ENVIRONMENTAL PROTECTION AGENCY

[WH–FRL–6893–6]

Revisions to the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Availability.

SUMMARY: EPA is announcing the availability of final revisions to the Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000) (hereafter ''2000 Human Health Methodology'') published pursuant to section 304(a)(1) of the Clean Water Act (CWA). The 2000 Human Health Methodology supersedes the existing Guidelines and Methodology Used in the Preparation of Health Effect Assessment Chapters of the Consent Decree Water Criteria Documents, published by EPA in November 1980 (USEPA, 1980) (hereafter ''1980 AWQC National Guidelines'' or ''1980 Methodology''). Today's Notice is intended to support the requirements of section 304(a)(1) of the CWA that EPA periodically revise criteria for water quality to accurately reflect the latest scientific knowledge on the kind and extent of all identifiable effects on health and welfare that may be expected from the presence of pollutants in any body of water, including ground water. These revisions are prompted by the many significant scientific advances that have occurred during the past 20 years in such key areas as cancer and noncancer risk assessments, exposure assessments, and bioaccumulation assessments. These revisions are not regulations and do not impose legally-binding requirements on EPA, States, Tribes, or the public.

DATES: Technical Support Documents (TSD) on exposure assessment guidance and bioaccumulation guidance applicable to the 2000 Human Health Methodology are expected to become available early in calendar year 2001.

ADDRESSES: The 2000 Human Health Methodology is published in the document entitled, Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000). This document is available on the EPA website at *www.epa.gov/OST/humanhealth.* A Technical Support Document (TSD) volume on risk assessments applicable to the 2000 Human Health Methodology is also available from the website. Materials in the public docket will be available for public inspection and copying during normal business hours at the Office of Water Docket, 401 M St., SW, Washington, DC 20460 by appointment only. Appointments may be made by calling (202) 260–3027 and requesting item W–97–20. A reasonable fee will be charged for photocopies.

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I. Background Information

A. What are Human Health Ambient Water Quality Criteria?

Human health ambient water quality criteria (AWQC) are numeric values for pollutant concentrations in ambient waters considered to be protective of human health. The criteria are developed under section 304(a) of the Clean Water Act (CWA) and are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. Protective assumptions are made regarding the potential human exposure intakes. These criteria do not reflect consideration of economic impacts or the technological feasibility of meeting the chemical concentrations in ambient water. Section 304(a)(1) of the CWA requires EPA to develop and publish, and from time to time revise, criteria for water quality accurately reflecting the latest scientific knowledge. The criteria are used by States and authorized Tribes to establish water quality standards and ultimately provide a basis for controlling discharges or releases of pollutants. The criteria also provide guidance to EPA when promulgating Federal regulations under CWA Section 303(c) when such actions are necessary.

In 1980, we published AWQC (*i.e.,* Section 304(a) criteria) for 64 pollutants/pollutant classes and provided a methodology for deriving the criteria. The 1980 AWQC National Guidelines for developing human health AWQC addressed three types of endpoints: noncancer, cancer and organoleptic (taste and odor) effects. Criteria for the protection against noncancer and cancer effects were estimated by using risk assessment-based procedures, including extrapolation from animal toxicity or human epidemiological studies. Basic human exposure assumptions were applied to the criterion equation. When using cancer as the critical risk assessment endpoint, which was assumed not to have a threshold, the AWQC were presented as concentrations associated with specified incremental lifetime risk levels. When using noncancer effects as the critical endpoint, the AWQC reflected an assessment of a ''no-effect'' level, based on an assumption of a threshold for noncancer effects.

B. How Is the Human Health Methodology Used?

The Methodology is used by EPA to derive or revise its section 304(a) criteria. It provides the detailed means for developing the water quality criteria, including systematic procedures for evaluating cancer risk, noncancer health effects, human exposure, and bioaccumulation potential in fish. This Methodology is also guidance for States and authorized Tribes to help them establish water quality criteria to protect human health. States and authorized Tribes must develop water quality standards that include designated uses and water quality criteria necessary to support those uses.

C. Why Was the Methodology Revised?

EPA periodically revises water quality criteria to ensure that they reflect the latest scientific knowledge on the kind and extent of all identifiable effects on health and welfare that may be expected from the presence of pollutants in any body of water, including ground water. Since 1980, many significant scientific advances have occurred which prompt revisions to the Methodology. Specifically, advances in such key areas as cancer and noncancer risk assessments, exposure assessments, and bioaccumulation make the revisions appropriate at this time. We therefore updated the Methodology to provide States and authorized Tribes with the most current procedures to reflect these changes in risk and exposure assessment. States and authorized Tribes can use the Methodology to modify their water quality criteria, as appropriate, to ensure that their criteria are protective of designated uses.

Another reason for these revisions is the need to address differences in the risk assessment and risk management approaches used by the EPA Office of Water for the derivation of AWQC—under the authority of the CWA—and Maximum Contaminant Level Goals (MCLGs)—under the authority of the Safe Drinking Water Act (SDWA). Three notable differences in these revisions include the treatment of chemicals designated as Group C possible human carcinogens under the 1986 Guidelines for Carcinogen Risk Assessment (USEPA, 1986a), the consideration of non-water sources of exposure when setting an AWQC or MCLG for a noncarcinogen, and cancer risk ranges.

1. *Group C Chemicals.* Chemicals classified as Group C—*i.e.,* possible human carcinogens'under the existing (1986) EPA cancer classification scheme have been typically classified as such for any of the following reasons.

(1) Carcinogenicity has been documented in only one test species and/or only one cancer bioassay, and the results do not meet the requirements of ''sufficient evidence.''

(2) Tumor response is of marginal statistical significance due to inadequate design or reporting.

(3) An agent causes benign, but not malignant, tumors and no response in a variety of short-term tests for mutagenicity.

(4) There are responses of marginal statistical significance in a tissue known to have a high or variable background rate.

The 1986 Guidelines for Carcinogen Risk Assessment (hereafter ''1986 cancer guidelines'') specifically recognized the need for flexibility with respect to quantifying the risk of Group C agents (USEPA, 1986a). The 1986 cancer guidelines noted that agents judged to be in Group C, possible human carcinogens, may generally be regarded as suitable for quantitative risk assessment, but that case-by-case judgments may be made for them.

EPA has historically treated Group C chemicals differently under the CWA and the SDWA. It is important to note that the 1980 AWQC National Guidelines for setting AWQC under the CWA predated EPA's carcinogen classification system, which was proposed in 1984 and finalized in 1986 (USEPA, 1984, 1986a). The 1980 AWQC National Guidelines did not explicitly

differentiate among agents with respect to the weight of evidence for characterizing them as likely to be carcinogenic to humans. For all pollutants judged as having adequate data for quantifying carcinogenic risk—including those now classified as Group C—AWQC were derived based on cancer incidence data. In the November 1980 **Federal Register** Notice, we emphasized that the AWQC for carcinogens should state that the recommended concentration for maximum protection of human health is zero. At the same time, the criteria published for specific carcinogens presented water concentrations for these pollutants corresponding to individual lifetime cancer risk levels in the range of 10^{-7} to 10^{-5} (ranging from one case in a population of ten million to one case in a population of one hundred thousand).

In the development of national primary drinking water regulations under the SDWA, EPA is required to promulgate a health-based MCLG for each contaminant. Our policy has been to set the MCLG at zero for chemicals with strong evidence of carcinogenicity associated with exposure from water. For chemicals with limited evidence of carcinogenicity, including many Group C agents, the MCLG was usually obtained using a Reference Dose (RfD) based on its noncancer effects with the application of an additional factor of 1 to 10. If valid noncancer data for a Group C agent were not available to establish an RfD, but adequate data were available to quantify the cancer risk, then the MCLG was based upon a nominal lifetime excess cancer risk calculation in the range of 10^{-6} to 10^{-5} (ranging from one case in a population of one million to one case in a population of one hundred thousand). Even in those cases where the RfD approach has been used for the derivation of the MCLG for a Group C agent, the drinking water concentrations associated with excess cancer risks in the range of 10^{-6} to 10^{-5} were also provided for comparison.

It should also be noted that in actions taken under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA's pesticides program has applied both of these methods for addressing Group C chemicals and finds both methods (quantified ''C's'' and nonquantified ''C's'') applicable on a case-by-case basis. Unlike the drinking water program, however, the pesticides program does not add an extra uncertainty factor to account for potential carcinogenicity when using the RfD approach.

The EPA is in the process of revising its cancer guidelines, including its descriptions of human carcinogenic potential. Once final guidelines are published, they will be the basis for assessment under this Methodology. In the meanwhile, the 1986 cancer guidelines are used and extended with principles discussed in EPA's 1999 Guidelines for Carcinogen Risk Assessment—Review Draft (hereafter ''1999 draft revised cancer guidelines''). These principles arise from scientific discoveries about cancer made in the last 15 years and from EPA policy of recent years supporting full characterization of hazard and risk both for the general population and potentially sensitive groups such as children. These principles are incorporated in recent and ongoing assessments such as the reassessment of dioxin, consistent with the 1986 cancer guidelines. Until final guidelines are published, information is presented to describe risk under both the 1986 guidelines and the 1999 draft revisions. To bring in new science and characterization principles, draft revisions have weight-of-evidence narratives for hazard characterization that use consistent descriptive terms (USEPA, 1999a). In order to provide some measure of consistency in an otherwise free-form, narrative characterization, standard descriptors are utilized as part of the hazard narrative to express the conclusion regarding the weight of evidence for carcinogenic hazard potential. There are five standard hazard descriptors: ''carcinogenic to humans'', ''likely to be carcinogenic to humans'', ''suggestive evidence of carcinogenicity but not sufficient to assess human carcinogenic potential'', ''data are inadequate for an assessment of human carcinogenic potential'', and ''not likely to be carcinogenic to humans.'' Each standard descriptor may be applicable to a wide variety of data sets and weights of evidence and are presented only in the context of a weight-of-evidence narrative. Furthermore, more than one conclusion may be reached for a pollutant. For instance, using a descriptor in context, a narrative could say that a pollutant is likely to be carcinogenic by inhalation exposure and not likely to be carcinogenic by oral exposure.

In the 2000 Human Health Methodology, we quantify those pollutants considered ''carcinogenic to humans'' or ''likely to be carcinogenic to humans.'' In practice, even though the terminology of the 1999 draft revised cancer guidelines differs, this is the approach currently used by the EPA pesticides program.

2. *Consideration of Non-water Sources of Exposure.* The 1980 AWQC National Guidelines for setting AWQC recommended that contributions from non-water sources, namely air and non-fish dietary intake, be subtracted from the Acceptable Daily Intake (ADI), thus reducing the amount of the ADI ''available'' for water-related sources of intake. In practice, however, when calculating human health criteria, those other exposures were generally not considered because reliable data on those exposure pathways were not available. Consequently, the AWQC were usually derived such that drinking water and fish ingestion accounted for the entire ADI (now called RfD).

Through the mid-1980s, the drinking water program generally used a similar ''subtraction'' method in the derivation of MCLGs, albeit inconsistently. More recently, the drinking water program has used a ''percentage'' method in the derivation of MCLGs for noncarcinogens. In this approach, the percentage of total exposure typically accounted for by drinking water is applied to the RfD to determine the maximum amount of the RfD apportioned to drinking water reflected by the MCLG value. This percentage is called the relative source contribution (RSC). In using this percentage procedure, the drinking water program also applies a ceiling of 80 percent of the RfD and a floor of 20 percent of the RfD. That is, the MCLG cannot account for more than 80 percent of the RfD, nor less than 20 percent of the RfD.

The drinking water program usually takes a conservative approach to public health by applying an RSC factor of 20 percent to the RfD when adequate exposure data do not exist, assuming that the major portion (80 percent) of the total exposure comes from other sources, such as diet.

The 2000 Human Health Methodology includes guidance for routine consideration of non-water sources of exposure [both ingestion exposures (*e.g.*, food) and exposures other than the oral route (*e.g.*, inhalation)] via an approach called the Exposure Decision Tree. RSC estimates will be made by EPA using this approach, which allows for use of either subtraction or percentage methods, depending on chemical-specific circumstances, within the 20 to 80 percent range described above.

3. *Cancer Risk Ranges.* In addition to the different risk assessment approaches discussed above for deriving AWQC and MCLGs for Group C agents, there have been different risk management approaches by the drinking water and

ambient surface water programs on using lifetime excess risk values when setting health-based criteria for carcinogens. The surface water program historically derived AWQC for carcinogens that generally corresponded to lifetime excess cancer risk levels of 10^{-7} to 10^{-5}. The drinking water program has set MCLGs for Group C agents based on a slightly less stringent risk range of 10^{-6} to 10^{-5}, while MCLGs for chemicals with strong evidence of carcinogenicity (that is, classified as Group A (known) or B (probable) human carcinogen) are set at zero. The drinking water program is now following the 1999 draft revised cancer guidelines to determine the type of low-dose extrapolation based on mode of action.

It is also important to note that under the drinking water program, for those substances having an MCLG of zero, enforceable Maximum Contaminant Levels (MCLs) have generally been promulgated to correspond with cancer risk levels ranging from 10^{-6} to 10^{-4}. Unlike AWQC and MCLGs which are strictly health-based criteria, MCLs are developed with consideration given to the costs and technological feasibility of reducing contaminant levels in water to meet those standards.

The 2000 Human Health Methodology states that EPA will publish its national 304(a) water quality criteria at a 10^{-6} risk level, which we consider to be appropriate for the general population. Again, consistent with the 1999 draft revised cancer guidelines, there are no more alphanumeric categories. We will only quantify those considered ''carcinogenic to humans'' or ''likely to be carcinogenic to humans.'' We are increasing the degree of consistency between the drinking water and ambient water programs, given somewhat different requirements of the CWA and SDWA. We will use the same hazard characterizations of dose-response.

B. What Specific Scientific Advances Have Occurred Since 1980?

Since 1980, EPA risk assessment practices have evolved significantly in all of the major Methodology areas: cancer and noncancer risk assessments; exposure assessments; and bioaccumulation. EPA first published guidelines on cancer risk assessment in 1986. EPA published Proposed Guidelines for Carcinogen Risk Assessment in 1996 (hereafter ''1996 proposed cancer guidelines''; USEPA, 1996a). These were recently revised following review by the Agency's Science Advisory Board (SAB) and receipt of their comments in May 1999. The most recent document is the July 1999 draft revised cancer guidelines (USEPA, 1999a). The 1999 draft revised cancer guidelines discuss the use of mode of action (MOA) information to support both the identification of carcinogens and the selection of procedures to characterize risk at low, environmentally relevant exposure levels. They also address the development of new procedures to quantify cancer risks at low doses to replace the current default use of the linearized multistage (LMS) model. In noncancer risk assessment, we are moving toward the use of the benchmark dose (BMD) and other dose-response methodologies in place of the traditional NOAEL approach to estimate an RfD concentration or other point of departure (POD) divided by an uncertainty factor (UF). In addition, several risk assessment guidelines have been published. For example, in 1986 EPA published Guidelines for Mutagenicity Risk Assessment (USEPA, 1986b). In 1991, EPA published the Guidelines for Developmental Toxicity Risk Assessment (USEPA, 1991a), and in 1996, it published the Guidelines for Reproductive Toxicity Risk Assessment (USEPA, 1996b). In 1998, EPA also published the Guidelines for Neurotoxicity Risk Assessment (USEPA, 1998a). In May 1999, EPA published the Draft Guidance for Conducting Health Risk Assessment of Chemical Mixtures (USEPA, 1999b). In addition, the Agency is developing a framework for cumulative risk assessment, and the Office of Pesticide Programs has developed draft guidance for assessing cumulative risk of common mechanism pesticides and other substances.

In 1986, EPA made available to the public the Integrated Risk Information System (IRIS). IRIS is a database that contains risk information on the cancer and noncancer effects of chemicals. The IRIS assessments represent EPA scientific consensus positions across the Agency's program offices and regional offices.

In exposure analysis, several new studies have addressed water consumption and fish tissue consumption. These exposure studies provide a more current and comprehensive description of national, regional and special population consumption patterns that we reflected in the 1998 Draft Water Quality Criteria Methodology: Human Health (hereafter ''1998 draft Methodology revisions''; USEPA, 1998c). In addition, more formalized procedures are available to account for human exposure to multiple sources when setting health goals such as AWQC that have previously addressed only one exposure source. The Exposure Factors Handbook was updated in 1997 (USEPA, 1997a). In 1992, we published the revised Guidelines for Exposure Assessment (USEPA, 1992a), which describe general concepts of exposure assessment, including definitions and associated intake rate parameters, and provide guidance on planning and conducting an exposure assessment. In 1986, the Agency published the Total Exposure Assessment Methodology (TEAM) Study: Summary and Analysis, Volume I, Final Report (USEPA, 1986c), which presents a process for conducting comprehensive evaluation of human exposures. The Agency has recently developed a revised relative source contribution (RSC) policy for assessing total human exposure to a contaminant and apportioning the RfD among the media of concern for use in deriving or revising AWQC. In 1997, we developed Guiding Principles for Monte Carlo Analysis (USEPA, 1997b). Also in 1997, we published the Policy for Use of Probabilistic Analysis in Risk Assessment (USEPA, 1997c; see *http://www.epa.gov/ncea/mcpolicy.htm*). The Monte Carlo guidance document can be applied to exposure assessments and risk assessments. The Agency has moved toward the use of a bioaccumulation factor (BAF) to reflect the uptake of a contaminant from all sources (*e.g.*, ingestion, sediment) by fish and shellfish, rather than just from the water column as reflected by the use of a bioconcentration factor (BCF) in the 1980 Methodology. We have developed detailed procedures and guidelines for estimating BAF values for use in deriving or revising AWQC.

C. What Process Did EPA Follow in Revising the Methodology?

We began by developing (along with other Federal agencies, State health organizations, Canadian health agencies, academies, environmental and industry groups, and consulting organizations) an issues paper that described the 1980 Methodology, discussed areas that needed strengthening, and recommended revisions. The paper was distributed for review and comment and was examined at a national workshop, where more than 100 participants discussed critical issues. Based on individual expertise, attendees were assigned to specific technical workgroups. The workgroups' topics included cancer risk, noncancer risk, exposure, microbiology, minimum data and bioaccumulation in fish.

A summary document based on the workshop recommendations was submitted for review and comment by the EPA SAB. Once final comments and

revisions were received from the SAB, the recommendations were again reviewed at a meeting of the Federal-State Toxicology and Risk Analysis Committee, where state representatives presented their opinions on the preliminary draft recommendations. (A more detailed chronology of this process was provided with the 1998 draft Methodology revisions.)

EPA subsequently developed the 1998 draft Methodology revisions (USEPA, 1998c) and the Ambient Water Quality Criteria Derivation Methodology Human Health Technical Support Document (TSD) (USEPA, 1998d) that provides greater detail on the Methodology guidance—including case study examples, data tables, and other supporting information. These were published in the **Federal Register** in August 1998. A four-month public comment period followed. In May of 1999, a fifteen-member independent peer review workshop was held, and a public stakeholder meeting followed. The 2000 Human Health Methodology reflects, in part, the input received from the public and peer review experts, in addition to more recent scientific information and science policies since the 1998 draft publication.

F. What Are the Major Revisions to the Methodology?

The major revisions are in four assessment areas: Noncancer, cancer, exposure and bioaccumulation. Equations have been developed for deriving AWQC, which include parameters relevant to those four assessment areas. These parameters are derived from scientific analysis, science policy and risk management decisions.

For noncarcinogens, the process for deriving a level of exposure considered to be without appreciable risk of effect—known as the Reference Dose (RfD) value—has evolved over time.

- EPA has developed guidance on assessing noncarcinogenic effects of chemicals and for the RfD derivation.
- The Methodology revisions recommend consideration of other issues related to the RfD process including integrating reproductive/developmental, immunotoxicity, and neurotoxicity data into the calculation.
- EPA is recommending the use of quantitative dose-response modeling for the derivation of RfDs.
- EPA has provided additional guidance (in its Risk Assessment TSD) to allow States and authorized Tribes greater flexibility in conducting their own risk assessments.

For carcinogen (cancer) risk assessment, more sophisticated methods for determining the likely mechanism that causes human carcinogenicity are being recommended, as well as consideration of all biological information (rather than just tumor findings) and full risk characterization for the general population as well as sensitive groups such as children.

Changes in the area of exposure assessment include the following.

- States and authorized Tribes are encouraged to use local studies on fish consumption that better reflect local intake patterns and choices.
- EPA will recommend default fish consumption values for the general population, recreational fishers and subsistence fishers.
- A factor to account for other sources of exposure, such as food and air, is included when deriving AWQC for noncarcinogens and for carcinogens based on a nonlinear low-dose extrapolation (*i.e.*, water and fish consumption are not the only exposures considered).

The 2000 Human Health Methodology places greater emphasis on the use of BAFs compared to the 1980 Methodology for estimating potential human exposure to contaminants via the consumption of contaminated fish and shellfish.

- BAFs reflect the accumulation of chemicals by aquatic organisms from all surrounding media (water, food, sediment). Compared with BCFs, which reflect chemical accumulation by aquatic organisms from water only, BAFs are considered to be better predictors of chemical accumulation by fish and shellfish for chemicals where exposure from food and sediment is important (*e.g.*, highly persistent, hydrophobic chemicals).
- EPA gives preference to the use of high quality field data over laboratory or model-derived estimates of BAFs, since field data best reflect factors that can affect the extent of bioaccumlation (*e.g.*, chemical metabolism, food web structure).

G. How Will EPA Use the Human Health Methodology?

Our future role in developing AWQC for the protection of human health will include the following.

- Further refinement of the Methodology as the science and EPA's science policies evolve;
- Development of revised AWQC for pollutants of high priority and national importance (including, but not limited to chemicals that bioaccumulate, such as PCBs, dioxin, and mercury); and
- Development or revision of AWQC for some additional priority pollutants.

We plan to fully update the most environmentally important criteria developed in 1980 (or those updated as part of the 1992 National Toxics Rule (NTR)). Partial updates of substantially more criteria may be warranted. We encourage States and authorized Tribes to use the 2000 Human Health Methodology to develop or revise AWQC to reflect local conditions. EPA believes that AWQC inherently require several risk management decisions that are, in many cases, better made at the State or Tribal level (*e.g.*, selection of specific fish consumption rates or target risk levels). We will continue to develop and update necessary toxicology and exposure data needed for the derivation of AWQC that may not be practical for the States or Tribes to obtain. More information on implementation issues and the effect of the 2000 Human Health Methodology on States and authorized Tribes is discussed below.

II. Implementation Issues

Water quality standards consist of designated uses, water quality criteria to protect those uses, a policy for antidegradation, and general policies for application and implementation. As part of the water quality standards triennial review process defined in section 303(c)(1) of the CWA, States and authorized Tribes are responsible for maintaining and revising water quality standards. Section 303(c)(1) requires States and authorized Tribes to review, and modify if appropriate, their water quality standards at least once every three years.

A. How Does EPA Use Its Recommended 304(a) Water Quality Criteria?

EPA's recommended 304(a) water quality criteria form the basis for Agency decisions, both regulatory and nonregulatory, until superseded by EPA publication of new or revised 304(a) water quality criteria. For example, these criteria are used in the following ways: (1) As guidance to States and authorized Tribes in adopting water quality standards; (2) as guidance to EPA in promulgating Federal water quality standards; (3) in establishing National Pollutant Discharge Elimination System (NPDES) water quality-based permit limits, where the criteria have been adopted by a State or authorized Tribe or promulgated by EPA; and (4) for all other purposes of Section 304(a) criteria under the Act. It is important to emphasize again two distinct purposes which are served by the 304(a) criteria. The first is as guidance to the States and Tribes in the development and adoption of water quality criteria which will protect designated uses. The second is as the basis for promulgation of Federal water

quality standards for States or authorized Tribes when such action is necessary.

B. What Water Quality Criteria Must a State or Authorized Tribe Adopt Into Its Water Quality Standards?

States and authorized Tribes must adopt water quality criteria that protect designated uses. Such criteria must be based on sound scientific rationale and must contain sufficient parameters or components to protect the designated uses. Criteria may be expressed in either narrative or numeric form. States and authorized Tribes have four options when adopting water quality criteria for which EPA has published 304(a) criteria. They can establish numerical values based on 304(a) criteria, 304(a) criteria modified to reflect site-specific conditions, other scientifically defensible methods, or establish narrative criteria where numeric criteria cannot be determined. (See 40 CFR 131.11.)

EPA's recommended 304(a) water quality criteria for States and authorized Tribes to use as guidance in adopting water quality standards consistent with Section 303(c) of the Act and the implementing Federal regulations at 40 CFR part 131 are contained in EPA's last compilation of National Recommended Water Quality Criteria (USEPA, 1998e) (corrected in USEPA, 1999c). In the future, we will be publishing new and revised 304(a) water quality criteria based upon the 2000 Human Health Methodology for pollutants of high priority and national importance. Because the revision of existing 304(a) human health criteria to reflect the 2000 Human Health Methodology will take time, EPA encourages States and authorized Tribes to make appropriate changes to their existing numerical, pollutant-specific criteria in their water quality standards to reflect this new Methodology prior to publication of a revised 304(a) criteria where they determine that such actions are necessary. For example, a pollutant of concern in a particular State may not be a high priority on the national level and revision of the national 304(a) criteria may not occur for several years. In this case, the State or a group of States, might choose to use this new Methodology to revise their water quality standards prior to EPA publication of a revised 304(a) criteria for that pollutant. EPA will recognize criteria that are revised pursuant to the 2000 Human Health Methodology as scientifically defensible and promptly approve such revised criteria as enforceable elements of State or Tribal water quality standards.

