Chemicals Risk Evaluation and lessons learned

Content of this presentation

- Hazard assessment and characterization
- Exposure assessment
- Risk characterization
- Lessons learned

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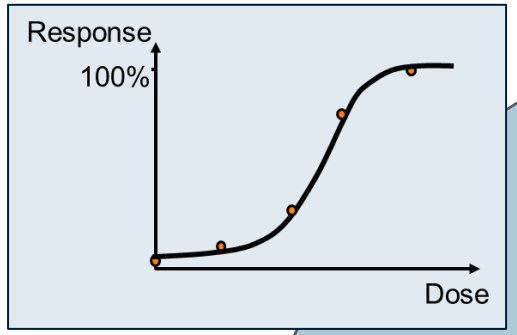
Risk assessment of chemicals – the overall process

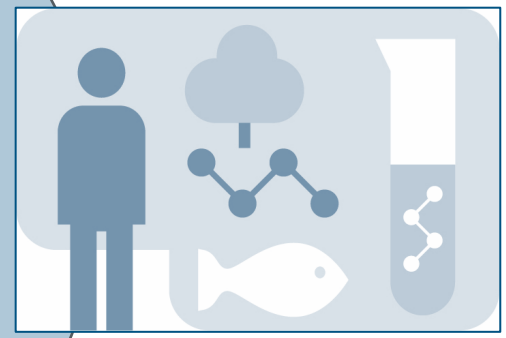


(1) Hazard identification

Classification and labelling

(2) Hazard characterization + guidance/ reference value

(3) Exposure assessment



(4) Risk characterisation

Risk >1 → Risk management

Risk <1 → Acceptable use

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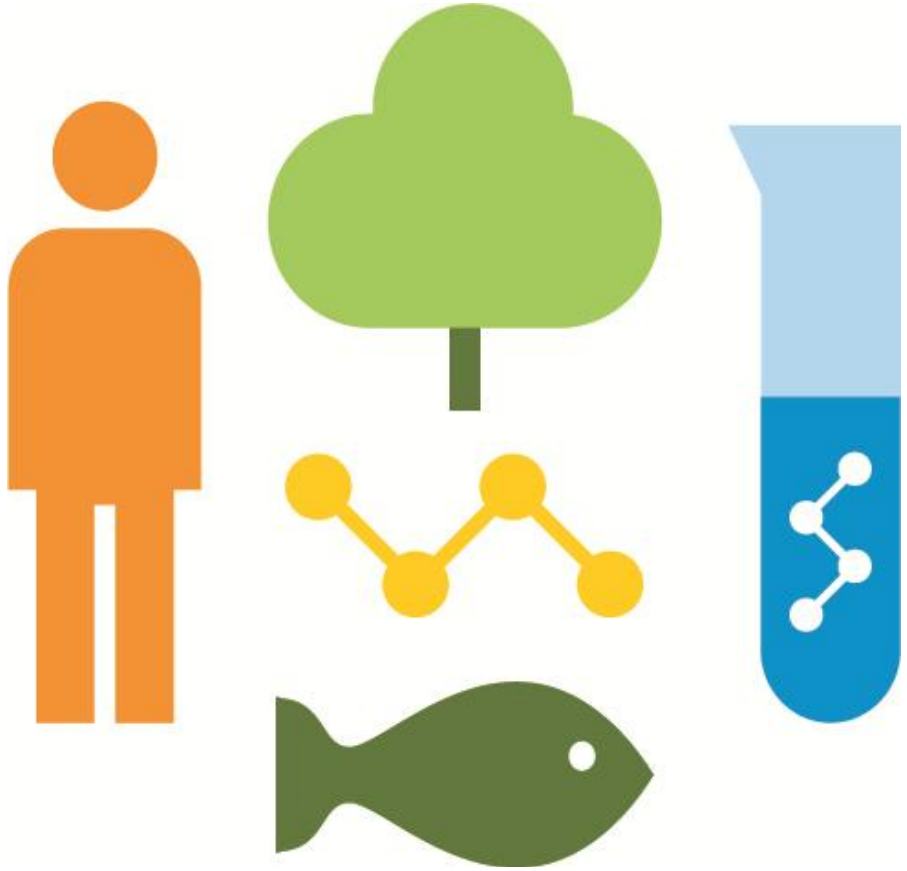
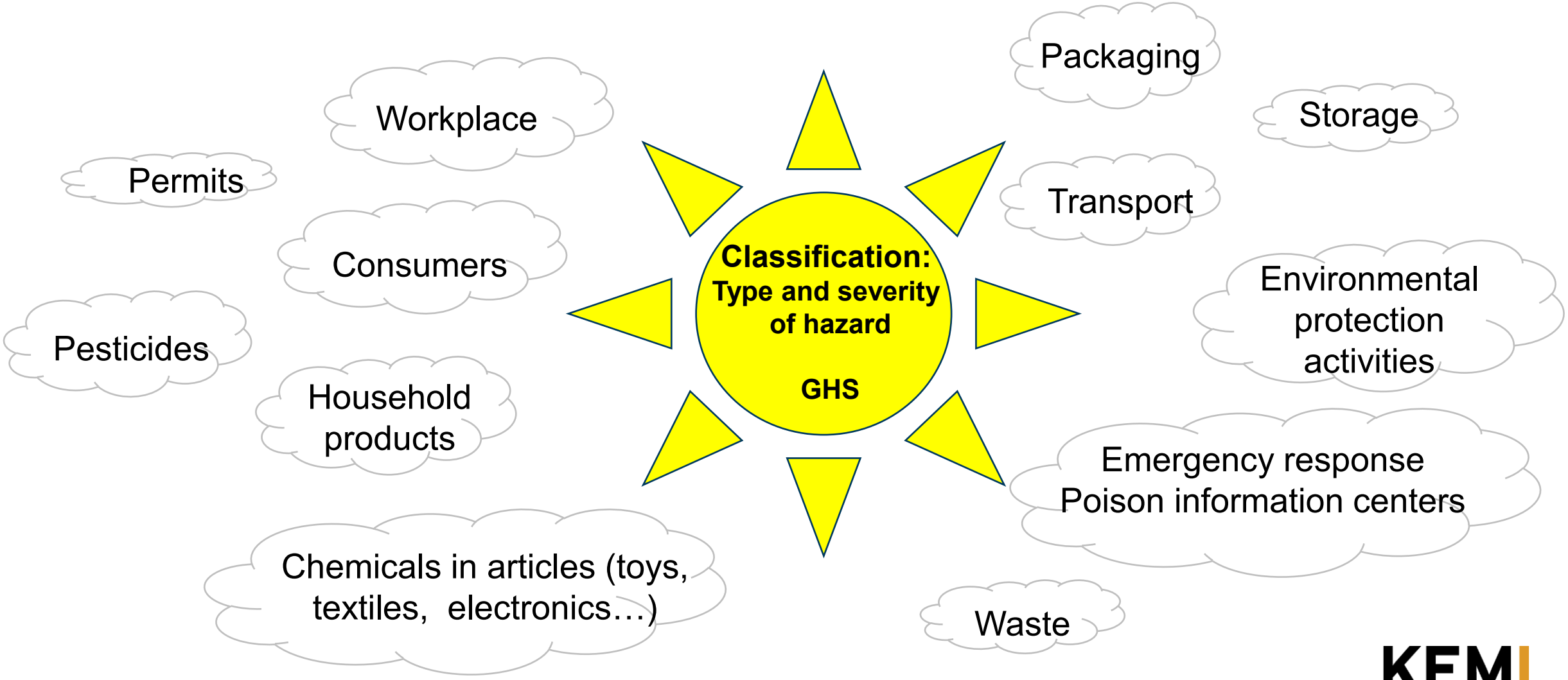
(1) Hazard identification

