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Federal Water Quality Coalition

COMMENTS OF FEDERAL WATER QUALITY COALITION ON EPA NOTICE OF AVAILABILITY OF UPDATED NATIONAL RECOMMENDED WATER QUALITY CRITERIA FOR THE PROTECTION OF HUMAN HEALTH

The Federal Water Quality Coalition (the "Coalition" or the "FWQC") hereby submits the following comments on EPA's Notice of Availability of Updated National Recommended Water Quality Criteria for the Protection of Human Health (the "Criteria Notice"). (79 Fed. Reg. 27303, May 13, 2014).

The Coalition is a group of industrial companies, municipal entities, property owners, and trade associations that are directly affected, or have members that are directly affected, by regulatory and policy decisions made pursuant to the Federal Water Pollution Control Act (the Clean Water Act). Coalition members for purposes of these comments are as follows: Alcoa, Inc., American Chemistry Council, American Coke and Coal Chemicals Institute, American Forest & Paper Association, American Iron and Steel Institute, American Petroleum Institute, Association of Idaho Cities, Auto Industry Water Quality Coalition, City of Superior (WI), Edison Electric Institute, Freeport-McMoRan Copper & Gold, Inc., General Electric Company, Hecla Mining Company, Indiana Coal Council, Kennecott Utah Copper LLC, Mid America CropLife Association, Monsanto Company, National Association of Home Builders, Orange County Sanitation District, Pharmaceutical Research and Manufacturers of America, Rayonier Corporation, Rubber Manufacturers Association, Shell, Utility Water Act Group, Western Coalition of Arid States, Western States Petroleum Association, and Weyerhaeuser Company.

FWQC member entities or their members own and operate facilities throughout this country. Those facilities operate pursuant to NPDES permits that impose control requirements with respect to wastewater discharges. Many of those permits include effluent limits based on water quality criteria developed for the protection of human health. The recommended criteria being developed by EPA will be used by many States and authorized Tribes as they adopt new or revised human health water quality standards. In turn, those standards will determine the effluent limits in permits for FWQC members. The FWQC therefore has a direct interest in the recommended criteria being developed by EPA.

The Coalition appreciates the opportunity to submit these comments. However, we are concerned that the public comment period of 90 days was much too short to allow for effective review of the background materials supporting the Criteria

Federal Water Quality Coalition

Notice and development of comprehensive comments regarding the scientific issues raised by those documents. As set forth below, our initial review has identified serious scientific concerns regarding the methodology used to derive the new recommended criteria. We urge the Agency to allow additional time for public review and comment concerning the criteria, to ensure that the new criteria truly reflect sound scientific conclusions as to the levels that are necessary to protect public health.

In reviewing the Criteria Notice and the background scientific materials, the Coalition has worked with scientific experts from two organizations: ARCADIS and the National Council for Air and Stream Improvement ("NCASI"). Detailed reports from those two organizations are attached to these comments, and are incorporated by reference. Based on those two reports, and its own review of the criteria and background documents, the Coalition has identified several overall concerns regarding the criteria, as well as a series of specific problems as to particular elements of EPA's methodology. These issues need to be addressed before the Agency finalizes any new recommended criteria.

GENERAL COMMENTS

- The methodology used to develop the new criteria reflects significant changes from EPA's own adopted Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (http://water.epa.gov/scitech/swguidance/standards/criteria/health/methodology/index.cfm). It is improper to develop new criteria using a methodology that differs from EPA-adopted procedures. Before adopting new criteria, EPA should propose revisions to its own methodology, so the public can comment on those methodology changes before reviewing new criteria that are developed using the new process.
- Many of the changes in the new criteria process are the result of policy changes, rather than being due to new science. This is true, for example, in how the Agency addresses marine fish in determining fish consumption rates, in the use of a single default Relative Source Contribution (RSC) value, in the use of Great Lakes-specific model parameters for waters outside of the Great Lakes Basin, and in the use of a model that limits the ability to develop site-specific solutions. These policy changes should be made transparent in a new draft methodology, which is opened to public review and comment, before criteria are developed (and implemented) that are based on the new policies.
- The record supporting the new criteria lacks sufficient technical detail to allow stakeholders to determine if many of the changes are scientifically justified.
- EPA has not addressed issues raised by its own Science Advisory Board regarding the Agency's method for developing criteria. Those concerns should be considered, and appropriate revisions made, before new criteria are adopted using this approach.
- EPA has used a deterministic procedure, and selected upper-percentile values for nearly all of the parameters in the criteria derivation equation. This has resulted

in criteria that are far more stringent than is necessary to protect public health. Use of a probabilistic approach, which provides much more realistic estimates of risk, is feasible to use and should be seriously considered by the Agency for use in developing scientifically sound, realistic water quality criteria.

- EPA has just released a Risk Assessment Forum White Paper on probabilistic risk assessment (PRA). (http://www.gpo.gov/fdsys/pkg/FR-2014-08-12/pdf/2014-19065.pdf.) The White Paper identifies situations in which PRA "may be particularly useful," including situations in which "uncertainty in some aspect of the risk assessment is high, and decisions are contentious or have large resource implications," as well as situations in which "the scientific rigor and quality of the assessment is critical to the credibility of the EPA decision." The development of water quality criteria to protect human health fits well into those criteria for use of PRA, further supporting the need for the Agency to apply the PRA approach in developing these criteria.
- A number of regulated parties, including FWQC members, have supported development of a statistical tool that will enable agencies to readily calculate water quality criteria using a PRA approach. That tool has been presented to EPA, and the FWQC supports its use. EPA should use that tool to develop PRA-based criteria, and it should allow States to use the tool as well.
- The new criteria are, in general, much more stringent than EPA's existing recommended criteria, and are not scientifically justified. Moreover, some of the criteria are set at levels that are considerably lower than measured ambient concentrations in waterbodies. (An example is the Ohio River, where ambient levels for various organics are much greater than the new criteria: www.orsanco.org/organics-detection-system-84.) Use of the new numbers will result in many new impaired waters, many new total maximum daily loads (TMDLs), many new, stringent permit limits, and resulting high compliance costs for regulated facilities, with little or no public health benefit.
- EPA's use of compounded conservative assumptions in developing the new criteria is not only improper as a scientific matter; it is also contrary to EPA's own policy documents, which recognize that the Agency does not need to use excessively conservative input values on all equation parameters in order to yield adequately protective regulations.

SPECIFIC COMMENTS

- The method used by EPA to derive fish consumption rates (FCRs) has not been adequately peer-reviewed by experts outside of the Agency, and the data and supporting documentation needed to allow an external review have not been made publicly available.
- EPA has not provided an adequate rationale for the use of its unvalidated FCR method instead of the recognized method established by the National Cancer Institute (NCI).
- In deriving FCRs, EPA has improperly factored in marine species that are not

exposed to pollutant levels in local waters for significant periods of time.

- EPA's assumption that people drink 3 liters of water per day has no relation to the actual amounts of untreated surface water ingested by humans, and contributes to an unrealistic exposure scenario that is used to develop the criteria.
- EPA has not adequately justified use of a Relative Source Contribution (RSC) value in its criteria equation, which inappropriately compensates for sources of the pollutant unrelated to fish and water exposure by reducing the water quality criteria levels.
- If an RSC value is to be used, EPA's default RSC value is unnecessarily conservative and contributes to an inaccurate risk calculation. Data-based RSC values have been derived for many substances, and they are generally much higher than EPA's 20% value.
- EPA assumes that all fish and shellfish that are consumed are caught in local waters, so that the water quality criteria for those waters must reflect high consumption of the fish and shellfish that are present. This assumption has no basis – over 90% of seafood consumed in the U.S. is imported.
- For pollutants whose toxicity is based on developmental effects, EPA's use of adult exposure parameters (i.e., assuming lifetime exposure) in deriving criteria results in levels that are lower than the actual toxicity data justify.
- In calculating the criteria, EPA uses fish lipid levels that are much higher than the lipid levels seen in most species present in U.S. waters. Again, this assumption contributes to unrealistically low criteria.
- For all water quality criteria updates, the Agency should ensure that it uses the best available science. For example, the criteria updates for chloroform, 1,2-dicholoethane, and toluene all use data from dated Integrated Risk Information System (IRIS) assessments that are more than a decade old. EPA should be mindful that these dated assessments may not be the most relevant or up-to-date sources of data for the revision of these criteria. In addition, IRIS is undergoing significant reforms, especially in its Problem Formulation, Evidence Integration, and Uncertainty Assessment areas. These elements of systematic review should be acknowledged and provided for in developing water quality criteria.
- The model and methodology used by EPA to derive bioaccumulation factors (BAFs) have substantial problems, when used to derive criteria, which bring into question the scientific basis for those criteria. Some of those problems are:
    - The model is based on the Great Lakes food web, so it overstates bioaccumulation in waters in other areas of the country.
    - The model does not account for metabolism of substances in the gut, which plays an important role in determining the extent to which those substances will actually bioaccumulate in the food web.
    - EPA has ignored cautions stated by the SAB as to whether the model used here, without further consideration of bioaccumulation, is appropriate to be used in developing criteria.
    - EPA appears to have consistently chosen high default values for the input values in its equation, resulting in a high bias in the derived BAFs (and

correspondingly low criteria values).

- The EPA model derives estimates of bioaccumulation that are far higher than if water column and fish levels of a substance are measured directly. As a result, the new approach treats substances as bioaccumulative, needing stringent criteria, that show little or no evidence of actual bioaccumulation in the food web.
- The model used by EPA is not conducive to recalculations using site-specific food web data, so it will be difficult to develop site-specific BAFs and criteria that more accurately reflect real-world situations. This is inconsistent with existing EPA policy, which indicates a preference for site-specific BAFs.
- Other ways of estimating bioaccumulation are available, which EPA should evaluate to determine if they can provide more defensible estimates than the model chosen by EPA.

CONCLUSION

The FWQC appreciates the opportunity to review the proposed human health criteria, and the methodology that was used to develop those criteria. In these comments and the supporting reports, we have identified major scientific and other concerns with the proposed criteria and the methodology. In addition, we are concerned that the time allowed for public comment has not been sufficient to allow for a careful review and the development of fully informed comments. Therefore, we recommend that EPA pursue the following course of action:

- First, EPA needs to develop new criteria using a probabilistic risk assessment (PRA) approach. It also needs to address the major scientific problems raised in these comments.
- Once it has taken those actions, the Agency should finalize its new human health criteria methodology, issue new technical support documents (TSDs) that present the new methodology and all supporting information, and then present those TSDs for review by the Science Advisory Board (SAB) and then for public review and comment.
- After those actions have been taken, and a new, final methodology is in place, EPA can develop new recommended human health water quality criteria, which should also be issued for public review and comment.

We look forward to continuing to work with the Agency on these important issues. If there are any questions regarding the issues and recommendations contained in these comments, please feel free to contact the FWQC Coordinator, Fred Andes, at 312/214-8310 or fandes@btlaw.com .

August 13, 2014

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Report on Selected Aspects of EPA's Draft 2014 Update of Human Health Ambient Water Quality Criteria

Docket Number: EPA–HQ–OW–2014–0135

Prepared for Federal Water Quality Coalition (FWQC)

August 13, 2014

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Executive Summary

In May 2014, the United States Environmental Protection Agency (EPA) released its draft updated recommended water quality criteria for human health (HHWQC) for 94 chemical substances. According to EPA, the 2014 updates reflect the latest scientific information and also include updated fish consumption rates. ARCADIS has prepared these comments on select aspects of the draft updated HHWQC as they pertain to the overall approach used by EPA for development of the draft updated criteria and specific issues related to EPA's methodology and documentation on behalf of the Federal Water Quality Coalition (FWQC).

EPA has attempted to update the HHWQC methodology through the application of scientific knowledge in the fields of dietary consumption and bioaccumulation estimation. In particular, the use of a fish consumption rate representative of long-term fish consumption behaviors, instead of relying on the results of short-term surveys, and of use bioaccumulation factors (BAFs) where appropriate instead of bioconcentration factors (BCFs), can lead to HHWQC that have a scientific basis more appropriate than that of current HHWQC and are protective of public health. However, the specific methodology EPA has used for deriving the draft updated HHWQC requires substantial revision. Once such revisions are completed, the draft updated HHWQC can be revised and reissued for additional public comment.

Comments contained in this document are organized into the categories listed below.

- Comments pertaining to certain aspects of EPA's derivation of usual fish consumption rates (UFCRs) and life-cycle apportionment of marine fish species.
- Comments pertaining to EPA's assumptions regarding human exposure and toxicity benchmarks.
- Comments on EPA's selection the BCFBAF™ model for estimating national BAFs.
- EPA's choice of input parameters for the BCFBAF™ model, including a sensitivity analysis on select input parameters.

However, an overarching comment is that the overall process used by EPA to derive the draft updated HHWQC is not transparent, in large part because many decisions are presented with little or no discussion or justification. This contrasts with EPA's historical and highly commendable efforts to explain the basis for its decision making regarding development of HHWQC (e.g., EPA 2000, 2003, 2009). This lack of transparency

combined with the absence of crucial information prevented us from providing EPA a full and thorough review of the draft HHWQC and the methodology used by EPA to derive the draft updated HHWQC. As a consequence, these comments should not be considered complete until all the information is provided to the public for review.

EPA's draft updated HHWQC are based on a UFCR that includes a contribution from marine fish under the pretext that fish classified as marine but caught in near shore waters (within approximately three miles of the shoreline) represent "local" fish that could be affected by chemicals at a concentration equal to the draft updated HHWQC. The key assumption is that near shore waters have concentrations of chemicals equal to the draft updated HHWQC. However, marine fish, even those caught in near shore waters, are expected to have substantially lower exposures to chemicals discharged to fresh or estuarine waters than true freshwater or estuarine fish species. Because of this, before including marine fish in the UFCR used to derive HHWQC, EPA needs to demonstrate that such exposures make a significant contribution to the chemical-specific body burdens found in marine fish caught in near shore waters. Regardless, if marine fish are to be included in the draft updated HHWQC, EPA needs to provide all the information used to develop the marine fish apportionment enabling the public to understand the contribution of marine fish to the overall UFCR.

The exposure assumptions selected by EPA to derive the draft updated HHWQC are representative of adult lifetime exposure, yet the toxicity benchmarks for some of the chemicals for which HHWQC have been proposed have been adjusted to account for exposures that occur during the pre-adult portions of a person's life (e.g., childhood). EPA should carefully consider whether adjusting toxicity factors to account for the assumed potential increased sensitivity of early lifestages when deriving updated HHWQC is appropriate and address the uncertainties embedded in this adjustment.

The draft updated HHWQC rely on the BCFBAF™ (formerly called BCFWIN™) model contained in EPA's Estimation Program Interface Suite (EPI Suite™) software. The BAF estimation algorithm of this model is based on the screening level bioaccumulation model originally published in Arnot and Gobas (2003), which in the authors' own words was developed "to screen new and existing chemicals for their potential to bioaccumulate" (Arnot and Gobas, 2004). The supporting literature for Arnot and Gobas (2003) also mentions the model as a screening tool (Gobas and Arnot, 2003; Costanza et al., 2012). It is not scientifically appropriate to derive nationwide HHWQC using a model developed primarily as a screening tool. Even if the BCFBAF™ model were not a screening tool, its current application in the derivation of nationwide HHWQC is not appropriate for the reasons listed below.

- BCFBAF™ does not allow users to employ site-specific parameters that affect bioaccumulation. This contradicts general scientific understanding about bioaccumulation and is inconsistent with previous EPA guidance on the use of site-specific BAFs to derive HHWQC.
- Some of the data used by EPA to parameterize/calibrate BCFBAF™ are representative of the Great Lakes and, therefore, the resulting BAFs should not be used to estimate BAFs for all waters of the United States.
- Several of the inputs to BCFBAF™ used by EPA to develop national BAFs appear to overestimate bioaccumulation in many waters of the United States.
- Food web structure and other site-specific parameters are embedded in the food web biomagnification factor, so cannot be modified to reflect site-specific conditions.
- Aquatic invertebrates were not included in the training or validation dataset of the whole-body biotransformation rate constant (kM) model within BCFBAF™ even though they are commonly consumed by humans (e.g., shrimp, clams, crabs, lobster). It is not clear whether BAFs derived using the model are applicable to invertebrates and, therefore, whether the draft updated HHWQC are under or over protective of human populations consuming these species.
- EPA's documentation of the BCFBAF™ model is often not fully transparent and/or is absent for many assumptions and processes used by the model.
- EPA has included the BCFBAF™ model in EPI Suite™ and proposed its use in the methodology for deriving HHWQC. This is contrary to the guidance of EPA's Science Advisory Board (SAB) which questioned whether BCFBAF™ has been sufficiently verified to be used in even screening assessments and requested review before EPA added BCFBAF™ to EPI Suite™.

Each of these points is discussed in detail in the following sections of these comments.

