Paula Wilson

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Ms. Wilson: Attached are the comments of the Federal Water Quality Coalition ("FWQC") regarding the negotiated rulemaking on water quality standards (Docket No. 58-0102-1201). These comments consist of three documents: (1) a set of key issues that should be considered in determining fish consumption rates when developing human health water quality criteria; (2) a paper on the use of conservative assumptions in developing human health criteria; and (3) a set of questions to address in setting fish consumption-based human health criteria. If you have any questions concerning these materials, please feel free to call. Thanks.

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KEY ISSUES TO CONSIDER IN DETERMINING FISH CONSUMPTION RATE WHEN DEVELOPING HUMAN HEALTH WATER QUALITY CRITERIA

States adopt numeric water quality standards for particular substances, subject to approval by USEPA. Those standards consist of designated uses and water quality criteria. The designated uses establish the categories of uses of particular waterbodies – such as warm-water fish habitat, cold-water fish habitat, fish consumption, and industrial use. The water quality criteria specify the acceptable levels of particular substances that are consistent with protecting those designated uses. In addressing the fish consumption designated use, States adopt water quality criteria that are intended to protect human health from consumption of fish with high levels of contaminants.

USEPA has published guidance that States can use in developing these human health criteria. One of the key components of the calculation process is determining the amount of fish consumed by people on an average daily basis. The higher the fish consumption rate, the lower the human health criterion needs to be in order to ensure that people are not exposed to unsafe contaminant levels. The default national fish consumption rate in USEPA guidance is 17.5 grams per day. This is protective of the vast majority of the U.S. population, since most people do not eat 17.5 grams of fish or more per day. The USEPA guidance provides that in geographic areas where there are subpopulations with higher levels of fish consumption, the State can set site-specific water quality criteria using a higher fish consumption rate. This can have a dramatic effect on the resulting criteria – if the consumption rate is doubled, for example, to 35.0 grams per day, then the criteria are reduced by 50%, to half of their original levels. This results in more stringent permit limits for dischargers to that particular waterbody, to ensure protection of the high-consumption group.

Recently, as States have been performing their triennial reviews of water quality standards, some States have been considering using a different approach than recommended in the USEPA guidance. Instead of adopting criteria based on protecting the general population, and issuing site-specific criteria for areas with high fish-consuming populations, those States have been considering applying the consumption rates for the higher fish-consuming subpopulations on a State-wide basis, regardless of the actual fish consumption rates of the general population or the users of specific waterbodies. This practice results in extremely stringent water quality standards, down to part-per-billion levels or lower. Use of these higher fish consumption rates goes far beyond what is necessary to protect human health, and is simply not consistent with basic scientific principles. In addition, in many instances these levels will be impossible to attain, even after imposing enormous compliance costs on municipalities and businesses. Below, this paper identifies key concepts that States should follow in determining the proper fish consumption rate to use in developing human health criteria.

As an initial matter, it is important to note exactly what the State's obligation is when it sets water quality criteria, and what EPA's role is in reviewing those State actions. In developing water quality criteria, States are required to focus on protection of their designated uses. The Clean Water Act (Section 303 (c) (2)) specifies that criteria for toxics are to be set "as necessary to support such designated uses." EPA's regulations, in turn, provide that these criteria must be "sufficient to protect the designated use." 40 CFR 131.11(a)(2). If the State sets criteria that are protective of the uses, EPA is required to approve them. EPA's role in reviewing these standards is a limited one: to determine whether the State standards are "scientifically defensible and protective of designated uses." *NRDC v. EPA*, 16 F.3d 1395, 1401-02 (4th Cir. 1993). If the State meets those tests, then its standards must be approved by EPA, and become effective under the Clean Water Act. The recommendations below are intended to help States to implement their responsibility to set appropriate water quality criteria that are both scientifically defensible and protective of the designated use of fish consumption.

PRINCIPLES FOR DETERMINING PROPER FISH CONSUMPTION RATE

1. Look at local data on fish consumption, rather than data from national datasets or from other geographic areas. There are significant differences in fish consumption between regions, and local data will provide the most useful and relevant information.

2. In the derivation of the fish consumption rate, count only fish that are actually present and consumed in the local area. Studies that include other fish will give an unrealistic picture of actual exposure.

