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Policy brief

Environmental and Chemical legislation

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The interlinks
and synergies

Policy Brief

EU Environmental and Chemical legislation:

Water Framework Directive, Marine Strategy Framework Directive, IPPC/Industrial Emissions Directive, REACH and Waste Framework Directive

Interlinks and Synergies

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Abbreviations

BAT	Best Available Techniques
BREF	BAT Reference Document
CA	Competent Authority
CLP	Classification, Labelling and Packaging Regulation
DNEL	Derived No-Effect Level
DPD	Dangerous Preparations Directive
EPER	European Pollutant Emission Register
E-PRTR	European Pollutant Release and Transfer Register
ECHA	European Chemicals Agency
ELV	Emission Limit Value
ES	Exposure Scenario
EQS	Environmental Quality Standard
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
HS	Hazardous Substance
IED	Industrial Emissions Directive
IPPC	Integrated Pollution Prevention and Control
MS	Member State
MSFD	Marine Strategy Framework Directive
PNEC	Predicted No-Effect Concentration
POM	Programme of Measures
RBMP	River Basin Management Plan
REACH	Registration, Evaluation, Authorisation and Restriction of Chemical Substances
RIPE	REACH Information Portal for Enforcement
SDS	Safety Data Sheet
SEA	Socio-Economic Analysis
SVHC	Substances of Very High Concern
WFD	Water Framework Directive
WWTP	Waste Water Treatment Plant

Introduction

This policy brief aims to demonstrate interlinks between several EU legal acts that include provisions on chemicals management. Substances hazardous to the environment and environmental risks are the focus. We understand interlinks as:

- > **Formal links via direct references from one legislation to another** (e.g. partial exemption from authorization of substances regulated under IPPC/IED or the reference to the candidate list for authorization in the IED directive for emission monitoring);
- > **Informal links/possible synergies** from using methods or information generated under one legislation in the context of another;

by companies (e.g. using REACH information to apply for permits or REACH methods to document compliance; by modeling environmental concentrations),

by authorities (e.g. using PNECs to derive or justify ELVs).

The Water Framework Directive 2000/60/EC, the IPPC Directive 2008/1/EC (IED 2010/75/EU), the REACH Regulation 2006/1907/EU and the Marine Strategy Framework Directive 2008/56/EC are some of the main pillars of EU environmental law. The implementation of this legislation presented many challenges to the new Member States and still continues to do so.

Installations regulated under IPPC/IED may impact on the water environment, such as through direct or indirect discharges of pollutants, water abstraction, etc. Installation permits should ensure that industrial emis-

sions do not undermine environmental quality standards established by EU and national law, including those derived under water legislation. REACH is expected to deliver comprehensive information on chemicals, including substances hazardous to the aquatic environment, which could support the implementation of water legislation.

This policy brief examines how different legislation could be implemented in a way that synergies and mutual enforcement of respective goals could be achieved. Particular focus is placed on how the IPPC/IED and REACH could support the implementation of WFD and MSFD goals. This document outlines the most important interlinks between these frameworks and highlights related challenges to the competent authorities in the Baltic states and Poland and how these might be addressed.

This document aims to provide:

- > an introduction to parts of EU environmental law and legal interlinks for all interested persons;
- > concrete ideas and recommendations on how to create synergies in legal implementation and greater effectiveness and efficiency of chemicals control;
- > a starting point for further policy discussions at the national and EU level.

This policy brief is mainly targeted to the national competent authorities and regional authorities responsible for the implementation and enforcement of hazardous substances legislation in the context of the mentioned policies, especially authorities issuing installation permits and monitoring industrial effluents as well as those defining emission reduction measures for hazardous substances.

1. Legal frameworks

This document focuses on chemical emissions and exposures in the water sector in other EU environmental and installation-related acts because:

- a) the water sector is of priority concern as it is the sink for many direct and indirect emissions, adverse effects are observed in the aquatic environment and it is the basis of the aquatic food chain;
- b) air quality legislation focuses on traditional pollutants and effects from hazardous substances (HS) are unlikely¹ because of high dilution and rapid par-

1 Persistent organic pollutants (POPs) are an exception, as they are transported via air but eventually end-up in the environment by deposition and accumulate there. However, as POPs are quite strictly and specifically regulated, this part of environmental law is not considered in the subsequent discussion.

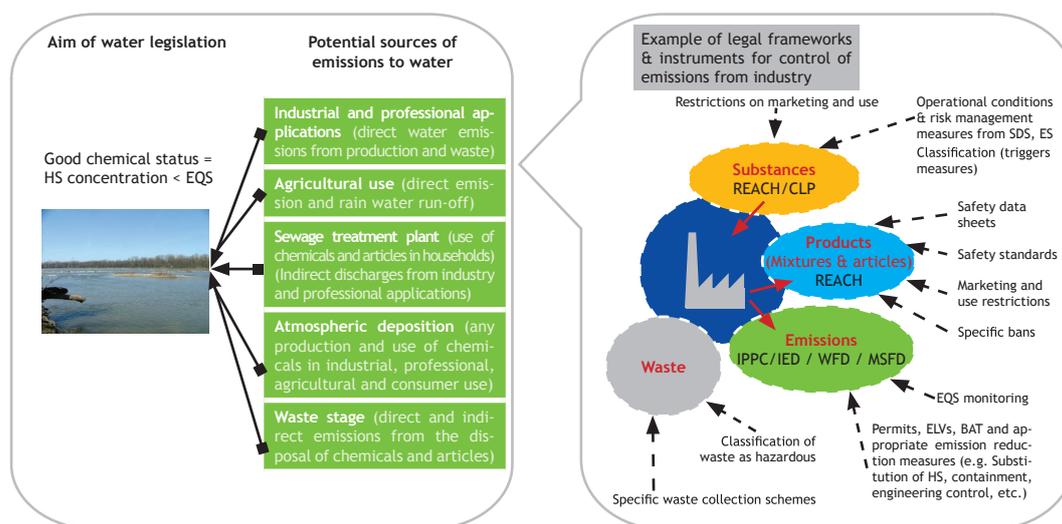
tioning to other components for most substances and

- c) comprehensive soil protection legislation does not yet exist that could be looked at with a view to potential interlinks to REACH and installation- and water-related legislation.

Water legislation aims at achieving a good quality of surface waters, however, respective implementation instruments are minimally addressed.

Good status of surface waters, with regard to the chemical status, is dependent on the control of hazardous substance emissions to water. The sources of these emissions are regulated by other pieces of legislation. Figure 1 illustrates the coverage and the most important regulatory instruments of the legislation discussed in this policy brief.

Figure 1. Potential emission sources of hazardous substances to water and legal frameworks and instruments for their control



In order to have a holistic picture of interlinks between the various legal frameworks and how they influence each other and impact on water quality, a basic under-

standing of each piece of legislation is needed. Therefore, a brief overview on the most relevant legal frameworks is presented in the following sections.

1.1. Water Framework Directive & Environmental Quality Standards

1.1.1. GOALS

The Water Framework Directive - WFD (2000/60/EC) was adopted to establish a new, comprehensive regime for the protection of inland surface waters, transitional waters, coastal waters and groundwater inter alia through measures to address chemical pollution by priority (hazardous) substances.

The WFD specifies the following long-term goals for priority substances:

- > to prevent deterioration of surface and groundwater quality to achieve **good chemical status** for surface water and groundwater by **2015** through protection, enhancement and restoration of all surface water and groundwater bodies;
- > to progressively **reduce pollution from priority substances** and **cease or phase out emissions,**

discharges and losses of priority hazardous substances to surface waters by 2020.

Good chemical status is achieved for a water body when compliance with all environmental quality standards for the priority substances and other pollutants listed in Directive 2008/105/EC, a ‘Daughter’ Directive of the WFD.

Directive 2008/105/EC defines a European “priority list” of substances posing a threat to or via the aquatic environment and establishes environmental quality standards (EQS). EQS in the WFD define the concentration of a substance in water, sediment or biota which is regarded as safe for the environment and human health and which should therefore not be exceeded. In November 2012, 33 groups of substances were identified as major concerns. 13 substances and substance groups have been identified as priority hazardous substances. This means that their discharges, emissions and losses must be phased out by 2020. The current list (2012) is provided below in the Table 1.