To provide an example of the potential bias associated with EPA's choice of input parameters for the BCFBAF™ model, a sensitivity analysis was conducted for select input parameters built into the model that may vary among surface waters of the United States. The sensitivity analysis demonstrates that BCFBAF™ appears to use values for several, but not all, key parameters that lead to overestimates of BAFs rather than central estimates of BAFs. This results in BAFs that overestimate bioaccumulation of most chemicals and lead to more conservative HHWQC than necessary to protect public health at the levels recommended by EPA.

Based on the information presented in these comments, we recommend that EPA develop and provide to the public for review and comment technical support

documents (TSDs) detailing the processes and rationale behind the multiple scientific and policy decisions EPA has made as part of deriving the draft updated HHWQC. The current draft updated HHWQC should not be finalized until these TSDs have been prepared and subjected to review by EPA's SAB. Once the SAB review has been addressed, EPA can revise the draft updated HHWQC and release an updated proposal for review by the public. In particular, the TSDs should include a full presentation of the derivation of the UFCR and guidance on how state regulators and other interested parties can cost-effectively develop state-, region-, or water body-specific BAFs, which is the preferred option under existing EPA guidance. As part of this, EPA should specifically justify selection of the proposed approach to developing BAFs, especially any choice to use a QSAR model over a mechanistic food web model. Given that EPA itself has explored use of the AQUAWEB model (Arnot and Gobas 2004), EPA should, at the very least, provide a detailed justification for adopting BCFBAF™ over AQUAWEB. Ultimately, a simplified version of the AQUAWEB model allowing States and authorized Tribes to use site-specific inputs for highly-sensitive parameters, but established default values for less sensitive parameters, may be more appropriate than the current proposal based on BCFBAF™.

Specific Comments

Comment 1. Marine species should not be included in the fish consumption rate used to develop the draft updated HHWQC.

Summary: Dilution provided by the large volume of water, tides, and ocean currents present in most near shore waters indicates that concentrations of chemicals regulated by HHWQC in near shore waters will be small compared to concentrations present in fresh and estuarine waters. Additionally, marine species caught in such waters may not have been present in such waters for a long enough time to have accumulated tissue concentrations assumed by the HHWQC. As a result, concentrations of chemicals in marine fish caught in near shore waters are likely to be much lower than assumed by the draft updated HHWQC. Regardless, the chemical-specific body burdens in true marine species reflect bioaccumulation in the marine environment, which is outside the jurisdictional control of States and authorized Tribes. This means that including any marine species in the UFCR would result in HHWQC that, almost by definition, can never be achieved based on actions any one state, or any group of states, could take. Based on these observations we recommend that EPA continue its past practice of excluding marine fish from the UFCR used to derive the draft updated HHWQC. If marine fish are to be included we recommend EPA provide data and analyses demonstrating that tissue concentrations in marine fish caught in near shore waters are larger than tissue concentrations of such fish caught in open oceans.

Discussion: The UFCR used to develop the draft updated HHWQC incorporates marine species under the pretext that fish classified as marine but caught in near shore waters represent "local" fish that could be affected by chemicals at a concentration equal to the draft updated HHWQC. The key assumption is that near shore waters (within approximately three miles of the shoreline) have concentrations of chemicals equal to the draft updated HHWQC and that the fraction of marine species harvested from such near shore waters have spent sufficient time in such waters to have their tissue concentrations be in equilibrium with the concentration in the near shore waters, where the equilibrium concentration is defined by the BAF. Neither of these assumptions is likely to be representative of near shore waters and, thus, of marine fish harvested from such waters. In fact, the chemical concentrations in such waters and marine fish caught from such waters are likely to be much lower than assumed by the draft updated HHWQC.

To the extent near shore waters are affected by concentrations of chemicals regulated by HHWQC, those chemicals are present in such waters because they were

discharged in a freshwater environment, transported to the near shore waters by way of a river, and then released into the near shore waters at the mouth of the river. Even if one assumes that the concentration of the chemical in the river water at its mouth prior to release to the ocean is equal to the HHWQC, which is a very unrealistic assumption given that most discharges are diluted by river flow, the concentration in the near shore waters will be greatly diluted by the volume of the ocean, tidal exchange, and ocean currents. Therefore, the concentration of chemicals in near shore waters as defined by EPA will be substantially lower than the HHWQC. Indeed, the concentrations may be so much lower as to not to lead to a material increase in exposure.

Moreover, concentrations of many chemicals in mussels and oysters collected from near shore waters have been decreasing over the past two decades or more (O'Conner and Lauenstein 2006). EPA should provide data justifying the need to include potential exposures associated with fish caught from near shore waters in the draft updated HHWQC when such fish were not included when the existing HHWQC were established and concentrations of chemicals in near shore biota were higher.

We recommend that EPA provide an evaluation of the potential contribution of freshwater releases to near shore waters to document the need for inclusion of marine fish. If near shore waters are shown to be affected by freshwater releases approaching the HHWQC, EPA should then document that the marine species caught in those waters have or are expected to have concentrations that are in equilibrium with the water concentrations. This will depend upon assumptions about uptake and depuration and time spent in the near shore waters versus open ocean waters. EPA needs to provide specific examples of species for which this is a concern and why those examples are likely to be representative of other (all) marine species harvested in near shore waters.

We acknowledge that ocean discharges represent a possible special, localized condition. EPA should examine how many such discharges occur and how the volume compares to freshwater discharges. EPA should also document that harvesting of marine fish occurs near such discharges. If such discharges are frequent enough and of a large enough magnitude to warrant consideration when setting HHWQC, we recommend that EPA develop a process that is transparent enough and flexible enough that regulatory agencies responsible for establishing allowable water concentrations can use the approach recommended by EPA to establish more stringent site-specific HHWQC for such situations. The special case of ocean

discharges should not be the basis for including marine fish in the UFCR, assuming such discharges require such inclusion in the first place.

The above comments suggest that it is very unlikely that marine fish caught in near shore waters can be considered to have the same potential to accumulate chemicals as fish that reside in and are caught in fresh and estuarine waters. Based on the reduced potential, we recommend that EPA exclude marine fish from the UFCR, and that if marine fish are to be included, EPA provide data and analyses that demonstrate such exposures are material and need to be accounted for by HHWQC.

Comment 2. EPA has not adequately documented its methodology for estimating fish consumption rate and life-cycle apportionment for marine species.

Summary: The apportionment of species to freshwater, estuarine, and marine habitats is not thoroughly documented by EPA. We recommend that EPA make transparent the process by which the apportionment was conducted such that members of the public interested in the process can duplicate EPA's findings and determine the fraction of the overall fish consumption rate that is comprised of freshwater and estuarine fish versus marine fish. To facilitate this we recommend that EPA provide a summary of the commercial landings data, species-specific life history data, and species-specific fish consumption data EPA used to arrive at the apportionments shown in Table 1 of EPA (2014a).

Discussion: In contrast to EPA's existing HHWQC that do not include marine fish when deriving HHWQC, EPA's draft updated HHWQC are based on a fish consumption rate that includes a contribution from marine fish. That contribution is based on apportioning the fraction of marine species that are harvested in estuarine and near shore waters versus open ocean waters. The habitat apportionment process is poorly documented. Furthermore, for anadromous fish (i.e., those that spend part of their lives in marine waters and part of their lives in estuarine and near shore waters), this assumption oversimplifies the process by which the chemical body burdens of fish are accumulated.

EPA (2014a) states that the assignments of species to freshwater, estuarine, and marine habitats were completed by a fisheries biologist. While Appendix A of EPA (2014a) provides the results of this analysis, the methodology that was used to arrive at these assignments is not clear. For select species, EPA (2014a) states that it used NOAA landings data to apportion the species-specific consumption rate to various

habitats. However, for a number of species, what appear to be generalized habitat apportionments are assigned without a strong scientific basis. For example, grouper are apportioned 50% estuarine and 50% marine, with the note that there are "150 species", some of which are "marine only, some estuarine and marine." Similarly, rockfish are apportioned 50% estuarine and 50% marine, with a similar note simply indicating that "approximately half are found in estuaries (in addition to marine habitats)." Scallops are assigned as entirely estuarine. However the NMFS landings data referred to by EPA (2014a) indicate that about 99% of scallops are ocean scallops and not bay scallops (57,540,043 pounds of ocean scallops landed in 2010 and 376,827 pounds of bay scallops). Based on the landings data, scallops should be weighted almost entirely marine and not estuarine. Because species specific consumption rates are not provided, the effect of this misclassification on the UFCR used to derive the draft updated HHWQC cannot be determined. In these cases and others, the technical justification for habitat assignments needs to be clearly documented including references to life history information used to make judgments about habitat use.

While EPA (2014a) recognizes that habitat apportionment is complicated by the fact that some species live in multiple habitat types at different life stages, the method used to apportion consumption of anadromous fish to estuarine/near shore and marine habitats is unclear. For example, an apportionment of 15% estuarine and 85% marine is assigned to both chum salmon and coho salmon, with a note simply indicating that "some populations spend many months in estuaries." In the past, EPA has designated Pacific salmon as marine species, effectively excluding them from the UFCR used to derive HHWQC (EPA 2002), as it was commonly accepted that salmon accrue most of their body mass and chemical body burden in marine waters. However, in recent years, the treatment of salmon and other anadromous species in the FCR used to derive WQC has been called into question (e.g., WDOE 2013). Not only are salmon of particular cultural significance in the Pacific Northwest, but their life histories are varied and complex. While all current research supports a conclusion that the majority (i.e., >90%) of the bioaccumulative chemical body burden in adult Pacific salmon is acquired in the marine phase of their life (Cullon et al. 2009, O'Neill and West 2009), this has not necessarily been proven for all anadromous fish. Therefore, there is some debate about the best approach to apportionment for these species. If EPA wishes to include some consumption of anadromous fish in the UFCR it needs to carefully weight apportionment based on residence time (i.e., apportionment of consumption based on relative amount of time each species spends in marine waters) vs. growth patterns (i.e., apportionment of consumption based on where and when each species accrues body mass) vs. catch location (i.e., apportionment of consumption based on where fish

are caught). Whichever method is ultimately used, EPA should provide clear justification for it's selection, and the process as executed should be clearly and thoroughly documented so that reviewers can understand and reproduce the results.

EPA needs to provide all necessary information to enable stakeholders to reproduce the apportionment upon which the draft updated HHWQC are based. To that end, we recommend that EPA provide a summary of the landings data used in the habitat apportionment process. We also request that EPA provide the species specific UFCRs that were combined with the habitat apportionment estimates to determine the overall freshwater, estuarine, and near shore consumption rates.

Comment 3. EPA has not consistently applied assumptions related to toxicity and exposure.

Summary: The exposure assumptions selected by EPA to derive the draft updated HHWQC are representative of adult lifetime exposure, yet the toxicity benchmarks for some of the chemicals for which HHWQC have been proposed partially apply to exposures that happen during specific portions of a person's life (e.g., childhood). We recommend that EPA carefully consider whether adjusting toxicity factors to account for potential increased sensitivity of children when deriving the draft updated HHWQC is appropriate. If EPA wishes to retain the early lifestage adjustment, we recommend that EPA discuss the uncertainty associated with this adjustment. EPA also needs to apply this adjustment consistently for all chemicals believed to act through a mutagenic mode of action.

Discussion: All of the exposure assumptions used by EPA to derive the draft updated HHWQC are representative of adults and assume a lifetime of exposure. Body weight, drinking water intake, and fish consumption rate are all derived from data for adults 21 years of age or older. Exposure duration and averaging time are not explicitly included in the equation used to derive EPA's draft updated HHWQC and are, thus, implicit assumptions that combined have the effect of assuming daily exposure for an entire lifetime but using only exposure assumptions representative of adults. Yet the toxicity benchmarks for some of the chemicals for which HHWQC have been proposed partially apply to exposures that happen during specific portions of a person's life (e.g., childhood).

For cancer risk assessments, EPA recommends modifying the carcinogenic toxicity factors [cancer slope factors (CSFs)] for chemicals acting through a mutagenic mode of action using age-dependent adjustment factors (ADAFs) before estimating a cancer

risk (EPA, 2005). ADAFs are intended to account for potential early lifestage susceptibilities to the carcinogenic effects of mutagenic chemicals. As the name implies, ADAFs are specific to certain age ranges, or life stages. During the first two years of life, the default ADAF is 10 (i.e., the expected response to a given dose is 10 times greater at this age compared to adults). For ages 2 to 16, the ADAF is 3, and for ages 16 and onward, the ADAF is 1. Without adjusting for early lifestage sensitivity, the cumulative lifetime risk associated with a given dose of a hypothetical chemical received over 70 years is calculated using the equation shown below[1]:

Lifetime risk = CSF x Dose.

If one assumes that the dose received by a given person remains constant throughout his or her lifetime, and that early lifestages demonstrate increased sensitivity to the chemical as described by the default ADAFs, a cumulative lifetime toxicity adjustment factor can be derived as follows:

Age 0 to 2 risk = Duration (2 years/70 years) x ADAF (10) x CSF x Dose
= 0.32 x CSF x Dose;

Age 2 to 16 risk = Duration (14 years/70 years) x ADAF (3) x CSF x Dose
= 0.6 x CSF x Dose;

Age 16 to 70 risk = Duration (54 years/70 years) x ADAF (1) x CSF x Dose
= 0.77 x CSF x Dose;

Lifetime risk = Sum of age-specific risks
= 1.7 x CSF x Dose.

Of the 94 chemicals for which EPA derived updated HHWQC, EPA assumes 11 act through a mutagenic mode of action (EPA, 2014b). EPA modified the carcinogenic

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[1]For simplicity, the linear cancer risk equation is shown in these comments. This equation is a special case of the more general equation: lifetime risk = $1-e^{-(\text{cancer slope factor x dose})}$. As long as the product of "cancer slope factor x dose" is less than about $1x10^{-2}$, as by definition it will be for HHWQC based on an allowable risk level of between $1x10^{-6}$ or $1x10^{-4}$, the linear equation provides an accurate representation of the cancer risk estimated by the more general exponential equation.

toxicity factors for eight of the 11 mutagenic chemicals to account for potential increased sensitivity of children (Table 1). The cumulative lifetime toxicity adjustment factor of 1.7 was applied to all of the chemicals for which this modification was made, with the exception of vinyl chloride, for which the CSF was derived using the linearized multistage method for continuous lifetime exposure from birth. While the adjustment factor of 1.7 is assumed to account for the limited duration of exposure during sensitive lifestages, a critical assumption embedded in the adjustment factor is that the dose remains constant throughout a person's lifetime. In other words, the assumption is that the dose received by an infant is the same as that received by an adolescent or an adult. However, the dose a person receives is determined by the physical and behavioral characteristics of that person (i.e., drinking water intake, fish consumption rate, body weight), which change throughout the stages of a person's lifetime.

Table 1 Mutagenic Chemicals with Updated HHWQC

Mutagenic Chemical	Toxicity Factor Adjusted for Early Lifestage Exposure?
Benzidine	No
Benzo[a]anthracene	Yes
Benzo[a]pyrene	Yes
Benzo[b]fluoranthene	Yes
Benzo[k]fluoranthene	Yes
Chrysene	Yes
Dibenzo[a,h]anthracene	No
Ideno[1,2,3-cd]pyrene	Yes
Methylene chloride	Yes
Trichloroethylene	No*
Vinyl chloride	Yes**

* Adjustment omitted for trichloroethylene because it applies only to the kidney cancer component of the total cancer risk estimate, the impact of which was considered minimal.
** The cancer slope factor for vinyl chloride was derived using the linearized multistage method for continuous lifetime exposure from birth.

To illustrate how dose might change over the course of a lifetime, hypothetical risk estimates were calculated using 50th percentile and 90th percentile age-specific fish consumption rates and drinking water intakes. These hypothetical risk estimates use an age-specific "dose" calculated as ingestion divided by body weight. Each age-specific dose is then normalized to the adult (i.e., age 21 and older) dose and multiplied by the age-specific exposure duration and ADAF to determine hypothetical risk. The results of this analysis demonstrate that the approach used by EPA to account for early lifestage exposures (i.e., applying an adjustment factor of 1.7, which assumes a constant relative dose at each lifestage) might overestimate risk by up to 50% when considering the fish consumption exposure pathway or underestimate risk by up to 20% when considering the drinking water exposure pathway (Tables 2 and 3). The

degree to which the total fish consumption risk is over estimated depends on the segment of the population considered, as the relative dose received by children compared to adults appears to be lower for the general population than for upper-end consumers. Whether the total risk is over- or underestimated when the fish consumption and drinking water exposure pathways are combined will ultimately depend on the chemical in question. The fish consumption exposure pathway is the dominant pathway for chemicals that have large BAFs; that is to say, the chemical dose received by consuming fish is considerably higher than the dose received by drinking water for such chemicals. Conversely, the drinking water exposure pathway is the dominant pathway for chemicals that have small BAFs in fish tissue. EPA needs to consider the changes exposure at various lifestages and clarify whether application of ADAFs is ultimately justified.

