income communities, communities of color and nonprofit organizations struggling to protect waterways would be disproportionately impacted. The added costs of testing the new complex fish tissue testing proposals could have a significant impact on the ability of communities to protect the health of their cherished waterways. The complexity of this implementing the proposed Draft Criterion will also make it more difficult and expensive to implement for state agencies, industries, and concerned citizens.	
236	EPA-HQ-OW-2004-0019-0323-A1; California State Water Resources Control Board; Posted 7/30/2014 Second, in the highly hydromodified urban drainages typical of southern California, it is extremely difficult to obtain sufficient gestating female fish to assess egg/ovary selenium concentrations, which supersede all other elements of the criterion, in any meaningful statistical analyses. Therefore, in the Newport Bay Watershed, we have focused on whole body fish tissue, which is also more relevant to assessing risk to the aquatic-dependent birds that feed on freshwater fish. In our opinion, U.S. EPA needs to make it clear that States can choose to adopt only those elements of the criterion that in the State's professional judgment are scientifically appropriate, supported by the data, and relevant to the State's beneficial uses.	
263	EPA-HQ-OW-2004-0019-0257-A2; Wyoming Department of Environmental Quality (WDEQ);	

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	Posted 6/16/2014 *Samples Sizes* The draft criteria document is silent on the variability of selenium concentrations in the various types of fish tissue included in the recommended criteria. Likewise, the criteria document is silent on sufficient sample sizes for fish tissue sampling. Does EPA expect states to use a single fish tissue exceedance to indicate that the aquatic life use is impaired in a waterbody? Similarly, should a state determine that the aquatic life use is attained if a single fish tissue sample is found to be below the criteria? Since EPA compiled the data on egg/ovary, muscle and whole-body concentrations during development of the criteria, WDEQ/WQD requests that EPA include a discussion on the variability in tissue concentrations, including the intra-fish, intra-species, and inter-species variability within the revised criteria document. Furthermore, WDEQJWQD requests that EPA include recommendations on sample sizes for the various fish tissue elements to minimize mischaracterization of a waterbody as either attaining or not attaining the criteria. Variability in concentrations and sample size recommendations will help facilitate adoption of the criteria by states since most states will need to determine acceptable sample sizes for determining attainment, sufficient samples sizes necessary for adoption of site-specific criteria, etc., prior to adopting the criteria. Although states could deviate from EPA's recommended sample sizes, providing guidance on the number of samples necessary to eliminate and/or reduce inaccurate conclusions about attainment of water quality standards would be particularly helpful.	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. Because (a) the derivation of the 30-day averaging period, and the subsequent derivation of the intermittent criterion, 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. Unfortunately, residence time was not a common metric available in the available studies. 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] data from the same fish. The whole body [selenium] 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] was determined. Hermanutz (1996) and Hardy (2005) apparently measured whole body and egg selenium 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
274	EPA-HQ-OW-2004-0019-0322-A1; American Petroleum Institute (API); Posted 7/30/2014 The mechanism for translating the draft criteria into water-quality-based permit limits is unclear. Fish are highly mobile, and simply because selenium was measured in fish tissue above selenium criteria does not mean dischargers near where the particular fish was sampled caused or contributed to that exceedance. API requests EPA provide detailed implementation guidance.	
320	EPA-HQ-OW-2004-0019-0322-A1; American Petroleum Institute (API); Posted 7/30/2014 Bioaccumulation factors are specific to the organism and to the particular selenium species (zerovalent selenium, selenium ion, selenite, selenite, organo-selenium, selenocyanate, etc.), and yet the draft criteria are not specific to particular organisms or to particular selenium species. Thus, the applicability of the draft criteria to a particular water body may be technically unsound and inappropriate. EPA must provide detailed implementation guidance to address bioaccumulation of selenium in different organisms, and the bioaccumulation and toxicities of the various chemical forms of selenium.	

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344	EPA-HQ-OW-2004-0019-0256-A1 [Comment 0346-A2 is a duplicate of 0256-A1]; Peabody Energy Corporation; Posted 6/16/2014 Criterion Statistic: Regarding the fish tissue standards, there is no discussion of what statistical measurement is used to compare to the standard. Based on the variability observed in fish tissue concentrations, both inter- and intra-species, the mean or geometric mean fish tissue concentration should be used for comparison with the standard. Use of a mean or a geometric mean is more representative of a stream segment as a whole and the resident fish population. This approach also minimizes the skewness that can result from a few anomalous high values in a dataset that is otherwise in compliance. Use of a simple test statistic can also minimize the number of fish necessary for a valid sample, protecting already limited fish populations in smaller streams. Lastly, due to the transient nature of fish, it is not certain that an individual fish is a resident of the stream segment in question and tissue concentrations from an individual fish cannot be interpreted with that level of confidence.	fish (carcass and visceral tissue) is homogenized, and then a sample of the homogenized tissue is collected and analyzed for selenium. The whole body criterion element is ranked as a lower tier than the egg-ovary criterion element because of the additional uncertainty associated with variable selenium concentrations across tissue types. Regarding the timing of paired water, particulate fish samples, 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. These documents will be made available for public comment after the publication of the final criteria document. Regarding the concern over the relationship between fish tissue and water column elements is "primacy" or "precedence and misinterpretation. EPA has considered this issue and has modified the language to “supersede”, in place of primacy or precedence in the 2016 final criteria document (Tables in Executive Summary and Section 4). Regarding the relationship of the 2016 final selenium criterion with the selenium criterion in the GLI, CWA section 118(c)(2)(C) requires that states shall adopt standards that are “consistent with” with EPA’s Great Lakes Rule promulgated at 40 CFR 132. EPA will continue to work with Michigan and other Great Lakes states to ensure appropriate protective and scientifically-defensible selenium criteria apply.
354	EPA-HQ-OW-2004-0019-0256-A1 [Comment 0346-A2 is a duplicate of 0256-A1]; Peabody Energy Corporation; Posted 6/16/2014 Implementation into Water Quality Standards and NPDES Permits The draft criterion document does little to explain how this complex four-part criterion is to be incorporated into State or Tribal water quality standards and associated NPDES permits. In order to properly evaluate the criterion you must understand how it will be implemented. However, based on the subject document the following points are provided as suggestions and requested clarifications. Cost: The draft criterion document gives precedent to the egg-ovary standard over the whole body standard and precedent to all of the tissue standards over the water column standard. However, the draft criterion document does not provide any guidance as to which parts of the criterion should be applied under different sets of circumstances. Peabody believes that while all four criteria may apply to a stream, in the majority of cases it is not necessary to sample for water column concentrations and both types of fish tissues. Egg / ovary, whole body, and muscle tissue sampling and analyses are extremely costly compared to standard water column analyses and should not be applied unless warranted. Instead, this criterion should be applied with a tiered approach. Ambient selenium is present in many areas thus the requirement to sample for selenium is increasing rapidly. The unwarranted high costs of imposing all four requirements may be a waste of both state and industry resources. Tiered Approach: Peabody believes that a tiered approach, similar to the approach recently approved by EPA in Kentucky, is appropriate. The water column standard should be used as an initial screening trigger before requiring costly biological tissue sampling. This is reinforced by the criterion document's	

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	verification of the water column standards using binary classification statistics that showed false negative exceedances of tissue concentrations would be minimized using the water column standards of 4.8 µg/L and 1.3 µg/L. The second tier of this approach occurs when the applicable water column standard is exceeded, at which point fish tissue sampling would be appropriate. Deciding between egg / ovary, whole body, or muscle tissue may be based on a number of site specific factors, including but not limited to, fish species and life stages, State agency preference, analysis cost, and analytical method availability. However, in no event should all tissue sampling types be required.	
355	EPA-HQ-OW-2004-0019-0256-A1 [Comment 0346-A2 is a duplicate of 0256-A1]; Peabody Energy Corporation; Posted 6/16/2014 <u>Timing of Fish Tissue Sampling in Relation to Water Column Concentration:</u> EPA should discuss the timing issues associated with water quality sampling and fish tissue sampling. States, Tribes, and permittees have raised questions about the representativeness and protectiveness of fish tissue sampling that occurs after water column concentrations have exceeded a certain level. Fish tissue concentrations could depend on the residual time of selenium in fish tissue concentrations due to habitat restrictions, anadromous and catadromous behavior, life-stage, seasonal changes in selenium concentrations, and the delay between the water column concentration and the resulting fish tissue concentrations as uptake occurs through the trophic levels. Because tissue concentrations tend to lag behind water column concentrations, using the water column concentration as an initial trigger for subsequent fish tissue sampling is actually more representative than simultaneous sampling events. The lag that would occur between water column sampling and any subsequent fish tissue sampling event would allow the water column selenium to be taken up through trophic levels and incorporated into the fish tissue.	
357	EPA-HQ-OW-2004-0019-0257-A2; Wyoming Department of Environmental Quality (WDEQ); Posted 6/16/2014 *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 magnitude of the fish egg-ovary element is derived from analysis of the available toxicity data. The magnitudes of the fish wholebody element and fish muscle elements are derived from the egg-ovary element coupled with data on concentration ratios among tissues. The magnitudes of the water column elements are derived from the egg-ovary element coupled with bioaccumulation considerations.	

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	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, in a manner that 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. The draft criteria document, however, is silent on situations where there is only water column data available. WDEQ/WQD is concerned that the lack of discussion on this topic will result in the placement of many waters on state's 303(d) List when aquatic life uses are actually supported.	
358	EPA-HQ-OW-2004-0019-0266-A2; Transportation and Storm Water Department, City of San Diego, California; Posted 6/17/2014 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~~ through testing of the water column than ~~for~~ of 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 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 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 the protection of the designated uses. Therefore, clarifying and explanatory language needs to be included to ensure that the water column elements are not inappropriately applied over tissue-based elements for a given water body. One potential approach is to limit the applicability of water concentration elements to instances where tissue is not collected in the same calendar year.	
359	EPA-HQ-OW-2004-0019-0266-A2; Transportation and Storm Water Department, City of San Diego, California; Posted 6/17/2014 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*[12] (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 4.2.5 of the 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 selenium water	

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	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 Draft Selenium Criterion, only two of the 69 sites (one lentic and one lotic) are assigned water column concentrations which are appropriate (neither over- nor under-protective). [12] California State Water Resources Control Board. 2009. Water Quality Control Plan for Enclosed Bays and Estuaries Part 1 Sediment Quality. California Environmental Protection Agency. Effective August 25, 2009.	
365	EPA-HQ-OW-2004-0019-0322-A1; American Petroleum Institute (API); Posted 7/30/2014 API is pleased to provide these comments on EPA's notice of availability of draft selenium freshwater quality criteria for protection of aquatic life (79 FR 27601, May 14, 2014, hereafter "Notice"). API is a nationwide, non-profit, trade association that represents over 600 members engaged in all aspects of the petroleum and natural gas industry, including exploration, production, refining, and distribution of petroleum products. API members engage in operations that routinely require discharges regulated by National Pollutant Discharge Elimination System (NPDES) permits and thus are subject to permit limits based on ambient water quality criteria, including criteria for selenium. API's comments on the draft selenium criteria include concerns about site-specific criteria implementation through Section 303 of the Clean Water Act, in addition to concerns about criteria derivation. The Notice provides insufficient detail or clarity concerning criteria implementation, in the following areas: the mechanism for translation of criteria to water-quality—based permit limits, accounting for background concentrations, and water body applicability (lentic/lotic and freshwater/saltwater water distinctions). Our specific comments are as follow: Translation to Water-Quality-Based Permit Limits The mechanism for applying the draft criteria to determine whether water is impaired is unclear. Are initial determinations to be made based on fish tissue analysis and comparison with fish tissue criteria? Then will water column measurements be taken and compared with the water column criteria? Having carried out these comparisons, which determination in fish tissue or in the water column or both establishes an impairment and 303(d) listing? Implementation guidance should clarify that water column testing should be required before an impairment decision is made, and should an impairment be found the subsequent total maximum daily load (TMDL) should be based on the water column criteria, not the fish tissue criteria. API requests EPA provide detailed implementation guidance.	

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366	EPA-HQ-OW-2004-0019-0322-A1; American Petroleum Institute (API); Posted 7/30/2014 Bioaccumulation factors are specific to the organism and to the particular selenium species (zerovalent selenium, selenium ion, selenite, selenite, organo-selenium, selenocyanate, etc.), and yet the draft criteria are not specific to particular organisms or to particular selenium species. Thus, the applicability of the draft criteria to a particular water body may be technically unsound and inappropriate. EPA must provide detailed implementation guidance to address bioaccumulation of selenium in different organisms, and the bioaccumulation and toxicities of the various chemical forms of selenium.	
367	EPA-HQ-OW-2004-0019-0322-A1; American Petroleum Institute (API); Posted 7/30/2014 Depending on the matrix and especially the TDS/conductivity of the sample, commercial laboratory method detection limits for selenium are typically around 1.0 µg/L and could be as high as 2.0 µg/L. Reporting limits are typically as high as 5.0 µg/L. The sensitivity of these analytical methods poses a severe limitation in accurately and precisely measuring for compliance against the draft criteria. EPA should provide guidance as to how impairments will be determined, or compliance with stringent water-quality-based permit limits accurately and precisely measured.	
368	EPA-HQ-OW-2004-0019-0322-A1; American Petroleum Institute (API); Posted 7/30/2014 Accounting for Background Concentrations In carrying out a TMDL, or in applying intermittent selenium criteria (see below) EPA does not address situations where high background (upstream, nonpoint, sediment, etc.) concentrations are near or even above a water column criterion. In such situations, will the regulatory authority impose water-quality-based permit limits for local dischargers well below the criterion? Background concentrations are often attributable to natural sources of selenium as a mineral, and/or to local runoff, and not to local point source discharges. API requests EPA provide implementation guidance as to how nonpoint, upstream, and sediment sources of selenium will be addressed. Imposed water-quality- based permit limits must be achievable by demonstrated treatment technologies.	
370	EPA-HQ-OW-2004-0019-0341-A1; West Virginia Coal Association (WVCA); Posted 8/5/2014 EPA has not explained how the Draft Selenium Criteria can be dovetailed into the aquatic life criteria in the State water quality standards, which are generally based upon acute and chronic criteria for each parameter. • The egg/ovary criteria are not equivalent to chronic criteria, as they are instantaneous criteria. • The water column criteria for monthly average and intermittent exposures are not equivalent to an acute or chronic criterion either, due to differences in the duration and frequency of exposure	

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	assumed in preparation of the criteria.	
372	EPA-HQ-OW-2004-0019-0313-A2; Wisconsin Department of Natural Resources (WDNR); Posted 6/27/2014 Implementation • How does the EPA envision the elements of this criterion will be applied to NPDES permits? For example, how would effluent limits based on the different WQC (water, tissue, egg/ovary) be expressed in permits? Would the EPA accept permit limits based solely on the ambient concentration of the receiving waters? More details are necessary than are provided in the support document. • Is a model or tool available to calculate site-specific permit limitations if fish tissue data indicate that more restrictive effluent limitations are necessary beyond the calculated limitation using the receiving water concentration? How would the model or tool be utilized? • Because there is not a corresponding acute selenium criterion, the methodology for deriving permit limits specified in EPA's "Technical Support Document for Water Quality-based Toxics Control" (March 1991) is not appropriate. WDNR recommends an impracticability demonstration accompany the criterion so that states are not required to calculate daily maximum limitations or can use an alternative method for deriving these daily maximum limitations if they are determined necessary.	
373	EPA-HQ-OW-2004-0019-0313-A2; Wisconsin Department of Natural Resources (WDNR); Posted 6/27/2014 Assessment • Wisconsin does not provide recommendations for people on consumption of fish related to the benefits or risks of selenium in fish nor have we used this data for regulatory or water quality assessment purposes to date. However, the WDNR has quantified total selenium in fish samples on a limited basis. Wisconsin's data suggests total selenium concentrations in Wisconsin fish from many locations are below EPA's proposed tissue criteria with concentrations in skin on fillets ranging from non-detect to 1.08 ppm (representing 187 samples, 20 species, 33 collection locations, 1985-2012) and concentrations in whole fish ranging from non-detect to 1.33 ppm (representing 26 samples, 8 species, 20 locations, 1989-2009). Does EPA expect the states to change their surface water monitoring programs to include more collection of fish tissue, in order to evaluate compliance with this WQC? • For the fish tissue elements to be applicable for waterbody assessment, the WDNR will need to develop a standardized method of analysis, determine when/where monitoring is required, and which entity is required to perform the analysis. Some aspects of this may require rule-making.	

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	• The lack of an EPA approved method for the analysis of selenium in fish tissue will hamper this process. • Will EPA accept 303(d) listing decisions that are solely based on in-stream selenium concentrations and not fish tissue data?	
374	EPA-HQ-OW-2004-0019-0316-A1; Alaska Department of Environmental Conservation (ADEC); Posted 7/25/2014 I. Technical Issues Toxicity thresholds for aquatic species can be expected to vary widely within and between species. Uncertainty regarding which tissue, endpoint, life stage, and effect level for deriving a threshold, and whether thresholds are actually related to population-level effects have not been fully addressed for Alaska-specific conditions. In addition, implementation of tissue-based standards would require the collection of tissue from wild populations of fish for water quality criteria attainment assessments, and would be an added expenses for both regulatory agencies and the regulated community. Further EPA's recommended criterion is to be based on egg/ovary tissue that requires sampling specifically during key portions of each fish species' reproductive cycle. Given the extent and remoteness of waters in Alaska, it is unlikely to be feasible to collect the data necessary to implement this type of criteria in most cases. Recommendation: EPA should propose a performance base methodology when considering the implementation of a national selenium criterion to address regional or sub-regional criteria. Such an approach could be similar to the pH and temperature-dependent ammonia criteria and the hardness-dependent metals criteria used by many states.	
376	EPA-HQ-OW-2004-0019-0316-A1; Alaska Department of Environmental Conservation (ADEC); Posted 7/25/2014 2. Determination of Permit Limits for National Pollutant Discharge Elimination System (NPDES) When states adopt the proposed selenium water column concentration criterion, existing implementation procedures used for other acute and chronic aquatic life protection criteria as well as conducting reasonable potential determinations and establishing water quality-based effluent limitations (WQBELS) per 40 CFR 122.44(d) would be appropriate. However, if states also decide to adopt the selenium fish tissue criterion element values for NPDES permitting purposes, additional state WQS implementation procedures will be needed to determine the need for and development of WQBELs necessary to ensure attainment of the fish tissue criterion. ADEC does not consider the fish tissue approach practicable. ADEC is concerned that EPA may	

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	choose to recommend the tissue-based criteria alone rather than allowing the water column method to continue to be applied. Such an action would severely limit the ability of ADEC to adopt and implement the new criteria. Recommendation: EPA should provide additional guidance on implementing fish tissue criterion for NPDES permits.	
377	EPA-HQ-OW-2004-0019-0316-A1; Alaska Department of Environmental Conservation (ADEC); Posted 7/25/2014 4. Monitoring and Assessment The Clean Water Act (CWA) establishes an EPA approval process for certain analytical methods used in the National Pollutant Discharge Elimination System (NPDES) program and for section 401 certifications. EPA has several approved methods for measuring selenium in water under 40 CFR 136. However, since there are no EPA approved methods for the analysis of selenium in fish tissue, states and tribes may use analytical methods not approved by EPA to evaluate the attainment of water quality standards or to develop or implement Total Maximum Daily Loads provided that these methods are scientifically sound (40 CFR 122.21(g)(7)). Recommendation: EPA should clarify methods for the analysis of fish tissue and assistance to states to implement such methods.	
378	EPA-HQ-OW-2004-0019-0316-A1; Alaska Department of Environmental Conservation (ADEC); Posted 7/25/2014 Regulatory Implications Monitoring egg tissues is not a practical long-term assessment approach to gauge compliance of non-compliance with a criterion. Collecting egg tissue require fish be monitored at a specific time of year and while the general spawning period may be known, capture of pre-spawn female fish requires a larger effort than the simple collection of fish for whole body tissue analysis. Recommendation: EPA should develop feasible monitoring protocols in order for states to effectively use a criterion based on effects in eggs, especially in Alaska where remote settings are the limiting factor.	
380	EPA-HQ-OW-2004-0019-0342-A2; State of Michigan, DEQ; Posted 8/5/2014 Thank you for the opportunity to provide comments on the External Peer Review Draft, Aquatic Life Ambient Water Quality Criterion for Selenium – Freshwater 2014. The aquatic life value for selenium is of interest to the Michigan Department of Environmental Quality (MDEQ), Water Resources	

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	Division (WRD), since there are some surface waters in Michigan with elevated selenium levels. Michigan promulgated into our state rules the selenium Criterion Continuous Concentration of 5 micrograms per liter derived by the United States Environmental Protection Agency (USEPA) as part of the Great Lakes Initiative. Michigan has also promulgated the methodology for deriving surface water values protective of aquatic life, but does not have a promulgated method for developing a fish tissue level-based water quality standard (WQS). Please also note that Michigan cannot revise its selenium WQS until the USEPA revises the numerical WQS in the Great Lakes Initiative. We have the following comments on the draft document:	
381	EPA-HQ-OW-2004-0019-0342-A2; State of Michigan, DEQ; Posted 8/5/2014 The USEPA should enhance fish species selection guidance for criteria attainment measurement. Species selection for tissue-based criteria attainment measurement is critical. It is also inherently more complicated than water-based criteria attainment measurement because many different fish species might be considered for attainment sampling. Because of this complexity, the USEPA should enhance the fish species selection guidance for tissue-based criteria attainment measurement. The USEPA's key recommendations for species selection are excerpted below: "The species most sensitive to selenium are those in the Salmonidae family. Thus, states and tribes should target nonanadromous species in the Salmonidae family such as trout when they are present." " States and tribes should target nonanadromous species (species that do not migrate from salt water to spawn in fresh water), because selenium exposure and subsequent bioaccumulation occurs over a relatively long period of time through the consumption of locally contaminated aquatic organisms. If nonanadromous fish species in the Salmonidae family is absent, states and tribes should target the resident fish species likely to have the highest exposure and sensitivity to selenium. In aquatic systems with resident fish species of unknown selenium sensitivity and bioaccumulation potential, factors such as ecological significance can be factors in choosing which species to target." The USEPA's recommendation to sample nonmigratory salmonids, or species likely to have the highest exposure and sensitivity if salmonids are not present, is incompletely conceived. There is no assurance that any resident species would be likely to have both "the highest exposure and sensitivity to selenium." Both the sensitivity and bioaccumulation rates of species selected for sampling need to be carefully considered. For example, in many northern Michigan waters, brook trout (Salvelinus fontinalis) are the dominant trout species. However, brook trout are substantially less sensitive than Oncorhynchus species, and much less sensitive than brown trout (Salmo trutta). So, selecting brook trout only for sampling might result in underprotection of more sensitive species. The same concept	

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	applies to bioaccumulation rate. Selecting a species with a low bioaccumulation rate than other species could result in underprotection of other species. The sensitivity and bioaccumulation rates of many species are not known. The USEPA attempts to address this with the recommendation to consider "factors such as ecological significance" when species of unknown selenium sensitivity and bioaccumulation potential are resident. This recommendation should be further explained. Selecting a linchpin species might result in protection of that species, but other species with higher bioaccumulation potential and/or sensitivity could still be adversely affected. Finally, the USEPA should develop recommendations on how to sample to address the sensitivity and bioaccumulation potential of species that are resident to the site, but have been temporarily extirpated by selenium exposure.	
382	EPA-HQ-OW-2004-0019-0347-A2; Southern Nevada Water Authority; Posted 8/5/2014 Lastly, the Authority would like to point out that in some cases EPA requirements are in direct conflict with other EPA regulations. In the case of stormwater one of the Best Management Practices for stormwater is infiltration. In a location like Las Vegas infiltration of stormwater will only increase the mobilization of selenium and the volume of the shallow groundwater table.	
383	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 2.3 Timing of Tissue Data Collection EPA evaluated the effect of sample collection time on correlation coefficients of Se measurements in particulate material, invertebrate tissue, and fish tissue. According to EPA (page 73 of the 2014 draft criteria document) "The results of this analysis suggest that the relationship between selenium concentrations in particulate material and invertebrate tissue and between invertebrate tissue and fish tissue is somewhat insensitive to relative collection time within a one year time period" and "On the basis of this analysis, EPA concludes that selenium measurements from samples collected at the same aquatic site within one year of each other are reasonable acceptability criteria for matched pairs of measurements….". We support these conclusions 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	

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	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 should consider laying out specific guidelines for data collection as part of this criteria document. EPA has done a thorough review of the implications of tissue sample collection at various times and this information would be beneficial to the end users of this document. Based on our experience, many state agencies are unclear of the science behind Se bioaccumulation and trophic transfer in aquatic ecosystems, and providing guidelines on timing of tissue data collection would greatly assist the States in incorporating these criteria in NPDES permits and performing 303(d) assessments.	
384	EPA-HQ-OW-2004-0019-0352-A1; Western Coalition of Arid States (WESTCAS) [Comments 0319-A2 and 0321-A1 are duplicates of 0352-A1]; Posted 8/7/2014 It is imperative that guidance is written, peer reviewed, and published to standardize the time of year when data collection is performed and type of samples collected and that the fish species sampled are appropriate, analyzed properly, and are consistent between studies. This guidance should be published as a stand-alone document prior to implementation of the criterion, or incorporated into the criteria document, to ensure states will apply a national tissue criterion as intended by the U.S. EPA. We also recommend that EPA publish a companion document that discusses, in more general terms, the flexibilities available to states in implementing the revised selenium criteria, similar to the document published by EPA regarding the recently revised ammonia criteria (Flexibilities for States applying EPA's Ammonia Criteria Recommendations, EPA-820-F-13-001, April 2013).	
385	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 8/7/2014 One topic from EPA's 2004 selenium proposal that the Service fully supported was the need for fish - tissue based criteria to be accompanied by implementation guidance for such novel criteria. It appears that the DSP defers development of implementation guidance to the States and Tribes. Lemly and Skorupa (2007) identified numerous challenges to developing scientifically sound implementation guidance that could easily lead to disparate outcomes on a State-by-State basis. Since EPA continues to administer the Clean Water Act program for a few States, the Service recommends that EPA consider developing implementation guidelines for those States that can be used as a template for other States and Tribes.	
386	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 8/7/2014 We recommend that the analysis consider how fish movements, particularly in open lotic systems, will be accounted for with adoption of fish tissue based criteria.	

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586	EPA-HQ-OW-2004-0019-0256-A1 [Comment 0346-A2 is a duplicate of 0256-A1]; Peabody Energy Corporation; Posted 06/16/2014 Application to Downstream Segments: Although EPA discusses when to consider downstream uses and waterbodies when implementing the criterion, there is no discussion of application of this criterion to headwater streams, ephemeral streams, or streams with limited aquatic life. Peabody operates a number of large mines located in headwater areas with ephemeral streams that flow infrequently or intermittent streams that flow only seasonally. In many cases flow in these streams is lost through transmission loss to the underlying alluvium prior to connection with perennial streams. Should this criterion be applied to streams that do not contain fish but do support macroinvertebrates (limited aquatic life)? Does this criterion apply to streams that contain only small populations of minnows and other small non-game fish species that were not considered in the development process? Application of this criterion to headwater streams should consider two aspects 1) distance and composition of the nearest downstream fish population, and 2) amelioration of the selenium concentration by downstream dilution and adsorption to instream and riparian sediments.	
356	EPA-HQ-OW-2004-0019-0256-A1 [Comment 0346-A2 is a duplicate of 0256-A1]; Peabody Energy Corporation; Posted 6/16/2014 Because of the inherent variability associated with the data that is being used, it should be stressed that an exceedance of the water column criteria does not directly infer an impact to the instream aquatic life and should only trigger further testing of fish tissue. Furthermore, an exceedance of the water column criteria should not qualify as an excursion in NPDES permits or 303(d) attainment evaluations. Excursions of the selenium criterion should only be applicable to the fish tissue concentrations, rather than the water column concentrations.	
223	EPA-HQ-OW-2004-0019-0334-A2; Appalachian Mountain Advocates et al.; Posted 7/30/2014 II. 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	

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	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[3] 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	

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	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. 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. EPA's proposal 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. 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 permitee 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? 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? 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? 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	

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	populations often receive discharges from many different sources such that responsibility for violations of the standard will be extremely difficult to assign. 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. 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 62. The model developed by USGS 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. EPA's Draft Criterion document explains that the expected and measured relationships between egg-ovary concentrations and water column concentrations are "highly correlated."[4] Draft Criterion at 134. 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 4-5. That statement essentially eliminates any benefits from including water column elements. The better approach would be to adopt only a translated water column criterion and to eliminate the fish tissue elements. Not only is a translated water column criterion scientifically defensible, it is also vastly more useful as a regulatory tool. 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. 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	

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	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.[5] [3] Available at http://www.epa.gov/scipoly/sap/meetings/2008/october/aquatic_life_criteria_guidelines_tissue_08_26_05.pdf [4] EPA could create an even more robust water column criterion by collecting additional data correlating fish-tissue concentrations to water column concentrations. See Draft Criterion at 135 (explaining that minor variability in correlation could be due in part to small sample size). Regardless, the uncertainty in translating protective fish tissue values to water column numbers is likely far outweighed by the uncertainty in determining compliance with the fish tissue elements in the absence of robust tissue sampling protocols. [5] As explained below, the fish tissue elements of EPA's Draft Criterion are too high to protect sensitive aquatic life and should be revised downward significantly. The water column criteria should be based on fish tissue concentrations that are revised to ensure protection of such species.	
352	EPA-HQ-OW-2004-0019-0349-A1; Colorado Wastewater Utility Council (CWWUC); Posted 8/5/2014 There are several components of the draft Se criteria which will directly impact the regulated community that EPA should expand upon and clarify in the criteria document. EPA did not provide any specific recommendations for determining attainment with Se criteria in streams without fish. In the West, where water is extremely limited, we have a large number of ephemeral or intermittent streams, in many of these streams fish populations are not necessarily limited by water quality but by water quantity. Section 3.5 of GEI's review provides recommendations for developing site-specific standards in these situations. In addition, 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 three years on average.	
375	EPA-HQ-OW-2004-0019-0316-A1; Alaska Department of Environmental Conservation (ADEC); Posted 7/25/2014 II. Implementation Issues Currently, Alaska regulations determine compliance with WQC through a single water-column chronic criterion (EPA 1987). It is expected that challenges to implement a fish-tissue criterion will occur due	

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	to the multitude of factors (species of fish, biogeochemical influences of the water column, speciation of selenium, temperature, etc.) that affects the allowable concentration of selenium in surface waters to protect aquatic life. Implementation of a water quality criterion for selenium may require the ability to detect and measure the concentration of selenium in effluent, ambient water, tissue, and other media that is below the detection limit or limit of quantification that some analytical methods can provide leading to greater uncertainty in determining selenium contamination. ADEC has additional implementation concerns related to: • National Consultation for Endangered Species Act (ESA) • National Pollutant Discharge Elimination System (NPDES) • Downstream Protection • Monitoring and Assessment	
197	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 3.5 Recommendations for Streams without Fish EPA did not provide any specific recommendations for determining attainment with Se criteria in streams without fish. However, it seems to be implied that in the absence of fish the criteria default to the water-column values. We feel there needs to be additional guidance for these situations and defaulting to a nationwide water-column is not appropriate. In the case of ephemeral or intermittent streams and in small headwater streams, fish populations are not necessarily limited by water quality but by water quantity. Lack of perennial flow or insufficient flow in these types of streams precludes establishment of permanent fish populations. In addition, viable reproducing fish populations cannot become established in stream reaches with limited or unsuitable habitat, as is often found in ephemeral/intermittent or headwater streams. In many cases, the water in these streams is only flowing in certain reaches of the stream and never actually meets downstream waters, which also contributes to the lack of fish at these sites by limiting any potential migration of fish from receiving waters into the upper sites. Although we do not agree with EPA's use of invertebrate chronic toxicity data that has been translated to an expected fish tissue concentration (discussed previously in Section 3.1.1.5), we do feel these chronic invertebrate data could be useful in establishing site-specific criteria for streams that do not support fish populations but do support benthic invertebrates. 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. This value was calculated by applying a TTF of 2.2	

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	(average for this study) to the concentration of Se in the periphyton diet, 11 mg/kg dw. It is unclear why the authors did not just use the concentration of Se found in the adult mayfly at the level at which effects were seen (27.5 mg/kg dw). The criterion could then be set as an invertebrate tissue concentration 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. The EC10 calculated for rotifer growth was 37.84 µg/g dw wb, and effects were seen with oligochaetes at levels greater than 140 mg/kg dw wb. Therefore, based on these data, an invertebrate Se tissue concentration of 24.2 mg/kg dw would be protective of these invertebrates. The key issue is to ensure protection of downstream waters. 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.	
114	EPA-HQ-OW-2004-0019-0316-A1; Alaska Department of Environmental Conservation (ADEC); Posted 7/25/2014 3. Protection of Downstream Waters EPA regulations at 40 CFR 131.10(b) provide that "[i]n designating uses of a waterbody and the appropriate criteria for those uses, the state shall take into consideration the water quality standards of downstream waters and ensure that its water quality standards provide for the attainment and maintenance of the water quality standards of downstream waters." In cases where a discharge occurs at a lotic location and downstream waters are lentic waterbody types (e.g., lakes, impoundments), or harbor more sensitive species, ADEC is concerned that the downstream selenium criterion may be more stringent than that required to protect in-stream uses. This situation is further complicated when there are multiple transitions, of differing residence times, between lotic and lentic. There may be no direct correlation between the discharge and fish tissue concentration due to discharge characteristics, fish behavior, or water-body-specific selenium fate and transport; however, the limit would apply to the upstream discharger if executed in a permit. Recommendation: EPA should provide additional guidance on how to address downstream protection for areas where waters change from lentic to lotic resulting in a change in water column criteria. EPA should specifically allow states the latitude to use professional judgment when making a determination of where the water column criteria will apply. EPA should also provide guidance on how permit compliance with fish tissue-based limits could be implemented in a situation where fish tissue limits are exceeded. The guidance should provide legally defensible rationale that addresses a fish tissue limit exceedance and corrective action methods that could be applied to the permittee.	

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160	**EPA-HQ-OW-2004-0019-0256**-A1 [Comment 0346-A2 is a duplicate of 0256-A1]**; Peabody Energy Corporation**; Posted 6/16/2014 Lastly, in areas with ephemeral or intermittent streams that contain either no fish, or limited and/or seasonal populations of fish, how should a site-specific criterion be developed? Some of these ephemeral and intermittent streams can also contain high water column selenium concentrations due to ambient conditions. Without fish present, should the site-specific criteria be based on macroinvertebrates only and the limited aquatic life that is present?	
200	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 6.2 Other Considerations Another issue that requires reevaluation and clarification is how to establish criteria for streams with no existing fish populations. There is some discussion of this in Appendix I, but the recommendations are not appropriate for all stream types. It appears the default would be 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 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, 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. Finally, we have also provided additional field data for CFs, trophic transfer functions, and percent moisture for EPA to incorporate and improve their database (GEI Appendix A).	
301	EPA-HQ-OW-2004-0019-0316-A1; Alaska Department of Environmental Conservation (ADEC); Posted 7/25/2014 2. Water Column-based criteria: EPA has derived the chronic criterion element for the water column through modeling the trophic transfer of selenium, via the food web, resulting in the fish tissue concentration that yields the chronic reproductive effects of concern. While EPA recognizes the bioaccumulation potential of selenium depends on many different biogeochemical factors that characterize a particular aquatic system, the criterion is simplified to reflect two categories of aquatic systems (i.e., lentic and lotic). The transformation reactions that EPA accounts for to determine the chronic effects in the aquatic systems may not be adequately protective with respect to cold water systems and the associated bioaccumulation potential.	

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	Recommendation: EPA should provide additional information to help clarify use of the water column criteria. Specifically, how do states differentiate between when lentic and lotic criteria would be used? How shall states take into account seasonal variations that affect temperature and flow regimes or that storm water and surface water runoff may change ambient conditions that could limit or increase bioavailability during the 30-day averaging period? What "limiting" factors that should be considered during the 30 day average? How do states set criteria in water systems that have naturally occurring selenium concentrations above water column concentrations? How should states account for residence time of species and hydrogeological information necessary to protect downstream uses? Specific guidance to clarify these issues should be provided.	
361	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 Expectations for sampling must be clarified in terms of the number of samples required and on what frequency given the fact that tissue concentrations are not likely to change as quickly as water concentrations.	
362	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 Guidance should be provided on whether fish whole-body tissue measurements include organs or not. A definition of this should be included.	
363	EPA-HQ-OW-2004-0019-0271-A2; Coordinator, Barnes & Thornburg LLP on behalf of the Federal Water Quality Coalition; Posted 6/17/2014 It is not clear how impairments would be determined and, if there is an impairment, the fish tissue criteria would be implemented in the form of water quality-based permit limits. There is precedent for implementation of fish tissue criteria, and the Agency has issued guidance on implementation of its recommended fish tissue criteria for mercury. EPA should consider issuing analogous guidance for the selenium criteria.	
364	EPA-HQ-OW-2004-0019-0271-**A2**; Coordinator, Barnes & Thornburg LLP on behalf of the Federal Water Quality Coalition; Posted 6/17/2014 EPA should consider how to address situations in which selenium levels may be high in fish tissue and/or the water column, but the biological community is not exhibiting signs of selenium-induced stress.	
369	EPA-HQ-OW-2004-0019-0328-A2; County of San Diego, Department of Public Works (DPW) and Watershed Protection Program (WPP); Posted 7/30/2014 The County of San Diego's Watershed Protection Program (WPP) appreciates the opportunity to provide comments on the External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for	

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	Selenium — Freshwater 2014, posted in the Federal Register Vol. 79 No. 93 on May 14, 2014 (herein referred to as the "Proposed 2014 Selenium Criterion"). The County's main concern is related to one key issue which is the lack of clarity regarding the monitoring which is required to be conducted. This concern is addressed in more detail in the body of this letter and is accompanied by the County's recommendation. Required Monitoring: The Proposed 2014 Selenium Criterion states that all four elements of the United States Environmental Protection Agency's (EPA) 2014 External Peer Review Draft Freshwater Selenium Ambient Water Quality Chronic Criterion for Aquatic Life (Table 15 of the Proposed 2014 Selenium Criteria) should be included "in a manner that 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." In addition, the Proposed 2014 Selenium Criterion states that "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." However, the Proposed 2014 Selenium Criterion lacks clarity regarding whether states and tribes should require attempts to obtain fish egg-ovary, and/or fish whole-body, or muscle tissue measurements where monitoring in the water column has sufficiently demonstrated whether beneficial uses of a waterbody are being protected. Recommendation: Language should be added to the Proposed 2014 Selenium Criterion stating that, although the primacy of the whole-body or muscle elements over the water column element, and the egg-ovary element over any other element should be explicitly affirmed, EPA does not recommend that states and tribes require fish tissue monitoring to be conducted where monitoring is currently only being conducted in the water column.	
371	EPA-HQ-OW-2004-0019-0313-**A2**; Wisconsin Department of Natural Resources (WDNR); Posted 6/27/2014 Criterion promulgation • Given the format of the proposed criterion (i.e., one criterion with four elements), it is unclear how the proposed selenium criterion meets the independent applicability requirements of water quality criteria pursuant to EPA guidance. Please clarify how these criteria meet these requirements and how states should implement these criteria given the need to maintain the independent applicability of water quality standards. • This 4-part criterion format has not been addressed previously in WI. This would entail multiple rule-making efforts to update the derivation method, the criterion itself, and to specify how the WDNR will implement this WQC.	

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	• Would EPA accept state selenium criteria that are solely based on the receiving water concentration thresholds and using this value in permitting decisions? If not, how would EPA envision this criteria being implemented? • Additional clarification is needed on when the intermittent element would apply and how this would impact NPDES permits (e.g., how would an effluent limit based on this criterion be expressed in permits?). • How would this criterion apply to "macroinvertebrate only" waters (i.e., waters classified as "limited aquatic life" in Wisconsin), wetlands, or bogs given that the criterion is derived to protect fish reproduction and the MDR for crustaceans were excluded from the criterion derivation? • Through the proposed criterion changes, will selenium be considered a bioaccumulative chemical of concern (BCC) in either the Great Lakes Basin or the Mississippi River Basin?	
401	EPA-HQ-OW-2004-0019-0267-A2; Water Quality Division, District Department of the Environment (DDOE), Government of the District of Columbia; Posted 06/17/2014 Comment 2. DDOE is concerned about EPA not providing implementation guidance for the purpose of monitoring Selenium in waters. Can EPA provide how a "30-day average" is to be sampled for the assessment of the criteria? For example, the E. coli standards have a suggested 5 samples in the 30 days.	
405	EPA-HQ-OW-2004-0019-0276-A1; Indiana Department of Environmental Management (IDEM); Posted 06/20/2014 (1) Footnote 3 (stated as 'dissolved total selenium') on page 4 (summary of criteria) needs clarification. Should this be, instead, 'total dissolved selenium'? If so, is Method 3114 B the preferred method for determining water column selenium concentration s? (2) Would fish tissue sampling be based on 'Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories (EPA 823-B-00-007)' or will there be additional guidance for the determination of selenium concentrations in egg/ovary and tissue?	
458	EPA-HQ-OW-2004-0019-0356-A1; Idaho Department of Environmental Quality (DEQ); Posted 09/30/2014 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	

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	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.	
460	EPA-HQ-OW-2004-0019-0356-A1; Idaho Department of Environmental Quality (DEQ); Posted 09/30/2014 The document leaves it unclear how depth profile~ 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.	
467	EPA-HQ-OW-2004-0019-0356-A1; Idaho Department of Environmental Quality (DEQ); Posted 09/30/2014 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.	
526	EPA-HQ-OW-2004-0019-0339-A2; West Virginia Department of Environmental Protection (DEP); Posted 7/30/2014 Criteria "Primacy" - In chapter 5 of the draft document, EPA outlines the primacy of the four criterion components and includes further information in footnotes 1 and 2 of Table 15 on how the tissue components "override" the water quality components, and DEP fully agrees with and supports this approach. We do request that EPA further define this primacy approach in the body of the final document and include a statement that clearly defines that if a tissue component is met but a water component exceeds a standard, this will not equate into a violation so long as there are assurances that the fish utilized were resident and in the area of exposer. We propose the following as an example of what EPA could include in chapter 5 of the final document: *"If the tissue criteria component(s) are met, any exceedence of the water quality component(s) will not count as a violation of the selenium criterion"*	
527	EPA-HQ-OW-2004-0019-0339-A2; West Virginia Department of Environmental Protection (DEP); Posted 7/30/2014 Criteria implementation - DEP requests that EPA include information concerning the implementation of the final selenium criteria, including information or guidance on how to include it in NPDES permits	

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	and how to properly use it for 303(d) assessment and impairment decisions. By including guidance for these two key state level actions, there will be fewer questions once the new criteria is adopted and allow for a more streamlined approach when incorporating into state programs. DEP also requests further guidance into the application of the fourth component- "Intermittent Exposure".	
553	EPA-HQ-OW-2004-0019-0335-A2; County of Orange, OC Pubic Works; Posted 7/30/2014 SUMMARY OF KEY TECHNICAL ISSUES • 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 criterion fails to consider physical aspects of fish habitats. In a habitat where there is no resident fish as a result of the constraints from the physical parameters (bottom substrate, shade, water temperature, etc.), the criterion will impose undue limitations on water column selenium concentration with no benefit to aquatic life. As noted by the Colorado Wastewater Utilities Council, 64% of nationwide lentic waters exceed the 1.3ppb criterion, and many of these waters are not impacted by anthropogenic processes.	
575	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 We support EPA's conclusions regarding the timing of tissue data collection that samples collected within one year of each other are reasonable for acceptability. However, we feel EPA should emphasize this and consider laying out data collection and analysis guidelines as part of the criteria document that may be used by the States for implementation in NPDES permits and 303(d) assessments.	
587	EPA-HQ-OW-2004-0019-0256-A1 [Comment 0346-A2 is a duplicate of 0256-A1]; Peabody Energy Corporation; Posted 06/16/2014 This analysis should also include a cost component that would show the potential costs that would be incurred due to implementation of the proposed rules, current lack of adequate data, and the additional fish-tissue testing and analysis that is necessary.	
403	EPA-HQ-OW-2004-0019-0268-A1; Nevada Division of Environmental Protection (NDEP); Posted 06/17/2014 The final criterion package needs to contain guidance on appropriate methods of sampling and data evaluation when determining compliance with the proposed Selenium criteria. Some questions that need to be addressed are as follows: 1. When sampling fish tissue, should certain species and age classes be targeted? Are egg	

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	and ovary levels affected by the timing of the sampling? If so, should spawning periods be targeted or avoided? The criteria document states that the fish tissue criteria are "never to be exceeded". Is this intended to apply to any of the fish samples - If one fish tissue sample out of 20 exceeds the criteria, does this indicate impairment? Or should this analysis be based upon an average of all tissue samples for a given sampling event? 2. How are states/tribes to evaluate compliance with a 30-day water column criterion when it is rare to have more than 1 sample per month? Nevada will often have only 1 sample every 3 months at many of our monitoring locations. These samples may or may not be indicative of 30-day average concentrations. 3. The 2nd full paragraph on Page 98 provides a brief discussion on implementation of the criteria in the NPDES program. The 2nd and 3rd sentences mislead the reader to believe that some of our water quality numeric criteria are applicable for NPDES purposes, while other criteria are not applicable for permits. Nevada does not differentiate between criteria to be used for NPDES permits and criteria not to be used for permits. All the numeric criteria can potentially be used to set WQBELs.	
489	EPA-HQ-OW-2004-0019-0258-A2; National Association of Clean Water Agencies (NACWA); Posted 6/16/2014 Development of Water Column Numbers to "Ease Implementation" Sends Mixed Messages While EPA includes and expresses its preference for use of the tissue-based criterion, it is clear that EPA intends to "ease implementation, particularly for developing water quality based effluent limits for National Pollutant Discharge Elimination System (NPDES) permits" (EPA Fact Sheet, p.2) by also including water column criteria values. EPA modeled accumulation in whole body tissue using trophic transfer functions or TTFs, and developed whole-body to egg-ovary conversion factors to make the linkage between fish tissue levels and water column numbers. EPA notes that its use of TTFs is similar to the use of bioaccumulation factors, with both quantitatively representing the relationship between the chemical concentrations in multiple environmental compartments, but that the TTF provides advantages over BAFs because it is "derived from knowledge of the ecological system…[and] can be inferred for an aquatic system using existing knowledge and reasonable assumptions, without the considerable time and cost of collecting and analyzing tissue and water samples" (Draft Criterion Document, p. 66) that would be necessary to calculate site-specific BAFs. NACWA appreciates EPA's desire to ease implementation, but as outlined in the review conducted by GEI Consultants, Inc., there are significant concerns with EPA's methodology in developing the water column elements of the criteria. NACWA's 2005 comments on EPA's previous draft revision to the selenium criterion highlighted the ongoing debate over whether to convert fish-tissue based criterion for methylmercury into water-	

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	column numbers to make permitting easier. NACWA continues to believe that using "bioaccumulation considerations" to convert fish-tissue values to water concentrations is inappropriate and unnecessary. There is now precedent for implementation of fish tissue criteria and the Agency has now issued guidance on how to do so for methylmercury. Similar guidance should be developed for selenium. The inclusion of multiple expressions of the criteria, while working to strike a balance between the science and ease of implementation, could also cause confusion. EPA recommends that the states adopt all four elements of the criterion into their standards in a manner that "affirms the primacy" of the whole-body and/or muscle elements over the water column elements, and the egg-ovary element over any other element. But it will fall to states to first adopt all four elements and then ensure that there are data adequate to implement the non-water column based approaches. NACWA is concerned that in the absence of existing tissue data, the states will default to reliance on the water column elements of the criteria in all cases. In addition, the Draft Criterion Document sends the states mixed messages, with the Agency contemplating a scenario where a state might solely rely on the water column criteria element for permitting purposes: *Where states adopt the selenium water column concentration criterion element values only 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. However, if states also decide to adopt the selenium fish tissue criterion element values 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). (p. 98)* EPA should clearly state its preference for use of the tissue-based criteria elements for all Clean Water Act purposes, including permitting.	
446	EPA-HQ-OW-2004-0019-0351-A2; Stakeholders Implementing TMDLs in the Calleguas Creek Watershed, California; Posted 08/05/2014 DETAILED COMMENTS FOR KEY TECHNICAL ISSUES The Stakeholders have the following specific technical comments related to the summary of key issues above: 1. Clarification Is Needed Regarding the Applicability of the Four Elements of the Criterion to	

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	Ensure that Fish-Tissue Elements Supersede the Water Column Elements. The Stakeholders strongly support the approach recommended by USEPA on Page 97 of the 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.[2, 3] 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 7, Section 2 of the Draft Selenium Criterion: *"...fish-tissue values better 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 direct waterborne route."* Selenium bioaccumulation and toxicity cannot be predicted based solely on selenium concentrations in water.[4] 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.[5] 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 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 of many is the figure on Page 3 of the Executive Summary. The figure summarizes the structure of the criterion, but the tiered or prioritized structure is absent. Another example is on Page 96 where the four-part criterion is identified. Again, language is absent to note that the fish tissue elements supersede the water column elements. 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 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 Draft Selenium	

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	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 98 of the 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, footnote 1 and 2, respectively, in Table 15 on Page 97 of the Draft Selenium Criterion state (emphasis added): *"Overrides any whole-body, muscle, or water column elements when fish egg/ovary concentrations are measured." "Overrides any water column elements when both fish tissue and water concentrations are measured."* 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 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 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 Draft Selenium Criterion to clearly establish that the fish tissue elements supersede	

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	the water column elements: o Modify the terminology throughout the document from "primary" and "precedence" to "supersedes" o Modify Table 15[6] as follows: ▪ Modify Footnote 1: "~~Overrides any~~ Supersedes all whole-body, muscle, or water column elements ~~when fish egg/ovary concentrations are measured~~." ▪ Modify Footnote 2: "~~Overrides any~~ Supersedes all water column elements ~~when both fish tissue and water concentrations are measured~~." ▪ 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. o Provide more direct and explanatory language throughout the document that clearly limits the applicability and use of water column elements, including but limited to the figure on Page 3 of the Executive Summary and Page 96 of Section 5 (Nation Criterion for Selenium). Example modified language for Page 98, first paragraph: o "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. 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	

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	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." [2] Hamilton, S.J. 2003. Review of residue-based selenium toxicity thresholds for freshwater fish. Ecotoxicology and Environmental Safety, Volume 56, pp. 201-210. [3] 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, 22-28 February 2009, Pensacola, Florida. [4] Stewart R, Grosell M, Buchwalter D, Fisher N, Luoma S, Mathews T, Orr P, Wang W-X. 2010. Bioaccumulation and Trophic Transfer of Selenium. 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. Chapter 5. Society of Environmental Toxicology and Chemistry (SETAC) Publications. CRC Press, Boca Raton FL (USA). pp. 93-139. [5] *Ibid.* [6] Corresponding changes would need to be made throughout the documentation, including but not limited to the table on Page 4 of the Fact Sheet.	
572	EPA-HQ-OW-2004-0019-0344-A1; Sanitation District No. 1 of Northern Kentucky (SD1); Posted 8/5/2014 Proposed actions Based on these comments and observations from the scientific literature (presented above), SD1 advises the EPA revise the draft criterion and accompanying guidance information by: • Recalculating the lentic and lotic water quality criteria using appropriately data censored TTFs, • Withdrawing the Interim-Exposure Water Criterion Element as unsupported at this time, and • Developing a site-specific criterion development guidance document that provides assistance to both regulators and the regulated community on the appropriate steps in recalculating CFs to develop site-specific egg/ovary, muscle, and whole-body criteria.	

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228	EPA-HQ-OW-2004-0019-0348-A1; Gopher Resource LLC; Posted 8/5/2014 EPA's suggestion that States may use water quality concentration values alone to set selenium WQBELs ignores selenium's site-specific bioaccumulative effects and is inconsistent with the Peer Review Draft's emphasis on the "primacy" of fish tissue data. The entire rationale for EPA's ten-year review of the fresh water selenium water quality criterion is selenium's status as a bioaccumulative pollutant. Selenium is a naturally occurring chemical element that is nutrionally essential in small amounts but toxic at higher concentrations.[3] In addition, selenium's bioaccumulative effects vary markedly based on location.[4] As a result, the Peer Review Draft sets forth a selenium water quality criterion with four elements, including a water quality concentration value and fish tissue concentrations. The Peer Review Draft acknowledges, however, that fish tissue-based concentration is a more direct measure of selenium toxicity to aquatic life than water column concentrations, and specifically states that the fish tissue elements should supersede water column elements when both types of data are available.[5] In addition, the Peer Review Draft recommends that States and Tribes incorporate in their water quality standards "a selenium criterion that includes all four elements [set forth in the Draft], expressing the four elements as a single criterion composed of multiple parts, in a manner that explicitly affirms the primacy of the whole-body or muscle element over the water-column elements, and the egg-ovary element over any other element."[6] In sum, the Peer Review Draft appropriately recognizes selenium's site-specific bioaccumulative effects and articulates the "primacy" of fish tissue and egg-ovary data over water column values. Suggesting that States may use national selenium water quality concentration values alone to set WQBELs is inconsistent with the Peer Review Draft's emphasis on the "primacy" of fish tissue and egg-ovary data.[7] It is also contrary to a decade of research on selenium bioaccumulation.[8] EPA should strike the suggestion from the Peer Review Draft. [3] Notice of Availability of 2014 USEPA External Peer Review Draft Aquatic Life Water Quality Criterion for Selenium-Freshwater, 79 Fed. Reg. 27601, 27602 (May 14, 2014). [4] U.S. EPA External Peer Review Draft Aquatic Life Ambient Water Quality Criteria for Selenium-Freshwater 2014 at 1. [5] *Id.* at 4 [6] *Id.* [7] *Id.* [8] *Id.* at 1-2.	

