The SOLUTIONS project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement no. 603437

Solutions for present and future emerging pollutants in land and water resources management

THEME

ENV.2013.6.2-2

Toxicants, environmental pollutants and land and water resources management

Start date of project: 1st October 2013 Duration: 5 years

Deliverable

D7.1 Policy recommendations for maximum synergies between policy frameworks

Due date of deliverable: 30/09/2017

Actual submission date: 20/10/2017

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Dissemination Level		
PU	Public	
PP	Restricted to other programme participants (including EC)	
RE	Restricted to a group specified by the consortium (including EC)	**X**
CO	Confidential, only for members of the consortium (including EC)	

1.1 Summary

Effective and transparent regulation of chemicals is necessary both to protect human health and the environment, and to achieve the overarching goal of an environmentally sound management and safe use of chemicals. This study provides an overview of existing regulatory frameworks for chemicals and some general recommendations on how regulatory actions can be improved to provide an increased protection of environment and human health from chemicals. These recommendations could constitute the first steps towards a more holistic and efficient legislation.

The overview reveals a fragmented situation with a number of regulatory frameworks designed for specific groups of chemicals and for protection of different end-points. Also the life cycle stages trade and use are not covered to the same extent by the studied regulatory frameworks. An increased efficiency could be achieved if all regulatory frameworks considered protection of both human health and the environment. Cooperation between existing regulatory frameworks on e.g. exchange of information on use, emissions, occurrence and effects in the environmental can also give rise to a more coherent and efficient regulation. Another step towards cooperation and harmonisation would be to introduce common procedures for risk assessment and prioritisation. And as the market for chemicals is global, there is a need to discuss chemicals management on a global level and thereby strengthen the cooperation between EU and relevant international organisations.

1.2 Graph

Life cycle stages covered by the regulatory frameworks. (The production step includes processes such as raw materials extraction and formulation of mixtures).

Contents

1 Introduction

Chemicals are used in our daily life in all parts of the society and they contribute significantly to our economies. The global production of chemicals has increased from 1 million tonnes in 1930 to several hundreds of million tonnes today.[1] Several ongoing initiatives highlights the importance of reducing the negative impacts of chemicals which are hazardous for human health and the environment, via environmentally sound management and safe use of chemicals (for example UN's 2030 Agenda for Sustainable Development, UN Environment's Strategic Approach to International Chemicals Management (SAICM) and European Union's Environment Action Programme to 2020). These initiatives also mention cooperation and synergies between different initiatives and stakeholders on different levels of society (local, regional and global) as important aspects in order to achieve the goals that have been set up.

A number of regulatory frameworks (EU directives and regulations, international agreements and conventions), which aim to reduce risks and impacts of chemicals to both human health and the environment, have been developed and implemented over the last decades. These regulatory frameworks have different and sometimes overlapping scopes (chemicals (as such or in mixtures) in articles, emissions or concentration levels in the environment) and geographical scales (local, regional and global). The number of chemicals regulated per framework spans from only a few to thousands of substances. These regulated chemicals constitute an important fraction of the total number of chemicals present in society and in the environment[2].

Some of the chemicals that are not regulated but represent a potential risk are sometimes denoted as emerging chemicals or Chemicals of Emerging Concern (CECs). CECs present in the environment are not necessarily new chemicals. They can also be substances that have been present in the environment for long but whose presence and significance are now being elucidated (NORMAN, 2017a).

The continued appearance of emerging chemicals from new or newly detected sources and with varying properties will require the adaptation of current regulatory frameworks to ensure protection of human health and the environment.

[1] https://echa.europa.eu/chemicals-in-our-life/why-are-chemicals-important

[2] Major groups which are not regulated are naturally occurring substances, metabolites and transformation products.

Benefits can be gained from interactions between existing chemicals legislations, especially with regards to adding substances, information on properties of chemicals and requirements for environmental reporting.

1.1 Policy advice and the solution-focused approach

Providing advice for the development of the regulatory system for CECs in general and specifically in relation to the Water Framework Directive (WFD) is a main objective of the SOLUTIONS project (Brack et al., 2015). The advice from the SOLUTIONS project will to a large extent be based on newly developed methodologies and approaches for identifying and prioritizing chemicals of emerging concern (Altenburger et al., 2015; Brack et al., 2016). In Brack et al. (2017) a number of specific recommendations focused on chemical and biological monitoring, modelling and combined methodologies such as effect directed analysis (EDA) as well as some general advice on policies were provided.

Apart from direct advice to policy development, a main characteristic of the SOLUTIONS project is the solution-focused approach which forms the foundation of the conceptual framework developed at the initiation of the project (Munthe et al., 2017). A key characteristic of this approach is to improve the utility of risk assessment outcomes by including an early evaluation of options for reducing risks (Finkel, 2011). In this approach, the traditional steps included in the risk assessment (e.g. evaluation of risks based on emissions, exposure and hazardous properties) are complemented with a structured approach to evaluate abatement options (technical and non-technical) as well as policy options for managing the problem. The traditional risk-based approach is thus complemented with a parallel evaluation of measures to reduce risks with the purpose of providing solutions at an earlier stage. The conceptual framework and the on-going scientific research necessary to make the solution-focused approach operational is presented in Munthe et al. (2017) and in van Wezel et al. (2017), with a more in-depth discussion of technical and non-technical abatement options including the design of a mitigation database.

1.2 Aims and scope

The aim of this study is to provide an overview of existing regulatory frameworks for chemicals and to provide some general recommendations on how regulatory actions can be improved to provide an increased protection of environment and human health from chemicals and to prepare for regulation of additional substances, when relevant. As a first step, existing regulatory frameworks (EU Regulations and Directives and Multilateral

Environmental Agreements) have been evaluated and compared.

The study is to a large extent focussed on the future protection of inland aquatic ecosystems in the EU (and thus the WFD), but also includes regulatory frameworks with a broader perspective.

The evaluation includes an overview of the selected regulatory frameworks in relation to:

1. Objectives of the regulatory frameworks
2. Receiving environmental media
3. Life cycle stages
4. Strictly regulated substances
5. Geographical coverage
6. Regulatory mechanisms including:
    a. Regulation of substances
    b. Procedures for inclusion of additional substances
    c. Exchange of information

This overview is used as a basis for a discussion of gaps and identification of some recommendations for actions to improve these regulatory frameworks. In addition to this report, more extensive documentation of the evaluated regulatory frameworks can be found in SOLUTIONS ID 7.1. Information on the different regulatory frameworks and regulated substances can also be found in the form of a database accessible at http://apps.ivl.se/solutions and via www.solutions-project.eu.

2 Evaluated regulatory frameworks

There are a number of regulatory frameworks related to chemicals. In this study, focus has been on regulatory frameworks that 1) cover substances that can cause negative impacts in the aquatic environment, 2) are complementary to the WFD and could lead to improved implementation of the WFD and 3) focusing on European or global scale. In a wider perspective, the assessment of these regulatory frameworks can also contribute to the future development of guidelines for a safe sustainable use of chemicals.

In total, 19 regulatory frameworks have been included in the study, see Table 1. The selected set of regulatory frameworks is not exhaustive; also other existing regulatory frameworks can contribute to improved future implementation of the WFD. We do not consider regulatory frameworks for the protection of the marine aquatic environment, such as HELCOM and OSPAR.

Table 1 Selected regulatory frameworks on chemicals.