Once a new or revised 304(a) criteria reflecting this new Methodology is published, EPA expects States and authorized Tribes to reassess their water quality standards and, where necessary, establish new or revised water quality criteria consistent with one of the four options described above. Because of the critical role that human health ambient water quality criteria play in protecting human health, EPA will work with States and authorized Tribes to revise existing water quality standards promptly following EPA publication of revised section 304(a) criteria.

C. May States and Authorized Tribes Adopt Water Quality Criteria Based on Local Conditions?

In keeping with their primary responsibility in establishing water quality standards, we encourage States and authorized Tribes to develop and adopt water quality criteria to reflect local and regional conditions. States and authorized Tribes will have access to EPA regional, laboratory, and headquarters staff when help is needed to interpret today's Human Health Methodology and to make critical risk assessment decisions. For the purpose of deriving criteria based on the 2000 Human Health Methodology, EPA is publishing default values for risk level, fish intake, drinking water intake, and body weight. Default BAF values and RSC factor values will be published as chemical-specific criteria are developed or revised. (Other RSC estimates will be made when data are adequate to make them.) We believe these default values result in water quality criteria protective of the general population, and we will use these values when deriving 304(a) criteria. States and authorized Tribes may use other values more representative of local conditions if data have been collected supporting the alternative values. However, when establishing a numerical value based on a 304(a) criterion modified to reflect site-specific conditions, or water quality criteria based on other scientifically defensible methods, we strongly caution States and authorized Tribes not to selectively apply data in order to ensure water quality criteria less stringent than EPA's 304(a) criteria. Such an approach would inaccurately characterize risk.

D. What Cancer Risk Level Should States and Authorized Tribes Use When Establishing Water Quality Criteria?

In deriving 304(a) criteria based on the 2000 Human Health Methodology or when promulgating Federal water quality standards under section 303(c) of the CWA, EPA intends to use a 10^{-61} cancer risk level, which we believe reflects an appropriate target risk level for the general population. EPA acknowledges that at any given cancer risk level for the general population, those segments of the population that are more highly exposed face a higher relative risk. For example, if fish are contaminated at a level allowed by criteria derived on the basis of a risk level of 10^{-6}, individuals consuming up to 10 times the assumed fish consumption rate would still be protected at a 10^{-5} risk level. States and authorized Tribes have the flexibility to adopt water quality criteria that result in a risk level higher than 10^{-6}, up to the 10^{-5} level. EPA recommends adoption of such criteria if the State or Tribe has identified the most highly exposed subpopulation within the State or Tribe, has demonstrated that the chosen cancer risk level is protective of the most highly exposed subpopulations, and has completed all necessary public participation. EPA notes that special scientific circumstances and assessment of natural contaminants may lead to numbers outside the 10^{-6} to 10^{-5} risk range. (For additional discussion on this issue, including restrictions on selection of a cancer risk level, refer to the response on the comment for cancer risk ranges summarized in Section III of this Notice, below.)

E. How Does the Review and Approval of State and Tribal Water Quality Standards Rule Affect Water Quality Criteria Adopted by States and Authorized Tribes?

Consistent with the Review and Approval of State and Tribal Water Quality Standards rule revision (USEPA, 2000a), water quality criteria adopted into law or regulation by States and authorized Tribes prior to May 30, 2000, are in effect for CWA purposes unless superseded by replacement Federal water quality standards (see, for example, the National Toxics Rule, 40 CFR 131.35; Water Quality Standards for Idaho, 40 CFR 131.35). Water quality criteria adopted into law or regulation by States and authorized Tribes after May 30, 2000, are in effect for CWA purposes only after EPA approval of any new or revised water quality standards.

F. While EPA is Re-Evaluating a 304(a) Criterion, What Criterion Is in Effect?

Until such time as EPA reevaluates the 304(a) criteria, subjects the criteria to appropriate peer review, and subsequently publishes revised 304(a) criteria, the existing 304(a) criteria remain in effect for the purposes of EPA review of State and Tribal water quality standards under section 303(c). Where EPA has not published a revision of a

304(a) criteria reflecting the 2000 Human Health Methodology, EPA will not require the revision of State water quality standards to reflect this new Methodology. As noted above, however, EPA will assist those States or Tribes that choose to use the new Methodology to revise their existing water quality standards prior to publication of a revised criteria under section 304(a).

G. What Design Stream Flow Should Be Used to Implement Human Health Criteria?

Human health criteria represent ambient pollutant concentrations that are acceptable based on a lifetime (70 years) of exposure. Accordingly, discharges of pollutants should be regulated such that criteria will not be exceeded under stream conditions that represent long-term average conditions. Current EPA guidance recommends the use of the long-term harmonic mean flow to implement criteria for carcinogens and the 30Q5 flow to implement criteria for noncarcinogens (USEPA, 1991b). The harmonic mean flow is the sum of the reciprocals of individual flow measurements divided into the total number of individual flow measurements, and the 30Q5 flow is defined by the lowest 30-day average that has an expected return frequency of once every five years. With today's Human Health Methodology, EPA is revising its guidance to recommend harmonic mean flow be used to implement both carcinogen and noncarcinogen human health criteria. Harmonic mean flow should be used to implement human health criteria because, by and large, human health criteria are designed to protect an individual over a lifetime of exposure. As stated in the 1998 draft Methodology revisions, we are not recommending the development of additional water quality criteria similar to the drinking water health advisories that focus on acute or short-term effects. These are not seen as routinely having a meaningful role in the water quality criteria and standards program because the chronic health effects associated with chemical contaminants are usually the most sensitive health endpoint. Human health criteria based on cancer potencies and risk levels are based on models that extrapolate animal data to a human lifetime. Similarly, a human noncancer criterion is based on an RfD, which is an acceptable daily exposure over a lifetime. Therefore, we have attempted to match the longest stream flow averaging period (using harmonic mean) with the criterion which is protective over a human lifetime.

In rare instances where a human health criterion or value is based on a short-term toxicological effect (*i.e.*, the critical effect upon which the criterion/value is based is significantly less than lifetime and may be an acute effect), the design flow should be adjusted accordingly. This does not pertain to RfDs in which a short-term study has been used as the RfD basis and an uncertainty factor has been used to account for less than lifetime study results; that is, the short-term study has been used to estimate a lifetime RfD value. This pertains only to those situations where the critical effect is a short-term effect (and where no additional uncertainty factor has been used to account for less than lifetime exposure). A good example of this is EPA's RfD for nitrate. The critical effect, upon which the RfD is based, is toxicity to infants after a short-term exposure. In this case, harmonic mean flow would be an inappropriate design flow for such a short-term effect. In this case, a 7Q10 or a 4Q3 design flow may be more appropriate.

H. What Is the Relationship Between the Agency's Recommended Section 304(a) Water Quality Criteria and Drinking Water Standards?

EPA recommends that States and authorized Tribes use this 2000 Human Health Methodology to develop their own AWQC for all pollutants of concern using the latest scientifically defensible data and principles. Sources of scientifically defensible data include published toxicological literature or recent EPA assessments, including those that underlie IRIS values, the most recently published recommended Section 304(a) water quality criteria or the most recently promulgated SDWA MCLGs.

When adopting water quality criteria to protect CWA Section 101(a) fishable uses, States and authorized Tribes need to ensure such criteria adequately address fish consumption as an exposure route.

When States and authorized Tribes do not develop their own AWQC, EPA recommends that States and authorized Tribes use the most recently published recommended Section 304(a) water quality criteria for ''water and organisms'' based on this new Human Health Methodology to protect CWA Section 101(a) fishable uses and waters designated for drinking water. This ensures that the water quality criteria adequately address fish consumption, bioaccumulation and drinking water uses.

When EPA publishes the annual compilation of new and revised national recommended Section 304(a) water quality criteria, those criteria represent the Agency's most current recommended Section 304(a) water quality criteria and should be used by States and authorized Tribes when reviewing their water quality standards.

When States and authorized Tribes do not develop their own AWQC, and there are no recommended Section 304(a) water quality criteria for a pollutant of concern, or the recommended Section 304(a) water quality criteria have not yet been revised based on this new Human Health Methodology [1]:

1. For a pollutant for which EPA has published a recommended Section 304(a) water quality criterion for ''water and organisms'' based on the 1980 Methodology and for which EPA has not promulgated an MCLG, EPA will recognize the current Section 304(a) water quality criterion, or a criterion that is developed or revised pursuant to the 2000 Human Health Methodology and approved by EPA.

2. For a pollutant for which EPA has published a recommended Section 304(a) water quality criterion for ''water and organisms'' based on the 1980 Methodology and for which EPA has more recently promulgated an MCLG, EPA generally recommends the MCLG for noncarcinogenic pollutants, or a criterion derived by recalculating the MCLG at an acceptable cancer risk level (*i.e.*, a level within the range of 10^{-6} to 10^{-5}, as specifically discussed in Section II.D, which notes that special scientific circumstances and assessment of natural contaminants may lead to numbers outside the to 10^{-6} to 10^{-5} risk range).

3. For a pollutant for which EPA has not published a recommended Section 304(a) water quality criterion for ''water and organisms'' and for which EPA has promulgated an MCLG, EPA generally recommends the MCLG for noncarcinogenic pollutants, or a criterion derived by recalculating the MCLG at an acceptable cancer risk level (*i.e.*, a level within the range of 10^{-6} to 10^{-5}, as specifically discussed in Section II.D, which notes that special scientific circumstances and assessment of natural contaminants may lead to numbers outside the 10^{-6} to 10^{-5} risk range).

EPA no longer recommends that an MCL be used where consideration of available treatment technology, costs, or availability of analytical methodologies

[1] New criteria and criteria revised under this new Methodology are published annually as the ''Compilation of National Recommended Water Quality Criteria and EPA's Process for Deriving New and Revised Criteria'' at www.epa.gov/ost/standards/.

has resulted in an MCL that is less protective than an MCLG.

States and authorized Tribes continue to have the flexibility to adopt water quality criteria that are more protective than EPA's recommendations, as long as such criteria are protective of the designated uses and scientifically defensible.

I. How Are Health Risks to Children Considered in the Methodology?

In recognition that children have a special vulnerability to many toxic substances, EPA's Administrator directed the Agency in 1995 to explicitly and consistently take into account environmental health risks to infants and children in all risk assessments, risk characterizations and public health standards set for the United States. On April 21, 1997, President Clinton signed Executive Order 13045, ''Protection of Children From Environmental Health Risks and Safety Risks,'' which assigned a high priority to addressing risks to children. In May 1997, EPA established the Office of Children's Health Protection to ensure the implementation of the President's Executive Order (E.O.). Circumstances where risks to children should be considered in the context of the 2000 Human Health Methodology are discussed in the Noncancer Section (in terms of developmental and reproductive toxicity) and in the Exposure Section (for appropriate exposure intake parameters).

All of EPA's risk assessment guidelines should be consulted when conducting a risk assessment to ensure that information from studies on carcinogenesis and other health effects are considered together in the overall characterization of risk. This is particularly important in the case in which a precursor effect to tumor is also a precursor or endpoint of other health effects and is used in dose-response assessment. The overall characterization of risk will be the basis for carrying out assessments of instances in which fetuses, infants, or children are at risk.

III. Summary of Comments Received on the 1998 Draft Methodology Revisions and EPA's Responses

A. Implementation

1. Application of Human Health Water Criteria Within Mixing Zones

C*omments*—Commenters stated that human health criteria should start with the local relevant fish consumption rates and then make adjustments to reflect the actual relevant fish consumption rate related to the discharge and the mixing zone. It was also suggested that implementation in the NPDES program inherently needs a translator mechanism to adjust the standards to reflect actual consumption associated with allowed mixing zones.

Response—Application of human health water criteria within a mixing zone is not within the scope of this Methodology. At this time, EPA's current recommendations regarding the application of human health criteria within mixing zones are contained in the Technical Support Document for Water Quality-Based Toxics Control (USEPA, 1991b) and the Water Quality Standards Handbook (USEPA, 1994). We also note that mixing zones are an optional policy that not every State and authorized Tribe has adopted into their water quality standards. For States and Tribes that have authorized mixing zones, the designated uses of a waterbody as a whole must be maintained and protected.

2. Application of Human Health Water Quality Criteria to Marine Waters

Comment—A question was raised as to whether human health water quality criteria are applicable to marine waters, given the vastness of most marine waters.

Response—EPA believes human health water quality criteria should be applied to near-shore waters (specifically within a three-mile limit) wherever dischargers are located to protect aquatic food organisms, but not to include the drinking water consumption parameter. These water quality criteria are then used to derive permit limits that will ensure water quality criteria are not exceeded within the vicinity of an outfall. This protects organisms that are sessile and other organisms that may be attracted to the effluent and that are food sources. In the absence of data specific to the coastal site indicating that particular marine species are impacted by those discharges, we recommend our human health criteria to protect coastal waters. [Note: EPA's recommended national default fish intake value, which excludes marine species, supports this position. Estuarine species that are more likely to be found in near-shore waters are included in the default intake value. Potential exposure from open-ocean marine species are not ignored; the marine species exposure pathway can be accounted for as part of the RSC factor.]

3. Cancer Risk Range

Comments—Many comments were received on the appropriateness of the cancer risk range. Numerous commenters stated that the permissible range and recommended default of 10^{-6} are appropriate and approved of the range's consistency with other Agency programs. EPA was asked to reconcile the statements that both 10^{-6} and 10^{-5} are acceptable for the general population, that 10^{-6} is appropriate for promulgation of Federal water quality standards under Section 303(c) given that we have said 10^{-5} is appropriate for the Great Lakes, and that a 10^{-5} risk level along with a 17.8 g/day fish intake assumption will protect the highest consumers at a 10^{-4} risk level. Other comments are listed as follows.

- The Methodology should use a 10^{-5} risk level.
- 10^{-6} represents a change in the acceptable risk level.
- The 10^{-6} risk level represents a binding regulatory constraint that will provide no State flexibility.
- 10^{-5} is used by most States, and EPA should retain this default because the Agency has not determined that it is inadequate.
- A range of 10^{-4} to 10^{-5} is advocated.

In addition, we received comments that allowing highly exposed groups to potentially experience cancer risks an order of magnitude higher than the general population is unjust and disregards Native American treaty rights. A commenter supported the idea that a 10^{-4} risk level can be protective and believed highly exposed populations are few in number. Another stated that the cancer risk range should apply to total contaminants (*i.e.*, a cumulative cancer risk ceiling). It was cautioned that the concept of relative risk could result in selection of inappropriate target populations and intake rates. Others agreed that States and authorized Tribes should have the flexibility to select cancer risk levels as risk management decisions and requested that EPA explicitly state that it will support risk levels chosen by a Tribal authority, while another requested the flexibility without requiring involved demonstrations specific to the subpopulation at issue. A commenter recommended changes in EPA's Methodology to ensure that the resulting water quality criteria are more applicable to exposed populations. Others asked EPA to indicate the percentile of the exposed population that would meet the 10^{-6} risk level.

Response—With the 1980 Methodology, EPA presented three separate 304(a) criteria for carcinogens at risk levels corresponding to 10^{-7}, 10^{-6}, and 10^{-5} for States and authorized Tribes to choose from. However, the 10^{-7} risk level has not been used by any State or authorized

Tribe when adopting water quality standards. Furthermore, since that time, EPA's guidance and regulatory actions have utilized a 10^{-6} risk level as an appropriate target risk for the general population.

With the 2000 Human Health Methodology, our position is that both 10^{-6} and 10^{-5} are appropriate targets for health protection of the general population and that highly exposed populations should not exceed a 10^{-4} risk level. We also note that special scientific circumstances and assessment of natural contaminants may lead to numbers outside the 10^{-6} to 10^{-5} range. However, we are not automatically assuming that 10^{-5} will protect ''the highest consumers'' at the 10^{-4} risk level. One commenter referred to specific data indicating high intake levels that would not satisfy such an assumption. Nor are we advocating that States and authorized Tribes automatically establish criteria based on assumptions for highly exposed population groups at the 10^{-4} risk level. We acknowledge that fish consumption rates vary considerably, especially among subsistence populations, as is evident from the studies summarized in the Exposure TSD. Indeed, it is the variation of fish consumption among these population groups that could make either 10^{-5} or 10^{-6} protective of those groups at a 10^{-4} risk level. Specifically, if a State adopted a criterion based on a 10^{-5} risk level and a 17.5 g/day consumption rate, a high-end subsistence consumption of 1,750 g/day would exceed a 10^{-4} risk level.

It is important to understand that criteria for carcinogens are based on chosen risk levels that inherently reflect, in part, the exposure parameters used to derive those values. Therefore, changing the exposure parameters will also change the risk. Specifically, the incremental cancer risk levels are *relative*, meaning that any given criterion associated with a particular cancer risk level is also associated with specific exposure parameter assumptions (*i.e.,* intake rates, body weights). When these exposure values change, so does the relative risk. As we have previously indicated for a criterion derived on the basis of a cancer risk level of 10^{-6}, individuals consuming up to 10 times the assumed fish intake rate would not exceed a 10^{-5} risk level. Similarly, individuals consuming up to 100 times the assumed rate would not exceed a 10^{-4} risk level. Thus, for a criterion based on EPA's default fish intake rate (now 17.5 g/day, based on the most recent survey data) and a risk level of 10^{-6}, those consuming a pound of fish per day would potentially experience between a 10^{-5} and a 10^{-4} risk level (closer to a 10^{-5} risk level). Even if a criterion were based on high-end intake rates and the relative risk of 10^{-6}, then an average fish consumer would not exceed a cancer risk level of approximately 10^{-8}. The point here is that the risks for different population groups are not the same.

EPA believes that the adoption of a 10^{-6} or 10^{-5} target risk level, both of which States and authorized Tribes have historically chosen, represents a generally acceptable health protection decision, noting again that special scientific circumstances or assessments of natural contaminants may necessitate additional considerations. EPA recommends adoption of water quality standards that include water quality criteria based on either the 10^{-5} or 10^{-6} risk level if the State or authorized Tribe has identified the most highly exposed subpopulation, has demonstrated that the chosen risk level is adequately protective of the most highly exposed subpopulation, and has completed all necessary public participation. States and authorized Tribes also have flexibility in how they demonstrate this protectiveness and obtain such information. A State or authorized Tribe may use existing information as well as collect new information in making its determination as to an appropriate level of protection. In addition, if a State or authorized Tribe does not believe that the 10^{-6} risk level adequately protects highly exposed subpopulations, water quality criteria based on a more stringent risk level may be adopted. However, we are now adding that a generally specific analysis should be made and presented to ensure that highly exposed groups do not exceed a target 10^{-4} risk level. In cases where fish consumption among highly exposed population groups is of a magnitude that such a 10^{-4} risk level would be exceeded, a more protective risk level should be chosen. These determinations should be made by the State or authorized Tribe and are subject to EPA's review under Section 303 of the CWA. Guidance on choosing appropriate exposure parameters is discussed in both the 2000 Human Health Methodology and the Exposure Assessment TSD.

Given the relatively significant variation in fish consumption rates, EPA intends to derive Section 304(a) criteria at the 10^{-6} risk level, based on an intake rate of 17.5 g/day. We believe that basing our 304(a) criteria on general U.S. population exposures is most appropriate, given their use as a default value for the nation as a whole. Most States have, in fact, already adopted a 10^{-6} risk level with their criteria for carcinogens, not the 10^{-5} risk level claimed by one commenter. This default would, in turn, be protective for fish intakes of up to 1,750 g/day at the 10^{-4} risk level. However, in the Exposure Assessment TSD, EPA has recommended that States and authorized Tribes give priority to identifying and adequately protecting the most highly exposed population by adopting more stringent criteria, if the State or authorized Tribe determines that the highly exposed population would not be adequately protected by criteria based on protecting the general population. States and authorized Tribes have the option to derive their criteria at a 10^{-6} risk level, as EPA will do with its 304(a) criteria. They also have the flexibility to combine the 10^{-6} risk level with fish consumption rates for highly exposed population groups. Thus, States and authorized Tribes may choose to adopt criteria that are more protective than EPA's 304(a) criteria. We intend to support the health protection decisions made by States and authorized Tribes as long as they use the risk range that EPA has stated here and in the 2000 Human Health Methodology. EPA has made reasonable and conservative assumptions in choosing exposure parameters with the goal of protecting the majority of the population. However, we do not believe it is possible to calculate the exact percentile of the population that would be protected at a given risk level in terms of the overall combination of exposure parameters. We emphasize that the criteria are derived to be protective, not predictive of an exact percentile of the total population that is protected.

Regarding the use of a 10^{-5} risk level in the Great Lakes Water Quality Initiative (GLI), the criteria values were based on fish consumption estimates that reflected intake data among sportfishers, a group that consumes more fish than the general population. Again, we recommend that States and authorized Tribes base their criteria on more highly exposed population groups, if they would not be adequately protected by criteria based on intake rate estimates for the general population. Regarding the application of a cumulative cancer ceiling, the commenter has misunderstood EPA's policy when setting 304(a) criteria for carcinogenic effects based on linear low-dose extrapolation. With these carcinogens, the AWQC are set with respect to the incremental lifetime risk posed by the substance in water and are

not being set on an individual's total cancer risk from all sources of exposure.

4. Coordinating the Human Health Methodology With Other EPA Programs

Comments—Numerous commenters recommended that the Methodology revisions be coordinated with the drinking water program (specifically, MCLs/MCLGs required under the SDWA) and believed that the drinking water portion of AWQC and MCLGs should be equivalent. Several commenters stated that the burden of achieving health goals should be borne by dischargers and other polluters, not by water users or the environment. Commenters also recommended that EPA use MCLs when AWQC are less protective or for chemicals when AWQC do not exist. Another recommended that an additional margin of safety be included if the MCL were used, in particular for chemicals not effectively removed by conventional drinking water treatment, and also stated that neither the availability of MCLs or MCLGs should deter development of AWQC. Some commenters believed that the use of an MCLG is an acceptable alternative for chemicals of drinking water concern because, like the AWQC, it is a health-based value. However, others recommended that MCLGs not be used when they are more stringent than AWQC because they are not regulatory standards. Two commenters stated that EPA should not abandon its policy of setting AWQC for carcinogens at zero for ''maximum protection of human health'' and recommended that the ''Group C'' chemicals also have AWQC set at zero (referring to non-zero MCLs as inconsistent with the intent of a zero MCLG). However, other commenters recommended that AWQC be set at one-half of the MCL when the MCLG is zero, at a 10^{-6} risk level, or by calculating both and choosing the lower of the two. Two commenters urged EPA to unify the national Human Health Methodology with the GLI guidance. Another discussed microbial pathogens and, in addition to recommending development of criteria for specific microbial contaminants, recommended coordination with the drinking water program [i.e., the SDWA's Candidate Chemical List (CCL)] and stated that microbial criteria need to be set for more than recreational waters.

Response—EPA intends to continue deriving AWQC that include a drinking water pathway, applicable to waters that are potential sources of drinking water, and agrees that the drinking water component of AWQC should be consistent with the MCLG (if one has been established). Therefore, we intend to use a similar methodology for deriving AWQC and MCLGs. We also intend to coordinate with the Agency's safe drinking water program when prioritizing chemicals for AWQC derivation/revision (see also response to Comment A.11, Proposed Chemical List). Regarding the relationship between AWQC and the drinking water MCLs and MCLGs, we have clearly stated our position in the **Federal Register** Notice for the 1998 draft Methodology revisions (USEPA, 1998c) on this relationship and our approach to considering when an MCL or MCLG may be appropriate to use in lieu of AWQC. That discussion is excerpted in the 2000 Human Health Methodology document, along with clarification of our policy on the circumstances and limitations under which either should be used. We do not necessarily assume that a chemical's concentrations in ambient waters and drinking water are equivalent but are aware that chemicals may not be effectively removed by conventional drinking water treatment.

Commenters who referred to EPA's abandonment of its policy of setting AWQC for carcinogens at zero have substantively misstated our policy based on both the 1980 Methodology for deriving AWQC and our 1998 draft Methodology revisions, and are directed to the **Federal Register** Notice cited above. We did state in our 1980 Methodology that for the maximum protection of human health from potential carcinogenic effects, the ambient water concentration should be zero, based on an assumption of a linear dose-response relationship at low doses. The 1980 Methodology also indicated that zero levels may not have been attainable at that time. This remains the case at present. The combination of background levels of carcinogens from natural sources and global background levels from anthropogenic sources make attainment of zero levels for many potential carcinogens impossible. In addition, more recent and sophisticated toxicological information on carcinogenicity suggests modes of action for carcinogens that would lead to nonlinear low-dose extrapolation. Note that the 1980 Methodology preceded the Agency's original 1986 cancer guidelines, which are now being revised. We are maintaining our policy to derive AWQC for carcinogens to correspond to incremental lifetime cancer risk levels, applying a risk management policy that ensures a reasonable level of protection for the general population.

