UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8
1595 Wynkoop Street
DENVER, CO 80202-1129
Phone 800-227-8917
http://www.epa.gov/region08

Ref: 8EPR-EP 12/12/11

Amanda Smith
Executive Director
Utah Department of Environmental Quality
195 North 1950 West, 4th Floor
P.O. Box 144810
Salt Lake City, Utah 84114-4810

RE: EPA Action on the Gilbert Bay Selenium Criterion and Footnote (14)

Dear Ms. Smith:

The U.S. Environmental Protection Agency has completed its review of the Gilbert Bay selenium criterion and associated Footnote (14) that were adopted by the Utah Water Quality Board (Board) on November 10, 2008 and submitted to the EPA for review with a letter dated April 8, 2009. A letter from the Office of the Attorney General, certifying that the revisions were adopted pursuant to State law, was enclosed with the submittal letter. Receipt of the revisions on April 29, 2009 initiated the EPA's review pursuant to Section 303(c) of the Clean Water Act (CWA or the Act) and the water quality standards regulation. The EPA acted on many of the revisions in a letter dated September 30, 2009. The EPA has now completed its review of the remaining revisions, including the Gilbert Bay selenium criterion and associated Footnote (14). This letter is to notify you of our action.

We commend the Department of Environmental Quality (DEQ) and the Division of Water Quality (Division) for their excellent collaboration with stakeholders when developing the Gilbert Bay selenium criterion. Several years of collaboration efforts including the development of a Steering Committee and expert Science Panel produced an egg tissue-based selenium criterion protective of aquatic dependent birds that nest in Gilbert Bay. This criterion is the first numeric criterion adopted for the Great Salt Lake. We thank the DEQ and Division for their commitment to protecting birds that utilize Gilbert Bay and for the considerable effort that was put into the development of the new and revised water quality standards.

CLEAN WATER ACT REVIEW REQUIREMENTS

CWA § 303(c)(2) requires States and authorized Indian Tribes[1] to submit new or revised water quality standards to the EPA for review. The EPA is to review and approve or disapprove the submitted standards. Pursuant to CWA § 303(c)(3), if the EPA determines that any standard is not consistent with the applicable requirements of the Act, the agency shall notify the State or authorized Tribe and specify the changes to meet the requirements. If such changes are not adopted by the State or authorized Tribe, the EPA shall promulgate the needed standard pursuant to CWA § 303(c)(4). The EPA's goal has been, and will continue to be, to work closely with States and authorized Tribes throughout the standards revision process as a means to develop approvable water quality standards revisions.

TODAY'S ACTION

Today, the EPA is approving the Gilbert Bay selenium criterion and taking no action on the remaining provisions in the associated Footnote (14).[2] Enclosure 1 presents the rationale for the EPA's action.

ENDANGERED SPECIES ACT REQUIREMENTS

Section 7(a)(2) of the Endangered Species Act (ESA) requires federal agencies, in consultation with the U.S. Fish and Wildlife Service and/or the National Oceanic and Atmospheric Administration Fisheries Service (Services), to ensure that actions they authorize, fund, or carry out are not likely to jeopardize the continued existence of federally listed endangered or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. 16 U.S.C. § 1536 (a)(2). However, consultation with the Services is not required where the action has no effect on listed species or designated critical habitat. 50 CFR § 402.14. Because there is no occurrence of listed species or critical habitat for listed species in Gilbert Bay, the EPA concludes that its approval of Utah's Gilbert Bay selenium criterion has no effect on listed species or designated critical habitat.

---

[1] CWA Section 518(e) specifically authorizes the EPA to treat eligible Indian Tribes in the same manner as States for purposes of CWA Section 303. See also 40 CFR Section 131.8.

[2] The EPA disapproved the 6.4 mg/kg trigger value in its September 30, 2009 action letter. The remaining provisions in Footnote (14) do not alter the magnitude, duration, or frequency of the criterion or any of the provisions that constitute the water quality standards for Gilbert Bay, or are otherwise not revisions requiring a CWA § 303(c) action.

CONCLUSION

The EPA thanks DEQ, the Board, and the Division for their efforts to review and revise Utah's water quality standards. The EPA looks forward to working with the State to make additional improvements to the water quality standards that apply to the Great Salt Lake ecosystem. If you have any questions concerning this letter, contact Lareina Guenzel on my staff at 303-312-6610.

Sincerely,

Carol L. Campbell

Carol L. Campbell
Assistant Regional Administrator
Office of Ecosystems Protection
and Remediation

Enclosure

cc: Walt Baker, Director, Division of Water Quality

Enclosure 1

RATIONALE FOR THE EPA'S ACTION ON THE REVISIONS TO UTAH WATER QUALITY STANDARDS

Today's EPA action letter addresses the new Gilbert Bay selenium criterion adopted into Utah's water quality standards by the Water Quality Board (Board) on November 10, 2008. This enclosure identifies the new selenium criterion as well as the EPA's rationale for approving the criterion for the purposes of Clean Water Act (CWA) §303(c). The enclosure also acknowledges certain portions of Footnote (14) upon which the EPA is taking no action.

Gilbert Bay Selenium Criterion and Associated Footnote (14)

The Board adopted a selenium criterion of 12.5 mg/kg dry weight in bird egg tissue that is a geometric mean over the nesting season to be applied to Gilbert Bay of the Great Salt Lake (GSL). The Board also adopted Footnote (14) which states:

> *The selenium water quality standard of 12.5 (mg/kg dry weight) for Gilbert Bay is a tissue based standard using the complete egg/embryo of aquatic dependent birds using Gilbert Bay based upon a minimum of five samples over the nesting season. Assessment procedures are incorporated as a part of this standard as follows:*
>
> *Egg Concentration Triggers: DWQ Responses*
>
> *Below 5.0 mg/kg: Routine monitoring with sufficient intensity to determine if selenium concentrations within the Great Salt Lake ecosystem are increasing.*
>
> *5.0 mg/kg: Increased monitoring to address data gaps, loadings, and areas of uncertainty identified from initial Great Salt Lake selenium studies.*
>
> *6.4 mg/kg: Initiation of a Level II Antidegradation review by the State for all discharge permit renewals or new discharge permits to Great Salt Lake. The Level II Antidegradation review may include an analysis of loading reductions.*
>
> *9.8 mg/kg: Initiation of preliminary TMDL studies to evaluate selenium loading sources.*
>
> *12.5 mg/kg and above: Declare impairment. Formalize and implement TMDL.*
>
> *Antidegradation*
> *Level II Review procedures associated with this standard are referenced at R317-2-3.5.C.*

On September 30, 2009, the EPA Region 8 identified the portion of Footnote (14) dealing with the 6.4 mg/kg trigger value (i.e., the text from "6.4 mg/kg" to "an analysis of loading reductions") as a new water quality standard. The EPA disapproved that portion of Footnote (14) because it would not adequately maintain and protect assimilative capacity for selenium in the eggs of aquatic dependent birds using

Gilbert Bay. In this enclosure, the EPA acknowledges the remaining portions of Footnote (14), but takes no action upon them as they are not new or revised water quality standards.

