

Legislative Mapping: Lead

Project Ref. EEA/HSR/RO/19/001

Summary Document

prepared for

European Environment Agency (EEA)

31 January 2020



RPA
Europe

Legislative Mapping: Lead

31 January 2020

Summary Document

Quality Assurance	
Project reference / title	J1061/ EEA HBM4EU Policy Briefs 2.0
Report status	Summary Document
Author(s)	Rebecca Johansen Anthony Footitt Max Le Vedrine Liam Wakefield
Approved for issue by	Meg Postle
Date of issue	31 January 2020

Table of Contents

1	Introduction	1
1.1	How to use the excel database.....	1
1.2	Outline of this Summary Document	2
2	Summary of Lead legislation	3
3	International Conventions and Implementing EU Legislation.....	4
4	Cross Regulation Activities	5
4.1	PACT List	5
5	REACH Regulation.....	6
5.1	REACH	6
5.2	Current and future public consultations or calls for evidence	8
6	CLP Regulation	9
7	OSH Legislation.....	10
7.1	Signs at work.....	10
7.2	CAD	10
7.3	Young Workers	10
7.4	Pregnant & breastfeeding workers	10
8	Professional and Consumer Legislation.....	12
8.1	Fertilisers.....	12
8.2	Cosmetics Regulation.....	12
8.3	Toy Safety Directive	12
8.4	Food contact materials and articles	12
8.5	Maximum levels for certain contaminants in foodstuffs	13
8.6	Undesirable substances in animal feed	13
8.7	Medical Devices	14
8.8	In Vitro medical devices.....	14
8.9	Restriction of the use of hazardous substances (RoHS) in electronic equipment	14
8.10	Tobacco Products.....	14
9	Waste Legislation	16
9.1	Waste Framework Directive	16
9.2	Waste batteries and accumulators.....	16

9.3 Packaging and packaging waste	16
9.4 ELV	17
9.5 Waste Shipments	17
10 Environmental Legislation.....	18
10.1 Water Framework Directive	18
10.2 Environmental quality standards directive.....	18
10.3 Groundwater Directive	18
10.4 Drinking Water Directive	18
10.5 Industrial Emissions Directive	19
10.6 Ambient air quality Directive	19
10.7 National Emissions Ceilings Directive	19

1 Introduction

This document provides a summary of the legislative status of lead under the European Chemicals legislative framework and International Conventions on chemical risk in order to provide an overview of relevant requirements for placing on the market, use and handling.

This document provides a tabulated summary of relevant legislation grouped by legislative area. It is to be used as an indication of those pieces of legislation which are applicable to the substances within this group. In order to provide more detailed information in an easier to read format, this document is supported by an excel database.

1.1 How to use the excel database

The Excel database provides detailed information, with links where appropriate, on the specific Article, Annex or Appendix which is applicable to the substance concerned. Substance identification information is provided for all substances including name, CAS number, EC number, HBM4EU category, and whether the substance is considered of high or medium priority by the HBM4EU Chemical Group Leads. All pieces of legislation are linked to the legal text on Eur-Lex. The database contains fourteen tabs which relate to groups of legislation or processes. The tabs are as follows:

- Table 1 – Links to information pages for each substance. This provides links to the Substance Information Pages, Brief Profiles (where applicable), and the CLI inventory on the ECHA website.
- Public consultations – summary of the status on public consultations for relevant regulatory processes. Includes Restriction intentions and SVHC intentions under REACH, CLH intentions, OELs.
- Table 2 – Legislative map. An overview of the applicable individual pieces of legislation. Where a piece of legislation is applicable to an individual substance it is marked by a Y (indicating yes). At the top of each section there is a link, which when clicked on will take you to the more detailed table found in subsequent tabs.
- Table 3 – POPs Regulation and PIC Regulation. Status and explicit provision.
- Table 4 – REACH Restriction process. Outlines specific entry within Annex XVII and the status of a Restriction intention.
- Table 5 – REACH SVHC/ Authorisation process. Outlines the specific entry in Annex XIV, whether a substance appears on the Candidate List and the status of an SVHC intention.
- Table 6 – REACH Evaluation process. Outlines the status on the PACT List and the CoRAP.
- Table 7 – CLP Harmonised Classification process. Current harmonised classification and the status of submitted CLH intentions.
- Table 8 – REACH Registration and Biocides. Outlines the Registered uses under REACH and the current status under the Biocidal Products Regulation.
- Table 9 – OELs on CAD/CMD. Status of OEL activity list status.
- Table 10 – other limit values. This provides the DNEL list of the DGUV, limit values under the Drinking Water Directive, Environmental Quality Standards, Groundwater limit values.
- Table 11 – Professional and Consumer legislation. Identifies the specific Article or Annex which is applicable to certain substances.
- Table 12 – OSH and Waste legislation. Specific Articles or Annexes applicable to certain substances.
- Table 13 – Environmental legislation. Specific Articles or Annexes applicable to certain substances.

1.2 Outline of this Summary Document

The summary information on legislative status presented in the Summary Document has been split by legislative group.

- Section 2 – International Conventions and Implementing EU Legislation.
- Section 3 – Cross Regulation Activities
- Section 4 – REACH Regulation
- Section 5 – CLP Regulation
- Section 6 – OSH Legislation
- Section 7 – Professional and Consumer Legislation
- Section 8 – Waste Legislation
- Section 9 – Environmental Legislation

As mentioned in the introduction, the information is tabulated and presents a tick-box style matrix, where a “Y” indicates the legislation is of relevance to the substance. Brief summaries are provided of the purpose of the relevant legislation. The tables indicate the substance identification information (name, CAS number) and indicates the HBM4EU category. Substances deemed of high importance to the HBM4EU Chemical Group Leads are highlighted in green and those of medium importance are highlighted in yellow. The categorisation of substances under HBM4EU is:

- Category A – substances for which HBM4EU data are sufficient to provide an overall picture of exposure levels across Europe, and interpretation of biomonitoring results in terms of health risks is possible. Improvement of knowledge for these substances will therefore focus on policy-related research questions and evaluation of the effectiveness of existing regulatory measures.
- Category B - substances for which HBM data exists, but not sufficiently to have a clear picture across Europe. Also, knowledge on the extend of exposure, levels and impact on the human health should be improved, in order to give policy makers relevant and strategic data to establish appropriate regulations and improve chemical risk management. Analytical method and capacities to monitor the substances across Europe might have to be improved.
- Category C - substances are substances for which HBM data scarcely or doesn't exists. Efforts to develop an analytical method to obtain relevant HBM results need to be done Hazardous properties of the substances are identified, yet greater knowledge on toxicological characteristics and effects on the human health is needed. Interpretation of HBM data is not possible, due to the lack of HBM guidance values.
- Category D - substances are substances for which a toxicological concern exists but HBM data are not available. HBM4EU research may be focused on the development of suspect screening approaches permitting to generate a first level of data enabling to document the reality of human exposure and better justify further investment in a full quantitative and validated method development.
- Category E - substances are substances not yet identified as of toxicological concern and for which no HBM data are available. A bottom-up strategy will be applied, consisting to non-targeted screening approaches coupled to identification of unknowns capabilities for revealing, and further identifying, new (i.e. not yet known) markers of exposure related to chemicals of concern for HBM (parent compound or metabolite).¹

¹ HBM4EU (no date) Categorisation of Substances. Available at: <https://www.hbm4eu.eu/categorisation-of-substances/> [Accessed 28/10/2019]

2 Summary of Lead legislation

The below table summarises the legislation which affects lead.

