ACWA Monitoring, Standards & Assessment Committee Call
Wednesday, April 17, 2013

Subject: Discussion on EPA's new FAQ: *Human Health Ambient water Quality Criteria and Fish Consumption Rates Frequently Asked Questions*: http://water.epa.gov/scitech/swguidance/standards/criteria/health/methodology/upload/hhfaqs.pdf

Comments from Washington & Idaho:

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Overall comment:

Several states are dealing with development of human health criteria as they revise standards. Washington and Idaho are both starting the process and are dealing with particularly complex issues because of abundance of fisheries for anadromous fish, subpopulations that consume large amounts of anadromous and local fish and shellfish, a lack of state-specific data on the fish and shellfish consumption patterns of the general population, and a very motivated and concerned set of stakeholders who all have important interests to address. In addition, in Idaho and Washington there have been recent communications with EPA Region 10 that indicate that EPA is considering development of regional guidance or other decision-making processes on human health criteria development that could seriously affect the ability of the states to make the risk management decisions that have historically and appropriately been made by states – decisions on such issues as risk levels and fish consumption rates. This had led to an uncertain rule-making environment, and a real concern that EPA might develop guidance that could act as rule. Launching this FAQ into such a highly charged environment, without the benefit of state review and consideration of the issues being addressed in state rule-makings, is of significant concern.

Specific comments:

In the left column below is a copy of the EPA FAQ. The FAQ is divided below into a table format to facilitate discussion of individual Question/Response topics. State comments/concerns with the information in the FAQ are in the right column. Specific comments in each section are numbered across the columns to clarify the linkage between highlighted FAQ language and state comments/concerns.

Document Title:
Human Health Ambient water Quality Criteria and Fish Consumption Rates
Frequently Asked Questions
[Note: the answers below reflect existing EPA policy and guidance, as articulated in the 2000 Human Health Methodology]

Abbreviations:
HHC – Human health criteria, WQS = water quality standards, SDWA = Safe Drinking Water Act, CWA = Clean Water Act, RSC = Relative Source Contribution, MCLG = Maximum Contaminant level Goal, MCL = Maximum Contaminant Level

EPA FAQ Language	State Comment/concern
This guidance does not have a disclaimer.	EPA's new FAQ on multiple discharger variances (EPA-820-F-13-012, March 2013) contains some introductory language that clarifies the role of that FAQ – explaining that it is guidance and not rule. A similar disclaimer is desirable for this Fish Consumption Rate FAQ (EPA variance FAQ language below): ***DISCLAIMER*** *These Frequently Asked Questions (FAQs) do not impose legally binding requirements on the EPA, states, tribes or the regulated community, nor do they confer legal rights or impose legal obligations upon any member of the public. The Clean Water Act (CWA) provisions and the EPA regulations described in this document contain legally binding requirements. These FAQs do not constitute a regulation, nor do they change or substitute for any CWA provision or the EPA regulations.* *The general description provided here may not apply to a particular situation based upon the circumstances. Interested parties are free to raise questions and objections about the substance of these FAQs and the appropriateness of their application to a particular situation. The EPA retains the discretion to adopt approaches on a case-by-case basis that differ from those described in these FAQs where appropriate. These FAQs are a living document and may be revised periodically without public notice. The EPA welcomes public input on these FAQs at any time.*

Q1. What is the goal of the human health ambient water quality criteria? Clean Water Act (CWA) section 303(c)(2)(A) requires that water quality standards (WQS) protect "public health or welfare, enhance the quality of the water and serve the purposes of [the Act]." CWA section 101(a)(2) establishes as a national goal "water quality which provides for protection and propagation of fish, shellfish, and wildlife, and recreation in and on the water, wherever attainable." EPA has interpreted the "fishable" language in section 101(a)(2) to refer not only to protecting water quality so the fish and shellfish thrive, but when caught they can also be safely eaten by humans. Thus, 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.1 1 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 EPA's recommended 304(a) water quality criteria to protect these "fishable" designated uses, and accompanying risk assessment methodologies, reflect the longstanding interpretation that a designated use consistent with the goals of the Act means that State and Tribal waters should support safe consumption of fish and shellfish. EPA has consistently implemented the Clean Water Act to ensure that the total rate of consumption of freshwater and estuarine fish and shellfish (including estuarine species harvested in near coastal waters) reflects consumption rates demonstrated by the population of concern. In other words, EPA expects that the standards will be set to enable residents to safely	**Comment 1.** Suppression effects are a very sensitive topic for many groups in the Pacific Northwest, and it is difficult to apportion the amount of suppression caused by different factors. Unfortunately the concepts of *availability* of fish and *contamination* of fish get mixed up. Some specific language here that speaks directly to the possible causes of suppression, and then directly pinpoints the suppression linked to contamination, would be useful for readers. It would also be helpful to acknowledge the difficulty in accurately quantifying suppression.

