

**Summary Minutes of the  
U.S. Environmental Protection Agency (EPA)  
Science Advisory Board (SAB)  
Ecological Processes and Effects Committee (EPEC) Augmented for the Advisory  
on EPA's Aquatic Life Criteria**

**Public Teleconference, June 23, 2008**

Panel Members: See Committee Roster – Appendix A

Date and Time: Monday, June 23, 2008, 1:00 – 4:00 p.m. Eastern Daylight Time

Location: By telephone only

Purpose: The purpose of this teleconference was to prepare for the Committee's advisory meeting on June 30 – July 1.

Attendees: Committee Chair: Dr. Judith Meyer

Committee Members:

- Dr. Fred Benfield
- Dr. G. Allen Burton
- Dr. Peter Chapman
- Dr. Kenneth Dickson
- Dr. Karen Kidd
- Dr. Wayne Landis
- Dr. Ellen Mihaich
- Dr. Charles Rabeni
- Dr. Amanda Rodewald
- Dr. James Sanders
- Dr. Daniel Schlenk
- Dr. Heiko Schhoenfuss
- Dr. Geoffrey Scott
- Mr. Timothy Thompson
- Dr. Glen Van Der Kraak

EPA SAB Staff: Thomas Armitage, Designated Federal Officer  
Anthony Maciorowski

EPA Staff:

- Gary Ankley EPA/ORD
- Joseph Beaman EPA/OW
- Heidi Bethel EPA/OW
- Russell Erickson EPA/ORD
- Dale Hoff EPA/ORD
- James Lazorchak EPA/ORD

Others Present: Nancy Bettinger, Massachusetts Department of Environmental Protection  
Daniel Caldwell, Johnson & Johnson Worldwide Environment, Health and Safety  
Jamie Heisig-Mitchell, Hampton Roads Sanitation District  
Philip Markle, Water Quality Soils and Engineering, Los Angeles County Sanitation  
Tyler Linton, Great Lakes Environmental Center  
Alan Roberson, American Waterworks Association  
Scott Slaughter, Center for Regulatory Effectiveness

### **Meeting Summary**

The discussion followed the issues and timing as presented in the meeting agenda (Appendix B).

### **Convene Teleconference**

Dr. Thomas Armitage, Designated Federal Officer (DFO) convened the teleconference at 1:00 p.m. He stated that the call was being held to prepare for an SAB Ecological Processes and Effects Committee meeting on aquatic life water quality criteria for contaminants of emerging concern. He stated that teleconference was being held in accordance with Federal Advisory Committee Act (FACA) procedures. He stated that summary minutes of the teleconference meeting would be prepared and certified by the Chair. He noted the Committee's compliance with ethics requirements and stated that the SAB Staff Office had determined that there were no conflict-or-interest or appearance of lack of impartiality issues for any of the advisory committee members participating on the teleconference. He noted time had been reserved on the agenda for public comments, but no requests had been received from the public to offer comments.

### **Purpose of the Call and Review of the Agenda**

Dr. Judith Meyer, Committee Chair, thanked the participants for calling. She reviewed the purpose of the teleconference and agenda. She stated that the purpose of the call was to receive background briefings from EPA and review material that would be discussed at the Committee's advisory meeting on June 30 – July 1. She noted that, at that meeting, the Committee would provide advice to EPA on derivation of aquatic life water quality criteria for contaminants of emerging concern (CECs). Dr. Meyer also stated that at the meeting, the Committee would develop responses to charge questions concerning an EPA White Paper that contained recommendations to address technical issues associated with derivation of aquatic life criteria for CECs. She noted that both the White Paper and charge questions had previously been sent to the Committee. In reviewing the

teleconference agenda, Dr. Meyer noted that Dr. Russell Erickson of EPA's Office of Research and Development would present an overview of EPA's 1985 guidelines for deriving aquatic life criteria (Guidelines). In addition, Mr. Joe Beaman of EPA's Office of Water and Dr. Dale Hoff of EPA's Office of Research and Development would present a briefing on the EPA White Paper. Dr. Meyer stated that the Committee would then discuss the charge questions and review the agenda and assignments for the June 30 – July 1 meeting.

