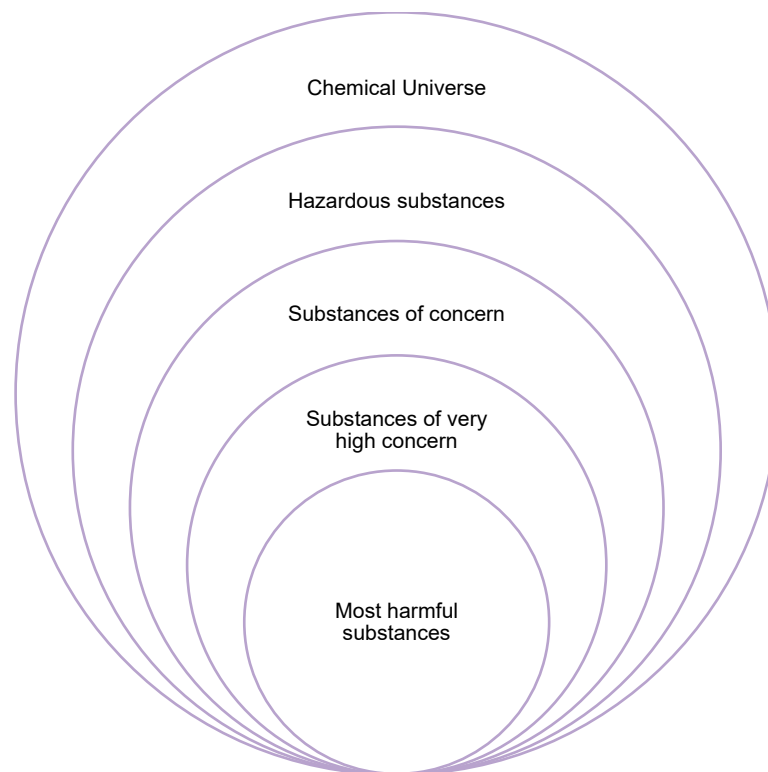


REACH reform – insights paper

The typology of hazardous substances

Visualisation of the chemical universe



The size of the bubbles is not representative of the real proportions of each category in the chemical universe

Typology on hazardous substances and the properties they cover

Most harmful substances

Also sometimes called “most hazardous substances” (MHS) are defined by the Chemical Strategy for Sustainability as the

“chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative” (including PBT, vPvB, PMT and vPvM) as well as “those affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ”.¹

From this list, nearly all the properties are defined in the CLP Regulation 1272/2008 as it is, or modified by the recently adopted Delegated Act not yet entered into force. A substance may be considered, for example, a carcinogenic chemical if it meets the criteria set in the CLP Regulation. An indication that the criteria are met can be:

- An EU act identifying them as such (candidate listing under REACH or harmonised classification – so called “CLH” under the CLP Regulation);
- The self-classifications of companies – available in the C&L inventory;
- Available data confirming their properties.

The potential scope of what can be considered most harmful substances changes depending on whether the identification relies on only one or all of these sources: the scope will be smaller if only the first source is considered, grow with the second and grow even more with the third.

Substances of very high concern

Defined by Art. 57 of REACH as

- a) substances meeting the criteria for classification as carcinogenic category 1 A and B in accordance with the CLP Regulation
- b) substances meeting the criteria for classification as mutagenic category 1 A and B in accordance with the CLP Regulation
- c) substances meeting the criteria for classification as toxic for reproduction 1 A and B in accordance with the CLP Regulation
- d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of this Regulation;
- e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of this Regulation;

¹2020 Chemical Strategy for Sustainability, p.10.

- f) substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis.

The list of properties is shorter than for the most harmful substances, but this category is nonetheless broader, grateful to provision (f) which offers a safeguard for properties not listed, but of equivalent concern to the ones listed from (a)-(e). What is an “equivalent purpose” is intentionally left open, to catch emerging risks. Considerations that may lead to an equivalent concern are diverse, including the irreversibility of the impact or of the presence in the environment, the impossibility or difficulty to set a safe threshold, etc.

