4FUN

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1 Introduction

1.1 General context

The Risk Analysis involves three functionally separated components:

- risk assessment,
- risk management,
- risk communication (Houghton et al., 2008).

The process of risk assessment has been defined by the Codex Alimentarius Commission as a scientifically based process, consisting of:

i. hazard identification;
ii. hazard characterisation (e.g. dose (concentration) - response (effect) assessment);
iii. exposure assessment;
iv. risk characterisation (Houghton et al,. 2008).

Risk assessment shall be carried out for the three inland environmental compartments, i.e. aquatic environment, terrestrial environment and air, and for the marine environment (EC, 2003).

Risk management is defined as the process of weighing policy alternatives that emerge as a consequence of the results of risk assessment, as well as selecting and implementing appropriate control options, including regulatory measures. Risk management is always based on best available scientific knowledge but also takes into account social, political and legal considerations. In the absence of full scientific certainty the precautionary principle is applied.

Risk communication is described as the interactive exchange of information and opinions concerning risk and risk management among risk assessors, risk managers, consumers and other interested parties (Houghton et al., 2008).

The essential elements and principles for successful risk assessment, risk management and risk communication are similar across disciplines (human and environmental), product categories, and national boundaries (Figure 1) (HEROIC, 2012).

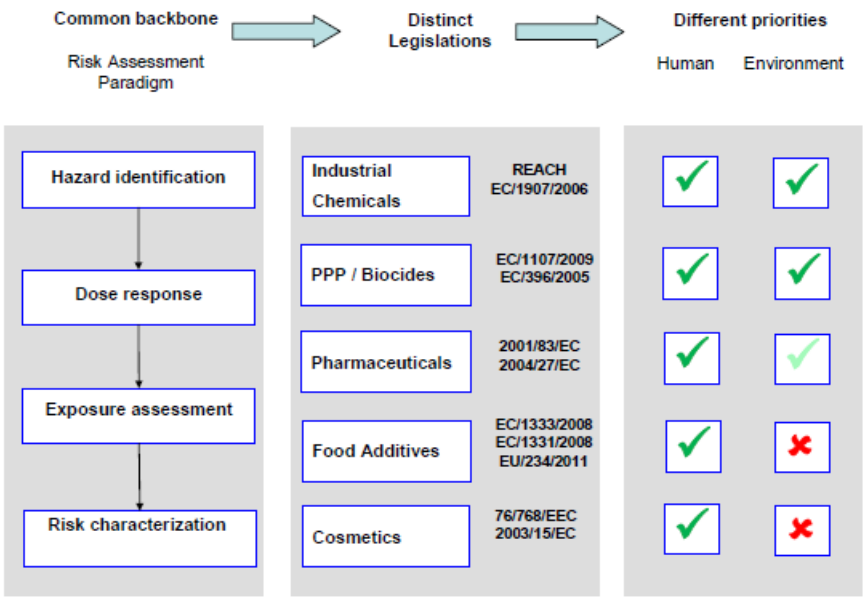

Figure 1 – Commonalities and differences in the regulatory systems.

In the European Union, the Commission defines the mandates of the different regulatory bodies. According to their mandates, the regulatory bodies focus on distinct areas and product categories. For each product category, distinct pieces of legislation regulate product authorization. Each regulatory body uses a risk assessment framework to inform regulatory

decisions. All frameworks foster collaboration and coordination among the regulatory bodies and provide guidance on how to solve disagreement within and between regulatory bodies. Furthermore, all frameworks aim to transparency through the involvement of the relevant stakeholders.
In the past, the framework in which the practice of Risk Analysis has been included has assumed that risk communication is shaped by and results from risk management, which, in turn, is informed by the outcome of risk assessment (e.g. Fischer et al., 2005). More recent frameworks have assumed some integration among the three elements of Risk Analysis (for example, see FAO/WHO, 1998) (Houghton et al., 2008). These recent significant changes, which have mainly occurred in terms of legislative frameworks and institutional structures, lead to public or stakeholder involvement and engagement. On the one hand, this means to achieve improvement in risk analysis; on the other hand incorporating stakeholders at various stages of the risk analysis process presents a considerable challenge (Houghton et al., 2008). In this context new needs arise to connect different stakeholders, and to improve communication among regulators, policy makers, scientific community, and consultancy.

The development of the MERLIN-Expo tool within the 4FUN project for human exposure assessment to chemicals will have an impact on several sectorial policies dealing with chemicals' management.
Therefore, it was decided to establish an observatory in order to raise awareness on the policy developments on risk assessment and management of chemicals in Europe and to build a strong connection among stakeholders.
Aims, description and future developments of the observatory will be described in the following paragraphs.

1.2 Aims of the '4FUN Observatory'

The '4FUN Observatory' mainly aims to regularly monitor information on European legislation and policies related to risk assessment and risk management of chemicals and to disseminate this information in an easily comprehensible way.
Moreover, the activities carried out to set up and maintain the '4FUN Observatory' will be useful to meet broader objectives; in particular:

- to guarantee that the development and implementation of MERLIN-Expo tool is policy and SME driven and respond to the latest policy developments;
- to develop a stronger connection between the political level (e.g. policy makers, regulators), the research sector, and consultancy SMEs;
- to raise awareness on the policy developments in Europe among all stakeholders.

Therefore, the '4FUN Observatory' will observe and collect any updates and news on a regular basis throughout the project duration in order to answer specific needs of different stakeholder groups (e.g. information on new laws, development plans, policy programmes, standard requirements and policy gaps on a European level). At the end of the project its value and efficacy will be assessed for the future use.
Different steps were identified, and followed, in order to set up the '4FUN Observatory':

1. identify the EU authorities/agencies responsible for risk evaluation of chemicals, including exposure;
2. identify the relevant legislation/guidelines about risk evaluation of chemicals, including exposure;
3. select and summarize information on the European legislation and policies, and prepare the information to be disseminated in an easily comprehensible way;
4. structure the page '4FUN Observatory' for the 4FUN website;
5. identify the European exposure and risk managers in order to create contact between them and the 4FUN project;
6. keep the information updated on the 4FUN website until the end of the project.