Name of regulatory framework	Short name/Acronym
EU Regulations	
Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (EC/1907/2006)	REACH
Plant Protection Products Regulation (EC/1107/2009)	PPP
Biocidal Products Regulation (EC/528/2012)	BPR
Cosmetic Products Regulation (EC/1223/2009)	Cosmetics
Regulation on Procedures for the authorisation and supervision of Medicinal Products for human and veterinary use and establishing a European Medicines Agency (EC/726/2004)	Medicinal prod.
EU Directives	
Water Framework Directive (2000/60/EC)	WFD
Ground Water Directive (2006/118/EC)	GWD
Marine Strategy Framework Directive (2008/56/EC)	MSFD
Drinking Water Directive (98/83/EC)	DWD
Urban Waste Water Treatment Directive (91/271/EEC)	UWWTD
Sewage Sludge Directive (86/278/EEC)	SSD
Industrial Emissions Directive (2010/75/EU)	IED
Mining Waste Directive (2006/21/EC)	Mining waste
Restriction of the use of certain Hazardous Substances in electric and electronic equipment (2011/65/EU)	RoHS
Toy Safety Directive (2009/48/EC)	Toy
Multilateral Environmental Agreements	
Stockholm Convention	Stockholm conv.
Convention on Long-range Transboundary Air Pollution	CLRTAP conv.
Protocol on Pollutant Release and Transfer	PRTR protocol
Rotterdam Convention	Rotterdam conv.

3 Coverage of regulatory frameworks

3.1 Objectives of the regulatory frameworks

The studied regulatory frameworks all regulate chemicals, but with different objectives. Some are intended to ensure a high level of protection of both human health and the environment, while other focus solely on human health or the environment. The regulatory frameworks were categorised into three different categories based on the endpoints which they are intended to protect according to the objectives of the legal text: 1) human health, 2) human health and the environment or 3) the environment (Table 2). Approximately half of the studied frameworks cover both human health and the environment, while one fifth only covers human health and one third only the environment.

Table 2 Objectives of the regulatory frameworks according to the legal text.

Human health	**Human health & Environment**	**Environment**
Cosmetic Products Regulation	REACH	Water Framework Directive
Medicinal Products Regulation	Plant Protection Products Regulation	Ground Water Directive
Drinking Water Directive	Biocidal Products Regulation	Marine Strategy Framework Directive
Toy Safety Directive	Sewage Sludge Directive	Urban Waste Water Treatment Directive
	RoHS	Industrial Emissions Directive
	Mining Waste Directive	Protocol on Pollutant Release and Transfer Registers (PRTR)
	Stockholm Convention on Persistent Organic Pollutants (POPs)	
	Convention on Long-range Transboundary Air Pollution (CLRTAP)	
	Rotterdam Convention	

3.2 Receiving environmental media

Chemicals in the environment can be covered by reporting requirements either as emissions to, or as occurrence in different receiving environmental media. In Figure 1, an overview is given of reporting requirements for receiving media (air, water and land) that are covered by the studied regulatory frameworks. Figure 1 also indicates whether the regulatory action is directed towards *emissions* of the substances, towards the *occurrence* of the substance in the receiving environmental media. Many of the studied regulatory frameworks only regulate emissions and/or occurrence in one receiving media, such as the Water Framework Directive or the Marine Strategy Framework Directive. The Stockholm Convention and PRTR on the other hand regulate emissions to all three receiving media. The product-related regulatory frameworks do not include reporting requirements with regard to the environment, i.e. emissions and occurrence in different receiving environmental media.

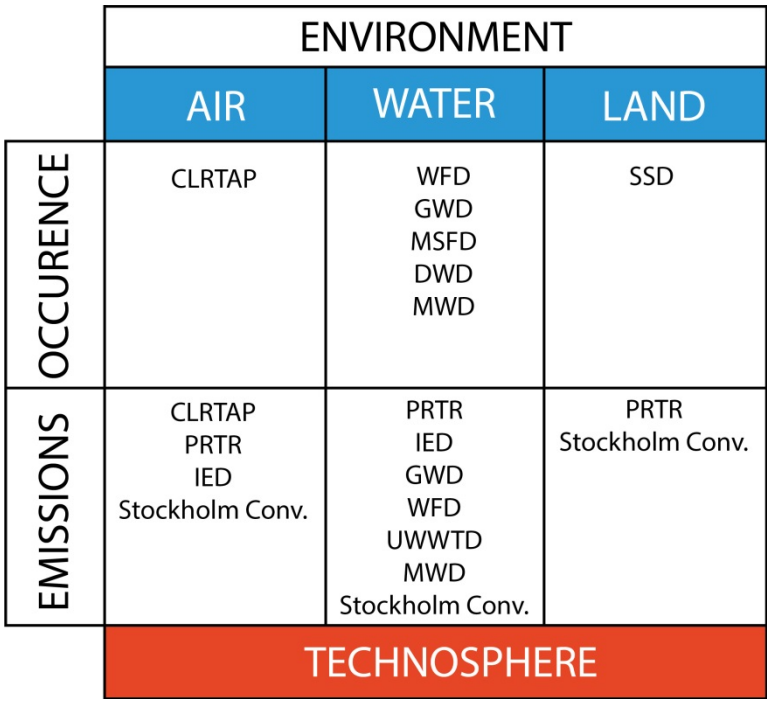

Figure 1 Receiving environmental media regulated by the regulatory frameworks.

3.3 Life cycle stages

The life cycle of a product can be divided into different life cycle stages: 1) production (including raw materials extraction and formulation of mixtures), 2) trade, 3) use and 4) waste management/recycling. Each regulatory framework was categorised based on which life cycle stage it regulates (Figure 2). The red arrows in Figure 2 indicate the different life cycle stages, the blue parts of the rings inside the arrows show which life cycle stages that are covered by the different regulatory frameworks, while the grey parts indicate areas not covered. Some of the regulatory frameworks do not regulate specific life cycle stages; instead they regulate overall ecosystem contamination levels, such as the WFD. Regulatory frameworks covering aquatic ecosystem contamination levels are visualised in the blue circle in the middle. It should be noted that this figure does not consider the number of regulated substances or the efficiency of the regulation in the different frameworks.

