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EPA *FACT SHEET*

Revised Methodology for Deriving Health-Based Ambient Water Quality Criteria (2000)

Abstract

The U.S. Environmental Protection Agency is publishing revisions to the 1980 Ambient Water Quality Criteria National Guidelines to better protect human health. The 1980 Ambient Water Quality Criteria National Guidelines outline the methodology used by states and tribes to develop human health water quality criteria. Revisions to the 1980 guidelines incorporate significant scientific advances in key areas such as cancer and non-cancer risk assessments, exposure assessments, and bioaccumulation in fish. The revised methodology will provide more flexibility for decision-making at the state, tribal and EPA regional levels. It is most likely that the methodology will result in more stringent criteria for bioaccumulatives and generally similar values of nonbioaccumulatives.

Human Health Water Quality Criteria

Human health ambient water quality criteria (AWQC) are numeric values limiting the amount of chemicals present in our nation's waters. Human health criteria are developed under Section 304(a) of the Clean Water Act of 1972 and are designed to protect human health. Water quality criteria are developed by assessing the relationship between pollutants and their effect on human health and the environment. These criteria are used by states and Indian tribes to establish water quality standards and ultimately provide a basis for controlling discharges or releases of pollutants.

The Clean Water Act (CWA) requires EPA to develop, publish and revise ambient water quality criteria (AWQC). In 1980, EPA published AWQC for 64 pollutants/pollutant classes and provided a methodology for deriving the criteria. These national guidelines addressed three types of endpoints: noncancer, cancer and organoleptic (taste and odor) effects.

The states and tribes use these criteria to develop water quality standards for each water body. EPA is required to review periodically criteria adopted by states and tribes. The revisions to the EPA's 1980 methodology will help states and tribes establish water quality criteria and standards that protect human health. They provide detailed means for developing water quality criteria, including systematic procedures for evaluating cancer risk, noncancer health effects, human exposure, and bioaccumulation potential in fish.

EPA Methodology for Deriving Criteria

States and tribes must develop water quality standards that include designated uses and water quality criteria necessary to support those uses. The Methodology is the guidance for states and tribes to help them establish water quality criteria and standards to protect human health. It provides 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.

Risk assessment practices have evolved significantly since 1980, particularly in the areas of cancer and noncancer risk assessments (with new information, procedures, and numerous published Agency guidelines), exposure assessments (with new studies on human intake and exposure patterns, and new science policy guidelines) and methodologies on accounting for bioaccumulation in fish.

General Background of the Revision Process

Revisions began with a national workshop in 1992, where participants discussed critical issues.

Based on individual expertise, attendees were assigned to technical workgroups including cancer risk, noncancer risk, exposure, and bioaccumulation in fish.

EPA submitted recommendations from the workshop for review and comment by the EPA Science Advisory Board. EPA created a workgroup in 1994, including program office and regional participants, to revise the methodology. Numerous stakeholder participation activities were conducted between 1995 and 1998, including presentations to the Federal-State Toxicology and Risk Analysis Committee and several multi-regional water quality coordinator's meetings in 1996 and 1997, which included participants from EPA regions, states, tribes and some industry.

Following publication of the draft Methodology revisions, written public comments were accepted. Further presentations included the 1998 Annual Meeting of the Society For Risk Analysis and the 1999 Annual Meeting of the Society of Toxicology. In May 1999, a peer review workshop was held. A public stakeholders meeting was also held then. EPA received extensive input on the Methodology from each of these groups. EPA considered all comments and incorporated a substantial portion of them into the final AWQC Methodology Revisions.

Major Methodology Revisions

Publication of final revisions satisfies the requirements of the CWA that EPA periodically revise criteria for water quality to reflect accurately 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. These Final AWQC Methodology Revisions to the 1980 AWQC National Guidelines are necessitated by the many significant scientific advances made during the past 20 years in the key areas of cancer and noncancer assessments, exposure assessments, and bioaccumulation in fish.

The major revisions are in four assessment areas: cancer, non-cancer, exposure, and bioaccumulation.

For carcinogen (cancer) risk assessment:

- Recommend more sophisticated methods to comprehensively determine the likely mechanism of human carcinogenicity.
- Recommend a mode of action (MOA) approach to determine the most appropriate low-dose extrapolation for carcinogenic agents.

For noncarcinogens:

- Use EPA guidance on assessing noncarcinogenic effects of chemicals and for the Reference Dose (RfD) derivation.
- Recommend consideration of other issues related to the RfD process including: integrating reproductive/ developmental, immunotoxicity, and neurotoxicity data into the calculation.
- Recommend the use of quantitative dose-response modelling for the derivation of RfDs.
- Provide guidance for states and tribes on the use of an alternative value from the RfD point estimate, within a limited range, to reflect the inherent imprecision of the RfD.

For exposure assessment:

- Encourage states and tribes to use local studies on fish consumption that better reflect local intake patterns and choices.
- Recommend default fish consumption values for the general population, recreational fishers and subsistence fishers.
- Account for other sources of exposure, such as food and air, when deriving AWQC for noncarcinogens and nonlinear carcinogens.

For bioaccumulation:

- Focus on the use of bioaccumulation factors (BAFs), instead of bioconcentration factors (BCFs) for estimating potential human exposure to contaminants via the consumption of contaminated fish and shellfish.
- Use high quality field data over laboratory or model-derived estimates for deriving BAFs, since field data best reflect factors which can affect the extent of

bioaccumlation (e.g., chemical metabolism, food web structure).

EPA does not plan to completely revise all of the criteria developed in 1980 or those updated as part of the 1992 National Toxics Rule. Partial updates of all criteria may be necessary. EPA will continue to develop and update toxicology and exposure data needed in the derivation of AWQC that may be impractical for the states and regions to obtain.

Methodology Revisions Implementation by EPA/States

EPA's future role in developing AWQC for the protection of human health will include:

- The development of revised criteria for chemicals of high priority and national importance (including, but not limited to, chemicals that bioaccumulate, such as PCBs, dioxin, and mercury).
- The development or revision of AWQC for some additional priority chemicals.
- Technical assistance to states and tribes on the toxicology, exposure and bioaccumulation methods, and review of state/tribal water quality standards.

EPA encourages states and tribes to use the revised methodology to develop or revise AWQC to reflect local conditions appropriately. EPA believes that AWQC inherently require several risk management decisions that are, in many cases, better made at the state and regional level (e.g., fish consumption rates, target risk levels).

Effect on State and EPA Regional Offices

The revised methodology will provide more flexibility for decision-making at state, tribal and EPA regional levels. EPA believes the AWQC require several risk management decisions that are often better made at the state, tribal and regional level. The methodology will probably result in more stringent criteria for bioaccumulatives (due to the use of BAFs instead of BCFs) and generally similar, or less stringent, values of nonbioaccumulatives.

Information

For additional information concerning these recommended methodology revisions, contact Denis R. Borum, Health and Ecological Criteria Division (4304), Office of Science and Technology, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, D.C., 20460 (telephone: 202- 260-8996).

You may view the Federal Register (FR) Notice and the AWQC Methodology revisions on the Internet at: http://www.epa.gov/waterscience/humanhealth. The FR Notice explains how to obtain additional information and how to review the complete administrative record for these Methodology revisions.