When EPA developed the methodology to derive human health criteria for the waters of the Great Lakes System, the Agency was mindful of the need for consistency with the planned changes in the Human Health Methodology presented today for deriving national AWQC for the protection of human health. Throughout the 1998 draft Methodology revisions, references were made to comparisons of the two methodologies, especially whenever differences occur due to regional exposure assumptions made for the Great Lakes System. The GLI guidance consisted of water quality criteria, detailed methodologies to develop criteria for additional pollutants, implementation procedures, and antidegradation policies and procedures tailored to the Great Lakes system; these reflected the unique nature of the Great Lakes ecosystem. Those States and authorized Tribes are to use the GLI methodology to establish criteria for the waters of the Great Lakes system, which allows appropriate flexibility to States and authorized Tribes to develop equitable strategies to control pollution sources and to promote pollution prevention practices. The 2000 Human Health Methodology is undertaken pursuant to Section 304 of the CWA, and is independent of, and does not supersede, the GLI. Although consistency in State water quality standards programs is an important goal for EPA, we also recognize that it is necessary to provide appropriate flexibility to States and Tribes, both Great Lakes States and non-Great Lakes States, in the development and implementation of place-based water quality programs. Recognition of a general need for flexibility is not incompatible with the requirements for the Great Lakes States and Tribes established in Section 118(c)(2) of the CWA. We have harmonized the two, where appropriate, while maintaining parameters and provisions that are appropriate for Great Lakes-specific criteria.

EPA has identified development of microbial water quality criteria as part of its strategy to control waterborne microbial disease, by controlling pathogens in waterbodies and by protecting designated uses, such as recreation and public water supplies. The program fosters an integrated approach in order to protect both ground-water and surface water sources. EPA plans to conduct additional monitoring for *Cryptosporidium parvum and Escherichia coli*, and determine action plans in accordance with the results of this monitoring.

5. Designated Uses

Comments—Commenters indicated that designated uses for waterbodies

that cross State boundaries and that fail to take into account downstream uses may effectively prohibit downstream waters from being used as a water supply; the AWQC should reflect the use of a waterbody as a drinking water source unless the use patterns of the entire waterbody indicate that this is not a current or future possibility.

Response—EPA regulations at 40 CFR 131.10(b) state:

> In designating uses of a water body and the appropriate criteria for those uses, the State shall take into consideration the water quality standards of downstream waters and shall ensure that its water quality standards provide for the attainment and maintenance of the water quality standards of downstream waters.

We believe this requirement is sufficient to address the concerns raised by the commenter and to ensure downstream uses are maintained and protected.

6. Developing National 304(a) Criteria

Comments—Commenters stated that EPA should not derive national 304(a) AWQC and stated their preference for regional measurements, and that national 304(a) criteria could be overly stringent or underprotective from State to State. Instead, they recommended that EPA simply provide specific ''algorithms'' to force States to develop their own criteria. However, they also said that EPA should develop a single criterion for each chemical based on the most relevant toxic endpoint and appropriate target population. A commenter recommended that EPA develop criteria for both cancer and noncancer endpoints because their comparative protectiveness may not be clear until permit limit design flows are determined. Another commenter stated that relying on default parameter values would inhibit the process for developing criteria/implementing standards because the regulated community will not accept such criteria. Two commenters stated that the amount of information on adverse impacts to water quality, fish, birds, wildlife, and human health warrants regulatory action to eliminate those toxicants. They recommended that EPA include all biotic pathways using the water source, including wildlife and plant life, and advocated protecting cultural and religious uses. A commenter stated that limited information exists for development of criteria in arid regions and that resources would be better spent gaining knowledge on the impacts of chemicals in regional watersheds. Another questioned how AWQC can be derived when ambient levels are below analytical detection limits. Several commenters supported the derivation of fish tissue criteria.

Response—Section 304(a) of the CWA requires EPA to develop national water quality criteria recommendations for States and authorized Tribes to use as guidance in adopting water quality standards. It is not an option for EPA to ignore this requirement. As such, the national 304(a) criteria that EPA periodically publishes are generally applicable to the nation's waters. Although we encourage States and authorized Tribes to use the Methodology to develop criteria based on local/regional information and believe that water quality criteria reflecting such local conditions are desirable, we have not abandoned our obligations under the CWA. The commenter should be aware that States have adopted EPA's recommended 304(a) criteria. Furthermore, in contrast to another commenter's suggestion, under the CWA, 304(a) criteria are not enforceable regulations; these criteria are guidance and do not impose legally binding requirements.

States and Tribes always have the option to undertake their own evaluations to develop water quality criteria, as long as such criteria are consistent with the CWA and the implementing Federal regulations. States have derived water quality criteria for their waters in the absence of EPA guidance and may continue to do so. However, the recommended criteria serve as guidance to States and authorized Tribes, and EPA cannot force States or Tribes to conduct their own evaluations. We are well aware that the resources and expertise within States and Tribal authorities vary greatly and, while encouraging them to pursue their own criteria development programs, we anticipate that many will continue to rely on our expertise and recommended 304(a) criteria. We included guidance on site-specific modifications for States and authorized Tribes to derive their own water quality criteria and will expand this information as part of the TSD volumes for the 2000 Human Health Methodology.

Although we have provided numerous default parameter values for different population groups, we intend to derive or revise AWQC based on the most sensitive health endpoint and the population group most relevant for that endpoint. Regarding measurable levels of chemicals in the water column, the CWA clearly states that limitations in analytical methods will not be considered when deriving AWQC. Rather, the AWQC represent health-based considerations only. However, analytical method limitations are taken into account in the implementation of water quality standards. We believe that deriving AWQC based on fish tissue concentrations may be appropriate in some instances to overcome this problem when there is a health concern for that chemical (for greater discussion of fish tissue criteria, see response to Comment F.7). Regarding cancer versus noncancer endpoints, it is EPA policy to develop criteria for the most sensitive endpoint in order to be protective of both potentially relevant cancer and noncancer effects. EPA intends to continue this practice. Regarding design flows, see the response on this issue under Comment A.9. Finally, these Methodology revisions apply to the protection of human health only. Other EPA efforts to develop methods and criteria for the protection of birds or other wildlife are not part of this guidance and will not be addressed here. Considerations such as religious or cultural uses cannot be quantitatively factored into the AWQC equation for setting pollutant criteria values.

7. Developing Organoleptic Criteria

Comments—Commenters suggested that EPA should provide guidance for States to develop organoleptic criteria for ambient waters that are sources of drinking water, and develop specific organoleptic criteria. Taste and odor are strongly associated with consumer perceptions and confidence in water quality. They suggested that EPA should provide organoleptic criteria and allow States to make decisions about their use. Others stated that organoleptic criteria should not be developed because they are not relevant to protection of human health and because they should only be considered for drinking water standards.

Response—The 2000 Human Health Methodology is focused on deriving toxicity-based criteria because they, not organoleptic criteria, are directly related to potential adverse human health effects. We have received much support for our position on this issue since initiating the Methodology revisions. EPA acknowledges that if organoleptic effects (*i.e.,* objectionable taste and odor) cause people to reject the water and its designated uses, then the public is effectively deprived of the natural resource. EPA encourages the development of organoleptic criteria when States and Tribes believe they are needed to protect designated uses and have indicated this in the 2000 Human Health Methodology.

8. Establishing EPA's Most Recent Federally Recommended Water Quality Criteria

Comment—A commenter stated that the proposed California Toxics Rule (CTR) established EPA's most recent federally recommended water quality criteria, and because EPA did not propose to promulgate arsenic in the CTR, there is no federally recommended water quality criterion for arsenic.

Response—With regard to arsenic and the Agency's policy on applicable 304(a) criteria, EPA clearly stated in the 1998 draft Methodology revisions that until such time as the Agency re-evaluates a chemical and subsequently publishes revised chemical-specific 304(a) criteria, the existing criteria remain in effect. Although the 2000 Human Health Methodology represents improvements to the 1980 Methodology, EPA believes that the existing 304(a) criteria are fundamentally sound from a scientific standpoint. We have long supported this position. Our recommended water quality criterion for arsenic remains the value published in EPA's Goldbook in 1986 (USEPA, 1986d) and promulgated in 1992 as part of the NTR. Federal promulgations for individual States take into account the needs of the individual State and site-specific conditions of waterbodies within the State. Federally promulgated water quality standards for a State may not always result in water quality criteria that are nationally applicable. We understand there has been some confusion regarding the current recommended water quality criteria in light of State-specific promulgations, and as a result, in 1998, we published National Recommended Water Quality Criteria (USEPA, 1998b) to clarify our national recommendations. This list will be updated approximately on an annual basis to contain our most current recommended water quality criteria for States and authorized Tribes to use as guidance in adopting water quality standards.

9. Flows

Comment—Comments received suggested that EPA should adequately consider and account for regional differences, such as highly variable flows, lower exposures, and lack of fish habitat due to no-flow conditions in many Southwestern washes (*i.e.*, waterbody flow only following a storm event).

Response—EPA believes there is sufficient flexibility in the current regulatory program for States to modify designated uses and water quality criteria to protect those uses to address the conditions that exist in waterbodies such as intermittent streams and washes. Modifications to the water quality standards program are unwarranted at this time.

10. Implementation on a Waterbody Basis

Comment—Commenters stated that human health criteria should be met within the waterbody on a long-term average basis instead of short-term maximums never to be exceeded. It was recommended that States be able and even encouraged to develop site-specific standards for waterbodies to reflect relevant fish consumption rates.

Response—The 2000 Human Health Methodology incorporates long-term exposure into the development of water quality criteria. Determination of when human health criteria are met within the waterbody is beyond the scope of this document. However, EPA guidance addresses this issue (USEPA, 1991b). We recommend harmonic mean flow to calculate permit limits and taking the geometric mean of ambient water samples to determine attainment. Both of these recommendations account for the long-term exposure effects of chemical water quality criteria.

EPA recommends that States develop site-specific water quality criteria to reflect relevant fish consumption rates. We have published default fish consumption rates in the Methodology as recommendations to States and Tribes in adopting water quality standards when a State or Tribe lacks information on local fish consumption rates. EPA's preference, however, is that States and Tribes adopt human health criteria reflecting local fish consumption rates.

11. Proposed Chemical List

Comments—Commenters suggested that EPA integrate the AWQC prioritization process with the drinking water program (*i.e.,* with the Candidate Contaminant List). Other comments suggested that EPA's short list of pollutants (for revision) would result in a greater burden for States that will need to develop more criteria. EPA was asked to strengthen efforts to develop criteria for persistent chemicals and to add endocrine disruptors. It was pointed out that the short priority list published in the 1998 draft Methodology revisions includes numerous banned pesticides. Additional chemicals and microbial contaminants for EPA to consider in its prioritization of criteria to revise/develop are suggested, as follows:

Atrazine
Benzo(a)pyrene
Chlordane
Cryptosporidium parvum strains
Cyanazine
Endrin
Giardia lamblia
Heptachlor
Heptachlor epoxide
Hexachlorobenzene
Methyl-tertiary-butyl-ether (MTBE)
Lead
Other PAHs (specifically advocated use of Relative Potency Factors)
Total Organic Carbon (TOC)
Toxaphene

Response—We will evaluate all suggested pollutants based on the following factors: relative toxicity; occurrence in fish tissue, water, and sediments (frequency as well as concentration levels); and for chemicals, information on the chemical's bioaccumulation. This strategy, previously published in the 1998 draft Methodology revisions, received general support, and we will consider these suggestions along with priorities identified by both the Office of Pesticide Programs and the Office of Ground Water and Drinking Water, and other input received from States and Tribes. Regarding a State's need to revise more criteria, see the response to Comment A.13, Revising Existing 304(a) Criteria.

12. Publishing Existing 304(a) Criteria Information

Comments—EPA received support for its proposal to occasionally publish a list of its criteria and information on revisions or new criteria in progress. Some commenters stated that EPA should publish a list in the **Federal Register** annually, and one suggested that EPA post any changes during the interim on the Agency's website. It was also suggested that EPA should identify which criteria were changed and why. One commenter stated that a timeframe of 3 to 5 years is more appropriate because little is likely to change in just one year. Another commenter expressed support for publishing an annual list of EPA drinking water regulations and health advisories.

Response—EPA believes that regular updates on its website are the most efficient way to make accurate information available to the public. We hope this will be helpful for States and authorized Tribes in reviewing and revising their water quality standards during the triennial reviews required under 40 CFR 131. We will consider further the circumstances and frequency with which **Federal Register** publications may be used. The commenter who referred to drinking water standards and health advisories misunderstood EPA's intention, which is to publish a list annually on the

304(a) water quality criteria similar to that done for the drinking water program.

13. Revising Existing 304(a) Criteria

Comments—EPA received support for revising its Methodology and for providing clear indication of the scientific components versus the science policy components. Commenters supported the idea of EPA revising criteria based on partially updated components of the criteria equations. One expressed a preference for comprehensive revisions but also stated that partial updates should be done as soon as possible, referring to components such as fish consumption rates and ''interspecies conversion of doses'' as those that can automatically be inserted, thereby enabling revision of all criteria within a week of effort. [**Note:** It is unclear whether the commenter is referring to the new body weight/surface area scaling factor or something else by the term ''interspecies conversion of doses,'' because it is not specified.] A commenter stated that as any component is updated, so should the criteria. Another suggested that EPA partially revise all criteria for the components that current information would allow. On the other hand, a commenter stated that EPA should not revise criteria based on the new scaling factor or other pieces of data, but should conduct literature searches for new available data applicable to the Methodology. Other comments were that priority should be given to chemicals with significant new toxicity information; the use of partial updates is not scientifically sound, will produce overly conservative criteria, and restricts the public's right to comment; and all revision actions should be subject to public review and comment.

Response—EPA ideally seeks to conduct re-evaluations of every component used in the derivation of 304(a) criteria before revising any criteria. However, we have discussed updating a limited number of 304(a) criteria over the course of the next several years based on one or more components of the criteria equation (a ''partial update'') rather than a complete set of components, realizing that updating some of these (*e.g.,* the BAF, the exposure parameters) is not as time- or resource-intensive as completing a toxicological evaluation. Recent actions taken by EPA represent this option; both the NTR and the GLI were partial updates. We intend to focus our limited resources on revising (either partially or completely) those pollutants that we consider highest priority in terms of both toxicological concern and frequency of occurrence.

EPA has indicated that it does not believe it is desirable to revise criteria based on piecemeal information, such as the interspecies scaling factor, when there may be other information (*e.g.,* new toxicity studies) that could also change the risk assessment and, thus, the criteria. We have also cautioned the States and Tribes not to selectively apply data or methods that would inaccurately characterize risk (*e.g.*, in order to ensure a water quality criterion that is less stringent than an EPA 304(a) criterion). For a water quality criterion revision based on a partial update to be considered acceptable to EPA, a component of the criterion (*e.g.*, the toxicological risk assessment) would need to be comprehensive (*e.g.*, a new or revised RfD or cancer dose-response assessment, as opposed to simply a new scaling factor), should stand alone and be based on new national or local data. A toxicological update should be on a weight-of-all-of-the-evidence basis, as called for under EPA's risk assessment guidelines. This should incorporate the latest published toxicological literature and risk assessment approaches. States or authorized Tribes seeking to establish ambient water quality criteria are urged to continue using the IRIS noncancer and cancer risk assessments if they cannot conduct a complete evaluation to update toxicological values.

The Agency has developed an improved process that it intends to use when deriving new criteria or conducting a major reassessment of existing criteria. The process is intended to provide expanded opportunities for public input and to make the process more efficient. When deriving new criteria or when initiating a major reassessment of existing criteria, we will publish a notice in the **Federal Register** and on the EPA website announcing our assessment or reassessment of the pollutant. References relied on will be provided, and we will solicit additional data or information useful in deriving new or revised criteria. After input is received and evaluated, we will develop draft recommended water quality criteria. Next, EPA will initiate an independent external peer review of the draft criteria. The public will also be able to submit views on issues of science pertaining to the information used in deriving the draft criteria. We will then revise the draft criteria as necessary, incorporating peer review and public input, and announce the availability of the final water quality criteria in the **Federal Register** and on the EPA website. In addition to developing new criteria and conducting major reassessments of existing criteria, EPA also from time to time will partially revise criteria based on new information pertaining to individual, stand-alone components of the criteria. Because such recalculations normally result only in changes to single parameters of the criteria (not in the underlying scientific methodologies) and reflect peer-reviewed data, EPA will typically publish such recalculated criteria directly as the Agency's recommended water quality criteria. If substantial revision is done, we will follow the process of peer review and public input outlined above. Further discussion of this process can be found in the **Federal Register** Notice compilation of recommended water quality criteria and notice of process for new and revised criteria (USEPA, 1998e).

14. State Evaluation of Data Supporting Criteria

Comment—One commenter asserted that ''states should be allowed to critically evaluate all data and disregard data that, for one reason or another, are unrepresentative or unreliable'' and further asserted that States should be allowed to critically review EPA's published 304(a) criteria and to decline to adopt any criteria they feel are inappropriate.

Response—EPA disagrees with underlying assumptions of the comment. EPA's 304(a) criteria are guidance. States and authorized Tribes may develop their own scientifically defensible, peer-reviewed criteria. Moreover, States and any other interested parties have the opportunity to participate in development of water quality criteria published under Section 304(a) of the Act. Prior to publishing any new or revised 304(a) criteria, EPA provides stakeholders with an opportunity to review and provide scientific views. EPA maintains that at the time of publishing of new or revised 304(a) criteria, the criteria are scientifically defensible and establish guidance to States for adopting water quality standards under section 303(c) of the Act. Under 40 CFR 131.11, States continue to have the option of adopting water quality criteria based on 304(a) criteria modified to reflect site-specific conditions, or other scientifically defensible methods.

15. Streamlined Approach to Developing Criteria Documents

Comment—EPA received support for the streamlined format used in the example criteria documents published in 1998.

Response—We acknowledge this support.

16. Treaty Rights and Trust Obligations/ Government-to-Government Relations

Comments—Commenters recommend EPA fully incorporate treaty rights and Federal trust obligations to Indian tribes in its national AWQC guidelines. It was reiterated that EPA has an obligation to maintain government-to-government relations with Tribal Governments.

Response—As stated in the 1998 draft Methodology revisions, ''risk levels and criteria need to be protective of tribal rights under federal law (*e.g.*, fishing, hunting, or gathering rights) that are related to water quality.'' We believe the best way to ensure that Tribal treaty and other rights under Federal law are met, consistent with Federal trust responsibility, is to address these issues at the time EPA reviews water quality standards submissions.

B. General Policy

1. AWQC Derivation Equation Errors

Comments—Commenters pointed out that the term ''RSC'' (relative source contribution) in the Linear Cancer Effects equation of the 1998 draft Methodology revisions was incorrect and should have been ''RSD'' (risk-specific dose).

Response—The commenters are correct; this was a misprint and should have been RSD for the linear equation.

2. Chronic Human Health Effects Assumption

Comments—EPA received support for its assumption that, by and large, AWQC are set to protect against long-term (chronic) human health effects.

Response—We acknowledge the commenter's support.

3. Protectiveness of the Methodology

Comments—A commenter stated that inherent uncertainties in EPA's risk assessments make them useless and that EPA must adopt the most conservative methodologies in order to protect human health, while also acknowledging the presence of uncertainties in assessing adverse health impacts. They suggested that EPA should tighten regulations for chemicals of national priority, develop criteria for additional priority chemicals, and take the most conservative approach regarding reproductive and developmental effects. Other commenters advocated that EPA incorporate pollution prevention policies into its risk assessment methodologies. One commenter asked EPA to provide guidance to States for developing AWQC less restrictive than AWQC for the general public, and suggested that engineering and administrative controls could reduce exposures. Another stated that the population groups identified represent appropriate categories and that the corresponding default parameter values are reasonable. The same commenter advocated use of the same percentile value for each default parameter (''*e.g.*, 95th percentile''). Another commenter recommended that EPA determine distributions of exposure in order to assess whether a significant subgroup is more highly exposed than the general population, especially in the context of the chosen exposure parameter values. Others stated that the general population should not be targeted and that EPA should instead target the population group most at risk, or that protection of health should apply to all humans. Commenters also expressed uncertainty over the segment of the population that the AWQC are designed to protect, and questioned whether EPA would evaluate all subpopulations for all chemicals. Two commenters requested an analysis of the overall impact that each parameter has on the criteria and how that relates to the conservativeness of the estimated risk, with one criticizing EPA for not conducting probabilistic analyses of exposures or other methods to evaluate the interaction of exposure parameters. This commenter stated that the Agency has used ''high confidence-level'' values for all parameter values and, therefore, the AWQC are ''inordinately conservative.'' Furthermore, EPA should specify the level of protection within the high-end proportion of the general population (*e.g.*, ''the 95% level'') and adjust the exposure parameter values within ''their defined distributions.'' Concern was expressed that the flexibility regarding infants and children (*i.e.,* for developmental effects) conflicted with the fact that chronic lifetime effects cover persons when they are children and adults. A commenter recommended consideration of tissue effects, as well as organ-level effects. Another stated that increasingly strict criteria/discharge limits represent regulatory environmental injustice, and that discharges in effluent-dependent streams are necessary for trees, vegetation, and wildlife.

Response—EPA believes that it has made appropriately conservative assumptions in conducting risk assessments where uncertainties exist. Furthermore, for this effort we will rely on the Agency's peer-reviewed, published risk assessment methodologies, which incorporate procedures to address uncertainties in the risk assessments. We will continue to make the most appropriate risk management decisions when developing or revising criteria, including determining pollutants of high priority. EPA does consider tissue-level effects in addition to organ-level effects when conducting its risk assessments. We acknowledge the comment regarding integrating pollution prevention policies with our risk assessment methodologies and specifically discuss this in the context of CWA goals in the 2000 Human Health Methodology. We also believe that we have selected appropriate default parameter values. Regarding the idea of criteria that are less restrictive than EPA's 304(a) criteria, a State or authorized Tribe would have such flexibility as long as it could clearly demonstrate that the criteria it calculated would be protective of its population. Such alternate assessments and the resulting proposed State or Tribal standard would be subject to EPA's triennial review process. Furthermore, the AWQC are health-based criteria, and therefore potential effects of engineering and administrative controls are not part of criteria.

By and large, the AWQC are derived to protect most of the overall population from chronic adverse health effects. However, States and authorized Tribes also need to understand that there are RfD's based on developmental or other short-term adverse health effects, perhaps where an exposure of one day could result in the effect. Long-term averaging of exposure would not be appropriate in such circumstances. States and authorized Tribes are also encouraged to consider protecting population groups that they determine are at greater risk and, thus, would be more protected using alternative exposure assumptions. We do not intend to derive multiple criteria for all subpopulation groups for every chemical. The commenter who discussed probabilistic analyses has misunderstood EPA procedures. We have used median and mean values, and percentile estimates, not high confidence-level values, as suggested by the commenter. We also disagree that the resulting criteria represent inordinately high levels of conservativeness. In general, we are doing what the commenter recommended about targeting the overall protection at the high end of the general population, even though the criteria have not been subjected to an assessment of whether a 95% level has been achieved (as recommended by the commenter). Although we have not subjected the parameter values chosen

to a rigorous analysis, we have not used high-end percentiles for all parameters. The assumed body weight value used is an arithmetic mean, as are the RSC intake estimates of other exposures, when data are available. The BAF component data values are based on median (*i.e.,* 50th percentile) values. The drinking water and fish intake values are 90th percentile estimates. We believe this will result in water quality criteria that will be protective of a majority of the population. That is our goal. The commenter has not provided a method that would allow us to determine the overall percentile associated with the criteria calculations. EPA has provided additional language in the 2000 Human Health Methodology to clarify the population the AWQC are intended to protect.

Finally, if EPA determined that pregnant mothers/fetuses or young children are the population basis of a chemical's RfD or POD/UF, then we would derive our 304(a) criteria using exposure parameter values for that subgroup. This would be relevant only for less-than-lifetime exposure situations and, therefore, does not conflict with the fact that chronic health effects potentially reflect a person's exposure during both childhood and adult years.

4. Setting Criteria to Protect Both Fish and Drinking Water Versus Fish Only

Comments—EPA received strong support for deriving one AWQC value to protect both drinking water and fish intakes and another to protect for fish intakes only, given that the designated uses of waterbodies vary and drinking water may not be a designated use. One commenter stated that in addition to these two types of criteria, EPA should also develop criteria for water ingestion only. They indicated that waters may exist where fishing and consumption of fish are not relevant but water ingestion is relevant. Furthermore, they pointed out that EPA's Advanced Notice of Proposed Rulemaking for Water Quality Standards discussed protection for aquatic life and, therefore, stated that flexibility is needed so that fish consumption is not inappropriately applied to all waters. A commenter questioned whether ambient waters that are fished are also sources of drinking water, and whether contaminant levels in the two water types could be equivalent. Others stated that the drinking water pathway should not be included in the AWQC, given the way AWQC are implemented (*e.g.*, AWQC apply to waste water discharges and MCLs apply to public drinking water system exposures) and that MCLs may consider affordability and treatability. A commenter stated that AWQC to protect fish/shellfish are not justified and should be dealt with under other regulatory programs (*e.g.*, the Food Quality Protection Act).

