Hazardous substances of environmental concern – what does that mean?

Baltic Actions for Reduction of Pollution of the Baltic Sea from Priority Hazardous Substances

Balt Act Haz

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Baltic Actions for Reduction of Pollution of the Baltic Sea from Priority Hazardous Substances
Project LIFE07 ENV/EE/000122 – BaltActHaz

List of abbreviations

BAT	Best Available Techniques
BCF	Bioconcentration factor
BSAP	Baltic Sea Action Plan
CAS	Chemical Abstracts Service number
CLP	Classification, Labelling and Packaging of chemical substances and mixtures (European Union regulation - CLP Regulation)
CMR	Carcinogenic, mutagenic, toxic for reproduction
DDT	Dichlorodiphenyltrichloroethane
DOC	Dissolved organic carbon
EQS	Environmental quality standards
EU	European Union
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HELCOM	The Helsinki Commission, the governing body of the "Convention on the Protection of the Marine Environment of the Baltic Sea Area" - the Helsinki Convention
IPPC	Integrated pollution prevention and control
Kow	Octanol-Water Partition Coefficient
NOEC	No Observed Effect Concentration
PBT	Persistent, Bioaccumulative and Toxic chemicals
POPs	Persistent organic pollutants
REACH	Registration, Evaluation, Authorisation and restriction of CHemicals (European Union Regulation of 18 December 2006)
SIEF	Substance Information Exchange Forum
SVHC	Substances of Very High Concern
UN ECE	United Nations Economic Commission for Europe
US EPA	U.S. Environmental Protection Agency
vPvB	very persistent and very bioaccumulative chemicals
WFD	Water Framework Directive
WWTP	Waste Water Treatment Plant

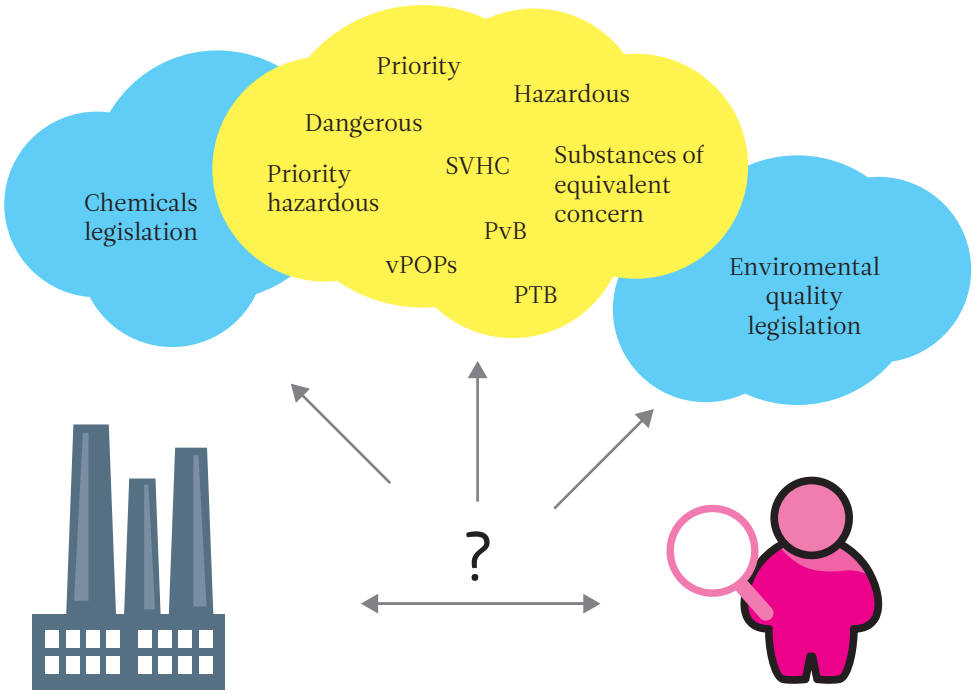
Why

do we talk about hazard concept?

Nearly every industrial company faces chemicals in its production, no matter whether substances are synthesised, preparations mixed or articles produced, such as furniture, textile, engines etc. Company can get chemicals as raw materials or auxiliary, introduce them into the process and/or product, emit to air or discharge to water or dispose with waste. Different legal requirements exist and should be applied for any of these specific steps. As the legislation usually regulates hazardous substances (either towards environment or human), it is essential for a company to know whether the chemical they use is hazardous or not and how it should be tackled in the right way. However companies often face a problem here as various legislative frameworks (chemical risk management and the environmental (aquatic)) explain and define **hazardous substances** in a different way, based on different criteria, often even using different naming in the same type of legislation, e.g. "hazardous" and "dangerous". Therefore it is important to be clear on which definitions exist and which one is applied in the concrete work situation to avoid confusion and misunderstanding.

This brochure aims at bringing the reader to a better understanding on the **hazard concept** as it is meant in EU (although there is no clear explicit definition on it). Whereas the definition of a "hazardous substance" only comprises the definition of inherent substance properties, methods to determine them and respective cut-off values[1], the hazard concept is viewed as a wider framework explaining not only the term "hazardous substance", but also providing the justification for dealing with these substances as priority, as well as making the assumptions on why regulatory action is required and how hazardous substances should be managed transparently. Hence, the clarification of "hazard concept" in this brochure regards the definition and naming of substances and the overall approach towards hazardous substances management. This knowledge is important to ensure consistency and orientation in reasoning, decision making and actions during the practical work.

This brochure is meant for industry and specialists from the state authorities, first of all those directly dealing with industry (permitting and controlling authorities) who should have very versatile understanding of the concept of hazardous substances under different frameworks. This publication aims at bringing the reader to more general view and holistic understanding on the hazard concept in EU while the following publications within project will focus more on the practical tools and hints for the implementation and enforcement of the hazardous substances related legislation (it can be followed on http://www.baltacthaz.bef.ee).



Different hazardous substances terminology in legislative acts in EU.

[1]CLP regulation ((EC) No 1272/2008) defines 'cut-off value' as a threshold of any classified impurity, additive or individual constituent in a substance or in a mixture, above which threshold these shall be taken into account for determining if the substance or the mixture, respectively, shall be classified.

Which

substances are of relevance for the environment?

The term "hazardous" is usually used to indicate potential hazard of chemical. In principle, being "hazardous" is a consequence of one or more intrinsic properties of a substance. It may derive from physico-chemical property of a substance, toxicity to human health or toxicity to the environment (aquatic/soil organisms, bees, flora, fauna, deplete ozone layer, cause long-term effects in the environment etc.).

When talking about **environmentally hazardous** substances, only those properties are of real importance, which **impair the functioning of ecosystems**. This means that only those adverse effects of chemicals are relevant, which threaten the stability of the entire population of micro-organisms, plants or animals (by weakening immune system, disturbing reproduction, inhibiting photosynthesis). For example, as the use of DDT threatened the Bald Eagle population by thinning of the eggshell. Acute toxicity to single organisms is considered by EU environmental legislation as not so important due to the nature's ability to regenerate itself. Furthermore the environment has great potential to destroy and dilute the chemicals. For example, CMR substances, which are neither persistent nor bioaccumulative, do not cause irreversible efects to the surrounding environment or people as such CMR substances are destroyed/ diluted before reaching the environment.