There is a big difference between referring to “substances that meet the criteria” for substances of very high concern (any substances that meet the criteria – for example as interpreted by the SIN list) and substances of very high concern identified under Art. 59 REACH (the substances EU institutions decided to place on the Candidate List.²)

Substances of concern

The Chemical Strategy identifies them as:³

- The substances having a chronic effect for human health or the environment, identified as the substances of very high concern which are already included in the REACH Candidate List and the substances submitted to a harmonised classification under the CLP Regulation; and
- Those which hamper recycling for safe and high quality secondary raw materials. Not all substances that hamper recycling are toxic – an ink for example can have no toxicity but still create issue with recycling because it limits the use of the recycled materials.

The terminology of substance of concern is now used in the proposal for the Ecodesign for Sustainable Products Regulation (ESPR) as well as in the proposal for the reform of the Packaging and Packaging Waste Directive, which refers to the ESPR. They are referred to as the substances present in products, or used in their manufacturing processes, which negatively affect products sustainability.

In Art. 2.28 ‘substance of concern’ means a substance that:

- a) meets the criteria laid down in Art. 57 and is identified in accordance with Art. 59(1) of Regulation (EC) No 1907/2006; or
- b) is classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 in one of the following hazard classes or hazard categories:
 - carcinogenicity categories 1 and 2,
 - germ cell mutagenicity categories 1 and 2,

² <https://echa.europa.eu/fr/candidate-list-table>

³ P.2.

- reproductive toxicity categories 1 and 2, (to be added in the course of the legislative procedure once Regulation (EC) No 1272/2008 contains these hazard classes: Persistent, Bioaccumulative, Toxic (PBTs), very Persistent very Bioaccumulative (vPvBs); Persistent, Mobile and Toxic (PMT), very Persistent very Mobile (vPvM); Endocrine disruption),
 - respiratory sensitisation category 1,
 - skin sensitisation category 1,
 - chronic hazard to the aquatic environment categories 1 to 4,
 - hazardous to the ozone layer,
 - specific target organ toxicity – repeated exposure categories 1 and 2,
 - specific target organ toxicity – single exposure categories 1 and 2; or
- c) negatively affects the re-use and recycling of materials in the product in which it is present

Hazardous substances

Hazardous substances are defined in Annex I of the CLP Regulation lists, which includes physical hazards (explosives for example) as well as environmental, health and other hazards. In addition, the substances identified as hazardous, are those that have the following properties:

- As already listed for “most harmful” above: CMR, EDC, PBT, vPvB, PMT, vPvM, STOTS, respiratory sensitisers
- But also: acute toxicity; skin corrosion/irritation; serious eye damage/eye irritation; skin sensitisation, aspiration hazard, hazardous to the aquatic environment, hazardous for the ozone layer.

Chemical universe

At the global level, there are an estimated 350,000 chemicals on the market.⁴ In terms of the diversity of chemicals on the EU market, over 26,600 chemicals were registered under the EU REACH legislation in December 2020.⁵ However, this number omits chemicals on the market at volumes below 1 tonne, as well as polymers, active substances in pesticides, biocides and pharmaceuticals.⁶ It is generally considered that the number of monomers of the EU market is over 100 000⁷, with estimated 200 000 polymers.

⁴ Wang et al., 2020

⁵ ECHA, 2022b

⁶ See EEA 2023 [briefing Managing the systemic use of chemicals in Europe](#).

⁷ See EEA 2020 [State of the environment, chapter on chemical pollution](#).

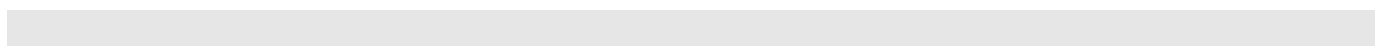
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