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OFFICE OF
WATER AND WATERSHEDS

November 6, 2015

Don Essig
Idaho Department of Environmental Quality
1410 N. Hilton
Boise, Idaho 83706

RE: EPA Comments on Idaho's Revised Human Health Toxic Criteria, Proposed Rule, Docket No. 58-0102-1201

Dear Don:

The EPA appreciates the opportunity to provide comments to the Idaho Department of Environmental Quality (DEQ) on its proposed updated human health ambient water quality criteria, which were published for public comment on October 7, 2015. The enclosed comments reflect many of the issues the EPA identified in our previous comment letters to DEQ and, in some instances, provide additional clarification. The EPA continues to recognize the challenging work undertaken thus far in revising Idaho's human health criteria.

The EPA commends Idaho for using state of the art survey methodology to characterize current fish consumption rates for the general population and anglers in Idaho. Given the regulatory importance of these survey results, EPA strongly recommended that DEQ have the results peer reviewed by individuals with the necessary expertise, and address peer review concerns prior to fully incorporating this work into a regulatory context. EPA understands that DEQ has decided to conduct a peer review and is supportive of that effort.

The EPA also supports DEQ's decision to incorporate many of the EPA's latest scientific and policy recommendations consistent with the EPA's 2015 updates to its 304(a) national human health criteria recommendations. At the same time, the EPA remains concerned about some of DEQ's proposed decisions in deriving human health criteria. In particular, the EPA is concerned with DEQ's approach to calculating its fish consumption rate because DEQ has not adequately demonstrated how criteria derived using the proposed fish consumption rate would be scientifically defensible, would be protective of designated uses in Idaho (as informed by reserved rights of tribal consumers), and would ensure the attainment and maintenance of water quality standards in downstream waters in Oregon and Washington.

The EPA is available to further discuss our comments and we remain committed to providing assistance as DEQ develops the final rule. If you have any questions, please feel free to contact me or Lisa Macchio at (206) 553-1834.

Sincerely,

Angela Chung, Manager
Water Quality Standards Unit

Enclosures

EPA Comments on Idaho Department of Environmental Quality's (DEQ)
October 7, 2015 Proposed Rule Revisions to Idaho's Human Health Criteria for Toxics
Docket No. 58-0102-1201
November 6, 2015

The Idaho Department of Environmental Quality (DEQ) provided proposed new and revised surface water quality standards (WQS) found at IDAPA 58-0102-1201 to the public for review and comment on October 7, 2015.[1] The EPA reviewed the state's proposed rule and associated documents and provides the following comments for DEQ's consideration. The comments are organized as follows:

A. Fish Consumption Rate (FCR)
    1. DEQ's Fish Consumption Survey Analysis and Results
    2. Exclusion of Market Fish (Other than Rainbow Trout)
    3. Exclusion of Anadromous Fish
    4. Tribal Reserved Fishing Rights
B. Other Input Variables
    1. Cancer Risk Level
    2. Relative Source Contribution (RSC)
    3. Bioaccumulation Factor (BAF)
    4. Body Weight and Drinking Water Intake
    5. Toxicity Factors: Reference Doses (RfDs) and Cancer Slope Factors (CSFs)
C. Pollutant Scope
D. Use of Probabilistic Risk Assessment
E. Downstream Waters Protection
F. Specific Comments on DEQ's Proposed Rule Language

Please note that the EPA's positions described in the comments below, regarding the state's proposed WQS, are preliminary in nature and do not constitute an approval or disapproval by the EPA under the Clean Water Act (CWA) Section 303(c). Approval and/or disapproval decisions will be made by the EPA following adoption of the new and revised standards by the state of Idaho and submittal of revisions to the EPA. In addition, the EPA's comments do not constitute, and are not intended to be, an Administrator determination under CWA Section 303(c)(4)(B).

A. Fish Consumption Rate (FCR)

As the EPA has long acknowledged, it remains our practice to encourage states and authorized tribes to make appropriate adjustments to reflect local conditions affecting fish consumption.[2] Thus far, Idaho has not yet presented the EPA with a rationale that is adequate to establish that Idaho's proposed FCR is appropriate and will lead to criteria sufficient to protect Idaho's CWA Section 101(a)(2) uses (e.g., Primary and Secondary Contact Recreation, IDAPA 58.01.02.100.02(a)&(b)), as required under 40 CFR 131.11. While reserving final judgment on

[1] DEQ, *Water Quality Docket No. 58-0102-1201 - Proposed Rule,* http://www.deq.idaho.gov/58-0102-1201.
[2] USEPA. 2000. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. EPA-822-B-00-004. http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf.

this issue until we receive Idaho's final submission and supporting rationale, we emphasize that Idaho's approach currently appears to be inconsistent with the CWA and its implementing regulations. We outline our concerns in more detail below, and recommend that Idaho modify its approach consistent with the comments below.

1. DEQ's Fish Consumption Survey Analysis and Results

The EPA contracted with Westat, a well-known statistical consulting firm, to review DEQ's fish consumption survey results as reported in the Fish Consumption Survey report prepared by Northwest Research Group.[3] Westat identified a number of issues that DEQ should review (see attached memoranda from Westat), and EPA is available to discuss this information further. For example, Westat determined that the frequency of fish consumption declined over the seven day recall period. DEQ did not account for this trend, which could result in an underestimation of fish consumption. As previously noted, it is important for DEQ's fish consumption survey results to be peer reviewed by individuals with the necessary expertise. The Westat review provides information that DEQ should consider along with the results of its peer review. In particular, it is important that the National Cancer Institute (NCI) analysis, which involves many assumptions and employs statistical methodology not generally accessible to the lay person, be adequately reviewed. In addition, it is important that DEQ's final peer review findings be readily available and distributed to support the credibility of DEQ's survey results.

2. Market Fish (Other than Rainbow Trout)

CWA Section 303(c)(2)(A) requires that WQS protect "public health or welfare, enhance the quality of water and serve the purposes of [the Act]." CWA Section 101(a)(2) establishes as a national goal "water quality which provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water [wherever attainable]." The EPA has previously interpreted the "fishable" language in Section 101(a)(2) to refer not only to protecting water quality so the fish and shellfish thrive, but also so that when caught they can be safely eaten by humans. Thus, in order to be consistent with Section 101(a)(2), the applicable criteria for such "fishable" designated uses must not only protect the aquatic organisms themselves but also protect human health through consumption of fish and shellfish.[4]

The EPA's recommended 304(a) water quality criteria to protect human health (and the EPA's accompanying risk assessment methodologies) reflect this longstanding conclusion about the CWA: consumers of fish and shellfish are to be assured that if criteria are met in a waterbody designated with the uses specified in Section 101(a) of the CWA, then that means they can safely eat fish and shellfish drawn from that waterbody.[5] Thus, the EPA has consistently implemented the CWA to ensure that the total rate of consumption of fish and shellfish from inland, estuarine, and near-coastal waters reflects the consumption rates that are characteristic of the population of concern. In other words, the EPA expects that the standards will be set such that residents can safely consume from local waters the amount of fish they would normally consume from all

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[3] Northwest Research Group, Idaho Fish Consumption Survey. August 25, 2015.

[4] EPA's interpretation of the CWA is consistent with years of past practice. As evidence, see memorandum from Geoffrey H. Grubbs and Robert H. Wayland (October 2000) posted at http://water.epa.gov/scitech/swguidance/standards/upload/2000_10_31_standards_shellfish.pdf

[5] See discussion in *Revisions to the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*, 65 Fed. Reg. 66465 (2000).

inland and near shore waters. The EPA recognizes that consumers of fish and shellfish might not be limiting their consumption of fish and shellfish to those that were sourced from their own state's fishable waters. However, the relevant objective is to assure that they can do so without concern for their health.

Idaho's approach is to exclude from the FCR the fraction of the consumption of freshwater and estuarine fish and shellfish that is currently associated with fish originating from waters outside of Idaho.[6] Idaho justifies its approach on the grounds that Idaho lacks regulatory authority over fish caught outside of its borders. Based on the information and rationale EPA has received from Idaho to date, we note the following reasons why Idaho's justification for this approach is not scientifically sound:

- The purpose of including consumption from waters outside of Idaho's borders in the FCR is not to support any purported regulation of such waters by Idaho. Rather, the purpose of including this fish consumption in the FCR is so that a determination that a particular Idaho water body is "fishable" will result in adequate health protection for Idahoans should they consume, from local waters, the amount of fish they would normally consume from all inland and near shore waters.
- The approach of excluding "market fish" appears to assume that there is no exposure to pollutants from fish that were sourced outside of Idaho. This is because the full allowance for acceptable pollutant levels is given exclusively to local state waters. Consider if every state took this approach. For a non-carcinogenic pollutant with a specified Reference Dose, the criteria development equation would allocate this full dose to fish originating from the individual state. If a person then consumes overall 25 grams/day (g/day) of fish, comprised of 5 g/day each from 5 different states (and each state set a state-specific consumption rate of 5 g/day), then the consumer could potentially receive five times the acceptable pollutant dose.