Background

The Utah Division of Water Quality (UDWQ) established a multi-tiered review process to aid in the development of the Gilbert Bay selenium criterion. This process included the organization of a Steering Committee, Science Panel, and public involvement program that provided guidance, technical expertise and perspectives from a broad range of interests. The Steering Committee was composed of a wide range of stakeholders and included one or more representatives from the Utah Department of Natural Resources, EPA Region 8, U.S. Fish and Wildlife Service (FWS), U.S. Geological Survey (USGS), Utah Artemia Association, various industries that discharge to the GSL, GSL Alliance, University of Utah, the Nature Conservancy, West Side Associated Duck Clubs, and the Utah Department of Environmental Quality. The Science Panel was formed by the Steering Committee to provide technical guidance, oversight, and a review of the required research necessary to develop the criterion. The Science Panel was also tasked with providing recommendations to the Steering Committee on what would be considered a protective selenium criterion for Gilbert Bay of the GSL. Finally, the public involvement program included a number of stakeholder workgroup meetings, the development of a website, poster sessions, and public participation in the water quality standards hearing process. The EPA commends UDWQ and the Board for their commitment to the protection of wildlife as well as their signification public participation efforts that went beyond the 131.20(b) public participation requirements.

Multiple original research projects were organized by the Steering Committee and Science Panel to support the development of the Gilbert Bay selenium criterion. One example is a study that focused on analytical methods for measuring selenium in water samples collected from the GSL. Data collected from earlier studies showed high variability in water column selenium concentrations. Results from the recent study indicate that much of the variability in the historic data was due to interferences caused by the high salinity, total dissolved solids (TDS), and alkalinity of GSL water when analyzed using inappropriate methods, rather than actual variability of selenium in the water column. Furthermore, a round-robin laboratory study concluded that only two methods (hydride generation atomic absorption and graphite furnace atomic absorption) produce relatively consistent and accurate results. Therefore, only selenium data generated with these two methods were considered acceptable for use in the criteria development.

Additional studies focused on a conceptual model of selenium cycling in the GSL. Development of a conceptual model was necessary to answer questions concerning the sources, fate, transport, and trophic transfer of selenium in the GSL. The model developed in this effort focused on five components including: (1) selenium in the upper food chain; (2) selenium in the lower food chain; (3) selenium in the shallow layer of the lake; (4) selenium in the deep layer and sediment of the lake; and (5) selenium loading to the lake. Although the version of the model available when the standard was adopted was still considered preliminary, it provided information on how selenium cycles in the GSL and was taken into consideration by the Steering Committee and Science Panel when making criteria recommendations to the Board.

Several scientific studies were conducted to answer questions on the current concentration of selenium in shorebirds and potential effects of selenium on shorebirds of the GSL. These studies focused on bird species that actively feed and nest on the GSL including American avocet, black-necked stilt, California gull, eared grebe, and common goldeneye. Data collected included selenium concentrations in adult blood and liver, food chain invertebrates, water column, and bird eggs, as well as multiple parameters that evaluate the reproductive success of shorebirds (see Appendix C and D of the Final GSL Selenium report). [1] Study results showed egg selenium concentrations of birds utilizing the GSL were relatively low. Concentration of selenium in American avocets and black-necked stilt eggs ranged from 1.2 to 9.2 mg/kg, with a mean of 2.7 mg/kg. Concentration of selenium in California gull eggs ranged from 2.0 to 4.3 mg/kg, with a mean of 2.9 mg/kg. The average concentrations are within the range of concentrations that are considered background (Ohlendorf 2003).

Results from the reproductive success studies confirm that the existing low concentration of selenium in shorebird eggs is not affecting bird populations utilizing Gilbert Bay. Hatchability of American avocet and black–necked stilt eggs ranged from 94-100%.[2] These hatching success rates are within the range of conditions expected to be observed at non-contaminated sites. Additional results showed that in American avocet eggs, selenium concentrations of nests with 100% hatchability were not significantly different from nests with lower hatchability. Finally, of the 142 eggs that were dissected and observed for deformities, no malformations were observed and only one American Avocet egg had a possible Type I malposition.[3]

Finally, the Science Panel was tasked with developing toxicity thresholds for birds that utilize the GSL. To accomplish this task, the panel considered the sensitivity of multiple aquatic-dependent birds and endpoints protective of reproductive success and body condition. Species that were evaluated included, but were not limited to, the American avocet, black-necked stilt, California gull, and mallard duck. From these reviews, it was determined that selenium-related impairment of the open waters of the GSL should be defined by the most sensitive endpoint of the most sensitive species. This resulted in the development of a criterion to protect the hatching success of the mallard duck.

Details on the specific duties and objectives of the Steering Committee and Science Panel, as well as final reports and criteria recommendations are included in the Final GSL Selenium report available on UDWQ's website.

Criteria Development

CWA § 101(a)(2) establishes as a national goal the achievement of water quality that provides for the protection and propagation of fish, shellfish, and wildlife and recreation in and on the water. CWA § 304(a)(1) requires the Administrator to develop and publish criteria for water quality that accurately reflect the latest scientific knowledge on the (1) kind and extent of all identifiable effects on health and welfare including, but not limited to wildlife, that may be expected from the presence of pollutants in any body of water; (2) concentration and dispersal of pollutants through biological, physical and chemical processes; and (3) effects of pollutants on biological diversity, productivity, and stability.

The EPA does not have national guidance for deriving wildlife criteria. Therefore, the agency has not formally addressed endpoints necessary to protect wildlife on a national level. However, the Agency has taken a position on the level of protection for wildlife criteria as part of the Great Lakes Initiative (40

[1] Great Salt Lake Water Quality Studies. Development of a Selenium Standard for the Open Waters of Great Salt Lake. Final Report May 2008. Prepared by CH2MHILL for the State of Utah Department of Environmental Quality, Division of Water Quality. http://www.deq.utah.gov/Issues/GSL_WQSC/docs/GLS_Selenium_Standards/index.htm

[2] Hatchability was calculated as the #eggs hatched/# full term eggs in nest.

[3] Malposition was classified according to Romanoff and Romanoff 1972. Type I malposition is when the head is between the thighs, when the head under the right wing is considered normal.

CFR § 132 Appendix D). In this effort, the agency used the no observed effect concentration (NOEC)[4] in diet to calculate tissue-based wildlife criteria for DDT, mercury, PCBs and 2,3,7,8-TCDD. The final avian wildlife value was calculated as the geometric mean of the kingfisher, gull, and eagle species-specific thresholds (EPA/820/B-95/008). Utah adopted a wildlife criterion for selenium using a methodology that fit toxicological data from six laboratory studies to a mathematical equation and then determined the concentration that would correspond to a hypothetical 10% adverse effect (EC_{10}) for the most sensitive species. The resulting criterion is not significantly distinguishable from a criterion concentration derived from the same data using the NOEC concentration (see below). EC_{10}s and NOECs are generally of similar magnitude, but EC_{10}s have the advantage of being more reproducible and reliable than NOECs, and are generally recommended as the replacement for NOECs (Crane and Newman 2000; Van der Hoeven 1997; Warne and van Dam 2008). Overall, use of an EC_{10} for wildlife criteria is generally less than or equivalent in magnitude to a NOEC, but more reliable than a NOEC and therefore is considered consistent with previous approaches approved by the EPA.