consume from local waters the amount of fish they would normally consume from all fresh and estuarine waters (including estuarine species harvested in near coastal waters). EPA does not necessarily expect all consumers to eat only fish from a single State, but individuals or groups should be able to do so without concern for their health. (see **comment 1** at right)It is also important to avoid any suppression effect that may occur when a fish consumption rate for a given subpopulation reflects an artificially diminished level of consumption from an appropriate baseline level of consumption for that subpopulation because of a perception that fish are contaminated with pollutants. This approach is consistent with a principle that every State does its share to protect people who consume fish and shellfish that originate from multiple jurisdictions. In addition, the goal of water quality criteria for human health is to protect people from exposure to pollutants through fish and water over a lifetime, and the goal of a State's designated use should be that the waters are safe to fish in the context of the total consumption pattern of its residents. Likewise, because people are expected to continue consuming fish and shellfish throughout their lifetime regardless of where they live, and this consumption leads to similar exposure to pollutants, it is appropriate to derive protective human health criteria in State and Tribal water quality standards assuming a lifetime of exposure. Although the human health ambient water quality criteria (AWQC) are based on chronic health effects data (both cancer and noncancer effects), the criteria are intended to also be protective against adverse effects that may reasonably be expected to occur as a result of elevated acute or short-term exposures.	

Q2. What does the fish consumption rate (FCR) indicate in the calculation for human health ambient water quality criteria? The FCR indicates the amount of fish and shellfish in kilograms consumed by a person each day. For the purposes of human health ambient water quality criteria, the fish and shellfish to be reflected in the FCR include all of the fish and shellfish consumed that are species found in fresh and estuarine waters (including estuarine species harvested in near coastal waters). (see **comment 1** at right)Because the overall goal of the criteria is to allow for a consumer to safely consume from local waters the amount of fish they would normally consume from all fresh and estuarine waters, the FCR does include fish and shellfish from local, commercial, aquaculture, interstate, and international sources. It is not necessary for the FCR to include fish and shellfish species designated as marine species, as that exposure is addressed by relative source contribution (see question 4 for more detail). However, partitioning of fish and shellfish into the different habitats in order to develop a FCR can only be done where sufficient data are available for this to be done in a scientifically defensible manner. For example, if a State were to determine through scientifically collected data that its citizens consumed 25 grams of fish and shellfish per day where 5 grams came from marine fish, 5 grams came from a local fresh water stream (see comment 1 at right) 5 grams came from a neighboring state's fresh waters, 5 grams came from international imports of estuarine shellfish, and 5 grams came from aquaculture of a freshwater species, then the FCR would be 20 grams per day. Only the marine fish component would be excluded from the FCR (see discussion below on relative source contribution). (see **comment 2** at right) All of the other components represent the amount of fish and shellfish that could	**Comment 1.** If the overall goal is to allow consumers to safely consume freshwater and estuarine fish resources from local waters, then including all the fish and shellfish consumed from interstate and international sources does not make sense. The amount of consumption associated with the commercial availability of these sources does not necessarily reflect the amount of fish or shellfish that are, were, or might be attainable in local waters. For instance, a person from a state with no marine coastline might eat large amounts of prawns and bivalves harvested in a foreign country and purchased at the supermarket. This consumption does not reflect exposures from local waters or the fishery resources that would naturally be there. This consumption should be considered during the development of the RSC (if data are available to document contaminants in these new fishery sources (such as mercury in tuna)), but not in the overall FCR. Aquaculture resources are complex. Many types of aquaculture are practiced. Some types are almost completely dependent on the local waters for support (e.g. oyster industry), others use a mixture of in-situ exposure of local water and commercial or proprietary feed stock (e.g. net pens), and still others use upland facilities with waters piped to the facility in a manner analogous to industrial water use and combined with commercial or proprietary feed stock (upland facilities raising tilapia). The first type of aquaculture venture could closely fit the definition of locally harvested resources, the second is more ambiguous, and the third is more similar to an industrial operation and not a local waterbody harvest issue. Including all resources from aquaculture in the FCR does not take the complexity of these different types of exposure sources into account. The different sources merit further discussion to

