Background information on „The EU hazard concept“ and EU approaches towards chemicals management

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Introduction

In this paper basic information on the European hazard concept of chemical substances and mixtures is presented. The paper has been developed in the project “Capacity building hazardous substance Management in North West Russia” in order to facilitate a comparison of the EU-systems and approaches with the current system on chemicals in Russia

1 Background to “hazardous substances”

The various (legal) frameworks in the context of EU regulation explain and define “hazardous substance” differently. It is important to be clear on which definitions exist and which is applied in the concrete work situation. In principle, being “hazardous” is a consequence of one or more intrinsic properties of a substance. “Environmentally hazardous” is a subset of “hazardous”.

1.1 GHS / CLP regulation[1]

The term “hazardous” in relation to chemical substances is legally defined in the EU by the CLP-regulation[2]. All substances fulfilling the criteria of at least one hazard class of the CLP-regulation are called hazardous. The hazard classes comprise physico-chemical, human health and environmental hazards. From the perspective of environmental protection, only a sub-group of substances defined as hazardous are relevant.

Dangerous substances are a subset of “hazardous substances”, excluding hazard classes, which don’t exist under the EU Classification and Labelling Directive (67/548/EEC)[3].

The definition of the CLP-regulation of a hazardous substance includes all its hazard classes: physico-chemical, human health and environmental hazards- and contains testing methods and cut-off values for deciding whether or not the criteria of a specific hazard class are met.

1.2 EU Classification and Labelling Directive[4]

The EU classification and labelling Directive defines dangerous substances. The term “hazardous” does not exist.

A substance is regarded as dangerous if one or more of the criteria for a dangerous property are fulfilled. “Dangerous” includes physic-chemical, human health and environmental dangers. The term hazardous does not exist.

1.3 EU Definition of a substances of very high concern (REACH)

Neither the term “hazardous” nor the term “substance of very high concern” are unambiguously defined in REACH. However, it is commonly understood that substances of very high concern are defined by the criteria of Article 57 of REACH. This is evident as the term is used in the guidance documents and the recitals of REACH.

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[1] 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

[2] REGULATION (EC) No 1272/2008, Article 3: „A substance or a mixture fulfilling the criteria relating to physical hazards, health hazards or environmental hazards, laid down in Parts 2 to 5 of Annex I is hazardous and shall be classified in relation to the respective hazard classes provided for in that Annex.“

[3] The term dangerous has been defined in the CLP-regulation in order to limit the consequences of reclassification or additional classifications under downstream legislation, which makes reference to substances classified as “dangerous”.

[4] Directive 67/548/EEC

Substances of very high concern (SVHC) are substances meeting the following criteria:

1. carcinogenic category 1 or 2 (Dir. 67/548/EEC)
2. mutagenic category 1 or 2 (Dir. 67/548/EEC)
3. toxic for reproduction category 1 or 2 (Dir. 67/548/EEC)
4. persistent, bioaccumulative and toxic in accordance with Annex XIII of REACH[5]
5. very persistent and very bioaccumulative in accordance with Annex XIII of REACH
6. substances not fulfilling the above criteria, but for which a case-by-case assessment has shown that there is scientific evidence of probable serious effects to human health or the environment giving rise to equivalent concern[6].

SVHC are identified either by the registrants based on the testing required for registration or by the competent authorities in the frame of the procedure to identify candidates for the authorization process, which may also involve additional testing and case-by-case assessments of substances. The candidate list for authorisation is regularly updated and is available at the ECHA website[7].

Under REACH, substances of very high concern exhibit either CMR properties (human health), are PBTs/vPvBs (environment) or are regarded as “of similar concern”. Testing methods and cut-off values are defined in the Classification and Labelling Directive and the REACH Annex XIII. A sub-set of SVHCs will be/is listed on a candidate list for authorisation and/or Annex XIV. Substances are identified either by the registrants or by the Commission and Member States

1.4 EU definition of a PBT/vPvB (REACH)

REACH defines PBTs/vPvBs in Annex XIII. They are normally determined based on their persistence (half-lives), tendency to bioaccumulate (bio-concentration factor) and toxicity (chronic aquatic toxicity, CM (cat 1 or 2), R (cat 1,2 or 3) or chronic human health effects (R48). For all endpoints, cut-off values are defined. A PBT/vPvB may be identified by a registrant based on testing for the registration or by the competent authorities in the frame of identifying SVHC.