Therefore only those substances which are **persistent** and have a potential to **bioaccumulate** and at the same time are **toxic** are of particular concern. These substances are not destroyed, their concentrations in the environment build up during the time, they concentrate in fatty tissue of animals and may interrupt the human food chain inducing irreversible, severe effects, including the impact to future generations. Some of these substances are subject of long range transport because of their physico-chemical properties. They are transported to any location in the world, reaching also the most remote areas and pristine environments, which provide natural habitats for the endangered species. Here the POPs – persistent organic pollutants are of the highest concern.

Some substances, although not fulfilling the above mentioned criteria might be also of high importance with regard to environment. They are called **"substances of equivalent concern"** and includes such properties as

- endocrine disrupters (disturb hormone system in organisms, which can show e.g. impaired reproductive functions, changes in behaviour or weaken the immune system),
- degradation to hazardous substances (emitted compound itself is not regarded as of high concern but it degrades in the environment to very dangerous compounds or PBTs/vPvBs),
- substances which enhance the effects of other substances (synergetic effect) or have neurotoxic effects (e.g. changing the behaviour of organisms),
- substances which are believed to be PBTs/vPvB but do not fulfil the criteria, e.g. because they cannot be tested due to low water solubility.

Due to the above listed these properties **substances can harm ecosystems and further on also human health** when released to the environment from products and processes. When hazardous substances accumulate in organisms and in the food chain, concentrations in bodies may exceed levels above which adverse effects occur. By being at the end of many food chains, humans are exposed to these substances via food.

Substances of relevance for the aquatic environment

- Persistent, liable to bioaccumulate and toxic (PBT)
- very persistent and very bioaccumulative (vPvB)
- substances of equivalent concern (endocrine disrupters, degrading to hazardous substances, having synergistic or neurotoxic effects etc...)
- CMR only if they are persistent and liable to bioaccumulate

Persistent substances	**Bioaccumulative substances**	**Toxic** to algae, daphnia, fish, mammals, human	**Endocrine disrupters**
• remaining in the enviroment for a long time. • consentration in the enviroment rises over the time. • get transported very long distances from original emission source.	• accumulate in algae and microphytes • accumulate from water in abimal fatty tissue (e.g. to fish, mussels) and further on contaminate the food of human consumption • found in breast milk	• may kill • may cause cancer • may harm the unborn child • may impair fertility • may cause genetic defects • may cause damage to the nervous system • may damage the function of internal organs • may cause development disorders	• may cause feminisation or masculisation in wildlife • may harm the human immune system

THERE IS NO SAFE CONCENTRATION FOR THESE SUBSTANCES!

Legal

frameworks & hazardous substances

From the perspective of the aquatic environment, the following frameworks are the most relevant for our countries and contain definition of hazardous substances:

- Regulation No 1272/2008 on classification, labelling and packaging of chemical substances and mixtures (CLP);
- Regulation No 1907/2006 on registration, evaluation, authorisation and restriction of chemicals (REACH);
- Water Framework Directive 2000/60/EC (WFD) and Directive on Priority Substances 2008/105/EC;
- Helsinki Convention on the Protection of the Marine Environment of the Baltic Sea Area (HELCOM).

Classification, labelling and packaging of chemical substances and mixtures

The new EU regulation (EC) No 1272/2008 on classification, labelling and packaging of chemical substances and mixtures, the so called CLP Regulation entered into force on 20 January 2009. The CLP Regulation will gradually replace the Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive (1999/45/EC). Both Directives will be repealed on 1 June 2015; however the new requirements for classification, labelling and packaging of substances must be applied already from 1 December 2010.

The CLP regulation stipulates the criteria and rules for classifying and labelling of substances and mixtures.

The term **"hazardous"** defined in Article 3 of the regulation states that all substances (and mixtures) fulfilling at least one of the criteria of a hazard class are hazardous. The hazard classes comprise of physico-chemical, human health and environmental hazards. Substances fulfilling the criteria for being hazardous have to be labelled according to the provisions of the CLP.

In the current system of classification and labelling (Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive (1999/45/EC)) the term "hazardous" does not exist and the term **"dangerous"** is applied. The criteria of these two systems are similar but not fully corresponding.

CLP regulation obliges first of all the manufacturers and importers of chemical substances and mixtures to identify all the physico-chemical, toxicological and ecotoxicological properties of substances which may constitute a risk during normal handling and use, however it puts obligations with regard to classification also on downstream users.

Due to the "Regulation status" CLP regulation applies in Estonia, Latvia, and Lithuania directly.

	Physical-chemical properties	Toxic properties	Ecotoxic properties
Symbols according current system			
Symbols according new system-CLP			

Hazard symbols according to the current classification and labelling system and pictograms according to the new GLP regulation.

REACH regulation

REACH regulates the production and use of all chemicals in the EU market. It sets the requirements for registration, evaluation, authorization and restriction of substances, as well as communication on chemicals along the supply chain (e.g. safety data sheet) and between industry and authorities.

Although not legally defined, the term "substance of very high concern" (SVHC) is used to identify the group of priority substances under REACH. Article 57 defines SVHC as a group of the following substances:

- **CMR category 1 or 2** (based on criteria of Directive 67/548/EEC; CLP regulation);
- **PBT** or **vPvB** in accordance with Annex XIII of REACH;
- **Substances of equivalent concern** (no clear criteria exists; case-by-case assessment has shown that there is scientific evidence of potential serious effects to human health or the environment giving rise to equivalent concern, e.g. having endocrine disrupting or neurotoxic properties).

There are several regulatory provisions within REACH to regulate the production and use of SVHC:

- If the registrant during his assessment finds out the substance to be a PBT/vPvB, he has to provide his customer with a safety data sheet. The assessment is required if the substance is registered in amounts exceeding 10 t/a.
- Substances identified as SVHC and included in the candidate list for authorisation (see Table 3 for the first preliminary proposal for candidate list) have to be supplied with a safety data sheet as well. The identification happens through proposals by the Member States or the Agency via a technical dossier.
- If SVHC on the candidate list for authorisation are contained in articles, a notification to the agency and the provision of information to the customer may be required (Article 7).
- Some of the substances on the candidate list may be selected for inclusion in the Annex XIV for authorisation. Substances included in Annex XIV have to be authorized before the use by a company wanting to use it or by an actor up the supply chain.

The criteria for PBTs/vPvBs on EU level are defined in Annex XIII of REACH. They are determined based on their persistence (half-lives), tendency to bioaccumulate (bio-concentration factor) and toxicity (chronic aquatic toxicity, CM (category 1 or 2), R (category 1,2 or 3) or chronic human health effects (R48)), see also Table 1.

REACH regulation first and foremost applies to manufacturers and importers of chemical substances (on its own, in preparations and in articles), however the downstream users should intensively contribute with the communication routines, follow the risk management measures as well as might get direct obligations in specific cases.

