Lecture Series: Concepts and Tools for Sustainable Chemicals Manufacture

Introduction of the Occupational Exposure Assessment

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27-02-2025

Presenter

Meet Today's Presenter: Gerald Bachler

- **Current Role: Regulatory Officer | European Chemicals Agency** (2024 – Present)
- **Previous Roles:**
  - **DuPont (2019–2024):** Manager, Product Stewardship & Regulatory Affairs; Led global regulatory submissions, risk assessments, and safety initiatives.
  - **Vitis Regulatory (2017–2019):** Principal Exposure Scientist; Specializing in exposure and risk assessment for industrial chemicals.
  - **Shell (2015–2017):** Exposure Scientist/Industrial Hygienist; Handling risk assessments and ensuring REACH and CLP regulatory compliance.
- **Education:**
  - **PhD in Nanotoxicology,** ETH Zürich; **MSc in Health Care Engineering**, Technical University of Graz; **MSc in Health and the Environment**, Cranfield University.
- **Certification:** Swiss Certified Safety Engineer.

Context and Disclaimers

About This Lecture

This lecture provides an **introductory framework**, with some topics simplified for ease of understanding.

Disclaimer

- The content presented herein does not necessarily reflect the opinions, views, or positions of the presenters' employer or any affiliated organizations.
- References to specific organizations, tools, or entities are for illustrative purposes only and do not imply endorsement or critique.
- While every effort has been made to ensure the accuracy of the information presented, errors or omissions may occur.

Learning Objectives

1) Explain the fundamental concepts of exposure and risk assessment

2) Compare and contrast the primary methods used for occupational exposure assessment

3) Understand how exposure assessments contribute to the development of sustainable chemical manufacturing practices

Content

- **Introduction to Exposure Assessment**
- Selection of an Occupational Exposure Limit (OEL)
- Types of Exposure Assessments
- Occupational Risk Management
- Occupational Exposure Assessment in SSbD
- Summary

Introduction

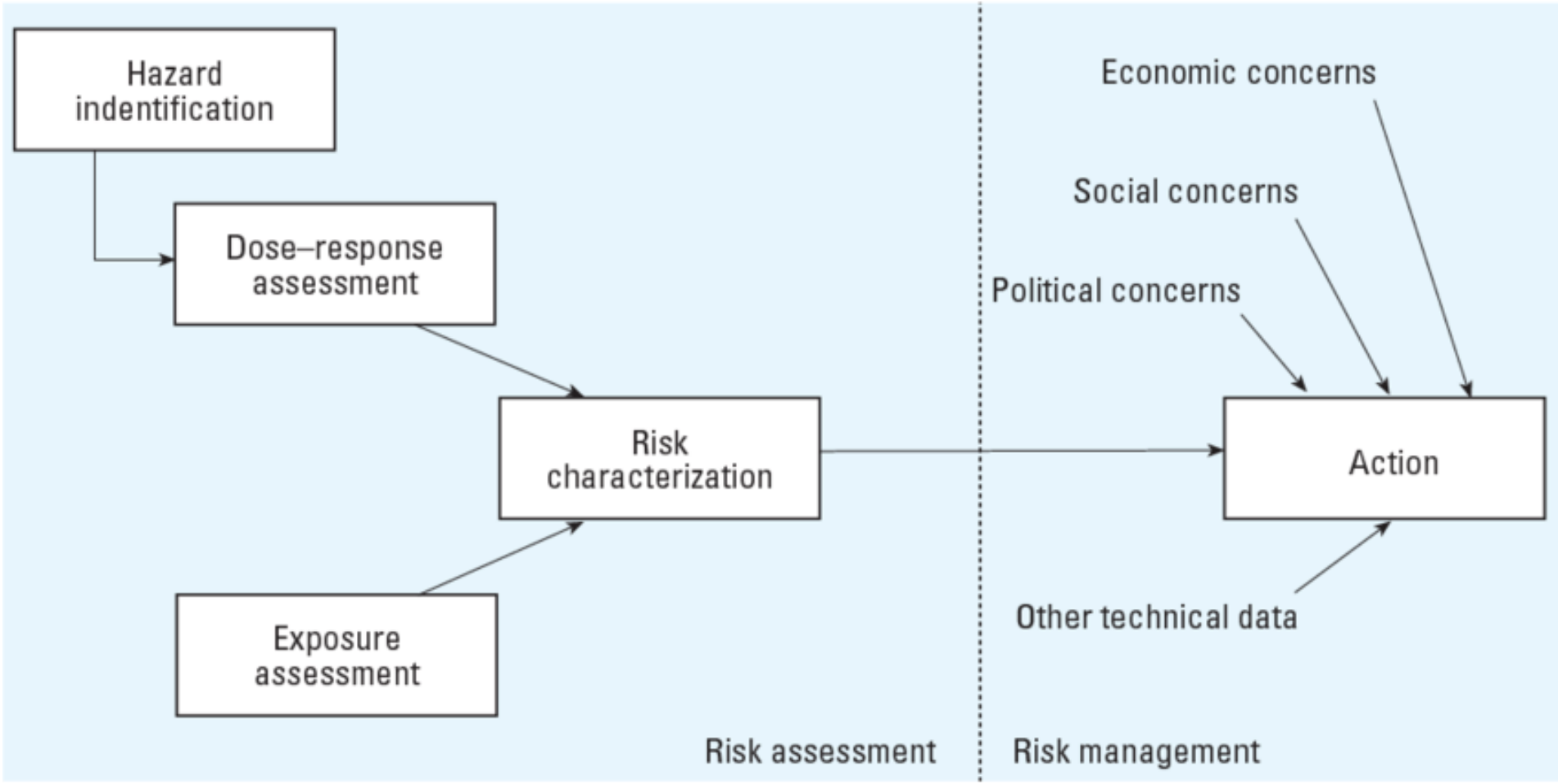
Definition:

Exposure Assessment is the process of measuring or estimating the intensity, frequency, and duration of human or environmental exposure to harmful agents.

Key Aspects:

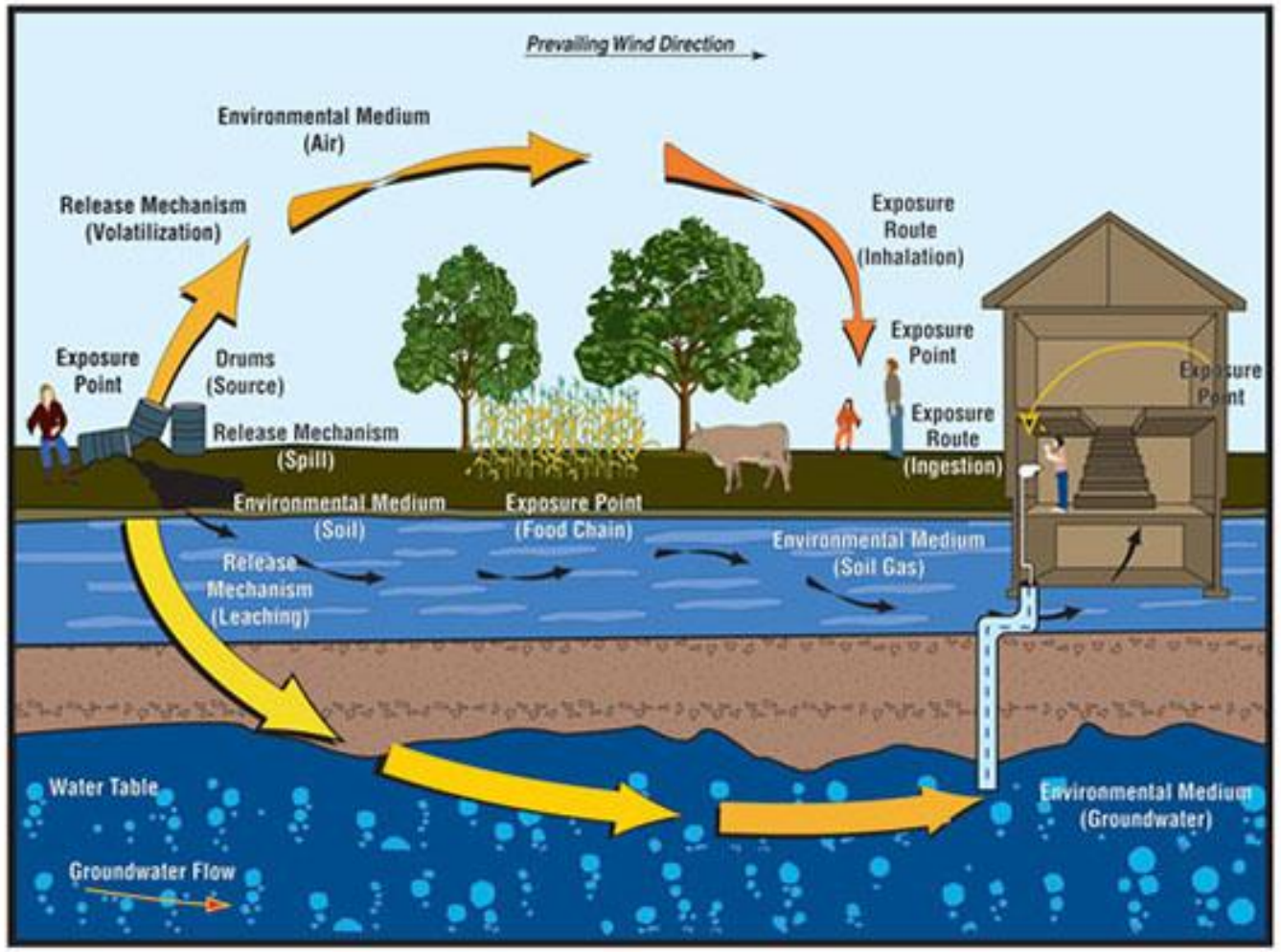
- Can involve a variety of **chemical, biological, or physical agents**.
- Identifies **exposure pathways and sources** of harmful environmental agents.
- Plays a **key role in identifying** the health or environmental **risks** posed by these agents.

Risk Assessment Paradigm



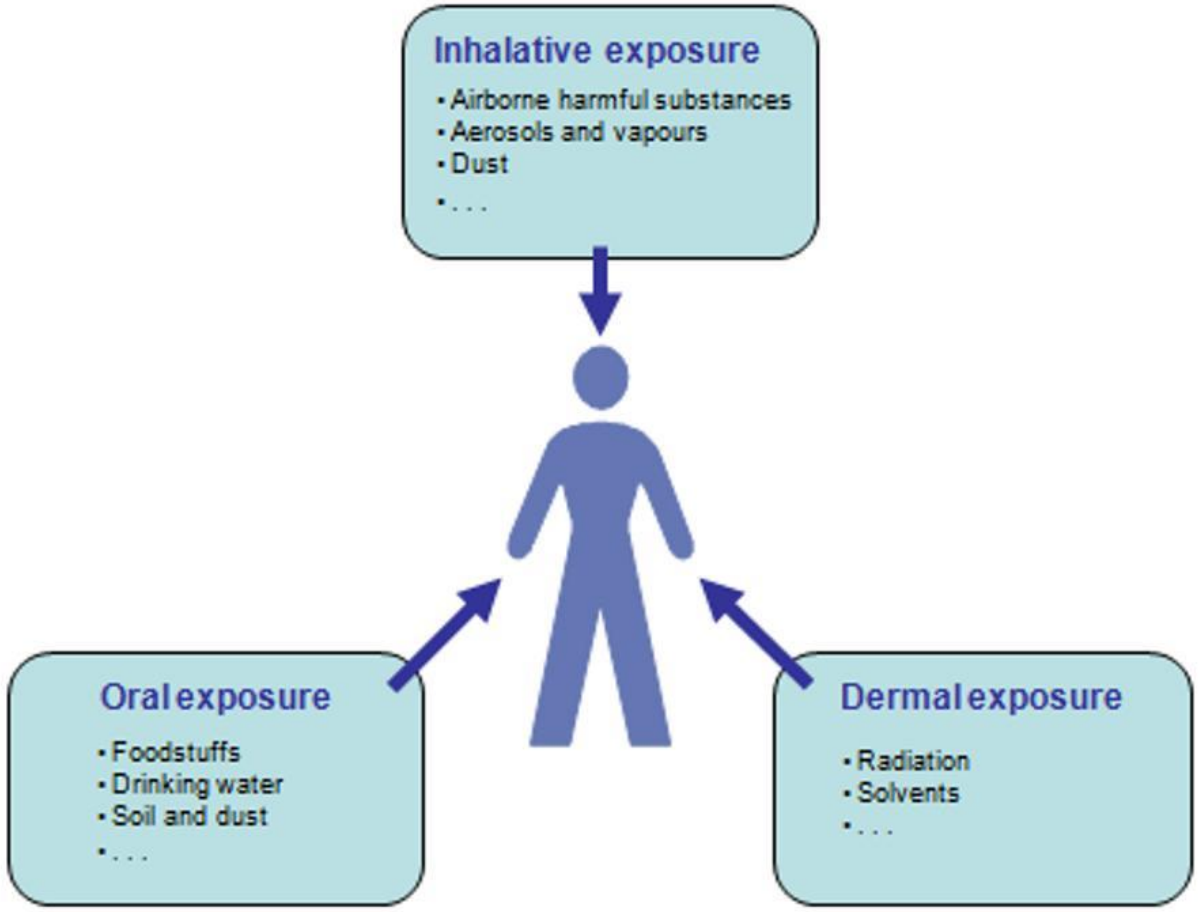
Source: Cogliano *et al*. 2004, https://doi.org/10.1289/ehp.6950

Source-Pathway-Receptor Model



Source: Agency for Toxic Substances and Disease Registry, www.atsdr.cdc.gov

Exposure Pathways



Source: German Government Environmental Agency, www.umweltbundesamt.de

Primary exposure routes:

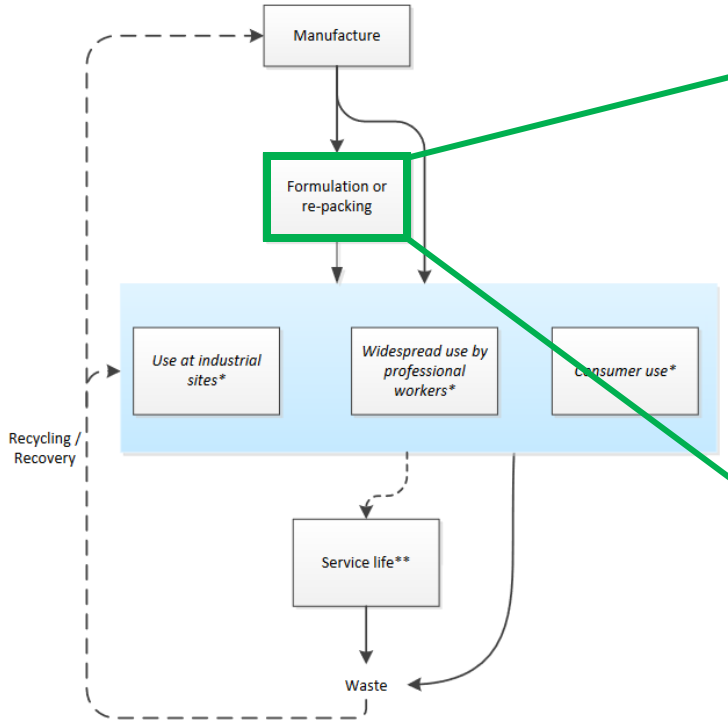
- **Inhalation**: Through the lungs
- **Oral**: Through the digestive tract
- **Dermal**: Through the skin

Effectiveness of absorption by route:

Inhalation > Oral > Dermal

Exposure Scenario I

The exposure scenario (ES) describes how a substance (or mixture/article) is produced or used **throughout its lifecycle**, including recommended control measures to minimize human and environmental exposure.



