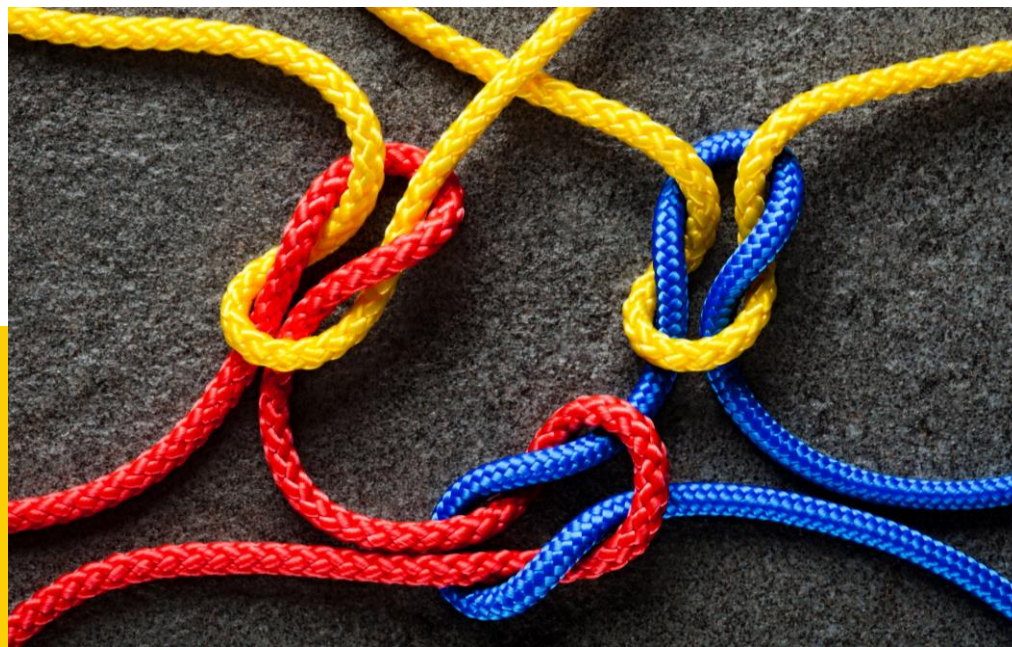




# State of the Science of Occupational Exposure Limits Methods & Guidance

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**GM Product Stewardship**

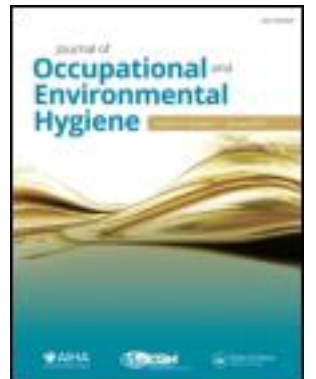


## **Purpose:** present the global landscape of Occupational Exposure Limits (OELs) – harmonisation principles to guide limit selection\*

