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July 24, 2007

James H. Price, CIH
Director of Science
American Conference of Governmental Industrial Hygienists
1300 Kemper Meadow Drive
Cincinnati, OH 45240-1634

Dear Mr. Price:

With reference to my letter of July 28, 2006, the Independent Lubricant Manufacturers Association ("ILMA") submits these additional comments on the American Conference of Governmental Industrial Hygienists' (ACGIH) proposed Threshold Limit Value - Time Weighted Average for "Mineral Oil Used in Metal Working."

ILMA, established in 1948, is a national trade association of 135 manufacturing member companies. As a group, ILMA member companies blend, compound and sell over 25 percent of the United States' lubricant needs and over 75 percent of the metalworking fluids (MWF) utilized in the country. Independent lubricant manufacturers by definition are neither owned nor controlled by companies that explore for or refine crude oil to produce lubricant base stocks. Base oils are purchased from refiners, who are also competitors in the sale of finished products. Independent lubricant manufacturers succeed by manufacturing and marketing high-quality, often specialized, lubricants. Their success in this competitive market also is directly attributable to their tradition of providing excellent, individualized service to their customers.

In this letter, ILMA re-emphasizes key points made in our letter of July 28, 2006, highlights several new relevant technical publications, and proposes to review progress on our plans to organize a symposium on how to address health effects of MWFs observed.

In 2006, ILMA suggested three fundamental defects in the proposed TLV: (1) definitional defects; (2) conceptual defects, and (3) quantitative/measurement defects. Additionally, ILMA presented an in-depth technical review of key references upon which ACGIH relied in their determination. We concluded that these defects, coupled with the technical analysis then presented, precluded the proposed TLV from presenting any positive value in the effort to protect worker health and safety. Based on these continuing conclusions, we again respectfully request that the proposed TLV for "Mineral Oil used in Metal Working" be withdrawn.

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Definitional Defects

We noted last year that most MWF products fall into four basic categories: (1) straight or neat oils; (2) soluble oils; (3) semi-synthetics; and, (4) synthetics. We also noted that three of the four general categories of MWFs, straight, soluble and semi-synthetics, all contain some quantity of mineral oil, ranging from as little as 5% (in some semisynthetics) to over 90% (in many straight oils). Though the proposed TLV did not define "Mineral Oil Used in Metal Working," it noted that the proposed TLV of 0.2 mg/m³ was "recommended for occupational exposure to mineral oil aerosols in metal working operations where additives and metal or microbial contaminants are present." We said that this statement appeared to suggest that any MWF that contained some unspecified amount of mineral oil would be subject to the proposed TLV for mineral oil. Though ACGIH's stated goal was to reduce the alleged health impacts of mineral oil mist, the practical impact was to regulate thousands of metalworking products, some of which contain only a small fraction of highly refined mineral oil.

We noted that the practical effect of the definition (setting a TLV for most metalworking fluids regardless of mineral oil content) was in direct conflict with ACGIH's decision to limit TLV documentation to studies on straight mineral oil used in metalworking operations only, and to expressly exclude studies on the alleged health effects of metalworking fluids. ACGIH, in other words, proposed a *de facto* TLV for metalworking fluids while simultaneously and expressly excluding all studies of metalworking fluid.

Both of these definitional defects with the proposed TLV are still present.

Conceptual Defects

ILMA noted last year that the TLV distinguished between "pure" mineral oils and mineral oils used in metal working operations. The proposed TLV for "pure" mineral oil 5 mg/m³ was twenty-five times higher than the proposed TLV for mineral oil used in metalworking, *i.e.*, 0.2 mg/m³. It appeared ACGIH premised this distinction primarily on the presence of additives in metalworking fluids (the existence of metals and microbial contaminants was also cited).

ILMA also noted that the proposed TLV also contained the following language:

A wide range of additives are used at concentrations ranging from a few parts per million to about 20% to modify the physical and/or chemical characteristics of mineral base oils in order to provide the performance requirements of specific applications. Additives are often proprietary materials and composition details will vary between individual supplier.

This distinction suggested that the alleged health effects of mineral oil in metalworking operations were *due to constituents other than highly refined mineral oil* - the additives, microbial contaminants and small pieces of metal commonly known as "fines" or "swarf"

generated by the metalworking process. ACGIH identified neither additives nor microbial contaminants with any specificity, other than noting that these things "vary."

It stood to reason then and stands to reason now that if ACGIH's hypothesis was that constituents "in" or "added" to mineral oil when mineral oil is used in metalworking are the source of the alleged health effects, most of their attention should be focused on those constituents. In other words, rather than dramatically lowering the TLV for mineral oil when used in metalworking, ILMA again recommends that efforts should be undertaken to at least identify *which* constituents or combination of constituents (be they additives, microbial contamination or metal fines or swarf) could be associated with any of the alleged occupational health effects.

Once identified, suspect additives or microbial contamination phenomena should then be studied directly. This is an important point: by proposing to dramatically lower the TLV for mineral oils used in metalworking, ACGIH again misses the significant opportunity to focus the resources of the organization on what might be truly causing the adverse health effects sometimes observed: microbial contamination.