2 Identification of EU authorities/agencies responsible for risk evaluation of chemicals, including exposure

There are more than 30 agencies in Europe related to chemical risk evaluation. These agencies have got an important role in implementing EU policies, especially connected to technical, scientific, operational and/or regulatory tasks.

In order to select EU authorities/agencies responsible for risk evaluation, all relevant EU authorities/agencies were identified, and a research on their websites was made to verify their relevance according to the aims of the '4FUN Observatory'.

1) European Agency for Safety and Health at Work (EU-OSHA)

The European Agency for Safety and Health at Work (EU-OSHA) is committed to improve working conditions in Europe, promoting risk prevention at work. EU-OSHA raises awareness and disseminates information on the importance of workers' health and safety. Furthermore, it identifies and assesses new and emerging risks at work, and mainstreams occupational safety and health into other policy areas, such as education, public health, and research. More information can be found at https://osha.europa.eu/en.

Human exposure to chemicals may also occur at work, and therefore the MERLIN-Expo tool could be used to assess this kind of exposure too. For this reason, EU-OSHA website was considered to be interesting. In fact a link between EU-OSHA and the 4FUN project could be useful to obtain information on relevant legislation in this field.

2) European Centre for Disease Prevention and Control (ECDC)

The Centre for Disease Prevention and Control (ECDC) is a European agency with the aim to strengthen Europe defenses against infectious diseases. The mission of ECDC is to identify, assess and communicate current and emerging threats to human health posed by infectious disease. More information can be found on the ECDC website at http://www.ecdc.europa.eu/.

The aim of the 4FUN European Observatory is not strictly connected to this topic. Therefore, the ECDC was not taken into consideration any further.

3) European Chemicals Agency (ECHA)

The European Chemicals Agency (ECHA) works on implementing the EU chemical legislation for the benefit of human health and the environment. ECHA helps companies to comply with the legislation, advances the safe use of chemicals, provides information on chemicals and addresses chemicals of concern. More information can be found on the following website, at: http://echa.europa.eu/.

The safety of chemicals is the mission of ECHA, therefore this agency was considered relevant for the aims of the 4FUN European Observatory, not only for gathering information on relevant legislation, but also for building a link between the agency and the 4FUN project.

4) European Environment Agency (EEA)

The European Environment Agency (EEA) provides independent information on the environment, being a major information source for those involved in developing, adopting, implementing and evaluating environmental policy, and also the general public. More information can be found on the EEA website at http://www.eea.europa.eu/.

EEA's mandate is to help the Community and member countries to make informed decisions about improving the environment, integrating environmental considerations

into economic policies, and moving towards sustainability, and to coordinate the European environment information and observation network. Therefore, EEA resulted to be significant for the aim of 4 FUN Observatory, both for searching legislation, and for creating a contact between the agency and the 4FUN project.

5) European Food Fisheries Control Agency (EFCA)

The European Fisheries Control Agency (EFCA) is an EU body established to organise operational coordination of fisheries control and inspection activities by the Member States and to assist them to cooperate so as to comply with the rules of the Common EU Fisheries Policy, in order to ensure its effective and uniform application. More information can be found on the EFCA website at http://www.efca.europa.eu/.

Since it focuses especially on promoting common standards for control, inspection and surveillance under the Common Fisheries Policy, EFCA is outside the aims of the 4FUN project, and therefore it is not investigated any further.

6) European Food Safety Authority (EFSA)

The European Food Safety Authority (EFSA) was created to improve EU food safety, ensure a high level of consumer protection, and restore and maintain confidence in the EU food supply. EFSA provides independent scientific advice and clear communication on existing and emerging risks to provide a sound foundation for European policies and legislation. More information can be found on the EFSA website at http://www.efsa.europa.eu/.

EFSA's remit covers food and feed safety, nutrition, animal health and welfare, plant protection and plant health performing environmental risk assessments of genetically modified crops, pesticides, feed additives, and plant pests. Therefore, EFSA resulted to be relevant for the aim of the 4 FUN Observatory, both as a source of legislation, and to create a contact between the agency and the 4FUN project.

7) European Medicine Agency (EMA)

The European Medicines Agency is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union. Its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use. More information can be found on the EMA website at http://www.ema.europa.eu/.

The mission of EMA is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health. Therefore , it was considered significant for the scope of 4 FUN Observatory and the EMA website was explored to find relevant legislation.

8) Consumers, Health and Food Executive Agency (Chafea)

The Consumers, Health and Food Executive Agency - Chafea - has started its activities on 1 January 2014. Chafea is the successor of the Executive Agency for Health and Consumers (EAHC), which was created by the European Commission in 2006 to manage the technical and financial implementation of the Public Health Programme and from 2008 the Consumers Programme and the Better Training for Safer Food initiative.

Chafea promotes and protects the health, safety and consumer rights of Europeans. The Agency implements the EU Health Programme, the Consumer Programme and the Better Training for Safer Food initiative. More information can be found on the EAHC website at http://ec.europa.eu/eahc/.

The EAHC strives to attract the best proposals in the field of public health, consumer affairs, and food safety to promote the objectives of the European Union. The Agency provides management skills and scientific expertise to ensure cost-efficiency and high quality of outcomes.

EAHC's tasks resulted not to be related for the aims of the 4FUN project.

9) Research Executive Agency (REA)

The Research Executive Agency (REA) is a funding body created by the European Commission to maximize the efficiency and impact of EU research and innovation programs. The Agency focuses on managing the research proposals and funded projects. More information can be found on the REA website at http://ec.europa.eu/rea/index_en.htm.