Due to the "Regulation status" REACH regulation applies in Estonia, Latvia, and Lithuania directly.

Water Framework Directive and Directive on Priority Substances

The WFD directive aims to regulate the management (use and protection) of European surface water bodies. It aims to ensure good ecological status of surface water by 2015.

The WFD distinguishes between **priority substances** (the emissions of those should be reduced as far as possible) and **priority hazardous substances** (the use of those should be ceased or emissions, discharges and losses should be phased out by 2020).

The WFD prioritises substances posing risks to and via the environment, hence both environmental and human health hazards are considered. Priority substances are defined as being of Community wide concern for the aquatic environment. Priority hazardous substances are those among the priority substances that are toxic, persistent and liable to bio-accumulate, and other substances which give rise to equivalent level of concern. There is no definition and criteria for determining priority (hazardous) substances in the WFD. The list of 33 substances is proposed based on EU risk assessments or simplified assessment using a) ecotoxicity and human toxicity data and b) evidence of widespread environmental contamination (monitoring) or c) information indicating widespread environmental contamination (high production and use volumes, wide spread use etc.).

The list of **33 priority substances**, which have been shown to be of major concern for European Waters is provided in Annex II of Directive on Priority Substances (2008/105/EC). Within this list **20 substances** have been identified as **priority hazardous substances** which are of particular concern for the inland, transitional, coastal and territorial waters. Another **13 substances** were identified as **being subject to revision for identification as possible priority (hazardous)** substances and listed in Annex III (it means that in the near future the requirement for reduction or ceasing out might be applied to these substances). See table 3 for the lists of substances.

There are no separate regulatory instruments in the WFD for the management of priority (hazardous) substances but they are included and controlled under other (environmental) legislation, such as:

- Directive on Priority Substances → Annex I sets environmental quality standards (EQS) for priority (hazardous) substances. EQS means "the concentration of a particular pollutant or group of pollutants in water, sediment or biota which should not be exceeded in order to protect human health and the environment". EQS are defined as annual average concentrations and maximum allowable concentrations in inland and other surface waters.
- Directive on Integrated Pollution Prevention and Control 96/61/EC (IPPC), which requires to identify used and emitted priority and priority hazardous substances when applying for environmental permit and to apply BAT to reduce or cease the emissions.

Corresponding legislation in Lithuania/Estonia/Latvia … also IPPC and directive on priority substances if transposition done already

Helsinki Convention on the Protection of the Marine Environment of the Baltic Sea Area

The HELCOM convention is signed by the countries surrounding the Baltic Sea and defines objectives, methods and research areas for the protection of the Baltic Sea, among other from chemical pollution. HELCOM Recommendation 19/5 specifies the approach towards hazardous substances → substances on the list should be avoided and emissions minimized in order to reach their concentrations close to the natural levels. It is aimed to achieve by 2021.

Within HELCOM substances are defined as hazardous if they are toxic, persistent and bio-accumulative (PBT), or very persistent and very bio-accumulative (vPvB). Moreover, substances having an equivalent level of concern such as substances with effects on hormone and immune systems are also considered as hazardous. Recommendation 19/5 defines hazardous substances as PBTs and substances for priority actions for which it was agreed that action is required, although the criteria are not met. Among these, substances with synergistic effects on other pollutants and substances which may degrade to compounds that are PBTs are included. See Table 3 for the list of substances.

HELCOM defines hazardous substances based on intrinsic properties regarding environmental and human health hazards as well as considerations based on exposure and risks. The selection is based on a common procedure of the Convention parties. A list of substances selected for priority action is contained in the Recommendation 19/5. Furthermore, in 2007 HELCOM has developed a specific tool - Baltic Sea Action Plan (BSAP) to ensure that all possible measures are taken to reduce pollution in the Baltic Sea and to repair the damage done to the marine environment. It specifically focuses on 13 substances (see Table 3) where the national implementation programmes should be developed by 2010 and their effectiveness evaluated in 2013.

The HELCOM Convention is not binding to the contracting parties but set recommendations towards emission controls and reaching the goals for the Baltic Sea. In principle substitution is the first option in emission control, further general measures as applying best practice / BAT, restriction of use, polluter pays principle are recommended.

The Helsinki Convention was ratified by Latvia on 1994.
The Helsinki Convention was ratified by Estonia on 1995.
The Helsinki Convention was ratified by Lithuania on 1997.

Why

to bother about chemical legislation when dealing with water?

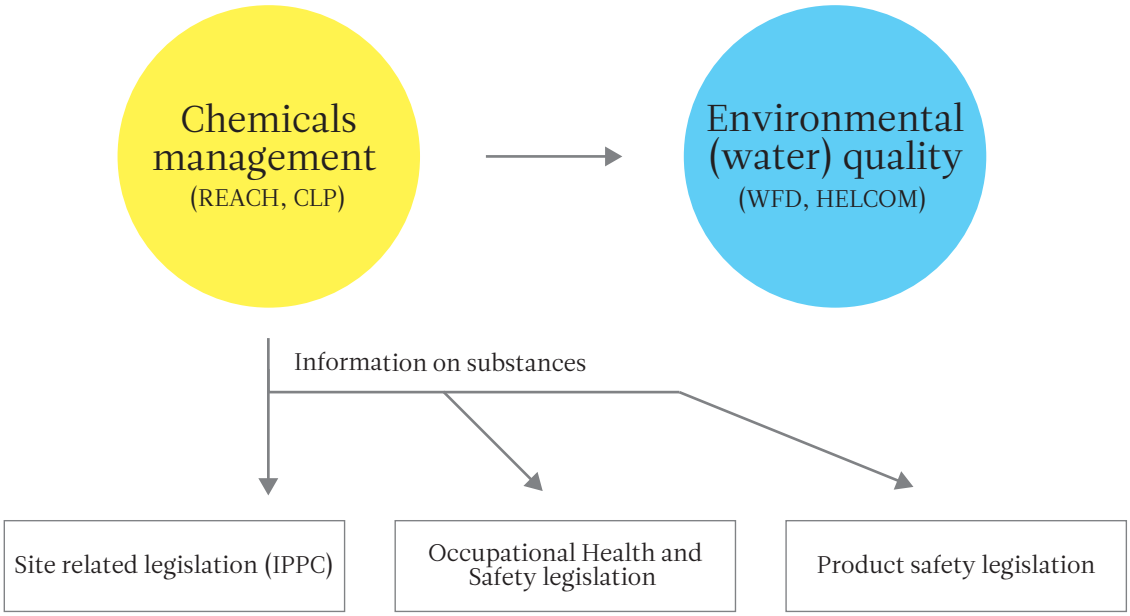
Proper implementation of the chemical legislation is the important precondition for effective implementation of other pieces of legislation (such as water legislation, occupational health and safety, integrated pollution prevention and control (IPPC) etc.) as it should generate all necessary data about the relevant properties of the substance (i.e. physico-chemical, toxicity to human and to the environment, fate of substance in the environment etc.) and ensure communication of this information along the supply chain. It is very important to acknowledge that if this information is not available and provided down the supply chain, it is principally impossible to implement properly other legislation in the company. That is one of the biggest obstacles in our country for the effective implementation of environmental legislation. Therefore improvements and enforcement of the environmental legal frameworks should be addressed together with chemical legislation.