Table 1. List of priority substances in the field of water policy (Directive 2008/105/EC)

No	Name of priority substance	Identified as priority hazardous substance	No	Name of priority substance	Identified as priority hazardous substance
1	Alachlor		21	Mercury and its compounds	X
2	Anthracene	X	22	Naphthalene	
3	Atrazine		23	Nickel and its compounds	
4	Benzene		24	Nonylphenols (4-nonylphenol)	X
5	Brominated diphenylether (Pentabromodiphenylether (congener numbers 28, 47, 99, 100, 153 and 154))	X	25	Octylphenols (4-(1,1',3,3'-tetramethylbutyl)-phenol)	
6	Cadmium and its compounds	X	26	Pentachlorobenzene	X
7	Chloroalkanes, C10-13	X	27	Pentachlorophenol	
8	Chlorfenvinphos		28	Polyaromatic hydrocarbons (Benzo(a)pyrene)	X
9	Chlorpyrifos (Chlorpyrifos ethyl)			(Benzo(b)fluoranthene)	X
10	1,2-Dichloroethane			(Benzo(g,h,i)perylene)	X
11	Dichloromethane			(Benzo(k)fluoranthene)	X
12	Di(2-ethylhexyl)phthalate (DEHP)			(Indeno(1,2,3-cd)pyrene)	X
13	Diuron		29	Simazine	
14	Endosulfan	X	30	Tributyltin compounds	X
15	Fluoranthene			(Tributyltin-cation)	X
16	Hexachlorobenzene	X	31	Trichlorobenzenes	
17	Hexachlorobutadiene	X	32	Trichloromethane (chloroform)	
18	Hexachlorocyclohexane	X	33	Trifluralin	
19	Isoproturon				
20	Lead and its compounds				

As part of the WFD the list of priority substances is reviewed every 4 years by the European Commission. The substances have been selected on the basis of scientific evidence that they may pose a significant risk to health. The selection is based on a review of approximately 2000 substances considering their hazards, production volumes, uses and concentrations in surface waters.

1.1.2. KEY LEGAL INSTRUMENTS/ PRINCIPLES TO ACHIEVE THE GOALS

The WFD contains some important instruments to achieve its goals: River Basin Management Plans (RBMP) with programmes of measures (POM), environmental quality standards (EQS) and monitoring of the ecological or chemical status of surface water.

River basins and River Basin Management Plans

The WFD targets the entire drainage basin of a river to assure good water quality throughout, irrespective of administrative boundaries. Development of **River Basin Management Plan (RBMP)** for the entire area of the river basin prevents shifting of problems to a different jurisdiction.

Consequently, the main administrative instrument of the WFD is the **RBMP**, which Member States are required to establish for each river basin district lying entirely within their territory. For international river basin districts

lying within the Community, Member States are required to ensure coordination with the aim to elaborate a single international river basin management plan, if possible. RBMP must be reviewed by competent authorities on a regular cycle of 6 years. The first RBMPs were published in December 2009, setting out actions until 2015.

The RBMPs describe in detail how the objectives for the river basin are to be reached within the required timescale. Each RBMP comprises of several important elements:

- > **Assessment of the water body's status.** This process involves characterisation of the river basin including the identification of the chemical status. In addition, an analysis of pressures from human activities like emissions and discharges of hazardous substances and an economic analysis of water use is necessary.
- > **Programmes of measures.** Each RBMP is to contain programmes of measures to achieve good water quality on a river basin scale.
- > **Monitoring and review.** Chemical monitoring according to the WFD covers all surface waters and aims to check compliance with the EU-wide EQS. In addition, Member States must identify and define specific EQS for hazardous substances of national concern and include them in the monitoring programmes. Authorities are required to monitor the status of water bodies and the effects of the programmes of measures.

Figure 2. The transboundary Daugava and Nemunas River basins. These basins span the countries of Russia, Latvia, Lithuania, Belarus and Poland, and the rivers drain to the Baltic Sea. Source: http://enrin.grida.no/databasin/index_maps.cfm



1.1.3. MEASURES

It is up to the individual Member State to decide which measures to implement to achieve good water quality status. A non-exhaustive list of exemplary measures is provided in the WFD. The measures are divided into ‘basic’ and ‘supplementary’ measures:

- > **Basic measures** include measures required under existing Community law, e.g. emission controls, emission limit values and permitting under IPPC/IED or the Nitrates Directive. Also local legislation can contribute to achieving the goals of the WFD. Importantly, the WFD stresses that where a quality objective or quality standard requires stricter conditions than those resulting from the application of existing Community law, more stringent conditions shall be set accordingly².

- > **Supplementary measures** are those measures designed and implemented in addition to the basic measures “to fill in the remaining gaps” with the aim of achieving the objectives.

Compulsory measures for water bodies, which do not meet the environmental objectives include

- > investigation of the causes of the failure (e.g. investigation of sources of pollution);
- > reviewing all relevant authorisations and discharge permits;
- > reviewing and adjusting monitoring measures as appropriate;
- > implementation of additional measures for discharges of pollutants if necessary.

XVII of REACH or set stricter requirements regarding emissions e.g. in permits for water discharge than described in Best Available Technology Reference Documents, if justified by the need to meet a quality objective under the WFD.

2 This means that Member States could pass stricter restrictions for a substance than defined in Annex

INFORMATION TOOLKIT ESTONIA

Competent authority	Environmental Board of Estonia: http://www.keskkonnaamet.ee/est
List of priority substances	Regulation of Minister of Environment 21.07.2010 nr 32 (Veekeskonnale ohtlike ainete ja ainerühmade nimistud 1 ja 2 ning prioriteetsete ainete, prioriteetsete ohtlike ainete ja nende ainete rühmade nimekirjad)
EQS	Regulation of Minister of Environment 09.09.2010 nr 49, changed 04.08.2011 (Pinnavee keskkonna kvaliteedi piirväärtused ja nende kohaldamise meetodid ning keskkonna kvaliteedi piirväärtused vee-elustikus)
ELV	Regulation of Government 31.07.2001 nr 269, changed 01.04.2010 (Heitvee veekogusse või pinnasesse juhtimise kord)
River basins in Estonia	http://www.keskkonnaamet.ee/vesikonnad/
RBMP and POM	http://www.envir.ee/vmk
Monitoring programme	http://eelis.ic.envir.ee:88/seireveeb/
Monitoring results	http://eelis.ic.envir.ee:88/seireveeb/

INFORMATION TOOLKIT LATVIA

Competent authority	Latvian Environment, Geology and Meteorology Centre http://www.lvgmc.lv
List of priority substances	Cabinet of Ministers Regulation Nr. 34, 22.01.2002. (Ministru kabineta 2002. gada 22. janvāra noteikumi Nr.34 “Noteikumi par piesārņojošo vielu emisiju ūdenī” ar grozījumiem, kas izdarīti līdz 14.08.2010)
EQS and ELV	Cabinet of Ministers Regulation Nr. 118, 12.03.2002. (Ministru kabineta 2002. gada 12. marta noteikumi Nr. 118 “Noteikumi par virszemes un pazemes ūdeņu kvalitāti” ar grozījumiem, kas izdarīti līdz 30.12.2009)
River basins in Latvia	
RBMP and POM	http://www.meteo.lv/public/29935.html
Monitoring programme	
Monitoring results	

INFORMATION TOOLKIT LITHUANIA

Competent authority	Environmental Protection Agency of Lithuania http://gamta.lt
List of priority substances	The Regulation on Wastewater Treatment approved by Order No D1-236 of the Minister of Environment of the Republic of Lithuania of 17 May 2006 (Official Gazette, 2006, No 59-2103; 2007, No 110-4522; 2010 No. 59-2938)
EQS and ELV	
River basins in Lithuania	
RBMP and POM	http://vanduo.gamta.lt
Monitoring programme	
Monitoring results	

INFORMATION TOOLKIT POLAND

Competent authority	Krajowy Zarząd Gospodarki Wodnej, www.kzgw.gov.pl
List of priority substances	Decree of the Minister of Environment of 8th July 2004 on conditions for introducing sewage to water environment and on substances especially dangerous to water environment,
EQS and ELV	Revision pending
River basins in Poland	http://www.rdw.org.pl/river-basin-districts.html
RBMP and POM	http://www.rdw.org.pl/river-basin-management-plans.html
Monitoring programme	http://www.rdw.org.pl/monitoring-en.html
Monitoring results	http://www.gios.gov.pl/artykuly/podkategoria/184/State-Environmental-Monitoring

1.2. Marine Strategy Framework Directive

The Marine Strategy Framework Directive (MSFD - Directive 2008/56/EC) establishes a framework for Community action in the field of marine environmental policy. The MSFD complements the Water Framework Directive, extending environmental protection into EU marine waters beyond the coastal waters.

1.2.1. GOALS

The overall aim of the Directive is to achieve or maintain good environmental status of the EU's marine waters by 2020. It aims at protecting human and animal health as it relates to pollution causing significant impacts on or risks to marine biodiversity. The MSFD foresees a regional approach to implementation and establishes European Marine Regions on the basis of geographical and environmental criteria.

The MSFD covers marine waters, including coastal waters, but only in so far as particular aspects of the environmental status of the marine environment are not

already addressed through the Water Framework Directive or other EU legislation. With regard to territorial waters, these are covered by the Water Framework Directive with respect to chemical status.

1.2.2. KEY LEGAL INSTRUMENTS/ PRINCIPLES TO ACHIEVE THE GOALS

Each Member State (cooperating with other Member States and non-EU countries within a marine region) is required to develop strategies specific to each marine region or marine sub-region. Strategies should contain a detailed assessment of the state of the environment, a definition of good environmental status at the regional level, clear environmental targets and monitoring programmes, and a programme of cost-effective measures designed to achieve or maintain good environmental status. These measures should be evaluated using impact assessments and detailed cost-benefit analysis. Member States are not required to take specific steps where

there is no significant risk to the marine environment, or where the costs would be disproportionate, taking into account the risks to the marine environment, provided that any decision not to take action is properly justified.