3. Consider available, reliable information as to what substances these fish accumulate, and the manner and extent of that accumulation. Different fish are sensitive to different substances, and to different extents – it is not appropriate to assume that one species of fish will accumulate a given substance in the same way as another species.

4. Perform separate analyses as to the risk to the general population and to highly exposed subpopulations (if present), using appropriate exposure and other parameters for each group. As noted above, assumptions that are relevant for high-level consumers do not necessarily apply to the general population or to all waterbodies. Criteria decisions need to be based on a careful assessment of the actual extent of risk, not arbitrary assumptions.

5. Factor in the size of each subpopulation in assessing total risk. If there is an extremely small subpopulation present in a particular area, it may not be appropriate to develop broad-based standards based on that component of the risk. There may be other means to protect that subgroup.

6. In assessing the need to increase the conservatism of the fish consumption rates used, consider the conservatism already built into the standards process through other inputs. Many of the other parameters used in calculating standards are also conservative, and the combination of those high values leads to standards that are much more stringent than necessary for the protection of human health, and are inconsistent with targets set by Federal and State regulatory programs to protect human health.

7. Evaluate consumption data for shellfish separately, since shellfish accumulate contaminants differently than fish do. Some subpopulations eat large amounts of shellfish, and exposure through this consumption should not be combined with fish consumption in setting standards.

8. Do not include consumption of anadromous fish in determining consumption rates for freshwater bodies. These fish are born in fresh water, spend most of their lives in the ocean, then return to fresh water to spawn, so contaminant levels in these fish are not relevant when determining standards for freshwater systems.

9. In developing standards for arid Western areas, consider the unique nature of the fish populations. Native species are very low in diversity and abundance, and introduced fish raised in hatcheries are not exposed to the same contaminants for the same time period as native fish are elsewhere.

10. For many substances that can bioaccumulate in fish (such as mercury, dioxin or PCBs), loadings to the waterways from active point sources are very low. Therefore, imposition of stringent standards and permit limits, based on use of extremely conservative fish consumption rates, will achieve little in the way of actual risk reduction, but will carry enormous compliance costs.

USE OF CONSERVATIVE ASSUMPTIONS IN DEVELOPING HUMAN HEALTH CRITERIA

Water quality criteria for the protection of human health are developed by States, using EPA guidance and other relevant information. These criteria are designed to protect humans exposed via drinking water, consumption of fish, and/or dermal contact. The criteria are generally derived using EPA-recommended equations that include parameters for risk, toxicity, and exposure. Often, the parameter values chosen are extremely conservative – i.e., more protective than is necessary. This paper explains those choices, and discusses how the compounding of those conservative values for multiple parameters leads to water quality criteria that are far more stringent than is necessary or justified, in comparison to health protection targets established by other state and federal regulatory programs.[1]

The equations used to derive human health criteria are composed of explicit parameters (i.e., those that are listed and defined), and implicit parameters (i.e., those that are embodied in the application of the explicit parameters). The table below lists the explicit and implicit parameters used in the criteria derivation process. Also shown are parameter values recommended by EPA. The third column in the table indicates whether the recommended value reflects a central, upper-end, or maximum in the range of values that could be chosen for each parameter. It is clear from the table that, in nearly every case, the values recommended by EPA are selected from the upper end of the range of possible values.

[1] The information and recommendations in this memorandum are derived primarily from material presented in the following scientific paper: "A review of methods for deriving human health-based water quality criteria with consideration of protectiveness." National Council for Air and Stream Improvement, August 2012.

Parameter Values used in HHAWQC Derivation and
Location in the Range of Possible Values

Parameter	Recommended Value	Location in Range of Possible Values[1] (maximum possible, upper-end, or central tendency)
Explicit Parameters		
substance toxicity	substance-specific	upper-end
body weight of a person	70 kg (actual mean is 80kg)	central tendency
drinking water intake	2 L/day (86th percentile), but assumes drinking water is untreated surface water	(extreme) upper-end
fish ingestion/consumption rate	17.5 g/day (90th percentile of sport fishers)	upper-end
substance exposure from other sources	80%	upper-end
Implicit Parameters		
cooking loss	0% (no loss due to cooking)	maximum possible
duration of exposure	70 years	(extreme) upper end
exposure concentration	at HHAWQC 100% of the time	maximum possible
relative bioavailability	1	maximum possible
bioaccumulation/concentration factor for fish	substance-specific	substance-specific (not evaluated)

[1]"maximum possible" would be the most conservative choice possible, "upper-end" a very conservative choice, and "central tendency" a typical or average value for a population. "Extreme" denotes a value that is very near maximum.

