

**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, September 16, 2008

Panel Members: See Committee Roster – Appendix A

Date and Time: Tuesday, September 16, 2008, 1:00 – 4:00 p.m. Eastern Daylight Time

Location: By telephone only

Purpose: The purpose of this teleconference was to discuss Committee's draft advisory report on aquatic life water quality criteria for contaminants of emerging concern.

Attendees: Committee Chair: Dr. Judith Meyer

Committee Members: Dr. Fred Benfield
Dr. G. Allen Burton
Dr. Peter Chapman
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: Joseph Beaman EPA/OW
Russell Erickson EPA/ORD
Dale Hoff EPA/ORD

Others Present: Linda Boyle, Aurora Water
Kristin Brugger, Dupont, Co.
Geoffrey Grubbs, Consultant

Katie Holmes, BASF Corp.
Jay Honniker, Monsanto Co.
Steven Levine, Monsanto Co.
Nick Poletika, Dow Agrosiences
Richard Schwer, DuPont Engineering Technology
Scott Slaughter, Center for Regulatory
Effectiveness
Jonathan Strong, Inside EPA
John Thorne, CropLife America

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 discuss the Committee's draft report on aquatic life criteria for contaminants of emerging concern. He stated that the teleconference was being held in accordance with Federal Advisory Committee Act (FACA) procedures. He stated that summary minutes of the teleconference 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-of-interest or appearance of lack of impartiality issues for any of the advisory committee members participating in the teleconference. He noted that time had been reserved on the agenda for public comments, but no requests had been received from the public to provide oral comments. He stated that one set of written comments had been submitted by CropLife America, and that these comments had been sent to Committee members.

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 Committee's draft report on aquatic life criteria for contaminants of emerging concern (8/27/08 draft) had been sent to the Committee members for review. Dr. Meyer noted that members had commented on a previous draft of the report and that their comments had been incorporated into the 8/27/08 draft. She also noted that a summary of member comments was emailed to committee members, and that summary would help structure the initial discussion during the teleconference. This summary is provided in Appendix C. Dr. Meyer stated that she wanted to reach agreement on any additional changes needed in the report before sending a revised draft to the Committee for concurrence.

Discussion of the Draft Advisory Report

The Committee discussed and reached agreement on a number of changes needed in the draft report.

Interactive effects of mixtures

The Committee discussed parts of the report that recommended taking into consideration interactive effects of mixtures of contaminants when deriving aquatic life criteria. A member stated that many of her comments on the previous draft had been incorporated into the report, but she was a bit concerned about making recommendations to consider mixtures in deriving aquatic life criteria. She noted that, although the Committee's report recommended considering mixtures, no specific guidance had been provided on how this should be done. She noted that it would be very difficult to develop such guidance. Another member agreed, but stated that the possibility of considering mixtures in the criteria development process should not be excluded.

A member stated that the report should indicate that it was important to consider the issue of mixtures. Another member stated that the report should note that in the future, criteria may need to be revised up or down based on knowledge of the interactive effects of contaminants of emerging concern. The Chair agreed. She stated that the report should acknowledge the importance of considering interactive effects among compounds with similar modes of action. A member commented that the report should emphasize the importance of developing risk-based criteria, and that consideration of mixtures should be included in a conceptual model for deriving risk-based criteria. Another member stated that EPA's 1985 Guidelines had established a process for deriving aquatic life criteria, and that this process had focused on criteria for individual chemicals. However, he agreed that EPA should be encouraged to consider interactive effects in future criteria development.

The Committee discussed whether the interactive effects of mixtures of contaminants could be considered in the implementation of aquatic life criteria. EPA staff stated that the criteria were published as guidance to states for use in promulgating water quality standards. Staff noted that in implementation of criteria (i.e., promulgation of standards), the sum total of effects could be considered.

A Committee member, Dr. Scott, volunteered to develop additional report text to address the importance of considering of mixture effects, and possibly revising criteria in the future. Dr. Meyer thanked Dr. Scott and asked him to send the revised text to the DFO.

Endangered species protection

The Committee discussed parts of the report that addressed protection of endangered species. A Committee member noted that the report stated that use of toxicity tests with

non-resident species may not protect certain endangered species. She expressed the view that if this statement were to be included in the report, it would be important to clearly indicate why use of such test data may not be protective of endangered species. Another member stated that the report could be revised to stress the importance of protecting sensitive species (not just endangered species). Dr. Scott volunteered to develop additional language to clarify this part of the report and describe the importance of protecting sensitive species such as marine mammals that require special consideration. He noted that some marine mammals may be more sensitive to contaminants than other taxa. The Chair thanked Dr. Scott and asked him to send this text to the DFO.

