

State of the Science of Occupational Exposure Limits Methods & Guidance

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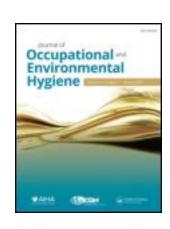


Purpose: present the global landscape of Occupational Exposure Limits (OELs) - harmonisation principles to guide limit selection*

Presentation topics

- Underlying reasons for variability in OELs
- Proposal: a framework for identification & systematic evaluation of OEL resources to support risk characterisation & risk management decisions in situations where multiple potentially relevant OELs exist
- Proposal: harmonisation of risk-based methods used by OEL-deriving organisations

^{*}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 Journal of Occupational and Environmental Hygiene, 12:sup1, S127-S144, DOI: 10.1080/15459624.2015.1060327



Availability of traditional international OEL resources

- OELs are derived by various organisations around the world.
- Because these global OEL efforts are in general not directly coordinated among organisations, a confusing landscape of traditional OELs has emerged.



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Hierarchy of OELs

Most Extensive Data Requirements

(human epidemiology studies or animal studies > MOA data) > quality > certainty

Moderate Data Requirements

(in vitro and animal studies and anecdotal reports of human health effects) > quality > certainty

Least Data Requirements

(in vitro and animal studies)

Traditional OELs

Regulatory, Authoritative (TLVs, MAKs, WEELs, PELs, RELs)

Working provisional OELs

(Internal company, trade association, vendor limits)

Prescriptive Process Based OELs

(REACH, DNELs/DMELs)

Hazard Banding Strategies

Pharmaceutical banding Occupational exposure bands

Control Banding = Hazard Bands + Exposure Risk Assessment

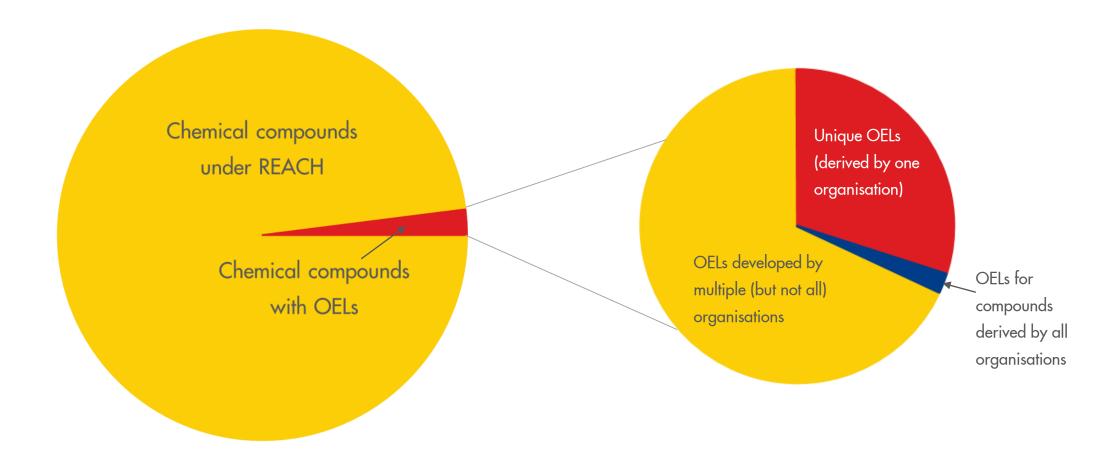
As more toxicological

and epidemiological data

up the hierarchy of OELs

become available, we move

The patchwork landscape of OELs *

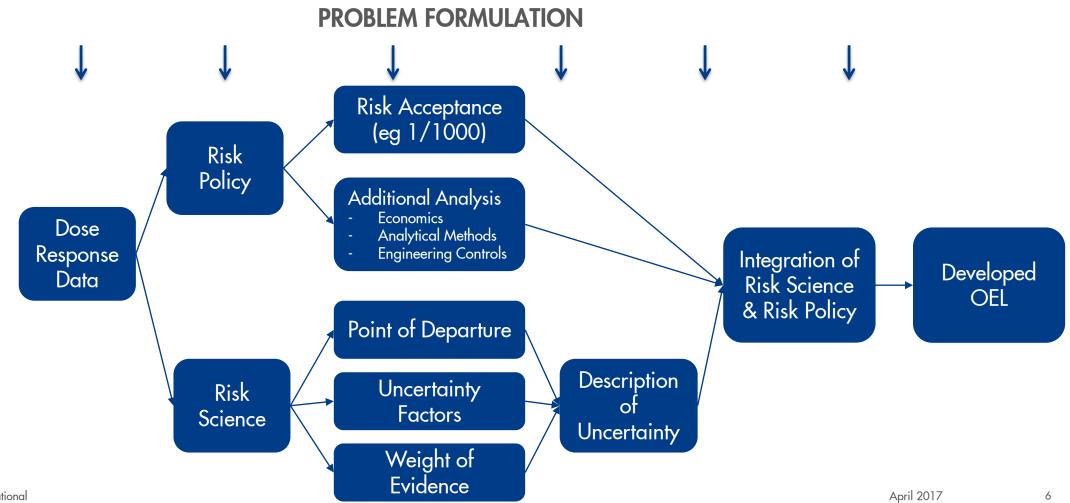


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^{*} Data from Schenk et al., 2008a; ECHA, 2011