The practice of selecting "upper end of range" values for multiple parameters in a risk equation will lead to over-conservative estimates of risk, which then lead, in this situation, to human health criteria that are more stringent than needed to protect human health. EPA's own Risk Assessment Task Force has suggested, instead, that "an exposure estimate that lies between the 90th percentile and the maximum exposure in the exposed population [should] be constructed by using maximum or near-maximum values for one or more of the most sensitive variables, leaving others at their mean values" (EPA 2004). This concept, however, has not generally been followed when setting human health criteria.

The values commonly used for each parameter in developing human health criteria can have the effect of lowering the calculated criteria by large factors. For example:

- Substance toxicity values are commonly reduced by 10 to 3000 times below demonstrated toxicity thresholds as a means of ensuring protection of human health.
- Assumptions about chemical exposure via drinking water result in some criteria being as much as 30 times lower than needed to afford the degree of protection targeted by most states and EPA.
- The assumption is made that a person lives in the same place and is exposed to the same level of contamination for a 70 year lifetime, which results in criteria that are up to 8 times more stringent than if a median exposure period were assumed.
- The assumption is made that waters would contain the substance at the allowable criterion for 70 years. That is inconsistent with water management policies in virtually all states, and it results in criteria values that are 1.5 to 6 times more stringent than would be the case if actual water quality management policies were considered.

Each of the factors listed above, and the other implicit assumptions that are used in deriving criteria, are combined (i.e., compounded) when used in the same equation to derive criteria. The result is criteria that are many times lower than would be the case if, consistent with the advice of EPA's Risk Assessment Task Force, upper range values were used for one or more the most sensitive variables, and mean values were used for the other variables.

In addition to the use of multiple conservative assumptions, there are several other bases for concluding that human health criteria developed using EPA guidance are generally much more stringent than necessary to achieve recognized health protection targets. For example:

- If higher fish consumption rates are assumed, EPA fish tissue data would indicate that virtually all surface waters in the US would exceed the human health criteria for PCB, mercury, and likely a number of other substances. In contrast, for example, health agencies have established fish consumption advisories for PCBs on only about 15% of water bodies, indicating that the human health criteria are lower than the levels deemed to justify fish consumption advisories.
- Based on an analysis of the daily intake of several substances for which human health criteria exist, intake of those substances from other foods was greater than the intake from fish, and exceeded the intake rates used to establish human health criteria. Thus, application of more stringent water quality criteria may not provide a measureable public health benefit.
- Various federal and international agencies that have the charge of regulating the food supply to protect public health have established concentration limits for fish as a food in commerce. Levels set by these agencies show that EPA-recommended human health criteria set limits on fish tissue concentrations that are substantially (10s to 1000s of times) lower than the levels considered by other agencies to be insignificant from a public health viewpoint.

QUESTIONS TO ADDRESS IN SETTING FISH CONSUMPTION-BASED HUMAN HEALTH WATER QUALITY CRITERIA

Water quality criteria for the protection of human health (HHWQC) are derived using United States Environmental Protection Agency (EPA) recommended equations that include parameters for toxicity, exposure and an allowable risk. When states develop their own criteria, they may revisit the values for each parameter used in the equations—some of which are explicit, and some of which are implicit--to determine the extent to which the equations incorporate newly-available science, and are reflective of conditions in the State. The EPA has also determined that it is appropriate for States to adjust the values for equation parameters based on risk and other state-specific policy choices.

This paper presents a series of questions that States should consider in setting HHWQC.[1] The questions are divided into three categories. The first are questions about explicit parameters in the equations used to derive HHWQC. Explicit parameters are those that are shown as a variable in the equations and require an input value (i.e., a point estimate or a distribution). The second category presents questions about implicit parameters. Implicit parameters represent assumptions that affect the derivation of an HHWQC but are not shown as variables in EPA's equations. Hence, they do not require an explicit input value when deriving an HHWQC using EPA's equation, yet an implicit assumption is made about that input value. Lastly, the third category contains some general questions related to the HHWQC derivation and implementation process.

