Navigating the Complex Landscape of Occupational Exposure Limits

Andy Maier, Ph.D., CIH, DABT

2024 SCHC Annual Meeting

Background in OEL Science

- Science management of the volunteer WEEL Committee – Committee setting OELs for 40 years
- Former Fellow with NIOSH – team member for exposure banding, IDLH, and skin notation methods
- Instructor and prior faculty in industrial hygiene at the University of Cincinnati
- Former site IH for petrochemical and manufacturing plants
- Principal Scientist at Integral Consulting Inc. – a science consulting firm (amaier@integral-corp.com)

View Resume

Why This Topic Now?

- Very active focus on occupational health and occupational exposure limits (OELs)
  - OECD Harmonisation
  - EPA TSCA Occupational Scenario Risk Evaluations

- Despite significant history in OEL setting
  - Confusion on differing OELs
  - Significant push to harmonize methods

- Merging of General Population and Worker Limits
  - Suggestions that “traditional OELs” may not be adequately not protective
  - Push for adopting EPA methods for all worker assessments

Role of OELs in Occupational Health Programs

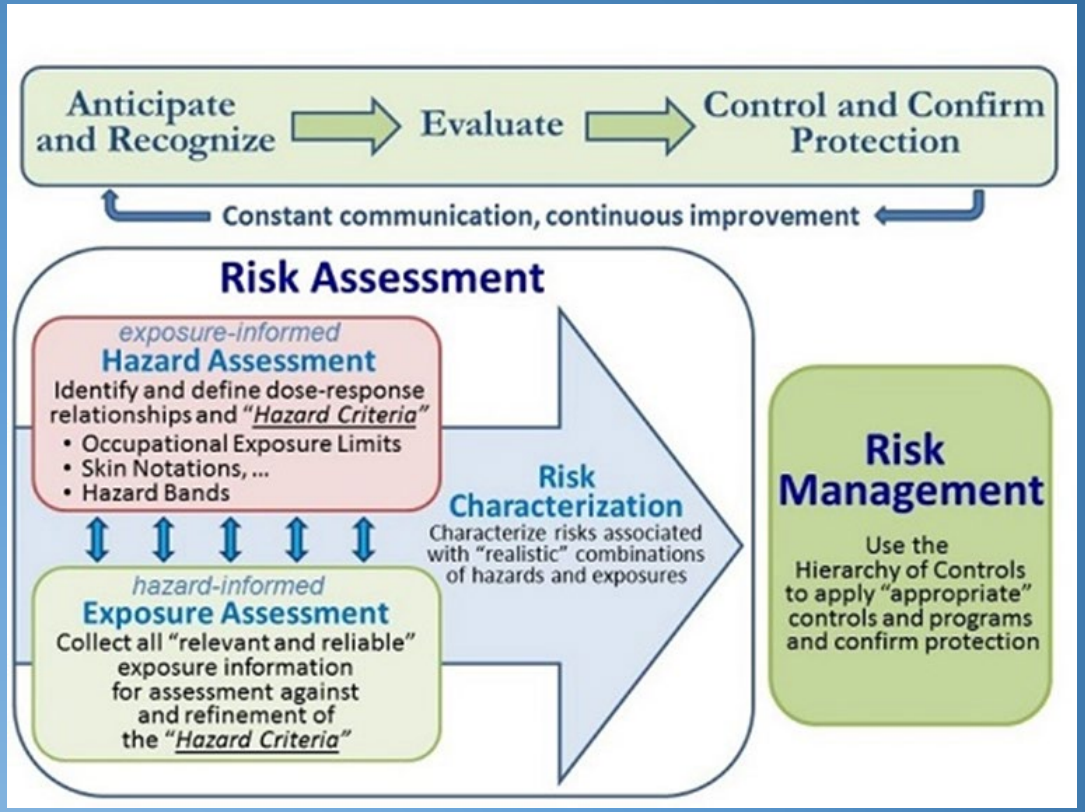
Integral to risk assessment and management process

Most IHs do not have deep toxicology expertise – rely on expert values

ALARA not an adequate approach

Key component of design decisions for exposure control

Aid in medical and health surveillance programs



Jahn et al., 2015. A Strategy for Assessing and Managing Occupational Exposures. Fourth Ed. AIHA.