be taken and consumed from local waters if the consumer chose to do so.	determine whether they should be included in the FCR and when they should be considered for development of the RSC. **Comment 2.** The last sentence states that all of the "*components represent the amount of fish and shellfish that could be taken and consumed from local waters if the consumer chose to do so*." This does not make sense. The international and national market for fisheries has created a market situation where people who previously would have little harvest available locally could (by eating commercially available non-local fish or shellfish) enhance their consumption to levels that would more closely mirror locally supported consumption patterns in areas with locally abundant fishery resources – but do not mirror the "*amount of fish and shellfish that could be taken and consumed from local waters if the consumer chose to do so.*"
Q3. How is the exposure to a pollutant due to marine fish consumption accounted for in the human health ambient water quality criteria? Human health ambient water quality criteria are to account for all sources of exposure to the pollutants for which they are developed. The exposure to pollutants from marine fish and shellfish species that are not included in the fish consumption rate should be accounted for in the relative source contribution (RSC) when setting criteria for threshold non-carcinogens and non-linear carcinogens.	**No comment.**

Q4. What does the relative source contribution (RSC) indicate in the calculation for the human health ambient water quality criteria? The relative source contribution component of the human health ambient water quality criteria (AWQC) calculation for threshold non-carcinogens and non-linear carcinogens allows a percentage of the reference dose's exposure to be attributed to ambient water and freshwater and estuarine fish consumption (including estuarine species harvested in near coastal waters) when there are other potential exposure sources. (see **comment 1** at right) The rationale for this approach is that for pollutants exhibiting threshold effects, the objective of the AWQC is to ensure that an individual's total exposure from all sources does not exceed that threshold level. The RSC includes, but is not limited to, exposure to a particular pollutant from marine fish consumption (not included in the fish consumption rate), non-fish food consumption (fruits, vegetables, and grains), dermal exposure, and respiratory exposure. In the absence of scientific data, the application of the EPA's default value of 20 percent RSC in calculating 304(a) criteria or establishing State or Tribal water quality standards under Section 303(c) will ensure that the designated use for a water body is protected. (see **comment 2** at right – boldface added) This 20 percent **default for RSC can only be replaced where sufficient data are available to develop a scientifically defensible alternative value**. If appropriate scientific data demonstrating that other sources and routes of exposure besides water and freshwater/estuarine fish are not anticipated for the pollutant in question, then (see **comment 3** at right – boldface added) the RSC **may be raised to the appropriate level, based on the data, but not to exceed 80 percent.** The 80 percent ceiling accounts for the	**Comment 1.** The 20%/80% RSC approach in the EPA 2000 guidance was developed as part of a process to "harmonize" the SDWA and the CWA. See EPA 2000 (bottom of page 1-5): "*Another reason for the 2000 Human Health Methodology is the need to bridge the gap between the differences in the risk assessment and risk management approaches used by EPA's Office of Water for the derivation of AWQC under the authority of the CWA and Maximum Contaminant Level Goals (MCLGs) under the Safe Drinking Water Act (SDWA). Three notable differences are the treatment of chemicals designated as Group C, possible human carcinogens under the 1996 proposed cancer guidelines, the consideration of non-water sources of exposure when setting an AWQC or MCLG for a noncarcinogen, and cancer risk ranges.*" The SDWA MCLG derivation procedures use a 20%80% approach. Applying this RSC range to CWA HHC provides some harmonization between the two Acts, but does not take into account that the MCLG is not a regulatory level (it is a goal), and that the CWA human health criteria (HHC) are regulatory levels enforced both as ambient concentrations in the water body (303(d) listing process and through NPDES permit limits.) Under the SDWA the MCLG is modified to create an at-tap regulatory level (the maximum contaminant level - MCL) by taking into account factors such as available treatment and available analytical methods. Here is an example for nitrate taken from EPA's website (boldface added) at http://water.epa.gov/drink/contaminants/basicinformation/nitrate.cfm that gives some explanation of how MCLs are developed from MCLGs:

