Borderlines between CLP and other EU legislations

Agenda item 3.2

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Topics that are covered in this presentation:

- BPR
- PPPR
- Detergents
- Medical Devices
- Cosmetic Products
- Toy Safety
- FCM
- DWD
- IED
- Seveso
- WFD
- OSH

Biocidal Products Regulation

'A **substance of concern**' (SoC) = any substance, **other than the active substance**, which has an inherent capacity to cause an adverse effect, and is present or is produced in a biocidal product in sufficient concentration to present risks of such an effect:

— classified as hazardous

— meets the criteria for being a POP, or the criteria for PBT or vPvB.

Many active substances do not have CLH -> may fail to be identified as SoCs

=> should be considered SoCs if they are present in the biocidal product at a concentration ≥0.1%

Co-formulants that are evaluated as an AS and for which a draft final CAR is available, should be considered as SoC

Where these co-formulants (e.g. in-can preservatives or others) do not lead to the classification of the biocidal product, these co-formulants may not be a SoC since the definition in Article 3(1)(f) of the BPR may not be met

Plant Protection Products Regulation

- Plant protection products and their active substances
- Approval of active substances, safeners and synergists, and authorisation of the plant protection product.

Approval criteria include:

- impact on human health (CMR, endocrine disruptor),
- fate and behaviour in the environment (POP, persistence, bioaccumulation, potential for long-range environmental transport, PBT, vPvB)

Co-formulants are unacceptable if their use or their residues have a harmful effect on human or animal health or have an unacceptable effect on plants or on the environment:

- substances with CLH as CMR, category 1A or 1B,
- substances identified as PBT or vPvB,
- substances identified as SVHC due to ED properties,
- substances identified as POP,
- substances restricted under REACH where their use as a co-formulant in PPPs is covered by the restriction

Detergents Regulation

- CLP applies
- Mainly addresses the use of surfactants + risks for the environment (not human health).

- Sets criteria for biodegradability of substances used as surfactants. If the product does not meet the criteria, it is prohibited from being placed on the market unless derogation is obtained from the Commission (only for industrial and institutional detergents)

- Safeguard clause: Member States may take temporary measures to prohibit or restrict the placing on the market of a specific detergent that complies with the requirements of the Regulation if there are justifiable grounds to believe that it poses a risk to human health, animal health or the environment. The MS must inform the Commission, which will take a decision on the measures.

- Sets requirements for labelling of detergents, including for fragrance allergens.
  - In addition to "perfumes", independent from concentration: optical brighteners, enzymes, disinfectants, preservation agents
  - Allergenic fragrances only if above 0.01%

(EU) 2017/745

Medical Devices Regulation

- Medical devices that are inserted inside a natural body orifice and come into direct contact with the human body or that are used to (re) administer, transport or store medicines, body liquids or other substances to/from the human body shall **not contain CMR Cat 1A or 1B** in a concentration above 0,1% or **ED** substances on Candidate List.

- The use of these substances in medical devices above this concentration limit is only allowed when a **proper justification** by companies based on a benefit-risk assessment can be provided.

- Can cover detergents

Cosmetic Products Regulation

- Safety assessment must take into account the intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in a final formulation

- The use of substances classified as CMR 1A or 1B is prohibited.
- The use of substances classified as CMR 2 is prohibited, unless the substance has been evaluated by the Scientific Committee on Consumer Safety (SCCS) and found safe for use in (specific) cosmetic products. However, the use of CMR substances may be allowed if:
  - they comply with the food safety requirements as defined in Regulation (EC) No 178/2002;
  - there are no suitable alternative substances available, as documented in an analysis of alternatives;
  - the application is made for a particular use of the product category with a known exposure; and
  - they have been evaluated and found safe by the SCCS for use in cosmetic products, in particular in view of exposure to these products and taking into consideration the overall exposure from other sources, taking particular account of vulnerable population groups.

- Environmental effects are NOT assessed*

- Annexes on prohibited/allowed substances:
  - substances prohibited in cosmetic products (not a direct correlation with CLP classification, include CMRs, but also drugs, antibiotics, etc.),
  - substances subject to the restrictions,
  - allowed colorants, preservatives, and UV filters.

*but probably will be after Cosmetic PR revision
+ prohibition on ED, PBT, immune/neurotox, STOT

2009/48/EC

Toy Safety Directive

Manufacturers must carry out an analysis of the chemical and other hazards that the toy may present, as well as an assessment of the potential exposure to such hazards.

Annex II (III)

- CMR 1A, 1B or 2 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys. Certain derogations exist when
  - (a) the concentration of the substance/mixture is below the classification limit
  - (b) the substance/mixture is inaccessible to children in any form, including inhalation, when the toy is used
  - (c) a decision has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A.

    (no exposure/no suitable alternative/and no REACH restriction)

- List of prohibited allergenic fragrances
- List of (metallic) substances with migration limits

Food contact materials

General requirements for all food contact materials + mandate for specific measures on a list of groups of materials and articles in Annex I.

