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# Definition of “hazardous“ substances in different frameworks

BaltActHaz LIFE07 ENV/EE/000122

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# Content

Main EU and international legislation related to HS

Aims/targets/measures of legislation towards HS

Terms, definitions, groups of substances, what they mean

Lists of substances

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# Why to talk about it?

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The various legal frameworks explain and define "hazardous substance" differently…

Priority

Dangerous

POPs

SVHC

Priority hazardous

PBT

vPvB

Hazardous

# Frameworks

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**Environment (water) quality** ← **Chemicals management**

↓ ↓

**WFD, HELCOM, POPs** | **REACH, C&L (GHS)**

↓ ↓

**Environmentally hazardous** ← **Hazardous/dangerous**

# Classification and labelling

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**EU Classification and Labelling Directive (67/548/EEC)**

↓

Dangerous

If the certain criteria for the dangerous property is fulfilled →
Physico-chemical properties, toxicity to human health

Categories of danger (e.g. explosive, cancerogenic)
R-phrases (level of danger and exposure route)
S-phrases (how to protect oneself)
Labels to contain information on hazards/dangers

Dangerous for the environment (1979, 6th amendment)

↓

Aquatic toxicity
Bioaccumulation potential
Persistence
PBT/vPvB as category of substance of very high concern

↓

Annex 1 → 3366 classified substances

# C&L → GHS

67/548/EEC → GHS in EU → Regulation (EC) 1272/2008 classification, labelling and packaging of substances and mixtures (CLP), entered into force on 20 January 2009

Dangerous → **hazardous**

Preparations → mixtures

A substance or a mixture fulfilling at least one of the criteria relating to physical hazards, health hazards or environmental hazards → hazardous

Annex I of Directive 67/548/EEC →Table 3.2 in Annex VI to CLP

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# Transition to CLP (GHS)

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**20 Jan. 2009**

- substances can be still C&L&P according 67/548/EEC
- mixtures can be still C&L&P according 1999/45/EC
- if GHS applied earlier, then both classifications in SDS; L&P according GHS

**1 Dec. 2010**

- **substances** classified according both C&L&P and GHS
- **substances** to be labelled and packed acc. GHS
- **substances** placed on the market before, can be still re-labelled and re-packed by 1 Dec. 2012
- **mixtures** can be still C&L&P according 1999/45/EC
- if GHS for **mixtures** applied earlier, then both classifications in SDS; L&P according CLP

**1 June 2015**

- **substances and mixtures** to be C&L&P only according GHS
- **mixtures** placed on the market before this date, can be still re-labelled and re-packed by 1 June 2017
- information in SDS only according GHS

# REACH

Applies to all substances on the EU market → regulates production and use of chemicals

**Substances of very high concern (SVHC)** (Article 57) → authorisation scheme

1. **CMR category 1 or 2** → criteria in Dir. 67/548/EEC or GHS

- Category 1: sufficient evidence to establish causal relation between human exposure and the development of effect
- Category 2: sufficient evidence to provide strong presumption that human exposure may result in the effect (appropriate long-term animal studies, other relevant information)

Many legally classified in Annex I of Directive/ Annex VI of GHS

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# REACH

**SVHC**

2. **Persistent, bioaccumulative and toxic (PBT)** and **very persistent and very bioaccumulative (vPvB)** → criteria in Annex XIII of REACH
3. **Substances of similar concern** - substances for which scientific evidence gives rise to **equivalent concern**, because of their potential to cause severe damage to humans or the environment → no criteria defined
   - Some substances are of concern, but don't fit into the schemes (inorganic substances (due to persistence), degradation products are of concern…)
   - It was predicted that the substance 'disappears' but it is found in the environment (far distance from emission sources, in top predators)
   - There are indications of adverse effects in organisms not sufficiently reflected in standard testing (endocrine disruption, neurotoxicological effects...)

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# Why?

- Effects of substances are
  - Irreversible
  - Very severe
  - Affect future generations

- Ecosystem functioning
  - entire populations threatened, food chains interrupted
  - Irreversibility of “imbalances” and “depth” of impacts
- Emissions practically irreversible
- Concentrations may build up
- Exposure possible far from emission sources, due to atmospheric transport
- Loss of biodiversity
- Substances may reach human food chain
- Not all effects can be determined/tested?

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# SVHC under REACH

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**General measures:**

- In case of lack of scientific evidence, **precaution** is justified if there is a suspicion of an effect
- Hierarchy of measures, explicit for workers and implicit for consumers:
  - **prevention (substitution)** of risk, if not possible, then
  - **minimisation of exposure**

**Specific measures:**

- PBT/vPvB found → provide SDS to customer; assessment if >10t/a
- SVHC identified and included to candidate list for authorisation → SDS
- "candidate substance" in the article → notification to agency and information to customer may be required (0.1% w/w)
- "candidate substance" included to Annex XIV for Authorisation → to be authorised before the use

