REACH Regulation: revision and implications for OSH

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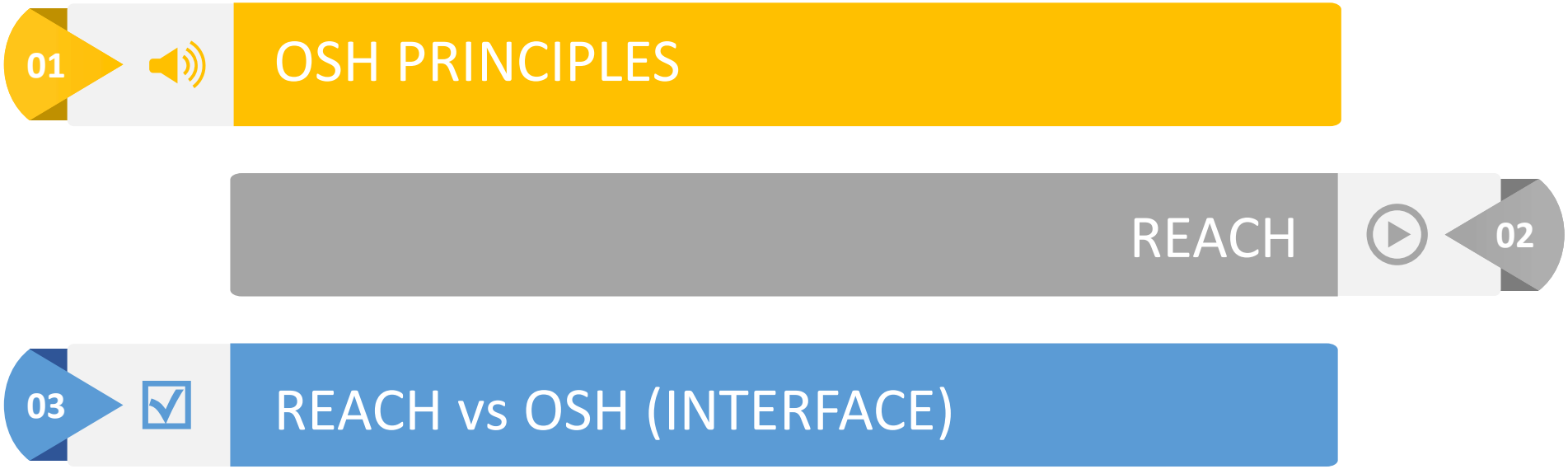
13-14 June 2024