Explicit Parameters

1. Reference Dose (RfD) - Estimate of daily exposure likely to be without appreciable risk of adverse effects over a lifetime; Risk-specific dose (RSD) - Risk-specific dose for carcinogenic effects based on a linear low-dose extrapolation (mg/kg-day) and a selected target risk level.

- Some States are planning to use a probabilistic approach to estimate exposure when deriving HHWQC. If such an approach is used, should it be extended to the estimates of toxicity used in the derivation of HHWQC, to more accurately convey the meaning of selecting the 90th percentile of the exposure distribution to establish HHWQC? Some States instead use point estimates of toxicity, which are generally considered conservative, but that conservatism is not quantified. Should the State instead use probabilistic methods for both exposure and toxicity assumptions and base HHWQC on the 90th percentile of risk (not just the 90th percentile of exposure)?

- Alternatively, in the interest of transparency, should the State indicate to the public that the 90th percentile of exposure does not correspond to the 90th

[1] These questions are based on a scientific memorandum originally developed for the Florida Pulp and Paper Association, which has been submitted to the State of Florida for its consideration in developing human health criteria. Appropriate revisions have been made to ensure that the questions as set forth here are generally applicable.

percentile of the risk distribution but rather, a much higher percentile of the risk distribution (e.g., the 99^{th} or 99.9^{th} percentile depending upon the chemical)? Should a "plain English" estimate of risk to the average State resident be presented, to better communicate the level of protectiveness associated with the proposed HHWQC derivation approach?

2. Relative Source Contribution (RSC) – Fraction of total exposure attributable to surface water exposures and consumption of freshwater/estuarine fish.

- Should the State be specific and transparent as to how the relative source contributions were determined, so others can assess if that determination was done in an appropriate manner?

- Should an RSC apply to carcinogens? EPA HHWQC development guidance indicates that incorporation of an RSC in HHWQC for carcinogens is not appropriate.

- Should the State document the scientific basis for each RSC and confirm that each RSC is justified based on data that exist today?

3. Drinking Water Intake (DI) – Daily drinking water intake.

- Should the State assume that adult fish consumers also consume untreated surface water? Is such an assumption consistent with the water consumption profile of State residents? If not, how should the distribution be adjusted?

4. Fish Intake (FI) – The average daily fish consumption rate.

- What species of fish should be considered for developing the appropriate fish consumption rate used in either deterministic or probabilistic analysis to set HHWQC?

- In States where a small amount of the fish consumed by State residents are freshwater inland species and the remainder are coastal and ocean species, how should the life cycle of coastal and ocean fish be used to adjust the fish consumption rate distribution? Should the assumed exposure concentration be adjusted to account for most fish species being exposed to lower concentrations than assumed by the HHWQC?

- In States where commercially and recreationally-caught fish provide only a small amount of the actual fish and shellfish being consumed by State residents, how should the fish consumption rate be adjusted?

- To determine if a particular fish consumption rate is reasonable to use in developing HHWQC, it is important to look at the overall picture of sustainable fish productivity. Multiplying the population of potential consumers in the State by the assumed fish consumption rate for the average State resident results in a total daily intake of a certain number of grams of edible fish per day. That number should be compared to general information on the amount of edible fish that can be produced sustainably by Territorial, coastal and inland waters. If the calculated fish consumption rates are shown to exceed the sustainable production of fish from waters of the State, how should the approach for deriving HHWQC be modified to reflect State-specific fish productivity?

5. Bioconcentration Factor (BCF) – Ratio of the concentration in fish tissue to the water column concentration (normalized to 3% fish tissue lipid content).

- Most bioconcentration factors listed in EPA's guidance documents are more than two decades old and generally were developed using short-term (days or weeks versus months or years) studies to evaluate how water column concentrations might bioconcentrate in fish. In many cases, the whole fish – not just the edible fish tissue - was analyzed for the presence of the chemical. There is also a very conservative assumption that all finfish and shellfish bioconcentrate chemicals equally, irrespective of water column concentration or species behaviors. Should the State update BCFs based on longer term studies and better analytical methods, with a specific focus on data and information that addresses bioconcentration in edible tissue?