A member questioned whether the report should specifically recommend the use of test data for salmonid species to derive aquatic life criteria. In response to this comment, EPA staff stated that the 1985 Guidelines called for the use of salmonid test data to derive criteria, and that EPA was not recommending dropping those requirements. However, EPA staff also noted that the Agency was recommending that test data for certain taxa may not be needed to derive criteria if the taxa were not sensitive to particular contaminants of emerging concern. The Chair noted that the Committee's report recommended involving an expert panel to provide advice in making such decisions.

Principles for revising the 1985 Guidelines

The Committee discussed parts of the report that recommended articulation of principles for revising EPA's 1985 Guidelines. Dr. Chapman stated that additional text should be included in the letter to the Administrator and in the body of the report to emphasize the importance of developing risk-based criteria. He volunteered to send additional text to the DFO to incorporate this change. The Chair thanked him and stated that his revisions would be included in the next draft of the report.

Separation of Parts I and II of the white paper

The committee discussed those parts of the report that recommended integrating Parts I and II of EPA's white paper on aquatic life criteria for contaminants of emerging concern. A member stated that he thought this particular recommendation should be removed from the Committee's report. He stated that Part II of the white paper was well written, and that the Committee should not recommend integrating it with Part I. Another member agreed, noting that various statements and examples in Part II could be included in Part I as text boxes. Another member agreed. He stated that Part II should be kept as a separate document. However, he noted that it would be useful to discuss examples of other endocrine disrupting chemicals (in addition to ethynylestradiol) in Part I to make the framework more useful. Another member agreed. He stated that although ethynylestradiol was used as an example in the white paper, the importance of other contaminants of emerging concern should be acknowledged. He noted that this was not clearly articulated in the white paper.

A Committee member stated that the letter to the Administrator in the draft report specifically identified endocrine disrupting chemicals as chemicals of emerging concern.

She stated that that the Committee's report should clearly indicate that guidance was needed for other kinds of contaminants of emerging concern as well as endocrine disrupting chemicals, and that the letter to the Administrator should also reflect this. Dr. Meyer agreed with suggestions to remove the recommendation calling for integration of Parts I and II of the white paper. She stated that she would revise the Committee's report to recommend: 1) including additional examples in Part I as text boxes, and 2) including discussion of other chemicals of emerging concern (in addition to ethynylestradiol).

Recommendations concerning EC_x

The Committee discussed the recommendation in the report to use EC_x to derive aquatic life criteria instead of NOEC/LOEC. Several members stated that the use of NOEC/LOEC was not supportable. A member questioned how testing might be done differently if the EC_x were to be used in criteria derivation. She stated that in many cases, sufficient data were not available to use EC_x. She also questioned whether the Committee should recommend the use of a particular value of x for criteria development. Dr. Landis volunteered to provide additional text to clarify the Committee's recommendation to use EC_x. He stated that his revised text would further discuss why it was advantageous to use EC_x and the data needed for this kind of analysis. Dr. Meyer thanked Dr. Landis and asked that he send the revised text to the DFO for incorporation into the next draft of the report.

Other revisions

Committee members suggested several other revisions in the draft report. A member suggested including revisions to clarify recommendations concerning: testing of marine organisms, harmonization of test methods, and requirements for data and test method validity. Members suggested incorporating additional references regarding the use of surrogate test organisms to evaluate possible effects on endangered species. A member noted that such studies were cited in the comments submitted by CropLife America. Dr. Scott stated that he would draft additional text to clarify recommendations concerning use of surrogate test species, and that additional references would be included in his text.

The Committee discussed parts of the report addressing the need to test for possible transgenerational effects when deriving aquatic life criteria. A member stated that EPA should consider possible transgenerational effects in deriving criteria. He also noted that the Committee's report should more clearly define the term "transgenerational effects." Several members stated that transgenerational effects could be evaluated in full life-cycle tests. The Committee then discussed the use of life-cycle test data in deriving aquatic life criteria. A member stated that, when appropriate, EPA should evaluate transgenerational effects using data from full life-cycle studies and that, when warranted, multigenerational effects should also be considered in criteria derivation. Dr. Van der Kraak volunteered to revise the appropriate parts of the Committee's report to reflect the discussion on the teleconference. Dr. Meyer thanked him and asked that he also send his revisions to the DFO for incorporation into the report.

