CropLife ☆AMERICA☆

September 8, 2008

Dr. Thomas Armitage
Designated Federal Officer
EPA Science Advisory Board (1400 F)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, D.C. 20460-0001

Dear Dr. Thomas Armitage,

Thank you for the opportunity to offer comments for the consideration of the Science Advisory Board (SAB) Ecological Processes and Effects Committee (EPEC) as the committee deliberates on EPA's Aquatic Life Water Quality Criteria for Contaminants of Emerging Concern. CropLife America (CLA) is the national trade association representing developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CLA member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by American farmers.

The U.S. Environmental Protection Agency's (EPA) Office of Water recently convened a SAB EPEC (the "Committee") to review and provide guidance on EPA's recommendations outlined within *Aquatic Life Criteria for Contaminants of Emerging Concern* (CECs) (the "White Paper"). The Committee was charged by EPA to address four overall areas related to the recommendations outlined in the White Paper. These charge questions were principally focused on the "technical merit, practicality, and implementability of the recommendations" for deriving water quality criteria for CECs, and included the following six specific technical areas:

- *Relevance of acute toxicity effect concentrations in setting aquatic life criteria for CECs*
- *Defining minimum data requirements regarding taxonomic coverage*
- *Use of non-resident species in criteria development*
- *Defining appropriate chronic toxicity data*
- *Selection of effect endpoints upon which to base criteria*
- *Involvement of an expert panel*

Based on the charge to the Committee, EPA requested the Committee's input on these six specific technical areas. CLA commends the thoroughness of EPA's proposed recommendations and the Committee's response and input for each of these six technical areas. However, as outlined within the Committee's draft advisory report

(http://yosemite.epa.gov/sab/sabproduct.nsf/ea5d9a9b55cc319285256cbd005a472e/ed6165a29bdc0e83852574b9006b117e/Body/0.4F0!OpenElement&FieldElemFormat=gif), the Committee has provided recommendations within the following three scientific areas that appear to be outside the scope of EPA's specific charge to the Committee and are more relevant to a general revision or expansion of the 1985 *Guidelines*:

- *Assessment of potential "transgenerational" effects*
- *Assessment of interaction effects of environmental mixtures*
- *Evaluation of appropriate surrogate species for protection of federally listed species*

Within the draft advisory report, the Committee recommended that these three areas should be considered by EPA when setting aquatic life criteria for CECs (and other chemicals). CLA comments on each of these three areas are summarized below. CLA usually submits more detailed comments, including identification of specific areas where CLA agrees with the Committee's recommendations. However, as the draft advisory report was just released on September 3, 2008, there was insufficient time for CLA to do so in this case.

Assessment of potential "transgenerational" effects

CLA requests that the Committee explicitly define "transgenerational" effects, as this term is often used when describing effects observed in unexposed offspring from exposed parents (e.g., epigenetic-related phenomenon). Rather, it appears as though the Committee recommended evaluation of effects following continuous exposure to multiple generations (e.g., exposure of F_0 and F_1 generation). CLA believes this is an important distinction that should be clarified in the Committee's final advisory report.

EPA specifically requested input from the Committee on whether at least one fish full life-cycle (FFLC) test (F_0 egg to F_1 offspring) should be required for setting the Criterion Continuous Concentration (CCC) for all chemicals. EPA did not request input regarding the utility of studies specifically designed to assess transgenerational or multi-generational effects. Therefore, the Committee's suggestions appear to be outside the scope of EPA's charge and are not relevant to EPA specific recommendations.

Because of the length, complexity, and resource requirements for the FFLC study, CLA suggests that the FFLC study should not be the default test for setting CCC's for all chemicals. CLA agrees with EPA and the Committee that a FFLC study should be conditionally required when necessary after considering mode of action, data from shorter term studies, and general sensitivity comparisons between FFLC and shorter studies. When data are available from early life-stage (ELS), partial life-cycle (PLC), or FFLC studies, transgenerational studies are not likely to improve EPA's ability to define aquatic life criteria for CECs and other chemicals and require a significant investment in time and resources. Rather, data derived from ELS, PLC, or FFLC studies (e.g., survival, growth, fecundity, etc.) could be directly used to predict potential effects on multiple

generations via population growth models (e.g., Leslie Matrix-based models) without the need for additional testing.