Table 2-1: Simplified Summary Lead	
	Lead 7439-92-1
REACH	Y
CLP	Y
PACT	Y
Signs at Work Directive	Y
CAD	Y
Young Workers Directive	Y
Pregnant & Breastfeeding workers Directive	Y
Fertilisers Regulation	Y
Cosmetic Products Regulation	Y
Toy Safety Directive	Y
Plastic Food Contact Materials Regulation	Y
Recycled Plastic Food Contact Materials Regulation	Y
Maximum levels food contaminants Regulation	Y
Undesirable substances animal feed Directive	Y
Medical Devices Regulation	Y
In vitro medical devices Regulation	Y
RoHS Directive	Y
Tobacco Directive	Y
Waste Framework Directive	Y
Waste batteries and accumulators Directive	Y
Packaging and packaging waste Directive	Y
ELV Directive	Y
Waste shipments Regulation	Y
Water Framework Directive	Y
Environmental Quality Standards Directive	Y
Groundwater Directive	Y
Drinking Water Directive	Y
Industrial Emissions Directive	Y
Ambient Air Quality Directive	Y
National Emissions Ceiling Directive	Y

3 International Conventions and Implementing EU Legislation

Lead is not currently subject to relevant International Conventions.

4 Cross Regulation Activities

4.1 PACT List

The Public Activities Coordination Tool (PACT) provides an overview of the substance-specific activities being undertaken by authorities under the REACH Regulation and the CLP Regulation. The activities under the PACT List are carried out in line with ECHA's Integrated Regulatory Strategy.

The PACT List provides up-to-date information on ECHA's and/or Member State Competent Authority's (MSCA) planned, ongoing or completed activities for a given substance in the following areas:

- Data generation and assessment – dossier evaluation, substance evaluation, informal hazard assessment (PBT/vPvB/ED);
- Regulatory Management Option Analysis (RMOA);
- Regulatory risk management – harmonised classification and labelling (CLH), SVHC identification, restriction.²

Table 4-1 below indicates how lead is regulated by cross regulation activities.

Table 4-1: PACT List and CoRAP entries			
Cat.	Substance Name	CAS No.	PACT List
A	BPA	80-05-7	Y

² ECHA (no date) Public activities coordination tool. Available at: <https://echa.europa.eu/pact> [Accessed: 28/10/2019]

5 REACH Regulation

5.1 REACH

Legislative Act: [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](#)

Staged over three phases, the 2008 REACH Regulation requires manufacturers and importers (MIs) of chemicals to register all chemical substances manufactured or imported and used in quantities of >1t per year per MI. All substances manufactured or imported in quantities of >100 t per year per MI and all known CMRs 1A/1B/PBT/vPvB over 1t per MI per year have completed registration. The final REACH Registration deadline was 1 June 2018 for substances manufactured or imported in quantities of 1-100 tonnes per MI per year.

Through ‘Restriction and Authorisation’ the REACH regulation has provisions to ensure that the risks from substances of very high concern (SVHC) are controlled and substances are progressively replaced by suitable alternative substances or technologies.

For all substances, information must be generated, and classifications made according to CLP. Even where Restriction/Authorisation provisions are not applied, hazard classifications can trigger parallel community legislation and information must be passed to downstream users using safety data sheets. Substances manufactured or imported at >10t per year per MI must also conduct a chemical safety assessment for all identified uses, where this must demonstrate adequate control of any identified risks.

Tables 5-1 and 5-2 below indicate how lead is registered under REACH and its registered uses.

Cat.	Substance Name	CAS No.	FULL REACH Registration	Intermediate REACH Registration	NONS REACH Registration	Information on REACH registered uses
B	Lead	7439-92-1	Y	Y		Y

Cat.	Substance Name	CAS No.	Consumer uses	Article service life	Widespread uses by professional workers	Formulation or re-packing	Uses at industrial sites	Manufacture	Intermediate only
B	Lead	7439-92-1			Y	Y	Y	Y	

5.1.1 Restriction and Authorisation of Substances of Very High Concern (SVHC) under REACH

The REACH regulation has provisions to ensure that the risks from substances of very high concern (SVHC) are controlled and substances are progressively replaced by suitable alternative substances or technologies.

