



INDEPENDENT LUBRICANT MANUFACTURERS ASSOCIATION

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November 13, 2006

OSHA Docket Office
Docket No. H-022K
Room N2625
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

RE: Docket H-022K; Advanced Notice of Proposed Rulemaking

Dear Sir or Madame:

The Independent Lubricant Manufacturers Association (“ILMA”) submits the following comments on the Occupational Safety and Health Administration’s (OSHA) Advanced Notice of Proposed Rulemaking (“ANPRM”) on modifications to the Agency’s Hazard Communication Standard (“HCS”), 29 CFR 1910.1200, to implement the Globally Harmonized System of Classification and Labeling of Chemicals (“GHS”). 71 Fed. Reg. 5317 (Sept. 12, 2006).

Introduction of ILMA

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 (“MWFs”) 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 is a proud member of OSHA’s Alliance Program.

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ILMA's Response to OSHA's Request for Input

In its ANPRM, OSHA posed 20 questions to the regulated community and the public at large. For the sake of clarity, we include both OSHA's specific question (in italicized text) and ILMA's response thereto (in plain text).

1. How many hazardous chemicals as defined by the HCS do you produce, import or distribute? How many hazardous chemicals do you export? How many different labels or data sheets do you need to prepare for each chemical you export?

ILMA's membership is composed primarily of "small businesses" as defined by the U.S. Small Business Administration. Though there is no "typical" ILMA company, the following assumptions made by the Association may serve as a useful benchmarks: approximately 25% of ILMA Manufacturing Members buy 100 different chemicals as raw materials and formulate approximately 100 lubricant products from these chemicals. Some ILMA members have smaller operations; many are much larger -- a number of ILMA members formulate several hundred different lubricant products and rely on an even greater number of chemicals ingredients. Currently, many ILMA members produce material safety data sheets ("SDS") in US, Canadian and European Union ("EU") formats. Further, companies translate their US or EU SDS into many languages, including Chinese, Korean and Japanese.

The wording of this question suggests a possible misconception by OSHA about how HCS compliance occurs and the associated burdens borne by the regulated community. As a general matter, with lubricant and chemical products customers insist on an SDS for each product, regardless of whether a given product is hazardous. Furthermore, in some limited cases, ILMA members may not know if the chemicals they buy are "hazardous" until they receive and review the SDS from their respective suppliers.

2. Who is responsible for reviewing the data on chemicals and preparing appropriate labels and safety data sheets? What is their professional background? Do you make independent determinations or rely largely on labels or data sheets developed by others (suppliers, materials available on the Internet, etc.)?

In our industry, SDSs may be prepared by a technical person, usually a research chemist, technical service representative, or by a staff of hazard communication specialists. Except for the largest of companies, this duty is typically a part-time responsibility. The persons preparing SDS in our industry rely heavily on the hazard evaluations in vendor SDS to evaluate the hazards of products blended from purchased chemicals.

3. How long does it take on average for each hazardous chemical to complete the review and prepare new labels and safety data sheets? How much does it cost for each chemical product? Please break down the cost for the classification, preparation of a new label, and revision of a safety data sheet.

A company's technical staff will likely spend one hour reviewing each GHS-compliant SDS from a supplier. Assuming that the typical company purchases 100 chemicals, this task would take 100 hours.

Technical staff would also spend two to three hours on each of the company's products to, in turn, make the products' SDS GHS-compliant. Assuming the typical company produces 100 products, this task would take approximately 250 hours.

We also estimate that it would take, in the aggregate, 100 hours for a company's technical writer to become familiar with the mixture rules and decide how to adjust formats and phrases to be used in the GHS-compliant SDS and labels.