01
OSH PRINCIPLES
REACH
02
03
REACH vs OSH (INTERFACE)

OSH Principles


Occupational risks prevention

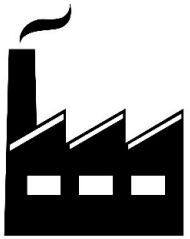

Workers protection at workplace


Risk factors and risk elimination


Information and training for workers


Workers and representatives consultation

REACH



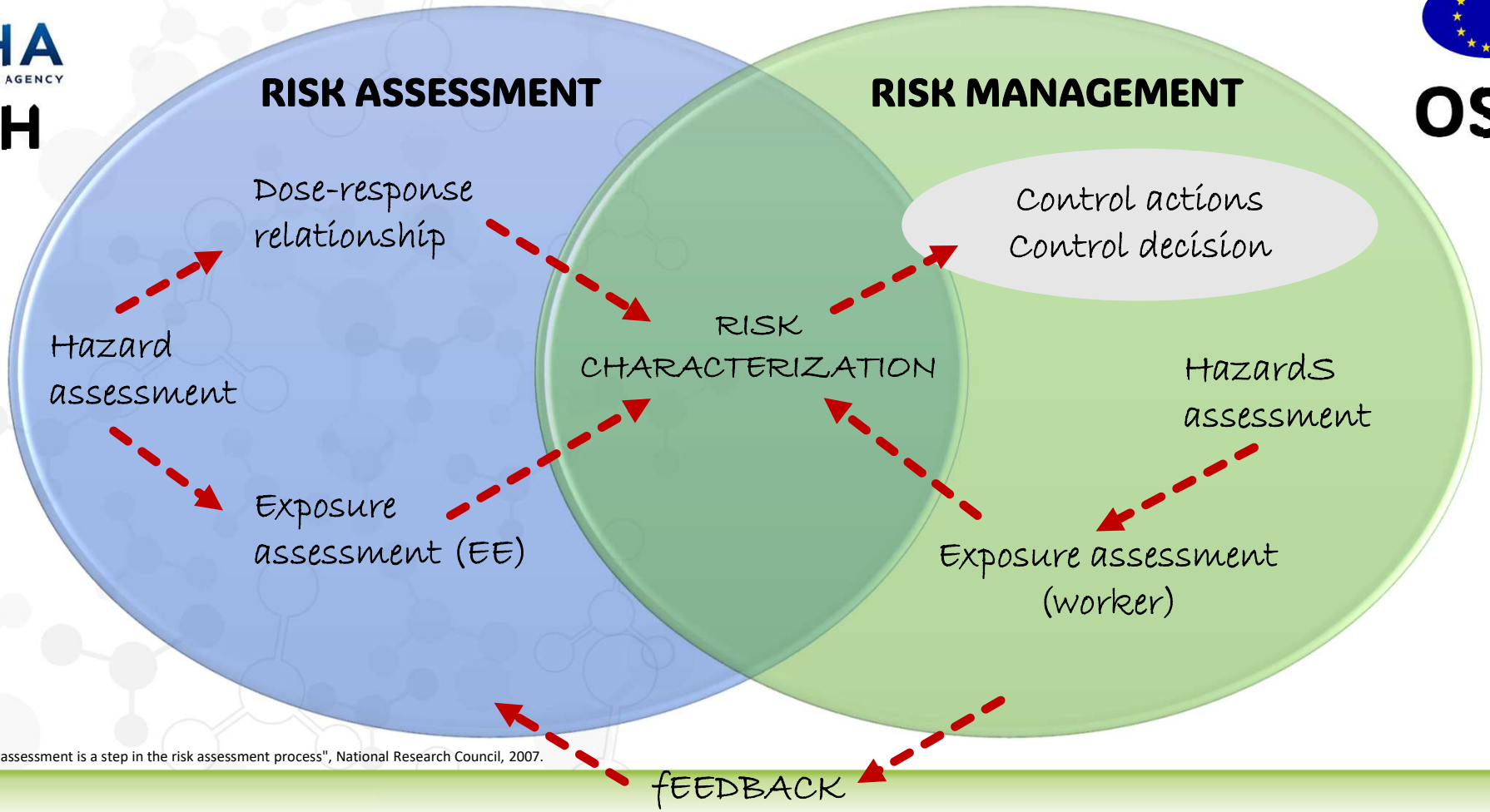
Hazard elimination

Authorisation
Restriction
Candidate list

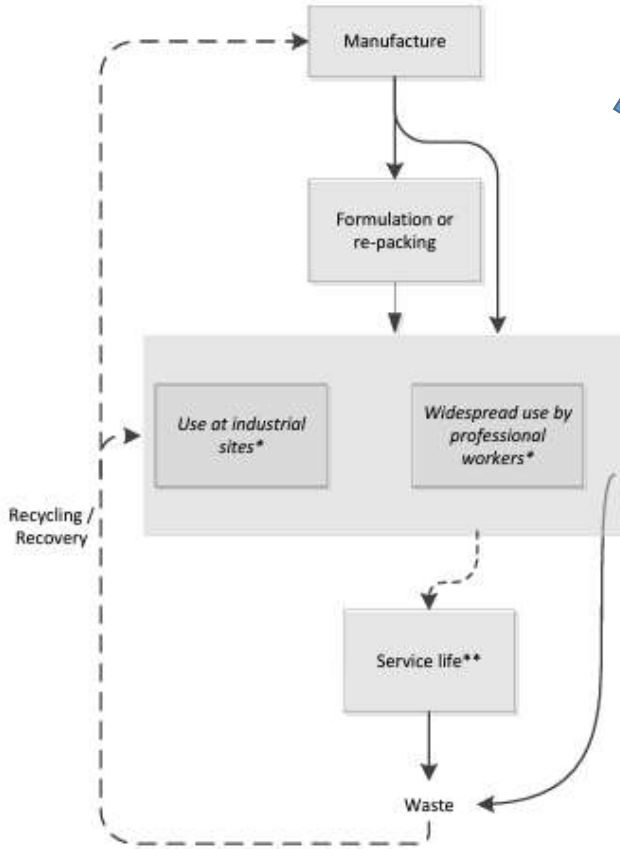
OSH Principles	REACH
Occupational exposure limit values, indicative limits, binding national and European limits, biological limit values	DNELS/DMELs
Consideration of combined exposures(> substances/mixtures) & other risks, factors	✗
Hierarchy of control	✓
Risk assessments updates (frequently)	✗

ECHA
EUROPEAN CHEMICALS AGENCY
REACH

OSH



Adapted from: "Dose-response assessment is a step in the risk assessment process", National Research Council, 2007.