Why

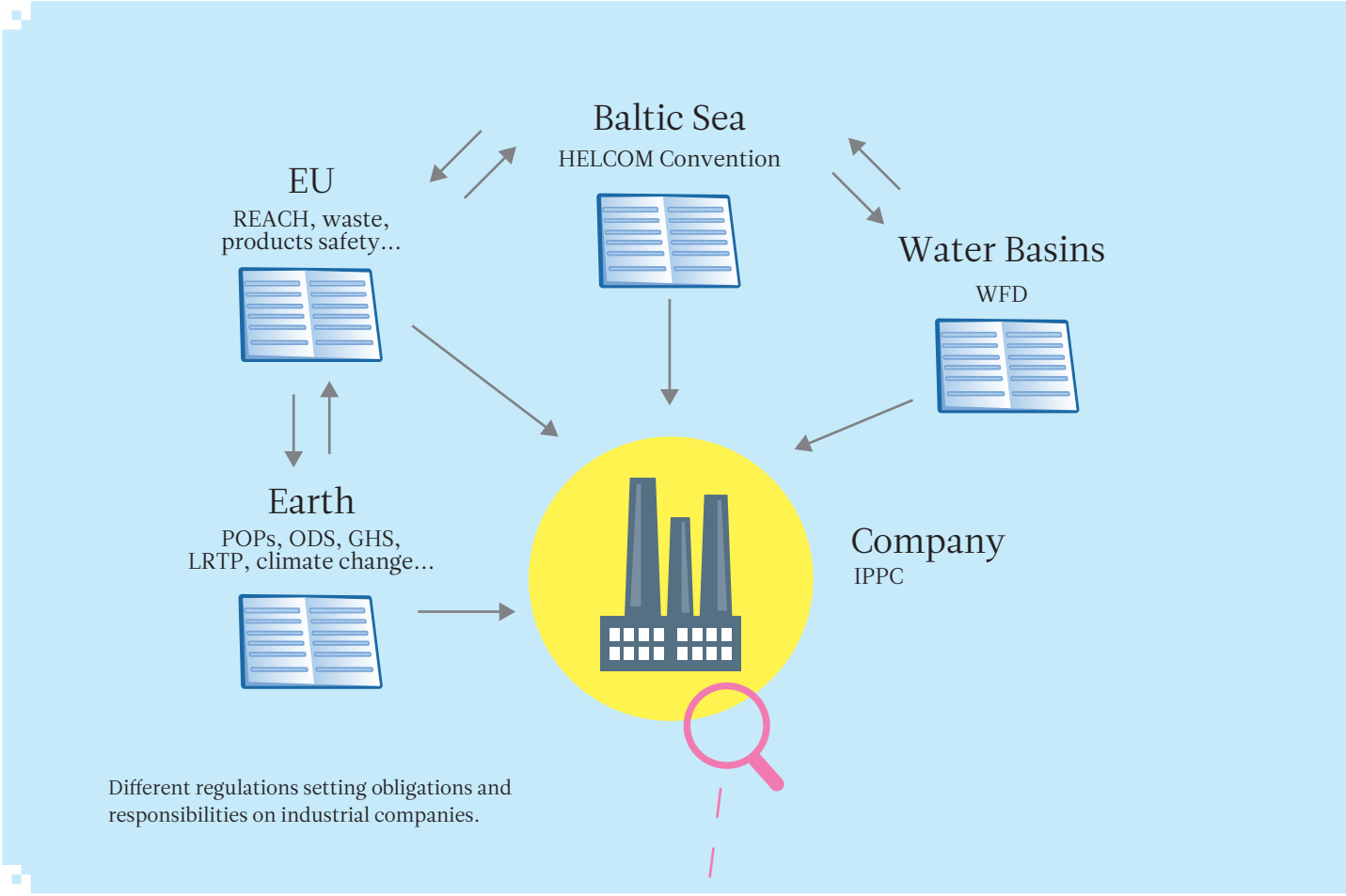
do we have so many different legislations dealing with hazardous substances?

Hazardous substances may be emitted from every stage of the product chain: from the raw material (chemical products), from the production process, including the ones built up during the process (e.g. dioxins), when transported, when used as an article or handled as a waste. Each of these steps is regulated to prevent/avoid/reduce release of hazardous substances in order to prevent/avoid/reduce negative impact to human and environment as much as possible.

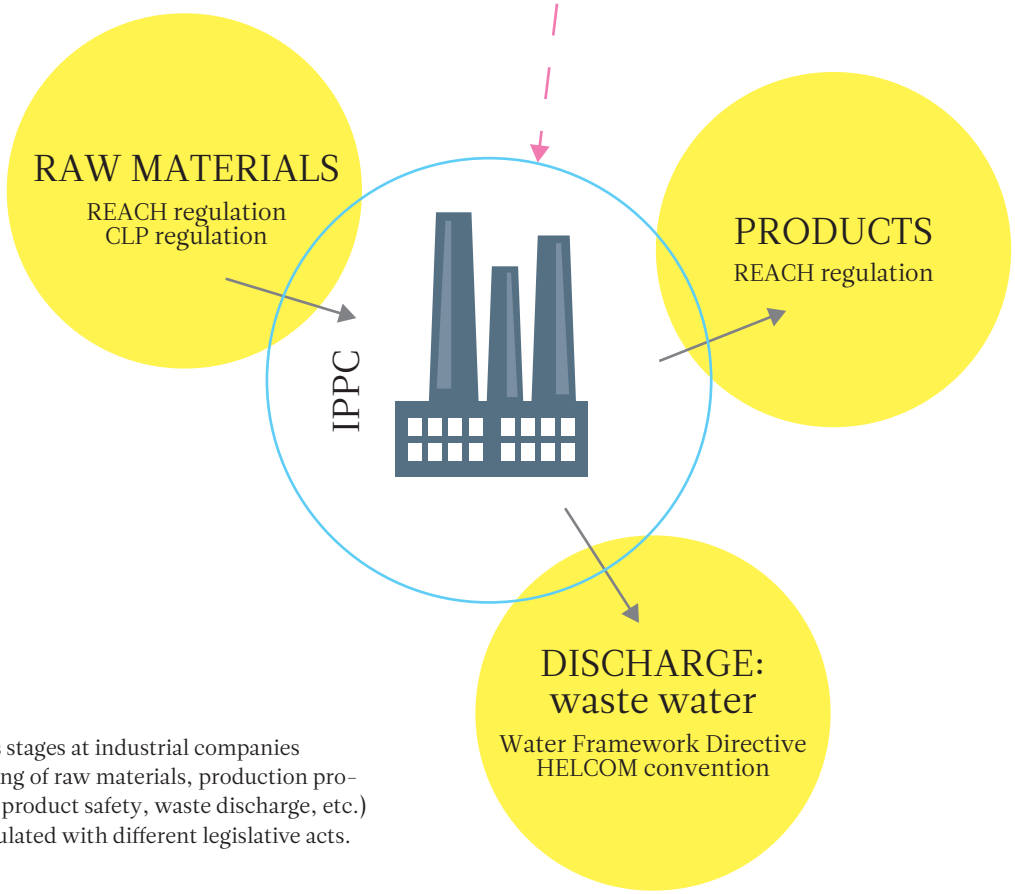
Still hazardous substances reach the environment with direct discharges from companies to surface waters, discharges through municipal WWTP, emissions to air and further atmospheric deposition, old stocks, contaminated soil, leaking from landfills etc. Depending on the scale of potential impact of released substances and sensitivity of the receiving environment further specific legislation might be applied, e.g. Helsinki convention for the Baltic Sea, other international conventions or agreements (POPs, etc.).



