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Martha Hankins
Toxics Cleanup Program
Washington Department of Ecology
P.O. Box 47600
Olympia, WA 98504-7600

Subject: ***Fish Consumption Rates Technical Support Document*** **(September 2011)**

I am submitting this letter to provide comments on the Washington State Department of Ecology's (Ecology's) *Fish Consumption Rates Technical Support Document* (September 2011), which has been posted for public review. I am submitting these comments as a concerned private citizen, and these comments should not be construed as representing those of my employer or any of my clients. I appreciate Ecology's interest in protecting the public from exposure to chemicals in fish (and, more broadly, seafood in general, including shellfish) at concentrations that result in unacceptable risks to human health, and I recognize the important treaty rights of Native American tribes to harvest and consume traditional seafood items. It is apparent that Ecology has put considerable effort into preparing this document, and it obviously represents a valuable compilation of a lot of information on the topic of fish (and other seafood) consumption rates in Washington State. However, I have serious concerns about Ecology's intended use of the fish consumption rates put forth in that document, and with the way those rates were developed.

No Indication of How These Rates Will Be Used

The most fundamental problem with the document is that it considers fish consumption rates in a vacuum, with very little mention of how those rates might be used in specific regulatory programs. Clearly, there are intended uses of these rates in establishing water quality criteria under the state Water Quality Standards, surface water cleanup standards under the state Model Toxics Control Act (MTCA), and sediment cleanup standards under the state Sediment Management Standards. However, the report states (on page 73):

> "This report does **not** examine the implications or results of updating the fish consumption rates in these various regulations. This report is focused solely on the data available on fish consumption in the state of Washington. Other materials being prepared concurrently will examine in detail the policy considerations and implications."

I believe that the utility of these rates can only be understood in the context of their exact uses in these regulatory programs. I am aware that some of the fish consumption rates referred to in this document have already been included both as the basis for risk assessments at state-lead sediment sites under MTCA and in the evaluation of open-water disposal of dredged materials under the Dredged Material Management Program (a joint program of the U.S. Environmental Protection Agency (EPA), Ecology, the Washington Department of Natural Resources, and the U.S. Army Corps of Engineers). It can also be expected that these rates, if adopted by Ecology, will be used in the federal Comprehensive Environmental Resource and Compensation Act (CERCLA) and Resource Conservation and Recovery Act (RCRA) programs within Washington State. I am also aware of what I consider to be totally inappropriate use of fish consumption rates, such as attempts by both Ecology and EPA to backcalculate upland groundwater and soil cleanup levels that would be protective of human health based on the tribal seafood consumption rates, assuming chemicals in soil would migrate to groundwater, and the groundwater would be discharged to surface water bodies without dilution. It is important that implications of the application of fish consumption rates be understood in the context of all regulatory programs in which they are to be used. In some cases, as described below, I believe that the application of these rates will lead to untenable regulatory gridlock.

Allowable Tissue Concentrations Below Background

The *Fish Consumption Rates Technical Support Document* is based on the premise that the existing default fish consumption rates used in regulatory programs in Washington State are too low to protect significant numbers of consumers. Consequently, consideration is being given to revising upward those default rates (currently 54 g/day under MTCA and 6.5 g/day under the state Water Quality Standards). However, it is not at all clear that fish consumption rates above 54 g/day would allow for a greater degree of consumer protection. To understand why this would be so, it is necessary to calculate the tissue concentrations of common bioaccumulative contaminants that would be necessary to achieve acceptable risk levels. This is a subject that the technical support document is silent on, but something that is sorely needed. It is relatively straightforward to calculate the allowable tissue concentrations using standard risk assessment equations; all that is needed is selection of appropriate values for a few input variables (e.g., average consumer body weight, exposure duration, exposure frequency, acceptable risk level, fish diet fraction). For example, under MTCA, the target risk level for carcinogens is 1×10^{-6} excess cancer risk; using that risk level and MTCA's standard default values for the other variables, one can calculate the tissue concentrations of bioaccumulative contaminants that would be necessary to achieve an acceptable risk level. In the case of polychlorinated biphenyls (PCBs) and dioxins (two of the most common carcinogenic contaminants found in fish), the allowable tissue concentrations at a fish consumption rate of 54 g/day would be 1.3 μg/kg ww (parts per billion, or ppb) and 17 pg/kg ww (parts per quadrillion, or ppq), respectively. In the case of PCBs, this allowable concentration is roughly an order of magnitude below (i.e., only about one tenth of) the background concentrations of PCBs in Puget Sound fish; for dioxins, this allowable concentration is well over an order of magnitude below background. Under MTCA, if a calculated risk-based level is below background, the cleanup level defaults to background (i.e., a risk-based goal below background is assumed to be unachievable). If a fish consumption rate greater than 54 g/day was selected, the allowable tissue concentrations would be even further below background, so no greater level of consumer protection could be expected.

Fish Held to a Higher Standard than Other Foods

Such calculations of the tissue contaminant concentrations that would be necessary to achieve specified target risk levels are also of interest by comparing those concentrations to the concentrations of those contaminants in other food products. For example, other protein sources such as beef, chicken, pork, and dairy products all contain PCBs and dioxins at concentrations that would represent unacceptable risks if these foods were consumed at the rates put forth in the technical support document. Indeed, as indicated on page E-11 of Appendix E of the technical support document, even wild Chinook salmon from southeast Alaska have PCB concentrations that would represent unacceptable carcinogenic risks if consumed at the MTCA default fish consumption rate, let alone the higher rates now being proposed by Ecology. Indeed, because of the worldwide atmospheric distribution of ubiquitous contaminants such as PCBs and dioxins, it is unlikely that any fish in the world have concentrations of these contaminants low enough to represent acceptable risks. I believe that it is unreasonable for Ecology to suggest that somehow fish in Washington State should be held to a higher standard than other commonly consumed foodstuffs. Similarly, it is disingenuous to discourage public consumption of fish, recognizing that the public may turn to other protein sources without realizing that those also pose unacceptable risks by the stringent criteria of MTCA. It is incumbent on Ecology to do a much better job of risk communication on such issues if the public is to understand the risks associated with fish consumption in the context of other risks we all face in everyday life.

