

September 24, 2001

Christine Todd Whitman  
Administrator  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

Dear Governor Whitman:

We are writing in regard to the EPA's August 2001 External Review Draft of a document entitled *Trichloroethylene Health Risk Assessment: Synthesis and Characterization*, produced by the National Center for Environmental Assessment, which was publicly released on 19 September 2001.

The agency's reassessment of trichloroethylene (TCE) has been conducted according to a new procedure in which recognized experts outside government were commissioned by the agency and other parties to document the literature and analyze key complex scientific questions, forming a basis on which the agency could draw in completing its assessment. These "state-of-the-science" papers were published together in an *Environmental Health Perspectives* Supplement in May 2000.

We write as authors of papers that have been part of this process. We wish to express our concern that readers of the *Synthesis and Characterization*—including readers inside the EPA—may inappropriately conclude that we as state-of-the-science paper authors contributed to and endorse the conclusions and findings of the EPA document.

Our concern arises because, throughout the reassessment process, in professional meetings and in publications, the agency has widely publicized its intent to rely on this set of reviews and analyses by outside experts, which were produced as a part of its trichloroethylene re-assessment process. The *Synthesis and Characterization* document itself states (p.xi) that "[i]ts conclusions draw from" these papers. Even the EPA document's sole disclaimer (p.xii) that "[t]hese authors...were not asked for consensus on its overall conclusions" could be misread to imply a degree of endorsement, as it follows a listing of the state-of-the-science authors in the section labeled "Authors, Contributors, and Reviewers." Overall, the impression seems to be given that the EPA has simply articulated and summarized a set of conclusions that emerged from the state-of-the-science reviews.

In fact, the conclusions and findings in the *Synthesis and Characterization* document are based on EPA's own decisions and its own interpretations of the scientific evidence. The document contains additional arguments, analytical procedures, and characterizations of evidence on scientific issues that were not drawn from the state-of-the-science papers, and the state-of-the-science authors did not participate in defining the findings or writing the EPA synthesis.

Indeed, we wish to make clear that there are a number of findings and conclusions about trichloroethylene in the EPA *Synthesis and Characterization* with which we as state-of-the-science paper authors do not agree and which we would not endorse. These include consequential matters such as the weight of evidence regarding TCE's potential human carcinogenicity, the methods employed for characterizing potency for cancer and noncancer endpoints, and the importance of caveats and limitations regarding the strength of conclusions that can be drawn from available studies.

Simply because the EPA has "drawn on" papers that we produced as participants in this process, no reader should assume that the agency's conclusions must therefore represent a consensus of the assembled group of authors. No such consensus was sought and, in our view, if it were to be sought it would not be achieved by the document as it now stands.

Of course, the agency may draw its own conclusions based on its own judgments about the bearing of the available scientific literature, including our own papers. We wish to emphasize that this is just what the agency has done—that the conclusions and judgments in the *Synthesis and Characterization* are those of the EPA, not ours.

We continue to endorse the idea of using commissioned state-of-the-science reviews and analyses produced by outside experts as the agency grapples with scientifically complex risk assessment questions, and we are happy to have participated in the agency's reassessment process for TCE. We feel that the scientific credibility that EPA seeks in including outside experts as reviewers and analysts of the scientific literature would be enhanced to the degree that the conclusions, findings, and weighing of all the scientific evidence drawn from such reviews can represent a broad scientific consensus of participants in the analytical process. We stand ready to discuss specific aspects of the scientific underpinnings of trichloroethylene risk assessment and their interpretation with the hope that such a broader consensus can be achieved.

Sincerely,

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cc: George Alapas, Acting Director, National Center for Environmental Assessment