

UNITED STATES HOUSE OF REPRESENTATIVES

BEFORE THE

**THE SUBCOMMITTEE ON WORKFORCE PROTECTIONS
OF THE COMMITTEE ON EDUCATION AND THE WORKFORCE**

STATEMENT

OF THE

INDEPENDENT LUBRICANT MANUFACTURERS ASSOCIATION

ON

**EXAMINING THE USE OF NON-CONSENSUS STANDARDS IN WORKPLACE
HEALTH AND SAFETY**

April 27, 2006

The Independent Lubricant Manufacturers Association (ILMA) submits this statement for inclusion in the record of the Subcommittee on Workforce Protection's April 27, 2006 hearing, examining the use of non-consensus standards in workplace health and safety. The Association appreciates this opportunity to share its views on this matter with the Members of the Subcommittee.

Executive Summary

Protecting worker health and safety at the national level through regulation is a daunting task. Over the years, federal agencies have wisely looked to the private sector to help do the job properly. To assist federal agencies better leverage the energy and know-how of the private sector, Congress passed the "National Technology Transfer and Advancement Act of 1995" (NTTAA). Pursuant to the NTTAA, as supplemented by OMB Circular A-119, federal administrative agencies are *directed* to take into account privately developed consensus standards that relate to their regulatory activities. For a standard to be *consensus*, the development process must have the following attributes: (1) openness; (2) balance of interests; (3) due process; and, (4) an appeals process.

While the reliance on consensus standards typically enhances the regulatory efforts of federal agencies, the use of *non-consensus* standards can hinder, confuse and, in some cases, damage such efforts. The process that creates non-consensus standards often generates inferior and possibly defective information. Premising regulatory action on such inferior or defective information is not unlike building a house at a choice location using the finest materials, but neglecting to first lay a foundation. Without a solid foundation, a stylish new home is expensive in the short term, and ultimately useless in the long term.

The American Council of Government Industrial Hygienists (ACGIH) recently developed a Threshold Value Limit (TLV) for "Mineral Oil Used in Metal Working." This TLV is a non-consensus standard. Because it was developed in a closed, secretive process, ILMA asserts that it contains a number of conceptual and measurement defects.

Notwithstanding the presence of these defects, the Occupational Safety and Health Administration (OSHA) is poised to incorporate by reference the TLV once it becomes finalized by ACGIH. Once incorporated by reference, this TLV will instantly have legal status under OSHA regulations and may be the foundation of enforcement decisions made by OSHA and other administrative agencies. The defects in this TLV will undermine any subsequent regulatory action premised on the TLV.

The fact that OSHA has incorporated non-consensus standards into its regulatory programs for years is somewhat curious in and of itself, given that the Occupational Safety and Health Act has an express definition of "national consensus standard." 29 USC § 652 (3)(9). There is a gap between this definition in OSHA's enabling legislation and the Agency's practice of incorporating by reference non-consensus standards. This gap is further accentuated by OSHA's continued reliance on non-consensus standards despite Congress' mandate in the NTTAA.

Congressional action is needed to fill this gap. An efficient solution would be to require OSHA to rely only on “national consensus standards” as that term is *already defined in the Occupational Safety and Health Act* and is consistent with the NTTAA.

Introduction of ILMA

The Independent Lubricant Manufacturers Association (ILMA), established in 1948, is a national trade association of 135 manufacturing member companies. The overwhelming majority of these companies are “small businesses” as defined by the Small Business Administration. 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.

ILMA believes that non-consensus standards should have little or no role in the development of workplace health and safety policies in the United States, and that immediate legislative action is needed to remedy the improper reliance that various federal agencies, especially OSHA, place on these non-consensus standards.

Given the closed nature of their development, non-consensus standards are substantially more susceptible to severe conceptual and measurement defects than consensus standards developed in an open, accountable and transparent process. Developing workplace health and safety policy in the shadow of these defects presents unacceptable threats to the health of American workers and creates costly burdens on businesses (large and small) across many industries.

ILMA’s Current Nexus with Non-Consensus Standard Setting Organizations

ACGIH has enjoyed a long track record of doing a tremendous amount of good for the field of industrial hygiene and the protection of both the American workforce and workforces around the globe. Since the 1940s, ACGIH developed TLV recommendations for hundreds of chemicals and substances to which workers may be exposed in the workplace. For many years, ACGIH developed TLVs using an open, transparent development process based on sound scientific conclusions. All stakeholders in worker health and safety matters (those from government, academia and industry) had a seat at the table in developing TLVs. Unfortunately, this balance among stakeholders is no longer the case.