Derivation of the Selenium Criterion

The Gilbert Bay criterion was derived from a regression meta-analysis of six different laboratory studies that evaluated the effect of selenium on mallard egg hatchability (Heinz et al. 1987, 1989; Heinz and Hoffman 1996, 1998; Stanley et al. 1994, 1996). Having determined that mallards are the most sensitive known species, a logistic curve was fitted to the combined, control normalized data from the six mallard studies. The logistic curve was used to estimate the egg selenium concentration that corresponds to an EC_{10} for mallard egg hatchability (Figure 1). This value was thereby found to be 12.5 mg/kg.

Six of the nine Science Panel Members recommended adoption of the 12.5 mg/kg dry weight in bird egg tissue criterion to the Board.[5] The Science Panel Members that recommended adoption of the 12.5 mg/kg criterion indicated that setting the Gilbert Bay criterion to the mallard EC_{10} is an appropriately conservative site-specific criterion since: the mallard duck is the most sensitive bird species tested to date; egg hatchability is the most sensitive endpoint; and the mallard duck is more sensitive to the effects of selenium than aquatic dependent birds that commonly feed and nest at Gilbert Bay (e.g., black-necked stilt).[6] Based on these recommendations, recommendations from the Steering Committee, and public comments, the Board adopted 12.5 mg/kg as the criterion for Gilbert Bay.

[4]A NOEC is the highest tested concentration that did not yield an effect that is statistically significantly different from the control. The detectability of an effect depends on the quality and size of the experiment and the statistical procedure.
[5]One Science Panel Member recommended adoption of a no effect concentration of 5.0 mg/kg, another Science Panel member recommended adoption of 10.4 mg/kg, and another Science Panel member abstained from making a recommendation.
[6]When reviewing the Gilbert Bay criterion, the EPA also evaluated the sensitivity of the black-necked stilt to selenium. An extensive field dataset (n = 673 nests) has revealed that egg hatchability is also the most sensitive endpoint for black-necked stilt. Similar to the mallard duck, the EC_{10} values for stilt are sensitive to the method by which the data are organized and the model used to fit the data. When using a triangular tolerance distribution analysis, the median EC_{10} 14.6 mg/kg when data are grouped into 10 bins. The stilt egg counting was conducted on a nest-wise or hen-wise basis (n = number of nests with typically 4 eggs per nest) rather than an egg-wise basis (n = number of eggs), which was used for the mallard duck studies. These counting methods are not directly equivalent, with the nest-wise approach typically producing more conservative results.

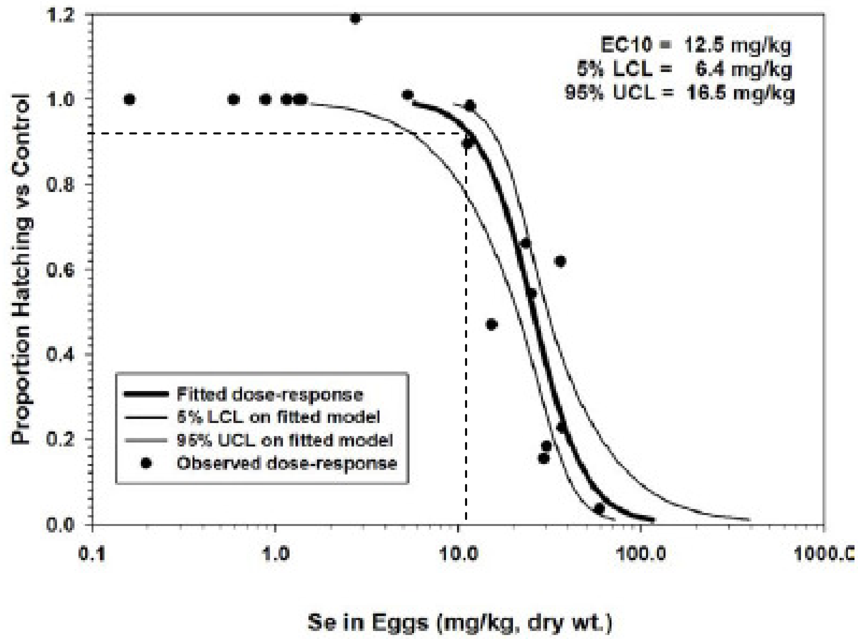

Figure 1: Mallard egg hatchability as a function of selenium concentration in eggs. Figure modified from Ohlendorf (2003). Dashed line identifies the 10 percent effect concentration (EC_{10}). The data were normalized to their respective control hatchability values. LCL = lower confidence limit. UCL = upper confidence limit.

The EPA closely examined the logistic curve model used to derive the 12.5 mg/kg EC_{10}. Using the data from the six mallard studies, the EPA performed an independent evaluation, fitting the data using a variety of different approaches. In its analysis, the EPA eliminated certain treatments from the Stanley et al. (1994) study because they were potentially confounded by arsenic exposure, which was part of the study design. Removal of these data, however, did not have a significant influence on the final results.

Some authors suggest that control normalization is inappropriate because control responses also contain variability. Normalizing for control response effectively removes this estimation error from the control values (OECD 2006). To address this concern, the EPA also analyzed the six-study data set without normalizing for control hatchability. Using a triangular tolerance distribution analysis, the EPA obtained an EC_{10} of 12.3 mg/kg, which is within 2% of the Gilbert Bay criterion of 12.5 mg/kg. The fit is shown in Figure 2. Using a Gaussian tolerance distribution analysis, which is more similar to the analysis performed by Ohlendorf (2003), the EPA obtained an EC_{10} of 12.0 mg/kg, which is within 4% of the Gilbert Bay criterion.

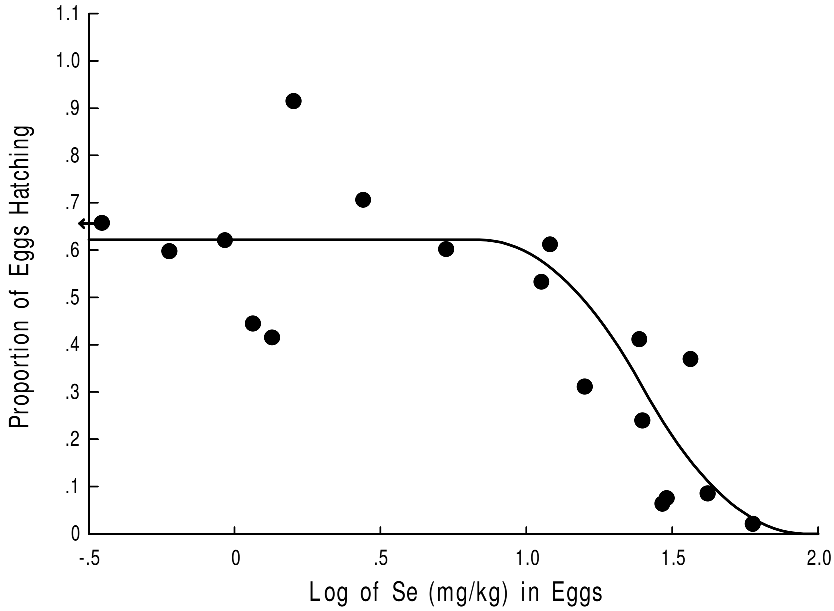

Figure 2. Mallard egg hatchability in the six studies, fitted by triangular tolerance distribution, without normalization to control values.