The definition of good environmental status at the regional level should be based on centrally agreed criteria and methodological standards. The Commission decision on criteria and methodological standards on good environmental status contains a number of criteria and associated indicators in relation to the 11 descriptors of good environmental status laid down in Annex I to the Directive.

Two of the eleven qualitative descriptors are related to contaminants, i.e. hazardous substances which present a risk to or via the marine environment:

- > Descriptor 8: concentrations of contaminants are at levels not giving rise to pollution effects;
- > Descriptor 9: contaminants in fish and other seafood for human consumption do not exceed levels established by Community legislation or other relevant standards.

Descriptor 8 relates to substances or groups of substances which exceed the relevant EQS in coastal or territorial waters adjacent to the marine region or sub-region and are listed as priority substances in Annex X to the WFD. It is also relevant to substances, which are discharged into the concerned marine region, sub-region or subdivision and are contaminants the total releases of which may pose significant risks to the marine environment. This means that e.g. EQS from the WFD should be considered.

INFORMATION TOOLKIT ESTONIA

Competent authority Ministry of Environment: <http://www.envir.ee/1107554>
Legislation Water Act (consolidated text Dec 2011)

INFORMATION TOOLKIT LATVIA

Competent authority Ministry of Environmental Protection and Regional Development <http://www.varam.gov.lv>
 Latvian Institute of Aquatic Ecology www.lhei.lv
Legislation Law on protection and Management of Aquatic Environment (2010)

INFORMATION TOOLKIT LITHUANIA

Competent authority Environmental Protection Agency: <http://gamta.lt>
Legislation The Regulation Describing the Procedure for Evaluation of Environmental Status, Properties, Environmental Protection Goals, Monitoring Program and Tools of the Baltic Sea approved by Order No D1-500 of the Minister of Environment of the Republic of Lithuania of 14 June 2010 (Official Gazette, 2010, No 72-3680; 2012, No 124-6250)

INFORMATION TOOLKIT POLAND

Competent authority General Inspectorate for Environmental Protection, www.gios.gov.pl
Legislation To be amended through “Water Law” bill

1.3. Waste legislation in brief

1.3.1. STRUCTURE OF WASTE LEGISLATION

The Waste Framework Directive (2008/98/EC) defines the overall framework for the management and disposal of waste. It is complemented by Regulation (EC) 1013/2006 which defines the legal frame for the shipment of waste. The Commission Decision 2000/53/EC establishes a list of waste, structured and classified according to the sector of origin and nature (sludge, ash etc.). According to this classification system, for many wastes, so-called “mirror entries” exist for hazardous wastes. Waste generators must decide whether or not the waste is to be classified hazardous and, if so, mark it with an asterisk.

Waste legislation includes separate directives on how landfills and waste incineration should be operated as well as specific acts defining and detailing reporting obligations on the waste management system by Member States.

There are also some legal acts which address specific products, such as electric and electronic equipment (WEEE), batteries, cars or packaging wastes and set collection and recovery targets. This legislation may also be connected to product legislation or contain product related requirements which ban or restrict the use of certain hazardous substances in order to avoid contamination of material streams and thereby making waste recovery and recycling more complex or impossible (e.g. Restrictions Of Hazardous Substances in electric and electronic equipment (RoHS) or Directive on End-of-Life Vehicles).

Under the Waste Framework Directive for specific wastes, e.g. plastics, glass or metals, so called end-of-waste criteria are being defined at the EU level to provide a harmonized approach for deciding on the status of a material generated from waste and clarification on the legislative regime it falls under.

1.3.2. HAZARDOUS WASTE

Waste is classified as hazardous if it fulfills one of the hazard criterion defined in the Waste Framework Directive. Most of these criteria are harmonized with the hazard categories and the classification criteria / thresholds of the classification and labeling rules according to Directive 67/548/EEC and Directive 99/45/EC (respectively the regulation on the classification and labelling of hazardous substances and mixtures (EC) No 1272/2008)³. The

3 “1. Attribution of the hazardous properties ‘toxic’

testing methods of chemicals legislation (classification) are applicable also for wastes in general. However, due to the waste matrix, some modifications are necessary. There are no obligations to perform testing to determine if a waste is hazardous. The conventional method of “calculating” the hazardousness of a waste may be used to classify wastes for human health and/or environmental hazards. In many cases this will be difficult, as the composition of wastes is not fully known. The classification of wastes is not fully harmonized with chemicals legislation, because the rules, criteria and thresholds are different in some cases. This is currently under discussion.

1.3.3. COVERAGE OF WASTE - BORDERLINE BETWEEN REACH AND WASTE LEGISLATION

REACH makes reference to the definition of waste under the Waste Framework Directive. Wastes are generally excluded from the scope of REACH. Hence, “any substance or object which the holder discards or intends or is required to discard;”⁴ is a waste and may not be subject to any of the provisions of REACH.

This definition implies that the actor who handles a substance, mixture or object decides if it is a waste or not (intention or requirement to discard). Consequently, the status of a substance, mixture or object cannot be decided objectively, but must take into account its intended use (disposal or use as a product).

Where end-of-waste criteria exist, at the end of the waste phase and, consequently, the beginning of the “product phase” of a substance, waste treatment actors claiming that the criteria for a mixture or an object are fulfilled must provide necessary documentation.

(and ‘very toxic’), ‘harmful’, ‘corrosive’, ‘irritant’, ‘carcinogenic’, ‘toxic to reproduction’, ‘mutagenic’ and ‘eco-toxic’ is made on the basis of the criteria laid down by Annex VI, to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

2. Where relevant the limit values listed in Annex II and III to Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations shall apply.
- 4 Waste Framework Directive, Article 3.1; definition of „waste“

INFORMATION TOOLKIT ESTONIA

Competent authority	Environmental Board of Estonia: http://www.keskkonnaamet.ee/est
Legislation	Integrated Pollution Prevention and Control Act (consolidated text Dec 2006)
BREFs	Summaries in Estonian: http://www.ippc.envir.ee/english/bat.htm
Example permit application: format of permit application and permit	http://www.ippc.envir.ee/english/guidelines.htm
Issued permits	Information system about the issued permits: http://klis.envir.ee/klis

INFORMATION TOOLKIT LATVIA

Competent authority	State Environmental Service of Latvia http://vvd.gov.lv
Legislation	The Law On Pollution (15.03.2001) with amendments until 25.10.2007. Cabinet of Ministers Regulation No 1082 adopted on November 30, 2010 "Procedures by which Polluting Activities of Category A, B and C shall be Declared and Permits for the Performance of Category A and B Polluting Activities shall be Issued".
BREFs	Summary in Latvian: http://www.vpvb.gov.lv/lv/piesarnojums/lptp-vadlinijas
Example permit application: format of permit application and permit	http://www.varam.gov.lv/in_site/tools/download.php?file=7files/text/Likumd/piesarnojums/1082_2010.pdf
Issued permits	http://www.vpvb.gov.lv/lv/piesarnojums/a-b-atlaujas

INFORMATION TOOLKIT LITHUANIA

Competent authority	Environmental Protection Agency of Lithuania http://gamta.lt
Legislation	The Regulations for Issue, Update and Cancellation of Integrated Pollution Prevention and Control Permits approved by Order No D1-330 of the Minister of Environment of the Republic of Lithuania of 29 June 2005 (Official Gazette, 2005, No 103-3829; 2006, No 120-4571).
BREFs	Summaries in Lithuanian: http://gamta.lt/cms/index?rubricId=70160852-bcfc-4e18-881e-01868bf61adb
Example permit application: format of permit application and permit	http://gamta.lt/cms/index?rubricId=266d9067-c315-4045-a548-0150f9e9196a
Issued permits	Issued permits are kept in Regional Environmental Protection Departments, which should be contacted to get acquainted with specific permit.

INFORMATION TOOLKIT POLAND

Competent authority	Ministry of Environment, http://ippc.mos.gov.pl/ippc/?id=90
Legislation	http://ippc.mos.gov.pl/ippc/?id=98
BREFs	http://ippc.mos.gov.pl/ippc/?id=192
Example permit application: format of permit application and permit	http://ippc.mos.gov.pl/ippc/?id=156
Issued permits	Issued permits are kept with relevant local and regional authorities.

1.4. Directive on Integrated Pollution Prevention and Control / Industrial Emissions Directive in brief

1.4.1. GOALS

The Integrated Pollution Prevention and Control Directive - IPPC (2008/1/EC) requires EU Member States to regulate emissions to air, soil and water from certain industrial and agricultural installations on a local scale by permitting and enforcement. IPPC aims at prevention, reduction and elimination of pollution at source.

The IPPC-Directive applies only to large industries falling under six categories: energy, production and processing of metals, minerals, chemicals, waste management and 'other'. The 'other' group includes facilities operating in the areas of pulp and paper production, textile treatment, tanning, food production, and the intensive rearing of poultry and pigs. The total number of such installations across the EU is around 52,000.

The IPPC-Directive has been recast and several Directives have been merged into one, resulting in the Industrial Emissions Directive (IED). Thereby, also smaller installations are covered with special provisions⁵.

