

AIHA's White Paper on Permissible Exposure Limits (PELs)

The focus of this white paper is on the regulatory permissible exposure limits (PELs) for airborne chemicals as promulgated by the Occupational Safety and Health Administration (OSHA). However, recognizing that OSHA has not been able to set up-to-date PELs for every chemical of concern in the workplace, these comments go further to suggest what employers and industrial hygienists may do to fill the need.

1. Exposure limits such as OSHA's PELs are a primary tool in disease prevention and are an essential part of a comprehensive occupational safety and health program.

The concept of the use of exposure limits as a means of protecting worker health has evolved from the industrial hygiene community's 50 years of experience⁽¹⁾ in developing and using such limits. Maximum Allowable Concentrations (MACs), Threshold Limit Values (TLVs), Workplace Environmental Exposure Levels (WEELs), Recommended Exposure Limits (RELs), and industry-developed Occupational Exposure Limits (OELs) have been essential tools of the practicing industrial hygienist. While the goals, where stated, may differ⁽²⁾ (e.g., to limit occupational cancer to 1 case in 1000 exposed workers over a working lifetime or to protect "nearly all workers"), these exposure limits are all designed to reduce the occurrence of worker illness or impairment resulting from exposure to chemicals. The use of exposure limits to prevent occupationally-related illness has been an effective tool used by industrial hygienists for more than five decades. AIHA recognizes the controversies that are often involved in the setting of these limits both in the regulatory and voluntary arenas. In developing PELs the major concerns include scientific soundness, feasibility, timeliness, documentation, and opportunity for involvement of affected parties in the decision-making process. We believe that when these considerations are a part of the limit-setting process and when the limits are applied as part of a comprehensive occupational safety and health program they are a primary tool in disease prevention.

2. OSHA should seek whatever resources or legislative changes are needed to allow the updating of all existing PELs to current science and to set such new PELs as are necessary to protect worker health. In the meantime OSHA should select chemicals for PELs based on scientific principles and specific criteria developed with all stakeholders.

It is a disservice to worker health that the majority of OSHA PELs are based on recommendations that were made almost 30 years ago (i.e., 1968 Threshold Limit Values of the American Conference of Governmental Industrial Hygienists). AIHA supports the concept that OSHA should review and update the PELs on a regular (three-to five-year) cycle based on National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limits (RELs), the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs), AIHA Workplace Environmental Exposure Levels (WEELs), and other appropriate national and international standards that are based on good science. All of the limits noted above are developed by technical-professional associations (AIHA and ACGIH) or a government agency (NIOSH), and they undergo extensive technical reviews and follow a formal process for development, review, and approval of individual limits. While the procedures and rationales may differ, all of these limits provide a scientifically sound starting point and foundation for prompt and continuing upgrading of the OSHA PELs. By starting with such a foundation, the past record (new PELs for only about two dozen substances in more than 25 years) can be markedly improved and worker health protection will be enhanced by promptly considering new information.

Without a regular review and update process, many more PELs will become out of date. Researchers and other professionals are constantly developing new information regarding toxicity at the molecular, organ, and whole body levels. This information must be incorporated into the PEL update process. To make this periodic update faster and more efficient, OSHA should make maximum use of work done by the professional groups previously identified as well as those within the international community that have developed science-based values.

By itself, this approach may not pass challenges in the courts unless the burden-of-proof requirements for adopting PEL updates are more flexible than those in the present OSHAct. This is suggested by the decision by the 11th Circuit Court that vacated the 428 PELs adopted in January 1989. One suggested approach is to continue to require OSHA to follow fully the Administrative Procedures Act (to ensure adequate review and comment), but to establish legislatively a "not arbitrary or capricious" criterion rather than a "substantial evidence on the record" criterion regarding adoption of PELs by the Agency. There may be other legislative approaches that will provide a balance between adequate technical/scientific review and the requirements defined by legislation in the courts. A balance

must be struck between the opportunity for the regulated community to review and input to a standard-setting process and the need to reduce the time period for regulatory action. The present criteria clearly need modification when one considers OSHA's limited accomplishments in this area since 1970.