### **Remarks from EPA**

#### *Overview of the White Paper*

Mr. Joseph Beaman of EPA's Office of Water provided a brief overview of EPA's White Paper. His presentation slides are provided in Appendix C. He discussed how aquatic life water quality criteria are developed and used. He stated that EPA had developed the White Paper to describe how the Agency planned to address certain technical challenges faced in deriving aquatic life criteria for CECs (such as endocrine disrupting chemicals). He noted that the White Paper provided information that could assist EPA in developing supplemental water quality criteria guidance for CECs. Beaman described the organization of the White Paper, stating that Part I of the document identified the technical challenges and presented recommendations to overcome the challenges, and Part II described how EPA's recommendations might be implemented in the case of a synthetic estrogen, ethynylestradiol. Beaman then reviewed the charge questions that had been given to the SAB. Committee members asked Mr. Beaman and other EPA staff on the call a number of questions.

A member asked whether EPA intended to develop additional guidance after the White Paper had been finalized, and whether such guidance would be reviewed by the SAB. EPA staff responded that before deciding how to proceed, the Agency wanted to receive the SAB's advice on the draft White Paper. EPA staff stated that the Agency had not planned ask the SAB to review additional Guidance.

The Chair asked EPA staff for clarification concerning the scope of the charge to the Committee. She noted that some of the Committee's comments would probably focus on future activities needed to facilitate implementation of aquatic life criteria for CECs. She suggested that some of this advice could be presented in the response to charge question #4. EPA staff responded that it would be helpful to include this kind of advice in the response to charge question #4.

A member remarked that the White Paper focused on developing aquatic life criteria for endocrine disrupting chemicals. She asked whether EPA wanted to receive advice pertaining to other kinds of chemicals of emerging concern, such as persistent organic pollutants. EPA staff responded that the Agency would be interested in receiving recommendations applicable to endocrine disruptors as well as other chemicals.

A member asked whether EPA intended to use only the processes and procedures set forth in the 1985 Guidelines to derive aquatic life criteria for CECs, or whether EPA would develop new guidance. EPA staff responded that it would be necessary to adapt the existing Guidelines to derive criteria for some contaminants of emerging concern. The member stated that it appeared EPA might need a new set of guidelines to address challenges posed by different kinds of contaminants. EPA staff responded that the existing Guidelines should be viewed as a starting point for criteria derivation for CECs. The purpose of the White Paper was to identify Guideline modifications that could address the technical challenges associated with deriving criteria for CECs.

The chair asked how EPA regulated the discharge of chemicals for which there were no aquatic life criteria. EPA staff responded that there were other ways to regulate the discharge of these chemicals. EPA Staff stated that one way to regulate discharge of such chemicals was through the use of whole effluent testing, which took into consideration the nature of the entire effluent. EPA staff also stated that, in addition to the EPA Office of Water, other offices such as the Office of Pesticide Programs regulate chemicals under the authority of various statutes. Staff noted, however, that the white paper pertained to the derivation of aquatic life criteria under the authority of the Clean Water Act.

The Chair asked whether the aquatic life criteria took into account physical stressors like pH. EPA staff responded that some water quality criteria did address physical and chemical factors, but the criteria did not address joint toxicity (e.g., consideration of when temperature may be lethal). However, criteria had been derived for ammonia and metals taking into consideration physical and chemical factors. Generally, however, the criteria did not address multiple stressors. A member asked whether EPA's 1985 Guidelines provided guidance on how to address physical stressors. EPA staff responded that there was some broad guidance in the Guidelines. Some procedures took into consideration factors such as water hardness. EPA staff noted, however, that a limitation of the Guidelines was that they are 20 years old. The Chair remarked that physical stressors were not addressed in the White Paper. EPA staff responded that in cases where physical and chemical factors were important, such factors would be considered as part of the routine criteria development process.

A member asked whether EPA had considered evaluating the effects of emerging contaminants on ecological processes. He stated that it would be important to consider ecological process endpoints when deriving aquatic life criteria for some emerging contaminants. EPA staff responded that the Agency had not had that type of discussion as it developed the White Paper. However EPA staff noted that the Agency had conducted research on function inhibition.

A member asked EPA to describe the end product that would be developed from the White paper and how the end product would be used. EPA staff responded that the Agency's immediate goal was to determine the next step to be taken in the process of developing aquatic life criteria for CECs. Information in the White Paper would be brought to bear on the criteria development process. EPA would consider how concepts in the White Paper could be implemented in Clean Water Act Programs. A member

stated that implementability was an important consideration, he also noted that it was important to consider the effects of contaminants on human and wildlife consumers of aquatic organisms. EPA staff responded that in the White Paper, the Agency had not explicitly considered the issue of bioaccumulation and impacts of contaminants on fish consumers. EPA staff noted that some contaminants of emerging concern did bioaccumulate, but this issue had not been considered in the White Paper.