### 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

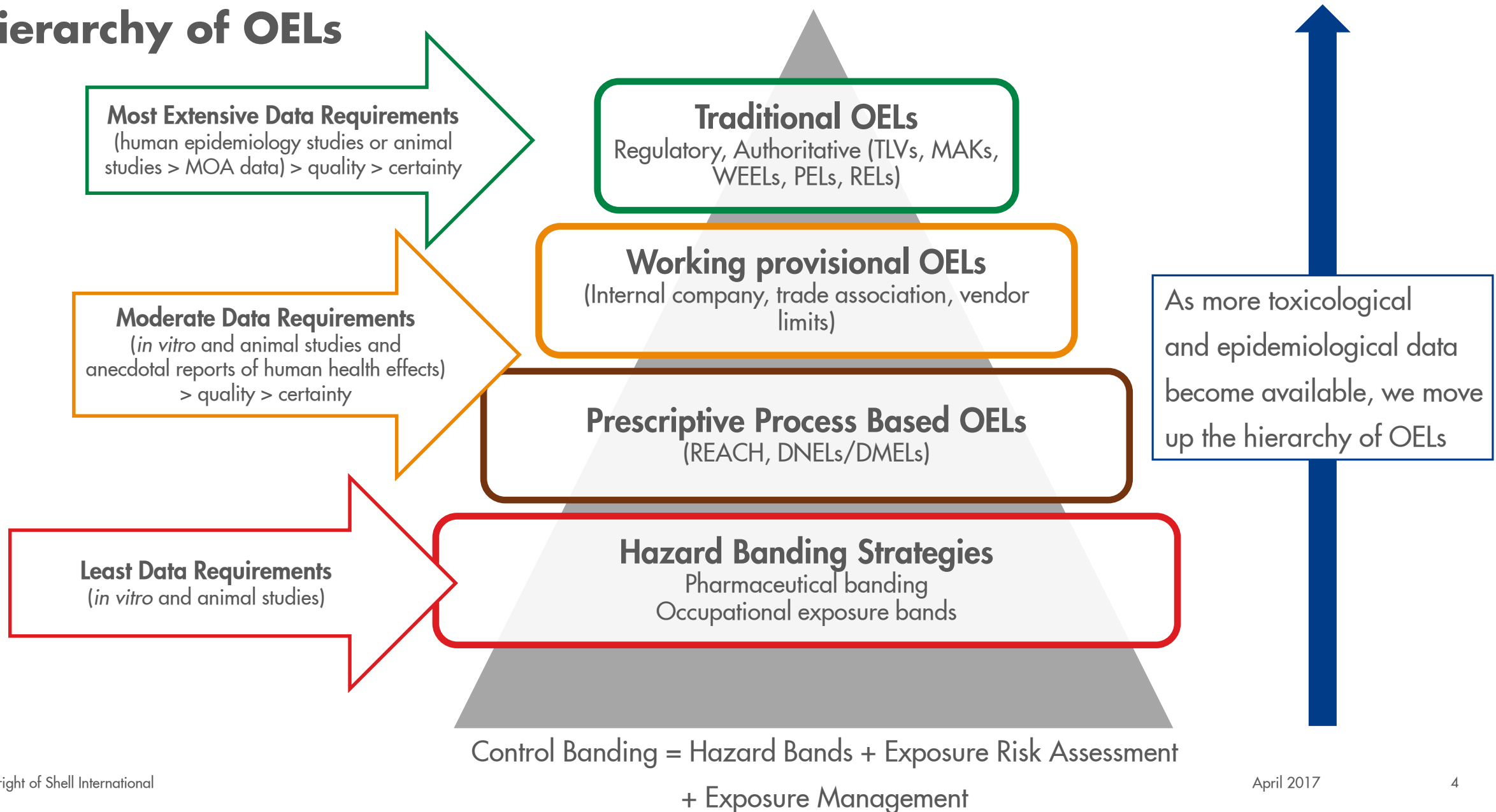


## ***Availability of traditional international OEL resources***

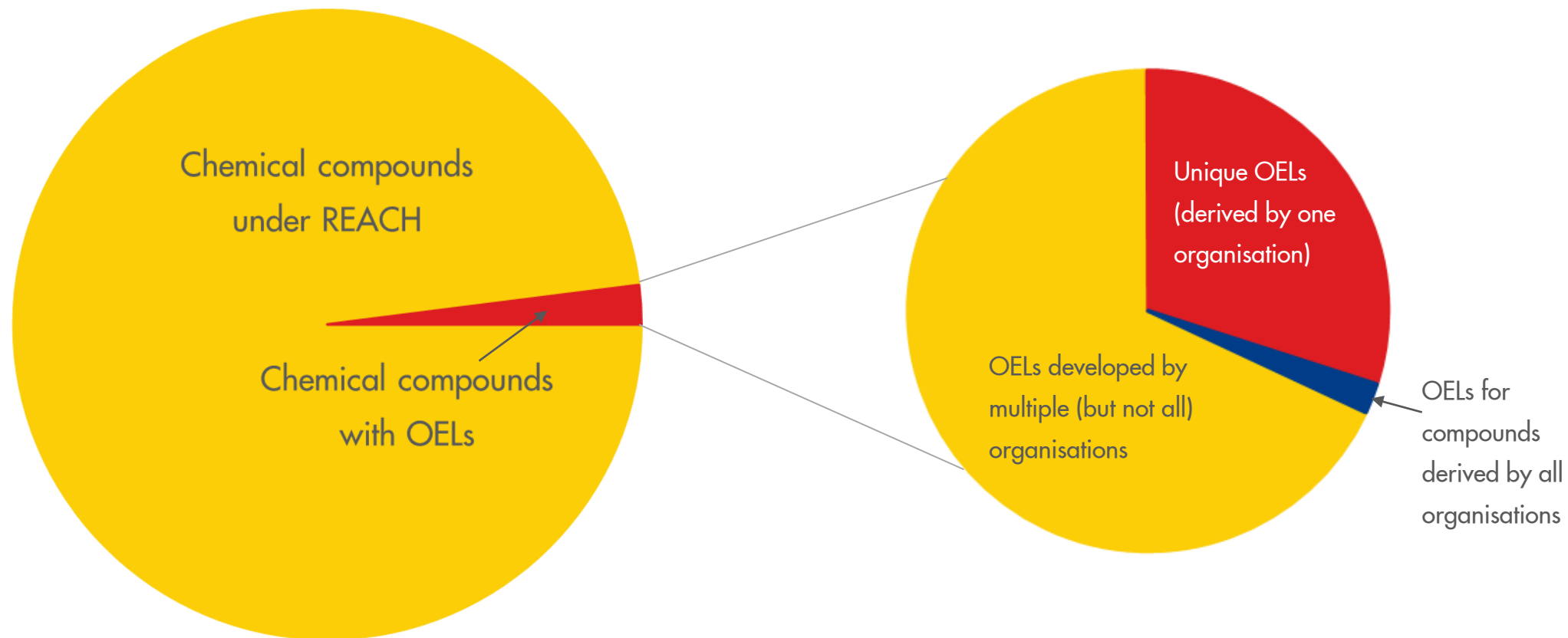
- OELs are derived by various organisations around the world.
- Because these global OEL efforts are in general not directly coordinated among organisations, a confusing landscape of traditional OELs has emerged.