ES name: *Formulation of liquid mixtures*

Environment	
1: *Formulation of mixture in closed and open systems*	ERC 2
Worker	
2: *Receiving and charging of the substance*	PROC 8b
3: Mixing or blending in batch processes; Closed systems	PROC 3
4: Mixing or blending in batch processes; Open systems	PROC 5
5: Transfer of substance or mixture (charging/discharging) at non dedicated-facilities	PROC 8a
6: Transfer of substance or mixture (charging/discharging) at dedicated facilities	PROC 8b
7: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)	PROC 9
8: Equipment cleaning and maintenance	PROC 28

Source: European Chemicals Agency, echa.europa.eu

Exposure Scenario II

ES name: *Formulation of liquid mixtures*

Environment	
1: *Formulation of mixture in closed and open systems*	ERC 2
Worker	
2: *Receiving and charging of the substance*	PROC 8b
3: Mixing or blending in batch processes; Closed systems	PROC 3
4: Mixing or blending in batch processes; Open systems	PROC 5
5: Transfer of substance or mixture (charging/discharging) at non dedicated-facilities	PROC 8a
6: Transfer of substance or mixture (charging/discharging) at dedicated facilities	PROC 8b
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ment cleaning and maintenance	PROC 28

1.2.3. Control of worker exposure: Mixing or blending in batch processes; Closed systems (PROC 3)

Product (Article) characteristics
Covers concentrations up to 100.0 %
Amount used (or contained in articles), frequency and duration of use/exposure
Covers use up to 8.0 h/day
Technical and organisational conditions and measures
Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition
Local exhaust ventilation. Inhalation - minimum efficiency of 90.0 %
Provide a basic standard of general ventilation (1 to 3 air changes per hour).
Supervision in place to check that the risk management measures in place are being used correctly and operation conditions followed.; Ensure control measures are regularly inspected and maintained.
Conditions and measures related to personal protection, hygiene and health evaluation
Wear suitable gloves tested to EN374.; For further specification, refer to section 8 of the SDS.
Use suitable eye protection.; For further specification, refer to section 8 of the SDS.
Other conditions affecting workers exposure
Indoor use
Assumes process temperature up to 40.0 °C

Source: European Chemicals Agency, echa.europa.eu

Risk Characterisation

Risk Characterisation Ratio (RCR):

Formula: $$RCR = \frac{\text{Exposure Estimate}}{\text{Threshold Limit Value (e.g., OEL, DNEL)}}$$

Interpretation:

RCR ≤ 1: No concern, exposure is within acceptable limits

RCR > 1: Additional risk management may be required

Designed by Freepik

Margin of Safety (MoS):

Formula: $$MoS = \frac{\text{No–Observed–Adverse–Effect Level (NOAEL)}}{\text{Exposure Estimate}}$$

Interpretation:

MoS > 100: Generally considered a safe margin

MoS < 10: Indicates higher risk and need for action

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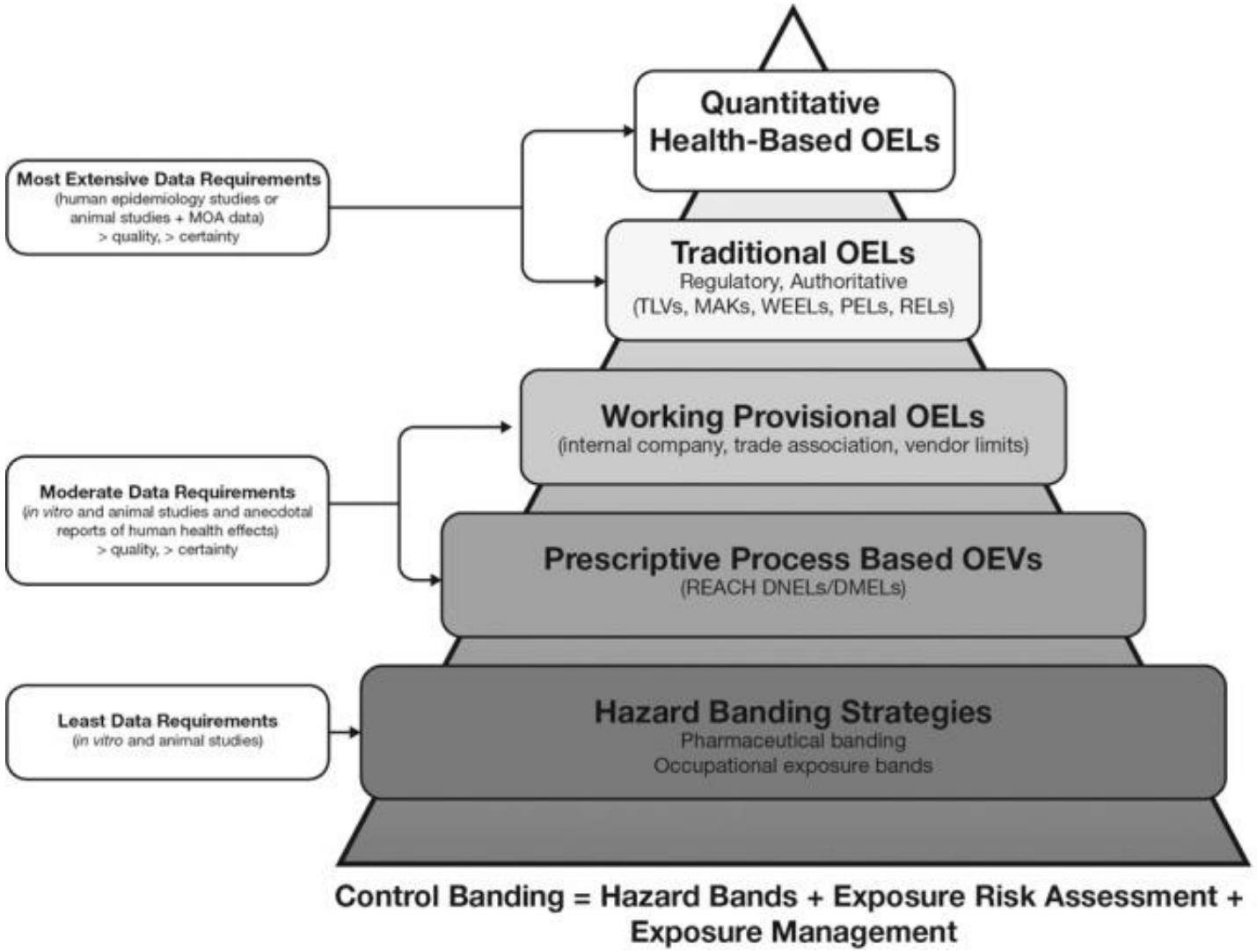
Occupational Exposure Limits I

Selecting an appropriate OEL is essential for accurate risk characterisation

- **Exposure route:** Inhalation, dermal and oral – internal.
- **Exposure duration:** Celling limits, short-term limits (15 minutes), long-term limits (8/12 hours), working life.
- **Regulatory considerations:** Legally binding (bOEL, PEL, MAK, WEL, etc.) or guidance values (e.g. iOEL, TLV, WEEL, REL, etc.)