The purpose of the hazard identification step is to determine the hazardous properties of the chemical



Hazard classification is fundamental for risk assessment and risk reduction



Is the substance hazardous to humans?

Assessment and evaluation criteria based on

- **Test data, preferably** generated in accordance with validated and internationally accepted methods (e.g. OECD TG)
  - In vivo (animal tests)
  - Ex vivo (tissue)
  - In vitro (cell-based tests)
  - In silico (computer-based)

- **Epidemiological data and human experience**
  - General public
  - Work environment
  - Accidents

Health hazard – Toxicity in humans

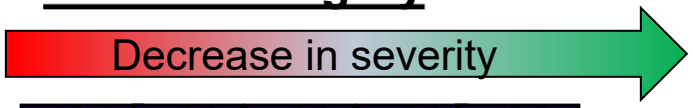
Acute toxicity	Chronic toxicity
Single exposure	Repeated exposure
High dose	Low dose
Clinical symptoms	No overt clinical symptoms
Treatment	Treatment not always possible
Recovery	Sustained/irreversible damage

Most relevant as basis for risk assessment but also for classification and labelling

Most relevant for classification purposes

GHS Health hazard classes and categories

Test data or other types of information needed to identify the hazards



Hazard Class	Hazard Category
Acute Toxicity	1 2 3 4 5
Oral	1 2 3 4 5
Dermal	1 2 3 4 5
Inhalation	1 2 3 4 5
Skin Corrosion/Irritation	Corrosive: 1A 1B 1C; Irritant: 2 3
Serious Eye Damage/Irritation	1 2A 2B
Sensitization	
Respiratory	1A 1B
Skin	1A 1B
Germ Cell Mutagenicity	1A 1B 2
Carcinogenicity	1A 1B 2
Reproductive Toxicity	1A 1B 2 Lactation
STOT - Single Exposure	1 2 3
STOT - Repeated Exposure	1 2
Aspiration hazard	1 2

https://unece.org/about-ghs

Environmental hazards – toxic to populations

- **Biota** (living)
  - Hazardous to the **aquatic** environment – acute and chronic (**GHS**), three trophic levels
  - Identification of hazards dependent on:
    - Aquatic toxicity data (short and long term)
    - Degradation (biotic or abiotic) of organic chemicals
    - Potential for (or actual) bioaccumulation
  - Hazardous to the **terrestrial** environment
  - Hazardous to the **microorganisms** in Sewage Treatment Plants
  - Hazardous to the top **predators** (Secondary poisoning)
- **Abiota** (non-living)
  - Hazardous to the **ozone** layer (**GHS**)

PBT assessment

- To protect systems/trophic levels where risks are difficult to estimate since they may arise later or far away
- The precautionary principle enables decision-makers to adopt precautionary measures when scientific evidence is uncertain, and the stakes are high

- **Persistence**: The potential to persist for a long time in the environment ($T_{1/2}$*)
- **Bioaccumulation**: The potential of the substance to accumulate in biota and eventually, to pass through the food chain (bioconcentration factor, BCF)
- **Toxicity**: The substance show high long-term toxicity to marine and/or freshwater species (NOEC) and/or
- CMR/chronic toxicity