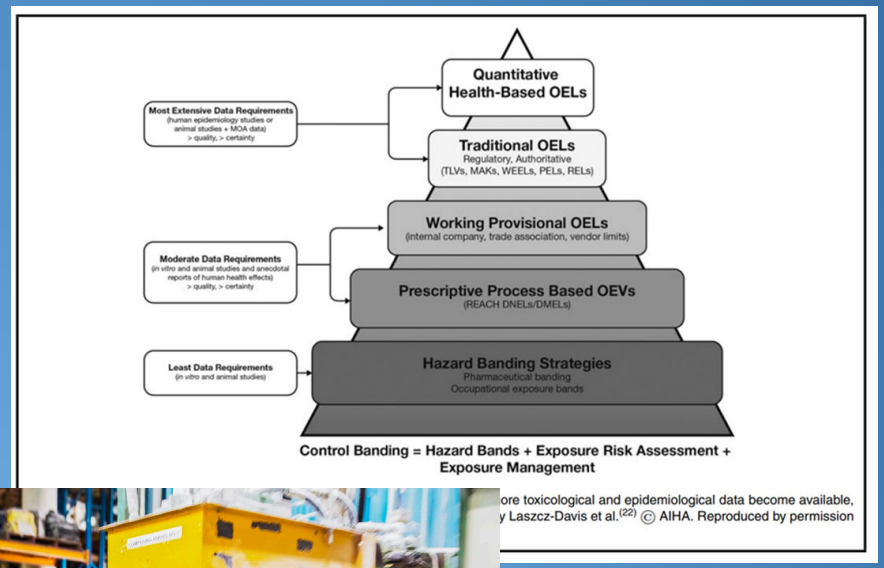
What Question Are We Trying To Answer?

- ☹ Which of these OELs is “correct”?
- ☹ Which OEL is most protective?
- ☺ What is the likely upper bound range for occupational exposure that is safe for most workers?
- ☺ What is the lowest value that can be derived consistent with current methods and the existing data?
- ☺ Will an OEL range suffice for control planning?

Recent OELs for Diacetyl	
Organization	**TWA OEL**
NIOSH REL	5 ppb
ACGIH TLV	10 ppb
EU SCOEL	20 ppb
Maier et al.	200 ppb
Beckett et al.	200 ppb

What Happens With No OEL?

- Some may treat chemical as minimal hazard
  - GHS approaches and SDS may not warn if information not available
    - Not tested for a key endpoint
    - No OEL derived or published
- Opportunity
  - Developing and educating on hierarchy of OELs
  - Banding tools continually improving

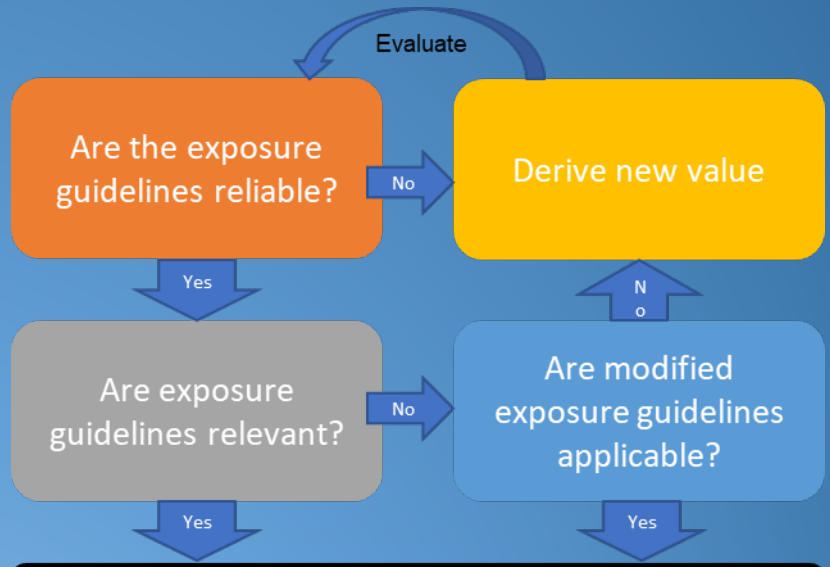


From Deveau et al. 2015 published in JOEH

What Happens With Many OELs?

- Challenges:
  - No single source for all global OELs – challenging to find
  - Confusion at site level – which OEL to use?

