

## **SAB Comments on Aquatic Life Water Quality Criteria for Contaminants of Emerging Concern**

### **1. Dr. David Dzombak:**

*(a) Are the original charge questions to the SAB Panel adequately addressed in the draft report?*

The SAB Ecological Processes and Effects Committee (EPEC) review panel has addressed all of the charge questions. Each of the charge questions appears to be addressed in sufficient depth, and specific recommendations have been developed for each of the charge questions and sub-questions.

*(b) Is the draft report clear and logical?*

The organization of the draft report by the SAB EPEC review panel follows the charge questions directly and is easy to follow. The Executive Summary is rather long considering the short length of the main report, but I don't think it's a problem and would not recommend condensing the Executive Summary further. There are two issues in the draft report that I recommend be addressed to improve clarity and strengthen it.

(i) I have identified a statement made in the letter to the Administrator, in the Executive Summary, and in the body of the report that is somewhat misleading and that I recommend be clarified. This statement is made on page 2 of the letter, on page xii of the Executive Summary, and on pages 25 and 37 of the main report. The version that is in the letter to the Administrator serves to illustrate my concern.

“The derivation of aquatic life criteria needs to be risk-based, using a transparent and consistent framework that provides necessary flexibility not presently possible within the algorithm approach of the 1985 Guidelines. Hence, the SAB recommends that, to the extent practicable, the derivation of aquatic life criteria be risk-based using the principles defined in EPA's 1998 *Guidelines for Ecological Risk Assessment*.”

The recommendation that EPA risk assessment procedures for determination of aquatic life criteria make direct use of the 1998 Guidelines is fine, but the preamble to this recommendation as given here and at the other locations in the report cited above implies that the 1985 Guidelines do not involve risk assessment, and thus that risk assessment has not been previously employed in establishing aquatic life criteria. This is not the case, and I recommend that the recommendation about use of the 1998 Guidelines be reworded to clarify the nature of the 1985 Guidelines.

(ii) In the Executive Summary (page xiii, bullet 1; page xxi, bullets 1 and 4) and in the main report (page 33, bullet 2; pages 36-37, item 1; and

perhaps elsewhere), the review panel discusses the potential for contaminants of emerging concern (CECs) to be from classes of chemicals other than pharmaceuticals and personal care products, and recommends that the Agency “consider expanding the definition of CECs to include chemicals and other substances of increasing environmental concern due to anthropogenic activities and inadequate regulatory approaches.” The review panel recommends that the Agency “look for opportunities to leverage EPA research with ongoing research in other federal agencies, international agencies, and industry groups.” These are useful and important observations and recommendations, but not mentioned in any of the discussion is the TSCA new product review process in which data are supplied by chemical manufactures in relation to the pre-manufacture notification required under TSCA. The search for possible CECs should begin at this stage. The TSCA new product review and its relationship to aquatic life criteria determination is not discussed in the report at all. At a minimum, aquatic life toxicity data provided by manufacturers in this process could be used to help set aquatic life criteria. There are other possibilities that could be considered, such as integrating parts of the aquatic life criteria establishment process into the TSCA new product review to aid in the assessment of the new product notifications. Also, data and other information supplied for the new product review could help the Agency prioritize CECs. Whatever the level of integration the review panel believes is appropriate, the main point is that aquatic life criteria determination for CECs should be conducted with knowledge of the data for new chemical products coming into commercial use provided by the TSCA new product review process.

*(c) Are the conclusions drawn, and/or recommendations made, supported by the information in the body of the draft SAB report?*

The conclusions drawn and recommendations made are supported by the information in the body of the draft report.

## **2. Dr. Meryl Karol:**

*a) Are the original charge questions to the SAB Panel adequately addressed in the draft report?*

The draft report clearly addresses the charge questions.

*b) Is the draft report clear and logical?*

The report is superb; clear and logical. One of the best reports I have read

*c) Are the conclusions drawn, and/or the recommendations made supported by information in the body of the report?*

Yes.