Under REACH, criteria and values for identifying PBTs/vPvBs are defined. The criteria include both environmental and human health hazards. Substances may be defined as PBT/vPvB even if they don’t fulfil the criteria in Annex XIII. Substances are identified either by the registrants or by the Commission and Member States)

There are several regulatory steps within REACH to regulate the production and use of substances of very high concern:

1. If the registrant identifies a substance to be a PBT/vPvB he is to provide his customer with a safety data sheet with respective information. The PBT/vPvB assessment is required if the substance is registered in amounts exceeding 10 t/a
2. Information on PBTs/vPvBs has to be forwarded in the supply chain via the safety data sheet, unless the concentration in mixtures remains under 0.1% w/w
3. If substances are identified as SVHC and included on the candidate list for authorisation by Member States or the ECHA registrants have to adopt that classification (if not yet part of their own assessment) and safety data sheets have to be provided.

[5] Annex XIII sets out the criteria for the identification of PBT and vPvB substances. The Commission carried out a review of the Annex XIII to take into account current and new experience and concluded that an adaptation of the criteria is necessary. A respective Commission Regulation is expected by the end of 2010

[6] These may be substances e.g. having endocrine disrupting properties or having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which are not determined in standard testing but by other means.

[7] http://echa.europa.eu/consultations/authorisation/svhc_en.asp

4. If “candidate substances” are contained in articles, a notification to the agency and the provision of information to the customer may be required (REACH Article 7[8]).
5. Of the substances on the candidate list, some may be selected for inclusion in the Annex XIV (substances to be authorized). Inclusion of SVHC into Annex XIV requires another formal process, supported by a technical dossier and complemented by commenting and discussions with the stakeholders. Substances included on the Annex have to be authorized before their use by the company wanting to use it or by an actor up his supply chain.

Substances of “equivalent concern” can only be determined on a case by case basis and no clear criteria exist. It is likely that these substances will only be identified by the authorities in the process of evaluation or making proposals for authorization.

1.5 Priority and priority hazardous substances[9] of the Water Framework Directive

The Water Framework Directive (WFD) distinguishes between priority substances (21) for which a progressive emission reduction is aimed at and priority hazardous substances (12) for which the ultimate aim is the cessation or phasing out of emissions, discharges and losses. Single substances and groups of substances are listed in Annex X of the WFD[10].

Priority substances are substances listed in Annex X WFD which are 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 an equivalent level of concern. There is no definition of PBT and “equivalent level of concern” in the WFD.

The Community wide concern may be identified by EU risk assessment or by a 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 first list of priority substances was decided in 2001 and has been established based on a method called COMMPS[11]. The list has been replaced by a new Annex, which also contains environmental quality standards (values for annual average concentrations and maximum allowable concentrations of 33 substances in inland and other surface waters).

The WFD prioritises substances posing risks to and via the environment, hence environmental and human health hazards are considered. There are no separate criteria and cut-off values for determining priority (hazardous) substances. The Commission is to propose substances based on conclusions of EU risk assessments, results of the COMMPS procedure and priorities set in other frameworks. Decisions are taken by the Member States.

1.6 Hazardous substances under HELCOM

The HELCOM convention defines objectives, methods and research areas for the protection of the Baltic Sea, among other from chemical pollution. The HELCOM convention is signed by the countries surrounding the Baltic Sea. There is a convention secretariat organizing the work and

[8] The conditions are that the SVHC is contained in concentrations above 0.1% w/w that the total amount per article producer exceeds 1 t/a and that the SVHC has not yet been registered for that use.

[9] The “old” Annex X has been replaced with an Annex that includes environmental quality standards for the priority and priority hazardous substances by DIRECTIVE 2008/105/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council

[10] According to Article 2.30 „Priority substances means substances identified in accordance with Article 16(2) and listed in Annex X. Among these substances there are .priority hazardous substances. which means substances identified in accordance with Article 16(3) and (6) for which measures have to be taken in accordance with Article 16(1) and (8).“

[11] This method consists of a combination of monitoring and modelling data in order to determine a risk and set respective priorities

agreements among the contracting parties. Several different work areas exist. Recommendation 19/5 specifies the approach towards hazardous substances. In principle, substances on the HELCOM list of hazardous substances should be avoided and emissions minimized in order to reach natural background concentrations.