→ ***Sources for OEL selection:*** *Use trusted authorities and organizations*

Occupational Exposure Limits II



- Available for ca. 1,000 substances
- Largely limited to inhalation route
- Often legally binding
- May consider technical feasibility (SEA)
- Determined individually via independent expert groups

- Available for ca. 10,000 substances
- Often available for all exposure routes
- Legally not binding
- Don't consider technical feasibility (SEA)
- Typically derived following a defined framework by an expert

- Available for most substances
- Available for all routes
- Don't consider technical feasibility (SEA)
- Often derived *in silico*
- Basis for screening novel substance
  → see SSbD Step 1

Deveau *et al.* (2015): http://dx.doi.org/10.1080/15459624.2015.1060327

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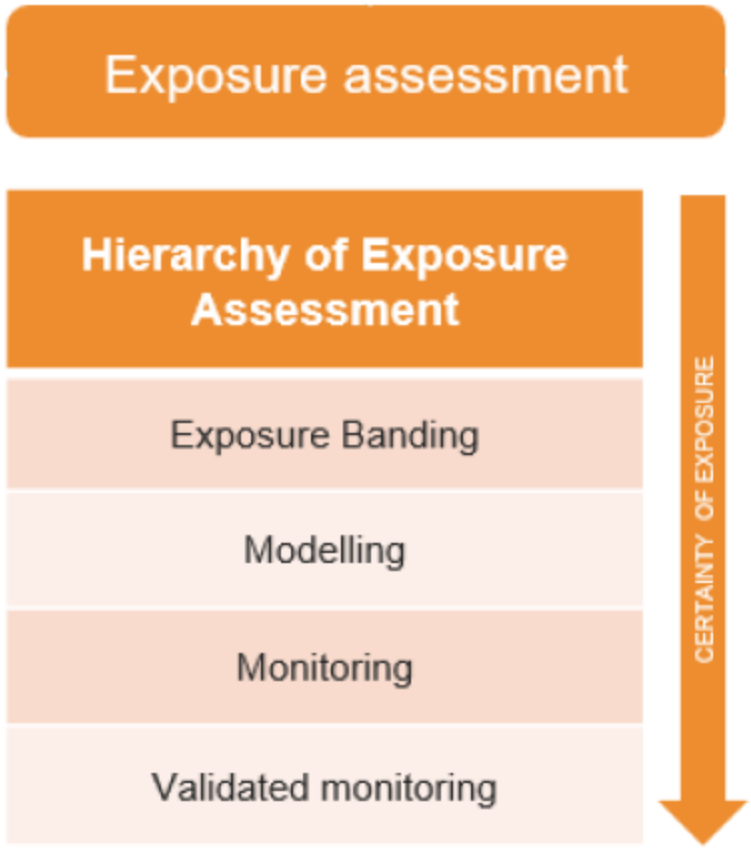
Exposure Assessment



Tiered Exposure Assessment Hierarchy:

→ Adjust exposure assessment based on available data

→ Align exposure assessment detail with hazard assessment detail

→ Align exposure assessment detail along the complete life cycle

→ For product comparisons, apply the same assessment level to all products

Source: Joint Research Centre, joint-research-centre.ec.europa.eu

Exposure Banding I

Workplace risks are grouped into control categories or “bands” based on assessing hazard and exposure information.

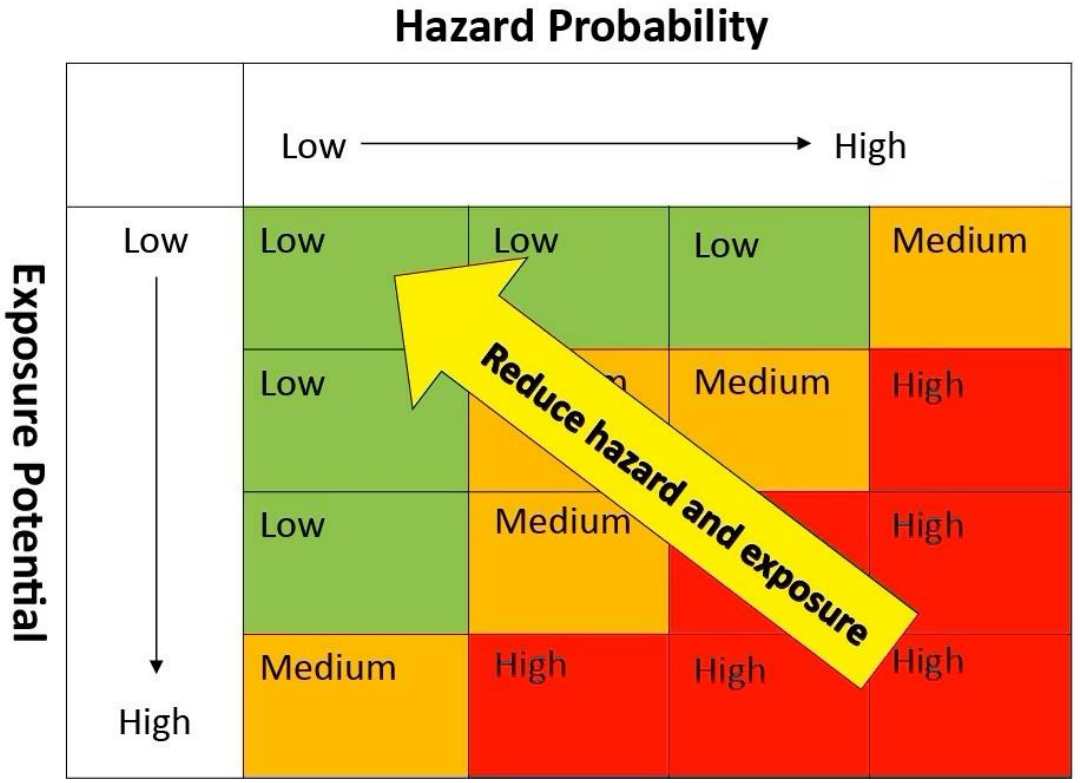
A "band of hazards" might be:

- skin/eye irritant,
- very toxic, or
- carcinogenic, among others.

The potential for exposure (low, medium, high) is also considered. The exposure potential includes the following considerations:

- duration of task,
- amount of chemical handled,
- or the form of the chemical.

Examples: COSHH Essentials, EMKG, ECETOC TRA, MEASE



Source: Centers for Disease Control and Prevention, www.cdc.gov

Exposure Banding II

HAZARD GROUP A				
	Volatility/Dust			
Amount used	Low volatility or dust	Medium volatility	Medium dust	High volatility or dust
Small	1	1	1	1
Medium	1	1	1	2
Large	1	1	2	2
HAZARD GROUP B				
	Volatility/Dust			
Small	1	1	1	1
Medium	1	2	2	2
Large	1	2	3	3
HAZARD GROUP C				
	Volatility/Dust			
Small	1	2	1	2
Medium	2	3	3	3
Large	2	4	4	4
HAZARD GROUP D				
	Volatility/Dust			
Small	2	3	2	3
Medium	3	4	4	4
Large	3	4	4	4
HAZARD GROUP E				
In this hazard group risk level is always 4				

Risk levels for COSHH Essentials

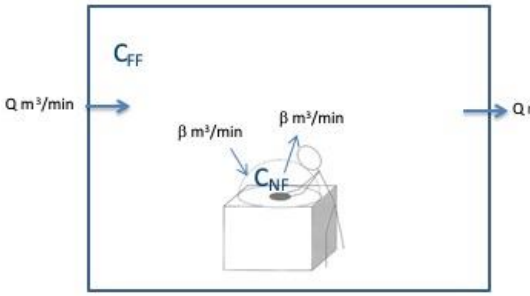
Source: German Federal Institute for Occupational Safety and Health, www.subsportplus.eu

Exposure Modelling I

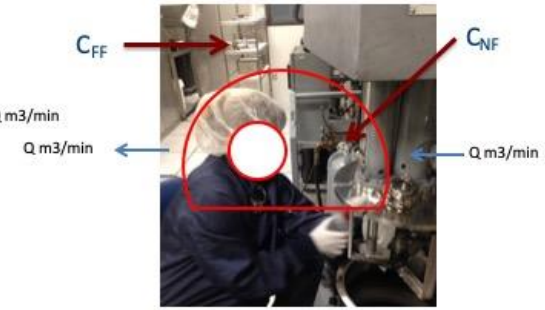
Occupational exposure modelling is the process of estimating worker exposure to hazardous substances using data and simulations to assess health risks.