To the extent that an additive, a combination of additives or microbial contamination actually does present an occupational exposure risk, a TLV for mineral oil used in metalworking does *nothing* to protect against *other* occupational exposures to the same additives or combination of additives or contaminants. Since those same additives or contaminants could be found in synthetic metalworking fluids or metalworking fluids containing animal or vegetable oil - neither of which contain any mineral oil - ACGIH misses a significant opportunity to focus its resources on what could be responsible for the occupational health effects observed.

Measurement/Quantitative Defects

In our letter of last July, ILMA said there were a number of critical quantitative interpretation and measurement errors in the proposed TLV and submitted the document, "The Independent Lubricant Manufacturers Association Technical Review of the ACGIH Draft Proposed TLV-TWA for Mineral Oil Used In Metalworking, 0.2 Mg/M³, Inhalable Particulate Mass, July 28, 2006," in which these errors were cited.

ILMA drew the following conclusions in that technical review:

- 1) There was significant cross-contamination between straight and soluble MWF aerosols at the plant that was the subject of the principal study upon which ACGIH relied (Kriebel et al. [1997]). As a result, the observed health effects reported in the study were not due to straight MWF aerosol exposure as ACGIH concluded.
- 2) Other references cited by ACGIH did not support the proposed TLV.

- 3) 13-week subchronic laboratory animal tests of aerosolized formulated lubricants had not shown significant adverse health effects.
- 4) The preponderance of evidence suggested that respiratory impacts experienced by machinists are not due to mineral oil, but to a combination of other causes including microbial and microbial decay products, irritation from specific chemical components, and possible effects of hypotonicity and pH.
- 5) Mineral oil was not an appropriate surrogate for formulated MWFs.

ILMA believes the conclusions noted in our 2006 technical review are still valid today.

New Technical Publications

Since our letter of last year, several authors have presented new technical information which suggest even more strongly that contaminants in in-use MWF, primarily bacteria and bacterial decay products, are responsible for the acute respiratory effects sometimes noticed among workers exposed to MWF. For example:

- Gordon, et al., (2006) found that hypersensitivity-like histological changes occurred in 3 of 8 strains of mice treated with heat-killed and lysed *M. immunogenum* and with used MWF contaminated w/ *M. immunogenum*. Virgin MWF did not produce similar responses.
- Thorne, et al. (2006), with C57B1/6J mice exposed intranasally for 3 d/week for 3 weeks to *M. immunogenum*, to endotoxin, and to MWFs spiked with endotoxin and/or MI or used MWFs, found that mice exposed to MI in MWFs developed lung pathology consistent with HP. Endotoxin coexposure augmented lung pathology.
- Wang, et al. (2007), found relatively higher concentrations of endotoxin in MWF mist particles below 0.39 μm , which is smaller than the size of intact bacterial cells. The authors recommended size-selective measurement of MWF mist and endotoxin for a more comprehensive exposure assessment.
- Cohen and White (2006) recommended Integrated approach to MWF, including:
 - Management of MWF systems (ORC, OSHA)
 - Establishment of and compliance to MWF OEL (1 mg/m³ suggested) with provision of administrative controls or PPE if exposures > 2 mg/m³
 - Medical surveillance, because, with potential for microbial contamination of MWF, exposures below an OEL may not protect workers against some of the most serious complaints and illnesses.

These publications, not reviewed by ACGIH, add to the body of evidence that it is the contaminants in MWF, not the MWF as formulated, which are primarily responsible for any adverse respiratory health effects observed.

Conclusion

ILMA believes now, as it did in 2006, that many of the health issues associated with MWF use have very little, if anything, to do with how these products are currently manufactured, but rather how they are used. We suggested then and suggest again now that a traditional "single number" industrial hygiene model may not be the best approach to protect worker health and ensure occupational safety and that a multi-dimensional approach, including focus on microbial contamination, would be far more fruitful than a single-minded focus on a TLV for mineral oils used in metalworking.

Last year, ILMA suggested that symposium on how best to address the health effects of MWFs sometime in the near future would be of benefit. In the last year, ILMA has made significant progress in progressing this idea and we will contact you by telephone in the next couple of weeks to schedule a mutually convenient time to review the progress we have made.

Sincerely,



Celeste M. Powers, CAE
ILMA Executive Director

cc: Safety Health Environment & Regulatory Affairs Committee, ILMA

References:

Gordon, T., et al., *Mycobacterium immunogenum* Causes Hypersensitivity Pneumonitis-Like Pathology in Mice, *Inhalation Toxicology*, **18**: 449 - 456 (2006)

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Wang, H., et al., Size distribution of airborne mist and endotoxin-containing particles in metalworking fluid environments, *J Occup Environ Hygiene*, **4**:3 157-65 (2007)

Cohen, H. and White, E.M., Metalworking Fluid Mist Occupational Exposure Limits: A Discussion of Alternative Methods, *J Occup Environ Hygiene*, **3**:9 501-507 (2006)