Health Care Without Harm Europe

European healthcare's phase-out list for chemicals of concern | Annotated

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The phase-out list is a collaborative effort to increase participation from healthcare procurement in demanding products that can meet these requirements or, when no safer alternatives exist, to move the market in the right direction by filling the innovation gap and overcoming technical barriers.

A common list of chemicals of concern for the healthcare sector simplifies the reporting requirements for suppliers in tenders and contract follow-up. It further facilitates reductions in these chemicals by leveraging purchase power. It should be used when no certified products exist which meet the criteria for absence of these chemicals.

The list also attempts to avoid so-called "regrettable substitution", referring to chemicals that are replaced with chemicals that simply have different or unknown hazards, by regulating substance groups instead of individual substances.

Phasing out chemicals of concern is essential for patients, for workers in the supply chains, and hospital staff, who daily come into contact with chemicals that can be harmful. More broadly, it addresses the concern of chemical pollution, which intensifies and impacts biodiversity loss, contaminates our natural resources, and contributes to climate change.

The following annotated list further describes the intent and rationale for avoiding the listed substances.

Chemicals of concern

1. Candidate list of substances of very high concern (SVHC)

Rationale: The Candidate list[1] contains substances subject to authorisation under the REACH Regulation. Substances with the following properties may be identified as SVHCs, and hence included in the Candidate list:

[1] Candidate List: echa.europa.eu/da/candidate-list-table

- Chemicals that can cause cancer, alter DNA or damage reproductive systems, known as Carcinogenic, Mutagenic or Toxic to reproduction (CMR).
- Harmful substances that do not easily break down and also accumulate in the food chain, known as Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB).
- Substances that give rise to equivalent levels of concern in terms of potential damage to health and the environment. This includes endocrine-disrupting chemicals.

2. Carcinogenic, mutagenic or substances toxic to reproduction (CMR substances of category 1A or 1B)

Rationale: The Medical Device Regulation (MDR)introduces stricter requirements related to the use of chemicals of concern. Manufacturers are required to provide a benefit-risk assessment if articles contain substances classified as CMR and/or endocrine disruptors.

This requirement is, for now, limited to those medical devices listed in the relevant provisions of the MDR. In order to fulfil this requirement, manufacturers and suppliers have to know the chemical content of their articles and information about CMR substances or endocrine disruptors in the device should be readily available.

3. Polyvinyl chloride (PVC)

Rationale: PVC plastic is problematic because of the toxicity of monomers required to make PVC (a polymer). During the manufacture and disposal of PVC, the generation and release of hazardous compounds is also a concern. PVC requires more additives, many with their own toxic properties, when compared to other plastics. PVC is difficult to recycle. PVC materials are also difficult to incinerate as the gas produced is highly corrosive.

4. Phthalates

Phthalates are a group of industrial chemicals used as plasticizers that add flexibility and resilience to many plastic consumer products. Phthalate plasticizers are not chemically bound to plastics, such as PVC; they can leach or migrate, resulting in human exposure, and cling to dust, which may become airborne.

Rationale: The hazard profiles of phthalates vary, but adverse effects include hormone disruption, reproductive and developmental impacts, and kidney toxicity. Exposure to some phthalates is also associated with an increased risk of asthma.

The Candidate List contains substances identified as SVHCs and the SIN List[2] contains chemicals that have been identified by the non-profit ChemSec as being SVHCs based on the criteria defined within the chemicals regulation REACH. The Restriction List[3] contains substances that pose unacceptable risks to human health and/or the environment. The restrictions on the Restriction List may apply to all uses of a substance or specific uses. The healthcare's phase-out list restricts all areas of use regardless of the conditions specified in the Restriction List. This requirement is in line with the precautionary principle.

5. Bisphenols

Bisphenol A (BPA) is an organic compound used as a monomer or additive in the manufacturing of polycarbonate plastic, epoxy resins, and other applications. BPA and structurally similar bisphenol analogues are commonly used in products such as building materials, food containers, thermal paper, and plastics including packaging.

Intent: Eliminate residual BPA and related structural analogues. Not intended to eliminate polycarbonate or epoxy.

Rationale: BPA, historically the most used of all bisphenol analogues, is a reproductive and developmental toxicant and endocrine disruptor. Emerging evidence finds an association between prenatal or postnatal exposure to BPA and a variety of adverse health outcomes.

BPA, which has been replaced with other Bisphenols, is an oft-mentioned case of so-called "regrettable substitution". Other Bisphenols are also prohibited because there is sufficient evidence to conclude that they have similar toxic profiles to BPA.

The leachable fraction is generally 1/500 to 1/2000 of the total fraction for BPA. Assuming 1/1000, a 0.1 weight by weight limit would mean the product requires 100% BPA (w/w). The limit here is based on the previous migration limit for children's toys, as children are exposed to diverse hospital equipment.

This limit is 0.1 mg/L, according to Commission Directive (EU) 2017/898 for BPA. This limit was subsequently lowered to 0.04 mg/L for BPA, but 0.1 mg/L is used here for all bisphenols. It is also noted the acute toxicity to aquatic species is 0.011 µg/L; therefore, such a migration limit is also protective of environmental emissions.

[2] SIN List: sinlist.chemsec.org
[3] Restriction List echa.europa.eu/da/substances-restricted-under-reach

6. Flame retardants

Intent: Reduce the overall amount of chemicals and reserve the use of flame retardants for essential use. When flame retardancy is essential, the substance should be selected based on the same principle as phthalates.

Rationale: Flame retardants can be persistent and have a variety of toxic properties depending on the specific flame retardant. Non-polymeric flame retardants can migrate out of products into the environment, resulting in human exposure.

7. Antimicrobial agents

Rationale: Human toxicity and ecotoxicity profiles differ among antimicrobial agents, but none are entirely benign. The addition of antimicrobials where there is not a clear benefit can also contribute to more widespread antibiotic resistance.

8. Per- and polyfluoroalkyl substances (PFAS)

Rationale: PFAS compounds are generally highly persistent chemicals or break down into highly persistent chemicals. They have been nicknamed “forever chemicals” because of their extreme persistence. Some substances in the group bioaccumulate. They are regularly found in people and animals in all areas of the planet. Because of their persistence, continued use will inevitably lead to increasing environmental concentrations of PFAS compounds. The most studies health effects include increased risk of high cholesterol, thyroid disorders, pregnancy-induced hypertension and preeclampsia, cancer (testicular and kidney), and altered metabolism.

This approach aligns with EU level initiatives to restrict PFAS as a group.