- Opportunity:
  - Implement systematic OEL selection program
  - Increase efforts for Harmonisation
  - Increase education for assessors



The Global Landscape of Occupational Exposure Limits—Implementation of Harmonization Principles to Guide Limit Selection

M. Deveau, C-P Chen, G. Johanson, D. Krewski, A. Maier, K. J. Niven, S. Ripple, P. A. Schulte, J. Silk, J. H. Urbanus, D. M. Zalk & R. W. Niemeier

To cite this article: M. Deveau, C-P Chen, G. Johanson, D. Krewski, A. Maier, K. J. Niven, S. Ripple, P. A. Schulte, J. Silk, J. H. Urbanus, D. M. Zalk & R. W. Niemeier (2015) The Global Landscape of Occupational Exposure Limits—Implementation of Harmonization Principles to Guide Limit Selection, Journal of Occupational and Environmental Hygiene, 12:sup1, S127-S144, DOI: 10.1080/15459624.2015.1060327

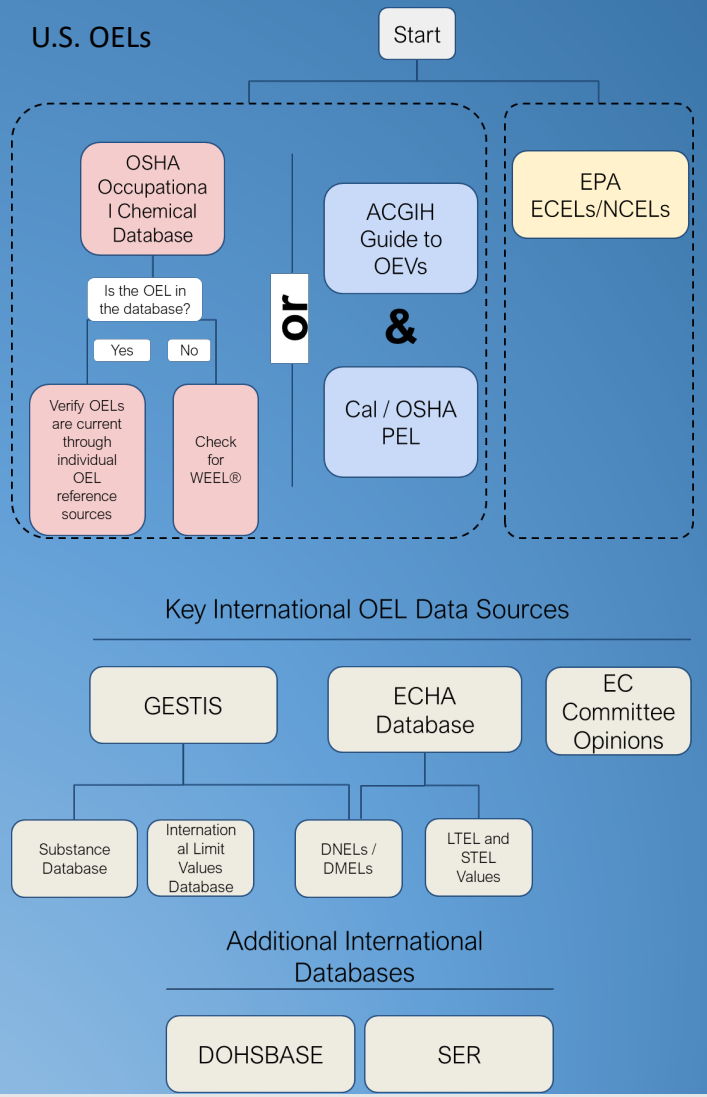
Poll Question 1

How often do you consult OEL resources from diverse organizations before engaging in risk assessment activities? Which sources do use the most for your internal occupational risk management?

A. OSHA & NIOSH
B. EPA
C. International guidelines
D. Volunteer guidelines
E. Internal company derived values

What OELs Do I Need To Find?

- OSHA HCS: Section 8 of an SDS
  - OSHA permissible exposure limit (PEL),
  - American Conference of Governmental Industrial Hygienists (ACGIH®) Threshold Limit Value (TLV®),
  - and any other exposure limit or range used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet, where available.
- EU content: Add Derived No Effect Levels (DNELs)
- Country specific requirements and OELs