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562	EPA-HQ-OW-2004-0019-0332-A2; J.R. Simplot Company; Posted 7/30/2014 Control and Background Tissue Concentrations Idaho's fish tissue protocol workgroup has developed a compilation of a broad range of fish tissue samples from a variety of location across southeast Idaho. A number of locations where fish tissue have been monitored have been designated as control sites, where no mining or influence of the Phosphoria formation is present. Of the 262 records of fish tissues, 6 tissue samples consisting of brown trout and sculpin tissues (range: 8.2 to 9.48 g/kg dw) would exceed the whole body tissue criterion of 8.1 mg/kg dw. The remainder of the 256 tissue samples had a selenium tissue concentration range of 0.77 to 7.78 mg/kg dw in whole body. At the upper end of this range, nine samples of brown trout, Yellowstone cutthroat trout, and sculpins had tissue concentrations ranging from 7.1 to 7.78 mg/kg dw. Background tissue samples have also been collected. These samples come from locations where mining is absent, but streams flow through known outcrops of the Phosphoria formation. These streams are often connected to downgradient areas where mining has or is presently occurring. Brown trout tissue samples (n = 23) from these areas ranged from 8.16 to 10.6 mg/kg dw and would exceed the whole body tissue criterion of 8. 1 mg/kg dw. To eliminate the possibility of migration influence, tissue data from sculpin species were also examined. Because sculpins are not migratory, they can reasonably be assumed to have gained all their exposure from the site where they were captured. Of the 167 records for sculpins from background areas, 57 tissue concentrations from sculpins would exceed the 2014 Draft Criterion for whole body tissue concentration (8.1 mg/kg dw). The range of these tissue concentrations spanned from 8.18 to 30 mg/kg dw. Several of these samples come from the Deer Creek Drainage where a small footprint (<3 acres) of a mine is present which largely occupies its footprint in an opposite ridge flowing away from this drainage. While there is no apparent influence of this mine in the Deer Creek drainage, to be transparent, those samples were eliminated from consideration. The remaining sculpin samples (n=15) are all considered background samples with no known mines present. Of these 15 samples, all would exceed the 2014 Draft Criterion for whole body of 8.1 mg/kg dw with tissue concentrations ranging from 8.18 to 13.8 mg/kg dw. These data include several examples of where individual fish tissue samples from control and background areas would exceed the whole body tissue criterion. Unnecessary expenses would be required to collect egg/ovary tissues from these streams to demonstrate compliance with the 2014 National Criterion as it is currently written. This observation leads to two primary conclusions: (1) the 2014 Draft Criterion using the lower brown trout effects threshold (of the thresholds available and described in the document) is more conservative than it needs to be, and (2) use of an instantaneous	

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	never to be exceeded threshold will likely yield a high frequency of criterion exceedances. For Table 7A and Table 1, the conversion factor listed for brown trout is based on samples from Formation (2011) and Osmundson et al. 2007. The conversion factors developed for the Osmundson samples, that involve a two-step translation, seem high. Formation has six additional brown trout samples of egg and corresponding adult whole body tissue analyses for trout that were sacrificed to evaluate if they were gravid and carrying eggs. Inclusion of these six tissue pairs and exclusion of the Osmundson et al. 2007 data does not change the median ratio (1.45), but does offer a better fit in terms of the relationship of egg to whole body with an R^2 value of 0.866. We did not include these data since they were not part of the 26 wild trout that were used in the reproduction study, but have provided these data below should EPA wish to include them (Table 4). *Original letter contains Table 4 – Concentrations of Selenium in Egg and Whole Body Tissues for Additional Brown Trout Not Used in the Adult Reproduction Study (unpublished data). See original letter.* On page 73, first sentence of the first paragraph it states that, "The results of this analysis suggest that the relationship between selenium concentrations in particulate material and invertebrate tissue and between invertebrate tissue and fish tissue is somewhat insensitive to relative collection time within a one year time period." Hardy et al. (201 0) examined selenium depuration from cutthroat trout fed a range of selenium diets, then converted the feeding regime to the basal low selenium diet. The depuration rates and differences in whole body trout tissue concentrations after 32 weeks were significant. More importantly, he derived the T ½ for elimination periods for diet treatments of 5.2, 7.2, 9.2, and 11.2 µg/g selenium. The respective T ½ values were 73.56, 18.73, 14.75, and 11.51 weeks, suggesting that fish fed a higher dietary selenium depurated selenium faster, but they did it in a relatively short amount of time. These findings are contrary to EPA's analysis that paired data collected within one year of each other for EFs and TTFs are usable, given the speed at which trout eliminated selenium from their body once the dietary concentrations were reduced. Simplot observed that selenium concentrations in whole body trout and sculpin tissues did vary at a site between high and low flow periods, and in response to changes in exposure that accompanied those flow events. Likewise, periphyton, sediment, and benthic tissues were variable from year to year and season to season. If data separated by a long period of time is all that is available to evaluate relationships between particulates and benthos, benthos to fish, or forage fish to predatory fish, it is important to be aware that the likelihood of uncertainty will increase as the time span increases, particularly in systems that experience fluctuation in selenium concentrations on a seasonal basis.	

<table>
<tr><th>Comment tracking number</th><th>Docket ID, Attribution, Comment</th><th>Response</th></tr>
<tr><td colspan="3">Comment Category 2.8 – Comments Concerning the Protection of Threatened or Endangered Species
Summary: Some commenters were concerned that the criterion would not protect ESA-listed species and urged coordination with U.S. Fish and Wildlife Services and other relevant agencies.</td></tr>
<tr><td>462</td><td>EPA-HQ-OW-2004-0019-0356-A1; Idaho Department of Environmental Quality (DEQ); Posted 09/30/2014
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.</td><td rowspan="3">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.

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. In such cases, stakeholders should work with EPA to develop SSC that will insure protection of the sensitive species at that site.

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</td></tr>
<tr><td>523</td><td>EPA-HQ-OW-2004-0019-0316-A1; Alaska Department of Environmental Conservation (ADEC); Posted 7/25/2014
1. National Consultation for Endangered Species Act

EPA continues to issue revised water quality criteria without developing the biological evaluations and consultation of the effects of criteria levels on endangered species as required under the Endangered Species Act (16 U.S.C. 1531-1544). ESA consultations done after state adoption of criteria can delay EPA approval of state criteria for years.

Recommendation: ADEC strongly urges EPA to complete ESA consultation before issuing final criteria. National ESA consultation prior to publishing final criteria would be most effective in protecting endangered species and would alleviate further burden on states and delays in EPA action on state water quality standards.</td></tr>
<tr><td>524</td><td>EPA-HQ-OW-2004-0019-0334-A2; Appalachian Mountain Advocates et al.; Posted 7/30/2014
VII. 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</td></tr>
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	listed species. USFWS records show that there are currently 154 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.[9] 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 139–40. 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. Moreover, as USFWS has noted to EPA, use of the EC10 effect level that EPA has employed here, see Draft Criterion at 25–26, 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. 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. [9] Available at http://ecos.fws.gov/tess_public/pub/Boxscore.do. That is in addition to the 35 listed amphibian species, 25 listed crustacean species, and 88 listed clam 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. Regarding early coordination on selenium with the Services, EPA has had the opportunity to consult with USFWS on several state related selenium adoptions. Recently, in April 2016, the USFWS concurred with a EPA Region 4 Biological Evaluation determination of Not Likely to Adversely Affect (NLAA) for the whole body criterion adopted by Kentucky (8.6 mg/kg dw vs EPA's 2016 final value of 8.5 mg/kg). Also EPA Region 6 received a concurrence a NLAA determination on site-specific criteria from USFWS for unionid mussels after running a year-long in situ exposure with Epioblastoma species, a resident unionid mussel in the waterbody. **Responses to other issues brought up in these comments:** For information concerning items consider out of scope, refer to responses to Comment Category 2.5. For information on use and calculation of EC_{10}, refer to responses to
534	EPA-HQ-OW-2004-0019-0293-A2; Pennsylvania Department of Environmental Protection; Posted 6/26/2014 DEP recommends EPA provide sufficient and early coordination and consultation with the U.S. Fish and Wildlife Service as the Service continues to raise issues related to the protection of endangered mussels. The Service recently blocked EPA approval of the nationally recommended aquatic life criterion for Nonyiphenol that was adopted by DEP in Pennsylvania's most recent triennial review of water quality standards, because they believe the national recommended criterion is not protective of endangered mussels. This same issue may be of particular concern with selenium since Table 9 in this draft proposal, EPA-derived Tropic Transfer Function (TTF) Values for Freshwater invertebrates, suggest that mollusk have the highest tropic transfer rate.	

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		Comment Category 3.1.

Comment Category 3.1 – Comments on Use and Calculation of EC_{10} Summary: This section focuses on the use and calculation of EC_{10}. Comments in section include those on the selection of EC_{10} as the most appropriate endpoint.

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250	EPA-HQ-OW-2004-0019-0320-A2; National Mining Association (NMA) and GEI Consultants, Inc. (GEI); Posted 7/29/2014 1.0 Positives In our original review document, we highlighted several areas in which we agreed with EPA's approach and decisions made in criteria development. Specifically, we detailed our support of the following core components of the 2014 draft criteria document: • Reliance on tissue-based standards, • Use of EC_{10}s, and • Timing of tissue data collection. We would like to point out one additional point which we strongly agree with. We support EPA's decision to not use 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)	Response to concerns with the use and calculation of EC_{10}: When considering the use of the EC10 versus the EC20, an EC10 was determined to be a more appropriate endpoint for tissue-based criteria given the nature of exposure and effects for this bioaccumulative chemical. EC20s 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 over time. 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. Furthermore, it was found that the dose-response curves for selenium across a broad range of fish genera are very steep, such that a small change in selenium tissue concentration yielded a large increase in observed adverse effect. In many cases, the selenium data indicated a change from control effect levels to effects in excess of 50% for larval mortality or deformity over a few mg/kg dry weight increase in selenium detected in fish tissue. These issues call for use of a lower level of effect to attain sufficient protection. 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, to be addressed more thoroughly. The selenium criterion is relatively "data rich" for endangered species and surrogates (with sturgeon, cutthroat and rainbow trout, Dolly Varden [bulltrout surrogate], pupfish, cyprinids, and centrarchids [darter surrogate]. EPA also offers recommendations for anadromous salmonids (use of whole body at smolt stage in freshwater since reproductive stages are not relevant to criteria due to lack of exposure in freshwater). Further, published data indicate 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.

Comment tracking number	Docket ID, Attribution, Comment	Response
466	EPA-HQ-OW-2004-0019-0356-A1; Idaho Department of Environmental Quality (DEQ); Posted 09/30/2014 The rationale provided on page 25-26 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. 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, and expected population level effects, deserves greater discussion.	
502	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 For the proposed criterion to be more scientifically defensible, the chronic EC_{10} values used to derive the criterion must be substantiated to ensure that they are distinguishable from background concentrations or control/reference concentrations.	
592	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 08/07/2014 The Service continues to have concerns regarding EPA's technical basis for deriving the proposed fish-tissue criteria. However, we view EPA's transition to EC-10 point estimates of toxic risk (rather than EC-20 point estimates) for populating fish toxicity data sets as a major improvement compared to EPA's 2004 proposal. That being said, 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. We recommend working together to address and resolve this issue prior to finalizing Section 7.3 of the DSP.	
83	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014	

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	2.2 Use of EC10s We agree with the use of EC10 values to develop the tissue-based Se criteria, as data allow. Use of EC10s 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., EC20) 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 EC10 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.	
25	EPA-HQ-OW-2004-0019-0326-A1; Utility Water Act Group (UWAG); Posted 7/30/2014 Use of 5th Percentile An Improvement EPA's criteria calculations use the recommended 5th percentile calculation accounting for the relative sensitivities of all species in the data set[2]. This represents an improvement over the use of a single, most sensitive (e.g., Lemly bluegill), study as a default approach used in 2004. We agree that EPA's use of the EC10 values is more precise because it does not lie somewhere between two proximal "effect boundaries," i.e., the no observed effect concentration (NOEC) and the lowest observed effect concentration (LOEC). We also believe use of the EC10 values likely results in over-conservatism sufficient to alleviate any concerns regarding the protectiveness of the criteria for species not represented in the taxonomic database, i.e., a species more sensitive than brown trout. [2] Reference 1985 Guidelines.	
249	EPA-HQ-OW-2004-0019-0317-A1; Intermountain Region, Forest Service, United States Department of Agriculture (USDA); Posted 7/29/2014 Page 58. It is recommended that EPA reconsider using the 95th percentile method for selenium. This approach mixes different toxicity endpoints (fish vs invertebrates) and requires translation of invertebrate tissue endpoints to equivalent fish tissue units. These steps increase computational complexity with an associated increase in uncertainty. As stated in the draft document, a basic premise of the draft criteria is that that fish reproduction is a sensitive environmental indicator of selenium toxicity. Using the resulting fish toxicity endpoint as the basis for the selenium criterion would be more consistent with this basic premise.	
Comment Category 3.2 – Comments on Studies of Fish Reproductive Effects Used in Numeric Criterion Derivation 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 two of the four most egg ovary sensitive genera (i.e., bluegill and brown trout). In general, commenters questioned the validity and applicability of specific studies.		
26	EPA-HQ-OW-2004-0019-0332-A2; J.R. Simplot Company; Posted 7/30/2014	Responses concerning studies on fish reproduction effects:

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	Data Decisions and Calculations to Develop Genus Mean Chronic Values Lack Scientific Validity. The data decisions and calculations used to develop genus mean chronic values (GMCVs) and species mean chronic values (SMCVs) for the fathead minnow, bluegill, and brown trout show a conservative bias. An examination of the methods used to calculate the EC10 values for each of these species shows that a number of conservative decisions and assumptions were made in these calculations. This "compounded conservatism" distorts the actual level of toxicity determined in these studies in freshwater systems. Specific studies that need reexamination include the fathead minnow, the bluegill and the brown trout.[1] Our comments are focused on the brown trout study discussed extensively by EPA in the draft criterion document, as that study is our work. Specially, the following assumptions and calculations need to be reexamined by EPA: • How to account for the fish lost during an equipment malfunction? EPA used the worst-case assumption in their calculations. • How to account for and score deformities? The most conservative approach is to assume any deformity, however so slight, is a deformity that would impair a fish to grow, survive, or reproduce. This however, may include fish with slight deformities that could occur naturally without significant selenium exposure. • For the field generated data for brown trout tissues and trophic transfer information, EPA needs to correctly use the brown trout data where it was collected and not use the total trout data where brown trout were not collected. For each of these areas, by opting to use the worst case scenario for the most sensitive endpoint (fully normal fry) of the most sensitive species, EPA opted for a multi-layer extremely conservative approach, which is based on faulty assumptions concerning this dataset. Removing the incorrect and faulty assumptions and utilizing a combined endpoint, the EC10 should be between 20.49 and 21.16 mg Se/kg dw egg instead of EPA's calculated EC10 value of 15.91. Furthermore, correct use of the brown trout field data will change some of the information EPA presents at several levels in various sections of the document. II. The Derived Criterion Value of 15.2 mg/kg is Overly Conservative: Review of the Brown Trout Study EPA included Simplot's brown trout adult reproduction studies (Formation 2011 and AECOM 2012) in its derivation of the Draft National Criterion. In reviewing the data presented in the document, we find that they have been accurately conveyed in terms of the values for survival (except for the five treatments where swim up did not occur) and deformities. The values for egg selenium data are correctly represented.	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 (represented in the derivation of the whole body criterion element), and concluded that the egg-ovary transformed whole body criterion element of 8.5 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 EC10 are provided in toxicity Section 3 of the 2016 Criterion document, and several descriptions for particular species are summarized below for reference. Brown Trout Study Regarding the brown trout study, EPA re-analyzed the available data on the Formation 2011 study after issuing the External Peer Review Draft Selenium Criterion document in 2014. The Agency also re-evaluated the study a second time after public comments were received on the 2015 draft criterion. Regarding public concerns pertaining to the Formation brown trout, the study data were re-evaluated. Ultimately, EPA determined that the model instabilities resulting in uncertainty surrounding the EC10 value, such as multiple minima for the optimistic and worst-case deformity endpoint, were the result of high variability in deformities at low selenium concentrations, as well as the assumptions associated with how to interpret the health and survival of fry lost to overflow caused by a clogged drain during a 15-day post swim-up feeding trial. Most maternal transfer studies do not include a post swim-up test, and for this test, the uncertainty introduced by the laboratory accident was concluded to outweigh the additional information gained by extending the test. Also, in Simplot's June 24, 2014 comments to EPA Simplot states (page 6, number 2) clearly that the experimenters preferentially

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	Some of the assumptions that EPA made in the analyses that utilized these data are the focus of comments that follow. During the second phase of the test, the 15-day post swim up feeding trial, fish from some of the test chambers escaped due to overflow pipes that drained the test cells being clogged with uneaten food, resulting in an overflow of some of the test cells. This occurred for 10 of the 26 wild fish treatment cells and the numbers of fish lost ranged from 16 to 45 fish (Table 1). In their analyses of the survival and deformity endpoints for Simplot's brown trout studies, EPA made two assumptions about fish that escaped during the last portion of the study (15-day post swim up feeding trial), an "optimistic" scenario and a "worst case" scenario. The optimistic scenario assumed that escaped fish were no different than those assessed. The result of this scenario is that data for treatments where fish escaped were used as they were reported at the end of the test, so if the test was started with 100 organisms and 18 escaped, and the remaining 82 fish survived, then survival would be 100 percent for the 82 fish remaining. The worst case scenario assumed that for any treatment where fish escaped, those fish were either dead or deformed or both. They were added to the total number of fish assessed for their respective treatment cells (for survival or deformities) and used as the divisor for those fish that survived or those fish that were normal. In the same example used above, survival would be 82 percent. Simplot's analysis of these data was conducted using the optimistic scenario. The 2014 Draft Criterion presented the dose response curves for each analysis (i.e., worst case and optimistic) for each endpoint, including survival, proportion normal, and a combined endpoint of surviving and fully normal (Figure 13, Section 7.1.4) along with their rationale for selection of the EC10 to be used as the criterion. Of the six possible EC10 values, EPA chose the lowest possible value derived (i.e., 15.91 mg/kg dw egg selenium) which was based on a worst case scenario for deformities, stating "The use of the lowest of the above values (15.91 mg Se/kg) for setting the chronic value for brown trout provides a greater margin of protection than would one of the higher values". By opting to use the worst case scenario for the most sensitive endpoint (fully normal fry) of the most sensitive species, EPA opted for a multi-layer extremely conservative approach, which is based on faulty assumptions concerning this dataset. <u>a. "Worst Case" Scenario Assumptions Are Incorrect</u> Several lines of evidence are provided below that indicate the assumptions for the worst case scenario are incorrect and ultimately biases the Draft Criterion lower than it should be. 1. Once the overflow pipes were observed to be clogged and remedied, escaped fry were observed swimming in the water bath where the treatment containers were being held. These fry congregated near the treatment cells. Dead or dying fish were not observed.	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 EC10. Therefore, the EPA's statistical re-evaluation of the brown trout (Salmo) data (Formation 2011) was confined to observations and data from the exposure period prior to the lab overflow accident. As a result of the statistical re-evaluation, the new EC10 increased from 18.5 mg/kg dw to 21.0 mg/kg dw. For more detail please see Section 3 of the 2016 final selenium criterion document. Bluegill Study Regarding the comment on bluegill, following the peer review, EPA reanalyzed the Hermanutz bluegill study using a combined endpoint of larval survival and edema. Including larval survival in the endpoint eliminated the more variable nest data since it was not possible to measure survival in the nest. EPA recognizes the discrepancy between the bluegill tissue between Study I and II is 10 µg/L in streams. However, the 10 µg/L treatment from Study I was only one data point in the analysis and it did fit the curve well, so it was included. The 30 µg/L fish all died by the end of the test and selenium accumulation was apparently affected by its toxicity. EPA asserts that the Hermanutz bluegill study is scientifically defensible, despite the uncertainties, based on the revised analysis and has retained it in criterion development. The data reanalysis mentioned above (Hermanutz 1992, 1996, as corrected by Tao, 1999) in described in the 2016 criterion resulted in a superior fit to the previous TRAP-derived EC10. As a result, the new EC10 increased from 11.36 mg/kg dw to 14.7 mg/kg EO dw. For more detail please see Section 3, and Appendix C of the 2016

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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.
3. None of the highest egg selenium treatments experienced any loss of fish due to overflow (Samples LSV2C-003, 004, 005, 010, 021). It is highly likely that these treatments had a similar potential for overflow to those that did overflow, yet fish remained in the treatment cells. The activity level of fry in these treatments was low and these fish were either too weak or not developed enough to swim out. These five treatments had the highest deformity rates and mortalities. The 2014 Draft Criterion states, "The peer review conducted by ERG (2012) did not provide a consensus on expectations of whether less healthy organisms were more likely to have been lost in the overflow". Based on the data from these five treatments where egg selenium and deformities were the highest and survival was the lowest, it is apparent that the less healthy the fish, the less likely it was to escape.
4. Fish culled at the end of the test for growth assessment (target n = 20) were surviving, but no assessment of deformities was made because these fish were dried for dry weight analysis. Using the logic of the worst case scenario, these fish would have to be assumed to be deformed, although they were surviving. The fish for the growth assessment were randomly selected and free of any visual deformities before being culled. As these data are currently used in the analysis, these fish are removed from the population of total fish assessed for deformities which follows the logic of the optimistic scenario.
5. Very few fry died during the 15-day post swim up feeding trial except in the five highest treatments where the derivation of the proposed criterion sets the mortalities for these treatments to 100 percent. For all other treatments, mortalities were 3 or less with most treatments recording zero mortality (Table 1). For the wild fish treatments where fish escaped, survival prior to the initiation of the 15-day feeding trial ranged from 88.5 to 99.3 percent (hatch to swim up). For those treatments where the overflow occurred and fish escaped, based on the high survival rates prior to and during the 15-day post swim up trial, and observations of escaped fish swimming around in the adjacent water bath, there is no reason to believe that these fish died once the feeding trial began. Similarly, because the testing laboratory culled fish prior to the initiation of the 15-day feeding trial (with attention paid to deformed fish), there is no reason to believe that the fish that escaped were deformed.

Original letter contains Table 1 – Percent Survival Prior to 15-Day Post Swim Up Feeding Trial, Numbers of Missing Fish, and Number of Dead Fish During the 15 Day Trial. See original letter.

b. Survival Endpoint

The five lines of evidence presented above remove much of the uncertainty regarding the health of
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final selenium criteria document, While EPA's analysis indicated that the Hermanutz EC10 was the lowest of the 3 bluegill studies (Hermanutz, Coyle, and Doroshov) at 14.7 mg/kg dw, the geometric mean of the studies (bluegill SMCV) was 20.6 mg/kg dw.
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Other Species
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.

White Sturgeon:
Data were included for the white sturgeon (Acipenser transmontanus; Linville 2006) in the 2015 draft after identification of the study in a literature review as a result of interactions with Region 9 and the USFWS on site-specific criteria for selenium in the San Francisco Bay and Delta. EPA independently reviewed the study and derived an EC10 of 16.27 mg/kg which was included in the 2015 draft. Re-evaluation of the study was based on comments received during the public process pursuant to the publication of the 2015 draft. The re-analysis resulted in a superior fit to the previous TRAP-derived EC10. 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 Selenium 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, and Appendix C of the 2016 selenium criteria document,

EPA examined Buchwalter's (Conley et al. 2013) recent study. There were two 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
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	the escaped fish that EPA cited. The optimistic scenario used in EPA's approach is logical and does not make assumptions that are contrary to the data or observations reported by the testing laboratory. This is the preferred analysis approach and is consistent with how Simplot originally analyzed these data. For the survival endpoint, EPA elected to agree with USFWS comments (USFWS 2012) that those fish that did not attain swim up should be considered mortalities even though at the end of the test they were still alive. The rationale was that by not attaining swim-up these fry would have likely died in the wild. It is possible that trout fry not attaining swim up may die in the wild. However, an accurate representation of these data is needed and the survival values for those five treatments where swim up did not occur should be shown. The text and subsequent analyses could then state the assumption and rationale for the assumption. The number of surviving fish that were normal in these five treatments (LSV2C-003, 004, 005, 010, and 021) were 2, 16, 8, 5, and 8, respectively. Resulting percent survival for these treatments was 2.2, 19.7, 24, 10.2, and 21 percent. In EPA's worst case scenario, those fish that escaped during the 15-day post swim up feeding trial were also assumed to be dead. As noted above, fish that escaped were observed swimming in the water bath where the treatment cells were held. Because the laboratory staff could not identify which cells those fish came from, they could not be returned to the treatment cells. The assumption that non swim-ups would die (and survival for these treatments set to zero) in the treatment cells identified above is already a conservative assumption that should not be compounded by the assumption that escaped fish were dead. For the wild fish treatments where fish escaped, prior to the initiation of the 15-day post swim up feeding trial survival ranged from 88.5 to 99.3 percent (hatch to swim up) (Tables 1 and 2 Appendix C, page C-60-69). There is no reason to believe that these fish immediately died once they escaped after the feeding trial began. <u>c. Deformity Endpoint</u> To assess deformities, fry were scored on a basis of 0, 1, 2, or 3. A zero score indicated no deformities, 1 slight, 2 moderate to severe, and 3 severe. In its analysis of the brown trout deformity data, EPA elected to use a count of normal fish (i.e., score = 0) relative to the number of fish assessed for deformities. The worst case scenario and optimistic scenario conditions were applied. Collectively, both of these approaches are conservative, and the worst case scenario approach is inaccurate. These conservative approaches may have also introduced unwanted uncertainty into the analysis. In two sections of the 2014 Draft, EPA noted that the elevated rate of deformities in background and hatchery fish creates uncertainty in the analysis of these deformity data. • Page 45 Section 4.1.1, "There are two experimental complications that affect the interpretation	selenium toxicity effect. These data are discussed in the revised draft 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 the comment on adding new studies, the Formation Environmental Yellowstone cutthroat trout study has been analyzed and added to the database. Regarding the Doroshov et al. (1992) catfish study, 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 peer reviewers agreed with the exclusion of the injection route of exposure, and several provided additional lines of reasoning for excluding injection studies from consideration. In addition, 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 ictalurids, despite the absence of valid egg-ovary test data. Whole Body The majority of the data for the egg-ovary to whole body [selenium]

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	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." • Page 108 Section 7.1.4, "Uncertainties in the EC10 appropriate for this species stem from the observed high background deformity rates and by a lab accident causing overflow loss of some organisms from several aquaria during the post swim-up portion of the test." The loss of fish from the treatment cells during the 15-day post swim portion of the test is addressed further in section II A above. In this section, we focus on the concept of fully normal fish versus insignificant deformities. MacDonald and Chapman (2009) conducted a QA review on a number of larval deformity assessment studies for selenium and 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. Dr. Kevin Bestgen, head of the Larval Fish Laboratory at Colorado State University (CSU), was asked about whether or not fish ranked as 1 would likely impair the ability of fry to survive, grow, or reproduce and he commented that those slight deformities were not likely to impact an individual's potential to survive and compete in the environment. The most conservative approach is to assume any deformity, however so slight, is a deformity that would impair a fish to grow, survive, or reproduce. This however, may include fish with slight deformities that could occur naturally without significant selenium exposure. For example, examination of figures 13a and b on page 110 of the Draft Criterion for proportion of fully normal fry indicates that for hatchery fish and wild fish at a concentration of less than 25 (log 1.4) mg/kg dw egg selenium, there is a wide range of normal fish (from about 35 to 85%). At a concentration greater than 25 mg/kg dw egg selenium, there is a clear separation of the data with the numbers of normal fish being very low. As indicated early on in the 2014 Draft Criterion, there is a narrow margin between	relationship analysis came from Osmundson et al (2007) who did have egg data and whole body [selenium] data from the same fish. The whole body [selenium] 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] was determined. Hermanutz (1996) and Hardy (2005) apparently measured whole body and egg selenium 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. The whole body criterion element is ranked as a lower tier than the egg-ovary criterion element because of the additional uncertainty associated with variable selenium concentrations across tissue types. Regarding the suggestion for EPA to consider using empirically measured whole-body selenium (or muscle selenium) data for those species where they are available, rather than applying CFs to egg/ovary selenium data (EPA's current approach) using conversion factors, EPA has modified its approach for deriving whole body and muscle criterion elements in the 2016 final document. EPA now uses empirically –determined whole body or muscle [Se] preferentially to CF-estimated values. EPA then uses median CFs (based on a hierarchy of taxonomic proximity, rather than a median of all fish) to determine the egg/ovary translated whole body (or muscle value. The modification of the method is located in Section 3 of the criteria document, and a comparison of CF derivation methods (regression vs median) is located in Appendix N. Regarding the validity of the 5'" percentile, the value is derived

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	sufficiency and toxicity. This kind of steep dose response curve is found for most of the reproduction studies. A less conservative approach, and likely more realistic approach, would be to include fry ranked as 0 or 1 as insignificant deformities and to include fry ranked as 2 or 3 as significant deformities. Simplot presented these data to EPA and IDEQ in response to the USFWS comments (Simplot 2013). When considering deformities based on these two categories for the wild fish, the mean proportion for insignificant deformities (i.e., ranked as 0 or 1) was 92.3 percent (range: 67 to 99%) at an egg Se concentration of 20.5 mg/kg dw[2] 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 Se 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%). Based on the evaluation of these data, it is apparent that the uncertainty questions EPA raises in the 2014 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. The result of analyses using these data as described above is increased certainty in the EC10 values derived from data with this level of detail. d. Combined Endpoint EPA used a combined/integrated endpoint for surviving fish that are fully normal. A combined endpoint seems logical and smooths out some of the data spread introduced from the deformity data (i.e., proportion fully normal). However, use of a less conservative endpoint for the proportion normal fish as mentioned above would have a similar effect and outcome regarding derivation of the EC10. Using EPA's approach to derive a combined endpoint, Simplot derived an endpoint for surviving fish with insignificant deformities (i.e., 0 and 1 rankings) (Figure 1). The EC10 for this approach is 20.49 (LCL = 19.87, UCL=21.04) mg/kg dw egg selenium.[3] The EC10 for surviving fish with insignificant deformities is only slightly lower than the worst case scenario for the combined endpoint. Given the	using the standard 1985 Guidelines methodology for deriving an HC05. That is a censored log triangular distribution using a least squares regression fitted to the curve for the 4 GMCVs closest to the 5th percentile of the overall distribution. In the case of selenium, given the “N” =14, this happens to be the lowest 4 GMCVs. Several species not explicitly represented in the distribution, as well as invertebrates, are counted toward the N in terms of the number of GMCVs. Invertebrates are included implicitly as they serve to fulfill the 8 minimum MDRs required by the 1985 Guidelines. A more detailed description of these requirements is located in Section 2 of the 2016 final criteria document. Regarding the use of the biphasic model for the assessment of the Hamilton 1990 study, the biphasic model should not be applied indiscriminately to data sets. To use the model correctly, there must be sufficient low dose exposures to capture both a beneficial response and a low toxic response, particularly if the EC10 is the effect concentration of interest. Given that the diets were made up of Oregon Moist salmon meal and mosquitofish meal (Se-contaminated and uncontaminated), it is speculative to assert that the decrease in survival from 99% to 66.7% in less than 30 days was due to selenium deficiency, given that selenium in the control diet was ~ 3 mg Se/kg dw. This concentration is similar to selenium observed in naturally-reared coho smolts (3.6 mg/kg dw). Regarding the USFWS concern about the use of Conley’s mayfly studies, Conley et al. (2011) was not reviewed until after the 2014 draft document was released, but was evaluated for inclusion in the 2015 draft document. The reproductive impairment observed for C. triangulifer appeared when food was limited (1x ration), but was not observed at higher food densities (2x ration). This result suggests that the effects of selenium exposure cannot be separated from resource availability/nutrition in this study. Therefore the study is not used in the criterion calculation. Section 3.1.4 of the 2016 final criteria document presents a summary of the Conley et al. 2009, Conley et al. 2011, and Conley et al. 2013 studies.

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	relatively insignificant difference between 20.49 mg/kg egg selenium (insignificant deformities), 21.16 mg/kg egg selenium (optimistic scenario), and 20.65 mg/kg egg selenium (worst case scenario), a combined endpoint that reduces uncertainty by eliminating the subtle differences between no and slight deformities (which are not expected to cause effects on survival, growth, or reproduction) is a logical choice. By including fry ranked as 0 and 1, the analysis appears to be more robust (although we have no statistical proof of this) and would likely set the stage for future assessments to reduce uncertainty in deformity characterization of fry by promoting use of a graduated severity index ranking system. Future studies may opt to use a normal/not normal ranking system simply to avoid teasing out these subtle differences and the potential issue that any fish ranked with a slight deformity (even if due to preservation) will be considered fully deformed. [1] Comments from the National Mining Association and the North American Metals Council address the fathead minnow and bluegill studies, along with the brown trout study. [2] The egg selenium value of 20.5 mg/kg dw is used here because it represents an obvious break in the data relative to absolute effects and no or low levels of effects and represents a highly probable threshold of effects for this dataset. [3] This EC_{10} was derived using a Tolerance Distribution and a triangular data distribution with fitted data for the Logx50 of 1.34 and Y0 of 0.87 using the Toxicity Relationship Analysis Program (TRAP), version 1.21A (USEPA 2012). An earlier version was also used: TRAP version 1.2 (USEPA 2008).	Regarding the concern about EPA's re-evaluation of the Muscatello study, EPA did exhaustively examine the Esox data and does not concur that the authors' EC10 calculation is scientifically defensible and useable. The spacing between exposures is too large to estimate the EC10 either by the authors' linear regression approach, or by EPA's nonlinear regression approach. Based on its cluster of three values with concentration near 34 mg/kg, having 24% effect, EPA estimates that Esox is somewhat sensitive, but not among the four most sensitive. Regarding the use of invertebrate toxicity studies, EPA removed the comparison of the invertebrate chronic values to the fish chronic values after applying conversion factors to express invertebrate values as fish egg ovary values. EPA retained the 3 invertebrate genera, as well as the benthic and pelagic crustacean MDRs in the count of the total "N" for the 5th percentile calculation. Please see discussion in the sections "Assessment Endpoints" (Section 2) and "Derivation of Tissue Criterion Element Concentrations" (Section 3) of the 2016 final criteria document for a discussion of EPA's rationale for implicit inclusion of these taxa. Regarding the inclusion of the Westslope cutthroat trout study, the data from Hardy et al. (2010) were identical to the data included in the original report (Hardy et al. 2005), which was analyzed by EPA (page C-45 in the 2014 draft document). As noted by the commenter, these data were not used in the numeric criterion derivation because the highest egg selenium concentration represented an unbounded no observed effects concentration (NOEC). EPA has also reviewed the Formation Environmental (2012) Yellowstone cutthroat trout study and has included it in the 2016 final selenium criterion document.
54	EPA-HQ-OW-2004-0019-0331-A1; The Fertilizer Institute; Posted 07/29/2014 II. The Proposed Chronic Value is too Low The chronic value calculated was based on EC10s from a number of species (see Table 1). A review of these studies shows that several of the EC10 values calculated by EPA are overly conservative. Specifically, the calculation by EPA of EC10s for brown trout and bluegill species introduces a conservative bias into the chronic value calculation. The EPA review of the Brown trout study (Formation 2011) focuses considerably on how to handle the data from a problem that arose during the study: plugged drain pipes in some of the testing apparatus treatment cells resulted in some test organisms escaping to the adjacent water bath. How these lost organisms are classified (e.g., alive, deformed, or both) affects the calculated EC10. EPA notes that a range of EC10s from 15.91 to 21.16 mg Se/kg dry weight ("dw") egg is possible and EPA calculated six different EC10 values. EPA then chose the lowest EC10 value (15.91 mg Se/kg dw) to use in the derivation of the proposed national criterion. This choice is not technically defensible for several reasons: (a) there is no basis for the assumption that organisms lost in the lab accident were	

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	dead, dying or deformed; (b) EPA failed to use a combined survival and deformities endpoint; and, (c) the use of the TRAP model (Toxicity Relationship Analysis Program - EPA 2008, 2011) shows the best-fit TRAP calculation (for the combined endpoint surviving and normal) has an EC10 result of 21.16 mg Se/kg dw[1]. *Original letter contains Table 1 – Ranked Genus Mean Chronic Values for Fish Reproductive Efforts. See original letter.* EPA calculated a bluegill reproductive genus mean chronic value ("GMCV") as the geometric mean of EC10s from three studies: 20.05 mg Se/kg dw egg from Doroshov et all (1992); 24.55 mg Se/kg dw egg from Coyle et al. (1993); and, 12.68 mg Se/kg dw ovary from the two studies done by Hermanutz et al. (1992, 1996). However, the results between the two Hermanutz studies are inconsistent; a review of the TRAP model curves shows a very poor fitting curve (see Figure 1). *Original letter contains Figure 1 – Hermanutz et al. (1992, 1996) Trap Model Results Figure Draft Criterion Document (page C-113). See original letter.* Since the Dorosohv et al. (1992) and Coyle et al. (1993) studies are not problematic like the Hermanutz (1992, 1996) studies, EPA should not rely on the inconclusive Hermanutz studies. The removal of the Hermanutz results and recalculation of the Brown trout EC10 value would result in a final chronic value greater than 17 mg Se/kg dw. Such a value is more technically defensible, but still environmentally protective. [1] The comments prepared by NAMC have an extensive discussion of the Brown trout study. TFI refers EPA to those comments for a detailed technical review of EPA' s use of the Brown trout data.	
242	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 Conservative Assumptions Reflected in the Egg/Ovary Criteria The egg/ovary final chronic value (FCV) of 15.2 mg/kg dw is likely overly conservative, particularly for recovering systems, because of the multiple conservative assumptions that were made to address uncertainties. The critical conservative assumptions of the critical studies used in the derivation of the criterion include: • Use of chronic EC10 values that are essentially no effect levels. o For example, high rates of deformity at background concentrations were observed in the brown trout study, which may result in an EC10 that is indistinguishable from a no effect level (see Figure 13, page 110);	

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	• Assumption that all fish lost in a lab accident in the brown trout study (overflow which occurred during the 15-day post swim-up portion of the test) were dead, dying or deformed (see page C-61); • Exclusion of bluegill (Lepomis macrochirus) studies in recovering streams that assessed biological recovery in which selenium tissue concentrations were elevated, but no reproductive effects were observed (see pages 47-50); and • Selection of an EC10 from a conservative fitted line for observed edema in bluegill instead of from a model fit that reduced vertical and horizontal errors (see section 7.1.5; Figure 14). The selection of the lowest, most conservative ECIO value of 15.91 mg Se/kg dw for the brown trout (Salmo trutta) from the study conducted by Formation Environmental (2011) is given far too much weight in the document given to experimental complications cited in the study that affect the interpretation of the data. The lowest of six ECIO values derived from the study's data ranging from 15.91 to 21.16 mg Se/kg egg dry weight was selected by the U.S. EPA based on the assumption that this is representative of a worst case scenario. Selecting the value for the worst case scenario is an overly conservative approach especially since the value of 15.91 mg Se/kg dry weight becomes the lowest GMCV included in the distribution curve, thus greatly influencing the derivation of the criterion value (15.2 mg Se/kg dry weight). The effect of the uncertainty in this value on the derivation of the egg-ovary criterion would greatly enhance the transparency of the derivation and would provide additional confidence in the final value. Implications on the use of conservative assumptions in deriving the draft egg/ovary FCV are detailed below: • A GMCV of 21.16 rather than of 15.91 mg Se/kg dw for Salmo would have been calculated if the following assumptions were made: the chronic value for combined survival and deformities, and the optimistic case for fry lost in the lab accident. This would result in an FCV of 18.0 mg Se/kg dw rather than of 15.2 mg Se/kg dw derived by the US EPA. • The U.S. EPA acknowledges that the best supported EC1p values fall within the range of 15.91 to 21.16 mg/kg dw. However, no analysis was provided to demonstrate the effect of the uncertainty of this number on the overall derivation of egg-ovary criterion. • A GMCV of 20.84 rather than of 18.41 mg Se/kg dw for Lepomis would have been calculated if the following assumption was made: a chronic value of 18.40 mg Se/kg dw based on a model fit that reduces vertical and horizontal errors instead of 12.68 mg Se/kg dw. • If the alternate value for Lepomis was considered in combination with the GMCV of 21.16 mg Se/kg dw for Salmo, the resulting FCV would be 19.8 mg Se/kg dw instead of 15.2 mg Se/kg dw, an increase of 30%.	

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	• It seems that the egg-ovary FCV was calculated from regression analysis of the four most sensitive GMCVs, in this case extrapolating to the 5`h percentile of the distribution represented by the tested genera. However, the documentation indicated that 14 GMCVs were considered and a sensitivity analysis was conducted in Section 7.1.6 on the effect of the number of GMCVs on the egg-ovary criterion. Therefore, there seems to be a disconnect with respect to the methodology for developing the egg-ovary criterion. The draft criterion document states that the FCV directly serves as the fish tissue egg-ovary criterion concentration element without further adjustment because the underlying EC10s represent a low level of effect (as outlined in the Guidelines, Stephan et al. 1985). The distribution used to derive the FCV should be clarified. • The presentation of the results in Section 4.1.5 is not transparent. Figures 5 and 6 in the document present the genus-level sensitivity distribution data for the fish egg-ovary tissue criterion and the fish whole-body tissue criterion, respectively. The figures include GMCVs for fish, mosquito fish (a live-bearer), and invertebrates, totaling N=14 genera (including planktonic and benthic crustaceans that did not have quantified GMCVs). However, the figures do not provide any curves. The fitted curve parameters for the entire curve or for the four most sensitive genera are also not reported making it difficult to assess the validity of the derived criterion values. It would also be helpful to show on the figures the intersection of the fitted curve with the 5'" percentile which determines the criterion value. The draft criterion document also does not report the tool that was used to generate the distribution curves thus making it difficult to validate their results.	
245	EPA-HQ-OW-2004-0019-0271-A2; Coordinator, Barnes & Thornburg LLP on behalf of the Federal Water Quality Coalition; Posted 6/17/2014 The fish tissue criteria concentrations are too low. They are driven by a conservative interpretation of a study of brown trout; there are other interpretations that yield higher EC10s for that study. Given the elevated control deformities and loss of fish during the post swim-up phase, those endpoints should be disregarded. Data for % hatched and survival to swim-up are adequate and could be used instead.	
258	EPA-HQ-OW-2004-0019-0339-A2; West Virginia Department of Environmental Protection (DEP); Posted 7/30/2014 General comments regarding EPA's Draft Selenium Criteria EPA use of questionable results - The inclusion of two studies in which potentially erroneous data were used or improperly derived results were used in the calculation of protective egg/ovary thresholds has led to proposed tissue limits below which most published literature suggests is protective for any Effect Concentrations (ECs) or any portion of an exposed population (e.g. most	

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	studies indicate egg/ovary EC10's are in the range of 20 ppm Se-dry). The utilization of these data, particularly in regard to the recalculation of thresholds based upon hypothetical deformity rates among lost specimens, does not meet the experimental rigor required for inclusion in such considerations. The study involving brown trout, *Salmo trutta*, which represented the lowest reproductive effect concentration in the genus mean chronic value calculation (GMCV), experienced a "laboratory accident" where individuals were lost. Inexplicably, the loss of individuals was attributed to selenium exposure in a recalculation of the study's results and the subsequent threshold became the lowest among the GMCV list. Another study, Hernanutz's (1996) examination of bluegill sunfish (*Lepomis macrochirus*) was used to derive EC10 thresholds based on larval edema at 12.68 ppm. This experiment, which utilized selenite exposure to induce prey uptake and subsequent fish tissue accrual, demonstrated low adult survival, larval impacts predominantly expressed via incidents of edema, and indicate higher exposures resulting in fewer effects. This study also contradicts two more relevant studies utilizing bluegill sunfish exposed to organic selenium and indicate effect concentrations nearer to 20 ppm, which is a value widely reported in the literature. The inclusion of these flawed results clearly projects bias, as it results in lower GMCV egg/ovary tissue thresholds which are not reflective of the aggregation trend near 20 ppm egg/ovary, indicating a physiological response, and is applicable to the majority of fish species but not to the most sensitive outliers. We request EPA remove the use of the recalculated results from the brown trout study and the outlier bluegill sunfish study from the criterion development calculation or provide further justification regarding why these studies are being included.	
156	EPA-HQ-OW-2004-0019-0353-A1; Mark C. Rigby, Parsons and University of California at Santa Barbara; Posted 8/7/2014 Comments **likely** to affect calculation of numeric criteria Table 5 includes several field studies (i.e., Muscatello et al. 2006, Nautilus Environmental 2011, and Rudolph et al. 2008) in which the fishes evaluated were (or may have been) exposed to elevated levels of other contaminants, in addition to selenium. The use of such studies in the derivation of a water quality criterion should be considered very carefully, as it may bias the results. At the very least, USEPA should show the effect of including and excluding these studies on the criterion derived. Where the original authors measured the concentrations of other contaminants that should also be reported in the appendices of the USEPA document so that the reader may evaluate whether other contaminants may have affected the results. Where concentrations of other chemicals were not measured, they may be suspected when the field study was performed to evaluate the effects of a release that isn't purely selenium; e.g., coal mining effluent, uranium mine effluent, etc.	
18, 19, 20, 28, 145,	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; U.S. Fish and	

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146, 154	Wildlife Service, Paul Souza; Posted 8/7/2014 A set of experiments in which use of a biphasic model makes a clear difference is that of Hamilton et al. (1990) in which the toxicity of selenium to juvenile Chinook salmon was tested. They found that the toxic effects of selenium were modest at 60 days of exposure, but were substantially more severe at 90 days of exposure. In the DSP EPA uses the 60 day (less severe) data, but puts aside the 90 day (more severe) data. The stated reason for this selective use of the data is that survival of "controls" at 90 days had declined to a point that indicated "compromised health." However, application of a biphasic model to the Hamilton et al. (1990) 90-day data in the figure below indicates that reduced survival of the "control" group was at least partly due to the fact that, for sensitive organisms, like juvenile salmon, the range between toxicity and deficiency is so extremely narrow that the "control" group probably suffered some selenium deficiency. In the figure below, the biphasic model was based solely on the Hamilton et al. (1990) 90-day data. The open circles represent data from a different experiment on a related species, the Atlantic salmon (Poston et al. 1976). The validity of using a biphasic model to model such dose-response relationships is strongly supported by the remarkable ability of the biphasic model to accurately predict the Atlantic salmon response to conditions of overt selenium deficiency. It should also be noted that, as part of this set of experiments (Hamilton et al. 1990) these investigators additionally and simultaneously ran control groups of juvenile salmon that were fed only commercial fish food (unlike the juvenile salmon in the published "control" and exposed treatments graphed below, all of which were fed diets that Included a large component of mosquitofish). These controls (the unpublished ones with a 100% commercial diet) experienced 100% survival throughout the 90-day duration of the experiments (Kevin Buhl, pers. com). This indicates that there was no experimental or procedural flaw resulting in general compromised health; rather, there was evidently some toxicity or dietary inadequacy resulting from a diet with a large component of mosquitofish. Whatever the cause of this phenomenon, it is evidently independent of, and should not detract from, the validity of the clear selenium exposure-response displayed by the 90 day data, shown in the graph below. These data indicate an LC10 of 1.84 mg/g in whole body tissue of juvenile Chinook salmon, a result far below the currently proposed whole body criterion of 8.1mg /g. We understand that the proposed criterion is probably not intended for measurement in juvenile fish, although in the absence of implementation guidance we are not certain of that assumption. We believe that by greater use of biphasic models EPA could make more complete use of available data for salmonids, such as Hamilton's 90-day results, and have a more representative weighting	

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	between salmonids and species like bluegill that are less sensitive (1.46 times less sensitive, on average, according to the study of Teather & Parrott 2006, as shown below). This concludes the technical topics that we will discuss in some detail at this time. The remainder of our comments constitute a topical list of technical issues we suspect would benefit from further examination and analysis, which perhaps we can develop in time for the next comment period. For now the Service hopes that some of these topics will be addressed more fully by the expert external peer reviewers. In no particular order of priority: With regard to the highly influential toxicity data for brown trout, at this time the Service simply notes that our review and analysis of the brown trout data (USFWS 2012a) reached a different conclusion than EPA's recent second-generation review and analysis. Accordingly, the Service plans to closely examine the brown trout appendix to see if we agree with and can replicate EPA's re-analysis of the enhanced brown trout toxicity data set that was not available to us for analysis in 2011. We expect to report our findings in the next public comment period. (2) Scientific basis for excluding the U.C. Davis Channel Catfish Study In Section 7.1.2 of the DSP titled "Reproductive Effects in Catfish (Ictaluridae)", it is explained that a major study of selenium reproductive toxicity in Channel Catfish (Doroshov et al. 1992) was not considered because the injection route of exposure differs from exposure routes in the environment (water column and diet). If Doroshov et al. (1992) had injected selenium directly into catfish eggs the Service would agree with EPA's decision to discard the study. It has been clearly established in the avian literature that egg injection studies, while reliable for establishing relative sensitivity to toxicants are not useful for establishing concentrations of maternally deposited toxicants that would represent reproductive toxicity thresholds (e.g., Heinz 2003; Heinz et al. 2009; Heinz et al. 2012). However, Doroshov et al. (1992) injected the selenium intra-muscularly (IM). Just as with dietary exposure, IM injection ultimately delivers the selenium to the maternal systemic circulation where it is processed and maternally deposited into eggs. So the crucial scientific question is whether selenium reaching an egg from the muscle-to-systemic circulation versus the gut-to-systemic circulation pathways should be expected to be processed any differently. In other words, should equal amounts of selenium reaching eggs by these two maternal deposition pathways result in different levels of toxicity to the egg/embryo/larva? Doroshov et al. (1992) related embryo-larval effects endpoints to concentrations of selenium in the eggs, not in maternal tissues.	