Table 2 Hypothetical Risk Calculations for Fish Ingestion Exposure Pathway

Age	Body Weight, kg (EPA 2011)	Duration (Fraction of 70 Years)	ADAF	Implicit Assumption in EPA's Use of ADAFs		Hypothetical Risk Using 50th Percentile UFCR				Hypothetical Risk Using 90th Percentile UFCR			
				Ratio to Adult Dose	Risk	50th Percentile UFCR, g/day (EPA 2014)	UFCR/BW	Ratio to Adult Dose	Risk	90th Percentile UFCR, g/day (EPA 2014)	UFCR/BW	Ratio to Adult Dose	Risk
0 - <1	7.83	0.014	10	1	0.1429	0	0	0	0	0	0	0	0
1 - <2	11.4	0.014	10	1	0.1429	0.6	0.053	0.842	0.120	4.7	0.412	1.499	0.214
2 - <3	13.8	0.014	3	1	0.0429	0.6	0.043	0.696	0.030	4.7	0.341	1.238	0.053
3 - <4	18.6	0.014	3	1	0.0429	0.7	0.038	0.602	0.026	5.8	0.312	1.134	0.049
4 - <5	18.6	0.014	3	1	0.0429	0.7	0.038	0.602	0.026	5.8	0.312	1.134	0.049
5 - <6	18.6	0.014	3	1	0.0429	0.7	0.038	0.602	0.026	5.8	0.312	1.134	0.049
6 - <7	31.8	0.014	3	1	0.0429	1.1	0.035	0.553	0.024	7.7	0.242	0.881	0.038
7 - <8	31.8	0.014	3	1	0.0429	1.1	0.035	0.553	0.024	7.7	0.242	0.881	0.038
8 - <9	31.8	0.014	3	1	0.0429	1.1	0.035	0.553	0.024	7.7	0.242	0.881	0.038
9 - <10	31.8	0.014	3	1	0.0429	1.1	0.035	0.553	0.024	7.7	0.242	0.881	0.038
10 - <11	31.8	0.014	3	1	0.0429	1.1	0.035	0.553	0.024	7.7	0.242	0.881	0.038
11 - <12	56.8	0.014	3	1	0.0429	1.1	0.019	0.310	0.013	8.3	0.146	0.531	0.023
12 - <13	56.8	0.014	3	1	0.0429	1.1	0.019	0.310	0.013	8.3	0.146	0.531	0.023
13 - <14	56.8	0.014	3	1	0.0429	1.1	0.019	0.310	0.013	8.3	0.146	0.531	0.023
14 - <15	56.8	0.014	3	1	0.0429	1.1	0.019	0.310	0.013	8.3	0.146	0.531	0.023
15 - <16	56.8	0.014	3	1	0.0429	1.1	0.019	0.310	0.013	8.3	0.146	0.531	0.023
16 - <17	71.6	0.014	1	1	0.0143	1.4	0.020	0.313	0.004	9.5	0.133	0.482	0.007
17 - <18	71.6	0.014	1	1	0.0143	1.4	0.020	0.313	0.004	9.5	0.133	0.482	0.007
18 - <19	71.6	0.014	1	1	0.0143	1.7	0.024	0.380	0.005	11.6	0.162	0.589	0.008
19 - <20	71.6	0.014	1	1	0.0143	1.7	0.024	0.380	0.005	11.6	0.162	0.589	0.008
20 - <21	71.6	0.014	1	1	0.0143	1.7	0.024	0.380	0.005	11.6	0.162	0.589	0.008
21 +	80	0.700	1	1	0.7	5	0.063	1	0.7	22	0.28	1	0.7
				Total Hypothetical Risk:	**1.7**			**Total Hypothetical Risk:**	**1.1**			**Total Hypothetical Risk:**	**1.5**

Notes:

BW = body weight

g/day = grams per day

kg = kilograms

UFCR = usual fish consumption rate

Hypothetical risk calculated as Duration x ADAF x Ratio to Adult Dose

Table 3 Hypothetical Risk Calculations for Drinking Water Exposure Pathway

Age	Body Weight, kg (EPA 2011)	Duration (Fraction of 70 Years)	ADAF	Implicit Assumption in EPA's Use of ADAFs		Hypothetical Risk Using 50th Percentile DI				Hypothetical Risk Using 90th Percentile DI			
				Ratio to Adult Dose	Risk	50th Percentile DI, mL/day (EPA 2011)	DI/BW	Ratio to Adult Dose	Risk	90th Percentile DI, mL/day (EPA 2011)	DI/BW	Ratio to Adult Dose	Risk
0 - <1	7.83	0.014	10	1	0.1429	525	66.957	3.533	0.505	1042	133	3.442	0.492
1 - <2	11.4	0.014	10	1	0.1429	300	26.316	1.389	0.198	772	67.72	1.753	0.250
2 - <3	13.8	0.014	3	1	0.0429	341	24.710	1.304	0.056	920	66.67	1.725	0.074
3 - <4	18.6	0.014	3	1	0.0429	437	23.495	1.240	0.053	933	50.16	1.298	0.056
4 - <5	18.6	0.014	3	1	0.0429	437	23.495	1.240	0.053	933	50.16	1.298	0.056
5 - <6	18.6	0.014	3	1	0.0429	437	23.495	1.240	0.053	933	50.16	1.298	0.056
6 - <7	31.8	0.014	3	1	0.0429	574	18.050	0.953	0.041	1186	37.30	0.965	0.041
7 - <8	31.8	0.014	3	1	0.0429	574	18.050	0.953	0.041	1186	37.30	0.965	0.041
8 - <9	31.8	0.014	3	1	0.0429	574	18.050	0.953	0.041	1186	37.30	0.965	0.041
9 - <10	31.8	0.014	3	1	0.0429	574	18.050	0.953	0.041	1186	37.30	0.965	0.041
10 - <11	31.8	0.014	3	1	0.0429	574	18.050	0.953	0.041	1186	37.30	0.965	0.041
11 - <12	56.8	0.014	3	1	0.0429	689	12.130	0.640	0.027	1829	32.20	0.833	0.036
12 - <13	56.8	0.014	3	1	0.0429	689	12.130	0.640	0.027	1829	32.20	0.833	0.036
13 - <14	56.8	0.014	3	1	0.0429	689	12.130	0.640	0.027	1829	32.20	0.833	0.036
14 - <15	56.8	0.014	3	1	0.0429	689	12.130	0.640	0.027	1829	32.20	0.833	0.036
15 - <16	56.8	0.014	3	1	0.0429	689	12.130	0.640	0.027	1829	32.20	0.833	0.036
16 - <17	71.6	0.014	1	1	0.0143	973	13.589	0.717	0.010	2298	32.09	0.831	0.012
17 - <18	71.6	0.014	1	1	0.0143	973	13.589	0.717	0.010	2298	32.09	0.831	0.012
18 - <19	71.6	0.014	1	1	0.0143	986	13.771	0.727	0.010	2617	36.55	0.946	0.014
19 - <20	71.6	0.014	1	1	0.0143	986	13.771	0.727	0.010	2617	36.55	0.946	0.014
20 - <21	71.6	0.014	1	1	0.0143	986	13.771	0.727	0.010	2617	36.55	0.946	0.014
21 +	80	0.700	1	1	0.7	1516	18.95	1	0.700	3091	38.64	1	0.700
				Total Hypothetical Risk:	**1.7**			**Total Hypothetical Risk:**	**2.0**			**Total Hypothetical Risk:**	**2.1**

Notes:

BW = body weight

DI = drinking water intake

kg = kilograms

mL/day = milliliters per day

Hypothetical risk calculated as Duration x ADAF x Ratio to Adult Dose

Furthermore, EPA should clarify why it used adjusted toxicity factors for some, but not all, of the mutagenic chemicals for which it has proposed draft updated HHWQC. EPA does note that the early lifestage adjustment for trichloroethylene was omitted because it applies only to the kidney cancer component of the total cancer risk estimate, the impact of which was considered minimal. However, no explanation is provided for the lack of early lifestage adjustments for benzidine and dibenzo[a,h]anthracene.

Given that the exposure assumptions selected by EPA are representative of adult lifetime exposure, we recommend that EPA carefully consider whether adjusting carcinogenic toxicity factors to account for potential increased sensitivity of children when deriving draft updated HHWQC is appropriate. If EPA wishes to retain the early lifestage adjustment, we recommend that this adjustment be applied consistently for all chemicals believed to act through a mutagenic mode of action following the lifestage specific methodology presented in EPA (2005) guidance. Furthermore, EPA should discuss the uncertainty associated with this adjustment, in particular the uncertainty associated with assuming that a person will receive the same level of exposure throughout his or her lifetime.

Comment 4. EPA has chosen to use the BCFBAF™ model to estimate BAFs without input from EPA's Science Advisory Board (SAB).

Summary: Despite historic cautions from EPA's Science Advisory Board (SAB) that the addition of any bioaccumulation model to EPI Suite™ should be subject to careful scientific scrutiny, EPA has included the BCFBAF™ model in EPI Suite™ and is proposing to use it for estimating national BAFs to derive HHWQC. Prior to use of BAFs derived using BCFBAF™ EPA should seek SAB input on the broad question of how to incorporate BAFs into the HHWQC paradigm, as well as the specific question of which is the best model to use for estimating BAFs. EPA should not adopt national BAFs without the input of the SAB on these questions.

Discussion: EPA has proposed development of national default BAFs (and/or BSAFs) in the past, and has published a technical guidance document (TSD) outlining, in detail, an approach for developing these BAFs (EPA, 2003) independent of the BCFBAF™ model currently being proposed for this purpose. Subsequently, EPA built on this first TSD in a second TSD (EPA, 2009), addressing development of site-specific BAFs. None of these documents address use of BCFBAF™ for developing national BAFs, and in this respect the current proposal is inconsistent with previous guidance.

When the Office of Pollution and Prevention and Toxics (OPPT) requested an SAB review of the EPI Suite™ software, EPI Suite™ did not include a model for estimating bioaccumulation (or BAFs) so the SAB provided comments (EPA, 2007) on BCFWIN only. However, the SAB recommended that a model for predicting bioaccumulation be added to EPI Suite™, and that this should be considered a priority. Of note, in their discussion of bioaccumulation models, the SAB cited the mechanistic food web model of Arnot and Gobas (2004) (AQUAWEB) as a candidate model, albeit with some concern over the ability of this model to deal with metabolism, but did not discuss nor mention the QSAR model of Arnot and Gobas (2003) that EPA has now added to EPI Suite™ as BCFBAF™. In addition, the SAB cautioned the following regarding the use of any BAF module for screening assessments (EPA, 2007):

In light of the widespread application of EPI Suite™, before the decision to add a new module, such as the BAF module, the Agency should assess to the extent practical, whether there is a consensus in the scientific community that the model has been or can be appropriately parameterized and has been sufficiently verified to be applicable in screening assessments.

In the proposed approach, EPA is using BCFBAF™ for the development of regulatory criteria, which implies a higher level of scrutiny than for application in screening assessments. Despite this caution, EPA has added the BCFBAF™ model to the EPI Suite™ package and is now using it to derive HHWQC apparently without requesting input from scientific community as to whether BCFBAF™ can be appropriately parameterized or from the SAB. Given that the incorporation of BAFs will result in significant shifts in numeric HHWQC, the input of the SAB seems a valuable prerequisite to use of any model for estimating BAFs. As a consequence, EPA should heed the guidance given by the SAB and request SAB input on the broad question of how to incorporate BAFs into the HHWQC paradigm, as well as the specific question of which is the best model to use for estimating BAFs. EPA should not adopt national BAFs without the input of the SAB on these questions.

Comment 5. The current approach is inconsistent with previous EPA guidance for the derivation of national BAFs.

Comment 5.01 The current approach for estimating the national BAF does not follow previous EPA guidance for the inclusion of site-specific information

Summary: Previous EPA guidance on deriving recommended HHWQC (EPA, 2000, 2003, 2009) has focused on the inclusion of site-specific inputs when estimating BAFs. In fact, the 2009 TSD (EPA, 2009) was specifically developed to provide guidance to States and authorized Tribes on how to develop their own site-specific BAFs for use in deriving HHWQC. Despite this, under EPA's current proposal users are unable to utilize critical site-specific information as part of developing site-specific BAFs (using BCFBAF™). This is contrary to existing guidance that provides using site-specific data as the preferred option for deriving BAFs. Rather, the national BAFs are entirely based on default values, including for parameters EPA has acknowledged have significant influence on BAFs for piscivorous fish. Thus, if adopted, the current approach will effectively limit the ability of States and authorized Tribes to develop site-specific BAFs. Further, EPA has provided no guidance on how to implement such modifications or whether such modifications are even permitted. Some of the inflexibility apparent in the current proposal results from EPA's decision to use BCFBAF™ as opposed to a mechanistic food web model to estimate BAFs, yet EPA has not provided any justification for the selection of BCFBAF™ over one of these alternatives. Because some mechanistic food web models allow use of site-specific values for a wider range of inputs than BCFBAF™, most specifically inputs reflecting site-specific food web structure, we urge EPA to consider adoption of one of these alternatives to BCFBAF™. AQUAWEB is an example of such a model, though it is likely more data intensive than necessary (see *Comment 12 Development of an alternative model or methodology to predict state-, region- and water body specific BAFs* for further discussion of key aspects of the ideal bioaccumulation model).

Discussion: As noted, EPA has historically (EPA 2000, 2003) stressed the importance of including site-specific input parameters (e.g., lipid content of organisms and the fraction of freely dissolved chemical in water (or dissolved organic carbon [DOC] and particulate organic carbon [POC] by proxy)) when developing BAFs, and EPA's methodology for deriving HHWQC (EPA, 2000) encourages States and authorized Tribes to make adjustments to national BAFs to reflect local conditions. Thus, EPA provided a stand-alone TSD (EPA, 2009) intended to assist States and authorized

Tribes in selecting site-specific information for use in estimating BAFs as part of deriving HHWQC.

Under EPA's proposed approach for deriving HHWQC, EPA has selected the BCFBAF™ model for estimation of the national BAFs. This model is based on a QSAR model originally published by Arnot and Gobas (2003), and requires as input a number of parameters that are likely to vary between sites, including:

- mean water temperature;
- dissolved organic carbon (DOC) and particulate organic carbon (POC), which relate to the fraction of freely dissolved (i.e., bioavailable) chemical in water (ϕ);
- lipid content of lowest trophic organisms; and
- lipid content of TL 2, 3 and 4 fishes.

Therefore, at first glance, it appears that the proposed approach follows EPA guidance (EPA, 2000, 2003, 2009) by using a model that allows accounting for site-specific input parameters. However, as applied by EPA, default assumptions are made for these key parameters and applied across all surface waters of the U.S. Two important examples are the site-specific lipid content of TL 2, 3 and 4 fishes and the amount of freely dissolved (i.e., bioavailable) chemical in water, the importance of which is stressed in EPA (2003) (emphasis added):

…These two factors are important in affecting the bioaccumulation of nonionic organic chemicals. However, baseline BAFs are not directly used to determine national human health AWQC, <u>because they do not reflect the lipid content of target aquatic organisms and the fraction of chemical that is freely dissolved in water for the sites to which the AWQC applies</u>.

In EPA (2003), baseline BAFs are derived from BAFs measured in the field, or total BAFs (i.e., based on the total concentration of the chemical in tissue compared to the total concentration of chemical in the water), to specifically-account for these two key site-specific parameters. The following equation is presented in EPA (2003) to convert from total BAF to baseline BAF:

$$Baseline\ BAF = \left[\frac{BAF_T^t}{f_{fd}} - 1\right] \times \frac{1}{f_R}$$

Where: BAF_T^t is the total BAF, f_{fd} is the fraction of the total chemical that is freely dissolved in the study water, and f_R is the lipid fraction of the fish in the study.

Essentially, the baseline BAF normalizes the total BAF based on lipid fraction and bioavailability of the chemical. EPA (2003) also includes the calculation method for the national BAFs, which are estimated from baseline BAFs using site-specific values for lipid fraction (f_R) and bioavailability (f_{fd}). The approach currently proposed by EPA fails to take these key site-specific parameters into account despite EPA having previously provided extensive guidance on how to take them into consideration.

Moreover, lipid fraction and bioavailability are not the only parameters that are likely to make site-specific BAFs different than the national defaults, et al. Additional site-specific factors expected to affect BAFs include, but are not limited to, the degree of sediment-water disequilibrium and the overall food-web structure (i.e., effective trophic level(s), benthic/pelagic character of the food web, etc.). In the BCFBAF™ model, no food-web structure-specific parameters can be modified by the user with site-specific information. Instead, these parameters are collectively subsumed in the β value obtained via calibration of the BCFBAF™ model. Thus, even though EPA (2003) stresses that the feeding preference of forage fish for pelagic (e.g., zooplankton) vs. benthic (e.g., benthic invertebrates) food items is perhaps the most important ecological factor affecting ultimate BAFs for TL 4 piscivores, there is no means of accounting for site-specific differences in feeding preferences under EPA's currently proposed approach. Furthermore, EPA has not provided any information on how the TL-specific β values are expected to vary among various types of surface waters in the U.S., nor has it provided any justification for t use of a single β value for each tropic level to describe biomagnification for all fishes across all waters of the United States.