Presently, ACGIH promulgates TLVs by way of committees that operate in secret with anonymous authors for the TLVs. Though industrial hygiene professionals in the private sector are still permitted to be ACGIH members, they are categorically banned from serving on any TLV committees. ACGIH further dampens industry input by routinely refusing telephone and in-person meetings to discuss TLV development. In short, industry has gone from having a seat at the table to being systematically barred from the TLV development process. Though the opportunity to provide written comments exists, there is no “appeal” process to challenge, question or even engage in a professional discourse with the people responsible for developing and finalizing the TLVs.

ILMA believes that by closing the TLV development process, ACGIH has severely compromised the scientific value and legitimate utility of TLVs. Although ACGIH remains a private entity and has the right to conduct its membership, internal governance and TLV development procedures as it sees fit, a massive problem is created by the unwarranted credence that federal agencies, namely OSHA, give to ACGIH’s TLV development process and how these agencies currently use newly-generated TLVs as a substitute for their own notice and comment rulemaking.

It is instructive for the Subcommittee to examine ACGIH’s statement of position on its TLV development process at <http://www.acgih.org/tlv/PosStmt.htm>. ACGIH acknowledges that it does not evaluate the economic and technical feasibility of its recommendations or the availability of acceptable methods to determine compliance. ACGIH also points out that it does not follow a consensus process as the TLV “does not represent a consensus position that addresses all issues raised by all interested parties.” While ACGIH makes these and other disclaimers about its TLV development process and the use of its TLVs, the group conveniently ignores that it knows how its TLVs are used. Moreover, ILMA suggests that the Subcommittee ask OSHA how much taxpayer money is spent each year on ACGIH publications, including the TLV handbook, and staff involvement in the organization.

There is a direct connection between the closed-process, secret development of ACGIH TLVs and affirmative worker health and safety regulatory responsibilities that American employers have under federal law. Under the Hazard Communication (HazCom) Standard, OSHA automatically adopts the latest version of ACGIH’s TLV list every year and requires that manufacturers, including ILMA members, list the latest TLV limits on any Material Safety Data Sheet (MSDS) that they generate for use in the workplace. OSHA also uses new TLVs as the basis for, and to support, rulemaking actions that it initiates. OSHA can issue citations to employers under its “General Duty Clause” for violations of TLVs.

More important than the fact that the TLV development process and subsequent incorporation into U.S. worker health and safety regulations is patently unfair and fundamentally inconsistent with the premise of federal regulations (notice and the opportunity to comment and ultimately appeal), this non-consensus process generates defective decisions that have the potential to compromise the health and safety of the very workers the TLVs are designed to help as well as creating expansive economic

burdens on the business community, particularly the manufacturing sector. To illustrate, consider ACGIH's efforts to create a new TLV for mineral oil and mineral oil used in metalworking operations.

ACGIH's Proposed TLV for Mineral Oil – The Metalworking Fluid Industry's Perspective

On February 3, 2006, ACGIH released a draft version of a TLV recommendation for "Mineral Oil Used in Metal Working" and "Mineral Oil, Pure, Highly and Severely Refined." When used in metalworking situations, the draft TLV proposes a reduction from 5 mg/m³ to 0.2 mg/m³, time-weighted average (TWA). For "pure" mineral oil, the TLV remains at the current 5 mg/m³ TLV-TWA. In both cases ACGIH classifies highly and severely refined mineral oil as non-carcinogenic (A-4).

In other words, ACGIH is proposing to single-out mineral oil when used in metalworking operations and to reduce the TLV in those circumstances by a factor of 25.

As noted above, ILMA members manufacture more than 75 percent of all MWFs used in the United States. The scientists and industrial health and safety professionals that work for ILMA member companies likely account for the highest concentration of expertise on MWFs in the nation, if not the world. Because of ACGIH's closed and secretive TLV development process, ILMA's members had no role in developing the proposed mineral oil TLV.

From ILMA's preliminary assessment of the proposed TLV, there also appears to be a number of fundamental defects that are: (1) definitional; (2) conceptual, and (3) measurement/quantitative in nature. There is also a lack of context for the proposed TLV. These defects preclude the proposed TLV from presenting any positive value in the effort to protect worker health and safety and will place an unconscionable economic and unnecessary regulatory burden on thousands of businesses, large and small.