A member asked whether states had provided any input into development of the White Paper or the process of supplementing the Guidelines. She noted that decisions made to address issues discussed in the White Paper would likely be of concern to states because they must implement the criteria. EPA staff responded that there had not yet been state involvement. EPA staff stated that implementation guidance had been developed for criteria approaches such as the biotic ligand model, but the Agency must determine what form criteria for CECs would take before implementation guidance was developed. If, for example, the criteria took the form of fish tissue concentrations, EPA recognized that implementation guidance would be needed to facilitate translation of criteria into state water quality standards.

Another member noted that the White Paper did address uptake of contaminants. He questioned whether uptake included “indirect” exposure from eating fish. EPA staff responded that the White Paper specifically addressed direct exposure (i.e., direct exposure to contaminants in water). The member remarked that EPA had been working on a water quality criterion for selenium and had considered bioaccumulation in developing this criterion. He asked whether bioaccumulative compounds like selenium were viewed as emerging contaminants of concern. EPA staff responded that, although the White Paper had focused on endocrine disrupting compounds, water quality criteria would be needed for CECs with other modes of action. EPA staff noted that a direct water exposure perspective was presented in the White Paper, and tissue residue criteria were not specifically addressed. However, EPA had not precluded developing tissue residue based criteria.

#### *Overview of EPA’s 1985 Aquatic Life Criteria Guidelines*

Dr. Russell Erickson of EPA’s Office of Research and Development presented an overview of EPA’s 1985 Guidelines for developing aquatic life criteria. His presentation slides are provided in Appendix D. Erickson stated that a large part of the White Paper addressed how current procedures in the guidelines might need modification to derive criteria for contaminants of emerging concern. He noted that criteria served as guidance to be used by states in developing their water quality standards. He noted that states could, however, pursue other approaches to develop water quality standards that were reviewed by EPA. He stated that the aquatic life criteria were currently derived according to procedures in the Guidelines. Dr. Erickson described the procedures followed to develop criterion continuous concentration (CCC) and criterion maximum (CMC) concentrations in order to establish water quality criteria (see attached presentation slides). He described the test data that were used and the taxonomic coverage requirements. In addition he stated that, while the Guidelines contained

standard procedures, flexibility was also built into the procedures. Members asked a number of questions about the Guidelines.

A member asked how uncertainty was addressed in the Guidelines. EPA staff responded that the Guidelines did not describe a process for a formal uncertainty analysis. However, criteria values were based on sensitivity distributions of the taxa tested. The member remarked that it was important to consider uncertainty.

A member asked whether plant data were considered in deriving aquatic life criteria. EPA staff responded that toxicity to plants was considered. A member asked how EPA had determined which species were to be used in deriving the criteria. EPA staff responded that although commercial and ecological importance of the species was considered in determining the acceptability of final criteria concentrations, the species selection was based on available tests that met Guidelines testing standards (provided that the tests as a whole also met minimum data requirements regarding taxonomic diversity). EPA Staff discussed the ammonia criteria as an example.

A member noted that the aquatic life criteria Guidelines appeared to have been designed to develop freshwater criteria. He asked how EPA developed criteria for marine waters. EPA staff responded that although the Agency's presentation on the teleconference had focused on freshwater, the Guidelines did describe parallel procedures for saltwater.

A member noted that seabirds and some mammals were ecologically important aquatic organisms and asked whether birds and mammals were considered when developing aquatic life criteria. EPA staff responded that the guidelines did not specifically address toxicity to birds and mammals.

A member noted that one of the charge questions addressed the use of non-resident species. He asked how EPA defined native and non-native species. EPA staff responded that the Guidelines indicated that criteria should be developed on the basis of tests with organisms native to the United States and Canada. EPA Staff further stated that some species had become established in the U.S. and Canada and had been used for criteria derivation. However, non-resident species were not currently used to derive aquatic life criteria. EPA staff stated that there was now an ongoing effort to identify test species that, although not resident, would be relevant for use in a risk assessment. EPA staff also noted that there was an ongoing effort through the Organization for Economic Cooperation and Development to develop test methods for endocrine disrupting chemicals. Staff stated that such methods had been developed for fathead minnows, Zebrafish, and Medaka. EPA staff also noted that the White Paper recommended including non-resident species data in the databases used to derive aquatic life criteria.

There were no further questions from the Committee so the Chair asked whether there were any public comments. No public comments were offered.