For the current draft updated HHWQC, EPA is effectively using a methodology that precludes the ability to modify the default BAFs for critical site-specific conditions. No guidance is provided on how a user should modify BCFBAF™ for this purpose even assuming the user has extensive site-specific data (e.g., tissue concentrations in multiple species, POC and DOC concentrations, sediment concentrations, water column concentrations, etc.). This suggests that, once adopted, it will be essentially impossible to modify the national default.

As discussed in Comment 12, we urge EPA to consider adopting a mechanistic food web model for estimating BAFs in place of the BCFBAF™ QSAR as these models generally allow for use of a wider range of site-specific input: a simplified version of the mechanistic food web model originally published in Arnot and Gobas (2004) (i.e., the

AQUAWEB model) is one example of such a mechanistic food web model. If EPA decides to follow through and use BCFBAF™ to develop national BAFs it should provide a thorough justification showing why use of BCFBAF™ is preferred over the use of a model such as AQUAWEB, including a direct comparison between the models demonstrating the utility each for derivation of national BAFs. This comparison should also explore how amenable each modeling approach might be to adjust for regional, state or water body-specific conditions.

Comment 5.02 EPA has failed to provide explanation of why the least preferred method for estimating national BAFs is used

Summary: EPA (2003) describes four methods of deriving baseline BAFs, or BAFs corrected for the fraction of freely dissolved chemical (i.e., fraction of chemical that is bioavailable) and the lipid fraction of the organism. EPA ranked these 4 methods in order of preference. In the current approach, EPA uses a single method for estimating BAFs, which closely aligns with the least-preferred method (estimation of BAFs via the K_{OW}), without providing any explanation of why the least preferred method) was chosen and why that specific single method was chosen over other, apparently more preferred methods. EPA needs to provide justification for the selection of a single method of estimating national BAFs (EPA, 2003) and how the currently proposed BCFBAF™ model is an improvement over historic EPA guidance on developing BAFs.

Discussion: In EPA (2003), a two-step process is described for the derivation of national BAFs. The first step involves the derivation of a baseline BAF for a particular compound, corrected for the lipid fraction (L_B) of the experimental organism (if using method 1 below, which requires experimental BAF data) and the fraction of freely dissolved chemical in water (ϕ). In the second step, trophic-level-specific national BAFs (i.e., TLs 2, 3 and 4) are calculated in each of three different food web structures (water, sediment, water and sediment) by applying site-specific information for L_B and ϕ to the baseline BAF.

EPA (2003) describes four methods for the derivation of the baseline BAF, ordered by method hierarchy, from highest to lowest:

- Method 1: Deriving the baseline BAF from experimental data (the fraction of freely dissolved chemical in water and lipid fraction are critical data points using this method, as the baseline BAF is essentially normalized for these two parameters);

- Method 2: Deriving the baseline BAFs from biota-sediment bioaccumulation factors (BSAF);
- Method 3: Deriving baseline BAFs from laboratory-measured bioconcentration factors (BCF) and food-chain multipliers (FCM); and
- Method 4: Deriving baseline BAFs from the octanol-water partitioning coefficient (K_{OW}) and the food-chain multiplier (presumably equivalent to the overall food web biomagnification factor).

Figure 3-1 of EPA (2003) shows a decision framework for selection of the method for deriving the baseline BAF. For a non-ionic substance with a log K_{OW} > 4.0 with low or unknown biotransformation, Figure 3-1 indicates that estimation from K_{OW} is the least-preferred of the four methods.

EPA needs to explain why the method based on K_{OW} was selected from the four methods presented in historical EPA guidance (EPA, 2003), focusing on how the proposed approach (using BCFBAF™ to estimate national BAFs) is an improvement over historic EPA guidance on developing BAFs, especially as it pertains to the ability to extrapolate BAFs from one ecosystem to another.

Comment 6. EPA's use of the BCFBAF model™ for estimating national BAFs is not appropriate given that the model was calibrated in large part with data representative of the Great Lakes.

Summary: The original QSAR model published by Arnot and Gobas (2003) is generally applicable to any water body provided the (extensive) data necessary for model calibration are available and Arnot and Gobas (2003) chose to use data representative of the Great Lakes in their work. Therefore, by default, results published by Arnot and Gobas (2003) reflect the chemical-, biological, and food web-specific parameters of the Great Lakes, a set of waters EPA considers so unique and distinct from other waters of the U.S. that it developed Great Lakes-specific HHWQC because national HHWQC were judged by EPA insufficiently protective of populations consuming Great Lakes fish (the Great Lakes Initiative (GLI)) (EPA, 1995a). This decision can be interpreted to be acknowledgment on the part of EPA that the resulting GLI HHWQC would not be applicable and would likely be overprotective if applied to other waters of the US. Despite this, EPA is now proposing that BAFs based in large part on Great Lakes data should be applied to all US waters. This is not only contrary to EPA's historic position, it is also scientifically indefensible.

Discussion: The Great Lakes constitute a highly unique ecosystem that is not representative of other U.S. surface waters. In fact, their characteristics are so distinct from other U.S. surface waters that specific water quality guidance was developed for the Great Lakes under the Great Lakes Initiative (GLI). Paragraph III.B. of the GLI preamble (60 FR 15369) states:

The final Guidance also reflects the unique nature of the Great Lakes Basin Ecosystem by establishing special provisions for chemicals of concern. EPA and the Great Lakes States believe it is reasonable and appropriate to establish special provisions for the chemicals of most concern because of the physical, chemical and biological characteristics of the Great Lakes System, and the documented environmental harm to the ecosystem from the past and continuing presence of these types of pollutants.

EPA's choice to calibrate the BCFBAF™ model for estimation of national BAFs using many data specific to the Great Lakes is somewhat ironic in that EPA has acknowledged the unique nature of the Great Lakes as the impetus for the GLI, yet is now proposing a methodology that assumes that several inputs specific to the Great Lakes are suitable for the rest of the country. This is a fundamental disconnect that will produce unreliable BAF estimates for U.S. surface waters and is not scientifically defensible. Bioaccumulation is based on many chemical-, biological- (e.g., organism weight, lipid fraction, metabolism rates), food web- (e.g., number of trophic levels, food web structure, feeding habits of foraging fish) and environmental-specific (e.g., water temperature) parameters, which as discussed in Comment 9 of this document, have a wide distribution of values across U.S. surface waters. The waters of the U.S. range from clear mountain lakes to stagnant bayous and from fast-moving, clear cold water streams to meandering, warm, black water rivers. Given the huge variation in physical, biological, and ecological characteristics of the surface waters in the U.S., EPA's proposed approach to use a single set of BAFs to describe bioaccumulation in the entire country contradicts common sense and is not scientifically defensible. In fact, as a large ecosystem, the Great Lakes themselves may not be similar enough to allow for a single set of scientifically-defensible BAFs to describe the complex process of bioaccumulation in TL 2, 3 and 4 fishes (e.g., Burkhard et al. 2006).

To demonstrate the bias associated with this approach, Comment 9 of this document compares values proposed by EPA for key input parameters to the distributions of these parameters in national surface waters. As is discussed in that comment, EPA appears to have selected values that are not representative of the country and that result in BAFs that overestimate bioaccumulation in most waters of the United States.

We urge EPA to develop a BAF modeling strategy that is transparent and accounts for the key parameters influencing site-specific bioaccumulation. Ultimately, whatever approach is used to estimate BAFs it should allow users to enter site-specific inputs, which reflect regional and state-specific differences, for the most sensitive parameters and establish default values for insensitive parameters (see the sensitivity analysis in this document showing sensitivity of the BCFBAF™ model to key input parameters). The AQUAWEB model originally published in Arnot and Gobas (2004) is a good example of a mechanistic model that allows users to enter site-specific information pertaining to chemical-, biological-, food web- and environmental-specific parameters. A trade-off exists between collecting the considerable amount of site-specific data required for any site-specific modeling versus just measuring the BAF directly. Therefore, a simplified version of the AQUAWEB model, which allows for inclusion of key site-specific parameters while incorporating default values for others shown to be less sensitive, would offer more flexibility to users by allowing them to use site-specific information (when available) rather than relying on national default assumptions for sensitive parameters.

Comment 7. Invertebrates were not included in the calibration of the biotransformation rate constant (kM) model in BCFBAF™.

Summary: As summarized in the BCFBAF™ user guidance document, the whole-body biotransformation rate constant (kM) "reflects the rate of change of the parent substance to another molecule or a conjugated form of the parent substance". The whole-body primary biotransformation rate constant model for fish used in BCFBAF™ was developed and validated against a database of kM estimates for several species of finfish (Arnot et al., 2008a), meaning that invertebrates were not considered for this model parameter. EPA needs to provide justification for the selection of a biotransformation model developed specifically for finfish to derive HHWQC that reflect consumption of aquatic invertebrates by humans and show that the proposed approach is protective of such exposures to chemicals in invertebrates.

Discussion: The whole-body biotransformation rate constant (kM) reflects the rate of change of the parent substance to another molecule or a conjugated form of the parent substance (i.e., the fraction of the mass in the whole body biotransformed per unit of time). The biotransformation model used in BCFBAF™ was developed and validated against a database of kM estimates found in Arnot et al. (2008a). In this paper, kM values are estimated (assuming first order processes) from laboratory-derived bioconcentration data for several species of finfish, including: rainbow trout, guppy, sheepshead minnow, fathead minnow, medaka, and bluegill sunfish (Arnot et al.,

2008a, 2008b). Invertebrates were not included in the development of this model even though many invertebrates, including shrimp, crabs, lobster and clams; are commonly consumed as part of the human diet and are included in the UFCR. Because these taxa were not included as part of the parameterization of BCFBAF™, which relies on kM estimates specifically for finfish, the level of protection afforded by the draft updated HHWQC is unknown. EPA needs to demonstrate the BAFs derived using BCFBAF™ are representative of invertebrates as well as finfish and that the proposed approach is protective of public health.

Comment 8. EPA has not provided sufficient documentation for key input values for the BCFBAF™ model.

Summary: EPA's proposed methodology includes a number of changes to the original input parameters described in Arnot and Gobas (2003) with insufficient description of what the updated values represent or justification of why they are suitable to estimate BAFs for all surface waters of the U.S. Most of the documentation that is provided is incomplete and not transparent. EPA needs to provide detailed documentation for the selection of each of the model's input parameters, particularly those that differ from the inputs of the Arnot and Gobas (2003), model and for each parameter, document why it is acceptable to use the proposed values for all surface waters of the U.S.

Discussion: The BCFBAF™ user guidance documentation is apparently the only source of documentation for the estimation of national BAFs used in the development of the draft updated HHWQC. The 94 chemical-specific *Draft Update of Human Health Ambient Water Quality Criteria* documents appear to contain no information justifying the basis for the methodology used to estimate the national BAFs.

Users interested in understanding the basis for the BAFs must rely on Arnot and Gobas (2003) and Arnot et al. (2009), which is presumably the publication upon which the biotransformation rate constant (kM) methodology in BCFBAF™ is based, to begin to understand the methodology EPA used to derive the BAFs used as the basis for the draft updated HHWQC. As shown in Table 4 below, many of the input parameters of Arnot and Gobas (2003) have been modified by EPA for BCFBAF™. In other cases, the inputs are the same between the models; however, the original publication fails to provide adequate documentation of its assumptions for model input parameters (e.g., lipid content of lowest trophic level organisms).

Table 4 Comparison of Key Input Parameters in Arnot and Gobas (2003) and the BCFBAF™ Model

Parameter	Arnot and Gobas (2003)	BCFBAF™ Model
Weight of organism (kg)	1 (TL4)	1.43 (TL4) 0.183 (TL3) 0.096 (TL2)
Mean water temperature	10 °C (Canadian conditions)	10 °C
Overall food web biomagnification factor	130 (TL4)	62.7 (TL4) 30.1 (TL3) 16.1 (TL2)
Maximum trophic dilution factor (τ)	1 (default value) $\tau = (0.0065/(kM + 0.0065))^2$ (TL4)	$\tau = (0.0065 / ((0.447kM + 0.0065))^2$ (TL4) $\tau = (0.01 / ((0.760kM + 0.01))^2$ (TL3) $\tau = (0.02 / ((0.889kM + 0.02))^2$ (TL2)
Lipid content of lowest trophic level organisms	0.01 (TL 1)	0.01 (TL 1)
Lipid fraction	0.2 (TL4)	0.107 (TL4) 0.0685(TL3) 0.0598 (TL2)
Fraction of freely dissolved chemical in the water	$1/(1+ c_{POC} * 0.35 * K_{OW} + c_{DOC} * 0.1 * 0.35 * K_{OW})$	$1/(1+ c_{POC} * 0.35 * K_{OW} + c_{DOC} * 0.08 * K_{OW})$

kM = biotransformation rate constant

K_{OW} = octanol-water partitioning coefficient

c_{DOC} = fraction of dissolved organic carbon

c_{POC} = fraction of particulate organic carbon

Each of these modifications is described below in more detail.

(a) Weight of organism

As shown in Table 4 above, Appendix K of the BCFBAF™ user guidance indicates default values of 0.096, 0.183 and 1.43 kg were assumed for TL 2, 3 and 4 fishes, respectively. EPA provides no documentation of how these weights were derived (i.e., do they reflect the median or 95th percentile on the mean) or why they are acceptable default values to reflect the weight of TL 2, 3 and 4 fishes in surface waters throughout the U.S.

(b) Mean water temperature

In the BCFBAF™ model, a default water temperature of 10 °C is assumed for all surface waters of the U.S. While Arnot and Gobas (2003) state that this temperature was chosen to reflect the mean annual temperature of Canadian surface waters, EPA provides no documentation to support using the same mean annual temperature for all waters of the U.S. In fact, the decision to apply a temperature originally selected for Canadian surface waters to all waters in the U.S. contradicts EPA's BCFBAF™ user guidance document, which acknowledges that the model results should not be used for regions deviating from the default assumption for water temperature:

The default temperature for the BCF and BAF calculations is 10°C (temperate regions); therefore, the model predictions are not recommended for arctic, sub-tropical or tropical regions or for comparisons with other vastly different conditions (e.g., laboratory tests at ~25°C). Site-specific food web models, bioaccumulation models and bioconcentration models are available for specific modeling requirements (e.g., http://www.rem.sfu.ca/toxicology/models/models.htm, http://www.trentu.ca/cemc).

A significant portion of the southern U.S. has a climate that results in water temperatures greater than 10 °C and perhaps even 20 °C for much of the year. The BCFBAF™ model user guidance explicitly states to not use the results of the model for such areas, yet by using BCFBAF™ with its default values for temperature for all waters of the U.S., EPA has used BCFBAF™ in exactly a way the guidance says it should not be used.

Supporting the influence of temperature on the estimated BAFs, Zhang et al. (2008) investigated the sensitivity of polychlorinated biphenyl (PCB) BAFs estimated by a bioenergetics model (originally published in Zhang, 2006) to temperature, using both

an average exposure temperature for a food web in Lake Michigan and a species-specific exposure temperature. The difference in responses between the average exposure temperature and individualized exposure temperature increased with increasing K_{OW} of the PCB and was typically greater than 60%. The authors conclude that "the fact that model outputs for highly hydrophobic PCB congeners are affected strongly by the values of exposure temperature suggests the importance of accurate characterization of exposure temperatures in the applications of food web models for real contaminant issues." They note that the results of their experiment do not extend to other bioaccumulation models such as the one originally published in Gobas (1993). They do caution that a "'food web-averaged' value for exposure temperature used in model simulations is an overly simplified representation of the real world situation and is likely to introduce potential substantial uncertainty in [the] model output."

EPA needs to provide justification for the selection of a water temperature of 10 °C to represent U.S. surface waters (ideally with actual data), including a discussion of why selection of a single temperature for all waters of the U.S. will not lead to biased results.

(c) Overall food web biomagnification factor (β)

Arnot and Gobas (2003) state that the default overall food web biomagnification factor (β) of 130 for TL 4 was derived by calibrating the model to the empirical BAF data and results in BAFs that are exceeded by only 2.5% of the available data (i.e., was selected to be conservative 97.5% of the time). They also state that "the calibration of the model to the data is designed to produce a QSAR for the BAF in higher trophic levels of a Canadian food web." Appendix K of the BCFBAF™ user guidance indicates β values of 62.7, 30.1 and 16.2 were selected for TLs 2, 3 and 4 (see also Table 4), respectively and provides the following explanation as the basis for the methodology "the overall food web biomagnification factors (β) in the BAF model are calibrated to each trophic level of measured BAF values (Arnot and Gobas, 2003)."