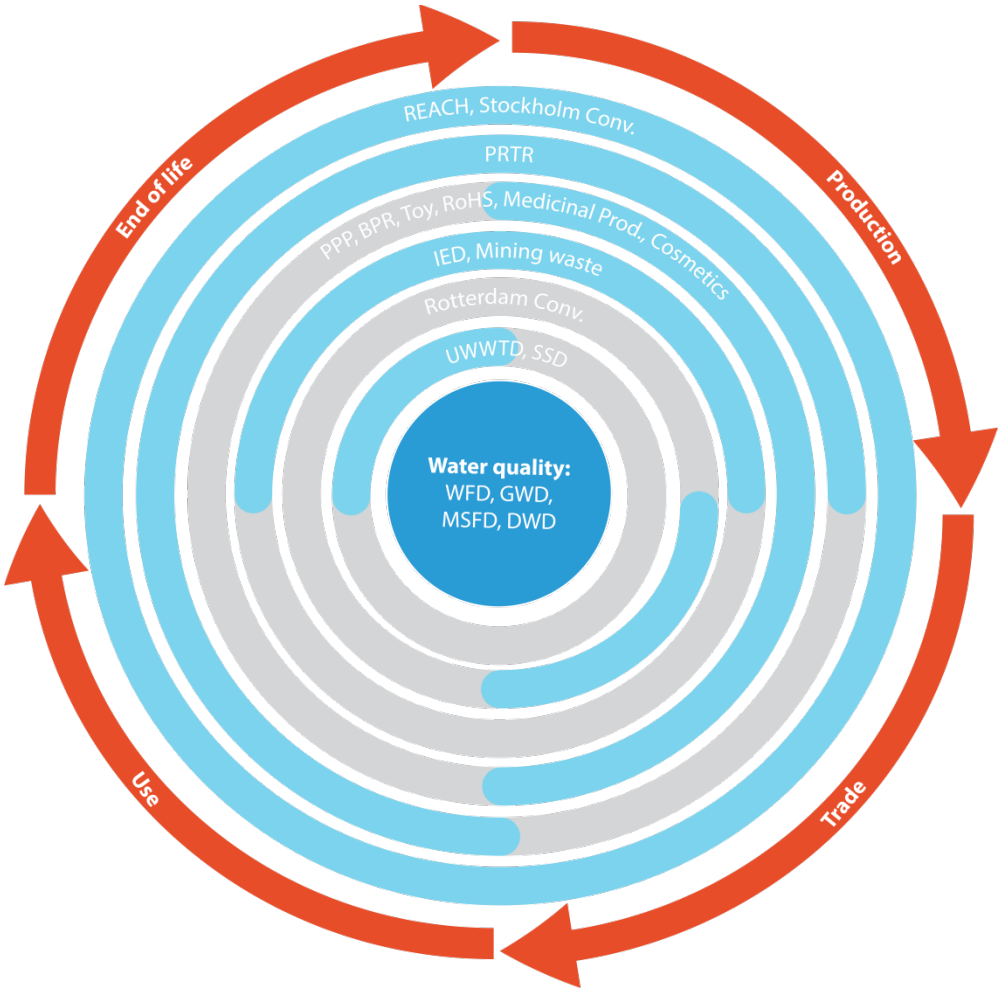

Figure 2 Life cycle stages covered by the regulatory frameworks. (The production step includes processes such as raw materials extraction and formulation of mixtures).

Many of the studied regulatory frameworks regulate the life cycle stages *production, trade* and *waste management/recycling*. The life cycle stages *trade* and *use* are not covered to the same extent by the studied regulatory frameworks. REACH and the Stockholm Convention primarily regulate the *use* phase of chemicals but are formulated to avoid negative impacts during all stages and are thus presented as covering the full life cycle. Several other regulatory frameworks cover chemicals in products, such as Toy Safety Directive and Cosmetics Directive, and could thus be defined as regulating the use phase. However, since these regulations set limit values for chemical contents in products, and do not cover how the product are used, they are here defined as covering the production rather than the use phase.

3.4 Strictly regulated substances

The studied regulatory frameworks have been categorised with regards to number of strictly regulated substances (e.g. banning, restrictions, authorisation for specific uses) and the properties of these substances (Table 3). All strictly regulated substances, with a CAS number, reported in the studied regulatory frameworks were compiled in the form of a database (accessible at http://apps.ivl.se/solutions). Based on The Classification, Labelling and Packaging (CLP) Regulation ((EC) No 1272/2008) the substances were categorised as:

- Carcinogenic, mutagenic and toxic for reproduction (CMR),
- Persistent, bioaccumulative and toxic (PBT),
- Very persistent and very bioaccumulative (vPvB) or
- Equivalent concern, such as endocrine disrupting chemicals, for which harmonized classification is under development in the EU.

A summary of the results is given in Table 3. The figures given in Table 3 are a minimal estimation of the substances covered since in some cases there are substance classes given instead of unique substances. Some regulations and directives do not restrict substances but instead define substances that are allowed for use in the specific application covered by the regulatory framework, i.e. the Plant Protection Products Regulation and the Biocidal Products Regulation. In these cases "Not Applicable" (NA) is given instead of numbers. REACH requires registration of a large number of substances. Substances which are only subject to registration are not included in Table 3. A minor part of the registered substances become subject to strict regulation, such as restriction or authorisation.

Table 3 Number of strictly regulated substances in the studied regulatory frameworks and the properties of these substance.

	Total number of strictly regulated substances	Properties of strictly regulated substances			
		CMR	PBT	vPvB	Aquatic toxicity
EU Regulations					
REACH	108+37+179[1]	43+31+145[1]	2+0+14[1]	1+1+16[1]	19+16+45[1]
PPP	NA[2]				
BPR	NA[2]				
Cosmetics	1379	740	5	3	230
Medicinal prod.	NA				
EU Directives					
WFD	114	32	9	4	36
GWD	9				
MSFD	NA				
DWD	34	7			4
UWWTD	5				
SSD	6				
IED	24				
Mining waste	NA[2]				
RoHS	6				
Toy	85	1			7
Multilateral Environmental Agreements					
Stockholm conv.	45	11	1		16
CLRTAP conv.	46	7	1	1	10
PRTR protocol	86	27	4	3	27
Rotterdam conv.	46	21	2		24
All frameworks	**2 215**	**1 065**	**38**	**29**	**436**

[1] Number of unique substances included in Annex XVII (Restriction List), Annex XIV (Authorisation List) and Candidate List of SVHC for Authorisation of REACH as of April 2017. Substances are added continuously to these lists. There are currently more than 100 000 substances pre-registered within REACH.
[2] NA = Not Applicable.

3.4.1 Regulation in relation to physical- chemical properties

All substances were searched in ChemProp (UFZ 2016) and 991 of the 2215 substances were matched in. For these 991 substances structure files were generated and molecular descriptors were calculated with the Dragon 6.0 software (Talete srl, 2015). Together with information on properties collected from ChemProp and QSARToolbox 3.4 (OECD, 2017), the substances were analysed with a Principal Component Analysis (PCA) with SIMCA 14.1 from Umterics. PCA can be considered a co-ordinate transformation from the original variable space to a model hyper-plane of much lower dimensionality that captures the variance in the data in the most efficient way. The scores, denoted t or T, are the co-ordinates in the new co-ordinate system and thus describe the objects (here: chemical substances). The loadings, denoted p or

P, describe the relation between the latent variables (principal components) that span the model space and original variables. The substantial dimensionality reduction achieved by applying PCA to molecular descriptor data sets leads to enhanced interpretation abilities which facilitate classification and clustering of substances. The resulting score plot from the PCA is shown in Figure 3.