The IED integrates and replaces the following seven directives:

- 1) Large Combustion Plant Directive (LCPD);
- 2) Integrated Pollution Prevention and Control Directive (IPPC);
- 3) Waste Incineration Directive (WID);
- 4) Solvent Emissions Directive (SED);
- 5) Three directives on Titanium dioxide on (i) disposal (78/176/EEC), (ii) monitoring and surveillance (82/883/EEC) and (iii) programmes for the reduction of pollution (92/112/EEC).

Compared to the former directives, in particular the IPPC, the IED tightens (the procedures for setting) emission limit values (ELVs). Installations have a transitional period and will have to comply with the stricter values by 2016.

The IED also seeks to strengthen the concept of 'Best Available Techniques' (BAT) and to make the application of BAT more consistent between Member States, i.e. setting of permitting conditions will be based on EU-wide recommendations based on BAT. In addition, the IED introduces a number of mechanisms for Member States to check and enforce improved compliance, among others for emissions monitoring, reporting and for inspections.

⁵ In November 2005 the European Commission launched a review of European legislation on industrial emissions and on 17 December 2010 the new Directive on Industrial Emissions - IED (2010/75/EU) was published and came into force on 6 January 2011

1.4.2. KEY LEGAL INSTRUMENTS/ PRINCIPLES TO ACHIEVE THE GOALS

The IED implements a combined approach to achieve the goal of a high level of environmental protection.

- > **Permits.** Each covered facility must obtain a permit for operation (authorization to operate) which may contain certain conditions. Important elements of the permitting are:

Best Available Techniques. Permits are to reflect BAT. This means that in determining an installation's conditions of operation it is to be considered what are technically possible (BAT). Based on this, the local conditions, the economic and technical feasibility and the environmental situation (e.g. concentration of substances in water in relation to the EQS) permit conditions shall be defined. BAT reference documents (BREF) exist for the regulated sectors and can be found at <http://eippcb.jrc.es/reference/>.

Emission limit values (ELVs) in permits must be as a minimum compliant with those set out in other EU law. There are a number of such ELVs (e.g. in the Directives on titanium dioxide, waste incineration, urban waste water treatment). However, the ELVs in permits may be much stricter, if as a conclusion from BAT assessment lower values are regarded as feasible. Furthermore, local environmental conditions must also be taken into account and, for example if an EQS (according to the WFD) is not met, stricter ELVs should be set and/or other measures have to be defined.

Monitoring. Member States must ensure that permit conditions are complied with, and that operators regularly provide the competent authorities with results of release monitoring. Monitoring and reporting obligations of the operator should be set out in permits. Normally the concentrations of specified pollutants emitted from the installation and a range of other aspects of installation operation (e.g. safety reporting, waste arising, etc.) has to be monitored and reported. In some cases (e.g. for large installations or those of concern), there may also be a requirement to monitor the surrounding environment. The IED includes the requirement for periodic monitoring in relation to hazardous substances likely to be on the site having regard to the possibility of soil and groundwater contamination. Operators additionally must provide the authorities with the necessary access and assistance to enable inspections and other monitoring functions to be carried out.

- > **Reporting on emissions.** Data on emissions from IED-installations have to be reported annually and are stored in the European Pollutant Release and Transfer Register (E-PRTR) (<http://prtr.ec.europa.eu/>). It provides access to key environmental data from industrial facilities and replaces the previous European Pollutant Emission Register (EPER).
- > **Permit review.** The IED requires a periodic review of permits. The frequency is not defined, but a number of circumstances are given, which require a permit review (and possible revision). These include changes in the understanding of BAT, new EU-wide ELVs or the need of improved safety measures. Furthermore, reviews may be triggered by information on the need to change significant impacts via new ELVs or that there are new obligations, such as EQS, in EU law.
- > **Inspection and enforcement.** The IED requires Member States to produce **inspection plans** which should include information on installations and a general assessment of relevant significant environmental issues. Based on the plans, inspection programmes shall be developed systematically targeting environmental risks. Respective potential risks may include the levels and types of emissions, the sensitivity of the local environment and the risk of accidents. Routine inspection shall cover the full range of relevant environmental impacts of the installation and shall be sufficient to determine not only whether permit conditions are complied with, but also whether the permit conditions are effective. This indicates that inspectors should consider why certain permit conditions have been applied and whether these are delivering what they are aimed at delivering (e.g. objectives in the local environment).

1.5. REACH & the Classification, Labelling and Packaging Regulation in brief

1.5.1. OVERVIEW

REACH stands for Registration, Evaluation, Authorization and Restriction of Chemicals. The REACH Regulation No. 1907/2006 came into force on June 1, 2007 and led to a fundamental reform of European chemicals legislation.

With REACH some key principles are implemented in the manufacture, import and use of chemicals, namely:

- > **No data no market** – no substances may be placed on the market above 1 t/a by individual manufactures or importers unless a registration dossier with data on at least its uses and hazards is submitted to the European Chemicals Agency (registration);
- > **Industry is to prove safe use** – the burden of proof that the use of a substance is safe is placed on industry;
- > **All substances are treated equally** – the same requirements apply to all substances, regardless of whether or not they have been on the market for a long time or not;
- > **Responsibility for safe use is shared among industry** – the manufacturers and importers, via their registrations are responsible to identify the conditions of safe use. The users of a substance as such, in mixtures or in articles are responsible to implement the conditions of use⁶.

The Regulation on classification, labelling and packaging of substances and mixtures (CLP) entered into force on 20 January 2009. It aligns previous EU legislation on classification, labelling and packaging of chemicals to the GHS (Globally Harmonised System of Classification and Labelling of Chemicals).

Its main objectives are to facilitate international trade in chemicals and **to maintain the existing level of protection of human health and environment**. Classification and labelling is the system to identify the hazardous properties of chemicals and to inform users about them through standard symbols and phrases on the packaging labels⁷.

The deadline for substance classification according to the new rules of the regulation was 1 December 2010. For mixtures, the deadline is 1 June 2015. The CLP-Regulation will ultimately replace the current rules on classification, labelling and packaging of substances (Directive 67/548/EEC) and preparations (Directive 1999/45/EC) after this transitional period.

The classification of substances and mixtures may trigger obligations under other legislation, amongst others REACH and IED.

1.5.2. KEY LEGAL INSTRUMENTS/ PRINCIPLES TO ACHIEVE THE GOALS

Registration

6 If this is not the case or not possible, there are several options for the users of the substance, e.g. that the supplier is requested to change the conditions in his assessment, the user performs an own assessment or that he changes suppliers or substitutes.

7 This information should also be included in safety data sheets, if the substance or mixture is classified. Respective requirements are included in REACH.

Manufacturers and importers of substances as such or in mixtures manufactured or imported in amounts exceeding 1 t/a are **required to provide** a set of **data** on hazards, uses and under certain conditions also on exposures and risks in the registration dossier to the European Chemicals Agency (ECHA). The information is to be used to identify how a substance can be used safely along its entire life-cycle (operational conditions and risk management measures). The safe conditions of use are to be communicated along the supply chain and implemented by the downstream users of the substances as such, in mixtures or in articles.

The registration deadline depends on the quantity and the properties of the registered substances. REACH will necessitate the registration of around 30,000 chemical substances in the EU over a period of 11 years according to the following schedule:

REGISTRATION DEADLINE FOR SUBSTANCES (Amounts per manufacturer/importer)	
Quantities of 1,000 tonnes/year and above	
Carcinogens, mutagens and substances toxic to reproduction (CMR categories 1 and 2) above 1 tonne per year	30/11/2010
Substances classified as very toxic to aquatic organisms (R50/53) above 100 tonnes/year	
Quantities of 100-1,000 tonnes/year	31/05/2013
Quantities of 1-100 tonnes/year	31/05/2018

This registration obligation applies to substances as such and in mixtures. A special registration regime applies for substances in articles (e.g. manufactured goods such as cars, textiles, electronic chips). **Failure to register means that a substance cannot be manufactured or imported** (except for substances which are exempted and imported/produced below 1 t/a).

The registration dossier contains different information on the registered substance, among others:

- > Information on the identification of a substance and how to analyse it;
- > Information on the **properties and the classification as well as guidance on safe use**,
- > Information on the uses of a substance as such, in mixtures and/or in articles;
- > For substances in quantities of 10 t/a or more a **chemical safety report** must be submitted. It includes an assessment of the hazardous properties and **an assessment of whether the substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB)**. If the substance is classified as a PBT/vPvB, the chemical safety assessment must also include an assessment of exposures and risks from the use of the substance along the supply chain.

ECHA is required to check the completeness of each registration. The quality or adequacy of data or justifications submitted is to be checked for at least 5% of the submitted registration dossiers.

Information on the physical-chemical, toxic and ecotoxic properties of registered substances is accessible via ECHA Registered substances database <http://echa.europa.eu/information-on-chemicals/registered-substances>. The database can be searched by chemical name and imported/produced tonnage.

- > Information in the supply chain - Safety Data Sheet

REACH requires that registrants supply their customers with information needed to use chemicals safely. The primary tool for information transfer is **safety data sheet (SDS)**. **SDSs have to be provided for all classified substances and mixtures**. Due to information generation and risk assessment for the registration of new information that has and will become available which may change the classification, it will also provide advice on risk management measures in existing safety data sheets.