# Hierarchy of OELs

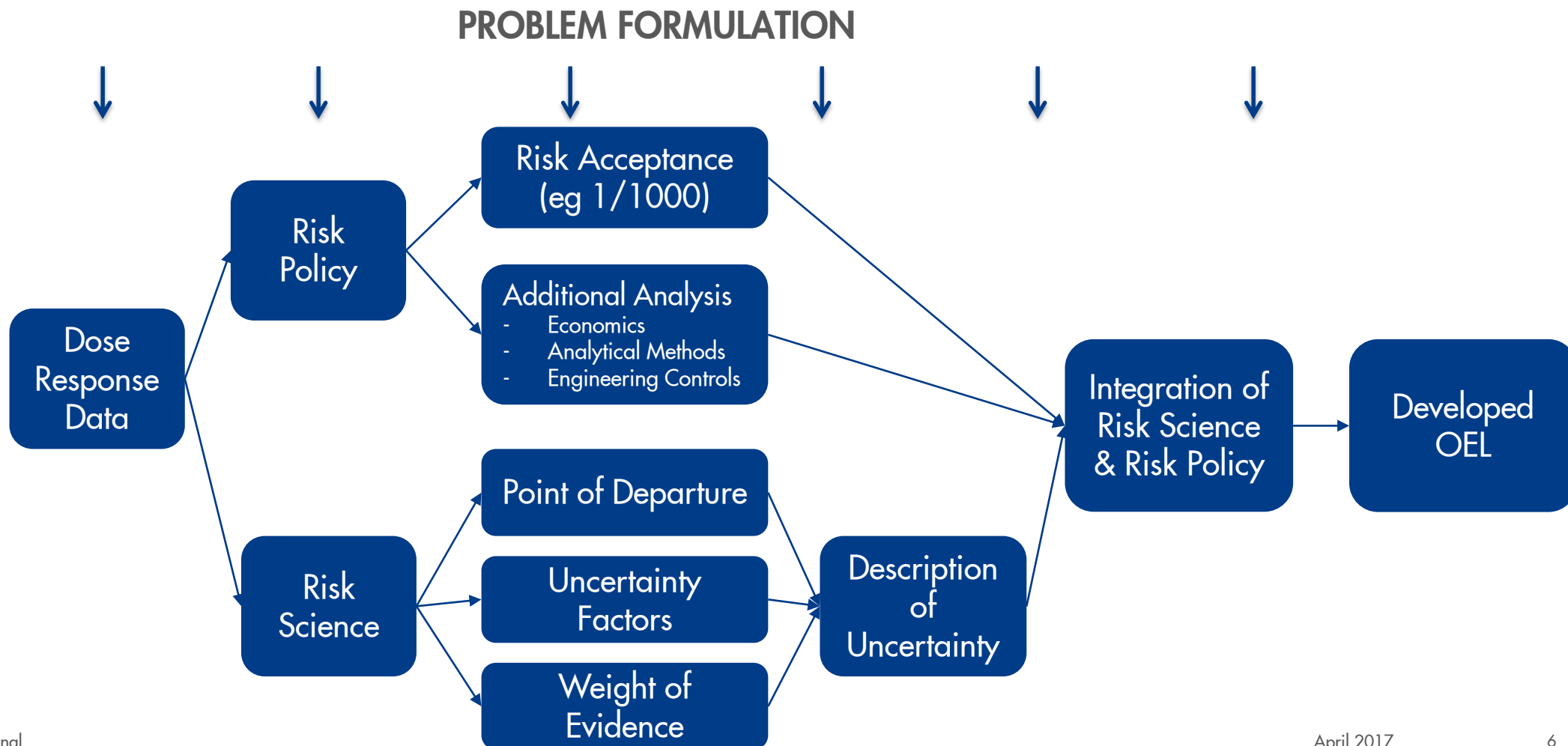


## *The patchwork landscape of OELs \**



\* 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.