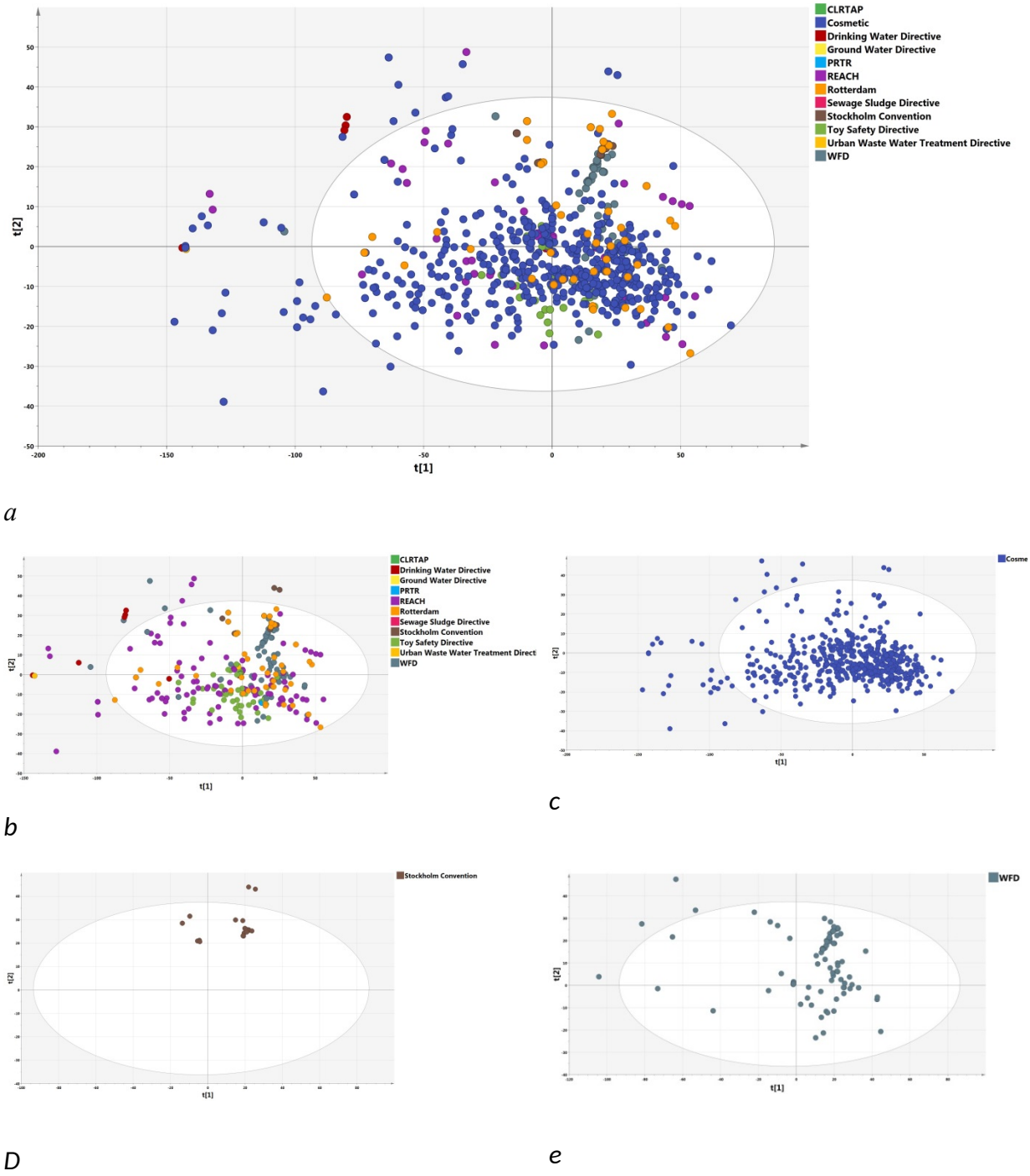

Figure 3. 3a Score plot from the PCA. Each dot representing one substance and colour coded according to the related regulatory framework. 3b Exluding substances from Cosmetic Directive. 3c Showing only substances

from the Cosmetic Directive. 3d. The Stockholm Convention and 3e Water framework directive.

The PCA explains 90 % of the variation in the data set studied. Chemicals with similar structure are located close to each other in the plot. Substances with a high molecular weight are located in the right part of the plot. Persistent substances are located in the upper right part of the plot. It can be noted that the substances regulated by the Cosmetic Directive are spread all over the score plot indicating that there is a big variation in the properties of these substances. However the Stockholm Convention substances are grouped together showing that they are more homogenous in both properties and structure. The same applies for the chemicals in the Toy Safety Directive.

3.5 Geographical coverage

The EU Regulations and Directives apply in the Member States of the EU. The Stockholm Convention, Rotterdam Convention and PRTR are global and open for accession by any UN Member State. CLRTAP is a regional convention, open for accession by the UN Economic Commission for Europe (UNECE) Member States.

4 Regulatory mechanisms

4.1 Regulation of substances

The studied regulatory frameworks have been categorised with regards to how they regulate substances in the technosphere or environment (Table 4). In the technosphere, substances can be subject to *registration, approval, restriction and prohibition* i.e. mainly considering if they can be used, and if they can be approved for specific uses or under specific restrictions. These terms are not always used in a harmonised way. An example of this is the term authorisation. In REACH, authorisation is used to ensure that substances of very high concern (SVHCs) are progressively replaced by less dangerous substances or technologies where technically and economically feasible alternatives are available. This means, it is not allowed to place substances that are subject to authorisation on the market or to use them if authorisation has not been granted for this specific use. In the Biocidal Products Regulation on the other hand, authorisation indicates that that a substance is allowed to be placed on the market. In addition, products in technosphere can be subject to authorisation for use or placing on the market. In the environment, substances can be regulated via emission limit values, concentration limit values or reporting requirements.

The EU Regulations focus on regulating the substances in the technosphere by either

approving or restricting the substances use or occurrence in mixtures and articles. The EU directives mainly focus on emissions or occurrence of the substances in the environment. The article related EU Directives, RoHS and Toy Safety Directive, aligns more with mechanisms of the EU Regulations than the other directives. The Multilateral Environmental Agreements regulate substances both in the technosphere and environment.

Table 4 Mechanisms for regulating chemicals and number of chemicals regulated within the EU (as of 2017-06-02).

	Technosphere (production and use)					**Environment**		
	Substances				**Products and use**	**Substances**		
	Registration	**Approval**	**Restriction**	**Prohibition**	**Authorisation for use or placing on the market**	**Emission limit values**	**Concentration limit values (EQS)**	**Reporting of emissions /concentrations**
EU Regulations								
REACH	X[1]		X[2]	X				
PPP		X		X	National			
BPR		X		X	National			
Cosmetics			X	X				
Medicinal prod.					Not specified			
EU Directives								
WFD							X	X
GWD							X	X
MSFD							Not specified	X
DWD							X	X
UWWTD						X		X
SSD							X	X
IED						X		X
Mining waste							X	X
RoHS			X					
Toy			X	X				
Multilateral Environmental Agreements								
Stockholm conv.			X	X				X
CLRTAP conv.			X	X		X		X
PRTR protocol								X
Rotterdam conv.			X	X				

[1] 17 669 unique substances registered under REACH (by June 2017). All substances produced or imported in quantities of one tonne or more per producer/importer and year shall be registered. The information required for registration depends on the annual amount of substance produced or imported per manufacturer/importer, where the information requirements increase with increasing amounts of substance. There are currently more than 100 000 substances pre-registered within REACH. It is expected that by May 2018 around 30.000 unique substances will become registered.

[2] In REACH, substances on the Candidate List of substances of very high concern are subject to evaluation for Authorisation and are not allowed to be placed on the market or to be used, except when authorisation has been granted for a specific use. Thus, the Authorisation mechanism in REACH is in fact a restriction mechanism.

4.2 Procedures for inclusion of additional substances

Most of the studied regulatory frameworks contain mechanisms for including additional substances (Table 5). The mechanisms for adding substances are based on single substances, rather than mixtures. Inclusion of additional substances is often preceded by nomination and evaluation of each substance. The evaluation is often performed by an evaluating body, which can consist of experts, or can be the same as the governing body. REACH, Biocidal Products Regulation, Cosmetics Regulation, Stockholm Convention and Rotterdam Convention have dedicated committees for the evaluation of substances. Some of the regulatory frameworks include additional substances via revisions of other regulatory frameworks, such as the Ground Water Directive and Mining Waste Directive. Risk assessment is used for prioritising substances in a number of the studied regulatory frameworks.

Table 5 Mechanisms for including addtional substances and mechanism for risk assessment of substances.