Near Field Far Field Model (NF FF)

Conceptually:



Practically:



$$C_{NF} = \frac{G}{Q} + \frac{G}{\beta} + \alpha_1 \, exp(\lambda_1 \times t) + \alpha_1 \, exp(\lambda_2 \times t)$$

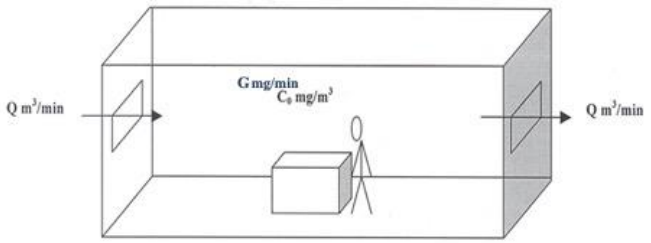
$$C_{FF} = \frac{G}{Q} + \alpha_1 exp(\lambda_3 \times t) + \alpha_1 exp(\lambda_4 \times t)$$

where $\alpha_1 = \frac{Q + k_L \times V}{V}$

C_{NF}: Near Field Concentration, mg/m³
C_{FF}: Far Field Concentration, mg/m³

Well Mixed Room (WMR) Model:

$$C(t), \frac{mg}{m^3} = C_0 \times exp\left[\frac{Q + k_L \times V}{V} \times t\right] + \frac{G + C_{IN} \times Q}{Q + k_L \times V}\left[1 - exp\left[\frac{Q + k_L \times V}{V}\right] \times t\right]$$



- Assumes constant emission throughout time period
- Assumes room is a perfectly mixed box

Source: John Hopkins University, publichealth.jhu.edu

Exposure Modelling II

Input:

- Physicochemical properties of the substance
- Use information
- Conditions of Use

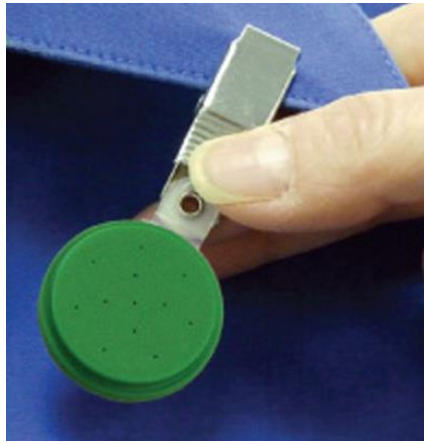
Output:

- Tier I: (Reasonable) Worst case exposure estimation
- Tier II+: Exposure distribution

Examples: Advanced REACH Tool (ART), Stoffenmanager®, IHMod™, RiskOfDerm

Exposure Monitoring I

Personal Sampling



Source: SKC Ltd, www.skcltd.com

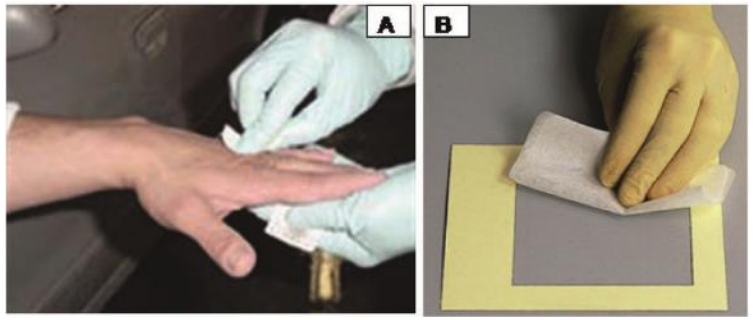
Area Sampling

Source: BioMax Environmental Inc., biomaxenvironmental.com

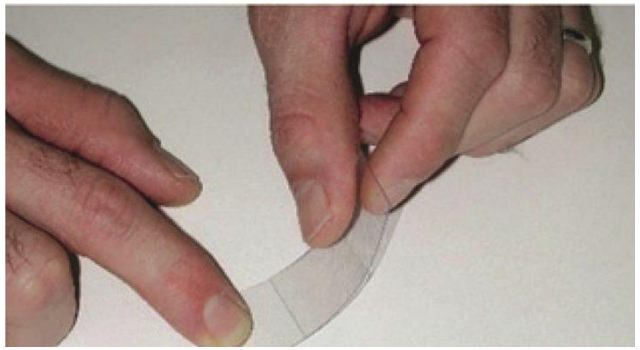
Source: Drägerwerk AG & Co. KGaA, www.draeger.com

Exposure Monitoring II

(Skin) Wiping



Tape Stripping



Patch Method

Glove/Whole Body Suits

Sources: Behroozy 2013, PMID: 23860542; Kim et al., 2014, https://doi.org/10.7585/kjps.2014.18.4.247; Babkevičs, www.linkedin.com

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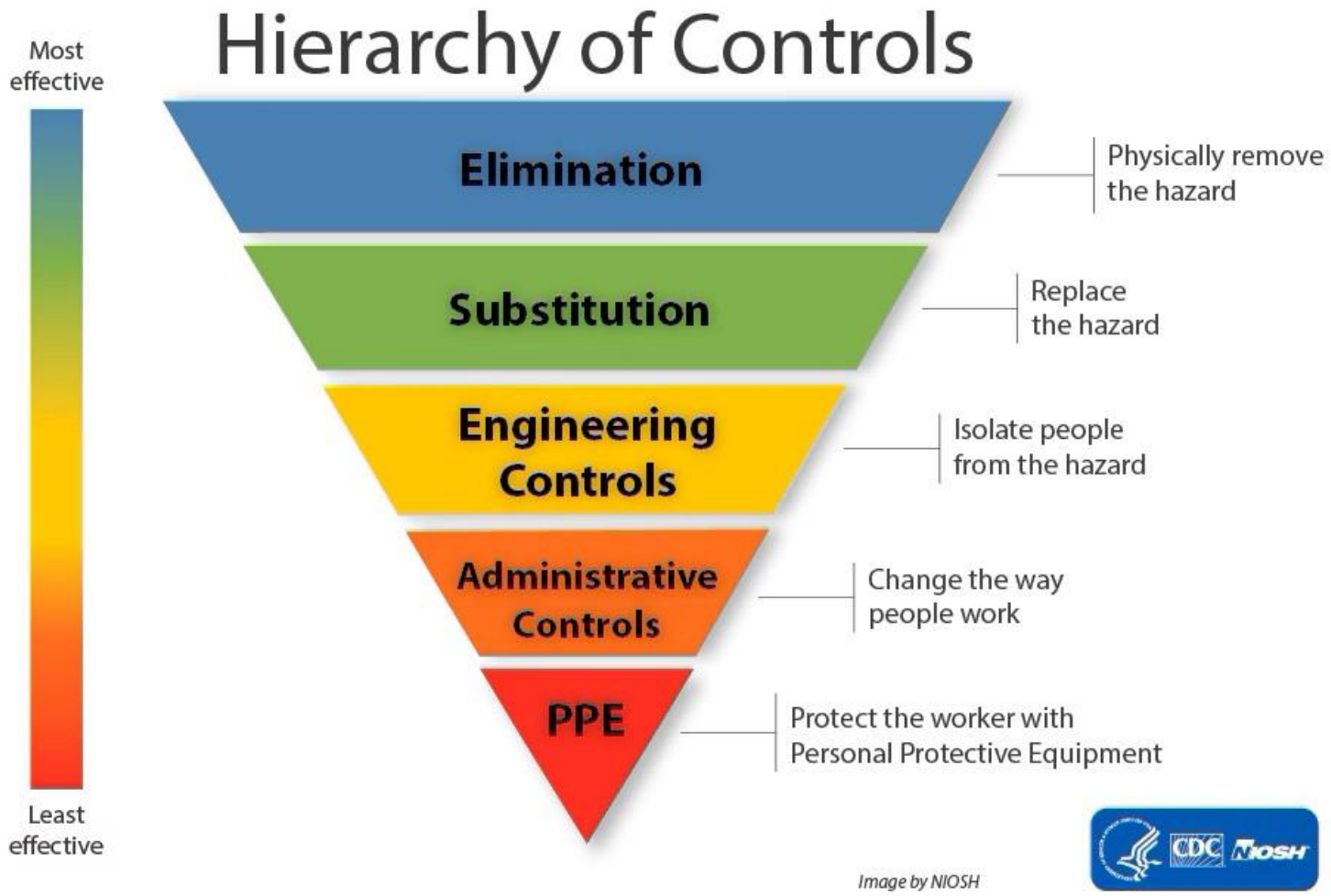
Risk Management Measures