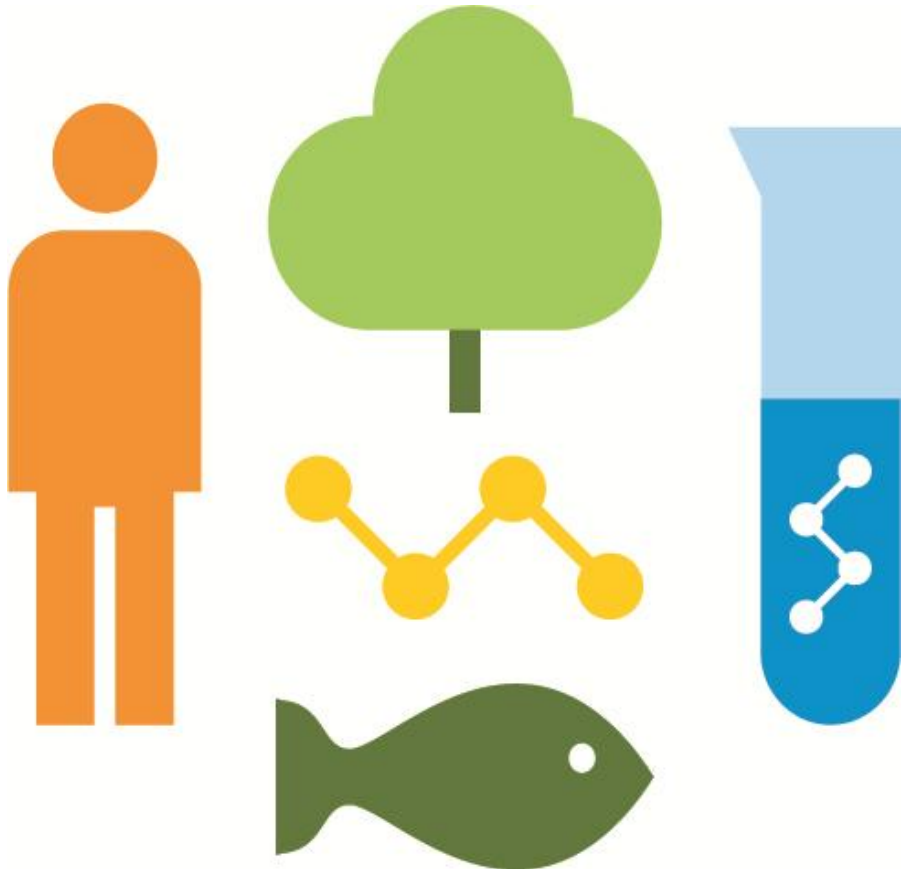
*the time it takes until 50 % of the substance is degraded

(2) Hazard characterization

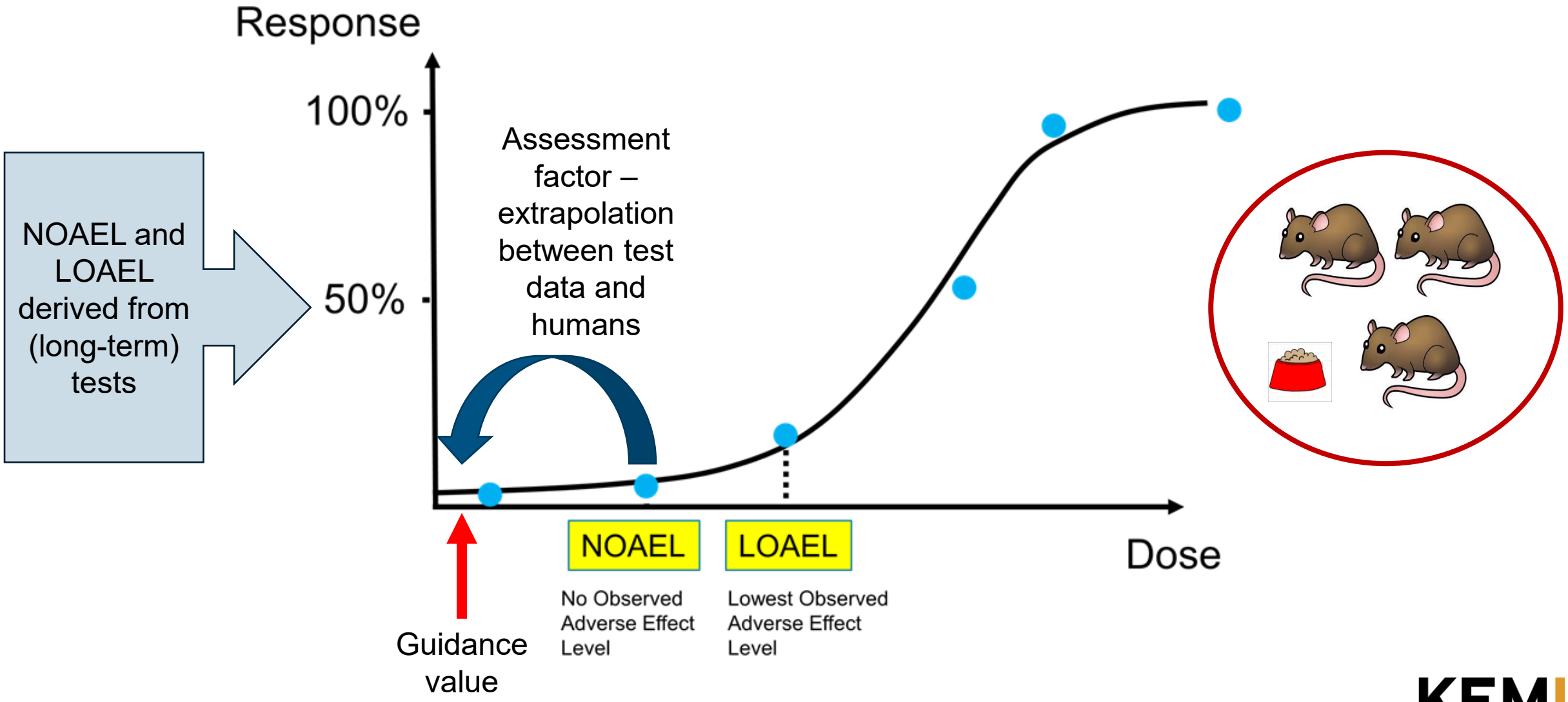
The quantitative description of inherent properties of an agent having the potential to cause adverse effects.