SVHCs under REACH are:

- Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1A or 1B in accordance with CLP (Regulation (EC) No 1272/2008)
- Substances which are persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with the criteria set out in Annex XIII of the REACH Regulation;
- Substances giving rise to an equivalent level of concern where these substances may have endocrine disrupting (ED) properties or have properties, that although not meeting the above criteria, there is scientific evidence of probable serious effects to human health or the environment

SVHCs may be added to:

- **The Authorisation List (Annex XIV of REACH)** along with recommendations on, amongst other things:
 - Sunset Date from which the placing on the market and the use of a substance is prohibited, unless an authorisation is granted, or the use is exempt from authorisation;
 - Latest application date by which applications must be received if the applicant wishes to continue the placing on the market or use of the substance after the sunset date;
 - Review periods for certain uses, if any; and
 - Uses exempted from the authorisation requirement, if any.

An application for authorisation is granted only if the applicant can demonstrate that the risk from the use of the substance is adequately controlled or when it is proven that the socio-economic benefits of using the substance outweigh the risks and there are no suitable alternative substances or technologies.

- **The Restriction list (Annex XVII of REACH):** Restriction under REACH limits or bans the manufacture, placing on the market or use of certain substances that pose an unacceptable risk to human health and the environment. A Member State, or ECHA on request of the European Commission, can propose additions to the Restriction list (Annex XVII). ECHA can also propose a restriction on articles containing substances in the Authorisation list (Annex XIV).

Producers and importers of substances which are candidates for the above must notify ECHA if a substance is present in their articles above a concentration of 0.1% weight by weight and if the total volume of the substance in articles is over one tonne per year. These notifications are called Substances in Articles (SIA) notifications.

Tables 5-3 and 5-4 overleaf indicate how lead is restricted and authorised under REACH.

Table 5-3: REACH Restriction				
Cat.	Substance Name	CAS No.	Restriction list (annex XVII)	Registry of restriction intentions
B	Lead	7439-92-1	Y	Y

Table 5-4: REACH Authorisation						
Cat.	Substance Name	CAS No.	Authorisation list (annex XIV)	Candidate List	Candidate list substances in articles	Registry of SVHC Intentions
B	Lead	7439-92-1	Y	Y	Y	Y

5.2 Current and future public consultations or calls for evidence

Table 5-5 below shows current and future public consultations and calls for evidence.

Table 5-5: Current and future consultations						
Cat.	Substance Name	CAS No.	Regulatory process	Activity	Start date	End date
B	Lead	7439-92-1	REACH restriction	Assess impacts of a possible restriction	03/10/2019	16/12/2019

6 CLP Regulation

Legislative act: [Regulation \(EC\) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation \(EC\) No 1907/2006](#)

This Regulation harmonises the criteria for classification of substances and mixtures, and the rules for labelling and packaging of these hazardous substances and mixtures. It outlines the obligations of:

- manufacturers, importers and downstream users to classify substances and mixtures before they can be placed on the market;
- suppliers to label and package substances and mixtures before placing on the market;
- and manufacturers, producers of articles and importers to classify those substances not placed on the market that are registered or notified under REACH.

There are two types of classification under CLP. Harmonised classification is the classification of a substance that has been agreed by independent experts at European level, and this classification is then legally binding. Harmonised classifications are listed in Annex VI of CLP. Mixtures are not subject to harmonised classification. Self-classification is carried out by a supplier who classifies the chemicals directly, where no harmonised classification exists. This is also necessary for mixtures.

The classification of a substance can have impacts on vertical legislative requirements, for example cut-off criteria under PPPR and BPR for substances that have a harmonised classification for CMR 1A or 1B. OSH legislation tends to apply to both self-classified substances and those with a harmonised classification.

Table 6-1 below indicates how lead is regulated under CLP regulation.

