November 7, 1994

Richard Niemeier, Director
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National Institute for Occupational Safety and Health
Robert A. Taft Laboratories
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Subject: Metalworking Fluids Review

Dear Dr. Niemeier:

NIOSH is to be congratulated for the open meeting to review health hazard and control information regarding metalworking fluids. The meeting was clearly a quasi-regulatory event. Considerable information was shared and the first steps taken to identifying potential areas of agreement on technical matters. Given that OSHA and EPA have apparently deferred to NIOSH in responding to both UAW petitions for action, the UAW is pleased that NIOSH is moving forward.

The most important next step is clearly the completion of the Hazard Review. The UAW looks forward to the promised completion date in January, and stands ready to assist in this completion. After last week's discussion, several technical tasks which NIOSH might complete in the interval came to mind. These are described in the attached comment paper.

I would suggest three additional actions for NIOSH.

First, I would hope that NIOSH would agree to take an active role in the organization of the Symposium on health effects of machining fluids proposed by AAMA. The auto industry representatives made a good faith effort to maintain some balance of views with regard to the open meeting in Cincinnati. However, it may be hard to maintain such balance given the ratio of 3 union representatives to over 100 management representatives in attendance at the Cincinnati meeting. NIOSH, representing the public interest and scientific community, must take a leading role.
Second, I would hope that NIOSH could develop an approach to incorporating the not-yet-released respiratory effects studies ongoing at GM and Chrysler. Data collection and analysis for three clinical studies are largely complete, but reports are not final. The laboratory studies, notably those of Dr. Brain at Harvard School of Public Health, have not yet been completely reported. These studies were performed under a joint arrangement that includes a review and release process. The study results have not been finally reviewed by the science panels, and so have not been reported to key union and management stakeholders or released to the study subjects. It is unlikely these reports will appear in the published literature for some time. Nevertheless, these studies are the most substantial body of information on the subject of respiratory effects of low level machining fluid exposures available. The preliminary data have been made available to NIOSH personnel (Dr. Larry Fine) on an informal basis. Perhaps joint discussion between NIOSH, the auto companies and UAW could provide a means to include these data in the Hazard Review without delaying the Hazard Review.

Third, I would hope that NIOSH could quickly identify data gaps which could be filled through the application of test rules under the Toxic Substance Control Act. Such rules could be promulgated by EPA through complete rulemaking or could be arrived at by a consent decree negotiated between the industry parties, EPA and the UAW as petitioner. The UAW would be pleased to participate in discussions leading to a proposed test rule.

The UAW believes that the available data regarding mortality and respiratory health effects fully support the limitation of exposure to 0.5 mg/M³, total particulate in machining areas. These observed health effects arise from "obligatory ingredients" common across virtually all formulations: base oil, sulfonate detergents, ethanalamine buffers, biocides, metal particles and production contaminants. However, it may be that there are specific ingredients that pose an unreasonable risk to public health or environment beyond the general hazards of the mixture. In addition, adverse effects of particular ingredients may pose an unreasonable risk only in the presence of other ingredients in the obligatory mixture. Indeed, each new formulation may present a significant new use of the material.

Such test rules would likely take two forms. First, there is a need for extensive toxiconology testing (such as carcinogenesis bioassay, inhalation toxicology for long term exposures) for a certain limited number of typical or exemplary ingredients in machining fluids. The immediate task is identification of such examplars.

Second, there is a need for routine and standardized testing of substantially all components both in themselves and in the matrix of other materials to which
people are exposed. Examples of such standardized testing would be the modified Ames or skin painting bioassay for base oils, or the acute respiratory irritancy bioassay (mouse respiratory rate bioassay). Both of these standardized test methods were described during the Open Meeting.

I would hope that NIOSH could move quickly to recommending such test rules to EPA, as described by EPA in the agency's reply to the UAW test rule petition.

If further discussion can facilitate response to these requests, please contact me at 313-926-5563.

Sincerely,

[Signature]

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Health and Safety Department
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Technical Comments and Recommendations for NIOSH Activities based on
the Open Meeting on Health of Effects of Metalworking Fluids.

by

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Health Effects Comments

1. Polynuclear Aromatic Hydrocarbon content of base oils. The oil
toxicologists expressed the opinion that skin tumors expressed during the skin
painting bioassay were unrelated to human health effects, or health effects other
than skin tumors. This opinion would appear to eliminate PAH as a cause of the
observed increased cancer rates among workers exposed to machining fluids.
This opinion would also contradict a belief that improved refining practices have
reduced the risk of cancer and would eliminate claimed improvements in refining
practices as a reason not to proceed with regulation.

The evidence presented would also appear to provide little support for the claim
that current oil stocks are qualitatively different from older, less refined materials.
The PAH content of more highly refined stocks is less than less refined, but not
zero. All oil base stocks currently termed highly refined may not have similar,
low PAH content. The literature on the skin painting bioassay should be
reviewed to determine whether oils termed "non-carcinogenic" by skin painting
or modified Ames bioassay are simply less potent and therefore fall below the
detection limit of the bioassay.

2. Historical Conditions. The opinion expressed by some that observed
cancer increases are due to "historical conditions," is of course correct but must
be placed in proper scientific context. The average personal exposures to
employees that prevailed during the time of the studies were on the order of 2 to
5 mg/m³, perhaps higher in some occupations. Exposures at these levels raised
the cancer risk among exposed workers to a level that could be detected in the
mortality studies. Present day exposures may well have reduced that risk to the
point where the increase in risk would not be observed directly were the study
to be repeated. Nevertheless, significant risk would still be present. The proper
role of risk assessment is to estimate the risk at present day levels of exposure
and determine an exposure level where significant risk still exists.
Specific Activities

[The following specific development tasks could be performed in parallel to the completion of the hazard review document]

3. Reconcile various air sampling methods, so as to provide convertibility between:

- thoracic particulate
- respirable particulate
- total particulate
- total extractable particulate
- oil mist
- optical sampling methods.

[There is some literature on this matter. Dr. Tom Smith and the group at Harvard and the group at the University of Massachusetts at Lowell are probably the best source.]

4. Determine whether oil fog is formed from condensation of the oil vapor generated by recirculating air cleaning devices.

5. Determine the composition of oil vapor. Does the oil vapor contain amines and sulfonates? Are amines present as vapor, or absorbed on particles?

6. Measure and describe the PAH content (mass and component spectrum) of various base and in-use oils, especially soluble oils. Are higher molecular weight constituents a constant fraction of the total, or is there a shift in composition with increasing PAH content?

7. Determine diethanolamine, and other mono- and diamine content of bulk fluids and aerosols.

8. Determine nitrite and nitrate content of in-use fluids.

9. Determine chemical transformations of amines and amides with use.

10. Determine population range of exposures in typical and exemplary machining fluid operations.

11. Determine what exposure level can be maintained with full utilization of conventional controls.

12. Develop a protocol for respiratory symptoms outbreak investigations.
13. Develop respiratory and dermal medical surveillance protocol, with logic for determination of occupational cases and strategy for further investigation and medical management.


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