The mission of REA is to deliver efficient and effective support to applicants, beneficiaries and independent experts, and establish close contact with final beneficiaries. Hence, it was considered not to be relevant for the aims of the '4FUN Observatory'. However, considering the whole project, REA resulted to be an Agency that should be monitored for possible future developments.

Therefore, among these agencies, the following were selected for the scope of the '4FUN Observatory': EU-OSHA, ECHA, EEA, EFSA, and EMA. Their websites were carefully checked in order to identify relevant policies and legislation about exposure and risk evaluation of chemicals.

Furthermore, the website "Summaries of EU legislation" (http://europa.eu/legislation_summaries/index_en.htm) was used as well. This website presents the main aspects of European Union legislation in a concise way.

3 Identification of relevant legislations about risk evaluation of chemicals

The MERLIN-Expo tool contains a library of models for human exposure assessment to chemicals coupling environmental multimedia and pharmacokinetic models. Therefore, the attention was focused on the European legislation and policies related to chemical exposure and chemical safety.

The information was collected from the websites of the different EU authorities, which were considered to be relevant for the '4FUN Observatory' and from the website "Summaries of EU legislation" (see Paragraph 2).

The information found in these websites is reported below. The full list of legislation and policies is reported in Annex A.

3.1 European Agency for Safety and Health at Work (EU-OSHA)

A wide variety of community measures in the field of health and safety at work have been adopted on the basis of Article 153 of the Treaty on the Functioning of the European Union (ex Article 137 TEC). These measures set out **minimum requirements** and **fundamental principles**, such as the principle of prevention and risk assessment, as well as the responsibilities of employers and employees.

The legislation found on the EU-OSHA website deals with air (both indoor and outdoor).

- **Air indoor**

  The directives included in this section regulates the time and the exposure limits of the substances for which the European Commission decide that limits of exposure are necessary in order to avoid health risks for workers. In time, three different lists of substances have been created, based on new information available. However, in some cases new exposure limits were given for substances previously considered. Furthermore, guidelines and European standards for the implementation of the directives are given, particular attention being paid to nanomaterials.

  - Directive 2009/161/EU - indicative occupational exposure limit values of 17 December 2009 establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC:

  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009L0161:EN:NOT

  - Directive 2006/15/EC - indicative occupational exposure limit values of 7 February 2006 establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC:

  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006L0015:EN:NOT

  - Directive 2000/39/EC - indicative occupational exposure limit values of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work:

  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=Celex:02000L0039-20100108:EN:NOT

  - Directive 2004/37/EC - carcinogens or mutagens at work of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) Directive 89/391/EEC):

  http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0037R(01):EN:NOT

- Directive 98/24/EC - risks related to chemical agents at work of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC):

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:01998L0024-20070628:EN:NOT

- Directive 91/322/EEC - indicative limit values of 29 May 1991 on establishing indicative limit values by implementing Council Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:01991L0322-20060301:EN:NOT

➢ **Air- outdoor**

In this section the directives are mainly related to management of asbestos, and therefore the activities are undertaken in open air, not in close buildings.

- Directive 2009/148/EC - exposure to asbestos at work of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (Text with EEA relevance):

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009L0148:EN:NOT

- Directive 83/477/EEC - exposure to asbestos at work of 19 September 1983 on the protection of workers from the risks related to exposure to asbestos at work (second individual Directive within the meaning of Article 8 of Directive 80/1107/EEC) as amended by Council Directive 91/382/EEC, Council Directive 98/24/EC, Directive 2003/18/EC and Directive 2007/30/EC:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:01983L0477-20070628:EN:NOT

Guidelines were available on the agency website as well, and a detailed list of them is given in the Annex A

3.2 European Chemicals Agency (ECHA)

The new EU chemicals legislation applies to all industry sectors dealing with chemicals and along the entire supply chain. It makes companies responsible for the safety of chemicals they place on the market.

The following regulations are substance based regulations, including the nanomaterials:

- **REACH** is a regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals (http://echa.europa.eu/web/guest/regulations/reach/legislation)
- **Biocidal Products Regulation** (Regulation (EU) 528/2012) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms, like pests or bacteria, by the action of the active substances contained in the biocidal product (http://echa.europa.eu/regulations/biocidal-products-regulation/legislation).

3.3 European Environment Agency (EEA)

In the EEA website, the following EU legislations were documented:

➢ **Air**

EEA (2013a) presents in the following table the legislation in Europe regulating emissions and ambient concentrations of air pollutants (air outdoor).

Policies \ Pollutants		PM	O_3	NO_2 NO_x NH_3	SO_2 SO_x S	CO	Heavy metals	BaP PAH	VOCs
Directives regulating ambient air quality	2008/50/EC	PM	O_3	NO_2	SO_2	CO	Pb		C_6H_6
	2004/107/EC						As, Cd, Hg, Ni	BaP	
Directives regulating emissions of air pollutants	2001/81/EC	(a)	(b)	NO_x, NH_3	SO_2				NMVOC
	2010/75/EU	PM	(b)	NO_x, NH_3	SO_2	CO	Cd, Tl, Hg, Sb, As, Pb, Cr, Co, Cu, Mn, Ni, V		VOC
	Euro standards on road vehicle emissions	PM	(b)	NO_x		CO			HC (hydrocarbons), NMHC (non-methane hydrocarbons)
	94/63/EC	(a)	(b)						VOC
	2009/126/EC	(a)	(b)						VOC
	1999/13/EC	(a)	(b)						VOC
	91/676/EEC			NH_3					
Directives regulating fuel quality	1999/32/EC	(a)			S				
	2003/17/EC	(a)	(b)		S		Pb	PAH	C_6H_6, HC (hydrocarbons), VOCs
International conventions	MARPOL 73/78	PM	(b)	NO_x	SO_x				VOC
	LRTAP	PM (a)	(b)	NO_2, NH_3	SO_2	CO	Cd, Hg, Pb	BaP	NMVOC

Note: (a) Directives and conventions limiting emissions of particulate matter precursors, such as SO_2, NO_x, NH_3 and VOCs, indirectly aim to reduce particulate matter ambient air concentrations.