**Review of Agenda and Assignments for the June 30 – July 1 Meeting**

The Chair reviewed the charge questions and agenda for the June 30 – July 1 meeting. She noted that members had been asked to provide initial written responses to all of the charge questions. She requested that members send these responses to the DFO as soon as possible so the responses could be compiled and made available to the entire Committee prior to the June 30-July 1 meeting. The Chair stated that on the first day of the face-to-face meeting the Committee would hear briefings from EPA staff and would have an opportunity to ask additional questions about the White Paper and the charge questions. The Chair stated that the Committee would then discuss the responses to each of the charge questions. The Chair reminded members that they had each been assigned lead responsibility for developing the written response to one of the charge question at the June 30-July 1 meeting. She asked members to keep track of important points raised during the discussion of their assigned questions so that these points could be included in the written responses. The Chair noted that the charge question assignments had been sent to the members along with the White Paper and charge questions. The Chair also asked that at the June 30-July meeting, members lead the discussion of the responses to their assigned charge questions. She stated that on the second day of the meeting, time had been reserved to develop and discuss the written responses to the questions. The Chair also noted that following the meeting she and the DFO would develop a complete draft of the report, and this draft would be discussed on a Committee teleconference before it was finalized.

There were no further questions so the Chair thanked all who were on the call for participating and adjourned the teleconference.

Respectfully Submitted:

Certified as True:

*/Signed/*

*/Signed/*

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Dr. Thomas Armitage  
Designated Federal Officer

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Dr. Judith Meyer, Chair  
SAB Ecological Processes and  
Effects Committee

## **APPENDICES**

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Appendix A: Committee Roster

Appendix B: Teleconference Agenda

Appendix C: Overview of EPA's White Paper

Appendix D: Overview of EPA's Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses

## Appendix A –Committee Roster

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### **U.S. Environmental Protection Agency Science Advisory Board Ecological Processes and Effects Committee Augmented for the Advisory on EPA's Aquatic Life Water Quality Criteria**

#### **CHAIR**

**Dr. Judith L. Meyer**, Distinguished Research Professor Emeritus, Odum School of Ecology, University of Georgia, Athens, GA

#### **MEMBERS**

**Dr. Richelle Allen-King**, Professor and Chair, Department of Geology, University at Buffalo, Buffalo, NY

**Dr. Fred Benfield**, Professor of Ecology, Department of Biological Sciences, Virginia Tech, Blacksburg, VA

**Dr. Ingrid Burke**, Professor, Department of Forest, Rangeland and Watershed, Stewardship, Colorado State University, Fort Collins, CO

**Dr. G. Allen Burton**, Professor and Director, Cooperative Institute for Limnology and Ecosystems Research, University of Michigan, Ann Arbor, MI

**Dr. Peter Chapman**, Principal and Senior Environmental Scientist, Environmental Sciences Group, Golder Associates Ltd, North Vancouver, BC, Canada

**Dr. Loveday Conquest**, Professor and Associate Director, School of Aquatic and Fishery Sciences, University of Washington, Seattle, WA

**Dr. Kenneth Dickson**, Regents Professor, Department of Biological Sciences, University of North Texas, Aubrey, TX,

**Dr. Karen Kidd**, Canada Research Chair and Professor, Biology Department, University of New Brunswick, Saint John, NB, Canada

**Dr. Wayne Landis**, Professor and Director, Institute of Environmental Toxicology, Western Washington University, Bellingham, WA

**Dr. Ellen Mihaich**, President, Environmental and Regulatory Resources, LLC, Durham, NC

**Dr. Charles Rabeni**, Leader of Missouri Cooperative Fish and Wildlife Research Unit, U.S. Geological Survey, University of Missouri, Columbia, MO

**Dr. Amanda Rodewald**, Associate Professor of Wildlife Ecology, School of Environment and Natural Resources, The Ohio State University, Columbus, OH

**Dr. James Sanders**, Director and Professor, Skidaway Institute of Oceanography, Savannah, GA

**Dr. Daniel Schlenk**, Professor, Department of Environmental Sciences, University of California, Riverside, Riverside

**Dr. Heiko Schoenfuss**, Professor of Aquatic Toxicology, Department of Biological Sciences, Aquatic Toxicology Laboratory, St. Cloud State University, St. Cloud, MN

**Dr. Geoffrey Scott**, Director, Center for Coastal Environmental Health and Biomolecular Research, National Ocean Services, National Oceanic and Atmospheric Administration, Charleston, SC

**Mr. Timothy Thompson**, Senior Environmental Scientist, Science, Engineering, and the Environment, LLC, Seattle, WA

**Dr. Glen Van Der Kraak**, Professor and Associate Dean, Integrative Biology, College of Biological Science, University of Guelph, Guelph, Canada