Source: Centers for Disease Control and Prevention, www.cdc.gov

Engineering Controls

Engineering controls **reduce or prevent hazards from coming into contact with workers**. Engineering controls can include modifying equipment or the workspace, using protective barriers, ventilation, and more.

Examples: Containment, Automation, Local exhaust ventilation (LEV), and General ventilation

Grinding mortar

With LEV

Cutting blocks

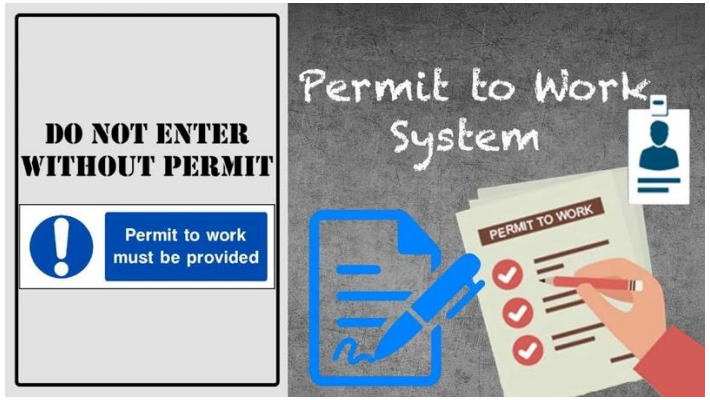
With water blanket

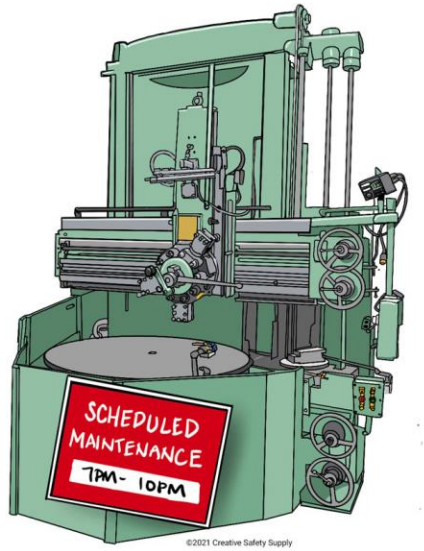
Source: Occupational Safety and Health Administration, www.osha.gov

Administrative Controls

Administrative controls establish **work practices that reduce the duration, frequency, or intensity of exposure to hazards**.

Examples: Work process training, Good housekeeping, Job rotation, Ensuring adequate rest breaks, Limiting access to hazardous areas or machinery, and Adjusting line speeds





Sources: Canadian Centre for Occupational Health and Safety, www.ccohs.ca; Creative Safety Supply, www.creativesafetysupply.com; Illah, www.linkedin.com

Personal Protective Equipment (PPE)

PPE is equipment **worn to minimize exposure to hazards**.

Examples: Respirators, Gloves, Safety glasses, and Hearing protection.

Least effective risk management measures. Often used as **secondary control measure**.

Source: European Agency for Safety and Health at Work, osha.europa.eu

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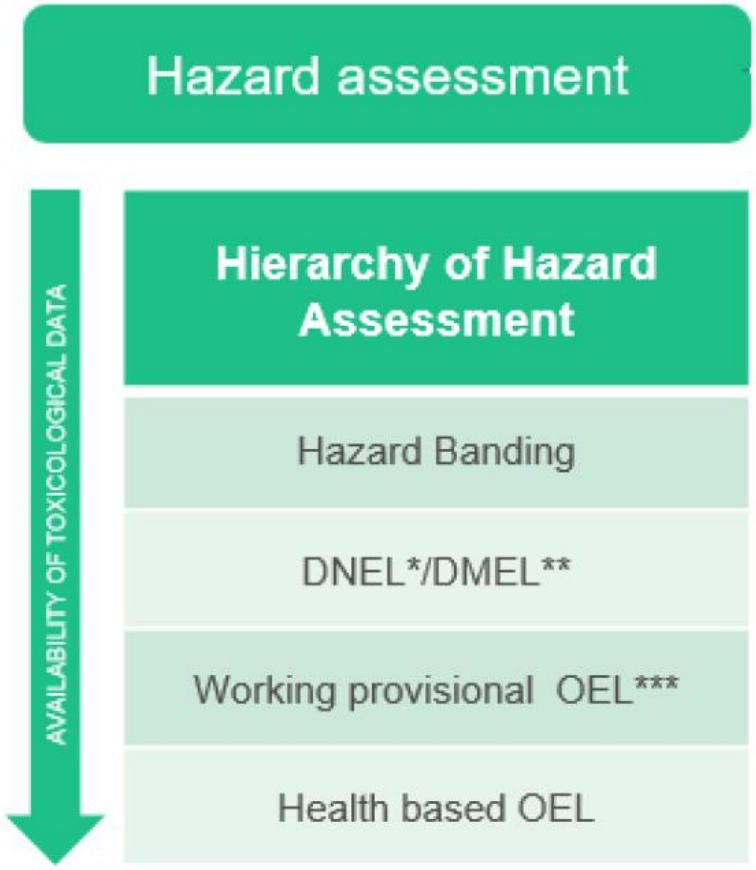
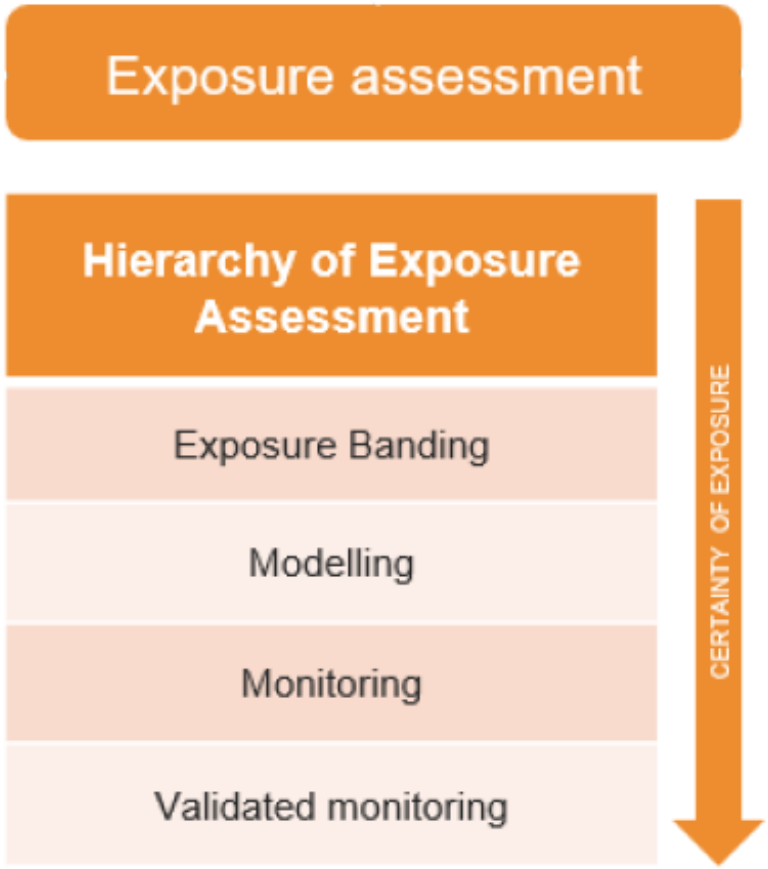
Align Data Certainty