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	To investigate this issue, the Service conferred with one fish physiology expert each from the National Marine Fisheries Service and the USGS's National Fisheries Contaminant Research Center hoping to find existing literature with a bearing on the questions posed above. Unfortunately, the experts did not know of any literature directly testing the comparative toxicity of selenium in fish eggs maternally deposited via the muscle-to-systemic circulation versus the gut-to-systemic circulation pathways. However, both experts independently offered their best professional opinion that the there is no differences between those pathways for the functional toxicity of selenium concentrations measured in the eggs subsequent to maternal processing and deposition to the eggs. The Service concludes is that there is no existing scientific literature on either side of this issue, and that either working hypothesis (i.e., that IM injection studies should be discarded or should not be discarded for assessments of toxicity thresholds for selenium in E/0 tissue) remains plausible. Under such circumstances we recommend considering using the Doroshov et al. (1992) channel catfish study by calculating the SSD 5th percentile value both with and without inclusion of the catfish results, and then splitting the difference. Without the catfish data point the result is the DSP's proposed E/0 tissue criterion of 15.2 mg Se/kg. Adding a value of 6.34 mg Se/kg for catfish from results reported in Doroshov et al. Tables 7 and 9 yields an SSD sth percentile estimate of 6.27 mg Se/kg using the method of Stephens et al. (1985). The average of those two estimates is 10.7 mg Se/kg. It is also observed in the DSP that channel catfish were still present at selenium-contaminated Belews Lake, North Carolina, after bluegill had become extirpated from selenium exposure. This observation infers that because Doroshov et al. found channel catfish to be more sensitive to selenium in E/O tissue than bluegill, the IM injection selenium delivery to the catfish must have produced erroneous results compared to the real world. However, a far more plausible explanation for the Belews Lake observation is that channel catfish have an average lifespan of 15-20 years and bluegill only 5-6 years. Thus, even if channel catfish at Belews Lake were in fact experiencing greater reproductive impairment than bluegill consistent with Doroshov et al.'s experimental findings, a remnant adult population of catfish would naturally persist distinctly longer than a remnant adult population of bluegill. An additional reason the Service recommends not to discard the Doroshov et al. channel catfish study is because the authors present a biologically plausible explanation for why catfish might be particularly sensitive to E/O selenium concentrations. It relates to the disproportionately large yolk in catfish eggs compared to other fish taxa and the disproportionately earlier development of major organs in catfish embryos compared to other fish taxa (Doroshov et al. 1992). We recommend using the full body of Justin Conley's work(Conley et al. 2009; 2011; 2013; and 2014), which extends the dietary threshold for toxic effects (reduced fecundity) in mayflies down from the 11 mg Se/kg cited in the draft technical package to 4 mg Se/kg. Conley et al. results ultimately led	

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	to question the prevailing dogma that if fish and birds are protected from selenium toxicity, sensitive species of aquatic invertebrates will also be protected. Furthermore, Conley et al. provide a much more rigorous basis for deriving mayfly TTF's than the source currently being utilized by EPA, and with very different results.	
22	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 The selection of the lowest, most conservative EC_{10} value of 15.91 mg Se/kg dw for the brown trout (Salmo trutta) from the study conducted by Formation Environmental (2011) is given far too much weight in the document given to experimental complications cited in the study that affect the interpretation of the data. High rates of deformity at background concentrations were observed in the brown trout study, which may result in an EC_{10} that is indistinguishable from a no effect level (see Figure 13, page 110). Assumption that all fish lost in a lab accident in the brown trout study (overflow which occurred during the 15-day post swim-up portion of the test) were dead, dying, or deformed.	
27	EPA-HQ-OW-2004-0019-0350-A1; Central Contra Costa Sanitary District (CCCSD); Posted 8/5/2014 Compromised data has been used in the final GMCV calculation. The key study (page MM) conducted on Brown Trout and used in calculating the GMCVs for Fish Reproductive Effects is cited on page 45 as having two experimental complications that affect the interpretation of data: 1. Elevated deformity rates among the offspring that served as method controls, and 2. Accidental loss of a number of individuals from several treatments. Data from the study is presented in Panels A and B of Figure 13 and clearly shows that the range of deformities seen in concentrations that fall within the first 25% of the response curve fall within the range of deformities seen in the unexposed fish. Data of this quality would fail acceptance criteria according to EPA testing protocols and cannot be used for NPDES whole effluent toxicity testing. CCCSD Comment: Due to the complication with the data used to establish this standard, it should not be used in the derivation of the water quality objective.	
147	EPA-HQ-OW-2004-0019-0353-A1; Mark C. Rigby, Parsons and University of California at Santa Barbara; Posted 8/7/2014 Doroshov et al. (1992) also performed a study in which catfish were injected with seleno-L-methionine. USEPA excluded this study because “the injection route of exposure is not an acceptable experimental protocol for studies used in criteria derivation due to its difference from exposure routes	

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	in the environment (water column and diet).” Where there is processing of the test substance in the gastrointestinal tract (e.g., acids and/or enzymes interact with the test substance and modify it), this is a valid argument. However, seleno-L-methionine appears to be absorbed directly in the gastrointestinal tract (Janz et al. 2010; Roman et al. 2013). Once seleno-L-methionine is absorbed, the effects of exposure via ingestion and injection should be the same. The question is whether there is any processing of seleno-L-methionine in the gut of fishes prior to adsorption and whether that leads to exposure to additional selenium species and affects toxicity. Unless USEPA can demonstrate that there is a substantial effect of ingestion vs. injection exposures for seleno-L-methionine in fishes, Doroshov et al.’s (1992) catfish study should not be excluded. This reviewer modeled the dose-response relationship between larval mortality and selenium concentrations in eggs (see methods above). This resulted in an EC10 of 4.47 mg/kg-dw in eggs. The dose-response relationship between larval mortality and the concentration of selenium in catfish eggs from Doroshov et al. (1992) is illustrated below.	
243	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 Uncertainties Inconsistencies and lack of reproducibility in the assessment regarding the level of larval deformity, as discussed by McDonald and Chapman (2009), is a source of uncertainty in the two studies with the lowest chronic values (Lepomis and Salmo). These authors found that, for 8 widely-cited selenium reproductive toxicity studies, which include Hennanutz et al (1992), the quality assurance/ quality controls for the larval deformity assessments were limited. Parameter uncertainty in larval deformity studies primarily arises from reliance on a subjective evaluation of the magnitude of the deformity. Few studies provided sufficient data to evaluate the reproducibility of larval deformity data. One case study was presented (Rudolph et al., 2008), where the larval deformity data was submitted to an outside observer to assess the graduated severity index scores (GSI) attributed to the different deformity endpoints (craniofacial, edema, finfold and skeletal). The findings indicated that there was poor reproducibility of the effects assessment between different observers for all types and magnitudes of larval deformities. The reproducibility of the edema endpoint was the poorest, with up to 61 % difference between observers in the frequency for GSI scores. This finding underlines the potentially large uncertainty that is inherent in the assessment of the level of larval deformities, especially for mild deformities, and the use of larval deformity endpoints in the derivation and application of tissue residue guidelines. The data used to derive the selenium criterion should be based on good study design and robust analytical techniques (preservation, methods, etc.). The conversion factor selected to estimate the dry weight selenium concentrations in ovaries from the	

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	wet weight measures reported in the Henmanutz et al. (1992 and 1996) bluegill studies is another source of uncertainty associated with the Lepomis GMCV. The US EPA assumed a value of 76% moisture for bluegill ovaries whereas DeForest et al. (2011) assumed a moisture content of 85%. If a moisture content of 85% for ovaries was assumed for Hermanutz et al. (1992 and 1996), the chronic value would increase by a factor of 1.6, or 60% above the selected value.	
468	EPA-HQ-OW-2004-0019-0356-A1; Idaho Department of Environmental Quality (DEQ); Posted 09/30/2014 Page 45, while assuming the worst case scenario for fry loss in the Formation Environmental (2011) brown trout toxicity studies is certainly the most conservative assumption it does not seem to be the most plausible assumption. Assuming the fry lost to have had the same rates of mortality and deformity as those not lost would be most plausible, it is not, as EPA states, the most optimistic assumption. EPA's limited range of assumptions suggests EPA has evaluated the fry loss as not accidental.	
495	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 The egg-ovary element in the draft criterion document is suspect due to the issues with the brown study used to develop it and it is unclear if the range of EC_{10} values for brown trout reflect this underlying uncertainty.	
500	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 The egg-ovary element in the draft criterion document is suspect due to the issues with the brown study used to develop it and it is unclear if the range of EC_{10} values for brown trout reflect this underlying uncertainty.	
565	EPA-HQ-OW-2004-0019-0332-A2; J.R. Simplot Company; Posted 7/30/2014 Page B-9, Brown Trout: This study should be updated to Formation (2011) instead of NewFields (2009). The six additional pairs of egg and whole body tissue concentrations of selenium in brown trout provided earlier in these comments should be included here to augment the brown trout data for conversion factors. The Osmundson et al. (2007) data, which provides values for whole body and ovary, appear to demonstrate a large transfer of selenium from the intake of selenium to ovaries. Page B-22, Cutthroat trout: At a minimum, the Yellowstone cutthroat trout paired egg and whole body tissue concentrations of selenium should be included here.	
118	EPA-HQ-OW-2004-0019-0326-A1; Utility Water Act Group (UWAG); Posted 7/30/2014 Use of Invertebrate Toxicity Studies Not Appropriate Where Data Missing	

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	UWAG does not agree with EPA's decision to use invertebrate toxicity studies where certain fish data were missing, however. In deriving the tissue criteria, EPA reviewed 37 diverse fish studies and calculated egg/ovary tissue thresholds for eleven fish species in nine genera. Draft Report, Table 5, p. 53. Tissue values were converted from wet weight to dry weight using conversion factors set forth in Appendix C of the Draft Report. Where fish data were missing, EPA decided to fill those data gaps with invertebrate data by converting invertebrate tissue concentrations to a concentration expressed as fish tissue. EPA derived a conversion formula that resulted in invertebrate concentrations approximately 3 to 12 times higher than fish whole body criterion and used this to conclude that a chronic criterion protective of the sensitive mean value for fish would also be protective for invertebrate. Draft Report, Table 6b, p. 56. UWAG does not agree that EPA's approach is scientifically valid. Simply put, translating invertebrate toxicity studies to expected fish tissue concentrations is not equivalent to fish tissue chronic values. Moreover, UWAG believes the toxicity database, with nine fish genera, are sufficient to conduct criteria calculations. Where the purpose of the criteria is protection of fish, the agency should use fish data to derive the criteria. In other words, EPA need not strain to meet the eight family requirement because it is not relevant for criteria that are based on fish tissue. Furthermore, we believe sufficient aquatic toxicity data exists to support that invertebrates are more tolerant of selenium than fish. Therefore, EPA's proposed criteria focused on fish tissue will also be adequately protective of invertebrates. We are concerned that EPA's attempt to incorporate the converted invertebrate data to fill missing fish data is unnecessary from the standpoint of protectiveness and creates defensibility issues. EPA should consider deleting use of these data in the final criteria document.	
87	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 4.3 Additional Review of Toxicity Studies Deemed Acceptable Muscatello et al. (2006) reported an EC10 of 20.4 mg/kg for larval deformities in northern pike. In the 2014 draft Se criteria document, EPA reported an EC24 of <34 mg/kg for this same study. EPA's value differed based on significant modifications to the way the data from this study were analyzed. In particular, EPA grouped the data differently and adjusted the data based on deformities in the control group. EPA combined the results of the study's exposures into two groups: 1. reference and low exposures (low exposure) and 2. medium and high exposures (elevated exposure). This combination of data was due to small sample sizes in the individual exposure groups as well as similarities in Se concentrations and deformities between the two sub-groups. Because two exposure concentrations are not enough to conduct parameter estimation in TRAP, EPA used a data normalization approach	

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	to adjust the deformity response to account for the 13.20% deformities observed in the low exposure group. This rescaling approach adjusted the 33.40% deformities observed in the elevated exposure group to a response of 24% deformities. This method is not consistent with the methods used to derive the other useable chronic values and is not a typical approach for deriving chronic values in any case. However, we agree that it could be appropriate to break the four exposure groups (control, low, medium, and high) into two, as the measured Se concentrations and observed deformity rates are extremely similar within the EPA's two sub-groups and the sample sizes of the individual groups are small. This study should be reevaluated to ensure consistency with EPA's approach for criteria development.	
89	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 3. Key Issues and Recommendations While the 2014 draft Se criteria are an improvement over previous criteria, there are some key areas of the criteria that we feel need closer examination and revision. Our recommendations for revisions to these key issues are provided below. 3.1 Review of Toxicity Studies Used for Criteria Development *3.1.1 Comments on Studies Deemed Acceptable* The 2014 draft Se criteria document includes reproductive toxicity study data for nine fish genera (Table 6a, page 52). As noted above, overall, we concur with most of the data usage decisions made by EPA. However, we 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). We believe incorporation of these suggested changes would result in an egg/ovary chronic criterion that is even more scientifically defensible and consistent with EPA's other data-usage decisions (see Section 3.2 below). 3.1.1.1 General We examined each of the data points deemed acceptable by EPA for use in the egg/ovary criterion calculation (Table 6a, page 52) to determine if we saw any potential issues with EPA's use of the data. We note that all of the chronic values (i.e., EC10s) developed by EPA in the 2014 draft Se criteria document differ from those they calculated from the same studies in the 2004 draft Se criteria document. These chronic values also differ from effects levels reported in the individual toxicity studies themselves. The primary reason for these differences is that EPA used the Toxicity	

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	Relationship Analysis Program (TRAP; EPA 2008, 2011) to calculate chronic values from each of the studies deemed useable for use in the chronic criteria in the 2014 draft Se criteria document. EPA recalculated the chronic values from every study, even those for which the study authors had already reported a chronic value. We assume the purpose of recalculating every data point using TRAP was to standardize the calculation of the chronic values and minimize the variability that can result from using different statistical programs and calculation methods. While we have some concerns with the use of TRAP for all data analysis (described in Section 4.2), we understand the value in standardizing the calculation of chronic values from each study by using one statistical approach. However, 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. 3.1.1.2 Fathead Minnow In the 2014 draft Se criteria document, EPA reports an egg/ovary fathead minnow chronic value of <23.85 mg/kg from Schultz and Hermanutz (1990). This study was also used in the 2004 draft Se criteria document; however, an update to the percent moisture value for egg/ovary tissues resulted in the lowering of the chronic value from this study. The 2004 draft Se criteria document used 85%moisture for fathead minnow ovary tissues (resulting in a chronic value of <39.3 mg/kg), while the 2014 draft Se criteria document uses 75.3% moisture based on data from GEI Consultants, Inc. (2008) and Rickwood et al. (2008). As the Rickwood et al. (2008) study does not present percent moisture data, it is assumed that EPA obtained these data from the authors. The 2014 draft Se criteria document did not utilize data from the fathead minnow maternal transfer study by GEI Consultants, Inc. (2008), citing high variability and insufficient response as the reasons for excluding this study. However, as shown in Table D-9 of the 2014 draft Se criteria document (page D-28), deformity rates do increase with increasing whole-body Se exposure, consistent with other studies used by EPA. While percent deformities in the three lowest exposures were all below 10%, deformity rates range from 17.23% to 20.32% in the highest exposures. This would suggest an EC10 value occurs between the two highest exposures (TGC and ETC; Table D-9), which had whole-body Se concentrations of 35.87 and 44.53 mg/kg dw. Using the data from Table D-9 in TRAP following the same approach used by EPA (e.g., see Doroshov et al. 1992, page C-103) and the data from Table D-9, we derived whole-body EC10 values of 42.067 mg/kg, 43.959 mg/kg, 42.335 mg/kg, and 42.265 mg/kg for larval craniofacial, skeletal, finfold, and edema effects, respectively. The lowest of these whole-body EC10 values, 42.067 mg/kg, is for craniofacial deformities (Figure 1 below); therefore, we recommend including the chronic value of 42.067 mg/kg in the derivation of a fathead minnow genus mean chronic value (GMCV). *Original letter contains Figure 1 – TRAP input and output for craniofacial defects in fathead minnow*	

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	larvae from GEI (2008). See original letter. Using the fathead minnow conversion factor (CF) of 2.00 from Table 7a of the 2014 draft Se criteria document, EPA translated the Schultz and Hermanutz (1990) egg/ovary value of <23.85 mg/kg to 11.94 mg/kg whole-body. The geometric mean of these two study results (i.e., 42.067 mg/kg and 11.94 mg/kg) results in a fathead minnow whole-body GMCV of 22.41 mg/kg. Translation of the GEI whole-body value of 42.067 mg/kg to an egg/ovary value using the fathead minnow CF of 2.00 results in an egg/ovary EC10 value of 84.134 mg/kg. Combined with the Schultz and Hermanutz (1990) value of <23.85, the fathead minnow egg/ovary GMCV is 44.80 mg/kg. Alternatively, we note that there is a better fathead-minnow specific CF of 1.4 (as presented in Section 4.4.1 of this document), which would be preferred over the generic median Cyprinidae value of 2.00 used by EPA. If this species-specific CF is used, the Schultz and Hermanutz (1990) egg/ovary value of <23.85 mg/kg would instead be translated to a whole-body value of 17.04 mg/kg. Using this value with the GEI whole-body value of 42.067 mg/kg would result in a fathead minnow whole-body GMCV of 26.77 mg/kg. Using the conversion factor of 1.4 the GEI whole-body value of 42.067 mg/kg translates to an egg/ovary value of 58.89 mg/kg. This value along with the Schultz and Hermanutz value of <23.85 mg/kg would result in a fathead minnow egg/ovary GMCV of 37.48 mg/kg. We recommend using the GEI Consultants, Inc. (2008) study and these updated values for fathead minnows in the derivation of the tissue-based criteria and note these would be consistent with data decisions by EPA for other studies/species. While the fathead minnow is not in the top four most sensitive genera in the egg/ovary database (before or after making the suggested updates), it is currently in the top four in the whole-body database (Table 7b of the 2014 draft Se criteria document). Updating the fathead minnow whole-body GMCVs as recommended above results in this species being ranked as the 8th most sensitive in the database. It is important to ensure all data in the toxicity database (e.g., Tables 6a and 7a of the 2014 draft Se criteria document) are accurate in case future site-specific recalculations result in use of these datapoints. Therefore, we recommend updating the GMCVs for fathead minnow egg/ovary and whole-body to 37.48 mg/kg and 26.77 mg/kg, respectively. 3.1.1.3 Bluegill In the 2014 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). EPA reported an egg/ovary EC10 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). We have the following concerns about combining the results of Studies I and II and the resulting analysis:	

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	• The studies were conducted one year apart, which resulted 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 (see pages C-107 and C-108 of the 2014 draft Se criteria document). For Study I, EPA calculated geometric means of two replicate Se concentrations (and used these geometric means to calculate the EC10, see page C-112), whereas for Study II, EPA calculated geometric mean concentrations (although the table says "average") but used individual replicates to calculate EC10s (see page C-112). • 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). 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 (28.8%) than Study II (57.1 – 57.7%). In the nest observations, the percent dead larvae in the 10 µg/L exposure was much higher in Study I (17%) than Study II (0.4 – 0.5%). • The ovary Se concentrations resulting from the same water exposures were quite 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. 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. 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. • There are a number of typographical errors in the tables on pages C-107 through C-112 of the 2014 draft Se criteria document. On pages C-107, C-108, and C-110, it appears EPA inadvertently typed a colon (:) in place of the micro symbol (µ) in the treatment column. In addition, on page C-112, most of the % survival data are not on the correct lines. Finally, on page C-108, the first control ovary Se (mg/kg ww) concentration should be 0.78 instead of 0.76 (the calculated geometric mean shown was correctly calculated using 0.78).	

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	Based on these concerns, we recommend that Study I be removed from the analysis so that only Study II is used. Using only Study II data, we used TRAP (using the same methods and parameters as EPA) to calculate an EC10 of 23.15 mg/kg (Figure 2). This value is much closer to the other two chronic values for bluegill (20.05 mg/kg [Doroshov et al. 1992] and 24.55 mg/kg [Coyle et al. 1993]) in the maternal transfer toxicity database (Table 5 of the 2014 draft Se criteria document), indicating that combination of Studies I and II by EPA was producing a potentially unrealistic value for this species. Use of this updated chronic value of 23.15 mg/kg results in an updated bluegill GMCV of 22.50 mg/kg, moving bluegill from second to third most sensitive in the egg/ovary database (Table 6a of the 2014 draft Se criteria document). This is the value we are recommending for this genus. Alternatively, as noted in another review of the document by the North American Metals Council-Selenium Working Group (NAMC-SWG 2014), given the various issues and weaknesses with these studies, 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 (20.05 mg/kg [Doroshov et al. 1992] and 24.55 mg/kg [Coyle et al. 1993]) are used, a bluegill egg/ovary GMCV of 22.19 mg/kg would be appropriate. *Original letter contains Figure 2 – TRAP input and output for edema defects in bluegill larvae from Hermanutz et al. (1996). See original letter.* *3.1.1.3.1 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. In addition, on pages 26 and 27 of the 2014 draft Se criteria document, EPA discusses how Se concentrations in eggs and ovaries are usually equal. Therefore, it would be helpful if EPA discussed why only egg data were used from these two bluegill studies. It may be that EPA chose to use only the egg data for the sake of consistency in the database – most of the data in the egg/ovary database (Table 5 of the 2014 draft Se criteria document) are for eggs. To evaluate the effect of using the average of egg and ovary Se concentrations, we derived EC10s using the average of the egg and ovary concentrations for the Doroshov et al. (1992) and Coyle et al. (1993) bluegill studies using TRAP. Using the concentrations provided in Table 1, we calculated egg/ovary average EC10s of 17.56 mg/kg and 25.46 mg/kg from Doroshov et al. (1992) and Coyle et al. (1993), respectively. These values are comparable to the egg-only EC10s used by EPA (i.e., 20.05 mg/kg and 24.55 mg/kg). *Original letter contains Table 1 – Egg, ovary, and the average of egg and ovary Se concentrations*	

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	and associated EC10 values from the Doroshov et al. (1992) and Coyle et al. (1993) bluegill studies. See original letter. Use of these egg/ovary average EC10s for Doroshov et al. (1992) and Coyle et al. (1993) and the updated EC10 of 23.15 mg/kg from Hermanutz et al. (1996) results in a bluegill GMCV of 21.79 mg/kg. This GMCV is higher than EPA's bluegill EC10 of 18.41 mg/kg but slightly lower than our recommended bluegill GMCV of 22.50 mg/kg. We recommend use of our recalculated 22.50 mg/kg GMCV, as using egg-only data is consistent with the majority of the data in the database. However, as discussed above, we recommend EPA provides 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. 3.1.1.4 Brown Trout In the 2014 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. 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). EPA chose to assume the "worst case" scenario and derived an egg/ovary EC10 of 15.91 mg/kg using the results from that scenario. It is unclear why EPA considered the scenario where the fry lost had the same mortality and deformity rates as those not lost to be an "optimistic" assumption. Rather than "optimistic," it seems that this scenario should instead be considered "realistic," as it reflects what was observed in the remaining population (i.e., the fish not lost to overflow). An "optimistic" scenario would be better defined as the assumption that all fry lost had zero deformities or mortalities. EPA did not provide any reasons for why they think the "optimistic" assumption is not a realistic scenario or why they think it is more appropriate to select the "worst case" scenario. In fact, on page 109 of the 2014 draft Se criteria document, EPA states "The peer review conducted by ERG (2012) did not provide a consensus on expectations of whether less healthy organisms were more likely to have been lost in the overflow". 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 (Photo 1) – not at the top, where fish would be more likely to be lost in an overflow event. Based on this lack of reasoning for assuming the worst, it seems more appropriate to go with a more realistic approach – that is, rather than using the data from the "worst case" assumption, EPA should use their "optimistic" (i.e., what we consider to be realistic)	

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	assumption. *Original letter contains Photo 1 – Dead/dying juvenile trout collecting at the bottom of the aquarium during toxicity testing at the GEI Consultants, Inc. laboratory (photo taken June 11, 2014). See original letter.* Using this "optimistic"/realistic approach, the reported EC10 is 18.36 mg/kg, which is more comparable to data for other Salmonids (Table 5 of the 2014 draft Se criteria document) than the EC10 of 15.91 mg/kg from the "worst case" approach. We strongly recommend EPA uses the EC10 of 18.36 mg/kg for brown trout in the calculation of the chronic criteria. Alternatively, in their comments on the 2014 draft Se criteria document, the NAMC-SWG derived an alternative EC10 using a modified calculation of the "worst case" scenario. They derived a value of 21.58 mg/kg, by better fitting a model in TRAP. This value is comparable to the "optimistic" approach EC10 of 18.36 mg/kg and further supports the case that the EC10 of 15.91 mg/kg is unreasonably low. Therefore, we recommend use of either the NAMC-SWG chronic value of 21.58 mg/kg or the "optimistic"/realistic assumption of 18.36 mg/kg, as an appropriate and protective brown trout chronic value.	
307	EPA-HQ-OW-2004-0019-0326-A1; Utility Water Act Group (UWAG); Posted 7/30/2014 SPECIFIC COMMENTS <u>Criteria Development Methodology – Fish Tissue Criteria; Approach Generally Workable, Some Inputs Inappropriate</u> UWAG strongly supports EPA's development of fish tissue-based selenium criteria focused on chronic effects, but we have concerns about certain aspects of EPA's development approach. *Four-Part Criteria Workable* While we agree with EPA that the most relevant tissue from an ecological standpoint is egg/ovary, we support the decision to incorporate whole-body and muscle tissue threshold elements into the four-part criteria. There are benefits to adopting this pragmatic approach, including the ability to continue to utilize data from long-term monitoring studies where the focus has been on tissue samples other than egg/ovary. These data should continue to play an important role in understanding the effects of selenium bioaccumulation, particularly when analyzing site-specific variables within different types of aquatic systems, i.e., lentic and lotic. *Many Enrichment Factors Highly Speculative* UWAG believes that many of the Enrichment Factors (EFs) cited for several species of fish that are	

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	based on results provided in Lemly (1985) are highly speculative, however. In addition, the calculated EC10 value for the "most sensitive fish species" (brown trout) was derived using multiple overly conservative assumptions. Specifically, the inclusion of Hermanutz, et al. (1992) bluegill study data and the Formation Environmental (2011) brown trout study results that yielded conservative EC10 values raises questions and warrants reevaluation for reasons described more fully below. First, with respect to Hermanutz et al. (1992) report, we are concerned that the exposed bluegills accumulated selenium in a manner inconsistent with an expected dose-response pattern (i.e., bluegills exposed to water concentration of 10 µg/L had a higher tissue concentration relative to fish exposed to 30 µg/L). We believe that results for this experiment should be removed by EPA in the calculation of the Lepomis genus mean chronic value. Next, we disagree with EPA's reliance on brown trout data from a 2011 Formation Environmental study that encountered technical problems resulting in a loss of fish during the post-swim-up phase of the study. For reasons EPA has not explained, EPA decided to use these data. In filling the data gap due to the lost fish, EPA adopted an assumption that all of the fish lost in the laboratory mishap were deformed. EPA's assumption resulted in an overly conservative EC10 of 15.91 mg Se/kg, this being the lowest Genus Mean Chronic Value (GMCV) of all the GMCV for other genera of salmonid in the data set. Draft Report, Figure 13, p. 110. While we understand EPA's desire to salvage the study, Figure 13 illustrates that other, perhaps more realistic, alternative scenarios existed. For example, EPA could have assumed the health of the missing fish was the same as those remaining. Under this statistically plausible alternative approach, the result would have been a significantly higher EC10 of 21.16 mg Se/kg. EPA admits that the lab accident creates uncertainties in the resulting EC10. Draft Report, p. 108. UWAG concludes that EPA's unexplained conservative assumptions and use of the failed brown trout study had the effect of significantly lowering the EC10 value and should be revisited. Particularly because this value is considerably lower than the GMCV of other genera of salmonid (*Salvelinus* and *Oncorhynchus*), we believe that the EC10 value applicable to the Formation Environmental study should be the arithmetic average of all determined EC10 values. There is no need for EPA to select the lowest calculated EC10 value when the degree of adverse effect at the next higher exposure concentration is relatively insignificant.	
123	EPA-HQ-OW-2004-0019-0332-A2; J.R. Simplot Company; Posted 7/30/2014 VI. Calculation of EC10 Value for Cutthroat Trout The 2014 Draft Criterion discusses two cutthroat trout studies (Oncorhynchus clarki lewisi- Westslope cutthroat). EPA calculated an EC10 of 24.06 mg Se/kg dw in eggs based on the two Oncorhynchus	

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	clarki lewisi studies. However there are two other cutthroat trout studies with Oncorhynchus clarki bouvieri (Yellowstone cutthroat) that warrant discussion. Hardy et al. (2010) conducted a 2.5 year feeding trial in which the trout were fed either a basal diet (1.2 IJg Se/g diet) or the basal diet with different rates of selenomethionine. Sub-lethal signs of toxicity were not observed; the average egg selenium concentration at 124 weeks was 16 1-Jg/g dw for the treatment group with the highest egg selenium concentration. While this study was considered in the 2014 Draft Criterion and some of the data were used for developing CFs, it was not used in the numeric criterion derivation because the highest egg selenium concentration represented an unbounded no observed effects concentration (NOEC). Simplot conducted two reproduction studies as part of its site-specific selenium criteria process. One study included brown trout which was included in the 2014 Draft, while another study was conducted using Yellowstone cutthroat trout (YCT) which was not included. Simplot believes the YCT studies should be considered by EPA. Similar to the brown trout studies, the adult reproduction study with YCT presented its own challenges. Findings from the YCT study allowed for survival and deformity EC10s to be derived, but only when a single sample was excluded. That sample had high egg selenium (47.6 mg/kg dw) and high survival values whereas the next highest egg selenium concentration in YCT (40.1 mg/kg dw) had low survival. The TRAP model output did not fit the data well, as confidence bands on the EC10 estimates were wide with this high selenium high survival data point included. Similar to the brown trout studies, there were some visually apparent breaks in the response data at less than 22.3 mg/kg dw and greater than 27.9 mg/kg dw egg selenium. Similar to a maximum acceptable toxicant concentration (MATC) where a no effect and low effect concentrations are averaged, an average egg selenium concentration was developed. The effects concentration was expected to be at some concentration > 25 mg/kg dw. The survival and deformity data for YCT suggested that YCT were less sensitive to selenium than brown trout. Using the combined/integrated endpoint proposed by EPA in the 2014 Draft, Simplot recalculated the YCT endpoint for survival and normal fish using two approaches, including only those fish ranked as zero (0) and surviving and those fish ranked as zero (0) and one (1) and surviving. The logic for this secondary approach was presented earlier in these comments. For YCT normal and surviving where fish were ranked as zero (0) only, indicating a complete absence of deformities, the EC10 was 26.99 (LCL= 25.55, UCL = 28.52) mg/kg dw egg Se (Figure 3 below). For YCT where fish were ranked as zero (0) or one (1), indicating insignificant deformities, the EC10 was 26.57 (LCL= 25.72, UCL = 27.44) mg/kg dw egg Se (Figure 4 below). Note that the scale for fraction surviving and normal indicates that for YCT ranked normal (zero), the decimal fraction values are low across the board for hatchery fish and wild fish. For YCT ranked with insignificant	

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	deformities (zero or one), the fraction normal and alive increased by more than 50 percent. For both analyses, the single data point for high selenium and high survival at 47.6 mg/kg dw was removed from the analysis. Addition of these data will provide for another species of cutthroat trout and may change the SMCV or GMCV for cutthroat trout to a slightly higher value. *Original letter contains Figure 3 – Fraction Alive and Normal vs. Log(Egg Se mg/kg dw). See original letter.* *Original letter contains Figure 4 – Fraction Alive and Normal vs. Log(Egg Se mg/kg dw). See original letter.* Paired egg/whole body tissue data for up to 31 individual females (15 wild collected YCT and 16 YCT from the Henry's Lake Hatchery) are available. The egg to whole body selenium tissue relationship results has an R2 = 0.877. Collectively, the median egg/whole body ratio for these data is 2.26. Table 2 below provides the data for YCT egg and whole body selenium concentrations. *Original letter contains Table 2 – Egg and Whole Body Selenium Concentrations in Yellowstone Cutthroat Trout (Formation 2012). See original letter.* Simplot believes that inclusion of these data in subsequent versions of the Draft Selenium Criterion is important to complete the cutthroat trout dataset and inclusion of these data will be valuable for other investigators looking to develop site-specific criteria where this type of cutthroat trout is prevalent. While some may view the variability of the hatchery as a limitation in its use in derivation of an EC10 for this species, the paired egg and whole body data will be valuable for the derivation. EPA's introduction of a combined endpoint allowed for a recalculation of Simplot's YCT data. This recalculation reaffirms an earlier estimation that the effects threshold for this species is > 25 mg/kg dw egg selenium. Further, it provides additional evidence that when using the combined endpoint or only the proportion normal endpoint, and the data are available to do so, consideration should be given to analyses that use the normal (0) and slight deformity (1) ranked fry together as a measure of insignificant deformities to reduce uncertainty in using deformity data across large datasets.	
23	EPA-HQ-OW-2004-0019-0320-A2; National Mining Association (NMA) and GEI Consultants, Inc. (GEI); Posted 7/29/2014 2.0 Additional Comments on Derivation of Tissue Criterion Elements 2.1 Update to Egg/Ovary Criterion Analysis We agree with several points we understand are being brought up in comments provided by the North American Metals Council-Selenium Working Group (NAMC-SWG) and have revised the egg/ovary calculations in our prior document (GEI 2014) to be consistent with their analyses. These revisions	

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	apply only to the EC10 values calculated for brown trout.[1] • First, upon reanalysis of the data using the tolerance distribution method in TRAP, it is evident that for this dataset TRAP is highly dependent on the initial estimate provided, particularly for the standard deviation. This relates to some of the issues with EPA's sole reliance on TRAP noted in our prior document (GEI 2014). Reanalysis of the data using an initial estimate of 0.05 for standard deviation, as suggested by the NAMC-SWG review, results in an egg/ovary EC10 of 21.94 mg/kg for the deformities endpoint using the "optimistic" assumption, which is slightly higher than the "optimistic" assumption EC10 of 18.36 mg/kg presented in the EPA 2014 draft Se criteria document. • Second, we agree with the NAMC-SWG in that 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 were provided in Appendix C, Figure 1 of the EPA 2014 draft Se criteria document. When these combined data are used, the EC10 for the "optimistic" assumption is 21.16 mg/kg, which is similar to the endpoint determined above for deformities only with the NAMC-SWG's revised TRAP analysis. [1] Note that for all the discussion below, as it relates to the test larvae "lost" during the test, EPA's "optimistic" assumption has been used. Justification for use of this assumption is discussed in our prior review, Section 3.1.1.4 (GEI 2014). And, again, we note that this really should be considered "realistic" assumptions, not "optimistic". Justification for calling this a "realistic" assumption is further supported by the NAMC-SWG review, in which they cite Simplot (2013) as noting that the fish that overflowed from the aquaria during the study were alive and swimming in the surrounding water bath and did not appear to have any deformities.	
60	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 4.2 Use of TRAP versus Other Statistical Methods We have some concern with the exclusive use of TRAP for determination of all EC10 values used in criteria development. TRAP may work well with certain data sets, but may pose problems for analysis of others. One potential issue associated with the TRAP model is the input of "Initial Guesses". TRAP (2008) suggests that the user provide initial guesses for X50, Stdev or S, and Y0: "These search methods require a starting point, so initial guesses must be made for the parameter values. These initial	

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	guesses will be made by the program if the user does not provide them. However, in some cases, program-calculated guesses might not result in successful parameter estimation (see Parameter Estimation Problems). In such cases, the user will need to modify these guesses to improve the analysis. The user might also want to try different initial guesses to confirm that the analysis has found the best fit." Model run trials performed by GEI indicate that the output can vary significantly based on the initial guesses provided by the user. This is likely to introduce bias into final EC10 calculations. Another point to consider is that the Tolerance Distribution Analysis and Gaussian Distribution Model Options are supposed to be "equivalent to probit analysis" (TRAP 2008). However, as described below, output from TRAP and NCSS probit analysis are considerably different. As an example of the potential difference between TRAP and NCSS probit output, in the GEI maternal transfer study (2008), EC10s were calculated using both methods, and TRAP EC10s were considerably different from those calculated using probit analysis (Table 10). There was no consistent relationship between the two sets of values; TRAP values were both higher and lower than probit values depending on the data set used. It also seems that, at the EC10 calculation level, TRAP is either not very accurate or highly impacted by "Initial Guesses". However, it seems that EC50 output from TRAP is able to identify the substantial differences in endpoint sensitivity. This sensitivity and accuracy issue presents major concerns regarding the use of EPA's TRAP model for all data. *Original letter contains Table 10 – Comparison of fathead minnow larval deformity EC_{10} estimates using probit analysis and TRAP (GEI 2008). See original letter.* In many of the studies provided in the 2014 draft Se criteria document, the EC10 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" used for analyses in the Appendix C.	
130	EPA-HQ-OW-2004-0019-0277-A1; Arkansas Department of Environmental Quality; Posted 6/24/2014 Section 4.1.1 Acceptable Studies of Reproductive Effects 1. Rainbow Trout Section: Additionally, it is stated that: The measurement of selenium in the otolith layers of rainbow trout collected in this watershed showed low selenium exposure in the fish's early life and a higher exposure to selenium during the fish's adult years (Palace et al. 2007), suggesting that individuals that reach adulthood do not tend to start their	

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	lives in elevated exposure streams even though they may reside there later. As selenium bioaccumulates and does not reach an equilibrium, it is expected that younger fish will have lesser selenium concentrations, unless it is demonstrated that offspring of selenium-exposed parents have higher or similar otolith selenium concentrations to concentrations in adult fish; this, however, was not mentioned.	
150	EPA-HQ-OW-2004-0019-0353-A1; Mark C. Rigby, Parsons and University of California at Santa Barbara; Posted 8/7/2014 On page 105, the USEPA draft document states the study by GEI Associates (2008) was excluded because "The response measurements for the embryo assessment endpoints were variable and lacked a relationship with selenium exposure." However, EC10s are shown in Table D-12 for this study, indicating that there is a relationship. It is possible that the EC10s were not significant, although that is not stated in the document. If the EC10s were significant (i.e., from a significant probit or logistic regression), they should not be excluded. Please clarify whether the relationships observed were significant or nonsignificant.	
16	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; U.S. Fish and Wildlife Service, Paul Souza; Posted 8/7/2014 (6) The use of biphasic statistical modelling EPA correctly notes (p. 20) that there is a narrow range between beneficial and toxic effects in the dose-responses of organisms to selenium. Adequate representation of this phenomenon may sometimes require the use of biphasic equations to model exposure-response relationships for selenium. Biphasic models have been available at least since 1989 (Brain and Cousens 1989), and more recently, improved general applicability biphasic models have been developed (Beckon et al. 2008). Nonetheless, EPA is still using a monotonic logistic equation (p. 25) for modelling exposure-response relationships that would be better represented by biphasic equations. An example is the EPA analysis of the set of experiments by McIntyre et al. (2008). In this case, use of a monotonic model, per se, makes only a slight difference, because the low exposure side of the range of the data (for experiment ES1) evidently extends into a region of only slight deficiency. Of more concern is the inclusion of data from Treatment 6 (highest exposure treatment), which was terminated after only 60 days of exposure, along with data for the other treatments at 182 days of exposure. More scientifically defensible treatment of these data (use of a biphasic model, and exclusion of the mismatched Treatment 6 data) yields an LC10 of 7.85 mg/g instead of the "EC10" of 9.27 mg/g produced by the EPA analysis (see figure below). *Original letter contains Figure – not numbered. Survival vs. Selenium concentration in fish for Bluegill.*	

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	See original letter.	
516	EPA-HQ-OW-2004-0019-0278-A1; Mark C. Rigby, Parsons and University of California at Santa Barbara; Posted 06/24/2014 On page 105, the USEPA draft document states the study by GEI Associates (2008) was excluded because "The response measurements for the embryo assessment endpoints were variable and lacked a relationship with selenium exposure." However, EC_{10}s are shown in Table D-12 for this study, indicating that there is a relationship. However, it is possible that the EC_{10}s were not significant, although that is not stated in the document. If the EC_{10}s were significant (i.e., from a significant probit or logistic regression), they should not be excluded. Please clarify whether the relationships observed were significant or nonsignificant.	
24	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014 3.6 Too Low Tissue Criteria Concentrations The proposed tissue criterion based on brown trout data is overly conservative and not technically defensible. A higher criterion would provide environmental protection without unduly penalizing human industrial or other activities, and without unnecessarily expending limited regulatory resources to the detriment of genuine environmental issues. 3.6.1 Brown Trout EC10 We commend the exhaustive effort that EPA has put into the analysis of this dataset. Nevertheless, we question the scientific defensibility of the brown trout EC10 of 15.91 mg/kg dw. EPA has selected the lowest of the six EC10 values presented.[8] The value EPA favors is based on deformities, assuming that individuals lost in the laboratory accident were deformed, which is questionable. The scientific defensibility of this EC10 is problematic in four respects, which are discussed in more detail below: (1) the model fit obtained by EPA does not fit the data well; (2) the correct best-fit Toxicity Relationship Analysis Program (TRAP) calculation for the deformities worst-case scenario endpoint is 21.58 mg/kg, not 15.91 mg/kg dw; (3) there is no sound basis for using either the survival endpoint alone or deformities endpoint alone when the combined survival and deformities endpoint is available; and, (4) there is no basis for the assumption that organisms lost in the laboratory accident were dead, dying, or deformed. *<u>1. The model does not fit the data well</u>*. Figure 13(b) on page 110 of the Draft Selenium Criterion Document demonstrates that the curve begins its downward bend too early, missing the points at 17.7 and 20.5 mg/kg dw, a concentration range critical for defining the threshold for any fish species thought to be sensitive to selenium. Visual inspection of the data points in Figure 13(b) does not	

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	suggest that the percent normal is reduced at those concentrations. To explore the issue quantitatively, we have presented EPA's count percentages for survival, deformities, and combined survival and deformities for the field samples in Table 2. We have excluded all the hatchery data to avoid the confound results inherent when including the eyed-embryo SPC hatchery samples, which performed differently from all other samples for reasons that cannot be related to selenium exposure. *Original letter contains Table 2 – Brown trout results (EPA's accounting) for field stations, arranged in increasing order of egg concentration. See original letter.* Having ranked the stations by increasing concentration, we now ask the question: how do results for station LSV2C-008 (17.7 mg/kg dw) and station LSV2C-017 (20.5 mg/kg dw) compare with the averages for all field stations with lower concentrations? The field samples at or below 20.5 mg/kg dw span a 3.3-fold concentration range (6.5 to 20.5 mg/kg dw), which would easily be enough to find differences in performance if selenium were having any effects within this range. *At 17.7 mg/kg dw:* Worst-case percent normal (61.5% normal): 1.12-fold better performance (higher percent normal, fewer deformities) than the average of field samples at lower concentrations (55.0% normal). "Optimistic" case percent normal (75.8% normal): 1.27-fold better performance than the average of field samples at lower concentrations (59.7% normal). *At 20.5 mg/kg dw:* Worst-case percent normal (65.1% normal): 1.18-fold better performance than the average of field samples at lower concentrations (55.3% normal). "Optimistic" case percent normal (73.3% normal): 1.21-fold better performance than the average of field samples at lower concentrations (60.6% normal). We believe that the above close examination of the data demonstrates that the calculated EC10 of 15.9 mg/kg dw is definitely too low. The observations at and below 20.5 mg/kg dw do not indicate an effect of selenium on deformities. As EPA notes in its Draft Selenium Criterion Document, the model's inability to fit the key data at 17.7 and 20.5 mg/kg dw is an artifact of the influence of the data configuration at >36 mg/kg dw.[9] We do not believe that oddities in the responses at >36 mg/kg dw provide a scientifically defensible basis for a brown trout EC10 of 15.9 mg/kg dw.	

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	2. The correct best-fit TRAP calculation for the deformities worst-case endpoint is 21.58 mg/kg, not 15.91 mg/kg. To obtain its solution, the computer program TRAP (cited in the Draft Selenium Criterion Document as USEPA 2011) starts with an initial parameter estimate. We have discovered that the tolerance distribution solution that TRAP version 1.21 obtains for the deformities worst-case endpoint is dependent on the initial estimate provided to TRAP. Table 3 shows the two results obtained by different initial estimates of the model parameter values. *Original letter contains Table 3 – TRAP output for the deformities, worst-case dataset, given two different initial estimates for the model parameters. See original letter.* Table 3 shows the error sum of squares for the model fit. For the tolerance distribution, TRAP does not provide this sum, but its "Model Fit Summary" provides everything needed to calculate it. Table 4 provides the information provided by TRAP, along with the calculated difference between prediction and observation, and its square. It can be seen that the model error is lower for the fit that yields EC10=21.58 mg/kg dw. Table 4 shows the error for each data point. *Original letter contains Table 4 – TRAP Model Fit Summary and calculated fitting errors for the alternative EC10s obtained for the deformities, worst-case dataset. See original letter.* It appears that the two alternative results represent local minima for errors, and to which of these minima TRAP converges depends on where the initial estimate tells it to start. As shown by Figure 4, the fit that yields an EC10 of 21.58 mg/kg dw is a natural one, and does not suffer any of the shortcomings that we present in our first constructive criticism of the 15.91 mg/kg dw EC10 above. Table 4 demonstrates that an EC10 of 15.91 mg/kg dw is not defensible; however, we believe our first argument, regarding the lack of apparent effects at key observed concentrations of 17.7 and 20.5 mg/kg dw, is actually the more important consideration. *Original letter contains Figure 4 – TRAP tolerance distribution graphical output for the model fit yielding the EC10 of 21.58 mg/kg dw for the deformities worst-case endpoint. See original letter.* *3. There is no 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 the Agency's past preference for combining the important endpoints, it seems reasonable to request the Agency to combine the survival and deformity endpoints as its first choice for the brown trout study. Production of normal healthy aquatic organisms would seem to be a goal everyone can understand and support. The counting of surviving normal individuals as a function of selenium concentrations	

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	thus seems the most logical approach, whenever it is possible. We recognize that the available studies do not always allow such a calculation. Data in the brown trout study, as revised (AECOM, 2012), however, do allow those calculations, which EPA has provided but not used. If TRAP had been unable to provide a good fit to the combined survival/normal endpoint, then we might understand why EPA could opt not to use it. But as EPA has demonstrated in Figure 13(e) and (f) on page 110 of the Draft Selenium Criterion Document, TRAP had no difficulty fitting the combined endpoint. Parallel with our assessment, above, for deformities, we have examined the performance at key exposures 17.7 and 20.5 mg/kg dw for the combined endpoint. From Table 2: *At 17.7 mg/kg dw:* Worst-case percent surviving and normal (60.5% normal): 1.15-fold better performance (higher percent normal survivors) than the average of field samples at lower concentrations (52.8% normal). “Optimistic” case percent surviving and normal (74.2% normal): 1.30-fold better performance than the average of field samples at lower concentrations (57.0% normal). *At 20.5 mg/kg dw:* Worst-case percent surviving and normal (55.8% normal): 1.05-fold better performance than the average of field samples at lower concentrations (53.3% normal). “Optimistic” case percent surviving and normal (61.8% normal): 1.07-fold better performance than the average of field samples at lower concentrations (58.0% normal). We believe that close examination of the results at these key exposures demonstrates the reasonableness of the TRAP EC10s for the combined endpoint. That is, 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 no logical explanation, other than an artifact of random noise, for why the effect on deformities or survival alone would yield lower EC10s than the combined endpoint. We do not believe it is scientifically defensible for EPA to choose the lowest value. Given the EPA past precedent for use of a combined endpoint, when available, we believe that use of an EC10 for combined survival and deformities, worst-case 20.65 mg/kg dw, “optimistic” case 21.16 mg/kg dw, would enhance the scientific defensibility of the proposed criterion. *<u>4. There is no basis for the assumption that organisms lost in the laboratory accident were dead, dying, or deformed</u>*. Prior to the review by the U.S. Fish and Wildlife Service (USFWS) (2011), EPA	

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	had assumed that the health of the organisms lost in a laboratory accident was the same as the health of those not lost. Subsequently, EPA accepted the USFWS (2011) idea, sans supporting evidence, that the organisms lost in the accident were dead, dying, or deformed. In contrast, in its response to the USFWS (2011) comments, Simplot (2013) noted that the fish that overflowed from their aquaria were observed to be alive and swimming in the temperature-control water bath surrounding the aquaria, and they did not appear to be deformed, as judged visually. Furthermore, Chris Mebane (ERG, 2012) has indicated that brown trout behavior would support what EPA calls the optimistic assumption: healthy swim-up brown trout fry are not strictly benthic and will move throughout the water column of an aquarium; moribund or dead brown trout fry do not float, but sink to the bottom. Consequently, we believe that what EPA has called the “optimistic” case should be relabeled the “unbiased probable” case, and being both unbiased and probable, should by default be the favored assumption. Given that EPA has no scientific evidence to support its assumption that individuals lost in overflows of the aquaria were unhealthy, a robust approach could sidestep the issue by using the effects endpoint that is not sensitive to the assumption, specifically the combined survival and deformities endpoint. For this endpoint, there is only a 2.5% difference between EC10s for the worst-case and the unbiased probable case (that is, what EPA calls the optimistic case): respectively, 20.65 mg/kg dw versus 21.16 mg/kg dw. This small difference cannot be environmentally significant relative to possible population-level effects. With the combined survival and deformities endpoint EC10s, we believe EPA could retain its worst-case assumption, thereby addressing USFWS (2011)’s concern. Since EPA cannot impose risk management assumptions having no scientific basis upon the states, use of the combined survival and deformities endpoint would have the added advantage of assuring greater consistency between states, since the criterion would be nearly the same under either assumption. By contrast, if EPA were to replace the questionable 15.91 mg/kg dw deformities worstcase EC10 with the 16.79 mg/kg dw mortality worst-case EC10, the scientific defensibility of the criterion would be undermined by the observation that the overflowed fish were alive, thereby indicating that the mortality unbiased probable EC10 (EPA’s mortality “optimistic case”) of 20.40 mg/kg dw would be more appropriate. Thus, the combined mortality and deformity endpoint is not only the most comprehensive endpoint, but also the only one available that can finesse the entire overflowed fish issue. [8] *Id.* at 110.	

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	[9] *Id.* at 108.	
36	EPA-HQ-OW-2004-0019-0320-A2; National Mining Association (NMA) and GEI Consultants, Inc. (GEI); Posted 7/29/2014 2.2 Update to Whole-Body Criterion Analysis As a result of our revision to the egg/ovary criterion in Section 1.0 above, it is also necessary to update the whole-body criterion using the revised brown trout number. As described in our prior review (GEI 2014), we recommend use of the regression-based conversion factors (CF) when possible and median CFs if regressions are not significant (Table 3).	
252	EPA-HQ-OW-2004-0019-0320-A2; National Mining Association (NMA) and GEI Consultants, Inc. (GEI); Posted 7/29/2014 While incorporation of the revised brown trout egg/ovary value does not result in any changes to the ranking of taxa, it does affect the calculation of the criterion itself. When the revised brown trout number is incorporated, the resulting whole-body tissue criterion would be 9.1 mg/kg (Table 4).	
339	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014 3.7.3 Rigorous Analysis of the Concept of Averaging As implied above, it is necessary to consider both the variability of tissue sample concentrations of a species obtained during a single event and the variability of such concentrations over time. We do not believe that this is a significant complication, because the approach we advocate handles both types of variability in the same way. Before we can be certain of our averaging recommendation, we need to address the question: is there some reason why averaging would prevent goals from being attained? The goal we are seeking, as set forth in EPA's Guidelines, is to prevent varied concentrations having an arithmetic mean equal to the criterion from causing an effect greater than an invariant concentration at the criterion. To understand what is involved here, we have explored the implications of the type of probabilistic effects prediction EPA presented in its Campbell (2011) approval of Utah's Great Salt Lake (GSL) criterion. That analysis coupled (a) the concentration-response curve underlying the GSL criterion, with (b) a distribution of hypothetical tissue sample concentrations (a histogram). The aggregate effect caused by the distribution of concentrations was calculated as the summation of products of (a) the effect that each particular concentration in the histogram would have (based on the concentration-response curve), multiplied by (b) the probability that the particular concentration would occur. Using that approach, Campbell (2011) found that use of the geometric mean ambient concentration	

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	would allow slightly greater than the 10% target effect level inherent in the EC10. While the amount of the effect was insufficiently above the target effect to form a basis for disapproval, the issue that it studied merits careful examination to determine the implications for the arithmetic mean we are recommending (as opposed to the geometric mean used by Utah). When comparing to the criterion, use of the ambient arithmetic mean is more stringent than use of the geometric mean because the ambient arithmetic mean is higher than the ambient geometric mean. Nevertheless, the question remains: will attainment as an arithmetic mean allow noticeably greater than 10% aggregate effect? The inherent problem with averaging stems from the non-linearity in the concentration-response curve as it transitions from the flat region of no effect at low concentrations to the steeply sloping region where deleterious effects rapidly increase with selenium concentration. Consider a concentration-response curve having a zero-effect threshold at some concentration; curves based on rectangular or triangular distributions are such examples. Consider a concentration-response curve having ECzero=20 mg/kg dw and EC10=24 mg/kg dw. Now consider an ambient monitoring dataset consisting of three samples of 16, 20, and 24 mg/kg dw. When the three sample concentrations are averaged together, their average is 20 mg/kg dw, which corresponds to 0% effect on our example response curve. In contrast, if the individual samples are individually compared to the concentration-response curve, and their calculated effects averaged, we average three predicted levels of effect: 0%, 0%, and 10%, thus yielding an average effect of 3.33%, which is higher than the 0% effect predicted by the average concentration. (We are not implying that the example difference is necessarily significant, we are merely illustrating how the calculations work.) The above example thus shows two different answers generated by two potentially reasonable approaches. The question is: which one is more accurate? If it is rigorously correct to average the sample concentrations before comparing to the concentration-response curve (and hence the criterion), then a comparison using individual sample concentrations will overstate the effect. On the other hand, if it is rigorously correct to use the individual sample concentrations with the concentration-response curve, then averaging the sample concentrations will understate the effect. After careful consideration of the data used to construct the concentration-response curves underlying the criterion, we have concluded that a substantial amount of concentration averaging is inherent in creating the concentration-response curves. Consequently, unless the variability in the ambient concentrations being averaged exceeds the degree of averaging inherent in constructing the concentration-response curves, it is rigorously correct to average the samples before comparing to the criterion as explained below. We have considered the data from which TRAP constructs a concentration-response curve. These data are of two types:	

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	1. Data from laboratory studies usually (but not always) represent treatment averages (or sometimes replicate averages). A treatment essentially corresponds to a site, assuming that a site is defined as a location having similar water quality conditions within it. Consequently, when comparing tissue measurements for a species at a site to a concentration-response curve generated from treatment averages, the site concentrations should be averages, in order to correspond to how the concentration-response curve was derived. 2. Data from field studies, such as by Rudolph et al. (2008) (and one laboratory study, by Carolina Power & Light, 1997) involve measurements of individual adult female fish, either their eggs or ovaries. Initially this might suggest that individual sample measurements, not site averages, are appropriate for comparing to the concentration-response curve. It must be recognized that the concentration-response curve is itself an averaging of observations, however. A prediction of effects from concentrations uses the central tendency curve that was fitted to the original data points. So the question becomes: how much noise variability existed in the data from which the concentration-response curve was derived? If the variability among samples at a site is equivalent to or less than the noise variability underlying the concentration-response curve, then it is appropriate to use the site average. If a site's sample variability is noticeably greater than the noise variability in the concentration-response curve, then the use of site averages may understate the effect. We now ask the question: what are the key studies where concentration-response curves from individual fish concentrations strongly influenced the criterion derivation? These are Formation Environmental (2011), the combined Holm (2002) and Holm et al. (2003, 2005), Carolina Power & Light (1997), Nautilus Environmental (2011), and Rudolph et al. (2008), which are discussed in that order below: • **Formation Environmental (2011), brown trout.** Given that the most appropriate concentration-response curve for this study remains to be determined, an analysis of the noise underlying its concentration-response curve must be deferred. • **Holm (2002) and Holm, et al. (2003, 2005), rainbow trout.** The concentration-response curve is shown in Figure 5, which we use to explain the assessment approach. *Original letter contains Figure 5 – Holm (2002) and Holm, et al. (2003, 2005) concentration-response curve for rainbow trout skeletal deformities. See original letter.* Given the rainbow trout figure we now ask the question: what is the range of individual measured concentrations that are associated with any particular level of effect? To answer this question, we examine the horizontal deviations from the central-tendency prediction line in the relevant portion of the graph. We calculate the central-tendency prediction associated with each relevant point by taking	

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	the logistic equation,[13] and solving it for x: x(predicted) = x50+(ln(y0/y - 1))/(4*S) For an observation having response y, the above equation shows the central-tendency concentration x(predicted) associated with that response; that is, it provides the exact value on the graphed line so that we do not have to work with the graph by eye. Values of parameters x50, y0, and S are given by the TRAP solution used by EPA. The background response points in the upper left portion of the graph cannot be used because there is a wide range of concentrations that are predicted to be associated with the background response. The equation cannot be solved for y values very near, at, or greater than y=y0 (background response) because there is no unique concentration associated with such responses. The point at zero percent normal likewise cannot be used; there is no unique concentration associated with y=0 and the equation cannot be solved. We also reject points having depressed percent normal at low selenium concentrations, which merely reflect the noise inherent in y0, not the noise inherent in the downward sloping curve. The purpose of selecting data points for analysis is to assure that we do not overstate the noise underlying the curve, and thereby overstate the allowable amount of variability in samples that can be averaged when comparing to the criterion. The approach is to treat the prediction line as the mean x associated with response y. Looking at the relevant points in Figure 5, we see the deviation from the line (measured horizontally) is small for some points and large for others. We measure the distance x – x(predicted), then square it. Summing the squares and dividing by N-1 provides the equivalent of a standard deviation. • **Carolina Power & Light** (1997), **largemouth bass.** The concentration-response curve is shown in Figure 6. This dataset provides nine relevant points, which were evaluated as described above. • **Nautilus Environmental** (2011), **cutthroat trout.** Inspection of the figure on page C-55 of the Draft Selenium Criterion Document indicates that this study provides only two relevant data points, too few to be meaningful. It was not further analyzed. • **Rudolph et al.** (2008), **cutthroat trout.** The concentration-response curve is shown in Figure 7. This dataset provides four relevant points, which were evaluated as previously described. *Original letter contains Figure 7 – Rudolph et al. (2008) concentration-response curve for cutthroat trout, with relevant data points for this assessment shown within the box. See original letter.* The combined results for the three studies represented by the above figures are shown in Table 5. *Original letter contains Table 5 – Observations, TRAP prediction line concentration corresponding to*	

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	the observed effect, horizontal error, and error squared for three studies. See original letter. The horizontal deviations from the downward sloping prediction line are equivalent to a coefficient of variation (CV) of 0.53. This may now be compared to typical variation in tissue samples collected for a species within a site. We have examined data collected at various sites during annual tissue sampling for selenium in Sand Creek, Colorado, 1996-2011, and in the Arkansas River and its tributaries, 2004-2006 (GEI 2007, 2013 and supporting materials). In both water bodies, the annual mean for a species consisted of five samples. For Sand Creek, there were 134 species-site-years having five samples. The CV was calculated for each of the 134 species-site-years; the median CV was 0.18. For the Arkansas River, there were 39 species-site-years having five samples; their median CV was 0.24. [13] *Id.* at 25.	