The HELCOM Convention text defines[12] substances as “harmful” if they are liable to pose hazards to human health or to cause harm to the environment/natural resources or to hinder the use of the sea, to impair its quality or to lead to a reduction of its amenity. In Annex I a procedure for identifying harmful substances is described: criteria consist of inherent substance properties (persistence, bioaccumulation, toxicity) as well as risk related information, such as the PEC/PNEC ratio, significance of long range transport, risks of undesirable (irreversible) changes in the marine eco-systems etc. A list of substances, which are already known to be of concern should be considered in priority setting for action. Furthermore, the production and use of some POPs should be banned and the use of pesticides (as listed) minimized by the contracting parties. Apart from the qualitative definition of a harmful substance and the general criteria, no cut-off values exist in the Convention.

Under Recommendation 19/5, hazardous substances are defined[13] as being either toxic, persistent and liable to bioaccumulative or as being (groups of) substances agreed by the Commission as requiring action, even if they do not meet the criteria. The latter are selected on a case-by-case assessment. Furthermore it is stated[14] that criteria should take account of general threats to the aquatic environment due to their hazardous properties, the existence of risk for human health or the marine environment or the actual occurrence or the likelihood of occurrence in the Convention area. The recommendation contains a list of substances selected for priority action.

HELCOM defines hazardous substances based on intrinsic properties regarding environmental and human health hazards as well as considerations based on exposure and risks. No cut-off values are defined. The selection is based on a common procedure of the Convention parties.

1.7 Hazardous substances under OSPAR

OSPAR defines hazardous substances as substances which are persistent, liable to bioaccumulate and toxic (PBT substances), or which give rise to an equivalent level of concern as PBTs (e.g. endocrine disruption). The initial establishment of a list of substances of potential concern was drawn up using a procedure called DYNAMEC[15]. This is a process at the end of which substances are identified as substances of potential concern based on their PBT properties and expert discussions and ranked them for priority action based on exposure information. The cut-off values[16] for the PBT properties are defined in an additional agreement.

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[12] "Harmful substance" means any substance, which, if introduced into the sea, is liable to cause pollution;“

"Pollution" means introduction by man, directly or indirectly, of substances or energy into the sea, including estuaries, which are liable to create hazards to human health, to harm living resources and marine ecosystems, to cause hindrance to legitimate uses of the sea including fishing, to impair the quality for use of sea water, and to lead to a reduction of amenities;

[13] “Hazardous substances” are substances which fall into one of the following categories:
(i) substances or groups of substances that are toxic, persistent and liable to bioaccumulate;

(ii) other substances or groups of substances which are agreed by the Commission as requiring a similar approach as the substances referred to in (i) even if they do not meet all the criteria for toxicity, persistence and bioaccumulation, but which also give grounds for concern; this second category will include both substances which work synergistically with other substances to generate such concern and also substances which do not themselves justify inclusion but which degrade or transform into substances referred to in (i) or (ii).

[14] The criteria used in these selection and prioritization mechanisms may include that the substances or groups of substances:

a) are a general threat to the aquatic environment due to their hazardous properties;

b) show indications of risks for the marine environment or may endanger human health via consumption of food directly or indirectly from the marine environment;

c) have been found in one or more compartments of the Convention Area;

d) reach, or are likely to reach, the marine environment, for instance from a diversity of sources through various pathways.

The application of these criteria should both reflect the hazardous characteristics of substances and groups of substances and give priority to their actual or potential occurrence and effects in the Convention Area.

[15] Dynamic selection and Prioritisation Mechanism for Hazardous Substances

[16] Persistency (P): Half-life ($T_{½}$) of 50 days[16] and Liability to Bioaccumulate (B): log K_{ow}>=4 or BCF>=500 and Toxicity (T)→ T_{aq}: acute $L(E)C_{50}$=<1 mg/l, long-term NOEC=<0,1 mg/l or $T_{mammalian}$: CMR or chronic toxicity

OSPAR substances of potential concern are defined by their being PBTs or of similar concern, based on environmental and human health hazards. They are selected by the Contracting parties.

