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Statement Before the
U.S. Environmental Protection Agency
Science Advisory Board
Panel on Dioxin
Stephen Lester, Science Director
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CHEJ has been engaged in the EPA's public process to reassess the health risks of dioxin since 1995. We remain very concerned about the exposure of the American people to this highly toxic substance. We have submitted detailed technical comments to EPA on the agency's *Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments* during the public comment period and have attached these comments to this statement. Our comments address three specific issue areas: 1) Transparency and clarity in the selection of key data sets; 2) Cancer risk assessment; and 3) The reference dose. I will highlight several of our key issues and concerns.

First, we found that the agency's response to the NAS comments provides the transparency and clarity on EPA positions that the National Academies has requested. It also provides clear logical responses to the questions and issues raised by the NAS committee about the agency's draft reassessment report on dioxins. The agency has clearly and objectively summarized and presented the three key recommendations from the NAS report and provided detailed analyses and extensive documentation of their responses that makes it clear and transparent what they have done and why.

The EPA has concluded that TCDD is carcinogenic to humans. The basis for this determination is the criteria defined in the agency's *2005 Guidelines for Carcinogenic Risk Assessment*. These guidelines call for using a weight of the evidence approach in which all available information is considered in making a determination on the carcinogenicity of a substance. The human epidemiological and animal bioassay data presented by EPA make it clear how and why the agency has come to this conclusion. We support and commend the agency for this clear and transparent presentation that scientifically justifies its determination that TCDD is carcinogenic to humans.

EPA calculated oral slope factors using human epidemiological and animal data by extrapolating from a point of departure (POD) using a linear non-threshold dose response model. We find that the approach EPA used to estimate cancer risk is scientifically justified and clearly described and documented. We further agree that it is appropriate for EPA to take a public health protective default position regarding the interpretation of toxicological and epidemiological data, especially when there is no information on the mode of action following the binding of TCDD to the Ah Receptor that ultimately leads to the development

of cancer. We strongly support the EPA's decision to follow its 2005 cancer guidelines that calls for the use of a linear no threshold model for extrapolating to low doses when calculating cancer risk.

EPA chose to derive a reference dose (RfD) for TCDD based on co-critical effects - male reproductive effects (Mocarelli et al. 2008) and changes in neonatal thyroid hormone levels (Baccarelli et al. 2008). We feel that the rationale for the selection of these critical effects is clearly described and scientifically justified.

We applaud the EPA for finalizing and releasing its response to the National Academies report on dioxin. This is a critically important step in finalizing and releasing the EPA's long-delayed *Dioxin Reassessment*, which has been a draft document for over 20 years.

We urge you to complete your review of the EPA's Response to the NAS comments as quickly as possible. The EPA cannot complete its reassessment of dioxin until this review is complete. As many of you no doubt know, the reassessment has been delayed for far too long. The previous dioxin review panel of the EPA's Science Advisory Board sent a letter to then EPA Administrator Christine Whitman urging the agency to "proceed expeditiously" to complete and release the Dioxin Reassessment. That was more than nine years ago and we are still debating the toxicity of dioxin and its public health significance. For some, we will never know enough to complete this draft document and that is an injustice to the American people who are being protected from exposures to dioxin using data that is more than 25 years old.

We anxiously look forward to the SAB completing its review and to the EPA finalizing the Dioxin Reassessment and moving forward in protecting the health of Americans from this potent carcinogen.