This explanation provides no reason for why the β value of 130 for TL 4 used by Arnot and Gobas (2003) was changed by EPA to 62.7. Nor does EPA provide documentation of the assumptions and methodology used to derive the β values used for the other trophic levels in BCFBAF™. Nor does the user guidance discuss the characteristics of food webs that affect β or the extent of variation of these characteristics among surface waters of the U.S. In short, EPA has provided essentially no explanation of or justification for the β values used for the three trophic levels in BCFBAF™. EPA should provide the public more information on the derivation of the default β values hardwired

into BCFBAF™ to permit a thorough review of the methodology, particularly given the results of the sensitivity analysis presented at the end of these comments that shows BAFs for compounds that have high K_{OW} values and are not metabolized are relatively sensitive to this parameter.

(d) Maximum trophic dilution factor (τ)

In Arnot and Gobas (2003), the maximum trophic dilution factor (τ) was set to a default value of 1, indicating no trophic dilution. However, an equation is presented, relating τ to the biotransformation rate constant (kM), as shown in Table 4 above:

$$\tau = \left[\frac{0.0065}{kM + 0.0065^2}\right]^{n-1}$$

Where, as stated in Arnot and Gobas (2003), 0.0065 "reflects the rate at which metabolic transformation becomes greater than the other routes of chemical elimination (i.e., k_2, k_E and k_G) for a lower trophic level aquatic species" and n is the trophic level being considered.

As documented in Appendix K of the BCFBAF™ user guidance, EPA has apparently retained the 0.0065 term for the highest modeled trophic level (i.e., TL4 fish) rather than for a lower trophic level species (as specified in Arnot and Gobas [2003]), and replaced the factor of 0.0065 with 0.02 and 0.01 for TLs 2 and 3, respectively. No documentation is provided in the guidance as to why 0.0065 was used for TL 4 instead of TL 2 or how the factors of 0.01 and 0.02 were derived for TLs 2 and 3. Additionally, whereas Arnot and Gobas (2003) include the term 1kM, as shown in the equation above, Appendix K of the BCFBAF™ user guidance includes terms of 0.889kM (i.e., $[0.016/0.01]^{-0.25}$), 0.760kM (i.e., $[0.03/0.01]^{-0.25}$) and 0.447kM (i.e., $[0.25/0.01]^{-0.25}$) for TLs 2, 3 and 4, respectively, with no documentation of what these terms represent or why they were included in the calculation. (Although, it is clear that a decrease in kM increases the trophic dilution factor which ultimately increases the estimated BAF for each trophic level).

(e) Lipid content of lowest trophic level organism and number of trophic interactions in the food web

Arnot and Gobas (2003) and the BCFBAF™ model user guidance both state that percent body mass that is lipid for the lowest trophic level (i.e., invertebrates or plankton) in the food web is 1%. No documentation is provided in either reference to

support a value of 1%. Given that waters of the U.S. are far more diverse than the Great Lakes and contain a variety of food webs, it is not clear that a single value for TL1 is appropriate nor is it clear that 1% is the appropriate lipid content. EPA needs to provide justification for the selection of 1% as the TL1 lipid content, particularly given the results of the sensitivity analysis presented later in these comments that show BAFs for several compounds are sensitive to this parameter.

(f) Lipid Fraction

As part of deriving the GLI BAFs, EPA developed consumption-weighted default mean values for the lipid content of TL3 and TL4 fish, and EPA provided a detailed narrative outlining the genesis of these numbers (EPA, 1995b). The resulting values were 1.82% for TL3 fish and 3.10% for TL4 fish (EPA, 1995b). These values theoretically reflect Great Lakes consumption patterns and lipid contents. These values were updated in EPA (2003), which proposed consumption-weighted mean lipid fractions of 1.9%, 2.6% and 3.0% for TL 2, 3 and 4 fishes, respectively. However, the BCFBAF™ model user guidance states that the assumed percent lipid fractions for TL 2, 3 and 4 fishes are 5.98, 6.85 and 10.7%, respectively. Therefore, in the current approach, the basis for the lipid fraction values used in the derivation of the draft updated HHWQC is unclear and not explained. It is also unclear whether they reflect whole-body lipid fraction or the edible tissue lipid fraction. Nor is it clear whether BAFs should be adjusted based on site, region or state-specific lipid contents. As described below in the sensitivity analysis, such data are available for several regions of the country and those data indicate lipid contents are substantially lower than assumed by BCFBAF™. EPA needs to provide the basis for the lipid contents used in BCFBAF™ and how BAFs are to be adjusted when lipid content of fish in other regions of the US differ from the values assumed by BCFBAF™.

(g) Fraction of freely dissolved chemical in the water (ϕ)

In Arnot and Gobas (2003), the fraction of freely dissolved chemical in the water (ϕ), is calculated as follows (as shown in Table 4 above):

$$\phi = \frac{1}{1 + \text{cPOC} * 0.35 * Kow + \text{cDOC} * 0.35 * 0.1 * Kow}$$

As documented in Appendix K of the BCFBAF™ user guidance, EPA has apparently replaced the α_{DOC} term of 0.35 cited in Arnot and Gobas (2003) with 0.08, as suggested by Burkhard (2000) and referenced in Arnot and Gobas (2004) without any

documentation of what the factor of 0.08 represents or how it was derived. EPA needs to provide such documentation.

(h) Summary

The user guidance for the BCFBAF™ model is incomplete and not sufficiently transparent to allow a thorough review of the BAF-estimation methodology used to develop the draft updated HHWQC. While the equations used by the BCFBAF™ model to estimate bioaccumulation are based on peer-reviewed publications and appear to be scientifically defensible, insufficient or no documentation is provided to verify the values used for most of the parameters in the equations or that those values can be used to represent surface waters throughout the U.S. Prior to use in the development of HHWQC, the BCFBAF™ documentation should be revised and expanded and provided to the public for review allowing for a full and thorough evaluation.

Comment 9. For several BCFBAF™ model parameters, EPA appears to have selected default inputs that will result in BAFs that will overestimate bioaccumulation in most waters of the U.S.

Summary: The predicted BAFs from BCFBAF™ reflect the values of the default inputs for each of the parameters that affect bioaccumulation. As described in preceding comments, EPA has provided little or no supporting documentation describing the basis for the default inputs. Nor has EPA provided any information on the sensitivity of predicted BAFs to changes in input values or the variability of key inputs likely to manifest across waters of the U.S. and the effect of such variation on BAFs predicted by BCFBAF™. For several key parameters (lipid content of fish in TLs 2, 3 and 4; DOC and POC concentrations; food-web biomagnification factor [β]), EPA appears to have selected inputs that are likely to overestimate BAFs, perhaps substantially. For other parameters (e.g., temperature) the default value may underestimate BAFs. And for still other parameters (lipid content of TL 1) relatively few data are readily available making it hard to discern the effect of applying the default value to all waters of the U.S.

This section provides an overview of the historical view EPA has taken for each of three key input parameters (lipid content of fish in TLs 2, 3 and 4; DOC and POC concentrations; and β) and compares those to the proposed input values. This section also presents a sensitivity analysis of six key input parameters to help identify several inputs to which the BCFBAF™ model appears very sensitive. Table 5 lists the default values selected by EPA for BCFBAF™ model parameters and also the values used in

the sensitivity analysis. This review indicates that EPA needs to provide justification for the proposed defaults used by the BCFBAF™ and also helps to prioritize those inputs for which predicted BAFs are the most sensitive and those defaults that appear to differ most from values expected in many waters of the U.S.

Table 5 Input parameters used for BCFBAF™ model sensitivity analysis

Name	Parameter	BCFBAF™ Value	Values for Sensitivity Analysis†
TL2 β	Food web biomagnification factor	16.1	1.6, 8.05, 32.2
TL3 β	Food web biomagnification factor	30.1	3.01, 15.1, 60.2
TL4 β	Food web biomagnification factor	62.7	6.27, 31.4, 125.4
DOC	Dissolved organic content (mg/L)	0.5	0.05, 5, 25
TL1 Lipid Fraction	Lipid fraction of lowest trophic level organism	0.01	0.005, 0.02, 0.1
POC	Particulate organic content (mg/L)	0.5	0.05, 5
Temperature	Water temperature (°C)	10	5, 20, 25
TL2 Weight	Organism weight (kg)	0.096	0.048, 0.192
TL3 Weight	Organism weight (kg)	0.184	0.092, 0.368
TL4 Weight	Organism weight (kg)	1.53	0.765, 3.06
TL2 Lipid Fraction	Whole-body lipid fraction of organism	0.0598	0.00524, 0.0093, 0.017
TL3 Lipid Fraction	Whole-body lipid fraction of organism	0.0685	0.0053, 0.0107, 0.017, 0.0195
TL4 Lipid Fraction	Whole-body lipid fraction of organism	0.107	0.00835, 0.0135, 0.017, 0.0247

† Values used in the sensitivity analysis were selected to be representative of possible values in U.S. surface waters.

Discussion:

(a) Lipid fraction

As discussed in Comment 8, EPA has not provided documentation supporting the proposed lipid fraction values of 5.98%, 6.85% and 10.7% for TL 2, 3 and 4 fishes. These lipid contents represent a 2 to 3-fold increase compared to lipid contents proposed previously by EPA (EPA 1995b, 2000, 2003). We compared the TL-specific lipid fraction input values obtained from the BCFBAF™ user guidance to TL-specific values obtained from the publically-available EMAP and STORET databases, both of which are maintained by EPA. As part of the water quality and toxicity data contained in both of these databases, fish lipid content is frequently reported. These databases provide a large quantity of lipid data from several regions throughout the United States and on numerous species and, thus, enable the development of specific fish lipid distributions based on region and trophic level. Distributions of lipid content in edible portions of fish were created using the observations obtained from the online databases noted above. Data points were subdivided into distinct geographic regions based on their location. Regions included Northern Atlantic, Mid-Atlantic, Midwest, and Hawaii. The databases did not include data from regions in the southern or western portions of the United States. Data were also subdivided into TLs 2, 3, and 4, based on trophic levels classified in EPA (2014a). The mean and 95th percentile upper confidence limit on the mean for all data, and for each region, as well as the default lipid contents used by BCFBAF™, is presented in Table 6. This table also shows the mean and 95th percentile upper confidence limit on the mean from a Florida statewide dataset of lipid content of near-shore marine and freshwater fish of all trophic levels.

Table 6 Regional Mean, 5th Percentile, and 95th Percentile Lipid Fractions

Dataset	BCFBAF™ Inputs*	Total			North-Atlantic			Mid-Atlantic		
		5%tile	Mean	95%tile	5%tile	Mean	95%tile	5%tile	Mean	95%tile
TL4 Edible tissue	0.107	0.0025	0.0135	0.0427	0.0015	0.00835	0.0215	0.0051	0.0247	0.0698
TL3 Edible tissue	0.0685	0.0027	0.0107	0.032	0.0029	0.00524	0.008	0.0009	0.0195	0.0444
TL2 Edible tissue	0.0598	0.0017	0.0093	0.022	0.0015	0.00524	0.0113	n/a	n/a	n/a
Florida	n/a	0.0076	0.017	0.033	nd	nd	nd	nd	nd	nd

* Not stated whether this is whole-body or edible tissue.

n/a = not applicable

nd = data not available

Lipid concentrations used in the BCFBAF™ model exceed the 95th percentile values of all trophic levels. In fact, the highest 95th percentile lipid value observed was 6.98% for TL 4 for the Mid-Atlantic region. Demonstrating the bias of EPA's lipid fractions, this 95th percentile for TL 4 is lower than the point estimate of 6.85% used by the BCFBAF™ model for TL 3. A comparison of the trophic level point estimates used by the BCFBAF™ model to the mean and 95th percentile of regionally composited distributions for each trophic level are displayed in Table 6. The BCFBAF™ model point values are substantially higher than all of the corresponding values from the distributions obtained using the national online databases.

Additionally, the BCFBAF™ model default inputs are higher than those developed in the past by several state agencies. For instance, Florida developed a statewide Florida specific distribution of lipid content of near-shore marine and freshwater fish of all trophic levels using methods consistent with EPA recommendations (FDEP, 2013). The 5th percentile, mean and 95th percentile values of this distribution (0.76%, 1.7% and 3.3%, respectively) correspond much more closely to the values obtained from the

distributions developed using national online databases than to the point values used by the BCFBAF™ model.

(b) Concentration of dissolved organic carbon (DOC) and particulate organic carbon (POC)

As part of historic guidance on development of national BAFs, EPA (2000, 2003) used default POC and DOC concentrations of 0.5 ppm and 2.9 ppm, respectively. According to EPA (2003), these values represent the median (50th percentile) values from approximately 110,000 DOC measurements and 86,000 POC measurements encompassing fresh and estuarine waters in all 50 states, and EPA consciously chose these central-tendency estimates "for consistency with the goal of national BAFs" (EPA, 2003). In the current draft updated HHWQC and without providing any justification, EPA is proposing to use a default value of 0.5 ppm for both POC and DOC, which is equivalent to using the median POC concentration but a DOC concentration less than the 5th percentile of DOC concentrations (EPA, 2003). The currently proposed concentration for DOC appears to be biased low by about 6-fold. EPA provides no basis for this change in DOC concentration or, for that matter, any documentation to support either the default POC or DOC concentrations.

(c) Food web biomagnification factor (β)

According to the BCFBAF™ model user guidance, EPA has selected food web biomagnification factor (β) values of 16.1, 30.1 and 62.7, which have been "calibrated to each trophic level of measured BAF values" (Arnot and Gobas, 2003). However, Arnot and Gobas (2003) caution that β is "highly dependent on the species of interest, food web structure, environmental conditions, and ecosystem characteristics" and, most importantly, that its selection should be based on calibration with an appropriate dataset. In the current approach, EPA uses a dataset based on a food web and conditions found in the Great Lakes to calibrate β for all other food webs in national surface waters. This approach fails to take many food-web specific factors into account, most notably that food web structures in the Great Lakes are likely to consist of a much larger food chain and thus, will produce higher BAFs, particularly among the higher trophic levels. Furthermore, the basis for food chains in deep water, cold lakes (such as the Great Lakes) is likely to be different from the basis in cold, shallow mountain streams, as well as in any shallow lake or estuary, where large amounts of submerged aquatic vegetation (SAV) can be present. Ultimately, EPA needs to provide some justification for the default β values used by the BCFBAF™ model. Such justification should include a discussion of how different water body and food web

characteristics affect β, a summary of β values either measured or predicted in a range of different U.S. waters, whether β varies in a predictable pattern either by water body type or geographic region of the U.S. and how BAFs are to be adjusted for state, region or water body-specific differences in β from the defaults assumed by the BCFBAF™ model.

Sensitivity analysis on select inputs for estimating national BAFs using the BCFBAF™ model

The sensitivity of the BCFBAF™ model to changes in several input parameters (organism whole-body lipid fraction, water temperature, DOC, POC, organism weight, and β) for six different chemicals (acenaphthene, aldrin, benzene, benzo[a]pyrene, chlordane, and chrysene) was examined. Table 5 lists the values used both by EPA in the BCFBAF™ model and the values used in the sensitivity analysis. Other parameters could have been included as well, but the limited information provided for the basis of the assumptions used by the BCFBAF™ model and the available time for review of the draft updated HHWQC precluded a full evaluation of the sensitivity of the model to all parameters. The range of values used for each parameter represents the range that might occur in surface waters across the U.S (Table 5). The six chemicals were selected to represent a range of chemical types (PAHs, volatile organics, and pesticides) and K_{OW} values (log K_{OW} values ranged from 2.13 to 6.50). The analysis was conducted by varying the input values for one parameter while holding all other parameters constant at the default value used by the BCFBAF™ model (Table 5). The apparent sensitivity of the model to each parameter is discussed briefly below and is plotted in Figures 1a-1c, where each figure represents the sensitivity analysis results for a specific trophic level. The sensitivity of BAFs predicted by the BCFBAF™ model to a particular parameter is represented by the height of the lines shown on the figures. Increases in BAFs compared to those predicted by the BCFBAF™ model are shown as lines above a ratio of 1.0 and decreases in BAFs compared to those predicted by the BCFBAF™ model are shown as lines below a ratio of 1.0.

Food web bioaccumulation factor (β) - Beta represents the overall biomagnification factor for each trophic level in the BCFBAF™ model, which uses default β inputs of 16.1, 30.1 and 62.7 for TLs 2, 3 and 4, respectively. The sensitivity analysis used input values ranging from a ten-fold decrease to a two-fold increase in β compared to the BCFBAF™ model's default inputs. The sensitivity analysis assumed β of 1.6, 8.05, and 32.2 for TL2, 3.01, 60.2, and 15.1 for TL3, and 6.27, 31.4, and 125.4 for TL4 (Table 5).The BAFs for aldrin and chlordane were the most sensitive to changes in β for all three trophic levels, while chrysene and benzo[a]pyrene were somewhat sensitive to β

for TLs 2 and 3. The range β typical of U.S. surface waters appears more likely to decrease rather than increase estimated BAFs (Figures 1a – c).

