The Hierarchy of OELs

A New Organizing Principle for Occupational Risk Assessment

BY CHRIS LASZCZ-DAVIS, ANDREW MAIER, AND JIMMY PERKINS

For the past decade, the need to update OSHA's permissible exposure limits (PELs) has been the top issue for occupational and environmental hygienists, as reflected in annual surveys by AIHA®. This response is consistent with the important role OELs play in occupational hygiene practice. Unfortunately, existing infrastructures for generating OELs do not support the demands for OEL development and desperately need strengthening.

For more than 60 years, various regulatory and authoritative organizations around the world have established OELs for airborne workplace chemicals. Some limits are exclusively health based; others consider the technical and economic feasibility of applying controls.

But the OEL landscape is shifting. Many global trends suggest that we need to re-examine the way we look at OELs. For example, instead of treating OELs as the sole source of exposure guidance for assessing occupational risk or compliance efforts, occupational hygienists now regard them as a set of benchmarks.

Global trends that have contributed to this shift include:

- the changing regulatory environment, particularly in Europe, which has greater expectations for proactive risk management (including hazard assessment, risk assessment, and management of exposure controls)
- shifting centers of manufacturing and a more global perspective on solving occupational and environmental health issues
- various methodologies related to risk assessment and greater ability to transfer knowledge using technology

- the rise of control banding and occupational exposure and hazard banding, and the proliferation of general control recommendations without exposure data when relevant OELs are lacking
- the simple fact that only 2,000 of more than 600,000 chemicals in use worldwide are either regulated by a government statute or have a traditional OEL

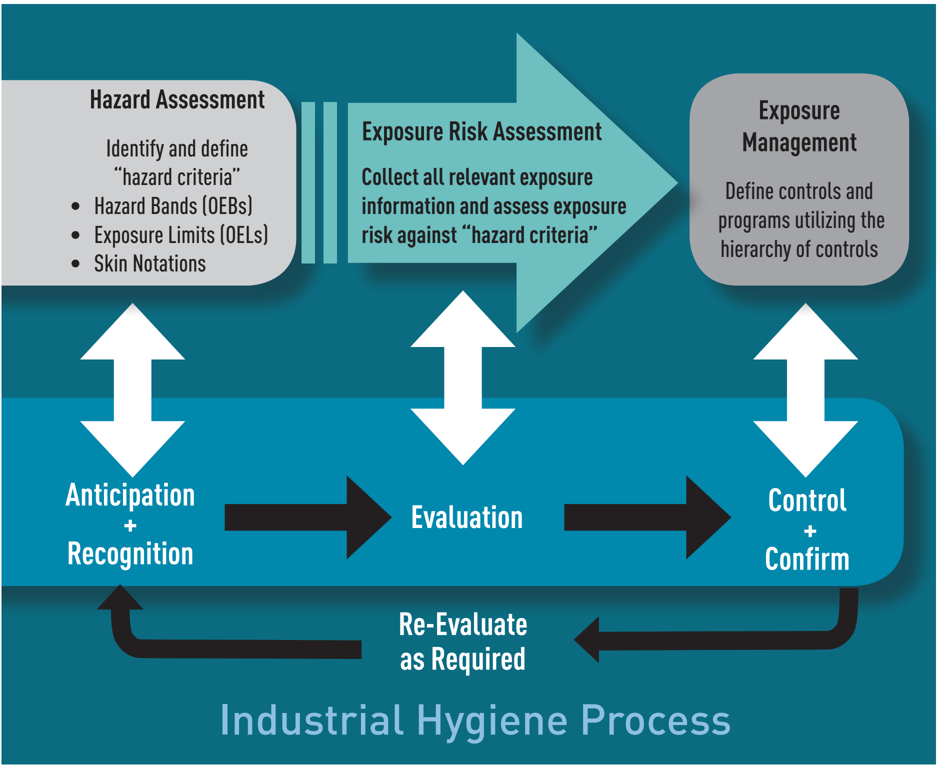
Given these global trends, this article proposes a hierarchy of OELs as an alternative paradigm for exposure risk management.