Also referred to as dose-response assessment.

Guidance/reference value identification



Calculating the guidance value for human health



Assessment Factors and Guidance values – human health

Assessment factor (AF) accounting for:		Default value
Interspecies differences	Rat to human	10
Intraspecies differences	Worker General population Children	5 10 10-100
Exposure duration	A larger AF is used if the data comes from a study of short duration	2-6
Dose-response	e.g. LOAEL to NOAEL	3-10
Quality of the whole database		1-10

Health based guidance value

Guidance/reference value =
NOAEL / Assessment factor

Examples:

- ADI (acceptable daily intake)
- TDI (tolerable daily intake)
- DNEL (derived no effect level)

General principle for calculating a reference value

Estimate a concentration below which harmful effects are not expected

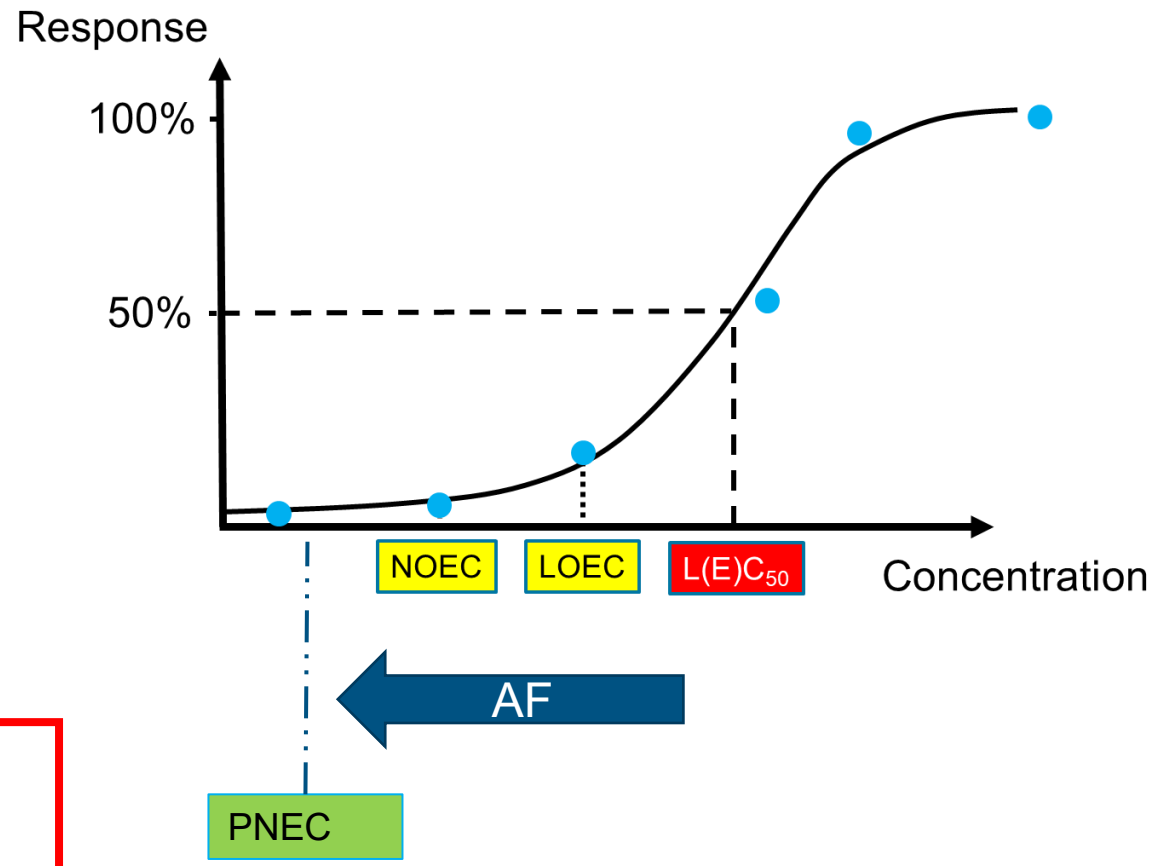
$$PNEC = \frac{lowest\ L(E)C_{50}\ or\ NOEC}{AF}$$

1. Identify highest reliable acute/chronic toxicity for the three trophic levels

2. Calculate concentration – response values:
   - $L(E)C_{50}$ for short term tests
   - NOEC (No observed effect concentration) for long term tests