Response—EPA believes that AWQC should include a drinking water pathway to protect waters designated as potable water sources. (Also see EPA's response to Comment A.4 regarding the relationship between MCLs/MCLGs and AWQC, Coordinating the Human Health Methodology With Other EPA Programs.) EPA strongly disagrees that AWQC to protect humans exposed through consumption of fish/shellfish should not be developed. Ensuring the protection of human health from consumption of contaminated fish and shellfish is clearly within the requirements of the CWA. We do not believe that 304(a) criteria to protect drinking water uses only are particularly useful, because by and large, State and Tribal standards for human health are set to protect waters with multiple designated uses, not merely drinking water use. The water quality standards program also protects aquatic life. The 2000 Human Health Methodology will not change our requirement to apply aquatic life criteria to protect aquatic species where they are more sensitive (*i.e.*, when human health criteria would not be protective enough) or where human health via fish or water ingestion is not an issue.

5. Setting Criteria to Protect Against Multiple Exposures From Multiple Chemicals

Comments—Several commenters thought EPA should consider multiple chemical exposures when setting AWQC and consider these exposures additive, at a minimum, while using information on synergistic impacts from the combination of chemicals. Commenters also suggested that certain Native American Tribes may have significant confounding factors (not specified) to be considered with any synergistic assessment. A commenter suggested that the cancer risk range apply to total contaminants or that a cumulative cancer ceiling be established. Another stated that the suggested alternate approach to account for inhalation and ingestion exposures (via the RfD and RfC equation) regardless of the target organ/endpoint was inconsistent with EPA's guidance on the use of hazard indices (HIs) and hazard quotients (HQs) to evaluate multiple noncarcinogenic toxicants. Commenters also questioned whether all exposure routes exhibit the same toxicity or stated that inhalation exposures should be disregarded if the pollutant in question does not affect the same endpoint.

Response—Assuming that all multiple exposures from multiple chemicals are additive, as the commenters suggest, is not scientifically sound unless they exhibit the same toxic endpoints and modes of action. We are aware of the complex issues and implications of cumulative risk and are developing an overall approach at the Agency-wide level. In particular, the Agency's program offices are engaged in ongoing discussions on how to address the great complexities, methodological challenges, data adequacy needs, and other information gaps, as well as the science policy and risk management decisions that will need to be made, as we pursue developing a sound strategy and, eventually, specific guidance for addressing cumulative risks. As previously indicated, the Agency is developing a framework for cumulative risk assessment, and the Office of Pesticide Programs has developed draft guidance for assessing cumulative risk of common mechanism pesticides and other substances. We have added discussion about the concept of cumulative risk and the state of the science in the 2000 Human Health Methodology and its TSDs. As a matter of internal policy, we are committed to refining the Methodology as advances in relevant aspects of the science improve. Regarding the alternate approach to use the HI/HQ equation (combining RfDs and RfCs), we do not intend to use this approach to combine chemicals when deriving criteria at this time. We requested comment on this as an alternate method to consider inhalation exposures for a given chemical, but would not consider its use in situations where existing information indicates that ingestion exposures and inhalation exposures affect different target organs. EPA intends to consider the comparative toxicity between exposure routes for Section 304(a) water quality criteria and has encouraged States and Tribes to do so. For the recommended national 304(a) criteria, cumulative risk approaches will not work since the mixture of pollutants present in water is inherently site-specific.

6. Uncertainty with the Derivation of 304(a) Criteria

Comment—Comments suggested that cumulative uncertainty guidance should be included in the Methodology, including a maximum acceptable uncertainty level.

Response—Establishing a maximum level of acceptable uncertainty is not part of the Methodology and will not be

factored into the decision of whether to develop or revise 304(a) criteria. However, issues regarding uncertainties with the risk assessments, exposure assessments, and bioaccumulation assessments will be addressed in the risk characterization sections of future criteria documents.

7. Toxicity Equivalency Factors (TEFs) for Dioxin-like Compounds

Comments—Several commenters addressed the use of TEFs for dioxin-like and other mixtures and classes of compounds. They believed the TEF approach has only limited application in risk assessment. Commenters indicated that complexities of the biology argue strongly against any more than limited and very cautious use of the TEF approach for assessment of human health from exposure to dioxin-like compounds.

Response—EPA agrees that there is a limitation to TEF use and that caution should be exercised when using it. More guidance can be found in the Guidance for Conducting Health Risk Assessment of Chemical Mixtures (USEPA, 1999b) and the Health Assessment for 2,3,7,8–Tetrachlorodibenzo-p-dioxin (TCDD) and Related Compounds, Internal Review Draft, February 14, 2000; Part II, Chapter 9: Toxicity Equivalency Factors (TEFs) for Dioxin and Related Compounds (USEPA, 2000b).

C. Cancer

1. Acceptable Risk Level for Carcinogens

Comments—Comments were received suggesting that regulations should be tightened or that AWQC for all carcinogens including the Groups C compounds (possible human carcinogens) should be set at zero, while others believed that cancer potency factors may overestimate actual risk. Some suggested the actual risk may be much lower, perhaps as low as zero, particularly for chemicals for which human carcinogenicity information is lacking. Comments also addressed the EPA cancer risk range for deriving AWQC.

Response—Regarding the permissible cancer risk range, see response to Comment A.3, Cancer Risk Range.

2. ED10 (central estimate) versus LED10 (lower bound on dose)

Comments—Several commenters preferred the use of ED10 over LED10 as the POD or BMD.

Response—The 1999 draft revised cancer guidelines provided a rationale for the selection of PODs. EPA's 1999 draft revisions provide for the use of the LED10. The EPA Science Advisory Board (SAB) suggests harmonization of the LED10 between the BMD approach for noncancer assessments and cancer assessments. The SAB also recommends reporting both the LED and ED (see USEPA, 1999d).

3. Group C Contaminants

Comments—One commenter stated that Group C compounds are treated differently under the SDWA and the CWA and wanted clarification on development of AWQC for Group C contaminants. Also, an ''integrated approach'' was suggested in evaluating nonlinear carcinogen and noncarcinogen assessments. However, the commenter's approach was to determine tentative AWQC for the contaminant as both a noncarcinogen and a carcinogen at 10^{-6} risk, and then choose the lower of the two values (*i.e.,* RfD vs. 10^{-6} risk) for setting the AWQC. Another commenter stated that integrating nonlinear and noncarcinogen assessments proposed by EPA is reasonable and it may be possible to replace this in the future with the categorical regression approach.

Response—The 1999 draft revised cancer guidelines require risk assessors to use the best science and consider mode of action in selecting an appropriate model to use. Under the 1999 draft revised cancer guidelines, Group C will no longer exist. The linear approach is used when there is insufficient information on mode of action, or the mode-of-action information indicates that the dose-response curve at the low dose is or is expected to be linear. The default approach for nonlinearity is to use a margin of exposure analysis. However, when the mode of action suggests both linear and nonlinear approaches, then both methods will be applied and considered. As for the integrated approach, EPA currently is working to increase the harmonization of both cancer and noncancer risk assessments. In the 2000 Human Health Methodology, we will only quantify cancer risks for those chemicals considered ''carcinogenic to humans'' or ''likely to be carcinogenic to humans.''

4. Guidance on Carcinogen Risk Assessment

Comments—Several commenters supported EPA's 1996 proposed cancer guidelines. They endorsed the proposed guidelines for considering all scientific data and using the latest information, including weight of evidence, mode of action, margin of exposure, and a nonlinear approach for certain contaminants. They thought the new approach is more in line with recent advances in understanding carcinogenesis. However, they requested more guidance on how and when to apply the cancer guidelines.

Response—We will provide more guidance when the guidelines are finalized.

5. Hexachlorobutadiene (HCBD)

Comments—Comments stated that EPA should not propose AWQC for HCBD before the 1999 draft revised cancer guidelines are final. Furthermore, for HCBD, there is inconsistency between the statement in the 1998 **Federal Register** (Appendix VI) and that in the example HCBD criteria document.

Response—The Agency is considering the comment and will postpone completion of the AWQC for HCBD until more recent data can be incorporated. In reference to the risk assessment of the chemical, the discrepancy is minor. The 1998 Methodology states that both linear and nonlinear approaches will be used by EPA. The criteria document presents both approaches.

Note: EPA also will postpone completion of the criteria for 1,3-dichloropropene. Because of the large volume of new scientific information available for acrylonitrile, additional effort will be necessary to review the material. Therefore, EPA will not complete the criterion for acrylonitrile at this time. For the same reason, we are not addressing the comments on this chemical at the present time.

6. Integration of Analyses for Cancer and Noncancer Effects

Comments—Commenters supported integration and harmonizing procedures for risk assessment of cancer and noncancer effects in ambient water and drinking water programs.

Response—EPA agrees that it is a good idea to use an integrated approach to assess both cancer and noncancer effects. Currently, EPA has Agency-wide efforts to investigate harmonization of cancer and noncancer risk assessments.

7. Margin of Exposure (MOE) Analysis

Comments—Commenters requested that EPA provide more guidance on how to do MOE analysis and how to select the MOE. They also requested a comparison of the BMD with the LED10.

Response—Guidance will be provided either in the final Guidelines for Carcinogen Risk Assessment or in a separate document from the Agency's Risk Assessment Forum in the future.

8. MOE Approach to Applying Uncertainty Factors (UFs)

Comments—A commenter disagreed with the proposal to apply a UF to account for the severity of a precursor effect. Another commenter opposed applying a UF of no less than 0.1 when humans are less sensitive than animals.

Response—The Agency will develop more specific guidance on the MOE approach, as recommended by the SAB in 1999. The guidance will be peer reviewed and published separately as part of the Agency's implementation activity for these guidelines.

9. MOE and MOP

Comments—Commenters seemed confused regarding MOE and MOP (''margin of protection,'' as defined by a commenter). They defined MOE = MOP = POD/RfD and claimed that the calculated MOEs for chemicals based on nonlinear low-dose extrapolation are 100 times higher than those for carcinogens based on linear low-dose extrapolation, and claimed that the MOE is implicitly linear and, thus, is an inadequate approach to dealing with ''nonlinear'' carcinogens.

Response—There is a significant misunderstanding on the part of the commenters. The MOE is defined as the POD (*i.e.,* NOAEL or LOAEL or LED10) divided by the environmental level of interest (actual exposure or possible criterion). The MOE approach is recommended for chemicals that have a nonlinear low-dose response. For carcinogens with a linear low-dose response, we estimate the slope of the line drawn between zero and the LED10, and use the equation presented in the Methodology to estimate the concentration in water for human heath protection (10^{-6} is the recommended risk level). EPA does not recommend using any formula such as the one presented [*i.e.,* MOE = (POD) /(RfD)] to estimate MOE for carcinogens with a linear low-dose response.

10. Oral Scaling Factor for Dose Adjustment

Comments—Several commenters endorsed EPA's use of the body weight raised to the three-quarters power as the scaling factor. It was also suggested that, if available, chemical-specific data should take precedence over the generic default scaling factor.

Response—EPA agrees.

11. Toxic Endpoints

Comments—A commenter stated that EPA should make clear in its Methodology that it intends to take into consideration the toxic actions of the individual chemicals for which criteria are being established so that an appropriate target population and consumption rate can be selected. The commenter suggested that if the critical toxic endpoint of a chemical is cancer or other chronic disease, then use of the adult population and long-term consumption rates are appropriate to develop the AWQC. However, if the most sensitive toxic endpoint of a chemical of interest is acute reproductive effects, it may be more appropriate to use short-term consumption rates and exposure parameters that are relevant for women of childbearing age in developing the AWQC.

Response—EPA agrees.

12. Weight-of-Evidence Narrative and Classification System

Comments—A commenter expressed support for the use of narrative statements, but found the guidance on the weight-of-evidence narrative to be overly general and confusing. They suggested that some sort of classification system such as the alphanumeric should be retained. They also stated that without such a system, practical use of the weight-of-evidence approach will be more difficult, particularly for States that do not have strong expertise and sufficient resources in the application of health-based risk assessment.

Response—Current revisions to the cancer guidelines and the use of descriptors and narratives have been endorsed by the SAB and other commenters and will be included in assessments and final guidelines because they provide important information to the risk manager that a number or letter cannot convey.

D. Noncancer

1. Benchmark Dose Methodology

Comments—Commenters supported the flexibility of having the NOAEL/LOAEL/UF, categorical regression, and benchmark options for derivation of an RfD but pointed out a variety of concerns or factors for EPA to consider as it revises the BMD guidance.

Commenters suggested that the BMD methodology will eventually have a prominent role in risk assessment, but checks and balances need to be set to ensure that it is applied intelligently and with a healthy scepticism for its results, especially those that vary significantly from the results of the conventional NOAEL/LOAEL approach. The following specific recommendations were presented for EPA's consideration:

- Prohibit extrapolations without some mechanistic foundation. Permit interpolation only within the experimental dose range, for example, between NOAELS and LOAELS.
- Present a range of BMD estimates from the use of multiple-dose models, including models with thresholds just below LOAELS; estimates with the high-dose results dropped sequentially from the analysis; and multiple response rates (*i.e.,* 1%, 5%, and 10% response rates as well as the response rate associated with the experimental detection limit).
- Estimate the BMD using several confidence bounds.
- Compare the results of the alternative modeling approaches and reconcile discrepancies.

Other comments are summarized in the following paragraphs.

The BMD methodology lacks a mechanistic basis. There is no connection between the mechanisms of action that underlie the observed responses. Because the methodology is devoid of a mechanistic basis, its use needs to be restricted to the observable range. Extrapolations below the lowest nonzero dose of a study have no scientific foundation. However, it is acknowledged that some extrapolation of the data below the observable range is inevitable.

An additional critique was that high-dose effects influence low-dose estimates. The curve fitting involved in estimation of the mathematical dose-response relationship permits the responses at the high end of the dose range to influence the estimated responses at the low end of that range. This will occur whether or not the high-dose observations are mechanistically related to the responses at low doses. Furthermore, response and dose estimates are model dependent. In some cases, both central estimates and lower-bound estimates of doses associated with various response rates are known to be highly unstable and fluctuate significantly in response to minor data manipulations or assumptions.

More research is needed on implementation of the benchmark model. Guidelines for selecting appropriate models/benchmark responses, handling lack of fit, or selecting a single benchmark dose when more than one is calculated should be developed by EPA to assist States and other users in implementing this methodology.

The central estimate rather than the lower bound on dose should be used as the POD for benchmark modeling. Such an approach provides greater opportunity to compare effect doses among chemicals. Uncertainty associated with wide confidence limits

can be accommodated in other portions of the risk assessment process. Furthermore, the most recent peer review of the BMD methodology (USEPA, 1996c) recommended use of the ED10 rather than the LED10.

Use of the benchmark model could introduce additional conservatism into the derivation of an RfD. Certain benchmark models as applied to developmental toxicity endpoints are substantially more conservative, on average, than the corresponding NOAELs. Using the benchmark approach in such a circumstance will introduce additional unjustified conservatism in the standard-setting process.

Caution should be taken when using different methods for RfD determination; that is, the degree of human health protection should be comparable from different methods. Because the BMD and categorical regression are relatively new methods, more studies are needed to compare the RfDs derived using the typical NOAEL/UF approach and those derived using the BMD and categorical regression methods.

EPA should closely coordinate adopting BMDs for noncancer endpoints under the Human Health Methodology with other Agency programs so that the policy is implemented identically throughout the Agency. However, because the benchmark approach makes better use of all data, the Agency should continue to work on its development.

Response—EPA agrees with the concerns regarding widespread application of the benchmark approach without consideration of the many factors addressed by commenters. The AWQC guidelines do not prescribe use of the benchmark approach in the derivation of an RfD. The guidelines allow the use of either the NOAEL/UF, benchmark, or categorical regression approaches. The risk assessor can select the approach most suitable to the available data. Accordingly, if the data do not support derivation of a BMD, then the NOAEL/UF approach can be selected for the RfD derivation rather than the benchmark approach. In addition, when selecting the appropriate equation for derivation of the BMD, one should consider goodness-of-fit along with the impact of high doses on the model results, confidence interval domains, and consistency of the dose-response pattern with the mode of action.

We do not anticipate that either of the new approaches, benchmark or categorical regression, will soon completely replace the NOAEL/UF approach. Both of the new approaches require more extensive data than the NOAEL/UF approach, and in many cases the data required to apply the methodology will not be available.

EPA is developing technical guidance that will assist in determining whether or not a particular data set is compatible with the BMD approach. Use of BMD methods involves fitting mathematical models to dose-response data obtained primarily from toxicology studies. When considering available models to use for a BMD analysis, it is important to select the model that best fits the data and is the most biologically appropriate. EPA has developed software following several years of research and development, expert peer review, public comment, subsequent revision and quality assurance testing. The software (BMDS, Version 1.2) can be downloaded from *http://www.epa.gov/ncea/bmds.htm.* BMDS facilitates these operations by providing simple data-management tools, a comprehensive help manual and online help system, and an easy-to-use interface to run multiple models on the same dose-response data.

As part of this software package, EPA has endorsed sixteen (16) different models that are appropriate for the analysis of dichotomous (quantal) data (Gamma, Logistic, Log-Logistic, Multistage, Probit, Log-Probit, Quantal-Linear, Quantal-Quadratic, Weibull), continuous data (Linear, Polynomial, Power, Hill) and nested developmental toxicology data (NLogistic, NCTR, Rai & Van Ryzin). Results from all models include a reiteration of the model formula and model run options chosen by the user, goodness-of-fit information, the BMD, and the estimate of the lower-bound confidence limit on the benchmark dose (BMDL). Model results are presented in textual and graphical output files which can be printed or saved and incorporated into other documents.

2. Categorical Regression

Comments—Commenters expressed reservations regarding use of the categorical regression methodology. They stated that the methodology presents difficulties in that it requires distinction of diverse endpoints and definition of severity categories, not as they apply to the animal studies, but as they apply to human health effects. Commenters also stated that categorical regression would allow the Agency to consider several endpoints simultaneously rather than use data for only the most sensitive endpoint. Some commenters believed that the major limitation of the approach is the need for classifying effects into categories (mild, moderate, frank).

Other commenters believed regression analysis offers attractive advantages but does not seem well enough developed at the present time to be incorporated into the Methodology. They suggested that because the approach makes better use of all data, the Agency should continue to work on its development. They also stated that when the data indicate that one of the new methodologies is clearly superior to the NOAEL/LOAEL/UF approach, it should be utilized.

Response—As stated in the response on BMD above, EPA does not anticipate that either of the new approaches, benchmark or categorical regression, will soon replace the NOAEL/UF approach. Both new approaches require more extensive data than the NOAEL/UF approach, and in many cases the data required by the methodology will not be available. We agree that the categorical regression methodology is less well developed than the benchmark method. However, we also anticipate that the number of chemicals evaluated with this approach will grow over time. Including the categorical regression methodology among the available options in the 2000 Human Health Methodology provides an opportunity for its application in appropriate situations.

3. Integrated Approach

Comments—Commenters stated that an integrated approach to assessing both cancer and noncancer effects for substances that are carcinogenic has merit, particularly when the systemic effects of concern occur at very low doses. However, they believed it is unclear how the nonlinear cancer assessment and the noncancer assessment would differ if the tumors were considered secondary to the systemic toxicity upon which the RfD is based. They stated that such considerations become more important when the systemic toxicity is unrelated to tumor formation, as in the case of lead and mercury. Some indicated that because EPA recommends different design flows to account for exposure scenarios that are appropriate for carcinogenic and systemic effects, the Methodology should develop and adopt similar criteria for both carcinogenic and systemic effects when appropriate. Some further stated that for some waters and pollutants, it will not become clear whether the systemic or carcinogenic criterion is more protective until the limits are developed using the different design flows. This was not previously a concern because a single human health design flow was used in most locales.

Response—The 2000 Human Health Methodology is not a stand-alone methodology. It depends on established or proposed Agency risk assessment guidelines for cancer and noncancer endpoints. We do not have the latitude to change Agency-wide risk assessment guidelines through the AWQC Methodology. Any changes must first be made to the supporting documents (*e.g.,* 1999 draft revised cancer guidelines, RfD methodology).

4. Integrated Risk Information System (IRIS)

Comments—Concern was expressed that EPA does not update the IRIS files in a timely manner. States use these assessments for their risk assessment work and do not have the resources to perform the types of detailed consensus risk assessment done under the IRIS process, according to comments received. They additionally pointed out that many IRIS assessments are more than 10 years old and suggested that EPA should update these assessments on a 3- to 5-year cycle.

Response—We realize the importance of the IRIS program and dedicate a portion of our resources to preparation of IRIS documentation for regulated chemicals. However, competing priorities throughout the Agency limit the effort that can be expended on IRIS by program offices and by the IRIS program.

5. NOAEL/LOAEL Approach

Comment—A commenter called attention to the facts that the NOAEL/LOAEL/UF approach is the current approach for establishing an RfD and that many present regulatory values are based on this approach. They stated that use of newer techniques that account for severity of effects and sample size seems reasonable, as long as the new techniques have been extensively reviewed and have wide acceptability among practitioners. However, the commenter also said that in some cases, the data needed to use the newer techniques may not be available, in which case it seems entirely appropriate to use the NOAEL/LOAEL approach as a default.

Response—See our responses to Comments D.1 and D.2, the benchmark dose and categorical regression comments, respectively.

6. Nonthreshold Approach for Noncarcinogens

Comments—The Agency requested comments on the suitability of using a nonthreshold approach for noncancer endpoints. Although open to the concept, commenters stated that a threshold should be considered the norm and a nonthreshold approach should be applied only if there are substantial scientific data supportive of a nonthreshold mechanism of toxicity. They stated that when receptor interactions are a component of the response, it is important that EPA differentiate between the receptor binding that might be without a threshold and subsequent biological responses such as enzyme induction or frank toxicity that would be expected to exhibit threshold dose-response relationships.

An additional concern was the use of nickel as an example of a chemical without a threshold. It was pointed out that double-blind studies indicate that there is a threshold for dermatological responses to nickel even in sensitized individuals.

Response—The Agency made modifications to the recommendations regarding a threshold approach for noncarcinogens, most specifically using lead as an example rather than nickel. We incorporated the commenters' suggestions in making the revisions.

7. RfD Range

Comments—The concept of establishing a range around the calculated RfD from which an alternative RfD might be selected in certain circumstances received considerable comment from the public. The primary criticism was the lack of a scientific basis for the breadth of the range and its correlation to the net uncertainty factor/modifying factor (UF/MF) product. The comments are summarized below.

The span of the range as described by EPA seems to be arbitrary and without any scientific support. It would be useful for the Agency to analyze a substantial number of past RfD determinations using the ranges the Agency has proposed to see whether they make practical sense. The Agency should provide more examples on how the factors that are to be considered in selecting a point within the range (i.e., bioavailability differences, sensitive populations, and slope of the dose-response curve) are related to the magnitude of the proposed range. Scientific data should be gathered and presented to support the use of these factors in influencing the range.

The Agency should give serious consideration to the possibility that the ranges of uncertainty surrounding the point estimate are not symmetrical. In particular cases, it may well be that most of the RfD uncertainty is on the high side of the point estimate.

The proposal to use a range is inconsistent with the purpose of the RfD. The proposal to use a range rather than a point value for the RfD would lead to the potential for double counting uncertainty. The UFs and MFs presently applied in calculation of the RfD allow for many of the factors that are presented as justifying selection of a point within a range as an alternative to the calculated RfD.

The range for the RfD would create more problems than it would prevent. The RfD, by nature, cannot be used to calculate the risk at a given level of exposure and is essentially a safety estimate that should be expressed as a single point estimate. The definition of the RfD recognizes the uncertainty in this assessment. The proposed approach would be difficult to implement, create unnecessary confusion and controversy regarding the RfD, and could result in prolonged unproductive debates between parties with differing interests.

If EPA chooses to define a range, the range should be developed by the scientists undertaking the RfD development. If a range is used, it is also strongly recommended that it be accompanied by detailed guidance on the factors for choosing a point estimate within the range. The uncertainty surrounding the point estimate of an RfD will be different for each chemical and study and should be clearly stated in any revised RfD.

An advantage of the range is that it would make more apparent to States the uncertainty in the RfD and the flexibility that now exists surrounding its use in the regulatory context. However, it is preferable to retain the presentation as a single point value but provide in accompanying text substance-specific information such as steepness of the dose-response curve that States can use in deriving standards based on other than the default single point RfD.

A range is useful to a risk manager or other decision-maker because actions can be taken with greater confidence in how likely it is that adverse health effects will be manifest at a particular point concentration. For example, slightly exceeding the MCL of 1 mg/L for nitrite with a UF of 1 is more likely to result in adverse health effects upon exposure than slightly exceeding a guideline of 70 μg/L for MTBE with a UF of 10,000.

Some of the factors EPA recommends in selecting a point within an RfD range should be used in determining the RfD itself rather than for deviating from it after it is derived. These include the seriousness and reversibility of the effect, whether it is based on a LOAEL,

and bioavailability within humans. The issue of considering the presence or absence of sensitive segments of the population is impractical and inappropriate in deriving an ambient water quality standard. EPA should delete this option and understand that States generally set water quality standards on a statewide level. It is impractical to ascertain whether infants or pregnant women live near and consume fish or water from a particular waterbody. It is not practical from an administrative standpoint to set different, separate standards for each waterbody.

The Agency should provide guidance regarding the development of scientific rationales for departure from the default RfD. The Agency should provide a methodology for deriving the range, along with supporting examples, and subject that methodology to peer review before using the concept in developing AWQC.

