Great Salt Lake Selenium Standard

Written Recommendation to the Steering Committee
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I. The Great Salt Lake's Unique Values Warrant a Highly Precautionary Approach

As summarized by Aldrich and Paul (2002):

The Great Salt Lake ecosystem is widely recognized to be unique and to have very high environmental and commercial value. Great Salt Lake is recognized regionally, nationally, and hemispherically for its extensive wetlands, and its tremendous and often unparalleled values to migratory birds. These values are derived from the lake's unique physical features, including its immense size, dynamic water levels, diversity in aquatic environments, extensive wetlands and geographic position in avian migration corridors. These features create a mosaic of habitat types that are attractive to literally millions of migratory birds that use the lake extensively for breeding, staging, and in some cases, a wintering destination. Great Salt Lake also has a rich history of wildlife management activities that were initiated in the late 1890's by private hunting clubs, <u>but were followed by substantial state, federal, and private investments in conservation programs</u>. [emphasis added]

Additionally, the Great Salt Lake produces a significant proportion of the world's supply of brine shrimp cysts and the commercial harvest has become internationally renowned for its high quality (CH2M HILL 2008). Mineral extraction represents yet another substantive commercial value associated with the Great Salt Lake ecosystem (CH2M HILL 2008).

II. Tolerably Toxic as Opposed to Nontoxic is Too Reckless an Approach for Such a High Value System With Such Substantive Remaining Uncertainties

High environmental and commercial value ecosystems such as the Great Salt Lake warrant full protection, not partial protection. Full protection, does not equate to zero discharge, it equates to setting standards based on a reasonable expectation that the resulting standard will be nontoxic. That reasonable expectation is derived from *a designed intent for the standard to be at or below the no-effect concentration*, called the NEC. Based on data from another western U.S. saline-sink lake, Abert Lake in Oregon, with a water selenium concentration of < 0.2 ug/L, the normal baseline for selenium in brine shrimp is probably about 1.5 ug/g dry weight (Westcot et al. 1990; California Department of Water Resources file data). Brine shrimp in the Great Salt Lake are currently estimated to be at about 4 ug/g Se dry weight (Marden 2008), or about 2.5-times above presumptive baseline indicating that substantive amounts of selenium have already been assimilated by the Great Salt Lake ecosystem without exceeding the NEC, at least for those endpoints that have been examined such as the eggs of California Gulls, American Avocets, and Black-necked Stilts (Cavitt 2008; Conover et al. 2008).

Setting the standard based on the EC10 for toxicity amounts to *a designed intent for a" tolerably toxic" objective*. The critical risk associated with this approach is in making an estimate of what level of poisoning is "tolerable". When entire categories of potential adverse effects, such as avian nonbreeding effects, are currently devoid of any useful assessment endpoint data for the Great Salt Lake (Science Panel Discussions), and when less than a handful of species among the full spectrum of breeding birds that occur at GSL have been examined, the uncertainties associated with assessing what is "tolerable" are very substantive. Overshooting what is truly tolerable is unlikely to be an error that would be easily corrected. Previous studies at Kesterson Reservoir, Belews Lake, Martin Reservoir (reviewed in Skorupa 1998), and in the Sierra Nevada (Maier et al. 1998) have shown that selenium is very efficiently recycled within aquatic ecosystems and that relaxation of selenium levels, even following complete cessation of discharge, can be a very long-term process. In short, while it is easy to raise the levels of environmental selenium it is not nearly as easy to lower them once a certain level has been allowed.