3. Anadromous Fish

The EPA recognizes that Idaho has included steelhead, an anadromous species, in the calculation of its FCR. However, the EPA continues to have concerns with DEQ's proposed policy decision to exclude all other anadromous fish from the FCR, and recommends that DEQ either include all other anadromous fish in the FCR or provide additional demonstration of how criteria derived using a lower FCR that excludes anadromous fish will protect downstream shared waters in the Columbia River basin and protect the tribal populations exercising their treaty-reserved rights (see comments below regarding consideration of tribal reserved fishing rights).[7]

While the EPA's 304(a) recommended criteria account for exposures to non-carcinogens and nonlinear carcinogens in anadromous fish using the relative source contribution (RSC), the EPA supports and recommends that states include anadromous fish in the FCR when there is credible and compelling evidence of significant consumption of anadromous fish. For example, Oregon and Washington chose to include salmon in the FCR used to derive human health criteria due to,

[6] Idaho makes one exception to this rule, with rainbow trout, on the grounds that the majority of the rainbow trout in the market comes from Idaho aquaculture facilities.
[7] EPA reference to anadromous fish in this letter refers to all other anadromous fish except steelhead.

amongst other reasons, the large amounts of salmon consumed by tribes, the variation in individual market basket preferences (i.e., the types of fish that people purchase and consume), and uncertainties in the sources of salmon contaminant body burdens from inland and near shore waters (e.g., salmon residing in Puget Sound). The EPA approved Oregon's human health criteria in 2011. Similarly, the EPA supports Washington's decision to develop human health criteria using a FCR that includes anadromous fish consumption.

The EPA also has reviewed recent work related to salmon contaminant acquisition from near coastal waters of the Pacific Northwest and recommends that DEQ also consider this available information. For example, the research conducted by Sandra O'Neill, James West, David Herman, and Gina Yitalo provides evidence that certain Pacific Northwest salmon species, most notably chinook and coho, acquire organic pollutants from near coastal marine waters. [8] O'Neill et al. assayed salmon and herring for several classes of persistent organic pollutants (POPs). The POPs of interest included polybrominated diphenyl ethers (PBDEs), polychlorinated biphenyls (PCBs), hexachlorobenzene (HCB), and the insecticide DDT. An analysis of these POPs in herring populations identified unique regionally-specific patterns of these chemicals or "fingerprints," thus showing herring are acquiring contaminants from waters under CWA jurisdiction. Chinook salmon harvested from specific locations were found to have the same contaminant "fingerprints" as those exhibited by co-located herring samples, suggesting that they are feeding on herring in near coastal waters. This work provides evidence that certain chinook salmon species are acquiring contaminants from near coastal waters of Washington and Oregon, as well as California and British Columbia. Similar but more limited data by O'Neill et al. indicate that coho salmon, which reside in coastal waters and have feeding preferences similar to chinook salmon, are also acquiring contaminants from waters under CWA jurisdiction.

In addition, EPA has communicated with Laurie Weitkamp and Peter Lawson from NOAA,[9] who have stated that chinook (and likely coho) salmon from Idaho reside in near coastal waters off the Oregon coast. Myers at al. 1998, analyzing coated wire tag recovery, has concluded that Snake River Chinook salmon have a coastal residence pattern.[10] O'Neill et al.'s work shows that resident chinook salmon from these waters have regional contaminant fingerprints specific to this area. Given the contaminant fingerprint correlation between herring and coastal resident salmon at all locations where both species were analyzed, it is very likely that coastal salmon originating in Idaho waters are acquiring contaminants from coastal waters under CWA jurisdiction.

EPA recognizes that salmon acquire most of their body weight and, therefore, most of their body burden of highly bioaccumulative contaminants during open-ocean feeding. However, it is

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[8] Ms. O'Neill and Mr. West are both with the Washington Department of Fish and Wildlife.
[9] L. Weitkamp,personal communication 5/19/2015. P. Lawson personal communication via phone, May, 2015.Dr. Laurie Weitkamp has extensively examined recovery of coated wire tags (CWTs) from adult salmon harvested in marine waters. CWTs, inserted into juvenile salmon in hatcheries, allow researchers to determine the relationship between spawning locations and ocean ranges of various salmon species. Dr. Peter Lawson has done genetic testing of adult salmon in marine waters. By matching unique DNA patterns of juvenile and adult salmonids, researchers can determine where adult salmon came from.
[10] Myers K.W., K.Y. Aydin, R.V. Walker, S. Fowler, M.L. Dahlberg. 1996. Known Ocean Ranges of Stocks of Pacific Salmon and Steelhead, as Shown by Tagging Experiments, 1956-1995. Submitted to the North Pacific Anadromous Fish Commission. Fisheries Research Institute. University of Washington School of Fisheries.

possible that salmon may acquire less bioaccumulative contaminants directly from water during their return spawning migration as adults.[11] EPA consulted with Frank Gobas, a well-known expert in bioaccumulation and bioconcentration in aquatic food webs, to evaluate this issue and prepare an analysis.[12] The analysis first involved the development of contaminant concentrations in salmon tissue that were associated with either a cancer risk of 1 in 1,000,000 or a non-cancer hazard quotient of 1. These risk-based concentrations assumed a fish consumption rate of 175 grams per day by an 80 kilogram person. Next, bioconcentration modeling was performed to determine the water concentration that results in a salmon tissue concentration associated with the aforementioned risk-levels.[13] The model includes quantitative structure activity relationship biotransformation of chemicals and the impacts of changing lipid content associated with migration energy expenditure.[14,15] The model also accounts for the time dependent nature of chemical uptake. This modeling utilized a range of migration times for spawning Idaho chinook and sockeye salmon associated with several harvest locations within Idaho. The longer the migration time, the greater the opportunity for contaminants to bioconcentrate. Finally, ratios of Idaho's proposed water quality criteria to modeled water concentrations were computed. The results showed, for example, toxicity ratios of 10 or greater for 13 chemicals with non-carcinogenic toxicity. In other words, for 13 non-carcinogenic chemicals, Idaho's proposed criteria could result in hazard quotients of 10 or more for populations consuming Idaho returning salmon at a rate of 175 grams per day or more. This far exceeds EPA's recommendation of limiting risks to non-carcinogens to a hazard quotient of 1 or less. Therefore, DEQ should consider these results. EPA has enclosed the analysis for your review and consideration (see attached spreadsheets).

Idaho cites work by Hope 2012, suggesting that salmon do not acquire contaminants from waters under CWA jurisdiction, to justify excluding anadromous species from the FCR used to develop DEQ's proposed criteria.[16] The Hope study's conclusions are limited by its focus on PCBs and not on other toxics, and the study does not consider salmon acquisition of contaminants from near coastal waters as demonstrated by O'Neill et al. Central to the modeling is the assumption that contaminant uptake occurs largely through diet. While this is true for PCBs, depending on a chemical's lipophilicity, direct uptake from water may be a significant contributor to an organism's contaminant body burden.[17] The Gobas work on contaminant bioconcentration in migrating adult Idaho salmon, described above, provides evidence that adult Idaho salmon may acquire contaminants directly from the water column through their gills, in addition to dietary

[11] Less bioaccumulative contaminants refer to contaminants with log octanol-water partition coefficients (log Kow) between two and four.
[12] Dr. Gobas is with Simon Fraser University in Vancouver BC.
[13] Lo et a. 2015, Environ Toxicol Chem. 2015 Oct;34(10):2282-94
[14] US EPA EPI SUITE v. 4.11
[15] Debruyn et al. 2004, Environ Sci Technol. 2004 Dec 1;38(23):6217-24
[16] Hope, B.K. 2012. "Acquisition of Polychlorinated Biphenyls (PCBs) by Pacific Chinook Salmon: An Exploration of Various Exposure Scenarios." Integrated Environmental Assessment and Management 8:553–562. Cited by DEQ in: Considerations in Deciding Which Fish to Include in Idaho's Fish Consumption Rate Policy Summary, State of Idaho Department of Environmental Quality.
[17] Qiao, P., A.P.C. Gobas, and A.P. Farell. 2000. "Relative Contributions of Aqueous and Dietary Uptake of Hydrophobic Chemicals to the Body Burden in Juvenile Rainbow Trout." Archives of Environmental Contamination and Toxicology 39:369–377.

uptake. Finally, the Hope study also does not discuss different patterns of contaminant uptake associated with the complex life histories of other salmonids, such as steelhead.

In conclusion, DEQ should consider the above-referenced scientific information when making its final decision on whether to include anadromous salmonids, other than steelhead, in calculating the FCR. The EPA remains concerned that Idaho's decision to exclude most anadromous salmonids results in human health criteria that are not adequate to protect Idaho's primary and secondary contact recreation uses.[18]

4. Tribal Reserved Fishing Rights

Per EPA's regulations at § 131.11(a), water quality criteria must contain sufficient parameters or constituents to protect the designated use, and for waters with multiple use designations, the criteria must support the most sensitive use. In determining whether WQS comply with the CWA and EPA's regulations, when setting criteria to support the most sensitive fishing designated use in Idaho, it is necessary to consider other applicable laws, including federal treaties. In Idaho, certain tribes hold reserved rights to take fish for subsistence purposes, including treaty-reserved rights to fish at all usual and accustomed fishing grounds and stations and in unoccupied lands of the United States, which in combination appear to cover the majority of waters under state jurisdiction.

