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WEIGHING RISK-COST TRADEOFFS

Industrial Hygiene and the Economics of Risk

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FEATURES

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THE BANDING MARCHES ON

NIOSH Proposes a New Process for Occupational Exposure Banding

BY LAURALYNN TAYLOR MCKERNAN AND MELISSA SEATON

We've all been late to the party at one point. Try as we might, day-to-day responsibilities don't always allow us to stay on the cutting edge of everything. Occupational exposure banding (also known as health hazard banding) may be one of those items for you. If so, that's okay. But given the scientific rigor being applied to occupational exposure banding, now is the time to learn about OEBs and consider using them in your daily practice.

In March, *The Synergist*® published an article describing the new risk assessment approach called the hierarchy of occupational exposure limits (see Figure 1). This approach illustrates diverse methods for generating occupational exposure benchmarks and guidance values. At the pinnacle of the hierarchy are chemicals for which sufficient data exist to create a quantitative, health-based occupational exposure limit. But without extensive data, most practitioners can't reach this summit, which is why the lower levels in the hierarchy, including the creation of OEBs, are paramount.

Several thought leaders have written compelling papers about how and why hazard banding can aid our profession. Our colleagues in the pharmaceutical industry have been developing and using occupational exposure bands for decades. So why is NIOSH exploring this avenue now?

NIOSH recognizes the importance of authoritative OELs. In the last five years, NIOSH has published several high-caliber recommended exposure limits, including the first authoritative recommendation for carbon nanotubes. However, we also recognize that chemicals are being introduced at a rate that significantly outpaces OEL development. While NIOSH develops new OELs and updates existing OELs, guidance is needed for the thousands of chemicals that lack exposure limits. The recently proposed NIOSH occupational exposure banding process will be useful for dealing with the myriad unregulated chemicals in commerce.

FIVE BANDS, THREE TIERS

To address this need for guidance, in late 2011 NIOSH invited many thought leaders from across the U.S. to share their knowledge of hazard banding. These expert opinions and experiences informed NIOSH's proposed approach to occupational exposure banding.

The process would sort chemicals into five bands (A through E), with each band representing a different hazard level. Chemicals with the lowest toxicity would be grouped in Band A, while Band E would include the most toxic chemicals. In general, chemicals in Bands D and E have the potential to cause irreversible health effects at relatively low doses, while chemicals in Band A have the potential to cause only mild and reversible health effects.

The proposed process comprises a three-tiered evaluation system (see Figure 2) and uses available toxicological data to define a range of concentrations for controlling chemical exposures. Users begin the OEB process by performing a Tier 1 evaluation, which relies on hazard codes and categories from the Globally Harmonized System for Classification and Labeling of Chemicals (GHS). The Tier 1 evaluation can be done quickly and is intended for chemicals for which relatively little information or expertise exists.

Next, users can decide whether sufficient information is available to refine the band and move to a Tier 2 or Tier 3 evaluation. Tier 2 involves review of authoritative summaries of chemical toxicity, while Tier 3 requires toxicological expertise and assessment of the scientific literature. These evaluations are data intensive, requiring users to walk through a more detailed process, health endpoint by health endpoint. Additional expertise is necessary to understand the criteria of each health endpoint, and professional judgment is required to select the appropriate band. During the Tier 2 evaluation, all endpoints are considered in their totality to determine whether enough high quality data exist to make an appropriate banding decision.