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140	EPA-HQ-OW-2004-0019-0353-A1; Mark C. Rigby, Parsons and University of California at Santa Barbara; Posted 8/7/2014 Table 5 includes studies by Hermanutz et al. (1992a, 1996) on bluegill. In their analysis of the Hermanutz et al.'s (1992a, 1996) data, USEPA used the treatment means for selenium concentrations as reported in Hermanutz et al. (1996). Since this study was performed by USEPA staff at a USEPA field station and funded by USEPA, USEPA should have the raw concentration data. USEPA should obtain the raw data and re-run their analyses as the use of treatment means assumes that the underlying data is normally distributed. Since this assumption is often not tested in toxicological studies, use of treatment means in nonlinear regressions may lead to biased results. Further, use of treatment means dramatically reduces the variation in the study and since that variation may not only be in the response but in the concentration, this can also lead to biased EC10s. Therefore, in general, USEPA should seek to use individual-level data instead of treatment means for dose-response modeling whenever possible. USEPA analyzed the dose response relationship for edema, lordosis, and hemorrhaging and found that edema was the most sensitive. However, since only treatment means are available, it would seem that USEPA should also perform pair-wise comparisons between each treatment and the control. This reviewer used the "nest observations" from Study II in a two-tailed Fisher's exact test (estimating the number of larvae with edema, lordosis, and hemorrhaging as the "#larvae collected" times the percentages given in Appendix C; using the sum of the two controls) and found that there was a significant difference in the proportions of larvae with hemorrhaging between the control streams and Stream 2 (2.5 g/L selenium, $p < 0.0001$), Stream 7 (2.5 g/L selenium, $p < 0.0001$), Stream 3 (10 g/L selenium, $p < 0.0001$), and Stream 8 (10 g/L selenium, $p < 0.0001$). The results are the same using a Chi-square test or using Yates' continuity corrected Chi-square test. Given that there is a significant treatment effect here, it would seem protective to use the ovary selenium concentration reported for fishes in Stream 2 of 7.58 mg/kg-dw as a LOEC instead of the EC10 modeled by USEPA of 12.68 mg/kg-dw. It would also be prudent to repeat this experiment and collect the data necessary to calculate an EC10 on individual-level results.	
5	EPA-HQ-OW-2004-0019-0353-A1; Mark C. Rigby; Posted 8/7/2014 Table 5 includes Doroshov et al.'s (1992) study on bluegills. However, when one reviews Appendix C, it is apparent that USEPA only modeled edema, which consists of treatment means. Strangely, however, USEPA also presents the larval mortality data from Doroshov et al. (1992), which appears to be individual level data, but did not model it. This reviewer modeled the dose-response relationship between larval mortality and selenium concentrations in eggs using the drc package in R. Percent mortality was arcsine (square root) transformed and the concentration data was log10 transformed. This resulted in an EC10 of 6.76 mg/kg-dw in eggs, which is substantially lower than the EC10 based on edema that USEPA estimated of 20.05 mg/kg-dw. USEPA should either use the EC10 based on	

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	larval mortality or explain why a less sensitive endpoint was used instead. The dose-response relationship between larval mortality and the concentration of selenium in bluegill eggs from Doroshov et al. (1992) is illustrated below. *Original letter contains Figure – not numbered. Doroshov's bluegill data (Table 21). See original letter.*	
251	EPA-HQ-OW-2004-0019-0320-A2; National Mining Association (NMA) and GEI Consultants, Inc. (GEI); Posted 7/29/2014 Based on these analyses, we believe that the EC_{10} of 21.16 mg/kg for combined endpoints (i.e., survival and deformities) is the most appropriate for the brown trout study. Use of this value changes the sensitivity ranking, with largemouth bass now being the most sensitive species and brown trout the second-most sensitive in the toxicity database (Table 1). Using the revised brown trout value in combination with our additional recommendations in our initial review, such as the revised bluegill value and recommendation to use only fish data in the calculation (i.e., N=9, not N=14), per GEI (2014), results in an updated egg/ovary criterion of 19.6 mg/kg (Table 2).	

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138	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 *3.2.2 Updates to Whole-body Criterion* In Section 4.1.5 of the 2014 draft Se criteria document, after presenting its approach for developing the egg/ovary criterion, 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 (see Table 6a of the 2014 draft Se criteria document) using egg/ovary to whole-body CFs (Table 7a of the 2014 draft Se criteria document). These converted values were then used to calculate a whole-body criterion of 8.13 mg/kg. EPA again used a sample size of 14, which included the three invertebrate-based values and the two crustaceans. As a result of our recommended updates to the fathead minnow, bluegill, and brown trout egg/ovary chronic values, the whole-body criterion will also need to be adjusted. In addition, as previously discussed, we do not agree with using the invertebrate data and nonexistent crustacean values to increase the sample size of the database (i.e., it is more appropriate to use N=9 based on the nine fish genera in the database). Incorporating our suggested modifications results in the fathead minnow being replaced by largemouth bass in the top four most sensitive species of the whole-body-based toxicity database (Table 4). In addition, the sample size drops from N=14 to N=9 as a result of removing the invertebrates data and crustaceans. It should be noted that data for both Gambusia species were originally reported as whole-body, so conversions from egg/ovary were not needed for this genus. Using the data presented in Table 5, an updated whole-body criterion of 8.25 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 – Updated calculation of whole-body fish tissue-based Se criterion based on modifications to Table 4 (N = 9 genera, R = sensitivity rank in database). See original letter.* S2 =Σ(lnGMCV)2 – (ΣlnGMCV)2/4 = 24.0485 – (9.7891)2/4 = 1.6561 S = 1.2869 ΣP –(Σ√P)2/4 1.0000 – (1.9436)2/4 L = [ΣlnGMCV – S(Σ√P)]/4 = [9.7891 – 1.2869(1.9436]/4 = 1.8220 A = S(√0.05) + L = (1.2869)(0.2236) + 1.8220 = 2.1097 Final Chronic Value = FCV = eA = 8.2459	

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21	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014 3.6.2 Bluegill EC10 from the Hermanutz et al. (1992, 1996) Studies EPA has obtained its bluegill reproductive GMCV as the geometric mean of EC10s from three studies: 20.05 mg/kg dw egg from Doroshov et al. (1992), 24.55 mg/kg dw egg from Coyle et al. (1993), and 12.68 mg/kg dw ovary from the combined Hermanutz et al. (1992, 1996) studies. The EC10 obtained from the Hermanutz et al. data is an outlier, and it is not scientifically defensible. EPA has used its computer program TRAP for the calculation of this EC10. We do not believe EPA has followed the instructions provided by the TRAP program developer, Russell Erickson, however. That program (version 1.21) has a help screen titled “A Final Friendly Warning,” which states: In the end, to effectively use this (or any similar) program, the user should examine the fitted curve relative to the data and decide if the various parameter estimates and confidence limits appear reasonable. The value of this type of toxicity relationship analysis is to provide some quantitative objectivity and assessment of uncertainty to the estimation of parameters of interest that the user already can approximate by inspection of the data. The computed toxicity relationship should be close to what someone could get by just "eyeballing" the data; otherwise, some aspect of the data, model, or analysis might be causing problems. This kind of analysis demands some judgment from the user - if the results don't look good, they probably aren't and more evaluation is needed. We believe that the model fit that yields the 12.68 mg/kg dw EC10 is counterintuitive and cannot be claimed to be close to anything one would obtain by eyeballing the data. In contrast, if it were essential to obtain an EC10 from the information available from the study, we believe that EPA’s alternate calculation of 18.40 mg/kg dw is closer to being appropriate.[10] Nevertheless, we are unsure that any EC10 can be confidently set forth for the Hermanutz et al. studies. Given that EC10s are available from the other two studies, Doroshov et al. (1992) and Coyle et al. (1993), neither of which is problematic in our view, we do not see how the use of the equivocal Hermanutz et al. (1992, 1996) data can reduce any remaining uncertainty about the sensitivity of bluegill. Consequently, we recommend that EPA dismiss the Hermanutz et al. (1992, 1996) results as inconclusive and unreliable when compared to the other two studies. It is our understanding that EPA is now reexamining files of raw data that had been generated during the Hermanutz et al. studies. Given that the EC10 that EPA has published for these studies is uncertain, we believe it would be appropriate for EPA to release the newly compiled information as soon as it is available. [10] *Id.* at 111.	

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Comment Category 3.3 – Comments on Deriving Egg-Ovary Criterion Element Value 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 and others requested clarification of the statistical methods used and why confidence limits were not included.		
66	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 8/7/2014 Intuitively, it is easy to understand that if the result had been 0.5 (equivalent to a 50:50 chance of having a 10% sensitive-tail species in our toxicity data set) then a natural probability-specific uncertainty factor of 2 (or the inverse of 0.5) would seem an appropriate way to account for the uncertainty of very limited data. In our case an appropriate probability-specific uncertainty factor would be the inverse of 0.6884 (i.e., (1/0.6884)) which equals 1.45. If a probability-specific uncertainty factor of 1.45 were applied to the DSP's proposed E/O tissue criterion of 15. 2 mg Se/kg, the resulting criterion proposal would be 10.5 mg Se/kg. If it were desired to be more protective vis-à-vis the uncertainty of limited data, then the same calculation could be conducted to determine the random probability of a 5% sensitive-tail species having already been included in the existing toxicity data set. That probability works out to be 0.4331. The associated probability-specific uncertainty factor would be 2.31 and the uncertainty-protected E/O tissue criterion would be 6.6 mg Se/kg. For the avian mercury example, with relative toxicity data now available for 23 species and 772 species of native seasonally resident birds the 10% sensitive-tail, probability-specific uncertainty factor works out to 1.09. That outcome is broadly consistent with Newman et al.'s (2000) finding that variance (uncertainty) in estimates of SSD 5th percentile values settles down substantially once a toxicity data base includes data for about 30 species.	Responses concerning the derivation of the egg ovary criterion element value: 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. Regarding the comments on transparency, all of the studies used quantitatively are discussed in detail (including regression analyses) in appendix C of the 2016 final criteria document. Regarding the concern over the use of TRAP, EPA conducted a special review of the regression analyses with ORD scientists during the internal agency review in 2016, resulting in re-evaluations of a number of studies, and yielding statistically superior fits to the TRAP analyses previously presented. Regarding the use of the Guidelines method for the calculation of SSDs, the dataset available for selenium was useful in generating a selenium criterion based on longstanding sensitivity distribution analysis practices per the 1985 Guidelines. Use of a standard method insures consistency across criteria. Regarding the comment on the logic for setting the number of
239	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 The values derived along with the approach and distributions used should be transparent and easy to validate. The curves should be provided in the figures outlining the species sensitivity distribution.	
241	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 Assessment Endpoints and Measures of Effect The assessment endpoints selected for the derivation of a chronic selenium criterion are appropriate and data requirements outlined in the 1985 Guidelines (Stephan et al. 1985) and follow-up guidance (U.S. EPA 2008; Chapman et al. 2010) appear to be met. The discussion provided under Section 3.7.1 (pages 28 and 29) demonstrates how the data needs required through the MDRs of the Guidelines (Stephan et al. 1985) are fulfilled and why the total number of available genus mean	

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	chronic values (GMCV) is 14 (N=14) despite the absence of quantified values for the planktonic and benthic crustaceans (as shown in Table 3 of the report). However, it is unclear how the sensitivity analysis discussed in Section 7.1.6 (page 112) examining the impact of the value of N on the criterion value was accomplished. The N=20 or N=25 GMCVs that were used to recalculate the FCV are not identified and the distribution curves are not shown. Furthermore, the statement that the egg-ovary value for selenium is not sensitive to the value of N does not seem to be substantiated through the analysis since a change in the value of N from 14 to 25 results in a change in the criterion from 15.2 mg/kg dw to 16.7 mg/kg dw While the draft criterion document provides a thorough description on how "measures of effect" are determined for use in the derivation of the various criteria, including detailed descriptions of all toxicity studies and values considered, little information is provided on the development of the genus sensitivity distribution curves of the aquatic community, which are ultimately used to derive the values of the fish-tissue elements (egg-ovary, whole-body and muscle tissue). In Section 1.4.5, information is lacking on the tool(s) used to calculate the distribution curves making it difficult to validate the value of the fish egg-ovary element (15.2 mg Se/kg dry weight) from which the values for the remaining elements are derived. In addition, the fit of the curve and curve fitting parameters are not presented, demonstrating a lack of transparency in the derivation of the selenium criterion. It would appear that only the four most sensitive endpoints are used in the derivation of the criterion, yet the document seems to indicate that 14 endpoints were used.	GMCVs, 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 for invertebrates as a point of reference to show that they were typically less sensitive then the fish represented in the sensitivity distribution (SD), and would therefore be expected to be protected by a tissue criterion based on fish. In the 2015 draft and 2016 final criterion documents, based on comments received, fish and invertebrate SMCVs and GMCVs are listed in separate tables. The results described indicate that, based on available data, invertebrates are less sensitive to selenium in fish, and while they are used implicitly in the SD 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). 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. EPA 304(a) criteria are developed to protect the entire 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 in 2014 and 2015, 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. The "N" in the 2016 final criteria document is 15, reflecting the addition of the GMCv for the white sturgeon which was added in the 2015 draft.
248	EPA-HQ-OW-2004-0019-0274-A2; National Mining Association (NMA); Posted 6/17/2014 As described in Section 3.1 and 3.2 of the GEI review, NMA has concerns with the data decisions and calculations used to develop genus mean chronic values (GMCVs) and species mean chronic values (SMCVs) for the fathead minnow, bluegill, and brown trout. NMA strongly encourages EPA to review these concerns, as well as GEI's reanalysis of the data from these studies, which resulted in scientifically defensible updates of the egg/ovary criterion to 17.3 mg/kg, the whole-body criterion to 9.2 mg/kg, and the muscle criterion to 11.3 mg/kg.	
255	EPA-HQ-OW-2004-0019-0320-A2; National Mining Association (NMA) and GEI Consultants, Inc. (GEI); Posted 7/29/2014 6.0 Conclusions As stated previously, 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	

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	modifications and updates, reflect the best science and are protective of aquatic life. In addition to our original review submitted on June 13, 2014, we recommend and reiterate the following based on the results of our reanalysis: EPA should consider updating the proposed egg/ovary, whole-body, and muscle chronic criteria to include our suggested changes (Table 9).	
257	EPA-HQ-OW-2004-0019-0327-A2; Colorado Wastewater Utility Council (CWWUC); Posted 7/30/2014 There are several other key issues we would like to bring to EPA's attention for further review. As described in Section 3.1 and 3.2 of the GEI review, we have concerns with the data decisions and calculations used to develop GMCVs and SMCVs for fathead minnow, bluegill, and brown trout. GEI's reanalysis of the data from these studies results in scientifically defensible updates of the egg/ovary criterion to 17.3 mg/kg, the whole-body criterion to 9.2 mg/kg, and the muscle criterion to 11.3 mg/kg.	
579	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 We have some concern with the 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. We are also providing additional field data for CFs, trophic transfer functions, and percent moisture for EPA to incorporate and expand their database. Overall, this document is a substantial improvement over previous Se criteria documents, and we look forward to the final draft document after public comments and internal peer reviews are complete and have been incorporated.	
514	EPA-HQ-OW-2004-0019-0278-A1; Mark C. Rigby, Parsons and University of California at Santa Barbara; Posted 06/24/2014 On page 33, the USEPA draft document states "The egg-ovary Final Chronic Value (FCV) was calculated from regression analysis of the four most sensitive GMCVs, in this case extrapolating to the 5th percentile of the distribution represented by the tested genera." Although this is indeed the method recommended in the 1985 "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses," this method does not make use of all of the data. Assuming USEPA also means that the lowest four GMCVs should be analyzed using a linear regression, this also means assuming that the overall species sensitivity distribution is linear. The	

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	recommendation in the 1985 guidelines was also a means to overcome the computation limitations in 1985. USEPA should also use other methods (e.g., nonlinear regression) to calculate the 5th percentile in a Species Sensitivity Distribution (SSD) and compare that to the results obtained following the 1985 guidelines. USEPA even has its own program to calculate SSDs; i.e., the Species Sensitivity Distribution Generator that is part of CADDIS (see http://www.epa.gov/caddis/da_software_ssdmacro.html). There is also a rich literature reviewing the methods used to calculate SSDs.	
88	EPA-HQ-OW-2004-0019-0349-A1; Colorado Wastewater Utility Council (CWWUC); Posted 8/5/2014 There are several other key issues we would like to bring to EPA's attention for further review. As described in Section 3.1 and 3.2 of the GEI review, we have concerns with data decisions and calculations used to develop GMCVs and SMCVs for fathead minnow, bluegill, and brown trout. GEI's reanalysis of the data from these studies results in scientifically defensible updates of the egg/ovary criterion to 17.3 mg/kg, the whole-body criterion to 9.2 mg/kg, and the muscle criterion to 11.3 mg/kg.	
131	EPA-HQ-OW-2004-0019-0277-A1; Arkansas Department of Environmental Quality; Posted 6/24/2014 Section 4.1.1 Acceptable Studies of Reproductive Effects 2. Salmonidae SMCV and GMCV Summary: The second sentence reads: The GMCV for the genus Oncorhynchus is 22.53 mg Se/kg dw in eggs, derived from the 21.1 mg Se/kg dw EC10 from the combined Holm (2002) and Holm et al. (2005) rainbow trout data, and the above mean of the Rudolph et al. (2008) and Nautilus Environmental (2011) Westslope cutthroat trout studies (24.06 mg Se/kg dw). This GMCV appears to be derived from otolith concentrations (21.1 mg/Se/kg dw EC10 from Holm (2002) and Holm et al. (2005) rainbow trout data and the mean 24.06 mg Se/kg dw from the Rudolph et al. (2008) and Nautilus Environmental (2011) Westslope cutthroat trout studies. Please justify using different tissues for determining the GMCV.	
132	EPA-HQ-OW-2004-0019-0277-A1; Arkansas Department of Environmental Quality; Posted 6/24/2014 Section 4.1.1 Acceptable Studies of Reproductive Effects 3. Table 5 Maternal Transfer Reproductive Toxicity Studies:	

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	The O. mykiss Chronic Value, SMCV, and GMCV all indicate that these are egg tissue concentrations, but the paragraph above states these were derived from otolith concentrations. Please clarify.	
576	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 We 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 fathead minnow, bluegill, and brown trout GMCVs or SMCVs, which result in updating the egg/ovary criterion to 17.3 mg/kg, the whole-body criterion to 9.2 mg/kg, and the muscle criterion to 11.3 mg/kg. These revisions are based on our reanalysis of the studies, recalculation of conversion factors, or both. And while we appreciate inclusion of appropriate invertebrate effects data in the document, we do not recommend they be used in the calculation of the fish tissue standards.	
135	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 3.2 Derivation of Tissue Criterion Elements *3.2.1 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 fathead minnow GMCV to 37.48 mg/kg o Includes the GEI (2008) data o Includes use of the fathead-minnow specific conversion factor of 1.4 presented in Section 4.4.1 of this document • Update the bluegill GMCV to 22.50 mg/kg o Result of modifying the Hermanutz et al. (1992, 1996) chronic value to exclude Study I • Update the brown trout SMCV to 18.36 mg/kg o Result of using the “optimistic”/realistic assumption for addressing the issue of the fry lost during the study • Exclude invertebrate-based chronic values • Exclude the nonexistent crustacean values (i.e., remove from sample size) The order and chronic values for the top four most sensitive species change as a result of the modifications to the bluegill and brown trout GMCVs (Table 2). In addition, the sample size drops from N=14 to N=9 as a result of removing the invertebrates data and crustaceans. Using the data	

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	presented in Table 3, an updated egg/ovary criterion of 17.29 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 2 – Modified version of Table 6a of the 2014 draft Se criteria document following adjustments to chronic values for fathead minnow, bluegill, and brown trout based on review and analysis of study data. See original letter.* *Original letter contains Table 3 – Updated calculation of egg/ovary fish tissue-based Se criterion based on modifications in Table 2 (N = 9 genera, R = sensitivity rank in database). See original letter.* Alternatively, use of the NAMC-SWG chronic value of 21.58 mg/kg for Salmo (see Section 3.1.1.4) results in an egg/ovary criterion of 19.81 mg/kg (calculations not shown). Either the egg/ovary criterion of 17.3 mg/kg (Table 3) or the alternate value of 19.8 would be appropriate and protective.	
127	EPA-HQ-OW-2004-0019-0342-A2; State of Michigan, DEQ; Posted 8/5/2014 The Genus Mean Chronic Values (GMCVs) used for the derivation of the draft egg-ovary criterion element should be better identified. It is unclear how the USEPA determined an "N" of 14 GMCVs used for the draft egg-ovary criterion element (page 58). We count 9 fish reproductive GMCVs, 7 nonreproductive fish GMCVs, of which 3 are already represented by reproductive GMCVs, leaving 4 nonreproductive fish GMCVs, and 3 invertebrate GMCVs. Our total then is 9 + 4 + 3 = 16 GMCVs.	
141	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 8/7/2014 (3) Scientific justification for using a 30-year old species sensitivity distribution (SSD) method to determine the egg/ovary tissue criterion As stated earlier, the core component of EPA's technical package is the proposed 15.2 mg Se/kg criterion for fish E/O tissue; all other components of the proposed chronic criteria are tiered, in one way or another, off of the proposed E/O tissue criterion. The E/O tissue criterion is determined by two factors: (1) the construction of the E/O toxicity database, and (2) the choice of an SSD statistical method for estimating the 5th percentile E/O tissue concentration from the E/O toxicity database. In the DSP, an SSD method is applied that was developed 30 years ago (Erickson and Stephan 1985). It was developed so long ago that its authors recognized only two categorically different statistical approaches, parametric and graphical. The fact that distribution-free methods (e.g., Newman et al. 2000) were not recognized as another alternative statistical approach by Erickson and Stephan (1985) is almost certainly because of the vastly limited computing power available to scientists in the mid-1980's compared to today. In fact, the relative lack of computing power in the mid-1980's directly influenced the SSD method development. As Erickson and Stephan (1985:1) stated, "In addition, it is	

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	desirable that the rationale for the calculation procedure be relatively easy to understand and that the computations be as simple as possible."	
203	EPA-HQ-OW-2004-0019-0353-A1; Mark C. Rigby, Parsons and University of California at Santa Barbara; Posted 8/7/2014 On page 33, the USEPA draft document states "The egg-ovary Final Chronic Value (FCV) was calculated from regression analysis of the four most sensitive GMCVs, in this case extrapolating to the 5th percentile of the distribution represented by the tested genera." Although this is indeed the method recommended in the 1985 "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses," this method does not make use of all of the data. Assuming USEPA also means that the lowest four GMCVs should be analyzed using a linear regression, this also means assuming that the overall species sensitivity distribution is linear. The recommendation in the 1985 guidelines was also a means to overcome the computation limitations in 1985. USEPA should also use other methods (e.g., nonlinear regression) to calculate the 5th percentile in a Species Sensitivity Distribution (SSD) and compare that to the results obtained following the 1985 guidelines. USEPA even has its own program to calculate SSDs; i.e., the Species Sensitivity Distribution Generator that is part of CADDIS (see http://www.epa.gov/caddis/da_software_ssdmacro.html). There is also a rich literature reviewing the methods used to calculate SSDs and guidance from other countries on how to calculate SSDs.	
142	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 8/7/2014 Although it was clearly recognized then, as it still is now, that all parametric methods for estimating the 5th percentile of a SSD require at least some assumptions about the distributional characteristics of the SSD-population, Erickson and Stephan clearly did not have the same breadth of modelling choices or methodological sophistication available to them as is available today. The task of estimating a critical value, such as the 5th percentile, from an SSD has received abundant attention since the mid-1980's (e.g., Posthumma et al. 2010). Since application of an SSD method in the DSP is one of the critical steps determining the DSP's core tissue criterion value, an examination by EPA of what constitutes best current SSD science and subsequent revision of the DSP in accordance with the results of that examination is warranted. Erickson and Stephan (1985:50) state that the SSD method relied on in the DSP "...is largely a formalization of the way one would obtain a FAV [i.e., 5th percentile for the SSD] by 'eyeballing' the data."	
143	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 8/7/2014 It is now clear that the determination of a 5th percentile value from an SSD can be quite sensitive to	

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	the statistical method applied for that purpose (e.g., Rodney and Moore 2008; King et al. In Press). For example, employing an SSD for atrazine reported by Solomon et al. (1996), Rodney and Moore (2008) calculated 5th percentile values using five different cumulative distribution functions (CDFs: Normal, Logistic, Gompertz, Weibull, and Fisher-Tippett) yielding about an 8-fold range of results for the 5th percentile value (5 µg/L to 40 µg/l; graphically estimated from Figures 2-1 to 2-5). It is important to know how dependent the DSP's E/O tissue criterion value (15.2 mg Se/kg) is on the particular statistical method used to derive it. It is likely to be found that methodology matters and therefore a best methodology must be selected on a scientific basis including such factors as how well the DSP's SSD meets the assumptions of different statistical methods (for example via residual plots, etc.) and the relative goodness of fit for different methods (for example via probability-probability plots, quantile--quantile plots, Anderson-Darling goodness of fit test, etc.). Alternatively, parametric methods might perform so poorly that a distribution-free option might be the scientifically most defensible option. In either case, confidence in the DSP's determination of a 5th percentile value relies on confidence that the SSD methodology represents best current science and that the 5th percentile value put forward in the DSP.	
144	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 8/7/2014 Finally, the DSP should rely on an SSD method that produces estimated confidence limits along with the estimated 5th percentile value. As King et al. (In Press) point out: "A good practice would be to consider the span of the confidence interval around the hazardous concentration of interest [15.2 mg Se/kg in the case of the DSP] and decide if the dataset is adequate for predicting such concentration or if more data need to be collected." This is an important issue when dealing with small sample-size SSD's as is the case for the DSP. Newman et al. (2000) recommended that given the wide variation typically associated with small sample sizes a conservative approach was warranted in which the concentration that protects 95% of species with 95% certainty would be the appropriate criterion value to derive from an SSD.	
Comment Category 3.5 – Comments on Deriving Muscle Criterion Element Value Summary: This section focuses on comments about EPA's method of deriving the muscle criterion element. It includes comments concerning recalculating the muscle criterion analysis. Also presented are comments concerning the use of the 5th percentile projection to select the final muscle criterion value.		
253	EPA-HQ-OW-2004-0019-0320-A2; National Mining Association (NMA) and GEI Consultants, Inc. (GEI); Posted 7/29/2014 2.3 Update to Muscle Criterion Analysis As with the whole-body number, it is also necessary to update the muscle criterion to reflect the updated brown trout egg/ovary value. Use of the revised brown trout egg/ovary number results in	Response to concerns with deriving the muscle criterion element: EPA has considered the variability and uncertainty inherent with this derivation and has made some modifications to the document, including incorporation of new data, and modification of the

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	Salmo becoming the fifth, rather than the second, most sensitive taxon (Table 5). When the revised brown trout number is incorporated into the calculation, the resulting muscle tissue criterion is 11.1 mg/kg (Table 6). *Original letter contains Table 5 – Reproductive-effect egg-ovary (EO) concentrations converted to muscle concentrations for acceptable toxicity tests following adjustments to chronic values for brown trout, ranked by muscle value (modification of Table 8 of the GEI 2014 review[2]). See original letter.* *Original letter contains Table 6 – Updated calculation of muscle fish tissue-based Se criterion (and modification of Table 9 of the GEI 2014 review) based on modifications to Table 5 (N = 9 genera, R = sensitivity rank in database). See original letter.* [2] Updates to the "Basis for EO/M Ratio" column in this table have also been made since the original submittal of the GEI 2014 review.	Conversion Factor (CF) methodology to better reflect taxonomic similarities as described immediately below. Regarding the methodology used to derive a CF value for conversion of egg-ovary to the whole body or muscle criterion elements; EPA modified the approach in 2015 based on comments from stakeholders. First EPA used directly calculated muscle measurements were available in the study and the data were amenable to an effect level determination. Table 3.3 of the 2016 final criteria document provides the chronic values for each fish genus and whether it was calculated directly or converted from the reproductive-effect egg-ovary concentrations to whole-body concentrations using a CF. The final EO/M CF applied to each taxon was determined using a hierarchical approach based on taxonomic relatedness, and is described in Section 3.2.2, and in greater detail in Appendix B of the 2016 criteria document. There were more individual species data available for muscle than for whole body conversions. This approach was also used for the whole body tissue criterion element. 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 development of CF and Trophic Transfer Factor (TTF) values that better reflected taxonomic similarities among species
34	EPA-HQ-OW-2004-0019-0317-A1; Nora B. Rasure, Regional Forester, Intermountain Region, Forest Service, United States Department of Agriculture (USDA); Posted 7/29/2014 Page 60. Instead of using the 5th percentile projection, it is recommended that EPA consider using the more direct approach of calculating the whole body criterion from conversion factors. These ratios are based on empirically derived paired tissue data, a one step process versus the proposed multiple step procedure. The values for CF are summarized for 14 species in Table 1-3 (Page 1-20, EPA 2014).	
35	EPA-HQ-OW-2004-0019-0317-A1; Nora B. Rasure, Regional Forester, Intermountain Region, Forest Service, United States Department of Agriculture (USDA); Posted 7/29/2014 Page 62. It is recommended that instead of using the 5th percentile projection for calculating the muscle tissue criterion, direct conversion from egg-ovary to muscle tissue would provide a more robust approach.	

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136	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 *3.2.3 Updates to Muscle Criterion* In Section 4.1.5 of the 2014 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 (see Table 6a of the 2014 draft Se criteria document) using egg/ovary to muscle CFs (Table 8a of the 2014 draft Se criteria document). These converted values were then used to calculate a muscle-based criterion of 11.8 mg/kg. EPA again used a sample size of 14, which included the three invertebrate-based values and the two crustaceans. As a result of our recommended updates to the fathead minnow, bluegill, and brown trout egg/ovary chronic values, the muscle criterion will also need to be adjusted. In addition, as previously discussed, we do not agree with using the invertebrate data and nonexistent crustacean values to increase the sample size of the database (i.e., it is more appropriate to use N=9 based on the nine fish genera in the database). Incorporating our suggested modifications results in the fathead minnow being replaced by largemouth bass in the top four most sensitive species of the muscle-based toxicity database (Table 8). In addition, the sample size drops from N=14 to N=9 as a result of removing the invertebrates data and crustaceans. Using the data presented in Table 9, an updated muscle criterion of 11.29 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 8 – Modified version of Table 8a of the 2014 draft Se criteria document following adjustments to chronic values for fathead minnow, bluegill, and brown trout based on review and analysis of study data. See original letter.* *Original letter contains Table 9 – Updated calculation of muscle fish tissue-based Se criterion based on modifications to Table 8 (N = 9 genera, R = sensitivity rank in database). See original letter.* Calculations: Chronic Muscle Criterion S2 =Σ(lnGMCV)2 – (ΣlnGMCV)2/4 = 29.8582 – (10.9148)2/4 = 1.3494 S = 1.1616 ΣP –(Σ√P)2/4 1.0000 – (1.9436)2/4 L = [ΣlnGMCV – S(Σ√P)]/4 = [10.9148 – 1.1616(1.9436]/4 = 2.1643 A = S(√0.05) + L = (1.1616)(0.2236) + 2.1643 = 2.4240 Final Chronic Value = FCV = eA = 11.2910	when species-specific data were not available to estimate TTF or CF values, EPA sequentially considered higher taxonomic classifications (i.e., species, genus, family, order, then class) until one or more taxa for which a calculated TTF or CF value was available matched the taxon being considered. If the lowest matching taxon was common to more than one species with a TTF or CF value available, EPA used the median TTF or CF from the matching species. See Appendix N of the 2016 criteria document for a comparison of approaches. In each site-species translation equation an egg-ovary selenium concentration is divided by the product of: a species (or closest taxonomical surrogate) specific CF, a species-specific component TTF, and a site specific EF. At many sites, site- specific data are not available to calculate site specific CFs and TTFs for each species, so the application of CFs and TTFs represents the best available information. 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 (2-3) fold in sensitivity observed even among species with repeated toxicity tests, 2-fold variability 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. Regarding the use of regression analysis to derive CFs, EPA has decided to retain the use of the median rather than OLS regression or as some stakeholders recommended. EPA has done a comparison of the CF methodologies; this is presented in Appendix N of the 2016 final criterion document.

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Comment Category 3.6 – Comments Concerning Other Toxicity Data Fulfilling Minimum Data Needs (N=15) Summary: This section contains comments about chronic effects studies of non-fish organisms, including crustaceans, other invertebrates, and their use in the minimum data requirements to fulfill EPA's guideline recommendations for calculating the criterion. Some commenters disagree with using invertebrate data and non-existent crustacean values in the criterion calculations. 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.		
30	EPA-HQ-OW-2004-0019-0350-A1; Central Contra Costa Sanitary District (CCCSD); Posted 8/5/2014 <u>Section 4.1.5 Derivation of Tissue Criterion Element Concentrations</u> Page 58 states, "With N=14 the Genus Mean Chronic Values, the 5th percentile projection yields and egg/ovary criterion of 15.2 mg Se/kg dw egg/ovary." In reviewing the Genus Mean Chronic Values (GMCVs) from Table 6a and 6b, there are only 12 GMCVs listed for use in calculating the 5th percentile projection. The 5th percentile projection from the tabled values is 17.3 mg Se/kg dw egg/ovary. CCCSD Comment: Please identify the 14 data points used for the final calculation of 15.2 mg Se/kg dw egg/ovary or recalculate the GMCV 5th percentile using the Table values.	Responses regarding use of other toxicity data: EPA agrees that the invertebrate and the Gambusia (livebearing mosquitofish) data should not be represented in the egg-ovary sensitivity distribution, and they have been removed from that distribution. Available data 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. In the final 2016 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 indicate that compared to fish, invertebrates are not as sensitive to selenium as fish, and do not comprise any of the four lowest GMCVs (also shown in Figure 6.2, 2016 final selenium criterion document). EPA agrees that additional data on invertebrate sensitivity to selenium would be useful to further support this conclusion. Consistent with the 1985 Guidelines, 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
73	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 3.1.1.5 Invertebrate Studies Section 4.1.3 of the 2014 draft Se criteria document presents EPA's review of three invertebrate chronic toxicity studies (Dobbs et al. 1996, Besser et al. 2006, and Conley et al. 2009). Having deemed these studies to be acceptable, EPA then used the chronic values from these studies to translate to predicted fish tissue (egg/ovary and whole-body) concentrations that would result from consuming invertebrates containing Se at these chronic values. To translate the values, EPA used a median trophic transfer factor of 1.27 and a median whole-body to egg/ovary conversion factor of 1.71. The resulting egg/ovary values were then considered to be GMCVs and were incorporated with the fish GMCVs into the criteria calculations (see Figure 5 of the 2014 draft Se criteria document). While we appreciate EPA's effort to follow criteria derivation protocols and meet the eight-family rule (see Table 3 of the 2014 draft Se criteria document), this approach is not toxicologically valid. The cited invertebrate studies were conducted to assess the toxicity of Se to invertebrates. Simply translating these values to expected fish tissue concentrations does not make them equivalent to fish tissue chronic values. Specifically, the translated values are not linked to fish toxicity in any way – rather, they only reflect what expected fish tissue concentrations would be if a fish consumed	

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	invertebrates containing Se concentrations found to elicit effects in invertebrates. We do not suggest any alternative approaches to using the invertebrate chronic values in the derivation of the fish tissue criteria; rather, we think they should not be included at all. Criteria intended to be protective of fish should be developed using fish toxicity data, not invertebrate toxicity data. Any attempt to include both types (i.e., fish and invertebrates) of data in the criteria calculations is unnecessary. Similarly, we do not agree with the approach of assuming crustaceans are less sensitive than fish and including two 'imaginary' crustacean values in the criteria calculations. Consideration of crustacean data is unnecessary because, as EPA suggests, a criterion based on protection of fish will be protective of other aquatic life. There are nine fish genera belonging to a variety of families in the toxicity database (see Table 6a of the 2014 draft Se criteria document) – while these fish genera alone do not meet the eight-family rule, nine genera are sufficient to conduct criteria calculations. In addition, for criteria that are based on fish tissues, it makes sense to use only fish tissue data to derive the criteria. The eight-family rule is not relevant here. Therefore, EPA should remove the three invertebrate-based chronic values and the two nonexistent crustacean values from the calculation. While these invertebrate data are not useful for the purpose of deriving fish tissue-based criteria, they are relevant and useful when considering invertebrate sensitivity to Se. Therefore, as discussed in Section 3.5, these data should not be discarded, as they could be useful particularly at sites that support an invertebrate community but are not able to support a reproducing fish community due to small size and flow constraints.	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. 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. Data presented in the 2016 final criteria document indicate that, based on available data, the selenium fish tissue criterion is expected to be protective of the aquatic community including invertebrates and amphibians.
74	EPA-HQ-OW-2004-0019-0350-A1; Central Contra Costa Sanitary District (CCCSD); Posted 8/5/2014 The study incorrectly co-mingles chronic toxicity data from reproductive effects studies for live bearing and spawning fishes with non-reproductive invertebrate data which have been translated across media and converted from whole body to egg-ovary concentrations using conversion factors that were derived exclusively for fish. The transformation of study results does not fulfil the intent of the EPA's minimum data requirements for development of criteria according to *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses* (Stephan et al. 1985). The intent of minimum data requirements is stated on page 22 of the document: "... protection of various components of an aquatic ecosystem." CCCSD Comment: The invertebrate data should not be translated into a fish tissue value for use in the final GMCV calculation. Additionally, the use of non-reproductive studies on invertebrate does not fit with the targeted chronic reproductive effects endpoint that is the basis of the 2014 selenium water quality standard and should not be used.	

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254, 256	EPA-HQ-OW-2004-0019-0320-A2; National Mining Association (NMA) and GEI Consultants, Inc. (GEI); Posted 7/29/2014 EPA should consider inclusion of an invertebrate tissue criterion for waters which do not support fish. 4.0 Additional Comments on Invertebrate Tissue Usage in Criterion Development As described in Section 3.5 of our original review (GEI 2014), we recommend and reiterate that the chronic Se toxicity data for invertebrates should not be back-calculated to a fish tissue value. Rather, those data are best used to develop criteria for streams naturally unable to support fish. The chronic value for the mayfly, the most sensitive species for which data are available, is 24.2 mg Se/kg dw wb. This value could be added as a third tissue criterion element, as shown in Table 9 of Section 6.0 below.	
496	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 The values derived along with the approach and distributions used should be transparent and easy to validate. The curves should be provided in the figures outlining the species sensitivity distribution.	
Comment Category 3.7 – Comments on Studies Not Used in Derivation of Fish Tissue Criterion Elements 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.		
148	EPA-HQ-OW-2004-0019-0353-A1; Mark C. Rigby, Parsons and University of California at Santa Barbara; Posted 8/7/2014 Although not native to North America, Japanese medaka (Oryzias latipes) and zebrafish (Danio rerio) are model organisms frequently used in laboratory toxicity tests. USEPA is even funding (EPA Grant Number: R835168) a study that uses zebrafish for toxicity screening and has guidelines for toxicity testing using medaka (EPA/600/3-91/063). Further, while these two species may not occur in North America, they are likely to be representative of fishes that do; e.g., zebrafish are from the family Cyprinidae, which does indeed occur in North America. Therefore, selenium toxicity studies using these species should be evaluated for inclusion in the derivation of the water quality criterion. These studies include, but are not limited to, the following: Penglase et al. (2014), Ma et al. (2012), and Thomas et al. (2013).	Responses concerning studies not used by EPA in the 2014 draft: 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. 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
149, 155	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 8/7/2014 Very recently Penglase et al. (2014), working in Norway, conducted a study of interaction effects between selenium and mercury toxicity on the reproductive performance of zebrafish (Danio rerio). They reported for their selenium only dietary treatments that the negative reproductive effects of Se	

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	occurred at an E/O tissue value of 7.2 mg Se/kg DW (Penglase et al. 2014:22). Also working with zebrafish in Canada, Thomas and Janz (2014) reported a reproductive lowest observable effects concentration (LOEC) in E/O tissue from maternal dietary exposure to selenium of 9.6 mg Se/kg DW (Thomas and Janz 2014: Figure 1). The no observable effects concentration (NOEC) of 6.0 mg Se/ kg DW illustrated by Thomas and Janz (2014: Figure 1) shows about a 7-fold greater percent cumulative larval mortality (i.e., about 70% vs. about 10%) than for E/O tissue containing 2.1 mg Se/kg dry weight (DW), suggesting low statistical power rather than the lack of a toxicologically real adverse effect at 6.0 mg Se/kg DW. Toxicity responses observed in the range of 6-10 mg Se/kg DW for E/O tissue naturally diminish the level of confidence associated with 15.2 mg Se/kg concentration recommended in the DSP. Zebrafish are not native to the United States and therefore results of toxicity tests on zebrafish would not be considered directly by EPA for criteria derivation purposes. However, zebrafish are a member of the Family Cyprinidae and there are 255 species of native freshwater fish in the United States in the same Family, yet only one native species of Cyprinid (Fathead Minnow) is represented in the DSP toxicity data base (Table 6a). This state of the data suggests that it would be prudent for EPA to view test results for zebrafish as a potential surrogate for the sensitive tail of the SSD for Cyprinidae in the United States and also as evidence that the current toxicity data base is not representing the sensitive tail of the all taxa SSD for fish as adequately as is hypothesized in the DSP. Furthermore, another recent study (Hitt and Chambers, In Press) examines changes in fish assemblages being subjected to pollution from mountaintop removal-valley fill mining in Appalachia, and cites a study authored by EPA scientists concluding that selenium was the primary cause of loss of fish richness and also cite another study authored by additional EPA scientists reporting a differential decrease in richness of fish species belonging to the Family Cyprinidae. Another factor to consider is the fact that 36 species from the Family Cyprinidae, representing 17 genera, are already ESA-listed species (count compiled from the Service's ECOS data base). The Service believes the body of work on razorback suckers should be considered appropriately. Hamilton's (2005b) published critique of the Beyers and Sodergren razorback sucker work provides plausible resolution of the differences between the two studies.	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 revised criterion. 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
Comment Category 4.1 – Comments on Translation Equation (Equation 18) Summary: This section contains comments about EPA's equation that translates egg-ovary concentration to an equivalent water concentration. It includes comments on the bioaccumulation model (Equation 1), EPA's decision to simplify Equation 1, 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.		
15	EPA-HQ-OW-2004-0019-0322-A1; American Petroleum Institute (API); Posted 7/30/2014 The Notice provides two-tier criteria, in fish tissue (whole fish, muscle, and ovaries) and in the water column. The fish tissue criteria rely on site-specific bioaccumulation factors (BAFs), and these site-specific BAFs, or the data to derive these BAFs, are not available for the vast majority of waters. How	Responses to comments on translation equation: Regarding the translating the tissue criterion to water, EPA re-evaluated conversion factors used and refined the approach to

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	did EPA establish the representativeness of the BAFs used in the derivation of the proposed criteria? EPA should discuss the derivation and applicability of alternative, site-specific water quality criteria based on site-specific BAFs.	reflect the most taxonomically proximate data in its criterion calculations, 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 failure to indicate exceedance of the egg-ovary criterion element via the water column element. 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.
264	EPA-HQ-OW-2004-0019-0256-A1 [Comment 0346-A2 is a duplicate of 0256-A1]; Peabody Energy Corporation; Posted 6/16/2014 Water Column Criterion <u>Conservative Assumptions in Criterion:</u> The translation of the egg-ovary criterion into a water column criterion relies on an EPA / USGS bioaccumulation model that may contain overly conservative assumptions for representative values of equation variables. In particular, the influence of the trophic transfer functions is compounded in the final water column criteria because of the multiple trophic levels being considered. However, the sensitivity analysis contained in Appendix G does not address the sensitivity of the model to the trophic transfer functions and the influence on the final water column criterion.	
279	EPA-HQ-OW-2004-0019-0339-A2; West Virginia Department of Environmental Protection (DEP); Posted 7/30/2014 Comments concerning tissue translation to water column values: <u>Dissolved selenium and particulate material</u> - In regard to EPA's translation of tissue-based criteria to water column limits, based predominantly on relationships derived from Presser's (2013) ecosystem-scale selenium assessment model, the general concept of dissolved selenium - selenium in the water column medium - serving as the dietary precursor for all facets of food chain accumulation is likely not identifying all pathways of dietary exposure in the lotic waters (e.g., West Virginia's streams). EPA should consider foodweb modeling that incorporates additional expose pathways of dietary selenium vectors/exposure and is, therefore, more accurately predictive of water column concentrations necessary to maintain such dietary sources. In order to identify the most accurate dietary exposure pathway(s), EPAs modeling should include information, for examples, on selenium concentrations of prey items (i.e., selenium concentrations of consumed materials in stomach contents) and not be solely reliant on foodweb models utilizing suspended particulate as the entire source of foodweb selenium. The data suggests that suspended particulates are mostly inorganic Se^{+6} arising from sediment sources, and not the result of dissolved transformations into suspended particles. In the modeling process, this suspended particulate material is assumed to be the main vector of dietary uptake; it is this material that is purportedly exposed to aquatic life and responsible for initial incorporation of selenium into the aquatic food web. However, it is unlikely that sufficient quantities of suspended	

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	particulate material are available to support the entire overriding food web and selenium accrual observed in biological tissues. Further, the exact fate regarding occurrence in biological tissues of this particulate material should likewise be apparent (i.e., what specific type(s) of primary producer organisms are assimilating the selenium into their tissues?) if this phase represents the most important basal food-chain initiator. Additionally, the types of organisms responsible for the aggregation of dissolved column selenium into larger particulates capable of being consumed by higher organisms should also be evident and described.	
312	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 3.3 Derivation of Protective Water Column Concentrations *3.3.1 Use of Probability Distribution of Water Column Concentrations* We do not agree with the approach used to derive the two default water column concentrations meant to be protective of fish-tissues. Table 12 on page 85 of the 2014 draft Se criteria document presents site-specific data for 132 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 (TTFcomposite) values based on expected trophic levels at the site. While the TTFs do differ based on the fish species present, it is unclear what other species TTFs were used to calculate the composite value, and in some cases different TTFs were used for the same species in the same system type (lotic or lentic) with no explanation as to why the selected TTFs differed. As will be discussed in Section 4.5.1.1 of our review, use of site-specific 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 11, page 89 of the 2014 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 Table 12). 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, 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 0.38 µg/L to 55.6 µg/L for lentic sites, and 1.4 µg/L to 98.1 µg/L for lotic sites, depending on the site-specific factors used in Equation 18. By selecting a 20th percentile value	

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	to use as the water column criteria, as EPA did, 80% of the sites in Table 12 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 a valid approach, but only on a site-specific basis. Figure 16 on page 134 attempt so to show the validity of the translator equation, and while there is a correlation between predicted egg/ovary concentrations and measured concentrations, there is quite a bit of scatter around the unity line, with a substantial number of points above the line, suggesting the model generally underestimates tissue values. EPA acknowledges on page 135 that there is uncertainty attributable to temporal or spatial variability in selenium exposure and local variability in aquatic food webs, which supports our assertion that site-specific water column criteria are more appropriate. A single nationwide standard for water column-based criteria for only two water body types (lentic or lotic) is not supported by EPA's own analysis.	
112	EPA-HQ-OW-2004-0019-0326-A1; Utility Water Act Group (UWAG); Posted 7/30/2014 Lentic and Lotic Variability Rightly Recognized; More Explanation Needed EPA rightly acknowledges bioaccumulation variability, but additional information is needed regarding EPA's approach to address these effects. *EPA Recognition of Variability Appropriate* The Draft Report recognizes that selenium bioaccumulation depends on many different biogeochemical factors that characterize a particular aquatic system and that uncertainty in the translation can be reduced by using site-specific data. Draft Report at 90. This is particularly important because selenium EFs tend to be greater in lentic systems than in lotic systems and field data are needed because these systems cannot be well-modeled in the laboratory. (DeForest et al., 2014). In deriving ambient water quality concentration values for lentic and lotic systems, EPA focused on differentiations between EF and residence time. EPA translated the egg/ovary criterion element to a set of water concentration values on the basis of the EF values calculated for 69 sites and food web models of the fish present in the systems. Draft Report, p. 85. However, EPA's input variables appear to have been taken from both laboratory and field studies. Draft Report, Table 12, pp. 85-89. *Additional Explanation of Data Needed* There are important differences in field versus laboratory data that should be evaluated and explained. For example, are TTFs and EFs more variable in field studies relative to laboratory studies	