Additional review of the model included an evaluation of the effect of mixing data from studies having substantial differences in control hatchability. To do this, the EPA excluded the two studies with low (<50%) control hatchability (Heinz and Hoffman 1996, 1998). This produced an EC_{10} of 12.7 mg/kg through the triangular tolerance distribution approach, which is within 2% for the GSL criterion. Thus reducing the range of control hatchability included in the analysis did not have a significant effect on the resulting criterion value.

The EPA also reviewed a logistic nonlinear regression fit to the data. The logistic nonlinear approach yields an EC_{10} of 9.7 mg/kg. Although this estimate of an EC_{10} is different than the Gilbert Bay EC_{10}-based criterion, the EPA can find no scientific basis for concluding that a logistic nonlinear regression fit is more or less appropriate than tolerance distribution fit described in the previous paragraph. In the absence of any meaningful scientific justification to prefer the one approach over the other, the different values derived from the application of these two models to the same data are equally scientifically defensible.

Protectiveness of the Adopted Criterion

Gilbert Bay is a Class 5A waterbody which includes protection of the following designated uses: frequent primary and secondary contact recreation, waterfowl, shorebirds and other water-oriented wildlife including their necessary food chain. Based on the scientific literature and available information for selenium specific to the GSL, protection of aquatic-dependent birds is the most sensitive use assigned to Gilbert Bay, and reproductive success or egg hatchability is the critical endpoint to be used in the selenium criterion that would be protective of that designated use.

The EPA considered multiple lines of evidence to determine if the adopted selenium criterion is protective of designated uses and approvable under the CWA and the EPA's implementing regulation at 40 CFR § 131.6. One line of evidence considered by the EPA was an evaluation of effects of selenium in egg tissue below the criterion of 12.5 mg/kg. Figure 3 shows the percent hatch in the six control treatments, one for each of six studies, and the selenium exposed treatments from those studies. The 12.5 mg/kg criterion is represented by the vertical line. Hatchability at all treatment concentrations less than 12.5 mg/kg are within the range of the controls and the lower 95% confidence range of the control mean, which is shown by the lower horizontal dashed line. By contrast, all treatment concentrations greater than the criterion yielded hatchability below the lower confidence bound for the control mean and below the hatchability of any control. These data suggest that the expected hatchability associated with the EC_{10}-based criterion of 12.5 mg/kg would be within the variability of background (control) responses, and that selenium concentrations up to the proposed criterion would not lead to additional reductions in hatchability beyond natural conditions.

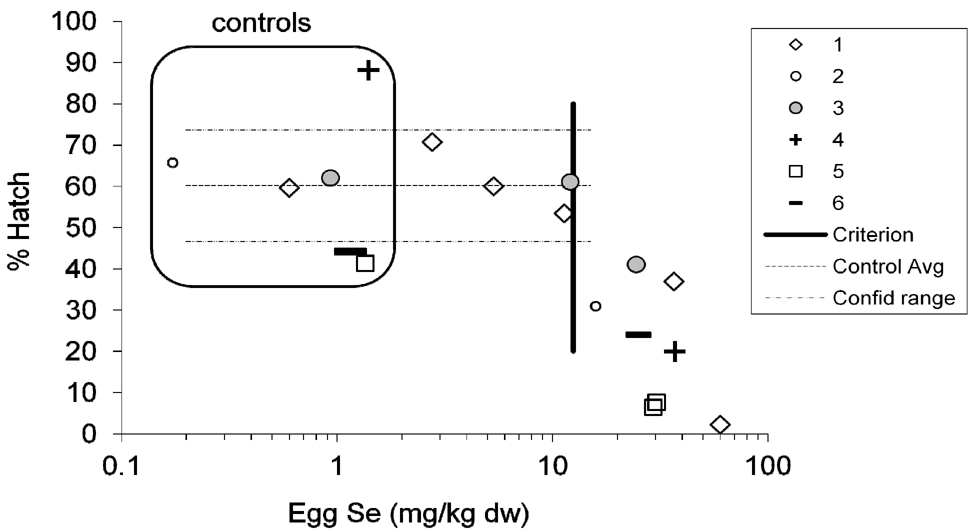

Figure 3: Mallard percent hatch v. egg concentration for six studies. Raw data without normalization to control values. 1 = Heinz et al. (1989); 2 = Heinz et al (1987); 3 = Stanley et al. (1996); 4 = Stanley et al. (1994); 5 = Heinz and Hoffman (1996); 6 = Heinz and Hoffman (1998).

Another line of evidence the EPA considered is a comparison of the Gilbert Bay selenium criterion to the NOECs and the lowest observed effect concentrations (LOECs)[7] of the six individual studies used to derive the dose response curve presented in Figure 1. NOECs and LOECs can only be a measured treatment concentrations, not interpolations, and therefore are strongly influenced by the number of selenium treatments. Use of the NOECs and LOECs alone is not a preferred method to analyze the available data (Van der Hoeven 1997; Warne and van Dam 2008), especially given the low number of selenium treatments for the majority of the tests; however, it is useful to recognize that the adopted criterion is less than the NOECs for three of the four studies for which a NOEC can be derived (Table 1). In the one study (Stanley et al. 1996) where the NOEC is less than 12.5 mg/kg, the NOEC is within the confidence limits of the EC_{10} (5% LCL = 6.4 mg/kg; 95% UCL = 16.5 mg/kg; see Figure 1). Overall, these data are not inconsistent with the concept that an EC_{10}-based criterion is protective of aquatic dependent birds utilizing Gilbert Bay.

[7] LOEC is the highest tested concentration that yielded an effect that is statistically significantly different from the control.

Table 1: NOEC and LOEC (mg/kg) for six studies evaluating egg hatchability in mallard duck. * Number of Se treatments excludes the control. The two Heinz and Hoffman (1996) treatments were fed the same selenium dose but differed in the form of selenium (seleno-DL-methionine vs. seleno-L-methionine). Differences between the two treatments were not statistically significant.

Study	#Se treatments*	NOEC	LOEC
Heinz et al. 1989	5	36.3	59.4
Stanley et al. 1996	2	11.6	23.4
Heinz et al. 1987	1	>15.2	--
Heinz and Hoffman 1998	1	>25.1	--
Heinz and Hoffman 1996	2	--	<29.4/<30.4
Stanley et al. 1994	1	--	<37

The EPA also considered how the criterion is expressed (i.e., geometric mean over the nesting season) when evaluating the protectiveness of the Gilbert Bay selenium criterion by estimating the site-specific risk associated with the existing selenium in eggs collected from Gilbert Bay. The Society for Risk Analysis (2011) definition of risk is "the potential for realization of unwanted adverse consequences to human life, health, property, or the environment; estimation of risk is usually based on the expected value of the conditional probability of the event occurring times the consequence of the event given that it has occurred." For the Gilbert Bay selenium criterion, the site-specific risk is the combination of the probability of bird eggs having particular concentrations multiplied by the effects predicted to be caused by those concentrations. It is the product of two mathematical curves, one describing the distribution of egg concentrations allowed by the criterion, and the other describing the concentration-response curve from which Utah derived their EC_{10}.

The EPA utilized the egg selenium data presented in the Final GSL Report (Projects 1A and 1B) and a response curve similar to that of Ohlendorf (2003)(see Figure 1) in its analysis. Among the 130 observations, the standard deviation of the natural logs of the egg concentrations is 0.33. (The base 10 log standard deviation is 0.33/ln(10).) In contrast to the arithmetic standard deviation, the log standard deviation is a measure of relative variability, independent of the sample mean or the units of measurement.