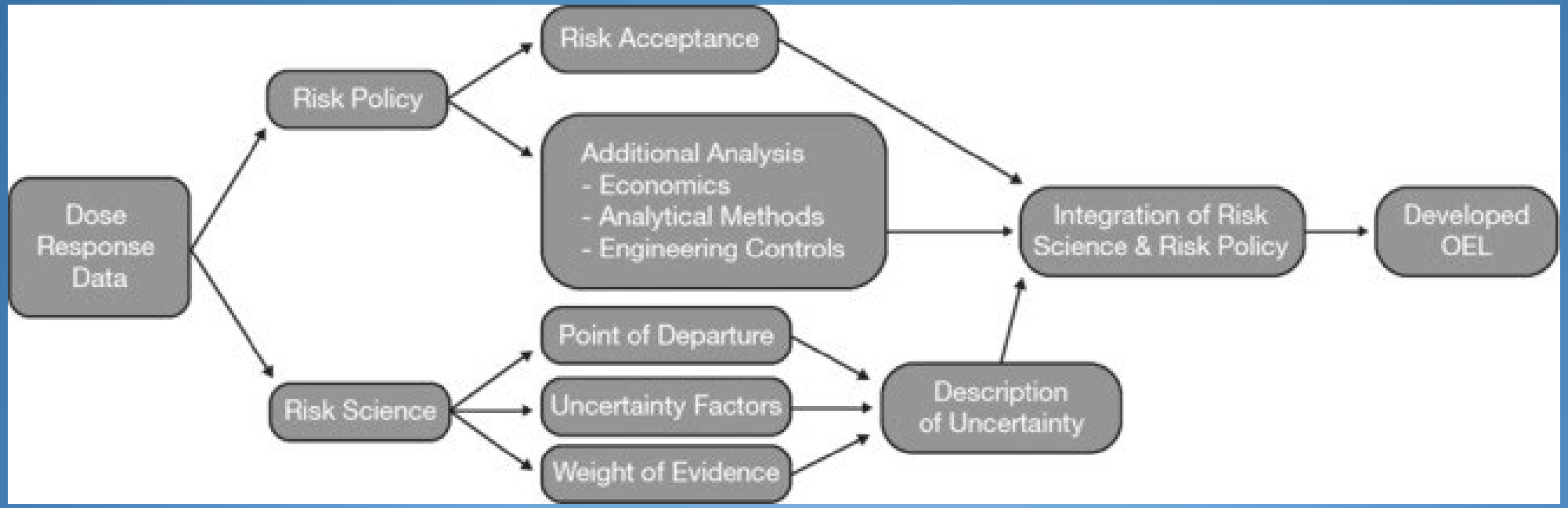


A Workflow to Optimize Occupational Exposure Limit Identification, Evaluation, and Selection, presented at AIHA Connect 2024

Some OEL Databases And Compilations

OEL Information Source	Notes
TLVs®, BEIs®, Guide to OEVs	• Copyrighted; not publicly available for no fee • Weight-of-evidence based • No default uncertainty factors • Values tend to decrease over time as methods evolve
Cal/OSHA PELs	• Not enforceable outside California (CA) • CA has the most extensive list of OELs of states with OSHA-approved State Plans
DOHSBASE	• Includes links to 6,000 workplace atmosphere and biological monitoring limits • Includes sub-databases tailored to the Netherlands, France, and Europe • Log-in and payment required
ECELs, NCELs	• Derived using reanalysis of data and standard EPA inhalation dose-response methods • Feasibility not considered in risk evaluation stage
ECHA Database	• Includes public data submitted to ECHA in REACH registration • Includes LTELs, STELs, DNELs, and DMELs
Committee opinions	• SCOEL Committee developed opinions from 1995-2019 • RAC Committee has developed opinions since 2019
GESTIS	• Substance database includes MAKs and EC OELs • International limit values database includes OELs for 25+ countries • Includes list of compiled DNELs
RELs	• Health-based, but also based on analytical (detection) feasibility
PELs	• Z-Tables are annotated with other select OELs • Most PELs are consensus values adopted in 1970 • Health-based; also include technical and economic considerations
OSHA Database	• Includes OSHA PELs, NIOSH RELs, ACGIH TLVs, and Cal/OSHA PELs
SER Database	• Includes OELs for more than 2,000 substances
WEELs™	• Documentation published in Toxicology and Industrial Health journal • Includes compounds without other authoritative OELs

Examine Basis for OEL Differences



Many other recent published reviews and analyses on differences among OELs

JOURNAL OF OCCUPATIONAL AND ENVIRONMENTAL HYGIENE
Taylor & Francis

J Occup Environ Hyg. 2015 Nov 25; 12(sup1): S99–S111. PMCID: PMC4685553
Published online 2015 Nov 19. doi: 10.1080/15459624.2015.1084421 PMID: 26302336

Exposure Estimation and Interpretation of Occupational Risk: Enhanced Information for the Occupational Risk Manager