# Candidate list for authorisation

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| | | | |
|---|---|---|---|
| 1 | Triethyl arsenate | 427-700-2 | C |
| 2 | Anthracene | 204-371-1 | PBT |
| 3 | 4,4'- Diaminodiphenylmethane (MDA) | 202-974-4 | C |
| 4 | Dibutyl phthalate (DBP) | 201-557-4 | R |
| 5 | Cobalt dichloride | 231-589-4 | C |
| 6 | Diarsenic pentaoxide | 215-116-9 | C |
| 7 | Diarsenic trioxide | 215-481-4 | C |
| 8 | Sodium dichromate | 234-190-3 | CMR |
| 9 | 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene) | 201-329-4 | vPvB |
| 10 | Bis (2-ethylhexyl)phthalate (DEHP) | 204-211-0 | R |
| 11 | Hexabromocyclododecane (HBCDD) and and all major diastereoisomers identified:<br>Alpha-hexabromocyclododecane<br>Beta-hexabromocyclododecane<br>Gamma-hexabromocyclododecane | 247-148-4<br>221-695-9<br>(134237-50-6)<br>(134237-51-7)<br>(134237-52-8) | PBT |
| 12 | Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins) | 287-476-5 | PBT, vPvB |
| 13 | Bis(tributyltin)oxide (TBTO) | 200-268-0 | PBT |
| 14 | Lead hydrogen arsenate | 232-064-2 | CMR |
| 15 | Benzyl butyl phthalate (BBP) | 201-622-7 | R |

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## REACH

- **generate data** for classification and labelling
- **assess** if substances are **PBTs/vPvBs**
- **assess risks** to human health and the environment and identify and **communicate relevant risk management measures** along the supply chain (only if “dangerous” and > 10 t/a)

## GHS

- **identify** whether substance is **hazardous**
- **harmonise classification** at global level
- allocate **hazard classes**

Other legislation

# WFD (2000/60/EB )

Regulates management of surface water bodies → to ensure good chemical status of surface water by 2015

**Priority substances (PS)** → of Community-wide concern for the aquatic environment (posing a risk to or via the environment)

**Priority hazardous substances (PHS)** → part of priority substances that are toxic, persistent and liable to bio-accumulate, other substances of equivalent concern

Article 16: PH → reduced; PHS → ceased by 2020

No criteria for PS/PHS → ready list in Annex X → **replaced by Annex II of EQS (2008/105/EB )**

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# EQS (2008/105/EB )

In force Jan. 2009 → transposition by 13 July 2010

Sets EQS as AA-EQS and MAC-EQS → to be reached by 2015

Annex II

- 33 priority substances → 20 priority hazardous substances

Annex I

- 8 other pollutants →

Annex III → 13 substances to review for possible identification as PS or PHS

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# HS under HELCOM

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Protect Baltic Sea, incl. chemical pollution → HELCOM Recommendation 19/5 → not legally binding

**Hazardous substances & Substances for priority action** → PBTs and other substances agreed as requiring action (due to synergetic effects, degradation products, other properties)

Requires:

- Avoid, control emissions → substitution, precautionary principle, polluter pays, BAT/BEP

↓

Baltic Sea action plan (BSAP)

# HS under BSAP

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To achieve a Baltic Sea in good environmental status by 2021

The goal is described by four ecological objectives:
- Concentrations of hazardous substances close to natural levels
- All fish safe to eat
- Healthy wildlife
- Radioactivity at pre-Chernobyl level

| | |
|---|---|
| • Medium-chain chlorinated paraffins (MCCPs)<br>• Octylphenols (OP)/Octylphenol ethoxylates (OPE)<br>• Perfluorooctanoic acid (PFOA)<br>• Decabromodiphenyl ether (decaBDE)<br>• Hexabromocyclododecane (HBCDD) | • use restrictions<br>• substitutions |
| • Endosulfan<br>• Pentabromodiphenylether (pentaBDE)<br>• Octabromodiphenylether (octaBDE) | • ban the use, production and marketing |
| • Perfluorooctane sulfonate (PFOS)<br>• Nonylphenol/nonylphenolethoxylates (NP/NPEs)<br>• Short-chain chlorinated paraffins (SCCPs) | • strict restrictions |

# Stockholm convention POPs

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To protect human health and the environment from chemicals that

• remain intact in the environment for long periods,

•become widely distributed geographically and

•accumulate in the fatty tissue of humans and wildlife

→ cancers, birth defects, dysfunctional immune and reproductive systems, greater susceptibility to disease and even diminished intelligence

→ Persistence, potential to bioaccumulate, long range transport, toxicity

# POPs – “dirty dozen”

| | |
|---|---|
| Chlorinated pesticides:<br>Aldrin, Chlordane, Dieldrin, Endrin, Heptachlor, Heksachlorobenzene, Mirex, Toxaphene, Polychlorinated biphenyls (PCB) | Elimination |
| DDT | Restriction |
| Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF)<br>Hexachlorobenzene (HCB<br>PCB | Unintentional production |

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# POPs – “dirty 21”

Many used in everyday consumer products.

