

February 23, 2010

Dr. Timothy Buckley, Chair
Dioxin Review Panel of the Science Advisory Board
Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Dear Dr. Buckley,

These comments are submitted on behalf of the Environmental Working Group (EWG), a non-profit public health, environmental research and advocacy organization based in Washington, DC, with offices in Ames, Iowa and Oakland, Calif. In March 2011, the dioxin review panel of the Environmental Protection Agency Science Advisory Board (SAB) will discuss its draft report reviewing EPA's proposal for a safety standard for 2,3,7,8-tetrachlorodibenzo-p-dioxin. This SAB review of EPA's risk assessment for dioxin is the latest step in a more than 25-year history of the agency's attempts to finalize its position on dioxin toxicity (EPA 2010).

Dioxins are a family of industrial contaminants with well-documented adverse effects on human health, including immune system, reproductive and hormonal changes and an elevated risk of cancer. Finalizing the safety standard for the most toxic member of this chemical group, 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), is the key step that would allow the agency to move forward with its visionary dioxin science plan (EPA 2009).

As a part of the peer review process, SAB was asked to review and comment on the draft EPA's 2010 "Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments". EWG strongly agrees with the SAB finding that "*In general, EPA was effective in developing a report that was clear, logical, and responsive to the three key recommendations of the NAS*" (SAB draft, p. 1). EWG also applauds the SAB for supporting EPA's derivation of the safety standard for TCDD and the classification of TCDD as "carcinogenic to humans". However, we find that the presentation of SAB findings and suggestions, particularly in the draft cover letter, has been surprisingly skewed towards the negative, focusing on what SAB draft terms "*major deficiencies*" (SAB draft, p. i) and failing to highlight the primary successes of the 2010 EPA risk assessment for dioxin. EWG strongly disagrees with the descriptor "major deficiencies" and urges SAB to correct this wrong characterization.

EWG anticipates that the dioxin review panel members would prepare a balanced final report that would acknowledge EPA's accomplishments while at the same time identifying areas for improvement. Specifically, the SAB report should bring greater focus on the aspects of the draft EPA assessment that were responsive and fully met the recommendations of the NAS (2006) report. We also urge SAB to recognize that EPA provided solid and clear reasons for those aspects of its risk assessment that disagreed with the NAS recommendations, an important feature that is not adequately represented in the draft SAB letter.

Further details and the rationale for our recommendations are listed below.

SAB should highlight areas where EPA met and exceeded the NAS recommendations.

The cover letter prepared with the draft SAB report places an inordinate emphasis on the areas where the EPA report “*did not respond adequately to the NAS recommendations*” (SAB draft, p. ii), even though, in the panel’s estimate, draft EPA assessment was responsive to many NAS recommendations (SAB 2011). Furthermore, the areas where the agency disagreed with the NAS are clearly justified and documented. Thus, the use of the expression “major deficiencies” in the second paragraph of the SAB letter creates an incorrect impression in the mind of the reader about the EPA draft and mischaracterizes the excellent work that EPA has done.

In fact, EPA has systematically responded to the NAS recommendations, for example, by:

- Improving transparency and clarity in the dataset selection;
- Employing scientifically justified and logical approaches to dose-response modeling;
- Deriving the reference dose for dioxin based on the best human data currently available.

As EWG remarked in our presentations to the dioxin review panel in July and October of 2010, new science continues to demonstrate dioxin toxicity to human health at very low doses (EWG 2010a; EWG 2010b). For example, the latest publication from the Seveso cohort further confirms that *in utero* and early-life exposure to low doses of dioxin causes adverse changes in the male reproductive system, permanently changing sperm quality and causing lower sperm count and decreased sperm motility in men 18-26 years of age (Mocarelli 2011).

EWG agrees with the SAB support for EPA’s classification of TCDD as “carcinogenic to humans”. Furthermore, EWG finds that linear approach for dioxin cancer risk characterization is consistent with the current knowledge on dioxin carcinogenicity and it also offers the necessary public health protection to vulnerable populations. EWG notes that in the detailed responses of the draft SAB report, the following statements are made:

“Panel members appreciated the attempts by the Agency to further develop cancer mode-of-action concepts based on available dioxin liver, lung, and thyroid toxicity data. Such innovative and explorative work is clearly fundamental to the continued need of further developing risk assessment sciences and to make more detailed and integrated use of already existing and published data. Panel members complemented the Agency for providing an up-to-date dioxin cancer mode-of-action section in its response to NAS comments.” (SAB draft, p. 33)

Clearly, the panel agrees that the EPA has done its utmost to advance reliable scientific analysis of dioxin carcinogenicity. We urge you to highlight these and many other strengths of the EPA risk assessment in the opening letter. From the public health perspective, EPA is done and the agency should be now allowed to “expeditiously finalize the IRIS document”, as SAB itself recommends in its letter. In closing, EWG emphasizes our support for the EPA’s Dioxin Science Plan and urges the SAB to provide feedback to the agency that would accelerate rather than slow down the overall scientific review of dioxins by EPA.

Olga V. Naidenko, PhD
Senior Scientist, Environmental Working Group

References

- EPA. 2009. EPA's Science Plan for Activities Related to Dioxins in the Environment. Available: <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=209690>
- U.S. EPA. 2010. National Center for Environmental Assessment. Dioxin. Available: <http://cfpub.epa.gov/ncea/CFM/nceaQFind.cfm?keyword=Dioxin>
- EWG. 2010a. Letter to the EPA's Science Advisory Board Dioxin Review Panel. July 12, 2010. Available: <http://www.ewg.org/dioxin/analysis>
- EWG. 2010b. Letter to the EPA's Science Advisory Board Dioxin Review Panel. October 19, 2010. Available: <http://www.ewg.org/dioxin/research>
- Hegstad, M. 2011. Science Advisers Find 'Major Deficiencies' In EPA's Dioxin Risk Estimates. February 11, 2011. Available at: <http://insideepa.com>
- Mocarelli P, Gerthoux PM, Needham LL, Patterson DG, Jr., Limonta G, Falbo R, et al. 2011. Perinatal Exposure To Low Doses Of Dioxin Can Permanently Impair Human Semen Quality. Environ Health Perspect: in press.
- NAS. 2006. Health Risks from Dioxin and Related Compounds: Evaluation of the EPA Reassessment. Available: http://www.nap.edu/catalog.php?record_id=11688
- SAB. 2011. Draft Report: SAB Review of EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments. Not for citation or attribution. Available: <http://yosemite.epa.gov/sab/sabproduct.nsf/0/9de6a0825a9c050f85257412005ea22a!OpenDocument&TableRow=2.2#2>.