Many areas where reserved rights are exercised cannot be directly protected or regulated by the tribal governments and, therefore, the responsibility falls to the state and federal governments to ensure their protection.[19] In order to effectuate and harmonize these reserved rights with the CWA, such rights appropriately must be considered when determining which criteria are necessary to adequately protect Idaho's waters used for consumption of fish (designated as Primary or Secondary Contact Recreation, IDAPA 58.01.02.100.02(a)&(b)).

Protecting Idaho's fishing designated uses necessitates protecting the population exercising those uses. Where a population exercising such uses has a legally protected right to do so under federal law such as a treaty, the criteria protecting such uses must be consistent with such right. Thus, in order to protect the applicable fishing designated uses in areas where such rights apply, as informed by the treaty-reserved right to continue legally protected culturally important subsistence fishing practices, the state must consider the tribal population exercising their reserved fishing rights in Idaho as the target general population for the purposes of deriving criteria that will protect the subsistence fishing use and allow the tribes to harvest and consume fish consistent with their reserved rights.

The data used to determine the FCR are critical to deriving criteria that will protect the subsistence fishing use. The data used to determine a FCR must reasonably represent tribal subsistence consumers' practices that reflect consumption unsuppressed by fish availability or

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[18]As DEQ has acknowledged, "if anadromous species data are omitted from the data set, it is possible that the resulting criteria may not be adequately protective of Idahoans who eat salmon, steelhead, or other anadromous fish." *Idaho Fish Consumption Rate and Human Health Water Quality Criteria; Discussion Paper #5: Anadromous Fish*, pg. 4, available at http://www.deq.idaho.gov/media/1117748/58-0102-1201-discussion-paper5.pdf.

[19] Note that for formal and informal reservation lands, eligible tribes can obtain treatment in a similar manner as a state (TAS) status and set their own WQS under the CWA, including human health criteria.

concerns about the safety of available fish. Deriving criteria using an unsuppressed FCR furthers the restoration goals of the CWA, and ensures protection of human health as pollutant levels decrease, fish habitats are restored, and fish availability increases. If sufficient data regarding unsuppressed fish consumption levels are unavailable, consultation with tribes is important in deciding which fish consumption data should be used.

With these principles in mind, the EPA has concerns with whether DEQ's decision to calculate the FCR based only on current consumption of Idaho fish, and to use a mean FCR for high consuming populations, will adequately protect the treaty-reserved subsistence fishing use. First, in calculating the FCR, DEQ has not considered suppression, specifically suppressed consumption amongst tribal populations in Idaho with reserved rights to fish for their subsistence. Current average FCRs for the Nez Perce and Shoshone Bannock tribes are below heritage rates documented for both of these tribes, as well as heritage rates for the Kootenai and Coeur d'Alene tribes, suggesting that current tribal consumption rates could be suppressed.[20] Second, given that tribal consumption rates are likely suppressed, DEQ has not provided adequate justification for how a rate based on the mean FCR for the tribal target general population will adequately protect tribal fish consumers exercising their treaty-reserved rights, including those whose consumption is not suppressed. Finally, as discussed in greater detail above, the omission of anadromous species from the FCR may result in criteria that are not adequately protective of Idaho's designated uses as informed by the reserved fishing rights of tribal consumers.[21] Based on local conditions in Idaho, it is particularly appropriate to include anadromous species in the FCR, because it is well documented that a large proportion of fish consumption for the tribal target population to be protected consists of anadromous species, such as salmon.[22]

Accordingly, EPA recommends that DEQ select a FCR that reflects the tribal subsistence consumers' unsuppressed fish consumption, including consumption of anadromous fish. If such data are unavailable at this time, the EPA recommends using an upper percentile of consumer-only data to account for uncertainty in the unsuppressed consumption rates of tribal consumers within the state and to help ensure that the resulting criteria protect the tribal target general

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[20] Polissar, N.L, Al Salisbury, C. Ridolfi, K. Callahan, M. Neradilek, D.S. Hippe, *A Fish Consumption Survey of the Nez Perce Tribe Volumes I-III.* Seattle, WA: The Mountain-Whisper-Light Statistics (2015); Polissar, N.L, Al Salisbury, C. Ridolfi, K. Callahan, M. Neradilek, D.S. Hippe, *A Fish Consumption Survey of the Shoshone-Bannock Tribes Volumes I-III.* Seattle, WA: The Mountain-Whisper-Light Statistics (2015); Ridolfi Inc., *Heritage Fish Consumption Rates of the Kootenai Tribe* (November 17, 2014); Ridolfi Inc., *Heritage Fish Consumption Rates of the Coeur d'Alene Tribe* (July 19, 2015).

[21] As DEQ has acknowledged, "if anadromous species data are omitted from the data set, it is possible that the resulting criteria may not be adequately protective of Idahoans who eat salmon, steelhead, or other anadromous fish" and "the complexity of Pacific Northwest fish consumption and its high inclusion of these fish species in the diets of all means that ignoring anadromous fish would be less protective of those within Idaho who enjoy consuming these types of fish." *Idaho Fish Consumption Rate and Human Health Water Quality Criteria; Discussion Paper #5: Anadromous Fish*, pg. 4 & 5, available at http://www.deq.idaho.gov/media/1117748/58-0102-1201-discussion-paper5.pdf.

[22] "Including marine fish in the fish consumption rate may be particularly appropriate if a large proportion of fish consumption for the population to be protected consists of marine fish (such as salmon) and this exposure is clearly documented." USEPA, *Human Health Ambient Water Quality Criteria and Fish Consumption Rates: Frequently Asked Questions*, pg 5, *available at* http://water.epa.gov/scitech/swguidance/standards/criteria/health/methodology/upload/hhfaqs.pdf.

population exercising their treaty-reserved rights. Additionally, government-to-government communications with affected tribes could inform, among other things, which fish consumption data should be used by DEQ.

B. Idaho's Other Proposed Human Health Criteria Inputs

1. Cancer Risk Level

The EPA supports DEQ's proposed policy decision to retain its 10^{-6} cancer risk level to derive human health criteria.

2. Relative Source Contribution (RSC)

In June 2015, the EPA published final updated ambient water quality criteria recommendations for the protection of human health for 94 chemical pollutants.[23] These updated recommendations reflect the latest scientific information and EPA policies, including updated body weight, drinking water consumption rate, FCR, bioaccumulation factors, health toxicity values, and relative source contributions (RSCs). The EPA supports DEQ's proposed approach to use RSC values specified in EPA's 2015 final 304(a) human health criteria recommendations.

3. Bioaccumulation Factors (BAFs)

As stated in DEQ's Technical Support Document (TSD) for the human health criteria, DEQ created an Idaho-specific BAF weighting equation using Idaho fish consumption survey data and stated that the approach they used was similar to the framework that EPA used to derive the BAF weighting in the EPA's 2015 final human health criteria recommendations.[24] According to the TSD, DEQ used food frequency data collected for the Idaho general population and dietary recall data for the tribal population. From these data, DEQ developed a trophic level weighted BAF using the following equation: $(FCR_{TL2} \times BAF_{TL2} + FCR_{TL3} \times BAF_{TL3} + FCR_{TL4} \times BAF_{TL4}) / (FCR_{TL2} + FCR_{TL3} + FCR_{TL4})$. This approach is appropriate and addresses the EPA's previous concern that Idaho tribal populations consume larger amounts of high trophic level fish relative to the U.S. general population. However, the EPA recommends that DEQ provide more information on the derivation of the trophic level specific FCRs used to compute weighted BAFs.

4. Body Weight and Drinking Water Intake

As discussed in the TSD, body weight estimates used in the calculation of Idaho's proposed human health criteria are based on use of a body weight distribution DEQ developed from the general population data from DEQ's fish consumption survey. Using this data, a logarithmic distribution was developed for body weight for calculation of Probabilistic Risk Assessment (PRA)-based proposed human health criteria.[25] EPA is supportive of DEQ's approach to using

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[23] Final Updated Ambient Water Quality Criteria for the Protection of Human Health, (80 FR 36986, June 29, 2015). See also: USEPA, 2015. Final 2015 Updated National Recommended Human Health Criteria. U.S. Environmental Protection Agency, Office of Water, Washington, D.C. http://water.epa.gov/scitech/swguidance/standards/criteria/current/hhfinal.cfm.

[24] Idaho Department of Environmental Quality. *Idaho Human Health Criteria, Technical Support Document.* October 2015.

[25] Ibid

the Idaho local data for estimating body weight and concurs that the body weight distribution was appropriately derived.

As discussed in the TSD, DEQ developed drinking water intake estimates for the PRA-based calculation of the proposed human health criteria based on the National Health and Nutrition Examination Survey (NHANES) 2003-2006 data as presented in the EPA's Exposure Factors Handbook. A distribution was fit to the body-weight normalized drinking water intake values to ensure an appropriate correlation with body weight. This distribution was then used in the PRA approach and applied to both Idaho general and tribal populations.[26] The EPA selected the 90th percentile of this distribution (2.4 liters/day) to derive the EPA's 2015 final 304(a) human health criteria recommendations. Although DEQ's approach to estimating drinking water intake differs from the EPA's, DEQ's drinking water rate distribution has been appropriately derived.