Carcinogenic Risks vs. Noncancer Health Outcomes

The aforementioned analysis touches on a related subject that also points out the need to consider these fish consumption rates only in the context of how they will be used in regulatory programs. That subject is the distinction between carcinogenic risks and noncancer health outcomes. Calculation of allowable tissue concentrations for contaminants such as PCBs, which have both carcinogenic and noncarcinogenic properties, will generally yield more stringent (i.e., lower) concentrations for carcinogenic effects than for noncarcinogenic effects. Using the standard risk assessment equations mentioned above with a target noncancer hazard index of 1 (as required under MTCA) yields an allowable tissue PCB concentration of 52 µg/kg ww (ppb), as compared to the allowable tissue PCB concentration of 1.3 µg/kg ww (ppb) for carcinogenic effects. Thus, the allowable tissue concentration to protect against noncancer effects may actually be above background concentrations, and therefore potentially achievable. It is notable that the Washington Department of Health issues seafood consumption advisories on the basis of noncancer effects, and not carcinogenic effects. There is good reason for this. In a recent journal article (Stone and Hope 2009; included as Attachment A) addressing this issue, the authors raise three arguments against using cancer risk as the basis for fish consumption advisories:

1. The benefits of fish consumption are widely recognized.
2. The standard methodology to predict cancer risk is likely to overestimate actual risk, often by orders of magnitude.
3. The public's real and perceived concerns about cancer may result in unintended consequences, such as avoidance of fish altogether.

As an alternative to cancer-based advisories, Stone and Hope suggest that future advisories incorporate a multidisciplinary public health framework focused on avoiding noncancer health outcomes and encouraging the public to consume a balanced diet rich in fish.

Unfortunately, both MTCA and CERCLA have risk targets for both cancer and noncancer effects, and I am aware of cases where both are being considered as the basis for establishing cleanup levels. As demonstrated above, it may not be possible to achieve acceptable risk levels for some of the most potent carcinogenic contaminants because the allowable tissue concentrations, calculated on the basis of highly conservative risk assumptions, are below background. On the contrary, achievement of tissue concentrations necessary to prevent noncancer health outcomes may be possible because they are above background. Hence, the identification of appropriate fish consumption rates for use in Washington State regulatory programs must consider what type of adverse health effects we are striving to avoid. If the state intends to consider cancer effects, the argument over what is the most appropriate fish consumption rate becomes a moot point. Even the current MTCA default consumption rate yields unachievable tissue concentrations (because they are below background), and the even higher fish consumption rates that are proposed in the technical support document would require even lower tissue concentrations. In either case, background becomes the default goal.

Risks for Individual Contaminants vs. Total Risks

Regulatory agency staff appear to be well aware that at high rates of fish consumption, allowable tissue concentrations of some of the most potent bioaccumulative contaminants will be below background concentrations. Nevertheless, some have voiced the opinion that these high consumption rates must still be considered in order to regulate other contaminants that may be less potent, and therefore have allowable tissue concentrations above background concentrations. This is a spurious argument, however. Fish everywhere have sufficiently high concentrations of potent bioaccumulative contaminants such as PCBs and dioxins as a result of worldwide atmospheric transport that they would represent unacceptable excess cancer risks if consumed at relatively high rates, even the MTCA default consumption rate of 54 g/day. Given that fact, it would be pointless to try to regulate the concentrations of much less potent contaminants in fish tissue because the overall magnitude of risk cannot be reduced below that associated with background concentrations of ubiquitous contaminants such as PCBs and dioxins. The risks of consuming fish and other seafood can only be meaningfully evaluated on the basis of the total risks associated with all contaminants they contain. Attempts to reduce risks by focusing on individual contaminants, while ignoring the risks associated with more potent and ubiquitous contaminants, would be futile. Ecology should recognize this fact, and not pretend otherwise.

Scientific Defensibility of Tribal Consumption Surveys

The technical support document goes into great depth describing the criteria that were applied to assess the scientific defensibility of the results of the various fish consumption surveys considered in the document. Ecology obviously recognizes the importance of making data available for scrutiny so that other researchers can verify results and test conclusions, and even refers on page 45 to a recent editorial in *Science* that makes that very point. However, the technical support document then states:

> "Many Pacific Northwest tribal organizations or tribal governments do not provide their raw seafood dietary data to researchers outside of their sovereign tribal government or organizations. They may consider survey data as confidential and not allow independent evaluations. Data evaluation typically occurs through government-to-government agreements or tribal technical personnel."

Despite all of the supposedly detailed assessment of the scientific defensibility of the fish consumption surveys that Ecology describes, I believe that the inability of anyone outside the tribes to independently evaluate the raw survey data seriously compromises the use of those data. For data that are to have such far-reaching and costly ramifications, I believe that a true assessment of the scientific defensibility of the surveys can only be conducted if the raw survey data are available for a complete and independent assessment of their conclusions. If the tribes truly want the results of these surveys to be considered, they should make the raw survey data available, and Ecology should then enlist the services of independent experts in the field of fish consumption surveys to evaluate those data to ensure that the conclusions can be supported. This is no different than if the tribes had their own scientists conduct studies of the toxicity of contaminants, but then put forth conclusions without allowing other scientists to see their results. The evaluation of any data considered for use in such regulatory settings must be totally transparent and subject to independent verification. I believe that the results of any fish consumption surveys that have not been subject to such scrutiny should not be used.

