Exponent
15375 SE 30th Place
Suite 250
Bellevue, WA 98007

telephone 425-519-8700
facsimile 425-519-8799
www.exponent.com

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Submitted via email to: fishconsumption@ecy.wa.gov

Washington State Department of Ecology
P.O. Box 47600
Olympia, WA 98504-7600

Subject: Comments on Publication No. 11-09-050, Fish Consumption Rates Technical Support Document, A Review of Data and Information about Fish Consumption in Washington
Project No. 0900083.026

To: Washington State Department of Ecology

The Washington State Department of Ecology ("Ecology") released a draft of the report, *Fish Consumption Rates Technical Support Document, A Review of Data and Information about Fish Consumptionin Washington* ("TSD") in September 2011.[1]The TSD summarizes available fish consumption studies for high-end fish consumers in the Northwest and related issues. Based on its review of the five available fish consumption studies, Ecology recommended a default fish consumption rate between 157 and 267 g/day. The recommendations from this report will be used in ongoing revisions to State Sediment Management Standards (SMS) and Surface Water Quality Standards (SWQS). The following commentsare provided in response to Ecology's request for public input on the TSD.

1. Site-specific Application to Sediment Cleanup Levels:Defining Background and Site Boundaries

At many, if not all cleanup sites in Puget Sound, sediment polychlorinated biphenyl (PCB) and dioxin concentrations would exceed cleanup criteria based on the current Model Toxics Control Act (MTCA) default fish consumption rate of 54 g/day. In fact, as noted by Jim West of the Washington State Department of Fish and Wildlife in his presentation at Ecology's Technical Workshop on Fish Consumption, most Puget Sound fish included in the state monitoring program have PCB concentrations above a fish tissue PCB criterion based on even the 1980 ambient water quality criteria fish consumption rate of 6.5 g/day (70% of English sole, 90% of

[1] Ecology. 2011. Fish consumption rates technical support document, a review of data and information about fish consumption in Washington.Publication no. 11-09-050, Version 1.0. September 2011. Washington State Department of Ecology.

coho, and 100% of Chinook and herring).[2] More than 50% of freshwater fish in the state would exceed such a criterion. Virtually all fish in state waters would exceed a PCB fish tissue criterion based on the current MTCA default fish consumption rate of 54 g/day and, by extension, virtually all sediments in state waters would exceed a PCB criterion based on the MTCA default fish consumption rate. Therefore, cleanup levels at these sites would default to background.

As another example, the current methylmercury fish tissue criterion for protection of human consumption of fish is 0.3 mg/kg and is based on a fish consumption rate of 17.5 g/day. According to data summarized by EPA from 1990 to 1995, that represents approximately the 80thpercentile for fish tissue mercury concentration for all fish in Washington State.[3] Application of the MTCA default fish consumption rate of 54 g/day would produce a fish tissue mercury criterion of approximately 0.09 mg/kg, which corresponds to less than the 30th percentile for fish in Washington. In other words, mercury concentrations in approximately 70% of Washington State fish would exceed the criterion. Virtually all fish in Washington State would exceed a fish tissue mercury concentration based on a consumption rate in the range recommended in the TSD, as would most fish from any source because background fish mercury concentrations would exceed the criterion. The most recent data from Ecology's freshwater fish mercury monitoring programs indicates a similar relationship.[4] Mercury levels in 14% of bass collected from freshwater bodies in Washington State exceeded the current water quality criterion of 0.3 mg/kg. Over 60% would exceed a criterion based on the current MTCA default fish consumption rate and 100% would exceed a criterion based on the low end of Ecology's recommended subsistence fish consumption rate range.

However, defining background for these chemicals provides a significant challenge to Ecology. It will require additional regional or site-specific analyses that will be difficult and costly to perform. In addition, MTCA defines the site boundaries (WAC 173-204-560 (4)(b)(i)) to include those areas were the individual contaminants exceed the applicable sediment quality standards as defined in WAC 173-204-320 through 340. This includes chemical and biological criteria. If we establish background as the cleanup level for these chemicals then the definition of a site boundary becomes even more difficult.

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[2] Ecology. 2011. Technical workshop on fish consumption in Washington. December 12, 2011, University of Washington South Campus Center, Seattle.Washington State Department of Ecology.

[3] U.S. EPA.1999. The National Survey of Mercury Concentrations in Fish, Data Base Summary 1990-1995.EPA-823-R-99-014.Office of Water, Washington, D.C.
Percentiles estimated from graph of Washington State data provided.

[4] Ecology. 2010. Measuring Mercury Trends in Freshwater Fish in Washington State, 2009 Sampling Results. Washington State Department of Ecology. Publication No. 10-03-058
Percentiles calculated based on individual largemouth and smallmouth bass concentrations estimated from Figure 5 of the document.