The general equation for relating concentrations in the normal (or probit) distribution curve is:

$$\ln x = \mu + \sigma z$$

In this case x is the EC_{10}; μ is $\ln(EC_{50})$; σ is the natural log standard deviation (and reciprocal of the log probit curve slope) and z is the normal deviate (from normal distribution tables or NORMSINV function) corresponding to 10% (for the EC_{10}). Solving for σ yields a log standard deviation of 0.56, the inverse of which is the probit slope.

The probability, p_i, of an individual having concentrations within some range increment $\Delta\ln(C_i)$ is:

$$p_i = \phi_i \, \Delta\ln(C_i)$$

where ϕ_i is the probability density function for the egg-ovary concentration C_i at the midpoint of each increment. (In Excel or Quattro Pro, ϕ is given by NORMDIST, selecting for the density function rather than the cumulative function. This is then multiplied by the increment breadth in natural log units.)

Figure 4 illustrates how the allowed Gilbert Bay egg concentration distribution is combined with the concentration-response curve. The bell-shaped, lognormally skewed probability density function is the allowed Gilbert Bay egg concentrations, having median and geometric mean of 12.5 mg/kg. The S-shaped concentration-response curve defines potential reduction in hatchability. The calculated total predicted potential effect or site-specific risk is the summation $\sum p_i E_i$ for all possible concentrations, C_i. For Gilbert Bay, the summation of these products yields a site-specific risk of 13.5%. Were the Gilbert Bay egg concentrations to have extremely low variability, the bell curve would be a narrow spike at 12.5 mg/kg, and the site-specific risk would be 10%. Higher variability widens the bell curve. Although half the sample concentrations would be below the EC_{10} and half above, the nonlinearity of the S-curve prevents the reduced effects at concentrations <12.5 mg/kg from counterbalancing the increased effects at concentrations >12.5 mg/kg, thus raising the aggregate above 10%.

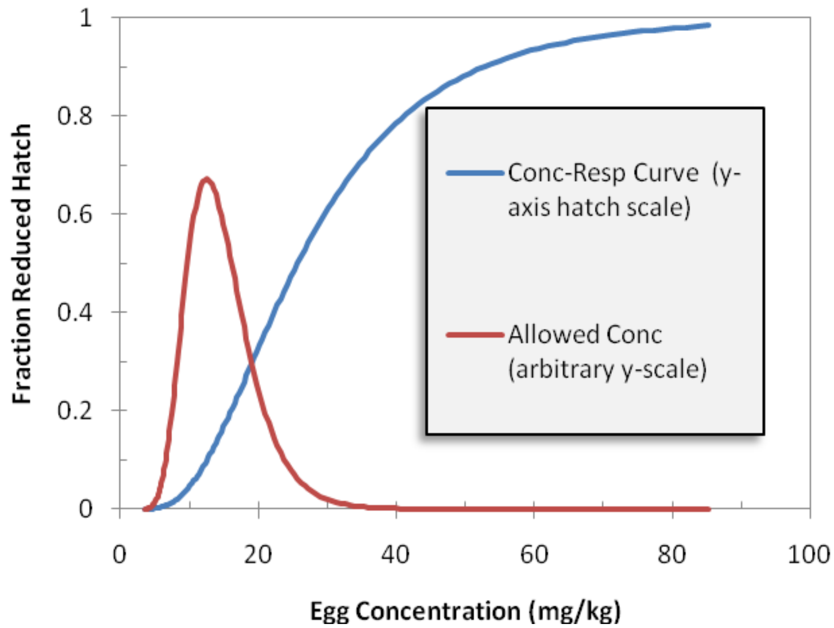

Figure 4. Allowed GSL egg concentrations (with current degree of variability) expressed as a probability density function on an arbitrary y-scale, coupled with a concentration-response curve, expressed as fraction reduced hatch. Plotted on the arithmetic x-axis, both curves are skewed or asymmetric.

To relate the site-specific risk to the protectiveness of the criterion, the EPA determined the egg concentration that would be predicted to yield the potential 13.5% reduction in hatchability using a response curve similar to that of Ohlendorf (2003) and compared this concentration to the raw data for each of the six studies used to develop the curve. The median egg tissue concentration associated with the site-specific risk of 13.5% is 13.8 mg/kg, which is greater than the highest concentration that is within the range of the control variability (12.07 mg/kg), but less than the lowest concentration that exceeds the control variability (15.86 mg/kg)(see Figure 3). A bird egg-tissue concentration of 13.8 mg/kg is also within the 95% confidence limit of the EC_{10} (5% LCL = 6.4 mg/kg; 95% UCL = 16.5 mg/kg; see Figure 1). Given the results of these analyses, the EPA has determined that expressing the criterion as a geometric mean is protective of the designated use given the relatively low variability of selenium concentrations in bird eggs in Gilbert Bay. In the event that new data become available, indicating that such variability has significantly increased, the EPA would expect Utah to reevaluate the protectiveness of the criterion in light of those new data, consistent with its obligations under 40 CFR § 131.20. The EPA would furthermore expect Utah to revise the criterion if those new data indicate that the criterion is no longer protective of the existing and designated uses.

Other Considerations

EC_{10} Estimates Using a Biphasic Model

One Science Panel member did not support the logistic analysis by Ohlendorf (2003) to derive an EC_{10}. Rather, he advocated deriving the EC_{10} using the biphasic model as described by Beckon et al. (2008) (Skorupa 2008). Beckon et al. (2008) analyzed the data of Heinz et al. (1989) using a biphasic model (formerly called a hormetic model) and reported an EC_{10} of 7.7 mg/kg. With this approach, data from only one of the six studies included by Ohlendorf (2003) was used to calculate an EC_{10}.

The EPA's review of the Gilbert Bay criterion included a careful evaluation of the Beckon et al. (2008) approach to estimating an EC_{10} using a biphasic model. The EPA has essentially reproduced the Beckon et al. (2008) result, obtaining an EC_{10} of 7.76 mg/kg, with the small difference due to the EPA using individual study values rather than cross-study averages in converting egg wet weight concentrations to dry weight concentrations.