(b) Directives and conventions limiting emissions of ozone precursors, such as NO_x, VOC and CO, indirectly aim to reduce troposphere ozone concentrations.

The recent major initiatives concerning indoor air quality appear by several Directives such as the **REACH regulation** (Regulation (EC) No 1907/2006), the **General Products Safety Directive** (2001/95/EC), the **Construction Products Regulation** (89/106/EEC), and subsequent **Constructions Products Regulation** (Regulation (EU) No 305/2011). All these Directives aim at better control of potentially dangerous substances contained in and/or from construction and other consumer products used indoors.

➢ **Water**

Water Framework Directive (WFD) (2000/60/EC) represents the single most important piece of legislation on the protection of water resources, both in terms of quality (chemical and ecological) and quantity.

3.4 European Food Safety Authority (EFSA)

As stated in the previous paragraph, EFSA deals with health and environment, and so the legislation found in its website can be applied to all the media. In fact it refers to different chemicals. The most relevant legislation is reported here, grouped by chemical types.

➢ **Plant Protection Products**

A large body of EU legislation regulates the marketing and use of plant protection products and their residues in food and environment (Plant protection – Legal Framework - European Commission, DG Health and Consumers):

- Directive 91/414/EEC regulates the placing of plant protection products on the market
- Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market, published on 24 November 2009, replaces Directive 91/414/EEC. It streamlines mainly the national authorisation procedures for plant protection products and enshrines EFSA's role in the assessments at EU level.
- Existing active substances decisions and review reports

- New active substances decisions and review reports
- Pesticide residues legislation
- Regulation (EC) No 396/2005 (and amendments) covers all matters related to the Maximum Residue Levels (MRLs) for pesticide residues in food and feed. Additionally, it covers monitoring and control pesticides residues in products of plant and animal origin that may arise from their use in plant protection. The Regulation repeals the previous fragmentary legislation and replaces all national MRLs with harmonised EU MRLs for all foodstuffs.

➢ **Dioxins and PCBs**

Dioxins and PCBs are found at low levels in many foods. Long-term exposure to these substances has been shown to cause a range of adverse effects. Their persistence and accumulation in the food chain continue to cause some safety concerns. Dioxins and some PCBs referred to as dioxin-like PCBs (due to their similar toxicological properties) are often considered together within the context of public health. Other PCBs referred to as 'non dioxin-like PCBs' have a different mechanism of toxicity but can also cause adverse effects on health. In 2001, the European Commission set for the first time maximum levels for dioxins, which were extended to dioxin-like PCBs in 2006:

- Regulation EU 1259/2011 setting maximum levels of dioxins and PCBs in food (EUR-Lex)
- Regulation EU 277/2012 setting maximum levels of dioxins and PCBs in feed (EUR-Lex).

➢ **Endocrine Active Substances (EAS)**

Endocrine active substances (EAS) are substances that can interact or interfere with normal hormonal action. When this leads to adverse effects, they are called endocrine disruptors. Examples of endocrine active substances include several pesticides, dioxins and PCBs, and some constituents of food contact materials such as bisphenol A (BPA).
Between 1996 and 2000, a Community strategy for endocrine disruptors was set up (Community strategy for endocrine disruptors, European Commission). This strategy defined the actions to be undertaken to address the potential environmental and health impacts of endocrine disruptors within the EU (Endocrine disruptors website, European Commission).
The Commission was called on to identify substances to be prioritised for immediate action. These lists of substances led to the development of European legislation to regulate their use in specific areas:

- **Chemicals** – Regulation EC 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) – substances having endocrine disrupting properties may be identified as Substances of Very High Concern (SVHC) and undergo authorisation
- **Pesticides** – Regulation EC 1107/2009 concerning the placing of plant protection products on the market – substances having endocrine disrupting properties that may be harmful to humans or non-target organisms cannot be authorised. However, non-approval does not apply if the exposure is negligible under the conditions of use, or if the substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods.
- **Biocides** – Regulation EU 528/2012 concerning the making available on the market and use of biocidal products – these substances are not approved if they have endocrine disrupting properties. However, non-approval does not apply if the risk to humans and the environment is negligible, if the substance is essential to combat a serious health risk, or if non-approval would result in disproportionate negative impacts on society relative to the risks to humans and the environment.
- **Cosmetics** – Regulation EC 1223/2009 on cosmetic products – endocrine disrupting substances are currently not restricted; however, this will be reviewed when EU or internationally agreed criteria for identifying substances with endocrine-disrupting properties are available, or at the latest on 11 January 2015.

- **Water quality** – Water Framework Directive (2000/60/EC) – sets out a strategy against pollution of surface waters by chemical pollutants and the substances of particular concern, including some candidate endocrine disrupting substances. In 2012, the Commission proposed to amend the list of priority substances. Although no direct reference is made, endocrine disruption could become an important criterion for sorting substances or groups of substances into this group.

➢ **Brominated flame retardants (BFR)**

The EU has adopted several legislations to reduce or halt the sale and use of certain BFRs in order to protect health and the environment:

- Directive 2003/11/EC on certain dangerous substances and preparations (EUR-Lex) amends Directive 76/769/EEC on the marketing and use of certain dangerous substances and preparations, and bans the sale of two commercial mixtures of PBDEs, known as PentaBDE and OctaBDE, in concentrations higher than 0.1% by mass
- Directive 2002/95/EC on certain hazardous substances in electrical and electronic equipment (EUR-Lex). From July 2006, under this Directive all new electrical and electronic equipment can no longer contain PBBs and PBDEs in any concentration
- Judgement of the ECJ in Case C-14/06 concerning 'DecaBDE' (EU Official Journal). In July 2008, DecaBDE (a PBDE mixture) was also banned by the European Court of Justice.

