

# A view to substitution

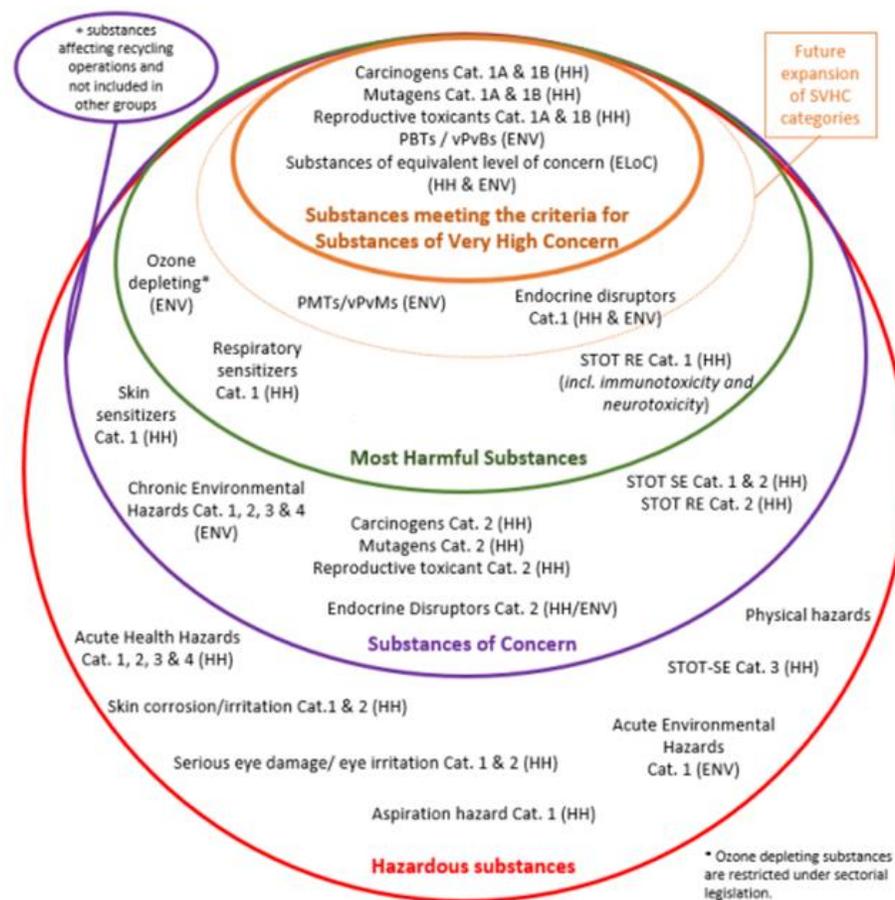
# Different groups of classification



- ❖ SVHC = Substances of Very High Concern
  - ❖ MHC = Most Hazardous Chemicals
  - ❖ SoC = Substances of Concern
- 
- Grouping of substances/mixtures based on their classification
  - Used for simplifications of regulatory measures

# Different groups of classification

## OVERVIEW OF HAZARD CLASSES SUBJECT TO REGULATORY ACTION ACCORDING TO THE CHEMICALS STRATEGY FOR SUSTAINABILITY



### Substances meeting the criteria for Substances of Very High Concern (SVHCs)

- Known & presumed carcinogenicity (Cat. 1A & 1B) (CLP H350)
- Known & presumed germ cell mutagenicity (Cat. 1A & 1B) (CLP H340)
- Known & presumed reproductive toxicity (Cat. 1A & 1B) (CLP H360)
- Persistent, Bioaccumulative, Toxic (PBTs) / very Persistent very Bioaccumulative (vPvBs) (identified in accordance with Art. 59 REACH following criteria in Annex XIII); criteria to be included in the CLP Regulation
- Substances of equivalent level of concern (ELOC, including some endocrine disruptors, respiratory sensitizers, immunotoxic, neurotoxicants, STOT RE, PMT/vPvM)

- **Persistent, Mobile and Toxic (PMT) / very Persistent very Mobile (vPvM) (criteria to be included in the CLP Regulation)**
- **Endocrine disruptors Cat. 1 HH/ENV (criteria to be included in the CLP Regulation);**

### Most Harmful Substances

- **Respiratory sensitizers Cat. 1 (CLP H334)**
- **Specific Target Organ Toxicity - Repeated Exposure Cat. 1 (CLP H372)**
- **Hazardous to ozone layer (CLP H420) \***