	Mechanism for revision of substance lists	**Evaluating body**	**Governing body**	**Mechanism for risk assessment of substances**
EU Regulations				
REACH	X	ECHA RAC & ECHA CSEA[3]	EU Commission	X
PPP	X	EU Commission	EU Commission	X
BPR	X	ECHA Biocidal Products Com	EU Commission	X
Cosmetics	X	Scientific Committee for Consumer Safety	EU Commission	X
Medicinal prod.	X	European Medicines Agency	EU Commission	X
EU Directives				
WFD	X	EU Commission	EU Commission	X
GWD	X[1]	EU Commission	EU Commission	X[1]
MSFD	X	EU Commission	EU Commission	X
DWD	X	EU Commission	EU Commission	X
UWWTD		-	-	
SSD		-	-	
IED		-	-	
Mining waste	X[2]	Via CLP	EU Commission	
RoHS	X	EU Commission	EU Commission	
Toy		-	-	
Multilateral Environmental Agreements				
Stockholm conv.	X	POPRC	Conference of the Parties	X
CLRTAP conv.	X	Expert Task Forces	Executive Body	
PRTR protocol	X	Working Group of the Parties	Meeting of the Parties	
Rotterdam conv.	X	Chemical Review Committee	Conference of the Parties	X
Total	**14 (19)**	**-**	**-**	

[1] Additional substances are included when the WFD revise its list of substances.

[2] Substances are regulated via their physicochemical properties following the classifications in CLP.
[3] ECHA RAC = ECHA Risk Assessment Committee & ECHA CSEA = ECHA Committee for Socio-Economic Analysis.

4.3 Possibilities for exchange of information

The majority of the studied regulatory frameworks have a mechanism which regulates public access to data obtained from the framework. Often, it is stated that data shall be made publicly available on the internet. However, some frameworks have clauses which allow for certain data to be treated as confidential, and thus not made publicly available. This concerns especially used amounts. This is common in the regulatory frameworks related to chemicals and chemical products, such as REACH and the Cosmetics Products Regulation. The confidentiality clauses often refer to the protection of commercial interests or the protection of privacy and the integrity of the individual as reasons for justifying confidentiality requests. In most of the regulatory frameworks, it is stated that Member States, companies or other parties shall share information with other Member States, companies, or other parties. In Table 6, the existence of procedures for exchange of information and confidentiality is indicated for the studied regulatory frameworks.

Table 6 Existance of procedures for exchange of information.

	Procedure for public access to information	**Procedures for confidentiality**	**Procedures for sharing information**
EU Regulations			
REACH	X	X	X
PPP	X	X	X
BPR	X	X	X
Cosmetics	X	X	X
Medicinal prod.	X	X	
EU Directives			
WFD	X		X
GWD	X		X
MSFD	X		X
DWD	X		
UWWTD	(X)[1]		
SSD			
IED	X		X
Mining waste	X		
RoHS			
Toy	X	X	X
Multilateral Environmental Agreements			
Stockholm conv.	X	X	X
CLRTAP conv.			X
PRTR protocol	X	X	X
Rotterdam conv.	X	X	X

[1] Public access only mentioned in the pre-amble.

5 Regulatory gaps and recommendations – Towards safe and efficient regulation of chemicals

Effective and transparent regulation of chemicals is necessary to achieve the overarching goal of an environmentally sound management and safe use of chemicals that have been set out in Agenda 2030, SAICM and EU's Environment Action Programme. The compilation of information presented above reveals a fragmented situation with a number of regulatory frameworks designed for specific groups of chemicals and for protection of different end-points. A number of gaps have been identified that need to be considered to improve coherence between different frameworks on chemicals and to reduce the negative impacts of chemicals which are hazardous for human health and the environment. Below, recommendations that could bridge these gaps and constitute the first steps towards a more holistic and efficient legislation, are discussed.

Harmonised objectives. Currently, the regulatory frameworks in this study aim at protecting different end-points, human health or the environment or both, see Table 2. An increased efficiency could be achieved if all regulations considered protection of both human health and the environment. Releases from chemical products and articles not only contribute to direct exposure but may also lead to emissions to the environment where effects on e.g. aquatic ecosystems may occur. Today, many of the product-related regulations (such as cosmetics and pharmaceuticals) only aim to protect human health and do not consider effects on the environment.

Receiving environmental media. The product-related regulatory frameworks do not include reporting requirements with regard to the environment, i.e. emissions and occurrence in different receiving media (see figure 1). For example REACH is intended to cover all stages of the life cycle of chemicals and thus has the potential and ambition to provide this more holistic framework. However, assessments and evaluations of risks associated with specific substances in REACH would benefit from also making use of information on e.g. monitoring data as well as ecotoxicological information available for substances under evaluation in the WFD and from the wider research literature. This information is also needed for the important groups of pharmaceuticals and pesticides, which have their own legislation and are therefore not covered by REACH.

Life cycle stages. In addition to focusing on different end-points (human exposure, environment), different regulations cover different parts of the chemicals life cycle i.e. from

production to disposal as illustrated in Figure 2. This introduces a risk for inefficient implementation and control, if all parts of the life cycle are not covered in the same regulatory framework. In Figure 2, risks for gaps in coverage are mainly visible for the trade and product use stages. To avoid gaps, a systematic analysis of the substances life cycle (in products or as chemicals used in industry or agriculture etc.) using a common approach and methodology would provide relevant information on all potential risks for releases of harmful substances or direct exposure.

Cooperation, harmonisation and exchange of information. Cooperation between existing regulatory frameworks can facilitate a more coherent and efficient regulation. Benefits can be gained from having a more harmonised process for selection of substances, both to gain synergies and reduce costs and thereby achieve a successful implementation. For example, many of the substances in the WFD are also listed in at least one other regulation – and by cooperation, exchange of information and formulation of common objectives between these regulations synergies and improved implementation can be achieved. The increasing number of chemicals on the market will require increased efforts to evaluate, assess and manage potential risks to human health and the environment within all of the evaluated legislative frameworks. By harmonising and streamlining environmental reporting, pooling resources and coordinating work, benefits can be realised.

Currently, terms relating to regulatory mechanisms of substances are not used in a consistent and harmonised way. Harmonisation of these terms would simplify interpretation and avoid misinterpretation. An example of this is the term authorisation. In REACH, authorisation is used to ensure that substances of very high concern (SVHCs) are progressively replaced by less dangerous substances or technologies where technically and economically feasible alternatives are available. This means, it is not allowed to place substances that are subject to authorisation on the market or to use them, except when authorisation has been granted for a specific use. In the Biocidal Products Regulation on the other hand, authorisation indicates that that a substance is allowed to be placed on the market in a broader sense.

To improve the implementation of all regulatory frameworks and reduce costs, information should be shared and made available in a transparent way. It is important that data is easy to retrieve and re-use. Examples of such information are physicochemical and toxicological properties of substances; use and emissions; monitoring data; and information on efficiencies, costs and applicability of different abatement options and potentials for substitution. It is

recommended to make an inventory and evaluate existing platforms for sharing information, such as the NORMAN databases (NORMAN, 2017b), ECHA databases (IUCLID) (ECHA, 2017), and take further action in developing a common platform for sharing information. To allow multiple uses of data and quality assurance, it is also necessary that such a platform also includes underlying information and that the information is transparent. This platform should also enable for exchange of information between different stakeholders such as authorities, regulatory bodies, academic and applied research. The on-going development of the SOLUTIONS database and EU´s joint database for monitoring data IPCHEM[3] (Information Platform for Chemical Monitoring) are first steps in this direction.

Another step towards cooperation and harmonisation would be to introduce common procedures for risk assessment and prioritisation. In order to safeguard both humans and the environment and to avoid regulatory sub optimization, such procedures should cover all steps in the life cycle (i.e. from production, use and disposal) and all possible uses of a substance. Risk assessments can also be improved by having access to robust data on production and use patterns of chemicals to be used for modelling and prediction of exposures and risks. At present, in most European countries national register on production and use do not exist for industrial chemicals. Only for Nordic countries such valuable information is available in the SPIN Database (Substances in Preparations in Nordic Countries).