➢ **Metals as contaminants in food**

Metals, such as arsenic, cadmium, lead and mercury, are natural occurring chemical compounds. They can be present at various levels in the environment, and can also occur as residues in food. People can be exposed to these metals from the environment or by ingesting contaminated food or water. Their accumulation in the body can lead to harmful effects over time.

- Regulation 315/93/EEC contains the basic principles of EU legislation on contaminants in food
- Regulation EC 1881/2006 lays down maximum levels for certain contaminants in foodstuff, including lead, cadmium, mercury and inorganic tin
- Regulation EC 333/2007 covers the methods of sampling and analysis for the official control of the maximum levels of the aforementioned metals
- Directive 96/23/EC specifies surveillance for residues of chemical elements in foods of animal origin.

3.5 European Medicine Agency (EMA)

The body of European Union legislation in the pharmaceutical sector is compiled in Volume 1 and Volume 5 of the publication "The rules governing medicinal products in the European Union" (Volume 1 - EU pharmaceutical legislation for medicinal products for human use; Volume 5 - EU pharmaceutical legislation for medicinal products for veterinary use).
The following normative, concerning medicinal products either for human or veterinary use, is valid for all environmental media (air, water, and soil):

- Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to **medicinal products for human use**
- Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to **medicinal products for human use** (Official Journal L 159, 27/6/2003 p. 46 - 94).
- Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to **medicinal products for human use** (Official Journal L 136, 30/4/2004 p. 34 - 57).
- Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of **good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use** (Official Journal L 262, 14/10/2003 p. 22 - 26)

- Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for **good clinical practice as regards investigational medicinal products for human use**, as well as the requirements for authorisation of the manufacturing or importation of such products (Official Journal L 91, 9/4/2005 p. 13 – 19)
- Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to **veterinary medicinal products**
- Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating **to veterinary medicinal products** (Official Journal L 136, 30/4/2004 p. 58 - 84)
- Commission Directive 2009/9/EC of 10 February 2009 amending Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to **medicinal products for veterinary use** (Official Journal L 44, 14/2/2009 p. 10 - 61)

Some additional normative, that takes into consideration food safety, is reported below. This is included in Volume 5 of "The rules governing medicinal products in the European Union", which refers to medicinal products for veterinary use.

➢ **Food**

- Commission Directive 2006/130/EC of 11 December 2006 implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of **criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription** (Official Journal on 12 December 2006)
- Commission regulation n° 37/2010 of 22 December 2009 on **pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs** of animal origin
- Council Regulation n° 1308/1999 of 15 June 1999 amending Regulation n° 2377/90 laying down a Community procedure for the **establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin**.

The basic legislation is supported by a series of guidelines published in "The rules governing medicinal products in the European Union" (see http://ec.europa.eu/health/documents/eudralex/index_en.htm for more information).

3.6 European Summaries of EU legislation website

The website “Summaries of EU legislation” was checked in order to avoid possible oversights. This website, in fact, presents the main aspects of EU legislation in a concise and easy-to-read way. It provides approximately 3000 summaries of European legislation, divided into 32 areas corresponding to the activities of the European Union (http://europa.eu/legislation_summaries/index_en.htm). This website offers user-friendly summaries of sometimes rather long and technical EU legislation.

Our attention was focused on the following themes: environment, agriculture and food safety, which are the fields of investigation related to the aims of the 4FUN project. The following legislation was found:

- Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the **protection of groundwater against pollution and deterioration**
- Council Directive 80/68/EEC of 17 December 1979 on the **protection of groundwater against pollution caused by certain dangerous substances**
- Council Directive 98/83/EC of 3 November 1998 on the **quality of water intended for human consumption**
- Directive 2008/105/EC of the European parliament and of the Council of 16 December 2008 on **environmental quality standards in the field of water policy**, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC,

84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council.

- Regulation (EC) n° 1223/2009 of the European Parliament and of the Council of 30 November 2009 on **cosmetic products**
- Council Directive 91/271/EEC of 21 May 1991 concerning **urban waste-water treatment**
- Regulation (EC) n° 850/2004 of the European Parliament and of the Council of 29 April 2004 on **persistent organic pollutants** and amending Directive 79/117/EEC
- Regulation (EC) n° 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to **fertilisers**
- Council Directive 86/278/EEC of 12 June 1986 on the **protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture**
- Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on **industrial emissions** (integrated pollution prevention and control)
- Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning **integrated pollution prevention and control**.

4 Description of the '4FUN Observatory'

4.1 Selecting and summarizing the information on the EU policies

The MERLIN-Expo tool allows building complex scenarios involving several pollutant classes (pesticides, heavy metals, etc…) and media (river, soil, plants, human, etc…) in order to estimate their concentrations in different environmental, food, and human compartments. In this way MERLIN-Expo is capable of conducting a full-chain human and environmental exposure assessment considering multiple exposure pathways.

Therefore, all the legislation listed in the previous chapter was gathered together and in order to organise it, and to make it more accessible to a heterogeneous readership, it was decided to consider the different media compartments (i.e. models) included in the MERLIN-Expo tool (see Figure 2) as a classification criterion.

In particular, the name of each model was considered as a topic to classify the legislation. For example, the River model was matched with all the legislation related to water, and the Atmosphere model with all the legislation dealing with air.

In this way, any reader/user can access the legislation in which they are interested, according to the model(s) they are using. We decided to choose the end-user's point of view, hypothesising that, when using a specific model, an interest towards the normative framework arises.