* End uses

** includes processing of articles at industrial sites

R12. ECHA guidance

Consumers

Workers

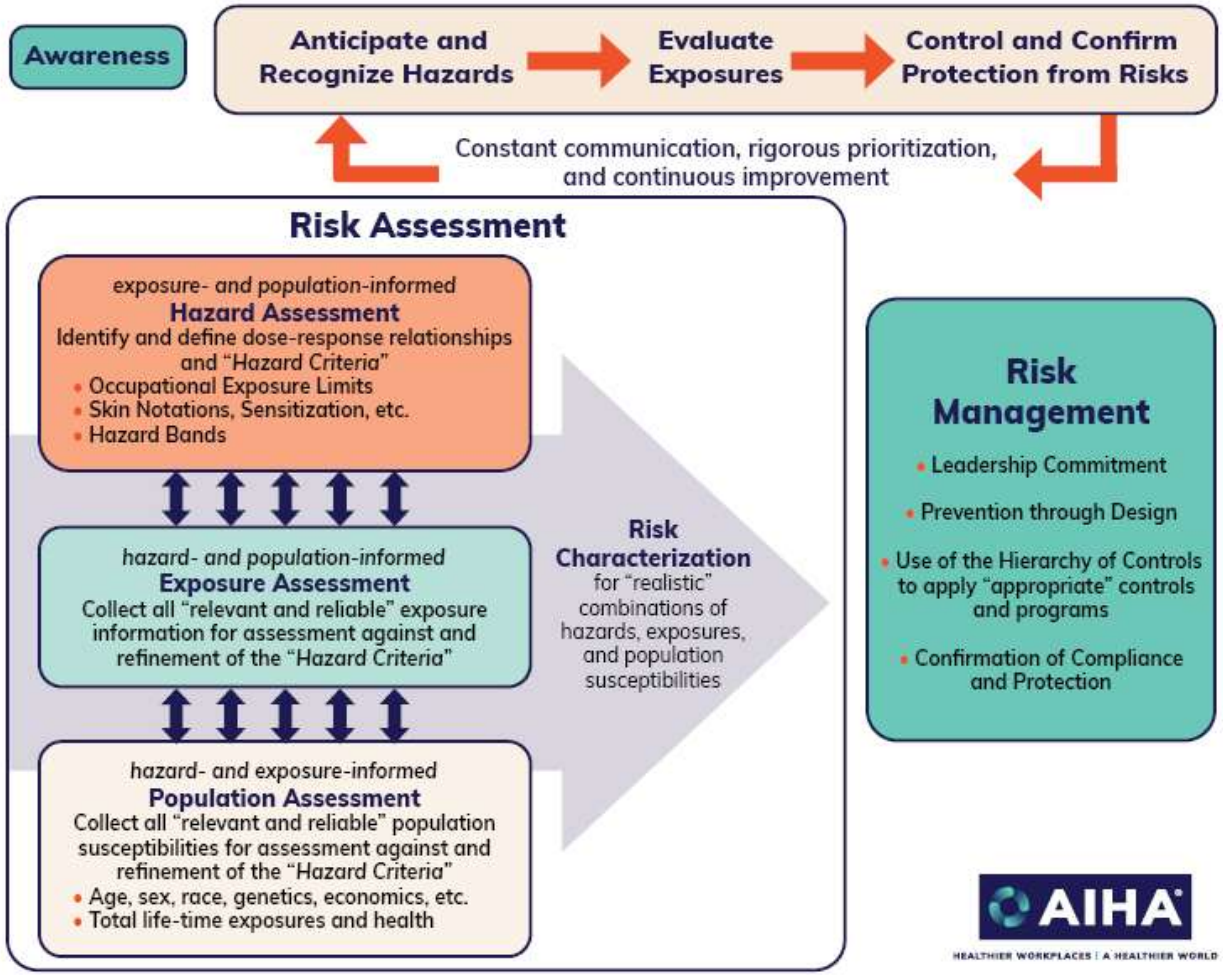
Environment

Substance Life cycle Stage (LCS)

REACH COMPLIANCE

ECHA EUROPEAN CHEMICALS AGENCY

REACH



QUALIFIED PROFESSIONAL

https://www.aiha.org/about-aiha (American Industrial Hygiene Association)

Chemical Safety Report (>10T)

1

Chemical Safety Assessment (Art.14.3):

a) Human health Hazard assessment;
b) Physicochemical Hazard assessment;
c) Environmental hazard assessment;
d) persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment.

Report

FDS

DN(M)ELs/PNECs

Threshold level

2

If hazardous (criteria Regulation CLP):

Each identified use

- **Exposure assessment:**
  - ❖Exposure scenarios
  - ❖Exposure estimation
- **Risk characterization**

