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]

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

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 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. 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.

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

That is, through the use of conservative assumptions with respect to both toxicity and exposure parameters, the resulting AWQC should provide adequate protection not only for the general population over a lifetime of exposure, but also for special subpopulations who, because of high water or fish intake rates, or because of biological sensitivities, have an increased risk of receiving a dose that would elicit adverse effects. The Agency recognizes that there may be some cases where the AWQC based on chronic toxicity may not provide adequate protection for a subpopulation at special risk from shorter-term exposures. The Agency encourages States, Tribes, and others employing the 2000 Human Health Methodology to give consideration to such circumstances in deriving criteria to ensure that adequate protection is afforded to all identifiable subpopulations.

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). 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, 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). All of the other components represent 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.

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. 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. 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 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 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.

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 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. 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.

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. 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 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.

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. An analysis of protectiveness of the criteria for the general population, recreational fishers and subsistence fishers should be included in the criteria documentation.

January 18, 2013