Although the raw survey data have not been made available for at least some of the tribal fish consumption surveys, there are enough incongruities and inconsistencies in some of the published results of those studies to raise serious questions. Although I have no reason to single out any one survey as causing concern, the results of the Suquamish tribal survey are sufficiently different from those of the other tribal surveys to warrant careful consideration. As shown in Table 1 of Appendix C of the technical support document, the Suquamish tribal fish consumption rates are substantially higher than those of the other four surveyed populations. For example, the mean Suquamish rate is 214 g/day, whereas the mean rates for the other surveys range from 63 to 117 g/day. The difference in the 95th percentile rates is even more pronounced: 796 g/day for the Suquamish vs. 176 to 306 g/day for the other four surveys. It is not readily apparent why the Suquamish rates should be so much higher. The very high 95th percentile rate is especially of concern because such high percentile values are often used to identify a "reasonable maximum exposure". When the number of people surveyed is relatively small, 95th percentile values are based on the responses of a very few individuals. In the case of the Suquamish, for example, there were 92 adults surveyed. For this number of respondents, the 95th percentile rate falls between the rates reported by the respondents with the 5th and 6th highest consumption rates among all of the respondents; the rates for all other respondents may be much lower but they have no bearing on the absolute value of the 95th percentile consumption rate. The fact that the 95th percentile rate for the Suquamish tribe is much higher than the reported rates for most of the tribal population surveyed is especially apparent in cumulative frequency plots in the Suquamish report; the top six or so respondents reported eating far more seafood than most of the other tribal members. Thus, the 95th percentile consumption rate for the Suquamish survey represents only a few individuals within the tribal population.

Review of the portion sizes (i.e., serving sizes per meal) reported in the Suquamish survey raises questions about the validity of these high seafood consumption rates. In Table T-8 of the Suquamish report (The Suquamish Tribe 2000), the mean, median, minimum, maximum, and 90th percentile portion sizes for various seafood categories are reported. Most of the tabled values appear plausible, with the exception of the maximum portion sizes for the various shellfish species. For bivalves (i.e., clams, mussels, oysters), the maximum reported portion sizes range from 1,134 g (2.5 pounds) for mussels to an incredible 2,720 g (6 pounds) for geoduck clams. I have a hard time envisioning anyone eating 6 pounds of geoduck clams in one meal. Without access to the underlying data, it is impossible to say what effect such extreme portion sizes might have had on the 95th percentile rate used in the HHRA. However, these extreme portion sizes certainly raise the question of whether the responses given by the individual(s) reporting such portion sizes are believable.

The issue of the credibility of survey respondents is a curious one. Although the same statistical consultants participated in the Tulalip, Squaxin, and Suquamish surveys, data "outliers" were treated differently. In the Tulalip/Squaxin survey report (Toy et al. 1996), the authors recognized that there were "a number of outliers representing unusually large consumption rates", and that "values such as these represent large but uncertain consumption rates". Rather than use these questionable values, the statisticians "recoded" these extreme values "to the largest reported consumption rate within three standard deviations of the arithmetic mean". That is, no reported consumption rate was allowed to be more than three standard deviations above the arithmetic mean of all respondents, regardless of what the individual tribal members reported.

In the Suquamish survey report (The Suquamish Tribe 2000), however, the authors (i.e., the same statistical consultants) reported that "a number of high consumption rates were included in calculations of the mean, standard errors, and percentiles, in contrast to some preceding surveys (e.g., Toy et al.) where high values were considered as outliers and were truncated to a smaller value, such as the mean plus three standard deviations." Furthermore, the authors stated that "these high values were believed to represent actual high consumption and were not treated as outliers" and that inclusion of these high values had only very minor effects on the percentiles and mean consumption rates. Without access to the underlying data, however, it is impossible to determine whether this is in fact true. Apparently, the authors never questioned whether these respondents were truthful and whether their responses should be included. Indeed, the authors further justified their decision not to adjust potential outliers by saying "the study staff were familiar with a number of the individuals with large consumption rates and maintained that the reported rates were likely to reflect real consumption." Given that there were some respondents who reported truly extreme shellfish consumption rates (e.g., 6 pounds of geoduck clams in a single meal), this position presses the limits of credibility, and draws into question whether the responses from such individuals should have been included at all. In the absence of access to the raw survey data, it cannot be determined how many responses from those surveyed would have been identified as outliers. However, if any of the highest consumption rates (i.e., those reported by the top five or six respondents) had been identified as outliers and either excluded from the survey or truncated to a lower value (as they were in the Tulalip/Squaxin surveys), the resulting 95th percentile value would almost certainly have been lower, although to an unknown degree. This points out the importance of having access to the raw survey data and having outside experts review and confirm the analyses of those data.

Similar Issues with EPA Region 10's "Framework Document"

Ecology's technical support document cites the earlier "framework document" prepared by EPA Region 10 (i.e., *Framework for Selecting and Using Tribal Fish and Shellfish Consumption Rates for Risk-Based Decision Making at CERCLA and RCRA Cleanup Sites in Puget Sound and the Strait of Georgia*; EPA 2007) as lending credence to some of the analyses in Ecology's document. Unfortunately, EPA's framework document suffers from the same lack of transparency associated with not having access to the raw survey data. EPA's framework document was prepared by staff from EPA Region 10, without the benefit of review by any other state or federal agencies (e.g., Washington State Department of Health, Ecology, any offices of EPA outside Region 10 [including EPA headquarters]) or any experts in the development and application of seafood consumption surveys.