Collectively, these three tasks would take 450 person-hours, exclusive of clerical and/or software support, or approximately 25% of a technical author/analyst's annual hours worked, assuming a 40-hour workweek. The following table summarizes likely compliance costs and incorporates other associated costs to a typical company in our industry:

Annual Software License Fee	\$12,000
25% of Technical author/analyst salary and benefits	\$20,000
25% of Clerical support salary and benefits	\$10,000
Annual postage and stationary	\$1,000
Total annual cost for 100 SDSs	\$43,000
Cost per SDS	\$430

4. Would the time required to prepare a GHS SDS be more, less, or about the same as currently required for preparing an SDS? What time and costs would be required to convert existing SDSs to the GHS format? Would the costs depend on the amount of time allowed for the conversion process?

The costs of conversion would actually rise by giving product formulators, such as the typical ILMA member company, sufficient time to do a quality job. The time would be used to evaluate, purchase and learn how to use better tools such as software packages that can assist the company interpret GHS and publish quality SDS and labels. Smaller companies that do not have dedicated SDS software will experience higher costs and need more time, because SDS consultants will be needed to bring them into compliance.

If OSHA does not give sufficient time to formulators to receive and review revised SDS in the GHS format from suppliers, many companies will not be able to change in time or rush to meet the deadline and publish poor-quality documents on a new standard they do not understand. The timeframe for roll-out should be staggered with single substances revised, followed by mixtures.

5. Please describe any electronic tools you have to assist with this process, such as systems that classify chemicals or prepare labels or safety data sheets. How long would it take to update those systems to make them GHS-consistent?

There are basically two types of chemical formulators that are similar in size and sophistication to the typical ILMA member company.

The first type uses no electronic tools to assist the preparation on SDS and labels. They evaluate the information provided by suppliers, make a decision on the applicability to their products and publish an SDS using a word processing template.

The second type represents an increasing number of companies that find they need a software package to help create SDS in a variety of formats and languages. These packages usually contain electronic databases of regulatory information to assist the author capture the correct content of the SDS based on product composition. The packages may also be tied to a company's internal database (e.g., batch instruction or hazard warnings in inventory).

Several of these software packages are produced by companies that have already prepared modules to meet basic GHS requirements. Some software companies are less successful and the change to GHS may put them out of business. In these cases, users will need time to convert to software packages that will be ready to offer GHS requirements and format as soon as they are finalized.

6. How many of your employees receive hazard communication training? How many hours of training at what frequency (on hire, annually, as needed, etc.)? How long would it take to teach employees to recognize GHS pictograms? Would more standardized labels and SDSs make it easier to use the available hazard communication information?

The typical ILMA member company has approximately 30 employees for which hazard communication training is required. Any change in these training programs adds substantial cost. With the effective date for GHS revisions to the HCS, an extra training session would be required at the average cost of \$750 per employee.

The SDS is currently a complex multiple page document; this will not change under GHS. Refresher training will be needed for the first two years to reinforce the understanding of the changes. Given the expected use of color pictograms, companies may need to acquire printing equipment with color capabilities.

7. What savings will you incur when you only have to classify a chemical once instead of multiple times depending on how many agencies and countries are involved? What other benefits do you anticipate?

It does not appear to be the case that, after the HCS is revised, chemicals will only need to be classified “once.” Indeed, rather than cost savings, we anticipate certain additional costs associated with the GHS transition.

The hazard classification of any given chemical may change several times over the first decade after GHS implementation for a number of reasons. We expect a correction of the initial hazard assessment for a high percentage of chemicals by many companies based on the lack of clear understanding of the new hazard criteria. Further, there is no guarantee that all the suppliers of a particular chemical will classify the same way – GHS still allows for scientific judgment, and there is no way to assure that all companies will be looking at the same data.

Corrections may occur after implementation due to the need for additional testing. Companies may do additional toxicology testing because existing studies are not interpretable because they did not anticipate the new GHS criteria or the old reports are no longer available in corporate records. For example, until recently, most companies did not run eye irritation protocols with 7 or 21-day reversibility phases. In addition, new data from the U.S. Environmental Protection Agency’s HPV testing program is coming out that will affect the hazard evaluations of many chemicals.