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	and, if so, how will this affect EPA's final concentration calculations? We believe EPA should provide a full explanation for how the agency accounted for variability among the data in calculating concentrations for specific aquatic systems. In addition, UWAG believes some of the data used in the calculations included in Table 12 should be reconsidered. Specifically, UWAG believes inclusion of EFs reported in the Lemly (1985) publication is problematic because the data are anomalous (Lemly reporting EF values of 2.09, 3.81, and 8.54 for six fish species). Notably, these values are significantly higher than other EFs for all other studies cited. For example, the EF for fathead minnows collected from the "BA" lake site is 8.54. This value is considerably higher than the other fathead minnow EF found in Table 12. The fathead minnow lentic EFs taken from the Birkner (1978) reference ranges between 0.87 - 2.37. Not surprisingly, the Lemly data result in exceedingly stringent chronic water criterion concentrations, varying from 0.38 - 2.70 µg/L. Another good example is Belews Lake, North Carolina. According to Table 12, using Lemly data, the calculated water quality criteria for the various Belews Lake fish species range from 1.69 - 2.55 µg/L. These values are unrealistic. In 1987, EPA determined that the portions of Belews Lake not affected by power plant ash pond waste water discharge, which at times Belews Lake had a water selenium concentration "near or below 5 µg/L." EPA subsequently used these data as the basis to establish a nationally-recommended chronic selenium aquatic life criterion of 5 µg/L. Because the Lemly data appear completely anomalous when compared to other data in the dataset and EPA's scientific conclusions with respect to Belews Lake, we request that the Agency re-evaluate the food chain transfer model variables that correspond to the Lemly (1985) study. These values have a marked effect on the final draft lentic water quality criterion of 1.3 µg/L; therefore, it is critically important, where these values are found suspect, they should be removed from Table 12 and the concentration should be recalculated.	
471	EPA-HQ-OW-2004-0019-0356-A1; Idaho Department of Environmental Quality (DEQ); Posted 09/30/2014 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. We urge EPA to seek out and incorporate data sets from waters with lower selenium levels to assure the relations described 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. 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	

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	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.	
326	EPA-HQ-OW-2004-0019-0341-A1; West Virginia Coal Association (WVCA); Posted 8/5/2014 Birds should be removed from the adapted ecosystem-scale model as evidence of significant selenium transfer to that trophic level has not been documented in WV.	
Comment Category 4.2 – Comments on Derivation of Trophic Transfer Function Values 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/food concentration ratios and ordinary least squares (OLS) for statistical verification.		
116	EPA-HQ-OW-2004-0019-0260-A2 [Comment 0314-A2 is a duplicate of 0260-A2]; Conley and Buchwalter; Posted 6/16/2014 4. Based on four studies conducted in our lab over 5 years, the TTF calculated for C. triangulifer from the study by Riedel and Cole (2001) (pages 76 and B-51) is too low. We consistently observe C. triangulifer adults with TTFs > 2 (see Table 2 below). This is important because the draft document describes the ability of states to determine site specific selenium criterion values using biodynamic modeling and back calculation. Providing a low value for the representative aquatic insect C. triangulifer of 1.28 underestimates the accumulation potential at this step in an aquatic foodweb. A value of at least ≥ 2.0 should be recommended for states when attempting to calculate site specific criteria.	Responses concerning derivation of TTF values: EPA modified the TTF methodology in the 2015 draft (retained in 2016 final document) to better reflect taxonomic similarities when data were lacking. Also, compared to EFs, TTFs are relatively small and less variable, and have less influence on a translated water value. 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 believes that confining its national assessment to a very small number of well-studied sites and to laboratory studies where such measurements are available would reduce rather than increase confidence in the appropriateness of the national criterion. 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
288	EPA-HQ-OW-2004-0019-0315-A1; USGS - Comment submitted by Theresa S. Presser and Samuel N. Luoma, National Research Program, U.S. Geological Survey, Western Branch, Menlo Park, CA; Posted 7/15/2014 3. Comparing the choice of a) modeled invertebrate taxa made in the DCD to those commonly occurring in ecosystems; and b) the quantitative trophic transfer factors (TTFs) associated with those invertebrates to those derived in the literature shows a downward bias in both cases (Table 1).	
294	EPA-HQ-OW-2004-0019-0315-A1; USGS - Comment submitted by Theresa S. Presser and Samuel N. Luoma, National Research Program, U.S. Geological Survey, Western Branch, Menlo Park, CA; Posted 7/15/2014 Revise compilation of TTF invertebrate values to correct negative bias (especially to reconcile the difference in the value cited for TTF mayfly with values given in the literature)	

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	Specific concerns to the application of science to the derivation of the water-column Se criteria are that 1) the values used by the USEPA to reflect the trophic transfer for mayfly, chironomid, corixid, and daphnia are less than those reported in the literature; and 2) TTFs were not derived for cranefly, stonefly, caddisfly, snail, and leech (Table 1). The derivation of TTFmayfly of 1.28 from laboratory data (DCD pg B-51; Riedel and Cole, 2001) fails to consider a dietary pathway thus underestimating the bioaccumulative potential of a common food web used throughout modeling in the DCD. The TTFmayfly derivation from field data was not used because of a calculated anomalously high ratio (DCD page B-61). However, documentation of the derivation of TTFmayfly and other aquatic insects from the literature showed successful determinations from both field and laboratory data, with a concurrence around the value of 2.8 (Presser and Luoma 2010a; Conley et al., 2009). For example, Presser and Luoma (2010a) derived a mean TTFinsect of 2.8 (range 2.3 to 3.2) based on matched field data sets for particulate and insect Se concentrations in freshwater environments for several species of aquatic insect larvae including mayfly, caddisfly, dragonfly, midge, and water boatman. These values generally compare well to laboratory-derived TTFs for aquatic insect larvae (e.g., combined mean 2.2; range 1.9-2.9; Conley and others 2009). A recent site-specific derivation for chironomid showed a value higher than 2.8 (i.e., 4.2). Similarly, a field TTFsnail of 5.5 was determined (Presser, 2013). In summary, Table 1 shows a tendency in the DCD towards the consideration of lower TTFinvertebrate than those available from the literature and exclusion of invertebrate taxa with higher bioaccumlative potentials. Overall, use of the DCD TTFs leads to several negative-bias quantitative consequences in modeling outcomes. For example, if the model is run using a single Kd, but different TTFs for mayfly (i.e., the DCD derived TTFmayfly of 1.28 versus literature and laboratory derived TTFmayfly of 2.8), then a 2.2-fold higher aquatic criterion for Se is derived (6.75 µg/L versus 14.8 µg/L). Finally, consider revising the statement (DCD, pg 140): …selenium does not significantly biomagnify moving up the food chain except in specific ecosystems with mollusk-based food-webs, unlike bioaccumulative chemicals such as mercury…because it is not an accurate assessment of Se food-web biodynamics as documented in the scientific literature and acknowledged by the rational of basing aquatic protection on a fish tissue concentration. Selenium concentrations are at least conserved and usually magnified at every step in a food web (Presser and Luoma, 2010a, Figure 6; Chapman et al., 2010).	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. Regarding the TTF for mayfly, EPA added the data from the Conley et al. papers, which increased the mayfly TTF to 2.38. These data were added to the other field data (Rinella et al 1994 and Casey 2005) to obtain the 2.38 TTF.(Table 3.9 in 2016 final criteria document. There are 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, where 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 OLS regression) has inherent strengths and weaknesses, and ultimately, the hybrid approach was determined to be the most robust. The analysis comparing the approaches is located in Appendix N of the final national criterion document. 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
281	EPA-HQ-OW-2004-0019-0341-A1; West Virginia Coal Association (WVCA); Posted 8/5/2014 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	

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	implement the fish tissue criteria as water column concentrations.	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. EPA understands that there are uncertainties associated with this assumption, but this approach was deemed necessary in order to obtain sufficient data from sufficient sites in order to develop water column criterion elements. It may be appropriate to collect site-specific data for a known impacted site to insure that both temporal and spatial considerations at the site are accounted for. Uncertainties are "backstopped" by the egg-ovary criterion, the ultimate indicator of ecosystem protection in a waterbody. Regarding the influence of Badin and High Rock Lakes, EPA agrees that they had 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 had 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. Previously in 2014, EPA used all water column values for all species present to generate distributions of translated water column values from lentic and lotic aquatic sites. However, the number of reported fish species at aquatic sites with an EF value varied from one to six fish species. Furthermore, the studies providing data for 31 of the 96 sites with EF values did not provide information on the species of fish that may have been present at the aquatic site. EPA
306	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014 3.4.4.3 Selenium Criteria Should Not Be Driven by Reference Area Data The above evaluation demonstrates that application of the selenium model parameters to reference areas such as Badin Lake and High Rock Lake results in over-prediction of egg selenium concentrations, which in turn results in translation to inappropriately low water selenium criteria concentrations. This assumes the data reported by Lemly (1985) are accurate or appropriately interpreted. As also noted above, the draft water selenium criterion of 1.3 µg/L is driven almost entirely by the data for these two reference lakes (Figure 1). The relevance of reference area data for derivation of water selenium criteria is questionable. First, an inverse relationship is consistently observed between EFs and TTFs and exposure concentrations. Thus, higher EFs and TTFs are almost always observed in waters with low water selenium concentrations. Not properly accounting for this can result in an erroneous application of these values. Should the Agency have data for sites where the selenium concentration in water is at 0.01 µg/L, the EF will be significantly larger but not representative of most aquatic environments that are typically in the range of 1 µg/L. Choice of reference area is important. The way around this is to model EFs as a function of concentration in the water. A second related issue is that a "hockey stick" relationship may be observed between tissue selenium concentrations and corresponding water selenium concentrations (e.g., Brix et al., 2005). There is also evidence of this relationship in the co-located fish and water selenium data for Badin Lake, High Rock Lake, and Belews Lake, albeit limited due to the narrow range of water selenium concentrations for the two reference lakes (Figure 2). The possibility of such a "blade" further emphasizes that EFs and TTFs are not constants across a range of exposure concentrations (i.e., it is along the blade where these factors vary the greatest). It was for this reason that reference area and laboratory control data were excluded from the recent analysis sponsored by the NAMC-SWG in which proposed water selenium screening criteria were developed (DeForest et al., 2014). *Original letter contains Figure 2 – Relationship between muscle selenium concentrations for six fish species and co-located water selenium concentrations for Badin Lake, High Rock Lake, and Belews Lake. See original letter.* Finally, because the draft lentic water selenium criterion was derived as the 20th percentile of the cumulative distribution, we question whether it is appropriate that the distribution represents individual species values or whether it would be more appropriate to define the distribution of sites (i.e., each data point would represent a single site). Based on the approach used by EPA, the two reference	

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	areas, along with the uncertainties and concerns in using these data, are being over-represented in the data set since data for six species in each lake are represented (i.e., 24% of the data are based on just two reference lakes).	corrected this methodological flaw in the 2014 draft criterion approach with an improved approach in the 2015 and 2016 analyses. In 2015 and 2016, EPA calculated one translated egg-ovary criterion element to water column value for each aquatic site with both an EF value and at least one reported fish species. When more than one species was reported at a site, the EPA used the lowest translated water value for that site. Using this methodology, EPA translated the egg-ovary FCV into water column concentrations at 26 lentic and 39 lotic aquatic sites. (Section 3.2.5 of the 2016 final criteria document. The uncertainty regarding TTFs and other aspects of the criteria derivation are discussed in Section 6.3. EPA provided information on approaches to deriving site specific criteria for selenium; this is contained in Appendix K. Regarding the binary classification analysis, in the 2015 draft, the methods to derive the lentic and lotic values was modified to correct overweighting problems in the datasets caused by waterbodies with multiple fish species sampled. Also data for some new waterbodies became available through the public process. EPA used binary classification analysis as a screening analysis in the first draft for ground truthing the selection of the 20th percentile of each water value. EPA also added new appendices (Appendix H with EF data and Appendix I with the observed vs predicted egg-ovary concentration data) to the revised 2016 draft document (were also in the 2015 draft). These appendices provide all the data that were used in the evaluation process and can be used to understand the derivation of the water values. Regarding the issue of protectiveness, selenium is no different than other water quality criteria in that the goal of national criteria is to protect most aquatic life (roughly 95% of genera) in most waters. For selenium we have provided approaches for site specific criteria/translations in Appendix K of the 2016 final criteria document. It features a comparison of the approaches using both the BAF method and the mathematical model approaches featuring data from Saiki 1993, a dataset used in the derivation of the national
316, 317	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 8/7/2014 In deriving both EFs and TTFs, the EPA uses the median of individual values. The validity of this procedure is based on the assumption that values used to derive the median represent a random sample effectively drawn from the same population. This assumption does not prove to be true in many cases. Both EFs and TTFs generally vary strongly and systematically with selenium exposure levels (concentrations at the lower trophic level of each transfer), so that EF and TTF values decrease with increasing exposure (see examples graphed below). Furthermore, it seems probable that studies of selenium concentrations in water and biota are more likely to occur in environments of relatively high selenium exposure because there is greater concern about such environments. Given the nature of trophic transfer and enrichment functional relationships illustrated above, these studies are likely to result in un representatively low values of EFs and TTFs.	
313	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 4.5 Derivation of Water Column-based Criterion Elements In Section 4.2 of the 2014 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 70: $Cwater = \dfrac{Cegg\text{-}ovary}{TTFcomposite \times EF \times CF}$ Where: Cwater = Concentration of selenium dissolved in water (µg/L) Cegg/ovary = Selenium concentration in the eggs or ovaries of fish (µg/g) TTFcomposite = Product of all trophic transfer functions EF = Enrichment function (L/g) CF = Whole-body to egg/ovary conversion factor (dimensionless ratio)	

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	There are several components of this equation that require further analysis and consideration. *4.5.1 Discussion of Trophic Transfer Functions (TTF)* 4.5.1.1 Importance of Site-specific TTFs Ranges of TTFs can vary widely due to site-specific factors. To demonstrate this, 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. Additionally, we calculated geomean ratios for each species, as this approach is often a better measure of the central tendency of data (rather than a 50th percentile or median value). Table 12 below includes species and median TTFs that were calculated by EPA (Appendix B, 2014 draft Se criteria document) as well as the ranges of TTFs reported and calculated geomean ratios. We also verified the median TTF values and found several errors in Tables 9 and 10 on pages 76 and 77; these values are also included in Table 12 (below) and the corrections are shown in bold with the incorrect values shown as strikeouts. Additionally, sunfish data were omitted from Table 10 on page 77 that should have been included (Table 12 below). Overall, TTFs for most species varied widely, which is likely representative of site-specific conditions that become masked through their use of median values. Use of median values for TTFs is not appropriate due to highly variable site-specific conditions. Generally, median ratios and geomean ratios for TTFs were similar; therefore, it does not appear that using the geomean would significantly change the results of the calculated water column criterion if central tendency values are used. In addition, several of the median TTF values that were miscalculated by EPA are significantly different and these could affect the resulting back-calculated water column criteria. Therefore, these corrections should be made and water column concentrations in Table 12 of the 2014 draft Se criteria document should be recalculated. Additional data to add to the TTF database from GEI studies are included in Appendix A. *Original letter contains Table 12 – TTF median ratios from Tables 9 and 10 in the 2014 draft Se criteria document and calculated ranges and geomean ratios. See original letter.* 4.5.1.2 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. On page 66, EPA states "Because each TTF is associated with a particular taxon, TTFcomposite can be inferred for an aquatic system using existing knowledge and reasonable assumptions, without the considerable time and cost of collecting and analyzing tissue and water samples" (emphasis added). As shown above in Table 10, TTFs can have considerable variability for a particular species within a specific system and site-specific information is extremely important in determining water column Se criteria. As noted in DeForest et al. (2014), the	selenium water column criterion elements.

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	difference in TTFs may seem relatively small compared to other factors, but it could be the difference between predicting whether or not a fish tissue-based Se criterion, or water column criterion derived from a tissue criterion, is exceeded. The TTFcomposite approach would require prey item-specific consumption rate/frequency data (ideally site-specific) to best characterize exposure. Trophic level 3 and 4 consumers such as fish are seldom specialists and are commonly opportunistic, feeding on multiple prey types. 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. Additionally it does not appear that any of the field studies have evaluated terrestrial invertebrate input, which could be a component of fish diets. This may be one additional reason for the wide range of reported TTFs from field data. Excluding this potential trophic level adds more uncertainty to the TTFcomposite values. Multiplying median TTF factors together also increases the inherent variability associated with each factor used, resulting in more uncertainty in the final 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. *4.5.2 Enrichment Factors (EF)* Pages 79-80 of the 2014 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)." Then on page 80, "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 included in Appendix A. *4.5.3 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. While this makes sense in theory, the resulting data have substantial overlap, indicating the differences are not that clear. Table 12 of the 2014 draft Se criteria document, which presents water column concentrations calculated to be protective of the fish tissue criterion, shows substantial overlap between lentic and lotic sites, with Se calculated concentrations ranging from 0.38 µg/L to 55.6 µg/L for lentic sites and 1.4 µg/L to 98.1 µg/L for lotic sites. EPA initially found that there were indiscernible differences between different waterbodies, and then moved to an analysis that was not as robust to demonstrate	

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	that these waterbodies do function inherently differently. Although we agree that these types of waterbodies are different, we believe this analysis actually supports the notion that 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, as is discussed previously in Section 4.1.2. *4.5.4 Validation of Translation Equation* 4.5.4.1 Use of Binary Classification Scheme The binary classification scheme is discussed in Section 7.2.2 and Appendix H of the 2014 draft Se criteria document. In Appendix H, page H-2, EPA states that 49 lotic species-site combinations and 83 lentic species-site combinations were generated using the binary classification format. It is not clear where those data and the binary classification section in the document body come from and how they were selected. Furthermore, the numbers of species-site combinations in Appendix H (49 lentic and 83 lotic) differ from those presented in the body of the text, which states on page 136 "…The EPA used these data to assess attainment or exceedance of 140 instances in lentic aquatic systems and 688 instances in lotic aquatic systems." It appears that two different datasets were used – one to calculate the binary statistics presented in the report body and another to calculate the statistics presented in Appendix H. As a result, the frequencies included in the lentic binary classification table (page H-2) differ from those presented in the same table included in the body of the document (Table 18, page 137). Which set of numbers is correct? The dataset used to generate these frequencies should be provided. Furthermore, the numbers presented in Table 18 (page 137) do not sum to 140 (rather, 96+16+10+13 =135), the number that is presented on page 136 as the number of lentic systems assessed. Overall, the data used to generate these binary tables are unclear and there are discrepancies between the tables presented in the body of the report and the same tables presented in Appendix H. The report body (page 90) states that "…EPA used an independent data set composed of measured concentrations of selenium from 2,588 lotic and 596 lentic sites to complete a verification or "ground-truthing" of the selected 20th percentile…". Were the 49 (lentic) and 83 (lotic) data combinations mentioned in Appendix H selected from the data collected at the 2,588 lotic and 596 lentic systems mentioned in the body of the report? Furthermore, it is not clear how false positive results are considered in the analysis. It is mentioned in the body of the report (page 37) that "ground-truthing" has determined that selecting the 20th percentile of water column values would minimize the occurrence of false negatives, but has any "ground-truthing" been done to determine what use of the 20th percentile means for the occurrence of false positive results?	

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<tr><td></td><td>4.5.4.2 Discussion of “Protectiveness”

Section 7.2.2 of the 2014 draft Se criteria document states that “These binary classification statistics indicate that the chronic water criterion element values are highly sensitive to exceedance of the egg/ovary criterion element (that is, when the egg/ovary criterion element is exceeded, it is highly likely that the water column criterion element will also be exceeded).” While this is true, this should also be evident based on our discussion of Figure 11 in Section 3.3.1, which demonstrates that the water column criterion at 80% of the sites shown is lower than necessary to protect the egg/ovary criterion. In other words, in order for the upper 80% of the sites shown in Figure 11 to exceed the egg/ovary criterion, the corresponding water column concentration would have to be significantly higher than the 20th percentile-based water column criterion. Again, this supports our previous discussion in Section 4.1.2 describing how site-specific water column values are needed to determine true protectiveness of the tissue-based criteria.</td><td rowspan="2"></td></tr>
<tr><td>293</td><td>EPA-HQ-OW-2004-0019-0315-A1; USGS - Comment submitted by Theresa S. Presser and Samuel N. Luoma, National Research Program, U.S. Geological Survey, Western Branch, Menlo Park, CA; Posted 7/15/2014

Construct food-web models that represent a cross-section of common species with differing bioaccumulation potentials

Research by the USGS indicates that the first step in modeling should be the construction of conceptual models to document the interaction of site ecology, biochemistry, and hydrology and species’ physiology and ecotoxicology as described in our publications (see especially Presser and Luoma, 2010a, Figure 6). In the context here, this means that sites and food webs chosen for modeling should encompass the range of known bioaccumulative potentials that exist within common ecosystems across the U.S. Fifty-three sites from 13 referenced citations have been selected by the USEPA for this task (DCD Table 12). Little information is given on how this set of sites was selected. The food webs for these sites were not illustrated in any comprehensive way. Our main concerns here are 3-fold:

• the type and number of sites in the database;
• the need to provide conceptual models for these sites to document choices and understand species-specific food web complexity; and
• the lack of representation of benthic food webs indicative of clams, mussels, snails, or worms (TTFinvertebrate > 2.5) in the site-specific criteria development dataset.

The sites chosen by the USEPA for analysis used a limited number of invertebrate taxa and some sites were represented by non-taxa specific invertebrate samples based on checking the data given in the original studies for the listed sites. Common taxa such as clam, mussels, and snails were not</td></tr>
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	used in the DCD food web examples for derivation of water-column criteria. Matching these prey taxa to predators is of further concern. For example, erroneously including crayfish in the diet of Iowa darter or speckled dace may result from not explicitly documenting choices in data analysis and lack of consideration of ecologically appropriate food webs. Selenium concentration data for particulate material, invertebrates, and fish need to be shown, along with dates of sampling to ascertain the spatial and temporal context for the modeled species and ecosystem. Limiting the suite of taxa analyzed limits the basis for prediction and the applicability of the derivation of water-column criteria. Without systematic assessment, compilation, and conceptual models, the underlying strength of derived water-column Se criteria is uncertain and the developed criteria may not be ecologically meaningful nor consistent. The number of sites and fish species in Table 12 is not so large as to preclude construction of food-web models as a practical matter. Linking ecological choices to mathematical decisions during data analysis is crucial to narrowing uncertainty. In terms of quantifying trophic transfer for the set of analyzed sites by the USEPA, a TTFcomposite (a combined TTFfish and TTFinvert) is shown in DCD Table 12. This type of approach is not helpful to understanding and quantifying the trophic transfer in an ecosystem and does not provide an adequate conceptualization on which to base protection. If values for TTFinvertebrate are calculated from the composite TTFs shown in DCD Table 12, then direct information on particulate material to invertebrate trophic transfer for the cross-section of invertebrates sampled is possible (Table 1). Table 1 compares the calculated TTFinvertebrate values shown in DCD Table 12 and the taxa-specific TTFinvertebrate shown in DCD Table 9 to those compiled in the literature. As shown, few calculated TTFs for invertebrates used in the derivation of criteria exceeded two, while those compiled to represent a cross-section of taxa do. A lower TTF means less bioaccumulation and therefore a higher predicted water-column criterion. By limiting the value of TTFinvertebrate mathematically to < 2, there is a negative bias in the model predictions that does not match ecological reality and would not provide adequate protection to ecosystems. This topic is discussed further below. Additionally, the data set compiled in Table 12 mainly does not take advantage of the entire set of sites sampled by the referenced authors (e.g., Hamilton et al, 1 of 28 sites; Birkner, 7 of 17 sites). In the case of studies by Hamilton et al., the one site chosen from his work was a site (East Mill Creek in Idaho) that was severely contaminated to the point of no fish being present at times and those that were present probably representing survivors. Particularly concerning is that the sites and data included from the National Irrigation Water Quality Program (e.g., Butler, Grasso and Stephens) seem to represent but a small fraction of the sites and biological data available (8,218 analysis of plant, invert and fish in the NIWQP database; on-line at http://www.usbr.gov/niwqp/datasynthesis/index.html). Additionally, other studies also are available for consideration by the USEPA (e.g., Presser and Luoma, 2010a; Presser, 2013). As noted in our	

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	summary comments, the DCD should be sufficiently transparent concerning what sites were chosen, the criteria for choosing sites, and the reason some data and not others were employed in designing a guideline. Assemblage of the raw data also is made difficult for readers because many reference citations shown for Table 12 are not listed (Butler et al. 1995, 1997; Casey 2005; Formation 2012; Grasso et al. 1995; Hamilton and Buhl, 2004; and Stephens et al 1988). Errors such as mischaracterizing Mud Slough and Salt Slough as lentic and accepting an unrealistic enrichment factor (EF) [or environmental partitioning factor (Kd) as described by the USGS] of 100 for Marsh 4720 site (DCD Table 12) also need to be corrected. Based on original referenced data, the flowing water-column Se concentration can be replaced with a marsh pond water-column Se concentration and matched with a particulate Se concentration from the pond ecosystem; then, an EF of 1,229 is calculated, which is within the range for lentic systems.	

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282	EPA-HQ-OW-2004-0019-0344-A1; Sanitation District No. 1 of Northern Kentucky (SD1); Posted 8/5/2014 Application of TTFs to Calculate Water Quality Criteria In contrast with the egg-ovary criterion, which is based on direct observation of field and laboratory data, the water quality criteria concentrations for lotic and lentic systems of 4.8 µg/L and 1.3 µg/L, respectively, were calculated using a series of conversion factors (CFs) and trophic transfer factors (TTFs) (U.S. EPA 2014a). As such, the assumptions and data transformations used in the development and application of these factors can have a significant influence on the final calculated criteria, particularly in that many of these assumptions were overly and unnecessarily conservative. This is particularly relevant in the calculation of TTFs, as these factors can vary significantly dependent on the exposure concentration used in their derivation. U.S. EPA (2014a) correctly noted that "many aquatic organisms tend to bioaccumulate more metals at low environment concentrations (McGeer et al. 2003, Borgman et al. 2004, Deforest et al. 2007, U.S. EPA 2007)", which results in high TTFs at low exposure concentrations and lower TTFs as exposure concentrations increase. It is our opinion that the process used by EPA to develop CFs and TTFs resulted in overly conservative values and should be revised. In selecting TTFs for use in calculating the Se water quality criterion, U.S. EPA (2014a) considered two approaches a ratio calculation and regression evaluation to estimate the TTFs used in developing the water quality criterion. The draft criterion was calculated using a hybrid approach in an effort to reduce the potential influence on measuring Se accumulation at very low and high concentrations. However, a review of DeForest et at. 2007 demonstrates that the TTFs calculated via this method still likely significantly over-estimate the accumulation of Se via the dietary pathway, which would then lead to overly conservative water concentration criterion for both lentic and lotic systems. For example, EPA (2014a) reports a bluegill TTF of 1.48 (Table 10, page 77). However, data presented in DeForest et al. 2007 clearly demonstrates that the significant bulk of bluegill TTFs are well below 1.0 (Figure 1). *Original letter contains Figure 1 – Whole Body Selenium TTFs for chinook, bluegill, and fathead minnows. See original letter.* The 1.5 to 3-fold difference in bluegill TTF, if consistent across species, would significantly lower the corresponding water quality concentration needed to protect these fish species from Se exposures. In contrast to the hybrid approach employed in development of the lotic and lentic water quality criteria, EPA should instead, use the ratio approach after censoring both high and low exposure concentrations, and then use a representative statistic, such as the median, of the remaining data to establish appropriately conservative water concentrations that are equally protective of fish as the tissue based criterion. Use of the current proposed water concentration criterion for lentic and lotic systems would be unnecessarily overly protective and burdensome to the regulated community and state regulatory agencies. This approach results in increased costs to comply with the Clean Water Act while providing no additional environmental benefit.	

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115	EPA-HQ-OW-2004-0019-0260-A2 [Comment 0314-A2 is a duplicate of 0260-A2]; Conley and Buchwalter; Posted 6/16/2014 3. There is a more recent study on the chronic toxicity of dietary selenium to the mayfly. Centroptilum triangulifer than the one utilized in the draft document (pages 55-56). In Conley et al. (2011) Ecotoxicology 20: 1840-1851 we utilized a larger range of dietary exposure concentrations and report dose response results for several performance endpoints. In that study C. triangulifer suffered reproductive impairment at a dietary selenium exposure level of 4.2 µg g-1 (dry weight). The mean TTF in that study was 2.8, which results in an adult tissue concentration of 11.8 µg g-1 (dry weight). This is less than half of the effect concentration calculated and utilized in the draft document (24.2 µg g-1, page 56) and should be utilized as a more representative value for aquatic insect toxicity effects from exposure to dietary selenium.	
Comment Category 4.3 – Comments on Derivation of Egg-Ovary to Whole Body Conversion Factor (CF) Values Summary: This section contains comments on deriving egg-ovary to whole body conversion factor (CF) values using empirical relationship of matched pairs and EPA's hybrid approach using ratios and ordinary least squares (OLS) for statistical verification. Many commenters noted the large variability problem and specifically the high standard deviations associated with brown and cutthroat trout CFs.		
31	EPA-HQ-OW-2004-0019-0260-A2 [Comment 0314-A2 is a duplicate of 0260-A2]; J. M. Conley and D. B. Buchwalter; Posted 6/16/2014 5. Egg/Ovary - Whole body conversion factors should not be exclusively defined on a per species basis, they can be dynamic and variable depending on the dietary source and selenium concentration. The draft document describes the simplicity of utilizing species specific conversion factors (page 59, 78-79), however research from our laboratory has shown that the movement of selenium into fish eggs can be dynamic and rapidly change based on the diet (Conley et al. (2014) Environmental Science & Technology 48: 2971-2978). A large proportion of the selenium transferred to eggs by female fish comes directly from the diet as opposed to being mobilized from tissue stores. Because of this, using confined conversion factors from female whole body to egg/ovary are context dependent from the diet being consumed at the time of sampling. Our research indicates that these conversion factors can vary up to almost three fold (CF = 1.0 - 2.8). The derivation of fish tissue selenium criterion values should account for the variation in conversion between female and eggs depending on the concentration of selenium in diet being consumed during egg production.	Responses concerning derivation of Egg-Ovary to Whole Body conversion factor values: 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, and the inter-species range of CFs for egg-ovary to muscle was comparable. Regarding inter-species variability in conversion factors, 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 (2-3) fold in sensitivity observed even among species with repeated toxicity tests, 2-fold variability 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. In the 2015 draft, and 2016 final document(s), EPA improved its
32	EPA-HQ-OW-2004-0019-0266-A2; Transportation and Storm Water Department, City of San Diego, California; Posted 6/17/2014 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.	

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33	EPA-HQ-OW-2004-0019-0271-**A2**; Fredric P. Andes, Coordinator, Barnes & Thornburg LLP on behalf of the Federal Water Quality Coalition; Posted 6/17/2014 There are uncertainties involved in converting data to fish tissue levels in whole body and muscle. There are several options available for addressing this uncertainty (including log/log plot regression, linear plot regression, and central tendency of the ratios), and EPA should explain how they can be used in this context.	methodology from the approach used in the 2014 draft to calculate CF values when matched pairs of selenium measurements in eggs and/or ovaries and whole body tissue were not available by using species-specific or most-closely- taxonomically-related muscle to whole body and egg-ovary to muscle conversion factors. The median ratio approach was used (and retained) because it was less subject to variability in slope imposed using the constrained regression (0 intercept) approach, which was problematic when the y- intercept was notably different from 0. Also, the median approach appeared less sensitive to issues encountered using unconstrained regression for those slopes where the y-intercept was notably different than zero. EPA considered all approaches, and determined the ratio-based approach to be less affected by issues related to outliers and y-intercept. For 16 of the 17 species for which data were available, egg-ovary/whole body CFs ranged from 1.38-2.44, with the egg-ovary/whole body ratio for mountain whitefish being 7.39. The egg-ovary to whole body ratio for all fish (based on a hierarchal taxonomic approach using available data) is 1.63. The mountain whitefish has a fairly small distribution in the US, when considering overlap with selenium enriched areas. Thus, median values are considered more appropriate. 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 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
37	EPA-HQ-OW-2004-0019-0315-A1; USGS - Comment submitted by Theresa S. Presser and Samuel N. Luoma, National Research Program, U.S. Geological Survey, Western Branch, Menlo Park, CA; Posted 7/15/2014 Summarized below are the USGS science-based review comments focusing on the implementation of the proposed fish tissue criterion (i.e., the methodology for the derivation of water-column Se concentrations as compiled in DCD Table 12) for consideration by the USEPA as the DCD is further reviewed and finalized. Toxicology sensitivity, as addressed in the DCD via the derivation of fish tissue criteria, is not reviewed here. Further, to correct the record, the USGS did not model from fish egg-ovary tissue to water as stated in the DCD, but rather from fish whole-body to water. Therefore, the USGS research cited in the references below did not investigate the species-specific nature of the conversion factors (i.e., partitioning among whole-body, muscle, or egg-ovary) and the associated uncertainty that it may introduce in the overall outcome of modeling.	
41	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 8/7/2014 (4) Tissue-to-tissue conversion factors (CF) that are used to tier the E/O chronic criterion down to whole body and muscle chronic criteria EPA's summary table of proposed selenium criteria (p. 4) indicates that the E/O criterion value of 15.2 mg Se/kg is "Never to be exceeded." Therefore, fish of any species achieving the whole body or muscle chronic criteria (8.1 mg Se/kg and 11.8 mg Se/kg respectively) should never lead to the exceedance of 15.2 mg Se/kg in E/O tissue. However, it is well documented that partitioning of selenium between different tissues is highly variable both between species and among individuals within a species (e.g., Osmundson and Skorupa 2011). Also median partitioning ratios for a single species at different sites can vary by several-fold as they do for brown trout in southeast Idaho (CF < 2) versus the Colorado River (CF > 7). Such widespread and pronounced variability is largely explained by the fact that for many fish species selenium in eggs is being directly incorporated from the diet as opposed to being mobilized from pre-existing internal tissue stores of selenium (Conley et al. 2014; Penglase et al. 2014). Thus, the selenium in E/O tissue represents a very different spatio-temporal integration of selenium	

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	exposure than whole body or muscle tissue. Whole body and muscle tissue both represent a more long-term averaging. Ratios of E/O selenium concentration to whole body or to muscle selenium concentrations can vary with short-term diets and movement patterns of individual fish during egg formation, as well as vary with patterns of spatial and taxonomic heterogeneity of selenium contamination in the prey base. Thus, there is no such thing as a stable, single, characteristic, species-specific CF. Instead there is a constantly changing distribution of individual CFs ephemerally reflecting the dietary and home range choices available at a particular time and place. The Service suggests that using the median will leave half of all individuals within a species under-protected. That is, whenever the whole body or muscle criteria are achieved, about 50% of spawning fish will exceed 15.2 mg Se/kg in E/O tissue. Conley et al. (2014:2976) recognized this problem and commented: "If Se water quality criteria are to be based on fish tissue, it may be prudent to characterize the distribution of egg:whole body [Se] both within and among a wide range of species in order to capture that variability. More fully understanding the range of uncertainty that is inherent to this biological process could then allow for the application of appropriate safety factors and/or the selection of an appropriately conservative ratio based on a well characterized distribution." The Service recommends that EPA assemble species-specific distributions of CFs, preferably pooled from multiple locations and then instead of using the median value for further modelling and calculations, chose an appropriately protective cut-point (80th to 90th percentile) from the distribution for subsequent use in modelling calculations. Likewise, the derivation of national whole body and muscle tissue criteria should not be based on a grand median CF for all fish species, but should also be based on a protective (80th to 90th percentile) cut-point from the distribution of appropriately protective species-specific CF's. Another factor contributing to variability in CFs from E/O to whole body and muscle is the stage of the reproductive cycle. These CFs systematically change over the course of a spawning cycle. When tissue data that is segregated by spawning stage is published, as in Osmundson and Skorupa (2011) for green sunfish and white sucker, EPA should consider using only the pre-spawning data for calculating CFs. The pre-spawning CFs are consistently higher (+3 to +14%) than the reproductively spent post-spawning ratios and more accurately reflect what the E/O selenium content will be if whole body or muscle criteria are achieved prior to spawning.	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. 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). The selenium egg values for the studies used in the criteria derivation were based on eggs just spawned or ripe for spawning (stripped and used for spawning), thus they have selenium levels representative of the embryo/larvae exposure. 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 technical information developed to assist for states in applying the criterion.
38	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014 3.5 Uncertainties in Conversions to Whole Body and to Muscle Appendix B of the Draft Selenium Criterion Document calculates species-specific CFs relating egg-ovary selenium concentrations to muscle or whole-body selenium concentrations. These CFs are used to convert reproductive effect egg-ovary concentrations to associated whole-body (Table 7a of the Draft Selenium Criterion Document) and muscle concentrations (Table 8a of the Draft Selenium	

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	Criterion Document) to support calculation of the whole-body and muscle criteria. These CFs are also used to back-calculate water criterion concentrations from the egg-ovary criterion (Equation 18 in the Draft Selenium Criterion Document). Thus, uncertainty in species-specific CFs translates directly into uncertainty in whole-body, muscle, and water criteria. Species-specific CFs were calculated in Appendix B from empirical ratios of egg-ovary to whole-body or muscle selenium concentrations. If linear regression of egg-ovary vs. whole-body or muscle selenium concentrations resulted in a significant fit ($p \leq 0.05$) with a positive regression coefficient, the ratio of the egg-ovary to whole-body or muscle selenium concentration of each matched pair was calculated and the median ratio was used as the CF for the species. For nearly all species tested, linear regression resulted in a significant fit with a positive regression coefficient. It is, however, apparent from the plots presented in Appendix B of the Draft Selenium Criterion Document that in many cases, the assumptions of linear regression were violated, and thus the results are unreliable. It is also apparent from these plots that approximately half of these linear regressions had intercepts different from zero and thus do not, strictly speaking, support the calculation of a single median CF ratio. (Calculating a single ratio is analogous to fitting a line with an intercept of zero.) To illustrate this point, bluegill egg-ovary and muscle selenium concentration data were extracted from Appendix B of the Draft Selenium Criterion Document and are plotted below as presented in Appendix B (left panel of Figure 3) and log-transformed (right panel of Figure 3). The untransformed bluegill regression exhibits heteroscedasticity and structured residuals. The regression is significant and positive, but unreliable. Furthermore, the pattern of data does not suggest a constant ratio of egg-ovary to muscle selenium concentrations, but rather a steep relationship with relatively high ratios (most between 1.5 and 2.5) at muscle selenium concentrations less than 10 mg/kg dw, and a shallower relationship with relatively lower ratios (most between 0.5 and 1.5) at muscle selenium concentrations greater than approximately 10 mg/kg dw. The median CF from these data does not reliably reflect the actual CF across the range of data. Bluegill is the most sensitive species in the whole-body criterion calculation and the second most sensitive in the egg-ovary and muscle criterion calculations. Thus, uncertainty in the bluegill CF bears directly on calculated criterion concentrations. The log-transformed analysis shown in the right panel of Figure 3 has improved heterogeneity of residuals and less residual structure, indicating that this is a more reliable regression than using untransformed data. The fitted slope of the line is 0.88, indicating that the best-fit curve is not a straight line, but rather a concave-down power function. A non-linear function such as this cannot reliably be represented by a single CF ratio. The median egg-ovary/muscle ratio for bluegill was calculated in Appendix B of the Draft Selenium Criterion Document to be 1.375. Using the log-log relationship shown in the right panel of Figure 3, the CF varies across the range of data. At an egg-ovary concentration of 15.2 mg/kg dw, the CF is	

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	calculated to be 1.108. The difference between the concentration-specific CF (1.108) and the median-ratio CF (1.375) is 24%, a difference that would translate directly into calculated muscle or water criterion concentrations. Ultimately, the relevant CF that is needed for calculating criterion concentrations is the CF that occurs at the criterion concentrations in egg or ovary. The analysis discussed above and illustrated in Figure 3 indicates that the median empirical ratio for any given species may or may not be a good estimate of this relevant CF value.	
39	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 *3.2.2.1 Updates to Whole-body Criterion Using Regression-based Conversion Factors (CFs)* In Section 4.1.5 of the 2014 draft Se criteria document, after presenting its approach for developing the egg/ovary criterion, 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 (see Table 6a of the 2014 draft Se criteria document) using median-based egg/ovary to whole-body CFs (Table 7a of the 2014 draft Se criteria document). These converted values were then used to calculate a whole-body criterion of 8.13 mg/kg. EPA again used a sample size of 14, which included the three invertebrate-based values and the two crustaceans. In the past, EPA has used regression-based CFs (e.g., bluegill CF from EPA's 2004 draft Se criteria document). However, in the 2014 draft Se criteria document, EPA developed CFs based on the median of available matched egg/ovary and whole-body Se data (e.g., Table 11 and Table B-5 of the 2014 draft Se criteria document). The NAMC-SWG (2014) review includes a very detailed analysis of EPA's use of median values, which EPA should consider. While we believe their analysis is very thorough, we also evaluated the effect of using regression-based translators instead of median-based translators to derive a whole-body-based criterion (see Section 4.4.1 for more information). Using 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 6 and Table 7). 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 14.88 mg/kg (Table 6). In addition, as discussed in Section 4.4.1, we corrected and updated the median-based CFs based on our review of EPA's data and addition of our data (see Table 11); these updates were incorporated here. Consistent with Section 3.2.1, the whole-body criterion should also be adjusted as a result of our updates to the fathead minnow, bluegill, and brown trout egg/ovary chronic values. In addition, as	

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	expressed in our discussion of the egg/ovary criterion, we do not agree with using the invertebrate data and nonexistent crustacean values to increase the sample size of the database (i.e., it is more appropriate to use N=9 based on the nine fish genera in the database). Incorporating our modifications to the egg/ovary to whole-body translators, updated toxicity values for fathead minnow, bluegill, and brown trout, and reducing the sample size from 14 to 9 results in the fathead minnow being replaced by largemouth bass in the top four most sensitive species (Table 6). Using the data presented in Table 7, an updated whole-body criterion of 9.22 mg/kg 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.	
40	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 4.4 Additional Discussion of Tissue Criterion Elements *4.4.1 Conversion Factors* As part of our evaluation of the conversion factors (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 (see Table 11). In addition, we calculated geometric means of the tissue-to-tissue ratios to determine how CF outcomes might vary under different statistical methods. 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). As a result of these data additions, it was possible to calculate new egg/ovary to whole-body CFs for creek chub and fathead minnow (Table 11). Without these species-specific CFs, it would be necessary to use CFs for similar species or families to convert between tissues, which introduces uncertainty into the translation. For instance, data for the fathead minnow, which were included in the tissue-based criteria calculations, were translated from egg/ovary to whole-body concentrations by EPA using a generic conversion factor of 2.00 (based on the median for Cyprinidae). However, sufficient data are available to calculate a fathead minnow-specific conversion factor. Using 45 matched datapoints from GEI (2008), we calculated the median of the 45 individual matched egg/ovary to whole-body ratios to develop an egg/ovary to whole-body CF of 1.4 for the fathead minnow (Table 11). When translating between fathead minnow tissues, this species-specific CF for fathead minnow is more relevant than a generic Cyprinidae CF. In addition, using the matched egg/ovary, whole-body, and muscle Se data provided in the 2014 draft	

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	Se criteria document, which was further updated by GEI as described above, we 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 3.2.2.1, we used the regression-based CFs for northern pike, bluegill, rainbow trout, Dolly Varden, Centrarchidae, and Oncorhynchus 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 (Table 11).	
42	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 8/7/2014 The Service notes that EPA's use of a single fixed CF of 1.27 for whole body to muscle translations is often applied in ways that makes it difficult to produce “species-specific” ecosystem-scale modelling results. We believe the translations can be more accurately accomplished using a conversion function such as those used by the USFWS (2012b: Figs. 12 and 13). A super imposition of EPA's fixed CF on the data set from USFWS (2012b) shows that the fixed CF performs poorly (see figure below). Also the Service notes that when between-tissue partitioning data are available for individual fish rather than as pooled means, the data for individual fish should be used. For example, in Appendix B pooled data for the endangered razorback sucker from Hamilton (2005a,b,c) is used by EPA instead data for individual fish samples from Hamilton's earlier (2001a,b) reports. Thus, where EPA calculated a species specific median CF of 1.12 for E/O to muscle tissue from pooled data for razorback suckers, the Service found that the matched data for individual fish in Hamilton's earlier reports yielded median CF's of 2.44 and 2.16 which are substantially higher. Using a CF of 2.3 for razorback sucker means that the 11.8 mg Se/kg proposed muscle criterion would translate to 27mg Se/kg in E/O tissue for the median individual. For about 50% of the individuals, the translation would be even higher. Additionally, the Service notes that with EPA's use of the median species-specific CFs in Table B-3, 7 of 15 species would not be protected (again, by definition half are not protected by the median) including roundtail chubs, a species of special concern for the state of Colorado and a potential surrogate species for two ESA-listed species, the boneytail chub and the humpback chub.	
Comment Category 4.4 – Comments on Derivation of Site-Specific Enrichment Factor (EF) Values		

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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.		
275, 276, 280	EPA-HQ-OW-2004-0019-0324-A1; West Virginia Coal Association; Posted 7/30/2014 In our original review, we highlighted several areas of concern. These additional comments are intended to supplement our original filing. Specifically, WVCA offers the following comments regarding "food-web" transfer of selenium. The characterization of particulate material as a "mixture of living and non-living entities" that can be instantaneously transformed from dissolved sources depending on site characteristics is insufficient to provide certainty of the type or phase of material being exposed to prey through the base of the food web and for subsequent ecosystem modeling. The critical initiator of food-web exposure being assumed, in stream settings, as filtering aquatic insects or direct transfer to stonerollers is also likely incorrect. It is unlikely, for example, that stonerollers are directly consuming sufficient suspended particulate materials (whether living or non-living) to initiate food web processes, since they are benthic grazers and do not feed on suspended particles. Likewise, literature-derived trophic transfer factors that were applied where field data is lacking may not accurately describe other food web interactions occurring in West Virginia streams. Since it is assumed that the primary consumers of the suspended particulate mixture are filtering aquatic insects (e.g., caddisflies), then their selenium body burdens should be significantly higher than other aquatic insects, yet they are not. Likewise, with the assumed direct uptake of suspended particulate material by stonerollers in stream environs, their selenium whole body burdens should be higher than other exposed fish species, yet their body burdens are comparatively low. This points to the possibility of other means of food web uptake not accounted for in the model. Finally, the characterization of suspended particulate materials as "organic-rich, fine-grained, biomass" seems misleading, since the primary component of the particulate material is inorganic dissolved selenium. There is no assurance that the selenium state of the particulate material is organic or related to food chain assimilation processes. The types of filter-feeding organisms (or lack of), the valence state or species of the selenium present (predominantly inorganic selenate), and short residence time (lotic versus lentic) for selenium suspended in the water column at any given location, all point to alternative processes behind selenium accrual in biological tissues of organisms residing in West Virginia streams. In fact, the source selenium initiating food web uptake, or suspended particulate material, represents an extremely small portion of overall selenium present. In comparison to other water column selenium analyses, which allow for comparisons of total and	Responses concerning derivation of site-specific enrichment factor values: Regarding the concerns of the use of the Presser and Luoma peer-reviewed, published bioaccumulation model, EPA maintains its use is scientifically well-founded, and based on extensively reviewed science. This is further substantiated by EPA's analysis of modeled versus measured concentrations as described in the 2016 criterion document. EPA identified 317 tissue measurements associated with one or more water column measurements. A predicted egg-ovary concentration was calculated for each water column concentration as described above. The predicted and measured concentrations are highly correlated (r=0.82, P<0.001). Data used to generate Figure 6.3 can be found in Appendix I of the 2016 selenium criterion.. An alternative regression-based 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. 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. The water column values calculated using this different approach 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 supports EPA's water column values, despite the use of different analytic approaches in the two approaches. EPA carefully re-examined the distribution of EFs and corrected the

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	dissolved concentrations in which particulate material would be the measured difference between total and dissolved, surface-grab water samples indicate dissolved portions to be over 98% of selenium present. Since dietary uptake is the principal exposure route, these analyses indicate that suspended particulate food sources, arising from aggregation of dissolved sources, are not available in sufficient quantity to account for selenium accrual throughout the food web. Furthermore, dissolved selenium transformation or aggregation into suspended particulate material, especially if the particulate material can be non-living/inorganic seems implausible. 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 4.2 of the Draft Selenium Criteria 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. The model uses a metric (Kd) for the partitioning of selenium between particulate material and dissolved phases as a basis for determining a dissolved selenium concentration that would be necessary to attain a site-specific selenium fish body burden. However, a substantial dataset exists in West Virginia that contradicts the use of Kd in the USGS model. The assumption that the basic source of selenium bioaccumulation in lotic waters is dissolved selenium partitioning to particulate selenium is not accurate. Based on extensive studies of streams where mining has occurred, the selenium in West Virginia streams is primarily inorganic selenate. EPA's calculations are premised upon the assumption that suspended particulate material initiates the web uptake of selenium. In the food web model, the dissolved selenium is purported to convert to particulate selenium through transformation reactions. If this is indeed occurring, particulate selenium would be detected in appreciable concentrations in water column samples. In West Virginia waters, the empirical data indicates that is not occurring. According to extensive analytical data, nearly all the selenium is present in the dissolved form, and selenate is the predominant species. The	data for overweighting by EFs measured in systems with unusually low or high waterborne selenium. A new appendix (H) has been created in the final 2016 criteria document that 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 included Minnow Environmental 2007 in the EF data set which includes the data contained in Orr et al 2006. EPA also added data in February 2016 associated with Deforest et.al.,2014. Regarding the issue of modifying factors, and particularly sulfate, EPA addresses this issue in Section 6.2.2 in the 2016 final criteria document. As noted above, 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 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*

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	USGS model is broken on a fundamental level that cannot be fixed or ignored. Likewise, the biology and hydrology of West Virginia headwater streams does not match the assumptions in the USGS model. Not only is the suspended particulate selenium lacking, so are the high body burdens of selenium in the aquatic insects that are presumed to uptake the selenium into the food web. Likewise, the body burden of selenium in stonerollers is not higher than in other fish. 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. For these reasons, WVCA urges EPA to reconsider the national recommended water column criteria for selenium. This effort is too broad, which leads to numbers that are consistently inaccurate. While WVCA understands and appreciates EPA's effort to create a shortcut for states that do not want to develop water column criteria, the development of generic numbers based on inaccurate assumptions and a simplified formula cannot replace science.	*high costs, it is difficult to comprehensively evaluate the influence of sulfate on bioconcentration and transfer up the food chain*."
305	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014 3.4.4.1 Uncertainty in the Selenium Enrichment Factors Derived from Lemly (1985) The 18 values derived from Lemly (1985) were from three reservoirs (six fish species each). The lowest values were based on data collected from Badin Lake, an uncontaminated lake with a water selenium concentration of 0.32 µg/L (Lemly, 1985), for which an EF of 8.54 L/g (8,540 L/kg) was derived. Tables showing derivation of the EFs do not appear to be included in the Draft Selenium Criterion Document, however, in Appendix C, the selenium concentrations in algae and sediment were reported as 8.20 and 0.91 mg/kg dw, and the arithmetic mean of these two particulate concentrations was 4.56 mg/kg dw (the mean particulate selenium concentration of 4.56 mg/kg dw was used to derive the invertebrate TTF in Appendix C of the Draft Selenium Criterion Document). Lemly (1985) reported selenium concentrations of 0.77, 0.87, and 0.91 mg/kg wet weight (ww) in periphyton, plankton, and sediment, respectively (all quite similar); thus, it appears that the algae selenium concentration reported in Appendix C was based on conversion of periphyton and plankton concentrations to dw concentrations assuming 90% moisture; while the sediment concentration was not converted to dw. This algal conversion is highly uncertain, as the moisture content of periphyton and plankton is highly variable. If the mean particulate selenium concentration of 4.56 mg/kg dw was used to derive the EF (as it was used in derivation of the invertebrate TTF in Appendix C), the resulting EF would actually be 14,250 L/kg (i.e., 4.56 mg/kg dw ÷ 0.32 µg/L × 1,000 µg/mg = 14,250 L/kg). This even higher EF only results in further questions regarding the relevance and application of these data for water selenium criteria development. In summary, we question the disparity between	

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	the values 8.2 µg/g (algae) and 0.91 µg/g (sediment) as it appears there is a unit conversion that is wrong and it is unclear why algae and sediment values should be averaged, especially if bedded sediment samples are used. In addition to uncertainties in how the selenium EF of 8,540 L/kg was derived for Badin Lake, it also appears that the sediment selenium concentration of 0.91 mg/kg dw used in the evaluation is erroneous as this was reported as a ww concentration in Lemly (1985). According to Lemly (1985), the mean moisture content in the sediment was 56%, which results in a sediment selenium concentration of 2.1 mg/kg dw. Consequently, the arithmetic mean of the algae and sediment selenium concentrations of 8.20 and 2.1 mg/kg dw is 5.2 mg/kg dw. Using the water selenium concentration of 0.32 µg/L for Badin Lake, as reported in Lemly (1985), the resulting EF of 16,250 L/kg would yet again be even larger than that reported in Table 12 of the Draft Selenium Criterion Document. Increasing the EF even further results in further questions regarding these questionable data. The same issue exists with the ww sediment selenium concentration for High Rock Lake and Belews Lake reported in Lemly (1985). 3.4.4.2 Uncertain Enrichment Factors Result in Questioning of Overall Approach for Developing Water Selenium Criteria Aside from the issue that the selenium EFs derived from Lemly (1985) are uncertain and potentially erroneous, selenium EFs of these magnitudes (whether 8,540, 14,250, or 16,250 L/kg in the case of Badin Lake) are all anomalously large. This anomaly can be evaluated by considering the fish tissue selenium data that were also reported in Lemly (1985). For example, if we apply the EFs, CFs, and TTFs from Table 12 of the Draft Selenium Criterion Document to the Badin Lake water selenium concentration of 0.32 µg/L (reported in Lemly (1985)), the egg selenium concentrations for the six fish species can be estimated. The predicted egg selenium concentrations for the six species, using the EPA model parameters in Table 12 of the Draft Selenium Criterion Document, range from 8.7 to 15.3 mg/kg dw (Table 1). The latter predicted egg selenium concentration exceeds the draft fish egg selenium criterion of 15.2 mg/kg dw, despite the fact that Badin Lake was defined as uncontaminated with a water selenium concentration of 0.32 µg/L (i.e., a false positive). If the higher calculated EF for Badin Lake (16,250 L/kg) is used to predict egg selenium concentrations for these six fish species, predicted egg selenium concentrations range from 16.6 to 29.0 mg/kg dw (Table 1). All of these predicted values are false positives, exceeding the draft fish egg selenium criterion of 15.2 mg/kg dw. For these reasons, we question EPA's reliance on the Lemly (1985) data. For comparison, Lemly (1985) reported muscle selenium concentrations in the six fish species. These concentrations were reported on a ww basis and converted to a dw basis assuming 75% moisture. The muscle selenium concentrations were used to calculate egg selenium concentrations using the CFs used in Table 12 of the Draft Selenium Criterion Document. On average, across all six fish	

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	species, the predicted egg selenium concentrations based on the EPA model were a factor of 1.9 greater than those calculated from actual measured muscle selenium concentrations. A similar pattern of over-predicted egg selenium concentrations is observed for High Rock Lake (another uncontaminated lake; water 0.67 µg/L selenium) and Belews Lake (contaminated lake; water 10.91 µg/L selenium) (Table 1). If the higher calculated EF for Badin Lake (16,250 L/kg) is used to predict egg selenium concentrations for these six fish species, predicted values are on average a factor of 3.5 greater than those calculated from actual measured muscle selenium concentrations (Table 1). *Original letter contains Table 1 – Predicted fish egg selenium concentrations in two uncontaminated reservoirs based on EF, CF, and TTF assumptions from Table 12 of the draft EPA report. See original letter.*	
315	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 8/7/2014 (5) EPA's derivation and use of enrichment factors (EFs) and trophic transfer factors (TTFs) for ecosystem-scale modeling The assumption in the DSP appears to be that all aquatic food webs (benthic, pelagic, etc.) build off of organisms that are equally influenced by sediment, detritus, and algae. Therefore, EPA uses the geometric mean of the median of individual EF values. However, organisms are not equally influenced by sediment, detritus, and algae.	
308	EPA-HQ-OW-2004-0019-0326-A1; Utility Water Act Group (UWAG); Posted 7/30/2014 <u>Criteria Development Methodology – Water Column Criteria; Approach Reasonable, More Explanation Needed</u> EPA, in collaboration with the Unites States Geological Survey, developed a model for translating the fish tissue (egg/ovary) concentration to an equivalent water concentration. EPA's model quantifies bioaccumulation in tissues by assuming that net bioaccumulation is a balance between assimilation efficiency (bioavailability) from diet, ingestion rate, rate of direct uptake in dissolved forms, loss rate, and growth rate. Draft Report, p. 62. EPA has simplified the model by removing both growth rate and uptake rate from the equation because these factors were determined inconsequential to predicting selenium bioaccumulation and uses a combination of empirical laboratory and field data to predict the remaining inputs. UWAG agrees that use of a parameterized mass transfer model, Equation 18, to translate a protective water column criterion from the egg/ovary criterion is a valid approach. However, we believe there are certain defects with the model that may limit its application. With the limited time to review, we explain our initial impressions below.	

