SCHC 2017

Safety Assessment for Occupational Settings: Occupational Exposure Level (OEL) Development and Exposure Modeling to Estimate Risk

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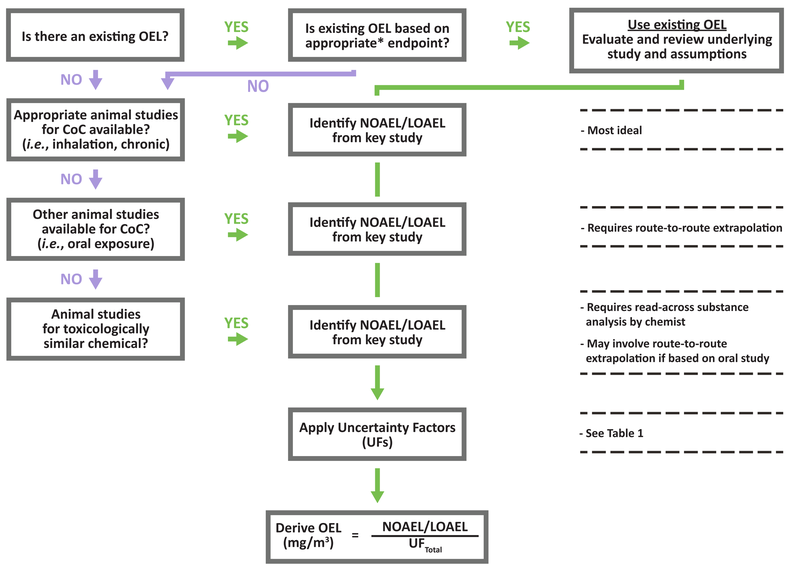
BACKGROUND

- Recent changes to regulatory programs, such as the Toxic Substances Control Act (TSCA) reform in the US and the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) legislation's requirement to acquire a derived no effect level (DNEL) in the European Union, highlight the need for companies to develop robust chemical stewardship programs with an increased emphasis on worker safety.
- While traditional monitoring programs often focus on chemicals with established occupational exposure limits (OELs) (*e.g.*, from the National Institute for Occupational Safety and Health [NIOSH] or American Conference of Governmental Industrial Hygienists [ACGIH]), many industries – from consumer products and cosmetics to manufacturers of building, technology, or clothing materials – are finding it necessary to monitor and develop safe exposure levels for chemicals that do not have an OEL from any authoritative agency.
- Here, we present a streamlined approach and framework for assessing worker safety with a screening-level risk assessment that compares derived safe inhalation exposure levels (such as OELs) with an estimate of worker exposure to a non-carcinogen.

TOXICITY ASSESSMENT AND OEL DERIVATION

- The purpose of developing an 8-hour time-weighted average (TWA) OEL is to define a safe or acceptable inhalation exposure level for workers during a typical 8-hour shift.
- This level is intentionally developed to be conservative (*i.e.*, health-protective) and is typically based on the most sensitive endpoint identified in a high-quality toxicology study.
- The level of effort required to develop an OEL is a function of the amount and type of data available for a particular compound. Important considerations include the amount of data (and whether those data are confirmatory or conflicting), whether the data are from human or animal studies, and the route of exposure.

Figure 1 OEL Development Process



*Notes: CoC = Chemical of Concern; LOAEL = Lowest Observed Adverse Effect Level; NOAEL = No Observed Adverse Effect Level. *Typically, OELs are for non-cancer health effects. If carcinogenicity is a concern, a different toxicity criteria value will usually be required.*

Table 1 Default Uncertainty Factors for Systemic Effects

UF	Accounts for Differences in:	Default Value
Interspecies	Differences in metabolic rate per body weight	Allometric scaling
	Remaining differences	2.5
Intraspecies	Worker	5
	General population	10
Exposure Duration	Subacute to subchronic	3
	Subchronic to chronic	2
	Subacute to chronic	6
Dose-Response	Use of LOAEL *vs.* NOAEL	3
Quality of Whole Database	Completeness and consistency of available data	3

Notes: Adapted from the ECHA, "Guidance on Information Requirements and Chemical Safety Assessment" (2012). Defaults may change on a case-by-case basis with proper scientific justification.

EXPOSURE ASSESSMENT

- Quantifying accurate exposure estimates for workers can vary in complexity.
- Screening-level models, such as the United States Environmental Protection Agency (US EPA) Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER) or the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) Targeted Risk Assessment Tool (TRA), can generate exposure estimates with modest data inputs and a relatively low level of effort.
- Because of the screening-level nature of these models and the conservative assumptions used, any exposure estimates calculated with these models will likely be overestimates.

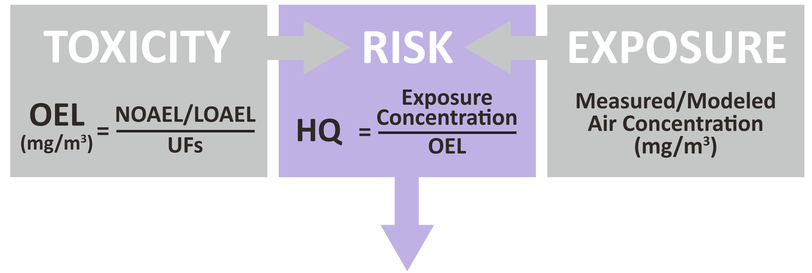
Table 2 Comparison of Exposure Modeling Tools for Occupational Exposure Estimates

	US EPA ChemSTEER	ECETOC TRA
Pros	• Can use exact values for chemical-specific and adjustable parameters • Accepted and used by US EPA to estimate workplace exposures • Methodology is well documented	• Widely used in European Union/under REACH • Easy to use and has low data input requirements
Cons	• Relatively complex model to run • May require additional user assumptions (*e.g.*, room ventilation, room volume)	• Parameter descriptions are crude ranges, not exact values • The model's preset exposure scenarios or occupational tasks are not transparent (*i.e.*, lacking exact parameters used to characterize the scenario)
Data Needs	• Exact values • Vapor pressure; activity duration; air speed; container opening diameter; room volume; room ventilation; number of workers in a room	• Categories, not exact values • Vapor pressure (4 categories); duration of activity (4 categories); fraction in mixture (4 categories); ventilation conditions (6 categories)

SCREENING-LEVEL RISK ASSESSMENT

- The risk posed by a chemical can be evaluated by comparing estimated worker exposure levels and derived safe levels of exposure to that chemical.
- For a screening-level risk assessment, the derived or established OELs are compared to the estimated worker exposures for a given substance to generate a hazard quotient (HQ).

Figure 2 Risk Evaluation Considers Toxicity and Exposure



If HQ ≤ 1 = NO RISK = OEL is sufficiently health-protective/safe

If HQ > 1 = POTENTIAL RISK = Recommend risk mitigation measures

CONCLUSIONS AND CONSIDERATIONS

- Many substances do not have authoritative OELs for employers to use when assessing workers' health and safety surrounding chemical exposures.
- Thus, employers must independently develop OELs, which may be a time-intensive process, depending on data availability.
- Exposure modeling efforts, however, proceed relatively rapidly once the exposure scenario is characterized.
- A screening-level risk assessment approach can proactively address potential worker health issues and limit liability by eliminating health risk concerns in specific occupational situations or prioritizing substances for further evaluation if more refined assessments are needed.
- Such analyses are useful for determining whether air monitoring and/or risk mitigation measures are warranted.