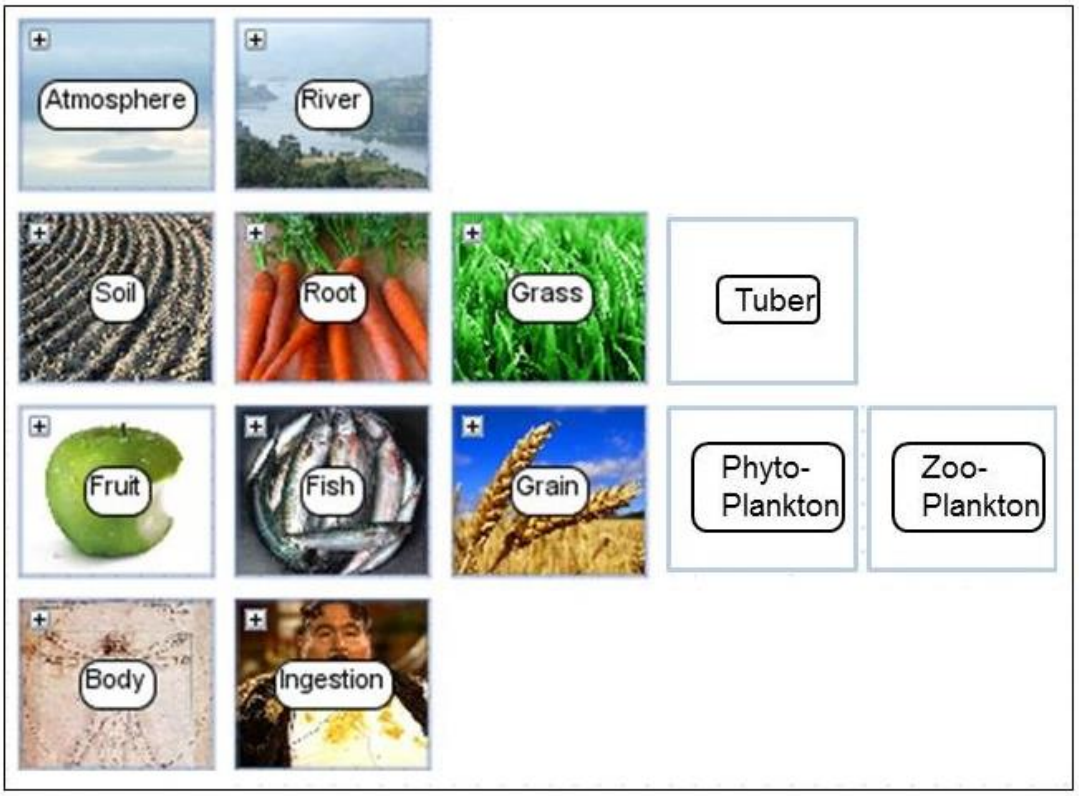

Figure 2 – List of the models (media compartments) included in the MERLIN-Expo tool.

Note: some of the models are not implemented yet.

4.2 Structure of the page '4FUN Observatory' for the 4FUN website

The '4FUN Observatory' page is added in the 4FUN website and can be found at the following link http://4funproject.eu/en/observatory/

The first page reports a general description of the observatory (aims, criteria, etc.), and a number of buttons corresponding to the different media compartments (models) included in the tool (i.e. River, Soil, Atmosphere, Fruit, Grass-leaf, Root, Tubers, Grain, Phytoplankton, Zooplankton, Fish, Human intake).
The layout of the main page is shown below:

The **MERLIN-Expo** tool allows the building of complex scenarios involving several pollution sources (pesticides, heavy metals, etc…) and media (river, soil, etc…) in order to estimate concentrations of chemicals in different environmental compartments.

In this way it is possible to evaluate the risk to exceed a given regulatory threshold for environmental risk. Furthermore, coupling environmental models with a human ingestion model it is possible to evaluate the risk to exceed a given regulatory threshold for human health.

Within the 4FUN project, it was decided to establish an observatory in order to raise awareness on the policy developments on risk assessment and management of chemicals in Europe.

The **'4FUN Observatory'** aims to regularly monitor and collect any updates and news on European legislation and policies related to risk assessment and risk management of chemicals and to disseminate this information in an easily comprehensible way.

Legislations related to risk evaluation of chemicals are divided according to the different media compartments available in the MERLIN-Expo tool. For example, the River model was matched with all the legislation related to water, and the Atmosphere model with all the legislation dealing with air.

Clicking on each media compartment you can access all relevant legislations related to that compartment and the EU agencies working in that field.

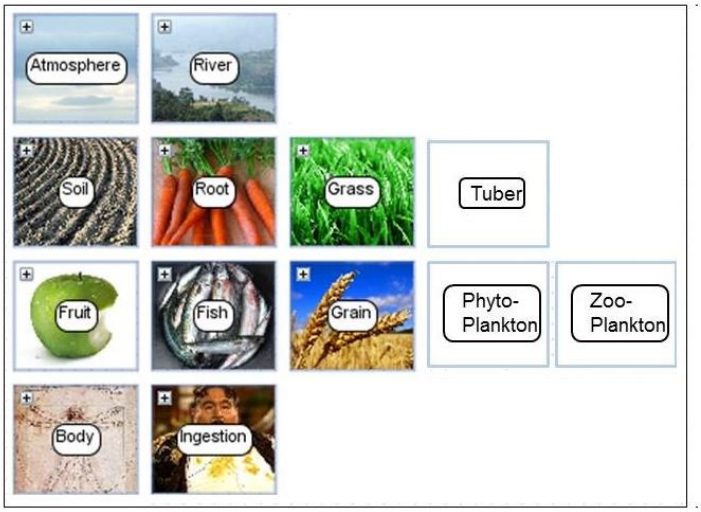

Figure 3 – Content of the first page of the '4FUN Observatory'.