Definitional Defects

MWFs are used in the processes of metal shaping, cutting and grinding. MWFs are also used to cool and lubricate in the metalworking environment. Though there are thousands of MWF products, most fall into four basic categories: (1) straight or neat oils; (2) soluble

oils; (3) semi-synthetics; and, (4) synthetics.¹ Three of the four general categories of MWFs, straight, soluble and semi-synthetics all contain some quantity of mineral oil. Some have quite a bit of mineral oil (straight oil can have upwards of 90 percent), and some have very little mineral oil (semi-synthetics concentrates can have as little as 5 percent), especially after the concentrates are diluted before use.

Though the proposed TLV does not define “Mineral Oil Used in Metal Working,” it notes that the proposed TLV of 0.2 mg/m³ is “recommended for occupational exposure to mineral oil aerosols in metal working operations where additives and metal or microbial contaminants are present.” This statement appears to suggest that any MWF that contains some unspecified amount of mineral oil would be subject to the proposed TLV for mineral oil. Indeed, virtually all metalworking fluid products contain performance additives and, as a consequence of being used, contain very small pieces of the metal being “worked.” Though ACGIH’s stated goal is to reduce the alleged health impacts of mineral oil mist, the practical impact is to regulate thousands of metalworking products, some of which contain only a small fraction of highly refined mineral oil.

There is a major “disconnect” between ACGIH’s stated purpose for proposing the new TLV (reduced occupational exposure to mineral oil mist) and the practical effect (setting a single TLV for a multitude of industrial products by way of an overly broad definition). The approach completely ignores not only the plurality of metalworking fluid products, but also the even larger plurality of industrial applications of metalworking fluid products. Furthermore, the practical effect of the definition (setting a TLV for most metalworking fluids regardless of mineral oil content) is 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, has proposed a *de facto* TLV for metalworking fluids while simultaneously and expressly excluding all studies of metalworking fluid.

ILMA believes that ACGIH’s proposed definition of “Mineral Oil Used in Metal Working” simply could not be generated by an organization that relies on an open,

¹ Straight oils, used in today’s MWFs typically consist of severely-solvent refined or severely-hydrotreated petroleum oil, or other oil of animal, vegetable or synthetic origin used singly, or in combination with performance additives. A movement toward exclusive industry use of severely refined base oil began in the 1960s and was complete by the mid-1980s, especially with the promulgation of the Hazard Communication Standard by the Occupational Safety and Health Administration.

Soluble oils contain severely-refined based oil, emulsifying agents and performance additives. The base oil content ranges from 30 percent to 85 percent, and these products, sold in concentrate, are then diluted with water at ratios ranging from 1:5 to 1:40.

Semisynthetics contain an even lower amount of severely refined base oil, maybe 5 percent to 30 percent (in the concentrate), and a higher fraction of emulsifiers and water (up to 50 percent of the concentrate). In concentrate, semisynthetics are translucent and are typically diluted with water at ratios ranging from 1:10 to 1:40.

Synthetics contain no mineral oil whatsoever.

consensus-based process for developing standards. The definitional inconsistencies between intended purpose and practical effect, not to mention the “Catch-22” documentation problem would just not make it through the brainstorming phase, let alone all the way to a proposed standard.

Conceptual Defects

The TLV distinguishes between “pure” mineral oils and mineral oils used in metal working operations. The proposed TLV for “pure” mineral oil 5 mg/m³ is twenty-five times higher than the proposed TLV for mineral oil used in metalworking, *i.e.*, 0.2 mg/m³. ACGIH premises this distinction primarily on the presence of additives in metalworking fluids.² The existence of metals and microbial contaminants is also cited.

The proposed TLV also contains 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 suppliers.³

This distinction suggests that the alleged health effects of mineral oil in metalworking operations are *due to constituents other than highly refined mineral oil* – the additives, microbial contaminants and small pieces of metal commonly known as “fines” or “swarfs” generated by the metalworking process. ACGIH identifies neither additives nor microbial contaminants with any specificity, other than noting that these things “vary.”

It stands to reason that if ACGIH’s hypothesis is 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. Rather than dramatically lowering the TLV for mineral oil when used in metalworking, efforts should be undertaken to at least identify *which* constituents or combination of constituents (be they additives, microbial contamination or metal fines or swarfs) 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 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.