VISUALIZING THE HIERARCHY

OELs are just one component of a larger body of occupational exposure benchmarks and guidance values (OEVs) that serve as hazard criteria in the exposure risk assessment and management process (see Figure 1).

When an OEL does not exist or cannot be derived easily, alternative risk assessment methods can be used. Figure 2 organizes these risk assessment methods into a five-tier hierarchy. These tiers represent diverse methods for generating OEVs that can be used in a manner similar to OELs for preliminary assessments, screening processes, or specific risk assessments. Each method has a significant history in health risk assessment for chemicals. The lower tiers in the hierarchy can be used where little or no toxicological or epidemiological data are available for the chemical or chemicals of interest or where screening approaches are sufficient for the risk assessment needs. If more data becomes available, the methods in the higher tiers can be used.

Figure 1. The industrial hygiene process.



Tier 1: Quantitative Health-based OELs

OELs in this category can be used to estimate the probability of health risk at exposures above and below the OEL. Quantitative health-based OELs are often relied on to reduce the probability of cancer to a specified population risk (for example, 1 in 1,000 cases of exposure at a given level). Knowing the probability of health risk is critical for risk management; for example, this information helps quantify the net health impact of further exposure reductions.

This tier is traditionally limited to chemicals with epidemiology datasets, which allow for direct dose-response modeling in the risk range of interest for occupational settings. Some OSHA PELs and NIOSH recommended exposure limits (RELs) are derived based on such methods. Also, some recently proposed methods can extend the development of similar quantitative health-based OELs to chemicals with limited human data or based on animal toxicology data.

There are two types of quantitative health-based OELs. For the first type, the level of risk is set at a prescribed level; OSHA, for example, typically uses a target risk rate for carcinogens of 1 in 1,000, although after technical and economic conciderations, it has never achieved this target with any of its complete PELs.

For the second type, the risk at the OEL is not set; instead, the risk rate is estimated for that level of exposure. The uncertainty associated with the estimated risk should be evaluated and presented as part of the OEL documentation. Using models, it is possible to assess the quantitative risk and uncertainty around the estimated risk for any health-based OELs discussed in this article.

Tier 2: Health-based OELs

OELs in this category reflect an integrated analysis of all relevant data on health effects, including epidemiology, toxicology, and mechanistic studies. This analysis identifies critical health effects, dose-response behavior for sensitive adverse effects, and extrapolation that accounts for uncertainties in the data to estimate a dose that protects all or nearly all workers.

OELs in this tier are often derived by expert committees that incorporate a formal peer review. Examples include ACGIH TLVs, the Workplace Environmental Exposure Levels (WEELs) of the Occupational Alliance for Risk Assessment (OARS), and the Indicative Occupational Exposure Limit Values (IOELVs) of the European Union's Scientific Committee on Occupational Exposure Limits (SCOEL).

In some cases, a health-based OEL is further modified to incorporate other risk policy elements such as technical or economic feasibility. Health-based OELs represent the majority of OELs used by industrial hygienists.

Tier 3: Working or Provisional Health-based OELs

Many companies have committees that derive OELs to use internally and to support their product stewardship efforts. In general, these companies use methods consistent with those of the expert OEL-setting committees. However, company OELs may reflect the use of proprietary data not available to external groups, and they often lack independent external peer review. Many companies indicate such limits on their safety data sheets.

Tier 4: Prescriptive or Process-based OEVs

Alternative quantitative exposure benchmarks (OEVs that are used in a manner similar to OELs for assessing worker health risk for defined scenarios) may be available. In general, such OEVs use a prescribed derivation method. While this approach is simple and transparent, it lacks the flexibility to integrate complex data.