In addition, the correlation between drinking water ingestion rate and body weight was adequately addressed in DEQ's PRA analysis. However, DEQ should re-evaluate the correlation between body weight and fish consumption rate using regression on log transformed fish consumption and body weight distributions (See enclosed Westat memoranda).

5. Toxicity Factors (Reference Doses (RfDs) and Cancer Slope Factors (CSFs))

The EPA supports DEQ's proposal to use RfDs and CSFs consistent with the EPA's 2015 final 304(a) human health criteria recommendations or, in some cases, toxicity factors based on the latest science.

C. Idaho's Proposed Pollutant Scope

The EPA is supportive of DEQ taking this opportunity to revise most of its currently applicable human health criteria and to include additional human health criteria for pollutants with EPA 304(a) criteria recommendations that Idaho had not previously adopted. DEQ is proposing to update or add criteria for 104 chemicals. As previously noted, the EPA published updated final 304(a) recommended human health criteria for 94 pollutants in June 2015.

D. Idaho's Use of Probabilistic Risk Assessment (PRA) to Derive Human Health Criteria

The EPA continues to question the fish consumption distribution that DEQ used in its PRA analysis (see the EPA's comments above regarding inclusion of market and anadromous fish in developing a FCR). Use of a FCR distribution that does not include consumption of market and anadromous fish will result in PRA-based criteria that will produce fish- and water-based contaminant exposures that exceed acceptable levels.

Additionally, DEQ's PRA for high fish consuming populations are derived using the assumption that, at the selected criteria, the mean of the hazard quotient distribution will equal one, and the mean of the risk distribution will equal 1×10^{-6}. EPA remains concerned with this approach. This approach will allow for a large fraction of high fish consumers, including tribes with reserved fishing rights (see above discussion on tribal reserved fishing rights), to have exposures

[26] Ibid

that either exceed an acceptable dose (i.e., the reference dose) for noncarcinogens or exceed a dose associated with a risk of 1 x 10^{-6} for carcinogens.

Another concern is development of an appropriate tribal fish consumption distribution for PRA. The National Cancer Institute (NCI) method cannot be used to characterize consumption of a particular grouping of fish (e.g., fish caught in Idaho waters) if the data necessary for the method are not available. Idaho has used tribal Food Frequency Questionnaire (FFQ) and NCI data in an attempt to develop "NCI-like" estimates of average tribal consumption of fish caught in Idaho waters. As previously noted, DEQ should include market fish, including anadromous species, in the FCR used to set Idaho's AWQC. The EPA also has methodological concerns about using FFQ and NCI data to derive "NCI-like" FCR statistics based on Westat's review of the PRA approach (see attached Westat memoranda). Thus, the EPA recommends that the NCI group 2 (i.e., anadromous, near coastal and inland fish and shellfish) FCR data for the Nez Perce Tribe be used to develop statistics representing current fish consumption.

E. <u>Idaho's Proposed Approach to Downstream Protection</u>

The EPA is encouraged by DEQ's inclusion of a downstream protection narrative criterion in the proposed rule, following the language in EPA's "*Templates for Narrative Downstream Protection Criteria in State Water Quality Standards*" (EPA publication No. 820-F-14-002). However, the EPA's *Protection of Downstream Waters in Water Quality Standards: Frequently Asked Questions* suggests that states consider a more tailored and specific narrative criterion and/or a numeric criterion in certain situations, such as when more stringent numeric criteria are in place downstream and/or environmental justice issues are relevant.[27] As mentioned above, most of Idaho's waters are in the Columbia River basin and are, therefore, upstream of Washington's and Oregon's portion of the Columbia River. The EPA strongly encourages DEQ to adopt numeric human health criteria (either in addition to or instead of a narrative criterion) that ensure the attainment and maintenance of downstream human health water quality criteria, or to provide additional rationale detailing how use of a narrative downstream protection criterion in combination with Idaho's numeric human health criteria will ensure the attainment and maintenance of downstream human health criteria, consistent with the EPA's regulations at 40 CFR 131.10(b).

F. <u>Other Specific Comments on Idaho's Preliminary Rule Language</u>

Section 010. Definitions.

<u>46. Harmonic Mean</u>. EPA supports DEQ's proposed revisions to this definition. However, EPA continues to suggest DEQ consider including the following equation in the definition for harmonic mean, as it provides additional clarity:

$$Q(harmonic) = n / \sum_{i=1}^{n} \frac{1}{Qi}$$

[27] EPA. June 2014. *Protection of Downstream Waters in Water Quality Standards: Frequently Asked Questions.* http://water.epa.gov/scitech/swguidance/standards/library/upload/downstream-faqs.pdf

Section 210. Numeric Criteria for Toxic Substances for Waters Designated for Aquatic Life, Recreation, or Domestic Water Supply Use.

210.01.a. Criteria for Toxic Substances. EPA supports DEQ's proposed revisions to the application of the human health criteria for toxics for the protection of consumption of water and organisms such that these criteria apply only to primary and secondary contact recreation uses and no longer apply to aquatic life uses. Given that the provision in Idaho's water quality standards at Section 100.02 a. and b. states in part that secondary contact recreation may include activities such as fishing, the application of the water and organisms human health toxic criteria to only recreation uses and not aquatic life is appropriate.

With respect to DEQ's proposed revision to the headings in the toxics criteria table, specifically for the human health criteria, EPA recommends DEQ retain the word "organisms" and not replace it with the word "fish." "Organisms" more closely represents the concept that consumption is meant to encompass more than just fish but rather fish, shellfish, and other aquatic life.

210.03. Applicability. DEQ has proposed clarifying language regarding mixing zones as well as revising the low flow design conditions applicable to human health criteria. Consistent with the 2000 Human Health Methodology, DEQ has proposed to revise its regulations to require the harmonic mean flow be used to implement both carcinogen and noncarcinogen human health criteria.[28] EPA supports this proposed revision.

210.03.d.ii. This provision provides a frequency and duration for human health criteria that are not to be exceeded based on an annual harmonic mean. EPA understands DEQ is attempting to clarify the frequency and duration for the state's human health criteria and is supportive of that effort. EPA's 304(a) recommendations for human health criteria are based on long-term average exposure over a lifetime (70 years). Idaho's proposed duration of one year is protective because it represents long-term or chronic exposure but within a reasonable timescale for the purposes of regularly assessing attainment of the criteria. However, the harmonic mean is an inappropriate measure of central tendency in this context, because it is likely to under-represent the presence of pollutants in ambient water. Harmonic means are an appropriate measure of central tendency when evaluating rates with varying denominators, such as flows or speeds. However, for measures of varying mass per volume, such as concentrations of contaminants in ambient water, the arithmetic (for skewed datasets) or the geometric mean is the more appropriate measure of central tendency. EPA recommends that DEQ delete reference to the harmonic mean and, instead, insert arithmetic mean.

210.05.a.iii. The proposed revisions update the reference from EPA's ACQUIRE database to ECOTOX database. EPA supports this revision.

210.05.b.ii. The EPA is concerned that this provision lacks specificity with regard to a fish consumption rate and the target population to be protected that will be used to derive numeric human health criteria in the future, when numeric criteria are not identified in the toxics table. It

[28] FR Vol 65 No. 214. Pg. 66450. Revisions to the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000).

would seem reasonable to specify an appropriate fish consumption rate as well as the target population and percentile of the target population that would be used to estimate a fish consumption rate consistent with how Idaho's numeric criteria in the table at Section 210 were derived. For example, the language in b.ii. refers to using a fish consumption rate that is representative of the population to be protected. The EPA suggests DEQ include specific language identifying the population to be protected consistent with EPA's previous comments.

284.04.b and c. DEQ combined the wording in 04.b. and c. and deleted any redundant language. These revisions are not substantive as they do not change where the criteria apply. The EPA supports the proposed revisions regarding the application of the site-specific criteria for the South Fork Coeur d'Alene River subbasin.

400.06 Intake Credits for Water Quality Based Effluent Limitations. This provision refers to the Idaho Pollutant Discharge Elimination System Program (IPDES) rules and is not a water quality standard. However, in EPA's October 2, 2015 letter from Michael Lidgard to Paula Wilson, EPA provided comments on IDAPA 58.01.25 regarding the proposed intake credit rule language as proposed in the IPDES rules. The EPA is continuing to coordinate with DEQ's IPDES program and has recommended that, if DEQ intends to adopt an intake credit provision into the IPDES rules, it be consistent with the Great Lakes Initiative (GLI). Another option is for DEQ to consider Oregon's intake credit provision rule language, as that language is most similar to the GLI and was approved by EPA.

Westat | An Employee-Owned Research Corporation

Memo

Date: October 19, 2015

To: Greg Frey, SRA

From: John Rogers, Rebecca Birch, and David Marker

Subject: Review of Idaho Fish Survey

Westat was requested by SRA and EPA to review three documents and a translation procedure, all related to the findings from the Idaho Fish Survey. Our comments are as follows.