The management of hazardous substances is regulated by different pieces of regulation.



Different regulations setting obligations and responsibilities on industrial companies.



Various stages at industrial companies (handling of raw materials, production processes, product safety, waste discharge, etc.) are regulated with different legislative acts.

Definitions

and criteria of hazardous substances

As described above, the legal frameworks dealing with hazardous substances unfortunately have different understandings and criteria to select the substances they aim to regulate. They even name substances of concern differently. Criteria might differ depending on the goals and priorities towards the environmental media to be protected from the hazardous substances.

The table below presents more detailed criteria (when available) for the environmentally hazardous substances in the different frameworks.

Legislation	Prioritised Legislation substances named as...
"Classification, Labelling and Packaging Directive (67/548/EEC)"	Dangerous
CLP	Hazardous
REACH	Substances of very high concern – SVHC (CMR, PBT/vPvB, substances of equivalent concern)
WFD	Priority substances Priority hazardous substances Other pollutants
Helcom Convention	Helcom Convention Substances for priority action

Table 1. Criteria for (environmentally) „hazardous substances" in different frameworks

Framework	Name used	Criteria persistence	Criteria bioaccumulation	Criteria toxicity	Other criteria and comments
CLP	Hazardous substance	Not readily degradable	BCF ≥ 500 (log K_{ow} ≥ 4)	(acute < 1 mg/l) Chronic < 100 mg/l	Any property leading to the classification of any of the hazard classes of the CLP
REACH PBT	Persistent, bioaccumulative and toxic substances	Not inherently degradable or $DT_{50,\,water}$ [60] 40d $DT_{50,sed}$ [180] 120d $DT_{50,\,soil}$ 120d	BCF > 2000	NOEC < 0.01 mg/l or C or M (cat 1&2) or R (cat 1,2 &3) Long term exposure could cause damage to health (R48)	
REACH vPvB	Very persistent and very bioaccumulative substances	Not inherently degradable or $DT_{50,water}$ > 60d $DT_{50,sed}$ > 180	BCF > 5000	–	
REACH SVHC	Substances of very high concern	See REACH PBT and vPvB	See REACH PBT and vPvB	Carcinogenic, mutagenic or reprotoxic category 1 or 2	Substances for which specific assessment shows scientific evidence of probable serious effects giving rise to equivalent concern
WFD	Priority substances and priority hazardous substances	Risks to human health and the environment		Taking account of prioritized substances in EU risk assessments and frameworks	
HELCOM	Hazardous substances Substances for priority action	Found in one or more compartments. Reach, or are likely to reach, the marine environment	Indications of risks for the marine envi_ronment or human health via food	General threat to or via aquatic environment due to hazardous properties	Other concerns are synergistic effects, degradation to PBTs or synergistically acting substances and "other concerns", such as endocrine disruption

Criteria in some other frameworks

Framework	Name used	Criteria persistence	Criteria bioaccumulation	Criteria toxicity	Other criteria and comments
OSPAR	Substances of potential concern Chemicals for priority action	Half-life ($T_{1/2}$) of 50 days	log K_{ow}>=4 or BCF>=500	T_{aq}: acute $L(E)C_{50}$=<1 mg/l, long-term NOEC=<0,1 mg/l or $T_{mammalian}$: CMR or chronic toxicity	Substances giving rise to similar concern may also be included (e.g. endocrine disrupters
UN POPs	Persistent organic pollutant (dirty dozen)	Half-life in water > 2 months or in sediment/soils > 6 months	BCF > 5000 or log K_{ow} > 5 or monitoring data in biota,	Evidence of adverse effect on hh or env or toxicity characteristics indicating damage to hh or env	Long range transport: Measured levels far from source or monitoring data in remote area or multi-media modelling evidence and half-life in air > 2 days
UN ECE POPs	Persistent organic pollutant	Half-life in water > 2 months or in sediment or soils >6 months	BCF > 5000 or log K_{ow} > 5	Potential to adversely affect human health and/or environment	Long range transport: Vapour pressure < 1000 Pa and half-life in air > 2 days or monitoring data in remote area
US EPA	PBTs	$DT_{50,water/soil/sediment}$ >= 60d and $DT_{50,air}$ > 2 days	BCF > 1000	Toxicity to Fish: Low Concern > 10 mg/l Moderate Concern 0.1 - 10 mg/l High Concern < 0.1 mg/l	
US EPA	vPvB	$DT_{50,water/soil/sediment}$ > 180d and $DT_{50,air}$ > 2 days	BCF >= 5000		

What these criteria mean?

BCF – Bioconcentration factor is used to describe the accumulation of chemicals in organisms, primarily aquatic, that live in contaminated environments. BCF is defined as the ratio of chemical concentration in the organism to that in surrounding water:

BCF = Concentration in Organism / Concentration in Environment

Bioconcentration occurs through uptake and retention of a substance from water only, through gill membranes or other external body surfaces.

BCF is related to the Octanol-Water Partition Coefficient via logBCF = 0.79 x logK_{ow} – 0.4 or log BCF=0.85 x logK_{ow}-0.7 or BCF=0.048 x K_{ow}

Octanol-Water Partition Coefficient (K_{ow})

Kow is defined as the ratio of a chemical's concentration in the octanol phase to its concentration in the aqueous phase:

K_{ow} = Concentration in octanol phase / Concentration in aqueous phase

Octanol is an organic solvent that is used as a surrogate for natural organic matter (e.g. soil humic material, colloidal humic materials, lipids in living organisms etc.).

Kow indicates the tendency (preference) of the chemical to partition between an organic phase (e.g., a fish, a soil) and an aqueous phase.

K_{ow} values range from 10^{-3} to 10^{7}, (log K_{ow} of -3 to 7).

Chemicals with low K_{ow} values (e.g., less than 10) may be considered relatively hydrophilic; they tend to have high water solubility, small soil/sediment adsorption coefficients, and small bioconcentration factors for aquatic life. Conversely, chemicals with high K_{ow} values (e.g., greater than 104) are very hydrophobic, have low water solubility, large soil/sediment adsorption coefficient, large

NOEC – No Observed Effect Concentration is the highest concentration at which no statistically significant effect (alterations of morphology, functional capacity, growth, development or life span) is observed in the exposed organisms compared with the same species and strain under the same conditions of exposure.