Dissolved organic carbon (DOC) and particulate organic carbon (POC) - The BCFBAF™ model uses default DOC and POC values of 0.5 mg/L. A sensitivity analysis was conducted separately for DOC and POC. Input values for DOC ranged from a ten-fold decrease to a 50-fold increase from the default EPA input values, reflecting the DOC data distribution (minimum to 95th percentile) found in USGS National Water Information Database (USGS, 2001). Input values for POC ranged from a ten-fold decrease to a ten-fold increase from the default EPA input value, reflecting the POC data distribution (minimum to 95th percentile) found in USGS National Water Information Database (USGS, 2001). For the sensitivity analysis the POC was assumed to be 0.05 and 5 compared to a default POC of 0.5 used by EPA in BCFBAF™ (Table 5). The POC values used in the sensitivity analysis correspond to a 10 fold increase and a 10 fold decrease, respectively, over the EPA default value. For the sensitivity analysis the DOC was assumed to be 0.05, 5, and 25 compared to a default DOC of 0.05 used by EPA in BCFBAF™ (Table 5). The DOC values used in the sensitivity analysis correspond to 10 fold decrease, 10 fold increase, and 100 fold increase, respectively, over the EPA default value. Model-calculated BAFs were very sensitive to changes in DOC and POC for aldrin and chlordane, and were somewhat sensitive for benzo[a]pyrene at all three trophic levels. Values typical of DOC and POC in U.S. surface waters appear to result in lower BAFs than predicted by the defaults used in the BCFBAF™ model (Figures 1a – c).

Lipid Content of Lowest Trophic Level (Level 1) - The default lowest trophic level (i.e., TL 1 or primary producers) lipid fraction value used in BCFBAF™ is 0.01, a value derived for Canadian surface waters (and to be representative of the Great Lakes) by Arnot and Gobas (2003). For the sensitivity analysis the lipid fraction of TL 1 fish was assumed to be 0.005, 0.02, and 0.1 compared to a default lipid fraction of 0.01 used by EPA in BCFBAF™ (Table 5). The TL 1 lipid fractions correspond to a 2 fold decrease, a 2 fold increase, and a 10 fold increase, respectively, over the default EPA value. Resulting BAF's calculated by the BCFBAF™ model appear to be sensitive to changes ranging from a two-fold decrease to a ten-fold increase from EPA's default value in lipid fraction inputs at each of the three trophic levels primarily for aldrin, benzo[a]pyrene, chlordane, and chrysene (Figures 1a – c). The sensitivity to the lipid fraction of TL1 occurs at all trophic levels. Whether BAFs are actually underestimated by as much 10-fold in some surface waters will depend upon the actual lipid content of TL 1 organisms and whether other parameters interact with the lipid assumption about TL1 to reduce bioaccumulation.

Water temperature - The BCFBAF™ model assumes a default water temperature of 10 °C, a value also used in the BCFBAF™ model developed by Arnot and Gobas (2003). This default parameter was selected to represent Canadian aquatic habitats by Arnot and Gobas (2003), and may be appropriate for northern U.S. waters, but is unlikely to be applicable to warmer waters found in the southern portions of the U.S. For the sensitivity analysis the water temperature was assumed to be 5, 10, and 25 °C compared to a default temperature of 10°C used by EPA in BCFBAF™ (Table 5). The water temperatures used in the sensitivity analysis represent a range of temperatures found in US surface waters (EPA STORET database).

BAFs calculated using the BCFBAF™ model do not appear to be very sensitive to water temperatures ranging from 5, 20, and 25 °C. Aldrin, benzo[a]pyrene, chlordane, and chrysene show the greatest variation in BAFs with variation in water temperature model inputs but only at some of the trophic levels (Figures 1a – c).

Organism weight - BAFs were calculated from the BCFBAF™ model over a range of organism weight inputs that ranged from a two-fold decrease to a two-fold increase from EPA's default input parameters for each trophic level. The sensitivity analysis assumed weights (in kg) of 0.048 and 0.192 for TL2, 0.092 and 0.368 for TL3, and 0.765 and 3.06 for TL4 (Table 5) compared to default values of 0.096, 0.184 and 1.53 kg for TLs 2, 3 and 4, respectively used by EPA in the BCFBAF™ model.

Changes in organism weight did not substantially affect the calculated BAFs at any trophic level for any of the six chemicals examined (Figures 1a – c).

Lipid content. The default organism lipid fraction values for each of the three fish trophic levels used in the BCFBAF™ model were based on values derived for Canadian surface waters in Arnot and Gobas (2003). These lipid fraction values are almost twice as high as lipid fraction mean and 95th upper confidence limit on the mean (UCL) values derived from EPA's own databases (STORET and EMAP; see Table 6). For the sensitivity analysis the lipid fraction of TL 2 fish was assumed to be 0.00524, 0.0093 and 0.017 compared to a default lipid fraction of 0.0598 used by EPA in BCFBAF™ (Table 5). The lipid fraction of TL 3 fish was assumed to be 0.0053, 0.0107, 0.017 and 0.0195 compared to a default lipid fraction of 0.0685 used by EPA in BCFBAF™ (Table 5). The lipid fraction of TL 4 fish was assumed to be 0.00835, 0.0135, 0.017 and 0.0247 compared to a default lipid fraction of 0.107 used by EPA in BCFBAF™ (Table 5). The sensitivity of the BCFBAF™ model to lipid content of TL 2, 3 and 4 appears to vary between chemical but not a great deal between trophic levels. Acenaphthene, benzene, and chlordane appear to be most sensitive to lipid content of

TL 2, TL 3 and TL 4 (Figures 1a – c). Because the default lipid contents in BCFBAF™ lie within the upper percentiles of the distribution of lipid content for several areas of the U.S., use of more representative lipid contents will result in lower BAFs, indicating that draft updated HHWQC for many chemicals are more stringent than necessary.

Summary of sensitivity analysis findings:

The BCFBAF™ model-calculated BAFs for the pesticides aldrin and chlordane appeared to be the most sensitive to changes in many of the input parameters examined in the sensitivity analysis. Although these two chemicals have the highest log K_{OW} values of the six chemicals examined (aldrin log K_{OW} = 6.50; chlordane log K_{OW} = 6.22), the PAH benzo[a]pyrene, which has a log K_{OW} value of 6.13, did not exhibit as much sensitivity to variations in most of the input parameters. The PAH chrysene was also moderately sensitive to most of the input parameters, while both the PAH acenapthene and the volatile organic benzene showed very little sensitivity to most input parameters, except for lipid fraction of the high, middle, and low fish trophic levels.

Model-calculated BAFs for all of the chemicals examined except chlordane and benzene exhibited little sensitivity to changes in the lipid fractions of organisms at the high, middle, and low fish trophic levels. This is surprising because as the lipid fraction of an organism increases, a proportional increase in the amount of chemical accumulation in that organism's tissue is expected. The apparent absence of such a predicted response by the BCFBAF™ model requires explanation. Aldrin, benzo[a]pyrene, chlordane, and chrysene were, however, sensitive to variation in the lipid fraction of the lowest trophic level.

Sensitivity analyses, such as the one presented above, can be used to help guide the development of documentation necessary for models such as BCFBAF™ and to determine whether such models can be used to develop BAFs for use in the derivation of national HHWQC. The results of the sensitivity analysis indicate that the BCFBAF™ model, as currently configured and used by EPA to develop the draft updated HHWQC, should not be used to derive national HHWQC. The review of available data indicate that several of the default inputs used by the BCFBAF™ model are not representative of most waters of the U.S. and that the defaults used by the BCFBAF™ model are likely to overestimate bioaccumulation in surface waters for large portions of the U.S. EPA needs to develop a transparent methodology using the BCFBAF™ model, or an alternative model, that allows users to incorporate region specific inputs

for key parameters that govern bioaccumulation and predict region, state and water body-specific BAFs.

Comment 10. EPA has not addressed the uncertainty associated with the default K_{OW} values used in the BCFBAF™ model.

Summary: EPA has chosen the BCFBAF™ model for the estimation of BAFs. Although K_{OW} is one of the primary predictive variables in the calculation of the BAFs in the module, EPA has largely ignored the uncertainty associated with the default K_{OW} values used in the BCFBAF™ module. EPA should seek SAB review of the K_{OW} selection methods utilized by BCFBAF module and clarify the selection of K_{OW} values, especially when multiple values are available.

Discussion: EPI Suite uses K_{OW} as a primary variable in the calculation of the BAF. The SAB reviewed the QSAR (Quantitative structure activity relationships) based method utilized by KOWWIN™ (USEPA, 2007). In addition, alternative QSAR based methods for the estimation of the portioning behavior of organic chemicals exist (e.g., Van Noort et al. [2010], Hawthorne et al. [2011]). For some PCB congeners, these methods can different from the KOWWIN™ values by as much as three orders of magnitude.

EPI Suite™ also includes a database of measured K_{OW} values compiled by SRC Inc. There is limited documentation regarding the criteria for inclusion in the database. As discussed in Beyer et al. (2002), experimentally derived K_{OW} values can vary by 30% or more. The SAB concluded that KOWWIN™ provides a suitably accurate estimation of K_{OW}. The SAB provides no review of the K_{OW} database and the process by which EPI Suite selects a preferred K_{OW} from this database. Neither EPI Suite™ nor the SAB provide guidance on how to resolve any differences between the experimental and modeled K_{OW} values. In addition, experimentally derived physicochemical parameters can be inconsistent and EPI Suite™ does not utilize methods such as those proposed by Beyer et al. (2002) to develop a consistent set of parameters.

The BCFBAF™ model uses experimentally derived K_{OW} values in preference to the KOWWIN™ derived values[2]. These two sets of values can vary significantly, resulting in significant uncertainty in the BAFs estimated by BCFBAF™. These differences are

[2] Note that the experimentally-derived K_{OW} is the default K_{OW} passed to all other EPI Suite™ modules.

summarized for the six chemicals included in the sensitivity analysis. Table 7 compiles the percent change in the BAF when the KOWWIN™ model K_{OW} was used in preference of the value from the K_{OW} database for these chemicals.

Table 7 Percent changes in estimated BAFs using KOWWIN™-derived K_{OW} values compared to values from the experimental K_{OW} database

	Acenaphthene	Aldrin	Benzo[a]pyrene	Benzene	Chlordane	Chrysene
Percent Change	0.00	29.12	0.69	34.59	8.14	13.50

The results show a change in the BAF of as much as almost 35% for these six chemicals when the values estimated by the SAB reviewed KOWWIN™ module are used in preference to the values selected from the K_{OW} database. An extensive evaluation of all 94 chemicals for which EPA had developed draft updated HHWQC was not conducted but it is reasonable to assume that differences of 30% or more are relatively common, with larger differences being almost certain. Beyer et al. (2002) similarly observed that the range of experimentally derived K_{OW} values routinely spans 30%, or more. Given that K_{OW} values are routinely reported in $\log_{10}$ units, differences of 30% in arithmetic units are often overlooked, but they are potentially significant nonetheless. The differences between QSAR based estimates of K_{OW} also results in different estimates of the BAF. For example, KOWWIN™ estimates a log K_{OW} of 8.27, resulting in a BAF of 7.05×10^6; while Hawthorne et al. (2011) estimated a $\log_{10}$ K_{OW} of 7.12, resulting in a BAF 8.0×10^6.

This simple analysis shows that the BCFBAF™ module is sensitive to routine variability in the estimate of K_{OW} for a single compound. The selection of the default K_{OW} values used by BCFBAF™ should be more thoroughly documented and based on a peer reviewed methodology.

Comment 11. The BCFBAF™ model does not account for metabolism in the gut.

Summary: EPA has proposed to use the steady-state bioaccumulation model originally published by Arnot and Gobas (2003) to predict substance-specific BAFs in fish from three trophic levels as input into calculations used to derive HHWQC. This model also incorporates a QSAR for estimating the biotransformation rate in fish tissue or kM (Arnot et al., 2009). This is an important modeling advance since this process

can significantly mitigate the extent of bioaccumulation for more hydrophobic substances. However, a key limitation of the current BCFBAF™ model formulation is that while metabolism in tissue is quantitatively considered, metabolism in the gut is ignored. As discussed below, this process is critical in limiting the role of dietary uptake and subsequent bioaccumulation in the food web for a number of chemicals.

Discussion: The key model parameter that is influenced by gut metabolism is the chemical assimilation efficiency (AE) which is expressed as a fraction of chemical absorbed to that ingested via the diet in an uncontaminated fish. Currently, this key process appears to be modeled with a simple relationship that predicts AE based on the substance's log K_{OW} as reported by Kelly et al. (2004) and is described by the following equation;

$$AE = 1/(5x10^{-8} \times K_{OW} + 2)$$

It is stated in this paper that this relationship is based on the much earlier compilation of empirical AE data in fish by Gobas et al. (1988) for recalcitrant compound classes. Figure 1 shows that empirical AE data reported in this paper for polychlorinated biphenyls (PCBs) and three chlorinated insecticides (DDT, chloroane, mirex) are consistent with the above equation as denoted by the solid red line. As a result, the present AE model cannot be assumed to be broadly reliable across chemical classes for which EPA has derived HHWQC.

To support this point, empirical data on AE values obtained with trout for polyaromatic hydrocarbons (PAHs) were compiled from three earlier studies (Table 8). These data are plotted in Figure 2 as blue symbols and show the significantly lower AE values than are assumed in the current BCFBAF™ model as a consequence of gut metabolism. These empirical data were used to fit a revised relationship:

$$AE = 1/(3 \times 10^{-4} \times K_{OW} + 2.5) + 0.01$$

This relationship provides a conservative upper bound value of 0.01 at high log K_{OW} and is shown for comparison to the default model used in BCFBAF™ (Figure 3).

PAHs are not the only class of compounds that exhibit lower AEs than recalcitrant compounds like PCBs. For example, studies with individual dialkyl phthalate esters (DPEs) in staghorn sculpin demonstrated that these compounds were very effectively transformed in the gut with no significant accumulation from dietary exposure indicating very low (<0.01) assimilation efficiencies (Webster et al., 2003).

Table 8 Experimental data characterizing AE in fish for selected chemicals

Substance	Log K_{OW}	AE	Reference
Acenathalene	3.94	0.32	Niimi and Dookhran (1989)
9H-Fluorene	4.02	0.14	Niimi and Palazzo (1986)
Anthracene	4.35	0.01	Niimi and Palazzo (1986)
Phenanthrene	4.35	0.04	Niimi and Palazzo (1986)
Phenanthrene	4.46	0.12	Hellou and Leonard (2004)
Pyrene	4.88	0.02	Hellou and Leonard (2004)
2-Methyl Anthracene	4.89	0.14	Niimi and Dookhran (1989)
9-Methyl Anthracene	4.89	0.01	Niimi and Dookhran (1989)
Fluoranthene	4.93	0.01	Niimi and Palazzo (1986)
Fluoranthene	4.93	0.06	Hellou and Leonard (2004)
Triphenylene	5.52	0.04	Niimi and Dookhran (1989)
Benzo[a]pyrene	6.11	0.01	Niimi and Palazzo (1986)
Perylene	6.11	0.02	Niimi and Dookhran (1989)
Butylbenzyl Phthalate	4.73	<0.01	Webster (2003)
Bis(2-Ethylhexyl) Phthalate	7.60	<0.01	Webster (2003)

To demonstrate the impact of AE assumptions on BAF predictions, the spreadsheet version of the BCFBAF™ model was obtained from Dr. Arnot and used to perform sensitivity analyses. For PAHs the dietary uptake term in column D of the worksheet for lower, middle and upper trophic level fish was modified by multiplying by this term by the ratio of the revised to default AEs determined by equations [2] and [1], respectively. For DPEs, an upped bound revised assimilation efficiency of 0.01 was assumed so that the ratio was computed by dividing this value by the default AE predicted using equation [1]. The default and revised AEs are summarized in Table 2. A comparison of the predicted BAFs obtained with the default model (i.e. BAFs included in EPA's supporting Table summarizing updated input values for 2014 draft updated human health criteria) to values generated using the revised AE assumptions is provided in Table 9.

