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Comments regarding

OSHA Docket No. H-022K - Hazard Communication - Advance Notice of Proposed Rulemaking (ANPRM)

Paul Hewett Ph.D. CIH

1 Introduction

The Globally Harmonized System of Classification and Labeling of Chemicals (GHS) has been adopted by the United Nations with a goal that the GHS be adopted by as many countries as possible by 2008. On September 12, 2006 (Federal Register 71(176): 53617-53627) OSHA requested comments on the issue of changing the Hazard Communication Standard (HCS) to conform with the GHS provisions. While general comments were requested, OSHA highlighted twenty issues. I will address Issue 13, which primarily focuses on whether or not OSHA should continue requiring that the ACGIH TLV list be used as one means of determining if a substance or mixture is a health hazard and also as one source for occupational exposure limits:

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?

Question 13 appears to be directed at two of the requirements of the HSC: hazard determination and the listing of relevant exposure limits. Its phraseology suggests a specific concern with using the ACGIH TLVs as a basis for determining if a substance is a hazard, while at the same time asking if other exposure limits should be included.

I suspect that Question 13 may owe its origin to the recent series of hearings held by the House Subcommittee on Workforce Protections, chaired by Charles Norwood (R) (see the transcripts for the April 27, 2006 and June 14, 2006 hearings). In these hearings the main issue has been the requirements of the HCS that the TLV list be used as one basis for determining if a substance poses a hazard to workers and the requirement that the TLV (if it exists for the substance) be included in the list of exposure limits. These hearings, which involved a considerable amount of grandstanding, nonsensical discussions, presentation of misleading information, and lists of invited speakers that were always 3 to 1 biased in favor of Mr. Norwood's side of the argument, all focused on forcing OSHA to remove the requirements in the HCS for including the ACGIH TLV in the list of exposure limits for the substance in question. OSHA appears to consider the proposed alignment of the HCS with the GHS requirements as a convenient opportunity to comply with Representative Norwood's expressed goal of stopping OSHA from

requiring the use of the TLVs whenever a company devises a SDS:

"The ACGIH is going to stop writing the laws of this land, if it's the last thing I do on this earth. They'd better get ready because I'm going to come after them. You guys at the Labor Department that are letting this happen are next on that podium, under oath. We're going to find out why you are allowing this to happen, under oath It's against what Congress wants you to do We tried to fix this but the Labor Department stopped it, and now it's war!" (April 17, 2006 House Subcommittee on Workforce Protections hearing)

My view is the opposite. Instead of removing references to the TLVs, I strongly suggest that OSHA not only retain such references, but supplement them with references to other sources of recognized exposure limits, such as the NIOSH Recommended Exposure Limits (RELs), AIHA Workplace Environmental Exposure Levels (WEELs), and the European Union (EU) Indicative Limits. I also suggest that OSHA not only continue the use TLV and IARC lists as two of the bases for determining if a substance is a hazard, but add other lists, such as the AIHA WEELs, NIOSH RELs, and EU Indicative Limit list.

2 Comments regarding Question 13 on hazard determination

"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?"

As currently stated in the HCS, the purpose of the Hazard Communication standard is as follows:

(a)(1) The purpose of this section is to ensure that the hazards of all chemicals produced or imported are evaluated, and that information concerning their hazards is transmitted to employers and employees. This transmittal of information is to be accomplished by means of comprehensive hazard communication programs, which are to include container labeling and other forms of warning, material safety data sheets and employee training. (29 CFR 1910.1200)

According to the ANPRM, the purpose of the HCS is get the best available information - i.e., state-of-the-art information - into the hands of companies and employees that use or may be exposed to a particular substance or mixture:

"The HCS is based on collecting and evaluating the best available evidence on the hazards of each chemical." (OSHA ANPRM)

Part of this information is a determination, by the manufacturer or importer, that the substance is inherently a "health hazard". The HCS defines a "health hazard" as "

[(c) Definitions ...] Health hazard means a chemical for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed

employees. The term "health hazard" includes chemicals which are carcinogens, toxic or highly toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents which act on the hematopoietic system, and agents which damage the lungs, skin, eyes, or mucous membranes.