Where chemical safety assessments are performed relevant **exposure scenarios** need to be annexed to the safety data sheet and have thus to be passed down the supply chain. Exposure scenarios give specific information on how to use a substance or mixture safely, i.e. how humans and the environment can be protected from potential risks. As such, they can be considered as an important risk management instrument, providing a possible interlink between REACH and IED.

Evaluation

REACH includes three different evaluation processes, namely the compliance check, the examination of testing proposals and the substance evaluation.

- > The **dossier evaluation** consists of checking the compliance of registration dossiers with the REACH requirements, including assessing the quality and adequacy of submitted information.
- > **An evaluation of testing proposals** is done when registrants have proposed to conduct tests on vertebrate animals (substances registered in amounts exceeding 100 t/a) in order to fill information gaps⁸.
- > The **substance evaluation** is carried out by the Member States and aims to clarify if a substance constitutes a risk to human health or the environment at Community level. Evaluation is to be performed for prioritized substances based on respective criteria considering hazard and exposure information (risk based prioritisation). In 2012 the first so-called Community Rolling

⁸ The aim of this evaluation is to prevent unnecessary animal testing and therefore, ECHA invites third parties to submit scientifically valid information or studies addressing the substance and hazard endpoints in question that could be taken into account by ECHA in preparing its decision on the testing proposal.

Action Plan (CoRAP) was adopted, which sets out a list of substances to be evaluated between 2012 and 2014.

Authorisation

The aim of the authorisation procedure is to ensure that **substances of very high concern (SVHC) are replaced by suitable alternatives or that at least their risks are properly controlled by emission and exposure reduction technologies.**

The principle mechanism of the procedures is that the use of substances subject to authorisation is prohibited, unless an authorisation is granted for a specific use by the EU Commission to the applicants.

Only SVHC may be subject to authorisation. They are identified based on the following properties:

- > CMR substances, cat 1 and 2;
- > PBT and vPvB substances⁹;
- > Substances of equivalent concern with scientific evidence of probable serious effects, such as having **endocrine disrupting properties** or which do not fulfil the criteria in Annex XIII, but which are identified as causing serious and **irreversible effects to humans or the environment.**

The authorisation process consists of three steps: 1) Identification of substances as SVHC and as candidates for authorisation (candidate list), 2) substances are included in Annex XIV and 3) industry wanting to continue the use of the substances submits an authorisation application which is decided on by the EU Commission.

The identification of candidate substances is a formal process involving Member States, ECHA and if no direct agreement is reached, the ECHA Committees. Furthermore, stakeholders are involved via a consultation. At the end of a process a substance is placed on the "Candidate List".

The inclusion of a "candidate substance" on the list for substances subject to authorisation (Annex XIV) is im-

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- 9 [Persistent, bioaccumulative and toxic substances and very persistent and very bioaccumulative substances in accordance with criteria in Annex XIII of REACH.](#)

plemented via a regulation adopted by the Commission. The regulation is prepared based on a recommendation by ECHA with commenting by interested parties (public consultation) and Committees of ECHA.

Substances on the Authorisation List cannot be placed on the market or used after the so-called "sunset date", which is individually set for each substance in Annex XIV, unless an authorisation has been granted for a specific use, or the use has been exempted from authorisation.

The current Candidate list for authorisation contains 84 substances or substance groups (updated on 16.11.2012): http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

Among these substances several have PBT or vPvB properties and even more are reprotoxic, for example, Bis(tributyltin) oxide (TBTO), Bis (2-ethylhexyl)phthalate (DEHP), Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins), 5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene), which are of particular concern under water legislation.

The inclusion of **SVHCs on the Candidate List triggers** obligations to industry if they are present in articles in concentrations above 0.1% (w/w). Suppliers of such articles have to provide sufficient information to allow safe use of the article to their commercial customers and, upon request, to consumers within 45 days. Producers and importers of articles must notify ECHA if their article contains a substance on the Candidate List in concentrations above 0.1% (w/w), if the total amount exceeds 1 t/a in all their produced or imported articles.

Restrictions

Restrictions may be developed for substances for which it is demonstrated that they cause community wide risks for human health or the environment. Restrictions target specific uses or products the substances occur in. They can consist of a total ban of the manufacture and use of a certain substance or conditions limiting their uses. Restricted substances and the conditions of the restrictions are listed in the Annex XVII of REACH.

INFORMATION TOOLKIT

Competent authorities

European Chemicals Agency ECHA <http://echa.europa.eu/>
 Estonia: Health Board of Estonia: <http://www.terviseamet.ee/>
 Latvia: Latvian Environment, Geology and Meteorology Centre <http://www.lvgmc.lv>
 Lithuania: Environmental Protection Agency of Lithuania <http://gamta.lt>
 Poland: Bureau for Chemical Substances, www.chemikalia.gov.pl, www.reach.gov.pl

Registered substances

<http://apps.echa.europa.eu/registered/registered-sub.aspx>

Information on chemical properties of registered substances

<http://echa.europa.eu/information-on-chemicals/registered-substances>

Candidate list for authorisation

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

Authorisation list

http://echa.europa.eu/reach/authorisation_under_reach/authorisation_list_en.asp

2. Interlinks of and synergies between legal frameworks

The lifecycle of a substance is rather complex. The substance may be contained in various types of products and may be handled by many different actors. The end of its lifecycle may be reached through destruction or “final containment”, e.g. in a landfill.

However, to enable a structured overview of a substance’s lifecycle, a simplified model can be assumed:

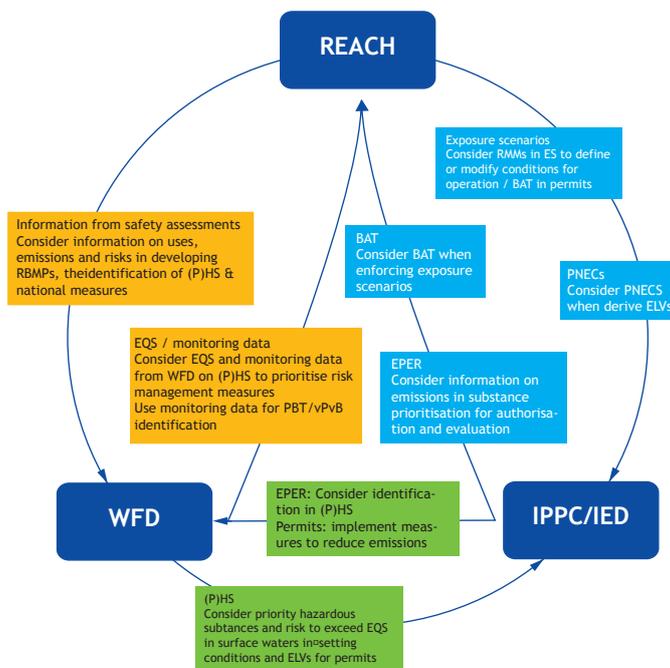
The lifecycle starts with the substance manufacture (manufacturing stage) and continues with a use to produce a mixture (formulation stage). Mixtures could be used by consumers or professional users and consumed,

e.g. shampoo or cleaning agents (use). They could also be used in the production of articles, e.g. inclusion of a lacquer onto a window (end-use). These articles, containing the substance, could be used again by consumers or commercial users (service life stage) until they reach the end of their service life (waste stage).

Substances could emit from all of these lifecycle stages and reach the human body or the environment.

Legislation aims to regulate the use and thereby the potential emissions of substances throughout this “lifecycle”. This is illustrated in a general scheme below.

Figure 3. Overview of interlinks between different EU legislation



The following table summarises the core characteristics of the above-described legislation.