Table 6-1: Harmonised Classification				
Cat.	Substance Name	CAS No.	Harmonised classifications in force from 1 May 2020 after ATP 13	Registry of submitted CLH
B	Lead	7439-92-1	Y	Y

7 OSH Legislation

7.1 Signs at work

Legislative act: [Council Directive 92/58/EEC of 24 June 1992 on the minimum requirements for the provision of safety and/or health signs at work](#)

This Directive is the ninth individual Directive within the meaning of Article 16 of the OSH Framework Directive. It lays down the minimum requirements for the provision of health and safety signs at work. Employers are required to provide health and safety signs where hazards cannot be avoided or reduced. The Annexes outline the minimum requirements for health and safety signs.

7.2 CAD

Legislative act: [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](#)

This Directive is the fourteenth individual Directive within the meaning of Article 16 of the OSH Framework Directive. It outlines the minimum requirements for the protection of workers health and safety arising, or likely to arise, from the effects of chemical agents in the workplace or the use of chemical agents at work. It applies where hazardous chemical agents are present or may be present at the workplace. Indicative occupational exposure limit values (IOELVs) are set at Community level. Member States are required to introduce a national occupational exposure limit value that takes into account the IOELV. Binding biological limit values (BBLVs) may be drawn up at Community level. Member States must establish a corresponding national binding biological limit value. There are a number of obligations for employers, including carrying out an assessment of the risk to health and safety arising from the presence of chemical agents and specific protection and prevention measures. The definition of a hazardous chemical agent is where it meets the criteria for classification under the Dangerous Substances Directive (67/548/EEC) or the Dangerous Preparations Directive (88/379/EEC). These classifications have been translated into CLP.

7.3 Young Workers

Legislative act: [Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work](#)

This Directive requires Member States to ensure that work by adolescents is strictly restricted and that children are prohibited from working. Employers are required to carry out an assessment of the hazards to young workers before they start work, this includes the nature, degree and duration of exposure to physical, biological and chemical agents. Further requirements exist in areas such as night work, rest periods, working time and breaks. The classifications of chemical agents are based on the Dangerous Substances Directive (67/548/EEC) but these are now translated to those of CLP.

7.4 Pregnant & breastfeeding workers

Legislative act: [Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding \(tenth individual Directive within](#)

This Directive is the 10th individual Directive within the meaning of Article 16 of the OSH Framework Directive (89/391/EEC). It aims to implement measures to encourage improvements in the health and

safety at work of pregnant workers and workers who have recently given birth or who are breastfeeding. Employers are obliged to carry out an assessment to establish the nature, degree and duration of exposure to agents, processes or working conditions under Annex I. This assessment should determine any risks to the health or safety and any possible effect on pregnancy or breastfeeding workers, and then to decide what measures should be taken. Pregnant workers are not allowed to perform duties where there may be exposure to agents or working conditions in Annex II, section A. Workers who are breastfeeding may not perform duties where there may be exposure to the agents and working conditions listed in Annex II, section B. Requirements are not limited to exposure, they also consider maternity leave, anti-natal examinations and prohibition of dismissal.

Tables 7-1 and 7-2 below indicate how lead is regulated under OSH legislation, and current calls for evidence.

Table 7-1: Relevant OSH legislation						
Cat.	Substance Name	CAS No.	Signs at work	CAD	Young Workers	Pregnant & breastfeeding workers
B	Lead	7439-92-1	Y	Y	Y	Y

Table 7-2: Current and future consultations						
Cat.	Substance Name	CAS No.	Regulatory process	Activity	Start date	End date
B	Lead	7439-92-1	OELs	Comments on proposed OELs	17/10/2019	16/12/2019

Notes from EU Policy Board regarding public consultation for lead:

“No, there is no second or additional consultation in the formal procedure, however if data were available before the scheduled plenary discussion in February/March (so by the end of January) or if there are draft reports/documents that could be submitted in the current public consultation and a final version submitted in January/February, then it may be possible to include these data in the discussions. However, it is our understanding the HBM4EU has been informed of these two public consultations when they started and one of the HBM4EU experts on occupational matters is a member of RAC.”