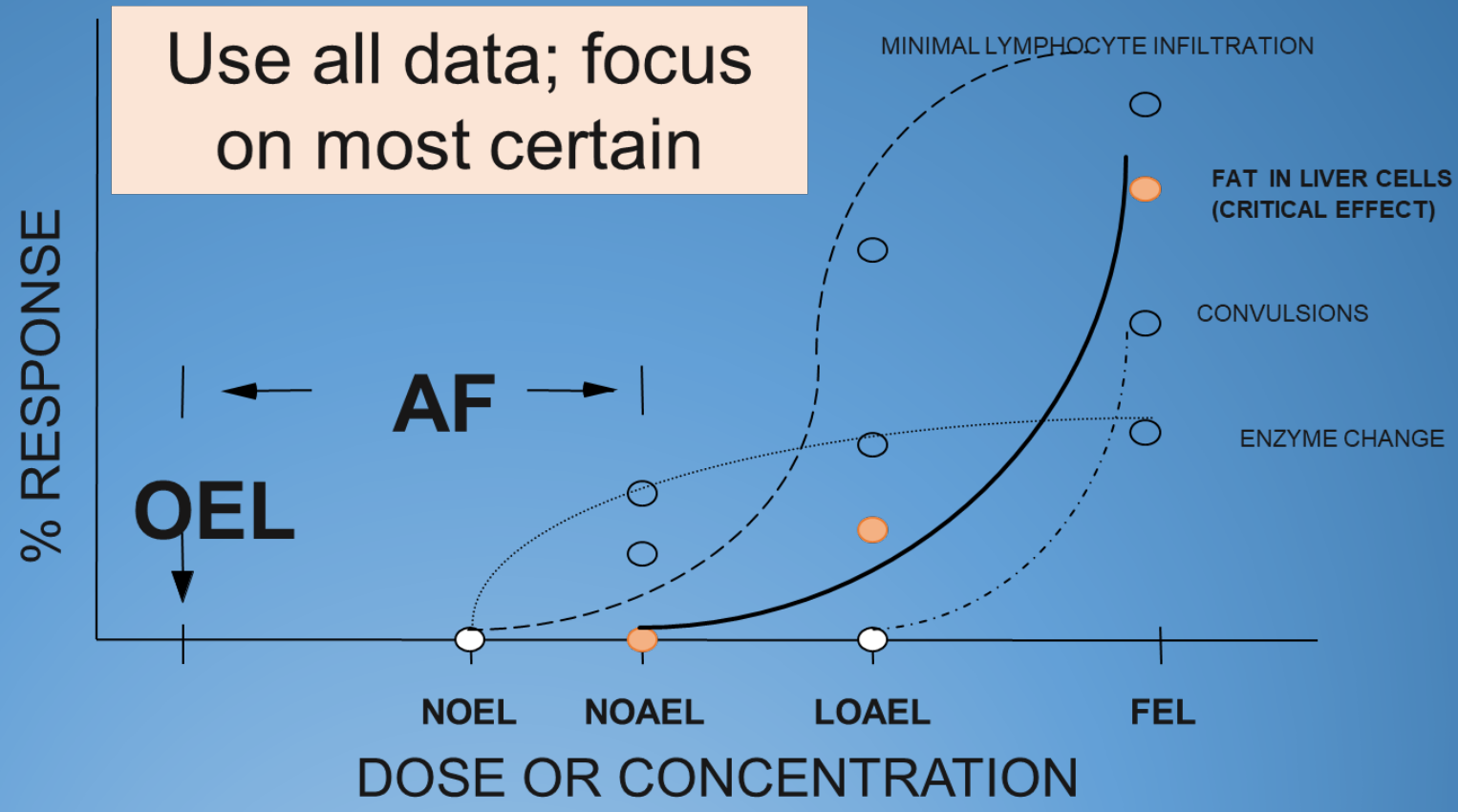
Martha Waters, [a,*] Lauralynn McKernan, [b] Andrew Maier, [c] Michael Jayjock, [d] Val Schaeffer, [e] and Lisa Brosseau [f]

Poll Question 2?