Response—EPA agrees that the method used to quantify the range from which an alternative to the calculated RfD can be chosen is not based on specific scientific or statistical data. It is purely an equal partitioning of a default, 10-fold uncertainty factor into four equal quarter log segments.

It is important to note that the range around the calculated RfD only establishes a domain from which a risk assessor can select a single point to use as an alternative to the RfD for a specific circumstance. The 2000 Human Health Methodology criteria for using a point within the range other than the calculated RfD when calculating AWQC clearly require the State to provide a detailed justification for that decision.

One example of a situation where a point other than the calculated RfD might be applied would be where there is a difference in the bioavailability of the contaminant in the water component of the AWQC as opposed to the fish component. In such an instance, the decreased bioavailability from fish tissues could be used to support selection of an alternative value greater than the calculated RfD if the critical study were one where the contaminant had been administered through drinking water. Most inorganic contaminants, particularly divalent cations, have bioavailability values of 20 percent or less from a food matrix, but are much more available (about 80 percent or higher) from drinking water. Accordingly, the external dose necessary to produce a toxic internal dose would likely be higher for a study where the exposure occurred through the diet rather than the drinking water. As a result, the RfD from a dietary study would likely be higher than that for the drinking water study if equivalent external doses were used.

The exposures considered in deriving AWQC include fish (food) and water. Thus, one might be able to justify an alternative value to the RfD point estimate that was slightly higher than the RfD estimate in cases where the NOAEL that was the basis for the RfD came from a drinking water study, but slightly lower than the RfD estimate if the NOAEL came from a dietary study.

Several commenters suggested that there would be value in applying the range concept to several relevant RfD values and then to evaluate the results. The range concept was considered in the peer review of the 1998 draft Methodology revisions, and the peer reviewers had many of the same concerns regarding the range. The revised Risk Assessment TSD gives examples of how one could justify an alternate RfD value that was lower or higher than the RfD estimate.

8. Severity of Effects

Comments—Several commenters supported consideration of severity of effects in determining AWQC, although there was considerable diversity in the opinions expressed, as follows.

Some believed that there was no science behind use of different UFs (*i.e.,* 3, 10) in making intraspecies decisions based on severity of effect. Some stated that EPA should provide a methodology that will define a severity scale prior to adopting use of severity in deriving RfDs and associated AWQC. Others commented that the severity scale could be alphanumeric, similar to that used for carcinogens under the EPA 1986 cancer guidelines, and the severity rating could be presented along with the RfD value. However, any severity scale must also consider whether it is consistent with the definition of an RfD as a dose below which no adverse effects are anticipated to occur in exposed populations.

Other commenters believed that making adjustments in the RfD value for severity of effects only confounds regulatory policy with toxicological science, and the Agency should explore alternative approaches to the problem of differences in severity of various toxicological endpoints. The Agency should not have considered severity in calculating an RfD because this practice could result in double counting of uncertainty. Severity should be considered in selection of a UF only when the RfD is based on a LOAEL. If the NOAEL were used, concerns for severity should be reflected in the MF.

Response—There are several situations in which EPA has considered the severity of effect in selection of the UF. The Risk Assessment TSD cites zinc as an example. The LOAEL used in establishing the RfD for zinc was a change in the activity of the enzyme superoxide dismutase. This effect compromises the ability of the individual to avoid damage to macromolecules, such as proteins and polynucleotides, in the presence of free radical oxygen. Although clearly adverse, this effect is not as severe as tissue necrosis or impaired organ function. Thus, a UF of 3 was used rather than the default of 10 for the adjustment of a LOAEL to a NOAEL. The nutritional requirements for zinc relative to the RfD supported the use of a UF of less than 10 in this instance.

As monitoring of molecular biomarkers of toxicity increases, the number of situations will most likely increase in which a LOAEL is early enough in the progression toward overtly adverse effects that factors of less than 10 can be used for the RfD calculation and will be supported by mode of action data. Past EPA practice is consistent with the suggestion that severity be considered where the RfD is based on a LOAEL and that an MF be used, if the data warrant, when calculating from a NOAEL.

We do not believe that establishing a scale for severity is necessary at this time. It would be extremely difficult to establish a scale for rating toxicological endpoints that could be easily applied to the spectrum of endpoints monitored in more recent toxicological studies. The present flexibility in UFs and MFs provides ample opportunity for severity adjustment.

9. Stochastic Modeling

Comments—Commenters encouraged EPA to use a stochastic approach (Monte Carlo and/or Latin square modeling) for setting RfDs. The commenters stated that this would allow EPA to better ''quantify the uncertainties and separate them from the variability in the data.'' They believed such methods would provide a sounder, more quantitative approach to determining whether a range of RfD values is needed.

Response—The guidelines for determination of the RfD are based on previously published, Agency-wide guidelines. The suggestion to use a stochastic approach has been noted and will be considered in the context of the Agency revisions to its risk assessment guidelines. Revisions to fundamental Agency guidelines are beyond the scope of the AWQC Methodology.

10. Synergistic Effects

Comment—Several commenters encouraged the Agency to consider multiple exposures to various chemicals and persistent bioaccumulative toxicants when establishing AWQC. For substances that do not persist or bioaccumulate in the environment, or do not cause reproductive, developmental, or neurological effects, EPA's risk assessment methodologies were deemed in need of reconsideration. However, as part of the reconsideration, EPA was asked to apply best science on synergistic impacts from exposures to a combination of chemicals. Other comments suggested sensitive subpopulations, such as Native American Tribes and other susceptible populations, may have significant confounding, underlying health problems that must be recognized with any synergistic assessment.

Commenters also stated that EPA should give specific attention to certain categories of contaminants: persistent organic pollutants and endocrine disruptors. The commenters identified two aspects to consider in applying this recommendation: (1) Individual contaminants with a similar mode of action whose cumulative effects may reach an unacceptable level; and (2) selection of specific biologic endpoints to use as the basis of an RfD. They also believed that tissue effects are valid measures of injury and should be used in addition to organ-level effects in people and biota. It was also considered important to include immunological, reproductive/developmental, and neurological effects to derive RfDs.

Response—The Risk Assessment TSD encourages States to consider synergistic and additive effects of individual chemicals in mixtures when establishing AWQC. The HI approach is suggested and described for situations where the chemicals have the same effect by similar modes of action. The Risk Assessment TSD also acknowledges that methods are not presently available for evaluating risk from mixtures where the individual chemicals have dissimilar health effects and recommends that chemicals in such mixtures be evaluated individually. Specific recommendations are found in EPA's Draft Guidance for Conducting Health Risk Assessment of Chemical Mixtures published in May 1999 (USEPA, 1999b).

The 2000 Human Health Methodology accommodates concerns regarding persistent bioaccumulative toxicants primarily through use of bioaccumulation factors in the calculation. Situations in which ambient waters may contain a group of chemicals that are persistent and bioaccumulative and have additive or synergistic effects can in some cases be factored into the HI approach. The description of the treatment of mixtures in the TSD was expanded to encourage States to consider persistence, bioaccumulation, and mixtures concerns in their risk assessments. The references to Agency mixtures guidelines were updated to include the most recent draft of the mixtures guidelines.

11. Target Population Adjustments

Comments—EPA was asked to consider the characteristics of the target population when determining AWQC. Commenters suggested that when the chemical is a carcinogen, it is appropriate that the target population consist only of residents of the United States. In cases where the effect is an acute reproductive effect, the commenters believed it is appropriate to specify adult women as the target population and to use short-term consumption rates and exposure parameters.

Response—The default input parameters for determining AWQC for human health apply to lifetime exposures and the adult population of the United States. However, the equations used for the calculation provide the flexibility to use body weight, water intake, and fish intake parameter values that are specific to other target populations.

12. Uncertainty and Modifying Factors

Comment—Additional guidance was requested on factors to consider in selecting UFs, particularly a UF for an incomplete database.

Response—In revisions to the Risk Assessment TSD for the 2000 Human Health Methodology, we increased the number of examples given to illustrate how UFs were selected in establishing RfDs included in the IRIS.

Comment—The suggestion was made to replace the interspecies UFs with a body weight to the three-quarters power and thereby harmonize the cancer and noncancer approaches.

Response—The peer reviewers of the 1998 draft Methodology revisions also suggested harmonizing the cancer and noncancer approaches with regard to the use of the body weight to the three-quarters power. This can be accomplished only through changes to the Agency documents on which the methodologies presented in the 2000 Human Health Methodology are based. The Agency currently is working on harmonizing the cancer and noncancer methodologies.

In addition, as pointed out by the peer reviewers, a body weight to the three-quarters power conversion adjusts for allometric differences between laboratory animals and humans. It does not reflect toxicodynamic differences between species that must still be included when adjusting for interspecies differences. The use of the scaling factor cannot totally replace the interspecies UF.

Comment—Another comment requested EPA to adopt more rigorous quantitatively supportable methods such as PBPK models to replace the more arbitrary and less well founded use of numerical scaling factors identified in UFs and MFs.

Response—The revisions to the Methodology clearly support use of toxicokinetic modeling when the data are available and use of the modeled data in lieu of the toxicokinetic portion of the interspecies UF.

13. Use of Less-Than-90-Day Studies in Determining an RfD

Comments—In general, commenters agreed with the scientific review board that false-negatives might result from use of less-than-90-day studies to develop an RfD. It was suggested that EPA evaluate data sets for groups of chemicals for which there are both chronic and less-than-90-day studies and compare RfDs. Any comparison of chronic and less-than-90-day studies should consider the purpose for which the less-than-90-day studies were conducted and whether they provide evidence relevant to the results of longer term experiments. A commenter agreed with the scientific review board that any RfD based on a less-than-90-day study should be used only temporarily.

Other comments pointed out that the Great Lakes methodology allowed use of less-than-90-day studies for determining an RfD but required a duration UF of 30 rather than 10. This factor when combined with a 10 for intraspecies variability and a 10 for interspecies variability would yield a total UF of 3,000, the maximum that is said to support RfD derivation. The commenter believed very few situations would qualify to use less-than-90-day studies, but their use should be allowed as long as the total UF is 3,000 or less.

Additional comments stated that reproductive, developmental, immunotoxicological, and neurotoxicity data provide an appropriate basis for determining an RfD even if they come from studies of less-than-90-day duration. However, one commenter also urged that data must be collected using

methods of sufficient accuracy and validity. It was also emphasized that evaluations should be conducted to determine how dose-response relationships developed for these toxic effects, particularly immunotoxicity, are related to modifications in function and evidence of overt pathology.

Response—In several instances, the Agency has developed an RfD based on data from studies of less-than-90-day duration (*e.g.,* nitrite, zinc), particularly where the data were from humans and evaluated endpoints of chronic as well as acute significance. Data from less-than-90-day studies of reproductive, developmental, immunotoxicological, and neurotoxicity data are also considered appropriate for an RfD if they identify the critical effect. However, such data are used for RfD determination only when supported by a rather complete database and a good understanding of the mode of action. The Agency does not use data from less-than-90-day studies purely because they are the only available data. When the database is inadequate to support an RfD determination, no RfD is calculated.

E. Exposure Assessment

Default Intakes

1. Assumption That All of the Drinking Water Consumed Is Contaminated at the Criteria Level

Comment—A commenter questioned the assumption that all drinking water consumed has been contaminated to the maximum extent allowed by the criteria.

Response—Refer to response on this same issue for Comment E.2, Assumption That All Fish Consumed Is Contaminated at the Criteria Level.

2. Assumption That All Fish Consumed Is Contaminated at the Criteria Level and All Fish May Come from One Waterbody

Comments—Commenters questioned the assumption that all fish consumed have been contaminated to the maximum extent allowed by the criteria. They state the assumption that all of the 17.8 g/day (now 17.5 g/day) could come from one source is unrealistic, and that EPA should specify ways to adjust the fish intake rates to reflect a *contaminated fish* consumption rate.

Response—As required under Section 304(a) of the CWA, EPA develops water quality criteria that reflect the latest scientific knowledge on effects of pollutants on human health. The Agency's recommended 304(a) water quality criteria are used by States and authorized Tribes to adopt enforceable water quality standards including designated uses of a waterbody consistent with Section 101(a) of the CWA (*e.g.,* fishing, swimming, propagation of aquatic life, recreation). In developing the 2000 Human Health Methodology, we have made assumptions about exposure to contamination from eating fish taken from surface waters of the United States. The purpose of the assumptions is to ensure that if criteria are met in a waterbody designated with the uses specified in Section 101(a) of the CWA, fish consumers can safely eat fish from that waterbody. In addition to the assumption that 17.5 g of fish are consumed per day based on the most recent U.S. Department of Agriculture (USDA) survey data (a value reflecting the 90th percentile of the general population), EPA also assumes that fish and shellfish are taken from water with pollutants present at the criteria level. In order to ensure that people can safely eat fish from waters designated with Section 101(a) uses, it is necessary to assume that all of the consumed fish is taken from waterbodies at the criteria level (*i.e.,* contaminated to the maximum safe level).

We recognize that fishing patterns (*i.e.,* extent and location of fishing) and the degree to which fish and shellfish bioaccumulate contaminants from waters across the United States may differ from the exposure assumptions used to calculate national 304(a) water quality criteria. However, the degree and frequency of such variation are not clearly known, and these potential differences do not relieve EPA from its CWA obligations to develop national water quality criteria (which States and authorized Tribes may modify) that are protective for the general population. Furthermore, we note that not all of these differences would lead to less restrictive (higher) AWQC. For example, some subpopulations may consume fish at a higher rate than the 17.5 g/day assumed in the national 304(a) criteria, and bioaccumulation might occur to a higher degree than the central tendency assumptions used in calculating the national default BAF. As indicated above, EPA believes that the data do not exist to enable us to account reliably for the myriad of spatial and temporal differences in fishing patterns and bioaccumulation and subsequent differences in exposure to fish contaminants at the national level. In addition, we have not received information from any stakeholder that would allow us to make such fine distinctions. Our goal is to ensure that populations who rely on a particular waterbody as the predominant source of their fish and shellfish are adequately protected, thus protecting the designated use of that waterbody. For these reasons, we believe that these assumptions are appropriate for the development of 304(a) criteria. Where States and Tribes have concerns regarding the level of protection afforded by EPA's national 304(a) criteria, we encourage States and authorized Tribes to make appropriate adjustments to reflect local conditions affecting fish consumption and bioaccumulation. Guidance for making such modifications is provided in the 2000 Human Health Methodology.

3. Body Weight Assumptions

Comments—Numerous comments were submitted on issues regarding the adequacy of the body weight default values recommended in the 1998 draft Methodology revisions and what age-based body weight categories are appropriate. Several commenters stated the proposed default body weights were appropriate and that the 70 kg default for adults is appropriate. One commenter stated that the difference between 70 kg and the 65 kg value for women of childbearing age is so small that to distinguish between the two is unimportant. Another believed that the recommended children's body weights are sufficient and that finer age categories would not be useful at this time. However, other commenters addressed the potential need to use finer age-category body weights if it is known that the adverse health endpoint affects a particular age group sensitive at that developmental stage, and one commenter stated that the broad-age default (*i.e.,* for 0- to 14-year-olds) would be inappropriate for an infant. Another commenter pointed out that the default assumption for children ages 1 to 3 (*i.e.,* 10 kg) is too low compared with data from EPA's Exposure Factors Handbook. Other comments advocated that EPA specifically define the percentile value associated with the defaults or recommended that EPA not specify default body weights for children.

Response—We believe it is useful to provide default parameters for various population groups of concern, where possible, and have received support for this from States and from the recent peer review workshop panel. The difference between the general adult default body weight and the weight for women of childbearing age is statistically significant and, therefore, we are providing this value for situations where the critical health endpoint is an *in utero* developmental effect. All parameters used for an exposure evaluation should reflect the specific population group of concern.

As stated in the 1998 draft Methodology revisions, EPA has not provided finer age group defaults for children because the fish intake data do not permit breakouts other than the broader age category. However, in spite of this limitation, we have included finer age group body weights for State and Tribal use (when they have local or regional fish intake data that allow for their use) in the Exposure Assessment TSD. In most cases, we have indicated the specific percentile from each data source for the default value chosen (based on the surveys used and not in the context of the total population because data are not available to conclusively describe the entire population), but we have clarified this in the 2000 Human Health Methodology. Associating a derived criterion with a specific percentile is not possible because such a quantitative descriptor would require more detailed distributional exposure and dose information than is available.

EPA acknowledges that the proposed value of 10 kg for a child ages 1 to 3 is lower than the values reported in the Exposure Factors Handbook (USEPA, 1997a). The 2000 Human Health Methodology uses default body weight values based on the more recent NHANES III data. Contrary to the one commenter's suggestion, the data were not chosen to overestimate exposures; we intended to choose the average body weight as a default. In all cases (*i.e.,* for the adult, childbearing woman, children aged one to ten, and infant/toddler categories), we chose average (mean) body weight values as defaults and do not believe these are overly conservative.

4. Combining Consumption Intakes and Body Weights

Comments—Several commenters stated that when possible or where appropriate, the intake values and body weight data should be combined to generate a ratio/correlation of consumption to body weight, in order to provide better estimates. One commenter requested that EPA consider deriving a 95th percentile value of the water consumption to body weight ratio as the basis for the national 304(a) criteria. However, the opposite opinion was also expressed; that is, several commenters supported the use of separate parameters in the derivation equation. One commenter stated that, based on mean intake and body weight rates in EPA's Exposure Factors Handbook, differences in fish and water intakes between pregnant women and adults in general are so insignificant that they are not worth distinguishing. Opinion was also expressed that differences in intake rates per unit body weight can be more significant for children. EPA was cautioned to make sure that if differences in body weight are considered for different age groups, then the variation of intake by each specific group also needs to be considered.

Response—EPA agrees that the intake rates and body weights for the specific population groups should match (*e.g.,* a body weight for women of childbearing age should be matched with a drinking water intake assumption for women of childbearing age). However, we believe that the exposure parameter choices should be based on the population of concern, regardless of how small the change in the resulting criterion might be compared with a general adult population default. We also believe that there is not always a direct relationship between consumption and body weight. When EPA presented the issue for review by the Agency's SAB, they provided the following advice:

> In theory it would be better to develop standards on a per kilogram body weight basis. However, in practice the results are not different enough to make much difference in the magnitude of AWQCs. In particular, data should not be rejected because individual body weights are not available, and funds should not be allocated for collecting such data since no conceivable benefit would accrue.

EPA has also received input from its State stakeholders regarding potential confusion over combining the two parameters. Most believe that the difference in accuracy is negligible but that the difficulty in associating the units of mg/kg-BW/day with a meal size, especially for public communication and understanding, is great and, therefore, not particularly useful. Several stakeholders believed that if the data were combined as part of a study, or if a strong, demonstrated correlation between intake and body weight exists, the combined parameter should be used. We have evaluated recent information on both drinking water intake and fish intake from the 1994 to 1996 CSFII data and have assessed the differences between the two units of measure—including an emphasis on the differences that result with smaller age categories and drinking water consumption rates for children when mL/kg-BW/day are used (USEPA 2000c,d). [**Note:** SAB's comment on the unavailability of individual body weights is not an issue with the CSFII; that is, this information is available.] EPA intends to base its national 304(a) criteria on the separate intake values and body weights because of the strong input received from its State stakeholders. However, we have also provided tables in the final Exposure Assessment TSD of all fish/population categories for both g/day and mg/kg-BW/day, if States or Tribes prefer their use. The TSD will also provide examples on deriving criteria using either, including identifying situations where the latter estimate may provide substantively more accurate estimates. Additionally, the TSD will provide tables listing comparable values in mg/kg-BW/day (fish) or mL/kg-BW/day (drinking water).

5. Combining Fish Intake and Body Weights

Comments—Several commenters recommended the use of separate fish intake and body weight assumptions because of clarity, familiarity among the States, and data availability. Specifically, the option of combining these values was not considered practical because most studies do not provide such information, even if potentially more accurate. Furthermore, it was suggested that this complicates the derivation process or introduces error (an example was cited), and States and Tribes have the flexibility to use intake values other than the default values provided. Another commenter stated that there is a direct proportional relationship between fish consumption and body weight and that selection of the 90th to 95th percentile value of fish consumption per unit body weight is an appropriate basis for deriving the criteria.

Response—EPA agrees that the use of separate fish intakes and body weights is more easily understood and provides reasonable and protective default estimates. For additional discussion, see our response to Comment E.4, Combining Consumption Intakes and Body Weights. We do not agree that there is necessarily a direct relationship between fish intake and body weight, especially in the context of intake on a per-unit-body-weight basis.

6. Default Drinking Water Intake Rates

Comments—One commenter stated that EPA has overestimated the amount of untreated surface water consumed by the population. However, another commenter believed that the 2 L/day rate is reasonable. A commenter stated that drinking water intake rates in hot, arid climates may be higher than the recommended default rate. Numerous commenters stated that incidental water ingestion should not be considered in deriving AWQC or that it is unimportant. One called for empirical data to support its use and believed that

EPA has implied that incidental ingestion occurs every day. However, other commenters believed that this route should be considered for waters not designated as drinking water sources. One of these requested that EPA provide additional guidance on incidental ingestion relevant to acute toxicity and exposures. Another recommended that EPA evaluate the circumstances to determine whether the incidental ingestion rate would make a difference. A commenter recommended that EPA use a 30 mL/hour assumption in cases where short-term effects may be considered in criteria derivation. One commenter stated that the 10 mL/day value would be too restrictive for use in all nonpotable waterbodies and would conflict with existing State guidance on incidental ingestion.

Response—EPA acknowledges that much of the population consumes water from public water supplies that receive treatment. However, we intend to continue including the drinking water exposure pathway in deriving AWQC for the reasons clearly stated in the 1998 draft Methodology revisions. Refer to that discussion for clarification on this issue [see **Federal Register** Notice, August 14, 1998; Appendix III, C.1.(b)]. We encourage States and Tribes to use alternative intake rates if they believe that water consumption is higher in arid climates than the recommended default rate. We have not assumed that incidental ingestion occurs every day. We have estimated an averaged rate based on available study information. When initiating the process to revise the methodology, several stakeholders identified recreational or accidental water ingestion as a potential health concern. A couple of States have indicated that they already have established incidental ingestion rates for use in developing water quality criteria. EPA agrees that the averaged amount is negligible and will not have any impact on the chemical criteria values representative of both water and fish ingestion. The lack of impact would likely also be true for chemical criteria based on fish consumption only, unless the chemical exhibits no bioaccumulation potential. However, we believe that the issue could be important for the development of microbial contaminant water quality criteria, and for either chemical or microbial criteria for States where recreational uses such as swimming and boating are substantially higher than a national average would indicate. Although we will not use the incidental ingestion intake parameter when deriving our 304(a) national chemical criteria, we will leave the guidance language in the final Exposure Assessment TSD in order to assist States and authorized Tribes that face situations where this intake parameter would be of significance.

7. Default Fish Intake Rates

Comments—EPA received strong support for its hierarchy of preferences regarding fish intake values; that is, use of local or regional studies, and studies characterizing similar populations and/or geography, over default values. EPA also received support for encouraging decisions on intake rates to be made at the State or Tribal level. EPA generally received support for its default fish consumption rates, including the national 304(a) criteria value of 17.8 g/day (now 17.5 g/day based on the 1994–96 CSFII data). There was support for the new default rates as more accurately representing current levels of fish consumption among the general population than the old assumption of 6.5 g/day. Support was also received for providing the variety of default values to protect highly sensitive or highly exposed population groups. One commenter advocated that EPA clearly state that using the 90th percentile value is a risk management decision. However, others stated that EPA has overestimated fish consumption for the population at large. A commenter stated that EPA should use the intake value that its Superfund program utilizes (*i.e.*, 54 g/day). EPA also received support for the default of 86.3 g/day for subsistence fishers (now 142.4 g/day based on the most recent USDA survey data). Some commenters disagreed with the use of a subsistence default as contrary to the purpose of AWQC (while conceding its use for site- or region-specific criteria) or recommended that EPA caution against the use of subsistence values without risk management decisions balancing risk benefits and costs. One commenter stated that subsistence populations are very rare and cannot generally be defined by socioeconomic factors and, thus, EPA's assumption of 86.3 g/day may be over-or underprotective. Several commenters stated their support for the subsistence default but also advocated that EPA should require States to consult with Tribes in order to select an adequate fish consumption rate. Other comments expressed the opinion that a Tribe would be obligated to use EPA's default value if the Tribe could not conduct its own survey or expressed concern over the extrapolation of data from the general population to subsistence populations. Several commenters questioned EPA's choice in selecting a value to represent the 90th percentile of the general population, in contrast to selecting average values for sportfishers and subsistence fishers. A commenter stated that the assumption of 17.8 g/day as a default for sport anglers was not supported by peer-reviewed studies and contradicts the EPA's Exposure Factors Handbook. Another commented that because 17.8 g/day is recommended to represent the general population, it should not be used to represent sportfishers and indicated that 39 g/day may be more appropriate. Other comments advocated the use of actual sportfisher/subsistence population data or making sure that the defaults chosen appropriately correspond to these groups.

