Hyped about Hazard Banding

New Hope for an Established Practice

BY SUSAN D. RIPPLE

Occupational exposure limits (OELs) are an important part of managing chemical health and safety programs. But constant changes in the work environment have resulted in an exponential increase in the number of chemicals for which adequate toxicity or exposure data—the information needed to set traditional OELs—are not available.

The majority of chemical substances in global commerce do not have formal OELs. Furthermore, employers and workers often have difficulty determining how to control exposures with OELs. In fact, the International Labor Organization has estimated that over 90 percent (about 2.7 billion) of the world's workers do not have the assistance of a professional to even assess the hazards in the workplace, much less provide guidance on proper risk management techniques.[1]

Control banding arose in response to this lack of guidance. Based on a process similar to the U.S. Centers for Disease Control (CDC) Biosafety Levels for control of pathogenic microbials, control banding is a qualitative strategy that allows industrial hygienists to manage risk in situations characterized by many uncertainties, particularly a lack of OELs. Control banding augments the traditional industrial hygiene approach—anticipation, recognition, evaluation and control of stressors—by grouping chemicals according to the severity of their effects.

A variety of control banding toolkits are used around the world. Users adapt the process to their needs and their risk management strategy. Because "control banding" does not translate well in many languages, terms such as "Risk Management Toolbox"[2] and "International Chemical Control Toolkit"[3] are being used with increasing frequency.

Control Banding Guidance from NIOSH

On Aug. 17, NIOSH issued Publication No. 2009-152, *Qualitative Risk Characterization and Management of Occupational Hazards: Control Banding*. The document reviews published literature and related proceedings on control banding and provides critical analyses of control banding strategies. To download the document, visit www.cdc.gov/niosh.

Hazard banding, the subject of this article, is simply the first step in the control banding process. Hazard banding groups agents of similar toxicity or similar toxic mechanisms into "hazard groups" or "hazard bands." For chemicals, hazard banding provides a range of acceptable exposure levels based on expert evaluation of the dose-response relationships determined through animal testing. Although many hygienists prefer the more official peer-reviewed OELs, control banding and hazard banding provide a mechanism for evaluating hazard and risk in situations where OELs do not exist.

For this discussion, hazard banding strictly refers to "health hazard banding" and does not include the often controversial qualitative exposure assessments (risk characterization) done in control banding, nor does it touch on the predicted control strategies that might be used to perform risk management in control banding. However, once the hazard banding process has been completed, the occupational hygienist can determine the risk assessment and control strategies, thereby completing the IH process. Hazard banding does not replace industrial hygiene expertise—specific operating knowledge and professional judgment are required for implementation of the best "reasonably practicable" combination of controls to minimize risks to workers.

Origins of Qualitative Risk Management

Prior to the creation of OELs, most large chemical manufacturers used qualitative exposure assessment processes and qualitative health hazard reviews. Since the early 1950s, for example, The Dow Chemical Company has assigned risk management control strategies based on a "health effects rating." Using these ratings in conjunction with information about the degree, duration and frequency of exposure, hygienists at Dow would create a monitoring plan to verify that a control strategy adequately controls exposures at the targeted levels.

The pharmaceutical industry has embraced control banding, also known as performance-based exposure control limits (PB-ECLs), extensively for over 20 years. In the late 1980s, the pharmaceutical industry began using PB-ECLs and controls to protect workers from exposure to drugs with known therapeutic effects. The high potency of some pharmaceutical compounds required alternatives to setting OELs, especially for early development compounds with limited information. Because there are rarely R-phrases for these drugs, utilization of the actual toxicity and therapeutic data are used in a matrix.

Although the pharmaceutical companies agreed on a strategy for categorizing the health hazards into safe PB-ECLs, there are still today as many control strategy schemes as there are pharmaceutical companies. Due to the varying degrees of risk in their facilities, some companies want more options for controls; others prefer to limit control options. For example, a company that manufactures only one or two products may need only five control options, particularly if those substances are all solid particles. Facilities that handle a variety of substances in various physical states, such as dusts and vapors, with a wide range of operating temperatures and pressures may desire more options to control exposure potential.

Applications of Hazard Banding

Decoupling hazard banding from control banding allows assessment of hazards to be utilized in hazard communication and awareness efforts after a substance has been introduced in a workplace. Better yet, the hazard assessment can aid the substitution or design of controls. Although hazard banding is not a substitute for OELs, it yields insight into the relative toxicity of substances. Occupational hygienists can use this information to provide expert guidance for hazard ranking and prioritization.

In the European Union–particularly in applications of the toolkit provided by the

Figure 1. A hazard-band evaluation of Dichloracetic Acid using the matrix provided by eCOSHH.