EPA Region 10 has been very careful not to refer to their framework document as a "guidance document", perhaps being aware that an EPA "guidance document" would be subject to considerably more scrutiny than this document was ever expected to receive. Indeed, the Office of Management and Budget (OMB) requires that a guidance document must be: (1) developed with appropriate review and public participation, (2) accessible and transparent to the public, (3) of high quality, and (4) not improperly treated as legally binding requirements. Among other things, a guidance document must also include the term "guidance" or its functional equivalent in the title, have a document identification number, and a citation to the statutory provision or regulation it interprets or to which it applies. The agency must post the guidance document on the section of its website designated for significant guidance documents, provide for public comment, and provide a link from the guidance document to the public comments. The agency must also designate an office to receive and address complaints by the public that the agency is not following the procedures required by the OMB. EPA Region 10 apparently did none of these things in developing the framework document and therefore it should not be considered to be guidance.

For documents such as the framework document, EPA Region 10 does require those preparing the document to complete a form titled "Region 10 Information Quality Guidelines Pre-dissemination Checklist." One of the questions to be answered is "Does the work product meet 'quality' objectives?" Normally, "formal, external peer review" is necessary to meet agency criteria for quality. In the absence of external peer review, the following questions must be answered:

1. Is the information accurate and reliable?
2. Is the information unbiased?
3. Is the information useful?
4. Is the information secure?

EPA Region 10's guidelines regarding the first question indicate that if the data were developed or funded by EPA, the information may not be considered accurate and reliable unless the data were obtained under an approved quality assurance project plan (QAPP). If the data were not developed or funded by EPA, the data must be assessed against agency assessment factors to determine whether they are accurate and reliable. As indicated earlier, EPA Region 10's framework document is based on seafood consumption surveys of the Tulalip, Squaxin, and Suquamish tribes. The Tulalip/Squaxin surveys (Toy et al. 1996) were funded by EPA, but there is no evidence of a QAPP having been prepared. The Suquamish survey (The Suquamish Tribe 2000) was funded by the Agency for Toxic Substances and Disease Registry (ATSDR), and administered through the Washington State Department of Health. Again, there is no evidence of a QAPP having been prepared. The Suquamish survey results are reported only in summary form in a publicly available document (The Suquamish Tribe 2000), but the underlying data have never been released to anyone, including EPA. A consultant to the Suquamish tribe conducted all statistical analyses of the data. Given that neither EPA nor anyone other than the Suquamish Tribe and their statistical consultant has ever seen the data, there is no way to know whether the statistics are correct. Hence, it is not apparent how EPA could vouch for the accuracy and reliability of the Suquamish data.

It also appears that EPA further failed to comply with EPA Region 10's Information Quality Guidelines, which state that "influential information" should be subjected to a higher degree of transparency about data and methods, than other disseminated information. Prior to dissemination of "influential information," all five of the following questions must be answered in the affirmative:

1. Is the source of the data presented?
2. Are the various assumptions employed fully described?
3. Are the analytical methods fully described?
4. Are the statistical methods fully described and discussed?
5. Do all the original and supporting data meet the above criteria, to the extent practicable, given ethical, feasibility, and confidentiality constraints?

Because EPA has not seen the underlying data from the Suquamish survey, it cannot answer all of these questions affirmatively. The lack of opportunity to review the underlying data used in development of EPA Region 10's framework document compromises the transparency of the process, which, just as in the case of Ecology's technical support document, is necessary for any document with such far-reaching implications.

Difficulty in Translating Allowable Tissue Concentrations to Other Media

There appears to be an implicit assumption in the technical support document that once an appropriate fish consumption rate is chosen, allowable tissue contaminant concentrations can then be calculated, and, based on those, it will be possible to calculate the allowable contaminant concentrations in environmental media (e.g., surface water, sediments) necessary to achieve those tissue concentrations. There are at least two ways to do this, one of which is very data-intensive, site-specific, and expensive, while the other is much simpler but subject to considerable uncertainty. The first way is through the application of food web models; such models have been applied to persistent, lipophilic contaminants such as PCBs and dioxins that bioconcentrate as they move up through a food web. Such a model was recently applied to PCBs in the Lower Duwamish Waterway Superfund site in Seattle, at the cost of several hundred thousand dollars. Despite the expenditure of such a large sum of money, the end result could likely have been predicted prior to modeling; the allowable tissue concentration is so low that an allowable sediment concentration could not be calculated, and therefore the allowable sediment concentration defaulted to background. The second way is to apply conversion factors known as bioconcentration factors (BCFs) or biota sediment accumulation factors (BSAFs) to convert tissue concentrations to surface water or sediment concentrations. Although commonly used, there is considerable uncertainty associated with the selection of appropriate values for such factors. Conversely, there are certain bioaccumulative contaminants (e.g., mercury, arsenic, carcinogenic polycyclic aromatic hydrocarbons [cPAHs]) whose uptake and bioaccumulation processes are much more complex and not amenable to either approach. Even if allowable tissue concentrations for these contaminants can be calculated, there is no easy way to translate those into surface water or sediment criteria.

Regulatory Implications

If Washington State were to adopt the fish consumption rates now being proposed by Ecology as the basis for such things as sediment and surface water criteria, there would be potentially enormous ramifications. First, it raises the public expectation that application of these consumption rates, in combination with the allowable risk ranges already inherent in MTCA and the state Water Quality Standards, means that Ecology believes that we could actually achieve acceptable risk levels. In reality, the sediment and surface water concentrations that would be necessary to achieve acceptable tissue concentrations, and thereby acceptable risks, would be below natural background. Therefore, we will never be able to achieve these very low risk levels. Ecology staff talk as though achieving natural background concentrations might be achievable within a few decades. In reality, centuries, or perhaps even millennia, might be more realistic, at least in urban areas.

If Ecology were to adopt the fish consumption rates proposed in the technical support document, we would be trying to regulate the contaminant concentrations in fish to much lower levels that allowable in other foodstuffs. Other protein sources such as beef, chicken, pork, and dairy products, not to mention fish from even relatively uncontaminated areas such as Alaska, all contain PCBs and dioxins at concentrations that would represent unacceptable risks if these foods were consumed at the rates put forth in the technical support document. Discouraging the public from eating fish because of contaminant concentrations that result in relatively low risks (i.e., any excess cancer risk greater than 1×10^{-6}), while ignoring the health benefits of eating fish, is not wise public policy, especially when alternative protein sources contain the same contaminants.