Given the difficulty OSHA has demonstrated in setting PEL standards it is necessary to consider prioritizing chemicals for update considerations. This discussion assumes that it is unlikely that OSHA would attempt to review, and possibly change, all exposure limits simultaneously. It also assumes that OSHA is unlikely to group chemicals into certain classes and regulate all chemicals in a certain class at the same time.

Paustenbach(3) articulates the concerns of the stakeholders in the PEL update. His two points regarding the setting of priorities in the updating of PELs should be considered.

"The prospect of a "list" of chemicals seems to bother everyone. To some extent, there is a general mistrust of any process wherein a certain chemical is targeted for regulation while another is not. One way to prevent this from being the focus of attack would be to drop the list entirely. Instead, the Agency might present a generic formula for different toxicological effects for calculating "preliminary" PELs for various classes of chemicals (e.g. carcinogens, irritants, and CNS depressants). Then when consensus is reached on the formulae, the information on the various chemicals need only be put in to the "master equations", which would yield a comprehensive list of PELs for hundreds of chemicals."

and

"The lack of transparency in OSHA's process for selecting the initial chemicals reinforced the perception that some special interest groups were more effective than others in preventing their chemicals from 'getting listed.' This issue needs to be hit 'head on' by the agency. There seems no better way than to share publicly the data and analyses that supported the Agency's proposal. OSHA should then encourage technical comments on this information. After having assembled up-to-date information that is 'more or less' accepted by the stakeholders, the Agency should then publish several different algorithms for establishing a priority list."

In summary, the process of choosing chemicals must be as objective as possible, based on sound scientific principles and specific criteria. The stakeholders must be given an opportunity to participate in every phase of this process. A weight of evidence process for judging the overall body of toxicological and epidemiologic data must be developed which clearly states procedures for evaluation of individual study data.

3. For compliance purposes OSHA has defined PELs as values not to be exceeded. However, when designing exposure monitoring programs employers must assign a statistical interpretation to the PEL. Therefore, OSHA should continue to provide guidance regarding suitable statistical interpretations. Employers can thus design effective performance-based exposure monitoring programs that are consistent with OSHA's expectations.

OSHA has provided some guidance regarding the statistical interpretation of various PELs. In the preamble to the 1987 benzene standard OSHA acknowledged that exposures derive from continuous distributions where there is some finite probability of a random overexposure, even in a controlled work environment. OSHA stated in both the benzene preamble and the preamble to the 1978 lead PEL that the long-term average exposure should be "well below" the PEL. The 1992 formaldehyde standard included a non-mandatory appendix that suggested that statistical tests could be used as part of an exposure sampling strategy:

"...a properly designed sampling strategy showing that all employees are exposed below the PELs, at least with a 95 percent certainty, is compelling evidence that the exposure limits are being achieved..."

This appendix was derived from the NIOSH 1977 Occupational Exposure Sampling Strategy manual, in which NIOSH stated:

"In statistical terms, the employer should try to attain 95% confidence that no more than 5% of employee days are over the standard."

Along similar lines the AIHA Exposure Assessment Strategies Committee (EASC) recommends that the exposure profile - or distribution of exposures - of a Similar Exposure Group (and by extension, the exposure profile of each

member of the exposure group) be controlled to the point that the 95th percentile exposure is less than the PEL. Compelling evidence that the exposure profile is controlled can be developed by statistically analyzing the data and determining if the 95% upper confidence limit for the 95th percentile is less than the PEL. If a substance is strictly a chronic disease agent, the EASC suggests that it is reasonable to focus attention on the long-term average exposure or mean of the exposure profile. In the absence of specific guidance, it is reasonable to set a Long-term Average Occupational Exposure Limit (LTA OEL) at one third or less of the single shift PEL. Several statistical tests are available for determining if the true mean is less than the LTA OEL.

In summary, the EASC recommends that, as a general principle, exposures be controlled so that the 95th percentile is less than the PEL. This is applicable to both short-term exposure limits and full-shift TWA exposure limits. As a general principle, the long-term exposure to chronic disease agents should be evaluated against a LTA OEL. If exposures are assessed (and when necessary, work practices evaluated and controls modified or introduced) using an exposure monitoring program designed using the EASC guidance there will nearly always be some finite probability of a random over-exposure (e.g., short-term exposure within a shift or full-shift TWA, depending upon the type of PEL). If exposures are monitored and controlled according to the EASC guidance this probability should be no more than 5%, and preferably less.

