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

May 14, 1992

MEMORANDUM

SUBJECT: Methyl Bromide (MeBr) Meeting with the Chemical Manufacturers Association (CMA) Methyl Bromide Industry Panel (MBIP)

TO: Penny Fenner-Crisp, Director

FROM: Linda Kutney, Chemical Manager

THROUGH: Esther Saito, Chief SACB/SAS

On May 6th, members of CMA MBIP met with EPA to discuss the rabbit teratology study, directed by William Breslin, and alternate use directions which are expected to be required soon. Attenders included Linda Kutney, Walter Francis, Larry Dorsey, David Jaquith, Steven Knott, Dick Schmitt, Gaylene Vasaturo (OGC), Lois Rossi, Marion Copley, and Karl Baetcke from EPA. Industry representatives included Dee Kuhn (CMA), Frank Handy (Great Lakes Chemical), Michal Eldan (Ameribrom), Tom Duafala (Trical), Louise Wen (Ethyl), and Bill Breslin (Dow Chemical).

Dr Breslin discussed the results of the rabbit teratology study. He mentioned the fact that there was a control as well as a "naive" control (a group untreated, and not subjected to the stress of the chamber). Effects seen in treated animals included a missing caudal lobe of the lung, agenesis of the gall bladder, CNS effects, body weight loss, paralysis, ataxia, missing sternum, and reduced body weight gain. The missing sternum was seen at high doses associated with maternal toxicity. The missing lobe of the lung was seen in the control group and was not judged to be treatment-related. Breslin argued that the agenesis of the gall bladder was not a unique example of developmental toxicity, that maternal toxicity and stress caused the effect spontaneously at rates above background. Breslin did concede, however, that the missing gall bladder was a repeatable dose-related event, and that the NOEL for developmental effects was 40 ppm.

When questioned whether we would agree with California's label of methyl bromide as a "birth defect" EPA's position was that MeBr is a "developmental toxicant," that although we can't equate loss of a gall bladder in rabbits with an equivalent human effect, we are dependant on animal models. EPA considers the loss of the gall bladder organ a "malformation" and not just a "variance." We also stated that we would follow California's example, and use the 40

PPM NOEL of the developmental rabbit study to calculate a margin of exposure.

The "Fact Sheet" collateral labeling to be required with the label was discussed briefly, the MBIP asserting that the additional required labeling would be a difficult requirement to comply with, and an unnecessary burden. They asserted that there was no need to include all the extra labeling for each technical active ingredient, but only for the end use products. The label requirement was described as an "interim measure" until the registrants submit required data, including exposure data, or until reregistration. The interim labeling (due in 30 days) basicly included aeration to 3 ppm, and a 72 hour aeration period using fan-forced aeration. Registrants are asked to voluntarily cancel their registrations, and immediately reapply for registration, with the new labeling and fact sheets. OGC stated that this was a policy and management decision and that the Agency had a choice of either asking for voluntary cancellation or canceling the product. OGC stated that the Agency wanted labeling on the Manufacturers Use Products as well as the End Use Products, in order to ensure all products containing the active ingredient had the new labels. The Registrant stated that it was a problem to find and label all gas cylinders. This discussion was deferred to a scheduled conference call with Dan Barolo the following day.

Tom Duafala said that monitoring of treated structures is being done now, and that field monitoring protocol, sampling methods, etc., would be determined by California Department of Pesticide Regulation, Work, Health and Safety, and likely include preplant soil and commodity scenarios.

In closing, EPA stated that until we received dissipation data, it might be ill-advised to start an expensive special study in the developmental toxicity area. The term developmental malformation did apply to the rabbit study, but the question about the term "birth defect" would be referred to OGC. The NOEL would stay at 40 ppm for the developmental rabbit study. A MOE or safety factor of 100 was generally believed to be acceptable, depending of data quality. The Agency agreed to check on the status of Dr Wen's neurotox protocol which was submitted for review about 6 weeks ago. The meeting was adjourned.

cc: Dick Schmitt