Table 9 Summary of predicted 2, 3 and 4 trophic level fish BAFs using default (BCFBAF™) and revised (including gut metabolism) assumptions for the assimilation efficiency of the substance from ingested diet

Substance	CAS Number	Log Kow	Default AE	Revised AE	Default BAF TL2	Revised BAF TL2	Default BAF TL3	Revised BAF TL3	Default BAF TL4	Revised BAF TL4
PAHs										
Acenaphthene	83-32-9	3.92	0.50	0.21	123	122	116	116	95	95
Fluorene	86-73-7	4.18	0.50	0.15	763	454	790	454	909	429
Anthracene	120-12-7	4.45	0.50	0.10	1212	844	1169	839	1151	787
Pyrene	129-00-0	4.88	0.50	0.05	1322	333	1058	303	785	227
Fluoranthene	206-44-0	5.16	0.50	0.03	790	575	563	513	388	380
Benzo(a) Anthracene	56-55-3	5.76	0.49	0.02	1577	603	749	537	406	398
Benzo(b) Fluoranthene	205-99-2	5.78	0.49	0.02	5325	1572	2643	1371	1165	993
Chrysene	218-01-9	5.81	0.49	0.02	8997	1700	4739	1555	1993	1154
Benzo(k) Fluoranthene	207-08-9	6.11	0.48	0.01	1883	479	676	398	301	288
Benzo(a) Pyrene	50-32-8	6.13	0.48	0.01	2736	500	984	419	396	300
Dibenzo(a,h)Anthracene	53-70-3	6.54	0.46	0.01	24690	1719	10700	1340	2863	889
Ideno(1,2,3-cd)Pyrene	193-39-5	6.70	0.44	0.01	5370	466	1465	354	317	243
DPEs										
Butylbenzyl Phthalate	85-68-7	4.73	0.50	0.01	62	23	55	21	40	16
Bis(2-Ethylhexyl)	117-81-7	7.60	0.25	0.01	17370	131	6120	56	1040	31

Results from Table 9 are depicted graphically by plotting the ratio of the default to revised BAF for each trophic level (denoted by different colored symbols) as a function of the log K_{OW} of the substance (see Figure 3). Result indicate that for substances with a log K_{OW} smaller than five, the additional conservatism introduced is within a factor of 5, while for substances with a log K_{OW} greater than five but smaller than seven, the factor increases to about 20 and for substances with a log Kow of greater than seven this factor can increase to more than100. Discrepancies are most pronounced for TL 2 fish as the role of fish biotransformation at subsequent trophic levels decreases the predicted BAF. These results have important implications for derivation of water quality criteria for these and other substances that are subject to transformation in the gut. Given the order of magnitude differences that are observed depending on AE assumptions it is apparent that the present BCFBAF™ model is overly conservative and cannot be reliably used to support criterion development without careful substance-specific calibration.

Comment 12. Development of an alternative model or methodology to predict state-, region- and water body-specific BAFs.

Summary: For the reasons described in the preceding comments, adopting single default values for national BAFs, especially if based on a Great Lakes food web, is not scientifically justified. In addition, many of EPA's default inputs to the BCFBAF™ model appear to contribute high bias to the resulting BAFs, particularly when taking into consideration characteristics of other U.S. waters. Such state-, region- and water body-specific characteristics, if they have an important effect on bioaccumulation, need to be accounted for. However, it appears that the BCFBAF™ model cannot fully accommodate user input of critical metrics that are known to vary on a site-specific basis. To address this critical shortcoming, we recommend that, prior to adopting any national BAFs, EPA evaluate alternatives to BCFBAF™ more amenable to development of state-, region- and water body-specific BAFs.

Discussion: There are alternative models for estimating BAFs which may be better suited for estimating site-specific BAFs, and EPA itself (Burkhard et al. 2006) has demonstrated an approach for extrapolating BAFs across ecosystems using AQUAWEB (Arnot and Gobas, 2004). In addition, AQUAWEB was identified by EPA's SAB (EPA 2007) as a potentially useful model for estimating BAFs (EPA 2007). Thus, it's unclear why EPA has selected to use BCFBAF™. Regardless, given the range of options for developing BAFs, EPA needs to provide some justification for its decision to use any one approach, including use of BCFBAF™. At the very least, EPA needs to directly compare the utility of BCFBAF™ and AQUAWEB for development of national default BAFs, paying particular attention to how amenable each approach might be to adjustment for site-, regional- or ecosystem-specific conditions. Ideally, EPA would request input for the SAB on this.

Ultimately, we suggest that EPA should specify use of some mechanistic food web model allowing use of site-specific values for all critical parameters for estimating site-specific BAFs and allow time for States and authorized Tribes to apply this model using region-, state-, or water body-specific data: a less preferred option would be for EPA to use the same model to develop default numeric BAFs appropriate for a range of waters (i.e., food webs) and afford some flexibility to States and authorized Tribes in identifying the correct BAFs for specific water bodies. Either of these options is preferable to simply adopting a single set of BAFs as national defaults. Finally, as we have stated multiple times throughout these comments, we believe it is very important that any methodology for estimating national BAFs should be reviewed by EPA's Science Advisory Board (SAB) prior to being used in development of HHWQC.

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Figures

Figure 1a - Sensitivity Analysis results for TL 2: Ratio of "user-defined BAF: BCFBAF™ default BAF" plotted for each each of six BCFBAF™ inputs (β, DOC, TL 1 lipid fraction, POC, water temperature, organism weight, and TL-specific lipid fraction) for six chemicals (acenaphthene, aldrin, benzo[a]pyrene, benzene, chlordane, and chrysene) for trophic level 2.

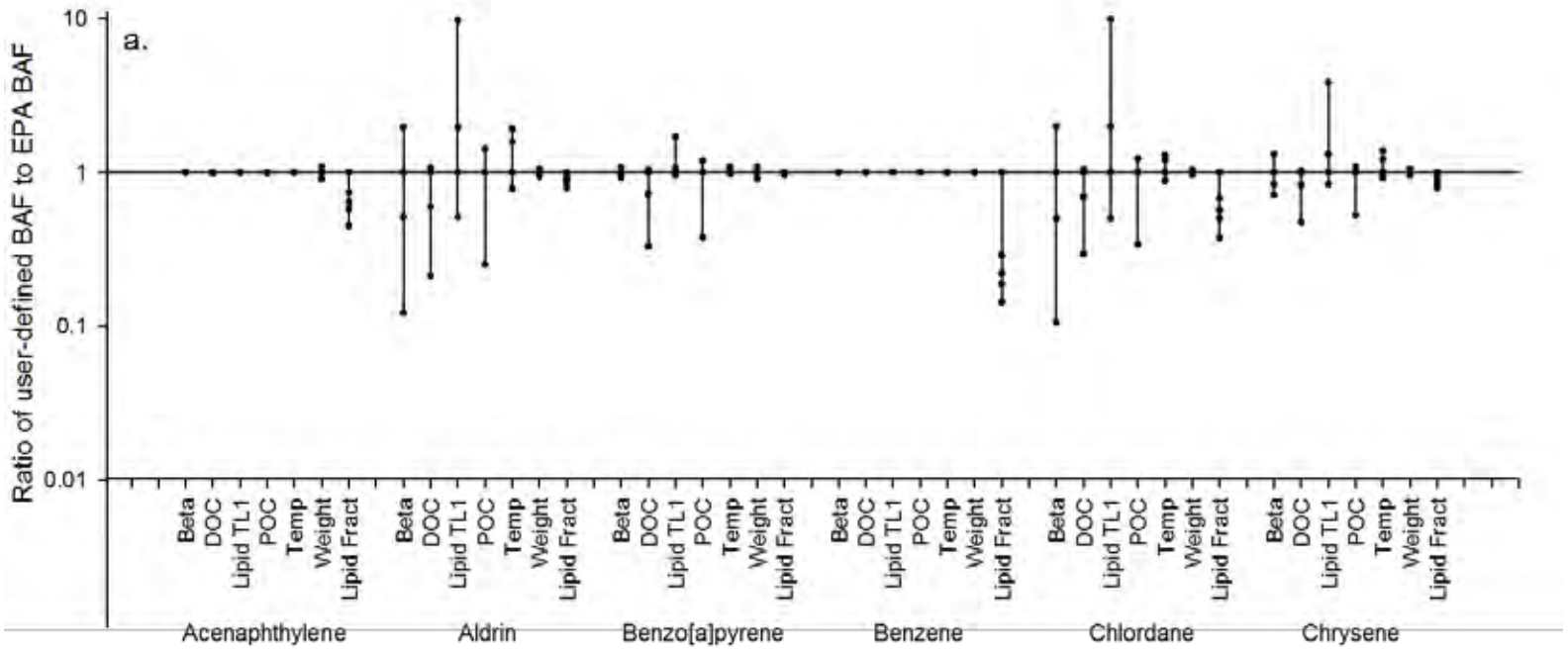

Figure 1b - Sensitivity Analysis results for TL 3: Ratio of "user-defined BAF: BCFBAF™ default BAF" plotted for each each of six BCFBAF™ inputs (β, DOC, TL 1 lipid fraction, POC, water temperature, organism weight, and TL-specific lipid fraction) for six chemicals (acenaphthene, aldrin, benzo[a]pyrene, benzene, chlordane, and chrysene) for trophic level 3.

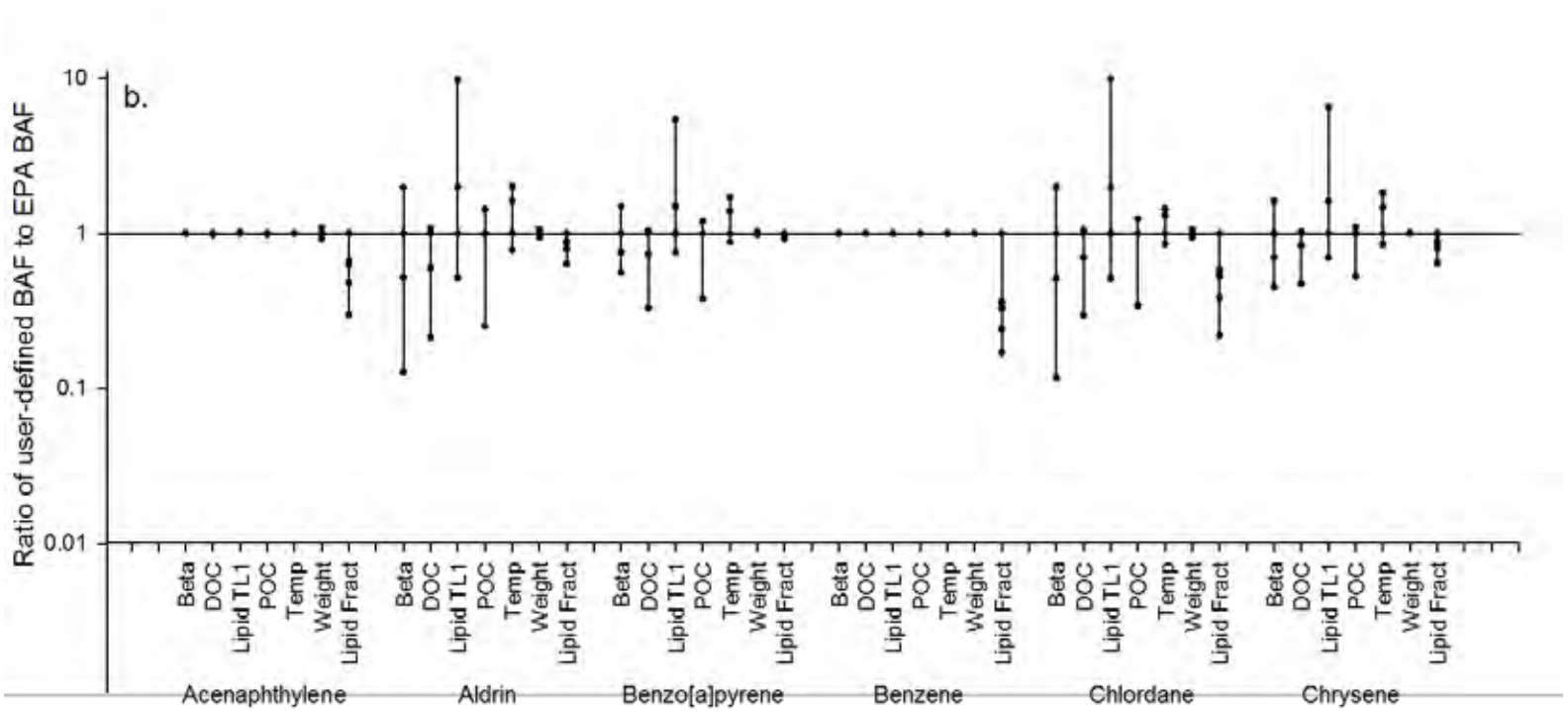

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Figure 1c - Sensitivity Analysis results for TL 4: Ratio of "user-defined BAF: BCFBAF™ default BAF" plotted for each each of six BCFBAF™ inputs (β, DOC, TL 1 lipid fraction, POC, water temperature, organism weight, and TL-specific lipid fraction) for six chemicals (acenaphthene, aldrin, benzo[a]pyrene, benzene, chlordane, and chrysene) for trophic level 4.

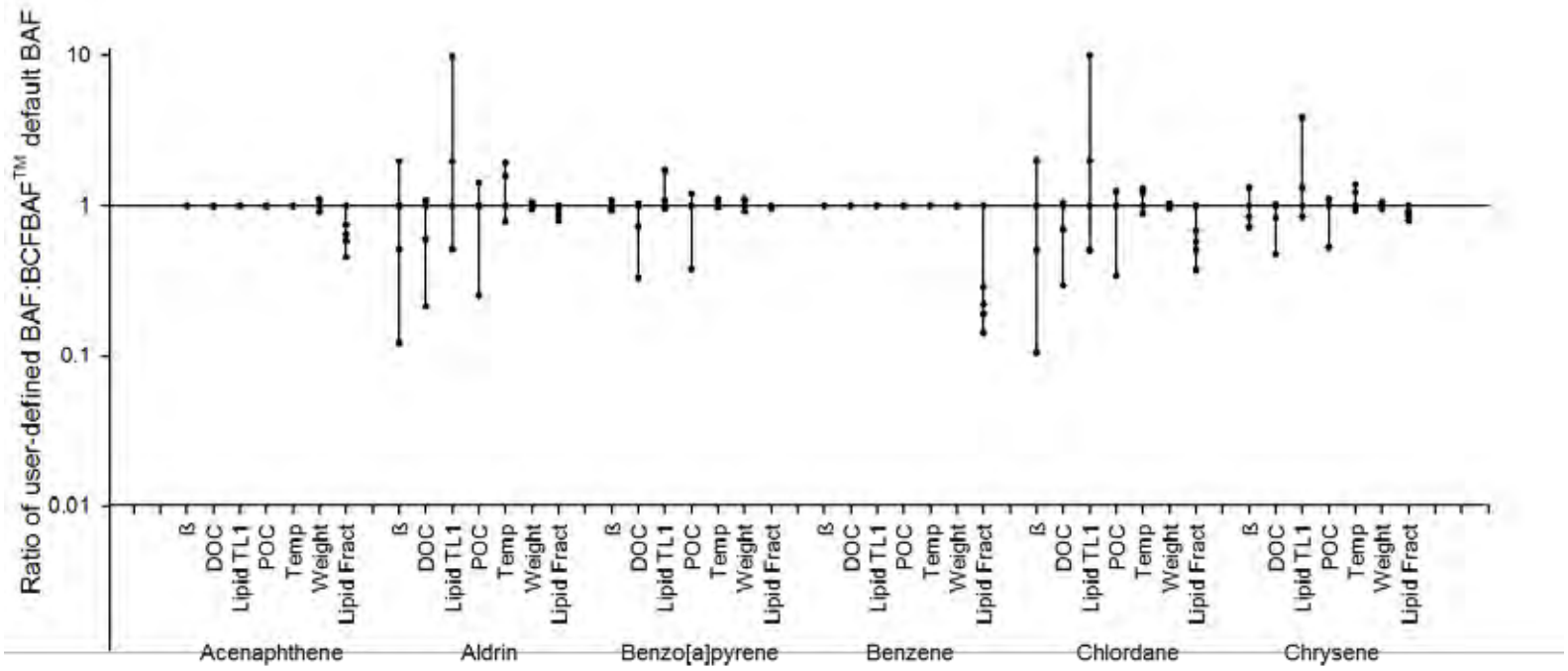


Figure 2. Relationship between substance assimilation efficiency in ingested diet for fish with substance Log Kow. Recalcitrant compounds (red); Polyaromatic hydrocarbons (blue).