### 3. Dr. Thomas Wallsten

I have read the three draft reviews. It appeared to me that all three adequately addressed the charge questions, were logically laid out, and provided supporting information for their conclusions and recommendations. I have three comments on the reports:

- a) The review of the White Paper on "Aquatic Life Criteria for Contaminants of Concern" mentioned the use of expert panels to provide professional judgment during criteria development (Section 4.1.6). I concur that such panels can be very useful. My question is whether EPA has, or has not considered, guidelines for how such panels should operate to assure careful, unbiased judgmental extrapolations from available data to end points of concern?
- b) The same white paper urges that attention be paid to the possible effects of mixtures of contaminants, not just contaminants acting alone. This point would seem to apply to the "SAB Advisory on EPA's Third Drinking Contaminant Candidate List," yet I did not see it mentioned there (although I may have missed it).
- c) Finally, only the review of "Toxicological Review of Acrylamide" included a list of abbreviations. While some acronyms are common (e.g., LOEL, NOEL, DNA), others may be unique to specific fields or topics (e.g., CEC, ROPC, WBDO). It would helpful for all reports to have a list acronyms.

### 4. Dr. Terry Daniel

*The original charge questions to the SAB Panel are adequately addressed in the draft report, the report is clear and logical, and the conclusions and recommendations are supported by the information in the body of the report.*

Some suggestions for extensions to some sections of the Committee review are presented below.

#### 4.1.1

The Committee recommends that the White Paper pay greater attention to the possible interactions within "mixtures" of similar contaminants (especially viz. mode of action) and to the potential for environmental "pulses" of higher than normal concentrations to occur frequently in some contexts. A similar issue not specifically noted is the potential for periodic environmental concentration of contaminants as may occur, for example, in ephemeral water bodies due to evaporation. Of course, mixtures of contaminants and pulse/concentration phenomena might also interact to further magnify toxic effects.

#### **4.1.2**

The issue of minimum data requirements with regard to taxonomic coverage is a classic “proof of the null hypothesis” problem (“proof of innocence” in the white paper), and the Committee has appropriately noted the need for a clear and explicit specification of criteria for determining when data and understanding are sufficient for determining no effect. In this context, the suggestion presented later (4.2) of revising/updating the Guidelines in the direction of the Guidelines for Ecological Risk Assessment is appropriate here as well. A major factor in determining “proof of innocence” should be an assessment of the potential consequences of incorrectly concluding that a contaminant would have no effect (i.e., the payoff matrix). The ecological data requirements for supporting a conclusion of no effect (i.e., the level of “power” deemed sufficient for detecting a specified consequential effect) depend at least in part on an assessment of the social and biological values at risk and the potential for consequential losses. Moreover, because current goals extend to the protection of ecosystems and their services, rather than individual targeted organisms or specific sub-systems, there is a greater need to assure that biological assessments adequately address a broad range of taxa and environmental contexts.

#### **4.1.3**

The use of non-resident species models is well addressed by the Committee. This section additionally provides an opportunity to extend the Committee’s discussion of how to define “resident species” to include how global climate change and other factors potentially make this distinction a moving target. It seems clear that resident species is a “social construct,” and so some explicit involvement of publics/stakeholders in identifying appropriate species targets in given environmental/social contexts, and in determining the relevance of data based on surrogate non-resident species would seem both useful and prudent.

#### **4.1.4**

The relevance of a risk assessment approach noted above for taxonomic coverage issues applies equally well to decisions about the sufficiency of partial versus full life-cycle tests (perhaps extending to trans-generational testing) for determining chronic toxicity effects. Such decisions would seem to require a consideration of tradeoffs between the costs of additional testing and the values at risk and potential losses from missing an important effect. That is, such decisions cannot be made on the basis of biological data considerations alone.