This conceptual bungling is not merely a theoretical or academic problem. To the extent that an additive, a combination of additives or microbial contamination actually does

² American Conference of Governmental Industrial Hygienists, Draft Total Limit Value Documentation, Mineral Oil (2006) at 1.

³ *Id.* at 2.

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. More specifically, the 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.

ILMA believes that these conceptual defects, just like the definitional defects would have been quickly rooted-out and corrected to the extent that ACGIH's TLV process was open and transparent rather than a closed, non-consensus process.

Measurement/Quantitative Defects

There are a number of critical measurement and quantitative interpretation errors in the proposed TLV that would not exist if the development process were open.

First, the test method contemplated to assure compliance with the new TLV does not just measure mineral oil; it measures “inhalable particulate mass.” This test does not directly and specifically measure oil mist by itself, but rather a collection of general particulates, oil mist, and any organic compound that adheres to the sample and measuring equipment.

Second, reliable measurements of total particulate at a level of 0.2 mg/m³ are not statistically feasible using standard measurement procedures. In other words, no generally available test procedure exists that would permit an industrial hygienist to even know whether a 0.2 mg/m³ is being achieved in any occupational setting. Conceptually, this is not unlike a state trooper using a radar device that can determine vehicle speed with an accuracy of +/- 5 miles per hour deciding to issue a speeding ticket for a motorist clocked at 66 mph in a 65 mph zone. The decision to set an exposure limit below what existing tests can tentatively measure would not pass muster in a true consensus standard setting process. Setting an exposure limit beyond what can be measured using state-of-the-art testing procedures is, in a word, silly.

Lack of Context for TLV Development

In addition to the manifold defects described above, ACGIH appears to have also largely ignored the fruits of an intensive discourse among the federal government, academia, industry and the courts regarding MWFs that has taken place over the past 13 years.

In 1993, the United Auto Workers (UAW), who is scheduled to testify at today's hearing, petitioned OSHA to regulate more stringently metalworking fluids and the components contained in the fluids (UAW sought to lower the Permissible Exposure Limit (PEL) for oil mist (mineral oil) from 5 mg/m³ to 0.5 mg/m³). The petition was unsuccessful, and UAW was also unsuccessful in asking the courts to force OSHA to take any regulatory action on MWFs. *UAW v. Chao*, 361 F.3d 249 (3rd Cir. 2004).

Concurrent with UAW's legal efforts, the federal government and industry continued to focus considerable attention on MWFs. Throughout the 1990s, industry, labor and the

federal agencies partnered on a series of joint committees, seminars, meetings and workshops to discuss and develop better ways to understand the potential occupational risks associated with MWFs and voluntary strategies to address those potential risks. Notable efforts included:

- Multi-day symposiums in 1995 and 1997 on the metalworking environment, respiratory health and metalworking systems management jointly sponsored by NIOSH and American Automobile Manufacturers Association (AAMA). The events drew hundreds of people, including those from labor, government and other stakeholders;
- Organizational Resource Counselors (ORC), a human resource and health/safety consulting firm, convened a metalworking fluid task force in 1996 and published a comprehensive “Metal Removal Fluids Management Guide” in 1997 to be used by machine operators;
- ILMA formed the Metalworking Fluids Product Stewardship Group (MWFPSG) and joined ORC’s efforts to issue a second edition of the Metal Removal Fluids Management Guide; and
- ACGIH held a two-day scientific symposium entitled “Health Effects of Mineral Oil Mist and Metalworking Fluids Symposium” in 2002, which was co-sponsored by ORC Worldwide, API, and the American Industrial Hygiene Association.

None of these above summarized efforts seem to have been incorporated into ACGIH’s draft TLV for mineral oil used in metalworking, especially many of the peer-reviewed papers presented at the 2002 ACGIH symposium.

The Ripple Effect – The Challenges That The Work Force and Business Community Face When Federal Agencies Incorporate Defective Non-Consensus Standards into Their Regulations

In the event that the proposed TLV for mineral oil used in metalworking is finalized by ACGIH and subsequently adopted by OSHA, a chain reaction of needlessly costly events would take place.

First, all businesses that manufacture or use metalworking fluid that contains mineral oil as either a base or ingredient will be required to revise their MSDS information for those products. Costs associated this revision would be, on average, in the low six figures for each MWF manufacturer.