	REACH	IPPC & IED	WFD / MSFD & EQS	Waste legislation*
Aim	<ul style="list-style-type: none"> > High level of protection of human health and the environment, while enhancing competitiveness and innovation of the EU industry > Generate information on hazards, exposures and risks in order to ensure that chemicals are manufactured and used safely in the EU 	<ul style="list-style-type: none"> > High level of protection of the environment taken as a whole > Integrated pollution prevention and control > Measures to prevent or reduce emissions to air, water and land, including waste measures 	<ul style="list-style-type: none"> > Maintain and improve quality of the aquatic environment (inland surface waters, transitional waters, coastal waters and groundwater) > Reduce or cease/phase out emissions, discharges and losses of priority substances 	<ul style="list-style-type: none"> > Ensure that waste prevented and treated in the most efficient way > Prevention of risks from the treatment of waste
Scope	<ul style="list-style-type: none"> > Manufacture, placing on the market and use of substances on their own, in mixtures or in articles 	<ul style="list-style-type: none"> > Industrial installations with significant pollution potential in specified sectors listed in the Annexes with a significant size 	<ul style="list-style-type: none"> > Water bodies 	<ul style="list-style-type: none"> > Wastes as defined in the framework legislation
Approach	<ul style="list-style-type: none"> > Focuses on substances > Industry provides information on hazard, exposures and control of risks during registration > Specific procedures exist to manage substances of highest concern > Regulates from the perspective of substances 	<ul style="list-style-type: none"> > Focuses on techniques to prevent/control emissions (BAT) > Industry applies for site-specific permit > Regulates from the perspective of installations 	<ul style="list-style-type: none"> > Focuses on prioritized substances > Establishes EQS for (prioritized) substances and requires setting national EQS for additional substances > Regulates from the perspective of the environment 	<ul style="list-style-type: none"> > Focus on wastes > Defines types of wastes and treatment technologies, requires management, communication and documentation systems > Regulates from the perspective of the environment and resource efficiency
Environmental media	<ul style="list-style-type: none"> > water, air, soil, sediments, biota, workers, consumers 	<ul style="list-style-type: none"> > water, air, soil 	<ul style="list-style-type: none"> > water, sediments, biota 	<ul style="list-style-type: none"> > water, air, soil
Responsible parties	<ul style="list-style-type: none"> > Manufacturers, importers and downstream users of substances > Producers and importers of articles containing substances 	<ul style="list-style-type: none"> > Manufacturers of substance > Users of substances as such and in mixtures to produce mixtures and other goods > Operators of waste treatment and energy producing installations 	<ul style="list-style-type: none"> > Member States' Competent authorities (point and diffuse sources of prioritized substances are indirectly addressed). 	<ul style="list-style-type: none"> > Operators of waste treatment installations > Industrial actors generating wastes
Level of harmonisation	<ul style="list-style-type: none"> > Registration, restrictions, authorization applies throughout the EU 	<ul style="list-style-type: none"> > When granting permit a CA has a possibility to deviate from BAT in justified cases 	<ul style="list-style-type: none"> > Same EQS for prioritized substances throughout the EU; for other pollutants differences possible at national or river basin level > At national or river basin level a Member State may establish stricter EQS for prioritized substances 	<ul style="list-style-type: none"> > Directives allow national transposition

* Waste legislation is included in this table, as it also contains interlinks with the other legislation as is explained subsequently.

The different instruments and timetables of the four pieces of legislation are illustrated for the phase-out / control of Di(2-ethylhexyl) phthalate (DEHP) (CAS No: 117-81-7).

Di(2-ethylhexyl) phthalate (DEHP) (CAS No: 117-81-7)			
REACH & CLP	IPPC & IED	WFD & EQS	Waste
INFORMATION ON CHEMICALS, RESTRICTIONS ON USE	USE OF CHEMICALS & CONTROL OF CHEMICALS EMISSIONS TO WATER THROUGH PERMIT	GOOD CHEMICAL STATUS (concentration of prioritized chemicals <EQS) by 12/2015	Safe waste treatment and disposal
Registration: no use without pre-registration/registration Classification: Repr. Cat. 2; R60-61 (May impair fertility; May cause harm to the unborn child) Authorisation: no use after 21 Feb 2015 (due to the toxicity to reproduction) Restrictions: no use as substances or in mixtures in concentrations greater than 0,1 % by weight in plasticised material used for toys and childcare articles.	Has to be monitored / reported because DEHP is on Annex X of the WFD	Emissions to be reduced by 2020 AA-EQS for waters - 1,3 µg/l Monitoring in the surface water: once-a-month	No specific provisions

There are also other links between this legislation, which are described below.

2.1. Key interlinks Between Water Framework Directive And Industrial Emissions Directive

The WFD and the IED are complementary. Permitting and enforcement will become more and more important for ensuring the realisation of WFD objectives for water quality.

The objectives and processes of WFD may affect the operational and monitoring conditions to be applied in permits and inform enforcement activity and permit review. The decisions made in implementing the IED are also critical in a number of aspects of the implementation of the WFD, such as the nature of programmes of measures, monitoring, inventories, etc. The key interlinks are described below.

Formal interlinks:

- > Substances in Annex X of the WFD must be reported under IED → WFD triggers requirements under IED with regard to monitoring;

- > IED permits have to consider the EQS in setting ELVs → authorities need to take EQS and the local environmental conditions into account in order to calculate what ELVs should be applied to an installation.

Possible synergies:

IED-permitting should take into account not only Annex X substances under WFD, but also national priorities;

- > If there are problems meeting EQS under the WFD, the permits under IED are an instrument to reduce emissions (stricter requirements to installations). This means that national particularities are taken into account and inspectors are better able to justify their permits. In some cases this might mean setting lower ELVs in order to reach EQS.

2.2. Key interlinks between Water Framework Directive and REACH

REACH provides opportunities for the enforcement of the WFD. Authorities dealing with obligations of the WFD can benefit from the risk management measures recommended under REACH, although the information cannot be used directly. River basin managers can benefit from safety information provided in exposure scenarios communicated with a substance to identify options to reduce emissions to water by appropriate end-of-pipe technologies.

Formalized and informal interlinks between REACH and WFD are described in more detail below.

Formal interlinks

- > REACH makes direct reference to the Water Framework Directive as it states that it shall apply without prejudice to 'environmental legislation, including Directive 2000/60/EC. This means that stricter con-

ditions or requirements than in REACH can be set up e.g. in specific permits for water discharge (if these exist in national transpositions of the WFD).

- > In selecting priority hazardous substances under the WFD, the Commission is required to take into account the selection of substances of concern under other relevant EU legislation. The selection of SVHC under REACH is therefore directly relevant, including the respective scientific dossiers (so called Annex XV-Dossier) prepared as the basis for the selection of priority hazardous substances under the WFD.
- > If a substance's EQS under the WFD is not met and the substance is also subject to authorisation under REACH, this may be a reason to review any granted authorisations¹⁰. The review may result in stricter authorisation conditions (or that no further authorisation is granted) if necessary to meet the EQS.
- > Risks for WFD priority substances may be omitted in an authorisation application. However good justification is needed demonstrating that discharges are subject to control measures under the WFD. This avoids double regulation, as the applicant for an authorisation may include reference to an existing permit which already controls the risks.

Informal links and possible synergies:

- > Many of the substances covered by the WFD and the EQS Directive are also regulated by REACH through authorisation or restriction. The WFD definition of hazardous substances is close to the criteria for substances of very high concern set by REACH.

10 Up to now, no authorisations have been granted. It is therefore unclear, if conditions may be included that refer to particular geographic locations or that refer to discharges to particular river basins.

Thus restriction and authorization under REACH can be used as a control measure to fulfil the objectives of the WFD related to priority substances.

- > REACH considers endocrine disruption as an equivalent level of concern as e.g. PBT/vPvBs (Article 57.f). Some endocrine disrupters, which also have other hazardous properties, are priority hazardous substances under the WFD. The derivation of EQS takes account of possible endocrine disrupting properties.
- > Under the WFD, Member States are required to monitor surface and groundwater as well as point sources. This monitoring information can be used for REACH risk assessments, e.g. in the context of substance evaluation. It can indicate specific concerns and thereby enhance prioritisation under REACH for further risk management procedures, such as restrictions or authorizations.
- > Data used to generate Predicted No Effect Concentrations¹¹ (PNECs) under REACH are a valuable starting point for the definition of new or the revision of existing EQS. However, the EQS setting is based on much more data, such as on short and long-term effects, and a greater emphasis is placed on risks from long-term or continuous exposure.
- > When a REACH authorisation concerns a substance considered as a priority hazardous substance under the WFD, the authorisation under REACH should not be granted if the use could lead to a breach of the legislation on water, as discharges, emissions and losses of these substances should cease or be phased out pursuant to the WFD.

11 PNECs are threshold values which describe the concentration of a substance in water, sediment, biota, soil or air below which it is expected that no adverse effects would occur.

2.3. Key interlinks between the Marine Strategy Framework Directive, the Water Framework Directive and REACH

There are several links between the WFD and the MSFD. Only a few of these are mentioned here.

Both MSFD and WFD take the concentration and effect of hazardous substances into account. Within the WFD, chemical status is divided into two classes: "good" and "not good", whereas ecological status is divided into five classes: "high", "good", "moderate", "poor" and "bad". Good Environmental Status (GES) within the MSFD is divided into two classes "good" and "not good" and refers to a set of 11 descriptors. Good chemical status should be

achieved by the year 2015 according to the WFD, whereas GES should be achieved by 2020 according to the MSFD.

Links and possible synergies

- > There are links concerning the definition of pollutants, hazardous substances and priority substances under MSFD and WFD. Descriptors of good environmental status 8 and 9 under MSFD are relevant as they relate to 'contaminants'. 'Contaminants' as such are not defined by the MSFD. However, the Commission Decision 2010/477/EU "Criteria and

methodological standards on good environmental status of marine waters” indicates what is considered as a contaminant under Descriptor 8. It defines contaminants as per the definition set by the WFD. Similarly, the Decision on criteria and methodological standards on good environmental status refers to substances for which an EQS has been set under the WFD or those listed as priority substances under Annex X of the WFD.

- > There are possible synergies through the use of data from REACH risk assessments carried out for registration, Annex XV dossiers and substance evaluations when defining good environmental status of marine waters, in particular with regard to descriptors related to contaminants. Good environmental status is established by each Member State and taking into account assessments carried out under other EU legislation. This means that e.g. EQS from the WFD and available PNEC values from REACH should

be considered. The environmental status of marine waters is not good when good chemical status under WFD is not achieved.

