Draft Strategy:
Proposed Revisions to the "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses"

Background and Purpose

The existing *Guidelines for Deriving Water Quality Criteria for the Protection of Aquatic Life* (the *Guidelines*) have not been updated since 1985. Although based on the science of that time, the past 17 years have witnessed substantial scientific advancement in aquatic toxicology, aquatic biology, fate, transport, and effects modeling, and ecological risk assessment. Such advancements, coupled with increasing complexity of water quality impairment issues requires criteria derivation approaches beyond the existing *Guidelines* methods.

EPA's Office of Science and Technology will establish an Aquatic Life Guidelines Revisions Workgroup of Agency scientists to identify, review, evaluate, and revise the existing *Guidelines*. The workgroup will focus on the most critical needs relating to aquatic life criteria derivation and identify five high priority subject areas they expect to address over the next three years. Technical guidance on these subject areas will be published as interim reports that will be integrated in a final publication upon completion. A second review of critical subject areas will be required in 2005 to evaluate the need to proceed with an additional three year process.

This document presents a preliminary draft strategy for revising the *Guidelines*. OST is requesting an informal consultation with the EPA Science Advisory Board to discuss the strategy. OST is interested in consulting with the SAB to assist us in refining the scope of the strategy, and would like to receive comment on:

1) the general scope of the proposed strategy;

2) the suitability of the preliminary list of scientific issues identified for revisions;

3) possible priorities for revision of individual scientific issues on the preliminary list;

4) any scientific issues that may be absent from the list.

Introduction

Since the early 1980's, EPA has developed water quality criteria for specific pollutants to protect aquatic life under Section 304(a) of the Clean Water Act. The criteria provide guidance to states and tribes for adopting water quality standards which are the basis for controlling discharges or releases of pollutants. The majority of EPA's aquatic life criteria have been derived from two methodologies: the 1980 *Guidelines for Deriving Water Quality Criteria for the Protection of Aquatic Life and Its Uses* , and the 1985 *Guidelines for Deriving Numerical*

National Aquatic Life Criteria for Protection of Aquatic Organisms and Their Uses.

The Office of Science and Technology (OST) and Office of Research and Development (ORD) agree that the guidelines need to be revised. Scientific revisions are necessary to ensure aquatic life water quality criteria are derived using the best available risk based scientific methods and procedures. A systematic revision of the Guidelines methodology will: reduce dependence on a proscriptive derivation methodology; provide flexibility for incorporating risk based approaches, weight of evidence, and other appropriate procedures; and advance the application of the recent science in criteria development. Several recent criteria have incorporated emerging science as specified in the 1985 *Guidelines*. However, these methods and procedures are not widely available beyond the specific criteria documents themselves. The lack of general availability of methods guidance has reduced the transparency of Agency decisions. In addition, peer reviewers of criteria documents have frequently commented on the need for a scientific revision of the 1985 *Guidelines.*

Components of the 1985 *Guidelines* that need evaluation and possible revision include: the final residue value; the final plant value; and the duration of the averaging period and the frequency of allowed exceedences. Advancements in aquatic toxicology and risk assessment methodology that should be considered for incorporation into the revised guideline methodology include: bioaccumulation; dietary routes of exposure; multiple chemicals; multiple stressors; threatened and endangered species; surrogate species; and indirect toxicity.

The Agency plans to review and evaluate the aforementioned areas for inclusion into the revised guideline methodologies to address the aforementioned concepts. It will also identify opportunities to describe areas of flexibility for applying the existing guidelines in the derivation and revision of criteria. Such areas may include: consideration of data for non-traditional endpoints such as endocrine disruption; indirect toxicity such as enhancement of microbial or pathogenic infection; non-standard test species; field data; weight of evidence analysis; and bench-mark dose models. The Agency will continue to look to peer review and public scientific input for the derivation and revision of any criteria during this interim developmental period for revising the guidelines.

Status Reports of Guidelines Committee

An Agency Guidelines Committee has met occasionally since 1991 and provided status reports of its deliberations. The Guidelines Committee meetings, as well as additional subject matter expert meetings, were held in September and November 1991, July and December 1992, January and May 1993. Additionally, an informal SAB Consultation in June 1993, an EPA Workshop 1990, and an OW/ORD/OPP Meeting 2001 were all held to address Guideline revision needs. A summary of the subject areas, issues, discussion and conclusions of these meetings will be compiled under contract to assemble and identify and summarize Guideline revision issues raised by subject matter experts.

Subject Areas for Consideration in Guidelines Revisions

The aforementioned meetings identified numerous issues for consideration in revising the 1985 *Guidelines*. A brief summary of the identified issues follows.