Second, businesses that use such metalworking fluids in their manufacturing operations (the customers of ILMA members) would be pressured to comply with the new dramatically lower TLV. One strategy would be to invest in costly new engineering controls in their facilities in an effort to try to meet the new impractical TLV. Such efforts would require expensive new machines or retrofitting existing machines, and the

costly installation or retrofitting of ventilation systems. Prohibitive costs across the industry would be substantial and would likely exceed the capabilities of many smaller companies. Another option would be for customers to switch to synthetic or vegetable-based metalworking fluid products, which tend to be relatively more expensive than metalworking fluids that contain mineral oil. Though some ILMA member companies that specialize in synthetic metalworking fluids would likely have some benefit, the change would cause palpable market disruption in the industry. The third option for many customers of ILMA members would be to move their manufacturing operations overseas.

In addition to these immediate steps, insurance rates could rise in anticipation of personal injury claims premised on the defective TLVs. Legal costs associated with such actions would burden these manufacturing businesses even further.

Putting a dollar figure on these events is difficult, especially given the intangible costs of industry's collective understanding of the confusing aspects of the TLV. Nevertheless, some of the estimates generated by the OSHA Metalworking Fluid Standards Advisory Committee process from 1997 through 1999 may prove instructive. During this process, the costs to retrofit existing automobile manufacturing facilities to achieve an exposure level for metalworking fluid of 0.5 mg/m^3 were estimated to be about \$1.9 billion for what was then the U.S. "Big Three," on top of the estimated \$1 billion voluntarily spent on exposure reduction projects. Given that one estimate suggested that large automotive machining plants represented about 10% of the overall metalworking, it was estimated that the costs to achieve a level of 0.5 mg/m^3 would be about \$19 billion (in 1998 dollars). The costs to achieve a 0.2 mg/m^3 TLV would be significantly higher.

The above-summarized defects are so serious as to render the proposed TLV effectively useless in any effort to improve occupational health and safety in the context of metalworking. Therefore, all monies spent and all actions undertaken by industry in response to this TLV being finalized and adopted by reference in OSHA's HazCom Standards will be money and time wasted. Further, because the focus is on mineral oil and *not* the additives or contaminants that might be truly causing the problem, dollars spent to retrofit existing machine tools with new engineering controls may still not yield a workplace setting fully protective of worker health and safety. The mistake will be measured in billions of dollars.

Possible Solutions to the Problem of the Federal Government's Improper Reliance on Non-Consensus Standards

In the scientific and research community, concepts and opinions (whatever the subject matter) that are not subject to challenge and peer-review by other scientists and researchers through an open, transparent process are generally accorded very little value. For these reasons, non-consensus standards, like TLVs now developed by ACGIH should be accorded very little value and should have minimal influence over industrial hygiene matters because they are patently non-consensus standards.

OSHA's tradition of annually adopting ACGIH's new TLV list has the practical effect of assigning an unwarranted and disproportionate importance to ACGIH's TLVs and sets into motion an absurd and needless "fire drill" for businesses impacted by the new TLVs and fosters an utterly false sense of security from the standpoint of occupational health and safety, because the TLVs are premised on the interpretation and evaluation of scientific data in a non-consensus setting.

If Congress enacted legislation (such as the provisions found in Senator Enzi's (R-WY) suite of OSHA reform bills, (S. 2066 to be specific)) that prohibits OSHA from adopting non-consensus standards, a number of very positive developments could take place.

First, in an effort to keep their TLV tradition alive, we suspect that ACGIH would voluntarily take efforts to reform the TLV development process so that it fit the notion of a "national consensus standard" as that term is defined in the Occupational Safety and Health Act (codified at 29 USC § 652 (3)(9)). OSHA would then also be able to rely on ACGIH's efforts in the manner contemplated by Congress in the NTTAA.

Second, by eliminating the monopoly that ACGIH has on developing occupational health and safety occupational exposure limits, other private organizations would have a legitimate opportunity to generate competing consensus standards. This competition would undoubtedly improve the integrity and quality of occupational health and safety data and the thoughtful application of the same in an effort to truly protect the American worker.

Third, and most importantly, the development of patently defective standards, such as the ACGIH TLV for mineral oil used in metalworking and other TLVs would no longer have artificially fertile ground in which to take root, and grow unchecked into flawed occupational exposure limits.

Conclusion

ILMA greatly appreciates the Subcommittee's continued interest in the topic of the use of non-consensus standards by federal agencies and respectfully urges that the Subcommittee take legislative action to assure that when federal agencies do use standards generated by the private sector, the standards are developed in an open, consensus process.

We are, of course, happy to respond to any questions this statement may have raised.

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