III. No Observed Effect Concentration (NOEC) is not the Same as a No Effect Concentration (NEC)

NOEC's are actually statistically based constructs that are highly dependent on the statistical power of the test that produced a particular NOEC. Such tests typically have very low power. For example, the mallard reproductive toxicity test for selenium published by Heinz et al. (1989) and associated with a dietary NOEC of 4 ug/g Se dry weight did not have the statistical power to detect anything lower than about a 40% difference between the response of the controls and the response of any treatment group (J. Skorupa, pers. obs.). Accordingly, the dietary NOEC of 4 ug/g indicates nothing more than that the toxic effects, compared to controls, at that diet were less than 40%. They could have been 39% or they could have been 0%, or anything between. Because of the interpretive drawbacks of NOEC's they are now widely avoided as a basis for setting standards and criteria whenever possible (and in our case it is possible to avoid relying on NOEC's). For example, there was an ISO resolution (ISO TC147/SC5/WG10 Antalya 3) as well as an OECD (Organisation for Economic Co-operation and Development) workshop recommendation (OECD, 1998) that the NOEC should be phased out from international standards (OECD 2006:14). Environment Canada (2005) notes, that there is a growing literature which points out many deficiencies of the NOEC approach (Suter et al. 1987; Miller et al. 1993; Pack 1993; Noppert et al. 1994; Chapman 1996; Chapman et al. 1996; Pack 1998; Suter 1996; Moore and Caux 1997; Bailer and Oris 1999; Andersen et al. 2000; Crane and Newman 2000; Crane and Godolphin 2000). Moore and Caux (1997) reported that 76.9% of NOEC's exceeded the estimated EC10 level of toxic effects. However, as illustrated above for the Heinz et al. (1989) mallard study, the toxicity equivalent of a particular NOEC is highly specific to the study that generated it and may range over quite a broad range of possibilities.

IV. Ultimately the Standard Should Be Linked to an Estimate of the NEC for Avian Eggs

Avian reproductive impairment is the most sensitive endpoint that can currently be assessed and monitored at the Great Salt Lake, and may in fact eventually be demonstrated as the most sensitive endpoint overall. The *potential* for avian reproductive impairment can be assessed from food web (diet) and/or water selenium concentrations, but it is the concentration of selenium in the eggs that directly determines the *realized* avian reproductive impairment, if any (Skorupa and Ohlendorf 1991). Thus, back-calculating a water standard from an adopted "not-to-exceed" objective for avian egg selenium is the approach that would be most directly linked to the controlling endpoint. Therefore, the remainder of this write-up will focus on a recommendation regarding a "not-to-exceed" objective for avian egg selenium based on the goal of providing a best estimate of the NEC for avian eggs. In the course of getting there, I will also offer a professional opinion on the best estimate of an EC10 value for avian eggs because there seems to be considerable interest in that value and because it represents the upper limit of what EPA may be willing to approve.

V. Best Estimate of EC10 for Mallard Egg Hatchability

Controlled feeding studies of captive mallards exposed to known dietary concentrations of selenium provide the best available set of data for estimating a generic avian egg hatchability EC10 (Heinz et al. 1987, 1989; Heinz and Hoffman 1996, 1998; Stanley et al. 1994,1996). It should be noted, however, that although mallards are believed to be a fairly sensitive species of bird to selenium toxicity, comparative toxicity profiles are available for very few bird species and of the handful of species that we do have data for at least two species, American coot (Ohlendorf et al. 1986) and chickens (reviewed in Detwiler 2002) are already known to be more sensitive to selenium than mallards. Based on my own 20+ years of experience monitoring reproductive performance of selenium-exposed waterbird populations and on data collected throughout the western U.S. for the National Irrigation Water Quality Program (Seiler et al. 2003) I expect that redhead ducks and Canada geese are also more sensitive than mallards. My current professional opinion (hypothesis) is that mallards are more likely to be closer to the upper 75th percentile of sensitivity than to the 90th percentile. If my hypothesis is valid, a given level of protection for mallards would also be equally, or more, protective of most other bird species, but less protective for perhaps the most sensitive upper quartile.