It is also unclear in the ANPRM how OSHA expects to address the impacts in terms of dollar costs and basic fairness raised by the intersection of GHS with (1) Europe’s present guide for hazard determination for thousands of chemicals, the EU Annex 1; and (2) its replacement, the REACH chemical substance registration program, beginning in 2010. Because there is no analogous initiative in the United States, there appears to be a great risk that these classifications will eventually become the *de facto* specification standard for global commerce, developed without any coordinated input from either OSHA or U.S. industry. Aside from the lack of coordinated input in development, it is unclear what protections or recourse U.S. industry will have if these *de facto* standards are erroneous.

8. What is a reasonable time period for phasing in the modifications? Should the phasing be done by size of business? Are there any other factors that should be considered to differentiate the phasing?

In November 1983, OSHA gave companies two years to comply with SDS and label requirements. Industry health and safety professionals that were responsible for conversion in 1985 agree that two years is inadequate. As stated above, chemical product formulators need to receive updated SDS from suppliers of chemical substances in order to comply.

ILMA understands that the EU is planning to allow chemical substance manufacturers three years to comply and seven years for chemical product formulators to comply. This phase-in period for compliance seems adequate for implementing the GHS changes to the HCS.

OSHA should consider harmonizing any effective date with the EU and Canada. If all countries had the same effective date, companies would no longer need to maintain several formats in possibly two or more SDS writing software packages. In addition, a harmonized effective date would likely reduce confusion as the industry transitions to the new HCS.

9. What is the normal cycle for updating labels and safety data sheets?

ILMA members strive to comply with the 90-day rule for changes on SDS. If an SDS has not changed in the last three to five years, companies will typically review the SDS to see if any changes are needed.

10. Do you have stockpiles of product that are already labeled? How long will those stockpiles last?

Assuming a reasonable conversion period, this question would be moot. Stockpiles usually last a period of months, and sometimes up to one year. As illustrated in question 8, OSHA should allow longer than two year for conversion of the HCS to GHS criteria.

11. Do you have any other information or data that would help OSHA determine the appropriate phasing in of the new requirements or other issues related to timing?

See the response to question 8.

12. Are there any health or physical hazards that are currently covered by the HCS that you think are not adequately addressed in the GHS criteria? What are they and why do you think they are not adequately addressed? Are there any health or physical hazards that are not covered in either the HCS or the GHS that should be added?

ILMA sees benefit in the new hazard criteria under GHS. They are more gradations of hazard severity than in the OSHA definitions, which is an improvement. On the other hand, no set of hazard criteria can be complete. OSHA demonstrated wisdom in crafting Appendix B of 29 1910.1200 in encouraging employers to think broadly in the hazard evaluation and use judgment about what constitutes a hazard. ILMA recommends that the new GHS definitions be a “floor” for hazard consideration and that OSHA not completely abandon the performance orientation of 1910.1200. If a company recognizes an unusual situation that presents a unique hazard not covered by GHS criteria, the company should be allowed to warn for it. This is especially important in the US where tort law subjects US companies to lawsuits for failure to warn. Lessons should be learned from lawsuits where companies needed to use mandatory EPA FIFRA labels and lost cases for failure to warn.

13. In addition to references to hazardous chemicals with OSHA PELs, should OSHA propose to include any other listing of hazardous chemicals when aligning the hazard determination provisions of the HCS to the GHS? Should OSHA propose that the mixture provisions only reference exceeding the OSHA PEL when revised to adopt the GHS? Should OSHA propose deleting the requirement that the ACGIH TLV be included on the SDS when the requirements are changed to be consistent with the GHS? Should other recommended exposure limits be included on the SDS?

OSHA PELs are established by rulemaking procedures that invite public comment, have critically necessary Due Process, and are subject to legal review. Reference to OSHA PELs for mixtures that contain more than 1% of an affected chemical should be retained to minimize the changes required under GHS. There should be limited reference to standards developed outside the rulemaking process, such as those developed by IARC or NTP.