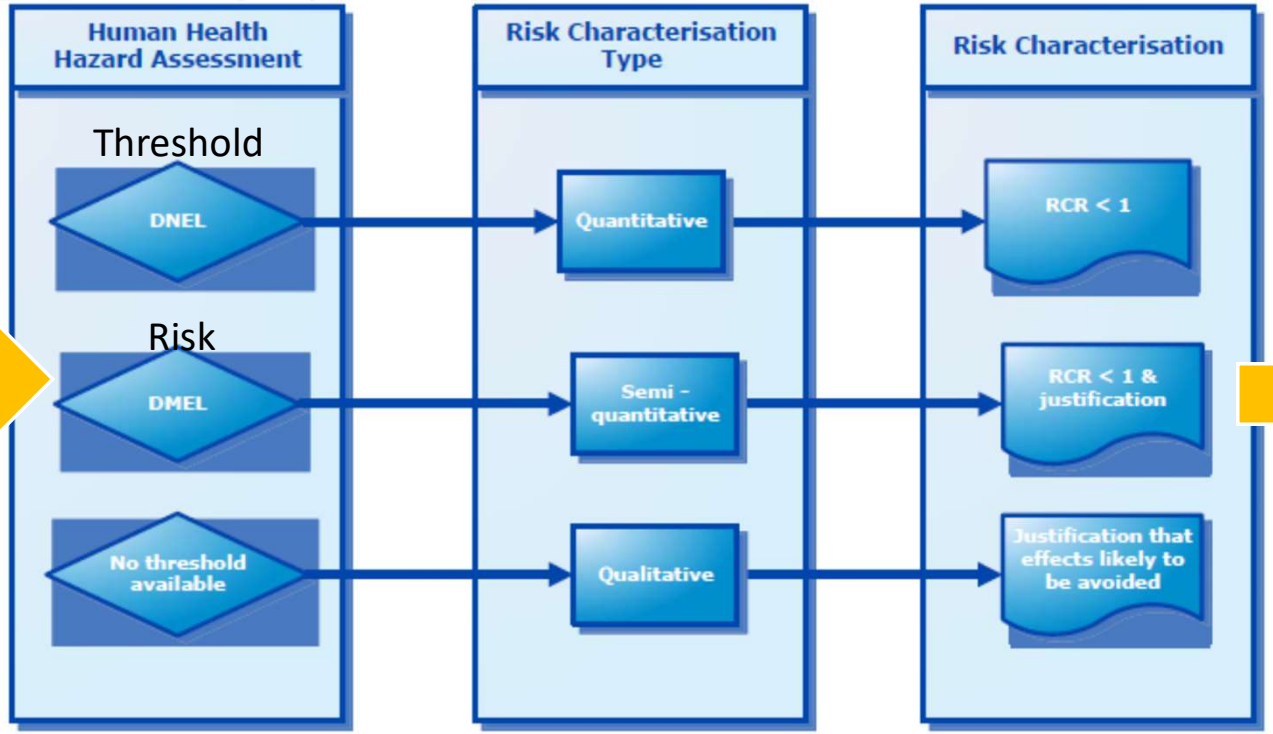
FDS-e

REACH COMPLIANCE

Types of chemical safety assessment