- Most traditional OELs are typically derived using the following equation?

a) OEL = POD (e.g., NOAEL) / composite UF
b) OEL = POD (e.g., NOAEL) X composite UF
c) OEL = POD (e.g., NOAEL) – composite UF
d) None – most OELS are based on cancer potency

Traditional OEL Derivation



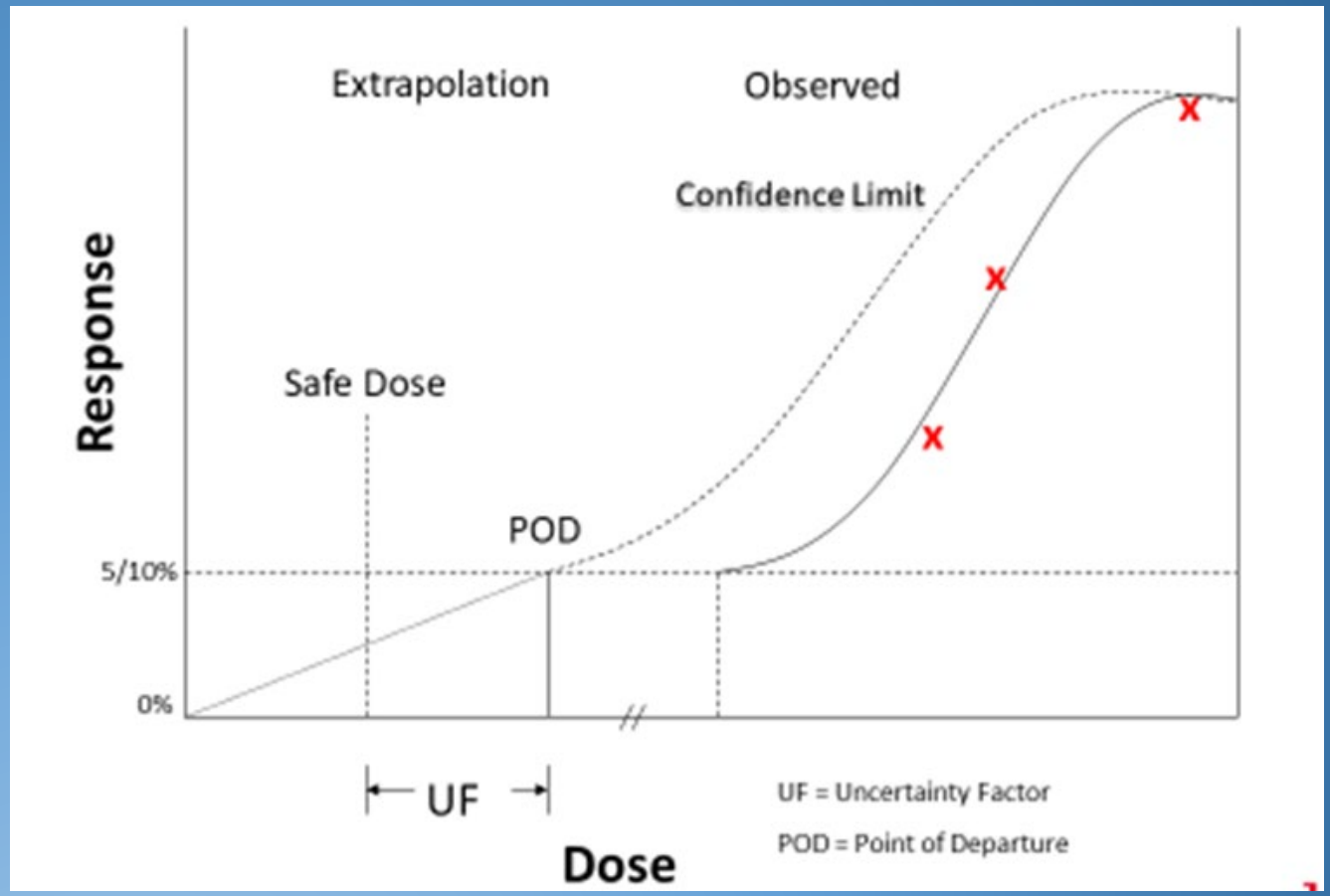
OEL Derivation

- POD = Point of Departure (a measure of dose-response)
- $UF_{1,2,3}$ = composite uncertainty factor (UF_1 * UF_2 * UF_3 …)
- MF = modifying factor (e.g. Breathing rate for workload)
- A = Absorption (bioavailability) correction factor
- V = Volume of air inhaled in 8-hr shift (10 m^3)

$$OEL = \frac{POD\ (mg)}{UF_{1,2,3} \times MF \times A \times V}$$

Low-Dose Linear Extrapolation Approach

- Primarily for non-threshold like carcinogens
- Can be used directly with epidemiology data sets if sufficiently large
- Low-dose slope (e.g. inhalation unit risk) allows calculation of exposure limit for a defined risk (risk specific concentration)
- Risk target depends on policy
  - Traditional PEL (about 1:1000)
  - NIOSH (1:10,000)
  - Some organizations moving toward 1:100,000 on case-by-case basis