$L(E)C_{50}$ – Lethal (Effect) Concentration is the concentration at which 50% of the test organisms die or are seriously affected in some other way. This measure is generally used when exposure to a chemical is through the animal breathing it in, while the LD_{50} (lethal dose) is the measure generally used when exposure is by swallowing, through skin contact, or by injection.

What these criteria mean?

Biodegradability is the ability of a substance to be broken down by organisms such as bacteria that live in the ground and surface water. Almost every substance is biodegradable to some extent. A substance is called **readily biodegradable** if it has successfully passed an OECD screening test, showing that more than 60% has biodegraded when measured by formation of CO_2/O_2 or 70% when measured as removal of dissolved organic carbon (DOC) over a 28 days period when exposed to certain micro organisms.
It is assumed that these substances are subject to a quick total degradation (mineralization) in an aquatic environment with sufficient oxygen supply.

Inherently biodegradable is defined based on the results of OECD biodegradability studies where more than 20% and less than 70% of the substance biodegraded within 28 days. A substance that is inherently biodegradable is not as easily broken down.

Half-life ($t_{0.5}$) is the time taken for the concentration of a substance to be reduced by one-half relative to its initial level, assuming first-order decay kinetics.

DT_{50} - Disappearance Time is the time within which the concentration of the test substance is reduced by 50%; it is different from the half-life $t_{0.5}$ when transformation does not follow first order kinetics.

Table 2. Example of four substances criteria on environmental hazardousness

Substance / Criteria	Chloroalkanes C_{10-13}	4-nonylphenol	Phenol	Acetonitrile
BCF	7 273 l/kg (freshwater fish)	1 280 l/kg (calculated)	17,5 l/kg	0,3-0,4 l/kg (calculated)
Log K_{ow}	~6 (4,4-8,7)	4.48	1.47	-0.34
Water solubility	< 0,5 mg/l	~6 mg/l (20 °C)	84 g/l (20 °C)	infinitely soluble
NOEC	10-60 µg/l fish 5 µg/l Daphnia	3,9 µg/l	not reported	not reported
LC50 (mg/l)	0,04-10 000 fish 0,01-10 Daphnia	0,128 fish endocrine effects 0,085 Daphnia (lowest values)	5-50 fish 4.3-20 Daphnia	730-7 000 fish > 100 Daphnia
Readily biodegradable	no	no	yes	yes
Inherently biodegradable	no -16%	probably	- (not relevant)	- (not relevant)
Half-time (or DT 50)	~1630 water 450 marine sediment	150 in water (k = 0,0023 d^{-1}) 300 in soil	$k_{bio\ water}$ 0,05 d^{-1} $k_{bio\ sed}$ 0,01 d^{-1} $k_{bio\ soil}$ 0,1 d^{-1}	- (not relevant)
Classification	N: R50-53 Xn: Carc. Cat 3; R40	Xn: R22 C: R34 N: R50-53 (endocrine disruptor)	T: R23/24/25 C: R34 Xn: 48/20/21/22 Muta Cat. 3; R68	F; R11 Xn; R20/21/22 Xi; R36
Any concerns?	Priority candidate for authorization (PBT and vPvB)	Measures are required to continue the reduction in levels of nonylphenol	There is need for additional information and testing regarding unintentional releases	No (risk reduction measures already sufficiently applied)

Information

sources – links to databases

N-CLASS Database on Environmental Hazard Classification

The database contains classification and additional information on approximately 7800 dangerous substances. It also contains information on substances which classifications are under consideration and substances that have not been classified but data have been produced. (English)

http://apps.kemi.se/nclass/default.asp

Risk assessments of existing substances

EU Risk Assessments gives an overview of conclusions, statistics and testing requirements (Chapter 1 and Chapter 3 contain summaries – conclusions provided). (English)

http://ecb.jrc.ec.europa.eu/home.php?CONTENU=/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/

ESIS database

ESIS is an IT System which provides information on chemicals, related to: EINECS (European Inventory of Existing Commercial chemical Substances), ELINCS (European List of Notified Chemical Substances), NLP (No-Longer Polymers), BPD (Biocidal Products Directive) active substances, PBT (Persistent, Bioaccumulative, and Toxic) or vPvB (very Persistent and very Bioaccumulative), C&L (Classification and Labelling), etc. Insert substance and choose IUCLID Chemical Data sheet, contains test data, but not summaries. (English)

http://ecb.jrc.ec.europa.eu/esis/ESIS

Candidate List of Substances of Very High Concern for authorisation

ECHA website for the identification of substances as Substances of Very High Concern and its inclusion in the Candidate List. Information on reason for inclusion and supporting documents are proivded. Substances are added to the Candidate List by ECHA, and the list will be updated when more substances are identified as SVHC.

http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

TOXNET – Toxicological Data Network

TOXNET is managed by the Toxicology and Environmental Health Information Program (TEHIP) in the Division of Specialized Information Services (SIS) of the National Library of Medicine (NLM). It is a free web-based system of integrated databases on toxicology, hazardous chemicals, environmental health and related areas. (English)

http://toxnet.nlm.nih.gov/

ECOTOX

The ECOTOX (ECOTOXicology) database provides single chemical toxicity data for aquatic life, terrestrial plants and wildlife. ECOTOX is a useful tool for examining impacts of chemicals on the environment. Peer-reviewed literature is the primary source of information encoded in the database. Pertinent information on the species, chemical, test methods, and results presented by the author(s) are abstracted and entered into the database. (English)

http://cfpub.epa.gov/ecotox/

PBT Profiler – Persistent, Bioaccumulative and Toxic Profiles for Organic Chemicals

Online screening tool for checking if substances may have PBT-properties. Conclusions are not sufficient for definite PBT determination, but chemicals that need further evaluation for PBT characteristics are identified. Analysis is based on modeling and estimates but not on experimental data. (English)

http://www.pbtprofiler.net/default.asp

Management

approach towards hazardous substances in EU

The **EU's regulatory approach** in the area of environmental protection has changed over time from a prescriptive system to a more **principle-based system.** This means that legislation defines objectives, roles and responsibilities but does not define exactly HOW to reach compliance. Legislation may define communication and cooperation as well as planning mechanisms and coordinate the implementation across the EU by setting time tables and collecting implementation reports. The way how to implement legislation, i.e. how to achieve the goals and which instruments to use (e.g. existing or new legislation, economic incentives, information or training) is left "open" for Member States and/or concerned parties.

Furthermore, the approach of chemicals control has changed over the time from regulating single substances to **regulating substances or substance groups with certain hazardous properties**, e.g. PBT/vPvB. At the same time the burden of proof has been shifted from authorities to the industry (in particular by REACH), making the industry now responsible for identifying hazardous substances.

The single substance approach has been maintained for specific substances, usually those which are of the highest priority for action (e.g. POPs) or for specific products (e.g. electronic devices, toys).

There are several overarching principles and approaches towards a better management of chemicals. The precautionary principle and the polluter pays principle are two essential elements of EU environmental legislation.