Potential sources of variability in science and policy decisions taken during the establishment of OELs



International harmonisation of OELs



- Selecting an OEL for occupational hygiene applications presents a challenge when the processes used by OEL-setting organisations differ significantly around the world.
- Harmonisation of the OEL derivation processes applied around the world has been suggested as a means of minimising variability in approaches.
- The International Programme on Chemical Safety (IPCS) Harmonisation Project Strategic Plan defines "harmonisation" as the establishment of:
 - "common principles, understanding and approaches and enhanced transparency in risk assessment, facilitating use for regulatory purposes."
- A goal of international harmonisation of OELs is to have compatible and not necessarily exact or standardised values in different countries as a result of the application of convergent methods and practices by different organisations.

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Existing harmonisation initiatives



- 1989: The Hague, Netherlands, workshop between the Directorate General of Labour in the Netherlands and the EC
- 1990: the EC created the Scientific Experts Group (now the SCOEL).
- 1998: publication of Concise International Chemical Assessment Documents (CICADs)
- Agreements between organisations or countries:
 - Nordic Expert Group (NEG)—a collaboration between Sweden, Norway, Denmark, Finland and Iceland that develops criteria documents for OELs. The NEG has also established agreements with NIOSH and the Dutch Expert Committee on Occupational Safety
 - The ILO encourages international collaboration, information and data sharing among countries.
 - As a result of data sharing, many of the OELs adopted around the world are based on those from other organisations, such as ACGIH, NIOSH, OSHA, and the EU.

To date, no single effort has seen global acceptance, but the trend is to increase

Copyright of Shell International data sharing and transparency (Role for IOHA?)

Benefits of harmonisation initiatives



- reduce the need for multiple OEL-setting entities;
- encourage work sharing between organisations,
- reduce confusion and economic inefficiencies (e.g. multi-national companies that are required to comply with many different mandatory OELs)
- reduction in inconsistent OEL derivation practices resulting in discrepancies in worker protection amongst countries.
- benefits for workers in smaller countries.
- greater use of best practices.

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Drawbacks of harmonisation initiatives



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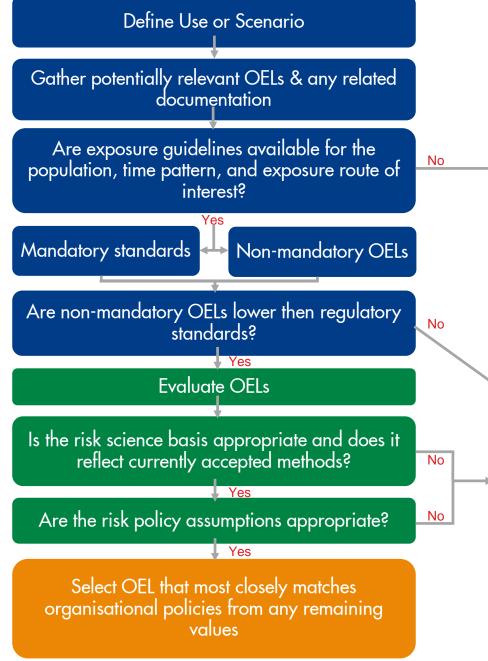
- differences among organisations and countries such as legal, regulatory, economic, political, and cultural
- inconsistencies between organisations
- magnification of existing problems with the OEL development process.
- decreased transparency and increased distance between regulators and the public,
 business owners, and workers
- less desirable approaches might be promoted leading to a lower margin of safety

An important value of harmonisation is the sharing of information on methods, while recognising the value of flexibility available through the application of alternative approaches

Framework for the selection of appropriate OELs

Assess availability and relevance of OELs

reliability o OELs



Evaluate relevance of any new or adjusted value

No Reliable Value Available

- Derive new value;
- Make adjustment to existing OELs
- Use other OEL surrogates from the hierarchy of OELs; and/or
- Use other risk management considerations, including communication or other administrative controls & hazard or control banding.

Apply the regulatory standard

Reject OEL

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Conclusions

- Exposure limit guidance is absent for most chemicals, and existing OELs often vary quantitatively among organisations around the world.
- The basis for differences in OELs for the same chemical reflects a mix of differences in risk policy and risk science methodology.
- A systematic framework can aid the occupational hygienist in documenting and selecting OELs when multiple relevant values are encountered, encouraging the most effective use of current OEL resources.
- Harmonisation of the approaches used to develop OELs can contribute to increased consistency in OEL derivation by organisations around the world.