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	<u>Use of Enrichment Factors Appropriate, Generally</u> We agree that the single most influential step in selenium bioaccumulation occurs at the base of the aquatic food webs where partitioning of selenium between the dissolved and particulate state, expressed as the Enrichment Factors (EFs), takes place. Draft Report, pp. 79- 80. It is also well supported that selenium EFs vary depending on site-specific physio-chemical parameters, which influence selenium speciation and bioavailability (Deforest et al. 2014). UWAG supports EPA's methodology that seeks to minimize uncertainty in the model by using only sites with sufficient data to calculate a reliable EF value. Id., p. 79. EPA matched site-specific particulate measurements with corresponding water column measurements from samples taken from the same sites and calculated the ratio of particulate concentration to water concentration. EPA used these calculated values to back-calculate protective water quality criteria for specific fish species present at the sites using site-specific information where available. Where site-specific data was unavailable, the food web was modeled using default typical diet and eating habits data. EPA's incorporation of "real world" food chain data, as EPA has done, is preferable to laboratory-derived or default, constant, values. <u>Explanation of Modifying Factors Impacting EF Needed</u> In addition, there are potentially several modifying factors that may influence bioavailability and bioaccumulation of selenium, which in turn would influence the EF. DeForest et al. (2014) astutely explains how modifying factors such as water sulfate and phosphate concentrations, seasonal variability or irrigation events, and time-varying primary production can influence selenium uptake and provides additional support for EPA's approach of using site-specific data for greater certainty. EPA should revise the Draft Report to provide discussion of each of these modifying factors and allow the inclusion of ancillary water quality variables where they are relevant on a site-specific basis.	
Comment Category 4.6 – Comments on Classifying Categories of Aquatic Systems 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 Se bioaccumulation and EPA's classification of the 69 EF sites.		
11	EPA-HQ-OW-2004-0019-0257-A2; Wyoming Department of Environmental Quality (WDEQ); Posted 6/16/2014 *Lotic and Lentic Criteria, Residence Time* EPA's draft selenium criteria recommends separate 30-day average water column values for lentic and lotic systems, with no discussion on specific water residence times to assist states in assigning the criteria to different aquatic systems. As EPA is aware, many lakes, reservoirs, ponds and	Responses on classifying categories of aquatic systems: Regarding the concern over the classification of lentic and lotic waterbodies, 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 (evaluating the classification used by the

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	wetlands have very short residence times and function much more like lotic systems than lentic systems. WDEQ/WQD is concerned that draft criteria, as written, will force states to apply the criteria inappropriately, based on this simplified classification, rather than use the more meaningful metric of residence time to assign the criteria to different aquatic systems. WDEQ/WQD recommends that EPA modify their analysis and discussion of differences in enrichment factors for aquatic systems beginning on page 81 of the draft criteria to include the mean residence times of the 69 aquatic sites. EPA could then use the measured residence times rather than broad categories of systems to establish criteria for systems with different residence times. EPA could then include a residence time break between lotic and lentic systems within the criteria document so that states can adopt the criteria based on the residence time of various aquatic systems rather than the simplified, subjective categories lotic and lentic. Including a mean residence time will make it easier for states to adopt and implement the criteria appropriately without concern that the criteria are over or under protective for particular systems.	study author(s)) 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 were not mis-classified as lotic. EPA revised the lotic and lentic section to better identify the difference between lotic and lentic in Section 3.2.4 of the 2016 final selenium criterion document. Unfortunately, a parameter like residence time was not available for most of the waters in the dataset. For site specific criteria or translations, it may be necessary to evaluate the residence time and other characteristics (important to selenium bioaccumulation) of a given system to ensure the proper water criterion element is applied.
105	EPA-HQ-OW-2004-0019-0260-A2 [Comment 0314-A2 is a duplicate of 0260-A2]; Conley and Buchwalter; Posted 6/16/2014 b. Determination of "lotic" or "lentic" is not necessarily straightforward. For example, the Tennessee River would technically be designated as a "lotic" site since it is a river, however it is heavily modified with multiple dams along the length of the river. As a result of flow modification, large sections of the "river" would actually be more biogeochemically similar to a lentic site (i.e., little to no flow, reduced aeration, increased reduction potential). In this case, using the lotic criterion when the site is actually more similar to a lentic system would place the aquatic community at elevated risk of selenium bioaccumulation and toxicity. There must be defined characteristics of a given site in order for a given criterion value to be applied without ambiguity or "cherry picking" of a higher value.	Regarding classification of specific waterbodies as lentic or lotic, EPA asserts that the classification of specific sites or waterbodies as lentic or lotic is best conducted by scientists familiar with the site. EPA did not independently classify any of the lentic or lotic sites used in the document, EPA is developing technical support documents to assist in implementation of the criteria, and will include information on sampling/plans to assist in the derivation of site specific criteria or translations.
106	EPA-HQ-OW-2004-0019-0271-**A2**; Coordinator, Barnes & Thornburg LLP on behalf of the Federal Water Quality Coalition; Posted 6/17/2014 It is not entirely clear how waters will be classified as either lentic or lotic. EPA should provide clear definitions of those terms that can be readily applied, considering factors such as flow rate, hydraulic residence time, selenium speciation, and (if appropriate) differing biological conditions.	
107	EPA-HQ-OW-2004-0019-0317-A1; Intermountain Region, Forest Service, United States Department of Agriculture (USDA); Posted 7/29/2014 <u>Comments</u> Recommend more clearly defining the water bodies that apply to each of the lotic (flowing) and lentic	

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	(still) categories.	
108	EPA-HQ-OW-2004-0019-0322-A1; American Petroleum Institute (API); Posted 7/30/2014 The Notice specifies both lentic and lotic criteria. Typical benchmarks for lentic/lotic waters are a 10-year residence time for lentic waters and a 2-week residence time for lotic waters. But how are waters in between these benchmarks classified? Waters in bays turn over fairly rapidly and should be considered lotic waters. EPA should provide clear and reasonable guidance.	
109	EPA-HQ-OW-2004-0019-0339-A2; West Virginia Department of Environmental Protection (DEP); Posted 7/30/2014 EPA must define lotic versus lentic - In West Virginia, only one natural waterbody would be considered lentic if the classification criteria requires the system be static or having no outlet. If, however, the intention of the categories was to separate waters according to retention time, then those lines of demarcation must be established. We request that EPA expand the definition and/or provide guidance to states on how to better identify or classify lentic and lotic waterbodies, such as using residence time in the final document.	
110	EPA-HQ-OW-2004-0019-0313-**A2**; Wisconsin Department of Natural Resources (WDNR); Posted 6/27/2014 Different water column criterion elements for lentic and lotic waters. WDNR currently does not have definitions of lentic and lotic waters in code. In order to implement this unique WQC in the different waterbody types, the WDNR will need to define which waterbodies are considered lentic vs. lotic. • Can the EPA indicate how these terms should be defined? • It is unclear how the criteria would apply to waterbodies that exhibit both lentic and lotic behaviors or are somewhere along the continuum (e.g., drainage lakes, reservoirs, and impoundments). Perhaps a water-residence time would be useful to classify waters? Currently, Wisconsin defines reservoirs as a "waterbody with a constructed outlet structure intended to impound water and raise the depth of the water by more than two times relative to the conditions prior to construction of the dam, and that has a mean water residence time of 14 days or more under summer mean flow conditions using information collected over or derived for a 30 year period." Would a definition such as this be applicable for defining lentic and lotic systems?	
111	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014 3.3 Clear Definition of Lentic and Lotic Waters The Draft Selenium Criterion Document appropriately differentiates lentic and lotic waters relative to	

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	potential selenium bioavailability and effects. The definition of lentic and lotic is not clear, however. We strongly recommend clarity and completeness in this definition as there is great potential for confusion and misapplication of criteria if water bodies are misidentified. Sources of our concern are further detailed below. 3.3.1 Definition of Residence Times for Lentic and Lotic Water Bodies EPA identifies in the Draft Selenium Criterion Document that the build-up of potentially reactive forms of selenium in aquatic environments is higher in environments where water residence times are extended.[5] This was the premise in developing a separate water criterion for lentic and lotic environments. While we agree with EPA on the need for different selenium criteria based on the aquatic system conditions, EPA needs to further clarify or parameterize this distinction between lentic and lotic environments. In the Draft Selenium Criterion Document, EPA identifies environments that have extended or long “water residence times” as wetlands, estuaries, lakes, and reservoirs.[6] The definition of extended or long “water residence times,” however, is not described in the Draft Selenium Criterion Document beyond water body type labels (lake, reservoir, etc.). If residence time is to be used to categorize aquatic environments, then guidance on residence times must be provided. There was no attempt to provide any technical guidance or correlation analysis on actual residence times in these water bodies and their enrichment factors (EF). NAMC recommends that such be provided. This is an area where the scientific literature is lacking and there may be a need for some site assessments that accompany selenium bioconcentration (enrichment) factors. 3.3.2 Statistical Grouping of Lentic and Lotic Studies In Figure 9 of the Draft Selenium Criterion Document, different water bodies are grouped by “residence times” (with no residence time actually provided): (1) lakes and reservoirs; (2) ponds and marshes; (3) rivers; and, (4) streams, creeks, drains, and washes. Non-parametric statistics were conducted on these four groups and no significant differences were found between the water body groupings and EFs except between the lakes and reservoirs group (group 1) and the streams, creeks, drains, and washes group (group 4). The other two groups that were not significantly different than lakes and reservoirs were allocated between each of the two groups significantly different than each other (groups 1 and 4), and then re-labeled overall as “lentic” and “lotic” in Figure 10 of the Draft Selenium Criterion Document. Ponds and marshes (group 2) were grouped with lakes and reservoirs (group 1) and classified as “lentic.” Rivers (group 3) were grouped with streams, creeks, drains, and washes (group 4) and classified as “lotic” in Figure 10 of the Draft Selenium Criterion Document. This is an inappropriate use of statistics. Statistics cannot be applied continually until a significant result is obtained on desired groupings as in the case here of the selenium lentic and lotic groupings.	

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	If all statistical combinations were studied and presented, this approach could be acceptable, but this was not done. Two groups not statistically significant from each other cannot be divided up and allocated to other groups arbitrarily without an a priori prescribed statistical design and evidence that they belong to the two larger groups. NAMC recommends that EPA appropriately and fully categorize and define lentic and lotic water bodies. It is clear from a science-based viewpoint that the key is the EF. From a regulatory viewpoint, there is an issue to resolve around lentic and lotic definitions in terms of the water concentration used to trigger tissue investigations. We would be pleased to discuss this further with the Agency. 3.3.3 Use and Definition of Estuaries in Freshwater Criteria EPA includes estuaries among aquatic environments having extended or long water residence times.[7] Estuaries and lakes, which the EPA links in the Draft Selenium Criterion Document, are very different from each other, however. Estuaries, in contrast to lakes, are not wholly freshwater environments. Estuaries were not included in EPA's analysis of residence times and EFs in Section 4.5.2 of the Draft Selenium Criterion Document. NAMC recommends further clarification of the use and definition of estuaries in the Draft Selenium Criterion Document. Specifically, NAMC recommends that, since the draft criteria are based on freshwater data, EPA should clearly state that they do not apply to estuaries or other transitional waters (e.g., coastal lagoons). 3.4 Too Low Lentic Water Criterion As detailed below, the proposed lentic water criterion is unnecessarily overly conservative. A higher criterion would provide environmental protection without unduly penalizing human industrial or other activities, and without unnecessarily expending limited regulatory resources to the detriment of genuine environmental issues. [5] *Id.* at 15. [6] *Id.* at 15, 16, and 82. [7] *Id.* at 15, 16, and 82.	
174	EPA-HQ-OW-2004-0019-0272-A2; Clark County Water Reclamation District; Posted 6/17/2014 The District requests that river systems and impoundments on river systems, like the Colorado and the reservoirs on the River, be considered "lotic" and be defined as such in EPA's selenium criterion. Currently, there are four categories in the criterion: 1) lakes and reservoirs; 2) ponds and marshes; 3) rivers; and 4) streams, drains, washes and creeks. In the case of reservoirs on the River, such as Lake Powell, Lake Mead, Lake Mohave, and Lake Havasu, there is a large flow between the reservoirs and they are an integral part of the River system. In normal years, eight to ten million acre	

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	feet (MAF) of water flow through these reservoirs, which is currently about the same volume of water that is stored in Lake Powell or Lake Mead, the two largest reservoirs on the system. Based on the amount of water moving through these bodies of water and their storage conditions, we believe they are lotic, and should be designated so under the selenium criterion. This determination is very important because the background concentration of selenium in the Colorado River system, due to the naturally occurring selenium in rocks and soils, varies from 1.6 to 2.9 µg/L from the entrance to Lake Mead to Morelos Dam, located near the Mexican border. The Authority has developed a database that houses approximately four million water quality records for samples taken along the Colorado River from Lake Powell to the international border with Mexico. Sixteen hundred selenium samples have been collected by various agencies at different locations and the results have been uploaded into the database. These data were searched and samples with results below the detection limit were discarded as data generated by insufficiently sensitive analyses. The remaining 1,364 results were analyzed by location and averaged (see figure below). The average background selenium concentration in River water entering Lake Mead is 2.9 µg/L (n = 39). Based on the data, it appears that the flowing portions of the River (Grand Canyon, stretch of River between Laughlin, NV and Needles, CA, etc.) will meet the lotic standard but the reservoirs in between will not meet the lentic standard. *Original letter contains Figure – not numbered. Average Selenium Concentrations in Colorado River from Lake Mead to Morelos Dam. See original letter.*	
322	EPA-HQ-OW-2004-0019-0350-A1; Central Contra Costa Sanitary District (CCCSD) ; Posted 8/5/2014 Section 7.2.2 Evaluating the Protectiveness of the Final Water Column Criterion Values Both Table 19 and 20 indicate the final water-column criterion for Lotic waters will result in erroneous classification of water. An accuracy rate of 62% for Lotic systems shown in Table 20. Binary classification statistics for lentic and lotic aquatic systems (page 138) captures false positives and false negatives. The false positive rate will require additional monitoring and analytical costs 30% of the time to determine if the monthly average water column values are met. No explanation is given for why the EPA is accepting the low accuracy rate for Lotic systems. Appendix H is offered for further detail on the binary classification for statistics, but there are no acceptance ranges published for the six classifications listed in Table 20. CCCSD Comment: Provide the acceptance ranges or a reference document where these ranges and their justifications are listed. Alternately, disregard EC10 values from the Brown Trout Study and Disregard calculated EC10 values for invertebrate species and recalculate the GMCV egg-ovary final	

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	concentration value. Using the new egg-ovary concentration, evaluate the protectiveness of the final water column criterion for both Lentic and Lotic systems.	
532	EPA-HQ-OW-2004-0019-0293-A2; Pennsylvania Department of Environmental Protection; Posted 6/26/2014 DEP would need to preform further assessment to determine if there is a need to adopt the water quality criterion for lentic aquatic systems in Pennsylvania.	
387	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 8/7/2014 We recommend that the analysis consider the potential risks associated with nearly universal connectivity between lotic and lentic aquatic systems in greater detail. Not only are downstream effects of allowing lotic systems to be loaded-up with selenium relative to lentic systems a concern, but off-stream effects are a concern should be considered. Just like toxicity standards for organisms must be set to protect the most sensitive life-stage even though that will be over-protective for other life stages, the Service recommends that water criteria be set to protect the most sensitive compartment of the interconnected hydrological system.	
459	EPA-HQ-OW-2004-0019-0356-A1; Idaho Department of Environmental Quality (DEQ); Posted 09/30/2014 What about different species at a site? 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.	

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546	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014 CONCLUSIONS The primary conclusions from our review of the Draft Selenium Criterion Document are that EPA has made some good, technically defensible improvements compared to previous criteria, however, there are errors in the document and, in addition: • Clarification is required regarding the definitions of lentic and lotic waters, and regarding tiered assessment beginning with water and proceeding to tissue selenium concentrations. • We are very concerned that the lentic water criteria concentrations and the tissue criteria concentrations are not technically defensible and are demonstrably overly conservative. These too low criteria concentrations will result in a serious misallocation of resources, thereby reducing rather than enhancing the nation's ability to address environmental problems. • We are also concerned, relative to addressing genuine environmental problems nationally, that the tissue criterion is inappropriately expressed as "never to be exceeded" on an instantaneous basis, particularly as this violates EPA's own Guidelines. We provide alternate recommendations that will provide a high degree of environmental protection and will assure attainment of biological quality goals. • Finally, we respectfully request that the planned second public comment time period be extended ahead of time to 60 days to allow adequate time for public review and comment.	
470	EPA-HQ-OW-2004-0019-0356-A1; Idaho Department of Environmental Quality (DEQ); Posted 09/30/2014 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 4.2.4). 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.	

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Comment Category 4.7 – Comments on Deriving Water Column Criterion Element Concentration Value Summary: This section contains comments on EPA's methods for deriving the water criterion element concentration value. This section also contains comments the use of the 20th percentile value for lotic and lentic water value distributions and modeling considerations.		
265	EPA-HQ-OW-2004-0019-0256-A1 [Comment 0346-A2 is a duplicate of 0256-A1]; Peabody Energy **Corporation**; Posted 6/16/2014 EPA should use the existing dataset to quantify the number of false positives that would result if the water column criteria were to be applied at all sites with fish tissue data. EPA did such an analysis to calculate the number of false negatives that would occur based on the water column criterion. However, there is no discussion on the number of false positive scenarios that result from use of the 20th percentile of the water column criteria (i.e. the number of times that the water column criteria showed an impact to the aquatic community that does not exist when fish tissue values are examined). It is recommended that EPA undertake such an analysis so that States and dischargers can more accurately assess the risk associated with these concentrations.	Responses concerning deriving water column criterion element concentration value: Regarding the selenium chronic water column criterion element's 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 could have 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. 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. Conversely, several lotic sites (e.g., McElmo Cr., Spring Creek at LaBoca, etc.) 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 comments on the 2014 criterion, 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 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, changes to several TTFs and CFs, reflecting incorporation of new information, were made yielding national values of 1.5 µg/L (lentic) and 3.1 µg/L (lotic) as recommended in
266	EPA-HQ-OW-2004-0019-0256-A1 [Comment 0346-A2 is a duplicate of 0256-A1]; Peabody Energy **Corporation**; Posted 6/16/2014 <u>Variability in Egg-Ovary Criterion Translated to Water Column Concentrations:</u> EPA goes on to show the water column criterion concentrations that resulted from the use of this EPA / USGS bioaccumulation model, following the translation from the egg-ovary criterion. Figure 11 of the draft criterion document shows that the resulting water column concentrations are highly variable and show a wide range of values. Lentic values ranged from =0.25 pg/L to =14.5 µg/L and lotic values ranged from =1.5 Vg/L to =100 pg/L. These wide ranges are directly related to the variation seen in the egg / ovary criterion and are likely a result of the variation in fish species, water quality characteristics, environmental conditions, etc., seen across sites.	
267	EPA-HQ-OW-2004-0019-0266-A2; Transportation and Storm Water Department, City of San Diego, California; Posted 6/17/2014 Table 12 and Figure 11 of the 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 these figures show that for 132 various lentic and lotic systems, the calculated range of protective water column concentrations varies by orders of magnitude (0.38 - 55.63 µg/L for lentic systems and 1.37 98.08 µg/L for lotic systems). Given the wide range of values calculated to be protective, it is 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.	

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268	EPA-HQ-OW-2004-0019-0271-A2; Coordinator, Barnes & Thornburg LLP on behalf of the Federal Water Quality Coalition; Posted 6/17/2014 The lentic water column concentrations are too low. They are affected by outlier algae/water ratios, and the underlying data base should be closely examined. Also, we do not understand the basis for using the 20th percentile of water concentrations. The current levels are so low that they will give rise to many false positives, particularly if used for definitive rather than screening purposes. EPA should assess whether a higher concentration, such as the geometric mean, would be just as protective.	the 2016 final criteria document. 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 15 GMCVs (not including the 2 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 19 non-reproductive toxicity values were obtained from 20 studies for 9 species. 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. Additional toxicity values from 22 studies 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 studies used for CFs and TTFs, 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
284	EPA-HQ-OW-2004-0019-0315-A1; USGS - Comment submitted by Theresa S. Presser and Samuel N. Luoma, National Research Program, U.S. Geological Survey, Western Branch, Menlo Park, CA; Posted 7/15/2014 Ecosystem-scale Se modeling was developed by the USGS to conceptualize and quantify the current state of knowledge concerning the dietary transfer of Se through ecosystems and to account for the differential bioaccumulation among food webs (Luoma and Presser, 2000, 2009; Presser and Luoma, 2006, 2009, 2010a and b). More recently, two articles detailing the site-specific application of ecosystem-scale Se modeling have been published (Presser and Luoma, 2013; Presser, 2013). The model developed by the USGS links Se concentrations across environmental media (water, particulate material, invertebrates, and tissue of predators). It can be used to forecast Se toxicity in fish under different management or regulatory proposals and as a methodology for translating a fish-tissue Se concentration guideline to a dissolved Se concentration. The approach also is applicable to predicting Se risk to predators other than fish, including aquatic birds. The model illustrates some critical aspects of implementing a tissue criterion: 1) the choice of fish species determines the food web through which Se should be modeled; 2) the choice of food web is critical because the particulate-to-prey kinetics of bioaccumulation differs widely among invertebrates; 3) the characterization of the type and phase of particulate material is important to quantifying Se exposure to prey through the base of the food web; and 4) the metric describing partitioning between particulate material and dissolved Se concentrations allows determination of a site-specific dissolved Se concentration that would be responsible for that fish body-burden in the specific environment. This linked approach illustrates a central quantitative conclusion that environmentally safe dissolved Se concentrations will differ among ecosystems depending on the ecological pathways and biogeochemical conditions in that system. Conceptualization or framing of a site-specific ecological occurrence of Se exposure is also paramount to the USGS methodology so that, used optimally, model scenarios adequately represent ecosystem variables and document important implications of ecosystem setting and inhabitants. The species- and site-specificity of modeling based in multi-disciplinary Se science is one of the great strengths of this model. This approach can lead to identifying the predators most at risk from Se and	

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	to understanding the location and time of greatest ecological Se sensitivity, thus narrowing model uncertainty. Making choices based on species-specific conceptual models and then applying seasonal analysis in terms of site water-column variability improves the certainty of model outcomes in terms of the broader context of fish communities and watershed management.	(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.
295	EPA-HQ-OW-2004-0019-0315-A1; USGS - Comment submitted by Theresa S. Presser and Samuel N. Luoma, National Research Program, U.S. Geological Survey, Western Branch, Menlo Park, CA; Posted 7/15/2014 **Consider separating species-specific modeling from site-specific modeling to narrow uncertainty in modeling and ecologically define protection.** Consideration of the quantitative importance of food-web influence in comparison to the influence of site hydrology is of concern. The USEPA has chosen the categories of lotic (rivers, streams) and lentic (ponds, lakes) for ecosystems sites on which to base their criteria. The values for Kd vary widely among hydrologic environments (i.e., in parts of a watershed such as wetlands, streams, or estuaries) and potentially among seasons and stream gradients (Presser and Luoma, 2010a; Presser, 2013). Consideration of the characteristics of the environment such as speciation, residence time, and/or particle type can be used to narrow this potential variability, but Kd remains a large source of uncertainty if translation to a water-column Se concentration is required. The ranges of water-column Se concentrations derived from a proposed egg-ovary criterion for lotic and lentic sites by the USEPA are considerable (1.37-98.08 µg/L and 0.38-64.94 µg/L, respectively). Choices concerning food webs are folded into this primary consideration by the USEPA, but it is unclear how the range of outcomes is linked to predator species to be protected. Modeling by the USGS showed that site biogeochemical transformation (Kd or EF) determines the concentration of Se available to the food web, but variability in TTFs, especially at the consumer level, is influential in determining how much Se different predators accumulate (Luoma and Presser, 2009; Presser and Luoma, 2010). Thus, choice of fish species is critical to protection of an ecosystem because it determines the food web, and hence the magnitude of biotransfer, through which Se is modeled. In the USGS approach, modeling is initiated from a particulate Se concentration and food-web biodynamics is the basis for validation. This approach is step-wise so that food-web modeling can be checked against field data at each media point for ecological consistency (Presser and Luoma, 2010a, Figures 3 and 4). Site hydrology is expressed by Kd (or EF) and is applied as a separate step in order to enable isolation of the most uncertain step. The consolidated approach of the USEPA also has ramifications for validating model predictions. In our understanding of USEPA's approach, validation encompasses direct correlation of water-column	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. Regarding those aquatic systems where fish and their prey species can experience significant bioaccumulation of selenium despite low water concentrations, EPA recommends fish tissue be collected in waters where available data (e.g., unusually large EFs) suggest the possibility of "toxicologically significant bioaccumulation" despite low selenium water concentrations. Furthermore, the national criterion can easily be adapted to site- specific situations using site-specific data using the modeling information provided in the document.

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	and egg-ovary Se concentrations (DCD, Figure 16) (see further discussion below).	
296	EPA-HQ-OW-2004-0019-0315-A1; USGS - Comment submitted by Theresa S. Presser and Samuel N. Luoma, National Research Program, U.S. Geological Survey, Western Branch, Menlo Park, CA; Posted 7/15/2014 Acknowledge under-estimation as shown in validation of model (Figure 16) and show line of regression (not the one-to-one line) Concern here is whether predicted Se concentrations calculated in the DCD are accurate based on the validation of the USEPA model. Figure 16 in the DCD shows the validation of the USEPA model to predict egg-ovary Se concentrations. Validation is necessary to establish sufficient confidence that the predictions from the developed model can be usefully applied to the selected ecosystems. This validation essentially tests if applied TTFs and Kds are accurate. The validation graph is unconventional in two respects. In Figure 16, the x-axis shows the predicted Se concentrations and the y-axis shows the observed Se concentrations. The usual case would be for the predicted Se concentrations to be on the y-axis since this parameter is the dependent variable. Secondly, the line of regression is not shown on Figure 16. It would be helpful if the regression line were shown, in order to demonstrate the deviation from the unity (one-to-one) line and give a realistic illustrative context for the data. Rather than using the correlation coefficient as proof-of-concept, it would be helpful to test the difference between the regression and the one-to-one relationship. Specifically, DCD Figure 16 shows that the USEPA model systematically under-predicts the egg-ovary Se concentration at the lower end of the curve by a factor of 4-5 (e.g., an observed concentration of 8 µg/g is a predicted concentration of 2 µg/g). The USGS estimation here would be improved if the regression line had been depicted on the graph or if the dataset for the graph was available. In terms of the higher end of the curve, we are unaware of observed fish egg-ovary Se concentrations of 250-600 µg/g dw and would be interested in obtaining the dataset for the generation of DCD Figure 16. The variability in DCD Figure 16 can be due to either variability of TTF or Kd in a consolidated approach, which will reduce the strength of the approach. The USGS approach separates prediction into a series of linked steps thereby reducing uncertainty and facilitating the documentation of the fundamentals underlying the derivation of effective Se criteria for the protection of aquatic life. This includes the importance of TTFs in determining toxicity for a fish community approach and Kds in determining the effect of hydrology for a watershed approach. Ecologically-defined scenarios can then quantify for decision-makers a range of predator vulnerabilities (measured as a combination of food-web bioaccumulation and response in Se toxicity tests) and site sensitivities. Encouraging the regulated community to collect local spatially and temporally matched Se data across media (water,	

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	particulate material, invertebrates, and predator tissue) with specificity of species and particulate type to add to the national database can ultimately assist in the development of site-specific criteria.	
304	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014 3.4.4 Underlying Database Should Be Closely Examined The draft waterborne selenium criterion of 1.3 µg/L for lentic waters is strongly influenced by a small number of uncertain EF derived from a single study. This draft criterion was derived based on translation of the draft fish egg selenium criterion of 15.2 mg/kg dry weight (dw) back to a water selenium concentration, using EFs, egg-to-whole body or muscle conversion factors (CF), and composited trophic transfer factors (TTF) for fish and their prey. A total of 51 back-translated water selenium concentrations were derived for lentic waters, which ranged from 0.38 to 55.6 µg/L (Table 12 in the Draft Selenium Criterion Report). Of these, 18 of the 26 lowest were derived from data presented in Lemly (1985). Further, of the 11 back-calculated water selenium concentrations that were ≤1.3 µg/L, ten were from Lemly (1985) (Figure 1). Accordingly, this single study has a profound influence on the draft selenium criterion of 1.3 µg/L for lentic waters, and is cause for concern.	
314	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 8/7/2014 We also support EPA's adoption of the USGS ecosystem-scale modelling approach for deriving water based chronic criteria, although there are facets of EPA's implementation of the USGS approach that do not seem to reflect best available published science, such as the trophic transfer function (TTF) assigned by EPA for mayflies. We understand that USGS modelling experts will be submitting review comments to EPA. We anticipate that EPA will then revise the model implementation in order to resolve the technical concerns. The problems associated with the procedure for implementing the bioaccumulation model are exemplified by the following two examples: First, the complete inability of the methodology to predict the most well-established characteristic of bioaccumulation "factors" (BAFs): that BAFs are highly dependent on level of environmental exposure, decreasing systematically with increasing exposure (see example graphed below). BAFs should more accurately be described as bioaccumulation functions. Using fixed values for EFs and TTFs, EPA's methodology inevitably predicts fixed BAFs, when in fact they vary with environmental exposure as illustrated in the graphs below. (*Original letter contains Figure – not numbered. Bioaccumulation Factor vs. Selenium in water for Fathead Minnow. See original letter.*) Second, EPA's "validation" of its translation methodology (p.134-135) actually appears to show that the translations are consistently biased even if there is a high correlation between predicted and	

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	observed egg/ovary concentrations. Our casual inspection of the validation graph (Figure 16) seems to show that predictions are substantially biased below observed concentration, and most observed concentrations appear to be at least two times higher than the corresponding predicted concentration. Two of the observed concentrations are more than ten times higher than the corresponding predicted concentration. A histogram of residuals (departures from equality between predicted and observed) should be presented. For this validation to be useful, similar comparative validations should be presented for alternative methodologies. These alternative methodologies should include: a) Implementing the bioaccumulation model using EFs and TTFs as functional relationships (regression equations from log-transformed relationships) rather than fixed median values. Widely available software (spreadsheet programs such as Excel) should facilitate making this refinement of the bioaccumulation model without too much additional effort. b) Examining the direct functional relationship between selenium in water and selenium in tissue of focal organisms for comparison. An example of such a relationship is shown below: (*Original letter contains Figure – not numbered. Selenium in tissue vs. Selenium in water for Bluegill. See original letter.)*	
85	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 6.3 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 3.3.1, 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, the intermittent-exposure criteria element of the water-column criteria seems oversimplified, and we feel a more scientific approach such as use of a biokinetic model would be more appropriate. 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	

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	every three 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 13). 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 13).	

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310	EPA-HQ-OW-2004-0019-0332-A2; J.R. Simplot Company; Posted 7/30/2014 VII. Lotic and Lentic Water Quality Values In Section 4.2.5 beginning on page 85, EPA presents an approach for deriving water column concentrations for selenium that are not to be exceeded more than once based on a 30 day average. These water quality values are derived from the 201 h percentile of translated water column values using the egg/ovary criterion as the target criterion. Table 12 of the document compiles the dataset for lotic and lentic translated chronic criterion values from a number of different field studies. Some issues arise in review of this section: (1) as written, the water quality values for both lentic and lotic system are presented as not to be exceeded values; (2) the lentic value is very low and may lead to a conclusion of impairment when in fact none exists; and (3) it is not clear how a species expected and likely to be less sensitive than brown trout has a lower translated chronic criteria value. a. Water Values Presented as Not to be Exceeded Values As indicated above in previous comments, the water value for both the lotic and lentic systems should serve as a screening or trigger value not an absolute criterion that is "not to be exceeded". While calculations exist to translate from the water back to an egg/ovary concentration, use of these generic calculations, particularly when no site specific data exists, may lead to a conclusion of site impairment when in fact no impairment exists. This is particularly true for lentic systems where somewhat limited data may cause sufficient uncertainty to be propagated through the translation process. The water quality value should be presented as screening or trigger value in a tiered approach that if exceeded triggers tissue monitoring. Because the water quality values are conservative, if they are not exceeded no additional monitoring would be warranted. b. Lentic Value is Too Low The single highest uptake of selenium from the environment occurs in the particulates (algae, detritus, sediments); therefore the EF plays an important role in the translation process from an egg/ovary to water value. At locations where the particulate and water concentrations are nearly the same, the EF will approach 1. At locations where the EF is greater than 1, the water concentrations are low and the particulate concentration will be higher. This typically happens at reference and background sites. Where the EF is less than 1, the water concentrations are high and the particulate concentrations are low. This tends to occur more at impacted or higher selenium sites. For the lentic dataset, EPA derived translated water quality values from 50 locations, approximately 16 of which had EF values less than 1, thus the majority of sites used in the dataset had EF values of greater than 1, suggesting these data possibly came from background or reference sites. Contrast the lotic dataset where approximately 68 of the 80 values had an EF <1. This can greatly affect the water quality values derived for the lentic dataset and ultimately the value for the 20th percentile. The EF is not the only factor resulting in a low or high translated water quality value. The TTF composite factors utilized for each particular species also are a multiplier in the translation equation. The distribution of both the lentic and lotic data, and the subsequent criterion values derived from the 20th percentile of those distributions are suspect (Figure 11). By using a dataset that was disproportionately weighted to what may have been background or	

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Comment Category 5.1 – Comments on Site Specific Modification of Fish Tissue Criterion Elements 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.		
182	EPA-HQ-OW-2004-0019-0344-A1; Sanitation District No. 1 of Northern Kentucky (SD1); Posted 8/5/2014 Site-Specific Approach Guidance Currently the site-specific approach outlined in Appendix I of U.S. EPA 2014b only provides guidance for the development of site-specific water quality concentration based criterion. EPA should expand the available guidance for the development of site-specific criterion to include revision of the tissue based criterion using the recalculation procedure (U.S. EPA 2013). In the recalculation process, species and species groups not present in the receiving waters are deleted from the species sensitivity distribution of the Genus Mean Chronic Values (GMCV) used to calculate the egg-ovary Final Chronic Value (FCV). The consequences of this approach can be seen in DeForest et al. 2011, which provides an example of recalculating species sensitivity distribution (SSD) approach using different, site-specific data, which raised the tissue based criterion to 20 µg/g dw for Canadian aquatic life. Equally important to include in Appendix I would be instructions on how to correspondingly recalculate species specific conversion factors (CF) used to develop whole-body and muscle tissue based criterion, as CFs were similarly based on the presence of specific fish species at the site under consideration. Establishing guidance for recalculating tissue-based Se criterion will provide the regulated community a complete set of tools for establishing criteria to protect the beneficial uses of the adjacent water bodies.	Responses concerning the site-specific modification of fish tissue criterion elements: EPA has developed the national criterion based on the best-available science. EPA also agrees on the utility of site-specific criteria developed using site-specific data to estimate risk in the most refined manner possible. BAF and mathematical modeling approaches to developing site-specific criteria are described in Appendix K of the 2016 final criteria document. Regarding those aquatic systems where fish and their prey species can experience significant bioaccumulation of selenium despite low water concentrations, EPA recommends fish tissue be collected in waters where available data (e.g., unusually large EFs) suggest the possibility of "toxicologically significant bioaccumulation" despite low selenium water concentrations. 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.
213	EPA-HQ-OW-2004-0019-0320-A2; National Mining Association (NMA) and GEI Consultants, Inc. (GEI); Posted 7/29/2014 EPA should consider removal of the default national water column criteria (lotic and lentic), with recommendation for emphasis on tissue-based criterion as the overriding criterion, with site-specific (or perhaps state and/or regional) water column values as appropriate.	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 protective 95% of organisms in ecosystems.
270	EPA-HQ-OW-2004-0019-0273-A2; Gopher Resource LLC; Posted 6/17/2014 Gopher Resource is concerned that EPA's proposed use of a water column translator is not suited to establishing a water quality-based effluent limitation (WQBEL) for selenium. Establishing the typical WQBEL involves analyzing a substance's toxic effects on biota in the receiving water. Under such circumstances, a water column value with national application may be warranted. Selenium, however, is different. Its toxicity arises from bioaccumulation, which varies from location to location based upon the type of selenium, the fish species in the receiving water, water chemistry, and other factors. EPA's	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

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	External Peer Review Draft recognizes the unique and variable nature of selenium bioaccumulation, which may necessitate a site-specific water quality criterion. According to the Peer Review Draft, "[b]ecause the factors that control the bioaccumulation of selenium vary from location to location, a site-specific criterion for the protection of aquatic life can be developed as needed (Appendix I), when establishing allowable concentrations in water or resident fish."[1] However, the Peer Review Draft inexplicably goes on to suggest that States may use selenium water quality concentration values to set WQBELs using the "existing implementation procedures ... for other acute and chronic aquatic life."[2] [1] U.S. EPA External Peer Review Draft Aquatic Life Ambient Water Quality Criteria for Selenium-Freshwater 2014 at 1. [2] *Id.* at 98.	function, prior to concluding that the designated use(s) are being met. Regarding the comment that EPA's inclusion of BAFs as a method to develop site-specific criteria *"contradicts U.S. EPA's repeated statements that selenium is accumulated primarily via diet. A BAF, whether field-derived or not, simply compares the selenium concentration in tissue to that in water*", EPA notes that a BAF integrates dietary and water column-based bioaccumulation. As defined in EPA's Technical Support Document Volume 3: Development of Site-Specific Bioaccumulation Factors (EPA-822-R-09-008) BAFs "account for chemical accumulation from all potential exposure routes (e.g., food, sediment, and water) that may be important in determining the chemical accumulation in the organism's body." As discussed in Appendix K of EPA's 2016 final selenium criterion document, both the mechanistic and empirical (BAF) modeling approaches have advantages and disadvantages. The mechanistic modeling approach has the advantage of not requiring extensive fish tissue sampling and analysis by using knowledge of aquatic system food webs. However, the mechanistic modeling approach includes uncertainty in the selection of model parameters such as the value for the enrichment factor parameter *EF* .The empirical BAF approach is conceptually and computationally simpler because it relies only on field measurements and does not require extensive knowledge of the physical, chemical, or biological characteristics of the aquatic system. However, obtaining a sufficient number of robust measurements in fish tissue and water may be logistically difficult and/or more expensive in applying the BAF approach.
303	EPA-HQ-OW-2004-0019-0323-A1; California State Water Resources Control Board; Posted 7/30/2014 Fourth, the biodynamic model was developed for whole body fish tissue, but the guidance on developing site-specific criteria (Appendix I) only addresses use of the fish egg/ovary criterion as the endpoint. This essentially rejects the tiered nature of the criterion which also allows the use of whole body fish tissue or muscle tissue rather than the egg/ovary criterion. The additional step needed to convert whole fish tissue concentrations to a fish egg/ovary endpoint in order to run the model results in more uncertainty through the use of generalized conversion factors that are based on median values. Additional guidance should be provided on the use of the model for whole body fish as it was originally designed, and specify the need to develop appropriate site-specific conversion factors to use it with fish muscle or egg/ovary tissue data. In addition, the site-specific guidance (Appendix I) allows the use of bioaccumulation factors (BAFs), which contradicts U.S. EPA's repeated statements that selenium is accumulated primarily via diet. A BAF, whether field-derived or not, simply compares the selenium concentration in tissue to that in water. It has been clearly demonstrated and acknowledged in the scientific literature that selenium partitioning is primarily biological mediated, therefore, BAFs have limited predictive value because they do not consider the intervening steps in the food web such as the uptake at the base of the food web which is the biggest accumulation step for selenium[4]. The only way a site-specific BAF method could be used to generate water column concentrations in a manner equivalent to the biodynamic model is to develop a BAF for each step (trophic level) in the food web, not just for fish tissue and water. Also in Appendix I, U.S. EPA provides two examples (7a and 7b) that use the lentic and lotic water column elements coupled with the fish egg/ovary criterion to determine what water column	

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	concentrations are needed to reduce existing egg/ovary concentrations so that they meet the egg/ovary criterion. This assumes that there is a direct link between selenium concentrations in egg/ovary tissue and water although U.S. EPA clearly acknowledges that the primary route of selenium exposure in dietary, and in fact, the science clearly shows that selenium more than any other trace element, is accumulated overwhelmingly from dietary exposure[5]. 4. The criterion should not allow the use of: simple, direct comparisons between selenium concentrations in tissue to water such as bioaccumlation factors or BAFs (allowed as an alternative to the biodynamic model); U.S. EPA's use of a binary classification scheme to "validate" their water column criterion elements; and in example 7a and 7b in Appendix I, which use the lentic and lotic water column elements coupled with the fish egg/ovary criterion to determine what water column concentrations would be needed to reduce existing egg/ovary concentrations to need the egg/ovary criterion. All of these methods assume that there is a direct link between selenium concentrations in tissue and water although U.S. EPA clearly acknowledges that the primary route of selenium exposure is diet, not water. [4] Stewart R, Grosell M, Buchwalter D, Fisher N, Luoma S, Mathews T, Orr P, Wang W-X. 2010. Bioaccumulation and Trophic Transfer of Selenium. Chapter 5 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. Chapter 5. Society of Environmental Toxicology and Chemistry (SETAC) Publications. CRC Press, Boca Raton FL (USA). pp. 93-139. [5] 2014 Draft Selenium Criteria document, Section 3.22 Bioaccumulation of Selenium in Aquatic Ecosystems, first paragraph, last sentence: "Selenium can then be transferred from these trophic level 1 organisms to aquatic primary consumers...and then to predators such as fish and birds..." and under the subsection Bioaccumulation in Prey, last sentence; "Because egg-laying vertebrates are the most sensitive groups to selenium, oviparous vertebrate consumers such as fish and birds are consequently the most vulnerable groups to selenium poisoning and the focal point of most environmental assessments..."	
193	EPA-HQ-OW-2004-0019-0335-A2; County of Orange, OC Pubic Works; Posted 7/30/2014 4. 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 County strongly supports the flexibility provided by the Draft Selenium Criterion on Page 100, Section 6 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:	

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	"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 County acknowledges 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 SSOs. In Southern California (and most likely throughout the arid western United States), all model validation efforts will be based on wholebody 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 Draft Selenium Criterion should explicitly provide the process for such a translation in Appendix I. Currently, Appendix I 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 Action: • Revise Section 1.1 and 1.2 of Appendix I to include the process for deriving a site specific water column concentration value from whole-body and/or muscle tissue criterion.	
202	EPA-HQ-OW-2004-0019-0266-A2; Transportation and Storm Water Department, City of San Diego, California; Posted 6/17/2014 The City strongly supports the flexibility provided by the Draft Selenium Criterion on Page 100, Section 6 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,*	

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	translation of the fish tissue criterion to a water concentration can be performed in a manner that accounts for site-specific conditions. " While the City acknowledges 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 SSOs. 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 Draft Selenium Criterion should explicitly provide the process for such a translation in Appendix I. Currently, Appendix I 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 I to include the process for deriving a site-specific water column concentration value from whole-body and/or muscle tissue criterion.	
260	EPA-HQ-OW-2004-0019-0316-A1; Alaska Department of Environmental Conservation (ADEC); Posted 7/25/2014 1. EPA's Chronic Fish Tissue Concentration-Based Criterion Elements The 2014 selenium criterion recommends use of tissue-based criteria rather than use of the numeric water column criterion. The rationale is that fish tissue-based concentrations are a more direct measure of selenium toxicity to aquatic life rather than water-column concentrations. EPA's research indicates: a) Aquatic life are primarily at risk through the food they consume rather than direct exposure; b) Selenium toxicity occurs through transfer to the eggs and has subsequent reproductive effects.	

<table>
<tr><th>Comment tracking number</th><th>Docket ID, Attribution, Comment</th><th>Response</th></tr>
<tr><td></td><td>c) Bioaccumulation and transfer through aquatic food webs constitute the major biogeochemical pathways of selenium in aquatic ecosystems.

EPA considers the proposed fish egg/ovary chronic criterion a more accurate measure of chronic selenium toxicity and, when available, is the preferred method for establishing water quality criteria. EPA recognizes that this measurement may not always be practicable and offers an alternative/supplemental fish tissue criterion based on whole body or muscle as well as water column criterion.

EPA acknowledges different fish species will have different selenium sensitivities; however, the national criterion places into one species sensitivity distribution. The national criterion is based on a number of species that are non-native to Alaska. ADEC questions whether excluding the non-native species data would impact a criterion recalculation or that enough data would be available to perform the recalculation procedure on a site-specific basis. Selection of a criterion based on the protection of an appropriately sensitive species should result in protecting most, if not all, less-sensitive species. However, not enough data is available to provide the validation necessary to draw that conclusion.

Recommendation: EPA should commission additional studies on aquatic species in location where selenium naturally occurs at higher levels, particularly under colder waterbody temperatures, and the effect on those species. This should include information on those factors that may mitigate the effect of high selenium concentrations (e.g., toxicity level) on aquatic life.</td><td></td></tr>
<tr><td colspan="3">Comment Category 5.2 – Comments on Modification of Water Criterion Using Equation 18
Summary: This section contains comments on site-specific modification of water criterion using Equation 18. Included are comments on selecting target fish species, determining primary food source for target fish species and appropriate Trophic Transfer Function (TTF), Enrichment Factor (EF), and Conversion Factor (CF) values. Commenters expressed a need for more guidance.</td></tr>
<tr><td>186</td><td>EPA-HQ-OW-2004-0019-0323-A1; California State Water Resources Control Board; Posted 7/30/2014
3. The biodynamic model was developed for whole body fish tissue; however, the guidance on developing site-specific criteria (Appendix I) only addresses the use of fish egg/ovary criterion as the endpoint. The guidance should be changed to include calculation of water column concentrations from whole body fish or muscle tissue.</td><td rowspan="2">Responses concerning the site-specific modification of fish tissue criterion elements:

Regarding those aquatic systems where fish and their prey species can experience significant bioaccumulation of selenium despite low water concentrations, EPA recommends fish tissue be collected in waters where available data (e.g., unusually large EFs) suggest the possibility of “toxicologically significant bioaccumulation” despite low selenium water concentrations. Furthermore, the national criterion can easily be adapted to site- specific situations using site-specific data using the modeling information provided in the document.

EPA supports the development of site-specific criteria, where data</td></tr>
<tr><td>311</td><td>EPA-HQ-OW-2004-0019-0349-A1; Colorado Wastewater Utility Council (CWWUC); Posted 8/5/2014
We also recommend EPA reconsider the methodology used to derive protective water column concentrations. As described in Section 3.3 of the GEI review, calculating single nationwide standards for only two water body types using a probability distribution of protective water column</td></tr>
</table>

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	concentrations is not appropriate. As parameters used to determine protective concentrations are highly variable depending on site conditions, EPA should only develop water column criteria on a site-specific basis - there is no defensible national water column number, as shown by EPA's own analysis. Section 4.5 of the GEI review discusses the elements of the equation used to translate fish-tissue to water column concentrations in more details, and some of the inherent uncertainty in the approach EPA has taken. Overall, this document is a substantial improvement over previous Se criteria documents, and we thank EPA for the opportunity to provide feedback and comments on this draft of the document.	are available and has specifically designed this criterion so that its modification from a national criterion to a site-specific value, using site-specific data, could be easily facilitated. Where sufficient site-specific data are available to support rate-based estimates of uptake of separate selenium species, interested parties could use those data to develop a site- specific criterion. Regarding transparency on the selection of sites, EPA selected sites based on having sufficient data (temporally representative – within 1 year) water, particulate, and fish tissue) to allow for its' use, and data quality to insure the derivation of a defensible value. EPA describes the criteria used to select the data used in the calculation of CFs, EFs, TTFs, etc., in Section 3.2 of the 2016 final criterion document, and the actual data used are given in the relevant sections within Appendices B and H. EPA did add new data to the data sets based on suggestions from the public and peer review comments. EPA also provided a comparison of the median and regression based approaches used in Appendix N of the final criteria document.
184	EPA-HQ-OW-2004-0019-0313-A2; Wisconsin Department of Natural Resources (WDNR); Posted 6/27/2014 Site-specific criteria for selenium • The procedure for deriving the water column criteria element from the egg-ovary element appears very complex. Are there computer programs/modeling tools that the EPA can make available to assist with the development of site-specific criteria? Will EPA directly reference a specific model and version in code?	
189	EPA-HQ-OW-2004-0019-0326-A1; Utility Water Act Group (UWAG); Posted 7/30/2014 *Site-Specific Criteria Preferable* EPA suggests that all four elements of the selenium criterion can be modified to reflect site-specific conditions where the evidence indicates that different values will be protective of aquatic life and provide for attainment of designated uses. Draft Report, p. 100 (Appendix I provides a process for deriving each parameter in Equation 18 to perform a site-specific translation). For reasons stated above, UWAG strongly supports use of site-specific variables where data are available. UWAG agrees with EPA that, for site-specific modifications, either the food web transfer model or bioaccumulation factors can be used. Furthermore, we believe there are circumstances when one of these methods is more appropriate than the other. Of particular importance to UWAG is EPA's acknowledgement of uncertainties associated with the Bioaccumulation Factor (BAF) approach. See Draft Report at Appendix 1-30. *BAF-Specific Challenges* Application of the BAF may be problematic for some water bodies, specifically, this is true where there is an inverse relationship between BAF values and site-specific selenium water concentration. This pattern has also been demonstrated for mercury (e.g., Brumbaugh et al., 2001). See DeForest at 10, referenced in fn. 3 of these comments. One hypothesis for the inverse relationship is that since	

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	selenium is a required metabolic nutrient for vertebrates, the metalloid is scavenged much more efficiently by fish and other animals at low water concentrations. Appendix I to these comments depicts calculated site-specific selenium water criteria for several streams that ranged in selenium exposure from high to very low. The geometric mean selenium water and bluegill whole body concentration data are taken from Reash (2012). As indicated in Appendix I, reference sites had the lowest calculated site-specific water concentration due to relatively high BAF values. Sites that had medium or high selenium (resulting in relatively high whole body concentrations), however, had less stringent site-specific criteria. This trend is counter-intuitive as one would expect a more stringent water criterion would be required to reduce selenium loads and lower tissue concentrations. These data establish that the BAF, like the food transfer model, has limitations and any site-specific criterion calculation using the BAF should be interpreted with caution and must “make sense” from a bioaccumulation standpoint. This is not to say that the BAF approach is inherently flawed and usage of this procedure leads to counter-intuitive results in all cases; rather, the Agency must understand the pattern of calculated site-specific chronic selenium water criteria across a gradient of ambient water concentrations. *Approach Where Species Not Present* EPA proposes a recalculation procedure for deriving site-specific egg/ovary concentration values by removing individual back-calculated water values for species that are not present at a site. This provides a scientifically sound approach to produce more accurate values where site- and species-specific information are known. However, UWAG requests clarification on using this approach. For example, if reproductive toxicity endpoint data for species that are not resident are excluded (for example, rainbow and brown trout), are the backcalculated protective water concentrations for those species similarly deleted? See Draft Report, Table 12. *Other Site-Specific Considerations* Additional questions regarding the proposed site-specific approach include: • Can a state or discharger request a less conservative back-calculated protective water concentration percentile value (i.e., higher than the 20th percentile) for site-specific application? • Can the site-specific determination of the enrichment factor variable (Appendix 1, pp. 1-18 to 1-19) be determined by calculating the ratio of total selenium to dissolved selenium in water (μg/L / μg/L)? From an analytical standpoint, the difference between the two values is the amount of selenium adhered to particles ≥ 0.45 μm.	