1. **Bioaccumulative pollutants and tissue residue-based criteria** – Evaluate and review the use and application of bioaccumulation models to national and site-specific criteria, as well as linkages between bioaccumulation/pharmacokinetic models and tissue-residue effects for assessing the risk of bioaccumulative chemicals.

2. **Route of exposure: Dietary** – Evaluate and review the role of dietary uptake of chemicals (e.g., metals) and subsequent exposure and effects in aquatic and sediment biota.

3. **Threatened and Endangered Species** – Evaluate and review the sensitivity of threatened and endangered species relative to traditional test species; identify species meriting special protection; and identify appropriate surrogates for t/e species in toxicity testing.

4. **Kinetic-based Modeling of Toxicity** – Evaluate and review the speed at which effects appear in different individuals and at different concentrations; the frequency of lethality in any long series of time-variable concentrations; and the application of approach to assess sublethal effects.

5. **Assessing the Impact of Toxic Events** – Evaluate and review the impact of a particular time series of concentrations on an exposed population (account for loss or replacement time of individuals and reproductive inhibition).

6. **Non-traditional endpoints** – Evaluate and review the role of endocrine disruption, indirect toxicity (e.g., enhancement of microbial or pathogenic infection), and sublethal effects in criteria derivation.

7. **Final Acute Value (FAV)** – Evaluate and review statistical approaches for calculating the FAV from small data sets; a minimum database to arrive at a FAV for freshwater and saltwater data; the comparison of static/flow-through and measured/non-measured tests with organic chemicals; and evaluation of acceptable data used in derivation of aquatic life criteria.

8. **Final Chronic Value (FCV)** – Evaluate and review the use of rapid chronic tests (RCTs) as surrogates for life-cycle tests; statistical procedures for modeling continuous data;

   predicting chronic toxicity from acute and sub-chronic toxicity test data; and uncertainties in acute-chronic ratios (ACRs).

9. **Adjusting Criteria for Physicochemical Factors** – Evaluate and review the derivation of temperature coefficients for adjusting toxicity values; and the effects of naturally occurring organic carbon on uptake and toxicity of organic xenobiotics.

10. **Final Plant Value (FPV) and Final Residue Value (FRV)** – Evaluate and review the continued use of a FPV and FRV.

11. **Averaging Periods and Frequency of Exceedences** – Evaluate and review fluctuations in chemical exposure; recovery of aquatic biota following exceedences of National Water Quality Criteria; issues pertaining to levels of protection and application of aquatic life criteria; and whether the current exceedence frequency (no more than once every three years) is overprotective.

12. **Uncertainty Analysis** – Evaluate methods for calculating uncertainty for criteria and provide technical guidance.

13. **Defining the Level of Risk Associated with Criteria** – Evaluate and review the level of protection set at the 5^{th} percentile; the risk of contaminants to populations of aquatic animals; and laboratory to field evaluations of industrial chemicals.

Proposed Approach

OST will establish a Water Quality Criteria Guidelines Revision Workgroup to prioritize and evaluate the above subject areas for consideration of inclusion in revised water quality criteria derivation guidelines. The workgroup will be comprised of OST and ORD subject matter experts. The workgroup will prioritize the aforementioned subject areas, and expand the list as necessary. Prioritization will be based on the degree of existing data and information, existing resources, the state of the science, and need within the Water Quality Criteria user community. The workgroup will consult recent Agency documents that identify program-specific needs (i.e., Water Quality Standards & Criteria Strategy) and research plans (i.e., NHEERL Aquatic Stressors Framework). Once a proposed prioritized list is assembled, it will be presented to OST management for consultation and concurrence.

Resources and Time Line

We anticipate that the proposed workgroup, working with consultants, would effectively address five of the major subject areas within three years. The following major milestones are

proposed:

Mar 2003:	Finalize Draft Strategy for performing revisions to the Guidelines
Apr 2003:	Conduct first meeting of Guidelines Revisions Workgroup
	Identify prioritized list of subject areas for the group to address (and consult additional experts as needed).
May 2003	Initiate activities on subject area #1.
Jun 2003:	Hold group meeting on subject area #1.
Jul 2003:	Continue activities on subject area #1
Aug 2003:	Continue activities on subject area #1
Sept 2003:	Provide Interim product report on subject area #1.
Oct 2003:	Initiate activities of subject area #2 and proceed with the same time lines and schedule as above (approx. 5 month schedule/subject area).

Each of the subject areas will be published as an independent technical document to provide the timely delivery and implementation of new approaches. At the end of the project, all technical updates will be consolidated and published as a single Guidelines publication.

Proposed Staffing and Resources

It is expected that fulfilling this strategy to revise and update the Guidelines will be a multi-year effort and require the commitment of several FTEs. The core Guidelines revisions group members would include a total of 5 FTEs (2 HECD, 2 ORD, 1 other OW/OPP). Technical experts would be consulted as needed per contract.