Overstating the risks associated with fish consumption by assuming overly conservative exposure scenarios has potentially very costly ramifications without a clear and documented benefit. It is already apparent that use of the high tribal fish consumption rates will drive sediment cleanups to background (and still not achieve acceptable levels of risk). Furthermore, the perceived risks have the potential to eliminate the open-water disposal of dredged material, potentially having onerous financial ramifications for ports, which could be required to place all dredged materials in landfills even though the chemical concentrations in those materials may be below background concentrations in the area of the open-water disposal site. Similarly, high fish consumption rates may drive water quality criteria for bioaccumulative contaminants to background or even laboratory detection limits. The cost for any entity with a wastewater discharge (i.e., not only industries, but also municipalities) to have to try to achieve such concentrations in their discharge will be enormous, and it is may not even be technically feasible to treat water to such low levels. I understand that Ecology intends to conduct an economic impact assessment for the current revision of the Sediment Management Standards only once a draft rule has been completed. I believe that it is incumbent on Ecology to consider the economic implications much earlier in the process; given the potential ramifications of the fish consumption rates on not only sediment standards, but also surface water quality criteria and surface water cleanup standards, such consideration of economic implications should occur now.

I fully recognize the sensitivity of Ecology's dealings with the tribes and the desire to protect tribal members in their treaty-protected right to consume traditional foods. Understanding the risks associated with high levels of seafood consumption is essential. However, as indicated earlier, Ecology's development of proposed fish consumption rates in the technical support document is seriously flawed in that there has never been an independent, outside review of at least some of the tribal fish consumption surveys that serve as the foundation of the process. Absent such an open review process, I believe that the technical support document cannot legitimately be applied as the basis for establishing higher fish consumption rates. If the tribes truly want the results of these surveys to be considered, they should make the raw survey data available, and Ecology should then enlist the services of independent experts in the field of fish consumption surveys to evaluate those data to ensure that the conclusions can be supported. Otherwise, the development of appropriate fish consumption rates is not the transparent process that it needs to be.

As noted at the beginning of this letter, many of the concerns raised in these comments stem from the lack of any indication on the part of Ecology about how these fish consumption rates will be used. The fish consumption rates cannot be fairly evaluated in a vacuum. It will only be possible to consider the full implications of the adoption of these fish consumption rates once Ecology has explained how they intend to use them.

Specific Comments

The following comments are directed at specific pages within the technical support document where errors were noted.

At several places in the technical support document, there are incorrect references to 284 as the number of adults included in the survey of the Suquamish Tribe's fish consumption. This error, which appears on pages 6, 56, 71, A-1, and C-1, apparently arose because Ecology relied on an Oregon Department of Environmental Quality report that contained the same error, rather than consulting the original Suquamish report. In the Suquamish report, it is stated that 284 adults were initially identified as being eligible to participate, but in reality only 92 adults were actually surveyed. Curiously, page 55 and Tables 3 and 4 in Appendix C of the technical support document report the correct number of adults included in the Suquamish survey (92); however, it cannot be determined whether Ecology actually used this number in the weighting of results from the various surveys.

Page 6: Why was the 95th percentile rate for the Suquamish survey omitted from Table 1, given that it is reported elsewhere in the report (Table 1 in Appendix C). Was there concern that including this value (796 g/day) in the body of the report would be too alarming?

Page 7: This page states that Ecology's recommended range for a default fish consumption rate is 157 to 267 grams per day. Page 103 cites the same range. Inexplicably, page 111 then reports the recommended range as 150 to 275 grams per day.

Page 18: The first bullet on this page states "The life cycle and life history of salmon results in recycling the contaminant body burden to future generations of salmon." This statement is misleading. In reality, all fish pass a portion of their contaminant body burden on to the next generation in their eggs. The total mass of contaminants contained within juvenile salmon migrating from freshwater habitats into Puget Sound (resulting both from that acquired from their parent and from feeding within the freshwater habitats) has actually been shown to represent only a tiny fraction (about 1 percent) of the contaminant body burden in adult salmon. The rest is acquired in saltwater environments.

Page 20: This page refers to two-thirds of the state harvest of bottomfish in 2006 being from coastal waters, with the other third harvested from the marine waters of Puget Sound. It is not apparent what is meant by "coastal waters" (e.g., Pacific Ocean, Grays Harbor, Willapa Bay, Strait of Juan de Fuca?).

Page 74: This page provides an equation, said to be used under MTCA, for calculating surface water cleanup levels. However, that equation is incomplete in that it omits several important variables. Also, that equation is applicable only for carcinogenic effects. There is a separate equation that should be included in the technical support document to calculate surface water cleanup levels based on noncarcinogenic effects.

Thank you for taking my comments into consideration. I trust that they shed some light on some of the problems with the approach Ecology is considering with regard to fish consumption issues.

Sincerely,

Lawrence McCrone
16233 S.E. 48th Street
Bellevue, WA 98006-4706

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Attachment

Stone, D. and B. K. Hope. 2009. Carcinogenic Risk as the Basis for Fish Advisories: A Critique. Integrated Environmental Assessment and Management 6(1): 180–183.