HOW best to do this?





Control Banding = Hazard Bands + Exposure Risk Assessment + Exposure Management

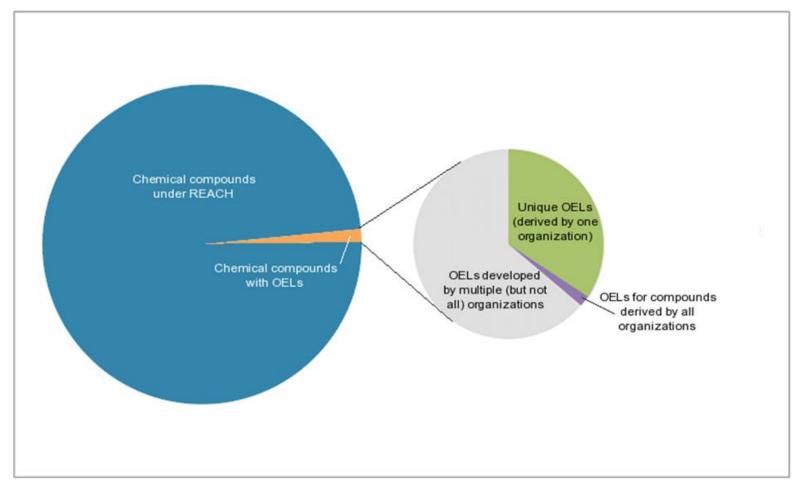
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OELs

epidemiological data

OELs.

The Patchwork Landscape of OELs *

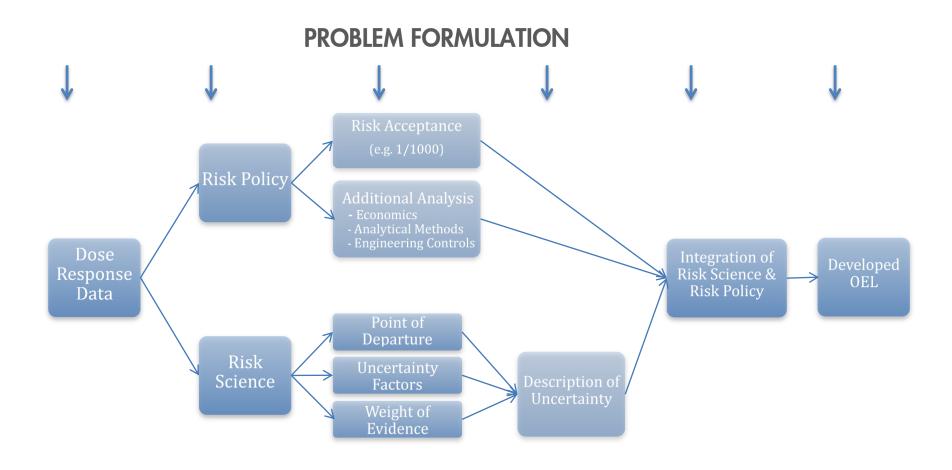


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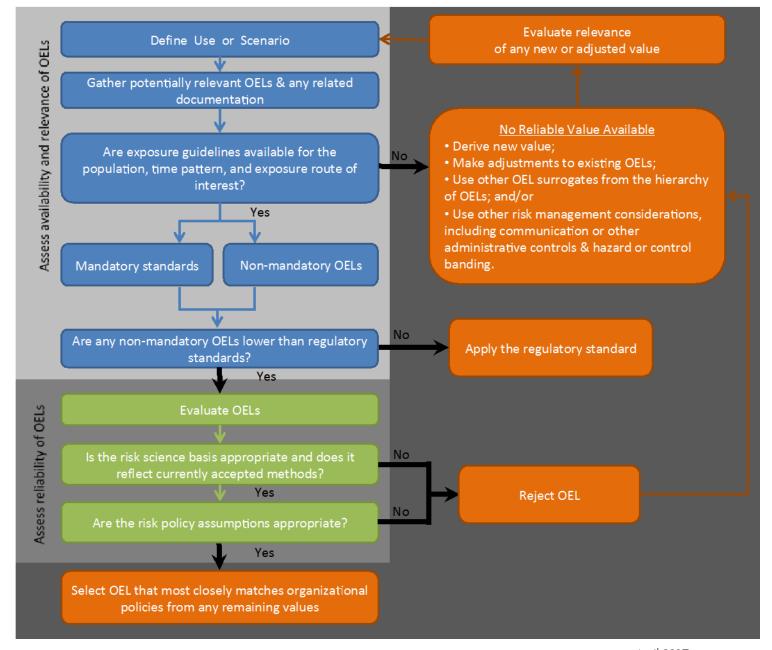
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Potential sources of variability in science and policy decisions taken during the establishment of OELs



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Framework for the selection of appropriate OELs



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