1.8 POPs at UN/UN ECE

A subgroup of substances are of particular concern because of their potential for long range transport, which may lead to wide-spread occurrence of these substances, even far from their emission sources. The criteria for POPs are defined in the frame of the Stockholm Convention[17] on POPs as well as by the UN ECE[18]. They relate to persistence, the potential to bioaccumulate, the potential for long range transport as well as their toxicity.

1.9 PBT-criteria in the US

The US EPA has set up a strategy on PBTs/vPvBs. The identification criteria for these substances are defined by a substances half-life[19], bioconcentration factor and the toxicity to fish. There are no criteria relating to human health hazards.

2 Definitions and criteria of hazardous substances

The various frameworks dealing with hazardous substances unfortunately have different understandings and criteria to select the substances they aim to regulate. Furthermore, they name the substances they cover differently. The following table gives an overview of the differences of criteria.

[17] UNEP POPs Convention: Criteria for persistence: Half-life in water > 2 months **or** in sediment/soils > 6 months, bioaccumulation: BCF or BAF > 5000 **or** log K_{ow} > 5 **or** monitoring data in biota, 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, toxicity: Evidence of adverse effect on human health or the environment **or** toxicity characteristics indicating potential damage to human health or environment

[18] UN-ECE POPs Protocol: Criteria for persistence: Half-life in water > 2 months **or** in sediment or soils >6 months, bioaccumulation: BCF or BAF > 5000 **or** log K_{ow} > 5, potential for long range transport: Vapour pressure < 1000 Pa **and** half-life in air > 2 days **or** monitoring data in remote area, toxicity: Potential to adversely affect human health and/or environment

[19] Persistent: half-life in water, soil, and sediment >= 60d and half-life in air > 2 days, or very persistent: half-life in water, soil, and sediment > 180d and half-life in air > 2 days, bioaccumulative: BCF > 1000 and very bioaccumulative: BCF >= 5000 and toxicity to Fish: Low Concern > 10 mg/l Moderate Concern 0.1 - 10 mg/l and High Concern < 0.1 mg/l

Table: 1: Criteria for (environmentally) „hazardous substances“ in different frameworks

Criteria Framework	“Name” of hazardous substances	Criteria persistence	Criteria bioaccumulation	Criteria toxicity	Other criteria and comments
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		
HELCOM	List of potential substances of concern; List of substances selected for immediate priority action	Found in one or more compartments; Reach, or are likely to reach, the marine environment	indications of risks for the marine environment or human health via food	General threat to the 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
OSPAR	OSPAR List of substances of potential concern; OSPAR List of chemicals for priority action	Half-life ($T_{½}$) 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.
CLP-regulation	Hazardous substance (here: only environment)	Not readily degradable	BCF ≥ 500 (log Kow ≥ 4)	(acute < 1 mg/l) Chronic < 100 mg/l	**Any property** leading to the classification of any of the hazard classes of the GHS
EU SVHC	Substances of very high concern	See EU PBT and vPvB	See EU PBT and vPvB	Carcinogenic, mutagenic or reprotoxic category 1 or 2	Substances for specific assessment shows scientific evidence of probable serious effects giving **rise to equivalent concern**
EU 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)	
EU vPvB	Very persistent and very bioaccumulative substances	Not inherently degradable or $DT_{50,water}$ > 60d $DT_{50,sed}$ > 180	BCF > 5000	-	
WFD	(List of) Priority and priority hazardous substances	Risks to human health and the environment			Taking account of prioritized substances in EU risk assessments and frameworks.

3 Which substances are of relevance for the environment?

Environmental damage is regarded as any impairment of the functioning of ecosystems. This means that those adverse effects of chemicals are relevant, which threaten the stability of an entire population of micro-organisms, plants and animals, e.g. by weakening the immune system, disturbing reproduction (less offspring is produced, leading to shrinking populations) or inhibiting photosynthesis. Adverse effects on single organisms due to e.g. a high acute aquatic toxicity are not regarded as so important, because of nature's ability to regenerate itself. Accidental releases of large amounts of chemicals may kill a lot of individual organisms but the population will most likely regenerate after some time. Therefore, neither a high aquatic toxicity alone nor dangerous physico-chemical properties are relevant for the definition of hazardousness to the environment.