2. Extrapolation methods to extrapolate lab data to the "real world":
   - Assessment Factors (AF = 10-1000)

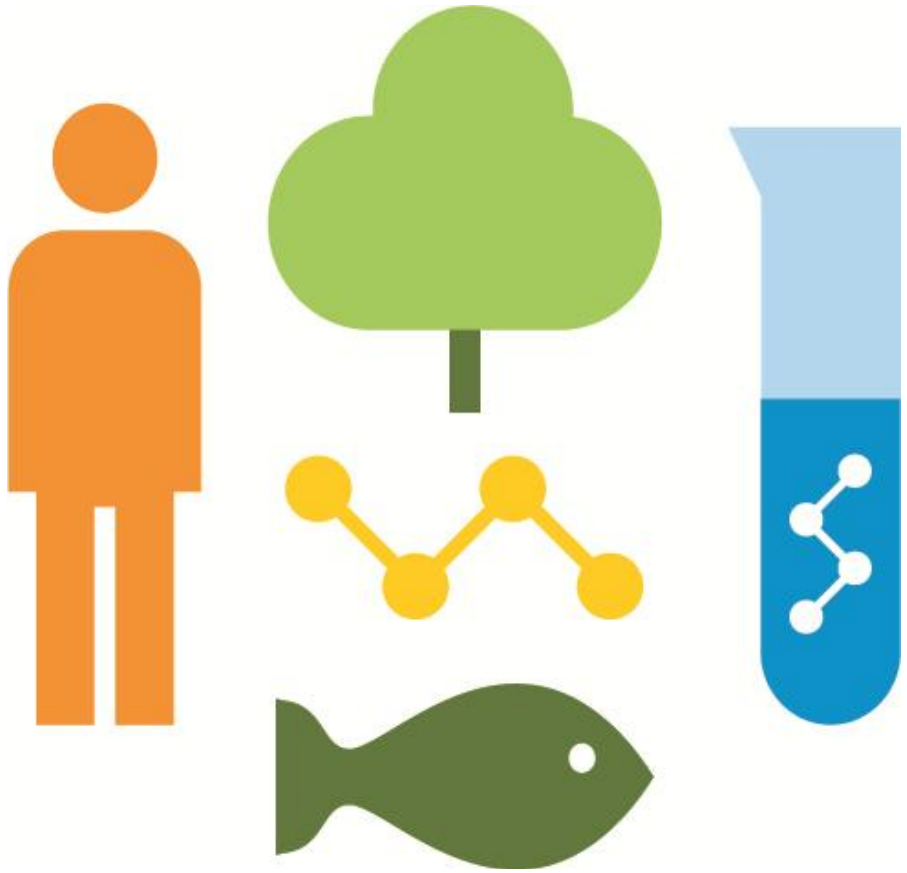
3. Calculate the reference value:
   - **P**redicted **N**o **E**ffect **C**oncentration (**PNEC**), various compartments



(3) Exposure Assessment

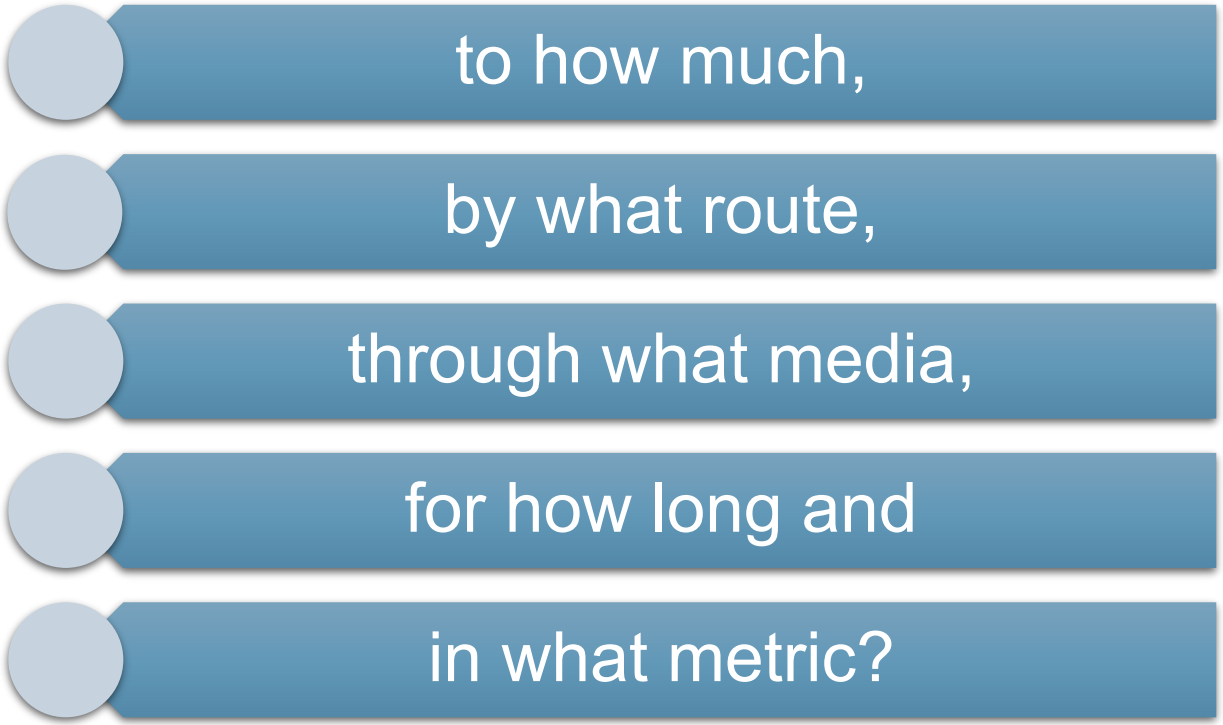
The process of determining the extent to which humans or the environment are exposed to chemicals.

It involves estimating or measuring the exposure to humans or the environment.



Exposure assessment for humans

- To determine if people get in contact with a potentially hazardous chemical, and if so:



Different ways to estimate exposure - pros and cons

Approach	Characteristics	Pros	Cons
Measured directly	Measures concentration in relevant media, requires appropriate devices, trade-off between cost and sample size, information about activity patterns, heterogeneity of the population (small/large subsets), environmental and biological monitoring	Most accurate/ relevant	Most time and resource intense
Estimated using models	Many, make use of available databases, based on given environmental media concentration, using exposure factors, may consider different types of PPE	Based on a range of sources	May require training
Generalized using existing data	Using accessible information from reputable and relevant sources	Simplest	Not always easily accessible/ representative

Exposure scenarios and information requirements

Determine the concentration of a chemical substance in a specific environmental matrix at a certain time

Examples of exposure

- emissions from industry (chimney, sewage)
- when applying pesticides (surface water runoff, spraydrift)
- chemicals used in households and outdoor activities (sewage water)
- use of chemical products (e.g. paint) and articles (emitting, wear and tear, waste disposal)
- etc