The "Chemical manufacturers, importers or employers" are required to do a hazard determination:

(d)(2) Chemical manufacturers, importers or employers evaluating chemicals shall identify and consider the available scientific evidence concerning such hazards. For health hazards, evidence which is statistically significant and which is based on at least one positive study conducted in accordance with established scientific principles is considered to be sufficient to establish a hazardous effect if the results of the study meet the definitions of health hazards in this section. Appendix A shall be consulted for the scope of health hazards covered, and Appendix B shall be consulted for the criteria to be followed with respect to the completeness of the evaluation, and the data to be reported.

(d)(5)(iv) If the chemical manufacturer, importer, or employer has evidence to indicate that a component present in the mixture in concentrations of less than one percent (or in the case of carcinogens, less than 0.1 percent) could be released in concentrations which would exceed an established **OSHA permissible exposure limit** or **ACGIH Threshold Limit Value** [emphasis added], or could present a health risk to employees in those concentrations, the mixture shall be assumed to present the same hazard.

In summary, the "Chemical manufacturers, importers or employers" are supposed to review the "scientific evidence" and if only a single study is positive - provided that study conforms to "established scientific principles" - the substance is to be deemed a "hazard". Recognize that "hazard" refers to an inherent property of the substance. If it is "**hazardous**" it is capable of causing an adverse effect. Whether or not, under the conditions of actual use, the user or employee is subject to non-existent, negligible, substantial, or excess **risk** is another issue (discussed later).

OSHA currently directs the manufacturer/importer to *automatically consider a substance a hazard* if (a) the substance has either a PEL or an ACGIH TLV, or (b) either OSHA, NTP, or IARC has designated the substance as a carcinogen (see 29 CFR 1910.1200, D4 and D5). Even if the substance is listed or covered by these agencies or organizations the manufacturer/importer is directed to conduct a review of the health-effects literature.

With the above questions, OSHA is basically asking whether or not the OSHA PEL list should be the sole list to be used for the *automatic* determination that a substance or mixture is a hazard. My view is that it should not be the only list. The OSHA 6a PELs, i.e., the PELs in Tables Z1, Z2, and Z3, were adopted in 1972 under Section 6a of the OSHA Act, and were based upon the 1968 ACGIH TLV and 1960's ANSI recommended exposure limits. The bases for these limits were, depending upon the substance, reviews of the health-effects literature from the 1960's and earlier. In fact, some of the 1968 TLVs were based upon health-effects data collected in the 30's and 40's. The OSHA 6b PELs, i.e., the single substance standards, while newer than the 6a PELs, are in most cases decades old. (Nearly all of these PELs should be updated and PELs adopted for commonly encountered substances that are not included in the 6a and 6b PELs. OSHA recognized this when in 1989 OSHA updated the PELs by adopting the majority of the then current TLVs. While this promulgation of revised and new PELs was eventually reversed in 1993, it did indicate that OSHA considered the PEL list as both outdated and incomplete.

The stated goal of conveying state-of-the-art hazard information to the user and employees will surely be undermined at the outset if the writers of SDS are forced by law to view the OSHA 6a and 6b PELs as the only *definitive* list of hazardous substances. I recommend that OSHA *expand* the lists to include not only the ACGIH TLVs, but the NIOSH RELs, AIHA WEELs, and list of EU Indicative Limits. Any substance on any of these lists should be considered a hazard. Whether or not there is excess risk is another issue.

OSHA indicated in the ANPRM that while the PEL list is sacrosanct, and will remain a required source of information for the determination of hazard and for the identification of an exposure limit, OSHA mentioned that a non-mandatory, but useful source of information will be the greater than 1300 "international chemical safety cards" that have been developed through the International Program on Chemical Safety (IPCS). While these "safety cards" may indeed be peer reviewed by numerous organizations, there is no guarantee that the hazard determinations and hazard class assignments are accurate, or even that these "safety cards" are reasonably up to date. For example, look up the safety card for diacetyl (i.e., artificial butter flavoring).

My view is that the writer of a SDS should be *required* to review several overlapping sources of hazard information and exposure limits, so that the goal of conveying state-of-the-art hazard information is more likely to be achieved for any single substance. If the manufacturer disagrees with what some non-industry group has published they are free to present alternative viewpoints (with documentation of course), but for SDS's to be successful and consistent is the required review of the several overlapping sources of hazard information.