The Derived No Effect Levels (DNELs) represent one example of such a process. DNELs are required under Europe's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation. DNELs should be used with caution because no formal peer review is involved in their creation, and no requirements exist to ensure the competency of those who carry out the derivations. (The REACH guidelines also state that the DNELs are not equivalent to formal health-based OELs and that they should not be used as OELs.)

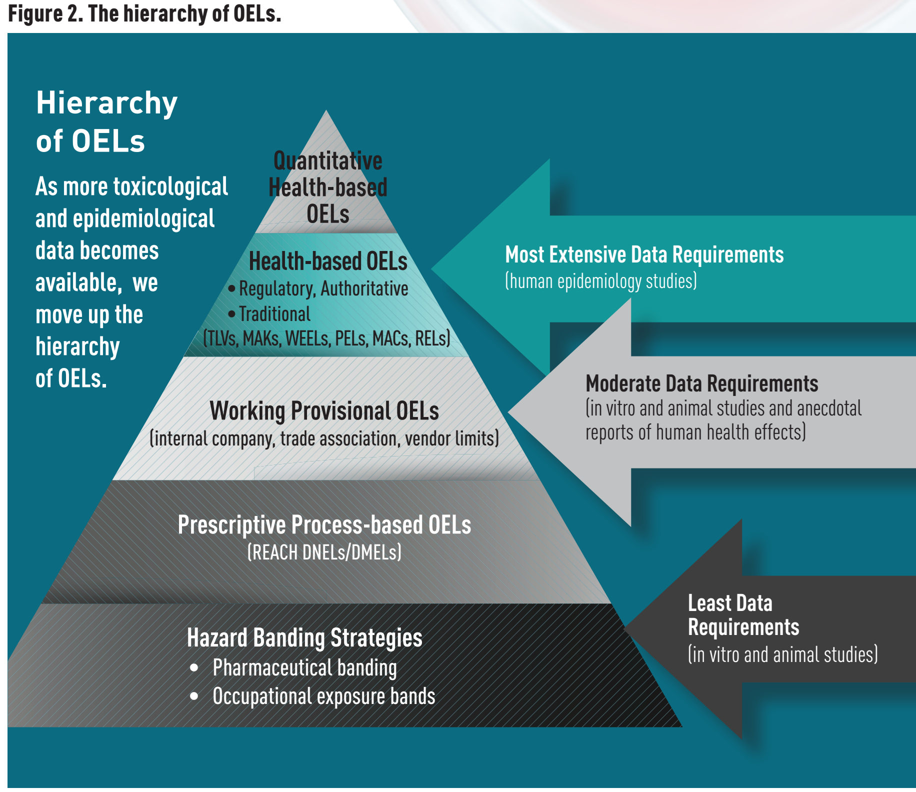
Tier 5: Hazard- or Category-based OEVs (Hazard Banding)

For many chemicals, data are too limited to derive a health-based OEL with the level of confidence desired. In cases where large numbers of chemicals must be assessed, a screening methodology is adequate for risk management decisions even though there may be adequate data to set an OEL. In either situation, hazard- or category-based OEVs that provide ranges of acceptable exposure can be employed to support risk assessment and risk management processes.

The methods for generating these OEVs are diverse. One technique, with a long history of successful application in the pharmaceutical industry, is hazard or occupational exposure banding (OEB). The OEB approach arranges health effects data (including qualitative descriptors) for various endpoints and, based on criteria established for each endpoint, places a chemical in a potency band. For many organizations, the potency bands are aligned with a provisional OEL range and predetermined risk management and control procedures. There is no published consensus method for setting OEBs, although many variations on the basic principle are available.

An alternative approach exists for chemicals with very limited data. This threshold-of-toxicological-concern (TTC) approach relies on basic chemical structure to assign exposure guidance from potency ranges derived from larger groups of representative chemicals. TTC is used extensively in food and pharmaceutical safety assessments, with potential extension to worker health and safety.

Figure 2. The hierarchy of OELs.