## ***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 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.

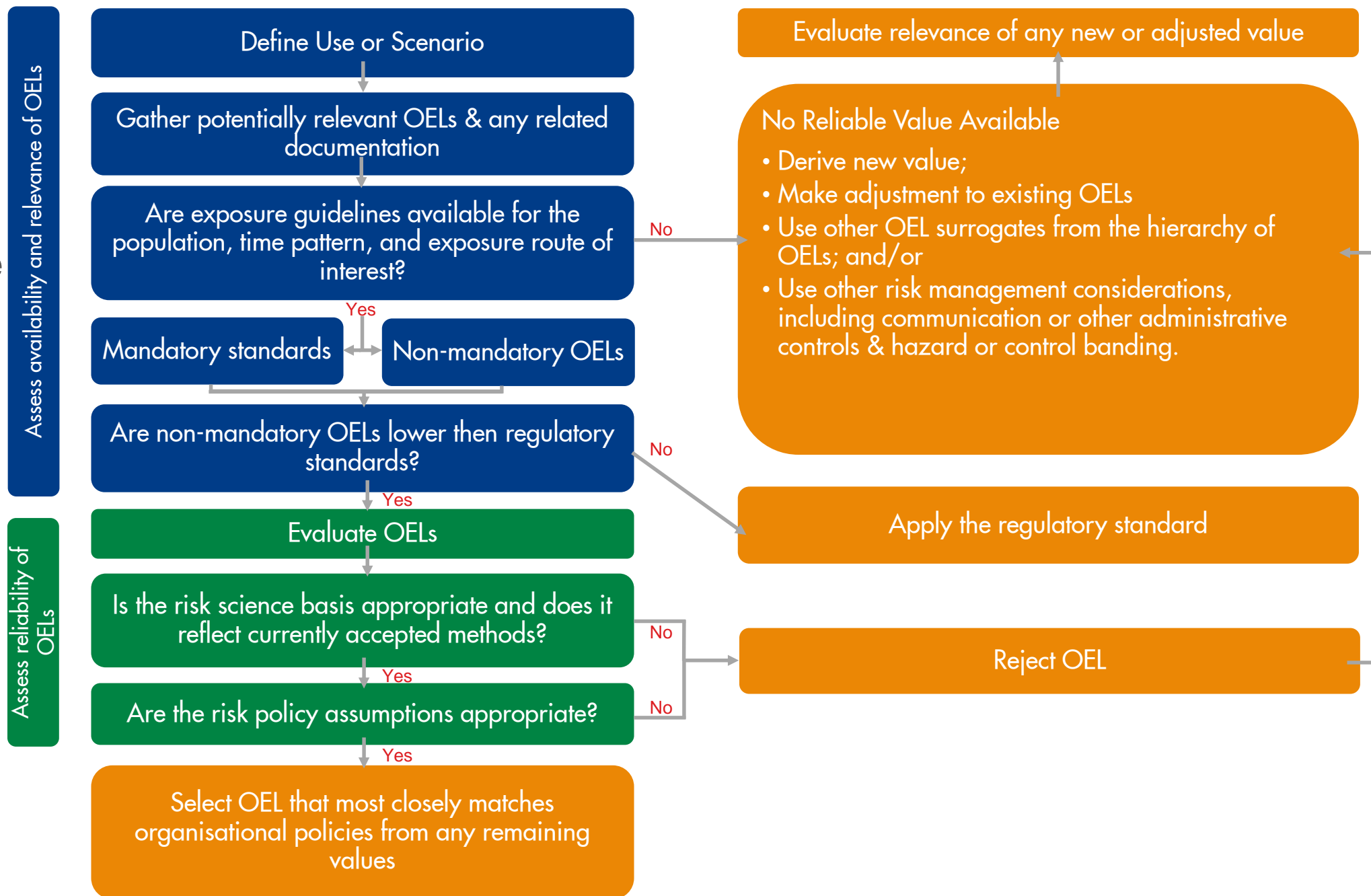
## ***Drawbacks of harmonisation initiatives***