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286, 287	EPA-HQ-OW-2004-0019-0315-A1; USGS - Comment submitted by Theresa S. Presser and Samuel N. Luoma, National Research Program, U.S. Geological Survey, Western Branch, Menlo Park, CA; Posted 7/15/2014 There are other specific points that are problematic. In summary, they include: 1. The DCD does not adequately capture the importance of choosing one or more fish species of concern as a first step in any aspect of the local or regional process. A local conceptual model is necessary to complete this step 2. 2. The DCD is insufficiently transparent as to what sites were chosen, the criteria for choosing sites, and the reason some data and not others were employed in designing a guideline..	
Comment Category 5.4 – Comments on Needing More Guidance on When to Develop Site Specific Criterion Summary: Commenters expressed the need for guidance in developing a site specific criterion, including situations in which the receiving water contains no fish or the receiving water contains high background levels of selenium.		
171	EPA-HQ-OW-2004-0019-0271-A2; Coordinator, Barnes & Thornburg LLP on behalf of the Federal Water Quality Coalition; Posted 6/17/2014 The Draft Criteria Document does not provide sensitivity values for many of the non-game fish that are present in the streams of the Western plains. These streams often do not have the larger fish for which EPA does provide information. Without selenium toxicity thresholds, bioaccumulation factors and other relevant information, it would be difficult for parties to develop site-specific criteria. EPA should consider generating this information for Western species.	Responses concerning the site-specific modification of fish tissue criterion elements: EPA supports the development of site-specific criteria, where data are available and has specifically designed this criterion so that its modification from a national criterion to a site-specific value, using site-specific data, could be easily facilitated. Regarding specific species not represented in the national database, EPA asserts that the species present are surrogates for the sensitivity ranges of untested species. The national criterion is designed to be protective for most aquatic species (~95% of genera), in most waters, most of the time. If there is concern that a particularly sensitive species is present at a site, and site specific criteria may be appropriate to insure its protection. Regarding the elimination of certain elements of the criterion, EPA recommends adopting all elements, to be fully protective of aquatic systems. Regarding consolidation of the USGS modeling approach, Section 5 of the document states that site-specific translation to water can be
180	EPA-HQ-OW-2004-0019-0340-A1; CONSOL Energy Inc.; Posted 8/5/2014 Given the wide variation in selenium sources, ecosystems and climate, the development of nationwide criteria is unreasonable. Criteria should be based on region specific information and data. CONSOL supports the efforts of the West Virginia and Kentucky state environmental agencies in developing region specific tissue based criteria. We believe EPA should give significant weight to these and other efforts by agencies nationwide in pursuit of developing scientifically defendable region specific criteria. Seasonally specific studies should be considered when attempting to standardize chronic criterion. The inclusion of multiple studies will determine scientifically defensible background levels in different regions, and at different times of the year.	
190	EPA-HQ-OW-2004-0019-0331-A1; The Fertilizer Institute; Posted 07/29/2014	

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	V. The Importance of Site-Specific Methodology Appendix I in the Draft Criterion provides guidance for the development of site-specific water quality criterion. As stated earlier in these comments, for specific situations (i.e., geographical location and fish species) the development of a site-specific criterion may be warranted because studies have shown a wide divergence in selenium concentrations in the water column and fish tissues and associated effects on the aquatic environment. For example, Canton (2010) discusses in detail elevated selenium concentrations (> than 5 µg/L) for the Arkansas River and associated tributaries near Pueblo, Colorado where viable and reproducing fish populations exist. In the upper Blackfoot River basin in Idaho, Oncorhynchus clarki bouvieri is the predominant trout species (IDFG 2007). This watershed is a candidate for a site-specific standard as the EC10 for Yellowstone cutthroat trout is greater than 24 mg Se/kg dw. This value is considerably higher than EPA's proposed value of 15.2 mg Se/kg dw. TFI supports the inclusion of guidance to develop site-specific standards and recommends that EPA encourage the use of such methodology.	done using procedures outlined in Appendix K (2016 final criteria document). Regarding additional information on site-specific translation, EPA will provide technical support information that will assist states, tribes, and stakeholders after the selenium criterion document has been finalized. Regarding uncertainties with the dissolved guidelines, the objective of the water criterion elements is to be protective and representative of accumulation tendencies in lentic and lotic systems. The 20th centiles of the translated water concentrations at lentic and lotic sites, respectively, were selected by EPA to insure that the goal of water quality criteria to protect the aquatic life in the most of the nation's waters, most of the time" is achieved. Because of the acknowledged variability in translated water concentrations, resulting in large part from site specific differences in enrichment factors, as well as differences in species and food web specific bioaccumulation rates, the EPA has also presented methods to develop site specific water quality criteria/translations as appropriate. The 2016 final criterion also clearly recognizes special circumstances: new inputs of selenium into a lentic or lotic aquatic system, and "fishless waters". New inputs will likely result in a greater concentrations of selenium in the food web and an increase in the selenium concentration in fish until the water concentrations from the new selenium release achieves a "steady state" balance in the aquatic system. Fishless waters are defined 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. Under these circumstances only, the water column concentrations will best represent selenium levels required to protect aquatic communities and downstream waters in such areas until steady state is established. T
194	EPA-HQ-OW-2004-0019-0347-A2; Southern Nevada Water Authority; Posted 8/5/2014 The Authority also requests that EPA further define how to develop a site specific standard. All of the tributaries to the Las Vegas Wash (Wash) are currently classified as impaired and will remain impaired based on the water column concentration for lotic systems in the new regulation. The Wash is the drainage point for the Las Vegas valley and contains urban runoff, shallow groundwater, treated wastewater, and stormwater. The tributaries to the Wash collect shallow groundwater, urban runoff, and stormwater but do not contain the diluting effect of the treated wastewater. Most of these tributaries are lined and unlined channels of questionable ecological significance. It would be helpful to have additional information in the regulation detailing how to develop a site specific standard if there are no fish in the stream. Can fish be added to the stream for a defined period of time and then removed and analyzed? If there are fish in a stream, how many fish should be analyzed and do they need to be a predetermined age or size? If downstream fish are analyzed, should it be fish in the Wash (closer) or fish in Lake Mead (miles away) that are analyzed? Also, further classification of the sentence in the document, "A site-specific selenium criterion protecting a limited aquatic environment may be appropriate if selenium levels are naturally high and fish were not previously present in the aquatic system" would be helpful (Draft Document Page I-13).	
211	EPA-HQ-OW-2004-0019-0273-A2; Gopher Resource LLC; Posted 6/17/2014 In sum, the Peer Review Draft appropriately recognizes selenium's site-specific bioaccumulative effects and articulates the "primacy" of fish tissue and egg-ovary data over water column values.	

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	Suggesting that States may use national selenium water quality concentration values alone to set WQBELs is inconsistent with the Peer Review Draft's emphasis on the "primacy" of fish tissue and egg-ovary data.[7] It is also contrary to a decade of research on selenium bioaccumulation.[8] EPA should strike the suggestion from the Peer Review Draft. [7] Id. [8] Id. at 1-2.	Regarding differences in the overall conceptual approaches between the US and the USGS, WQS must ensure that designated uses are protected; a range of WQ values (the USGS conceptual approach) does not provide the certainty of a specific level of protection required of WQS. Regarding the contents of Appendix I (now Appendix K) not describing 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. EPA has modified the Appendix and provides a comparison of method using data from the document. Data needs will be site specific and dependent on the characteristics of the site (size, hydrodynamics, aquatic community). EPA is developing technical support materials that detail aspects of fish tissue sampling to facilitate implementation of the selenium criterion to be released for comment after the final criterion document is issued. Regarding the comment "4.6.2 Discussion of Comparison of Mechanistic Bioaccumulation Modeling and BAF Approaches", EPA has modified the section in Appendix K of the 2016 final criteria document. The BAF vs mechanistic modeling approach section now features a comparison using an actual dataset (Saiki et.al). New data were considered as part of the development of the 2014 External Peer Review Draft, as well as data submitted as part of the 2014 and 2015 public comment periods. The 2016 final criteria document considered new data through February 2016, (receipt of data from stakeholders); these data added to the information used for the derivation of EFs and TTFs. Regarding the development of site specific objectives, refer to Appendix K of the 2016 criteria document.
290	EPA-HQ-OW-2004-0019-0315-A1; USGS - Comment submitted by Theresa S. Presser and Samuel N. Luoma, National Research Program, U.S. Geological Survey, Western Branch, Menlo Park, CA; Posted 7/15/2014 6. Consolidation of steps in the USEPA model will reduce the site-specific flexibility that is the strength of the USGS approach. Readers should at least be made aware of this problem. 7. 6. The DCD needs to emphasize the large uncertainties associated with proceeding with lotic and lentic guidelines; and clearly state the value in collecting local data and employing the model where stakeholders are unsatisfied with the dissolved guidelines.	
557	EPA-HQ-OW-2004-0019-0335-A2; County of Orange, OC Pubic Works; Posted 7/30/2014 • 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.	
166	EPA-HQ-OW-2004-0019-0266-A2; Transportation and Storm Water Department, City of San Diego, California; Posted 6/16/2014 A universal, nationally applicable water column value 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. As stated in Comment #1, the City strongly supports the approach recommended by USEPA in the 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 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	

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	selenium bioavailability and toxicity.[6, 7, 8, 9] 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 Newport Bay watershed, a relatively small watershed located in southern California, initial model runs[10] of the Luoma Presser model[11] for two tributaries, San Diego Creek and Big Canyon Wash, demonstrate a wide range of water column concentrations needed to protect fish: approximately 10 19.3 µg/L in San Diego Creek and 0.5 - 1.1 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 Kd values (i.e., EF) present in Big Canyon Wash. Even within this relatively small watershed, the use of a universally applicable water column concentration of 4.8 µg/L would be both significantly over- and under-protective. Given the site-specific nature of the selenium water column concentrations that are necessary to 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 result in a water column concentration that would attain the fish --tissue values. 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 selenium water column concentrations that are not directly linked to site-specific conditions. In addition to not being directly linked to beneficial use protection, utilizing selenium water column concentrations may unnecessarily require implementation of significant and costly BMPs with no net environmental benefit. In addition, utilizing selenium water column elements outside of a site-specific setting may ~~cause~~ have the unintended consequence of establishing effluent limits in National Pollutant Discharge Elimination System (NPDES) permits. These effluent limits would be ~~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 ~~discharges~~ they are in violation of their permits, even though the discharge is at a concentration that is fully protective of the designated uses. Utilizing the selenium water column concentrations elements of the criterion as an implementation tool would avoid this unnecessary and inappropriate outcome. 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 eliminate aspects of the criterion (e.g.,	

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	water column concentrations). The City strongly supports the approach in the Draft Selenium Criterion that states “all four elements of the selenium criterion can be modified to reflect site-specific conditions.”[13] 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 #1 and #2, site-specific factors can vary even within a relatively small watershed. 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. The need for this flexibility applies mostly to the water column elements, though certain States in the and West may also wish to focus on only whole-body fish tissue due to the practical limitations of obtaining egg/ovary samples. Notwithstanding Comment #2, if the USEPA maintains the water column element, States should be allowed to remove an element. Page 1-2 of Appendix I of the Draft Selenium Criterion cites the following rationale for recommending the water column elements of the 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 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, or infeasible 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 100, Section 6 of the 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	

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	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 L' • Revise Table 15 on Page 97 of the Draft Selenium Criterion to read as follows: o Add footnote 6[14] (place after "Fish Tissue" and "Water Column'): Each of the four elements can be modified through site-specific objectives, consistent with Section 6 and Appendix L o Add footnote 7[15] (place after "Egg/Ovary," "Monthly Average Exposure," and `Intermittent Exposure'): Through site-specific objectives, consistent with Section 6 and Appendix I, these elements can be eliminated as part of the criterion. • Revise Appendix I to provide guidance on the rationale, procedures, and pathways to eliminate certain elements of the Draft Selenium Criterion through SSOs. [6] Lemly, A.D. 1998. A position paper on selenium in ecotoxicology: A procedure for deriving site-specific water quality criteria. Ecotoxicology and Environmental Safety. Volume 39, pp. 1-9. [7] Luoma, S.N. and T.S. Presser. 2000. Forecasting Selenium Discharges to the San Francisco Bay-Delta Estuary: Ecological Effects of a Proposed San Luis Drain Extension. U.S. Geological Survey Open-File Report 00-416. [8] 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. US Geological Survey Professional Paper 1646. [9] Skorupa, J.P. 1998. Selenium Poisoning of Fish and Wildlife in Nature: Lessons from Twelve Real World Examples. In W. Frankenberger and R.A. Engberg, eds. Environmental Chemistry of Selenium. Marcel Dekker Inc., New York., p. 315-354. [10] Model runs based upon the Draft Selenium Criterion value of 8.1 mg/kg dw in whole-body fish tissue. See Comment Letter on the Draft Selenium Criterion submitted by the County of Orange. [11] This model has been adapted by Luoma and Presser for the Newport Bay watershed. It is the same mechanistic model used in the Draft Selenium Criterion. [13] Draft Selenium Criterion, Page 100, Section 6. [14] 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. [15] Note that prior comments request additional footnotes to this table. The actual numbering depends	

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	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.	
191	EPA-HQ-OW-2004-0019-0332-A2; J.R. Simplot Company; Posted 7/30/2014 V. Comments on the Site-Specific Criterion Process and Calculations to Arrive at a WQ Value (Appendix I) EPA has provided considerable flexibility in this section relative to derivation of a site specific water quality value for situations when empirical data are available and when data are not available. The 2014 Draft Criterion suggests that EFs can be derived empirically through collection of water and separation of water and particulates then measuring the selenium in both fractions. While this approach might work in a lake or reservoir setting or in a large slow moving river with oxbows, we do not believe it will provide a representative sample in a flowing river system where water is moving constantly. The particulate selenium concentration will need to be determined from algae (periphyton) and sediments, and possibly detritus if it can be found. It is also important to recognize that in the derivation of EFs, inclusion of sediments and detritus along with algae in the overall calculation can have an effect of lowering the EF values (Figure 2). This is somewhat less conservative than using algae only to derive EFs, but as indicated, it is important to derive a statistically significant relationship between the dissolved water fraction and the components of particulates prior to combining these components to derive an EF. Uncertainty will be introduced into the translation process if, for example, no significant relationship is found between sediment selenium and dissolved aqueous selenium, yet it is included in the derivation of the EF. Also note in Figure 2 that in the distribution of EFs, the magnitude of difference between the sediment and algae components becomes greater at the higher percentiles. In this case the higher percentiles represented smaller streams with lower selenium concentrations, higher gradients and fewer fine sediments. *Original letter contains Figure 2 – Distribution of EFs across Sample Locations Simplot Site Specific Selenium Study. See original letter.* Simplot agrees that a hybrid approach (discussed in Section 4.2.2, page 75 - 2nd full paragraph) to derivation of the TTF values is likely most appropriate. Establishing that a significant positive relationship is present between selenium concentrations in tissue of organisms and the food they ingest is an important step prior to derivation of any TTFs. There appears to be sufficient flexibility in the derivation of TTFs. Language and examples in the 2014 Draft Criterion suggest that making adjustments to diets can be done such that partial diets can be considered. Derivation of CFs for species where no CFs are available may introduce additional uncertainty into	

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	the translation process. As noted in Table 12, the value assigned to all ray finned bony fishes (class Actinopterygii) to convert from an egg criterion to a whole body tissue concentration (CF) is 1.71. EPA generated this value from the mean of the family level conversion factors shown in Table B-6 in Appendix B. While EPA recommends in Appendix I Section 2 for the BAF approach that migratory fish should not be used, it is obvious that in the derivation of site-specific criterion using site data where salmonids are the predominant species, salmonids would be sampled for tissue concentrations of selenium in order to obtain the data necessary for a site specific BAF. We suggest that EPA provide some guidance on how salmonids might be used to satisfy these data needs. As an example, working with a multi-agency work group for its site-specific criteria, Simplot approached this issue within the context of Idaho's Fish Tissue Protocol, where a separate working group was established by IDEQ and Idaho Department of Fish and Game (IDFG) to define a standardized set or protocols for sampling salmonid fish tissues for selenium. These protocols established (1) a target size for sampling (:51 00 mm, but can include up to approximately 150 mm fish), (2) gathered interested parties who might be sampling in southeast Idaho so each entity knew who was sampling and where they were sampling in order to avoid duplicate efforts, (3) established a target minimum number of samples from each site, and (4) mandated that a certain number of samples be provided for split laboratory analysis to assess tissue concentrations differences that may result from different analytical techniques. By targeting juvenile fish, the expectation was those juveniles were likely spawned there and as a result were representative of the site exposure because they had not migrated into or out of the area where they had been spawned. When adult fish were sampled, they were integrated within the database of juvenile data to assess if tissue concentrations between adults and juveniles were significantly different.	
285	EPA-HQ-OW-2004-0019-0315-A1; USGS - Comment submitted by Theresa S. Presser and Samuel N. Luoma, National Research Program, U.S. Geological Survey, Western Branch, Menlo Park, CA; Posted 7/15/2014 The USGS commends the USEPA for moving forward into a new ecosystem-based approach for regulating this important contaminant. The USGS realizes that establishing nationwide Se criteria is a complex process wherein many tradeoffs must be considered; and the USGS respects the hard work that has gone into this document. The USGS consulted extensively with the USEPA staff in headquarters during the early stages of developing the national criteria implementation methodology in 2007-2008 and briefly, on a generalized basis about the methodology, as the USEPA requested in 2010 and 2012. USGS input is evident in the current proposal and is valued. The DCD represents a	

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	reasonable summary of the state of knowledge with regard to Se. Although more than a decade in the making, this represents a major step forward from the nearly 30-year-old aquatic life criteria for Se that presently are being applied. The USGS is concerned, however, that at several steps in the series of processes that control Se bioavailability and trophic transfer there are compromises in the proposed USEPA methodology that could add uncertainty, perhaps unnecessarily. This increased uncertainty could result in a regulatory approach, at least in some environments, which may not take full advantage of the current state of environmental Se science. Therefore, described below are the aspects of the proposed criteria which could ultimately create the most uncertainty. Perhaps most important is the overall concept that the USGS methodology is not designed to provide a single choice for a site-specific standard. The model is designed to a) incorporate site-specific information into a guideline; b) constrain variability in the choices of a guideline value (e.g. when calculating a dissolved guideline from the fish tissue guideline); and c) give regulators and stakeholders a sense for the outcome of different choices and why those outcomes differ. The DCD does not explain this concept clearly. There is some variability in the data available at every step in the model and choices must be made; ultimately the DCD should give readers a well-defined strategy for understanding and constraining those choices within site- and species-specific applications. Hence, setting up the implementation process for informed choices is a critical part of criterion development and understanding.	
192	EPA-HQ-OW-2004-0019-0335-A2; County of Orange, OC Pubic Works; Posted 7/30/2014 3. 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 County strongly supports the approach on Page 100, Section 6 of the 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 #1 and #2, 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 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 practicallimitations of obtaining egg/ovary samples. As noted in Comment #2, the water column elements could be moved from the criterion to an implementation tool. If USEPA determines that approach is unworkable at the national	

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	level, States could implement such an approach if the criterion specifically allows for the elimination of the water column elements via SSOs.
	
	Page 1-2 of Appendix I of the Draft Selenium Criterion cites the following rationale for recommending the water column elements of the 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 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 aQ. 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 100, Section 6 of the 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 1."
	• Revise Table 15 on Page 97 of the Draft Selenium Criterion to read as follows:
	    o Add footnote 6[12] (place after "Fish Tissue" and "Water Column"): Each of the four elements can be modified through SSOs, consistent with Section 6 and Appendix I.
	    o Add footnote 7[12] (place after "Egg/Ovary," "Monthly Average Exposure," and "Intermittent Exposure"): Through SSOs, consistent with Section 6 and Appendix I, these elements can be eliminated as part of the criterion.
	• Revise Appendix I to provide guidance on the rationale, procedures, and pathways to eliminate	

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	certain elements of the criterion through SSOs. [12] 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.	
199	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 4.6 Site-specific Criteria *4.6.1 Deriving Site-specific Water Concentration Values from the Egg/Ovary Criterion* Appendix I of the 2014 draft Se criteria document describes a methodology to derive site-specific criteria using a mechanistic modeling approach. However, Appendix I 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. For example, does a state or tribe need to notify EPA that studies in support of site-specific criteria are going to be undertaken? Are there minimum data requirements? 4.6.1.1 Target Fish Species Appendix I page I-10 states: "States and tribes should target nonanadromous species (species that do not migrate from salt water to spawn in fresh water)". Clearly, the desire is for resident (i.e., non-migratory) fish species to be collected to reduce exposure-related uncertainty. However, only "nonanadromous" fish are mentioned, which might lead some readers to question if EPA intended for the term "nonanadromous" to include fish that migrate solely within freshwater (potamodromous), which is common. Furthermore, long-distance (e.g., > 1 km) fish movement is not isolated to movement related to/from spawning locations. Thermal regimes, resource availability, habitat limitations/alterations, etc. can drive/influence long-distance movement. Clarifications on these points are suggested. 4.6.1.2 Aquatic Systems with No Resident Fish and Selecting Target Species Appendix I pages I-12-13 provides guidance on methodology pertaining to locations where fish may be absent. The following comments relate to this section: • The section suggests using the decision tree in "Figure J-3" to identify downstream fish species to protect in the event that fish are absent from the current location(s), this reference should be changed to "Figure I-3". • Figure I-3 references "nonanadromous" species of the Salmonidae family. See comments	

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	above in Section 3.6.1.1 regarding potamodromous fish, etc. • Figure I-3 should clarify what is meant by the phrase “Target species with the highest ecological significance” (in the event that members of the Salmonidae family, Lepomis genus and Centrarchidae family are not present), as this phrase can be interpreted multiple ways. For example, would fathead minnows be considered the most ecologically significant if they were the primary prey of a gamefish that could not sustain a population in the absence of fathead minnows? Or, would the gamefish be the most ecologically significant? 4.6.2 Discussion of Comparison of Mechanistic Bioaccumulation Modeling and BAF Approaches Section 3.0 of Appendix I on page I-33 contains a table titled “Comparison of Mechanistic Bioaccumulation Modeling and BAF approaches”. This table seems to be lacking arguably critical entries and is vastly oversimplified. For example, where is the mention of levels of uncertainty tied to each approach? If cost is a primary concern for the site-specific BAF approach and is less of a concern for the TTF approach, then why is there not a cost-comparison? Further, a reader could easily interpret this table as suggesting that the BAF approach is superior to the TTF approach, but that is likely not the intent. Consideration should be given to removing the table, nesting it within introductory text early in Appendix I, or fleshing it out substantially if leaving as a stand-alone table in Section 3.0. This section might also greatly benefit from some comparisons of site-specific criteria development using the TTF approach vs. the BAF approach. In other words, if sufficient data were available to utilize either approach, what would the resulting criteria look like?	
170	EPA-HQ-OW-2004-0019-0271-A2; Coordinator, Barnes & Thornburg LLP on behalf of the Federal Water Quality Coalition; Posted 6/17/2014 Site-specific fish tissue and toxicity information is preferable to the use of generic toxicity relationships that were developed using data from a broad range of sites, and the Draft Criteria Document should make that preference clear. EPA should also explain what methods are available to develop site-specific selenium criteria, and how those can be implemented.	
175	EPA-HQ-OW-2004-0019-0272-A2; Clark County Water Reclamation District; Posted 6/17/2014 Additionally, the District also requests that EPA further define how to develop a site specific standard. All of the tributaries to the Las Vegas Wash (Wash) are currently classified as impaired and will remain impaired based on the water column concentration for lotic systems in the new criterion. The Wash is the drainage point for the Las Vegas Valley and contains urban runoff, shallow groundwater, treated wastewater, and stormwater. The tributaries to the Wash collect shallow groundwater, urban	

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	runoff, and stormwater but do not contain the diluting effect of the treated wastewater. Most of these tributaries are lined and unlined channels of questionable ecological significance. It would be helpful to have additional information in the criterion detailing how to develop a site specific standard if there are no fish present. Can fish be added to these channels for a defined period of time and then removed and analyzed? If there are fish in a system, how many fish should be analyzed and do they need to be a predetermined age or size? If downstream fish are analyzed, should it be fish in the Wash (closer) or fish in Lake Mead (miles away) that are analyzed? Also, further clarification of the sentence in the document "A site-specific selenium criterion protecting a limited aquatic environment may be appropriate if selenium levels are naturally high and fish were not previously present in the aquatic system" would be helpful (Draft Document Page I-13).	
181	EPA-HQ-OW-2004-0019-0341-A1; West Virginia Coal Association (WVCA); Posted 8/5/2014 The Draft Selenium Criteria 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.	
128	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014 3.8 Other Comments Typically, selenium water concentrations are expressed as a single digit (e.g., 4 µg/L, 5 µg/L, 6 µg/L). Thus, the reduction in the lotic water criterion from the current 5 µg/L to 4.8 µg/L is in practice a quantum jump -- reported values of 5 µg/L would now exceed rather than attain the water criterion. It is noted within the text of the Draft Selenium Criterion Document that, for this review draft, EPA has conducted a new literature review and reanalyzed data considered in the 2004 and 2009 draft criteria documents. For what additional years new data were considered and reanalyzed is not stated, however. It would be useful to know the cut-off date for data consideration and reanalysis. In Section 3.5 of the Draft Selenium Criterion Document, EPA discusses the interactions of mercury with selenium but these interactions, which can reduce selenium toxicity, were not fully evaluated. NAMC 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 should provide specific recommendations for assessing potential selenium effects and developing site-specific standards for water bodies where fish are not present due to water quantity, not water quality. Such water bodies include ephemeral or intermittent streams, and small headwater streams.	

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158	**EPA-HQ-OW-2004-0019-0256**-A1 [Comment 0346-A2 is a duplicate of 0256-A1]**; Peabody Energy Corporation**; Posted 6/16/2014 Flexibility in Site-Specific Criteria While the EPA does promote the use of site-specific criteria, the EPA seems to imply that all site-specific criteria must be translated to a water column concentration. There are situations where back-calculation of a water column concentration from fish tissue concentrations is problematic due to factors including overly conservative assumptions built into the calculation procedure, lack of representative values to use for equation variables, and numerous site-specific environmental conditions such as limited aquatic habitat, seasonal flows, or selenium tolerance. Furthermore, as repeatedly stated by EPA, the fish tissue concentrations, and specifically the egg-ovary concentrations, should take precedent over other forms of the criterion, such as water column. The EPA should discuss the use of a site-specific fish tissue based criterion, where it can be shown that the water column backcalculation should not be applied. For example, there may be a site that shows compliance based on the fish tissue concentrations and a healthy biological community, but the same site may show impairment based on the back-calculated water quality criteria. Therefore, it is necessary that EPA allow a site to calculate and impose a fish tissue-only criterion where applicable.	
159	**EPA-HQ-OW-2004-0019-0256**-A1 [Comment 0346-A2 is a duplicate of 0256-A1]**; Peabody Energy Corporation**; Posted 6/16/2014 In addition, as the EPA is aware, there are many areas of the United States, and particularly the western states, where ambient selenium concentrations in both the water column and fish tissue exceed the proposed standards and may also exceed a site-specific standard. One concern is how a site-specific standard could be addressed in an area with high ambient selenium. If the site-specific fish tissue and water column criteria are exceeded, but again the biological community is healthy as measured by other metrics, does the site-specific criteria still take precedent?	
178	EPA-HQ-OW-2004-0019-0327-A2; Colorado Wastewater Utility Council (CWWUC); Posted 7/30/2014 One topic that needs further consideration, and is of particular importance in Colorado, is providing guidance for situations where there are naturally elevated background Se concentrations, such as the ability to develop ambient based site-specific criteria where those elevated concentrations are unrelated to human-induced sources. Colorado has extensive areas with underlying geology contributing to elevated Se concentrations in ground and surface waters. GEI has provided a discussion of a case-study in Colorado, in which these elevated natural Se concentrations resulted in ambient-based criteria approved by both the state and EPA (Section 4.1.2). We recommend this type of ambient-based criteria be considered on a case-by-case basis nationwide. EPA's discussion of	

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	site-specific standard development is lacking and needs further clarification.	
198	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 *4.1.2 Incorporation of Background Conditions into Site-specific Criteria* Appendix I of the 2014 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. As discussed in Section 4.1.1 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 site-specific tissue criteria. In a 2011 and 2012 GEI conducted a study on the St. Charles River near Pueblo, CO 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 (Figure 4). Data were collected seasonally from 2011 – 2012 and included water samples, fish tissues, sediment, 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 at sites with very low Se concentrations, indicating no effect on juvenile recruitment in these reaches with elevated Se (GEI 2013). Fish also appeared unaffected by the Se concentrations throughout the study reach with whole-body 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 selenium (Canton 2010), which may be useful for EPA to consider in the criterion document. *Original letter contains Figure 4 – Shale-containing geologic formations and dissolved selenium concentrations in lentic systems in Colorado. Highest Se concentrations are plotted on top in instances when there were more than one datapoint at any given location.[2] See original letter.* Based on evidence provided by GEI during the 2013 Arkansas River Basin Hearing, the Colorado Water Quality Control Commission (WQCC) and the EPA approved both acute and chronic site-specific water quality standards (Se(ac) = 173.0 µg/L and Se(ch) = 50 µg/L) based on natural sources of Se which have not been “exacerbated by land use or other reversible anthropogenic factors” (5 CCR 1002-32). Similarly, two other streams in the vicinity, which have naturally elevated Se	

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	concentrations due to underlying geology and wide spatial and temporal variability of Se, also had site-specific water quality standards approved (Wildhorse Creek, Se(ac) = 2376 µg/L and Se(ch) = 2110 µg/L; Pesthouse Gulch, Se(ac) = 389 µg/L and Se(ch) = 369 µg/L) (5 CCR 1002-32). Data from the GEI study on the St. Charles River (GEI 2012) also demonstrated that Se concentrations in the water were reflected in the fish tissue (Figure 5). Thus, in addition to the importance of ambient site-specific water column Se criteria, it is also important to consider ambient site-specific tissue standards. *Original letter contains Figure 5 – Water column and whole-body fish tissue Se concentrations collected at sites along the St. Charles River near Pueblo, Colorado. See original letter.* [2] The information in this database is composed of data from the USGS National Water Information System (NWIS) and from the USEPA STOrage and RETrieval (STORET) Data Warehouse. The dataset was queried using sample media=water and the characteristics=selenium and selenium-75. Once data were obtained, they were filtered by site type=lake, reservoir, or impoundment. Database filtering steps: WBType: 'Great Lake', 'Lake,' Lake Reservoir Impoundment', and 'Reservoir'; ResultSampleFractionText: 'Dissolved'; ResultDetectionConditionText: 'Blanks'; ActivityTypeCode: Removed QC Samples; ActivityMediaSubdivisionName: Surface Water and Blanks QualifierCode : 'U'-qualified data was removed *Results that were reported as zero or a negative number were removed from the dataset Disclaimer - STORET: "The EPA does not change or filter incoming data. This means that when pulling data out of the Warehouse, users must be aware that they are responsible for screening the data for their use." As a result, this data obtained from STORET is being used in this review for comparative purposes only.	
448	EPA-HQ-OW-2004-0019-0351-A2; Stakeholders Implementing TMDLs in the Calleguas Creek Watershed, California; Posted 08/05/2014 3. 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 Draft Selenium Criterion that states "all four elements of the selenium criterion can be modified to reflect site-specific conditions."[14] 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 #1 and #2, site-	

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	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 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 #2, 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 1-2 of Appendix I of the Draft Selenium Criterion cites the following rationale for recommending the water column elements of the 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 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 100, Section 6 of the 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. <u>Furthermore, the egg/ovary element and the water column elements can be eliminated through site-specific objectives, consistent with Appendix I.</u>"	

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	• Revise Table 15 on Page 97 of the Draft Selenium Criterion to read as follows:
	  o Add footnote 6[15] (place after "Fish Tissue" and "Water Column"): Each of the four elements can be modified through site-specific objectives, consistent with Section 6 and Appendix I.
	  o Add footnote 7[15] (place after "Egg/Ovary," "Monthly Average Exposure," and "Intermittent Exposure"): Through site-specific objectives, consistent with Section 6 and Appendix I, these elements can be eliminated as part of the criterion.
	• Revise Appendix I to provide guidance on the rationale, procedures, and pathways to eliminate certain elements of the Draft Selenium Criterion through SSOs.
	
	[14] Draft Selenium Criterion, Page 100, Section 6.
	
	[15] 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.	

472	EPA-HQ-OW-2004-0019-0356-A1; Idaho Department of Environmental Quality (DEQ); Posted 09/30/2014 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? Could a criterion be based on a single native 'most-sensitive' species?	
449	EPA-HQ-OW-2004-0019-0351-A2; Stakeholders Implementing TMDLs in the Calleguas Creek Watershed, California; Posted 08/05/2014 4. 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 Draft Selenium Criterion on Page 100, Section 6 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	

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	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 Draft Selenium Criterion should explicitly provide the process for such a translation in Appendix I. Currently, Appendix I 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 1 to include the process for deriving a site-specific water column concentration value from whole-body and/or muscle tissue criterion.	

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461	EPA-HQ-OW-2004-0019-0356-A1; Idaho Department of Environmental Quality (DEQ); Posted 09/30/2014 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.	
Comment Category 6.1 – Comments Concerning Corrections and Typos Summary: Several typos and corrections were noted by commenters.		
43	EPA-HQ-OW-2004-0019-0323-A1; California State Water Resources Control Board; Posted 7/30/2014 Eighth, selenium is not a metal or metalloid; it is a non-metal that falls in the chalcogen group in the periodic table and has properties in common with the other elements in that group (oxygen, sulfur, tellurium and polonium)[9]. This should be clearly stated in the document and efforts should be made to move away from continuing to treat it as a metal both from a scientific and regulatory perspective. [9] Young T, Finley K, Adams W, Besser J, Hopkins WA, Jolley D, McNaughton E, Presser T, Shaw DP, Unrine J. 2010 What You Need to Know About Selenium. Chapter 3 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. Chapter 5. Society of Environmental Toxicology and Chemistry (SETAC) Publications. CRC Press, Boca Raton FL (USA). pp. 7-45.	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.
44	EPA-HQ-OW-2004-0019-0323-A1; California State Water Resources Control Board; Posted 7/30/2014 Lastly, we bring to U.S. EPA's attention several typographic errors in Appendix I: Several tables and figures and one equation (J-3) are labeled as "J-x" instead of I-x; there is a misspelling of truncation in the footnote to Table I-1: "Corbula amurensis" should be Portamcorbula amurensis; and a typographic error at the top of page I-23 should be "waste load allocations," not "alsites." There is a discrepancy in the main text of the criterion document (page 81, Section 4.2.3, Food Web Models) and Appendix I (page I-18, Section 1.2.3.4) in describing how TTFs for fish were derived	

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	when data for an individual species were not available. The draft report states that TTFs for roundtail chub (*Gila robusta*) and carp (*Cyprinus carpio*) were used to estimate a TTF for blacknose dace (*Rhinichthys atratulus*). However, roundtail chub is not listed in Table 10, and Appendix I states that a TTF for roundtail chub was estimated using the fathead minnow (*Pimephale promelas*) TTF[10]. This discrepancy needs to be corrected. [10] Water Board staff would also note that fathead minnow are lower trophic level than roundtail chub and that a better surrogate for estimating an appropriate TTF for roundtail chub would be the creek chub (Semotilus atromaculatus), which has a diet more similar to roundtail chub and occupies a similar ecological niche.	
45	EPA-HQ-OW-2004-0019-0350-A1; Central Contra Costa Sanitary District (CCCSD); Posted 8/5/2014 Page 83 states, "...the dashed line in figure 11" this should be "...the dashed line figure 10"	
46	EPA-HQ-OW-2004-0019-0353-A1; Mark C. Rigby, Parsons and University of California at Santa Barbara; Posted 8/7/2014 The first two paragraphs of Section 7.1.1 contain a number of incomplete sentences and incomplete ideas. For clarity, please provide complete explanations. Table 5 states that the "LOEC for larval edema and lordosis" is <23.85 mg/kg-dw in ovaries for Schultz and Hermanutz (1990) study on fathead minnows. However, this value is labeled as a NOAEC in Appendix C. Please correct Appendix C to indicate that this is a LOEC and not a NOAEC.	
47	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 General Errors The draft criterion document is very well-written but given the great length of the document (>600 pages) it is inevitable that several minor typographical errors are noted throughout the document. A few other errors were noted, including the following: • Table 6b, page 57 the SMCV/GMCV value of >l 00 mg/kg for Oligochaete (blackworm) should be >140 mg/kg as indicated in the text on page 55; the corresponding egg-ovary concentration should then be 303.8 mg/kg which is consistent with the value plotted on the genus-level sensitivity distribution curve in Figure 5. • In Appendix C, pages C- 105 to C-111, there may be some errors in some of the numbers in the tables for Study II.	
48	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2];	

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	GEI Consultants Review for CWWUC; Posted 8/5/2014 5. Summary of Errors or Noted Inconsistencies Noted typographical errors are described in this section with reference to the appropriate section of the original document. There are several errors in Tables 9, 10, and 11 of the 2014 draft Se criteria document. These errors are noted and revised values are shown in this document in Sections 4.4 and 4.5 in Table 9 and Table 10. Appendix B has incorrect data in Table B-6. The data in Table B-6 (page B-129) is a repeat of Table B-5 (page B-44) – it just contains a different caption title. Table B-6 should be revised accordingly. There are a number of typographical errors in Appendix C in the tables on pages C-107 through C-112 of the 2014 draft Se criteria document. On pages C-107, C-108, and C-110, it appears EPA inadvertently typed a colon (:) in place of the micro symbol (µ) in the treatment column. In addition, on page C-112, most of the % survival data are not on the correct lines. Finally, on page C-108, the first control ovary Se (mg/kg ww) concentration should be 0.78 instead of 0.76 (the calculated geometric mean shown was correctly calculated using 0.78). Appendix I contains multiple table and figure-referencing errors. All figure and table references should be cross-referenced, including the following corrections: • Pages I-14 and I-16, 1.2.3 – incorrectly refers to Tables "J-1 and/or J-2" – the correct tables are "Tables I-1 and/or I-2". • Page I-23, 1.4 incorrectly cites Tables 6 and 7 of the main text as the source of species-specific TTFs and Table 8 of the main text for CFs used in example calculations. The correct tables to cite are Tables 9 and 10 for species-specific TTFs and Table 11 for CFs.	
292	EPA-HQ-OW-2004-0019-0315-A1; USGS - Comment submitted by Theresa S. Presser and Samuel N. Luoma, National Research Program, U.S. Geological Survey, Western Branch, Menlo Park, CA; Posted 7/15/2014 7. There are errors (e.g., discrepancies between text and tables; missing references) throughout the DCD which suggest it is not yet ready for release.	
300	EPA-HQ-OW-2004-0019-0315-A1; USGS - Comment submitted by Theresa S. Presser and Samuel N. Luoma, National Research Program, U.S. Geological Survey, Western Branch, Menlo Park, CA; Posted 7/15/2014 5) While the USGS appreciates the working nature of the DCD, there are errors and discrepancies	

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	throughout the report. Some errors (Tables J1 and J2 in Appendix I) and missing references (7 missing out of 12 cited for Table 12) could have been corrected by an editorial review process prior to release. Errors concerning site names, site codes, and species names (e.g., Twin Butter Reservoir versus Twin Buttes Reservoir; Sweltzer Lake versus Sweitzer Lake; red sunfish versus red shiner; Carquinezitist vs Carquinez) occur throughout the DCD giving a lack of confidence for those familiar with the literature. For those looking closely at the document in order to follow the derivation of TTFs, the fact that paragraph two on page I-18 is replete with errors is disconcerting (i.e., there is no mangrove snapper nor roundtail chub in the analysis and there are three taxa instead of five for consideration) and may undermine the accuracy of the derivations in the minds of some reviewers.	
Comment Category 6.2 – Comments Requesting Clarification Summary: Several commenters requested better definitions of specific terms.		
9	EPA-HQ-OW-2004-0019-0277-A1; Arkansas Department of Environmental Quality; Posted 6/24/2014 Derivation of Averaging Period for Chronic Water Criterion Element The fourth paragraph states: For the second trophic level, invertebrates, values for kTL2 are tabulated in elsewhere in the document. Define where in the document	Response to requests for clarification: Regarding the clarity of the criterion as a freshwater criterion, EPA provided additional clarification in the 2015 draft document and 2016 final document, the document was clearly already labeled freshwater, and the data included in the criteria are all freshwater or anadromous/diadromous fish that have a significant life history in freshwater. EPA notes that a similar approach may be appropriate for deriving criteria for selenium in estuarine and marine waters. 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. EPA has clarified phrases and terms to enhance readability. Regarding the primacy of the tissue elements over the water element, EPA has revised the 2016 criteria document and uses the word "supersedes" when referring to the hierarchal structure of the criterion. Regarding the sensitivity analysis of growth rate and aqueous uptake, this analysis is contained in Appendix J of the 2016 final
29	EPA-HQ-OW-2004-0019-0350-A1; Central Contra Costa Sanitary District (CCCSD); Posted 8/5/2014 <u>General Comments for Clarification</u> The Executive Summary table on page 4 states that water column values are based on dissolved total selenium in water, but the last paragraph of the summary (page 8) states that, " These water quality criterion elements apply to the total of all oxidation states (selenite, selenate, organic selenium, and any other forms). CCCSD Comment: Please clarify this apparent contradiction.	
67	EPA-HQ-OW-2004-0019-0266-A2; Transportation and Storm Water Department, City of San Diego, California; Posted 6/17/2014 The 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 637 pages of the Draft Selenium Criterion to find the	

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	definitions and intentions of key terms. For example, footnote 3 of Table 15 of the Draft Selenium Criterion states that water column values are based on "dissolved total selenium" in water. However, the water quality criterion elements are identified on Page 8 of the Draft Selenium Criterion as applying "to." Further, "dissolved total selenium" is an ambiguous term as typically, total recoverable selenium is the terminology employed. The City requests the term "dissolved total selenium" be eliminated from the 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. In particular, such definitions must be added to Table 15 for clarity. Additionally, footnote 4 of Table 15 of the Draft Selenium Criterion defines the Cbkgmd variable as the "average background selenium concentration." However, the definition for Cbkgrnd is absent from the table. The definition is located on Page 93 of the Draft Selenium Criterion and identified as "the 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 Cbk d is necessary to interpret Table 15, a modified and more precise definition needs to be added. Requested Actions: • Define each term upon initial use and revise the language in Table 15 of the Draft Selenium Criterion to read as follows: o Modify footnote 3: "Water column values are based on ~~disolved total selenium in water~~ <u>the total of all oxidation states (selenite, selenate, organic selenium, and any other form)."</u> o Modify footnote 4: "...C_{bkgrnd} is the average background selenium concentration occurring during the remaining <u>time when elevated selenium concentrations are not occurring</u>..."	criterion document. In response to the comment regarding variability of factors in the model, this issue is discussed in Section 6.3 of the 2016 final criteria document. Regarding the concern over application to brackish water, the criterion applies to freshwater. EPA discusses selenium as a nonmetal in the 2016 final criteria document, Section 2. The term total dissolved selenium has been defined in the 2016 final criteria document to mean all dissolved forms (organic and inorganic) of selenium. Dissolved is typically determined by that fraction that passes through a 0.45 um filter. Total recoverable selenium implies that particulate and dissolved selenium will be quantified. It is critical to understand the partitioning between water and particulate (algae, sediment, periphyton, detritus), as this is the basis for the enrichment function EF, the critical step in determining selenium bioaccumulation to higher trophic levels. Instantaneous measurement is defined in the 2016 final criteria document, and further explained in the technical support document for fish tissue sampling.
68	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 The expectation of what a dissolved total selenium measurement in water includes (e.g., filtration and then preservation prior to analysis), should be defined to ensure consistent application. Total measurements may be compared to the criterion and discussion on this could aid in interpretation of data.	