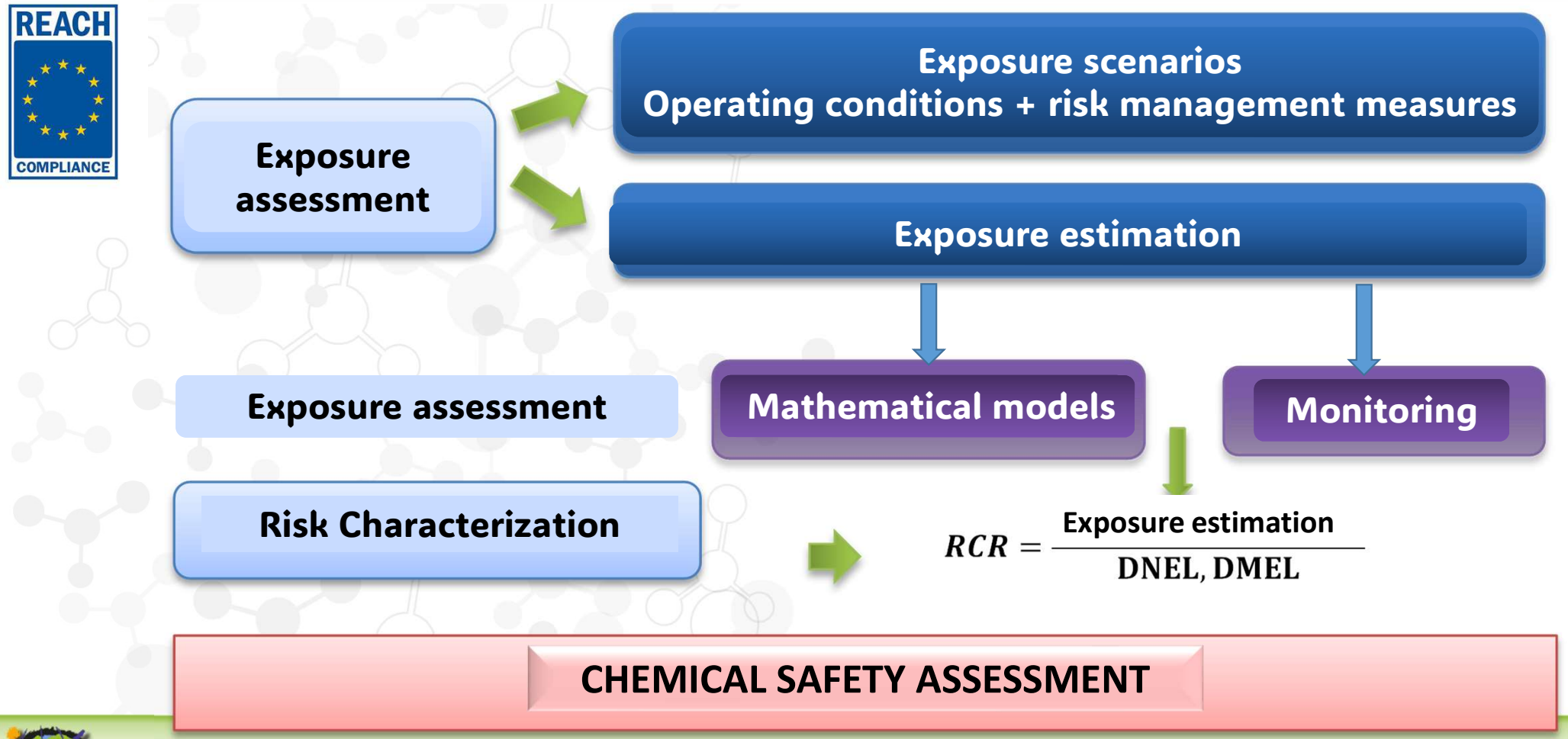
Tier 1 1
Human hazard assessment
DNEL, DMEL

