



**Patricia Kablach Casano**  
**Counsel, Government Affairs**  
**Corporate Environmental Programs**

GE  
1299 Pennsylvania Avenue, NW  
Suite 900  
Washington, DC 20004  
T 202-637-4228  
F 202-637-4414  
pat.casano@ge.com

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Dr. Anthony F. Maciorowski  
Deputy Director  
EPA Science Advisory Board Staff Office  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
maciorowski.anthony@epa.gov

Dr. Thomas Armitage  
Designated Federal Officer  
EPA Science Advisory Board Staff Office  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
armitage.thomas@epa.gov

Re: Dioxin Review Panel – Draft Advisory Report, 76 Fed. Reg. 6784 (Feb. 9, 2011)

Dear Drs. Maciorowski and Armitage:

The General Electric Company (GE) congratulates the Dioxin Review Panel ("Panel") upon its completion of the concise, well-organized evaluation of EPA's draft *Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments* ("Draft Reanalysis"). It is evident that members of the Panel carefully considered the voluminous information provided to the Panel before reaching the conclusions set forth in the draft advisory report ("Draft Report").

As with previous external reviews of EPA's evaluations of dioxin toxicity, the Panel has identified multiple deficiencies in the Draft Reanalysis. The key deficiencies include:

1. Failure to perform a good faith, nonlinear method of risk characterization as recommended in 2006 by the National Academy of Sciences Committee on EPA's Exposure and Human Health Reassessment of TCDD, which unanimously concluded "that the current weight of evidence on TCDD, other dioxins, and DLCs carcinogenicity favors the use of nonlinear methods for extrapolation beyond the point of departure (POD) of mathematically modeled human or animal data." NAS. 2006, p. 190. The Panel has concluded:

"The EPA Report did not respond adequately to the NAS recommendation to adopt 'both linear and nonlinear methods of risk characterization . . . .' Instead of adopting both . . . methods, the EPA argued that only a linear approach could be justified, and derived two examples of RfD development using a nonlinear approach that they characterized as an illustrative exercise only."

Draft Report, p. 38.

2. Failure to consider objectively all of the evidence relevant to the mode of action for dioxin.  
The Panel has concluded:

“A large amount of data related to the mode of action for the carcinogenicity of dioxin is described, but the focus appears to be on presenting evidence that supports the use of a default linear approach rather than providing a balanced evaluation of alternative mode-of-action hypotheses.”

Draft Report, p. 34.

3. Failure to perform a transparent, thorough, and clear uncertainty analysis, as recommended by the NAS.

“The Panel rejects EPA’s argument that a quantitative uncertainty analysis is unfeasible. Although a quantitative uncertainty analysis is challenging, the Panel does not agree that it is impossible or even impractical to undertake one.”

Draft Report, p. 43. As the Draft indicates, without an adequate uncertainty analysis, policy makers and risk managers will have difficulty answering fundamental questions such as –

- “How likely is it that TCCD is not a human carcinogen at current exposure levels? . . .
- “What is the probability that reducing TCDD exposures would not reduce cancer risk at all, . . . ?
- “What is the probability that reducing TCDD exposures would reduce cancer risk by less than 1 excess cancer case per decade (or per year or per century) in the whole U.S. population, under current conditions?
- “What is the probability that reducing TCDD exposures would increase cancer risk (e.g., if the dose-response relation is J-shaped or U-shaped)?”

Draft, pp. 45-46.

GE agrees that these deficiencies must be addressed if the Draft Reanalysis is to provide a sound scientific basis for decisionmaking by EPA.

GE also concurs with, and hereby adopts and incorporates by reference, the comments on the Draft Report submitted by the Chlorine Chemistry Division of the American Chemistry Council. In addition to those comments, GE has three substantive comments on the Draft:

1. Given that the Panel has identified serious deficiencies in the Draft Reanalysis, the Panel should edit the Draft to remove potentially confusing statements that contradict the clear message that the Panel is trying to convey. For example, the final advisory report should not include statements such as “the Panel found that, in general, EPA was effective in developing a report that was clear, logical and responsive to the three key recommendations of the NAS” (Draft Report, p. 2). That statement, while diplomatic, is wholly inconsistent with the Panel’s findings that EPA did not respond adequately to the NAS’s recommendations regarding adoption of a nonlinear approach to risk characterization and performance of a quantitative uncertainty analysis (*Id.*, pp. 7-8, 38- 46). (The statement also is inconsistent with the Panel’s conclusion that the entire report “would benefit from greater clarity in writing (*Id.*, p. 12) and “careful and extensive editing to revise and consolidate Section 2 and the Report

as a whole" (*Id.*, p. 14.)

2. The Panel should send a clear message to EPA that unless the Panel's and the NAS's recommendations are implemented fully, the final version of the Draft Reanalysis, and, ultimately, the final version of the dioxin reassessment, will not objectively and transparently reflect or embody the best available science.
3. Implementation of the Panel's recommendations necessarily will take both time and money. Given the measures that are in place to prevent/reduce releases of dioxin, and the substantial decline in environmental levels and human body burdens of dioxin over the past thirty years, the Panel should recommend that EPA consider whether there is any significant public health benefit to be gained by continuing efforts to prove that dioxin is more toxic than is believed by the World Health Organization's Joint Expert Committee on Food Additives, the European Food Safety Agency and other public health agencies around the globe.

Thank you for your consideration of these comments.

Sincerely,

Patricia Kablach Casano  
Counsel, Government Affairs  
Corporate Environmental Programs