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72	EPA-HQ-OW-2004-0019-0277-A1; Arkansas Department of Environmental Quality; Posted 6/24/2014 7.1.1 Principles for Using Studies for which EC10s Cannot Be Calculated 1. The first sentence states: When the data from an acceptable chronic test met the conditions for logistic regression analysis, the EC10. The EC10 was used? Please provide clarification.	
129	EPA-HQ-OW-2004-0019-0277-A1; Arkansas Department of Environmental Quality; Posted 6/24/2014 Section 4.1.1 Acceptable Studies of Reproductive Effects 1. Rainbow Trout Section: The third sentence reads: The temperature at which embryos were incubated was 8oC in 2000, with the exception of rainbow trout, which were incubated at 5oC in 2001 (Holm Do not distribute, quote, or cite 43 Draft Document 2002; Holm et al. 2005). This is the rainbow trout section; so only the rainbow trout conditions should be reported. How were the reference sites chosen in this study?	
157	EPA-HQ-OW-2004-0019-0340-A1; CONSOL Energy Inc.; Posted 8/5/2014 There is a wide variation in the number of significant figures in the reported concentrations from the various researches (from single digit to hundredths of an mg/kg). The analyses and resulting criteria should only be as precise as the least precise data used to derive the criteria.	
169	EPA-HQ-OW-2004-0019-0271-A2; Coordinator, Barnes & Thornburg LLP on behalf of the Federal Water Quality Coalition; Posted 6/17/2014 Since the criteria are based on freshwater data, EPA should state clearly that they do not apply to marine, estuarine or brackish waterbodies. The criteria that currently apply to those waterbodies (290 µg/l acute and 71 µg/l chronic) should continue to apply unless and until new criteria are developed that are based on toxicity data for those types of waters.	
232	EPA-HQ-OW-2004-0019-0266-A2; Transportation and Storm Water Department, City of San Diego, California; Posted 6/17/2014 Lastly, the current language provides for fish tissue elements to have "primacy" where tissue data are	

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	available. Page 98 of the 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, footnote 1 and 2, respectively, in Table 15 on Page 97 of the Draft Selenium Criterion state (emphasis added): "Overrides any whole-body, muscle, or water column elements ***when fish egg/ovary concentrations are measured***." "Overrides any water column elements when ***both fish tissue and water concentrations are measured***."	
233	EPA-HQ-OW-2004-0019-0266-A2; Transportation and Storm Water Department, City of San Diego, California; Posted 6/17/2014 Requested Action: Revise the Draft Selenium Criterion to clearly establish that the fish tissue elements supersede the water column elements Provide more direct and explanatory language throughout the document that clearly limits the applicability and use of water column elements, including but limited to the figure on Page 3 of the Executive Summary and Page 96 of Section 5 (National Criterion for Selenium). Example modified language for Page 98, 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. 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. Draft Selenium Criterion water column measurements should only be used to determine whether or not the selenium criterion	

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	is being met if fish egg, fish ovary, fish whole- body, and fish muscle tissue measurements are all not available. Further, as-although 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."	
269	EPA-HQ-OW-2004-0019-0271-A2; Coordinator, Barnes & Thornburg LLP on behalf of the Federal Water Quality Coalition; Posted 6/17/2014 The Draft Criteria Document cites Appendix G as containing a sensitivity analysis of growth rate and aqueous uptake. However, that analysis does not appear to be contained in the appendix. The assumption of low-impact processes needs to be documented.	
272	EPA-HQ-OW-2004-0019-0277-A1; Arkansas Department of Environmental Quality; Posted 6/24/2014 4.2.1 Chronic Water column-based Selenium Criterion Element 1. The paragraph after Equation 18 states: Because this approach uses food web modeling along with species-specific TTF and CF parameters to quantify most of the transfer between compartments, however, the only field measurements needed to relate selenium in egg-ovary and water are measurements from the water-column and particulate material sufficient to calculate EF. Please clarify, perhaps remove the word “however” or restructure the sentence.	
273	EPA-HQ-OW-2004-0019-0277-A1; Arkansas Department of Environmental Quality; Posted 6/24/2014 4.2.2 Equation Parameters 1. First paragraph, the numbers do not add up. There is a difference of 357 measurements. Please clarify.	
297	EPA-HQ-OW-2004-0019-0315-A1; USGS - Comment submitted by Theresa S. Presser and Samuel N. Luoma, National Research Program, U.S. Geological Survey, Western Branch, Menlo Park, CA; Posted 7/15/2014 Additional Detailed Comments 1) It would be helpful to explain or enumerate the various subsets of EPA’s database that are cited in the different stages of the derivation and validation of the water column-based Se criteria. For example: page 134, 300 predicted egg-ovary concentrations; page 136, 140 instances in lentic systems and 688 instances in lotic systems; and Table 12, 132 predicted water-column	

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	concentrations. 2) Similarly, note that the number of total, lentic, and lotic sites differs between the text and what is shown in DCD Table 12.	
298	EPA-HQ-OW-2004-0019-0315-A1; USGS - Comment submitted by Theresa S. Presser and Samuel N. Luoma, National Research Program, U.S. Geological Survey, Western Branch, Menlo Park, CA; Posted 7/15/2014 3) It would be helpful to summarize the results of the TTF and EF derivations in tables or figures to address the variability of the values.	
299	EPA-HQ-OW-2004-0019-0315-A1; USGS - Comment submitted by Theresa S. Presser and Samuel N. Luoma, National Research Program, U.S. Geological Survey, Western Branch, Menlo Park, CA; Posted 7/15/2014 4) As noted previously, data shown in Table 12 are difficult to confirm against food-web and predator datasets given in original reports, especially data cited in the Idaho study (i.e., Formation Environmental, DCD Table 12).	
69	EPA-HQ-OW-2004-0019-0335-A2; County of Orange, OC Pubic Works; Posted 7/30/2014 6. Key Definitions are Absent from Table 15 and Need to be Added or Modified in order to Interpret the Draft Selenium Criterion. The 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 637 pages of the Draft Selenium Criterion to find the definitions and intentions of key terms. For example, footnote 3 of Table 15 of the Draft Selenium Criterion states that water column values are based on "dissolved total selenium" in water. However, the water quality criterion elements are identified on Page 8 of the Draft Selenium Criterion as applying "to the total of all oxidation states (selenite, selenate, organic selenium, and any other form)." Further, "dissolved total selenium" is an ambiguous term as typically, total recoverable selenium is the terminology employed. The County requests that the term "dissolved total selenium" be eliminated from the 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. In particular, such definitions must be added to Table 15 for clarity. Additionally, Footnote 4 of Table 15 of the Draft Selenium Criterion defines the C_{bkgrnd} variable as the "average background selenium concentration." However, the definition for C_{bkgrnd} is absent from the table. The definition is located on Page 93 of the Draft Selenium Criterion and identified as "the	

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	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 C_{bkgrnd} is necessary to interpret Table 15, a modified and more precise definition needs to be added. Additionally, Footnote 5 of Table 15 of the Draft Selenium Criterion provides justification for the duration of the fish tissue elements of the 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 15. Requested Actions: • Define each term upon initial use and revise the language in Table 15 of the Draft Selenium Criterion to read as follows: o Modify footnote 3: "Water column values are based on ~~dissolved total selenium in water~~ the total of all oxidation states (selenite, selenate, organic selenium, and any other form)." o Modify footnote 4: " ...Cbkgrnd is the average background selenium concentration occurring during the remaining time when elevated selenium concentrations are not occurring... " o 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."	
137	EPA-HQ-OW-2004-0019-0341-A1; West Virginia Coal Association (WVCA); Posted 8/5/2014 The selenium studies should be re-evaluated for evidence that the alleged deformities were associated with electroshocking. This is particularly true for the adult female creek chub, where the alleged deformities were consistent with electroshocking damage and would have prevented the fish from reaching maturity if they were indeed developmental deformities.	
151	EPA-HQ-OW-2004-0019-0322-A1; American Petroleum Institute (API); Posted 7/30/2014 Water Body Applicability	

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	The Notice specifies the criteria to be freshwater criteria. These criteria, then, are not to be applied to brackish or saltwater. The existing saltwater criteria, 290 µg/L acute and 71 µg/L chronic are to be applied to these waters. By what salinity/TDS benchmark do regulatory authorities distinguish between freshwater and brackish/estuarine waters?	
152	EPA-HQ-OW-2004-0019-0323-A1; California State Water Resources Control Board; Posted 7/30/2014 6. The criterion does not address estuarine or saline waters, and does not indicate if or when criteria for these types of water may be developed.	
328	EPA-HQ-OW-2004-0019-0323-A1; California State Water Resources Control Board; Posted 7/30/2014 Sixth, while the criterion document does not state that selenium criteria for aquatic-dependent wildlife may be developed in the future, it does not address whether U.S. EPA plans to also develop selenium criteria for estuarine and saline waters. The criterion document should at least make reference to this regulatory gap and provide an estimated time frame by which U.S. EPA expects to develop selenium criteria for these types of waters.	
465	EPA-HQ-OW-2004-0019-0356-A1; Idaho Department of Environmental Quality (DEQ); Posted 09/30/2014 Particulate concentration / particulate matter, bottom Page 14 and 1st paragraph section 3.2.2. EPA needs to be clearer here what is meant by these phrases. Implication seems to be organic particulate matter such as living and dead algal and bacterial cells and not inorganic (e.g. sediment bound) particulate selenium, but this is not entirely clear. The sentence near the bottom of page 15 which refers to "other particulate-bound selenium sources" adds to the muddle. Stating what these "other particulate-bound sources" are and their relative importance may help clarify.	
469	EPA-HQ-OW-2004-0019-0356-A1; Idaho Department of Environmental Quality (DEQ); Posted 09/30/2014 On page 50, we suggest that sentence that says "Overall, the implication is that for some period of time, recovering systems might possibly exceed tissue criteria concentrations even though the effects of selenium have been mitigated," would make more sense if 'sources of selenium' were substituted for 'effects of selenium'.	
510	EPA-HQ-OW-2004-0019-0278-A1; Mark C. Rigby, Parsons and University of California at Santa Barbara; Posted 06/24/2014 The first two paragraphs of Section 7.1.1 contain a number of incomplete sentences and incomplete	

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	ideas. For clarity, please provide complete explanations.	
559	EPA-HQ-OW-2004-0019-0335-A2; County of Orange, OC Pubic Works; Posted 7/30/2014 Key Definitions are absent from Table 15 and need to be added or modified in order to interpret the criterion.	
563	EPA-HQ-OW-2004-0019-0332-A2; J.R. Simplot Company; Posted 7/30/2014 Page 108, C) - Last sentence on the page: the sentence refers to Figure 15f. It should refer to Figure 13f.	
566	EPA-HQ-OW-2004-0019-0332-A2; J.R. Simplot Company; Posted 7/30/2014 Page B-45, Table B-5: The CF for the broad category Class of Actinopterygii, is based on the median of the Family values found on Page B-44. Uncertainty introduced by the CF value of 1.71 in the translation process, which could contribute to over or underestimating a chronic criterion, should be noted. Page C-60 and C-61: The reference for this study should be identified as Formation (2011) with a note that the follow up QA document is AECOM (2012). Page C-61 first paragraph, LSV03 should be corrected to LSV2C. Page C-61, 2nd paragraph, last sentence. EC_{20} is identified and it should be EC_{10}. Page C-66, Table 3: The sample identified as SPC-002 should be SPC-003. Sample SPC-002 was carried through the test with 20 organisms simply to provide an additional sample for growth determination.	
596	EPA-HQ-OW-2004-0019-0266-A2; Transportation and Storm Water Department, City of San Diego, California; Posted 06/17/2014 • Key Definitions are absent from Table 15 and need to be added or modified in order to interpret the proposed criterion.	
599	EPA-HQ-OW-2004-0019-0323-A1; California State Water Resources Control Board; Posted 07/30/2014 8. Selenium is not a metal or metalloid and should not be classified or treated as such from either a scientific or regulatory perspective.	
451	EPA-HQ-OW-2004-0019-0351-A2; Stakeholders Implementing TMDLs in the Calleguas Creek Watershed, California; Posted 08/05/2014 6. Key Definitions are Absent from Table 15 and Need to be Added or Modified in order to	

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	Interpret the Proposed Criterion. The 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 637 pages of the Draft Selenium Criterion to find the definitions and intentions of key terms. For example, footnote 3 of Table 15 of the Draft Selenium Criterion states that water column values are based on "dissolved total selenium" in water. However, the water quality criterion elements are identified on Page 8 of the Draft Selenium Criterion as applying "to the total of all oxidation states (selenite, selenate, organic selenium, and any other form)." Further, "dissolved total selenium" is an ambiguous term as typically, total recoverable selenium is the terminology employed. The Stakeholders request that the term "dissolved total selenium be eliminated from the 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. In particular, such definitions must be added to Table 15 for clarity. Additionally, footnote 4 of Table 15 of the Draft Selenium Criterion defines the C_{bkgrnd} variable as the "average background selenium concentration." However, the definition for C_{bkgrnd} is absent from the table. The definition is located on Page 93 of the Draft Selenium Criterion and identified as "the 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 C_{bkgrnd} is necessary to interpret Table 15, a modified and more precise definition needs to be added. Additionally, footnote 5 of Table 15 of the Draft Selenium Criterion provides justification for the duration of the fish tissue elements of the 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 15. *Requested Actions:* • Define each term upon initial use and revise the language in Table 15 of the Draft Selenium Criterion to read as follows: o Modify footnote 3: "Water column values are based on ~~dissolved total selenium in water~~ the total of all oxidation states (selenite, selenate, organic selenium, and	

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	any other form)." o Modify footnote 4: "...Cbkgmd is the average background selenium concentration occurring during the remaining time when elevated selenium concentrations are not occurring..." o 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."	
452	EPA-HQ-OW-2004-0019-0356-A1; Idaho Department of Environmental Quality (DEQ); Posted 09/30/2014 The Idaho Department of Environmental Quality (DEQ) has reviewed the US Environmental Protection Agency's (EPA) *External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium--Freshwater 2014* published in the *Federal Register* on May 14, 2014 (FR Vol. 79, No. 93, pp. 27601-27604). 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. Idaho has been working since 2006 on a site-specific selenium criterion for selected waters in southeast Idaho. That effort stalled in 2012 due to EPA's delay in putting forth its national criterion update. More specifically because of EPA's review of brown trout toxicity data produced by Formation Environmental on behalf of Simplot Corporation and whose release became tied up in the national criterion document just now being reviewed. There are two reports referenced in the *External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium--Freshwater 2014* that Idaho DEQ has been waiting for two years. These are: Taulbee, K., D. Mcintyre and C. Delos. 2012. Analysis of the brown trout selenium toxicity study presented by Formation Environmental and reviewed by U.S. Fish and Wildlife Service. Report to EPA Health and Ecological Criteria Division, Contract No. EP-C-09-001, Work Assignment 4-04. 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. We respectfully request you now provide us copies of these reports as soon as practicable.	
Comment Category 6.3 – Comments Concerning the Additional Data, Informational Sources, and Alternative Approaches Summary: Several commenters recommended EPA incorporate additional studies in their analyses.		

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53	EPA-HQ-OW-2004-0019-0275-A1; Institute for Fisheries Resources; Posted 6/18/2014 Attachments 1. Technical Issues Affecting the Implementation of US Environmental Protection Agency's Proposed Fish Tissue-Based Aquatic Criterion for Selenium A. Dennis Lemly and Joseph P Skorupa Integrated Environmental Assessment and Management — Volume 3, Number 4—pp. 552-558 _ 2007 SETA 2. EPA's Draft Tissue-Based Selenium Criterion: A Technical Review 2004 Joseph P. Skorupa* United States Fish and Wildlife Service; Theresa S. Presser, United States Geological Survey; Steven J. Hamilton, United States Geological Survey; A. Dennis Lemly, United States Forest Service Southern Research Station	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. EPA evaluated new data presented as a part of the comment periods in 2014 and 2015, as well as conducting independent literature searches during that period to ensure that all information considered important to the selenium criterion would be included. EPA added data (associated with DeForest et.al 2014) as recently as February 2016, in response to a data submission pursuant to an earlier comment in the 2014 public comment period. EPA addresses the sulfate interaction issue in Section 6.2.1 of the 2016 final criteria document. Response to Comments on the SMCV for cutthroat trout. The SMCV for cutthroat trout is 26.2 mg/kg dw based on studies by Nautilus Environmental 2011, and Rudolph et.al., 2008. The studies cited by Simplot were reviewed and deemed to be of insufficient quality to be used quantitatively in the criteria document. EPA's SMCV of 26.2 mg/kg is a defensible EC10 that is similar to those cited in Simplot's comment, thus the Westslope cutthroat trout can serve as a reasonable surrogate for the Yellowstone cutthroat trout. Regarding the analysis of Hardy, 2005 and Hardy et.al. 2010, EPA is unable to replicate your analysis with the information provided in your comments. The high variability observed by Hardy that resulted in a non-significant ANOVA can be observed in the Se-egg mortality figure that was provided, and calls into question the statistical significance of the resulting EC10. Regarding Formation 2012, this study was evaluated by EPA and was deemed to be of insufficient quality for use in the derivation of national criterion for selenium. The study's evaluation is in Appendix G, unused data in the 2016 criteria document. EPA recognizes the potential for other mechanisms to play a role in
122	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014 3.2 Additional Recent Scientific Document for Consideration We recognize that it is not always possible for a document such as the proposed selenium criterion document to incorporate and integrate all of the emerging literature at the time of release, particularly if there is a large volume of research and publications being generated in the field. We note, however, there is a specific, recently-completed document that needs to be considered by EPA, and integrated into the next version of the selenium criterion document. Specifically, the NAMC-SWG has undertaken a three-year research effort, the product of which is a recently-completed final report entitled Selenium Partitioning between Water and Fish Tissue in Freshwater Systems: Development of Water-based Selenium Screening Guidelines."[3] Peer-reviewed publication of this report in an international scientific journal is anticipated in the near future. In addition to other new information, DeForest et al. derives and recommends 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. We urge EPA and its peer reviewers to consider the appended report and incorporate its findings in the next revision of the selenium water criterion document. We note that the draft EPA document mentions that selenate (SeO_4^{2-}) in the water column is taken up only slowly by bacteria, especially if competition with sulfate is involved.[4] There was no further attempt to quantify this sulfate parameter as an important moderator of selenium toxicity. The NAMC-	

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	SWG research studies reviewed in the appended report modeled and parameterized the influence of sulphate on selenium toxicity. We encourage EPA to consider applying this sulphate modification model to selenium water screening thresholds. [3] DeForest *et. al.* "Selenium Partitioning between Water and Fish Tissue in Freshwater Systems: Development of Water-based Selenium Screening Guidelines" (May 2014). *See* http://www.namc.org/docs/Selenium%20Integrated%20Report%20- %20Final%20(2014-05-20).pdf. [4] Draft Selenium Criterion Document at 14.	the toxicity of selenium to oviparous vertebrates. EPA has reviewed Kupsco and Schlenk (2014), and has added language in Section 2.3 regarding the potential for multiple adverse outcome pathways that may play a role in the developmental toxicity of selenium.
124	EPA-HQ-OW-2004-0019-0345-A2; Ohio EPA; Posted 8/5/2014 Selenium water column concentrations are not widespread concern in Ohio. However, Ohio has been monitoring a site-specific selenium problem in the Ottawa River (Lima, Ohio) in various aquatic compartments since 1986. We would like to bring to the reviewers' attention the fact that Ohio EPA has collected data on selenium concentrations in water, sediment, and aquatic organisms in the Ottawa River (Biological and Water Quality Study of the Ottawa River and Principle Tributaries, 2010). Based upon a review of our data, we feel that U.S. EPA's proposed selenium criterion is very close to the toxic threshold for selected target tissues and sensitive species. There appears to be little or no margin of safety associated with the NOEL for the proposed criterion. Our agency would like to offer to make Ohio's study available to the technical review panel if it would aid in the review of the current, proposed criterion.	
125	EPA-HQ-OW-2004-0019-0345-A2; Ohio EPA; Posted 8/5/2014 Ohio EPA has also reviewed our fish tissue database (used in the production of our annual Sport Fish Consumption Advisory report) regarding this issue. After adjusting selenium concentrations to a dry-weight basis, of more than 6000 fish tissue samples analyzed for selenium since 1981 we have only observed 6 exceedances of the proposed whole-body fish tissue threshold of 8.1 mg/kg. There were an additional 3 fillet samples that approached but did not exceed the fillet threshold of 11.8 mg/kg on a dry-weight basis. Ohio EPA is willing to make any of the above data, including our fish tissue data and the Ottawa River Study, available if U.S. EPA is interested in reviewing it.	
126	EPA-HQ-OW-2004-0019-0353-A1; Mark C. Rigby, Parsons and University of California at Santa Barbara; Posted 8/7/2014 Table 5 includes a study by Formation Environmental (2011) on brown trout that was performed for J.R. Simplot. However, the companion study by Formation Environmental (2012a,b) on Yellowstone cutthroat trout (Oncorhynchus clarki bouveri) that was also performed for J.R. Simplot is not included in the USEPA draft document. Please add the study by Formation Environmental (2012 a,b) or state	

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	why it was excluded.	
133	EPA-HQ-OW-2004-0019-0331-A1; The Fertilizer Institute; Posted 07/29/2014 IV. Inclusion of Other Fish Studies in the Criterion Analysis The Draft Criterion discusses two cutthroat trout studies (Oncorhynchus clarki lewisi – Westslope cutthroat) and, based on these studies, EPA calculated an EC10 of 24.06 mg Se/kg dw in eggs. However, there are two other cutthroat trout studies with Oncorhynchus clarki bouvieri (Yellowstone cutthroat) that warrant discussion. First, Hardy et al. (2009) conducted a 2.5 year feeding trial in which the trout were fed either a constant basal diet (1.2 µg Se/g diet) or a basal diet with different rates of selenomethionine. Sublethal signs of toxicity were not observed; the average egg selenium concentration at 124 weeks was 16 µg/g dw for the treatment group with the highest egg selenium concentration. While this study was considered in the 2014 Draft Criterion and some of the data were used, the data were not used in the numeric criterion derivation because the highest egg selenium concentration represented an unbounded no observed effects concentration (“NOEC”). Second, Formation Environmental (2012) conducted a multi-prong Oncorhynchus clarki bouvieri study. The study included both wild and hatchery trout; endpoints measured included reproduction, growth, deformities and survival. Examination of the survival data showed that the percent survival (hatch to test end) provided the best relationship to egg selenium concentrations. The wild trout data indicated a break in the survival data between 22.3 and 27.9 mg Se/kg dw egg. For those eggs at or below 22.3 mg Se/kg dw (n = 7 egg batches), median survival was 91.1 percent. For eggs equal to or greater than 27.9 mg Se/kg dw (n = 7 egg batches), median survival was 80.9 percent. Using the mean or median value (equivalent for n = 2) of the egg selenium concentrations for these two groups of wild collected fish indicates a value of 25.1 mg Se/kg dw, suggesting that an EC10 for survival is greater than 25 mg Se/kg dw. The summation of these studies indicates that for the two species of cutthroat trout studied the EC10 is greater than 24 mg Se/kg dw.	
134	EPA-HQ-OW-2004-0019-0332-A2; J.R. Simplot Company; Posted 7/30/2014 The Chronic Value for Cutthroat Trout Should Include an Additional Study. One additional study has been done looking at toxicity to cutthroat trout (Yellowstone Cutthroat Trout - Oncorhynchus clarki bouvien). The YCT study allowed for survival and deformity EC10s to be derived, but only when a single sample was excluded. The survival and deformity data for YCT suggest that YCT are less sensitive to selenium than brown trout. Using the combined/integrated endpoint proposed by EPA in the 2014 Draft, Simplot recalculated the YCT endpoint for survival and normal fish using two approaches resulting in EC10s of 26.57 and 26.99 mg Se/kg dw egg. Simplot believes that inclusion	

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	of these data in subsequent versions of the Draft Selenium Criterion is important to complete the cutthroat trout dataset and inclusion of these data will be valuable for other investigators looking to develop site-specific criteria where this type of cutthroat trout is prevalent.	
139	EPA-HQ-OW-2004-0019-0353-A1; Mark C. Rigby, Parsons and University of California at Santa Barbara; Posted 8/7/2014 On page 105, the USEPA draft document states the study by Hardy (2005 and Hardy et al. (2010)) was excluded because no effects were observed. This reviewer obtained the data from Dr. Hardy and was able to calculate (see above for methods) significant EC10s of 1.72 mg/kg-dw in eggs for mortality of eggs; 1.82 mg/kg-dw for hatching success, 1.90 mg/kg-dw for egg+larval mortality, and 8.74 mg/kg-dw for deformities in live larvae. Since the study was funded in part by USEPA, the data should be available to USEPA and USEPA should have obtained and analyzed the data instead of relying the published material, which only analyzed using the treatment means using an ANOVA. Part of the reason that the ANOVA did not show any effects was due to the substantial variability observed in the experiment. This is illustrated in the dose-response relationship between egg mortality and the concentration of selenium in trout eggs from Hardy et al. (2010) below: *Original letter contains Figure – not numbered. Dead eggs (%) vs. Log10 of selenium in eggs. See original letter.*	
504	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 Prior to the next public consultation period on this criterion, a full assessment of available peer-reviewed publications should be completed along with other available reports and publications.	
512	EPA-HQ-OW-2004-0019-0278-A1; Mark C. Rigby, Parsons and University of California at Santa Barbara; Posted 06/24/2014 Table 5 includes a study by Formation Environmental (2011) on brown trout that was performed for J.R. Simplot. However, the companion study by Formation Environmental (2012a,b) on Yellowstone cutthroat trout (*Oncorhynchus clarki bouveri*) that was also performed for J.R. Simplot is not included in the USEPA draft document. Please add the study by Formation Environmental (2012 a,b).	
515	EPA-HQ-OW-2004-0019-0278-A1; Mark C. Rigby, Parsons and University of California at Santa Barbara; Posted 06/24/2014 On page 105, the USEPA draft document states the study by Hardy (2005 and Hardy et al. (2010)) was excluded because no effects were observed. This reviewer obtained the data from Dr. Hardy and was able to calculate a significant EC_{10}s of 0.89 mg/kg in eggs for mortality of live eggs; 1.01 mg/kg for hatching success, 1.18 for egg+larval mortality, and 8.71 for deformities in live larvae. Since the study was funded in part by USEPA, the data should be available to USEPA and USEPA should have	

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	obtained and analyzed the data instead of relying the published material, which was only analyzed using an ANOVA. This reviewer has the data and would be happy to provide to USEPA.	
521	EPA-HQ-OW-2004-0019-0315-A1; USGS - Comment submitted by Theresa S. Presser and Samuel N. Luoma, National Research Program, U.S. Geological Survey, Western Branch, Menlo Park, CA; Posted 7/15/2014 Thank you for the opportunity to comment. The USGS looks forward to receiving your responses. Given the length and complexity of the material in the DCD and the brief amount of time given for comment, you may have questions. If you wish to follow-up with the USGS concerning our comments, we can schedule future discussions. Previous discussions with the USEPA mentioned other concepts and details for applications of modeling by the USGS that may be helpful to you. Considerable detail is given in a recent USGS publication (Presser, 2013) that applied ecosystem-scale Se modeling to watersheds in southern West Virginia affected by mountaintop coal mining. For further assistance please contact Theresa Presser (tpresser@usgs.gov).	
540	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014 We urge EPA and the peer reviewers to consider the appended report recently completed by the NAMC-SWG, *Selenium Partitioning between Water and Fish Tissue in Freshwater Systems: Development of Water-based Selenium Screening Guidelines*, in the review process. The report contains new information that fills existing data gaps on the translation of tissue-based criteria to water-based selenium screening levels.	
119	EPA-HQ-OW-2004-0019-0353-A1; Mark C. Rigby, Parsons and University of California at Santa Barbara; Posted 8/7/2014 Comments <u>unlikely</u> to affect calculation of numeric criteria On page 18, the USEPA draft document states "Recent research, however, suggests that selenium's role in oxidative stress plays a role in embryo toxicity, whereas selenium substitution for sulfur does not." As pointed out by Kupsco and Schlenk (2014), the "mechanisms behind Se induced teratogenesis and mortality remain unclear. Several studies point to oxidative stress as one mode of action for Se toxicity. However, oxidative stress is most likely only one factor influencing SeMet toxicity. The unfolded protein response (UPR) is a cellular and molecular response to perturbations in endoplasmic reticulum (ER) homeostasis… If the response is unable to attenuate the stress, the UPR will initiate cell death, often in the form of programmed cell death (apoptosis)." They concluded that "multiple adverse outcome pathways [i.e., oxidative stress, UPR, and apoptosis] may be responsible for the developmental toxicity of Se… and these pathways may be time dependent." Thus, the mechanisms behind the developmental toxicity of selenium appear to be far more nuanced that	

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	recognized in USEPA's draft document.	
Comment Category 7.1 – Comments about Inadequate Time for Review and Extension Requests Summary: Commenters expressed a concern that a 30-day comment period was not adequate.		
71	EPA-HQ-OW-2004-0019-0334-A2; Appalachian Mountain Advocates et al.; Posted 7/30/2014 I. EPA Provided Inadequate Time to Provide Detailed, Meaningful Comments on Such a Complex, Lengthy Scientific Document As an initial matter, commenters believe that, from the start, EPA should have provided more time for comments intended to inform external peer review of its Draft Criterion. The originally allotted 30-day comment period did not provide nearly enough time to fully evaluate and develop comprehensive, meaningful comments on a more than 600 page technical document. When presented with documents like EPA's Draft Criterion, citizen groups review the document, apply their own experience and expertise, and also seek input from recognized academic experts in the relevant field. Thirty days is not enough time to fully evaluate a lengthy technical document and solicit the views of experts, whose busy academic calendars leave them limited extra time to perform such outside reviews. When EPA put out a similar proposal regarding selenium in 2004—for which the technical support document was significantly shorter than the present document—the agency provided 120 days for the public to submit their scientific views on the criteria. 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 proposal with such great potential to impact the health of aquatic life and wildlife communities across the country should not be rushed through the public review process. EPA must allow sufficient time for public review and input, particularly because EPA's proposal departs from the long-standing	Regarding the total number of days for public comment, the "External Peer Review Draft 2014" was published May 14, 2014.The comment period was extended until July 28, 2014, for a total of 75 days of public comment. The 2015 draft was released for public comment on July 28, 2015, and public comment was extended until October 30th, for a total of 94 days of public comment. This equals an overall total of 169 days (approximately 5.5 months) of public comment, unprecedented in the EPA's national aquatic life criteria program. EPA is planning to issue a draft technical support documents in response to comments from stakeholders and the public asking EPA to develop information that would assist in application of the selenium criterion. Stakeholders and the public can continue to engage on these issues by participating in the state's process of adopting changes to their selenium criteria. The 304(a) recommendations do not foreclose further public engagement at the state level.

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	practice of using water column-based standards and instead adopts a novel, untested fish tissue-based approach. We appreciate EPA granting an extension of the original 30-day comment period. However, EPA's provision of a very short initial comment period, followed by a 30-day extension that was not granted until the last day of that period, made for a disjointed and inadequate comment process. By not providing the longer comment period from the start, EPA made it difficult for commenters to solicit the views of academic and other experts in the field and include those views in their comments. By waiting until the last day of the original comment period to grant an extension, EPA effectively provided two separate 30-day periods, neither of which provided sufficient time to obtain expert analysis of EPA's proposal. Moreover, commenters believe that, even with the extension granted, the comment period did not provide sufficient time to adequately weigh in on the Draft Criterion's 600 page supporting document. In the future, commenters request that EPA provide at least 120 days for scientific review of such complex, technical proposals.	
391	EPA-HQ-OW-2004-0019-0251-A2; Appalachian Mountain Advocates, Appalachian Voices, Kentuckians for the Commonwealth, Kentucky Waterways Alliance, Ohio Valley Environmental Coalition, Sierra Club, and West Virginia Highlands Conservancy; Posted 05/30/2014 On behalf of Appalachian Mountain Advocates, Appalachian Voices, Kentuckians for the Commonwealth, Kentucky Waterways Alliance, Ohio Valley Environmental Coalition, Sierra Club, and West Virginia Highlands Conservancy, I am requesting that EPA extend by sixty (60) days the deadline to submit public comments on the agency's draft aquatic life ambient water quality criterion for selenium, for which the Notice of Availability was published in the Federal Register on May 14, 2014. Those groups are working expeditiously to gather the comments and views of their members and experts in the scientific community. More time is needed to allow for a full and meaningful review of the large technical document that supports EPA's new draft criterion. To allow for development of comments that will be most helpful to EPA, we request that the deadline for submission of comments be extended from June 13, 2014 to August 12, 2014. Please contact me as soon as possible with any questions or to inform me of the agency's decision.	
392	EPA-HQ-OW-2004-0019-0252-A1; Tennessee Mining Association (TMA); Posted 06/05/2014 The Tennessee Mining Association (TMA) requests a 60 day extension of the comment period for the External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium – Freshwater 2014. The volume and technical nature of the proposed rule requires more analysis than the 30 day comment period provides. As the trade association representing Tennessee's coal industry, including coal miners, mineral owners, mining consultants, equipment suppliers and various other ancillary coal suppliers, TMA has	

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	a substantial interest in the proposed rule. Our members collectively possess academic and technical knowledge that would benefit EPA's stated goal of collecting scientific views on this policy. However, no meaningful analysis can be done in the allotted timeframe. Therefore, we again request a 60 day extension to the comment period.	
393	EPA-HQ-OW-2004-0019-0253-A2; The Colorado Wastewater Utility Council (CWWUC); Posted 06/05/2014 The Colorado Wastewater Utility Council (CWWUC) is a nonprofit organization whose membership is comprised of municipal and quasi municipal entities which provide wastewater treatment for Colorado businesses and home owners. The CVVVVUC's mission is to professionally and responsibly promote environmental protection by supporting legislation and regulations which achieve well-defined environmental benefits while maintaining local flexibility. The CWWUC is writing to urge you to extend the comment period for the Draft Aquatic Life Ambient Water Quality Criterion for Selenium-Freshwater 2014. Our members and consultants find the 30 day deadline quite difficult to meet given the size and complexity of the document, as well as the extensive reference list. Colorado has large portions of the state with underlying selenium rich shales and extensive databases that will allow for an important review of criteria document. The CWWUC requests the comment period be extended to 90 days to allow for a thoughtful and substantive review process. Thank you for your consideration of this request.	
395	EPA-HQ-OW-2004-0019-0255-A2; Idaho Department of Environmental Quality; Posted 06/10/2014 The Idaho Department of Environmental Quality (DEQ) is in the process of reviewing the US Environmental Protection Agency's (EPA) *External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium--Freshwater 2014* published in the *Federal Register* on May 14, 2014 (FR Vol. 79, No. 93, pp. 27601-27604). DEQ requests an extension of the public comment period of at least 30 days due to the length and complexity of the document as well as its high importance to Idaho's longstanding work on a site-specific aquatic life criterion for selenium for selected waters draining the Smoky Canyon Mine in southeast Idaho. DEQ appreciates the opportunity to provide input on this important matter and will submit general and specific comments on this proposal in a subsequent letter.	
397	EPA-HQ-OW-2004-0019-0261-A1; Mountain-Prairie Region, U.S. Fish and Wildlife Service, U.S. Department of Interior; Posted 06/16/2014	

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	The Mountain-Prairie Regional Office of the U.S. Fish and Wildlife Service (Service) has been delegated the lead for reviewing and commenting on the U.S. Environmental Protection Agency's (EPA) recently released *External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium — Freshwater 2014* (79 FR 27601, May 14, 2014). Due to the length and complexity of EPA's selenium technical package we are submitting a request for a 90-day extension of the initial "courtesy" public comment period. As EPA is certainly aware, historically, there have been multiple episodes of well documented selenium poisoning of the fish and wildlife resources that the Service is responsible for holding in trust for the American public. Many of those episodes have occurred in the Mountain-Prairie Region. We understand that the review and comment process for EPA's 2014 selenium package is structured differently than it was in 2004-2005, when the comment period was 120 days for a selenium technical package that was only 300+ pages versus the 600+ pages of the current package, and that unlike 2004-2005 there will be a second public review comment period following an external expert peer review of the proposed selenium criterion. We believe that this new review and comment structure makes it all the more essential that adequate time be allowed for this initial round of public review, because it is only in this round of review that the public, including sister Federal agencies, get the opportunity to "speak" to both EPA and the expert peer reviewers (who will be provided with the initial round of public comments). We believe that EPA will miss an important opportunity to enhance and support the upcoming work of the expert external peer reviewers if less than fully developed public comments are available for the peer reviewers' consideration. We also realize that the extension we are requesting would slightly delay the initiation of the external peer review process, but we also note that the current selenium criterion proposal presents ten years of EPA effort on technical revisions, against which an additional delay of three months must be put into reasonable context. In summary, the Service requests an extension for submission of public comments that would extend the closing date for comments from June 13, 2014, out to September 12, 2014. Without the extension we are requesting, the Service will be unable to provide technically sufficient comments prior to the external expert peer review, the precise time that our comments would be most helpful and least disruptive of EPA's efforts to revise the selenium criterion.	
404	EPA-HQ-OW-2004-0019-0269-A2; The Western Coalition of Arid States (WESTCAS); Posted 06/17/2014 This is to request a 90-day comment period in order to review the External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium referenced above. The current notice allows 30 days for comment from the scientific community. WESTCAS is an association with numbers of more than 100 water agencies, consulting engineering	

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	firms, and law firms located in Arizona, California, Colorado, Idaho, New Mexico, Nevada, Oregon, and Texas. Our mission is to encourage the wise use and development of water resources in our member states where there is little rain in many months and frequently less than 12 inches for the entire year. Considering this reality, our particular focus is working to ensure that Federal water policy and regulations are appropriate and reflect the reality of water resources in the Arid West. Our membership includes large urban water and wastewater agencies that often serve entire regions of their State and do so under the stringent conditions imposed by addressing the needs of growing populations in the midst of *long-term* drought. WESTCAS members believe that a longer period of time is necessary to adequately review the document and associated data. Thirty days is not sufficient for this review. WESTCAS requests that EPA increase the public comment period for an additional 60 days. Thank you for your consideration of our request. Our members are available to meet and/or discuss our ideas at any time during the process in order to provide additional information to assist with development of the final document.	
453	EPA-HQ-OW-2004-0019-0356-A1; Idaho Department of Environmental Quality (DEQ); Posted 09/30/2014 DEQ also requested an extension of the public comment period of at least 30 days on June 5th. Thus Idaho reserves the right to supplement or replace these comments if EPA does in fact grant an extension of the comment period.	
473	EPA-HQ-OW-2004-0019-0249-A1; National Mining Association (NMA), Utility Water Act Group (UWAG) and Fertilizer Institute (TFI).; Posted 05/22/2014 Attached please find a letter from the National Mining Association, Utility Water Act Group and The Fertilizer Institute requesting a 90-day extension of the public comment period for the U.S. Environmental Protection Agency's External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium – Freshwater 2014. Please do not hesitate to contact me with any questions. Thank you for your consideration.	
474	EPA-HQ-OW-2004-0019-0251-A1; Appalachian Mountain Advocates, Appalachian Voices, Kentuckians for the Commonwealth, Kentucky Waterways Alliance, Ohio Valley Environmental Coalition, Sierra Club, and West Virginia Highlands Conservancy; Posted 05/30/2014 Please find attached a request for extension of the public comment period for EPA's draft aquatic life ambient water quality criterion for selenium, Docket No. EPA-HQ-OW- 2004-0019, for which the Notice of Availability was published in the Federal register on May 14, 2014. Please contact me as	

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	soon as possible with any questions or to inform me of EPA's decision.	
475	EPA-HQ-OW-2004-0019-0252; Tennessee Mining Association (TMA); Posted 06/05/2014 Please see attached request for a 60 day extension of the comment period.	
476	EPA-HQ-OW-2004-0019-0253-A1; The Colorado Wastewater Utility Council (CWWUC); Posted 06/05/2014 Please find attached a request for an extension of the comment period for Selenium from the Colorad o Wastewater Utility Council.	
477	EPA-HQ-OW-2004-0019-0261; Mountain-Prairie Region, U.S. Fish and Wildlife Service, U.S. Department of Interior; Posted 06/16/2014 U.S. Fish and Wildlife Service requests a 90-day extension of the pre-peer review comment period	
478	EPA-HQ-OW-2004-0019-0269-A1; The Western Coalition of Arid States (WESTCAS); Posted 06/17/2014 Please see the attached letter from Ed Curley, President, Western Coalition of Arid States (WESTCAS) requesting an extension of the 30-day comment period on the EPA release of the External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium--Freshwater 2014 (EPA-822-P-14-001). Thank you for your attention.	
492	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 We appreciate that the U.S. EPA has provided this opportunity for public review. Based on past experience, Cameco would urge you to ensure that all stakeholder feedback and the associated responses are presented in a transparent manner before the draft criterion document is finalized. We would also encourage continued engagement with groups that are knowledgeable about the science related to selenium, such as the Canadian Industry Selenium Working Group (CISWG) and the North American Metals Council - Selenium Working Group (NAMC-SWG). Finally, in our view, a further opportunity to comment on any revisions made to the criterion document prior to finalization would enhance this process. However, a comment period of at least 60 days is requested to allow for a complete and thorough review of the material associated with the next version of the draft criterion document.	
493	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 In May 2014, the U.S. EPA published a draft document for external peer review outlining the basis for the derivation of a revised water quality criterion for the protection of aquatic life against harmful effects of selenium. The document entitled " *Aquatic Life Ambient Water Quality Criterion for*	

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	Selenium — Freshwater 2014" (the draft criterion document) provides a critical review of data quantifying the toxicity of selenium to aquatic organisms and a basis for a criterion that will ensure protection of population assemblages of fish, amphibians, aquatic invertebrates, and plants (U.S. EPA 2014). The draft criterion document was written in an effort to reflect the latest scientific consensus on the reproductive effects of selenium on aquatic life and their measure in aquatic systems and supersedes all previous national aquatic life criteria for selenium (e.g., 2004 and 2009 draft criteria). The comment period on the draft criterion document was only 30 days. Working within this constrain we developed the following comments. Both general and more specific comments on the draft criterion document are presented here.	
529	EPA-HQ-OW-2004-0019-0341-A1; West Virginia Coal Association (WVCA); Posted 8/5/2014 Conclusion While WVCA has not had sufficient time to develop detailed comments regarding all aspects of the Draft Selenium Criteria, we also have general concern regarding the following additional components of the document:	
388	EPA-HQ-OW-2004-0019-0248-A1; American Petroleum Institute (API); Posted 5/22/2014 The American Petroleum Institute (API) respectfully requests an additional 60 day extension to the External Peer Review Draft Ambient Water Quality Criterion for Selenium — Freshwater 2014 ("Proposed Selenium Water Quality Criteria"). The Proposed Selenium Water Quality Criteria is over 600 pages long, containing detailed technical information about how EPA arrived at its adjustment. The 30-day comment period established by EPA is simply not enough time for API or any other stakeholder to provide meaningful review and comment of this long, dense, and highly technical document. API is a nationwide, non-profit, trade association that represents over 500 members engaged in all aspects of the petroleum and natural gas industry, including exploration, production, refining, marketing, transportation, and distribution of petroleum products. API's member companies own and/or operate permitted facilities located on or near lakes, rivers, streams, ponds, and wetlands. It is paramount to undertake a thorough review of the accuracy of the science and the feasibility of the proposed reductions for at least three reasons. First, EPA's criteria for selenium will affect any numeric water-quality based permit limits for selenium for industrial stormwater runoff as well as discharges to surface waters. Second, it will also cause states to make parallel adjustments to corresponding criteria. Third, it may require the installation of additional intermediate recovery and	

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	wastewater treatment systems. To confirm, API is requesting an extension of 60 days beyond the initial 30 day comment period in order to submit meaningful comments to the record.	
389	EPA-HQ-OW-2004-0019-0249-A2; National Mining Association (NMA), Utility Water Act Group (UWAG) and Fertilizer Institute (TFI).; Posted 5/22/2014 The undersigned organizations request that the public comment period for the U.S. Environmental Protection Agency's (EPA) External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium – Freshwater 2014, be extended 90 days until Friday, Sept. 12, 2014. EPA published the draft criterion for public comment prior to initiating an external peer review so that technical comments received from stakeholders can be considered by the peer review panel during its review process. However, additional time is needed for stakeholders to develop substantive scientific comments on the draft criterion that will provide meaningful information to the peer review panel. Organizations The National Mining Association (NMA) is a national trade association that includes the producers of most of the nation's coal, metals, industrial and agricultural minerals; the manufacturers of mining and mineral processing machinery, equipment and supplies; and the engineering and consulting firms, financial institutions and other firms serving the mining industry. Many NMA members must obtain National Pollutant Discharge Elimination System (NPDES) permits issued pursuant to the Clean Water Act (CWA), and are therefore directly impacted by EPA's 304(a) water quality criteria development. The Utility Water Act Group (UWAG) is a voluntary, *ad hoc,* non-profit, unincorporated group of power companies and three national trade associations of energy companies: the Edison Electric Institute, the National Rural Electric Cooperative Association, and the American Public Power Association. The individual energy companies operate power plants and other facilities that generate, transmit, and distribute over fifty percent of the nation's total generating capacity. UWAG's purpose is to participate on behalf of its members in EPA's rulemakings under the CWA and in litigation arising from those rulemakings. The Fertilizer Institute (TFI) represents the nation's fertilizer industry including producers, importers, retailers, wholesalers and companies that provide services to the fertilizer industry. TFI members provide nutrients that nourish the nation's crops, helping to ensure a stable and reliable food supply. TFI's full-time staff, based in Washington, D.C., serves its members through legislative, educational, technical, economic information and public communication programs.	

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	Request for Extension EPA has spent a decade reviewing and updating the scientific underpinnings of the agency's 2004 draft freshwater criterion. The resulting 637 page document includes not only new toxicity data, but also multiple new implementation concepts that have never previously been proposed. The current 30 day comment period is woefully inadequate for stakeholders to analyze and produce technical comments on 10 years and hundreds of pages of scientific work, particularly as those comments must to be designed to provide meaningful information to a scientific peer review panel. As you are aware, many states 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, the undersigned respectfully request an additional 90 days to review the new draft criterion so that we and other interested parties may have sufficient time to provide meaningful substantive technical comments prior to the initiation of the external peer review process.	
398	EPA-HQ-OW-2004-0019-0264-A1; California State Water Resources Control Board; Posted 06/16/2014 The California State Water Resources Control Board and our nine Regional Water Quality Control Boards (Water Boards) appreciate the opportunity to comment on US Environmental Protections Agency's (U.S. EPA) External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium—Freshwater 2014 (2014 Draft Selenium Criterion), which was just released for public review on Wednesday, May 14, 2014. This revised criterion for selenium has been much anticipated and will likely impact selenium criteria that are being, or have recently been developed in several states (e.g., Utah, Kentucky, West Virginia). As you may be aware, California is also in the process of developing selenium criteria and Total Maximum Daily Loads (TMDLs) for North San Francisco Bay and for the Newport Bay Watershed. Water Board staff are working with U.S. EPA Region 9 staff on these efforts which address the site-specific nature of selenium in different watersheds. In addition, U.S. EPA Region 9 will be revising the California Toxics Rule (CTR) selenium criteria in the next few years, and this effort will be influenced by the national process. Over the last 10 years of development of the revised selenium criterion, U.S. EPA has compiled and assessed a considerable body of science regarding selenium impacts to aquatic resources. We strongly believe that the 30 day review period currently provided is inadequate to allow for a meaningful review of such a large, comprehensive, and scientifically complex proposal. The criteria document alone is 637 pages and includes new data and studies on selenium and also proposes several new implementation concepts for the first time. Any thorough regulatory and scientific review of the proposed criterion will require review and study of some of the thousands of references	

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	provided as well. We therefore respectfully request that U.S. EPA extend the comment period for review of their proposed 2014 Draft Selenium Criterion to 90 days, or September 12, 2014. This will allow time for Water Board staff to complete their review and evaluate how the proposed criterion may impact selenium TMDLs and criteria revision in California. Thank you for your consideration of our request for extending the commenting period for the 2014 Draft Selenium Criterion. If you have any questions about this request please contact me by email at rik.rasmussen@waterboards.ca.gov or by phone at 916.341.5549.	
399	EPA-HQ-OW-2004-0019-0265-A1; OC Public Works; Posted 06/16/2014 OC Public Works appreciates the opportunity to review and provide comments on the External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium- Freshwater 2014 (2014 Draft Criterion). We support the effort to update the freshwater criterion for selenium to reflect the latest scientific data as many additional research studies have been conducted since the last update in 1992 in the National Taxies Rule. The 2014 Draft Criterion, once finalized, will be used by States to set fish tissue selenium criterion and chronic water column criterion for freshwater receiving waters and consequently to regulate discharges from municipal separate storm sewer systems and in total maximum daily loads. Consequently it is a document of considerable importance with significant future ramifications. The short commenting deadline of June 13, 2014, however, makes it infeasible to adequately review the 2014 Draft Criterion due to the sheer volume of the document itself (637 pages}, large number of references therein (more than 1000), and a criterion matrix (Table 15) that is complex, stringent, and precedent-setting in a number of ways. We request that the commenting deadline be extended for 90 days, or to September 12, 2014, to allow for a thorough review of the document and related information. Thank you for your consideration of our request for extending the commenting period for the 2014 Draft Criterion. Please contact Chris Crompton at (714) 955-0630 if you have any questions.	
482	EPA-HQ-OW-2004-0019-0275-A1; Institute for Fisheries Resources; Posted 6/18/2014 Finally we urge USEPA to extend the comment period. Thirty days to review 600 pages of highly technical information is insufficient. Failing to provide sufficient time to review especially the scientific basis of the proposed standards will result in future unacceptable delays as states and other agencies attempt to comply and meet the requirements of the Endangered Species Act, Fish and Wildlife Coordination Act, Migratory Bird Treaty Act and Tribal fishing rights.	

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528	EPA-HQ-OW-2004-0019-0341-A1; West Virginia Coal Association (WVCA); Posted 8/5/2014 WVCA has concerns with a number of components of the Draft Selenium Criteria. However, WVCA is most troubled by the limited time provided for public comment regarding the Draft Selenium Criteria. US EPA only provided thirty (30) days for this public comment period, even though the file for the Draft Selenium Criteria is 637 pages long. While WVCA understands that additional opportunities for comment may be provided in the future, the most effective time to offer comments on the overall procedure and decision rationale is during the current comment period. According to the Federal Register, once this public comment period is complete, EPA will initiate an independent expert external peer review of the draft criterion document. Public comments will be made available to the peer reviewers for consideration during their review. WVCA believes that the peer reviewers should have the full benefit of timely, well prepared technical comments from the public. This is difficult to complete within a narrow thirty-day period. Specifically, the methodology utilized in calculating the Draft Selenium Criteria 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 are concerned regarding the calculation methodology, particularly for converting the egg/ovary criteria to water column numbers. The draft body burden numbers are based on Genus Mean Chronic Values (GMCVs) calculated from an extensive database, and the inclusion or exclusion of a specific study can materially affect the calculated selenium criteria. Adequate time has not been provided to review these studies. EPA's refusal to extend the public comment period to allow time for meaningful input indicates that the technical opinions of the public are not valued by the agency. Accordingly, WVCA offers these comments based on the limited review that could be completed prior to the expiration of the comment period. WVCA reserves the right to offer more detailed technical comments during the public comment period on the final draft selenium criteria to be published after the peer review.	
497	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 The next review period should be 60 days to allow for a complete and thorough review of the documents associated with the selenium criterion document.	
505	EPA-HQ-OW-2004-0019-0270-A2; Cameco Resources; Posted 6/17/2014 A comment period of at least 60 days is requested to allow for a complete and thorough review of the material associated with the next draft criterion document for selenium.	
533	EPA-HQ-OW-2004-0019-0293-A2; Pennsylvania Department of Environmental Protection;	

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	Posted 6/26/2014 The concepts and methodologies used by EPA to develop, and recommendations on how this multi-medium based criterion are to be implemented are relatively new. The projected timeline provided in the current notice of External Peer Review indicates EPA plans to revise the draft selenium criterion based on comments received during this External Peer Review and those received during a subsequent independent, contractor-led, external peer review. Once revised, EPA will publish another Federal Register notice announcing the availability of the draft proposed selenium criterion, and solicit scientific views for 30 days from the public. DEP recommends additional time should be allotted for review of technical documents and modeling concepts, and response to comments received during these peer reviews that were used to determine the draft proposed national selenium criterion; at a minimum 60 days, as is typical of other proposed criteria.	
535	EPA-HQ-OW-2004-0019-0320-A2; National Mining Association (NMA) and GEI Consultants, Inc. (GEI); Posted 7/29/2014 On behalf of the National Mining Association (NMA), GEI Consultants, Inc. (GEI) provided a review of the EPA 2014 draft selenium (Se) criteria document (EPA 2014), which was submitted to the EPA Docket ID No. EPA-HQ-OW-2004-0019 on June 13, 2014, the original submittal deadline. A comment extension notice was subsequently posted in the Federal Register June 26, 2014 (79 FR 36316, FRL-9912-94-OW) and the public comment re-opened, with a new deadline for comments extended to July 28, 2014. Although NMA submitted the original comments on June 13, it was acknowledged that if further information or analysis led to additional recommendations, a supplemental document would be prepared. This document is intended to supplement the analysis originally submitted by NMA and provide further comments and recommendations, as well as reiterate some of the initial points made in our prior review.	
544	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014 Finally, while we thank EPA for the extension of the 30-day public comment period to 60 days, we note that this extension came only hours before the original deadline for public comment and several weeks after we had been told that no extension was possible. We respectfully request that the planned second public comment time period be extended *a priori* to at least 60 days to allow adequate time for public review and comment.	
545	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014 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	

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	Agency's (EPA) May 14, 2014, request for public comment on a draft updated national recommended aquatic life criterion for the pollutant selenium.[1] We understand that there will be a second 30-day opportunity to comment on the draft criterion, following the external peer review, and that this second comment period on the Draft Selenium Criterion Document is planned for late 2014. NAMC intends to provide comments during this second opportunity. We respectfully request that this second public review comment period be extended to 60 days ahead of time. If this first opportunity for comment had been longer from the start, as requested by several organizations, including NAMC, we would likely have had additional comments. We thank EPA for the opportunity to provide the comments below. We applaud this approach and we look forward to the eventual adoption of a technically defensible selenium aquatic life criterion that is appropriately, but not unnecessarily protective. [1] EPA Office of Water, Office Science and Technology, "External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium – Freshwater 2014" (May 2014) (Draft Selenium Criterion Document).	
549	EPA-HQ-OW-2004-0019-0326-A1; Utility Water Act Group (UWAG); Posted 7/30/2014 The Utility Water Act Group (UWAG)[1] appreciates the opportunity to comment on the U.S. Environmental Protection Agency's (EPA or Agency) *External Peer Review Draft Aquatic Life Ambient Water Quality Criterion for Selenium - Freshwater 2014* ("Draft Report"). EPA solicited comments on the Draft by providing notice of a thirty-day public comment period, from May 14 to June 13, 2014. 79 Fed. Reg. 27,601 (May 14, 2014). UWAG submitted a joint letter, with the National Mining Association and The Fertilizer Institute, requesting that the Agency extend the public comment period an additional 90 days. Letter from Robert Wylie, UWAG Water Quality Chair (May 19, 2014). On June 13, 2014, EPA announced that it would extend the deadline by an additional thirty days to July 28, 2014. Email from Kathryn Gallagher, U.S. EPA, announcing extension of comment deadline by 30 days, June 13, 2014; 79 Fed. Reg. 36316 (June 16, 2014). UWAG appreciates the opportunity to provide comments early in the process to help inform the external peer review. We look forward to providing additional comments as future opportunities arise. [1] UWAG is a voluntary, ad hoc, non-profit, unincorporated group of 191 individual energy companies and three national trade associations of energy companies: the Edison Electric Institute, the National Rural Electric Cooperative Association, and the American Public Power Association. The individual energy companies operate power plants and other facilities that generate, transmit, and distribute electricity to residential, commercial, industrial, and institutional customers. The Edison Electric Institute is the association of U.S. shareholder owned energy companies, international affiliates, and	

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	industry associates. The National Rural Electric Cooperative Association is the association of nonprofit energy cooperatives supplying central station service through generation, transmission, and distribution of electricity to rural areas of the United States. The American Public Power Association is the national trade association that represents publicly-owned (units of state and local government) energy utilities in 49 states representing 16 percent of the market. UWAG's purpose is to participate on behalf of its members in EPA's rulemakings under the CWA and in litigation arising from those rulemakings.	
585	EPA-HQ-OW-2004-0019-0256-A1 [Comment 0346-A2 is a duplicate of 0256-A1]; Peabody Energy Corporation; Posted 06/16/2014 The 30-day comment period allowed for this rule is insufficient time for a detailed review of the 637 page draft selenium criterion document, thus many of the following comments are general in nature. Overall Peabody agrees with EPA that using a fish tissue criterion is more scientifically valid than previous criterion that imposed water column concentrations. However, the following comments identify some overarching concerns with the criterion as proposed.	
591	EPA-HQ-OW-2004-0019-0354-A2 [Comment 0355-A2 is a duplicate of 0354-A2]; Fish and Wildlife Service, Paul Souza; Posted 08/07/2014 The Service also thanks EPA for taking into consideration the many requests from interested parties for an extension of this initial public comment period. EPA's subsequent granting of a 30-day extension has enabled us to provide more complete initial comments than otherwise would have been possible. Given the length and complexity of the DSP we have not prepared detailed presentations for all of the technical issues warranting substantive analysis. All of the potential technical issues that we have identified to date will be listed in the enclosure, and a subset of the currently identified issues is presented in more detail at this time. Our intent is to continue to develop more detailed analyses for another subset of the identified issues in time for submission during EPA's planned second public comment period. We hope that both of our planned comment submissions, in aggregate, will prove helpful to EPA as the DSP is eventually revised into a final proposal that is as technically sound as possible.	
Comment Category 8.1 – References		
488	EPA-HQ-OW-2004-0019-0343-A2; Kentucky Division of Water; Posted 8/5/2014 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.	The references and new information provided in public comments received in 2014 and 2015 were re-evaluated and included as appropriate The complete list of citations used in the 2016 final criteria document is located in Section 7 of that document.

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598	EPA-HQ-OW-2004-0019-0315-A1; Comment submitted by Theresa S. Presser and Samuel N. Luoma, National Research Program, U.S. Geological Survey, Western Branch, Menlo Park, CA; Posted 07/15/2014 References Modeling basis, approach, and site-specific application Luoma, S.N., and Presser, T.S., 2000, Forecasting selenium discharges to the San Francisco Bay-	

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Comment Category 8.2 – Additional Data Summary: Several commenters provided EPA additional data for consideration in updating selenium criterion documentation.		
483	EPA-HQ-OW-2004-0019-0275-A2; Institute for Fisheries Resources; Posted 6/18/2014 Original letter contains additional information in the form of an attachment entitled, Technical Issues Affecting the Implementation of US Environmental Protection Agency's Proposed Fish Tissue-Based Aquatic Criterion for Selenium. See original letter.	Regarding consideration of additional data, EPA has acquired new data through the peer review and the 2014 and 2015 public processes and has evaluated and included these data, as appropriate, in the derivation of the final criterion as presented in the 2016 final criteria document.
484	EPA-HQ-OW-2004-0019-0275-A3; Institute for Fisheries Resources; Posted 6/18/2014 Original letter contains additional information in the form of an attachment entitled, EPA's Draft Tissue-Based Selenium Criterion: A Technical Review. See original letter.	
548	EPA-HQ-OW-2004-0019-0325-A1; North American Metals Council (NAMC); Posted 7/30/2014 Original letter contains additional information in the form of an attachment entitled De Forest et al. (2014). See original letter.	
583	EPA-HQ-OW-2004-0019-0349-A2 [Comments 0274-A3 and 0327-A3 are duplicates of 0349-A2]; GEI Consultants Review for CWWUC; Posted 8/5/2014 Original letter contains additional information in the form of an appendix entitled Supplemental Data. See original letter.	