At least three different statistical approaches to estimating a mallard EC10 from the results of the controlled feeding studies cited above have been pursued in recent years. Ohlendorf (2003) conducted logistic regression on a set of pooled results from different studies, the pooling of data being made possible by converting all results to a control-adjusted basis. Ohlendorf's maximum likelihood estimate of the EC10 is 12.5 ug/g (all results cited on a dry-weight basis), with estimated 95% confidence limits of 6.4 to 16.5 ug/g. An issue of concern related to Ohlendorf's analysis is the use of control-adjusted data. Selenium is a hormetic chemical, meaning that adverse effects can be caused by deficient dietary exposure as well as by excessive dietary exposure. Consequently, the classic concept of a control group as a zero (or nearly zero) exposure group is inappropriate for evaluating results of selenium toxicity tests. For a hormetic chemical, ignoring the potential effects of hormesis will always lead to potentially overestimating particular effects points such as the EC10 (Beckon et al. 2008). Potentially, at least some of the data points used in Ohlendorf's analysis may have been adjusted to an inappropriately estimated control, in turn raising the potential of upward-bias in the estimated EC-10. Even if selenium were not a hormetic chemical and the classic concept of a control group was fully applicable, the use of "control-adjusted" data is statistically improper unless the control values used for making adjustments were themselves estimated by model-fitting. For example, in the OECD (2006:31) document titled, "*Current Approaches in the Statistical Analysis of Ecotoxicity Data: a Guidance to Application*", the following guidance is presented:

A current habit in analyzing continuous data is to divide the observed response by the (mean) observed response in the controls. These corrected observations then reflect the percent change compared to the controls, which is usually the entity of interest. <u>However, such a pre-treatment of the data is improper</u>: Among other problems it assumes that the (mean) response in the controls is known without error, which is not the case. Therefore, this should be avoided, and instead the background response should be estimated from the data by fitting the model to the untreated **[**i.e., unadjusted**]** ***data. Thus, the estimation error in the controls is treated in the same way as the estimation errors in the other concentration groups. (see e.g. chapter 6.2.2 and 6.3.2).*** [emphasis added]

It is not clear to me what magnitude or direction of bias might be introduced by such improper pre-treatment of the data, or whether the bias would systematically be in only one direction, or even whether the bias would affect the maximum likelihood estimate of an EC10 at all, as opposed to only affecting the variance characteristics (confidence limits) of the analytical results. What does seem clear is that results from analyses that don't rely on simple control-adjusted data, in general, and for a hormetic chemical in particular, are preferable to those that do.

An analysis of the mallard toxicity data based on the statistical method of hockey stick regression was also provided to the Science Panel courtesy of Dr. William Adams, as documented by CH2M HILL (2007). Adams' maximum likelihood estimate of the mallard EC10 is 11.5 ug/g, with estimated 95% confidence limits of 9.7 to 13.6 ug/g. In common with Ohlendorf's analysis, Adams' analysis does not formally take into account the possibility of hormesis effects in the data and improperly (OECD 2006) relies on simple control-adjusted data as the input for statistical analysis. A cursory examination of Figure 4 (hockey stick regression) in CH2M HILL's "Thresholds Values" final technical memorandum (February 28, 2007) clearly shows that use of control-adjusted data artificially removes <u>all variance</u> in the response variable for low exposure data points (more than one-third of the total data set). As explicitly noted in CH2M HILL's final technical memorandum, hockey stick regression is sensitive to the scatter, i.e., estimation error characteristics, of the response variable. Another concern with this analysis is that it is based on duckling mortality rather than on egg hatchability. Egg hatchability is a strictly comparable response metric between the different mallard studies in question, while duckling mortality is not. Some of the experiments fed the ducklings the same selenium-treated diet that the hens producing the ducklings had been fed (which would mimic nature), while some studies did not. Some of the studies used different age cutoffs for assessing duckling survival. Because of these toxicologically critical differences between the studies, it is not valid to pool their results for statistical analysis as if they were all measuring comparable exposure and response metrics (Skorupa 1999). A final concern is that the hockey stick regression method was designed specifically to estimate the location of a threshold response (9.8 ug/g in Adams' analysis) not to estimate ECxx values. For example, see the discussion of hockey stick regression by Environment Canada (2005) in their publication titled, "*Guidance Document on Statistical Methods for Environmental Toxicity Tests*". Estimates of the EC10 from a hockey stick regression approach are probably not very appropriate unless the estimate of the location of the threshold response is very precise (which it usually isn't) because it is that estimate that determines which data points will be included and excluded from the response part of the hockey stick. Adams did not report the 95% confidence interval for his estimated 9.8 ug/g threshold point (which itself is improperly [OECD 2006] based on simple control-adjusted input data and therefore may be erroneous).