Substances can cause effects if they are present in concentrations in the environment or in biota that exceed their specific effect threshold. As the environment "destroys" (biodegradation as well as destruction by e.g. sunlight, oxidation etc.) and "dilutes" substances, only substances which are persistent (measured as half-lives or as inherent degradability) and which have a potential to bioaccumulate (measured as bioconcentration factor – BCF – or LogKow) are of particular relevance for the environment. These substances are not destroyed and they concentrate e.g. in fatty tissue (animal fat and eventually, if reaching the food chain also humans).

Some substances are subject to long range transport, because of their physico-chemical properties. This means they are transported mainly via the atmosphere to any location in the world, including remote areas and pristine environments. This happens to stable substances with specific vapour pressures – they evaporate, are transported in the air and are deposited again. Pristine environments are of high value, as they are largely untouched and undisturbed and therefore provide natural habitats for endangered species. To protect these areas, PBTs/vPvBs and among these the persistent organic pollutants – POPs - are of highest concern.

Humans may be exposed to hazardous substances via the environment through the food chain. By consuming animal and plant products hazardous substances may build up in the human body and eventually reach concentrations causing health damage. Therefore, substances with the potential for long-term adverse effects on human health (such as CMRs) and which are persistent and bioaccumulative are also of relevance, when dealing with substances in the frame of environmental protection. Substances which are CMRs but not persistent and bioaccumulative do normally not accumulate in the food chain and hence don't reach humans. Humans can also be exposed directly via the environment, e.g. when swimming in polluted waters, breathing polluted air or coming in touch with polluted soils. Mostly the concentrations of the dangerous substances are rather low and an effect does not occur.

It is an inbuilt assumption of the European view that for PBTs and vPvBs no safe threshold (PNEC) can be used to determine a risk[20] because the concentrations in the environment will build up and concentrate in certain areas. In addition, life-time exposure of mammals to a substance cannot be adequately reflected in laboratory testing.

Also for some CM substances, no safe thresholds can be derived, because exposure to only one molecule may cause an effect and dose-effect relationships from testing don't show the typical S-curve. Threshold values, e.g. at the workplace are derived based on considerations of minimised risk, technical feasibility and "accepted risk levels".

Under the term "substances of equivalent concern" several groups of properties can be included. Endocrine disrupters disturb the hormone system in organisms, which can show e.g. in impaired reproductive functions, but also in changes of behaviour or a weakening of the immune system. Substances which degrade to hazardous substances, which means the parent compound itself is not regarded as of high concern, but it degrades in the environment to compounds which are either PBTs/vPvBs or substances which are very dangerous, also fall into this group. Furthermore, substances which enhance the effects of other substances (synergistic effect) could

[20] In general, a risk is determined by comparing the safe threshold (PNEC) with the environmental concentration (PEC), which is either predicted by modelling or measured in the environment. If the quotient exceeds 1 a risk is assumed.

be grouped here or substances which have neurotoxic effects (e.g. changing the behaviour of organisms). Lastly, all substances which are believed to be PBTs/vPvBs, but do not fulfil the criteria, e.g. because they cannot be tested due to a low water solubility or because they are metals which are persistent by nature, are members of the group of substances with “equivalent concern”.

In summary, hazardous substance with relevance for the environment are substances which are persistent and bioaccumulative and toxic to the aquatic environment or human health as well as substances of equivalent concern.

Substances with CMR properties are included in the SVHC definition of REACH but are not in the focus of environmental regulation, except they are persistent and liable to bioaccumulate as well. It may have to be explained that substances which are ONLY CMRs are not relevant with regard to the environment, because they can be degraded and/or don’t accumulate.

4 Regulation and hazardous substances management

The hazard concept related to environmental protection from hazardous substances contains general considerations on how to approach problems and manage and control the use and emissions of chemical substances. There are several overarching principles and approaches.

The precautionary principle and the polluter pays principle are two essential elements of EU environmental legislation. The Maastricht Treaty of the EU recognises the precautionary principle as essential element in EU environmental policy. The principle is not legally defined but has been explained in a Commission communication in 2002. It is applied in all areas of EU policy, but has particular relevance in environmental legislation.

4.1 Precautionary principle

The precautionary principle states in general words that “As long as there is no proof of the opposite and there are indications of a risk[21], 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 applies where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU". It is most meaningful in connection with irreversible damage (e.g. loss of biodiversity).

In relation to the management of hazardous substances, the precautionary principle is implemented by the requirement to assess potential risks of the use of substances (REACH) and the responsibility of all actors to identify and implement risk reduction measures. Furthermore, the emphasis on preventing PBT/vPvB emissions to the environment shows that the uncertainty about potential adverse effects of such substances is regarded as unacceptable.