fact that some sources of exposure may be unknown. In cases where an 80 percent RSC is used, 20 percent of the exposure is reserved for unknown sources. Although the 20 percent RSC has not been consistently applied to national 304(a) criteria recommendations for non-carcinogenic pollutants, where there are inconsistencies between the 2000 Human Health Methodology recommendation and implementation in criteria, the Human health Methodology should prevail and the 20 percent RSC applied. EPA is moving to complete implementation of this guidance in existing 304(a) criteria.	*"The MCLG for nitrate is 10 mg/L or 10 ppm. EPA has set this level of protection based on the best available science to prevent potential health problems. EPA has set an enforceable regulation for nitrate, called a maximum contaminant level (MCL), at 10 mg/L or 10 ppm.* ***MCLs are set as close to the health goals as possible, considering cost, benefits and the ability of public water systems to detect and remove contaminants using suitable treatment technologies. In this case, the MCL equals the MCLG, because analytical methods or treatment technology do not pose any limitation."*** NPDES permitting tools can sometimes accommodate some of these considerations during implementation, but final limits must always be based on the HHC. The larger reason why the MCLG does not mirror the HHC is that the MCLG is not in itself a level that must be attained, while the HHC is always a level that must be attained in ambient waters. The roll-out of this difference is apparent with the application of the 303(d) program, the requirement for allocation of loads, and subsequent permitting requirements found at 40 CFR 122.4(i) and the Pinto Creek decision (http://cdn.ca9.uscourts.gov/datastore/opinions/2007/10/03/0570785.pdf . In this context, the HHC themselves are strong regulatory numbers that drive resource intensive programs. This is important because the risk management/policy decision to use a RCS of 20% to 80% in the MCLG itself has no regulatory outcome – it simply provides a backdrop for development of the MCL. The risk management/policy decision to use a 20% to 80%

	RSC in HHC development directly affects a regulatory value with potentially large economic consequences (see Pinto Creek decision). We believe this background discussion is relevant because maybe the risk management/policy decision to use the SDWA RSCs to harmonize with the CWA HHC should be reconsidered now that states have had time to examine more fully the EPA 2000 guidance. The decision to try to harmonize the development of the MCLG and the CWA HHC may be like trying to harmonize apples and oranges: both are fruit – both are different from each other. Different regulatory programs address the same chemicals and effects in different ways in order to fulfill the requirements of enabling legislation, regulations, and local needs. Applying a default assumption (RSC = 20% to 80%) that might have no affect on a regulatory level (the MCL) from one program, to another program (NPDES) where the assumption can drive huge resource and compliance issues (through requirements to meet HHC in ambient waters) does not necessarily make sense. Trying to harmonize programs or regulatory levels seems like a good idea on the surface, but trying to harmonize programs or regulatory levels that are not completely analogous is not necessarily a good idea. An alternative to using the 20%-80% range would be to apply 100% as the RSC. 100% has been the RSC value traditionally incorporated into HH criteria development for the non-carcinogens, unless additional data to identify other exposure pathways are available (e.g., the new mercury HH criteria). Maybe this is the way to go until this issue has had more discussion. An inherent assumption in how the RSC for HHC is developed is that all other sources of the contaminant are

	required to be considered in the exposure scenario, and the HHC get the "left over" part of the reference dose. This results in the odd situation where, as the contribution of a contaminant from water becomes less and less important (a smaller part of the RfD allowed in water), the HHC get more and more stringent – in effect becomes a bigger and bigger driver for more restrictive limits. Because other regulatory programs (e.g., FDA action levels and food tolerances, SDWA MCLs, Superfund clean-ups) target lower levels of protection, the CWA program is at the mercy of the regulatory levels set in other programs, and is expected to "clean-up" the waters that are allowed higher levels of pollution than these other sources (even when these other sources may be ongoing sources even after their regulatory requirements have been fulfilled). It would be interesting to have a broader national discussion on how the RfD for any individual chemical is allocated among different regulatory programs. Maybe it would make more economic sense, and more opportunities might be available, to try to cut down the levels of contaminants allowed in other regulatory programs (that are based on cost, feasibility, etc.) so that the CWA criteria could focus only on the designated uses and CWA-regulated pollution sources within the geographic jurisdiction of each state. **Comment 2.** This reads like rule language instead of guidance. **Comment 3.** This reads like rule language instead of guidance.
Q5. Should an RSC also be applied to carcinogens? In the case of carcinogens based on linear low-dose extrapolation, the AWQC is determined with respect to the *incremental* lifetime risk posed by a substance's presence in water, and is not being set	**Comment 1.** This statement in the FAQ causes confusion about who has the responsibility for making risk management decisions with regard to both risk level and FCR: EPA regions or the states? It would be useful for EPA to include a statement in