Two commenters stated that the recommended values for children and women of childbearing age were overly conservative and inappropriate because developmental effects would not result from short-term exposures. However, another commenter stated that evidence on reproductive/developmental effects should make EPA take the most conservative approach to protect pregnant women, fetuses, and young children. Other commenters found these values acceptable and believed that the approach is consistent with EPA developmental toxicity guidelines. One commenter noted that single meal or short-term consumption for these groups could easily exceed the EPA defaults. Other comments cautioned EPA to make sure that the exposure assumptions to protect against developmental health effects be used only with chemicals causing acute toxicity, or believed the defaults are unrealistically high and favored an averaged daily equivalent (mean or median value). Two commenters believed that basing both national and regional criteria on a fish consumption rate in the 90th to 95th percentile would be most appropriate, and one stated that the high-end percentile should be used with rates for children and women of childbearing age to protect against reproductive or developmental effects. Another commented that criteria to protect subsistence fishers or pregnant women should be left to the States and Tribes to consider. Still another suggested that EPA develop special fish consumption rates for populations that consume much higher amounts than average and, thus, not be overly conservative in its default assumptions. Two commenters questioned EPA's assumption that children consume more fish on a body weight basis than adults, and one commenter advocated use of childhood fish consumption rates. Concern was also expressed that all of

the default rates assume that consumers eat from a single source only, and that the RSC factor results in a double-counting of fish intake rates. One commenter said that EPA should not establish default values. Finally, one commenter advocated using mean consumption rates (not the 90th percentile) if the Agency intends on retaining its RSC factor.

Response—EPA acknowledges the support for the default fish intake rates. Our national 304(a) water quality criteria serve as guidance to States and authorized Tribes, who must in turn adopt legally enforceable water quality criteria into water quality standards. States and authorized Tribes have the option to develop their own criteria and the flexibility to base those criteria on population groups that they determine to be at potentially greater risk because of higher exposures, yet, EPA cannot oblige the States to specific consulting agreements because, again, criteria are guidance, not enforceable regulations, and do not impose legally binding requirements. Therefore, we recommend that States and Tribes give priority to identifying and adequately protecting their most highly exposed population by adopting more stringent criteria, if the State or Tribe determines that the highly exposed populations would not be adequately protected by criteria based on the general population. In all cases, States and authorized Tribes have the flexibility to use local or regional data that they believe to be more indicative of the population's fish consumption—instead of EPA's default rates—and we strongly encourage the use of these data. In most instances, using alternate fish intake rates should not be difficult, once the value has been determined, in that the criteria calculation is performed by substituting the State/Tribal intake rate in place of EPA's default rate. We believe that the assumption of 17.5 g/day (again, based on the recent 1994–96 CSFII data) will protect a majority of the population of consumers of fresh/estuarine finfish and shellfish, especially population groups who rely on a particular waterbody for most or all of their fresh/estuarine intake. It is our goal to utilize an intake rate that represents more of the population than would a central tendency value. Thus, we intend to derive our national 304(a) criteria using this 90th percentile assumption, based on the updated analysis of the 1994–96 CSFII data. EPA also acknowledges that other Agency programs may utilize different default assumptions. In the case of the Superfund program, the value used (54 g/day) represents a default used for recreational fishers. It reflects total fish consumption from both marine and fresh/estuarine sources; however, it includes only finfish, not shellfish. As such, it cannot be directly compared to our default based on the general population for finfish and shellfish from fresh/estuarine sources only. [*Note*: The comparable 90th percentile CSFII value from the 1994–96 data, if marine species were included, would be 74.87 g/day.] For the AWQC program, EPA believes it has selected an appropriate, not overly conservative default value, given the goals of the CWA and the criteria program.

For the rationale stated above, we strongly believe that providing a default rate for subsistence fishers is important for States and Tribes, if they choose to use it in lieu of their own study data. We disagree with the commenter that the concept is contrary to the purpose of AWQC. Moreover, the commenter appears to have incorrectly assumed that EPA would base its national 304(a) water quality criteria on the subsistence fishers intake value. We intend to base our national criteria on the recommended value for the general population. We emphasized in our 1998 draft Methodology revisions that States and Tribes should consider developing criteria based on highly exposed populations when those populations would not be adequately protected by criteria based on the general population. This is, in fact, consistent with the purpose of AWQC. We also acknowledge that there is variation in fish consumption patterns, especially among subsistence fishers. For the purpose of providing one national intake rate for subsistence fishers, we believe that the value of 142.4 g/day (an estimated national average value based on comparing the CSFII 1994–96 data with subsistence fisher studies) is appropriate. Although the exact percentile represented by the arithmetic mean varies from survey to survey, we believe this value is more appropriate and protective than a median or central tendency value—which we cautioned against using in the 1998 draft Methodology revisions, because median values in the available short-duration surveys may be zero. However, as indicated above, EPA strongly encourages the use of site or regional-specific studies instead of this default value, and the State's/Tribe's discretion in considering higher intake rates than an arithmetic mean. We reemphasize here our four-preference hierarchy, which is designed to give States and Tribes more options than simply conducting a survey or using our default. EPA's national 304(a) criteria are health-based values only and are not intended to account for cost/benefit analyses. As indicated in our 1998 draft Methodology revisions, risk management decisions regarding balancing risk benefits should be made at the State or Tribal level.

EPA believes it is appropriate to offer default fish intake rates for children and women of childbearing age for States and authorized Tribes to consider if exposures resulting in health effects in children or developmental effects in fetuses are of primary concern. We have recommended a 90th percentile from the 1994–96 CSFII for this potential situation, in order to protect a majority of these population groups. As stated in the 1998 draft Methodology revisions, EPA is not recommending the development of additional water quality criteria, similar to the drinking water health advisories, which focus on acute or short-term effects because these are not seen routinely as having a meaningful role in the water quality standards program. However, we disagree with the commenter that developmental effects cannot result from short-term exposures. To the contrary, we believe there may be instances where the consideration of acute or subchronic toxicity and exposure in the derivation of AWQC is warranted—specifically when such toxicity and exposure are the basis of an RfD, not a chronic effect. Only in this situation would EPA consider such a basis for its national 304(a) criteria. Using long-term consumption rates to evaluate potential developmental effects would not accurately reflect meal size and would be inappropriate for use in such assessments. The separate distribution of short-term (*i.e.*, consumers-only) consumption estimates represents the amount of fish an individual consumes in a day, or multiple days in a short time period, if the person eats fish on that day. The consumers-only consumption estimate approximates a serving size for women of childbearing age or for children. The intent is to characterize consumption over a very short period of time, not as an average or per capita value over a longer period of time. We recommend the use of the short-term (consumers-only) consumption values in assessing developmental risks to children or women of childbearing age. However, we intend to routinely base our national 304(a) criteria on the recommended fish intake rate for the general population. One commenter appears to have incorrectly assumed that EPA would normally base its national criteria on

acute toxicity scenarios. EPA acknowledges that it may have overstated the likelihood that children are more highly exposed in terms of the frequency of their consumption of freshwater and estuarine fish, although this may certainly be true for various subpopulation groups. However, the CSFII data clearly show that children do consume more fish per unit body weight than do adults. Therefore, as stated above, we believe it is useful to provide intake defaults to States and authorized Tribes for children, and we have specifically used childhood fish consumption rates (to the extent allowable by the CSFII data) as advocated by the commenter.

EPA disagrees with the comment that the sportfisher default assumption (*i.e.*, that 17.5 g/day based on the 1994–96 CSFII data represents average consumption rates for this population group) is not supported by available studies or by the Exposure Factors Handbook. The value of 17.5 g/day falls within the range of mean values from sportfisher/angler studies reviewed by EPA. The Exposure Factors Handbook indicates that mean intakes from recreational freshwater studies ranged from 5 to 17 g/day, with mean values from the key West *et al.* studies used in the GLI between 12.1 and 16.7 g/day (USEPA, 1997a). Furthermore, the default rate recommended here for the AWQC is representative of consumption of both freshwater and estuarine fish species, not freshwater species only. We are also aware that some of the sportfisher studies that support higher estimates (*e.g.*, 39 g/day) include marine species.

EPA's fish intake assumption is that all of the consumed fish is taken from one particular waterbody. This is to ensure that any population can safely eat fish from waters designated for fishing, including those who may rely on a single source for their fish (for additional discussion on this issue, see response to Comment E.2, Assumption That All Fish Consumed Is Contaminated at the Criteria Level).

EPA disagrees with the idea that using a 90th percentile value as a default is inappropriate because of the RSC factor. The RSC is used to account for other sources of exposure and, thus, is independent of potential exposures from fresh/estuarine fish. The fresh/estuarine species are not double-counted, as the commenter suggests. (For additional discussion on RSC, refer to the responses in the RSC section below.)

8. Effect of Cooking on the Contaminant Concentration

Comments—Commenters stated that the concept of changes in contaminant level caused by cooking is important to recognize. They recommended that a loss from cooking should be accounted for and that EPA should provide factors in order to calculate this loss into criteria. However, one commenter did not believe that increases caused by cooking should be factored into criteria. One commenter stated that it is not appropriate to assume no loss as a default when no data exist to account for it. Another recommended that the chemical structure be assumed as constant before and after cooking. One commenter stated that the relevance of cooking methods is not clear.

Response—EPA has stated its intention to assume no loss from cooking unless there are adequate data to characterize such a loss. We are aware of some studies on cooking loss and provide reference to quantified information in the 2000 Human Health Methodology. However, we believe it is important to consider both losses and gains in the chemical contaminant from cooking. EPA has also received input from several States regarding the difficulty in making such adjustments on a routine basis. We continue to evaluate this issue in the context of the national 304(a) criteria. We believe that providing guidance on making such adjustments may be useful in the Exposure Assessment TSD volume for States or Tribes that wish to modify their criteria accordingly. However, EPA does not intend to provide specific cooking loss default factors.

9. Inclusion of Marine Species in the Default Rate

Comments—A commenter stated that coastal States have a need to derive water quality criteria for saline waters under their jurisdiction and, therefore, requested additional consideration of marine fish consumption. Another commenter requested that EPA provide greater clarification on its policy not to include marine species, again believing that States and Tribes need to include this in their criteria development.

Response—In the 1998 draft Methodology revisions, EPA recommended inclusion of fresh/estuarine species only for the intake parameter, and accounting for the intake of marine species as part of the RSC. We consider this appropriate because the 304(a) water quality criteria are applicable to discharges from fresh and estuarine waters, not deep marine waters. EPA's 304(a) water quality criteria apply to navigable waters of the United States up the three miles off-shore. However, EPA also says that coastal States and authorized Tribes could consider total fish consumption (fresh/estuarine and marine species) when appropriate for protecting the population of concern. It is important that the marine intake component not be double-counted with the RSC estimate. We maintain our default policy decision and the flexibility afforded to a State or authorized Tribe to base its criteria on alternative assumptions.

10. Precision of the Drinking Water Parameter

Comments—A commenter interpreted EPA's discussion on significant figures as indicating that the drinking water intake should not be factored into that determination because the number represents a science policy value. The commenter also requested that EPA specify a level of protection represented by the AWQC.

Response—The commenter has misunderstood EPA's discussion in the 1998 draft Methodology revisions on significant figures; they have extended the discussion to an evaluation of overall criteria conservativeness via statistical analysis. We stated that the AWQC should not necessarily always be limited to one significant figure because the 2 L/day drinking water value, although supported by data, represents a science policy decision. The discussion only addresses the issue of significant figures, not characterization of criteria protectiveness. For discussion of the issue regarding the population protected by the criteria level, refer to the response for Comment B.3, Protectiveness of the Methodology.

11. Redesignation of Salmon as a Marine Species

Comments—Some commenters disagreed with EPA's reclassification of salmon to the marine category. They stated that EPA has ignored salmon biology and life history, that salmon is an anadromous species, and that salmon eggs, fry, and juveniles take up chemicals. Commenters specifically criticized EPA for ignoring steelhead salmon's life history. Three commenters thought the redesignation is reasonable. One had no objection to the redesignation for threshold toxicants but did object for carcinogenic effects based on a linear low-dose extrapolation, because it would not account for exposures of salmon to ubiquitous chemicals (*e.g.*, PCBs) contributing a substantial portion to total exposure. Another commenter who supported the redesignation advocated flexibility

regarding coastal sportfisher consumption.

Response—EPA has not ignored the life history of salmon. We provided information on the known biology and life history of the species consumed that were included in the CSFII survey, the basis of the default values, in our 1998 draft Methodology revisions. The term anadromous generally refers to a species that spawns in fresh water or near-fresh water and then migrates into the ocean to grow to maturity. It can also refer to an ocean species that spawns in fresh/near-fresh waters. The life cycles of anadromous species vary as to whether they remain in fresh/near-fresh waters until they die or whether they return to ocean waters after spawning. As such, the description provided by EPA in the 1998 draft Methodology revisions is correct and does not conflict with the term anadromous. The CSFII food codes for salmon do not indicate the source of the salmon (*e.g.*, land-locked freshwater, farm-raised, or wild). We based our allocation of salmon between freshwater and marine habitats on commercial landings data provided by the National Marine Fisheries Service for the period 1989–1991. All landings of Pacific salmon, including chum, coho, king, pink, or sockeye, were assigned to the marine habitat. All land-locked Great Lakes salmon and farmed salmon received the classification of fresh water. The resulting apportionment for salmon was 1.18% to the fresh-water habitat and 98.82% to the marine habitat. We believe this is appropriate for our national default intake rates.

EPA understands that steelhead salmon, also known as steelhead trout (*Oncorhynchus mykiss*), is an oceangoing version of rainbow trout with a complicated life history, and may spend a significant portion of its lifetime in fresh waters. States and authorized Tribes have the flexibility to use different assumptions in deriving their water quality criteria, as we stated in the 1998 draft Methodology revisions. That is, States and authorized Tribes could make alternative assumptions to specifically account for steelhead salmon intake. We strongly encourage States and authorized Tribes to do so, as reflected by the recommended fish intake hierarchy of preferences. However, we do not intend to ignore the contribution from salmon in the calculation of our 304(a) criteria. We recommended accounting for this as part of the RSC, thereby ensuring that the criteria would account for the contribution of a contaminant from marine salmon.

12. Studies on Sportfishers and Subsistence Fishers

Comments—Two commenters stated that in summarizing various sportfisher and subsistence fisher studies, EPA failed to provide direction on how States or Tribes can use and interpret the information. One commenter requested additional guidance on the use of local data, while cautioning about such data's reliability. Commenters also listed errors, discrepancies, or missing information from numerous studies that appear in the 1998 draft TSD. One commenter recommended separating studies by type, population, and basis for consumption rate (presumably referring to habitat designations of fish), along with providing comments on the studies. Another stated that many angler studies are biased because the respondents are more ''avid'' in their fishing habits, and a study of fresh-water anglers from Maine might serve better as the basis of EPA's default for sportfishers.

Response—It is EPA's intention to provide summaries of various studies for States and Tribes to consider using and, as such, the Agency is merely providing information, not critiquing or endorsing particular studies. We do not intend to rank the studies because there are significant differences in the purposes and limitations of each study, in addition to the fact that consumption rates vary significantly throughout the country. Therefore, any particular study may be most appropriate to the State or Tribe's particular circumstances. However, we are committed to providing accurate information and intend to correct errors or missing information that would make the summaries of greater use to States and Tribes. We have reviewed the commenters' listed errors or omissions and made appropriate changes. EPA disagrees that any of the sportfisher studies are biased from ''avidity'' among recreational anglers. Although the rates may vary significantly from study to study, the studies specifically sample fishing patterns of these groups and are the most appropriate data for prospective use by States and Tribes. We considered the Maine angler study along with the others presented in the 1998 draft TSD to evaluate the range of mean values before recommending the default value. However, we do not believe this particular study is necessarily best suited for deriving a national default value. Just as with EPA's national 304(a) criteria, States and Tribes always have the flexibility to use other local- or regional-specific studies. We have provided additional guidance on how to consider the studies included in the Exposure Assessment TSD.

13. USDA Continuing Survey of Food Intake by Individuals (CSFII)

Comments—Some commenters believed that the CSFII data are appropriate for deriving AWQC and supported their use in the hierarchy of choices. Others stated that the CSFII data are not appropriate because they include marine species, and combine recreationally and commercially acquired species. One commenter suggested that a significant fraction of the default rate would include farm-raised fish, which would not bioaccumulate the same as wild fish. One commenter stated that the default inappropriately assumes consumption from a single waterbody. Two commenters stated that the CSFII data are biased toward individuals consuming large quantities of fish (assuming constant consumption every day and failing to consider those people who consume less frequently). One of these stated that the CSFII assumes that participants who did not eat fish during the study period are not fish eaters. Several commenters recommended that longer term studies be used, one specifically stating the difficulty in estimating the upper end of the distribution. Comments also referred to or recommended data from NPD Research Inc. or the Tuna Research Institute, presumably referring to the National Purchase Diary (NPD). One commenter assumed that the CSFII default estimates exclude individuals who consume fish but did not report consumption during the sampling period. Another questioned dividing reported consumption by the days of the survey and incorporating nonconsumption. Instead, this commenter recommended using the positive values only (''acute consumers'') for determining default intake rates, which it believed to be consistent with the concept of identifying the population to be protected. One commenter also indicated that intake rates do not vary significantly for fish obtained from different sources—that is, fresh or marine waters. Another stated that the CSFII data assume short-term consumption is representative of long-term consumption. One commenter advocated that EPA use probabilistic methods to derive AWQC.

Response—The comments are incorrect about the exclusion of respondents who did not report fish consumption during the CSFII sampling period. The general population,

recreational fisher, and subsistence fisher default values all include both CSFII respondents who reported eating fish during the sampling period and respondents who reported zero consumption (what the commenter referred to as ''non-consumers''). The CSFII mean values are not biased. Specifically, the intraindividual variation does not bias estimates of the mean intake of the population. The estimates of the upper percentiles of per capita fish consumption based on the short sampling period data may be biased upward, thereby resulting in a conservative estimate of risk. However, the extent to which this is overestimated is not knowable. We note that we did not rely exclusively on the CSFII data; rather, the data were analyzed with those from other studies (especially for recreational fisher and subsistence fisher estimates) to evaluate and corroborate our decision. We believe the CSFII data are representative of fish intake rates among the general population. As part of the CSFII analysis, sampling weights were adjusted to account for nonresponse and were subsequently reweighted using regression techniques that calibrated the sample to match characteristics correlated with eating behavior.

EPA generated mean and percentile estimates of daily average per capita fish consumption based on the USDA 1994–96 CSFII. The strengths of this survey for supporting estimates of per capita food consumption are twofold. First, the survey design is structured to obtain a statistically representative sample of the U.S. population. Second, the survey is designed to record daily intakes of foods and nutrients and to support estimation of food consumption. These features are in direct alignment with the objective of producing current, per capita fish consumption estimates for the U.S. population. The 1994–96 CSFII collected two non-consecutive days of food consumption data from a sample of 11,912 individuals in the 50 states and the District of Columbia. The method employed to collect dietary intake data also strengthened the CSFII design for supporting per capita consumption estimates. For example, the survey was administered by an interviewer on both days of data collection. For these reasons, we believe that the 1994–96 CSFII is the best source of data on a nationwide basis for estimating fish consumption by the U.S. population.

The NPD study was conducted over 25 years ago. The NPD is the basis of the 6.5 g/day default value that EPA has historically used for fresh/estuarine fish consumption. We have received consistently strong input from many of our stakeholders (including States and Tribes) who consider the 6.5 g/day value inadequate and advocate the use of much more recent data. The Agency also believes that such an update is needed. We are not aware of any subsequent major survey conducted during a 30-day period as was done by the NPD. The Agency does not believe that the year-long study of 29 people mentioned by one commenter is appropriate to use for a national default value. The use of probabilistic methods was discussed earlier in our response to Comment B.3, Protectiveness of the Methodology.

EPA also believes that its discussion of identifying population groups to protect is not contradicted by its combining positive and zero values to estimate long-term or average consumption. We reiterate here that we believe the summation of the amounts of fish consumed by each individual across the 2-day reporting period for the CSFII 1994–96 data (formerly a 3-day reporting period), followed by dividing that total individual consumption by 2, is a reasonable approach to estimating average consumption. The CSFII did not specifically ask questions on whether respondents consume fish or how often and, therefore, it is not possible to distinguish fish consumers from fish nonconsumers. EPA is aware from other major surveys that most people consume fish—at least episodically—and, therefore, believes that using the positive and zero values from the CSFII is a reasonable method of estimating average intake. We contrast this to using only the subset of survey responses where fish was actually consumed as a method to estimate an ''acute consumer,'' that is, to provide an estimate of the amount of fish consumed in the context of acute or short-term exposures (not in the context of average or long-term exposures).

The commenters are also incorrect about the inclusion of marine species. The proposed default rates for the general population, as well as for children and women of childbearing age, are based on freshwater and estuarine species only. The CSFII study does include marine species and EPA has additionally provided States and Tribes with these data in the Exposure Assessment TSD; however, they are not included in the default estimates of national freshwater and estuarine fish consumption. According to the CSFII data, most persons in the general population appear to consume more marine species than fresh/estuarine species. However, EPA supports State/Tribal use of local or regional data that indicate otherwise. We have not made any specific assumptions regarding farm-raised fish and their contribution to the default intake rate, nor have we received any information that would allow us to characterize (or discount) the amount that farm-raised fish contributes to the national default value or to differentiate bioaccumulation levels.

14. Use of Uncooked or As Consumed Fish Weight for Default Intake Rates

Comments—One commenter stated that either raw weight or cooked weight can be appropriate as long as the effect of cooking on the contaminant is accounted for. Some commenters stated that the cooked weights are the most technically defensible, because they are the basis for the consumption estimates. However, others believed the default intakes should be adjusted to reflect uncooked weights, with one commenter concerned that a cooked weight would result in incomplete accounting of exposure to threshold toxicants. One commenter also pointed out the difficulty of making appropriate adjustments to the BAF because of uncertainties in concentration levels of contaminant due to cooking and that many cooking techniques result in retention of fish fluids. Another commenter stressed the need to use uncooked weights in order to be consistent with fish tissue studies and BAF values. One commenter expressed concern that use of cooked weights would produce an inadequately protective criterion for mercury, while another believed that cooked values introduce a source of uncontrolled variability.

Response—We have considered the pros and cons of using uncooked/as consumed weights on several levels. First, the intake parameters of the criteria derivation equation are intended to capture ingestion—that is, what people actually consume and are exposed to. By and large, people consume cooked fish, and if raw shellfish or sushi was consumed by the CSFII respondents, those intakes were included in the as consumed weights. This assumption is also consistent with the dietary estimates based on prepared foods (not raw commodities) that are made by both EPA's pesticide program and the Food and Drug Administration (FDA) Total Diet Study program. We also considered the ''consistency'' issue in the context of the fact that the CSFII survey respondents estimated the weight of fish that they consumed. Similar to the CSFII, EPA's GLI was based on a consumption survey of fish intakes for prepared meals. EPA additionally considered the effect of the

cooking process. There are comparatively few chemicals for which measurements are available, and the process is complicated further by the different parts of a fish where the chemical may accumulate, the method of preparation, and how the cooking process may transform the chemical. What is certain is that the mass of the contaminant will either remain constant or be reduced. The resulting concentration is harder to predict. In the 1998 draft Methodology revisions, we recommended the use of as consumed weights and an adjustment of the bioaccumulation factor for cooking loss, if information was available. Otherwise, we recommended using the as consumed weight along with the full bioaccumulation factor (unadjusted for cooking loss), which would produce slightly more stringent AWQC. We have also received input from stakeholders regarding potential confusion over the fact that uncooked weights are used in the Agency's fish advisory program and that having two sets of values may prove confusing to States and Tribes, as well as the general public. Furthermore, the measures of a contaminant in fish tissue samples that would be applicable to either compliance monitoring or the permitting program are related to the uncooked fish weights.

Therefore, EPA has reconsidered its position based on these facts and despite the fact that the as consumed values more accurately represent actual intake, we will derive our national 304(a) criteria on the uncooked weight fish intakes. The approach of using an uncooked weight in the calculation will result in somewhat more stringent AWQC (studies indicate that, typically, the weight loss in cooking is about 20%). We will also provide guidance on site-specific modifications in the Exposure Assessment TSD. Specifically, we will describe an alternative approach for calculating the AWQC using the as consumed weight (again, more directly associated with exposure and risk) which is subsequently adjusted by the approximate 20% cooking loss to a resultant uncooked equivalent. Thus, the AWQC conversion to an uncooked equivalent can be consistently used between State/Tribal standards programs and still represent the same relative risk as the as consumed value. It is important to understand that the two approaches will not result in the same AWQC value. Whereas the as consumed approach is more scientifically rigorous and represents a more direct translation of the as consumed risk to the uncooked equivalent, it may be too intensive a process to expect of State and Tribal organizations whose resources are already constrained.

Relative Source Contribution (RSC)

15. Default Percentages and RSC Floor of 20% and Ceiling of 80%

Comments—A commenter criticized EPA's recommended RSC default rate in the face of uncertainty about other routes of exposure. Another commenter considered the ceiling of 80% to be a redundant uncertainty factor. Other comments suggested the use of an 80% RSC for bioaccumulative chemicals so that the contribution from fish consumption would not be underestimated, did not support the range of 20% to 80%, or requested additional justification for the assignments of 20%, 50%, or 80%.