Using the biphasic model as described by Beckon et al. (2008) to derive the Gilbert Bay selenium criterion has several problematic implications. First, the EPA has determined that the recommendation from the majority of the Science Panel Members to utilize the data from all of the six studies and not only rely on the Heinz et al. (1989) data is reasonable. Reducing the number of observations in the data set substantially increases the uncertainty in estimating an effect concentration. When analyzed by logistic regression apart from the rest of the data, the Heinz et al. (1989) data yields a high EC_{10} estimate, 29 mg/kg, which would not be considered protective. Also, further statistical analysis by the EPA indicates that the Heinz et al. (1989) dataset, by itself, is too small to support the biphasic model.[8]

Additionally, Beckon et al. (2008) assumes that the Heinz et al. (1989) control was deficient in selenium since the percent hatch in the control was less than the percent hatch of the first treatment (59.6% vs 70.7%, respectively, see Figure 5).[9] This assumption was accepted by Beckon et al. (2008) even though the confidence bounds for the control (48.7 - 70.1) fall completely inside the confidence bounds for the first treatment (44.8 - 91.0). The Beckon et al. (2008) biphasic model relies on this difference in hatch not merely reflecting random experimental noise, but accurately reflecting a significant reduction in hatch due to a diet that was deficient in selenium. However, a post hoc statistical analysis of the raw data from the Heinz et al. (1989) study conducted by the EPA indicates that the difference between the control (59.6 percent hatch) and the first treatment (70.7 percent hatch) is not statistically significant at

[8]The EPA does not believe a criterion set the EC_{10} of 29 mg/kg would be protective. Nevertheless, when the Heinz et al. (1989) data are analyzed by themselves, statistical measures indicate that the logistic fit to the Heinz et al. (1989) data yielding the EC_{10} of 29 mg/kg is generally better than the biphasic fit yielding the EC_{10} of 7.7 mg/kg. To some degree this is shown by the higher R^2 (better fit) for the logistic model (0.95) compared to the biphasic model (0.86). More important are the results for the Akaike Information Criterion, AIC (Burnham and Anderson 2002). The AIC is used to evaluate the tradeoff between model accuracy and complexity. The ACI metric penalizes overfitting by accounting for the number of parameters. The biphasic model uses four parameters and the logistic model uses three. When comparing two models describing the same data, a *lower* AIC value is better. Uncorrected for finite sample size, the smaller (more negative) AIC of -10.74 for the logistic model, compared to -3.90 for the biphasic model indicates that the logistic model may be preferred over the biphasic model. Corrected for finite sample size, the smaller AIC_c of 1.26 for the logistic compared to 36.10 for the biphasic even more strongly indicates preference for the logistic model. These statistical measures indicate that the Heinz et al. (1989) dataset, by itself, is too small to support the biphasic model.

[9]In poultry, dietary Se concentration greater than 0.3 mg/kg dw are considered adequate for good adult health and Se egg concentrations less than 0.66 mg/kg dw may indicate inadequate Se in maternal diets (Puls 1988, Ohlendorf and Heinz 2011). Heinz et al. (1989) does not report the concentration of selenium in the control diet; however, Ohlendorf (2003) indicated that control diets typically contain 0.4 mg/kg selenium. The control egg concentration was 0.6 mg/kg dw.

either the α=0.05 or the α=0.5 confidence level.[10] That is, whether willing to accept a 5% or a 50% chance that the difference arose by chance, the difference is not statistically significant. Therefore, it cannot be concluded the difference in hatch is due to a selenium deficient diet.[11]

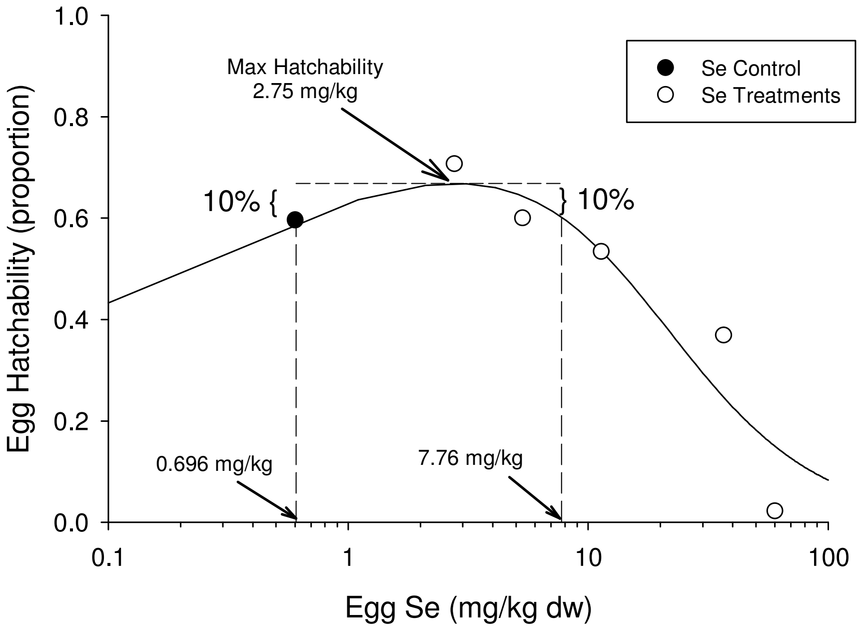

Figure 5. Biphasic analysis of Heinz et al. (1989) data assuming background egg concentration corresponding to the peak response.

Furthermore, when comparing the EC_{10} values derived using a logistic curve model (as proposed by Ohlendorf (2003) and adopted by the Board) and biphasic model (as proposed by Beckon et al. (2008)), sidestepping the above statistical problems with the Beckon analysis, the EPA has found that the major difference in the resulting EC_{10} is not a reflection of the model used to fit the data. Rather, the major difference is a reflection of the differing assumptions about the expected background response (percent hatchability) and background egg selenium concentration (collectively, we refer to this as background condition) in the absence of selenium contamination. When background conditions are similarly defined in both models, the difference between the EC_{10} values derived using the biphasic model and the logistic curve model is small.

[10]Using the Games and Howell (1976) procedure and the Dunnett-Tukey-Kramer pairwise multiple comparison test (Dunnett 1980).

[11]The response patterns observed in the five studies not used by Beckon et al. (2008) and Skorupa (2008) also appear to disaffirm the biphasic model predictions. Although none of those studies contain exposures near enough to the biphasic model's 2.7-2.8 mg/kg predicted optimum concentration range to allow visual determination of whether percent hatch attains a peak in that area, it is possible to examine the ratio of observed percent hatch at different concentrations within each study on either side of the biphasic model's predicted optimum range, and compare them to the ratios predicted by the Beckon et al. (2008) biphasic model and the Ohlendorf (2003) logistic model. For example, in Stanley et al. (1996) the observed hatch response at 11.6 mg/kg was 98% of the hatch response at 0.89 mg/kg. This can be compared to the biphasic model's predicted response ratio of 85% and the logistic model's predicted response ratio of 92%. Comparing such response ratios within each of the five studies not used by Beckon et al. (2008) and Skorupa (2008) yields an observed-predicted r^2 of 0.46 for the biphasic model and 0.72 for the logistic model. The five studies thus suggest that the monotonic response pattern of the Ohlendorf (2003) model (shown in Figure 1) is more appropriate than the biphasic response pattern of the Beckon et al. (2008) model (shown in Figure 5).

In both cases, 10 percent reduction in hatchability is estimated relative to background percent hatchability. Ohlendorf (2003) calculated the background percent hatchability as the average hatchability of the background (control) exposures estimated from the fitted model. In contrast, Beckon et al. (2008) estimates background percent hatchability as the single peak value of hatchability at an optimum egg concentration of 2.75 mg/kg that is estimated by the biphasic model (Figure 5). This difference in how background is defined (i.e., an average or range vs. a single peak value) is the primary reason for the difference between the Ohlendorf (2003) EC_{10} of 12.5 mg/kg and the Beckon et al. (2008) EC_{10} of 7.7 mg/kg. Neither Beckon et al. (2008) nor Skorupa (2008) discuss the appropriateness of assigning this single optimum value as the applicable background condition. This assignment is particularly significant because of its corollary: that all increases or decreases in background selenium concentration represent a movement away from the optimal selenium concentration.