Recommendations

A discussion should be provided in Chapter 7 regarding the impact that fish consumption rates have on the establishment of site cleanup criteria to background levels and the impact this has on developing site boundaries.

2. Interpreting Fish Consumption Survey Data for Regulatory Decision Making

Risks of concern for seafood ingestion include those that might result from life-long exposure. Fish consumption intake rates that are used for calculating fish consumption criteria must therefore represent an average daily intake over a long time period up to a lifetime, rather than a short-term (e.g., 24 hour period). Accurate measurement of usual daily food intake over a long-term period is a difficult undertaking. All standard dietary survey study designs are subject to limitations. Results can be highly influenced by participants' perceptions of how the data will be used, whether the food is "good for you" or not, and the expectations of the surveyor. Other important issues that must be assessed are survey method, sample size of individuals, number of survey days, and timing of the survey period relative to related events (e.g., harvest seasons and festivals). Therefore, it is extremely important that studies are peer-reviewed and that the limitations are evaluated in the context of how the results will/can be used. This is particularly important when a study is being considered to set practical public health policy.

These challenges can be illustrated with one of the primary studies considered by Ecology in the TSD, the Suquamish study.[5] As with all dietary survey studies, the Suquamish study has limitations that should be assessed and described in the context of how the results will be used. Ecology indicates in the TSD that studies were evaluated for: 1) survey methodology, 2) survey execution, 3) publication of results, 4) applicability and utility for regulatory decisions (for example, representativeness of the population surveyed relative to the regulatory decision), and 5) technical suitability for the decisions.

Survey Methodology and Execution

The primary survey instrument used in the Suquamish study to derive consumption rates was a food frequency and portion size survey. This type of survey asks participants to estimate the frequency at which they ate specific fish and shellfish species over the previous week (i.e., meals per day, week, or year) and the portion size of the typical meal. In addition, participants were also administered a 24-hour recall, in which participants are asked to recall what fish or shellfish they ate and how much during the last 24 hours only. The 24-hour recall results were not used to derive the final recommended consumption rates, but rather were provided for

[5] Suquamish Tribe. 2000. Fish consumption survey of the Suquamish Indian Tribe of the Port Madison Indian Reservations, Puget Sound Region. Suquamish Indian Trip.

comparison and validation. There are strengths and weaknesses with each survey method. For example, the food frequency covers a longer period of time so may be able to reveal long-term patterns, but accuracy of recall suffers over the longer period of time. The 24-hour recall is likely to more accurately reflect intake during the survey period (i.e., 24 hours), but may miss out on daily variation on an individual level or seasonal variation on a population level.

In the Suquamish study, 55% of participants reported no seafood consumption in the 24 hours prior to taking the survey. Correspondingly, the mean consumption rate measured in the 24-hour recall portion of the study (1.5 g/kg-day) was nearly half the consumption rate estimated in the food frequency survey (2.7 g/kg-day). The lack of seafood consumption during the 24-hour recall survey period does not, however, indicate those respondents are non-consumers in general because the food frequency survey revealed that all participants were seafood consumers. Study authors concluded that the "lower mean consumption rate for dietary recall suggests that a brief set of questions does not uncover all forms of consumption." However, this conclusion is not supported by scientific literature ondietary surveys. Although on an individual level the 24-hour recall does not capture day-to-day variability; on a population level it may provide a more accurate account of the consumption rate than the food frequency survey instrument. This type of dietary assessment (i.e., the 24-hour recall) has been shown to accurately reflect dietary patterns.[6] Retrospective diet history surveys, such as the Suquamish food frequency questionnaire that looked back over a year, may be more likely to overestimate usual consumption.[7] Results should be validated by summing reported consumption for individual food items, along with food groups not included in the survey, to determine if reported intake is consistent with energy requirements. Ideally, multiple non-consecutive day 24-hour recall surveys would be administered to study participants over a longer period of time to capture seasonal and individual variability. For example, Nobmann et al. (1992) conducted a study on dietary intake in Native Alaskans from 10 communities throughout Alaska. Their methodology included the use of multiple 24-hour recall surveys, completed during five seasons over an 18-month period. Nobmann et al. (1992) reported the typical caloric intake for native Alaskans as approximately 2,750 kcal per day for men and 1,950 kcal per day for women (Table 5-12; Nobmann et al. 1992). Caloric intake in the general U.S. population during that time period was approximately 2,550 kcal per day for men and 1,550 kcal per day for women (NHANES II, as reported in Nobmann et al. 1992).[8] Results would be validated with a small subset of participants completing diet records with weighed meals.