Response—EPA has recommended using the 20% RSC default when routes of water exposure other than oral or sources of exposure other than fish and water are anticipated, but adequate data are lacking to quantify those exposures. When data are adequate, they should be used instead of the default. If it can be demonstrated that other sources and routes of exposure are not anticipated for the chemical in question (based on information about its known/anticipated uses and chemical/physical properties), then the 80% ceiling is recommended. The ceiling is intended to provide adequate protection for those who experience exposures (from any or several sources) higher than available data indicate. For many of the chemical contaminants that EPA evaluates, data are not available on multipathway exposures. It is possible that as we progress with our development of a cumulative risk policy, we may find an 80% RSC to be underprotective. This concern was expressed during the scientific peer review workshop on the Methodology. One commenter misunderstood the application of lower ceilings (*i.e.*, 50%, 20%) when existing information indicates no other media-specific uses or sources. Also, some chemicals that bioaccumulate in fish also bioaccumulate in other meat and dairy products (*e.g.*, dioxins). Therefore, to simply assume an 80% default in all cases would not be appropriate. The RSC approach allows for an apportionment of 80% when information indicates that other exposures are not relevant for the chemical being evaluated. EPA has added discussion in the final Methodology to address these situations and to better explain the application of the lower ceilings.

16. Duplication of Fish Intake Assumptions

Comments—Commenters stated that applying an RSC factor results in a double-counting of fish from other sources.

Response—The commenters are incorrect. The fish intake default used in the equation accounts for fresh and estuarine species only. The RSC factor potentially applies to nonfish dietary intake, air exposures, and marine fish species. To protect humans who additionally consume marine species of fish, the marine portion should be considered as part of the ''other sources of exposure,'' that is, part of the RSC or dietary value. EPA specifically emphasized in the 1998 draft Methodology revisions that States and authorized Tribes need to ensure, when evaluating overall exposure to a contaminant, that the marine fish intake is not double-counted with the dietary intake estimate used. This applies if the State or authorized Tribe chooses to account for total fish consumption (*i.e.*, fresh/estuarine and marine species) in the fish intake parameter used in the AWQC equation.

17. Exposure Route Differences

Comments—EPA received support for its rationale on accounting for differences in bioavailability and absorption between exposure routes when data are available, and assuming equal rates when data are absent.

Response—We acknowledge this support.

18. Need for an RSC Factor/Considering Multiple Routes of Exposure

Comments—Commenters supported the greater emphasis on RSC, including the use of empirical data. Some stated that EPA should give full consideration to multiple routes of exposure (*i.e.*, ingestion, inhalation, dermal), with emphasis on the variety of water-related activities, cultural practices, and lifestyles. Several commenters pointed to published studies on assessing inhalation and dermal exposures, and two commenters advocated that EPA determine when there is a need to factor in these exposures, based on available information on the chemical. One commenter stated that there are circumstances where inhalation exposures can be a significant portion of total exposure (*e.g.*, for some chemicals during showering). However, another suggested that consideration of inhalation and dermal exposures is premature. Two commenters stated that uncertainty factors, severity of effects, essentiality, and additive/synergistic

effects should be factored into the RfD apportionment, with one believing that this should also include the option of developing less stringent criteria when there is great uncertainty in the data. Five commenters stated that they believe the RSC/Exposure Decision Tree concepts represent an unnecessary safety factor or should not be considered. One suggested that the water quality criterion should relate only to water exposures. Two commenters suggested that factoring in other exposures is ''penalizing'' the AWQC and makes them overall environmental exposure criteria. Another questioned the need to apportion the RfD, but focused on drinking water regulations, stating that accounting for other sources of exposure would likely have no benefit, presumably due to conservatism in the RfD derivation (yet acknowledging that those uncertainty factors are independent of the exposure assessment). Several commenters recommended that EPA reconsider the SAB's advice not to routinely apportion the RfD. Others believed that the RSC should be used only for site-specific criteria, or that States should have the flexibility to make adjustments for local conditions. Two commenters also stated that the Exposure Decision Tree is unclear, is overly complicated, or has unrealistic data requirements. Another stated that the approach is generally desirable but that EPA needs to provide a greater and more easy-to-follow explanation of the rationale, indicating policy judgments where they occur. However, other commenters supported the Decision Tree approach for its facilitation of identifying the decisions necessary to select the most appropriate RSC value and considered it scientifically valid. One commenter cautioned that if probabilistic analysis techniques are used, their application must be valid and underlying assumptions clearly indicated. Commenters expressed the need for data to avoid the 20% default, others stated that defaults should be avoided altogether, and one recommended a 100% RSC for highly bioaccumulative chemicals. One of the supporters believed that the approach is a reasonable compromise between avoiding problematic increases in exposures to substances and not setting unduly restrictive requirements. A commenter questioned how new data would be considered in the context of RSCs based on older data. Another recommended that non-zero values for other exposure sources not be assumed unless a significant number of samples are positive. It was also recommended that EPA coordinate the RSC policy with other Agency programs.

Response—EPA disagrees that the RSC represents an excessive or unnecessary safety factor. The purpose of the RSC is to ensure that the level of a chemical allowed by a criterion or multiple criteria, when combined with other identified sources of exposure common to the population of concern, will not result in exposures that exceed the RfD or POD/UF. The policy of considering multiple sources of exposure when deriving health-based criteria has become common in EPA's program office risk characterizations and criteria and standard-setting actions. Since the SAB expressed concerns in 1993, numerous Agency workgroups have evaluated the appropriateness of factoring in such exposures and concluded that it is important for adequately protecting human health. Consequently, Agency policy has evolved significantly over the last 6 years. Various EPA program initiatives and policy documents regarding aggregate exposure and cumulative risk have been developed, and include consideration of inhalation and dermal exposures. Additionally, accounting for other exposures has been discussed in recent mandates (*e.g.*, the Food Quality Protection Act) and, thus, is becoming a requirement for the Agency. The RSC approach has been shared with other EPA offices, and efforts to coordinate policies on aggregate exposure, where appropriate, have begun. EPA intends to continue developing guidance on the RSC issue and guidance to address the concern that human health may not be adequately protected if criteria allow for higher levels of exposure that, combined, may exceed the RfD or POD/UF. We also intend to refine the 2000 Human Health Methodology in the near future to incorporate guidance on inhalation and dermal exposures. As stated previously, we are required to derive water quality criteria under Section 304(a) of the CWA and do not intend to derive site-specific criteria for individual waterbodies. However, States and authorized Tribes do have the flexibility to make different exposure and RSC estimates based on local data.

Uncertainty factors used in the derivation of the RfD to account for intra-and interspecies variability and the incompleteness of the toxicity dataset(s)/animal studies are specifically relevant to the chemical's internal toxicological action, irrespective of the sources of exposure to humans. The Agency's policy is to consider and account for other sources of exposure in order to set protective health criteria. We disagree that uncertainty in the data should result in less stringent criteria. However, we have provided additional clarification on the guidance allowing less stringent assumptions when multiple sources of exposure are not anticipated.

The adequacy requirements for the Exposure Decision Tree are not unduly restrictive. The ideas of representativeness, quality assurance, and sampling size are fundamental to properly conducted monitoring studies. Furthermore, the minimal requirement of samples to make an (at least, nominally) acceptable estimate of average and high-end exposure from that relative source (*i.e.,* 45 samples) is not unreasonable guidance. EPA also believes that the number of decision points in the Decision Tree for any particular chemical are not excessive. We have provided additional discussion in the 2000 Human Health Methodology in order to clarify numerous issues on the Decision Tree approach, including the discussion on the use of defaults. We believe that probabilistic techniques are potentially appropriate for use and agree that they must be valid, appropriately applied, and clearly presented.

Regarding changes in ambient chemical concentrations that would affect the RSC calculation, States and authorized Tribes have the opportunity to make changes in their water quality standards during triennial reviews, and EPA would evaluate those changes based on information submitted with the proposed changes. Similarly, EPA would consider changes to AWQC when significant changes in sources of exposure occur that affect the default values.

19. Use of RSC With Carcinogenic Effects Based on Linear Low-Dose Extrapolation

Comments—A commenter advocated the use of an RSC factor with carcinogenic effects based on linear low-dose extrapolation in order to account for other sources of exposure.

Response—EPA does not apply the RSC to carcinogenic effects based on linear low-dose extrapolation because the AWQC are being determined with respect to the incremental lifetime cancer risk posed by a substance's presence in the exposure sources relevant to the specific criterion, not in terms of an individual's total cancer risk from all sources of exposure. In the case of carcinogens based on nonlinear low-dose response extrapolation or a noncancer endpoint where a threshold is assumed to exist, non-water

exposures (*i.e.*, non-drinking water and non-fish ingestion exposures, and inhalation or dermal exposures) are considered when deriving the AWQC. The rationale for this approach has been that for pollutants with effect thresholds, the objective of the AWQC is to ensure that an individual's total exposure does not exceed that threshold level. Health-based and medium-specific criteria values for carcinogens based on a linear low-dose extrapolation typically vary from other medium-specific criteria values in terms of the concentration value, and often the associated risk level. Therefore, the RSC concept could not apply unless all risk assessments for a particular carcinogen based on a linear low-dose extrapolation used the same concentration value and same risk level; that is, an apportionment would need to be based on a single risk concentration value and level.

20. Use of Subtraction or Percentage Methods in RSC Apportionment

Comments—One commenter advocated the subtraction method instead of the percentage method for RfD apportionment, and advocated the use of central tendency values. This commenter criticized the percentage method as irrational and likely to produce overly stringent criteria. In addition, it was stated that the percentage method would allow criteria that could result in exposure levels that exceed the RfD when combined exposures are high. Other commenters expressed concern over basing the RSC on current levels of contamination. However, one believed that the percentage apportionment was reasonable given the difficulty in alternative apportionment methods (for example, an apportionment that would minimize the costs of reducing total exposure to/below a certain amount). One commenter suggested using a multiple default system.

Response—The first commenter has significantly misunderstood EPA's policy goals. The argument against use of the percentage approach is based on the idea that the maximum possible amount of chemical concentration, after subtracting other sources, should be allocated to drinking water criteria or standards. This is not EPA's goal nor is it stated in any relevant mandate. The rationale of deliberately removing the entire cushion between precriteria levels (*i.e.*, actual levels) and the RfD, and thereby setting criteria at the highest levels short of exceeding the RfD, is counter to the goals of the CWA for maintaining and restoring the nation's waters. It is also directly counter to Agency policies, explicitly stated in numerous programs, regarding pollution prevention. EPA has advocated that it is good health policy to set criteria such that exposures are kept low when current levels are already low. The subtraction method generally results in prospective criteria values for a contaminant in a particular medium at significantly higher levels than the percentage method and, in this respect, is contradictory to these Agency goals. In fact, many chemicals have existing levels in environmental media, based on available monitoring data, substantially lower (compared with the RfD) than the resulting criteria allow. This is the case with most of the theoretical examples that one commenter provided to refute the method.

The Agency has modified its policy with the Exposure Decision Tree approach to allow use of the subtraction method when multiple media criteria are not relevant. The Agency RSC Workgroup recommended that, although combined exposures above the RfD may or may not present an actual health risk, a combination of health standards exceeding the RfD may not be sufficiently protective. Therefore: (1) Maintaining total exposure below the RfD is a reasonable health goal; (2) there are circumstances where health-based criteria for a chemical should not exceed the RfD (either alone or in combination); and (3) the best way to prevent exceedance of the RfD is to apportion it when multiple health criteria are relevant to a given chemical. We believe that the percentage method is rational in the context of the above goals when multiple media criteria are at issue. However, as a commenter suggested, the percentage method does not simply depend only on the amount of the contaminant in the prospective criterion source. It is not a set amount. It is intended to reflect health considerations, the relative contribution of other sources, and the likelihood for ever-changing levels in each of those multiple sources (due to ever-changing sources of emissions and discharges). The percentage method does not break any ''logical link,'' as a commenter suggested (the commenter referenced an unpublished report from discussions prior to the development of the Exposure Decision Tree approach). EPA is interested in knowing the amounts of current exposures, including water, and is always cognizant of their relationship to the RfD (one commenter suggested that EPA does not compare actual exposures to the RfD; this comparison is always known). We have historically evaluated chemicals in the context of their current levels (*i.e.*, ambient levels prior to either criteria development or regulatory activity). Evaluating these levels, along with the hazard identification, has historically formed the basis for prioritization and whether the Agency would pursue criteria or standards development. We disagree with the comment that criteria should be set without regard to the actual level of the contaminant. Actual levels are advocated by a commenter for use with the subtraction method. In the case of multiple criteria for a given chemical, the commenter's claim that the subtraction method will ensure that ''an individual's exposure to a chemical does not exceed the RfD'' is not necessarily guaranteed if criteria for other media allow for concentrations in environmental media that, combined, may result in exposures greater than the RfD. EPA acknowledges that the percentage approach outcome varies depending on the magnitude of current exposures, and we have sought to provide greater clarification on this policy issue in the 2000 Human Health Methodology. Of course, depending on the levels from each source, the subtraction method can also produce unstable values—that is, they could vary from very high, to moderate, to very low, even to a negative number.

As previously indicated, probabilistic analyses are appropriate when they are validated techniques that are applied correctly and supported by adequate data. However, much of the time, the amount of data available to describe distributions of exposure from various known sources to the U.S. population—for use in setting nationwide criteria—is inadequate to support meaningful probabilistic analyses. Nevertheless, rather than simply using a default value in every instance, the Agency attempts to compare exposure intakes based on available data to estimate their relative contribution to the total—given that understanding the degree to which their concentrations vary, or making any distributional analysis, is not possible. When multiple criteria are at issue, the criteria values are based on the best available information, with an assumption that there may be enough relative variability such that an apportionment (relating that percentage to the RfD) is a reasonable way of accounting for the uncertainty regarding that variability. Again, in the context of making an estimate of potential national exposures, there is great uncertainty in the range of exposures, and as previously stated, the goal is not to allow a water criterion to use up the

''space'' between the total exposure and the RfD. An example of the percentage apportionment's potential use is when pesticides are at issue. It does not make sense to allow the water criterion to use up that space when (in terms of the chemical's intended uses) the dietary route is obviously the ''direct'' source of exposure. When the course of pesticide tolerance-setting activities may, over time, vary the exact amount of the RfD taken up, an apportionment may also be best for pesticide program planning. The Exposure Decision Tree has allowed for the use of the subtraction approach when only one criterion is relevant. Also, given the future need to develop cumulative risk policies, the subtraction method in these cases could be a short-lived option.

Finally, one commenter incorrectly assumed that the percentage method would allow criteria that could result in exposure levels that exceed the RfD when combined exposures are high. Again, this commenter incorrectly assumed that EPA is not aware of the relationship of the estimated exposures to the RfD. The Exposure Decision Tree approach states that, in these situations, a risk management decision would be made in order to reduce exposures to levels that would prevent exceedance of the RfD. We have provided greater clarification on this issue in the 2000 Human Health Methodology. We have also provided clarification on the use of central tendency values when estimating exposures, which we do not believe to be fully adequate for protection of human health when setting national 304(a) criteria.

F. Bioaccumulation

1. Use of Bioaccumulation Factors (BAFs) in General

Comments—Overall, commenters were not adverse to incorporating bioaccumulation into criteria derivation, but were concerned with the methodology EPA proposed to use. Most comments received were focused on the general use of BAFs. Because of the site-specific nature that BAFs can take, several commenters are concerned with applying national BAFs developed from a limited set of data and array of aquatic systems, or from a model, to all waterbodies in the United States. Some commenters did not agree with EPA's proposed BAF tiered hierarchy. These commenters stated that EPA should not derive single national BAFs because there is substantial variation among waterbodies in factors that influence bioaccumulation (*e.g.*, food chain, metabolism, bioavailability, loading history). They recommended that BAFs be calculated on a site-specific basis, or that field-derived BAFs be used in conjunction with modeled BAFs in a weight-of-evidence approach to select a final BAF. Some commenters also wanted the BAF guidance to more clearly state how it applies to different groups of compounds (*e.g.*, nonionic organics, ionic organics, metals, organometallics). Several commenters did agree with EPA that field-derived BAFs better reflect potential exposure to chemicals from all sources than BCFs and incorporate factors in the field (*e.g.*, food chain, metabolism, chemical loading history, temperature) that can affect bioaccumulation.

Response—Although EPA acknowledges there are site-specific factors that affect bioaccumulation, we disagree that national BAFs should not be derived. For some pollutants (*e.g.*, PCBs, methylmercury), biomagnification through the food chain can be substantial. Using a BCF, which only accounts for exposure from the ambient water, could substantially underestimate the potential exposure to humans for some chemicals and result in criteria that are underprotective of the designated uses. Since publishing the 1980 Methodology, there has been a growing body of scientific knowledge that clearly supports the observation that bioaccumulation and biomagnification occur and are important exposure issues to consider for many highly hydrophobic organic compounds and certain organometallics (Russell *et al.*, 1999; Fisk *et al.*, 1998; USEPA, 1998d; Watras and Bloom, 1992; Oliver and Niimi, 1988; Swackhammer and Hites, 1988; Niimi, 1985; Oliver and Niimi, 1983). For highly persistent and bioaccumulative chemicals that are not easily metabolized, BCFs do not reflect what the science indicates. For this group of chemicals, bioaccumulation (*i.e.*, accumulation of a chemical in aquatic biota from all routes of exposure) should be accounted for in the derivation of water quality criteria in order to protect against unacceptable risks from contaminated biota. The use of properly derived BAFs will enable chemical exposure from all sources to be accounted for in water quality criteria. The lack of national BAFs would greatly hinder the development of water quality criteria because many States and authorized Tribes may not have the resources to develop site-specific BAFs. We continue to believe that using national BAFs is the most scientifically valid approach to deriving national AWQC.

EPA acknowledges that data available to derive national BAFs and to validate the overall bioaccumulation methodology are primarily limited to persistent, hydrophobic chemicals from selected locations (*e.g.,* Lake Ontario, Green Bay, Bayou d'Inde, Hudson River). However, we believe these chemicals and sites encompass a reasonable range of chemicals, locations, and ecosystems from which to evaluate the appropriateness of the bioaccumulation methodology. To obtain better representation of lotic (*e.g.,* river) systems, we also performed evaluation of the predictive BAF methods with PCB, pesticide, and chlorinated benzene data from the Hudson River and Fox River/Green Bay. In the vast majority of comparisons between the predicted BAFs and field-measured BAFs using all four methods, the predicted BAFs were in very good agreement with the field-measured BAFs. We further acknowledge commenters' concerns that certain portions of the methodology may not be applicable to some types of chemicals. As a result, we have developed additional guidance that restricts some aspects of the methodology to certain types of chemicals. For example, we have revised the 1998 draft Methodology revisions to remove the use of K_{ow}×FCM to estimate BAFs for chemicals that have been consistently shown to be metabolized substantially in aquatic biota (*e.g.,* certain PAHs) and have clearly differentiated which methods apply to ionizable chemicals and which do not.

We also recognize that there were some uncertainties in the 1998 draft Methodology revisions on how the BAF methodology would be applied both nationally and on a site-specific basis. In response to this, we made substantial revisions to the 1998 draft bioaccumulation methodology which we believe makes the revised methodology applicable on a national basis. First, we improved the readability and guidance presented in the bioaccumulation methodology based on public and peer reviewers' comments. Specifically, we separated guidance for developing national BAFs from guidance for developing site- or region-specific BAFs and revised the Methodology document to make it more clear to the reader on how EPA will derive national BAFs. Second, EPA expanded the guidance for deriving site- or region-specific BAFs to better enable such adjustments to be made by States and authorized Tribes. For example, we updated, expanded, and made more accessible the databases used to develop national values for lipid content in aquatic biota and organic carbon content

in water. Third, we plan to develop detailed guidance to assist States and authorized Tribes in designing and conducting field studies to measure site-specific BAFs and BSAFs (biota-sediment accumulation factors). This guidance will specify our recommendations for how, when, where, and how often one should sample water, biota, and sediment for producing reliable measurements of BAFs and BSAFs.

In addition to improved clarity and expanded guidance, EPA believes the changes we made to the national BAF methodology address concern indicated by some public commenters about uncertainty in various aspects of the methodology. We believe the changes we have made reduce the uncertainty in several components of the national BAF methodology. For example, development of separate procedures for deriving BAFs for different chemical classes (*e.g.,* high vs. low hydrophobicity, high vs. low metabolism in biota, ionic vs. nonionic organics) will reduce uncertainty in national BAFs and simplify procedures. As part of these revisions, we recommended that K_{ow}-based estimates of BAFs and food chain multipliers (FCMs) not be used for nonionic organics that are known to be metabolized substantially in targeted biota (*e.g.,* some PAHs). Restrictions have also been placed on the use of the BSAF methodology so that the method is used for the chemicals for which it is most appropriate.

We clearly recognize that even with these revisions incorporated into the national BAF methodology, significant uncertainty might exist in the assessment and application of national BAFs at some sites throughout the United States because of the influence of site-specific factors. Therefore, we have more clearly indicated that development of site-specific BAFs is encouraged and supported when it can be shown that a national BAF is inappropriate, or when a State or authorized Tribe prefers to derive a site-specific BAF.

EPA agrees with commenters that in some cases it may be appropriate to derive a BAF using several of the recommended methods (Methods 1–4), with the final BAF chosen using a weight-of-evidence approach. We have provided general guidance on the assessment of uncertainty in using field-measured BAFs (and BAFs derived using the other methods) when deriving national BAFs. However, we do not believe that the mere existence of uncertainty means that national BAFs (and resulting national 304(a) water quality criteria) cannot be implemented effectively throughout the United States. For more than two decades, we have developed and implemented our national 304(a) water quality criteria (aquatic life and human health) through State, Tribal, and on occasion, Federal water quality standards programs. Implementation of this program has relied on the use of national 304(a) criteria as a cornerstone but has evolved to allow the use of procedures to modify national criteria by States and authorized Tribes where appropriate. EPA's national bioaccumulation methodology is consistent with this programmatic practice, by enabling States and authorized Tribes to readily adopt national 304(a) water quality criteria into standards (based on National BAFs) that achieve the CWA goals of protecting public health while also allowing site- or State-specific adjustments in situations where national AWQC may be considered overprotective or in some cases, underprotective.

Comments—Some commenters questioned the application of the BAF prediction approaches (Tiers 2–4; referred to as Methods 2–4 in the revised Methodology) on a national scale because the data used to validate the approaches and develop predicted BAFs come primarily from chemical partitioning relationships observed from a limited set of studies (*e.g.,* Great Lakes region).

Response—EPA agrees that the locations for which the BAF methodology has been fully applied are limited in number (*e.g.,* Lake Ontario, Green Bay). To address this concern, we have conducted additional assessments and comparisons among the bioaccumulation approaches (Methods 1–4) to further validate their usefulness and have validated the methods using other locations (*e.g.* Bayou d'Inde, LA, Fox River/Green Bay, Hudson River, NY). We acknowledge that a model prediction is not a perfect simulation of what occurs in a natural aquatic ecosystem and that uncertainty exists in the BAFs. However, this does not invalidate the usefulness of models validated using data from the Great Lakes and Hudson River in predicting bioaccumulation in other ecosystems. Results of analyses that support using a predictive bioaccumulation approach for a variety of chemicals and aquatic ecosystems can be found in Burkhard et al. (1997), Burkhard (1998), Oliver and Niimi (1988), Swackhammer and Hites (1988), and Oliver and Niimi (1983). Data from these studies clearly indicate that the food web is a dominate exposure route for many highly hydrophobic chemicals and that use of BCFs only underestimates exposure. EPA's proposed BAF methodology does account for some site-specific differences in bioaccumulation (an issue expressed by commenters) by considering factors such as percent lipid in the fish consumed and the freely dissolved concentration of the chemical in the ambient water (*i.e.,* a baseline BAF). This allows a BAF developed from one set of data and location(s) to be ''normalized'' and applied to another location. We believe the approach in the 2000 Human Health Methodology appropriately balances protectiveness with the uncertainties surrounding the science currently available to predict bioaccumulation. Comparisons of field-measured and predicted BAFs demonstrate agreement within an order of magnitude in the vast majority of cases, and often within a factor of two to five. Burkhard (1998) observed good agreement between measured and predicted BAFs for the Lake Ontario food web using the Gobas and Thomann food web models. For individual commonly detected PCBs and chlorinated pesticides, the BAFs estimated using the two Gobas and Thomann models were on average within a factor of 1.2 and 2.5 of the observed (*i.e.* field-measured) BAFs, respectively (Burkhard 1998). The overall uncertainties in each of these two bioaccumulation models (expressed as the ratio of the 90th to 10th percentile predicted BAF for each model) were a factor 3.6 and 4.0 for the Gobas and Thomann models, respectively (Burkhard 1998). Furthermore, Burkhard et al. (1997) reported that predicted BAFs (using EPA's national BAF methodology) were within a factor of 5 for 94% (n=32, using laboratory measured BCFs and FCMs) and 90% (n=48, using predicted K_{ow}s and FCMs) in Bayou d'Inde (Lake Charles, LA). These data comparisons show the good predictability of the methods used in the national BAF methodology. Should States or authorized Tribes have information to suggest that a national BAF is inappropriate for their situation, the 2000 Human Health Methodology specifically allows and encourages development of site-specific BAFs. With this in mind, we will be developing guidance on how to collect and interpret field data for the purpose of deriving site-specific field BAFs. This guidance will specifically address major sources of variability, including spacial and temporal factors and species life history.

