

Dr. Thomas Armitage, Designated Federal Officer
EPA SAB Staff Office (1400F)
U.S. EPA
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

June 16, 2008

Dear Dr. Armitage,

Thank you for the opportunity to comment on EPA's white paper on Aquatic Life Criteria for Contaminants of Emerging Concern (CECs). The white paper provides a comprehensive discussion of the challenges posed by application of EPA's 1985 Guidelines for Deriving Water Quality Criteria (Guidelines) to CECs, particularly to endocrine disruptors that act through the gonadal axis. EPA proposes a number of well-reasoned adaptations of the existing Guidelines to make them more appropriate for CECs. The proposals represent positive steps in that direction, but the comments that follow ask the SAB to consider whether a more fundamental departure from the Guidelines is warranted.

Although the EPA white paper proposes several adjustments of the current Guidelines, it nevertheless maintains that derivation of criteria for CECs should follow the basic procedures specified in the Guidelines, with an emphasis on using "an appropriate distribution of taxa in the data set used for criteria derivation", in order to ensure that the criteria have the same technical rigor as the existing 304(a) criteria. Due to the nature of endocrine disrupting effects and the quality and quantity of available toxicity data, however, this approach could lead to criteria that are not adequately protective for some endocrine disruptors, and no criteria at all for others.

The guidelines are not well suited to account for the complexities of endocrine disruption modes-of-action and the wide range of endpoints for which toxic concentrations are reported. To date the Guidelines have generally been applied to data sets containing mainly survival rates measured by standard toxicity tests. In contrast, data sets for most endocrine disruptors are likely to contain toxicity data for a variety of different reproductive effects occurring over a wide range of concentrations. Even within the same species, different reproductive endpoints display wide variation in sensitivity. Further, for some endocrine disruptors, one or two extensive, well-designed studies show effects at relatively low levels, while a larger number of simpler studies report effects only at much higher levels. As a consequence, combining test data for multiple endpoints may not result in protective criteria for endocrine disrupting contaminants. For these reasons, I recommend that the SAB consider whether the current Guidelines provide a valid basis for deriving aquatic life criteria for endocrine disruptors, or whether, alternatively, a completely different framework would enable EPA to use existing data more effectively. Specifically, the SAB should consider whether procedures for developing aquatic criteria for endocrine disruptors should place more emphasis on data quality and interpretation and less emphasis on data quantity than the existing Guidelines.

In the white paper, EPA acknowledges that a downside to establishing a minimum level of information for criteria is that there may be chemicals for which regulatory guidance is needed, but for which toxicological data are insufficient to meet the minimum standards of the Guidelines. Ironically, the application of the Guidelines that were meant to "protect aquatic organisms and their uses" could actually result in an absence of guidance, regulation and protection for some CECs. For this reason, I recommend that SAB consider advising EPA to pursue alternative procedures more likely to result in criteria that approximate threshold concentrations for endocrine disruption effects in the environment.

Thank you for your consideration of these comments.

Sincerely,

Nancy Bettinger
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