Based upon the guidance in the preambles to the benzene and lead PELs and Appendix B of the formaldehyde PEL, it could be argued that such an exposure monitoring program would be considered appropriate for monitoring exposures to these substances. However, OSHA provides no similar guidance for assigning a statistical interpretation to the Z-table PELs or for the other single substance 6(b) standards. Furthermore, the sampling strategy specified by OSHA in each of the 6(b) standards will not reliably detect poorly controlled work environments.

AIHA recommends that OSHA clearly state both the immediate and long-range goals for chronic disease agent PELs. For example, the long-range goal might be to reduce the long-term mean exposure, as averaged over, say, one or several years of exposure, to below one half or one third of the single shift PEL. The immediate goal might be to limit the probability of exceeding the PEL to 5% or less. AIHA also recommends that OSHA clearly state the goal for controlling short-term exposures when there is a short-term exposure limit or ceiling standard. For example, the goal might be to limit within-shift exposure variation so that the probability of exceeding a short-term exposure limit or ceiling standard is no more than 5% or 1%, respectively.

Industrial hygienists could then design performance-based exposure monitoring and data analysis schemes that are both consistent with these goals - or statistical interpretations - and based upon state-of-the-art practices. Data collected, analyzed, and interpreted under such an exposure monitoring program would constitute "compelling evidence," as mentioned in formaldehyde standard, for demonstrating to OSHA that exposures are routinely controlled.

4. OSHA should adopt a peer-reviewed guideline for the derivation of PELs. AIHA believes that PELs must be based on the best scientific information available and must include a well-documented critical evaluation of the supporting information. Appropriate uncertainty factors also must be applied to compensate for the inherent uncertainties in the existing data and extrapolation to human populations.

A peer-reviewed guideline for the derivation of PELs is needed to provide consistency in this process. Such a guideline could also be used by the private sector to derive occupational exposure limits for agents that do not have legal or consensus standards. The guideline should address data collection and evaluation, identification of the critical endpoint, methodology or model selection in deriving the limit, and documentation requirements. Criteria for the selection of an 8-hr. TWA, STEL, and Ceiling Limit should be clearly established. Likewise, criteria for the designation of a skin notation should also be delineated. Since alternative work schedules have become more commonplace, they should be addressed in the PEL guidance. The body of knowledge concerning risk assessment and management will continue to grow as a result of strong research efforts in this area. Therefore, the methods used in establishing PELs must be part of a dynamic process, inclusive of innovative improvements as they are verified and peer-reviewed. There is a particular need to incorporate means whereby inherent uncertainties in the risk assessment process can be addressed.

PELs should be based on the best available data concerning relevant toxicity and exposure potential. Information sources can include on-line databases, standard texts, and solicitation of potentially important unpublished data from sources such as manufacturers and users. Every effort should be made to obtain original references for all data since review articles and other secondary references frequently contain errors or significant omissions of relevant information. Furthermore, it is often difficult to evaluate the technical merits of data cited in secondary references. Unpublished, confidential company reports should not be used unless a publicly available summary can be provided

which contains sufficient detail as to the methods used, results observed, and conclusions drawn, so as to permit a critical review of the adequacy of the report.

Data to be collected include physicochemical properties, toxicity, toxicokinetics, toxicodynamics, nuisance properties (e.g., odor), and exposure and population parameters. Available toxicity data vary widely in nature and quality from agent to agent. Therefore, all available data should be reviewed and its quality and value as a basis for setting a PEL determined. Several aspects of study design and reporting must be considered when assessing the quality of toxicity data; guidance is available from many sources.

Summaries of those studies determined to be adequate and appropriate for use in setting PELs should be included in the PEL documentation. Those data deemed valuable from studies judged inadequate will also be included with appropriate discussion of study inadequacies and data limitations; these data may be considered supporting in nature but should not be the basis of the PEL. The toxicity data documented for each PEL should include a summary of pertinent human and animal data, genotoxicity data, summaries of cancer hazard and reproductive hazard evaluations where available, and a summary of pertinent metabolism/toxicokinetic data. Some chemicals may cause effects in animals at inordinately high doses, under unusual exposure conditions, or under other unique circumstances. The relevance of such information should be considered. If available data on human experience establish results different from those obtained in animals, the human data should take precedence. Human experience should be emphasized to the extent credible data are available.