BENEFITS OF THE HIERARCHY

The hierarchy of OELs can help industrial hygienists select the most appropriate exposure benchmark for risk assessment and risk management. The hierarchy allows for the development of a quantitative benchmark for risk assessment for nearly all chemicals, even those with very limited data. At lower levels of the hierarchy, the available methods can accommodate less data and fewer analytical resources, and a greater number of chemicals are candidates for a given method. Therefore, industrial hygienists can use quantitative OEL alternatives even for data-poor chemicals. When only limited data are available, risk assessment requires fewer resources but likely has greater uncertainty, so the methods in the lower tiers are often designed to be precautionary in nature.

In some cases, adequate data may be available to set an OEL even if one of the methods in the lower tiers is selected for setting an OEV. For example, if the level of exposure to a chemical is very low, a preliminary or screening-level risk assessment using a precautionary OEL surrogate may be appropriate. This approach ensures health protection for the minimal exposure scenario and reserves resources for more robust OEL development for scenarios where the ratio between exposure and chemical potency is smaller (that is, the margin of safety is smaller).

OTHER INITIATIVES AND FUTURE DEVELOPMENT

The hierarchy of OELs evolved in response to changing dynamics in occupational risk assessment and risk management—the globalization of risk issues, enhanced ability for information transfer, and expectations that occupational risk assessments be addressed in a systematic way for a growing list of chemicals. The proposed hierarchy attempts to address these needs by organizing the tools and approaches already employed within occupational and environmental hygiene.

This effort to build an organizing principle for occupational risk assessment tools is consistent with other professional developments. For example, the International Programme on Chemical Safety is working to harmonize tools for chemical health risk assessment. In the U.S., several professional societies and nonprofit organizations are developing collaborative initiatives on OELs and related risk assessment methods. At their core, these collaborations, in addition to recent actions taken by government organizations, involve information exchange and transfer of technology.

For example, OSHA's recent decision to provide annotated references to existing health-based OELs as a supplement to their PELs is consistent with the hierarchy approach of providing information resources to meet the needs of occupational risk managers. OSHA's companion chemical substitution toolkit for determining safer chemical substitutions also supports this approach.

Regarding NIOSH, efforts to refine and harmonize hazard banding techniques (also called occupational exposure bands, or OEBs) is another example of technology transfer that helps occupational and environmental health professionals define risk and manage its consequences. NIOSH and AIHA are working jointly with OEL experts to categorize occupational exposure bands based on the Globally Harmonized System for Classification and Labeling of Chemicals (GHS).

The list of techniques in the hierarchy is not exhaustive. It is a beginning, and it will grow as new tools are developed. Moving forward, our profession has two main challenges regarding OELs. First, we need to start a dialogue with policymakers and regulators; the subject of OELs is one they need to "own." And second, we must engage stakeholders outside of the profession so we don't remain the lone voice on OELs. As multidisciplinary professionals within exposure science, we must become more inclusive to address this fundamental issue.

CHRIS LASZCZ-DAVIS, MS, CIH, is a director of AIHA and Principal, The Environmental Quality Organization, LLC, in Lafayette, Calif. She can be reached at chrisld@eq-organization.com.

ANDREW MAIER, PHD, CIH, is associate professor, Environmental and Occupational Hygiene, University of Cincinnati, Cincinnati, Ohio. He can be reached at maierma@ucmail.uc.edu.

JIMMY PERKINS, PHD, CIH, is a retired professor, Environmental Health Science, University of Texas School of Public Health. He can be reached at perkinsjl@uthscsa.edu.

This article was written with the assistance of the following individuals, who collectively have decades of experience in occupational and environmental health: Donna Heidel, CIH; Mike Jayjock, PhD, CIH; Perry Logan, PhD, CIH; John Mulhaussen, PhD, CIH; Karen Niven, PhD, MSc, RSP, CFIOSH, FFOH; David O'Malley; and Susan Ripple, MS, CIH.