1. Overall comments:

In our comments, "fish" refers to fish and shellfish.

It is not very unclear how many days of dietary recall data were collected. First, the daily dietary recall questions were only answered if question FFQ3 [did you eat fish in the last 7 days] is Yes. So someone who ate fish only on day 8 would be excluded from the dietary recall questions. It appears that 8 days of daily recall were reported for those who ate fish yesterday but only 7 days for those who did not eat fish yesterday. If FCR24_1 [did you eat fish yesterday] is Yes, the questionnaire collects data about yesterday's fish consumption. Then the instructions for questions FCR7D_1_A through FCR7D_3_B distinguish between "excluding yesterday how many meals did you eat ... that included fish or seafood in the past 7 days" [looks like 8 days total] if fish was eaten yesterday versus "... in the past 7 days how many meals did you eat ..." and "Not including today, what was the most recent day of the week when you consumed ..." if fish was not eaten yesterday [looks like 7 days total].

Given that the dietary recall data were collected only if the respondent said they ate fish in the past seven days, we think the fish consumption in the seven days prior to the call should be used when aggregating dietary recall data across multiple days, not 8 days.

The definition of consumption events is unclear. If two different types of fish are consumed at a meal, the FFQ seems to count this as one consumption event. Is this one or two consumption events in the dietary recall? Is every snack a consumption event regardless of size or how many types of fish were consumed?

Frequency of fish consumption was assessed using the FFQ and the multiple days of dietary recall data. The report says "the total number of consumption events estimated using the dietary recall questions is significantly lower than the total number of consumption events estimated using the food frequency questions" (page 81) but provides no data for comparison to quantify what "significantly lower" means. At the same time the report notes that the reported frequency of fish consumption drops as the days between the consumption event and the survey contact increases (page 75). Might this indication of recall bias explain some of the difference?

The report notes that there are differences between the portion size estimates from the FFQ and the average portion size estimates from the dietary recall. Interpretation of that difference is complicated by: 1) the skewed distribution of the amounts from the daily recalls; 2) how the respondent estimates long-term portion size; and 3) differences in what a portion means between the FFQ and dietary recall. If the respondent provides an estimate of the median portion size (as opposed to the mean), the difference between the log-transformed portion sizes may be less significant, and more normally distributed.

It is not clear how a "complete" survey was defined. Also the survey report gives weighted sample sizes (is this weighted population estimate scaled down to the sample size?). We would like to see unweighted sample sizes. Table 1 (page 10) in the IMS analysis report provides unweighted sample sizes. However, it is still unclear concerning the number of subjects that were consumers versus non-consumers.

In theory, usual fish intake can be estimated from 24-hour recalls or multiple-day recalls (in this case 7 or 8 day recalls). However, if the best estimate of usual fish intake is based on 24-hour recalls, then the decrease in the reported frequency of fish consumption with increasing length of the recall period (days between the consumption event and the survey contact) indicates that the estimate based on multiple-day recalls will be biased low. Correcting this bias requires making some assumptions (such as logit(probability of fish consumption) and log(amount consumed per day) changes linearly with the length of the recall period). With a reasonable assumption, this bias can be corrected by

1) fitting a more complicated version of the NCI model that includes an adjustment;
2) scaling the estimated usual fish consumption from the NCI model up to adjust for the bias (applying a multiplicative factor, perhaps (probability of fish consumption on Day 1)/(Probability of fish consumption on any day in the recall period)); or,
3) using only the first (yesterday) day of dietary recall to estimate usual fish consumption.

Using just the 24-hour recall, if separate models are fit for anglers and non-anglers, the NCI model may not converge due to few respondents with two recalls, both with fish consumption. Scaling the output when predicting data from several days may be the easiest option.

The NCI macro uses the NLMIXED procedure. The weights in the NLMIXED procedure are defined using the REPLICATE statement. The documentation for the REPLICATE statement states that "Only the last observation of the REPLICATE variable for each subject is used". Thus, the same weight is used for each recall within a person. The best weight to use is the weight for the respondent (used for the first recall). As a result, 1) the analysis file for the NI method should have the weight for the first recall on both the records for the first and second recall; and 2) the weight for the second recall defined by NRG is not used in the analysis.

In the IMS report, Table 1 (page 10) shows the sample sizes for anglers and non-anglers and the number of respondents used in the NCI model. It is not completely clear why some cases were not included in the NCI model. Does the line labeled "Annual Fish Consumption Unavailable" correspond to those that did not eat fish in the last year (non-consumers)? There are 243 cases labeled "Recall Data Unavailable (i.e. Missing)". What does this mean? There were 660 respondents that were dropped because various covariates were missing. Without knowing specifics about the missing values, perhaps imputed values could be used or missing values can be treated as a separate category of the categorical variables? How does the distribution of the demographic variables for those in the NCI model compare to the distribution for all fish consumers?

2. Idaho Fish Consumption Survey

SUBMITTED TO: Idaho Department of Environmental Quality
SUBMITTED BY: Northwest Research Group, LLC www.nwresearchgroup.com
DATE SUBMITTED: Final: August 25, 2015

We are interested in identifying any survey design factors that might introduce any uncertainty or bias/loss of accuracy in results of the fish consumption survey. In addition to whatever the reviewers identify as a potential issue, we would specifically like comments on the topics listed below.

2.1 Representativeness of sample using a telephone interview.

The methodology to collect data using a telephone interview using two frames (cell and landline) seems appropriate. According to the 2012 National Health Interview Survey only 2.7 percent of adults in Idaho are without a cell or land line phone. Those people will not be represented. While there may be some reason to think they have different fish consumption levels than others with otherwise similar demographics (since they are by definition living somewhat removed from society lives), there impact on overall estimates are likely to be small.

2.2 Methodology used to select land line and cell phone numbers and representativeness of sample

The methodology to select land line and cell numbers appears to be appropriate. The resulting samples of telephone numbers should be representative of the cell phone or landline populations. See item 2.11.

2.3 Stratification of sample based on Idaho health districts.

The stratification approach looks appropriate, trying to enforce geographic and gender representativeness in the sample minimizes variation in the weights.

2.4 Representation of anglers and non-anglers and weighting

They decided to use only the telephone landline and cell lists for sampling and classifying the anglers based on reported possession of a fishing license. This approach appears to be reasonable. The number of anglers estimated from the survey (33%) differs somewhat from the number estimated by IDFW (26%). It is possible that anglers were more likely to respond to a survey on fish consumption then non-anglers. At the same time, the list from IDFW has some uncertainty in that two lists of different sizes were provided.

2.5 Quotas for age, gender, and income and relation to representativeness of the sample

In general, enforcing the quotas helps to reduce the required effects of weighting. However, quota sampling has been discouraged for decades in government surveys because it can introduce biases that are not necessarily accounted for through the weighting process. In particular, it results in over-representing those who are easier to reach by telephone. Of particular interest in a fish consumption survey, those who spend a greater amount of time away from home (including fishing) are harder to reach, and thus are underrepresented in a quota sample. If they are reachable by cell phone this form of bias may be reduced, but it is hard to know for sure.

2.6 Consideration of race and representativeness of the survey sample

The racial breakdown of the population is only reported as White Alone versus Non-White (roughly 5%). Race was not used for weighting. Since quotas were not used for race, the sample may not be representative of the population racial distribution. A weighting adjustment based on race would improve the representativeness of the weighted sample with respect to race. See item 2.11.

The proportion of whites in the sample is higher than in the State of Idaho. Nationally, whites consume less fish than non-whites (EPA, 2014). If the weighting were to include race it might improve the accuracy of the estimates.

2.7 Impact of not being able to interview 5% of contacted households because of language issues.

Obviously, this subpopulation will not be represented in the survey results. To the extent that this subpopulation is similar to others with similar demographics, a weighting adjustment based on demographics might make the weighted sample more representative.

They report that early analysis indicated no significant differences in consumption rates between English speaking Hispanic and non-Hispanic respondents. However, this does not mean that there will be no difference between English speaking and non-English speaking respondents. They are assuming that English speaking Hispanics are more similar to non-English speaking Hispanics than they are to non-Hispanics in dietary behavior, which may or may not be true.

In particular, if the non-English speakers are Native Americans, their lack of English could be hypothesized to be correlated with following more traditional lifestyles, ones that involve consumption of much greater amounts of fish. In such a case their exclusion will underestimate the true fish consumption in Idaho.

2.8 Quantifying portion size:
2.8.1 Use of common objects to describe portion size

If the common object is familiar to the study population, it is likely easier for respondents to report their portion size in relation to the object than to estimate weight (grams or ounces) or volume (cups or tablespoons), unless they cooked it themselves. They did qualitative research among the population of interest to assist them in selecting common objects to be used as portion size references.

2.8.2 Asking respondents to quantify portion size in ounces

It is likely difficult for respondents to provide the amount of fish they consumed in ounces, unless they prepared the fish. However, they tested the use of portion size estimation aids (PSEA) to assess if using PSEAs would improve reporting of fish consumed in ounces. They report that the results showed saying the PSEA was equivalent to a specific number of ounces and asking respondents to then provide their consumption in ounces provided accurate estimates. This is the methodology they used. It seems reasonable and best available without pre-mailing (or directing to a website) portion size pictures like what are used in the ASA24.