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 precautionary principle is the basis for EU and Member State regulatory bodies to pass legislation or act in other ways if there is a suspicion of risk but no full scientific proof. This means that a preventive approach is taken and the regulators have a justification against e.g.

[21] Indications of a risk are e.g. high production volumes or wide dispersive uses. Under REACH, the ECHA will develop criteria to prioritize substances on the candidate list for inclusion in the list of substances subject to authorization. Currently PBT/vPvBs, substances with wide dispersive uses and/or high production volumes are respective selection criteria. These are likely to be modified as experience with the authorization is growing.

economic actors which may claim their right to market or use substances in the products and processes in the absence of scientific proof of damage.

4.2 Polluter-pays principle

The polluter-pays principle states that actors causing pollution and potential damage are responsible to pay for remedying the environment. The principle has also been included internationally in the Rio Declaration for Sustainable development. 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.

The polluter-pays principle 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 (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 registration of substances by producers / importers under REACH is also justified by the need to be able to trace back the origin of pollution and to make the respective actors responsible.

The consequence of the application of the polluter-pays principle is that environmental liability can be claimed by the authorities but also private persons. In connection with the precautionary principle it means that also activities and costs to determine risks are to be paid by the actor potentially causing the damage. The responsibility to assess risks and conduct tests to identify hazardous properties in the frame of substance registration under REACH is an expression of the application of the polluter-pays principle.

4.3 General regulatory approach

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[22]. 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".

Furthermore, the approach of chemicals control has changed over time from regulating single substances (first under workers' protection legislation and later also under environmental legislation) to regulating substances on "lists" to regulating substances or substance groups with certain hazardous properties, e.g. PBT/vPvB. At the same time the burden of proof has been reversed (in particular by REACH) from authorities identifying substances causing a risk to industry being responsible for this. This takes account of the high variety of substances and the limitations of resources in the authorities, as well as the long time periods needed to agree at EU level on the "status" of substances and appropriate measures.

The single substance approach has been maintained for specific substances, usually those which are of highest priority for action like POPs, or for specific products (e.g. electronic devices, toys). In the latter case, only a limited number of hazardous substances are usually present in such products/articles and a high level of protection is envisaged; it is therefore efficient to regulate them on a single substance basis.

[22] The Water Framework Directive defines environmental quality standards for the priority and priority hazardous substances (objectives/goals). It defines ecological areas (river basins and river basin districts) and instruments to manage them (river basin management plans). The Member States are responsibility for the definition of a river basin district and the existence of respective river basin management plans. There is a time plan for implementing specific measures under the Water Framework Directive, but the objectives and goals as well as necessary measures for a particular river basin district are up to the managing body.

4.4 Roles and responsibilities – supply chain

The approach of 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. Whereas the economic actors are obliged to assess substance hazards, exposures and potential risks and to identify and communicate adequate measures to eliminate or reduce potential risks, the roles and responsibilities of authorities comprise the supervision of enterprises and the European market, the in-depth evaluation of substances and ensuring the functioning of the system e.g. by conducting random checks. There is not general quality assurance by any authority with regard to industry information (no certification, no permits).

The regulatory measures in particular under REACH are shifted to the top of the supply chain: the registrant is to assess risks and prescribe the risk management measures for all actors in the supply chain using the substances. Registrants are also to identify and communicate for which uses a substance may NOT be applied. Hence, on the one hand the topmost actor has to identify the risks and develop the controls necessary for safe use. This is also a shift of responsibility to develop and communicate chemicals management measures from authorities to industry. The evaluation, authorization and restrictions procedures are complementing this and provide for several opportunities to introduce more specific and stricter regulations.

4.5 Cooperation and communication

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.

Some important cooperation instruments under REACH are the SIEFs (joint registrations or sharing of data but also discussion on uses and risk management measures) and the need to agree on harmonised classification and labelling. Cooperation is also required in order to determine conditions of use and risk management measures, apply for authorisations of substances etc.

Cooperation between industry and authorities is most visible in the various 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.

As substances which are imported into the EU (as substances, in mixtures and partly in articles) are also regulated under REACH cross-border cooperation between economic actors will become more relevant as well.