“If they (EEA) can meet the deadline set by ECHA for the scientific evaluation this would be the best outcome. However, if they cannot meet this deadline then it will still be helpful to have this information as there will be discussions in the ACSH, via the WPC, to consider socio-economic and technical feasibility aspects of any proposals for a new/revised OEL. Consequently, if the HBM4EU data is received after the ECHA deadline then clearly it will not be reflected in the RAC Opinion but the WPC will still be able to take it into account.”

8 Professional and Consumer Legislation

8.1 Fertilisers

Legislative act: [Regulation \(EU\) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products](#)

This regulation harmonises the requirements for fertilisers produced from phosphate minerals and from organic or secondary raw materials in the EU. It also sets harmonised limits for a range of contaminants.

8.2 Cosmetics Regulation

Legislative Act: [Regulation \(EC\) No 1223/2009 on cosmetic products \(formerly 76/768/EEC\)](#)

This Regulation lays out the rules that cosmetic products must comply with if they are to be made available on the market. The Cosmetic Products Regulation does not have to comply with the requirements of CLP, packaging and labelling requirements are instead outlined in the Cosmetic Products Regulation. Article 15 is the only area that has a link to CLP. This outlines the prohibition of CMRs in cosmetic products. Annex II lists the substances that are prohibited for use in cosmetics, these are not necessarily CMRs.

8.3 Toy Safety Directive

Legislative act: [Directive 2009/48/EC on the safety of toys \(formerly 88/378/EEC\)](#)

This Directive lays down the requirements for the safety of toys (for children under the age of 14) and the free movement of these products in the Community. Additional rules have been introduced for toys made for children under the age of 36 months or those which are intended for use in the mouth, in relation to specific concentration limits for bisphenol A, TCEP, TCPP, TDCCP. Obligations are outlined for manufacturers, importers, authorised representatives and distributors. Toys must conform to the essential safety requirements, including those for physical and mechanical properties, flammability, electrical properties, hygiene, radioactivity and chemical properties. Rules for chemical properties include 55 allergenic substances that are prohibited in toys, allergenic substances that require labelling, and migration limits for other substances which may not be exceeded. Substances that are classified as CMR 1A, 1B or 2 are prohibited for use in toys, although derogations do exist. The REACH Regulation also plays a part in the regulation of substances in toys, with restrictions existing for certain substances for use in toys.

8.4 Food contact materials and articles

Legislative Acts:

- Framework Regulation - [Regulation \(EC\) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC](#)
- [Commission Regulation \(EU\) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food](#)

- [Commission Regulation \(EC\) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation \(EC\) No 2023/2006](#)

This Regulation is a specific measure within the meaning of Article 5 of Regulation (EC) No 1935/2004. This Regulation establishes specific requirements for the manufacture and marketing of plastic materials and articles that are intended to come into contact with food, already in contact with food, or which can be reasonably expected to come into contact with food. It includes materials and articles that are made exclusively of plastic, of plastic multi-layer materials and articles held together by adhesives, those that are printed or covered by a coating, plastic layers or plastic coatings which form gaskets in caps and closures that together with the caps and closures are made of two or more layers of different types of materials, and plastic multi-material multi-layer materials and articles.

Only substances that are included in the Union list of authorised substances set out in Annex I can be used in the manufacture of plastic layers in plastic materials and articles, although derogations do exist. Each substance must not exceed its specific migration limit. Substances that are not listed in the Union list or the provisional list but have been approved for use cannot have a harmonised classification as CMR or be in nanoform.

8.4.1 Plastic Food Contact Materials

This regulation establishes the specific rules for plastic materials and articles to be applied for their safe use. It also repeals Directive 2002/72/EC on plastic materials and articles intended to come into contact with foodstuffs.

8.4.2 Recycled Plastic Food Contact Materials

This regulation shall apply to the plastic materials and articles and parts thereof intended to come into contact with foodstuffs which contain recycled plastic. It requires food contact material operators planning to introduce a plastics recycling process shall seek authorisation from the EU Commission. The products manufactured by these operators must meet the requirements of Regulations 10/2011 on plastics.