The **precautionary principle** means that "as long as there is no proof of the opposite and there are indications of a risk (e.g. high production volumes or wide dispersive uses), measures necessary to protect humans and the environment should be taken". It implies that it is better to prevent damage than to repair it and that there is (almost) never absolute scientific evidence for cause-effect relationships between chemicals and effects in the environment.

The precautionary principle assumes that anyone is responsible to protect humans and the environment from harm and that damage can be anticipated before it occurs (assessment of risk). Furthermore, if there is a suspicion of risk, the "burden of proof" that this is not the case lies with the actor causing the potential risk.

The **polluter-pays** principle states that actors causing pollution and potential damage are responsible to pay for remedying the environment. The aim of the principle is to allocate and internalise the costs of (preventing) environmental damage with the economic actors, with the aim of changing or eliminating the pollution source. This implies that also prevention activities in the scope of an actor's actions and substances/products should be financed by the polluter. The polluter-pays principle requires that it is possible to identify the polluter, that means to track the origin of pollution (in the case of hazardous substances - the emission source), to quantify and to repair the damage. This is only possible to a certain extent when dealing with chemicals, due to the many (diffuse) emission sources and contributors to contamination.

The approach of clear **roles and responsibilities** has been more explicitly introduced by the new REACH regulation, which defines the different economic actors in the chemical supply chain and allocates specific requirements to the role definitions (manufacturers, importers, downstream users (e.g. formulators and article producers) as well as distributors of chemicals). REACH also defines the roles and responsibilities of the EU and Member State authorities. It shifts not only burden of proof from authorities to industry but also responsibility to develop and communicate chemicals management measures.

Cooperation and communication are regarded as essential in managing hazardous substances. This is due to the fact that supply chains are very complex and knowledge on substances and their uses is dispersed with the actors at different supply chain levels. Taking preventive or protective action such as introducing technological or product innovations, substituting substances or proposing emission/exposure reduction measures, requires significant knowledge and cooperation between the economic actors.

As hazardous substances don't "stop at borders", also cooperation between countries is essential to efficiently manage substance risks. International cooperation may result in efficiency gains as well as in ensuring "fair trade" (same requirements to all enterprises, same level of protection for all consumers).

In the table below it is illustrated how the different management principles and approaches could be employed by the legislation.

Example: Water Framework Directive

WFD defines only

a) a goal – to achieve good chemicals status for waters
and therefore sets EQS for the priority and priority hazardous substances;
b) ecological areas – river basins and river basin districts and
c) instruments to manage them – river basin management plans,
d) time line for implementation of specific measures, e.g.

2009 – river basin management plan including progamme of measures finalised
2010 – pricing policines introduced
2012 – programmes of measures made operational

Managing bodies in the Member States are responsible for the identification of a river basin districts, setting the objectives and goals and developing respective river basin management plans including programme of measures for particular river basin distric .

Principles applied	How it is reflected in REACH regulation?
Precautionary principle	· requirement to assess potential risks of the use of substances · all actors have a responsibility to identify and implement risk reduction measures
Polluter pays	· activities and costs to determine risks and conduct tests are to be paid by the actor potentially causing the damage · the registration of substances is required to be able to trace back the origin of pollution and to make the respective actors responsible · the environmental liability can be claimed by the authorities but also private persons
Cooperation and commu-nication	· SIEFs à joint registrations or sharing of data but also discussion on uses and risk management measures, need to agree on harmonised classification and labelling · Cooperation required in order to determine conditions of use and risk management measures, apply for authorisations of substances etc. · The main communication instruments under REACH are the safety data sheet and the exposure scenarios which are supplied along with dangerous chemicals · cooperation between industry and authorities in the commenting and negotiation procedures on the identification of SVHC and inclusion on the list for authorization · cooperation between authorities is established via several fora in the Agency (enforcement, risk assessment, socio-economic analysis) and as inbuilt procedures in evaluation, authorization and restrictions · cross-border cooperation between economic actors required as substances are imported into the EU from other countries · there is also informal communication in the supply chain on uses and conditions of use of substances
Roles and responsibilities	· defines the different economic actors in the chemical supply chain and allocates specific requirements to the role definitions (manufacturers, importers, downstream users, distributors of chemicals) · defines the roles and responsibilities of the EU and Member State authorities

Table 3. Hazardous substances relevant in different frameworks

Substance	CAS	REACH authorisa-tion	REACH authorisa-tion candidate list	WFD priority subst.	WFD priority haz. subst.	WFD other pollutants	WFD subject to review	HELCOM Rec. 31E/1 (priority hazardous substances)
1-Methyl-2-pyrrolidone	872-50-4		X					
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	71888-89-6		X					
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	68515-42-4		X					
1,2-dichloroethane	107-06-2		X	X				
1,2,3-Trichloropropane	96-18-4		X					
2,2'-Dichloro-4,4'-methylenediani-line	101-14-4		X					
2,4-Dinitrotoluene	121-14-2		X					
2-Ethoxyethanol	110-80-5		X					
2-Ethoxyethyl acetate	111-15-9		X					
2-Methoxyaniline; o-Anisidine	90-04-0		X					
2-Methoxyethanol	109-86-4		X					
4,4'- Diaminodiphenylmethane (MDA)	101-77-9	X						
5-tert-butyl-2,4,6-trinitro-m-xyle-ne (musk xylene)	81-15-2	X					X	
Acrylamide	79-06-1		X					
Alachlor	15972-60-8			X				
Aldrin	309-00-2					X		
Aluminosilicate Refractory Ceramic Fibres[1]	-		X					
Ammonium dichromate	7789-09-5	*	X					
AMPA	1066-51-9						X	
Anthracene	120-12-7		X		X			
Anthracene oil	90640-80-5		X					
Anthracene oil, anthracene paste,distn. lights	91995-17-4		X					
Anthracene oil, anthracene paste, anthracene fraction	91995-15-2		X					
Anthracene oil, anthracene paste	90640-81-6		X					
Anthracene oil, anthracene-low	90640-82-7		X					
Arsenic acid	7778-39-4		X					
Atrazine	1912-24-9			X				
Bentazon	25057-89-0						X	
Benzene	71-43-2			X				
Benzyl butyl phthalate (BBP)	85-68-7	X						
Bis (2-ethylhexyl)phthalate (DEHP)	117-81-7	X		X				
Bis(2-methoxyethyl) phthalate	117-82-8		X					
Bis(2-methoxyethyl) ether	111-96-6		X					
Bisphenol-A	80-05-7						X	
Boric acid	10043-35-3 11113-50-1		X					
Brominated diphenylether	-				X			
Pentabromodiphenyl ether (pentaBDE)	32534-81-9			X				X
Octabromodiphenyl ether (octaBDE)	32536-52-0				X			X