#### **4.1.5**

The use of sub-lethal/”non-traditional” endpoints for toxicity assessments raises a number of issues addressed by the White Paper and refined by suggestions of the Committee. The rough implicit model is that biological

changes in individual organisms (in response to toxins) may produce changes in individual characteristics and behavior which may have implications for populations (and on to ecosystems). In that context, and consistent with the points raised by the Committee in recommendation 4, it should be noted that the model may at times work backwards, with social factors affecting individual behavior which in turn affects individual neurological and other systems and functions.

#### **4.1.6**

The discussion of expert panels emphasizes their use as a means for overcoming gaps in bio-ecological data and information. Consistent with the recommended move toward a risk assessment model (4.2) and with the issues raised in 4.1.2-4 above, this discussion might be extended to include both a wider range of disciplines (especially social sciences and economics) and some involvement of relevant publics/“stakeholders.” This may have been intended, but is not fully communicated by the call for a “balanced range of perspectives” in expert panels used for the development of aquatic life criteria.

#### **4.2**

The recommended shift toward an ecological risk assessment model (recommendation 1), including seeking inputs from diverse perspectives (recommendation 2), and aspects of several other recommendations in this section imply the need for explicit and systematic assessment of the concerns of relevant publics/stakeholders. This in turn implies the need for greater involvement of social and economic sciences in the aquatic life criterion setting process, especially in the context of identifying and prioritizing contaminants of emerging concern.

#### **4.3**

The Committee presents numerous good suggestions for improving Part II of the White Paper. The overall theme of many of these suggestions might be more forcefully presented in the Committee review—that the EE2 case should be presented more clearly as an example of the aquatic life water quality criterion setting process, rather than as a case study that is important in its own right (although the latter is certainly true). In that regard, more frequent and elaborated discussions of how the EE2 is similar to and contrasts with analyses for other classes of CECs and how the example illustrates points raised in Part I would be very useful. That is, the EE2 case could be used more forcefully to illustrate important issues and principles applicable across the breadth of CECs.

#### **4.4**

Perhaps the most important suggestion for implementing the recommendations in the White Paper is the need for some effective means to prioritize CECs and the related need for data to support the

development of criteria that are relevant to an expanded set of ecological and social goals (e.g., protection of ecosystems and ecosystems services). Consistent with the recommended risk assessment model and with the comments noted above, such prioritization can be facilitated by greater involvement of publics/stakeholders and relevant social sciences. Related to effective prioritization, there is also a need for some consistent classification of CECs into categories relevant to aquatic life criteria. The white paper, and the comments of the Committee suggest that mode of action may be a very useful basis for such classifications, as well as for addressing issues of mixtures of multiple contaminants and of environmental pulses and concentrations.

#### **5. Dr. Rogene Henderson**

I found this advisory to be exceptionally well-written. The charge questions were addressed in a clear and logical fashion and the recommendations were well-supported in the text. The tone of the report was supportive of the work of the Agency but the report also gave strong recommendations that should help the Agency improve their approach.

#### **6. Dr. David Allen**

Aquatic Life Water Quality Criteria Advisory: no comments.

#### **7. Dr. John Balbus**

a) Are the original charge questions to the SAB Panel adequately addressed in the draft report?

*Yes; the report is clearly organized according to the charge questions.*

b) Is the draft report is clear and logical?

*Yes; it is clearly written and appears logical.*

c) Are the conclusions drawn, and/or recommendations made, supported by information in the body of the report?

*Yes, the conclusions appear to be well supported by the text.*

#### **8. Dr. Valerie Thomas**

Overall, this advisory is well written, addresses the charge questions, is clear and logical, and the conclusions are supported by the body of the report. There are a few points which could be clarified, as discussed below:

Letter to the Administrator, p. 2, second paragraph: This paragraph would be more clear if the phrase “create a conceptual model to guide development of aquatic life criteria for CECs. Such a conceptual model should” were cut. By making this cut, the second sentence of the paragraph would read “In particular we urge EPA to include consideration of probably direct and/or indirect...” I think this would improve the clarity of the paragraph message because it would

emphasize the issues (topic of the first sentence of the paragraph) the Committee recommends EPA consider. If it is important to mention conceptual models, a new sentence could be added: “These issues could be incorporated through development of a conceptual model.”