- 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

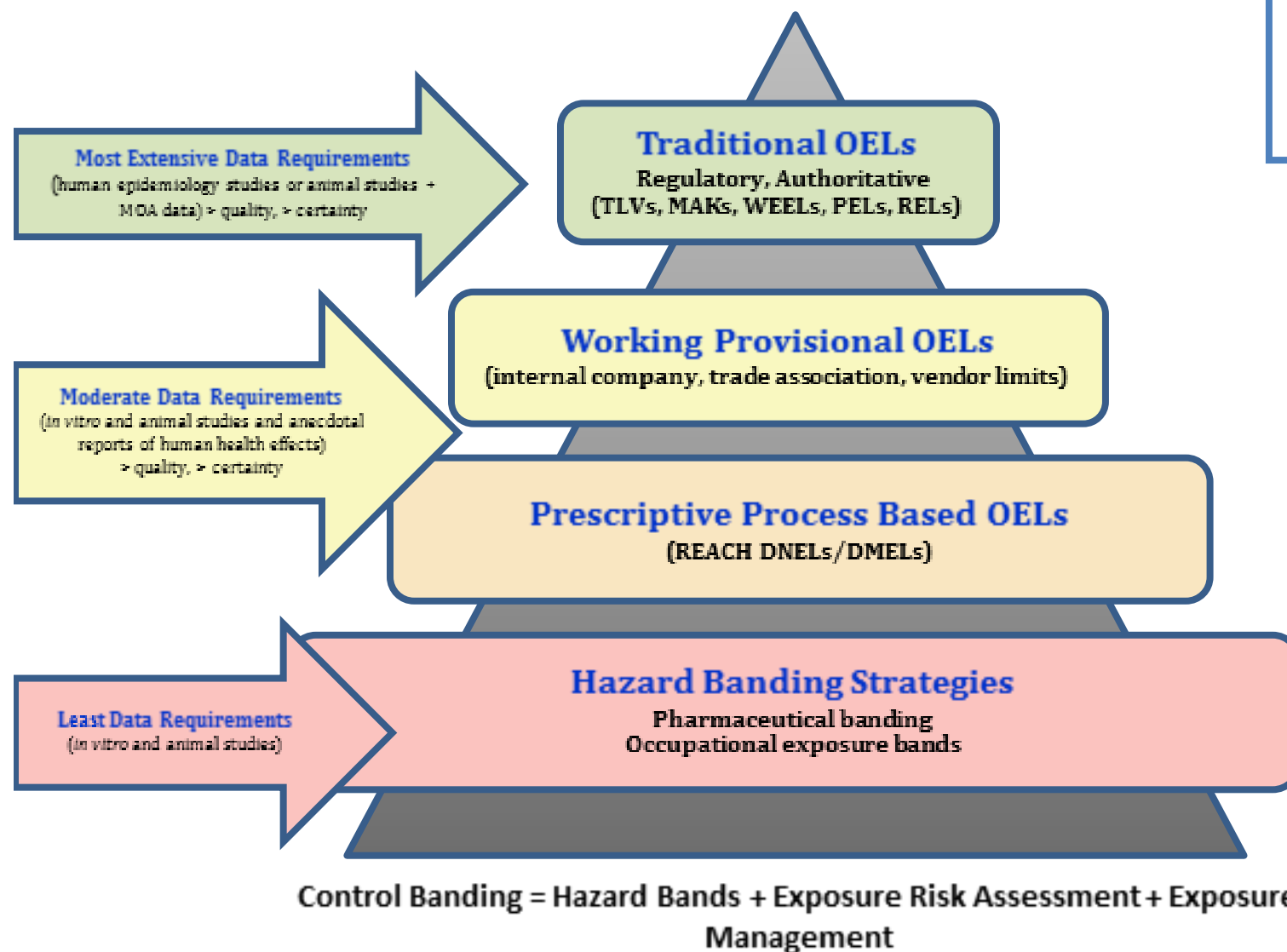


## **Conclusions**

- 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?**