Substance	CAS	REACH authorisa-tion	REACH authorisa-tion candidate list	WFD priority subst.	WFD priority haz. subst.	WFD other pollutants	WFD subject to review	HELCOM Rec. 31E/1 (priority hazardous substances)
Decabromodiphenyl ether (decaBDE)	1163-19-5			X				X
Cadmium and its compounds	7440-43-9				X			X
Calcium arsenate	7778-44-1		X					
Carbon-tetrachloride	56-23-5					X		
Chlorfenvinphos	470-90-6			X				
Chlorinated paraffins, short chained	85535-84-8		X		X			X
Chlorinated paraffins, medium-chain	85535-85-9							X
Chloroform (trichloromethane)	67-66-3			X				
Chlorpyrifos (Chlorpyrifos-ethyl)	2921-88-2			X				
Chromic acid Oligomers of chromic acid and dichromic acid Dichromic acid	7738-94-5 13530-68-2	*	X					
Chromium trioxide	1333-82-0	*	X					
Cobalt(II) carbonate	513-79-1	*	X					
Cobalt(II) diacetate	71-48-7	*	X					
Cobalt dichloride	7646-79-9	*	X					
Cobalt(II) dinitrate	10141-05-6	*	X					
Cobalt(II) sulphate	10124-43-3	*	X					
DDT total	-					X		
para-para-DDT	50-29-3					X		
Diarsenic pentaoxide	1303-28-2		X					
Diarsenic trioxide	1327-53-3		X					
Dibutyl phthalate (DBP)	84-74-2	X						
Dichloromethane	75-09-2			X				
Dichromium tris(chromate)	24613-89-6		X					
Dicofol	115-32-2						X	
Dieldrin	60-57-1					X		
Diisobutyl phthalate	84-69-5		X					
Dioxins	-						X	X
Disodium tetraborate, anhydrous	1303-96-4 1330-43-4 12179-04-3		X					
Diuron	330-54-1			X				
EDTA (ethylenediaminetetraacetic acid)	60-00-4						X	
Endosulfan	115-29-7				X			X
Endrin	72-20-8					X		
Fluoranthene	206-44-0			X				
Formaldehyde, oligomeric reaction products with aniline (technical MDA)	25214-70-4		X					
Free cyanide	57-12-5						X	
Furans (PCDF)	-							X
Glyphosate	1071-83-6						X	
Hexachlorocyclohexane (HCH)	608-73-1				X			
Hexabromocyclododecane HBCDD) and all major diastereoisomers identified: Alpha-hexabromocyclododecane Beta-hexabromocyclododecane Gamma-hexabromocyclododecane	25637-99-4 3194-55-6 134237-50-6 134237-51-7 134237-52-8	X						X

Substance	CAS	REACH authorisa-tion	REACH authorisa-tion candidate list	WFD priority subst.	WFD priority haz. subst.	WFD other pollutants	WFD subject to review	HELCOM Rec. 31E/1 (priority hazardous substances)
Hexachlorobenzene	118-74-1				X			
Hexachlorobutadiene	87-68-3				X			
Hydrazine	302-01-2 7 803-57-8		X					
Isodrin	465-73-6					X		
Isoproturon	34123-59-6			X				
Lead	7439-92-1			X				
Lead chromate	7758-97-6		X	X				
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)	12656-85-8		X	X				
Lead diazide, Lead azide	13424-46-9		X					
Lead dipicrate	6477-64-1		X					
Lead hydrogen arsenate	7784-40-9		X	X				
Lead sulfochromate yellow (C.I. Pigment Yellow 34)	1344-37-2		X	X				
Lead styphnate	15245-44-0		X					
Mecoprop (MCPP)	7085-19-0						X	
Mercury and its compounds	7439-97-6				X			X
Naphthalene	91-20-3			X				
Nickel and its compounds	7440-02-0			X				
Nonylphenol	25154-52-3				X			X
4-Nonylphenol	104-40-5				X			X
Nonylphenolethoxylate and the degradation/transformation products	9016-45-9							X
N,N-dimethylacetamide	127-19-5		X					
Octylphenol	1806-26-4			X				X
(4-(1,1',3,3'-tetramethylbutyl)-phenol)	140-66-9		X	X				
Octylphenol ethoxylates	9036-19-5							X
Polyaromatic hydrocarbons (PAH) (Benzo(a)pyrene) (Benzo(b)fluoranthene) (Benzo(g,h,i)perylene) (Benzo(k)fluoranthene) (Indeno(1,2,3-cd)pyrene)	50-32-8 205-99-2 191-24-2 207-08-9 193-39-5				X			
PCB (Polychlorinated biphenyls (dioxin-like))	1336-36-3						X	X
Pentachlorobenzene	608-93-5				X			
Pentachlorophenol	87-86-5			X				
Pentazinc chromate octahydroxide	49663-84-5		X					
Perfluorooctane sulphonic acid (PFOS)	1763-23-1						X	X
Perfluorooctanoic acid (PFOA)	335-67-1							X
Phenolphthalein	77-09-8		X					
Pitch, coal tar, high temp.	65996-93-2		X					
Potassium dichromate	7778-50-9	*	X					
Potassium chromate	7789-00-6	*	X					
Potassium hydroxyoctaoxodizincae-dichromate	11103-86-9		X					
Quinoxyfen (5,7-dichloro-4-(p-fluorophenoxy)quinoline)	124495-18-7						X	

Substance	CAS	REACH authorisa-tion	REACH authorisa-tion candidate list	WFD priority subst.	WFD priority haz. subst.	WFD other pollutants	WFD subject to review	HELCOM Rec. 31E/1 (priority hazardous substances)
Simazine	122-34-9			X				
Sodium dichromate	7789-12-0 10588-01-9	*	X					
Sodium chromate	7775-11-3	*	X					
Strontium chromate	7789-06-2		X					
Tetraboron disodium heptaoxide, hydrate	12267-73-1		X					
Tetrachloro-ethylene	127-18-4					X		
Tributyltin compounds (TBT)	-				X			X
Bis(tributyltin)oxide (TBTO)	56-35-9		X		X			X
Tributyltin-cation	36643-28-4				X			X
Trichloroethylene	79-01-6	*	X			X		
Trichlorobenzenes	12002-48-1			X				
Triethyl arsenate	15606-95-8		X					
Trifluralin	1582-09-8			X				
Trilead diarsenate	3687-31-8		X					
Triphenyltin compounds (TPhT)	-							X
Tris(2-chloroethyl)phosphate	115-96-8		X					
Zirconia Aluminosilicate Refractory Ceramic Fibres [2]	-		X					

* 19th of December 2011 ECHA has proposed the EC to add these substances to the Authorisation list

[1] Aluminosilicate Refractory Ceramic Fibres are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.2 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions:

a) oxides of aluminium and silicon are the main components present (in the fibres) within variable concentration ranges
b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm)
c) alkaline oxide and alkali earth oxide (Na2O+K2O+CaO+MgO+BaO) content less or equal to 18% by weight

[2] Zirconia Aluminosilicate Refractory Ceramic Fibres are fibres covered by index number 650-017-00-8 in Annex VI, part 3, table 3.2 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, and fulfil the three following conditions:

a) oxides of aluminium, silicon and zirconium are the main components present (in the fibres) within variable concentration ranges
b) fibres have a length weighted geometric mean diameter less two standard geometric errors of 6 or less micrometres (µm).
c) alkaline oxide and alkali earth oxide (Na2O+K2O+CaO+MgO+BaO) content less or equal to 18% by weight

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