The goal of the toxicity data review is the delineation of all adverse effects relevant to the setting of a PEL. The rationale for a PEL may be derived from epidemiology data or human experience. When human data are lacking, the PEL will be derived from animal data. The basis for the PEL should generally be the adverse effect and associated NOAEL/LOAEL occurring first on the dose-response curve; this is referred to as the critical effect. The NOAEL is defined as the exposure level at which there are no statistically or biologically significant increases in frequency or severity of adverse effects between the exposed population and its appropriate control. Effects may be produced at his level, but they are not considered to be adverse. The LOAEL is the lowest exposure level in a study or group of studies that produces statistically or biologically significant increases in frequency or severity of adverse effects between the exposed population and its appropriate control. The manner by which other adverse effects are prevented by protecting against the effect chosen as the rationale for the PEL should be indicated in the documentation.

A risk assessment methodology to characterize the dose-response curve and derive the PEL should be selected based on the nature of the effect and quality of data. Several quantitative risk assessment methods exist that can be applied to low dose risk estimation of carcinogenicity; these include linear, mechanistic, tolerance distribution, time-to-tumor and biologically motivated models. An uncertainty factor approach would be appropriate for nongenotoxic effects where exposure thresholds can be demonstrated. Limitations of the traditional uncertainty factor method in PEL setting include lack of risk comparisons, limited consideration of the slope of the dose-response curve, and use of NOELs that are dependent on test sample size and therefore, may not be highly certain. In order to address some of these limitations, different models could be considered to develop the dose-response curve. For example, the Benchmark Dose approach, which is a statistical confidence limit on a dose corresponding to a specific increase in the response rate over the background rate, may address these shortcomings in some instances. This method utilizes the entire dose-response curve, does not require that a NOAEL be identified, and allows estimation of risk at multiple exposure levels.

Comparative toxicokinetic data should be utilized when available to help address uncertainty related to interspecies extrapolation. Generally, if credible human data exist, minimal uncertainty factors should be applied as compared to situations where only animal data are available. The seriousness and reversibility of the critical effect should also be considered in developing an appropriate uncertainty factor. For example, a lower factor may be used where the PEL is based on avoidance of localized, reversible, sensory irritation whereas higher factors should be applied where the critical effect is systemic in nature. Default assumptions should only be used in the absence of adequate data and should be scientifically defensible. Supporting documentation for the risk assessment and PEL derivation should include a discussion of uncertainties identified and means by which they are addressed. Identified uncertainties should drive future research projects.

5. Employers have a responsibility to assess the risks to the health of their workers and adequately control worker exposures to hazardous substances or agents for which there are no PELs. Employees must be fully consulted in the development of these risk assessments and informed of the results.

AIHA recognizes that even a streamlined and simplified PEL rule-making process will be a relatively slow process that will never be able to generate exposure limits for all of the substances that are likely to present a health risk to employees. Furthermore, there may be other workplace hazards, such as biologic agents or physical hazards, for which Permissible Exposure Limits may not be applicable. As a result, there will be many substances or agents present in the workplace which do not have regulated exposure limits. In the absence of these limits, employers still have a responsibility to control exposure to protect against material impairment to health or diminished functional capacity.

To ensure workers are adequately protected, it is the AIHA's position that employers formally document an assessment of risks created by any work and the means for controlling these risks. This involves evaluating the hazards of the substances or agents (their anticipated health effects, likely target organs, and the synergistic effects which may occur from combined or sequential exposures to other substances), the likely routes of exposure (inhalation, dermal, ingestion, or subcutaneous), the nature of the extent to which work groups could be exposed (the duration, frequency, and intensity of exposure), and the effectiveness of controls. These risk assessments must be developed in consultation with and the involvement of affected employees. They should be reviewed regularly and whenever there is a significant change in the health information or in the work.

In some instances there may be sufficient information available from manufacturers, suppliers, the literature in occupational medicine, industrial toxicology or other disciplines to set a self-imposed working standard. In these situations employers should develop recommended exposure limits using the best scientific information as was previously described and to conduct exposure monitoring to confirm compliance with these limits. These proprietary exposure limits and useful information about effective controls should be provided to other users of these substances, perhaps on the Material Safety Data Sheet or in product literature.