<u>Implicit Parameters</u>

1. Cooking Loss – Fraction of a chemical lost during cooking (preparation) of a fish.

- Is the assumption by the EPA equation of no loss of chemicals during cooking consistent with losses of organic chemicals reported in the literature? If not, how should cooking loss of compounds be included in the State approach?

2. Exposure Duration – Number of years State residents are assumed to be exposed to the chemicals for purposes of deriving HHWQC.

- The EPA equation assumes a lifetime (i.e., 70 years) of exposure to chemicals in State surface waters and in fish caught from those surface waters. Yet, experience and census data indicate that most residents of any particular State either do not spend their entire lives in that State, or move from one area of the State to another and are not likely to obtain their fish from the same waterbodies. Moreover, it is very unlikely that individuals would consume fish at the same rate for their entire lives. How should these differences between actual and assumed exposure duration be accounted for to more accurately represent the exposure distribution of the State's fish consumers?

3. Exposure Concentration – The surface water concentration to which residents and fish living in a waterbody are actually exposed.

- The EPA HHWQC derivation equation assumes that a water body will contain a chemical at a concentration equal to the HHWQC all the time and, thus, exposure via drinking water and fish tissue will be equal to the maximum allowed concentration throughout a person's lifetime. Is this assumption reasonable considering that, as a practical matter, a stream could not exist over the long term at an average concentration equal to the HHWQC, because if that were the case, measured concentrations in the water body would exceed the HHWQC much of the time (i.e., values above the average) and thus trigger action by the State to reduce concentrations? How should the HHWQC be adjusted to reflect the existence of State regulations that protect waters from becoming impaired (i.e., frequently above established criteria) and federal and State statutory and regulatory requirements that impaired waters be restored?

4. Relative Bioavailability – Bioavailability from fish and water compared to bioavailability in the experiment from which the toxicity benchmark or bioconcentration factor was derived.

- EPA guidance does allow for the selection of an alternative RfD in cases where the actual vioavailability of the chemical is lower than the experimental bioavailability. How should the State account for HHWQC that may not appropriately reflect the actual relative bioavailability in the water column or in fish that would have the chemical in the form of indigestible complexes?

Other Considerations

1. Determination of Risk. The State will need to derive HHWQC based on goals for protection of the population – for example, the goals could be to protect the 90^{th} percentile individual in the general population at a risk level of one in a million for carcinogenic effects and a hazard index (HI) of one for noncarcinogenic effects. How does the actual degree of protection compare to the intended degree of protection? With respect to fish tissue concentrations, how do the HHWQC compare to contaminant levels considered by other agencies as protective of public health?

2. Relative exposure. A combination of the 90th percentile of exposure with conservative point estimate toxicity benchmarks would limit exposures for some chemicals via fish consumption to levels that are much lower than those experienced by the majority of State residents from background sources. For example, background dietary exposure to benzo(a)pyrene (BaP) for the majority of people has been estimated to range between 20 and 100 nanograms (ng)/day, yet an approach using the 90^{th} percentile and conservative benchmarks would limit exposure to all PAHs (not just BaP) to less than 10 ng/day. Background dietary exposure to total PAHs would be much higher than exposure to just BaP. What changes should be made to the HHWQC derivation procedure to assure that

the procedure does not lead to costly, unsuccessful efforts to reduce exposures to below background levels?

3. Policy decisions. Establishing thresholds for HHWQC involves policy decisions to be made throughout the derivation procedure. For example, setting the fish consumption rate distribution involves making decisions about which fish species to include or exclude, how to treat consumers versus non-consumers, and how to translate data from short-term recall surveys into estimates of long-term consumption habits, etc. Should the State provide specificity and transparency for the policy decisions made for each explicit and implicit parameter and the effects those decisions have on the HHWQC? How can the State quantify the degree of conservatism resulting from these various policy decisions?

4. Benefits of eating fish. It is now well recognized that regular consumption of fish confers important health benefits to fish consumers. Overly conservative HHWQC may lead to fish consumption restrictions on many waters in any given State. Observance of those restrictions by State residents may lead to a reduction in fish consumption. Should the HHWQC approach consider the benefits of fish consumption? If so, how should those benefits be accounted for? If not, are those benefits less important than the potential risks that the HHWQC are trying to minimize?