It is difficult to justify and unrealistic to assume that a single optimum would apply to all real-world ecosystems. In fact, optimal egg hatchability and background concentration of Se in eggs can range widely; therefore, the EPA believes it is reasonable to define the background condition as a range or an average when modeling a response. For the same toxicity data, Figures 6 and 7 illustrate other possible applications of the biphasic approach when other, equally valid, methods are used to estimate background concentrations. In each figure, the horizontal line represents an alternative background hatchability level from which a 10% reduction in hatchability can be estimated. In Figure 6 the background response is calculated from the control egg concentrations in four studies included in Ohlendorf (2003). This yields an EC_{10} of 10.64 mg/kg. In Figure 7 the background response is derived from a log-triangular distribution of egg-concentrations in the range of 0.1–3.0 mg/kg. It yields an EC_{10} of 11.96 mg/kg, less than 5% different from the Ohlendorf (2003) value. Overall, when measured against an average hatchability across a range of possible background eggs concentration, the difference between the EC_{10} derived by the biphasic model and EC_{10}s derived by other scientifically defensible methods decreases.

The EPA review of the biphasic approach suggests that the value of the biphasic model is context-specific. The EPA has determined it is not necessary to assume, as a starting point, that the background concentration of selenium is the optimum concentration to derive a protective criterion. Application of the biphasic approach may well best be confined to (a) studies specifically designed to elucidate the biphasic response – that is, studies designed to characterize both deficiency and toxicity; and (b) situations where the distribution of background concentrations is sufficiently well defined to reliably estimate the average background response against which a 10 percent reduction (EC_{10}) is measured. Based on the absence of such studies and data respecting background concentrations in Gilbert Bay, the EPA concludes that it was scientifically defensible, and consistent with CWA requirements, for Utah to derive the Gilbert Bay selenium criterion without relying on the biphasic approach, and without discarding the data from five of the six studies noted above. As described above, the logistic curve model that Utah employed is scientifically defensible and consistent with CWA requirements.

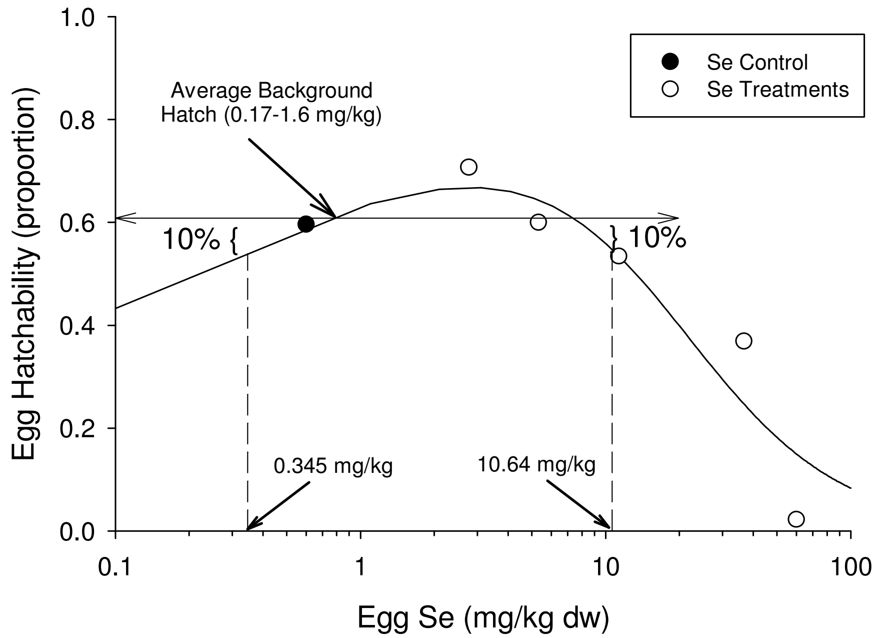

Figure 6. Biphasic analysis of Heinz et al. (1989) data, assuming background egg concentration equal to the average of four study controls in Olhendorf (2003).

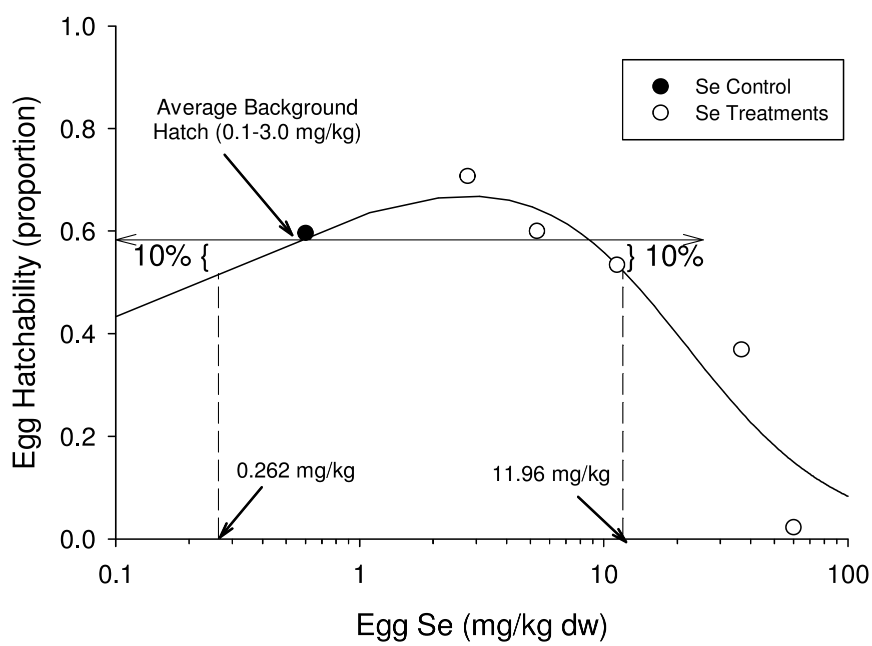

Figure 7. Biphasic analysis of Heinz et al. (1989) data, assuming background egg concentration a log-triangular distribution between 0.1 and 3.0 mg/kg

Use of Low-Level Effect Concentrations to Preclude the Possibility of Effects to Individual Migratory Birds.

The Gilbert Bay selenium criterion was derived using a scientifically defensible method for calculating a tissue-based selenium criterion (i.e., logistic-curve fit to the control normalized six study data set). The U.S. Fish and Wildlife Service (FWS) has suggested that the criterion should be set to an EC_0, rather than an $EC_{10,}$ to assure not only that Utah's designated use for wildlife will protected, but also that no individual migratory bird would ever experience any effect from exposure to selenium so long as selenium does not exceed the criterion concentration. The EPA's position is that it is not possible to calculate a criterion that would achieve that objective (i.e., that would preclude the hypothetical possibility that an individual migratory bird could be affected by selenium, so long as selenium remains below that criterion concentration).

With the Ohlendorf (2003) approach for deriving a tissue-based criterion, there is no threshold for determining no effect. The only EC_0 is 0.0 mg/kg. Setting the criterion to zero would not be a valid criterion because selenium is an essential element that is found in all organic material. While FWS has put forward 5 mg/kg as an alternative selenium criterion for Gilbert Bay (and characterized it as an EC_0), such a criterion would actually correspond to an EC_3 by their own calculation, and thus (akin to Utah's 12.5 mg/kg EC_{10} criterion) would not preclude the hypothetical possibility that an individual migratory bird could be affected by selenium at the criterion concentration.[12] While there is no criterion value that can preclude the possibility of calculating hypothetical, individual-level effects on migratory birds by one or the other model that has been proposed, an EC_{10} signifies a level of effect that cannot be distinguished from zero effect in real-world ecosystems. There is greater certainty regarding the mid-range levels of effect, between 20% to 50% (that is, EC_{20}s to EC_{50}s), but a corresponding certainty of effect does not exist with respect to an EC_{10}.