with regard to an individual's total risk from all sources of exposure. Thus, the AWQC represents the water concentration that would be expected to increase an individual's lifetime risk of carcinogenicity from exposure to the particular pollutant by no more than one chance in one million, regardless of the additional lifetime cancer risk due to exposure, if any, to that particular substance from other sources. For human health criteria, this exposure pathway considers consumption of freshwater and estuarine fish and shellfish (as described in the responses to Q1 and Q2) and drinking water ingestion. (see **comment 1** at right) EPA recommends that the incremental cancer risk from these exposure pathways not exceed more than 1 in 1,000,000 or 1 in 100,000 for the general population, nor exceed more than 1 in 10,000 for any sensitive sub-population (such as those who may consume a great deal more fish because of a subsistence lifestyle). States and tribes may consider adjusting the risk level according to guidance in the 2000 Human Health Methodology (and mentioned above), particularly if exposure to "other" sources besides water and fish is determined to be significant.	this FAQ similar to its statement in the 2000 Human Health methodology that: *"EPA believes that ambient water quality criteria inherently require several risk management decisions that are, in many cases, better made at the State, Tribal, or regional level."* This issue is particularly important, in an immediate sense, for Washington and Idaho. Both states have been told by EPA Region 10 that the Region is considering developing "region-specific" guidance (or some other framework to look at approvable criteria) on HHC, including risk levels and FCRs. The states have also been told that Region 10 thinks "the Oregon outcome was the right outcome." The Oregon outcome included risk management decisions, appropriately made by that state, for a FCR that included salmon consumption and application of that rate to a state-determined risk level. Washington and Oregon are concerned that development of regional guidance will usurp the risk management decisions appropriately and historically made by states, and instead have them made by EPA. If this is the approach then the issue of "rule-by-guidance" becomes important.
Q6. Could a state include a component of marine fish consumption in their FCR for deriving human health criteria? Yes, a state may include consumption of marine species in the FCR. (see **comment 1** at right) Coastal States and authorized Tribes that believe accounting for total fish consumption (i.e., freshwater/estuarine and marine species) is more appropriate for protecting the population of concern may do so. In the instance	**Comment 1.** As discussed above in the comments on Q2, commercial markets make marine fishery resources available to consumers in all states. Inland states may have just as much, or even maybe more, fish of marine origin sold in their markets than coastal states. This seems to be analogous to the inclusion of consumption of imported fish/shellfish from waters outside the US in the FCR used to calculate criteria. However, as

where the FCR includes freshwater, estuarine and all marine fish consumption, EPA recommends that states adjust the RSC estimate to reflect a greater proportion of the reference dose being attributed to water intake and the marine-inclusive FCR exposures. 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. Including marine fish in the fish consumption rate for criteria calculations would provide some calculations that are more stringent than those that don't include marine fish consumption, particularly for chemicals that are highly bioaccumulative.	discussed above, it seems that there is still much to discuss around the use, in HHC development, of commercially acquired fishery resources and resources from marine waters that are outside the jurisdictional boundaries of states. A serious national public policy discussion needs to take place about what we are trying to achieve by including non-local fish in the basis for water quality criteria that are going to be used to regulate local waters.
Q7. When fish consumption exposure is represented by a distribution of values, what are the appropriate percentiles to choose? In general, EPA considers protection of the general population to be represented by the 90th percentile of a total exposure distribution utilizing a "per capita" fish consumption distribution. If present in the state, subsistence fishers should be considered on a site specific basis. EPA has recommended the 99th percentile of a per capita fish consumption distribution as a surrogate for subsistence fishers, which corresponded to a range of average consumption estimates from actual surveys for subsistence fishers. (see **comments 1** at right) An analysis of protectiveness of the criteria for the general population, recreational fishers and subsistence fishers should be included in the criteria documentation.	**Comment 1.** We think it is clear from the EPA 2000 guidance, as reiterated in this FAQ, that final criteria development should be underlain by clear statements on risk management decisions made by the states and on the levels of risk/protection that are provided by new HHC. As stated at left, that clarity should apply to "the general population, recreational fishers and subsistence fishers." Note: Idaho's request for assistance in planning and/or conducting a survey of the general population of Idaho was recently refused by EPA. Given this FAQ direction, we would like greater clarification from EPA on why they were not supportive given their statement highlighted at left.