Integrated Environmental Assessment and Management — Volume 6, Number 1—pp. 180–183

Debate and Commentary

Carcinogenic Risk as the Basis for Fish Advisories: A Critique

David Stone† and Bruce K Hope‡*

†Oregon State University, Department of Environmental and Molecular Toxicology, 327 Weniger Hall, Corvallis, Oregon, USA
‡Oregon Department of Environmental Quality, Air Quality Division, 811 SW Sixth Avenue, Portland, Oregon 97204-1390, USA

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ABSTRACT

Fish advisories are important tools in public health practice and are primarily used to translate fish contaminant levels into consumption recommendations for consumers. Even when a targeted advisory is issued, it may alter broad food consumption patterns among the public, including diminishing intake of fish-based protein and polyunsaturated fatty acids. Such alterations may have both positive (e.g., reduced exposure to contaminants) and negative (e.g., loss of health benefits or cultural traditions associated with consuming fish) consequences. Currently, a fish advisory may be based on the potential for either noncarcinogenic or carcinogenic endpoints. Consumption recommendations based on a cancer outcome are likely to be highly restrictive, potentially diminishing opportunities for the recognized health benefits associated with a fish-rich diet. This possibility causes us to raise 3 arguments against using cancer risk as the basis for fish consumption advisories. First, the benefits of fish consumption are widely recognized. Second, the standard methodology to predict cancer risk is likely to overestimate actual risk, often by orders of magnitude. Third, the public's real and perceived concerns about cancer may result in unintended consequences, such as avoidance of fish altogether. As an alternative to cancer-based advisories, we suggest that future advisories incorporate a multidisciplinary public health framework focused on avoiding noncarcinogenic health outcomes and encouraging the public to consume a balanced diet rich in fish. We also suggest that decision makers need to 1) understand which elements of the advisory process are science and which are implicit or default policy, 2) consciously consider whether these policy elements are appropriate for their particular situation, and 3) if not, be willing to make and defend alternative policy choices. Integr Environ Assess Manag 2010;6:180–183. © 2009 SETAC

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INTRODUCTION

People need protein in their diet and there are a variety of protein sources (e.g., soy, corn, wheat, rice, eggs, milk, muscle from meat, poultry, and fish). The factors that influence which protein source is consumed include availability, cost, and cultural preference. Fish are an excellent source of protein and omega-3 fatty acids, and consumption of fish has been shown to have demonstrable health benefits (Bouzan et al. 2005; Cohen, Bellinger, and Shaywitz 2005; Köing et al. 2005; Teutsch and Cohen 2005). Some populations, particularly subsistence and tribal fishers, rely heavily on self-caught fish as an economical source of protein. Some fish may, however, contain chemical contaminants at levels that, if consumed in sufficient quantities, could pose an unacceptable risk to health. Federal, state, and tribal governments protect the public from this threat by monitoring their waters and issuing consumption advisories when contaminant levels in fish are determined to pose an unacceptable risk (USEPA 2000a). Typically, a consumption advisory will recommend people limit or avoid eating certain species of fish caught from specific lakes, rivers or coastal waters. Such restrictions, if followed, require fish consumers to make trade-offs with respect to health, recreation, economics, community and traditional activities, as well as personal interests and other perceived benefits of fish consumption. Specific to health outcomes, consumers are presented with a trade-off between the known health benefits of ingesting fish and the potential health risk of exposure to contaminants. Consumers may also face a dilemma between the health benefits and risk of ingesting fish versus the risk and benefits of consuming non–fish-based protein. Some fish consumers may alter this risk–risk trade-off by selectively avoiding consumption of the most contaminated fish species (e.g., higher trophic level piscivores). However, for consumers whose cultural practices and traditions revolve around consumption of just such fish species (e.g., salmon), such avoidance is simply not an option. For these consumers, this trade-off remains a zero-sum dilemma (Donatuto and Harper 2008).

To the extent that a fish advisory is part of the information that consumers use to weigh health trade-offs and make decisions, it must neither inappropriately over- or underestimate the risk associated with chemical contaminants (Foran et al. 2005). Most fish advisories in the United States are based on contamination with methylmercury, a noncarcinogenic compound (Egeland and Middaugh 1997; Cohen, Bellinger, Conner, et al. 2005). Some agencies, however, provide consumption recommendations based on potentially carcinogenic contaminants such as polychlorinated biphenyls (Reinert et al. 1991) and federal guidance provides meal recommendations based on carcinogenic endpoints with corresponding selected levels of acceptable risk (USEPA 2000b). Furthermore, academic studies that warn consumers of the cancer-causing potential of contaminated fish have received high media visibility, including recent articles proposing meal restrictions for salmon based on cancer endpoints (Hites et al. 2004; Huang et al. 2006). The question of how to balance the risk and benefits of fish consumption is complex, given the

* To whom correspondence may be addressed: hope.bruce@deq.state.or.us
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significant level of uncertainty in both risk and benefits. A recent review of these issues by the Institute of Medicine (NAS 2007) concluded that for most of the general population, following the current dietary guidelines provides a reasonable balance of risk and benefits associated with seafood consumption. Except in the specific instance where risk is defined as a carcinogenic endpoint with upward of a 10^{-6} probability of occurrence, we agree with these conclusions. However, unless the meaning of what are policy-based "acceptable" risk levels (c.f., Kelly 1995) is clearly acknowledged and understood, the public may respond in alarm and confusion, when, in fact, the actuality of an adverse health outcome may be exceedingly small (Barron et al. 1994; Lee et al. 2005).

ARGUMENTS

We considered whether restrictive consumption limits, predicated on the probability of developing cancer, are an appropriate basis for dissuading the public from consuming fish. We argue that cancer risk is an inappropriate basis for fish consumption advisories for 3 principal reasons. First, the acceptable excess cancer risk among U.S. regulatory agencies is typically minute, ranging from 1×10^{-4} to 1×10^{-6} additional excess lifetime cancers, relative to the probability of demonstrated benefits attributable to fish consumption. Our fundamental argument here is that the demonstrable benefits of fish consumption should be balanced against "real" (i.e., a future negative outcome with a high probability of actual occurrence) risk. That this risk is based on an endpoint (cancer) dreaded by the lay public only exacerbates the public's aversion to fish consumption, with a subsequent loss of health benefits. Second, the extrapolation models typically used to calculate the probability of low-dose cancer outcomes tend to overestimate risk, typically by several orders of magnitude. Many of the cancer endpoints observed in laboratory testing have uncertain relevance to human disease, especially at the dosing levels or exposure routes administered to test animals. The methods used to model cancer risk based on these dose–response tests tend to be overly conservative for situations in which health benefits are much more probable than realization of risk. Third, policy decisions have dictated an extremely low acceptable excess lifetime cancer risk that may have the unintended consequence of consistently elevating cancer risk above all other health concerns. This possibility, combined with the public's real and perceived concerns about cancer, can overwhelm any objective discussion of risk versus benefits.