By clicking on each button, it is possible to access another page, where all the agencies dealing with that topic (compartment) are listed. Each agency is briefly described and the link

to the agency website is also given. In addition to that, all the legislation related to that topic is listed in the page.
In order to help the reader finding the legislation of interest, keywords in the normative titles are written using a bold font. Furthermore, it is possible to access the full text via a hyperlink. An example for the RIVER compartment is shown below:

RIVER compartment - **Agencies** involved:

The **European Environment Agency** (EEA) is an agency of the European Union. Its task is to provide information on the environment. It is a major information source for those involved in developing, adopting, implementing and evaluating environmental policy, and also the general public. Currently, the EEA has 33 member countries. (http://www.eea.europa.eu/)

The **European Chemicals Agency** (ECHA) is the driving force among regulatory authorities in implementing the EU's groundbreaking chemicals legislation for the benefit of human health and the environment as well as for innovation and competitiveness. ECHA helps companies to comply with the legislation, advances the safe use of chemicals, provides information on chemicals and addresses chemicals of concern. (http://echa.europa.eu/)

The **European Food Safety Authority** (EFSA) is the keystone of European Union risk assessment regarding food and feed safety. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides independent scientific advice and clear communication on existing and emerging risks. (http://www.efsa.europa.eu/)

RIVER compartment – Relevant **legislation**:

- Council Directive of 15 July 1991 concerning the placing of **plant protection products** on the market (**91/414/EEC**)
  http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1396426800984&uri=CELEX:01991L0414-20110801
- Commission Regulation (EU) No **1141/2010** of 7 December 2010 laying down the procedure for the renewal of the **inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC** and **establishing the list of those substances**
  http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1396426992262&uri=CELEX:02010R1141-20130516
- Commission Regulation (EC) No **33/2008** of 17 January 2008 laying down detailed **rules for the application of** Council Directive **91/414/EEC** as regards a regular and an accelerated procedure for the **assessment of active substances** which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I
  http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1396427116382&uri=CELEX:02008R0033-20100129
- ……

Figure 2 – Content of the second page of the 4FUN European Observatory (example for the River model). Note that not all the legislation is reported in this figure.

5 Future steps of the ‘4FUN Observatory’

The webpage of the ‘4FUN Observatory’ will be maintained and regularly updated through the duration of the 4FUN project. The selected agencies websites will be regularly monitored.

Furthermore, in each agency risk managers will be identified and contacted in order to create a link between the 4FUN project and the relevant EU authorities. Therefore, a connection will be created with regulators and policy makers in order to be informed on news and changes in the regulatory and normative framework and to offer them the ‘4FUN Observatory’ as a platform to increase their visibility. Furthermore, if possible the link to 4FUN Project will be added in the agencies websites, in order to promote the standardisation, dissemination and training activities planned in the project.

6 References

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European Commission, 2003. Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances, Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market - Part II.

7 Annex A

Type of Legislation	CODE	Title
Council Regulation (EEC)	No 315/93	COUNCIL REGULATION (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food
Regulation (EC)	NO 396/2005	REGULATION (EC) NO 396/2005 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
Commission Regulation (EU)	No 1259/2011	COMMISSION REGULATION (EU) No 1259/2011 of 2 December 2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for dioxins, dioxin-like PCBs and non dioxin-like PCBs in foodstuffs
Commission Regulation (EC)	No 1881/2006	COMMISSION REGULATION (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
Commission Regulation (EC)	No 629/2008	Commission Regulation (EC) No. 629/2008 amending Regulation (EC) No. 1881/2006 setting maximum levels for certain contaminants in foodstuffs
Commission Regulation (EU)	No 277/2012	COMMISSION REGULATION (EU) No 277/2012 of 28 March 2012 amending Annexes I and II to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels and action thresholds for dioxins and polychlorinated biphenyls
Commission Regulation (EU)	No 37/2010	COMMISSION REGULATION (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin
Commission Directive	2006/130/EC	Commission Directive 2006/130/EC of 11 December 2006 implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription was published in the Official Journal on 12 December 2006
Regulation (EEC)	No 1308/1999	Council Regulation (EC) No 1308/1999 of 15 June 1999 amending Regulation (EC) No 2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.
Guidelines		Establishment of maximum residue limits (MRLs) for residues of veterinary medicinal products in foodstuffs of animal origin (volume 8 of "The rules governing medicinal products in the European Union")
Regulation (EC)	No 333/2007	Commission Regulation (EC) No. 333/2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs.
Council Directive	96/23/EC	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
Council Directive	91/414/EEC	Council Directive of 15 July 1991 concerning the placing of plant protection products on the market (91/414/EEC)
Commission Regulation (EU)	No 1141/2010	COMMISSION REGULATION (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances
Commission Regulation (EC)	No 33/2008	COMMISSION REGULATION (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I
Commission Regulation (EC)	No 1095/2007	COMMISSION REGULATION (EC) No 1095/2007 of 20 September 2007 amending Regulation (EC) No 1490/2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and Regulation (EC) No

		2229/2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC
Regulation (EC)	No 1107/2009	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
Directive	2009/128/EC	DIRECTIVE 2009/128/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides
Commission Regulation (EU)	No 283/2013	COMMISSION REGULATION (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market
Commission Regulation (EU)	No 284/2013	COMMISSION REGULATION (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market
Regulation (EU)	No 528/2012	REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal products
Regulation (EC)	No 1907/2006	REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
Directive	2003/11/EC	DIRECTIVE 2003/11/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 February 2003 amending for the 24th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (pentabromodiphenyl ether, octabromodiphenylether)
Directive	2002/95/EC	Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment
Directive	2000/60/EC	DIRECTIVE 2000/60/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 October 2000 establishing a framework for Community action in the field of water policy
Commission Regulation (EU)	No 847/2012	Commission Regulation (EU) No 847/2012 of 19 September 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards mercury
Commission Regulation (EU)	No 848/2012	Commission Regulation (EU) No 848/2012 of 19 September 2012 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards phenylmercury compounds
Directive	2006/118/EC	DIRECTIVE 2006/118/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2006 on the protection of groundwater against pollution and deterioration
Council Directive	80/68/EEC	Council Directive 80/68/EEC of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances
Council Directive	98/83/EC	COUNCIL DIRECTIVE 98/83/EC of 3 November 1998 on the quality of water intended for human consumption