The Committee discussed written comments provided by CropLife America. A member noted that CropLife America had expressed the view that use of the full life-cycle test data should not be a default requirement for deriving aquatic life criteria for all chemicals. Another Committee member stated that full life-cycle test data should be used in the right circumstances. Another member suggested that EPA consider developing a tiered testing approach to provide the rationale for the use of partial and full life-cycle test data in deriving aquatic life criteria. Other members agreed with this suggestion. Dr. Scott volunteered to draft report text addressing this issue and stated that he would send it to Dr. Chapman for review before sending it to the DFO.

A member suggested revising the report text that recommended use of an “expert system” to assist criteria derivation. She suggested clarifying this part of the report by removing the words “expert system” and inserting “guidelines, rules, or process.” Dr. Meyer asked the DFO to make this change. Following this discussion the Chair thanked Committee members for their comments, and asked EPA staff whether they wished to offer remarks

Remarks from EPA

Mr. Joseph Beaman, of EPA’s Office of Water, thanked the Committee for their comprehensive review of EPA’s white paper on aquatic life criteria for contaminants of emerging concern. He stated that the findings and recommendations in the Committee’s report would be very helpful to the Agency. He stated that the intent of the white paper was to develop recommendations for adapting procedures in the 1985 Guidelines in order to derive aquatic life water quality criteria for contaminants of emerging concern. He noted that some of the Committee’s findings and recommendations (e.g., those addressing the interactive effects of mixtures, development of risk-based criteria, and the use of EC_x) focused on issues that were somewhat beyond the scope and intent of the white paper. He stated that EPA could, however, consider those comments in the context of future efforts to strengthen the criteria development process.

Public Comments

The Chair thanked Mr. Beaman for his remarks and asked whether members of the public wished to offer comments. No public comments were offered.

Discussion of the Letter to the Administrator and Executive Summary

The committee discussed other specific editorial changes in letter to the Administrator, executive summary, and main body of the report. These changes focused on clarification of: 1) the discussion of nominal test concentrations, 2) the discussion of data needs for deriving aquatic life criteria for contaminants of emerging concern, and 3) recommendations concerning a “Pellston” workshop. In addition, the Committee agreed upon other minor changes to clarify text in the executive summary. Dr. Chapman reiterated that the letter to the Administrator should contain several additional sentences to emphasize the importance of a risk-based approach to criteria development. Other

members agreed and Dr. Chapman stated that he would send additional text to the DFO. Dr. Meyer thanked Dr. Chapman and asked Committee members whether they wished to discuss additional points. No additional concerns or issues were raised by the committee.

Summary and Discussion of Next Steps

Dr. Meyer thanked all of the participants on the call and reviewed the next steps for completion of the Committee’s report. She asked the DFO to send an email to the Committee summarizing the assignments discussed on the call. She asked members to submit their report revisions to the DFO by Monday September 22nd. She stated that the revisions would be incorporated, and that a revised draft of the report would be sent to the Committee for concurrence on Monday, September 29th. Dr. Meyer requested that members respond to the request for concurrence by Monday, October 6th in order to transmit the report to the chartered SAB for quality review at the Board meeting on October 28th. Members had no additional comments so the Chair adjourned the teleconference.

Respectfully Submitted:

Certified as True:

/signed/

/signed/

Dr. Thomas Armitage
Designated Federal Officer

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

APPENDICES

Appendix A: Committee Roster

Appendix B: Teleconference Agenda

Appendix C: List of Points to be discussed on the September 16th EPEC teleconference

Appendix A –Committee Roster

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

U.S. ENVIRONMENTAL PROTECTION AGENCY SCIENCE ADVISORY BOARD

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

Public Teleconference
September 16, 2008, 1:00 p.m.– 4:00 p.m. (Eastern Daylight Time)

AGENDA

1:00 p.m.	Convene Meeting	Dr. Thomas Armitage Designated Federal Officer EPA Science Advisory Board
1:10 p.m.	Purpose of the Call and Review of the Agenda	Dr. Judith Meyer, Chair
1:15 p.m.	Discussion of draft SAB EPEC Report	Dr. Judith Meyer and Committee
	<ul style="list-style-type: none">- Issues for discussion- Response to charge question 1 (Sections 4.1.1 – 4.1.5)- Response to charge question 2 (Section 4.2)- Response to charge question 3 (Section 4.3)- Response to charge question 4 (Section 4.4)	
2:45 p.m.	EPA Remarks	Mr. Joseph Beaman, EPA Office of Water
3:00 p.m.	Public Comments	Dr. Thomas Armitage Designated Federal Officer
3:15 p.m.	Discussion of draft Executive Summary Letter to the Administrator	Dr. Judith Meyer and Committee
3:50 p.m.	Summary and Discussion of Next Steps	Dr. Judith Meyer
4:00 p.m.	Adjourn	