The main communication instruments under REACH are the safety data sheet and the exposure scenarios which are supplied along with dangerous chemicals. There is also informal communication in the supply chain on uses and conditions of use of substances.

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).

5 Scientific discussion

There is a scientific discussion on hazardous substances (management). It relates on the one hand to the properties of substances used to identify the potential to cause environmental damage and how these properties are determined. Examples of discussion are among other relating to issues not yet covered in existing definitions of hazardous substances (e.g. the assessment of synergistic effects, particularities of the marine environment) not yet satisfactorily solved (e.g. assessment methods, difficulties in testing methods, substances the metabolites of which are more hazardous than the parent compound) or e.g. new endpoints (endocrine disruption) as well as different substance properties on nano-scale.

Some substances cannot be sufficiently well tested or testing methods don't work due to the substance properties and they can therefore not be identified as hazardous according to the standard criteria and cut-off values. For all these substances, the definition of a substance of high concern foresees the possibility to include them on a case-by-case assessment. Examples for such substances are metals (they are persistent by nature), substances which are not well soluble in water (they cannot be tested well for aquatic toxicity) UVCBs[23] (toxicity may change due to variable composition).

The standard testing methods for environmental hazardousness comprise degradability testing, logKow or determination of a bioaccumulation factor and the testing of aquatic short term toxicity using fish, daphnia and algae. In the context of the marine environment, there is a discussion whether marine species are more sensitive or have different effect mechanisms, which are not sufficiently well reflected in the freshwater testing. Currently most long-term toxicity data is extrapolated from acute testing, which is another issue discussed as potentially over- or underestimating a substance's hazardousness (use of safety factors). Testing methods for identifying endocrine disrupting substances are also not well established and standardised.

The environmental toxicity to terrestrial organisms and plants is not well developed and not reflected in the classification and labelling of substances, except in the implementation of the pesticides directive. This is another issue under discussion; there is work ongoing in the frame of the GHS.

Some substances are predicted to be well degradable and should thus not occur in the environment, but are nevertheless found in biota or environmental compartments. This could either be due to a different behaviour of the substance in the environment than in laboratory testing or due to an emission rate that well exceeds the degradation rate in the environment.

Synergistic effects of substances are rather an issue for human health effects but nevertheless may play a role in the environmental discussion as well, as different substances may accumulate in biota and enhance each others' effects. Exposures to combinations of substances which could interact synergistically are difficult to assess and are currently only looked at in scientific contexts and not at a practical level. There are discussions about which combinations to assess and how to prove synergies (e.g. in epidemiological studies), in particular with view to long term effects. At present there are no related tools available for practical application in enterprises. The topic is regarded as not relevant in the context of current work, as more basic issues need to be addressed first.

Some effects, like the endocrine disruption are not tested on a standard basis yet. Some scientific research is dedicated on the one hand to identify endocrine disrupters and to develop standardized tests.

The effects of nano-particles on the environment are not well known, because of the short period of their commercial use and the fact that they are extremely hard to detect. Research is directed to the questions of how nano-materials behave in the environment (do they degrade, oxidise, where do they migrate to, do they form clusters etc.?) how they are taken up (inhalation, food, direct contact) and which effects they could cause.

[23] substances of unknown or variable composition, complex reaction products or biological materials

The scientific discussion on hazardous substances is currently not relevant for explaining hazardous substances and how they are regulated. However, it is important in identifying uncertainties in related to the hazards of a substance as well as how to design an efficient assessment of substance risks (tiering approach) and related to the burden of proof of hazardousness / risk.

6 Methodological issues

A relevant discussion in the context of understanding and comparing the approaches towards hazardous substances in the EU and Russia are the concepts and methods for:

1. Prioritizing hazardous substances
2. “Phasing in” substances under different legislation
3. Establishing safety levels from toxicologically derived no-effect-levels
4. Deriving environmental quality standards and/or emission limit values for regulatory use

The core characteristics of these are summarized in the table.

6.1 Prioritizing hazardous substances

In the EU priorities with regard to the regulation of substances are based on the risk; information on hazardous properties is usually used to select substances whereas information on exposures determines the priority for action. This means that for determining if substances are placed on lists (e.g. the list of substances to be authorized under REACH) or are included in specific legislation, all of the following information is used:

- substance properties (SVHC)
- information on occurrence in the environment (monitoring data)
- information on production and use, like the total market volumes, products and processes in which substances are used including considerations on emission and exposure potentials
- information on risk management measures in place (existing legislation, state-of-the-art of technology and installations where substances are used, waste regime etc.)

