

methodology in the near future (*Technical Support Document Volume 2: Development of National Bioaccumulation Factors*). We developed the approaches to deriving bioaccumulation factors and applying them in AWQC presented from a process that included extensive review from EPA's Science Advisory Board, peer review workshops, and stakeholder meetings (65 FR 6644).

EPA's framework deriving bioaccumulation factors is designed to account for chemical, biological and ecological attributes. For example, we provide separate procedures for deriving national BAFs depending on the type of chemical (*i.e.*, nonionic organic, ionic organic, inorganic and organometallic). More specifically, EPA's framework recognizes that the derivation of BAFs for organometallic chemicals differs in several ways from procedures for organic chemicals. For example, there are no generic bioaccumulation models that can be used to predict BAFs for organometallic chemicals as a whole; therefore, EPA's preferred approach for deriving national BAFs for such chemicals is to use empirical field data.

EPA took this approach in deriving draft national BAFs for methylmercury (see *Water Quality Criterion for the Protection of Human Health: Methylmercury* (EPA-823-R-01-001, January 2001)). We found the empirically-derived draft methylmercury BAFs to be variable, reflecting the influences of various biotic factors and abiotic factors on methylmercury bioaccumulation that were not well understood at that time. EPA acknowledged that these factors resulted in uncertainty as to the ability of the BAFs to accurately predict bioaccumulation of methylmercury across the waters of the United States. However, in this same document, EPA noted that this is not the case for other highly bioaccumulative pollutants (*i.e.*, non-organometallics). For such pollutants, EPA has methods that improve the predictive capability of empirically-derived or model-predicted BAFs.

When it conducts a full re-evaluation of the human health water quality criteria for the chemicals included in this Notice, EPA will evaluate the best available evidence concerning BAF values. EPA will develop national BAF values to the extent possible given the best available data at the time. Where derivation of National BAFs is not possible, EPA's 2000 Methodology encourages States and authorized Tribes to derive BAFs that are specific to regions or waterbodies as appropriate.

e. Scientific validity of using cancer potency factors or RfDs to define thresholds of unacceptable adverse effects is questionable.

*Scientific view*—One submitter questioned the scientific validity of using cancer potency factors or RfDs to define thresholds of unacceptable adverse effects. EPA should explicitly address the "scientific gray area" that exists between human health effects and RfDs and a benchmark dose or the lowest observed effect level on which an RfD might be based.

*Response*—As discussed in *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)* (EPA-822-B-00-004, October 2000), human health water quality criteria are designed to minimize the risk of adverse effects to humans from chronic (lifetime) exposure to substances through the ingestion of drinking water and eating fish from surface waters.

The water quality criteria are based on chronic health effects data (both cancer and noncancer). However, the criteria also are intended to protect against adverse effects not only for the general population over a lifetime of exposure, but also for special populations (*e.g.*, sports fishers, children, elderly) who have an increased risk of receiving a dose that would elicit adverse effects due to their high water- or fish-intake rates or their biological sensitivities. Neither the benchmark dose nor a lowest observed effects level represent a "threshold" for response in the human or animal populations. Instead, those values typically are associated with a small proportional response level for the populations in question. EPA acknowledges the possibility that other populations might be more sensitive than those examined.

The Agency fully documents the derivation of its cancer potency factors and RfDs in IRIS. Those values were derived using the Agency guidelines for risk assessment, extensive peer review, and the best available information at the time the values were developed. The Agency continues to review and update the human health effects data in IRIS to ensure it considers the most current literature. That process, however, takes time. The IRIS Web (<http://www.epa.gov/iris/>) site describes EPA's policy on the "scientific gray areas" that reflect the use of uncertainty factors to cover certain types of data gaps.

## 2. EPA Should Adopt a Fish Tissue-Based Criteria in Lieu of the Proposed Water Column Criteria

*Scientific view*—EPA should derive fish tissue criteria, rather than water

column concentrations, for the 15 compounds to avoid the scientific deficiencies related to the inappropriate use of BCFs and BAFs. Compliance monitoring and site-specific adjustments also are simplified when criteria are based on fish-tissue measurements in lieu of water column criteria. The submitter also requested a table of the intermediate fish tissue levels used in (or derived from) the calculation of the proposed water column criteria.

*Response*—For the most part, EPA has published water column concentrations as their recommended water quality criteria values for protection of human health. The recent exception being the fish tissue concentration for methylmercury (see 66 FR 1344, January 8, 2001). When the new methylmercury criterion was published, EPA withdrew its previous ambient human health water quality criteria for mercury as the recommended section 304(a) water quality criteria. At that time, EPA also recognized that this approach differed from the traditional water column criteria approach and suggested ways to relate the fish and shellfish tissue criterion to concentrations of methylmercury in the water column. We must relate tissue concentrations to water column concentrations in order to use the criterion to establish discharge limits for point sources. Fish tissue criteria can be developed and potentially simplify compliance monitoring and site-specific adjustments, yet this does not eliminate the need to develop BAFs.

Using national BAFs is a scientifically valid approach to deriving national water quality criteria. EPA encourages States and authorized Tribes to develop BAFs based on field-measured data from local/regional fish, whenever possible, when developing their own water quality standards.

The 15 revised human health criteria do not incorporate BAFs, a component of the new methodology; rather, the revised criteria are based on previously-developed BCFs. Thus, we have not estimated intermediate fish tissue concentrations.

## 3. EPA Should Provide All Numeric Factors Used in the Derivation of the Proposed Criteria

*Scientific view*—One submitter stated that EPA should provide information and references for all components needed to calculate the proposed criteria, including  $K_{ow}$  values and food chain multipliers.

*Response*—EPA included all basic parameters necessary for deriving the criteria in the December 27, 2002,