Additional substances. Another key issue is the ability for all regulatory frameworks to inclusion of additional substances of concern and to continuously revise the list of substances as new information is gained. When regulating use and emissions of groups of substances, it is important to avoid ambiguity, and thereby clearly state which substances that constitute the group by listing CAS or EC numbers. This is currently not the case for all regulatory frameworks.

Consider mixtures. Regulation of chemicals also needs to consider mixtures. Recent research indicates that humans and the environment are constantly exposed to a multitude of substances, and that mixture toxicity can differ from the toxicity of single substances. This should be considered when setting human and environmental limit values (e.g. EQS) of chemicals in regulatory frameworks such as WFD, GWD and DWD to safeguard human health and the environment.

[3] https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html

International perspective. As the market for chemicals is global, there is a need to discuss chemicals management on a global level and thereby strengthen the cooperation between EU and relevant international organisations. Also, in spite of the regulations on European market authorization of chemicals used in the various sectors, an important share of the chemical emissions is related to chemical products and articles imported from outside the EU. It is therefore important to make sure that voluntary initiatives such as SAICM, that allows open discussions on how to reduce negative impacts of chemicals, to continue existing also in the future. Information on registered chemicals should be shared globally.

In conclusion, effective and transparent regulation of chemicals is necessary to protect human health and the environment and to achieve the overarching goal of an environmentally sound management and safe use of chemicals. This overview of some characteristics of different regulatory frameworks reveals a fragmented situation with a number of regulatory frameworks designed for specific groups of chemicals and for protection of different end-points. A more holistic view on regulation of production, use, and disposal of chemicals would provide the means of developing more efficient and transparent legislation.

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Supplementary information

1 Existing chemical legislation

1.1 EU Regulations

1.1.1 REACH (EC/1907/2006)

The REACH (registration, evaluation, authorisation and restriction of chemicals) Regulation (EC/1907/2006) aims at providing a comprehensive legislative framework for manufacturing and use of chemicals in Europe (European Commission, 2006c). Its objective is to ensure a high level of protection for human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It applies to all chemicals that a company manufactures or imports in quantities of 1 tonne or more per year. REACH shifts the responsibility for ensuring that chemicals produced, imported, sold and used in the EU are safe, from public authorities to the industry.

REACH comprises of four main processes. 1) Registration of substances: Companies must register all chemicals which they manufacture or import into the EU at or above one tonne per year in a central database. In order to manufacture or place chemicals on the EU market, companies must identify and manage any risks linked to the substances. They must also demonstrate how to use their substances (as such or in mixtures) safely and inform users of any risk management measures they should take to ensure safe use throughout the supply chain. The information requirements in the registration dossiers increase with increasing amounts of chemicals that a company manufacture or sell. 2) Evaluation of substances and registration dossiers: The European Chemicals Agency (ECHA) is responsible for performing compliance checks of the submitted registrations as well as evaluating the testing proposals, while Member States competent authorities perform substance evaluation for selected substances to clarify initial concerns for human health or for the environment and. 3) Authorisation: The authorisation process aims at controlling the risks of substances of very high concern (SVHC) and to ensure that these substances are progressively replaced on the market by suitable alternatives. Substances which are subject to authorisation cannot be placed on the market or used after a given date, unless an authorisation is granted for their specific use, or the use is exempted from authorisation. 4) Restriction: Restrictions under REACH are imposed when the risks by chemicals to human health or the environment are unacceptable. The restriction can limit or ban the manufacture, placing on the market or use of a substance. It applies to

substances on their own, in mixtures or articles and includes substances which are not subject to registration.

1.1.2 Plant Protection Products Regulation (EC/1107/2009)

The Plant Protection Products Regulation (EC/1107/2009) aims at ensuring a high level of protection of both human and animal health and the environment from risks posed by plant protection products (PPP), by laying down rules for the authorisation of plant protection products in commercial form and for their placing on the market, use and control within the Community (European Commission, 2009b). These rules are also intended to improve the functioning of the internal market as well as to improve the agricultural production. The Plant Protection Products Regulation applies to products used to protect or preserve plants, influence their growth or destroy and stunt undesired plants.

The Regulation applies a two-step approach of approval of plant protection products; 1) approval of the active substance, safeners and synergists, 2) authorisation of the plant protection product. For active substance, safeners and synergists, to be approved, they must be effective, have no immediate or delayed harmful effect on human health, no unacceptable effects on plants or the environment and not cause unnecessary suffering or pain to vertebrates. Active substances, safeners and synergists classified as carcinogenic, mutagenic or toxic for reproduction (CMR) categories 1A or 1B according to the CLP Regulation ((EC) No 1272/2008), endocrine disruptors, persistent, bioaccumulative and toxic (PBT) substances and very persistent and very bioaccumulative (vPvB) substances are subject to exclusion. Before placing a plant protection product on the market, companies must apply for authorisation to the EU country/countries where the plant protection product is intended to be placed on the market. The approval process is coordinated between the Member States. If an authorisation is issued and later the applicant wishes to place the same product on the market in another Member State(s), an application is made for mutual recognition of the product in the concerned Member State. Authorisations are valid for a time period of maximum 10 years and may be renewed for no more than 15 years.

1.1.3 Biocidal Products Regulation (EC/528/2012)

The Biocidal Products Regulation (EC/528/2012) aims to ensure a high level of protection of both human and animal health and the environment by harmonising the existing EU rules on making available on the market and use of biocidal products. It applies to biocidal products, articles and materials treated with biocidal products and active substances. (European Commission, 2012).

The Biocidal Products Regulation applies a two-step approach of approval of biocidal products; 1)

approval of the active substance on the Union level, 2) authorisation of the biocidal product either at Member State level or at Union level. Evaluation of active substances is carried out at EU level, where the approval is adopted by the European Commission. An active substance is subject to exclusion if it fulfils any of the following criteria; classified as carcinogenic, mutagenic or toxic for reproduction (CMR) categories 1A or 1B according to the CLP Regulation ((EC) No 1272/2008), endocrine disruptors, persistent, bioaccumulative and toxic (PBT) substances and very persistent and very bioaccumulative (vPvB) substances. The approval of an active substance is granted for a period not exceeding 10 years. Once an active substance is approved, it must also be authorised before it can be placed on the market. Authorisation can be applied for on either EU level or national level. If authorisation is given at EU level, the biocidal product can be sold in the entire EU. National authorisation can be extended to other Member States via mutual recognition of the authorisation of the product.

The Biocidal Products Regulation also sets rules for the use of articles treated with, or intentionally incorporating, one or more biocidal products. According to the regulation, articles can only be treated with biocidal products containing active substances approved in the EU.

1.1.4 Cosmetic Products Regulation (EC/1223/2009)

The Cosmetic Products Regulation (EC/1223/2009) establishes safety requirements for cosmetic products sold on the European market to ensure a high level of protection of human health, and lays down rules to ensure the functioning of the internal market. It applies to all cosmetic product made available on the EU market (European Commission, 2009c).

To ensure safe cosmetic products, the Regulation restricts or prohibits the use of certain substances such as CMR substances of category 1A, 1B or 2. However, CMR substances of category 1A, 1B or 2 can still be used in cosmetic products if they are found safe for use in cosmetic products and/or if certain conditions are fulfilled. The Cosmetic Products Regulations also lists which colorants, preservatives and UV-filters that are allowed to use in cosmetic products. Prior to placing a cosmetic product on the EU market, it must have undergone a safety assessment on the basis of the relevant information and a cosmetic product safety report must have been set up.

1.1.5 Medicinal Products Regulation (EC/726/2004)

The Medicinal Products Regulation (EC/726/2004) seeks to guarantee high standards of quality and safety of medicines, and includes measures to encourage innovation and competiveness. It sets out procedures for the authorisation and supervision of medicinal products for human and veterinary use.

