



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOVEMBER 23, 1983

OFFICE OF
THE ADMINISTRATOR

Mr. William D. Ruckelshaus
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Mr. Ruckelshaus:

The Environmental Health Committee of the Science Advisory Board has completed its review of revised drafts of the Health Assessment Document for 1,1,1-Trichloroethane (Methyl Chloroform) prepared by the Agency's Office of Research and Development. The major conclusions of the document state that in tests conducted to date, there is no adequate scientific basis for determining the carcinogenicity of Methyl Chloroform (MC). Recent information available on the biologic effects of MC and its role in contributing to an increased incidence of skin cancer as a result of ozone depletion also downplays the potential role of this chemical. As a result, a definitive evaluation of MC and its contribution to health hazards in the workplace or as the result of ambient exposures is not possible at the present time.

Drafts of the Health Assessment Document for Methyl Chloroform have been formally reviewed by the Committee on September 28-29, 1982 and December 8, 1982. In addition, a revised draft dated May 1983 has been discussed with the Committee at a public meeting on June 10, 1983. The Committee understands that the May 1983 draft will be further changed to reflect the most current status of the National Toxicology Program (NTP) 1983 rat study.

Agency staff have adequately responded to Committee advice for revising the document in terms of the discussion of the carcinogenicity issue as well as other issues. The Committee is satisfied that the revisions to the November 1982 and May 1983 documents present a thorough and balanced treatment of the existing scientific literature concerning this pollutant.

Committee comments and recommendations on these successive drafts of the document are summarized in the attached report. A full record of the Committee's review of Methyl Chloroform is contained in the transcripts on file at the Science Advisory Board. With the understanding that the final document will incorporate the further changes discussed with Agency staff, the Committee unanimously concludes that the assessment document is scientifically adequate.

Sincerely,



Herschel E. Griffin
Chairman
Environmental Health Committee
Science Advisory Board

Attachment

cc: Mr. Alvin Alm
Mr. Joseph Cannon
Dr. Bernard Goldstein
Dr. Lester Grant
Dr. Terry Yosie

Environmental Health Committee Key Findings, Conclusions
and Recommendations on the Revised Draft Health
Assessment Document for 1,1,1-Trichloroethane
(Methyl Chloroform) (May 1983)

1. The Summary and Conclusions chapter has been revised in response to recommendations made by the Committee. In the Committee's view these revisions have enhanced the quality of this chapter by:

- expanding the discussion of directly-induced health effects to delineate No-Observed Effects Level (NOEL) estimates from Lowest-Observed Effects Level (LOEL) numbers for Methyl Chloroform. These estimates have in turn been contrasted with the generally much lower level ambient Methyl Chloroform exposures.

- clarifying the role of Methyl Chloroform as a contributing factor to ozone layer depletion and to a consequent rise in the incidence of skin cancer. Recent evaluations of this issue by the World Meteorological Organization and the National Research Council suggest that the potential role for MC is smaller than indicated in previous drafts of this document.

2. The document and EPA staff discussion of the issue of the carcinogenicity of Methyl Chloroform is more straightforward in presenting and assessing the current state of knowledge. Staff have indicated that there is no adequate basis at the present time for evaluating the carcinogenicity

of this chemical. Acknowledgment is given to previous assessments of MC carcinogenicity and why those assessments have proven inconclusive.

The Cancer Assessment Group's (CAG) evaluation of the carcinogenicity of MC will not include a discussion in the document of the results of the lifetime animal bioassay carried out under the auspices of the National Toxicology Program (NTP). CAG staff have informed the Committee they will evaluate the results of this study when they are finalized and available from NTP. In the meantime, they and their colleagues in the Office of Research and Development plan to finalize the Health Assessment Document for Methyl Chloroform and to incorporate information on the current status of the NTP work. The need to modify or issue an addendum to the document to incorporate NTP results will be determined by EPA staff at the time of final issuance of the NTP results. The Environmental Health Committee concurs with the judgment reached by Agency staff on these matters.

3. The discussion of the biotransformation of Methyl Chloroform to reactive intermediate metabolites overstates the case. There is insufficient scientific evidence to support the EPA position as stated in the document. The final document should incorporate a revised statement that indicates that this issue has not been resolved. EPA staff have concurred with this recommendation.

4. Information has been added in several of the chapters that strengthen the document. This includes: updating of information on sources, emissions and ambient concentrations of MC (chapter 3); and including recent studies on metabolism and pharmacokinetics (chapter 4), and neurotoxicology, behavioral toxicology and mutagenicity (chapter 5).

5. As part of the overall assessment of Methyl Chloroform, major information gaps or research needs should be briefly identified.

The Committee made additional suggestions for improving the final document which are included in the transcripts of the Committee's meetings. With the understanding that these and other changes identified in this report will be incorporated in the final Health Assessment Document for Methyl Chloroform the Environmental Health Committee unanimously concludes that the document is scientifically adequate.