8.5 Maximum levels for certain contaminants in foodstuffs

Legislative act: [Commission Regulation \(EC\) No 1881/2006 of 19 December 2006](#)

This regulation sets maximum levels for certain contaminants in foodstuffs, with a view to protecting public health. It sets forth maximum levels for certain contaminants in foodstuffs to keep them at levels which are toxicologically acceptable.

8.6 Undesirable substances in animal feed

Legislative Act: [Directive 2002/32/EC on undesirable substances in animal feed](#)

This Directive sets maximum levels for undesirable substances and products (contaminants) in animal feed (including imports) available on the EU market. It limits the risks of contamination of animal feed

by substances and products that are toxic or adversely affect production; and applies to all products intended for animal feed, including raw materials for feed, additives and complementary feeding stuffs.

8.7 Medical Devices

Legislative Acts: [Regulation \(EU\) 2017/745 on medical devices, amending Directive 2001/83/EC, Regulation \(EC\) No 178/2002 and Regulation \(EC\) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC](#)

This Regulation aims to ensure the smooth functioning of the internal market as regards medical devices, a high level of protection of health for patients and users, and high standards of quality and safety for medical devices to meet common safety concerns as regards such products.

8.8 In Vitro medical devices

Legislative Acts: [Regulation \(EU\) 2017/746 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU](#)

This Regulation aims to ensure the smooth functioning of the internal market as regards in vitro diagnostic medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for in vitro diagnostic medical devices in order to meet common safety concerns as regards such products.

8.9 Restriction of the use of hazardous substances (RoHS) in electronic equipment

[Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment](#)

This Directive lays down the rules on the restriction of the use of hazardous substances in electrical and electronic equipment. It applies to all electrical and electronic equipment which falls within the categories of Annex I. It applies without prejudice to Union legislation on health and safety, REACH and particular Union waste legislation. The RoHS outlines the obligations of manufacturers, importers, authorised representatives, and distributors. Annex II lays out the substances that are restricted under Article 4(1) and their maximum concentration values. Although the substances under Annex II are restricted, there are exemptions from these restrictions in certain electrical and electronic equipment and this is outlined in Annex III. Annex IV provides a list of exemptions from the restriction for certain medical devices and monitoring and control instruments.

8.10 Tobacco Products

Legislative Acts: [Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products](#)

This Directive lays down the laws, regulations and administrative provisions of Member States with regard to:

- the ingredients and emissions of tobacco products, including reporting obligations for tar, nicotine and carbon monoxide;
- certain aspects regarding labelling and packaging of tobacco products, including health warnings, traceability and security features;
- prohibition of the placing on the market of tobacco for oral use;
- cross-border distance sales;
- notification of novel tobacco products;
- the placing on the market and labelling of certain products, which are related to tobacco products, such as electronic cigarettes and refill containers and herbal products for smoking.

Table 8-1 below indicates how lead is regulated by professional and consumer legislation.

Table 8-1: Relevant Professional and consumer legislation													
Cat.	Substance Name	CAS No.	Fertiliser	Cosmetic products	Toy safety	Maximum levels in food contaminants	Undesirable substances in animal feed	Medical devices	In vitro medical devices	RoHS	Tobacco	Plastic Food Contact Materials	Recycled Plastic Food Contact Materials
B	Lead	7439-92-1	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

9 Waste Legislation

9.1 Waste Framework Directive

Legislative Acts:

- [Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives](#)
- [Directive \(EU\) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste](#)

This framework Directive lays down the measures to prevent or reduce the adverse impacts of the generation and management of waste by reducing resource use and improving efficiency of use. There are certain wastes excluded from the requirements of this Directive, such as radioactive waste. These are outlined in Article 2. The Waste Framework Directive presents a waste hierarchy which applies as a priority order in waste prevention and management legislation and policy. Requirements of this Directive are outlined for prevention of waste, recovery, reuse and recycling, and disposal. The properties of waste which render it hazardous are outlined in Annex III.