2.8.3 Use of a deck of cards as the portion size estimation model

According to their research, most people thought about a deck of cards or palm of hand when estimating portion sizes and there was no difference in accuracy between these two PSEAs. They chose to go with a deck of cards. This choice seems reasonable given the research findings and that hand sizes vary by age and gender and other factors.

2.9 Use of an 8 day recall period, (SEE: p 24, item 6 describing recall issues for longer periods from qualitative research).

The use of a single versus multiple-day dietary recall for assessing usual fish consumption depends on a combination of bias and precision. The decrease in the reported frequency of fish consumption with increasing length of the recall period (page 75) will contribute to increased bias as the number of recall days increases. The bias can be corrected in various ways (an adjustment factor, modifying the NCI model, or using only the first day of dietary recall). The increasing imprecision of the respondent recall as the length of the recall period increases affects the precision of the estimates; but the NCI method can still be used to calculate those estimates if proper adjustments are made. As a result, increasing the recall period has diminishing benefit. We recommend either adjusting the estimates for bias associated with the longer recall period or calculating the usual fish consumption from only the first recall day. Disregarding this length bias, as was apparently done, can produce inaccurate estimates.

Assuming that respondents had a difficult time recalling fish consumption events beyond a few days (like they report), an 8 day recall period probably underestimates usual fish consumption due to the likely lowered estimated probability of consumption (for those that were reported no consumption and may have forgotten a fish consumption event).

2.10 Impact of response rate on survey results

Non-response contributes to possible bias and decreased precision of the survey estimates. NRG appeared to make reasonable efforts to increase or maintain response rates while collecting the data. Without independent estimates of fish consumption for the non-respondents it is not possible to truly assess the bias. A non-response adjustment to the weights can help to minimize the bias. An analysis of frequency and amount of fish consumption as a function of the effort used to collect the data (such as number of contacts to get a completed survey response) can be used to approximate the possible bias due to non-response. The non-response adjustment (post stratification) provides minimal adjustment for non-response. We recommend additional adjustments of the weights to account for different non-response rates for different demographic groups. NRG provided some adjustment of the weights for health region and gender; however did not provide more extensive adjustments for non-response (particularly with respect to an apparent imbalance in income) citing concerns for possible large weights in some health districts. While it is true that such adjustments may increase the variance, they will reduce the bias. In general this trade-off is worthwhile when the response rates are not high. We recommend additional non-response weight adjustments.

2.11 Weighting of results based on land vs. cell phones

The general approach to weighting the combined cell and landline samples, as represented by BW_1, is reasonable. However some details of the implementation are unclear or appear incorrect, in particular:

1) On page 35 they define CP as the number of cell phones but it appears to really be whether or not they have a cell phone used for making or receiving phone calls (this is ok, but should be corrected in the documentation)
2) On page 35, the numbers for the universe counts (ULL and UCP) seem very implausible....they must be larger. If these are in error, then obviously the weights are wrong.
3) On page 35, the formula for BW_1 is wrong (we assume it is just a typo, since the -1 should be an exponent)
4) They did not collect the number of adults in the household and therefore made a "fix" based on the number in the household; that is a potential source of bias
5) The question they used to determine phone service (TEL on page 104) is not a standard one and might lead to some errors. For example, the cell phone is based on personal use and the landline is household availability and the two are confused in this question.
6) The purpose and implementation of the adjustment in BW_2 on page 36 is unclear. Is the adjustment (BW_2) applied to all respondents in a health district or only the cell-phone-only respondents? It is not clear what some of the numbers in Table 12 are or where they came from. They appear to be household numbers; however the adjustment should be for adults; this may be a potential source of bias. Based on the numbers in the last three columns of Table 12, it looks like the purpose of BW_2 is to get the percentage of cell-only households in the sample to equal the corresponding percentage in the population; however, it is not clear how the equations for BW_2 and BWFinal achieve that for the "Non Wire-less Only" respondents.

2.12 Implementation of post stratification weighting

The post stratification provides some adjustment for non-response. However, it excluded adjustments by income level, household composition, and education.

2.13 Weighting for re-contact interviews

The weighting for the re-contact interviews provides a simple adjustment for non-response. If these weights were important, we would recommend a more complicated adjustment. However, since the NCI model only uses one weight per respondent (preferably the weight for the first recall, not a separate weight for each recall), the calculation of an adjusted weight for each recall is not required when using the NCI method for analysis.

2.14 Imputation used to populate missing values

The imputation used to populate missing values is not explained in detail. The discussion on page 42 says the values were imputed based on characteristics of their neighbors but provides no description of how "neighbors" are defined. It is not clear what values were or were not imputed. It is also not clear how the imputed values were used. Were they used to create Table 15? Were they used for weighting? The second bullet on page 42 seems to imply the imputed values were not used in the analysis file.

2.15 Data processing and calculations

We found no problems with what was presented. However, the description does not say how the 7 or 8 day fish consumption (average or sum?) was calculated from the daily values (only the calculation for daily values for yesterday is presented, we assume the other days consumption was calculated in a similar manner). We recommend the fish consumption be calculated for 7 and not 8 days, as noted in the overall comments.

2.16 Bootstrapping approach used to develop confidence limits

The Bootstrapping approach apparently does not incorporate the weights. As a result, for evaluating population differences, the confidence intervals may be smaller than appropriate. It is not clear how the confidence intervals were used. The word "significant" is used in several places. It is not clear if it refers to statistical significance.

2.17 Discussion Section

2.17.1 Addressing non-response bias

They say 25 percent is "significantly higher than the average response rate." Twenty-five percent is not unreasonable for a telephone survey these days, but it still leaves room for significant nonresponse bias if the respondents are not like the nonrespondents. It is difficult to know if the 75 percent that did not respond are systematically different in their fish consumption behaviors. This is of particular concern given that they used a quota sample rather than a traditional random sample. This might contribute to the over-representation of higher income individuals and anglers

– these groups may be more interested in the survey topic thus more likely to respond. Could non-response be adjusted for with weighting factors?

2.17.2 Impact of over-representation of higher income individuals and anglers

They mention that more complicated weights could be applied to adjust for these differences, but that could result in large weights within individual health districts. They could assess the impact of the over-representation by applying the weights, running the analysis, and comparing the results.

In general it is always true that weighting adjustments will reduce precision (larger standard errors for sampling), but the trade-off is that it will hopefully reduce bias. This is important because the confidence intervals, or tests of hypotheses, will only have the claimed level of accuracy (e.g. 95 percent) if the bias is trivial. If there are large biases all of these intervals will be incorrect. That is why we do typically adjust for known under-represented groups. In some cases it may be worthwhile to trim a few excessively large weights. This process is expected to produce smaller overall mean squared errors, and more appropriately-sized confidence intervals.

2.18 Review of the questionnaire and identification of any issues in accurately recording fish consumption. Of particular interest is review of the methodology for inquiry into consumption over the past 7 days.

As noted in the general comments above, clarification of when there is data for 7 days versus 8 days is needed. Also, given the decrease in the proportion of respondents reporting fish consumption with increasing length of the recall period, estimates based on multiple-day recalls are likely to be biased low without an appropriate adjustment.

3. NCI Method Estimates of Usual Intake Distributions for Fish Consumption in Idaho

This report was prepared under DEQ Contract K079 with Information Management Services, Inc.: Dennis W. Buckman, PhD, Ruth Parsons, BA, Lisa Kahle, BA, September 9, 2015.

We are interested in any NCI data analysis factors that might introduce uncertainty or bias/loss of accuracy in NCI results. We are particularly interested in whether or not the data analysis approach is sufficiently described. In addition to whatever the reviewers identify as potential issues, we would like comments on the topics listed below:

3.1 How well are the selection and impact of covariate choices documented?

The covariates used in the NCI model are listed in the report (page 11). No justification for using these covariates is provided. In addition to these covariates, three other variables that are apparently available are: gender, household composition (single versus multi-person, see page 40 of the survey report), and amount consumed from the FFQ. An easy approach to selecting covariates is to include all available covariates. Alternatively a combination of a weighted logistic regression (using the SAS SURVEYLOGISTIC procedure with the BRR weights created for calculating confidence intervals for usual fish consumption) predicting the probability of fish consumption in a recall, and a weighted linear regression predicting log-transformed (or Box-Cox transformed) amount of fish consumed (using the SAS SURVEYREG procedure), can be used to assess which predictors or interactions of predictors are statistically significant when predicting the outcome. For the NCI model, we recommend including the same predictors for both the probability and amount models, including predictors that are significant when predicting either probability of consumption or transformed amount. In general it is important to include predictors that are clearly significant ($p<.01$). Predictors that are believed to be related to fish consumption but not significant should also be included. We believe the amount consumed from the FFQ should be an important predictor of amount consumed in the NCI model. For continuous predictors (body weight, age, and amount consumed from the FFQ) the weighted regression models can be used to assess how the variables might be transformed and whether the relationships are linear.