- authorisation lists for substances for use in the manufacturing and/or special conditions for specific uses may be adopted by COM

  => **positive lists** (Union lists) have been adopted for: plastics, ceramics, regenerated cellulose film, and active and intelligent materials and articles.

Regulation (EU) No 10/2011 on plastic materials and articles:

- ✓ rules on the composition of plastic food contact materials (FCMs),
- ✓ Union List of substances that are permitted for use in the manufacture of plastic FCMs.

Council Directive 84/500/EEC relating to ceramic articles intended to come into contact with foodstuff

- ✓ limits for lead and cadmium migration from ceramics depending on the category of the ceramic article.

(EU) 2020/2184

Drinking Water Directive

- **Risk-based approach** to water safety

- ECHA to compile and manage an EU positive list of chemicals that can be safely used in materials that come into contact with drinking water.
  - starting substances, compositions or constituents for each group of materials (organic, cementitious, metallic, enamels and ceramic or other inorganic materials), which are authorised for use in the manufacture of materials or products in contact with water intended for human consumption, including, where appropriate, conditions for their use and migration limits

- The first positive list is expected to cover around 1 500 chemicals and will be adopted by the European Commission by 2024.

- For the purposes of updating the European positive lists, ECHA should deliver opinions on the inclusion or removal of substances, compositions or constituents

Industrial Emissions Directive

- A substance is regarded as 'hazardous' whenever it is classified. 'Relevant hazardous substances' subject to 'removal, control, containment or reduction'

- Substances or mixtures which, because of their content of volatile organic compounds classified as CMR, with H340, H350, H350i, H360D or H360F, shall be replaced, as far as possible by less harmful substances or mixtures within the shortest possible time.

- List of existing EU BREFs /BATC/REFs documents (sectorial approaches for addressing ENV releases under IPCC Directive and IED): https://eippcb.jrc.ec.europa.eu/reference/

Seveso III - control of major-accident hazards involving dangerous substances

- 48 named substances (Annex I, Part 2)
- All the rest covered on the basis of their classification, mainly related to physical hazards, but with some notable exceptions:

- Human health hazards:
  - Acute Toxicity Category 1, all exposure routes; Lower tier requirements: 5 tonnes, Upper tier: 20 tonnes
  - Acute Toxicity Category 2 all exposure routes and 3, inhalation; Lower tier: 50, Upper tier: 200
  - STOT SE1; Lower tier: 50, Upper tier: 200

- Environmental hazards:
  - Aquatic Acute 1 or Aquatic Chronic 1; Lower tier: 100, Upper tier: 200
  - Aquatic Chronic 2: Lower tier: 200, Upper tier 500

Waste Framework Directive

- **Waste** is to be classified as hazardous if it displays one or more of the hazardous properties listed in Annex III:
  - HP 1 (Explosive), HP 2 (Oxidising), HP 3 (Flammable), HP 4 (irritant – skin irritation and eye damage), HP 5 (specific Target Organ Toxicity (STOT)/Aspiration Toxicity), HP 6 (Acute Toxicity), HP 7 (Carcinogenic), HP 8 (Corrosive), HP 9 (Infectious), HP 10 (Toxic for Reproduction), HP 11 (Mutagenic), HP 12 (Release of an acute toxic gas), HP 13 (Sensitising), HP 14 (Ecotoxic = Aq ac; Aq chr; ozone depleting) and HP 15 (Waste capable of exhibiting a hazardous property listed above not directly displayed by the original waste).
  - All the requirements for the management of hazardous waste apply no matter which of the hazardous properties the waste displays.

- Each hazardous property refers to the CLP Regulation - but with deviations due to the nature of waste.

- Harmonised classification (and when not available, also self-classification) can be a decisive criterion whether a waste triggers the classification of waste as hazardous. See Commission notice on technical guidance on the classification of waste.

89/391/EEC

Occupational Safety and Health Directive

Leading principle: Replacing dangerous with non- or less dangerous

Occupational exposure limit (OEL) EU level or national level

- mainly to control/reduce inhalation exposure at the workplace.

EU indicative OEL (IOEL) = health-based values (based on threshold effects), derived from available scientific data (often human data)

- If an IOEL is set for a given substance, MS must establish national exposure limit values, which should be based on, but may be different from the IOEL. Hence, the same substance may have different national OEL in different MS.

EU binding OEL (BOELs) - typically developed for non-threshold effects

- If a BOEL is set for a given substance, MS must establish national exposure limit values, which may be more stringent than the BOEL.

National OEL – implements EU OEL at national level or is set at the MS's own initiative when there is no EU OEL.

If you are not interested only in how CLP is applied across downstream legislation, but want to search for information on your substances, find applicable laws and check what obligations you may have, the EU Chemicals Legislation Finder (EUCLEF) is a tool you can use to get started:

https://echa.europa.eu/legislation-finder

The message:
There may always be also another piece of legislation that needs to be taken into account

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