- > There is synergy between REACH and the MSFD, as relevant EU legislation, including REACH, is considered when selecting these contaminants under Descriptor 8 (Concentrations of contaminants are at levels not giving rise to pollution effects). For example, Descriptor 8 lists contaminants, the total release of which may entail significant risks to the marine environment, and information from the REACH registration process that would be useful when identifying such contaminants.
- > MSFD, similar to the WFD, can provide feedback on monitored levels of hazardous substances in the aquatic environment. These data can be used by industry in the registration of substances as well as by authorities in priority setting in actions pertaining to the REACH authorisation and restriction process.

2.4. Key interlinks between REACH and the Industrial Emissions Directive

Operators of installations covered by the IED must consider the environmental and safety implications of the operation of their installations, implement the conditions of their permits and comply with any emission limit values they have been given. They may be manufacturers and/or downstream users of substances covered by REACH. Therefore, they are also required to consider the recommendations on the safety of their substances in exposure scenarios and to apply appropriate risk management measures.

Formal links:

- > Risks for substances in IED need not be considered in an authorization application, but adequate justification must be provided why risks need not to be considered.

Informal links for authorities:

- > PNECs may be used to identify if emissions are critical or not; they may support setting of emission limit values.

- > Exposure scenarios may be used to determine ELVs.
- > Exposure scenarios may be used to prescribe risk management measures.
- > REACH information may be used to further develop BREFs and integrate the substance perspective and risk considerations into BAT development.
- > BREFs could be used for substance evaluations and checking registration dossiers (intermediates) and authorization applications.

In addition, industry can use BREFs to derive exposure scenarios for registration or to describe the conditions of use and risk management measures in a certain sector. However, due to the lack of substance specific information in most BREFs, basic information for emission estimation and/or the identification of efficiencies of risk management measures are missing.

2.5. Interlinks between chemicals legislation and waste legislation

2.5.1. RECOVERED SUBSTANCES

Waste treatment may result in the recovery of substances as such, in mixtures or in articles. In these cases, the

waste treatment operation is regarded as a manufacturing process according to REACH, because substances are extracted from a raw material (waste). Consequently, the substances recovered as such or in mixtures have to be

registered under REACH by the waste treatment operator (manufacturer), if the annual amount exceeds 1 t/a¹².

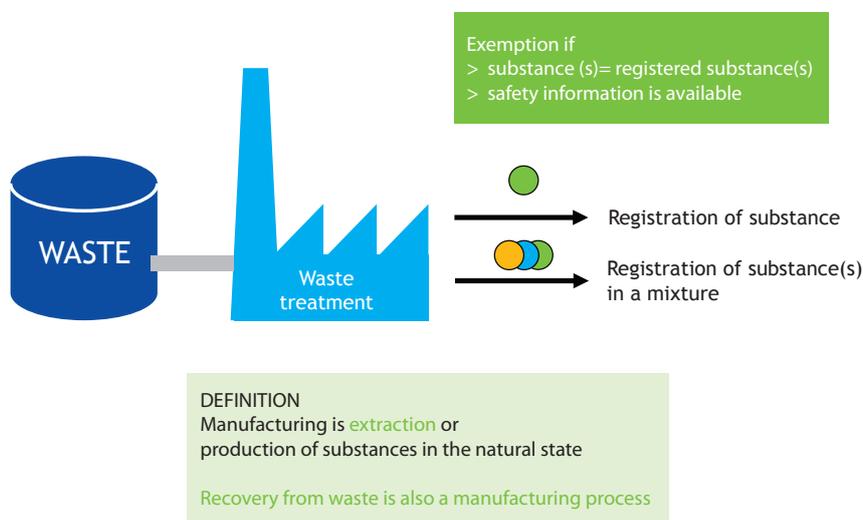
A waste treatment operator may claim an exemption from the registration if he can demonstrate that the sub-

12 The same registration deadlines apply for recovered substances as for substances manufactured from other raw materials than waste. If no pre-registration was made for these substances, the marketing is not in conformity with REACH, because only pre-registered (existing) substances benefit from the phase-in scheme with the staggered registration deadlines.

stance has been registered already (REACH Art. 2.7(d)). For this, he has to show that the recovered substance is identical to a registered one. In addition, operators must have information available at the site, which must be forwarded with the substance; i.e. safety data sheets need to be available for the recovered substance, if it is hazardous.

A recovered waste does not automatically cease to be waste when it is being pre-registered according to REACH (Figure 4). Whether it still is waste or not is judged from the perspective of the waste legislation.

Figure 4. Substance manufacture - extraction from waste.



If substances are recovered as articles from wastes, registration is not required. This corresponds to the regulatory status of articles under REACH. However, if the recovered articles contain substances of very high concern (SVHC) which are included in the candidate list for authorization, information according to REACH Article 33 has to be provided to the recipient of the article, if the concentration exceeds 0.1%. As a minimum, the name of that substance must be forwarded.

2.5.2. WASTE INFORMATION UNDER REACH

Although wastes are exempted from the scope of REACH, the waste stage of a substance must be considered in the chemical safety assessment by registrants and may be considered in substance evaluations and restriction proposals by authorities, as well as in the context of the authorization procedure.

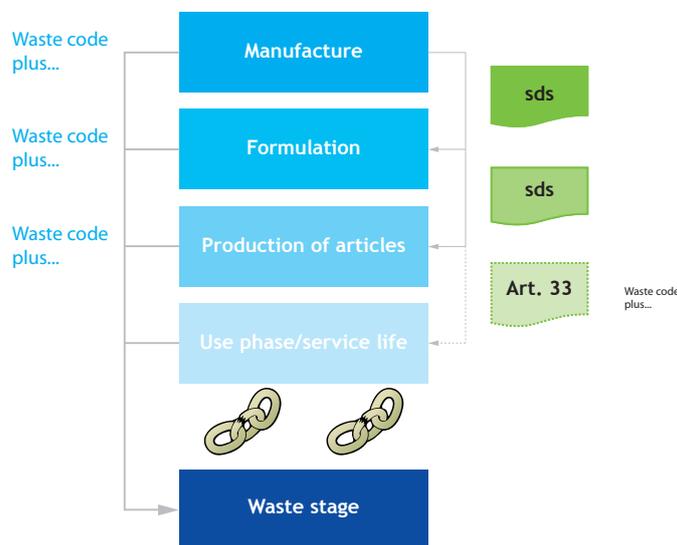
The assessment of chemical safety for substances registered in amounts exceeding 10 t/a and which are either classified as or are PBTs/vPvBs must identify the amounts and types of wastes generated by all supply chain actors (production wastes from manufacturing, formulation and article production, if applicable) and also from the end-of-life articles which are either subject to recycling, recovery or disposal operations.

The registrants are to generate this information in their assessments and communicate it to their customers via the safety data sheet. The information should, as a minimum, indicate the possible waste codes of the wastes generated along the supply chains and any treatment operation which is not suitable for a particular waste due to specific risks (e.g. halogenated organic substances may give rise to dioxin formation). This information should be forwarded also by the formulator with his safety data sheet, if the mixture he produces is dangerous. The communication under REACH is limited to SVHC when substances or mixtures are incorporated into articles; hence here information on hazardous substances is

lost. As most articles are disposed of via waste collection systems, no information transfer from the “last owners of articles” to the waste treatment operators takes

place. Hence, the information generated under REACH does not support the waste treatment operators.

Figure 5. Communication on hazardous substances in waste under chemicals and waste legislation



This situation is unsatisfactory, because on the one hand, registrants are obliged to make an assessment and communicate risk information on waste, but it does not reach the actors, which actually handle the waste at the end of the articles' service life (information flow on the right side of the figure). Only for production wastes, information is provided under the waste legislation (left side of the figure). Here, an important interlink is missing at the legislation level which should eventually be provided in order to improve the risk management at the waste treatment operation by obtaining more information on how to:

- > safely handle wastes (workers protection);
- > actually destroy hazardous substances and prevent their release to the environment ;
- > separate hazardous substances from wastes that should be recovered or reused.

2.5.3. DIRECT RELATION BETWEEN CHEMICALS AND WASTE

Although it may appear rather obvious, an important relation between hazardous substances management and waste is that the amount and type of hazardous substances used in the production of mixtures and articles have a direct impact on the amount and hazardousness

of wastes. Since the disposal of waste is an environmentally and economically relevant issue for companies, this link is pointed out here, as it can be an important argument supporting substitution, legal compliance and cost-efficient production.