3.2 Are there any issues associated with use of 8 days of dietary recall information rather than the last 24 hours?

Yes. At a minimum, compared to using only the last 24 hours, the estimates are biased without an adjustment for the decreasing frequency of reported fish consumption as the length of the recall period increases. See the general comments above.

3.3 Is the combination and weighting of general and angler populations done appropriately?

The details of how the NCI macros were applied to the data files are not completely clear. For each type of fish consumption, we suspect the NCI method was applied to the data from the angler and non-angler subpopulations in separate runs, that all runs used the survey weights, and the summary statistics calculated from the simulated usual intake values for each respondent (from the DISTRIB macro) were calculated using the survey weight associated with the first recall for each respondent. The summary statistics can be calculated after combining the output files from the runs of the DISTRIB macro. If these procedures were used, we believe the calculations were done appropriately.

3.4 How, and how well, is it documented that the results meet assumptions of the NCI model (e.g. transformed positive fish consumption rates are normally distributed)?

The report provides no information on the values of Box-Cox transformation parameter (lambda), whether the transformed consumption amounts are normally distributed (a normal quantile plot of the transformed consumption amounts (not the plot from the NCI Box-Cox macro that was used) would help), whether there are any outliers, and the estimates of the variance components from the NCI model fit (between person for the probability model and the within and between person components for the amount model). This information would help assess the model fit and why the NCI macro had problems estimating lambda and the correlation parameter. In our experience, setting lambda instead of fitting lambda in the model and ignoring the correlation parameter has little effect on the results when calculating usual intake of fish. Given the relatively large number of respondents with two recalls with reported fish consumption we are surprised that lambda and the correlation parameter could not be fit using the MIXTRAN macro; at the same time, we have no reason to question this result.

4. Development of Human Health Water Quality Criteria for the State of Idaho (Draft), Windward Environmental, September 15, 2015

We are interested in whether or not the probabilistic analysis is adequately described. Further, we are interested in any methodological issues that were inappropriately or incompletely addressed in the PRA. In addition to anything that the reviewers might provide, we are interested in the following topics:

4.1 Selection of input distributions, in particular development of a Nez Perce fish consumption rate distribution.

The distribution fit to the percentiles of body weight appears to provide a good fit to the data. The distribution fit to the percentiles of drinking water intake per body weight appears to provide a reasonable fit to the data. Given the limited data for fish consumption for the Nez Pierce tribe, interpolating while setting the lower 5 percent to the 5th percentile and setting a maximum value and interpolation for percentiles above the 95th percentile appears reasonable.

One might question how the maximum value was obtained. Based on the footnote on page 12 of the Windward report, the maximum was based on what might be the maximum simulated value from the NCI DRISTRIB macro for the Idaho general population (1,261 g/day) multiplied by 0.242. If we have understood the calculations, this approach appears somewhat arbitrary because 1) the maximum value depends on how many simulated values DISTRIB creates, and 2) the adjustment factor of 0.242 seems to be based on calculations that are unrelated to the relationship between the maximum of the two distributions. A possible alternative is to calculate the 95th and 99.9th percentile for the general Idaho population and assume the ratio of those percentiles is the same for the general Idaho populations and the Nez Pierce population.

4.2 Correlation

4.2.1 Between body weight and drinking water ingestion rate

Assuming the drinking water ingestion rate per body weight is independent of the body weight appears to be a reasonable assumption. If needed, analysis of NHANES data could be used to test the assumptions. Thus simulating body weight and independently simulating drinking ingestion rate per body weight appears to be reasonable.

4.2.2 Between body weight and fish consumption rate

We expect the fish consumption rate to increase with increasing body weight. The assumed distribution for the body weight appears to be a lognormal distribution. The distribution of fish consumption rate can often be reasonably approximated by a lognormal distribution. Thus, when assessing correlation, we strongly recommend plotting and calculating the correlation between the log-transformed body weight and the log-transformed FCR. The statistical assessment of correlation (here using regression) assumes the prediction errors are normally distributed with roughly constant variance. That assumption is clearly not true for the data plotted in Figure 2-3 of the Windward report. We expect a plot using the log-transformed values will have an approximate bivariate normal distribution.

5. Translation of NPT consumption of 'Group 2' fish to equivalent consumption of 'Idaho Fish'

We are interested in whether or not the approach is adequately documented and whether or not there are any issues with this analytical approach. In particular, we are interested in how IDEQ has processed weighting factors in deriving consumption rates of fish caught in Idaho.

In general the re-grouping of fish seems appropriate given the available data. We have three concerns:

1. The explanation of how the prorating was done is hard to follow. The prorating of event salmon (salmon + steelhead): If a participant reported 10 oz. of salmon at events and 6 oz. of chinook and 4 oz. of steelhead at nonevents, then they were assigned 4 oz. for event steelhead. Is this how it was done?

2. Why was Coho left out of the prorating? Is it sometimes confused with steelhead?

3. The fraction of salmon + steelhead that is chinook is apparently calculated separately for each respondent. Where does the 81.3% come from? This is apparently the weighted mean percent of chinook (out of salmon+chinook+ coho+steelhead) across all participants that reported nonevent salmon, chinook, coho, and steelhead, is that correct? Although the fraction you are interested in can be calculated for each respondent, the resulting fractions can be imprecise, resulting in biased overall estimates. As an alternative, we recommend calculating the ratio of the weighted mean chinook non-event consumption to the weighted mean salmon+chinook+ coho+steelhead non-event consumption and using one ratio for all respondents. If there is concern that the ratio may differ among respondents, the ratio can be calculated separately for different demographic groups.

The application of the weights seems appropriate. The resulting fraction of the Group 2 that was assigned as Idaho fish (0.242) was then multiplied by the results that were obtained from the NCI Method for the original Group 2.

Westat | An Employee-Owned Research Corporation

Memo

Date: October 26, 2015

To: Greg Frey, SRA, and Lon Kissinger, EPA

From: John Rogers

Subject: To-do list for improving the estimates of Idaho fish consumption

At the request of SRA, Westat provides the following recommended to-do list for predicting fish consumption from the ID survey. Note that these recommendations are based on our understanding of the data and the calculations used previously. The recommendations may need to be adjusted for unanticipated characteristics of the data. The to-do list refers to comments in our October 19, 2015 memo.

The to-do list:

Revise the survey weights:

- Recalculate the base weights, noting the comments in item 2.11.
- Review the imputation of the missing demographic variables. This needs to be described better.
- Adjust the base weights for non-response using raking. The variables used for raking would include those in Table 15 in the NRG report. This will create respondent weights adjusted for imbalance due to the sampling process and non-response, W_i. If a few weights are particularly large relative to most weights, those weights might be trimmed. The weights for other cases would be increased so that the sum of the weights is unchanged.
- Set the weight for the second recall to equal the weight for the first recall.

Revise the calculations to calculate fish consumption over 7 days.

- For each respondent and recall, calculate the quantity of fish consumed in each day of the recall ("yesterday" and the prior 7 days) as documented on page 116 of the NRG report, call this A_{ird}, i references the respondent (1 to N), r references the recall (1 or 2), and d references the day (1 to 8). Then calculate the average daily consumption over the first 7 days for each respondent and recall: $A_{ir(7)} = \frac{\sum_{d=1}^{7} A_{ird}}{7}$.

- Using only the first recall for each subject ($r = 1$), calculate the weighted mean of the fish consumption on the first day and the fish consumption across the first 7 days (the sums are over all completed recalls):

$$\bar{A}_1 = \frac{\sum_{i=1}^{N} A_{i11} W_i}{\sum_{i=1}^{N} W_i}$$

$$\bar{A}_{(7)} = \frac{\sum_{i=1}^{N} A_{i1(7)} W_i}{\sum_{i=1}^{N} W_i}$$

Note: this is a slightly different formula than outlined in the comments.

- Calculate the ratio for adjusting the NCI estimate of usual fish consumption to estimate usual fish consumption adjusted for decreased recall over time.

$$R = \frac{\bar{A}_1}{\bar{A}_{(7)}}$$

Fitting the NCI model

- Decide what cases to include in the NCI model. Is there a reasonable way to include cases with missing demographic variables, such as treating the missing values as a separate category or using imputed demographic variables?

- Create BRR replicate weights for calculating variances.

- Decide what predictors to use:

  - Use the SAS SURVEYLOGISTIC procedure to identify significant predictors of reported fish consumption (Yes versus No) using the BRR weights. First identify significant main effects. Second identify significant two-way interactions of the significant main effects. Candidate predictors would be demographic variables (including body weight) and FFQ variables (frequency of fist consumption, amount consumed). It is worth considering transforming or categorizing the FFQ variables to handle non-linear relationships. Although it can be done different ways, we suggest 1) including main effects that are significant at the 5% level; 2) including interactions of the main effects that are significant at the 1% level; and 3) including any other main effects believed to be associated with fish consumption.

  - Use the SAS SURVEYREG procedure to identify significant predictors of log-transformed (or Box-Cox transformed) reported amount of fish consumed using the BRR weights, using the steps above.

- In the NCI model, we suggest using the same covariates for the probability and amount models.