According to the OSHA ANPRM, even if the substance is on one of these lists, the manufacturer/importer is "still required to review the available information to determine specifically what the hazards of these chemicals are, and to disclose them on labels and safety data sheets". (But in reality, how often does this happen, particularly for small enterprises?) In the ANPRM, OSHA goes on to state that because the GHS criteria for defining health hazards is more specific than the criteria in the HCS the manufacturer/importer will no longer have to generate a "specific listing of hazardous chemicals as part of the hazard determination procedures". I fail to see why this is the case, but OSHA indicates that because of these more specific criteria "[c]hemical manufacturers and importers are much more likely to make consistent hazard determination evaluations", thus eliminating the need for reference to specific limits. OSHA goes on to say that "[c]hemical manufacturers and importers would retain the responsibility for evaluating all relevant data on the chemicals they produce or import".

My read of these statements (which occur at the end of Section C of the ANPRM), is that OSHA is of the opinion that the manufacturer will (1) actually perform an extensive, full-coverage literature evaluation for the substance or components of a mixture, and (2) for each substance accurately apply the GHS hazard determination criteria. Having done so there will be no need to consult any existing list of toxic substances, including I presume even the OSHA PEL list (which was left out of lists that would no longer be needed), since the manufacturer/importer will always do a quality literature search and extraction of the relevant information.

My suggestion to OSHA is not overly rely upon the abilities of the manufacturer/importer to fully review the literature and to properly interpret what is to be found. I strongly suggest that the references to lists be retained, and in fact expanded. It takes little effort to merely check the lists, even to check them twice, and to draw from the lists the health effects and concerns that led to the inclusion of the substance on the list. The real effort will lie in the actual review of the literature - if indeed every manufacturer/importer actually proceeds to this step and completes it with honors. Maybe there are additional or more important health effects that have just come to light, and have not been included in

the various lists. But just in case, for the manufacturer/importer that is less than conscientious, a required first step of consulting several well-known and reliable lists will help ensure that a minimal level of hazard assessment is done for the substance or components of a mixture.

3 Comments regrading Question 13 on relevant exposure limits

“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 requires that the manufacturer/importer first determine if the substance represents a hazard. As a means of conveying information on the toxicity of a substance and for determining if the conditions of use result in excess risk OSHA also requires the inclusion of exposure limits in the SDS. (Under GHS information on exposure limits will be presented in the “Exposure Controls/Personal Protection” category of the SDS.) OSHA currently requires the SDS writer to include not only the OSHA PEL, but the ACGIH TLV:

(g)(2) Each material safety data sheet shall be in English (although the employer may maintain copies in other languages as well), and shall contain at least the following information: ...

(g)(2)(vi) The OSHA permissible exposure limit, ACGIH Threshold Limit Value, and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the material safety data sheet, where available;

Again, the purpose here is to *inform* the user and employees. Even with exposure limits, the goal remains the same:

“The HCS is based on collecting and evaluating the best available evidence on the hazards of each chemical.” (OSHA ANPRM)

Exposure limits, when available, give us some idea regarding the concern that we should have regarding the substance or mixture. For example, an extremely low exposure limit suggests that the substance should handled with great care and inhalation (and/or dermal where appropriate) exposures should be appropriately minimized if not eliminated.

Reliable, state-of-the-art exposure limits also provide us a metric for determining if occupational exposures are properly managed or if there is a risk of an adverse outcome given a particular use scenario for the substance. Whether there is high, medium, low, or virtually non-existent risk has to do with how the substance is used, the control systems (if any), use of protective equipment, and any other factors that either cause or reduce employee exposure. A substance can be hazardous, but may pose little risk if, for example, the process is completely enclosed, protective equipment is utilized, or the employee exposures are maintained well below relevant, state-of-the-art, **health-based exposure limits**. (However, the HSC does not require the user to determine if indeed there is excess risk associated with the particular use of the substance. In fact, the OSHA regulations do not require this risk determination for any but the 6b substances, and even there the exposure monitoring requirements are minimal.)

With the above two questions OSHA is simultaneously asking permission to delete the requirement for including the substance TLV and permission to include other limits. OSHA obviously considers the OSHA

PELs superior in some fashion since OSHA states emphatically that they will continue to require the listing of PELs where applicable; whereas, the TLVs should be dropped:

“[in a modified HCS...] References to the chemicals for which there are ACGIH TLVs, and those chemicals addressed in IARC Monographs and the NTP lists, would no longer be specifically addressed in the HCS. ... Modifying the HCS to align with the GHS would also eliminate the current references to ACGIH TLVs as part of the mixture provisions.