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[6] Witschi, J.C. 1990. Short-term dietary recall and recording methods.p. 52−68. In: Nutritional Epidemiology: Monographs in Epidemiology and Biostatistics. W. Willett (ed). Oxford University Press, New York, NY.

[7] Rasanen, L. 1979. Nutrition survey of Finnish rural children. VI. Methodological study comparing the 24-hour recall and the dietary history interview. Am. J. Clin. Nutr. 32(12):2560−2567.

[8] Nobmann, E.D., T. Byers, A.P. Lanier, J.H. Hankin, and M.Y. Jackson. 1992. The diet of Alaska Native adults: 1987−1888. Am. J. Clin. Nutr. 55:1024−1032.

Publication of Results

The Suquamish study has not received the benefit of a formal, external peer-review, nor has it been published in a peer-reviewed journal. Equally important, for data that will be used as the basis of public health policy applicable to the general public, a transparent public review process is critical. However, because it is a tribal study, data from the study are not available to the public. In addition, the study report itself has not had the benefit of a public review and comment process to evaluate study design, results, and applicability for use in public health decision making.

Applicability for Regulatory Decisions

Regulatory criteria and associated risk assessment methods typically rely on the use of reasonable maximum exposure (RME) assumptions in order to provide a high degree of public health protection. As noted in the TSD, "The RME is designed to represent a high end (but not worst case) estimate of individual exposures. It provides a conservative estimate that falls within a realistic range of exposures….The RME is defined as reasonable because it is a product of several factors that are an appropriate mix of average and upper-bound estimates. RME estimates typically fall between the 90th and 99.9th percentile of the exposure distribution." In other words, when all assumptions are taken together, the resulting exposure estimate should be in the range of the 90th and 99.9th percentile. Therefore, each individual input (e.g., fish consumption rate, fish diet fraction, exposure duration) need not be at the high end of the distribution for the overall exposure estimate to be at the high end of the distribution. Ecology applies a RME in the range of the 90th to 95th percentiles for deriving cleanup standards, and has historically recommended use of a fish consumption rate representative of the 90th percentile for a given population or study.[9] The 90th percentile is consistent with the U.S. FDA's designation of high-end consumption rates as the 90th percentile from large national, 2 to 3 nonconsecutive day surveys of food intake by thousands of individuals.[10]

The specific percentile selected should be considered on a study-specific basis and will depend on such factors as the characteristics of the data distribution and the representativeness for the study population to which the fish consumption rate will be applied. In the case of the Suquamish study, the study population appears to be high-end consumers even compared with other high fish consuming populations included in the TSD. Even within the Suquamish study population, the data are highly skewed and the upper percentiles (90th and 95th) are greatly affected by a few individuals with very high reported intakes.

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[9] Ecology. 1999. Analysis and selection of fish consumption rates for Washington State risk assessments and risk-based standards. Publication No. 99-200. March 1999. Washington State Department of Ecology.

[10] U.S. FDA, 2006.Estimating dietary intake of substances in food. http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/foodingredientsandpackaging/ucm074725.htmAccessed January 13, 2012. Last updatedAugust 2006. U.S. Food and Drug Administration, Center for Food Safety andApplied Nutrition.

The intent of the RME approach is to ensure protection at the upper end of a distribution that includes the entire population (or in the case of fish consumption, all people who consume fish). A 95th (or 90th) percentile intake from the Suquamish study represents the high-end intake from one of the highest consuming groups. This rate would likely represent well over the 99thpercentile consumption rate for fish consumers in Washington and result in an RME estimate even higher. Even a 50th percentile consumption rate from the Suquamish study (~100 mg/day, excluding salmon) would provide a high-end exposure estimate for Washington fish consumers as a whole. Ultimately, the choice of specific percentiles of a population distribution, and on which population to base a RME estimate, is a policy decision that is not based solely on science. For example, public health policy makers have chosen to base soil cleanup levels on high-end soil ingestion estimates for a typical child rather than for children with pica, a significant subpopulation that ingests soil at a rate perhaps 10-times or more than the typical child.

Technical Suitability

Two issues should be addressed when considering the technical suitability of the Suquamish study for regulatory decision making. First, as discussed previously, the two survey instruments used in the Suquamish study resulted in very different fish consumption estimates. Which estimate is closer to actual typical daily consumption over a lifetime was not evaluated in the original study or in subsequent reviews by the U.S. Environmental Protection Agency or Ecology. Rather, higher estimates provided by the food frequency questionnaire were assumed to be more representative. Two survey instruments were included in the study to, at least in part, provide validation of the results. That results provided by the two instruments were not in accordance should raise questions about the methodology used, the accuracy of the results, or both.