PoD And Adjustment (Uncertainty, Assessment, Safety) Factors

POD_{adj} ÷

UFA - 1 (or AS) x 3.2
UFH – 1, 3, 5 or 10
UFL - 1, 3, or 10
UFS - 1, 3, 6 or 10
UFD – 1, 3 or 10

X PPM

Alternative Line of Evidence #1

Alternative Line of Evidence #2

Is the final result reasonable?

Weight of Evidence based OEL

EPA Defaults Vs. WEEL Practices From A 90-day Minimal LOAEC

10 ppm ÷

UFA - 3
UFH – 3
UFL - 10
UFS - 10
UFD – 3

0.003 PPM

Alternative Line of Evidence #1

Alternative Line of Evidence #2

Is the final result reasonable?

0.003 PPM - Weight of Evidence

EPA Defaults Vs. OEL Practices From A 90-day Minimal LOAEC

10 ppm ÷

UFA - 3 vs 1
UFH - 3 vs 3
UFL -10 vs 3
UFS -10 vs 3
UFD - 3 vs 1

0.003 vs 0.3 PPM

Alternative Line of Evidence #1 – limited epi suggests no effect at 1 ppm

Alternative Line of Evidence #2 – MOA indicates little no evidence for other sensitive or accumulating effect

Is the final result reasonable?

0.3 PPM - Weight of Evidence

Poll Question 3?

Which statement is true regarding OEL use in the EPA?

a) The only OELs derived in the TSCA program is an ECEL
b) EPA often adopts EU derived no effect levels (DNELs) for chemical registrations
c) EPA develops OELs or similar limits for numerous programs
d) EPA does not develop OELs – they rely on OSHA

TSCA Existing Chemical Exposure Limits

- Derived using EPA Reference Concentration Methods
- In all cases so far, lower than current OELs (PEL, REL, TLV®, WEEL™, EU RAC, etc.)
- Why Lower?
  - If similar study endpoint and effect level – usually larger combined uncertainty factor (often about 3 to 10-fold lower)
  - If a carcinogen – likely to use low dose linear assumption (often about 30 to 100-fold lower)
  - If some special study endpoint – can be much lower (often >100-fold lower)

Chemical	ECEL (ppm)	OEL (ppm)	Ratio (OEL/ECEL)
MeCl	2 ppm	25 (OSHA)	12.5
PCE	0.14 ppm	20 (EU RAC)	143
TCE	0.0011 ppm	10 (TLV)	9091
CCl4	0.03 ppm	1 (EU RAC)	33

Evolving Methods And Science Judgments

- Methods evolve over time (occupational and environmental convergence); transparency increasing
  - **BMD Modeling**
    - Default for ECELs, moving to default status for most government-based organizations
    - Some expert groups use on case-by-case: does it always add value beyond the NOAEL?
  - **Inhalation dosimetry adjustments**
    - Some default for ECELs, some default method for DNELs (but can modify using RAC OEL)
    - Highly variable application among organizations – most do not have a default methodology
    - Most organizations try to maximize use of available toxicokinetic data
  - **Probabilistic Assessment Factors**
    - Increasing in formal application in some countries, addressed qualitatively as “factors overlap” in most organizations
  - **New Approach Methods**
    - Desire for OELs with drive to move from animal testing increased role of in vitro and in silico methods
    - Mostly used for endpoint gap filling or banding