Recently, a subset of the mallard toxicity data (the data points from Heinz et al. 1989) were analyzed using a generalized biphasic response model that collapses down to a logistic model in the absence of a biphasic response (Beckon et al. 2008). This method of analysis differs from both Ohlendorf and Adams in that it explicitly accommodates hormetic effects in the data via a model that is mechanistically specific to the phenomenon being analyzed and his analysis did not rely on using control-adjusted input data. In both those respects, the analysis by Beckon et al. is statistically more valid and more relevant to known selenium biochemistry. Beckon et al.'s estimate of the mallard EC10 is 7.7 ug/g, however no 95% confidence interval was reported. Beckon et al. also demonstrated the substantive potential for upward bias in EC10 estimates when hormetic data is forced into a standard logistic regression model. The drawbacks of Beckon et al.'s analysis include that it doesn't report an estimated confidence interval and that it is based on fewer data points than the analyses of Ohlendorf and Adams. However, Ohlendorf and Adams gain their larger sample size only by improperly (OECD 2006) using simple control-adjusted input data, which is what makes it possible to pool data from different studies. As tempting as it is to improperly pre-treat the data in order to increase the sample size by pooling results from multiple studies, or to ignore fundamental experimental incompatibilities between studies (in the case of duckling mortality) also to increase the sample size, the reality is that we are limited to the Heinz et al. (1989) study for drawing inferences that are fully technically valid.

Therefore my recommendation regarding the best estimate of an EC10 for mallard egg hatchability is 7.7 ug/g Se on a dry-weight, whole egg basis, as per the biphasic model of Beckon et al. (2008).

VI. Estimating the No Effects Concentration (NEC) for Avian Eggs

As stated above, and for the reasons stated above, such as the high environmental and commercial value of the Great Salt Lake ecosystem, the great uncertainties still unresolved regarding selenium biogeochemistry in the Great Salt Lake and regarding what the most sensitive species and endpoints might be, my professional recommendation is for an egg standard that is more protective than an EC10. My professional recommendation is that the State of Utah be prudently precautionary by aiming to set the egg standard at a no effect concentration (NEC). Various methods of estimating the NEC have been proposed. In a human health context, EPA has proposed that the lower 95% confidence limit of the EC10 be used as an estimator of the NEC (EPA. 2000) and at least one text book, "*Statistics in Ecotoxicology*" also recommends such an approach more generally than just in a human risk management context (Sparks 2000). Consequently, the estimates of the NEC for avian eggs that would be associated with Ohlendorf's and Adams' analyses of the mallard EC10 are 6.4 and 9.7 ug/g respectively. The hockey stick regression method of data analysis was actually designed to estimate the NEC directly. Based on Adams' hockey stick regression results, that direct estimate would be 9.8 ug/g. Of course those three estimates for the NEC are made ignoring the concerns presented above regarding potential technical deficiencies in the underlying analyses that produced the confidence intervals, etc. Furthermore, two of these three estimates for the NEC are above what I consider to be the most technically valid estimate of the EC10, i.e., above 7.7 ug/g. With regard to hockey stick regression it has been recommended in a human risk management context that the lower confidence boundary on the threshold estimate be considered the NEC (e.g., Yanagimoto and Yamamoto 1979). However, Adams did not report a confidence interval for his threshold point of 9.8 ug/g.

Skorupa and Ohlendorf (1991) reported that normal background means for selenium in avian eggs extended up to about 3 ug/g. Therefore, my best professional estimate is that the mallard NEC for egg selenium lies somewhere between 3 and 7.7 ug/g. A well-founded basis simply does not exist for picking a particular number within that range. EPA often deals with such irreducible bounded zones of interest by settling on the geometric mean of the boundary values (see Clean Water Act water criteria derivation methodologies). In this case the geometric mean of our boundary values is 4.8 ug/g.

Therefore my recommendation regarding the best estimate of a No Effect Concentration (NEC) for avian eggs (measured as a sample mean) is 5 ug/g and I would expect this value to be precautionary enough to account for the fact that mallards are not the most sensitive species of bird to selenium toxicity.

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