Directive	2008/105/EC	DIRECTIVE 2008/105/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council
Regulation (EC)	No 1223/2009	REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products
Council Directive	91/271/EEC	Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment
Regulation (EC)	No 850/2004	REGULATION (EC) No 850/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC
Regulation (EC)	No 2003/2003	REGULATION (EC) No 2003/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 October 2003 relating to fertilisers
Council Directive	86/278/EEC	Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture
Directive	2010/75/EU	DIRECTIVE 2010/75/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 November 2010 on industrial emissions (integrated pollution prevention and control)
Directive	2008/1/EC	DIRECTIVE 2008/1/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 January 2008 concerning integrated pollution prevention and control
Directive	2001/82/EC	DIRECTIVE 2001/82/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to veterinary medicinal products
Commission Directive	2009/9/EC	Commission Directive 2009/9/EC of 10 February 2009 amending Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to medicinal products for veterinary use (Official Journal L 44, 14/2/2009 p. 10 - 61).
Directive	2004/28/EC	Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (Official Journal L 136, 30/4/2004 p. 58 - 84)
Directive	2001/83/EC	Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use
Commission Directive	2003/63/EC	Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (Official Journal L 159, 27/6/2003 p. 46 - 94).
Directive	2004/27/EC	Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (Official Journal L 136, 30/4/2004 p. 34 - 57).
Commission Directive	2003/94/EC	Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (Official Journal L 262, 14/10/2003 p. 22 - 26).
Commission Directive	2005/28/EC	Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (Official Journal L 91, 9/4/2005 p. 13 - 19).

Directive	2008/50/EC	DIRECTIVE 2008/50/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 May 2008 on ambient air quality and cleaner air for Europe
Directive	2004/107/EC	DIRECTIVE 2004/107/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 December 2004 relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air
Directive	2001/81/EC	DIRECTIVE 2001/81/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 October 2001 on national emission ceilings for certain atmospheric pollutants
Directive	2010/75/EU	DIRECTIVE 2010/75/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (Recast)
Standards		Euro standards on road vehicle emissions
European Parliament and Council Directive	94/63/EC	European Parliament and Council Directive 94/63/EC of 20 December 1994 on the control of volatile organic compound (VOC) emissions resulting from the storage of petrol and its distribution from terminals to service stations
Directive	2009/126/EC	DIRECTIVE 2009/126/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 on Stage II petrol vapour recovery during refuelling of motor vehicles at service stations
Council Directive	1999/13/EC	Council DIRECTIVE 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations
Council Directive	91/676/EEC	Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources
Council Directive	1999/32/EC	COUNCIL DIRECTIVE 1999/32/EC of 26 April 1999 relating to a reduction in the sulphur content of certain liquid fuels and amending Directive 93/12/EEC
Commission Directive	2003/19/EC	COMMISSION DIRECTIVE 2003/19/EC of 21 March 2003 amending, for the purposes of adapting to technical progress, Directive 97/27/EC of the European Parliament and of the Council relating to the masses and dimensions of certain categories of motor vehicles and their trailers
International Convention	MARPOL 73/78	International Convention for the Prevention of Pollution from Ships, 1973, as modified by the Protocol of 1978 relating thereto (MARPOL 73/78)
Convention	LRTAP	Convention on Long-range Transboundary Air Pollution
Directive	2001/95/EC	DIRECTIVE 2001/95/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 3 December 2001 on general product safety
Council Directive	89/106/EEC	Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products
Regulation (EU)	No 305/2011	REGULATION (EU) No 305/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC

Commission Directive	2009/161/EU	COMMISSION DIRECTIVE 2009/161/EU of 17 December 2009 establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC
Commission Directive	2006/15/EC	COMMISSION DIRECTIVE 2006/15/EC of 7 February 2006 establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC
Directive	2004/37/EC	DIRECTIVE 2004/37/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC)
Directive	2000/39/EC	Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.
COUNCIL DIRECTIVE	98/24/EC	COUNCIL DIRECTIVE 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)
Directive	91/322/EEC	Directive 91/322/EEC of 29 May 1991 on establishing indicative limit values by implementing Council Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work.
Guidelines		Minimizing chemical risk to workers' health and safety through substitution
Guidelines		Practical guidelines of a non-binding nature on the protection of the health and safety of workers from the risks related to chemical agents at work
Guidelines		Agreement on Workers Health Protection through the Good Handling and Use of Crystalline Silica and Products containing it
Guidelines	[SEC(2008) 2036]	Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee - Regulatory aspects of nanomaterials [SEC(2008) 2036]
Guidelines		ECHA Guidance on REACH and CLP implementation
Guidelines		ECHA guidance on CLP
Guidelines		A practical guide on best practice to prevent or minimize asbestos risks
Directive	2009/148/EC	Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (Text with EEA relevance)
Directive	83/477/EEC	Directive 83/477/EEC - exposure to asbestos at work of 19 September 1983 on the protection of workers from the risks related to exposure to asbestos at work (second individual Directive within the meaning of Article 8 of Directive 80/1107/EEC) as amended by Council Directive 91/382/EEC, Council Directive 98/24/EC, Directive 2003/18/EC and Directive 2007/30/EC.