**Dr. Ivor van Heerden**, Associate Professor and Director, Department of Civil and Environment Engineering, LSU Hurricane Public Health Research Center, Louisiana State University, Baton Rouge, LA

## Appendix B – Teleconference Agenda

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### U.S. ENVIRONMENTAL PROTECTION AGENCY

#### SCIENCE ADVISORY BOARD

#### Ecological Processes and Effects Committee Augmented for the Advisory on EPA's Aquatic Life Criteria

Public Teleconference  
June 23, 2008, 1:00 – 4:00 p.m. EDT

#### Agenda

- |           |  |   |
|-----------|--|---|
| 1:00 p.m. | Convene Meeting  | Dr. Thomas Armitage<br>Designated Federal Officer<br>EPA SAB Staff Office |
| 1:15 p.m. | Welcoming Remarks  | Dr. Anthony Maciorowski,<br>Deputy Director<br>EPA SAB Staff Office       |
| 1:20 p.m. | Purpose of the Call and Review of Agenda   | Dr. Judith Meyer, Chair   |
| 1:30 p.m. | Remarks from EPA   |   |
|           | - Overview of EPA's Guidelines for Deriving Numerical National Water Quality Criteria For the Protection of Aquatic Organisms and their Uses | Dr. Russell Erickson, EPA<br>Office of Research and<br>Development        |
|           | - EPA's White Paper on Aquatic Life Water Quality Criteria and the Charge to the SAB   | Mr. Joseph Beaman, EPA<br>Office of Water                                 |
|           |  | Dr. Dale Hoff, EPA<br>Office of Research and<br>Development               |
| 2:30 p.m. | Panel's Discussion of the Draft EPA White Paper and Charge   | Dr. Judith Meyer and<br>Committee   |
| 3:30 pm   | Public Comments  |   |

3:45 pm Review Agenda and Assignments for  
June 30 – July 1 Meeting

Dr. Judith Meyer, Chair

4:00 pm Adjourn

## Why the need for the white paper?

- Under the United States Clean Water Act (CWA) (33 U.S.C. Sections 1251-1387), EPA is required to take a number of actions to protect and restore the ecological integrity of the Nation’s water bodies.
- Under Section 304(a) of the CWA, EPA must develop and publish ambient water quality criteria. Ambient water quality criteria (AWQC) are levels of individual pollutants, water quality characteristics, or descriptions of conditions of a water body that, if met, should protect the designated use(s) of the water.
- AWQC for aquatic life (aquatic life criteria, ALC) developed under Section 304(a) reflect the “latest scientific knowledge” concerning “all identifiable effects” of the pollutant in question.

1

## Why the need for the white paper?

- In 1985, EPA published *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses* (hereafter referred to as the “*Guidelines*”; Stephan et al. 1985)
- The *Guidelines* have provided uniformity and transparency in the derivation methodology of ALC for a large number of compounds among several classes of chemicals.
- The majority of EPA’s currently recommended ALC have been derived using the methods outlined in the *Guidelines*.

1

## Why the need for the white paper?

- While the *Guidelines* remain the primary instrument the Agency uses to meet its broad objectives for the development of ALC, there have been many advances in aquatic sciences, aquatic and wildlife toxicology, population modeling, and ecological risk assessment that are relevant to deriving ALC.
- Some of the advances have been addressed through supplemental guidance on the derivation or site-specific modification of criteria (Prothro 1993; U.S. EPA 1994a), while others have been incorporated directly into derivation of individual ALC for certain chemicals (e.g., saltwater chronic ALC for tributyltin, U.S. EPA 2003).
- Recently, considerable attention has been generated by a widely ranging group of chemicals termed contaminants of emerging concern (CECs).

1

## Why the need for the white paper?

- Criteria development for CECs is needed
- CECs challenge the traditional derivation methods because of their toxicological properties not previously encountered and a general lack of toxicity data
- Adaptation of the guidelines is warranted to accommodate these issues but should still maintain the technical rigor of the 1985 Guidelines

1

## What is a Contaminant of Emerging Concern?

- Have no regulatory standard
- Recently “discovered” in natural streams
- Potentially cause deleterious effects in aquatic life at environmentally relevant concentrations
- Pollutants not currently included in routine monitoring programs
- Not necessarily new chemicals

1

## What is a Contaminant of Emerging Concern?

- CECs include several types of chemicals:
  - Persistent organic pollutants (POPs)
  - Pharmaceuticals and personal care products (PPCPs)
  - Veterinary medicines
  - Endocrine-disrupting chemicals (EDCs)
  - Nanomaterials

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## Why the concern about CECs?