- Fit the NCI model to $A_{ir(7)}$. If necessary, determine the Box-Cox transformation parameter (Lambda) before fitting the NCI model. If the correlated model cannot be fit, using the uncorrelated model is OK. Report the Lambda and the magnitude of the variance components from the NCI model when using the full sample weight.

- Multiply the usual fish consumption from the NCI DISTRIB macro by the ratio R from above to provide an unbiased estimate of usual fish consumption.

Do the calculations for the PRA:

- Revise the adjustment for estimating the top 5% of the Nez Pierce distribution, see comment 4.1.
- Consider a correlation between log-transformed body weight and log-transformed usual fish consumption. Alternatively, if the body weight is a significant predictor of usual fish consumption (in the probability and particularly the amount model), the distribution of fish consumption should be a function of body weight.
- Calculate the weighted fraction of chinook across all respondents when adjusting for different fish species categories (Group 2 versus ID fish). See comment 5, item 3.

Clarify various items, see comments, in particular:

- The process for developing imputed values when data were missing
- Weighting of angler and general populations in developing overall results
- Discussion in the NCI analysis report as to how well model assumptions are met

Review of DEQ Approach for Developing an NCI-Like Distribution of Idaho Caught Fish, 11/5/15

EPA requested Westat review DEQ's approach for developing an "NCI-like" fish consumption rate (FCR) distribution for fish from Idaho waters. This memo summarizes conversations between Lon Kissinger EPA Region 10 and Westat statistician Dr. John Rogers.

DEQ developed a Nez Perce distribution of consumption of Idaho caught fish by scaling the NCI-derived distribution for consumption of Category 2 fish, multiplying the percentiles by 0.242 to calculate the percentiles of the distribution of Nez Perce Idaho fish consumption. The scaling factor, 0.242, was the ratio of the average consumption of Idaho caught fish to the average consumption of Category 2 fish. Both of these averages were obtained from the Nez Perce FFQ survey. The resulting scaled or transformed NCI-distribution is referred to here as the "NCI-like" distribution.

After discussions with Westat regarding the relationship between the NCI-derived distributions for different types of fish, we suggest that further analysis be done on the approach used to develop a Nez Perce "NCI-like" distribution of Idaho caught fish. It appears that the current procedure is likely to underestimate the upper percentiles of the Idaho fish consumption distribution.

Given that FCR distributions are reasonably log normally distributed, there is likely a linear relationship between log transformed percentiles of the distribution of Idaho caught fish consumption and the distribution of Group 2 fish consumption (for which we have the NCI estimate of the distribution).

Let P_I represent percentiles of the distribution of Idaho caught fish consumption that are to be estimated. Let $P_{G2,NCI}$ represent percentiles of the distribution of Group 2 fish consumption estimated using the NCI method. Then assume:

$$Ln(P_I) = ln(S) + F*Ln(P_{G2,NCI}), \text{ or equivalently } P_I = S * (P_{G2,NCI})^F.$$

The problem is how to estimate S, a scaling factor, and F, a slope roughly equal to the ratio of the standard deviation of $Ln(P_I)$ to the standard deviation of $(lnP_{G2,NCI})$.

Using results from NHANES data previously analyzed for EPA Headquarters, Westat did a quick analysis comparing the NCI-derived distributions of fish consumption for different types of fish. Let R equal the ratio of the mean fish consumption for the fish type used as the dependent distribution to the mean fish consumption for the fish type used as an independent distribution. When predicting the distribution of a less consumed fish type from the distribution of a more consumed fish type (i.e., $R < 1$), it appears the F should be greater than 1.0 with higher slopes as R decreases.

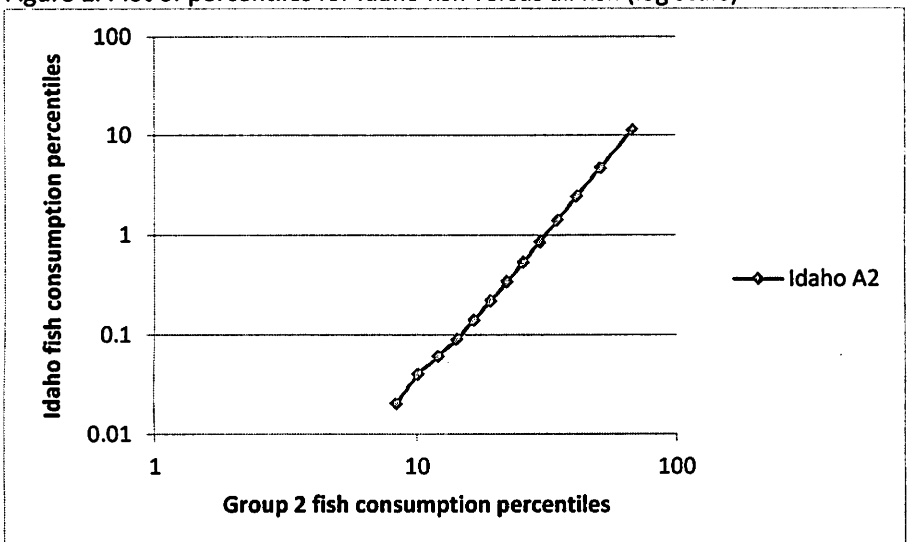
As an example of the calculations, Table 1 has the 35th through 95th percentiles of the consumption distributions for all fish and for Idaho caught fish from the Idaho state survey (see: NCI Method Estimates of Usual Intake Distributions for Fish Consumption in Idaho, Tables A1 and A2, using All Subjects). Lower percentiles were not included because the estimates were reported as "<.01" or were particularly imprecise.

Table 1 Percentiles of fish consumption for all subjects

Percentile	All Fish Table A1	Idaho fish Table A2
35	8.31	0.02
40	10.09	0.04
45	12.06	0.06
50	14.25	0.09
55	16.61	0.14
60	19.27	0.22
65	22.29	0.34
70	25.71	0.53
75	29.74	0.84
80	34.85	1.38
85	41.44	2.42
90	51.11	4.66
95	67.66	11.24

Figure 1 shows a plot of the percentiles of Idaho fish consumption as a function of the percentiles of all fish consumption, using log scales. As can be seen, the log-transformed percentiles fall on a roughly straight line.

Figure 1. Plot of percentiles for Idaho fish versus all fish (log scale)



Fitting a linear regression to predict the log-transformed percentiles for Idaho fish consumption from the log-transformed percentiles of all fish consumption gives a slope of F = 3.00. Although this analysis used selected percentiles, using all percentiles between the 1st and 99th percentiles and using more precision is recommended.

Different slopes will be obtained using different data or different subsets of the data (such as anglers only). For all subjects in the Idaho state survey the ratio of the means (R) is .106, smaller than the ratio of 0.242 estimated for the Nez Perce from the FFQ. Although one could use F = 3.00 for the Nez Perce, since F appears to increase as R decreases and R for the Idaho state data is less than for the Nez Perce, an appropriate slope for predicting Nez Perce Idaho fish consumption from Group 2 fish consumption may be less than 3.00. Some judgment is required to set the value of F. Considerations might include:

- calculations using Idaho data (as above),
- calculations using NHANES data, or possibly
- calculations using FFQ data (note that the precision and bias of FFQ data are uncertain and lower percentiles of FFQ estimated Idaho fish consumption are zero; it is not possible to calculate the log of zero).

Once F is set, calculate R, in the case of the Nez Perce based on the FFQ data. R is the ratio of the reported means of Idaho fish consumption and Group 2 fish consumption:

$$R = \mathrm{Mean}(I_{FFQ}) / \mathrm{Mean}(G2_{FFQ}) = 0.242$$

Also calculate the mean of $P_{G2,NCI}$ and $(P_{G2,NCI})^F$ across all percentiles (excluding the 0^{th} and 100^{th} percentile). These means are calculated using the percentiles from the DISTRIB macro because those are the data that are available.

The calculations assume the ratio of the mean Idaho fish consumption to the mean Group 2 fish consumption is the same for the FFQ data as for the NCI or "NCI-like" data, i.e.,:

$$\mathrm{Mean}(I_{FFQ})/\mathrm{Mean}(G2_{FFQ})=\mathrm{Mean}(P_i)/\mathrm{Mean}(P_{G2,NCI})$$

Since $\mathrm{Mean}(P_i) = S^* \mathrm{Mean}((P_{G2,NCI})^F)$, solving for S gives:

$$S = R * \mathrm{Mean}(P_{G2,NCI}) / \mathrm{Mean}((P_{G2,NCI})^F)$$

Finally, calculate the "NCI-like" distribution:

$$P_i = S * (P_{G2,NCI})^F$$

The mean of P_i across all percentiles (excluding the 0^{th} and 100^{th} percentile) should be equal to $\mathrm{Mean}(I_{FFQ})$. Note that if F = 1.0, then S = R and the scaled NCI distribution is the same as calculated previously by Idaho DEQ. Using a slope (F) greater than 1.0 spreads out the distribution, particularly the upper tail, compared to using F = 1.

We expect the approach outlined above, using an estimated value of the slope F, will provide a better estimate of Nez Perce Idaho caught fish consumption distribution than assuming F equals 1.0.