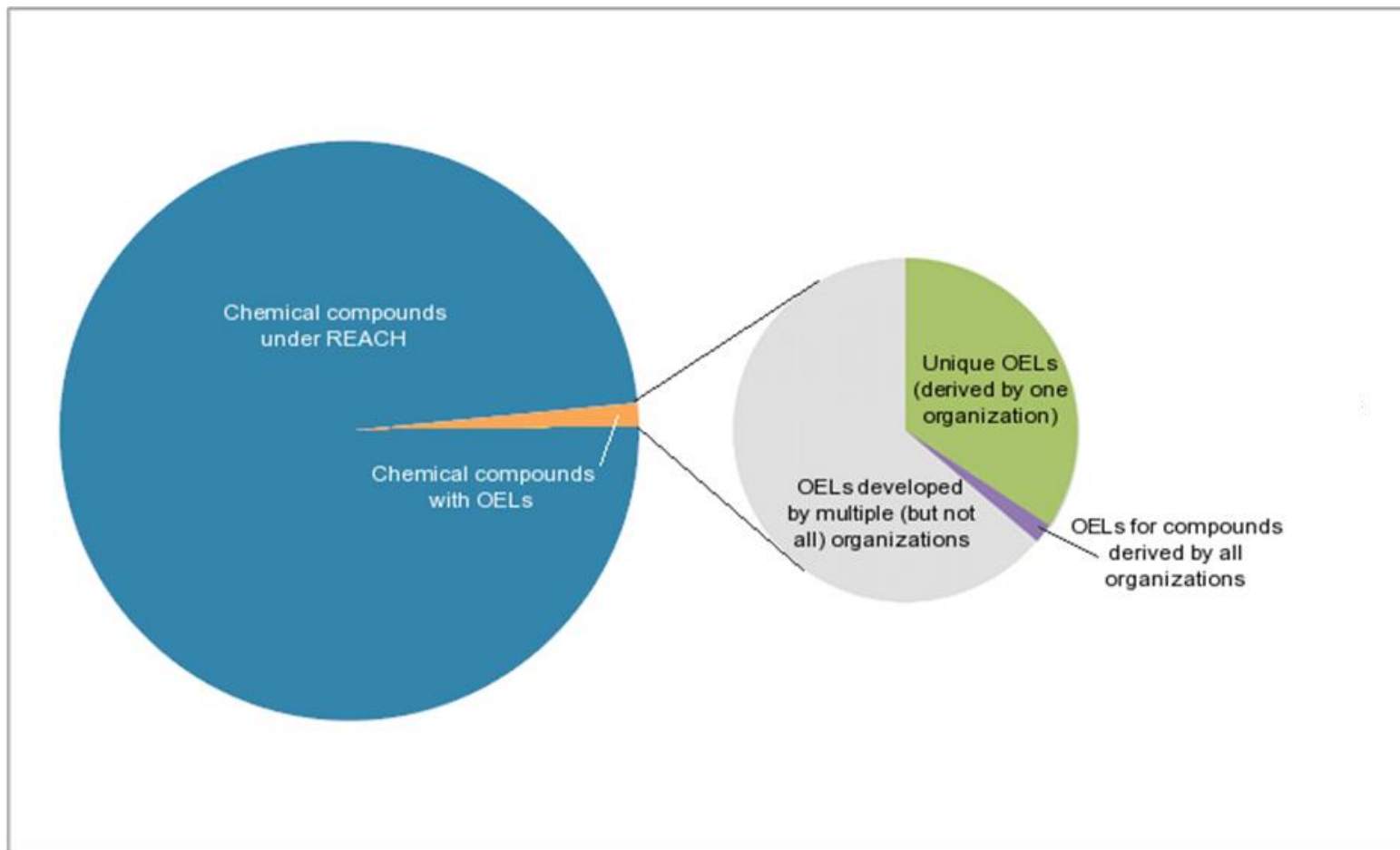


## Hierarchy of OELs

As more toxicological & epidemiological data become available, we move up the hierarchy of OELs.