The determination of an effect at a concentration at or less than an EC_{10} is more dependent on the selection of curve-fitting approach than the toxicity data set itself. Thus, any conclusion about whether an effect would or would not occur to an individual migratory bird, at a criterion set to a low level effect concentration, is heavily dependent on unverifiable assumptions built into the curve-fitting mathematics. Given that there is no objective scientific basis to preclude or establish that selenium produces individual-level effects on migratory birds at the EC_{10} level, the EPA disagrees that the hypothetical possibility of such effects weighs against approving Utah's selenium criterion for Gilbert Bay.

Revisions Upon Which EPA is Taking No Action

The EPA does not consider the remaining portions of Footnote (14) (i.e., the provisions other than the portion the EPA disapproved on September 30, 2009), to be new or revised water quality standards requiring a CWA § 303(c) action. This is because they do not describe a desired ambient condition of a waterbody to support a particular designated use. They neither alter the magnitude, duration, or frequency of the adopted selenium criterion nor any of the other provisions that constitute the water quality standards for Gilbert Bay. Instead they outline research and monitoring programs that Utah will implement if triggered by particular concentrations of selenium in egg tissue.

[12] Skorupa (2008) used a biphasic equation with the Heinz et al. (1989) data to calculate an EC_{10} (see above discussion) and an estimated 3.0 mg/kg as a background concentration to justify a NOEC of 5 mg/kg. However, when the 5 mg/kg value is evaluated with the biphasic model, it is the EC_3, not the EC_0. Therefore, the 5 mg/kg proposed by Skorupa (2008) as a NOEC would be modeled as a concentration with effect to individual migratory birds. With use of the biphasic model, an EC_0 is only equal to the optimal background concentration determined by the model.

Accordingly, the EPA is taking no action on these remaining portions of Footnote (14). Although the EPA is not acting on these remaining portions of Footnote (14), the EPA acknowledges them and commends the Board for adopting them. Footnote (14) requires routine monitoring of selenium in eggs collected from the Great Salt Lake and triggers increased monitoring and data collection if selenium concentrations exceed 5.0 mg/kg. These actions will provide early detection of potential selenium problems and allow the State to make proactive decisions to ensure the criterion will be effectively implemented.

References

Beckon W.N., C. Parkins, A. Maximovich, A.V. Beckon. 2008. A general approach to modeling biphasic relationships. Environ. Sci. Tech. 42: 1308-1314.

Burnham, K.P. and D.R. Anderson. 2002. Model Selection and Multimodel Inference: A Practical Information-Theoretic Approach. Second Edition. Springer-Verlag. New York, NY. 488 pp

Crane, M., and M.C. Newman (2000). What level of effect is a no observed effect? Env. Toxicol. Chem. 19(2):516-519.

Dunnett, C.W. 1980. Pairwise multiple comparisons in the unequal variance case. Journal of the American Statistical Association. 75 (372): 796-800.

Games, P.A., and J.F. Howell. 1976. Pairwise multiple comparison procedures with unequal N's and/or variances: A Monte Carlo study. Journal of Educational Statistics 1(2):113-125.

Heinz, G.H. and D.J. Hoffman. 1996. Comparison of the effects of seleno-L-methionine, seleno-DL-methionine, and selenized yeast on reproduction of mallards. Environ. Pollut. 91:169-175.

Heinz, G.H. and D.J. Hoffman. 1998. Methylmercury chloride and selenomethionine interactions on health and reproduction in mallards. Environ. Toxicol. Chem. 17:139-145.

Heinz, G.H., D.J. Hoffman, A.J. Krynitsky and D.M.G. Weller. 1987. Reproduction in mallards fed selenium. Environ. Toxicol. Chem. 6:423-433.

Heinz, G.H., D.J. Hoffman and L.G. Gold. 1989. Impaired reproduction of mallards fed an organic form of selenium. J. Wildl. Manage. 53:418-428.

Janz, D.M., D.K. DeForest, M.L. Brooks, P.M. Chapman, G. Gilron, D. Hoff, W.A. Hopkins, D.O. McIntyre, C.A. Mebane, V.P. Palace, J.P. Skorupa, M. Wayland. 2010. Selenium Toxicity to Aquatic Organisms. In: Ecological Assessment of Selenium in the Aquatic Environment. Edited by P.M. Chapman, W.J. Adams, M.L. Brooks, C.G. Delos, S.N. Luoma, W.A. Maher, H.M. Ohlendorf, T.S. Presser, D. P. Shaw. CRC Press, Taylor and Francis Group.

OECD. 2006. Current approaches in the statistical analysis of ecotoxicology data: A guidance to application. Series on Testing and Assessment, No. 54. Environmental Health and Safety Publications. ENV/JM/MONO(2006)18. Organization for Economic Co-operation and Development (OECD), Paris, France.

Ohlendorf, H.M. 2003. Ecotoxicology of selenium. Pages 466-500 in Handbook of Ecotoxicology. D.J. Hoffman, B.A. Rattner, G.A. Burton, Jr., and J. Cairns, Jr., eds. Lewis Publishers, Boca Raton, FL.

Puls, Robert. 1988. Mineral Levels in Animal Health. Clearbrook, British Columbia, CAN: Sherpa International.

Skorupa, J. 2008. Great Salt Lake Selenium Standard, Written Recommendation to the Steering Committee. Appendix M of *Great Salt Lake Water Quality Studies. Development of a Selenium Standard for the Open Waters of Great Salt Lake.* Final Report May 2008. Prepared by CH2MHILL for the State of Utah Department of Environmental Quality, Division of Water Quality.

Society for Risk Analysis. 2011. Risk Analysis Glossary. Accessed 21 April 2011. http://www.sra.org/resources_glossary.php

Stanley, Jr., T.R., J.W. Spann, G.J. Smith and R. Rosscoe. 1994. Main and interactive effects of arsenic and selenium on mallard reproduction and duckling growth and survival. Arch. Environ. Contam. Toxicol. 26:444-451.

Stanley, Jr., T.R., G.J. Smith, D.J. Hoffman, G.H. Heinz and R. Rosscoe. 1996. Effects of boron and selenium on mallard reproduction and duckling growth and survival. Environ. Toxicol. Chem. 15:1124-1132.

Suter, G. W. II, B. W. Cornaby, C. T. Hadden, R. N. Hull, M. Stack, and F. A. Zafran. 1995. An approach for balancing health and ecological risks at hazardous waste sites. *Risk Analysis* 15:221-231.

Van der Hoeven N., F. Noppert, and A. Leopold. 1997. How to measure no effect. Part 1: Towards a new measure of chronic toxicity in ecotoxicology. Introduction and workshop results. Environmetrics 8, 241-248.

Warne, M.S.J., and R. van Dam. 2008. NOEC and LOEC data should no longer be generated or used. Autralasian Journal of Ecotoxicology 14: 1-5.