Hazard assessment Hazard class



RISK MANAGEMENT MEASURES

How to undertake a qualitative human health assessment and document it in a chemical safety report. Practical Guide 15


REACH
COMPLIANCE
Exposure assessment
Exposure scenarios
Operating conditions + risk management measures
Exposure estimation
Exposure assessment
Mathematical models
Monitoring
Risk Characterization
$RCR = \frac{\text{Exposure estimation}}{\text{DNEL, DMEL}}$
CHEMICAL SAFETY ASSESSMENT

OSH

$$I = \frac{[C](t)}{OEL}$$

Cyclone Higgins - Dewell

Inhalation

Exposure index

ACSH

Advisory Committee on Safety and Health at Work (Working party on chemicals)

Binding OELs

- Chemical Agents:
  Directive 98/24/EC
- Carcinogens and Mutagens:
  Directive 2004/37/EC
  First Amendment - Directive 2017/2398
  Second Amendment - Directive 2019/130
  Third Amendment - Directive 2019/983
  Fourth Amendment - Directive 2022/431
- Asbestos:
  Directive 2009/148/EC
  First Amendment - Directive 2023/2668

REACH

$$RCR = \frac{Exposure\ (estimated/measured)}{DN(M)EL}$$

RAC

Risk Assessment Committee

Each use
Contributing scenarios
Scaling

Diisocyanates

Official Journal of the European Union

EN
L series

2024/869

19.3.2024

DIRECTIVE (EU) 2024/869 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 13 March 2024

amending Directive 2004/37/EC of the European Parliament and of the Council and Council Directive 98/24/EC as regards the limit values for lead and its inorganic compounds and for diisocyanates

OEL: Group -NCO

Endocrine disruptors (New Hazard classes) CLP

REACH: candidate list SVHC

LIST OF BINDING OCCUPATIONAL EXPOSURE LIMIT VALUES

Name of agent	EC No (1)	CAS No (2)	Limit values						Notation	Transitional measures
			8 hours (3)			Short-term (4)				
			µg/m³ (5)	ppm(6) (6)	f/ml (7)	µg/m³ (5)	ppm(6) (6)	f/ml (7)		
Diisocyanates (measured as NCO (10))			6			12			Skin (8) Dermal and respiratory sensitisation (9)	A limit value of 10 µg NCO/m³ in relation to a reference period of 8 hours and a short-term exposure limit value of 20 µg NCO/m³ shall apply until 31 December 2028.