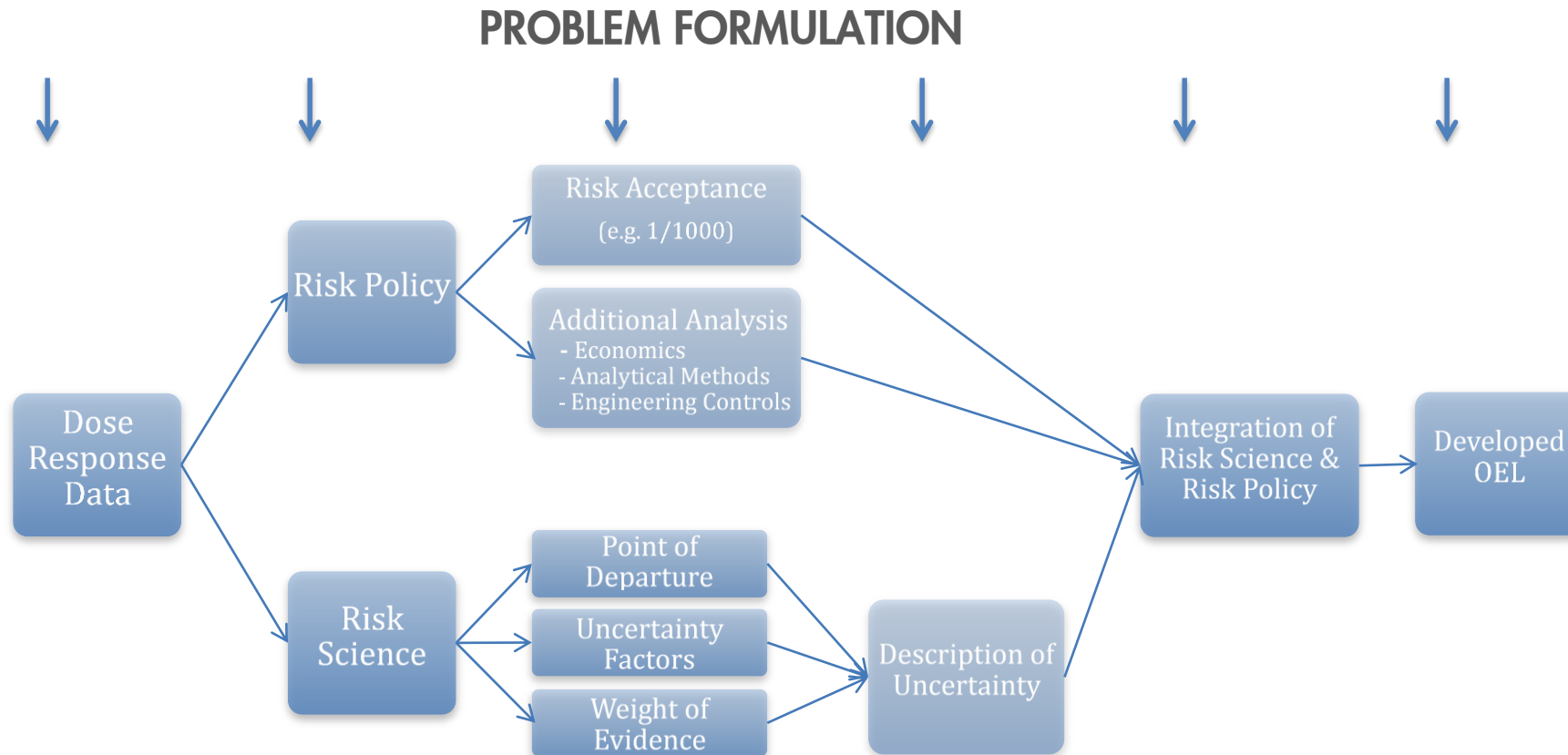


## ***The Patchwork Landscape of OELs \****



\* Data from Schenk et al., 2008a; ECHA, 2011

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



# Framework for the selection of appropriate OELs