CALCULATED RISK VERSUS PROBABLE BENEFITS

With respect to the relative probability of the benefits and risk attributable to fish consumption, consider the simple case of a health benefit X (with an occurrence probability p[B]), a cancer health outcome Y (with an occurrence probability p[C]) and a noncancer health outcome Z (with an occurrence probability p[NC]), so that an advisory would be recommended only when $(Xp[B]) - (Yp[C] + Zp[NC]) \leq 0$ (this equation is only illustrative; Ginsberg and Toal (2009) offer a quantitative approach to risk–benefit calculations involving fish consumption). It is evident that, if p[C] is at or below 1×10^{-6}, or even raised higher, to 1×10^{-4} for example, that the relevance of cancer to other outcomes will be de minimis if either p[B] or p[NC] is of any magnitude. The acceptable range for cancer risk in U.S. regulations is typically 1×10^{-4} to 1×10^{-6} for a lifetime excess cancer risk. This range is exceedingly small in the context of overall U.S. cancer incidence (458.2 age-adjusted cases of cancer per 100 000 people in 2004; CDC 2009). When risk is defined as an outcome with a $\leq 10^{-4}$ probability of occurrence, real health benefits are being compared with a nearly insignificant risk. Use of such a low range to issue an advisory results in consumption recommendations that are invariably more restrictive when compared with those drawn from noncancer outcomes. One might be tempted to argue that because many noncancer effects are nonfatal, $Y > Z$ in all cases. If, however, devastating but nonfatal noncancer health effects (e.g., neurobehavioral deficits in offspring from in utero exposure) occur early in life, both monetary and quality-of-life costs may be quite high and potentially irreversible. A truly meaningful comparison of relative risk, such as that between a cancer and noncancer endpoint, will ultimately require that noncancer consequences also be assessed probabilistically, rather than simply as a breach of some reference threshold (Baird et al. 1996). A recent NRC report suggests unifying the cancer and noncancerous dose–response assessment approaches to provide clearer estimates of population risk; information that is most useful for decision making, including informing risk trade-offs or cost-benefit analyses (NAS 2009). For fish consumption, while it may not be possible to state a precise value for p[B], there is sufficient information to indicate the probability of a benefit is considerably greater than one chance in one million (Cohen, Bellinger, and Shaywitz 2005). Thus, our key recommendation is that real health benefits be balanced against noncancer outcomes, where the link between exposure and outcome is more robust than one in a million and where the negative perceptions associated with cancer are not part of the conversation.

CANCER EXTRAPOLATION MODELS

Several of the organic contaminants found in fish tissue have been associated with excess tumors in animal laboratory tests when exposed to sufficient doses. These lipophilic compounds include polychlorinated biphenyls (PCBs); organochlorine insecticides, such as dieldrin, chlordane, and the DDT complex; and the dioxins and furans. The majority of these compounds are classified as either probable (based on animal studies) or possible human carcinogens in the US Environmental Protection Agency's (USEPA) fish advisory guidance (USEPA 2000b). Ideally, the evaluation of the human response to elevated contaminant levels in fish should be based on a robust process that is associated with a high degree of confidence in the methodology used, along with the underpinnings to support that methodology. We argue that the extrapolation models favored for calculating the probability of low-dose cancer outcomes from animal data overestimate risk, typically by several orders of magnitude, often with uncertain inference to human disease etiology (Gold et al. 1998) and without consideration of other influencing processes such as epigenetics (Trosko and Upham 2005).

For the prediction of cancer incidence at low doses, the observed relationship between lifetime daily dose and observed tumor incidence is fitted to a mathematical model. The traditional approach favored by EPA before the 2005 cancer guidelines was the linearized multistage model (LMS) and straight-line extrapolation. These models were used in the latest edition of the *National Guidance for Assessing Chemical Contaminant Data for Use in Fish*

Advisories (USEPA 2000b). In the LMS model, cancer slope factors are based on the upper 95% confidence limit on the coefficient of the linear term for additional cancer risk above background (Crump 1996; USEPA 1996). An important feature of the LMS and straight-line models is that the dose–response curve is linear at low doses, even if it displays nonlinear behavior in the region of interest. The generated potency factor is then used to derive a unit risk estimate—the plausible upper bound on excess lifetime risk of cancer per unit of dose. In general, these upper-bound potency measures from these models tend to overestimate risk. Sometimes this overestimate may be by several orders of magnitude and may be in the form of positive risk when the real risk is zero. There is also considerable uncertainty in the extrapolation from high to low doses, primarily because the shape of the dose–response curve at low doses is not derived from empirical observation but is inferred from theoretical considerations that cannot be directly corroborated with empirical evidence.

Recently, the USEPA outlined new guidelines to estimate carcinogenic risk that incorporated state-of-the-art science into cancer risk assessment (USEPA 2005). For chemicals that have sufficient data on mode of action, the USEPA details sophisticated options for assessing cancer, using a biologically based or case-specific dose–response approach. For chemicals without sufficient information, the recommended approach is based on a linear extrapolation to the origin, using a point of departure taken from the dose–response data, such as a LED_{10} (the lower 95% confidence limit on a dose that predicts a 10% extra risk, such as tumor incidence, over background). Regardless of whether the LMS approach or the LED_{10} point of departure model are used to estimate carcinogenic risk, the cancer slope factors generated are not substantially different from one another for most compounds (Subramaniam et al. 2006).