L 252/24 EN Official Journal of the European Union 4.8.2020

COMMISSION REGULATION (EU) 2020/1149

of 3 August 2020

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards diisocyanates

(Text with EEA relevance)

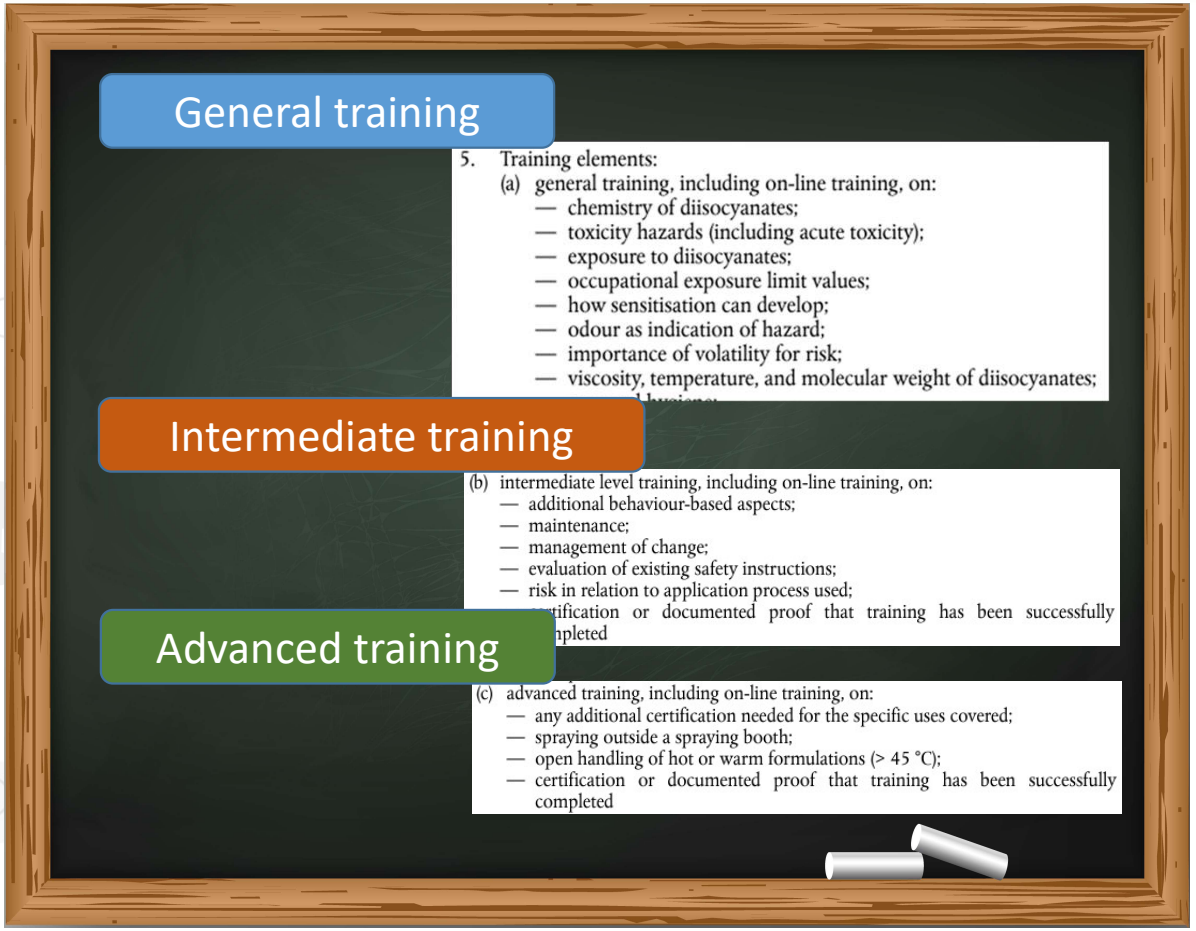
ECHA
EUROPEAN CHEMICALS AGENCY

ANNEX XVII TO REACH – Conditions of restriction

Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Entry 74
Diisocyanates, O = C=N-R-N = C=O, with R an aliphatic or aromatic hydrocarbon unit of unspecified length

Such training shall be conducted by **an expert on occupational safety and health** with competence acquired by relevant vocational training.