- Widespread
- Some indication of environmental persistence
- Indications of effects in natural systems
- Public concerns
- ALC not yet developed for many CECs

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## General Purpose of the white paper

- The white paper is meant to provide supplemental guidance that will facilitate the derivation of ALC for CECs
- Evaluate application of the guidance with the model CEC Ethinylestradiol

1

## General Organization of white paper

- Part I
  - Introduction
  - Current Aquatic Life Criteria Methodology
    - Summarize current methodology and identify areas in which procedures might be modified to address CECs
  - Implications for Criteria Development
    - Discuss specific CEC characteristics as they affect ALC procedures
    - Paths forward to address issues raised
  - Summary and Recommendations
- Part II
  - Illustrate the recommendations with the model CEC Ethinylestradiol

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## General nature of feedback desired from SAB Reviewers

- Comment on the scientific merits of the recommendations
- Comment as to what issues may have been missed
- Comment on any perceived implementation difficulties

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## Appendix D – Overview of EPA’s 1985 Guidelines for Deriving Aquatic Life Water Quality Criteria

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### Water Quality Criteria for the Protection of Aquatic Life (“Aquatic Life Criteria”)

- Aquatic Life Criteria (ALC) issued by the U.S.EPA Office of Water define limits on chemical exposures which are considered sufficient to preclude unacceptable effects on aquatic communities.

Common element of State water quality standards

National Pollutant Discharge Elimination System permits

Designated-use attainment from ambient monitoring data

Superfund site evaluations and remediation goals

Sediment toxicity assessments

1

- ALC are developed by EPA using procedures described in *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses* (Stephan et al. 1985).

- The Guidelines specify standardized procedures to use laboratory toxicity data to derive a “Criterion Maximum Concentration” and a “Criterion Continuous Concentration”; these concentrations are used in criteria as follows:

“Except possibly where a very sensitive species is important at a site, aquatic life should be protected if:

The four-day average concentration does not exceed the Criterion Continuous Concentration (CCC) more than once every three years on the average,

And the one-hour average concentration does not exceed the Criterion Maximum Concentration (CMC) more than once every three years on the average.”

1

## Criterion Maximum Concentration

- The CMC is intended to address severe acute effects (mortality, immobilization, etc.)
- The information used is 48- or 96-hr LC50s or EC50s (“Acute Values” or AVs) from laboratory tests
- AVs are required for species from at least eight genera of animals meeting the following taxonomic diversity requirements:
  - (1) From the family Salmonidae
  - (2) From another family in the class Osteichthyes
  - (3) From another family in the phylum Chordata
  - (4) A planktonic species from the class Crustacea
  - (5) A benthic species from the class Crustacea
  - (6) From the class Insecta
  - (7) From another phylum (not Arthropoda or Chordata)
  - (8) From a second order in the class Insecta or a fourth phylum

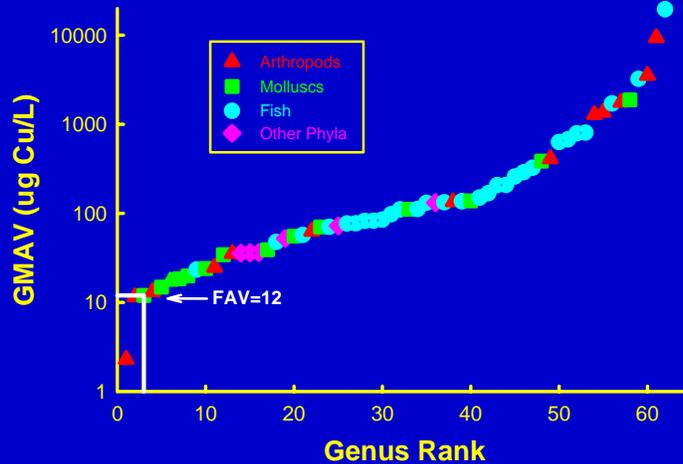
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## Criterion Maximum Concentration

- Species Mean Acute Value (SMAV) = geometric mean of the AVs for a species
- Genus Mean Acute Value (GMAV) = geometric mean of the SMAVs for species within a genus
- Final Acute Value (FAV) = estimated fifth percentile of a distribution represented by the available GMAVs
- If the FAV is higher than the SMAV of an “important” species, the FAV is lowered to this SMAV
- The CMC is set to half the FAV to correspond to a low mortality level for the fifth percentile genus