The present requirement to acknowledge American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs) should be dropped from the revised HCS because of the non-consensus manner in which TLVs are developed.

Comment: Do we really want to say this regarding NTP?

TLVs are developed by way of ACGIH committees that operate in secret with *anonymous* authors. 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. 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 because the TLV development process is closed, TLVs have compromised scientific value and limited utility in addressing occupational health and safety matters. Indeed, this non-consensus process can generate defective decisions that have the potential to compromise the health and safety of the very workers the TLVs are designed to help

In addition to issues of transparency and fairness, TLVs are developed without any regard to the economic and technical feasibility of its recommendations or the availability of acceptable methods to determine compliance. ACGIH’s own statement on the TLV development process is instructive: <http://www.acgih.org/tlv/PosStmt.htm>. Further, ILMA is not alone in the regulated community with respect to its deep concern with OSHA’s reliance on TLVs and other non-consensus standards. Attached are two recent hearing transcripts (April 27, 2006 and June 15, 2006) from the U.S. House of Representatives Committee on Education and the Workforce, Workforce Protections Subcommittee (Exhibits “1” and “2” to these comments).

ILMA endorses OSHA’s proposal to remove the requirement that TLVs be listed on SDS.

14. Within the health hazard criteria, are there any categories of hazard that should not be adopted in the HCS? For example, should OSHA adopt all of the categories addressed in the acute toxicity criteria? If not, what categories would be appropriate to address anticipated workplace exposures?

Acute oral criteria IV and V are unnecessary for expressing occupational hazards and should not be adopted to avoid confusion.

15. If OSHA changes the HCS to adopt the physical hazard criteria, how will that impact other OSHA standards that use the same criteria as the HCS? Does OSHA need to change those criteria at the same time the HCS is changed? Storage and handling requirements for flammable liquids are one example that has been identified as a potential problem if different definitions apply, and information on a safety data sheet is linked to the definition in the HCS but not consistent with other definitions.

ILMA maintains no opinion on this matter.

16. Are there any other technical issues that need to be considered in adopting the GHS? Please explain.

None recognized so far.

17. What products would be most useful to employers? Employees? Do you prefer paper publications? Electronic tools?

Though paper publications should always remain available, ILMA members generally prefer internet-based guidance supplemented with links to supporting documents. The guidance should be simple and written in plain English. ILMA participated in the OSHA Alliance Program's roundtables on the GHS and has offered its suggestions for compliance tools at these sessions. OSHA policymaking staff should review the minutes of these roundtable sessions.

18. What subjects would be of most interest? Classification criteria and procedures for substances and mixtures? Labels? Safety data sheets?

The guidance should address all topics listed in this question.

19. What is the best way to distribute the materials to reach affected employers and employees?

Via Internet and U.S. Mail.

20. Are there any types of materials that would be especially appropriate for small businesses? Most small businesses would be users of chemicals, rather than producers, so they will be receiving labels and safety data sheets prepared according to the new

approach. Are there training materials that would be helpful to learn or teach about the new approach? In particular, would training on symbols or pictograms be of use?

OSHA guidance needs to be complete, address all audiences and above all immediately available when the final rule is published far in advance of the effective date for conversion.

Conclusion

ILMA appreciates the opportunity to submit the foregoing comments. Our industry recognizes that there is palpable potential for greater business efficiency. However, this efficiency could easily be eclipsed if the transition from the HCS to GHS occurs without sufficient time for a variety of businesses to become compliant with the new system.

The Association is available to answer any questions its comments may have raised.

Sincerely,

A handwritten signature in black ink that reads "Celeste Powers". The signature is written in a cursive, flowing style.

Celeste M. Powers, CAE
Executive Director

Attachments (Exhibits 1 and 2)

cc: ILMA Safety, Health, Environmental and Regulatory Affairs Committee
Jeffrey L. Leiter, Esq.
Adam B. Cramer, Esq.