Executive Summary, p. xiv, lines 15-10. “Mixtures of CECs.... Therefore research is needed.” The overall discussion of the importance of mixtures throughout the document, and in particular the discussion of the availability of approaches from pharmacology to identify the potential impact of mixtures suggests that the Committee may not have meant simply to recommend more research, but to actually recommend that the potential effect of mixtures be incorporated into the aquatic life criteria. In particular, page xviii says “As stated previously, aquatic life criteria for CECs, should take into account the fact that aquatic organisms are exposed to mixtures of these chemicals.” But, as far as I can see, this was not state previously. On page 8, lines 19-27, the Committee does state that “Consideration of mixture effects is important.... The Committee feels strongly that mixture effects of compounds ... should be taken into account.” The strength of this recommendation is not reflected in the Executive Summary.

Executive Summary, p. xviii, lines 16-17. “we recommend that the Agency ... customize and update the 1985 Guidelines.” This is an excellent and key point; this should probably also be stated in the Letter to the Administrator.

Executive Summary, p. xviii, line 23: “(2) developing a robust conceptual model.” It is not clear what this really means. The implication is that the EPA currently does not have a “concept” on which the criteria are based; this five-word phrase does not make clear what will be the benefit of the model, and it is not clear what a robust versus non-robust model is. Perhaps this would be more clear if the Committee said what content would be included. For example, a phrase might go something like this (the Committee would need to develop its own content: “(2) going beyond the fate and direct effects of CECs by including, at least at the level of a conceptual model, consideration of probable direct and or indirect impacts on food webs, ecological processes and services, unique, endangered or keystone species or species of special societal value or concern.” (Text is taken from p. 24 lines 39-43.)

Executive Summary, p. xviii. “As stated previously, aquatic life criteria for CECs, should take into account the fact that aquatic organisms are exposed to mixtures of these chemicals.” As far as I can see, this was not state previously.

Page 8, lines 19-27, “Consideration of mixture effects is important....The Committee feels strongly that mixture effects of compounds ... should be taken into account.” This idea is again emphasized on p. 9 lines 15-17. The strength of this recommendation is not reflected in the Executive Summary.

p. 24 line 39-p. 25, line 8. This is the discussion of the conceptual model approach that is heavily recommended by the Committee. This discussion does not mention how such a model might or might not be “robust.” Especially because the committee emphasizes the criteria for determination of robustness in other parts of the document, the Committee could add discussion of the robustness issue here, or drop the word “robust” from discussion of the conceptual model approach in the Executive Summary (p. xviii, line 23; also page 26 line 20).

p. 37, lines 27-28: “As previously discussed, the Committee recommends that EPA incorporate the use of conceptual site models....” Where were “site models” previously mentioned? Is this the same as the recommendation for “robust conceptual models”? Should all of these models be site models? Is a site model a model for one type of location (site) only, and if so, how many site models would be needed for a single CEC?

## 9. Dr. Duncan Patten

**General Comment.** In all three cases, the SAB review committees have offered excellent review and advice to EPA. The reviews are comprehensive and in sufficient detail to allow EPA staff to reconsider their positions on topics of concern and to rewrite or rework the materials presented in the white papers.

In order to fully assess the responses of the SAB review committee, one would have to be more expert in the particular field of science than I am. Thus my comments are more general, but specific in some cases.

Here is an aside comment on Cumulative Effects and Synergism relevant to two of the reviews.