Additional considerations in the latest USEPA cancer risk assessment guidelines include the incorporation of human epidemiological data and characterization of compounds with a genotoxic mode of action. For genotoxic compounds, the guidelines indicate a linear-dose response should be applied. However, an expert panel asserted that this is not necessarily accurate, and nonlinear, genotoxic modes of action should be considered (Anderson et al. 2000). For many of the compounds that accumulate in fish tissue, their potential carcinogenic mode of action is unknown. Epidemiological studies in the latest guidelines are considered in the context of Bradford Hill's criteria for causality, which establishes rigorous standards to characterize epidemiological data. While human epidemiological data may be ideal in principle to guide dose–response assessment, applicable and robust data are usually limiting. This includes data that would provide a causal link between human cancer and the primary lipophilic contaminants found in fish tissue. Thus, the majority of lipophilic compounds that accumulate in fish tissue either do not have sufficient mode-of-action information, nor human epidemiological data, to use a biologically based or case-specific model. Therefore, a default linear model will likely be applied.

The adoption of linear models for regulatory purposes is based largely on a science-policy choice that emphasizes caution in the context of scientific uncertainty. Alternative models that yield lower risks or incorporate a threshold dose are plausible for many carcinogens. However, in the absence of compelling mechanistic data to support such models, regulators are reluctant to use them, either because this would suggest that more is known about the mode of action of a carcinogenic compound than is warranted or out of concern that public perception will demand the use of the most conservative estimate. Based on all of these considerations, we argue that the bar required to justify using a nonlinear, biologically based cancer model is often too high and, therefore, cancer risk assessment should not be used for setting fish consumption advisories.

RISK PERCEPTION

Regardless of its basis, a fish advisory may lead to alterations in overall fish consumption patterns. For instance, after release of the 2001 federal advisory targeting women of child-bearing age exposed to methylmercury, a time series analysis of over 2000 pregnant women demonstrated a decline of 1.4 servings of fish per month (Oken et al. 2003). Research in the social sciences has shown that people generally will not accept a risk, such as that of cancer, which they perceive suggests serious delayed and possibly irreversible effects, even if the likelihood of occurrence is very low (Klein and Stefanek 2007). Thus invoking cancer as the basis for a fish advisory is likely to generate significant alterations in fish consumption patterns, even if the cancer risk is de minimis. The important difference between the actuality of cancer and the one-in-one-million chance of excess cancer is fairly abstract and very low risk estimates tend to be viewed with less credibility among the public (Johnson and Slovic 1995). Thus, it is disconcerting that "cancer" is typically invoked on the basis of this 10^{-6} chance, the genesis of which, as well as its continued use as a regulatory default, are entirely policy choices, and not scientific mandates (Kelly 1995). Reaction of the public to their perception of cancer, rather than to any meaningful chance of adverse health effects, may steer public health officials into actions that are neither particularly health protective or cost-effective. Once "cancer" enters the conversation between health officials and the public, any objective consideration of cancer risk versus fish consumption benefits may be precluded. We, therefore, argue that this potential for disproportionate negative consequences based on perception does not justify invoking the specter of "cancer," particularly given the uncertainties inherent in current potency estimation methodologies. We also note that a focus on cancer, whose consequences may not appear for decades and whose etiology can be highly uncertain, can divert attention from the potential for noncarcinogenic outcomes that are more immediately expressed and probable.

SUMMARY

Fish consumption advisories are important tools in public health, which if not properly considered, may lead to unintended adverse consequences (i.e., a loss of health benefits). We conclude that the use of carcinogenic endpoints for fish advisories is not presently justified for 3 primary reasons. First, the policy-based acceptable range for additional lifetime cancers is exceedingly small (typically 10^{-4} to 10^{-6}) compared with the clearly acknowledged health benefits associated with eating fish. Second, the methods used to estimate cancer risk are overly conservative and not justifiable in situations where health benefits are much more probable than health risk. Third, the perception of cancer by the public may result in an overall decline in fish consumption and be unproductive for public health outreach. To minimize unintended consequences while continuing to protect public health, we advocate that risk managers derive consumption restrictions based on noncancer health outcomes only. We acknowledge that adopting this suggestion could create disparities in how state and federal programs regulate the same chemicals in differing situations (e.g., more tightly at hazardous waste sites, possibly less so for fish advisories). Yet such disparities are inherent if not all environmental problems are deemed identical or amenable to exactly the same management actions. This is why we also suggest (as has the USEPA itself) that decision makers need to 1) understand which elements of the advisory process are science and which are implicit or default policy, 2) consciously consider whether these policy elements are appropriate for their particular situation, and 3) if not, be willing to make and defend alternative policy choices. These recommendations are not particularly radical, given that the USEPA's own guidance provides flexibility and states that: "Carcinogenic toxicity has in the past often yielded the most health-conservative exposure limits, especially when coupled with a low level of 'acceptable' risk such as one in one million. Decision-makers may elect to choose a noncancer health endpoint or a less stringent level of acceptable risk..." (USEPA 2000b). What may be novel is our suggestion that cancer should not be considered in the assessment of adverse health effects from fish consumption unless detailed compound specific information is generated that warrants otherwise. Rather than attempting to estimate remote cancer outcomes, potentially carcinogenic compounds in fish should be addressed qualitatively through information on preparation and cooking recommendations to reduce exposure. To the extent practicable, advisories should be as specific as possible and targeted to a defined audience, location, and species of fish. When advisories are issued, health officials can use this visible opportunity to reiterate the benefits of a balanced diet that is rich in seafood. These efforts are less likely to result in unintended consequences and offer a refined message that addresses more probable risks while minimizing the loss of benefits.

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