Assessment of interaction effects of environmental mixtures

EPA did not request input regarding the impact of potential interaction effects of environmental mixtures on setting aquatic life criteria for CECs (and other chemicals) . Therefore, the Committee's recommendations appear not to be relevant to EPA's charge. Indeed, implementation of the Committee's recommendations would require a significant revision to the 1985 *Guidelines*, as they were designed to develop hazard-based numeric aquatic life criteria for individual chemicals and not mixtures. Therefore, given the complexity and departure of this recommendation from the original intent of the 1985 *Guidelines*, CLA suggests that the first focus should be on developing methodology for individual CECs. It may be appropriate to consider mixtures at some point after the methodology for individual CECs is established.

Evaluation of appropriate surrogate species for protection of federally listed species

EPA did not request input regarding the evaluation of appropriate surrogate species for protection of threatened or endangered species. Therefore, the Committee's suggestions appear to be outside EPA's charge and are not relevant to EPA specific recommendations. Moreover, EPA and the U.S. Fish and Wildlife Service (USFWS) previously compared the sensitivity of common fish species for testing (rainbow trout, fathead minnow, and sheepshead minnow) relative to federally listed fish species (Sappington *et al.* 2001; Dwyer *et al.* 1995; Dwyer *et al.* 2005; Besser *et al.* 2005).

In these studies, the authors generally concluded that the inclusion of rainbow trout as a surrogate species provides protection to federally listed fish species for acute and chronic exposure since rainbow trout tends to be more sensitive than fathead minnows and equally or more sensitive than federally listed species. Indeed, the final paper published by these authors, Besser *et al.* (2005) concluded that "the current study and other recent studies in our laboratory (Dwyer *et al.* 1999, 2005; Sappington *et al.* 2001) indicate that standard toxicity test methods can be successfully applied to many listed species." Therefore, based on previous studies conducted by EPA and USFWS, the use of standard surrogate species for toxicity testing will provide adequate protection for a wide range of threatened and endangered species. Any additional testing will require unnecessary financial and animal resources, and will likely not improve EPA's ability to define aquatic life criteria for CECs and other chemicals.

CLA appreciates the opportunity to present the U.S. crop protection industry's views on the SAP Ecological Processes and Effects Committee's important deliberations on EPA's Aquatic Life Water Quality Criteria for CECs. If you have any questions or would like to discuss these

comments further, please contact me by telephone: 202-833-4474, or via email: isiddiqui@croplifeamerica.org or Dr. Nick Poletika, Chairman of CLA's Water Quality Subgroup, by telephone: 317-337-3476, or via email: npoletika@dow.com.

Sincerely,

Isi A. Siddiqui, Vice President
Science and Regulatory Affairs
CropLife America

CC: Ecotoxicology Working Group members
Jay Vroom
Doug Nelson
Darren Pittman

References:

Besser JM, Wang N, Dwyer FJ, Mayer FL, Ingersoll CG. 2005. Assessing contaminant sensitivity of endangered and threatened aquatic species: Part II. Chronic toxicity of copper and pentachlorophenol to two endangered species and two surrogate species. *Arch. Environ. Contam. Toxicol.* 48:155-165.

Dwyer FJ, Sappington LC, Buckler DR, Jones SB. 1995. Use of surrogate species in assessing contaminant risk to endangered and threatened fishes. U.S. Environmental Protection Agency, Gulf Breeze, FL. EPA/600/R-96/029.

Dwyer *et al.* 1999. Assessing contaminant sensitivity of endangered and threatened species: Effluent toxicity tests. U.S. Environmental Protection Agency, Washington, DC. EPA/600/R-99/099.

Dwyer *et al.* 2005. Assessing contaminant sensitivity of endangered and threatened aquatic species: Part I. Acute toxicity of five chemicals. *Arch. Environ. Contam. Toxicol.* 48:143-154.

Sappington LC, Mayer FL, Dwyer FJ, Buckler DR, Jones JR, Ellersieck MR. 2001. Contaminant sensitivity of threatened and endangered fishes compared to standard surrogate species. *Environ. Toxicol. Chem.* 20:2869-2876.