2.5.4. INTERLINKS AT THE AUTHORITY LEVEL

There are several aspects on how authorities implementing and enforcing REACH and authorities implementing and enforcing waste legislation could cooperate and merge activities in order to benefit from information, procedures and competences of the other legal area, such as:

- > Waste authorities could use information in safety data sheets to check, whether or not companies correctly dispose of their wastes;
- > Waste and chemicals authorities could discuss and share views on the status of substances, mixtures and objects as “products” falling under REACH or as wastes being regulated under the waste regime;
- > Waste authorities could cooperate with chemicals authorities to check, whether or not an exemption from REACH has been rightly claimed (identity of the recovered substance and availability of safety data sheets);

-
- > Chemicals authorities could learn from waste authorities about the typical composition and origin of materials in recycled materials and derive conclusions on whether or not hazard communication is necessary;
 - > Information from the data base of registered substances could be used by waste authorities to check the correct assignment of waste codes.
- Information sources**
- > EU Waste legislation
<http://ec.europa.eu/environment/waste/legislation/index.htm>
 - > REACH guidance on waste and recovered substances
http://echa.europa.eu/documents/10162/13632/waste_recovered_en.pdf
 - > REACH guidance on chemical safety assessment of the waste stage
http://echa.europa.eu/documents/10162/13632/r18_v2_final_en.pdf
 - > End-of-waste criteria
http://ec.europa.eu/environment/waste/framework/end_of_waste.htm

3. Recommendations on first steps

As described in the previous chapters, all four legal areas - IED, WFD/MFSD, waste legislation and REACH are very complex and specific in their focus, but also with many linkages. Furthermore, their implementation and enforcement involve many institutions from different administrative levels (EU, national, regional, local) each with their own responsibilities. Therefore, the implementation of these frameworks brings with it many challenges both to authorities, as well as industry and requires good understanding of the principles of all those frameworks and even more importantly, good co-

operation and information exchange among the authorities and other stakeholders. Efficient environmental protection is only possible when industry and wastewater treatment plants and permitting, controlling and monitoring organisations are involved!

This chapter is intended to provide suggestions regarding how the four frameworks could be implemented in a more efficient and effective manner, what information is important to exchange and what could be the first steps to achieve this in the long term.

3.1. How to access and use information generated by REACH?

The information generated by REACH through registration is gathered at the EU level by ECHA. Part of this information is accessible only by MS competent authori-

ties, but the majority of information is publically available. The following table summarizes information, which could be relevant for environmental authorities.

Type of information	Access	Link	Information included
Registered substances	public	http://apps.echa.europa.eu/registered/registered-sub.aspx http://www.echemportal.org/	EC/CAS No., substance name, type of registration, availability of dossier.
Information on chemical properties of registered substances	public	http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp	Classification and labelling of substances, properties (physical-chemical properties, ecotoxicity, environmental fate and behaviour, toxicity), the result of each toxicological and ecotoxicological study, any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC), the guidance on safe use, analytical methods if requested in accordance with annexes IX or X of REACH which make it possible to detect a hazardous substance when discharged into the environment as well as to determine the direct exposure of humans.
Candidate list for authorisation	public	http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp	EC/CAS No., substance name, reason for inclusion, supporting documentation on substance.
Authorisation list	public	http://echa.europa.eu/reach/authorisation_under_reach/authorisation_list_en.asp	EC/CAS No., substance name, latest application date for authorization, sunset date.
Existing restrictions	public	http://echa.europa.eu/reach/restriction/existing_restriction_en.asp	EC/CAS No., substance name, conditions of restrictions.

The following are examples of how REACH information could be useful (information only partly accessible to Member States via the secured access ECHA database):

- > to search for manufacturers/importers of a specific substance that is of environmental concern, for example based on results of environmental monitoring;
- > to find extensive information on the properties of any specific substance(s), e.g. PNECs;
- > to verify that companies comply with REACH/CLP submission obligations;
- > to check if the information submitted for substance manufacturing corresponds with the situation on-site;
- > to check if the contents of the Safety Data Sheet are in line with information in the registration dossiers;
- > to check how the substance is used (it should be according to the intended uses indicated in the registration and also indicated in the safety data sheet);
- > to check if authorisation is applied for a specific substance of concern, etc. (applicants should have an authorisation number if a decision has not yet been taken; otherwise a number is to be placed in the SDS).

3.2. How to make permits “WFD proof”?

Currently, most of the permits issued focus on being “IED proof”, i.e. compliant with the IED. However, it is important to ensure that a permit is robust with regard to legal obligations in general, and that from a holistic legal and environmental point of view it is unacceptable if an installation receives a permit for operation although it breaches other legal requirements. This means that compliance with (other) legislation should be a precondition for any permit.

In order to make a permit “WFD proof”, i.e. compliant with the requirements of WFD/MFSD it is necessary to know whether the installation may impact surface or groundwater. Minimum requirements for a permit to be “WFD proof” are:

- a) there is no significant impact on the status of surface and groundwater;
- b) discharges to surface water and groundwater are strictly controlled and the levels of pollutants do not exceed the EQS as set out in the WFD/MSFD.

Additionally, other conditions in the permit need to be consistent, for example, measures set out in the RBMPs and monitoring obligations.

Therefore, when issuing permits specialists should take the following steps as a minimum:

- 1) Seek information on the chemical properties of specific pollutants discharged from an installation that are possibly relevant for the water body

concerned, e.g. derived PNECs, available exposure scenarios etc;

- 2) Access information on any concerns regarding individual EQS (water, sediments or biota) in the relevant water body, i.e. if any breaches of EQS;
- 3) Verify whether the discharges from the particular installation have a potential to influence the status of the water body (PNECs may be used to identify if emissions are critical);
- 4) Decide what are the appropriate measures to address in the permit conditions (exposure scenarios can be used to determine how emissions can be reduced; if the application of BAT is not sufficient, additional measures can be mandatory such as techniques stricter than BAT).

For example, a permit for an installation releasing a substance with an EQS under the WFD should ensure by its emission limit value, that the surface water concentration of those substances does not exceed the EQS. Hence, a risk assessment should be carried out to identify appropriate ELVs.

Furthermore, supervision and inspection authorities should ensure not only that specific permit conditions are complied with (basic inspection), but should also examine if the predicted consequences for EQS are being met. Results of inspections should be communicated to permitting authorities (for potential permit review) and water managers (e.g. for review of mixing zones).

3.3. How to make permits “REACH proof”?

The minimum to consider regarding compatibility with REACH when issuing permits is to ensure that the operator is in compliance with basic obligations:

- 1) Only **pre-registered** and/or **registered** substances can be used in the installation or substances, which are exempted from registration;

- 2) The installation should follow the **use restrictions**. Therefore, before issuing a permit the respective authorities (e.g. market surveillance) should be consulted and/or documentation on REACH compliance should be requested from the installation;
- 3) ECHA should inform the permitting authorities of any downstream user notifying the use of a substance under authorization. Such notifications should have a higher priority when carrying out regular inspections.

3.4. How to get most from monitoring data?

Both IED and WFD/MSFD include requirements for monitoring - of a process, discharges, water quality, biota, etc. In some cases the monitoring requirements are precise - IED-operators should monitor substances for which they have permit conditions; under the WFD monitoring should cover substances of concern and, additionally, more general monitoring of the water bodies is requested.

Of course, the type and frequency of monitoring under one regime may, or may not, be suitable for use within the monitoring/analytical processes of another. Therefore, care has to be taken simply to ensure that monitoring results can be integrated between regimes. The challenge for competent authorities is, therefore, to ensure that monitoring information is made readily available across environmental management regimes and is in a form to maximize its value.

Therefore, permitting and water authorities should discuss and exchange information on monitoring procedures and results:

- 1) Monitoring of IED installations provides important information on pressures on water bodies and water specialists should seek access to the results of such monitoring;

- 2) Where there is concern over the activity of an IED-installation, water specialists should discuss with the IED-permitting authority the possibility for the installation operator to fund and undertake monitoring on the local environment to investigate impacts of the installation;
- 3) Where there is concern over the breaching of EQS, operators/permitting authorities need to determine whether monitoring information, modelling analysis, etc., is available to examine the relationship between installation activity and an EQS and whether additional analysis needs to be undertaken;
- 4) In examining the results of monitoring, water managers should be ready to communicate to IED enforcement authorities any cases where the emissions of an IED-installation have unexpected consequences for water bodies; this may be due to non-compliant behaviour (which requires inspection) or due to an unforeseen behaviour of pollutants, etc., which might require a re-examination of operations and permit conditions.

3.5. What are the next steps?

- > Build a national working group with the REACH competent authorities, permitting authorities and authorities responsible for water and waste legislation to discuss interlinks between legislation. Quite often different institutions/departments are responsible for implementation of the mentioned legal acts. Information exchange is needed to successfully manage these interlinks.
- > Establish an agreement on regular experience exchange. This can be done in the frame of existing or new working groups.
- > Discuss between responsible authorities which substances are problematic and why. It is important to define which substances out of all of those which

are listed in different legal frameworks can be considered as national priorities. The evaluation can be based on monitoring data, scientific studies, results from research projects, national implementation plans and other sources considered to be reliable.

- > Organize training sessions where inspectors inform each other about what they do. Increasingly, senior employees/inspectors who are regularly participating in national working groups are becoming more aware of recent legal developments and national plans. This, accompanied by practical working experience, is a valuable source of information which does not require external speakers for trainings, big financial resources, etc.

Estonia	Baltic Environmental Forum Estonia www.bef.ee
Latvia	Baltic Environmental Forum Latvia www.bef.lv
Lithuania	Baltic Environmental Forum Lithuania www.bef.lt
Poland	Regional Environmental Center for Central and Eastern Europe Country office Poland www.rec.org



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