All substances with PBT/vPvB properties are an exception here, as the intrinsic properties are regarded as sufficient to aim at substitution and phase out of the use of the substance.

Priority setting procedures are frequently multi-step processes involving authorities at different levels as well as industry and other interested parties. A good example is the authorization procedure, with

a) proposal for identification of SVHC (Member States or Agency), agreement on inclusion on the candidate list (Member States and Agency with commenting procedure involving industry and third parties)

b) inclusion of substances on the Annex XIV via a technical dossier with respective justification (Member States, Agency), a commenting procedure (involvement of industry and third parties) and the agreement (authorities) on inclusion taking comments into account and

c) application for authorization (industry with proposals for risk management or substitution strategy) and granting of authorization (Commission).

6.2 “Phasing in” substances under different legislation

In general, regulatory measures regarding chemical substances were developed according to the following steps:

1. Substances are identified as very hazardous either through the existing substances programme (risk assessments at EU level) or because of new scientific knowledge or scandals
2. The uses of substances and the potential risks for different subjects of protection were inquired by the authorities at EU or Member State level
3. Instruments to regulate the use of chemicals were assessed, sometimes an impact analysis was carried out to find out costs and benefits of different options
4. The most efficient instruments were selected and legislation is passed, mostly in the form of Directives at EU level.

In principle these steps are still carried out, but some issues have changed due to REACH:

After the implementation of REACH, in particular the identification of hazardous substances will be more systematic, structured and complete, as industry will have to identify substance properties for the registration. This means that the information basis will improve and it will also be possible to compare substances and set priorities on the more hazardous ones (and not only the known ones).

For substances registered in amounts exceeding 10 t/a and having dangerous properties, information on uses and risk management measures will be provided. This will facilitate the decision making on the most efficient instruments of regulation.

REACH contains the authorization of substances as a new instrument to control the use of chemicals. It is anticipated that the amount of substance or product specific legislation will decrease under REACH.

6.3 Deriving no effect levels and safe thresholds from toxicity testing

The methods for deriving no-effect levels (LC_0, NOEC etc.) are described in the technical guidance documents of the EU (“old TGD” and new guidance for the implementation of REACH). The tests required to determine substance properties are either prescribed or proposed as means to enquire more in-depth (substances above 100 t/a). The testing logics allow to skip tests, if a certain property is very unlikely or impossible to test.

Safe thresholds (Predicted No Effect Concentrations - PNECs) are derived based on the concentrations or doses identified in testing. In principle, the highest test concentration of a substance at which no effect is observed is used. Depending on the amount and quality of test data, safety factors between 10 and 1000 are applied for the environment.

Safe thresholds for human health are derived similarly; however the method is more complex. The variety of tests is higher as well as the routes of exposure. Furthermore, the safety factors don’t only account for the amount and quality of data but also for extrapolation from different species (test on rats → information on humans), different metabolic rates, different human populations (children different than workers).

The safe thresholds are called PNEC for the environment and DNEL (derived no effect level) for humans.

6.4 Deriving environmental quality standards and/or emission limit values for regulatory use

The PNECs are primarily used to conduct risk assessments under REACH. There is a discussion to use them as environmental quality standards as well, but this is rather unlikely to happen, as the values are produced by industry and not the authorities.

Therefore, values to describe a good environmental status with regard to hazardous substances are derived in different contexts. Quality standards for air mostly take into account the inhalation risks for humans and hence are based on safe levels for humans. Quality standards for soil take into account considerations for the food chain (agriculture) and ground water and are hence also based on human considerations. Here, the acceptable daily intakes are parameters of relevance. The same applies for limit values for drinking water.

Environmental quality standards for surface waters don't exist at EU level, yet. A respective proposal of the EU Commission under the Water Framework Directive is still under discussion. The method to derive EQS is described in a separate document.

Environmental quality standards or "immission limit values", if existing, are taken into account in environmental permits with regard to waste water discharges. Installations in sensitive areas or discharging into surface waters, where the concentration of a substances is already very high, may receive stricter emission limit values than others. There is no direct connection between the EQS and the ELVs given in environmental permits.