(European Commission, 2004).

Authorisation is based on quality, safety and efficacy, lasts for 5 years, and is renewable. Similar principles, with some adjustment, apply to products intended for veterinary use. Authorisation may be refused on the grounds of health and welfare of animals or consumer safety, or if human food from treated animals could contain harmful residues. The Regulation also reinforces monitoring procedures. EU countries must inform the EMA and the European Commission where the manufacturer or importer fails to fulfil their obligations under an authorisation.

Where urgent action is essential to protect human health or the environment, an EU country may suspend use of a medicinal product. The holder of the authorisation must notify the EMA, the Commission and other EU countries of any such variation or suspension.

1.2 EU Directives

1.2.1 Water Framework Directive (2000/60/EC)

The Water Framework Directive (WFD) (2000/60/EC) aims at maintaining and improving the aquatic environment in the European Community by establishing a common framework in the field of water policy (European Commission, 2000). According to the environmental objectives of the WFD, Member States shall protect, enhance and restore all surface water bodies with the aim of achieving good status of surface water and groundwater throughout the Community by 2015. To ensure the achievements of the objectives and consistent implementation of the WFD, the implementation is planned cyclically in a three step process: 1) the characterisation of water bodies and identification of pressures and their impacts, 2) the establishment of monitoring programmes and status assessment of water bodies, 3) drafting of river basin management plans including specific programmes of measures.

The Water Framework Directive lists a number of substances, called priority substances, which are prioritised for action on Community level. These priority substances are substances which present a significant risk to or via the aquatic environment, for which specific measures against pollution of water shall be taken aiming at the progressive reduction of discharges, emissions and losses. The priority substances can also be classified as priority hazardous substances if they are toxic, persistent and liable to bio-accumulate and other substances or groups of substances which give rise to an equivalent level of concern. The priority hazardous substances are subject to cessation or phasing out of discharges, emissions and losses within an appropriate timetable not exceeding 20 years. The current list of priority substances include 45 substances or groups of substances, of which 21 substances are identified as

priority hazardous substances. Priority substances and priority hazardous substances are identified via risk assessments.

1.2.2 Ground Water Directive (2006/118/EC)

The Groundwater Directive (2006/118/EC) aims at preventing and controlling groundwater pollution by establishing criteria for assessing the chemical status of groundwater; establishing criteria for identifying significant and sustained upward trends in groundwater pollution levels, and for defining starting points for reversing these trends; and sets provisions to prevent and limit indirect discharges (after percolation through soil or subsoil) of pollutants into groundwater. (European Commission, 2006b)

According to the Ground Water Directive, Member States must set a threshold value for each pollutant identified in any groundwater body to be at risk. As a minimum, Member States must establish threshold values for ammonium, arsenic, cadmium, chloride, lead, mercury, sulphate, trichloroethylene and tetrachloroethylene. Members States must also set up monitoring programmes to identify any significant and sustained upward trend in levels of pollutants and programmes of measures to prevent indirect discharges of all pollutants into groundwater.

1.2.3 Marine Strategy Framework Directive (2008/56/EC)

The Marine Strategy Framework Directive (2008/56/EC) aims to achieve or maintain good environmental status of the EU's marine waters by 2020 and to protect the resource base upon which marine-related economic and social activities depend (European Commission, 2008). For that purpose, Member States shall develop marine strategies in order to protect and preserve the marine environment, prevent its deterioration or, where practicable, restore marine ecosystems in areas where they have been adversely affected; and to prevent and reduce inputs in the marine environment so as to ensure that there are no significant impacts on or risks to marine biodiversity, marine ecosystems, human health or legitimate uses of the sea.

The implementation of the Marine Strategy Framework Directive is planned in six year cycles using the following step-wise approach: 1) an initial assessment of the current environmental status of national marine waters and the environmental impact and socio-economic analysis of human activities in these waters, 2) determination of good environmental status, 3) establishment of environmental targets and indicators, 4) establishment and implementation of monitoring programme, 5) development and entry into operation of programme of measures.

1.2.4 Drinking Water Directive (98/83/EC)

The Drinking Water Directive (98/83/EC) aims to protect human health from adverse effects of any contamination of water intended for human consumption, by laying down EU wide quality standards for drinking water. These quality standards cover both microbiological and chemical parameters. (European Commission, 1998).

According to the Directive, Member States are obliged to take necessary measures to ensure the water does not contain concentrations of microorganisms, parasites or harmful substances that could be a danger to human health, and meets minimum microbiological and chemical standards. Member State competent authorities shall establish monitoring programmes to check that the water available to consumers meets the requirements of this Directive. Currently, the Drinking Water Directive lists 26 substances or groups of substances for which there are chemical standards for drinking water.

1.2.5 Urban Waste Water Treatment Directive (91/271/EEC)

The Urban Waste Water Treatment Directive (91/127/EEC) aims to protect the environment from adverse effects of discharges of urban waste water and discharges of waste water from certain industrial sectors. It sets requirements on the treatment of urban waste water and limits emissions of the eutrophying substances phosphorus, nitrogen and oxygen consuming substances (biological oxygen demand (BOD), chemical oxygen demand (COD) and total suspended solids (TSP)) in urban waste water (European Commission, 1991).

The Directive requires that all agglomerations with a population equivalent of more than 2 000 are provided with collecting systems for urban waste water and that the urban waste water entering collecting systems shall before discharge be subject to secondary treatment or an equivalent treatment. The treatment of the urban waste water is varied according to the sensitivity of the receiving waters, with more stringent requirements for urban waste water discharged into sensitive areas. Member States are also required to set up monitoring programmes, monitoring both discharges from treatment plants and the receiving waters.

1.2.6 Sewage Sludge Directive (86/278/EEC)

The aim of the Sewage Sludge Directive (86/278/EEC) is to regulate how sewage sludge can be used in agriculture to prevent harmful effects on the environment and human health (European Commission, 1986).

The Directive sets limit values for concentrations of seven heavy metals (cadmium, copper, nickel, lead, zinc, mercury and chromium) in sewage sludge intended for agricultural use and in sludge-treated soils and specifies rules for the sampling and analysis of sludges and soils. It also lays down rules regarding the use of sludge to avoid potential health risks from residual pathogens and requires that sludge should be used in such a way that account is taken of the nutrient requirements of plants and that the quality of the soil and of the surface and groundwater is not impaired. The Directive prohibits the use of untreated sludge on agricultural land unless it is injected or incorporated into the soil, and in certain situations, sewage sludge may not be used at all in agriculture.

1.2.7 Industrial Emissions Directive (2010/75/EU)

The Industrial Emissions Directive (IED) (2010/75/EU) aims to prevent and control pollution arising from industrial activities by establishing provisions designed to prevent or, where that is not practicable, to reduce emissions to air, water and soil and to prevent generation of waste, so that a high level of protection can be achieved for the environment as a whole (European Commission, 2010).

The Directive covers industrial activities with a major pollution potential, which have been divided into the following main categories: energy industries, production and processing of metals, mineral industry, chemical industry, waste management and other. Operators of these industrial installations are required to obtain an integrated permit from the authorities in the EU countries. The integrated approach means that the permit must take into account the whole environmental performance of the facility, such as emissions to air, water, land, generation of waste, raw material consumption, energy efficiency, noise, accident prevention and site restoration at closure. Permit conditions, including emission limit values (ELV), must be based on the best available technique (BAT). BAT conclusions (documents containing information about the emission levels associated with BAT) are used as reference for setting permit conditions. However, the Directive contains elements of flexibility by allowing licensing authorities to establish less stringent emission limit values in specific cases. Such measures are applicable only where an assessment shows that the achievement of emission levels in BAT conclusions would lead to disproportionately high costs compared to the environmental benefits. Member States competent authorities are required to conduct regular inspections of the installations. In addition, IED requires public participation in the decision-making process, and to be informed in of its consequences, by having access to; permit applications, permits; result of the monitoring of releases and the European Pollutant Release and Transfer Register (E-PRTR).

