2030 DOW CENTER
March 21, 1996

The Dow Chemical Company
Midland, Michigan 48674

Ms. Phyllis Yates
Health Standards Programs
Occupational Safety & Health Administration
U. S. Department of Labor
200 Constitution Ave., N. W.
Washington, D. C. 20210

Dear Ms. Yates:

Enclosed are three copies of comments of The Dow Chemical Company (Dow) to OSHA on Updating Permissible Exposure Limits (PELS) for Air Contaminants. These comments are in response to OSHA's January 24th Federal Register notice of the public meeting that was held on February 22nd. We hope that these written comments will be helpful to OSHA.

If there are any questions about these comments, or OSHA would like clarification of any issues, please do not hesitate to contact one of us. Thank you for your consideration.

Sincerely,

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COMMENTS OF

THE DOW CHEMICAL COMPANY TO THE

OCCUPATIONAL SAFETY & HEALTH ADMINISTRATION

ON

UPDATING PERMISSIBLE EXPOSURE LIMITS

FOR AIR CONTAMINANTS

MARCH 21, 1996

RICHARD D. OLSON, CIH

PROJECT MANAGER

SUSAN E. TAYLOR

ATTORNEY

the public meeting held February 22 was the proper forum for an exchange of data. At that meeting, participants were allowed a short period of time (ranging from 5 to 8 minutes) in which to make brief remarks, which for most participants elicited no substantive discussion with the OSHA panel. As a result, we believe the forum was ineffective for the purpose of setting a process. There was no time for discussion of positions nor did OSHA participate in a substantive discussion of their position. Since this process will be used to set regulations, we believe this activity should be carried out through normal rule-making procedures.

Dow is pleased that OSHA is developing a process that will be used to allow OSHA to routinely update existing PELs. The 6(b) process of setting chemical-specific standards is too cumbersome and time-consuming to keep PELs up-to-date. To allow OSHA to update PELs in a more timely manner, OSHA must establish a process which approximates consensus among stakeholders by allowing full and open participation and exchange while retaining OSHA authority over the endeavor. This may minimize the legal review that has occurred with previous attempts to revise PELs. The Chemical Manufacturers Association (CMA) has suggested a process which places a significant preliminary responsibility on the affected stakeholders to collect and evaluate the scientific and economic data necessary to develop proposed PELs. This can be accomplished in a way that does not compromise nor diminish OSHA's authority or responsibility to make the necessary scientific, policy and regulatory determinations regarding the appropriate PEL. This proposal should serve as a beginning from which OSHA can frame the debate over OSHA's new process. Dow occupational health professionals assisted in the CMA activities which led to the proposal and we support that proposal.

It is important that the process that OSHA establishes facilitates cooperation among the stakeholders. It will be important for OSHA to obtain data from the stakeholders to promulgate a standard that will ensure the success of the PEL promulgation. At the same time, it will be incumbent upon the stakeholders to provide real data, not just hypotheses, to OSHA to support the development of a PEL. The process must also balance the need to meet the legal challenge of the Eleventh Circuit, when it remanded the 1989 PELs, with the practical need to set a PEL which is feasible in the workplace and protects employees without disagreement over the level that leads to a call for legal review. We believe the process proposed by CMA achieves these goals.

It is important that OSHA develops their own process with input from other Agencies but not rely on those other Agencies to carry out the mandate of OSHA. One of the issues in Congress during 1995 was the issue of overlap between OSHA and EPA in the workplace with the desire that EPA should not be involved with employees in the workplace, as OSHA should have primacy in this area. EPA, for example, has a different mandate from OSHA and has very little experience with exposures in the workplace as they pertain

years ago and attempts to use that information to indicate priorities have shown the futility of using information that only indicates that a material is present in the workplace. An example of the amount of manufactured material not being an indication of exposure is ethylene dichloride (EDC), one of the materials OSHA has chosen on the first 20. EDC is manufactured in extremely large quantities, but it is used as an intermediate in the production of vinyl chloride, other chlorinated solvents and ethylene amine. Since it is an intermediate, the potential for employee exposure is very low and the potential for large numbers of employees being exposed is correspondingly low. Therefore, EDC is not one of the materials we think should be chosen as one of the first 20 PELs to be set.

OSHA's choice of chloroform is another choice which we disagree with on the first 20. Chloroform is a material which is mainly used as an intermediate in the manufacture of other chemicals and consequently there is little exposure potential and the exposures that occur are therefore minimal. The use of chloroform as a solvent has diminished significantly since it was identified as a potential carcinogen. As a result, we do not believe chloroform, nor EDC, rises to the level of a "significant risk" because of minimal employee exposure, therefore they do not justify regulatory action at this time.

Additionally, there are some technical issues in the calculation of BMD's that are important.

1. Expert groups have strongly recommended that the dose response curve be extrapolated only down to a 10% level (BMD_{10}), or possibly a BMD_{05} but not to a BMD_{01}. The rationale for this suggestion is that the data should not be extrapolated below the observed data because below that range the resulting extrapolation will become very uncertain (unstable).

2. This methodology is relatively new and has only been tested to any significant extent on discrete toxicological endpoints; e.g., percent of animals with tumors, percent of animals with a specific reproductive effect. It has not been subject to much evaluation for continuous outcomes; weight gain, organ weights, effects on blood chemistries, etc. Therefore the methodology needs further validation before use for those kinds of endpoints.

assessment and epidemiology should significantly increase the quality of TLVs and other OELs."

If 1 in a 1,000,000 risk levels were used consistently, many chemicals would have very conservative PEL's, far below those in existence today and many of which would not be appropriate given the risks involved. Following are six examples of this. The calculations for a 1 in a 1,000,000 risk level were done assuming a 40 hour per week, 49 weeks per year exposure and a 40 year lifetime dose. The standards would be as follows:

Material	Hypothetical PEL	Present PEL
Acrylonitrile	30 parts per trillion	2 ppm
Benzene	200 ppt	1 ppm
Ethylene oxide	30 ppt	1 ppm
Formaldehyde	300 ppt	0.75 ppm
Vinyl chloride	30 ppt	1 ppm
1,1,1-trichloroethane	200 parts per billion	350 ppm

In several of the cases, the PEL at a risk level of 1 in 1,000,000 would be well below known exposure monitoring capability. In some cases epidemiology data have indicated that these levels are not needed to assure protection of employees. This risk level creates feasibility problems; how is control achieved when the exposure level is not measurable? The deciding factor on what level is chosen as the PEL becomes what is feasible, and that can be a moving target.

As the Organization Resources Counselors, Inc. (ORC) stated at the OSHA public meeting, this issue raised in the notice seems an ominous issue to raise in the context of the PEL initiative. We agree with ORC that it is unlikely that a PEL initiative would succeed if OSHA intends to reexamine in this context its long standing position that regulating to excess risk levels in the range of 1 in 1,000 are appropriately protective. Again, the problem is one of perception that OSHA is using the PEL development process as a vehicle to test whether the Agency can apply more conservative scientific assumptions or policies in order to issue more protective standards than what may indeed be necessary or appropriate.

SUMMARY

In general, Dow supports OSHA's attempts to develop a process for setting PELs that will be more consistent and speedier than the present process. However, we have concerns over any process that is proposed and we have identified most of those concerns in this submission. We believe that OSHA must involve all stakeholders in this activity and it must be done with an honest exchange of ideas and through the appropriate rule-making process. If this is not done, OSHA will not achieve their goal.