Responsible product stewardship suggests that employers should observe OELs for the non-PEL substances present in their workplaces that may present a risk to their employees as a result of exposure. These limits could be based on RELs, TLVs, or WEELs or on the recommendations of the supplier or manufacturer of the substance. OELs should, ideally, be risk-based exposure values derived from human experience or toxicologic studies. Where such data are not available, structure activity relationships (SAR) may be used as a last resort. AIHA recommends that such risk-based exposure limits, together with explicit operational precautionary and control statements, be included as part of an enhanced hazard communication program that has as its core an "Operational Material Safety Data Sheet (MSDS)." Operational MSDSs provide the prescribed procedures, the results to be recorded and the criteria for defining adjectives such as "use a suitable respirator" or "employ good local ventilation." In practice, however, the burden of these requirements would fall on the producers of non-PEL substances (generally larger companies) since they would be the first employer to have such substances in their workplace and are presently required to furnish an MSDS to their customers. Adoption of these recommendations would be economically efficient since it would internalize the cost of providing the health protection data needed by the multiple users of non-PEL substances on the relatively few suppliers or importers of substances.

For some substances medical examinations and appropriate tests would be a critical element of worker protection. Employers need to establish programs to perform appropriate medical tests when needed.

The principles obligating employers to perform workplace risk assessments have been the framework of worker health legislation in many countries, particularly within the European Union. These requirements would logically be a part of any comprehensive health and safety program standard issued by OSHA. The AIHA recommends this approach be adopted to supplement programs for updating Permissible Exposure Limits.

6. PELs should be consistent across occupational populations and should be accepted by other federal agencies when the goal is protecting occupational health.

PELs are derived for use by occupational health professionals to protect the health of workers in their environments. To accomplish this certain assumptions are made. The population at risk is assumed to be healthy and ranging in age from 16 to 72 years. Exposures are usually periodic averaging forty hours per week. There may be susceptible or hypersensitive individuals for which the PEL will not prevent adverse effects.

PELs, TLVs and WEELs at times have been inappropriately applied in other public health situations (e.g., control of air pollution exposures for the general public). Vast differences in general population exposure conditions and protection goals rule out the application of occupational limits to the control of environmental exposures for the general public. Most often the goal of public health is the elimination of all risk to a population of all ages and varying

degrees of health which may be involuntarily and continuously exposed to an agent. In the occupational environment susceptible individuals can be protected by use of additional exposure controls with the guidance of an occupational health professional. These options are not usually available within a community. It is therefore inappropriate and scientifically unjustifiable to use these limits in non-occupational applications.

AIHA believes that PELs must be consistent across occupational populations including, for example, manufacturing operations and office environments. PELs are health-based levels, which must take into account the common finding that a single chemical can have varying adverse effects at different exposures or doses. For example, a chemical may be a potential systemic chronic health hazard at one dose level and also be a transient sensory irritant at a different exposure or dose level. AIHA believes that the development of a single PEL must take into account all known adverse effects associated with that chemical. PELs must be set to protect against the lowest documented effect level based on sound science, thereby also affording protection against effects occurring at higher dose levels. AIHA is opposed to the establishment of multiple "tiered" PELs intended to be applied in different occupational settings. To ensure consistency across the occupational work force, PELs must be derived to protect against adverse effects across both gender populations. PELs set to protect against teratogenicity would need to be used and enforced regardless of a worker's gender.

PELs should be set without regard to control feasibility in an industry or workplace. It is true that workplace exposures may vary between industries, but it is also true that an agent's adverse health effects remain constant. Since the ultimate goal of a PEL is to control adverse effects, it is inconsistent to derive limits for varying industries based on control technology. In instances where engineering control is not feasible, enforcement directives should allow compliance via additional alternate control strategies (e.g., administrative controls or respirators as a last choice). Because these control strategies, especially the use of respirators, are often less effective than engineering controls, they should be used under the direction of occupational health professionals.

To further ensure consistency, OSHA PELs should be accepted by other federal agencies when the goal is protecting occupational health. The ultimate goals of most other agencies are to protect the public health, which sets them apart from an occupational environment. OSHA's primary goal is occupational safety and health and as such is in the best position to understand, evaluate and promulgate appropriate occupational exposure standards.

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