One question that comes to my mind as I read the reviews, and thus responses to EPA questions, especially those for “Aquatic Life Water Quality” and “Drinking Water Contaminant Candidate List” deals with the concepts of “cumulative effects” and “synergism” in effects of contaminants. Why aren’t these concepts considered more critically in testing or selecting contaminants of concern? Only in the Aquatic Life Water Quality review is the concept of synergism (page 11) even considered, and apparently only in passing. Are not the synergistic interactions as well as cumulative effects among and within contaminants of importance in selection and testing of toxic effects?

Specifically on the SAB Advisory on Aquatic Life Water Quality Criteria for Contaminants of Emerging Concern.

Initial comments are tied to the Executive Summary which offers most of the points of the review. The comments tend to point out the importance of an SAB panel response rather than to point out omissions or weaknesses. This is because the panel has done an excellent job of responding to EPA’s questions.

The amendments to EPA's "contaminant continuous concentration" proposed by the SAB review committee (e.g., page xiii) include cautionary statements which are very appropriate here but may be appropriate where other suggested changes or procedures are offered. Perhaps precaution should be a guiding rule for both EPA in selection of "tools" and SAB in its suggestion of alternatives.

The suggestion that EPA should "place greater emphasis on information useful for development of aquatic life criteria, rather than just toxicity test requirements" (e.g. page xv) gets to the heart of the review. The white paper was to offer guidelines for "development of aquatic life criteria" without creating some form of sideboards such as toxicity tests.

Comments dealing with use of "non-resident" species again offer guidance of precaution in their use. Good guidance to those who must rewrite the white paper.

In its response to using endpoints (e.g., page xvii), the SAB panel recommends use of "non-traditional measures" (e.g., line 14, page xvii)... One assumes this means "non-traditional" sublethal endpoints... is that what was meant?

In "involvement of an Expert Panel," the SAB panel suggests developing "specific guidance of the role of expert panels" (line 42, page xvii). They probably should also suggest establishing criteria for selection of expert panels for specific CECs.

Response to Technical Issues, the SAB panel recommends "obtaining a wide range of inputs from diverse perspectives (line 23, page xviii). The panel should suggest what they mean, for example, literature, experts, practitioners?

Executive Summary dealing with Part II of white paper on Aquatic Life Water Quality.

The SAB panel makes an excellent recommendation which might be useful for other EPA efforts when they say "the process outlined for EE2 might be applied to other substances, particularly for those for which less data are available and which have different modes of action." (Lines 22-24, page xix).

Page xx, line 22. Is there some reason why only one species (fathead minnow) is cited here?

In the main body of the text, under section addressing "concerns regarding taxonomic coverage..." (pages 10-11), the SAB panel comments under "modes of action are not known for some CECs, that "different organisms may be affected in different ways by the same compound both as adults and at earlier stages..." and that "there is also the potential for synergism among CECs in mixtures and in interactions with environmental variables." This point should have a major

emphasis as tests of CECs are done individually and this does not represent most conditions found outside the laboratory.

**10. Dr. Bernd Kahn:**

I have read the three draft Reviews and consider them to be well written.

**11. Dr. LD McMullen:**

I have read the documents and have found them to be well organized and easy to follow. I believe they answer the charge questions that were provided to the committee. These documents are not in my area of expertise and as such I have little to add on there technical merit.

I realize that mixing zone for the discharge is not a part of the Water Quality Standard. However, it is important to realize that some aquatic life find wastewater discharges a nutrient rich environment and will spend a significant amount of time in the discharge plume.

**12. Dr. Timothy Buckley:**

The ALC report looks rock solid. It is well organized and clearly responsive to the charge questions. I have no suggested edits or revisions.

**13. Dr. Jerry Schnoor:**

I have read the 43 page report from the Ecological Processes and Effects Committee (EPEC) of the SAB reviewing the EPA Agency Draft White Paper on Aquatic Life Criteria for Contaminants of Emerging Concern (CEC), and I find it to be an excellent report. It is well written, well organized, and full of important recommendations regarding a process that is central to the Agency's mission of protecting aquatic life.