		Virtually Non-Toxic	Low Toxicity	Moderate Toxicity	Toxic	High Toxicity	Comments/Rationale
Criterion	**ND**	**A**	**B**	**C**	**D**	**E**	
Acute toxicity (Rat oral LD50)		>2,000 mg/kg Rats: 2820 to 4480 mg/kg Mice: 5520 mg/kg Dogs: >5000 mg/kg, dog emesis at 250 mg/kg	300-2,000 mg/kg	50-300 mg/kg	5-50 mg/kg	<5 mg/kg	
Acute toxicity (Rat inhalation LC50)- Not Available		>10,000 ppm	>10,000 ppm	1000-10,000 ppm	100-1000 ppm	1-100 ppm	Extrapolated from comments only
Sensory irritation (RD50)- Not Available		>3,000 ppm	>3,000 ppm	300-3000 ppm	30-300 ppm	1-30 ppm	Corrosive to respiratory tract
Skin or eye irritation		mild to moderate	moderate to severe	severe to corrosive	corrosive	corrosive	Corrosive to eyes, skin and respiratory tract; Inhalation of high concentrations can cause pulmonary edema
Irritation threshold (ppm)- Not Available	x	>1000	100-1000	10-100	1-10	<1	
Target organ toxicity NOEL **Neurotoxicity**		>1000 ppm >100 mg/kg/d	**>1000 ppm** **10-100 mg/kg/d**	**100-1000 ppm** **1-10 mg/kg/d** **Moser: 16 mg/kg/d** **LOAEL Neurotox**	10-100 ppm 0.1-1 mg/kg/d	1-10 ppm <0.1 mg/kg/d	
Severity of target organ toxicity		**severity of the toxicity can push the above NOEL into a higher cell**					
Repro/dev tox NOEL		>300 mg/kg/d	30-300 mg/kg/d	3-30 mg/kg/d	0.3-3 mg/kg/d LOAEL 12.5 mg/kg/d (90d study in dogs)	<0.3 mg/kg/d	LOAEL 12.5 mg/kg/day (sodium salt) in dogs 90 day study showed degeneration of testicular germinal cell epithelium and syncytial giant cell formation
Reproductive toxicity		**severity of the toxicity can push the above NOEL into a higher cell**					
Developmental toxicity		**severity of the toxicity can push the above NOEL into a higher cell**					14 mg/kg/day was identified as a NOAEL for dev. Tox
Genetox		negative	equivocal	likely / limited or based on in vitro	positive WOE including in vivo	positive WOE and potent	
Cancer dose-NOEL/NOAELs		>300 mg/kg/d	30-300 mg/kg/d	3-30 mg/kg/d	0.3-3 mg/kg/d	<0.3 mg/kg/d	
Carcinogenicity potential		**severity of the toxicity can push the above NOEL into a higher cell**					
Warning properties / odor		good: 0.04 ppm	good	fair to none	poor to none	poor to none	
OEL range (mcg/m^3 and ppm)		≥1000	≥100, <1000	≥10, <100	≥1, <10	<1	
Skin notation		No	Yes LD50=510 mg/kg				greater than 200 mg/kd
Sensitization notation		No	Yes				

Control of Substances Hazardous to Health regulations (COSHH)—health hazard bands are determined using regulatory risk phrases, or R-phrases. These R-phrases are assigned to a particular hazard or toxicity profile for each tested toxicity endpoint. For countries that do not utilize R-phrases, the EU toolkit offers little assistance. For example, in the U.S., workers, employers, and even hygienists must use the confusing toxicity phrases found in Section 11 of most material safety data sheets (MSDSs). Translating those phrases into R-phrases in order to determine hazard bands has been virtually impossible; experts must first translate the toxicity endpoints. As a result, various groups are working together to establish guidance for employers and workers on the relative (albeit qualitative) health hazard groups.

The United Kingdom Health and Safety Executive developed an electronic tool, referred to as the eCOSHH toolkit, to aid employers in performing the control banding risk assessments, with the ability to archive the assessment and return for future reference[3]. The simple matrix provided by the eCOSHH toolkit allows hygienists to derive a health hazard group—and thus an acceptable range of exposures for further controls. Figure 1 shows the evaluation of Dichloroacetic Acid (DCA) using the eCOSHH methodology.

The example in Figure 2 is an alternative matrix for evaluating the toxic effects of DCA utilizing a matrix that evaluates the toxicity endpoints. This matrix uses the toxicity dose-response data found in a compendium of toxicity studies and summarizes the most pertinent health effects. Figure 2 portrays a combination of the WEEL hazard banding project and matrices used by pharmaceutical and chemical companies. Both Figure 1 and Figure 2 derive essentially the same OEL-range to use for controls: < 1 ppm according to the eCOSHH matrix (Figure 1) and between 0.5 ppm and 5 ppm vapor according to the AIHA-WEEL matrix (Figure 2). If R-phrases are not readily available, the MSDS phrases and data found in the AIHA-WEEL matrix can supply the same or better guidance. (For more information about the AIHA-WEEL hazard banding project, see the sidebar.)