Appendix C – List of Points to be Discussed on September 16th EPEC Teleconference

Points to be discussed on the September 16th EPEC teleconference (page and line numbers refer to the clean PDF version of the 8/27/08 draft report on aquatic life criteria for contaminants of emerging concern)

1. Recommendations concerning mixture effects. In a number of places the report states that it is necessary to account for the fact that organisms may be exposed to mixtures of CECs with similar modes of action (see below). Does the Committee agree with the following statements?
 - Page ii (lines 22-25) “In addition, we note that consideration of specific issues such as the potential for synergism among CECs in mixtures and interactions with environmental variables is important to include in any effort to derive aquatic life criteria.”
 - Page ix (lines 9-11) “...research is needed to determine how aquatic life criteria can take into account the fact that aquatic organisms are exposed to mixtures of chemicals with similar modes of action.”
 - Page xiii (lines 19-22) “EPA should bolster consideration of mode of action in the aquatic life criteria derivation process...aquatic life criteria for CECs should take into account the fact that aquatic organisms are exposed to mixtures of these chemicals.”
 - Page xiv (lines 18-20) “Part II should discuss how the individual effects of EE2 on biota might be changed by mixtures of compounds, especially those with similar modes of action.”
 - Page 3 (line 11-12) “suggestions focus on ...consideration of a mixture strategy for CECs.
 - Page 8 (lines 18-20) “Thus a mixtures strategy is needed to guide development and interpretation of aquatic life criteria for CECs”
 - Page 9 (line 9-11) “The Committee suggests that EPA consider the mixture effects of compounds with similar modes of action when determining the range of environmentally relevant concentrations for criteria development.”
 - Page 19 (lines 25-26) “Research is needed to determine how aquatic life criteria for CECs can take into account the fact that aquatic organisms are exposed to mixtures of these chemicals.”
 - Page 27 (lines 19-21) “some guidance should be provided for site-specific applications where mixtures of compounds occur that may have additive effects that exceed individual aquatic life criteria.”
 - Page 28 (lines 35-39) “...the White Paper fails to address how the influence of EE2 might be affected by mixtures of compounds...”
 - Page 35 (lines 8-10) “As EPA develops a research plan to support derivation of aquatic life criteria for CECs, it may be useful to consider the following questions...How can aquatic life criteria be developed to take into account the fact that aquatic organisms are exposed to mixtures of CECs.”

2. Consideration of mode of action in criteria development. Does the Committee agree with the following statements concerning the use of parallel processes to develop aquatic life criteria for compounds with similar modes of action?
 - Page 27 (lines 11-21) “As mentioned previously, the Committee recommends that EPA use mammalian pharmacology data available from the drug discovery process, genomics / proteomics / metabolomics and QSARs to screen CECs for modes of action and assess potential multiple modes of action for individual CECs. This would facilitate exploration of the use of parallel processes to develop aquatic life criteria for CECs with similar modes of action. To increase efficiency when determining an aquatic life criterion for one compound (such as EE2), the process could be repeated (or developed in parallel) for compounds (such as estradiol or E2) with similar modes of action.”
 - Page 34 (lines 42-43) “It would make sense to develop aquatic life criteria for natural and synthetic estrogens using parallel processes.”
 - Page 37 (lines 14-19) “EPA should consider developing a mixture strategy to develop aquatic life criteria for classes of compounds with similar modes of action. As previously mentioned, parallel processes could be used to develop aquatic life criteria for broad classes of CECs with similar modes of action (e.g., the estrogens, SSRIs)”

3. Recommendations concerning protection of endangered species. In a number of places the report emphasizes the need to develop criteria that protect endangered species. Does the Committee agree with the report text?
 - Page x (lines 41-44) “EPA should support research that addresses the suitability of the use of surrogate species in assessing the responses of various resident aquatic species (e.g., endangered or long-lived species and species with varying life history strategies)…”
 - Page 15 (lines 24-27) “In order to protect endangered species, studies should be completed to compare toxicity test responses of common test species and endangered organisms and thereby determine the relevance of surrogates in the criteria development process.”
 - Page 37 (lines 4-8) “EPA should take into consideration appropriate additional factors to ensure that aquatic life criteria are protective of endangered and protected species…”

4. Principles for modifying the 1985 Guidelines. The report recommends that EPA articulate a set of principles that could be applied when modifying the 1985 Guidelines to develop water quality criteria for CECs. These principles include: seeking a wide range of opinions, determining appropriate receptors of potential concern, developing a robust conceptual model, developing multiple lines of evidence, and identifying uncertainties. Does the Committee agree with this text?