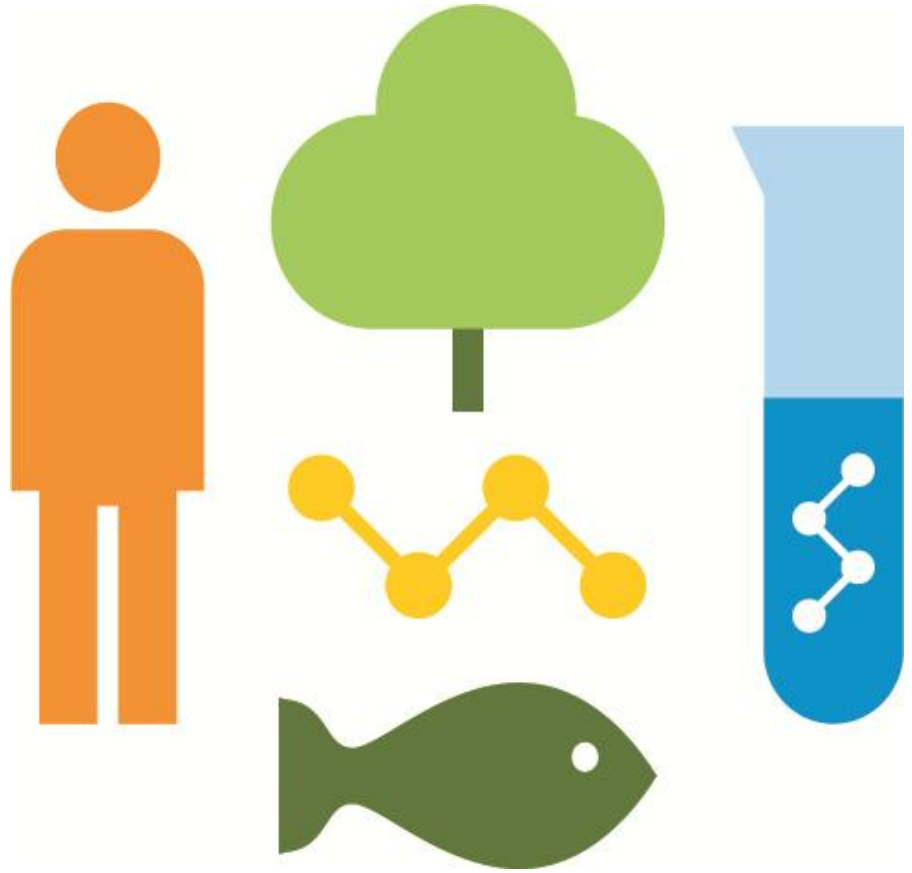
- Information needed:
- Use of the chemical
  - Used amount
  - Processes
  - ”Release”
- Inherent properties
  - Distribution and degradation
- Environmental factors
  - Spread
  - Distribution and degradation

PEC = Predicted Environmental Concentration
MEC = Measured Environmental Concentration

(4) Risk characterization

The process of integrating hazard and exposure information to estimate the likelihood and severity of adverse effects from chemical exposure.

This allows for a determination of whether the chemical poses a significant risk and whether risk management measures are needed.



Chemicals with a threshold
Risk characterisation ratios (RCRs)

RCR = Exposure / Guidance value

RCR < 1

- Unlikely to result in an adverse effect
- Acceptable use

RCR ≥ 1

- Sources, pathways and routes of exposure to be further evaluated
- Risk management

Risk characterisation ratio = RCR

- RCR<1, risk is acceptable
  - The evaluated use is considered acceptable
  - Risk is controlled
  - Should not be understood as: ”No risk”

$$RCR = \frac{PEC}{PNEC}$$

- RCR>1, risk is not acceptable
  - Refinement of risk assessment is necessary
  - Risk management measures are required!
  - May be necessary for regulatory action (risk reduction)
  - RCR >>1 may indicate severe problems that are hard to manage

What will my risk evaluation lead to?

1. **Identify hazards**
2. **Assess exposure**
3. **Evaluate risk**
4. Determine control measures
5. Implement and review