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## Genus Sensitivity Distribution



## Criterion Continuous Concentration

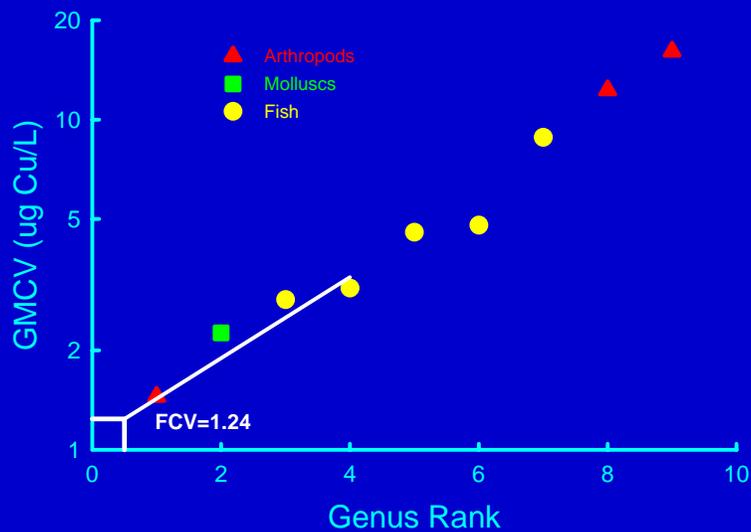
- The CCC is intended to address effects of longer-term exposures on survival, growth, and/or reproduction
- The information used is from life-cycle laboratory tests (or, for fish, partial life-cycle or early-life-stage tests)
- Each test is characterized by a "Chronic Value" (CV) that is the geometric average of the HNOEC and LOEC or the EC20 for the most sensitive endpoint
- Species Mean Chronic Values (SMCVs) and Genus Mean Chronic Values (GMCVs) computed from available CVs
- If the minimum data requirements are met, a Final Chronic Value (FCV) for animals is set analogously to the FAV (i.e., fifth percentile of GMCVs)

## Criterion Continuous Concentration

- If the minimum data requirements are not met, the FCV is set by dividing the FAV by a Final Acute:Chronic Ratio obtained from Acute:Chronic Ratios for at least 3 species
- If the FCV is higher than the SMCV of an “important” species, the FCV is lowered to this SMCV
- Available plant toxicity data is assessed to develop a Final Plant Value (FPV) – no specific methodology
- The CCC is set to the lower of the FCV and the FPV

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## Genus Sensitivity Distribution



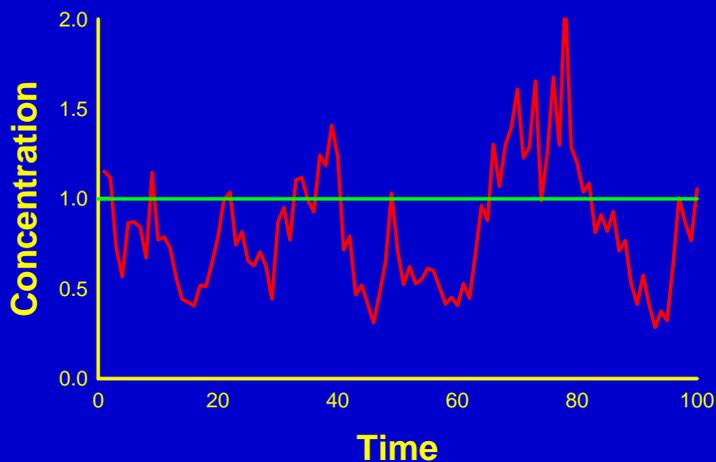
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## Averaging Periods

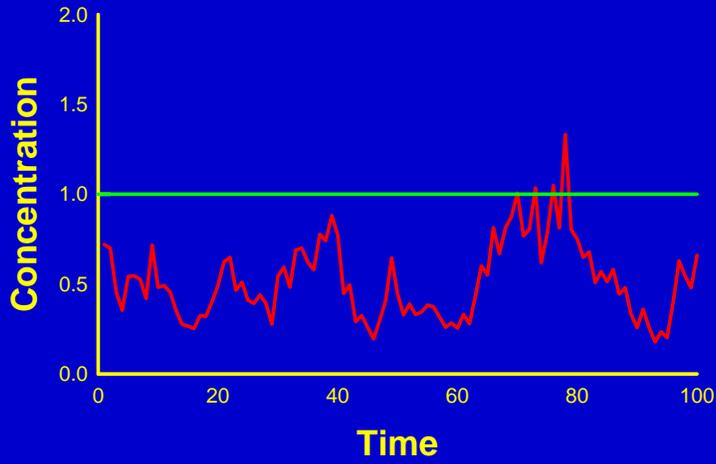
- CMC implemented as a restriction on one-hour average exposure concentrations
- CCC implemented as a restriction on four-day average exposure concentrations
- Averaging periods are shorter than test durations to preclude exposure time series with transient concentrations that might elicit effects even if longer-term average concentrations are below CMC or CCC
- Accommodates fast acting toxicants or toxic action during short critical period during test
- Averaging periods are not isolated exposures, but rather worst period in longer exposure

