

September 18, 2010

Mr. Thomas Armitage  
SAB Designated Federal Officer  
Docket EPA-HQ-ORD-2010-0395  
U.S. EPA Headquarters  
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**RE: PUBLIC COMMENT ON EPA/600/R-10/038A TO THE SAB REVIEW COMMITTEE**

Dear Mr. Armitage:

This letter is in response to EPA's May 21, 2010 release entitled, "EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments" (ERKI) (EPA/600/R-10/038A). The public comment period is extended until September 20, 2010.

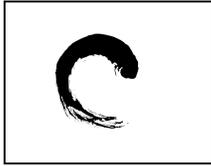
This draft report responds to some recommendations of the National Academy of Sciences (NAS) in a 2006 report, and provides a new analysis of potential human risk that may result from exposure to 2,3,7,8 – tetrachlorodibenzo-*p*-dioxin (TCDD).

General Comments

In the ERKI document EPA has limited its analysis of human dioxin risk to one species, TCDD, and primarily to data from one industrial accident, a trichlorophenol plant explosion in Seveso, Italy in 1976. Dioxin was not known as an environmental pollutant in 1976, and the chemical methods, reference human and biochemical data, and pertinent knowledge of dioxin-like species, did not occur until years later. The Seveso explosion involved 6 – 8 tons of reactive chemical species spread over several miles, with humans exposed both to TCDD, and to the reaction products that were present.

There are several reasons to reject Seveso as the singular event to relate human dioxin risk.

- The U.S. population is not exposed to dioxin in a fast, acute event such as an explosion. EPA currently uses a model of dioxin in air pollution and dispersed on vegetation, which leads to an ongoing (and decreasing) chronic exposure of the American public.
- No reasonable attempt was made by EPA to measure the contribution of primary chemical species in the Seveso discharge (non-dioxin species), which could account for all the effects EPA is attributing to TCDD.
- The U.S. population is not exposed to dioxin as a single species, TCDD, but to all 210 dioxin/furan compounds at very low levels. EPA has contributed to an integrated risk factor, the Toxic Equivalence Quotient (TEQ) that accommodates the additivity of these mixtures. Mixtures represent actual human exposure. Mixtures are not addressed in the current ERKI document.



Letter from M. Cooke (CCI) to T. Armitage (EPA)  
Dated September 18, 2010  
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For cancer risk EPA has limited pertinent data on dioxin exposure to the Seveso explosion, industrial hygiene studies, and animal tests. This process has filtered important studies on dioxin exposure in human populations, studies on cohorts exposed through routes published by EPA in the Dioxin Reassessment Report.

The 2004 National Academy of Science version of the Draft Dioxin Reassessment Report, focused on soft tissue sarcomas (STSs) and malignant lymphomas, as a main dioxin cancer risk, (c.f., Chapter 7, "Epidemiology/Human Data, Part A. Cancer Effects"<sup>1</sup>).

The SAB is directed to a 2004 publication by the Institute of Public Health in Finland, entitled "Soft-Tissue Sarcoma and Dioxin: A Case-Control Study"<sup>2</sup>. This Finland study was a carefully controlled cohort of soft tissue sarcoma victims, and controls, all with well-defined dioxin body burdens. This Finland population had been exposed to higher levels of TCDD and dioxin-like compounds, through dietary fish, than the American public. This study is summarized by the authors: "In conclusion, we found no increased risk of STS associated with increased dioxin exposure". This study goes on to challenge the use of acute exposures (fires, explosions, industrial hygiene) over human epidemiology.

Recently U.S. State regulators have examined impacts of EPA dioxin risk factors, citing many current regulations that will be revised<sup>3</sup>. They point out that taking fish from U.S. inland waters will be banned or severely curtailed affecting subsistence gathers and their families, drinking water standards will be altered, current use of municipal and agricultural wastes may be stopped, proposed soil clean up levels may require extensive re-remediation at existing (closed) Superfund sites, new clean air MACT standards may be applied to companies that are under compliance with approved control systems. The regulatory impacts of this Seveso-based risk assessment and its effect on the American economy are severe.

No one would suggest compromising public health: however, I respectfully ask EPA to evaluate modern and pertinent information, outside the limited ERKI criteria, before publishing a questionable risk standard that will cause such extreme and far reaching impacts on the American economy.

Sincerely,

W. Marcus Cooke  
WMC/ff

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<sup>1</sup> c.f., <http://www.epa.gov/ncea/pdfs/dioxin/nas-review/>, *Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds National Academy Sciences (NAS) Review Draft, Chapter 7. Epidemiology/Human Data Part A: Cancer Effects.*

<sup>2</sup> "Soft-Tissue Sarcoma and Dioxin : A Case-Control Study", Jouni T. Tuomisto <sup>1\*</sup>, Juha Pekkanen <sup>1</sup>, Hannu Kiviranta <sup>1</sup>, Erkki Tukiainen <sup>2</sup>, Terttu Vartainen <sup>1,3</sup> and Jouko Tuomisto <sup>1,4</sup>; <sup>1</sup>Department of Environmental Health, National Public Health Institute, Kuopio, Finland, <sup>2</sup>Department of Plastic Surgery, Helsinki University Central Hospital, Helsinki, Finland, <sup>3</sup>Department of Environmental Sciences, University of Kuopio, Kuopio, Finland, <sup>4</sup>Department of Public Health and General Practice, University of Kuopio, Kuopio, Finland, *Int. J. Cancer: 108, pp. 893-900, Wiley-Liss, Inc., 2004.*

<sup>3</sup> *Presentation and Formal Paper Number 1681. Regulatory Implications of the US EPA's Draft Oral Slop Factor and Reference Dose for Dioxin: ; Hay JT <sup>1</sup>, Aplin MA <sup>2</sup>; <sup>1</sup>Toxicology Division, Texas Commission on Environmental Quality (TCEQ), 12100 Park 35 Circle, Austin, TX, 78753, USA; <sup>2</sup> Technical Support Section, Remediation Division, TCEQ, 12100 Park 35 Circle, Austin, TX 78753, USA; *Proceedings of the 30<sup>th</sup> International Symposium on Halogenated Persistent Organic Pollutants, September 12-17, 2010, San Antonio, Texas.**