

TGG: JZK: MMG: RF
XF: LCCP/tickie 8/28

TO: Sid Pitts

FROM: Tom Grumbles

DATE: August 12, 1985

Interoffice
Communication

SUBJ: METHYL CHLORIDE EXPOSURE LEVELS

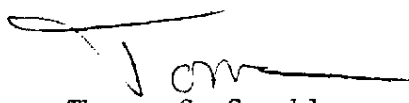
VISTA

Attached is a letter summarizing EPA's recent decision regarding TSCA Section (4) testing of MeCl and their proposed action. Basically, they determined no testing is needed but are considering some form of negotiated settlement on exposure controls.

In response the Methyl Chloride Industry Association has become active again. EPA is assuming a 1.0 ppm PEL is readily achievable in industry. Also, they assume that air sampling is no problem. To assist the MCIA in efforts with the EPA I need the following from the plant.

1. Exposure summaries from the last two years.
2. Any written reports you have on the sampling method work you did with the lab and GMD.
3. Your thoughts and opinions on meeting a 1.0 ppm exposure limit.

This information would be used as part of an overall MCIA response. You will of course review any written comments we give them.


Thomas G. Grumbles

ajo/7

Attachment

cc JAD

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~~File #~~ 2/18 File - MCIA

May 17, 1985

MEMORANDUM TO MCIA MEMBERS

- * 100 ppm level
- * EPA referred to CSMA
- * Exposure controls only
- * * Update exposure data

From: Robert M. Sussman
Richard A. Friedman

Re: EPA Withdrawal of Proposed Test Rule for
Chloromethane and EPA Proposal for
Discussions on Voluntary Exposure Control

Enclosed is a copy of the May 7, 1985, Federal Register Notice in which EPA withdrew its July 18, 1980, proposed test rule for chloromethane and announced its conclusion that no further health effects testing would be required. 50 Federal Register 19213-19219.

The Notice summarizes the results of the oncongenicity study performed on rats and mice at Battelle Laboratories and the results of the various studies later undertaken at CIIT. Based on these data, EPA has determined that it has sufficient information to characterize chloromethane's chronic toxicity, oncongenicity, teratogenicity, mutagenicity, and reproductive effects. EPA has concluded that chloromethane is a "possible human carcinogen" (50 Fed. Reg. at 19217, col. B) and is a "potential human germ-cell mutagen" (id. at 19218, col. C). The Agency also

believes that it has sufficient data to characterize the potential reproductive, teratogenic, and developmental toxicity of chloromethane in humans, but the notice does not present any risk assessment for these effects (id. at 19215, col. C; 19216, col. B). (We have asked Jim Bus of CIIT to comment on EPA's characterization of his work.)

EPA has not proposed any regulatory action in response to the test results and the Federal Register notice does not reveal the Agency's intentions in that regard. Phil Wirdzek of EPA's Test Rules Development Branch has told us that EPA would prefer to encourage voluntary workplace controls rather than engaging in regulation under TSCA. Wirdzek believes that Harry Teitelbaum, the Project Manager for methyl chloride in the Existing Chemicals Branch of EPA's Assessment Division, shares this preference for voluntary controls. Wirdzek also feels that Teitelbaum has persuaded his Branch Chief, Jeannette Wiltse, and the Director of the Division, Joe Merenda, that negotiated exposure controls should be pursued.

We also spoke to Harry Teitelbaum, who confirmed the Agency's interest in encouraging voluntary controls in lieu of regulation. He stated that the risk assessment he is currently drafting is very similar to a NIOSH-sponsored risk assessment completed in 1984 by Clement Associates, entitled "Carcinogenic Risk Assessment for Occupational Exposure to Monohalomethanes." (NTIS Pub. PB85-111623.) Enclosed with this memorandum are the title page, table of contents, and an excerpt from the Clement

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Associates report that explains the risk assessment for methyl chloride. We will provide a complete copy of the report (312 pages) upon request.

Harry Teitelbaum suggested that an informal discussion among representatives of EPA, industry and the unions involved would be a first step toward achieving a voluntary resolution. He stated that it would be difficult politically for EPA to discuss a voluntary resolution without participation by worker representatives.

Teitelbaum suggested that he is well advanced in drafting a risk assessment on methyl chloride. If this is correct, EPA would be close to completing the assessment phase (Phase III) of its five-phase process for evaluating existing chemicals. (Phase IV involves the consideration of risk reduction options, while Phase V involves regulatory action.)

Harry Teitelbaum suggested that a time-weighted average (TWA) concentration of 1 ppm in the workplace appeared to him to be an acceptable target for voluntary control, and he expressed the view that a substantial segment of the industry has achieved this level already. According to the Clement Associates risk assessment, a TWA of 1 ppm corresponds to a one in one million lifetime risk of cancer for a full-time worker with 54 years of occupational exposure. (See table at page 267 of enclosed report.)

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The current OSHA TWA is 100 ppm and the current ACGIH recommended TWA is 50 ppm. It is of interest that the Clement

Associates risk assessment concludes that a lifetime exposure (54 years) at 100 ppm would result in a one in one hundred maximum likelihood estimated (MLE) risk of cancer, and a lifetime exposure of 25 ppm would correspond to a one in two thousand MLE risk of cancer. (See table at page 271 of enclosed report.)

Even at this preliminary stage, the Clement Associates risk assessment and EPA's apparent concurrence with it raise a number of important questions. First, the Clement Associates report, completed in 1983, does not evaluate the data developed at CIIT, particularly the data indicating that methyl chloride might not be a genetic carcinogen and that the linearized risk assessment model used by Clement Associates might be inappropriate. Second, the risk assessment deals only with carcinogenicity, not with teratogenicity or other effects. It has been our understanding during the past year that EPA was developing the view that teratogenicity was the effect of greatest concern -- based on the heart malformations identified by the CIIT research -- and that achieving exposure controls sufficient to address the teratogenic risk would make the carcinogenic risk of subsidiary concern.

Under emerging EPA policies, if the Agency determines that regulatory action on methyl chloride is appropriate, the matter would probably be referred to OSHA under Section 9(a) of TSCA because the risk exclusively involves workplace exposure. Upon receipt of such a referral from EPA, OSHA will either act to evaluate the risk and initiate regulation under the OSH Act,

decline to take action, or refer the matter back to EPA. Recent developments on other chemicals suggest that OSHA generally leans toward exercising regulatory jurisdiction over chemicals referred to it by EPA. Teitelbaum did not mention the possibility of a Section 9(a) referral for methyl chloride, and it is unclear whether the EPA staff has focussed on the availability of this option. The negotiated approach suggested by Harry Teitelbaum would be a novel course of action for EPA. Although there has been a negotiated resolution of the PCB regulations, that involved a negotiated rule, not voluntary action in lieu of regulation.

We told Mr. Teitelbaum that we would discuss his interest in voluntary controls and the related issues with the industry. Teitelbaum said that he understands that it may take some time for the industry to formulate its views. He gave no deadline for an industry response and no timetable for EPA action.

We have discussed the above developments with Mr. Scarbel. He agrees that it would be helpful for MCIA to meet in the near future to reconstitute its membership and to discuss these important issues. After you have had an opportunity to review these materials, please call Richard Friedman to express

your preliminary views and discuss when an MCIA meeting might be arranged.

cc: T. Pullin
C. Bowman
D. DeNoon
H. Farber
T. Grumbles ✓
E. Hobbs
D. Liebeskind
A. Schumann
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