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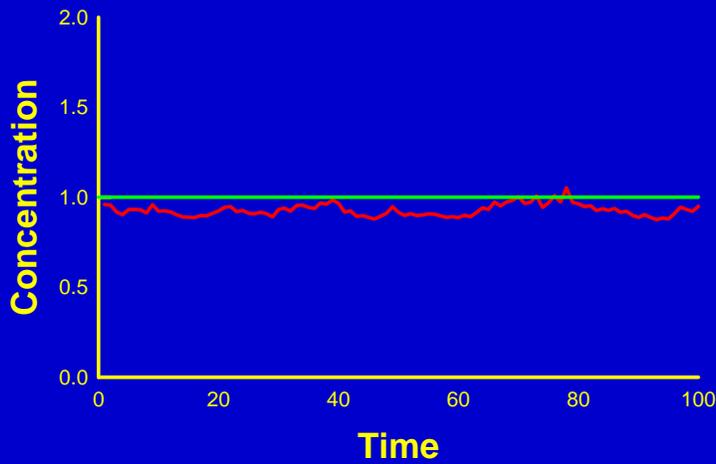
## Exceedences of CCC for Different Exposure Time-Series Shapes



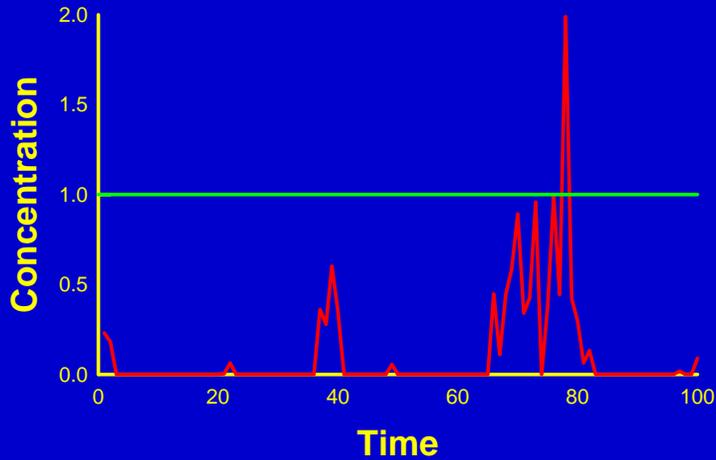
## Exceedences of CCC for Different Exposure Time-Series Shapes



## Exceedences of CCC for Different Exposure Time-Series Shapes



## Exceedences of CCC for Different Exposure Time-Series Shapes



## Exceedence Frequencies

- Based on one-hour average concentrations, CMC to be exceeded no more than once in three years on average (one-hour averages exceed CMC 0.004% of time).
- Based on four-day average concentrations, CCC to be exceeded no more than once in three years on average (four-day averages exceed CCC 0.4% of time).
- Exceedence frequency reflects a risk management decision that systems should not be in perturbed state for a substantial percentage of time. Exceedences are usually expected to have little effect, so are allowed to occur every few years, with major perturbations being rare.

## Guidelines Applicability and Flexibility

- The standard procedures in the Guidelines are intended to provide consistent criteria for diverse chemicals, regardless of toxicological properties.
- The need for flexibility in developing criteria and deviating from these standard procedures was recognized in the "Good Science Clause":

*"On the basis of all available pertinent laboratory and field information, determine if the criterion is consistent with sound scientific evidence. If it is not, another criterion, either higher or lower, should be derived using appropriate modifications of these Guidelines."*

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## Guidelines Applicability and Flexibility

- However, the same level of protection should result:

*"any deviation from these Guidelines should be carefully considered to ensure that it is consistent with other parts of these Guidelines."*

- Criteria development thus involves compilation of experimental and field data beyond that suitable for the standardized procedures; these data are evaluated and then used as justified in alternative approaches for setting criteria values.

1