

**E. I. DU PONT DE NEMOURS AND COMPANY (DUPONT) STATEMENT**

**TO**

**USEPA SCIENCE ADVISORY BOARD DIOXIN REVIEW PANEL**

**OCTOBER 27, 2010**

Good afternoon. My name is Timothy Bingman and, on behalf of the E. I. du Pont de Nemours and Company (DuPont), we appreciate the opportunity to provide comments on the “Draft Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments” (Draft Reanalysis), published by the U.S. Environmental Protection Agency (“EPA” or “the Agency”) in the May 21, 2010 Federal Register (75 Fed. Reg. 28610). It should be noted that DuPont has previously submitted written comments to EPA that were to be furnished to this Science Advisory Board (SAB) expert peer review panel for its July 13-15 public meeting on the Draft Reanalysis, as well as final comments to the EPA Docket on this issue.

DuPont is a science company. As such, DuPont’s vision is to be the world’s most dynamic science company, creating sustainable solutions essential to a better, safer, healthier life for people everywhere. In this light, and taking into account EPA’s own focus on incorporating the state of the science, we offer the following comments on the Draft Reanalysis.

As an initial point, we note that EPA’s dioxin reassessment and related regulatory proposals on dioxin have significant shortcomings, and do not adequately respond to key recommendations of both the 2003 and 2006 National Academy of Sciences (NAS) panels. While the agency has addressed some of the recommendations of the NAS, critical elements have been ignored or dismissed. As a result, the EPA’s analysis of the toxicity of dioxin remains significantly flawed, and consequently, policies that flow from its conclusions also will be defective, with negative, far-reaching consequences. We urge the SAB to call on the EPA to revisit the recommendations of the NAS, and to incorporate them before any related documents or policies are finalized.

In both of DuPont's previous written submittals, we supported technical comments provided (both orally and in writing) by the Chlorine Chemistry Division (C2), a business council of the American Chemistry Council (ACC) on a number of specific issues that EPA should consider. Similar to the NAS, these issues focused on technical issues on non-cancer and cancer endpoints.

In addition to our concurrence on the technical issues on non-cancer and cancer endpoints of TCDD addressed in the C2 comments, we provided additional comments prepared on our behalf by ToxStrategies on the issue of Toxic Equivalency Factors (TEFs). While we understand that the Draft Reanalysis currently under review by the SAB does not specifically address TEFs, and that EPA has issued a standalone document addressing TEFs, it appears that the USEPA has still not fully addressed the concerns about the TEFs raised by the NAS dioxin panel. Given the significance of these concerns, and since dioxin congeners rarely exist in isolation, we believe that it is important to again provide public comment on this topic. Since the toxicity of the other congeners and dioxin-like compounds are directly related to the toxicity of TCDD by the TEFs, it is critical that the toxicity issues of these compounds not be slighted as the toxicity of TCDD is finalized.

We urge the SAB to consider some key points echoed from the NAS review and follow up with EPA as recommended in the ToxStrategies review as follows:

First, EPA has yet to quantitatively address the uncertainty inherent in the 2005 World Health Organization (WHO) TEFs they chose to adopt. The NAS recommended that the EPA undertake a quantitative analysis of the uncertainty associated with these TEFs in order to facilitate a transparent characterization of risks represented by environmental exposures to dioxins and DLCs other than TCDD. We suggest that EPA develop and apply probability density functions for TEFs for those congeners where there are enough data, and should endorse the use of TEF probability density functions in risk assessment as part of the final standalone TEF document or the NAS response. Where point estimates continue to be used for congeners with paucity of data, EPA should promote development of additional data.

Second, the EPA has taken a conflicting position regarding the role that dietary and endogenous AhR ligands (“endodioxins”) play in the toxicity of DLCs. There is a clear contradiction in EPA’s position regarding the impact of endogenous and dietary AhR agonists on human health effects. Since it unclear how the Draft Reanalysis will relate to the earlier Dioxin Reassessment, it is important that contradictions like this be clearly resolved. We suggest that EPA discard its text that suggests naturally occurring AhR agonists are already inducing a level of AhR activity that may be of physiological significance. Furthermore, the EPA should not use this concept as support for the use of a linear dose-response model for the derivation of a low-dose TCDD cancer slope factor.

Third, the EPA should consider the development of endpoint-specific TEFs. In this instance, the NAS recommended that EPA develop TEFs that are specific to toxicological endpoints of concern. The NAS panel noted that an earlier SAB panel (USEPA SAB 2000) had reported significant differences in potency for some DLCs depending upon the endpoint under study, and recommended that this be considered. It is not clear that recommendations from either panel have been addressed. EPA should initiate a longer-term effort to develop endpoint-specific TEFs for cancer and non-cancer endpoints.

Finally, the EPA should consider new information that has become available since the last WHO re-evaluation of the TEF methodology. In its 2009 draft TEF guidance document, the EPA recognized the future development of a more refined relative potency database and the importance of additional examination of the uncertainties inherent to the TEF process. It is important that the EPA identify how the results of recent studies and any new WHO TEF updates might affect their application of the current TEFs in risk assessment. EPA should review the relevant papers in the recent literature, and should revise the standalone TEF document or the response to NAS accordingly, and should also revise the Agency’s application of TEFs in risk assessment.

In summary, EPA's approach to dioxin regulation has been criticized by the NAS and appears to be out of step with the rest of the world, including the governments of Great Britain and Japan, the European Union, and the World Health Organization. On a positive note, environmental and human exposure levels have declined dramatically over the past 20 years. Hence, EPA's current dioxin plan does not address a public health imperative. However, it appears that EPA now wants local governments and citizens to spend more resources on this issue, potentially causing serious unintended consequences for people's lives and livelihoods. We suggest that EPA listen to the experts, adhere to the best available science, and uphold its commitment to scientific integrity, transparency, and open government to make sure it gets it right with dioxin regulation.

In our preliminary comments, we had urged the EPA and its SAB to allow due time for proper review and input from the public on this complex and lengthy Draft Reanalysis. We are pleased that this additional SAB review has been scheduled. While we appreciate this effort, we hope that sufficient time will be allotted to hear and respond to the scientific merit of all submittals on this important scientific issue.

Thank you for this opportunity.

Respectfully submitted,

Timothy Bingman, D.A.B.T.