...

“Countries may choose what to require in these sections [i.e., the Exposure Controls/Personal Protection section] in terms of occupational exposure limits, but it is anticipated that OSHA would require the PELs to be included.” (OSHA ANPRM)

Fist of all, let us deal with the issue of “**consensus exposure limits**”. It will no doubt be recommended by one or more industry groups responding to this ANPRM that only existing PELs or bonafide “consensus exposure limits” (or some similar phraseology) be permitted in the SDS. However, the inclusion of recommended exposure limits cannot be limited to consensus exposure limits because they simply do not exist - never have and probably never will. The concept of “consensus exposure limits” is a bogus concept, solely invented for the purpose of denigrating the TLVs and to mislead both OSHA and congress.^a All of the exposure limits - PELs, RELs, TLVs, WEELs, corporate OELs, etc. - were created by small groups of professionals that *do not in any meaningful, balanced way* represent the interests of both industry and labor. Some of the limits are based entirely upon control or measurement feasibility (e.g., the OSHA 6b PELs), some are largely health-based (e.g., the TLVs and WEELs), and some combine both considerations (e.g., the NIOSH RELs). And those organizations that *promote* (but do not guarantee) consensus standards (e.g., ANSI and ASTM) have not in the last thirty or so years tackled the onerous and often thankless task of evaluating the literature, and recommending and justifying an exposure limit for any regulated or unregulated (i.e., non-PEL) substance. In summary, I am not aware of a single current “consensus exposure limit”, as defined and portrayed in the recent hearings of the House SubCommittee on Workforce Protections. All of the limits above represent organization-specific consensus exposure limits (i.e., a limit reached by consensus within the limit-setting group of the organization). (OSHA itself in the ANPRM refers the ANSI standard on MSDSs as an “industry consensus standard”, recognizing no doubt that the ANSI standard was developed by a group composed overwhelmingly of industry representatives.)^b

In conclusion, exposure limits from different sources represent different views at different points in time regarding a suitable metric against which worker exposure measurements can be compared for purposes of assessment and managing risk. The writers of SDS should be required to include all exposure limits form recognized sources of exposure limits - such as OSHA, MSHA, NIOSH, EPA (i.e., NCELs), ACGIH, AIHA, and the EU. If the industry, trade organization, or company has an issue with a particular limit, either its value or its basis, then the company can recommend their own exposure limit (and provide suitable documentation regarding their procedure for arriving at the value per requirement d6 of the current HCS).

4 General Comments

At some point in the distant future we may have a comprehensive list of chemicals that reliably provides

^a See the transcripts of the House SubCommittee on Workforce Protections for April 17, 2006 and June 14, 2006.

^b The ASTM does have a recommended standard for monitoring exposure to silica containing dusts. The standard mentions the PEL and TLV, but does not attempt to review the health-effects literature and either recommend or endorse a limit for silica.

all of their health hazards, hazard classifications, appropriate control bands, substance-specific exposure limits, use scenarios, recommended control strategies, and so on. Not only that, but that both industry and labor, producers and users, employers and employees, consumers and government all agree on all the information provided in this comprehensive list. Perhaps even industry (via trade associations or consortiums) will step up to the plate and start doing the health effects studies and risk assessments that should have been required of them in the original 1969 OSHAct. When all this happens, the need for independent professional and governmental organizations such as the ACGIH, AIHA, IARC, NIOSH, and the NTP program may be substantially diminished. But until that point, if we ever reach it, it seems to me that the only way to realize OSHA's goal for HCS - that it be "based on collecting and evaluating the best available evidence on the hazards of each chemical" (OSHA ANPRM) - is to (a) require the manufacturer/importer (i.e., the SDS writer), when doing the initial hazard determination, to review as many of the current lists of toxic substances as possible, and (b) when listing exposure limits, to include as many *sources and opinions* as possible, to include at a minimum the OSHA PELs, NIOSH RELs, ACGIH TLVs, AIHA WEELs, and the EU Indicative Limits, as well as industry-recommended limits when available. All of this represents *information*, and it is the transmittal of pertinent, reliable, state-of-the-art information that at the core of OSHA's Hazard Communication standard.

Paul Hewett Ph.D., CIH
phewett_2006_07@oesh.com

Exposure Assessment Solutions, Inc.
1270 Kings Road
Morgantown, WV 26508
304.685.7050