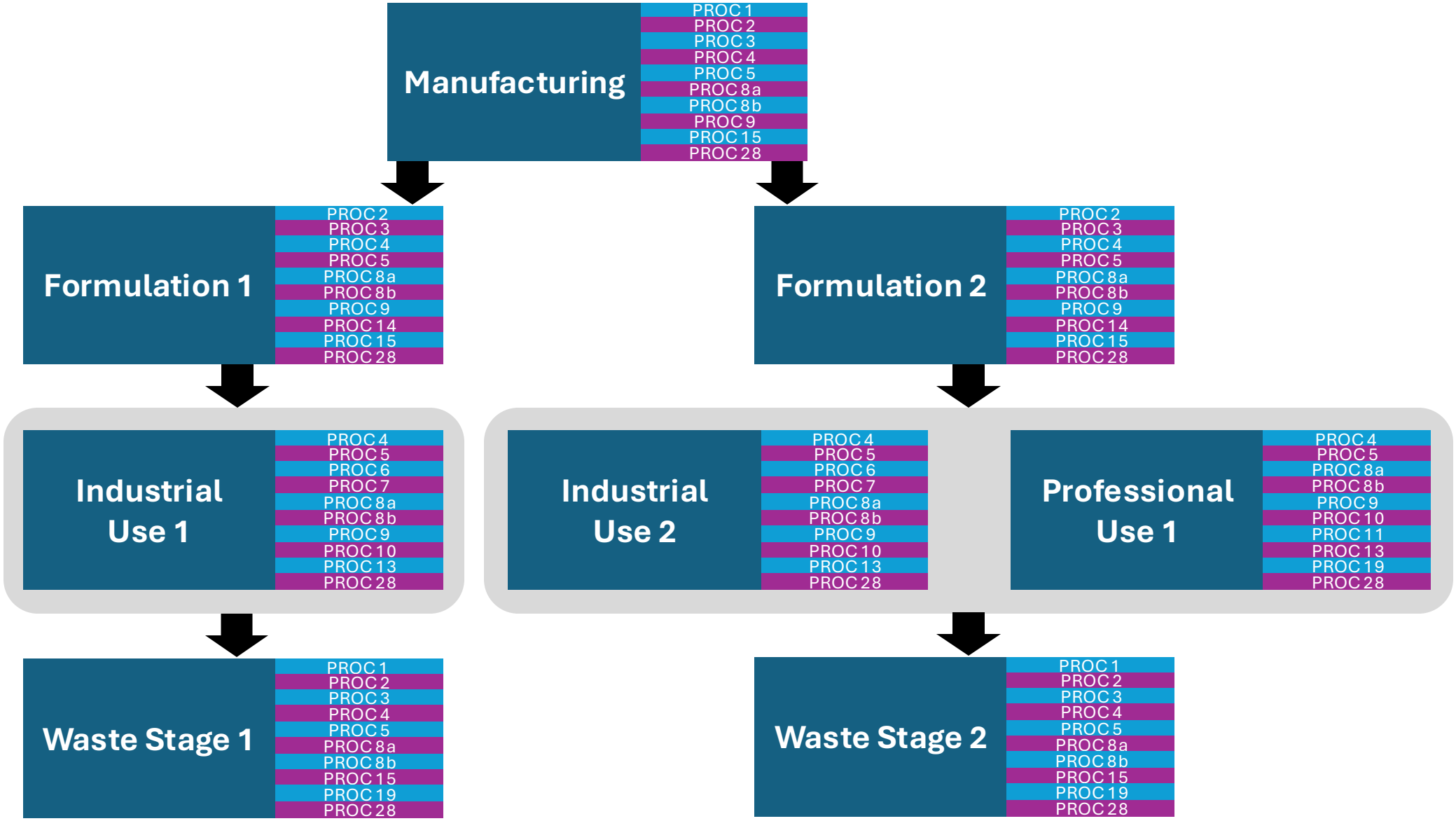


*Derived No Effect Level
**Derived Minimum Effect Level
***Occupation Exposure Limit