Finally, to further address concerns that the predictive approaches used to derive BAFs may not be applicable at a

national scale, we revised the 1998 draft Methodology to clarify and limit for which chemicals and under what conditions BAFs based on Methods 2 to 4 are most applicable. For example, chemicals were grouped into broad categories based on their persistence and bioaccumulation potential (*e.g.,* high vs. low hydrophobicity, high vs. low biota metabolism, ionic vs. nonionic), and we have limited the use of predicted BAF approaches to selected groups of chemicals for which the data reasonably support their use (*i.e.,* highly hydrophobic chemicals that are not expected to be metabolized appreciably). The national BAF methodology was also changed to indicate that for those chemicals with sufficient data to indicate they are metabolized, model-predicted BAFs are not recommended; rather, field BAFs or laboratory BCFs are recommended. The use of the BSAF methodology has been restricted to chemicals that are highly hydrophobic (*e.g.,* log $K_{ow} \geq 4$).

EPA believes these revisions to the 1998 draft Methodology have improved the Methodology and have addressed many of the commenters' concerns and questions about uncertainty in applying the various approaches and BAFs on a national scale.

Comments—One commenter suggested that it is ''scientifically indefensible to use the field-measured BAF procedure to derive BAFs for benthic systems.'' They commented that in a benthic-based aquatic food web, the water column concentration of a chemical is not directly related to aquatic organism exposure potential for that chemical. Therefore, their view is that a field-measured BAF may over- or underestimate bioaccumulation in benthic-based systems.

Response—EPA acknowledges that the concentration of a chemical in the water column is not directly related to what pelagic organisms (*i.e.,* fish) are exposed to in a benthic-based system. However, the concentrations of a chemical in water, sediment, and fish are interconnected, although they may not be equally partitioned into each compartment, and residues in fish can be predicted equally well using either a sediment or water concentration as the starting basis. In the revised TSD on Bioaccumulation, the relationships between BAFs and BSAFs have been shown more clearly in order to demonstrate this interconnectedness. In the BAF methodology, we are assessing exposure through all routes (*i.e.,* from water, sediment, and contaminated food) in the aquatic ecosystem. By including all routes of exposure, the BAFs do not assume simple water-fish partitioning; rather they are an overall expression of the total bioaccumulation using the concentration of the chemical in water column as a reference point. Thus, a field-measured BAF or BASF at any given time is reflective of historic chemical loadings and bioaccumulation that has occurred. EPA does agree that a BAF may change over time because of differential chemical loadings; however, some frame of reference has to be chosen as the starting point to assess bioaccumulation. EPA has chosen to use the water concentration as that reference point. Science has shown that bioaccumulation occurs and is an important exposure pathway to humans for many chemicals, and EPA cannot ignore bioaccumulation in development of its AWQC simply because variability and uncertainty exist. In situations where chemical loadings are highly variable or are reduced substantially, EPA believes that a field-measured BAF will still be predictive of what will bioaccumulate in fish until the concentrations in sediments and benthic organisms are reduced enough to lead to reduced bioaccumulation. In situations such as this, a revised site-specific field BAF can be developed to reflect the change in chemical loading and partitioning.

This issue of field-measured BAFs and benthic-based food webs was also brought up in public comments made at the stakeholders meeting held in May 1999. At that time, we asked commenters if they could recommend another approach to assess bioaccumulation in benthic-based systems. No other approaches were suggested. We have concluded that in the absence of any other approaches, field-derived BAFs are good predictors of bioaccumulation because they integrate biological, chemical, and physical factors that influence bioaccumulation.

2. Guidance for Deriving Field Bioaccumulation Factors (BAFs)

Comments—Several commenters agreed with EPA that field-derived BAFs should take precedence over modeled BAFs. However, many commenters discussed the need for guidance on how to collect and review field data so that high-quality, field-based BAFs can be derived. Commenters noted that there are numerous site-specific biological, chemical, and physical factors that affect bioaccumulation, which should be considered during design of field sampling programs.

Response—We agree that properly derived field BAFs should take precedence over modeled BAFs; we have clearly indicated in the 2000 Human Health Methodology that this is our preferred approach for deriving a BAF. We also acknowledge that, as with any field measurement, there can be errors in determining field-measured BAFs. In the development of national BAFs, EPA will attempt to minimize potential errors or uncertainties by carefully screening the data based on the criteria outlined in the Bioaccumulation TSD. Furthermore, an additional validation of national BAFs will be conducted as part of the external peer review process that occurs for all published 304(a) water quality criteria. We continue to assert that for many chemicals, a field-measured BAF is a better gauge of what is occurring in nature than a laboratory-measured or predicted BCF; the BAF measures the actual effects of bioavailability, concentration in the water or sediment, growth dilution, metabolism, and biomagnification rather than predicting them through use of a model. We do agree with commenters concerned about the difficulty of collecting and interpreting field-measured BAFs; however, we believe that States and Tribes can adequately design and interpret field studies. To assist them in this task, we will be developing guidance concerning field data collection and interpretation for site-specific field-measured BAFs and BSAFs.

3. Use of Biota-Sediment Accumulation Factors (BSAFs)

Comments—Several commenters stated that the use of the BSAF approach for deriving a BAF is inappropriate. Some comments centered around the perceived lack of validation and peer review of the BSAF approach, and others focused on the relationship between the water column concentration of a chemical and its sediment concentration, represented by the factor Π_{socw}. One commenter noted that the BSAF method is simply a means to predict a water concentration of a chemical of interest from the sediment concentration of that chemical, the water and sediment concentration of a reference chemical(s), and the ratio of K_{ow} for the chemical of interest and the reference chemical(s). A commenter indicated that loading history of a given chemical directly affects what the value of Π_{socw} would be at any given time, and that Π_{socw}/K_{ow} (disequilibrium ratio) for the chemical in question and the reference chemical has to be constant under the assumptions of the BSAF approach. The commenter stated, however, that Π_{socw}/K_{ow} will not be constant because of

differential loading histories, and that because the concentration of the chemical of interest cannot be measured in water, the assumptions about Π_{socw}/K_{ow} cannot be verified. In their view this made the use of BSAFs invalid.

Response—The method of predicting BAFs from BSAFs has been evaluated for certain pesticides, PCBs, chlorinated benzenes, and dioxins using two data sets from Lake Ontario (Oliver and Niimi,1988;USEPA, 1990) and one from Green Bay (USEPA, 1992b). EPA has also recently completed further evaluation of this method for certain PCB congeners, pesticides, and chlorinated benzenes in Lakes Ontario, Green Bay, and the Hudson River. This additional evaluation and validation work is included in the Bioaccumulation TSD. The evaluations show that in the vast majority of situations, the BSAFs predict field-measured BAFs very well.

EPA agrees with the commenter who noted that the BSAF method is structured to predict water concentrations for chemicals that cannot be measured for the purpose of directly measuring a field BAF. However, the BSAF method is more important for its ability to capture the net effect of biomagnification, food web structure, hydrophobicity, bioavailability factors, and metabolism on a specific chemical's net potential for bioaccumulation. The BSAF method is needed to predict BAFs for chemicals with nondetectable and difficult-to-predict concentrations in water (*e.g.,* dioxins). No alternative methods to predict BAFs for such chemicals were identified by either public commenters or peer reviewers. The BSAF method equation has been modified (see below) in the Bioaccumulation TSD to clarify the essential data components of the method. The revised BSAF equation shows that measured concentrations in water and surface sediment, not a complete BSAF, are needed for the reference chemical. The equation also shows that a measured BSAF for the chemical of interest is the most important component for determination of a BAF when the concentration in water cannot be measured.

EPA agrees with commenters that the BSAF method should not be used for all organic chemicals that may be addressed through the 2000 Human Health Methodology, and accordingly have restricted application of the method to nonionic organic chemicals with log K_{ow}s ≥ 4.0. We have also provided more specific guidance on selection of reference chemicals and use of multiple reference chemicals to secure the most accurate estimate of a chemical's BAF.

One commenter contended that the BSAF approach for deriving BAFs is seriously flawed. The concern is that the approach is valid only if a reference chemical (chemical r) can be found with a sediment-water fugacity ratio (which represents the differential partitioning of a chemical between water and sediment) equal to that of the chemical for which the BAF is being determined (chemical of interest). The commenter contends that the BSAF approach could validly be used only if it could be shown that the fugacity ratio is a constant for the chemical of interest and the reference chemical. The commenter submitted figures to demonstrate conceptually that two chemicals with radically different loading histories will have dissimilar fugacity ratios. EPA disagrees that in order for the BSAF to work, the fugacity ratio has to be constant, but does agree that in order to best use the BSAF approach, a general knowledge of chemical loading histories to an ecosystem is needed to help provide a basis for choosing appropriate reference chemicals. Such information may be obtained from chemical production records, historical fish residue monitoring data, or dated sediment core analysis. We recognize that due to various factors (loading histories, microbial degradation, etc.) fugacity ratios for both chemical (i) and (r) may shift over time, leading to the potential for temporal variability of sediment-water distributions of nonpolar organic chemicals. Although it was not shown explicitly in the 1998 draft TSD, an important benefit of the BSAF approach is that it can account precisely for such differences in sediment-water distributions of nonpolar organic chemicals. The BSAF method is robust to the extent that the choice of reference chemicals is based on meeting the sediment-to-water fugacity ratio condition: That the ratios be similar—they do not have to be constant. The extent that these ratios for chemicals with log K_{ow}s ≥ 4 may change with chemical loading over long periods of time after sediments become contaminated, and thereby contribute to small shifts in BSAFs and larger shifts in BAFs, is an issue of possible concern that EPA recognized in the 1998 draft TSD. EPA noted on page 188 of the TSD (USEPA, 1998d) that ''BSAFs measured for systems with new chemical loadings or rapid increases in loadings may be unreliable due to underestimation of steady-state C_{soc}s.''

To better address the water-to-sediment relationship issue, EPA has revised the equations that serve as the basis for deriving a BSAF. In the revised equations, a factor $D_{i/r}$has been added, which is defined as the ratio of the fugacity gradient (modeled as Π_{socw}/K_{ow}) between sediment and water for chemical (i) in comparison to that of a reference chemical (r). The revised equations are as follows:

$$\frac{\left(\prod_{socw}\right)_i}{\left(K_{ow}\right)_i} = \left(D_{i/r}\right)\frac{\left(\prod_{socw}\right)_r}{\left(K_{ow}\right)_r} \qquad (1)$$

$$\text{thus, } \left(\prod_{socw}\right)_i = \frac{\left(D_{i/r}\right)\left(\prod_{socw}\right)_r\left(K_{ow}\right)_i}{\left(K_{ow}\right)_r}$$

By definition, Π_{socw} can be used to relate chemical i's BSAF to its BAF_{ℓ}^{fd}:

$$\left(\prod_{socw}\right)_i = \frac{\left(C_{soc}\right)_i}{\left(C_w^{fd}\right)_i} = \frac{\left(BAF_\ell^{fd}\right)_i}{(BSAF)_i} \qquad (2)$$

$$\text{thus, } \left(BAF_\ell^{fd}\right)_i = (BSAF)_i\left(\prod_{socw}\right)_i$$

By substituting rearranged Equation 1 into rearranged Equation 2:

$$\left(BAF_\ell^{fd}\right)_i = (BSAF)_i \frac{\left(D_{i/r}\right)\left(\prod_{socw}\right)_r\left(K_{ow}\right)_i}{\left(K_{ow}\right)_r} \qquad (3)$$

where:

$(BAF_\ell^{fd})_i$ = BAF expressed on a freely dissolved and lipid-normalized basis for chemical of interest ''i''.

$(BSAF)_i$ = Biota-sediment accumulation factor for chemical of interest ''i''.

$(C_{soc})_i$ = Concentration of chemical of interest ''i'' in sediment normalized to sediment organic carbon.

$(C_{soc})_r$ = Concentration of a reference chemical in sediment normalized to sediment organic carbon.

$(C_w^{fd})_i$ = Concentration of chemical of interest ''i'' freely dissolved in water.

$(C_w^{fd})_r$ = Concentration of the reference chemical freely dissolved in water.

$D_{i/r}$ = ratio between Π_{socw}/K_{ow} for chemicals ''i'' and ''r'' (normally chosen so $D_{i/r} = 1$).

$(K_{ow})_i$ = octanol-water partition coefficient for chemical of interest ''i''.

$(K_{ow})_r$ = octanol-water partition coefficient for the reference chemical ''r''.

$(\Pi_{socw})_i$ = sediment organic carbon to water freely dissolved concentration ratio of chemical of interest ''i''.

$(\Pi_{socw})_r$ = sediment organic carbon to water freely dissolved concentration ratio of reference chemical ''r''.

Equation 3 is intended to provide an improved representation of how the BSAF method/model works. By using $D_{i/r}$, the new equation accounts for differences in sediment to water column concentrations that might exist between the chemical of interest and the reference chemical because of factors such as loading histories or degradation. Unlike one commenter's analysis, in which an equation was derived without the BAF or BSAF, equation 3 shows these quantities as central to the model; that is, the BSAF is measured and then transformed into a BAF by estimating the chemical's Π_{socw}/K_{ow}. This model could alternatively be described as a determination of $(C_w^{fd})_i$ from a measured value of $(C_{soc})_i$ combined with a measured value of $(C_\ell)_i$ to give an accurate measure of $(BAF_\ell^{fd})_i$. However, we believe that equation 3 best describes the BSAF method as allowing measured BSAFs to be transformed into BAF_ℓ^{fd}s for the specific purpose of developing either national or a site-specific water quality criteria when directly measured BAF_ℓ^{fd}s cannot be obtained.

When good-quality data are available for reference chemicals (r) that should have equal or similar sediment-water fugacity ratios as a chemical (i) whose $(BAF_\ell^{fd})_S$ cannot be measured directly, then $D_{i/r} = 1$. When $D_{i/r} \leq 1$, it may be estimated based on properties of the chemicals and knowledge of their loading histories to the ecosystem. Equation 3 provides a greater degree of flexibility for use of the BSAF method than the original equation. This flexibility highlights a logical stepwise transition from measured to fully modeled site-specific BAFs that can incorporate estimates of $D_{i/r}$ through fate modeling, should interested parties choose to do so. In such a situation, if the uncertainty associated with choice of $D_{i/r}$ is perceived to be too great, a determination of a site-specific $(BAF_\ell^{fd})_i$, which still takes advantage of measured values of $(C_\ell)_i$ and $(C_{soc})_i$, could be accomplished if a mass balance model, specifically calibrated with $(C_\ell)_i$ and $(C_{soc})_i$, is used to predict $(C_w^{fd})_i$. Such an approach would be time consuming and expensive but would allow prediction of $(BAF_\ell^{fd})_i$ over time as a function of changes in $(\Pi_{socw})_i$ associated with anticipated changes in mass loading of the chemical into an ecosystem. In cases where the intended use of the site-specific criterion is to determine permit conditions or establish a TMDL, a mass balance model presumably would have to be developed, and thus use of the model for providing a $(BAF_\ell^{fd})_i$ would not require an extraordinary effort. However, as with the BSAF method, it should be noted that mass balance model predictions of $C_w^{fd}{}_i$ also cannot be directly validated through measurements. EPA's appreciation for the value of hybrid models comes from recognition that incorporation of measured bioaccumulation potentials, including those provided by the BSAF method, are especially advantageous for those chemicals with transformation rates, such as metabolism throughout the food chain, that are presently not accurately known or incorporated into mechanistic bioaccumulation models.

Finally, we disagree with the circular argument that the BSAF approach has ''extremely limited utility'' because ''it will not be possible to demonstrate that Π_{socw}/K_{ow} is a constant'' because Π_{socw}/K_{ow} cannot be measured directly for one chemical. The inherent limitation for validation of a predicted BAF because of the inability to measure the concentration of freely dissolved chemical in water (C_w^{fd}) applies to any approach/model available and is not a just criterion for rejection of a BAF method. Validation may be based on the ability of the BAF to predict concentrations in fish from predicted values of C_w^{fd}. Data from the Great Lakes clearly show that such predictions are possible, and accurate (USEPA, 1998d). It should also be noted that during the external peer review of the BSAF approach, the peer reviewers stated ''for the chemicals examined (persistent and bioaccumulative), extrapolation to other circumstances may be reasonable,'' thereby disagreeing with public commenters. EPA believes that restricting the use of the BSAF method to highly hydrophobic chemicals, clarifying the use of reference chemicals, elaborating on the primacy of the sediment-water fugacity equivalence

condition for use of the method, and validation with additional data sets alleviates concerns about using this new method.

4. Dissolved Organic Carbon (DOC) and Particulate Organic Carbon (POC)

Comments—Two comments were received on the DOC/POC approach used to determine the bioavailable fraction of organic chemicals in surface water and sediments. Rather than solely use default organic carbon values, commenters wanted to the ability to select DOC/POC values they believe are more representative of their waterbody type or site-specific conditions.

Response—In the 2000 Human Health Methodology, EPA allows use of site-specific DOC and POC data when normalizing the BAF to organic carbon content. One can either conduct studies to generate the necessary site-specific data or modify the national organic carbon database to their particular site and conditions. To facilitate the latter, we have updated and expanded the organic carbon database used to develop the national default POC/DOC values to enable the regulated community to choose which values best represent their site conditions and will provide defensible site-specific DOC and POC estimates. The national DOC/POC database will be made available for use by all States, Tribes, and other members of the regulated community.

5. Fish Lipid Content

Comments—A commenter stated that lipid content can affect the results of the Gobas model used to derive national default FCMs. The commenter noted that the model is relatively insensitive to fish lipid content but more sensitive to benthic invertebrate lipid content. They believed this should be considered in the development of FCMs.

Response—EPA agrees that lipid content can affect the results of the Gobas model and is only using the Gobas model with default lipid values to derive national BAFs when there are no data to derive a field-measured BAF. In cases where a State or authorized Tribe has site-specific data on fish lipid content, the revised methodology allows input of those site-specific data to estimate bioaccumulation. Furthermore, to facilitate the generation of site-specific lipid values, we have updated and expanded the lipid database used to develop the national default values based on a whole range of organisms commonly consumed by persons in the United States. We will include additional guidance for States and authorized Tribes on how to adapt the national default lipid values to reflect State and local consumption patterns. To enable such adaptions, EPA will make the raw data available to States and authorized Tribes.

6. Use of Food Chain Multipliers (FCMs)

Comments—Several commenters stated that the use of model-derived FCMs (Gobas 1993) to calculate a BAF from either a BCF or a K_{ow} (Methods 3 and 4) is inappropriate. The commenters noted issues with several of the default input parameters (*e.g.*, food web, lipid, Π_{socw}, temperature). The primary concern of commentors is that Gobas model-based national default FCMs do not account for site-specific factors that influence bioaccumulation, such as food web structure, nor does the current use of the model account for metabolism. Commenters expressed concern that use of default FCMs in predictive approaches may lead to overestimates of bioaccumulation. Some commenters preferred the use of field-based FCMs or direct use of the Gobas model, which allows for input of site-specific data and metabolism rates if available, rather than uses of model-derived default FCMs.

Response—EPA is using a state-of-the-art food web model for deriving FCMs, which incorporates the latest thinking and knowledge on the processes occurring in aquatic food webs. Commenters suggested that the assumptions used in constructing these models are not appropriate. We recognize that any modeling formulation of contaminant behavior in aquatic food webs requires simplification of a very complex biological system in order to assemble a tractable model. These simplifications do not imply or mean that our scientific understanding of all processes occurring in food webs is complete. As documented in the scientific literature, these simplifications provide reasonable model formulations with good predictive power. The suggestion that every modeling assumption has to be completely understood and validated under all circumstances before using or constructing a useful modeling tool is unreasonable. EPA has performed a detailed analysis of the importance and sensitivities of individual input parameters for food web models and of the overall uncertainties associated with predictions from food web models (Burkhard 1998). We have provided a discussion in the Bioaccumulation TSD of the Gobas model and implications that uncertainties in their respective input parameters have on derived FCMs. EPA has retained the use of Gobas model to derive default FCMs.

To address national versus site-specific concerns expressed by some commenters, the methodology has been revised to separate the BAF methodology into national and site-specific guidance. The national methodology for deriving national BAFs retains the use of default FCMs based on a mixed benthic/pelagic food web and national averages of various model input values. We believe this food web is the most broadly applicable food web encountered in nature; its use results in FCMs that are midway between pure benthic and pure pelagic structures. The revised guidance includes a brief discussion of the uncertainties associated with our selection of the mixed benthic/pelagic food web. In the site-specific guidance, the 2000 Human Health Methodology provides guidance on which of EPA's recommended FCMs to use depending on the situation. In addition, we encourage direct use of the Gobas model by stakeholders so that changes could be made to the default food web inputs to reflect site-specific factors that influence bioaccumulation, and also encourage derivation of field-based FCMs. States and authorized Tribes have the option to generate site-specific FCMs by conducting site-specific field studies, reviewing published literature, or using other scientifically defensible models.

Although several commenters criticized the national application of the Gobas model because metabolism rate is set equal to zero, the peer review panel acknowledged EPA's position that there are currently no acceptable methods available to adequately determine species and chemical-specific metabolism rates for use in the Gobas model. Because EPA agrees that for certain chemicals metabolism can be an important factor in bioaccumulation, the revised methodology does not use FCM-based predictions for chemicals that are expected to be metabolized substantially. To assist users of the 2000 Human Health Methodology in determining for which chemicals or groups of chemicals metabolism should be of little concern, we have developed a table of chemicals that are not substantially metabolized or are likely very slowly metabolized. This table has been put in the Bioaccumulation TSD. The table is not all inclusive because there are numerous chemicals (*e.g.*, hundreds of thousands in use commercially today) for which few or no metabolism data exist, but is representative of chemicals or groups of chemicals that are likely to be commonly encountered in aquatic systems. When metabolism is suspected,

users of the 2000 Human Health Methodology might be more inclined to use or develop field data and/or measure a BCF in the laboratory in these situations. It should also be noted that in the future, should appropriate chemical and species-specific metabolism data become available, the Gobas model can incorporate it with little effort.

Finally, EPA partially agrees with commenters that certain procedures of the 1998 draft Methodology revisions (*e.g.*, K_{ow} and FCM-predicted BAFs) might lead to overestimates of BAFs for certain types of pollutants, such as those that are metabolized substantially to chemical forms not addressed by the AWQC. In response to this issue, and as discussed previously, additional guidance and limitations have been placed on several of the procedures in the revised methodology. However, EPA does not agree with the notion that our methodology would lead to a general over prediction for all BAFs. We use central tendencies where possible for all inputs in the Gobas model, and a geometric mean BCF for chemicals that have more than one BCF for a given trophic level. Thus, we know of no reason why laboratory-measured BCFs multiplied by a FCM would always result in overestimates of BAFs, or why the BSAF and K_{ow} * FCM-predicted BAFs applied to highly hydrophobic contaminants that do not metabolize substantially would be biased a priori toward overestimating BAFs. These views are supported by information in the 1998 TSD (Exhibits 2.4.1, 2.4.3, and 2.4.6 for BSAFs), Burkhard *et al.* (1997) for the K_{ow}*FCM method, and information presented in the Bioaccumulation TSD.

7. Fish Tissue Criteria

Comments—A few commenters suggested that for selected highly bioaccumulative chemicals that are difficult to measure in water, criteria based on fish tissue concentration may be more appropriate than ambient water column concentration criteria.

Response—Regarding fish tissue criteria, EPA agrees that the development of human health criteria for highly bioaccumulative chemicals which are expressed in terms of tissue residues in aquatic organisms is worthy of consideration. However, such tissue residue criteria would still require a mechanism to relate chemical loads and concentrations in water and sediments to concentrations in tissues of appropriate aquatic organisms (*i.e.*, bioaccumulation factors or bioaccumulation models). EPA is presently exploring the feasibility of developing tissue-based criteria and is evaluating numerous issues associated with implementation of tissue-based criteria. At an appropriate in the future, EPA will consider development of additional guidance on tissue residue criteria pending the outcome of this evaluation.

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This Notice finalizes revisions to EPA's 1980 Methodology for the development of water quality criteria to protect human health. The revisions reflect scientific advancements since 1980 in a number of areas, including cancer and noncancer risk assessments, exposure assessments and bioaccumulation. The revised Methodology provides guidance to States, Tribes, and the public on the approach that EPA expects to take in developing recommended human health criteria. The revised Methodology also provides guidance to States and Tribes that they may use in developing human health criteria as part of their water quality standards; States and Tribes use such standards in implementing a number of environmental programs, including setting discharge limits in NPDES permits. The revised Methodology does not substitute for the Clean Water Act or EPA's regulations; nor is it a regulation itself. Thus, the revised Methodology cannot impose legally-binding requirements on EPA, States, Tribes or the regulated community, and may not apply to a particular situation based upon the circumstances. EPA and State/Tribal decision-makers retain the discretion to use different, scientifically defensible, methodologies to develop human health criteria on a case-by-case basis that differ from this guidance where appropriate. EPA may change the Methodology in the future through intermittent refinements as advances in science or changes in Agency policy occur.

This criteria Methodology incorporates scientific advancements made over the past two decades. The use of this Methodology is an important component of the Agency's efforts to improve the quality of the Nation's waters. EPA believes the Methodology will enhance the overall scientific basis of water quality criteria. Further, the Methodology should help States and Tribes address their unique water quality issues and risk management decisions, and afford them greater flexibility in developing their water quality programs.

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J. Charles Fox,

Assistant Administrator for Water.

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