- Page 23 (lines 30-33)
 - Page 24 (lines 13-27)
 - Page 25 (lines 1-31)
5. Recommendations concerning minimum data requirements for taxonomic coverage. Does the Committee agree with the report text concerning interpretation of the minimum data requirements for taxonomic coverage?
- Page 9 (lines 37 -42) “The Committee agrees with EPA’s recommendation [to interpret the minimum data requirements for taxonomic coverage as information requirements instead of toxicity test requirements]. However,...the Committee recommends that EPA define 1) what constitutes a sufficiently robust set of chronic data for criteria derivation, and 2) what constitutes a reasonable understanding of mode of action that may allow inferences concerning the insensitivity of particular taxa.”
 - Page 10 (lines 29-43) “There is a need to maintain broad taxonomic coverage for development of aquatic life criteria...”
 - Page 11 (lines 36-42) “EPA needs to define what constitutes a sufficiently robust set of chronic data...”
6. Recommendations concerning the use of non-resident species. The report states that a criterion should not be developed on the basis of non-resident species data alone. It also states (in the context of the EE2 example) that results from non-resident species may not be generalized to resident species without comparative sensitivity studies. Does the Committee agree with the report text?
- Page 15 (lines 16-27)
 - Page 29 (lines 6-7)
7. Recommendations concerning the development of tissue-based criteria. The report states that for bioaccumulative CECs where food chain transfer is a concern, EPA should consider developing tissue-based criteria (i.e., expressing the criterion as a concentration of the pollutant in fish tissue rather than a concentration in the water). Does the Committee agree with the report text?
- Page xv (lines 37-40)
 - Page 33 (lines 6-14)
 - Page 36 (lines 17-27)
8. Recommendation to integrate Parts I and II of the White Paper. The report recommends integrating parts I and II of the White Paper and making Part I the sole document. Does the Committee agree with this text?
- Page xiv (lines 10-16)
 - Page 28 (lines 23-29)

9. Are our statements regarding Part II elsewhere in the report consistent with the recommendation to integrate Parts I and II?
- Page xi (lines 42-43) “The Committee finds that Part II is a well-written and thorough review of the existing literature on EE2.”
 - Page xiv recommendations re Part II.
 - Page 2 (lines 43-44) “In particular we suggest that EPA more explicitly describe how the illustration in Part II was developed from the recommendations in Part I of the White Paper.”
 - Page 30 (lines 23-33) This first sentence is not consistent with the earlier statements about the clarity of the document. Do the second and third sentences make sense if we are asking them to combine parts I and II? “If Part II of the White Paper is to remain as a separate document, the Committee finds that its clarity and transparency could be improved in a number of areas. In particular, the authors need to more explicitly describe how the illustration was developed from the recommendations in Part I of the White Paper. Part II of the White Paper also needs to be more explicit regarding how specific conclusions and assessments were derived from the data. The following specific revisions are suggested”
 - Page 31 (lines 19-22) “Part II should in this case also provide an overview of how the process is expected to ultimately influence the criteria derived (in other words, what is the bottom line in terms of how the new recommendations changed the final outcome?).” Can they do this if the two are combined?
10. Use of EC_x value instead of NOEC/LOEC. The report recommends use of EC_x instead if NOEC/LOEC. Does the Committee wish to recommend that a particular x value be used in derivation of criteria for CECs?
- Page xiv (lines 37-44)
 - Page 29 (lines 45-46) and Page 30 (lines 1-5)
11. Additional references. Additional references have been requested to support the following statements.
- Page 20 (lines 40-41) “Nonyl phenols have multiple modes of action other than direct binding to the ER that lead to feminization.”
 - Page 21 (lines 2-4) “correlations between fecundity and vitellogenin in females have been observed to be strong even though this may not indicate a mode of action.” Also indicate whether higher vitellogenin levels have been correlated with higher fecundity.