The EPEC Report clearly speaks to the charges from the EPA to the Science Advisory Board on: 1) Reviewing the technical merit, practicability, and implementability of the White Paper; 2) Identifying the appropriate issues for deriving aquatic life criteria; 3) Providing suggestions for improving the utility of the Part II ethynlestradiol (EE2) case example; and 4) Providing guidance on implementing the recommendations.

The Executive Summary is rather long (10 pages), but it reflects quite accurately the discussion and recommendations found in the body of the report. Regarding EPEC's review of Part II, the case example on EE2, I might add that the Agency could probably benefit from the exercise of Part II with several other CECs of differing modes of action such as polybrominated diphenyl ethers (PBDEs), bisphenol A, and perfluorinated octynyl sulfonate (PFOS). These are also problematic and controversial CECs that have raised questions in the mind of the public over the capability of EPA's risk assessment procedures and aquatic life criteria to protect health and the environment. Also, these chemicals which differ from the stated concern in the White Paper over pharmaceutical and personal care products entering the aquatic ecosystem from wastewater treatment plants. But

they are nonetheless important and instructive case studies that might shed new light on revising the outdated 1985 Guidelines document. The EPEC Report recognizes this possibility in several parts of the report (p. 29, lines 29-35 and lines 40-44). I applaud the call to rely more on risk-based considerations, weight-of-evidence, and increased use of judiciously chosen expert panels to improve the 1985 Guidelines document and procedures.

Some specific comments on the EPEC Committee Report follow.

- a) Page xvii, lines 29-30) on vitellogenin as a biomarker. The fourth point here is a little unclear and not quite the way that the point is expressed in the main text of the Committee's report. I believe the report is overly cautious and subtly varies in its recommendations regarding vitellogenin as a biomarker (see page 22, lines 31-32, and page 23 lines 14-16). Gender alteration is listed as an important biological effect in Figure 1 on page 25. Certainly, if the sex ratio in humans changed due to chemical exposure, it would be an endpoint of considerable concern (not simply a biomarker of exposure). "Evidence of absence" of population change is not the same as "absence of evidence", and our techniques for detecting population changes *in situ* may not be sufficiently sophisticated for endocrine disruptors. In this case, a more precautionary approach may be recommended.
- b) Page xviii, lines 34-45. I whole-heartedly agree with this Committee recommendation. Grouping chemicals by their modes of action is a good research strategy for EPA. We need creative methods of simplifying the process if possible. It may accelerate EPA's ability to make ALC determinations and improve their efficiency. However, the Committee contradicts itself a bit on page 11 (lines 16-24) when it states that modes of action are not well known, and it casts some doubt on the whole exercise. In balance, I am in favor of recommending the grouping of chemicals by dominant modes of action, at least as a matter of research during the development of ALCs.
- c) Page xx, lines 17-27. I may have missed it, but I did not see any discussion of EC<sub>10</sub> and EC<sub>20</sub> in the main text of the report, only here in the Executive Summary.
- d) Page 9, lines 8-9. One order of magnitude seems a little excessive to me in Recommendation #3. I would suggest 1-2 orders of magnitude allowing some judgment regarding the uncertainty of the data and the possibilities of unmeasured pulses of chemical discharge.
- e) Page 10. References should be Brain et al., 2007 (not 2008); and Pennington et al., 2001.

#### **14. Dr. Steve Roberts:**

The panel has done an impressive job responding to charge questions related to a review of the subject EPA White Paper. Each of the charge questions is addressed in full, and the responses are clearly articulated. The organization of

the report is excellent, making the discussion and recommendations on specific topics easy to find and follow. The recommendations are logical and should be valuable to the Agency, both in finalizing the White Paper and in creating a scientifically sound process for developing aquatic life criteria for contaminants of emerging concern. I have no criticisms of the report.

**15.**