### Substances of Concern

- **Chronic hazard to the aquatic environment Cat. 1, 2, 3 & 4 (CLP H410-413),**
- **Skin sensitizers Cat. 1 (CLP H317)**
- Suspected carcinogenicity (Cat. 2) (H351)
- Suspected germ cell mutagenicity (Cat. 2) (H341),
- Suspected reproductive toxicity (Cat. 2) (H361)
- **Specific Target Organ Toxicity - Single Exposure Cat. 1 & 2 (CLP H370 & H371)**
- **Specific Target Organ Toxicity - Repeated Exposure Cat. 2 (CLP H373)**
- **Endocrine disruptors (Cat. 2) HH/ENV (criteria to be included in the CLP Regulation)**

### Hazardous substances

- Acute health hazards Cat. 1, 2, 3 & 4 skin (CLP H300-302), dermal (H310-312), inhalation (H330-332),
- Specific Target Organ Toxicity - Single Exposure Cat. 3 (CLP H335-336)
- Skin corrosion/irritation Cat. 1 & 2 (CLP H314-315),
- Serious eye damage/irritation Cat. 1 & 2 (CLP H318-319),
- Aspiration hazard Cat. 1 (CLP H304)
- Acute hazard to the aquatic environment Cat. 1 (CLP H400)
- Physical hazards: explosive (H200-205), flammable (H220, 221, 230-232), aerosols (H222, 223, 229), oxidising gas (H270), gases under pressure (H280, 281), flammable gases, liquids and solids (H224-226, 228), self-reactive substances/mixtures (H240-242), pyrophoric (H250), self-heating (H251-252), substances that in contact with water emit flammable gases (H260, 261), oxidising liquids and solids (H271-272), organic peroxide (H240-242), corrosive to metals (H290)

# Where does it matter?

- ❖ SVHC = Substances of Very High Concern
  - e.g. REACH-authorisation, WFD
- ❖ MHC = Most Hazardous Chemicals
  - e.g. GRA
- ❖ SoC = Substances of Concern
  - e.g. EDPR, PPWR, Taxonomy

# „Substitution-principle”



*“The replacement or reduction of hazardous substances in products or processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organisational measures.”*

(source: ECHA)

- ❖ Final objective of REACH-authorisation
- ❖ Can be also found e.g. in the BPR, OSH, PPP
- ❖ Right now focus on MHC, SVHC and SoC
- ❖ Assessment of alternatives (chemical or other)
- ❖ Substitution plan
- ❖ COM is working on a substitution-framework

# Hazard- vs. risk-based approach



Hazard = a source of danger

Risk = possibility of loss or injury

(source: Merriam Webster Dictionary)

A Hazard is something that has the potential to harm you.

Risk is the likelihood of a hazard causing harm.

(source: EFSA)

→ Risk = Hazard \* Exposure

# Hazard- vs. risk-based approach



**Risk = Hazard \* Exposure**

→ If at least Exposure or Hazard is 0 then also Risk is 0

Examples from the chemicals legislation:

- There is no risk, if you can exclude exposure
  - Registration-exemption for intermediates, if under strictly controlled conditions (Exposure = 0)
- The (chemical) risk of a non-classified substance is 0
  - No need for a SDS nor CLP-labelling

**→ Under the risk-based approach “Risk=0” means “safe use”**

# Hazard- vs. risk-based approach



Hazard-based approach focuses stronger on properties:

$$\text{Risk} = \underline{\text{Hazard}} * \text{Exposure}$$

And postulates that Exposure will always be  $>0$

$$\text{Risk} = \text{Hazard} * \text{Exposure} (>0)$$

→ Risk can be only 0, if Hazard = 0

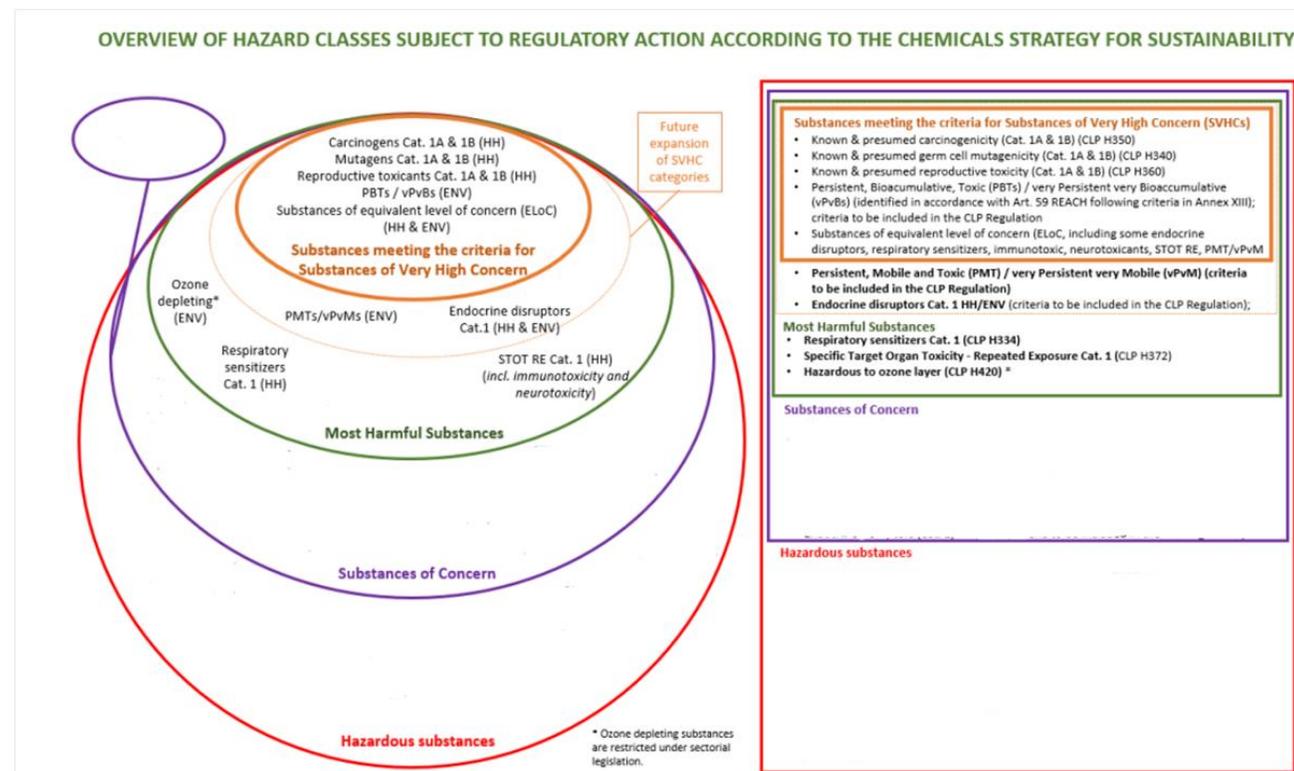
Now we need to agree as society, which hazards we accept

→ BP active substances: knock-out-criteria for CMR 1A/B, EDs

→ REACH-restriction: ban of CMR 1A/B substances in consumer uses

# Generic approach to risk-management

- ❖ GRA: Generic approach to risk management
- ❖ Comes from the CSS
- ❖ Strong focus on precautionary principle
- ❖ Hazard-based approach
- ❖ Should be applied to
  - consumer uses
  - some professional uses
  - not industrial uses
- ❖ for MHCs



# Generic approach to risk-management



- ❖ Should address current weakness and inefficiencies
- ❖ Speed up regulation
- ❖ Part of the envisaged reform of the REACH authorisation and restriction, once REACH is revised
  
- ❖ In principle, nothing new, but the extend is wide:
  - REACH-restrictions (consumer uses, CMR)
  - product legislation (e.g. toys, cosmetics)
  - diverse exclusion criteria (e.g. active substances, additives)

# Essential use concept



- ❖ EUC: Essential use concept
- ❖ Comes from the CSS
- ❖ Published in April 2024 as [Communication](#) of the Commission
- ❖ Not legally binding
- ❖ It should improve protection of human health and environment
- ❖ Focus on MHCs
- ❖ MHC should be only allowed when:
  - there use is essential for society and
  - there are no alternatives available.
- ❖ Legislation should become more predictable and faster

## 2.1 Criteria for essential use

A use of a most harmful substance is essential for society<sup>16</sup> if the following two criteria are met:

- 1) that use is necessary for health or safety or is critical for the functioning of society,
- and**
- 2) there are no acceptable alternatives.

### ❖ 4 crucial concepts:

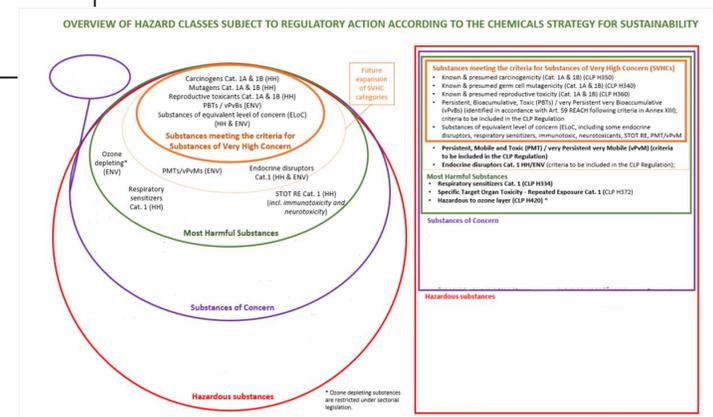
- MHC
- Necessary for health or safety
- Critical for the functioning of society
- No acceptable alternatives