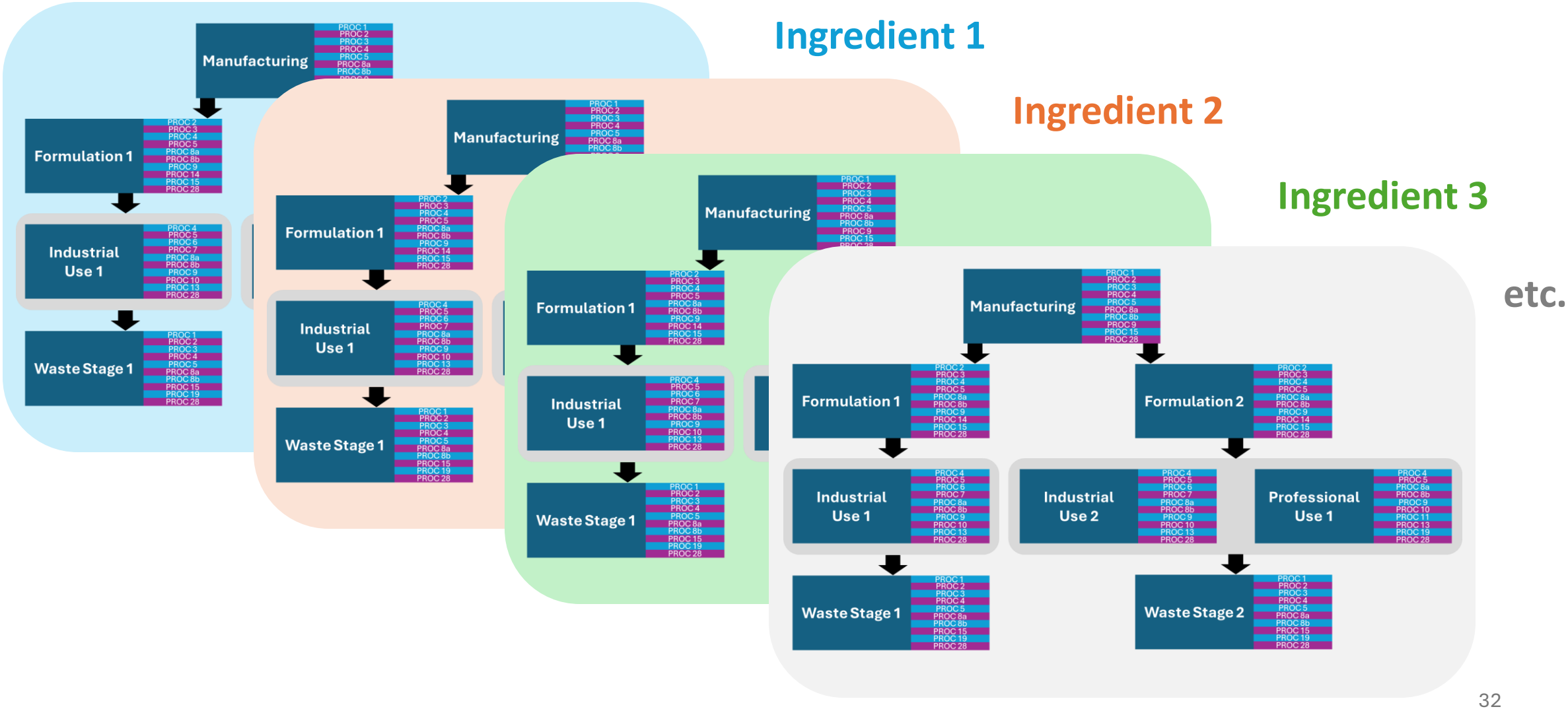


Source: Joint Research Centre, joint-research-centre.ec.europa.eu

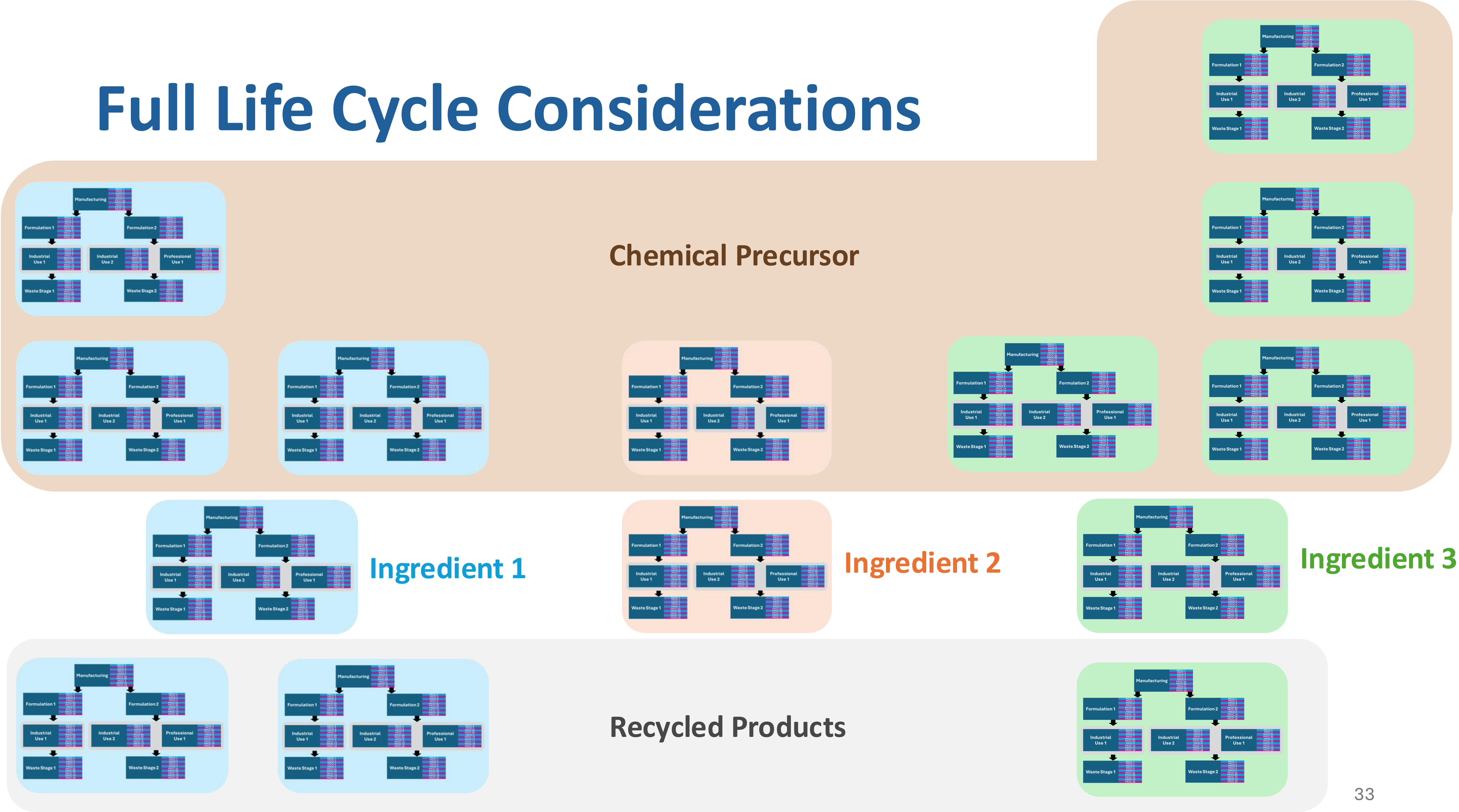
Product Life Cycle Considerations



Mixture Considerations



Full Life Cycle Considerations



SSbD Human Health Criteria

Options for a possible scoring according to JRC SSbD Framework:

- **Step 2:** Human health aspects in the chemical/material production and processing phase

For each contributing scenario (CS), *i.e.*, PROC	
If total RCR<1	3
If total RCR>1 but all individual RCRs<1	2
If total RCR>1 but at least 1 individual RCRs>1	1
If total RCR>1 and more than one individual RCRs>1	0

- **Step 3:** Human health aspects in the final application phase

Final use, Total Risk Characterization Ratio (RCR)	
<0.5	3
0.5-1.0	2
1.0-1.5	1
>1.5	0

Source: Joint Research Centre, joint-research-centre.ec.europa.eu

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Summary: Key Take Aways

- Sustainability exposure assessment **follows standard risk assessment methods**, similar to those in occupational safety and health
- Clearly **define the scope and limitations** of the sustainability assessment
- **Ensure consistent detail** in risk assessment throughout the entire life cycle
- **Expert judgment is essential** to interpret the conclusions of the occupational exposure assessment

References

- **Introduction to Exposure Assessment**

  KEMI (Swedish Chemical Agency): Guidance on national chemicals control - Hazard and risk assessment of chemicals – an introduction. 2020. Article number: 511 380.

- **Selection of an Occupational Exposure Limit (OEL)**

  Deveau *et al.* (2015). The Global Landscape of Occupational Exposure Limits—Implementation of Harmonization Principles to Guide Limit Selection. Journal of Occupational and Environmental Hygiene. https://doi.org/10.1080/15459624.2015.1060327.

- **Types of Exposure Assessments**

  ECHA (European Chemical Agency): Guidance on Information Requirements and Chemical Safety Assessment - Part D: Framework for exposure assessment. Version 2.0. 2016. ECHA-16-G-08-EN.

- **Occupational Risk Management**

  EU-OSHA (European Agency for Safety and Health at Work): OSHwiki. Available via: https://oshwiki.osha.europa.eu/en

- **Occupational Exposure Assessment in SSbD**

  JRC (Joint Research Center) Technical Report: Safe and Sustainable by Design chemicals and materials - Application of the SSbD framework to case studies. 2023. JRC131878.

Thank you very much!