This would lead to elimination or restriction of the production, use, export and import of the chemicals.

| |
|---|
| Alpha hexachlorocyclohexane (Alpha HCH) |
| Beta hexachlorocyclohexane (Beta HCH) |
| Chlordecone |
| Hexabromobiphenyl (HBB) |
| Lindane |
| C-Octabromodiphenyl ether (OctaBDE)<br>Hexabromodiphenyl ether (HexaBDE)<br>Heptabromodiphenyl ether (HeptaBDE) |
| C-Pentabromodiphenyl ether (PentaBDE)<br>Tetrabromodiphenyl ether (TetraBDE)<br>Pentabromodiphenyl ether (PentaBDE) |
| Pentachlorobenzene (PeCB) |
| Perfluorooctane sulfonate (PFOS)<br>PFOS and its salts<br>Perfluorooctane sulfonyl fluoride (PFOSF) |

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# Overview

| | |
|---|---|
| EU Classification and Labelling Directive (67/548/EEC) | Dangerous |
| GHS | Hazardous |
| REACH | SVHC (CMR, PBT/vPvB, other) |
| WFD + EQS | Priority substances<br>Priority hazardous substances<br>Other pollutants |
| Helcom | Hazardous substances<br>Substances for priority action |
| Stockolm convention | POPs (persistent organic pollutants) |

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# Frameworks

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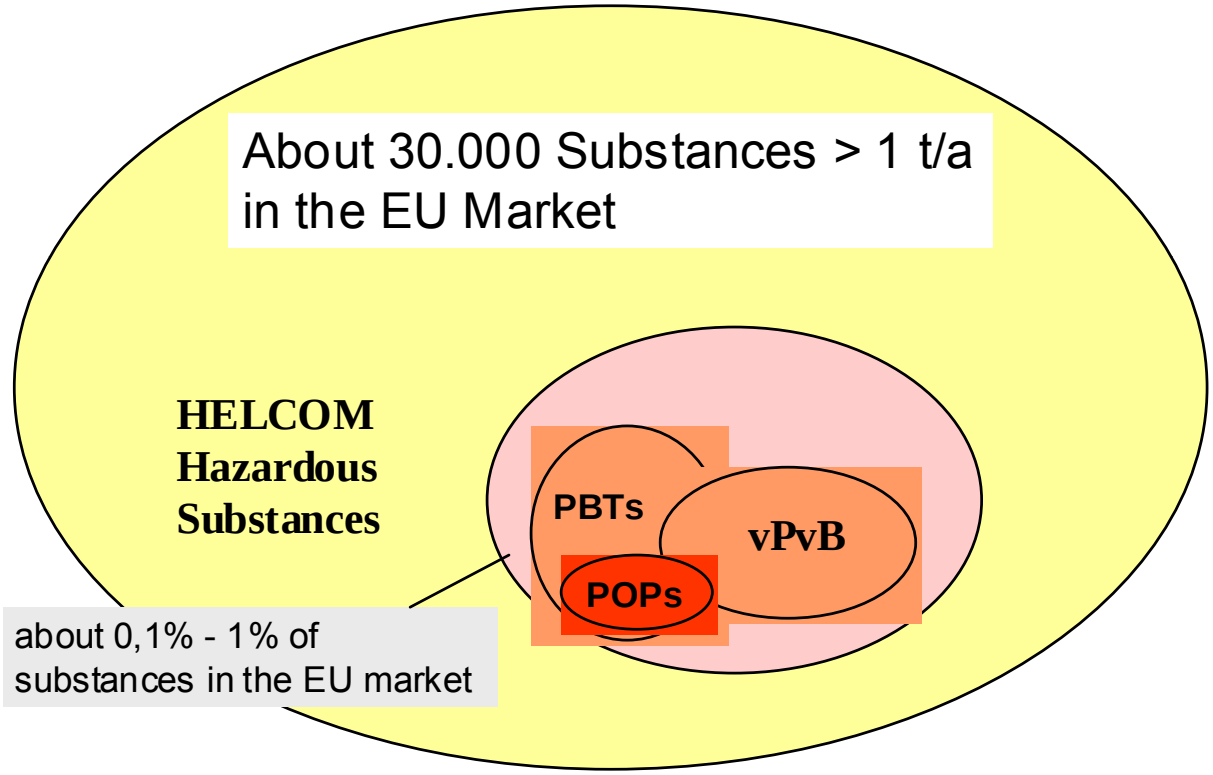
**Environment (water) quality** ← **Chemicals management**

↓ ↓

**WFD, HELCOM, POPs** | **REACH, C&L (GHS)**

↓ ↓

**Environmentally hazardous** ← **Hazardous/dangerous**


About 30.000 Substances > 1 t/a in the EU Market
HELCOM Hazardous Substances
PBTs
vPvB
POPs
about 0,1% - 1% of substances in the EU market

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# Environmentally hazardous

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Impairment of the functioning of ecosystem → threaten stability of an entire population of micro-organisms, plants, animals → weakening immune system, disturbing reproduction, inhibiting photosynthesis…

- **PBT**, **vPvB**
- **POPs**
- **Substances of equivalent concern** (endocrine disrupters, degradation products…)
- CMR only if persistent and bioaccumulative