# MHC - Most Hazardous Chemicals

Most harmful  
substances

A most harmful substance has one or more of the following hazard properties<sup>17,18,19</sup>:

- Carcinogenicity Cat. 1A and 1B
- Germ cell mutagenicity Cat. 1A and 1B
- Reproductive/developmental toxicity Cat. 1A and 1B
- Endocrine disruption Cat. 1 (human health)
- Endocrine disruption Cat. 1 (environment)
- Respiratory sensitisation Cat. 1
- Specific target organ toxicity – repeated exposure (STOT-RE) Cat. 1, including immunotoxicity and neurotoxicity
- Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative (PBT/vPvB)
- Persistent, mobile and toxic/very persistent and mobile (PMT/vPvM)<sup>20</sup>
- Hazardous to the ozone layer Cat. 1<sup>21</sup>



# Necessary for health or safety

Necessary for health or safety

The use of a most harmful substance is necessary for health or safety if the use and the technical function of the substance in that use are necessary in order to:

- Prevent, monitor or treat illness and similar health conditions
- Sustain basic conditions for human or animal life and health
- Manage health crises and emergencies
- Ensure personal safety
- Ensure public safety

These elements are described in Annex section III.b, table 2.

# Critical for the functioning of society



Critical for the functioning of society

The use of a most harmful substance is critical for the functioning of society if the use and the technical function of the substance in that use are critical in order to:

- Provide resources or services that must remain in service for society to function (e.g. ensure the supply of energy and critical raw materials or resilience to supply disruption)
- Manage societal risks and impacts from natural crises and disasters
- Protect and restore the natural environment
- Perform scientific research and development
- Protect cultural heritage

These elements are described in Annex section III.b, table 3.

# No acceptable alternatives

|                         |   |
|-------------------------|---|
| Acceptable alternatives | <p>Acceptable alternatives are substances, materials, technologies, processes or products, which, from a societal point of view:</p> <ul style="list-style-type: none"><li>(i) are capable of providing the function and the level of performance that society can accept as sufficiently delivering the expected service; AND</li><li>(ii) are safer (their overall chemical risks to human or animal health and the environment throughout the whole life-cycle are lower in comparison to the most harmful substance).</li></ul> <p>Acceptability of alternatives takes a societal perspective. The notion of an “acceptable alternative” is normally defined with specific requirements in each piece of legislation, and for most pieces of legislation also includes a technical and/or economic feasibility assessment. These existing definitions (for example, technical and/or economic feasibility) should be considered if and when implementing the essential use concept in such areas.</p> |
|-------------------------|---|

# Assessment of a use of a substance



## ❖ 2 steps

- Assessment of the necessity for health or safety and the criticality for the functioning of society
- Assessment of alternatives

❖ There is no order, which assessment happens first.

❖ In principle, it should be a filter to quickly exclude all cases of clear essential and non-essential uses.

# Assessment - health/safety/society

## Step 1 – Assessment of necessity for health or safety and criticality for the functioning of society

Questions to consider (section III.b):

- i. Is the technical function of the most harmful substance needed for the final product to deliver its service?
- ii. Does the use of the most harmful substance fulfil at least one element specified in tables 2 or 3 below so that it fulfills the criterion of being necessary for health or necessary for safety or critical for the functioning of society in the particular use?

*(the answer to both questions must be 'yes')*

NO

The use is *non-essential* for society. No further assessment needed.

YES

The use is necessary for health or safety or critical for the functioning of society.  
Assessment of lack of alternatives is needed to determine if the use is essential for society.

# Assessment - alternatives

## Step 2 – *Alternatives assessment*

Questions to consider (section III.c):

- Are acceptable alternatives lacking? (description of acceptable alternatives section 2.2)

NO

The use is *non-essential* for society and the substance in this use should be substituted. No further assessment needed.

YES

The use is currently *essential* for society. Before allowing it, conditions for the use should be set (section IV).

# Putting in perspective to Green Chemistry



- ❖ The EU has different tools that directly / indirectly promote substitution
- ❖ Substitution does not necessarily point to greener chemicals, also safety is an issue
- ❖ Hazard based approach dominates
- ❖ Potential of conflicts between different objectives
- ❖ Can support innovation towards green solutions

# Now I am looking forward...



... for your questions and opinions!

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- ❖ Let´s develop a new concrete product for the EU-market.
- ❖ Now:
  - Analyse the relevance and possible consequences of a classification for product development in the light of Green Chemistry.
  - For this:
    - » organise in two groups of 4;
    - » you have 25 minutes working time;
    - » then each group presents her results;
    - » continued by a joint discussion and analysis.