Advantages and Disadvantages

Hazard bands are screening-level hazard groups, often based on limited data. Critical limitations of hazard banding include the lack of standardized hazard phrases in MSDSs and the lack of expertise to translate those phrases into hazard

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Figure 2. Dichloroacetic acid matrix evaluation of toxicity endpoints.

Hazard Group vs. Target Exposure Range

Hazard group	Target airborne concentration range	R phrases
A -Skin and eye irritants	>1-10 mg/m3 dust >50-500 ppm vapor	R36, R38 All substances that do not have R phrases in groups B - E
B - Harmful on single exposure	>01-1 mg/m3 dust >5-50 ppm vapor	R20/21/22, R40/20/21/22
C -Severely irritating & corrosive, skin sensitizers	>0.01-0.1 mg/m3 dust >0.5-5 ppm vapor	R48/20/21/22, R23/24/25, R34, R35, R36/37, R37/38, R36/37/38, R37, R39/23/24/25, R41, R43
D -Very toxic on single exposure, reproductive hazard	< 0.01 mg/m3 dust < 0.5 ppm vapor	R48/23/24/25, R28/27/28, R39/26/27/28, Carc Cat 3 R40, R60, R61, R62, R63
E - Carcinogen, occupational asthma	*Seek Specialist Advice*	Muta Cat 3 R40, R42, R42/43, R45, R46, R49
S: Skin and eye contact	***Prevention or reduction of skin and/or eye exposure***	**R21, R24, R27, R34, R35, R36, R38, R41, R43, R48/21, R48/24, plus R -phrase combinations containing these. Skin**

Hazard Banding's Role in WEEL Development

BY ANDREW MAIER

The mission of the AIHA® Workplace Environmental Exposure Levels (WEEL) Committee is to develop health-based airborne chemical occupational exposure limits (WEELs) where adequate guidance for use by health professionals is not available. WEELs are developed using science-based risk assessment methods by a multidisciplinary volunteer team of industrial hygienists, epidemiologists, occupational medicine professionals and toxicologists. The committee uses a tiered review process that includes a scientific review of all the health effects, exposure, and toxicity information for the chemical. The product of this effort is the WEEL documentation that summarizes the data and provides the rationale for the WEEL and any notations that are assigned. The full WEEL documentation is published, and the WEEL value and notations are also published in the *WEEL Handbook*. Currently, over 100 WEEL values are available.

A cornerstone of developing a WEEL is the critical examination of the available data. Hazard banding has provided an important tool to organize the available data, identify key data gaps that affect the overall weight of evidence for the WEEL, and help set priorities for WEEL development. If the evaluation indicates that data are too limited for a WEEL, then the data matrix may be used by other groups for hazard banding to provide interim guidance. The WEEL committee continues to evaluate and validate hazard banding methods and is studying best practices for making use of this tool.

AIHA members interested in lending their expertise to developing additional occupational exposure limit resources for the profession or who want to learn more about WEEL development are encouraged to visit the WEEL web page at www.aiha.org or contact Andrew Maier, WEEL Committee chair, at maier@tera.org.

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groups by non-toxicologists. Since hazard banding is a preliminary attempt to categorize relative hazards of a substance to assist OEHS personnel in assigning the right controls, such as ventilation and PPE, the inability to categorize hazards can seem insurmountable. Another concern is that, for substances that are solid particles or aerosols, hazard banding confronts the same dilemma that exists for setting an OEL: insufficient inhalation toxicology data.

But, where hazard data exist, hazard banding compares a substance's relative hazard risk to other, better characterized substances. Some experts are working to validate aspects of control banding and hazard banding, including their estimation of exposure limits, prediction of exposures and adequacy of controls. Verification of these methodologies might build occupational hygienists' confidence in control banding and hazard banding. In their current form, control banding and hazard banding will not reduce the need for OELs, but they can protect workers in situations where guidance is not available.

Hazard banding provides a tool for EHS professionals to anticipate, recognize and evaluate hazards in the workplace. This is the goal we all try to achieve in our practice. The AIHA Control Banding Working Group and the WEEL Committee believe that providing the relative hazard bands for the substances under review by qualified and seasoned toxicology and IH specialists will serve the IH community in the qualitative aspects of risk management.

Volunteers Sought for Control Banding Working Group

AIHA members interested in promoting effective control banding strategies are encouraged to join the Control Banding Working Group (CBWG). For more information, visit the CBWG web page at www.aiha.org or contact Susan Ripple, CBWG chair, at SDRipple@dow.com.

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CONNECT FOR CREDIT

Resources

1. **International Labour Organization (ILO):** ILO Toolkit. [Online] Available at www.ilo.org/public/english/protection/safework/chemsfty/index.htm (accessed Mar. 9, 2007).
2. **International Labour Organization (ILO):** ILO Toolkit. [Online] Available at www.ilo.org/public/english/protection/safework/ctrl_banding/rm_toolbox.pdf (accessed Aug. 26, 2009).
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4. **Health and Safety Executive:** COSHH Essentials. [Online] Available at www.coshh-essentials.org.uk/ (accessed Aug. 26, 2009).