Section of the SDS	Sum of sections: info not adequate/ not present	No. of sections: info is present but not adequate/ not appropriate	No. of sections: info is not present	Total no. checked for this section	% of SDSs checked with issues in this section
8.1. Control parameters	59	45	14	157	38%
- 8.1.1 National limit values	67	18	49	148	45%
- 8.1.2 Information on currently recommended monitoring procedures	115	3	112	133	86%
- 8.1.3 If air contaminants are formed when using the substance or mixture as intended	99	0	99	120	83%
- 8.1.4 The relevant DNELs and PNECs for the substance/s for the exposure scenarios	89	6	83	139	64%
- 8.1.5 Details of any control banding approach used	102	0	102	109	94%
8.2. Exposure controls	73	66	7	151	48%
- 8.2.1 Appropriate engineering controls	83	43	40	155	54%
- 8.2.2 Individual protection measures, such as personal protective equipment	85	66	19	169	50%
- 8.2.3 Environmental exposure controls	105	14	91	150	70%

Section 2.1 Classification of the substance or mixture:

Section of the SDS	Sum of sections: info not adequate/ not present	No. of sections: info is present but not adequate/not appropriate	No. of sections: info is not present	Total no. checked for this section	% of SDSs checked with issues in this section
2.1. Classification of the substance or mixture	43	36	7	127	34%
- Substance - Regulation 1272/2008 (CLP)	21	5	16	36	58%
- Mixture - Regulation 1272/2008 (CLP)	71	48	23	181	39%

8.2.2: 50% indicate a problem, with the majority pointing to inadequate information. More Remarks were made for this that any of the other subsections of Section 8, and a clear issue is observed. The PPE specification is missing, mainly for gloves but also respiratory protection (most comments refer to EN standards, glove material, thickness etc. not being provided). Seems a clear case where the DU can communicate with the supplier that the information is not sufficient (e.g. via the Dutch SDS check tool).

RISK ASSESSMENT & MANAGEMENT (OSH)

TAILORED TO SPECIFIC “IN SITU” SITUATION

REACH

REACH Revision

- Generic Risk Management Approach
- Essential use concept
- Simplifying Authorisation and Restriction process
- Unaddress risks (ED, insufficient compliance,…)
- Strengthen enforcement

8 th European **Conference on standardization, testing and certification** in the field of occupational safety and health

CII REACH OSH

Cross-Industry Initiative
for better regulation in chemicals management

SEARCH
DISCLAIMER

ABOUT THE CII / WHAT WE STAND FOR / MEMBERS / POSITIONS / CONTACT

POSITION PAPER | ENGLISH | DEUTSCH | FRANÇAIS | ITALIANO

Recommendations by an EU-wide cross-industry initiative for ***better regulation*** in chemicals management

Better regulation in chemicals management requires identification, implementation and enforcement of the most effective risk management option, tailored to tackle a specific risk. Please find the document below in English, German, French and Italian.

The 18 September session of the ***CII REACH-OSH Forum*** was a success!

We are delighted that more than 90 experts from all over Europe joined us for the 18 September CII REACH-OSH Forum. As a reminder, the aim of this Forum is to provide an informal platform for the European Commission, Member States' experts, trade union and industry representatives and other relevant stakeholders to exchange views and discuss solutions to clarify the REACH-OSH interface. Please find below the

CII comments on the ***'Paper to inform joint CARACAL and ACSH/WPC discussions on the interface between REACH and OSH'*** (CA/05/22)

The CII welcomes the organisation of the 1st Joint Meeting of CARACAL and the ACSH/WPC, as well as the related

Thank you!!

Ruth Jiménez **INSST**