Risk reduction and risk management

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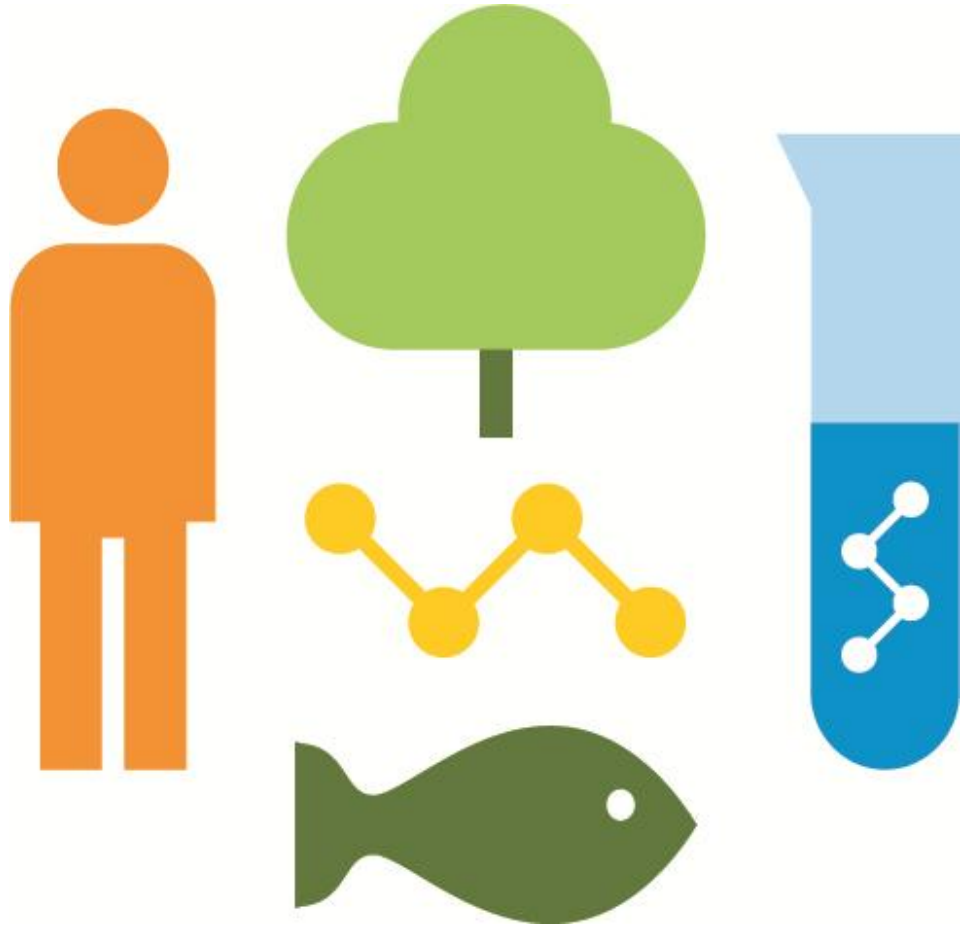
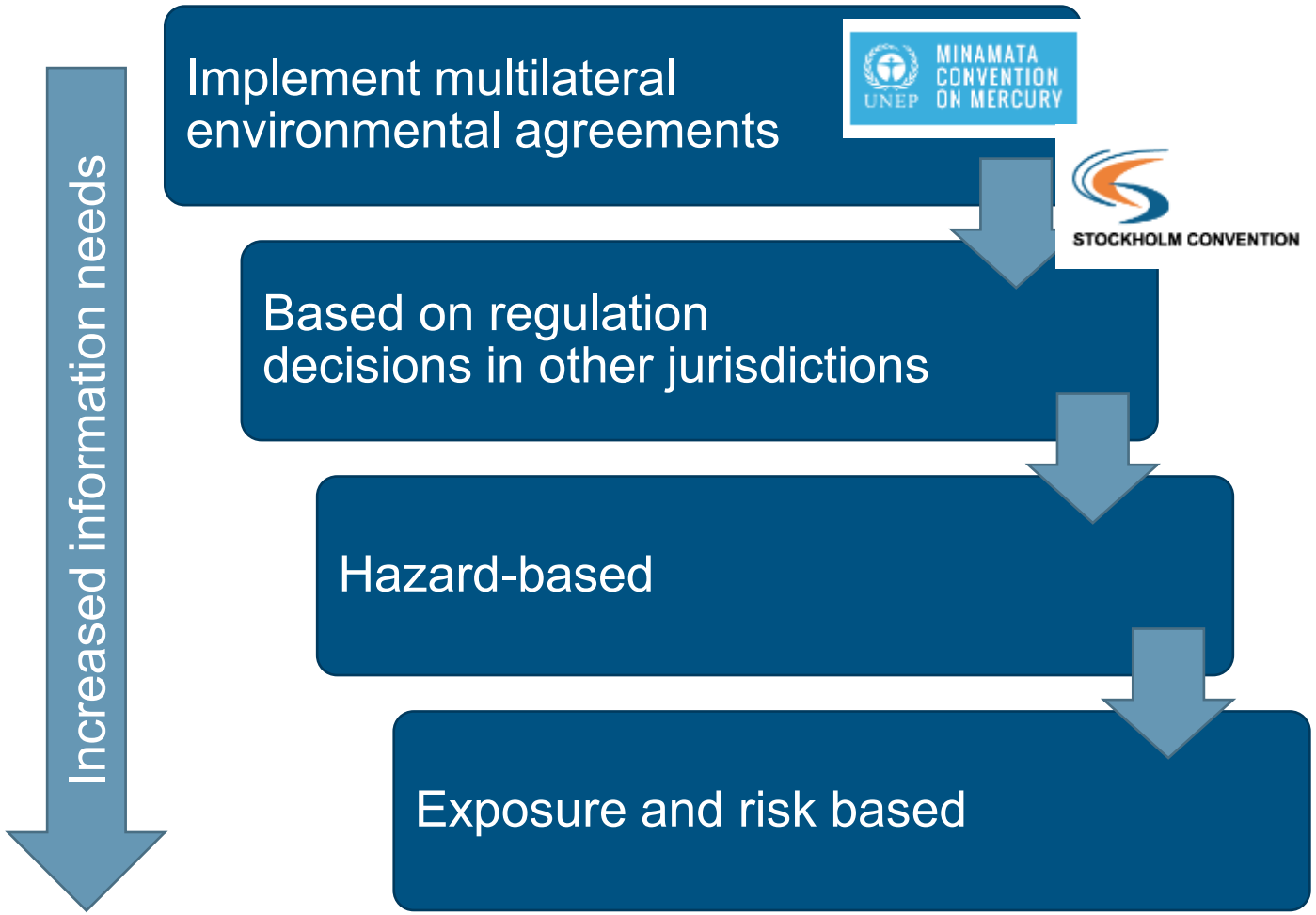
Lessons learned

- Prioritization
- High risk substances
- Different risk management options
- Grouping (PFAS)
- The need for different types of expertise



Lessons learned: Prioritization of substances for assessment and control



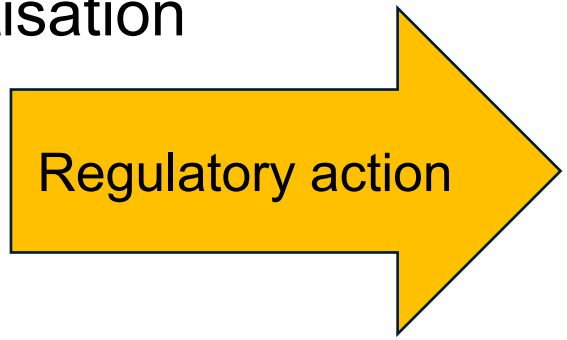
- **Example of regulation decisions**
  - EU Candidate list of substances of very high concern (SVHC) – formal decisions to include in list
- **Hazard-based typically**
  - CMR, respiratory sensitisation
  - ED HH and/or ENV
  - PBT or vPvB,
  - PMT and/or vPvM
- **Exposure and risk based**
  - wide-dispersive use,
  - high volumes
  - additional aspects relevant for the recommendation can be considered.