Annex II to the IED lists the covered polluting substances and substances or mixtures with specific

properties (persistent, cancerogeneous).

1.2.8 Mining Waste Directive (2006/21/EC)

The Mining Waste Directive (2006/21/EC) introduces measures for safe management of waste resulting from the extraction, treatment and storage of mineral resources and the working of quarries. The Directive also provides procedures and guidance to prevent or reduce as far as possible any adverse effects on the environment, in particular water, air, soil, fauna and flora and landscape, and any resultant risks to human health, brought about as a result of the management of waste from the extractive industries. (European Commission, 2006a).

In the Management of waste from extractive industries directive the Member States shall ensure that the operator draws up a waste management plan for the minimisation, treatment, recovery and disposal of extractive waste, taking account of the principle of sustainable development. In this context one point is to use less dangerous substances for the treatment of mineral resources, where dangerous substances means a substance, mixture or preparation which is dangerous within the meaning of Directive 67/548/EEC or Directive 1999/45/EC.

1.2.9 Restriction of the use of certain Hazardous Substances in electric and electronic equipment (2011/65/EU)

The RoHS (Restriction of the use of certain Hazardous Substances in electric and electronic equipment) Directive (2011/65/EC) aims at protecting human health and the environment by laying down rules on the restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE) and on the environmentally sound recovery and disposal of waste EEE (European Commission, 2011).

The RoHS Directive sets maximum concentration values for the heavy metals lead, mercury, cadmium, and hexavalent chromium and the flame retardants polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) in homogenous materials in electric and electronic equipment which are placed on the European market. Exemptions from the maximum concentration values can be granted for specific applications if the elimination or substitution is scientifically or technically impossible, if reliable substitutes are not available or if the total negative environmental, health and consumer safety impacts caused by the substitution are likely to outweigh the total benefits thereof.

1.2.10 Toy Safety Directive (2009/48/EC)

The Toy Safety Directive (2009/48/EC) aims at protecting human health by laying down rules on the

safety of toys, there among safety requirements with regard to chemical properties of toys (European Commission, 2009a).

According to the safety requirements of the Directive, substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys. Migration limits have been set for 19 substances from toys or toy components, and specific limit values have been set for 4 substances used in toys for children under 36 months or in other toys intended to be placed in the mouth. Allergenic fragrances are either completely forbidden, if they have a strong allergenic potential, or have to be labelled on the toy if they are potentially allergenic for some consumers.

1.3 Multilateral Environmental Agreements

1.3.1 Stockholm Convention on Persistent Organic Pollutants (POPs)

The Stockholm Convention is a global treaty that aims to protect human health and the environment from POPs[4]. The overall objective shall be achieved by prohibiting or restricting the production, use, trade and storage and to minimize or, if possible, eliminate releases of unintentionally produced POPs. Each party of the Convention is required to prepare a plan that includes an assessment of the national situation concerning POPs, as well as activities planned or undertaken to implement the Convention. The Convention identifies 23 different POPs, which cause adverse effects to humans and the environment. The chemicals are listed in three different Annexes to the Convention; Annex A (Elimination), Annex B (Restriction) and Annex C (Unintentional production).

The EU ratified the Protocol on 30 April 2004 and the Stockholm Convention on 16 November 2004. Regulation (EC) No 850/2004, known as the POPs Regulation, implements in the law of the Union the commitments set out in the Stockholm Convention on Persistent Organic Pollutants and in the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants.

1.3.2 Convention on Long-range Transboundary Air Pollution (CLRTAP)

The Convention sets up an institutional framework bringing together research and policy. It is a regional treaty that aims to protect man and his environment against air pollution and shall endeavour to limit and, as far as possible, gradually reduce and prevent air pollution including long-range transboundary air pollution. This shall be achieved by the Parties by developing policies and strategies to combat the discharge of air pollutants through exchanges of information, consultation, research and monitoring.

[4] http://chm.pops.int/TheConvention/Overview/tabid/3351/Default.aspx

Today the convention has been extended by eight different that identify specific measures to be taken by Parties to reduce emissions by including sulphur, nitrogen oxides, heavy metals, volatile organic compounds and POPs.

The EU has ratified the Convention and all protocols except the Geneva- and the Helsinki Protocol. Regulation (EC) No 850/2004 implements in the law of the Union the commitments set out in the Stockholm Convention on Persistent Organic Pollutants and in the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants.

1.3.3 Protocol on Pollutant Release and Transfer (PRTR)

The overall objective of the Protocol on PRTRs is to enhance public access to information through establishment of coherent, integrated, nationwide pollutant release and transfer registers (PRTRs), which could facilitate public participation in environmental decision-making as well as contribute to the prevention and reduction of pollution of the environment.

The Protocol states that the register shall contain information on both point sources and diffuse sources. Annex I to the Protocol lists 64 different economic activities grouped into nine different sectors[5]. Annex II to the Protocol lists 86 different pollutants and categories of substances[6]. The substances are divided into different categories such as greenhouse gases, ozone-depleting substances, heavy-metals, pesticides, acidification precursors and persistent organic compounds. The register shall cover releases to air, water, land, and off-site transfers of pollutants through the wastewater and off-site transfers of waste. The PRTR register must present the information on releases of pollutants from diffuse sources in an adequate spatial disaggregation, which can be done by using Geographic Information System (GIS).

The EU ratified the PRTR Protocol the 21st of February 2006. The Protocol is transposed into EU legislation by the EC regulation No 166/2006, which establishes an integrated pollutant release and transfer register at EU level in the form of a publicly accessible electronic database and lays down rules for its functioning. The European register (E-PRTR) covers more substances than the UN-ECE Protocol (91 substances), to take account of existing EU legislation on water and persistent organic pollutants.

[5] http://www.unece.org/fileadmin/DAM/env/pp/prtr/Protocol%20texts/PRTR_Protocol_e.pdf

[6] http://www.unece.org/fileadmin/DAM/env/pp/prtr/Protocol%20texts/PRTR_Protocol_e.pdf

1.3.4 Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

The aim of the Convention is to promote shared responsibility and unified efforts between Parties in the international trade with certain hazardous chemicals in order to protect human health and the environment from potential damage and to contribute to an environmentally friendly usage of such chemicals. This is to be achieved by facilitating information exchange regarding the properties of such chemicals, by the way of introducing a national decision-making procedure for import and export of such chemicals (the so-called PIC procedure) and distributing information of decisions to the Parties. The PIC procedure and information exchange are the most important provisions of the Rotterdam Convention. The chemicals that are subject to the PIC-procedure are listed in Annex III to the Convention; 33 are pesticides (including 4 very hazardous blends of pesticides) and 14 are industrial chemicals.

The EU has ratified the Convention and it is implemented in the EU legislation through regulation (EG) no 289/2008, the so-called PIC regulation. In Annex I to the PIC regulation those chemicals for which a prior export notification is required are listed, and Annex V contain a list of those chemicals for which export is prohibited[7]. The regulation contains information requirements that are, in part, more extensive than the requirements under the Convention.

[7] http://www.kemi.se/sv/Innehall/Lagar-och-andra-regler/EU-forordningar/Export-och-import-av-farliga-kemikalier/Mer-om-export--och-importforordningen/ (available in Swedish)