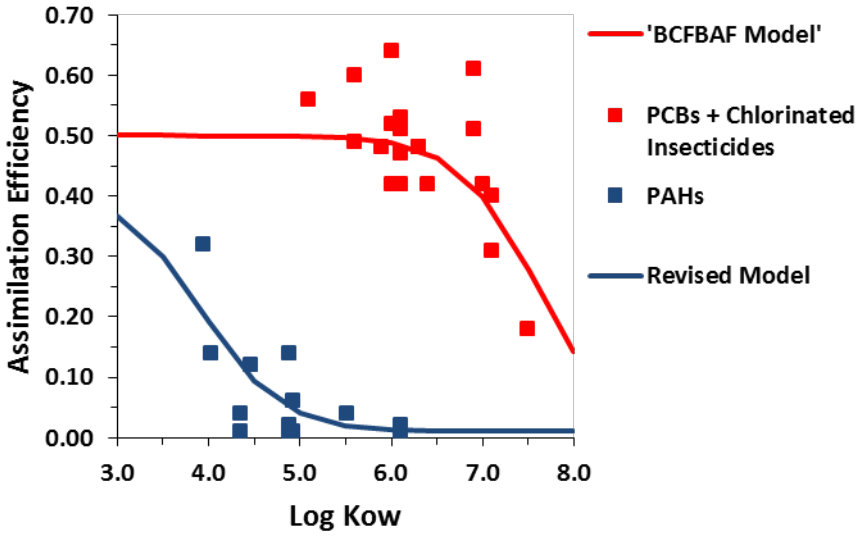
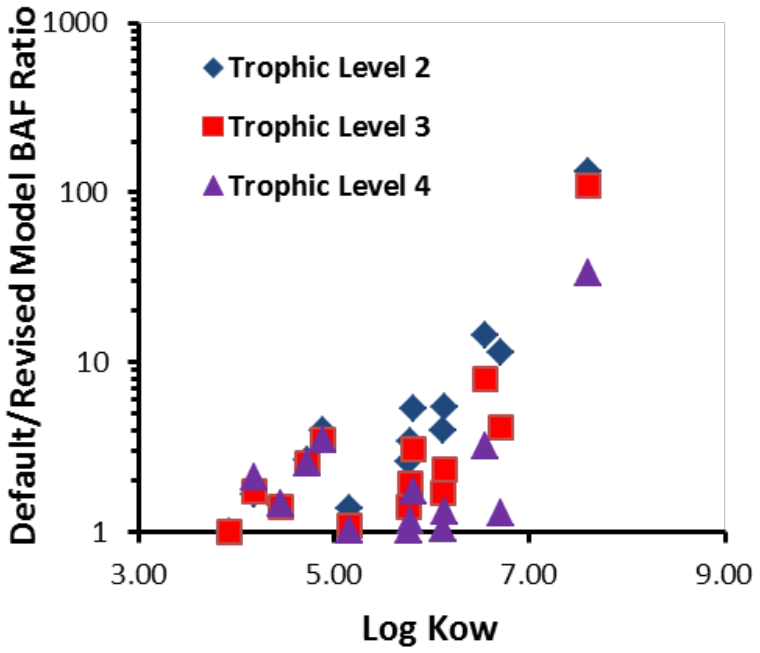


Figure 3. Sensitivity of BCFBAF model predictions to different assumptions for the substance specific assimilation efficiency (AE) input parameter.



NCASI Comments on Selected Aspects of EPA's Draft
2014 Update of Human Health Ambient Water Quality Criteria

Comment 1: Use of a deterministic approach with most parameter values taken from the upper-percentiles of underlying data distributions is overly conservative and does not follow EPA's previously expressed philosophy on this topic, which is to avoid the problem of compounded conservatism (recognized by EPA's own scientists as well as others) by using mean or median values in place of some of the upper percentile values.

Summary: The deterministic equation used by EPA to derive the HHWQC contains numerous parameters that describe a substance exposure scenario. That exposure scenario reflects a combination of circumstances that is essentially an impossible occurrence because nearly all values used for these parameters are selected from the upper end or maximum possible values in a distribution of values. In EPA's current approach, only one of about eight explicit and implicit exposure assumptions[1] is selected at a median value (body weight) while all other values represent higher percentiles in the range of possible values. One consequence of these choices is known as "compounded conservatism," which is recognized by scientists involved in risk analysis, including those at EPA. Following EPA's previously stated philosophy of using mean or median values in place of some of the upper percentile values would make the exposure scenario used for criteria derivation more realistic.

Discussion: In order to derive HHWQC that are "adequately protective," EPA has previously stated, in the document titled "Methodology for deriving ambient water quality criteria for the protection of human health," that it had selected default parameter values that are "a combination of median values, mean values, and percentile estimates [that target] the high end of the general population" (EPA 2000). Further, EPA (2000) noted that it "believes that this is reasonably conservative and appropriate to meet the goals of the CWA…"

An EPA staff paper on risk assessment principles and practices (EPA 2004), expresses that same principle, suggesting "when exposure data or probabilistic simulations are not available, 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 appears to be an acknowledgement that adequately protective assessments do not require that each, or even most, component parameter(s) be represented by a 90th or 95th percentile value.

In the 2005 Cancer Risk Assessment Guidelines, EPA (2005) explains the rationale behind the choice to base risk assessments on default values that represent a combination of median values, mean values, and percentile estimates targeting the high end of the general population:

> Overly conservative assumptions, when combined, can lead to unrealistic estimates of risk. This means that when constructing estimates from a series of factors (e.g., emissions, exposure, and unit risk estimates) not all factors should be set to values that maximize exposure, dose, or effect, since this will almost always lead to an estimate that is above the 99th-percentile confidence level and may be of limited use to decision makers.

In a recent report on the economics of health risk assessment, Lichtenberg (2010) addressed the use of conservative default parameters in risk assessment, stating that "the numbers generated…can't really be

[1] Explicit and implicit exposure variables include: body weight, drinking water intake, fish consumption rate, water column concentration, duration of exposure, cooking loss, relative bioavailability, and contributions from other exposures (NCASI 2012, available online at http://www.ecy.wa.gov/programs/wq/swqs/NCASIWhitepapr-humanhealth-basedwqc082012copy.pdf).

thought of as estimates of risk, since they bear only a tenuous relationship to the probability that individuals will experience adverse health consequences or to the expected prevalence of adverse health consequences in the population." Lichtenberg (2010) went on to say:

> …regulators continue to patch together risk estimates using a mix of "conservative" estimates and default values of key parameters in the risk generation process. Such approaches give rise to the phenomenon of compounded conservatism: The resulting estimates correspond to the upper bound of a confidence interval whose probability is far, far greater than the probabilities of each of the components used to construct it and which depends on arbitrary factors like the number of parameters included in the risk assessment.

In spite of the widely recognized problem of "compounded conservatism," which occurs when numerous upper-percentile default values are used for a series of factors representing exposure and effect, EPA, in its draft 2014 update of Human health Ambient Water Quality Criteria, has again chosen to rely on conservative upper-percentile defaults for most of the parameters used in criteria derivation. In addition to these explicit examples of relying on upper-percentile defaults, EPA has also chosen to base various implicit parameters embodied in the derivation process on upper-percentile assumptions. These include assumptions that 100 percent of the fish and drinking water consumed by an individual over a 70 year period is obtained from a single waterbody (or that a chemical is ubiquitous in all water), that the chemical is present at the HHWQC at all times, an individual consumes fish every year at the selected upper bound consumption rate, and that no loss of the chemical of interest occurs during cooking.

In addition to upper-percentile defaults and assumptions stated or implied in the HHWQC derivation methodology document (EPA 2000), the draft 2014 update adds an additional element of conservatism: that HHWQC "need to be set to enable residents to safely consume from local waters the amount of fish they would normally consume from all fresh and estuarine (including near coastal) waters." This adds an underlying assumption that not only does an individual consume fish every year at the selected upper bound consumption rate, but that 100% of that fish is caught in local waters. The latter assumption certainly does not reflect the habits of the general population as NOAA reports that the US imports 91%, of its seafood (http://www.fishwatch.gov/farmed_seafood/outside_the_us.htm). All of these assumptions and defaults taken together produce an exposure assessment that applies to a vanishingly small portion of the population: the above-the-99th-percentile estimate that EPA (2005) itself warned against due to its "limited use to decision makers".

Comment 2: A probabilistic approach to the derivation of HHWQC offers a scientifically sound and superior alternative to the deterministic approach.

Summary: Probabilistic approaches to criteria development are considered by risk assessment scientists to be preferred over deterministic approaches for reasons including reducing the effect of compounded conservatism, allowing a more direct matching of criteria to risk management targets, incorporation of more information describing human exposures, and improving transparency in the criteria derivation process. Tools for deriving HHWQC using a probabilistic process are available and have been used by at least one state. Use of probabilistic methods would allow EPA to update the science with respect to criteria derivation.

Discussion: EPA has previously supported and endorsed the use of probabilistic approaches to risk assessment. The agency has released guidance documents, such as "Guiding Principles for Monte Carlo Analysis" (EPA 1997) and "Risk Assessment Guidance for Superfund: Volume III - Part A, Process for Conducting Probabilistic Risk Assessment" (EPA 2001). The state of Florida (FDEP 2014) has used a probabilistic approach for the derivation of HHWQC which has the advantage of allowing the risk

assessor to specify the desired risk management endpoint and then demonstrate that the endpoint is met by the HHWQC. In addition, the Northwest Pulp and Paper Association (NWPPA) recently supported the development of the Probabilistic Ambient Water Quality Criteria Calculator (PAWQCC), which uses @Risk (Palisade Corporation), a probabilistic add-on program for Excel.

EPA's continued use of the deterministic approach in this draft update despite their own internal guidance documents supporting the probabilistic approach raises concerns related to the use of multiple upper percentile level default parameter values and associated compounded conservatism that could be lessened through the use of a probabilistic approach. Given that two different recently developed probabilistic approaches exist for the development of HHWQC and that EPA has previously endorsed the use of probabilistic risk assessment, EPA's decision to proceed with a deterministic approach does not represent the best or most recent science in this area. Indeed, two of EPA guidance documents on the probabilistic approach are at least 13 years old and the Agency just recently issued additional documents on the use of probabilistic techniques for risk assessment (*Federal Register* 8/12/2014).

Comment 3: The "EPA Method" used to derive fish consumption rates (FCRs) has not been adequately reviewed by experts outside EPA and the data and support documentation needed to allow external review have not been made publicly available. EPA should provide all information necessary to allow its analysis to be fully vetted by external scientists. This is necessary not only for purposes of scientific transparency, but also to allow state agencies the opportunity to reconsider certain assumptions and more state-specific data for purposes of deriving appropriate state water quality criteria

Summary and Discussion: EPA did invite four outside experts to conduct a peer review of the draft version of the document titled "Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations (NHANES 2003-2010)." However, at least one of those peer reviewers clearly did not feel comfortable commenting on some of the statistical analyses, with responses to, for example, Charge Question 5, of "[d]efer to the statisticians." The method developed by EPA to derive fish consumption rates is complex and is used to analyze large and complex data sets. Such a method should receive a more formalized in-depth Science Advisory Board (SAB) review.

In addition, one of the peer-review experts, Dr. Janet Tooze, is one of the developers of the NCI Method and thus has detailed knowledge of the statistical processes that can be used to adjust short-term data for predictions of long-term consumption. Dr. Tooze had numerous criticisms of, and questions about, the EPA Method, as detailed in the Final Peer Review Report (Publication No: 820-R-14-003). For example, Dr. Tooze stated:

> "However, there are serious concerns about the validity of the estimates produced by the modified EPA method. In particular, this method makes a number of approximations to the NCI method, but it does not fully explore the implications of each of these approximations, nor does it fully justify the approximations that are made. Furthermore, details were lacking regarding some of the statistical methods including: validation of the modified EPA Method, construction of BRR weights, inclusion of covariates in models, and construction of subgroup estimates. From the report, it is not apparent that the time savings from making a number of approximations in the modified EPA method is worth the potential loss in bias and efficiency of the estimates produced."

In Appendix H of the final version of "Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations (NHANES 2003-2010)," EPA replies to the peer reviewers comments, but it is not clear whether Dr. Tooze and the other peer reviewers are satisfied by any revisions made for the final

version nor is it clear to the reader whether those revisions do indeed adequately concerns expressed by the peer-reviewers. The transparency of this process as well as the ability of stakeholders to understand EPA's criteria derivation process would be greatly improved by explicit explanations of changes made in response to comments and suggestions by these peer reviewers. Appendix H would also be improved by and the inclusion of additional reaction from the reviewers regarding those changes.

Comment 4: It is not clear that the reasons given for using the EPA Method justify the use of an unvalidated model with limited outside review (the EPA Method) instead of the NCI Method in the development of the draft updated HHWQC.

Summary and Discussion: EPA's primary rationale for developing the EPA Method is that, because of restrictions on its use of non-publicly available data, using the NCI Method for multiple parameters is too time consuming. However, the FCR used in the derivation of the draft 2014 updated HHWQC (22 g/day) is based on relatively few parameters (freshwater + estuarine fish, adult (21 and older) consumers). In addition, it is not clear that there is any compelling need for the use of non-publicly available data. If this FCR had been derived using the NCI Method and publicly available data, it would have the added weight of being easily replicated by states, tribes, and other stakeholders and of having been developed using a validated, widely accepted method of correcting for biases associated with the use of short-term surveys to predict long-term consumption rates.

Comment 5: Use of 3 L/day as the default drinking water intake value is unnecessarily conservative and contributes to the derivation of HHWQC that are overly conservative and exceed EPA's stated protectiveness goals. The use of a water consumption rate that refects a more realistic level of consumption of untreated surface water is more scientifically defensible.

***Summary*:** EPA's estimate of the drinking water intake rate bears no relation to the actual amount of untreated surface water ingested by humans. Rather, the current and proposed updated values, (2 and 3 L/day, respectively), reflect goals related to pollution prevention and water quality maintenance rather than actual risk to those consuming drinking water from typical sources. As such, these values contribute to excessive conservatism in HHWQC and do not represent a realistic exposure scenario.

Discussion: EPA (2000) cites several reasons for including the drinking water exposure pathway in the derivation of HHWQC:

(1) Drinking water is a designated use for surface waters under the CWA and, therefore, criteria are needed to assure that this designated use can be protected and maintained.

(2) Although rare, there are some public water supplies that provide drinking water from surface water sources without treatment.

(3) Even among the majority of water supplies that do treat surface waters, existing treatments may not necessarily be effective for reducing levels of particular contaminants.

(4) In consideration of the Agency's goals of pollution prevention, ambient waters should not be contaminated to a level where the burden of achieving health objectives is shifted away from those responsible for pollutant discharges and placed on downstream users to bear the costs of upgraded or supplemental water treatment.

These reasons make it clear that the default water consumption rates of 2 L/day in 2000 (EPA 2000a) and 3 L/day in the current draft 2014 update were selected in support of larger goals related to pollution

prevention and maintenance of designated use and do not represent a consideration of actual direct risk of adverse effect to any individual consumer. As EPA itself noted (2000), it would be rare for anyone to use untreated surface water as a source of drinking water. The only direct consumption of untreated surface waters that might be considered to be routine is incidental ingestion during swimming, for which the EPA (2011b) recommended upper percentile default rates are 120 mL/hr for children and 71 mL/hour for adults. Using the 95th percentile estimate for time spent swimming each month (181 minutes) (EPA 2011b), annual daily average water consumption rates of 0.012 L/day (children) and 0.007 L/day (adults) can be calculated.

The draft default water consumption rate does not represent a realistic level of consumption of untreated surface waters, which is likely to occur only as an incidental event of water-related recreational activities. In spite of this, EPA has selected a default value, 3 L/day, that represents multiple conservative choices, including:

- selecting the 90th percentile value rather than a mean or median value;
- using "all sources of water" data instead of "community water;" and
- choosing a "consumers only" value instead of a "per capita" value, in spite of the fact that EPA (2011) has previously stated that "[i]n general, per capita intake rates are appropriate for use in exposure assessments for which average daily dose estimates are of interest."

By using 3 L/day in the calculation of the HHWQC, EPA is deriving criteria values that are based on the assumption that the general population is indeed consuming 3 L/day of untreated surface water, either through direct consumption as a beverage or indirectly following addition to food. The use of the 90th percentile value alone (3 L/day) reduces some of the the recommended criteria by almost one-half as compared to using the NHANES mean value and thus the choice acts to further compound the level of conservatism embodied in these criteria.

Comment 6: Use of the default value of 20% for Relative Source Contribution (RSC) is unnecessarily conservative since data-based RSC values have been derived for many of the substances for which HHWQC have been derived.

Summary: EPA's default RSC value of 20% is unreasonably conservative. Evaluations done in California and Florida have demonstrated that data are available to allow estimates of substance-specific RSCs and that the vast majority of such values are greater than 20% with some approaching 100%. Reviewing the literature (as Florida has done) for all substances for which RSCs apply and providing an estimate appropriate for that substance is a more scientifically defensible approach than simply relying on default lower and upper values (20% and 80%, respectively).

Discussion: EPA (2000) has provided a decision tree methodology for calculating chemical- or site-specific RSCs. Although the lowest allowable value, 20%, is specified as the default RSC, EPA (2000) notes "[the default value of 20%] is likely to be used infrequently with the Exposure Decision Tree approach, given that the information [required to calculate a chemical-specific RSC]…should be available in most cases." Indeed, the California Office of Environmental Health Hazard Assessment (OEHHA) concluded that the default use of an RSC of 20% is "unreasonably conservative for most chemicals" (Howd et al. 2004). For 22 of the 57 chemicals listed by Howd et al. (2004), a RSC value greater than 20% was used in the calculation of California Public Health Goals for those chemicals in drinking water. Howd et al. (2004) also noted that "[a] default RSC of 0.2 is based on tradition, not data."

Recently, the state of Florida developed specific RSC values for 21 of the 35 non-carcinogenic compounds for which it derived HHWQC (FDEP 2014). Sixty-three percent of the RSC values used by Florida were greater than 0.2 (FDEP 2014). These RSC values, along with those of Howd et al. (2004), provide a data-based alternative to the 20% default RSC and could easily be adopted by EPA, with the 20% default RSC being applied only to those substances for which FDEP and Howd et al. did not develop an RSC.

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