Second, fish consumption rates should reflect the reality of metabolic energy needs over long time periods (i.e., how much food does a person need and how much can they reasonably consume to maintain weight, health, etc.). The amount of fish consumption must make sense in the context of the entire diet. Unfortunately, the Suquamish study, like the other available fish consumption studies, considers only fish and shellfish consumption and not total diet. Without understanding the usual intake of other foods, it is not possible to accurately assess the results, particularly with regard to factors that may shift the overall distribution of consumption rates because of systematic biases. The daily energy requirement of an active adult male of average size is approximately 2,900 kcal/day[11]; more for a larger or more active person and less for a smaller or less active person. Ideally, a survey assessing usual intake of most/all foods would be administered to at least a subset of study participants in order to validate the fish

[11] Average caloric energy requirements as calculated on U.S. FDA *Human Fluid and Caloric Requirements* calculator for a person with a height of 5'10" and weight of 70 kg. http://www.accessdata.fda.gov/scripts/cder/onctools/caloricquery.cfm

consumption estimates.A similar analysis could be conducted regarding limits to the amount of protein intake that could be sustained over a longer time period. In the absence of such data, results should at least be evaluated using other means of estimating total diet intake (e.g., follow-up studies in the survey group,literature values for similar populations).

Discussion of the Suquamish study is provided as an example, but the same issues should be considered for all of the studies included in the TSD. However, the issues stand out more distinctly with the Suquamish study because the estimated consumption rates are significantly higher when compared with the other studies.

Recommendations

A more in depth, critical evaluation of the available fish consumption studies should be conducted addressing, among other issues, those identified in the precedingdiscussion of the Suquamish study. The Suquamish study, in particular, requires further evaluation in light of the internal validation issues presented by the difference in results from the two survey instruments utilized. More generally, data and studies that will be used to set public health policy for all Washington residents warrant a more open public access and review policy.

3. Should Salmon be Included in a Default Fish Consumption Rate

The TSD devotes considerable effort in evaluating the relative contribution of Puget Sound, estuarine, and freshwater environments to salmon contaminant body burden. Ultimately, the question is to what degree Washington waters/sediments contribute to salmon chemical body burden. If it is a significant contribution, salmon consumption would logically be included in the fish consumption rate used to derive sediment and water quality criteria. If not, salmon should be excluded from the fish consumption rate in the same way that store bought fish is excluded. The information provided in the TSD (and Appendix E of the TSD) appears to support the conclusion that for most salmon, body burden of bioaccumulative chemicals (e.g., PCBs, dioxins, mercury) derives mostly from marine waters. However, Washington waters/sediments may contribute to body burden depending on the species, run, chemical, life cycle characteristics, and a range of environmental physical characteristics. This variability, dominated by a lack of significant contribution, argues for evaluating the situation on a site-specific basis with exclusion of salmon being the default.

Recommendation

Exclude salmon consumption from the default fish consumption rate, but evaluate whether it should be included on a site-specific basis.

4. Implications for Risk Communication and Public Health

Ecology acknowledges that implications of the TSD on regulatory programs are not considered. However, the fish consumption data reviewed in the TSD would result in significant changes if implemented in the SMS, SWQS, and MTCA. Use of high subsistence-level fish consumption rates to set statewide standards for water, sediment, and/or fish tissue will result in elevated risks from background concentrations of several priority pollutants (e.g., mercury, PCBs, dioxins). This will imply that consumption of fish from any water body in Washington State, or even fish from the grocery store is unsafe. This is a challenging risk communication issue and potentially a detriment to public health if it results in people eating less fish.

It is unclear whether use of subsistence fish consumption rates for sediment and water quality standards would result in a public health benefit. As noted above, sediment criteria for chemicals such as PCBs, dioxins, and mercury are likely to be based on background concentrations. Thus, any increase in the assumed fish consumption rate would not result in a lower sediment cleanup levels for these chemicals. But it would result in higher estimated risks associated with eating fish and, as noted above, a significant public health and risk communication challenge. Given that the vast majority of Washington residents consume much less fish than the highest subsistence consumers on which Ecology is considering basing the new recommended consumption rate, the resulting criterion would be misleading with regard to potential health risks faced by Washingtonians. The estimated risks may also lead people to believe that no fish should be consumed.

Recommendations

The TSD should include a risk-benefit analysis addressing: 1) how the recommended fish consumption rate(s) will be implemented in regulatory framework (SMS, SWQS, MTCA), 2) the level of public benefit expected, and 3) the potential public health risk if people eat less fish.

We appreciate the work Ecology has expended in this document and look forward to receiving Ecology's response to the comments presented in this letter.

Sincerely,

Mark W. Johns, Ph.D.
Principal Scientist

Michael R. Garry, Ph.D.
Managing Toxicologist