Lessons learned: Prioritization based on hazard and use

Authorities can act when risks are unmanageable.

Screening of information based on registration dossier within REACH submitted by the company:

- CMR, respiratory sensitisation
- ED HH and/or ENV
- PBT or vPvB,
- PMT and/or vPvM
- wide-dispersive use,
- high volumes



- Harmonized hazard classification (legally binding in the EU)
- Restrictions (certain uses banned, everything else allowed)
- Authorization (completely banned except for authorized use)

Lessons learned: A toolbox of different risk management options

Lessons learned: Grouping of substances and the proposed restriction of PFAS with over 10 000 substances covered

Regulatory approach and considered restriction options

A REACH restriction – the best way to minimize the risk:

- Possibility to use a **group-based** approach: Prevents regrettable substitution by targeting all PFASs
- **Source control**: Addresses manufacture, use, and placing on the market, including imports

The uses of PFASs and their emissions

- A large number of sectors investigated
- Total volumes and emissions from the use of PFASs

Impact assessment for the sectors – methodological approach

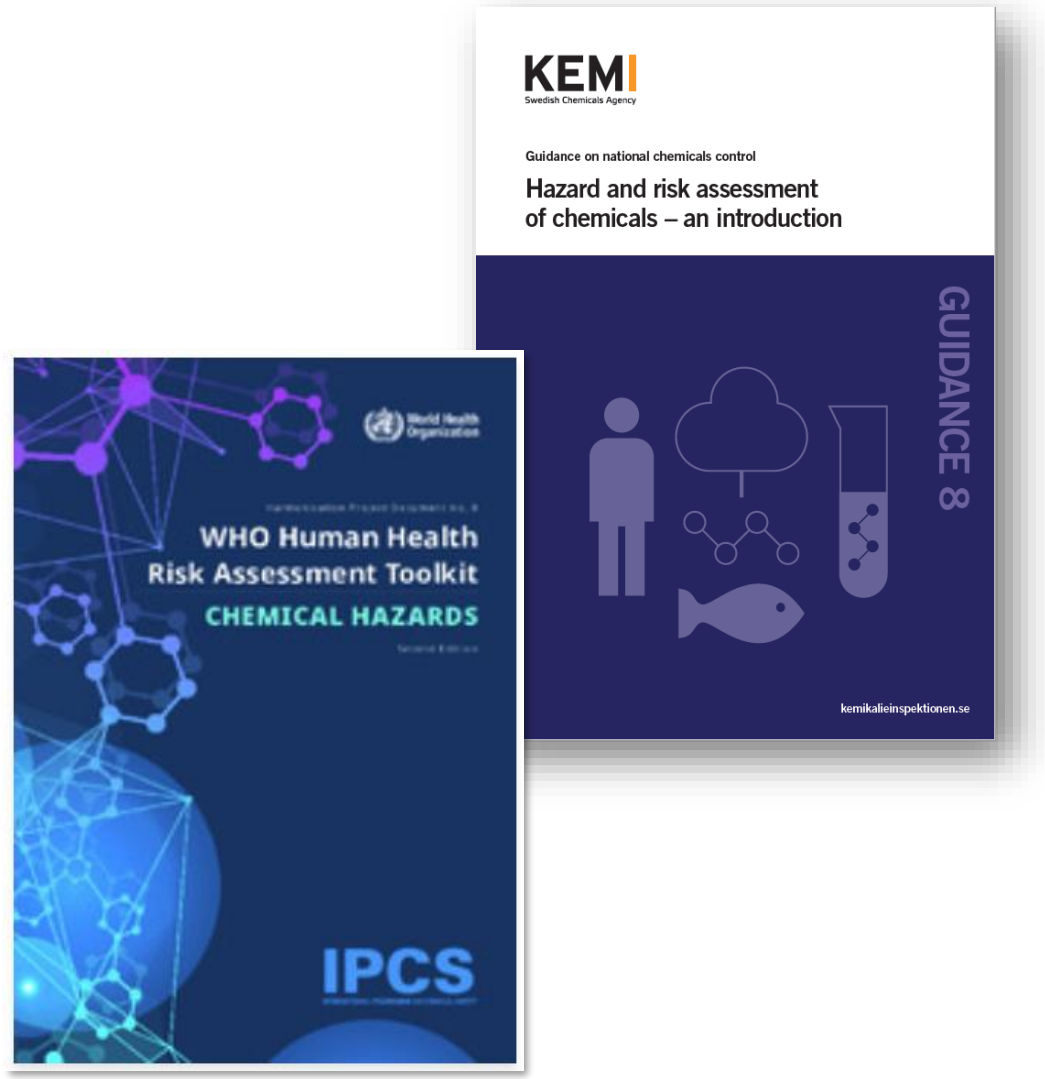
- A detailed impact assessment is conducted for each of the sectors

Different types of expertise

- Chemists
- Eco-toxicologists
- Experts on fate and behaviour in the environment
- Toxicologists
- Socio-economists

Take home messages

1. Focus on the purpose of the risk evaluation
2. Don´t make it more complex than necessary, use what´s available
3. Do it stepwise (e.g. grouping)
4. Explore different risk management options
5. Prioritize and try to find efficient ways forward



https://www.kemi.se/en/publications/guidance-on-national-chemicals-control-for-other-countries/hazard-and-risk-assessment-of-chemicals---an-introduction

https://www.who.int/publications/i/item/9789240035720

Thank you for your attention

QUESTIONS?

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