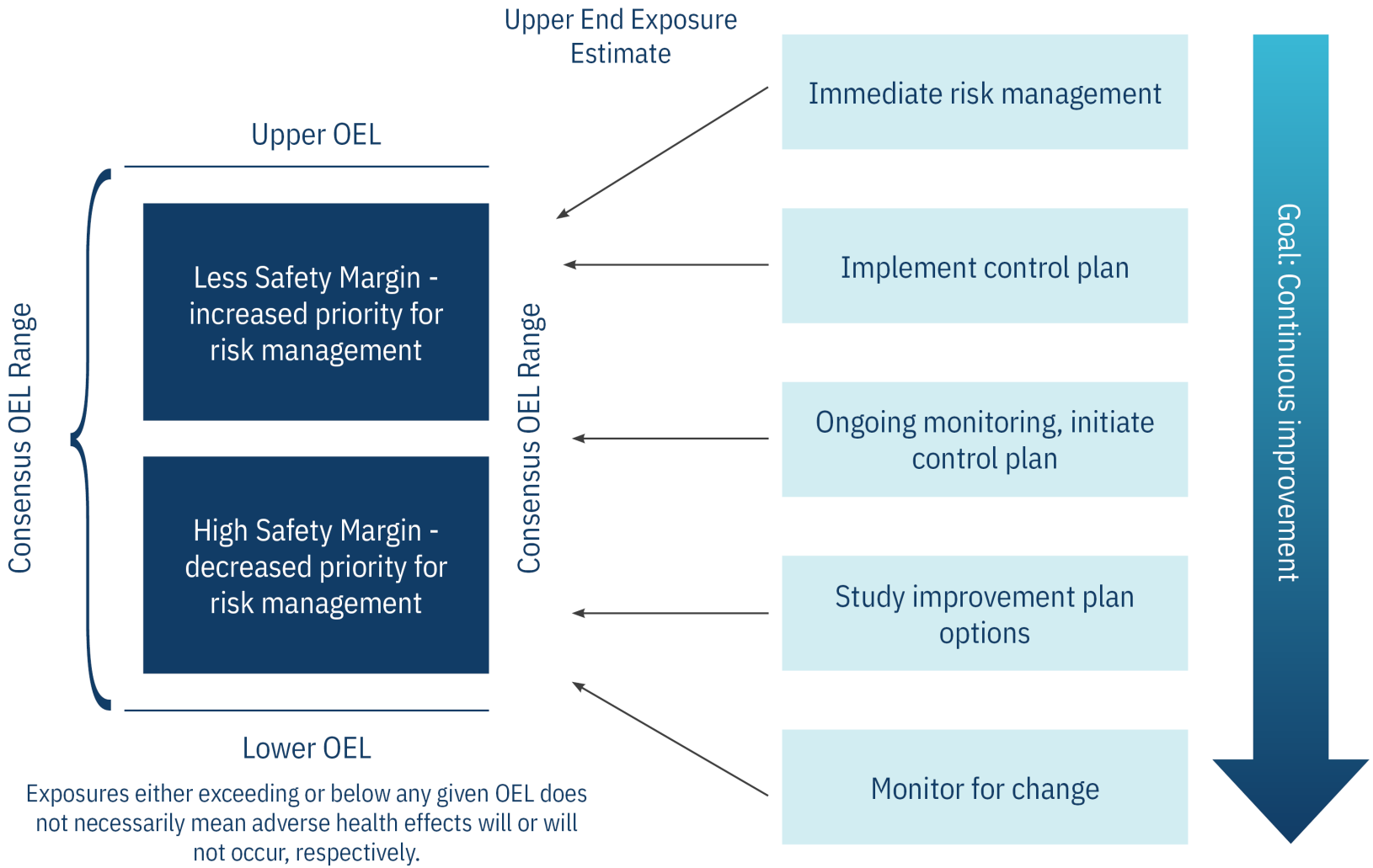


Figure in Journal Review do not duplicate – contact Andy Maier

22

What Happens When OELs Change?

- Evaluate the basis for the change – to understand context
  - OEL higher (rare) expect in moving from band to OEL approach
  - OEL lower because new hazard identified
    - New hazard data
    - New interpretation of extant data
  - OEL lower because new policy decision or regulation
- Update risk assessments and risk management plans
  - Need to consider comparative risks or unplanned risks
    - Assess poorly studied substitutions
  - IHs apply judgment and control packages designed to minimize overall risk
    - Do not add a new hazard (e.g., ergonomics, PPE requirements)
  - Worker hazard communication plan needed

Summary

- OELs are a key resource for occupational risk managers
- There is no single open domain source for all OELs
- OEL values vary considerably – which can cause confusion for risk managers
- A systematic OEL management program is needed – includes identification, selection, and communication

Discussion

Intellectual Property Statement

The material contained in this presentation is the work of expert(s) selected by the Program Committee of SCHC and is intended solely for the purpose of professional development and continuing education. Material in an SCHC-sponsored presentation does not constitute a recommendation or endorsement of any kind. This material is believed to accurately represent current regulatory requirements and industry standards for hazard communication. However, SCHC cannot guarantee the accuracy or completeness of this information. Users are responsible for determining the suitability and appropriateness of these materials for any particular application.