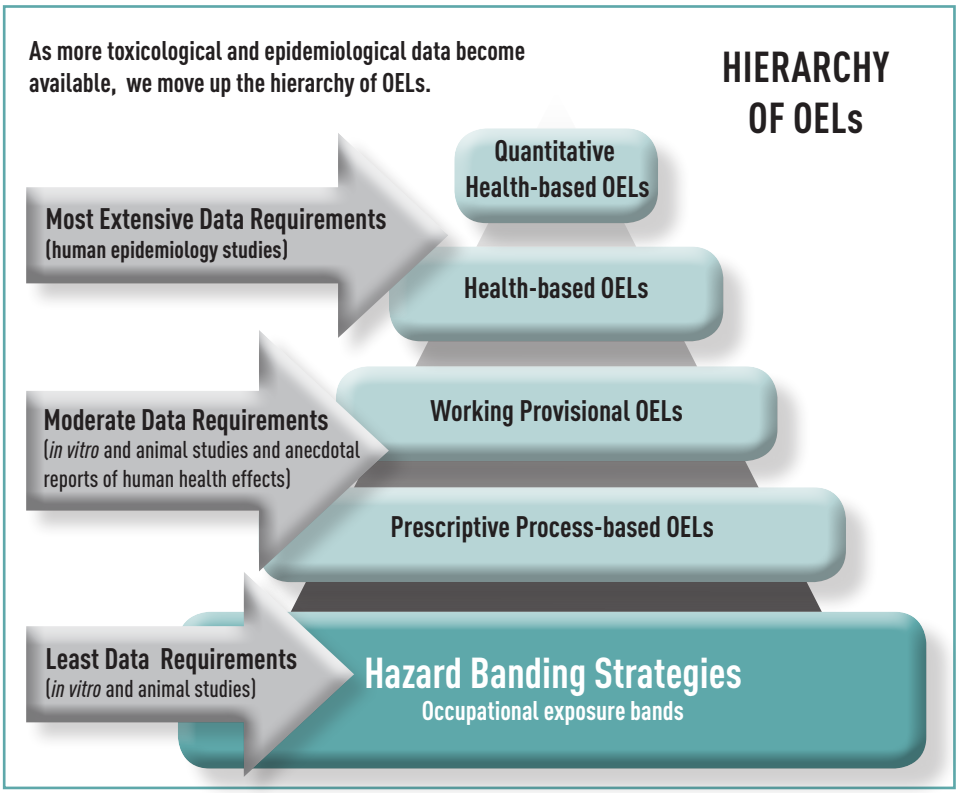
The value of the Tier 1 process is that it allows the user to quickly identify the bad actors (those in Bands D and E) and target those chemicals for elimination and substitution. Occupational exposure banding is designed to supplement existing OELs and could be used as a prelude to OEL development.

CONSISTENCY AND FLEXIBILITY

To aid with risk characterization, the proposed NIOSH occupational exposure banding process is consistent with GHS hazard codes and categories. GHS is a unified way of communicating information regarding hazardous materials to workers who may be exposed to these materials. It was designed to make classification and labeling of elements for hazardous materials more consistent. OSHA adopted GHS in the 2012 revision of its Hazard Communication Standard. The proposed NIOSH occupational exposure banding process utilizes GHS hazard codes and categories to determine the exposure band that best fits a given chemical in Tier 1. In addition, the toxicological criteria for each band are aligned with GHS criteria. This consistency increases the applicability of NIOSH's proposed process.

Another strength of the process is that it allows users to incorporate their knowledge of specific chemical toxicity. The Tier 1 evaluation requires GHS hazard codes to evaluate chemicals; because users are sometimes aware of hazards for which GHS hazard codes may not be available on public databases, the proposed process

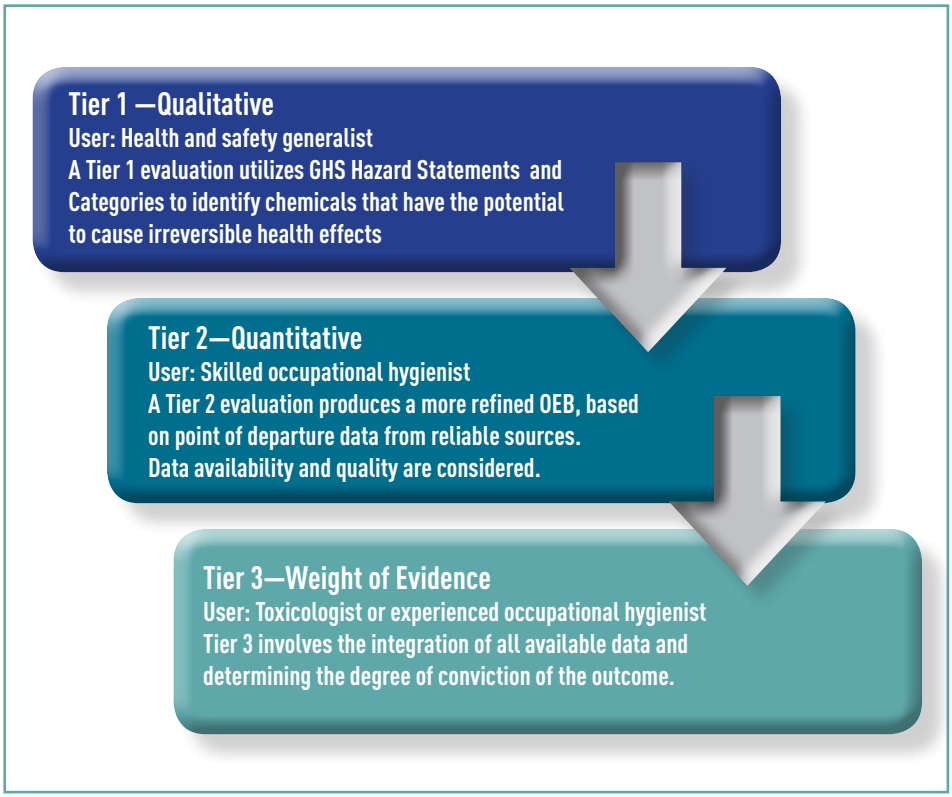
Figure 1. The hierarchy of OELs.



THE BANDING MARCHES ON

allows users to input their own hazard codes based on what they know about the chemical. Because of this flexibility, users can assign a hazard band for proprietary chemicals about which they have toxicological information but no GHS designations.

Figure 2. The NIOSH proposed Occupational Hazard Banding process includes a three-tiered evaluation system.



VALIDATION

To validate the proposed NIOSH occupational exposure banding process, we need to ascertain how well the procedures produce accurate results that concur with what authoritative bodies have said about chemical toxicity. We have spent significant time validating Tier 1 and have just begun validating Tier 2.

To validate Tier 1, we compared the OELs of approximately 800 chemicals to the occupational exposure bands (OEBs) that resulted from a Tier 1 evaluation of those chemicals. Since each of the five bands represents an estimated range of exposure limits, we can determine whether the assigned OEB range includes the existing OEL value for that chemical. Our criterion for acceptance of the Tier 1 evaluation was that the assigned OEBs would either contain the OEL or be more protective than the OEL for 80 percent of the chemicals. The analysis of the validation results has strengthened our banding procedure. Our full Tier 1 validation, including detailed descriptions of lessons learned, will be published with the proposed NIOSH occupational exposure banding process, tentatively scheduled for later this year.

PITFALL AND PROMISE

With all the potential OEBs have to help protect worker health, we would be wise to recognize a potential pitfall: the old adage "garbage in, garbage out" still applies. Although the extensive data requirements supporting quantitative risk assessment are not needed for OEBs, you still need some high quality data to have confidence in the resulting band. Recent events have given us an opportunity to attempt an OEB assignment for some understudied chemicals spilled at a work site. In this case, we couldn't locate enough publicly available data to fulfill our established minimum data requirements for OEBs; therefore, we couldn't band the chemicals. This unfortunate scenario will remain a possibility. But the built-in flexibility of the process allows users to incorporate specialized knowledge about a chemical into a Tier 1 evaluation when GHS codes and categories are unavailable.

In addition to OEBs, occupational hygienists have many other tools in our toolbox—tried and true approaches that are still valid and should be used whenever appropriate. But OEBs hold much potential for protecting worker health. Plenty of chemicals that lack sufficient information to set an OEL do have enough to create an OEB. The proposed NIOSH occupational exposure banding process can be used with limited information and resources, and can be performed quickly by toxicologists, occupational hygienists, and health and safety specialists. Through OEBs, companies can protect their workers from many of the tens of thousands of chemicals that lack OELs. This is where OEBs hold their great promise for our profession. S

Acknolwedgements: The NIOSH team developing the NIOSH occupational exposure banding process also includes Andy Maier, George Holdsworth, Chris Whittaker Sofge, Bernard Gadagbui, Steve Gilbert, T.J. Lentz, and Christine Uebel. Donna Heidel (formerly NIOSH) was also critical for the process.

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