9.2 Waste batteries and accumulators

Legislative act: [Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC](#)

This Directive lays down the rules for the placing on the market of batteries and accumulators, including the prohibition of the placing on the market of those containing hazardous substances. It also includes specific rules for the collection, treatment, recycling and disposal of waste batteries and accumulators. This Directive applies to all types of battery and accumulator unless they are used in equipment connected to the protection of Member States' essential security interests, arms, munitions and war material, unless not intended for specific military purposes, or equipment designed to be sent into space. Batteries and accumulators cannot contain more than the specific concentration of certain metals as outlined in Article 4.

9.3 Packaging and packaging waste

Legislative act: [European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste](#)

This Directive aims to harmonise national measures concerning the management of packaging and packaging waste to prevent or reduce impacts on the environment of Member States and third countries. The main priorities are to prevent the production of packaging waste through reusing, recycling and recovery of packaging. It covers all packaging placed on the market, including all packaging waste whether it is used or released at industrial, commercial, office, shop, service, household or any other level, regardless of the material used. The concentration levels of heavy metals in packaging must be controlled by Member States in accordance with Article 11.

9.4 ELV

Legislative Act: [Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles](#)

This Directive lays down the measures to prevent waste from vehicles, through reuse, recycling and other forms of recovery of end of life vehicles and their components. The ELV outlines the rules for collection, treatment, reuse and recovery of end of life vehicles and their components. The minimum treatment requirements are laid out in Annex I. Article 4(2)(a) requires Member States to ensure that materials and components of vehicles put on the market after 1 July 2013 do not contain lead, mercury, cadmium or chromium VI other than in the specific cases of exemption listed in Annex II.

9.5 Waste Shipments

Legislative Act: [Regulation \(EC\) No 1013/2006 of the European Parliament and of the Council of 14 June 2006 on shipments of waste](#)

This Regulation establishes the procedures and control regimes for the shipment of waste, depending on the origin, destination and route of the shipment, the type of waste shipped and the type of treatment to be applied to the waste at its destination. The requirements of this Regulation apply to shipments of waste between Member States; imported into the Community from third countries; exported from the Community to third countries; in transit through the Community between third countries.

Certain wastes are subject to the procedure of prior written notification and consent, these are outlined in Article 3. The notification procedure is explained in Chapter 1, which includes the contract, financial guarantee, transmission of notification and consents by the competent authorities of destination, dispatch and transit. This Regulation also outlines the additional provisions for interim recovery and disposal operations. The following Annexes provide lists of waste for which there are particular measures:

- Annex III - the list of wastes subject to the general information requirements laid down in Article 18.
- Annex IV - the list of wastes subject to the procedure of prior written notification and consent.
- Annex V – waste subject to the export prohibition in Article 36.

Table 9-1 below indicates how lead is regulated under waste legislation.

Cat.	Substance Name	CAS No.	Waste Framework Directive	Waste batteries	Packaging and packaging waste	ELV	Waste shipments
B	Lead	7439-92-1	Y	Y	Y	Y	Y

10 Environmental Legislation

10.1 Water Framework Directive

Legislative act: [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](#)

This Directive aims to establish a framework for the protection of inland waters, transitional waters, coastal waters and groundwaters. The priorities are to: prevent further deterioration and enhance the status of aquatic ecosystems and, with regard to their water needs, terrestrial ecosystems and wetlands directly dependant on aquatic ecosystems; promote sustainable water use; enhance protection and improvement of the aquatic environment through the reduction of discharges, emissions and losses of priority substances; enhancing the progressive reduction of pollution of groundwater and preventing further pollution; and to contribute to mitigating the effects of floods and droughts.

10.2 Environmental quality standards directive

Legislative act: [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](#)

This Directive sets out the environmental quality standards (EQS) for priority substances and certain other pollutants in line with Article 15 of the Water Framework Directive in order to achieve good surface water chemical status. Member States must apply the EQS that are laid down in Annex I for surface water. Member States must also establish an inventory, including maps, of emission, discharges and losses of all priority substances for each river basin district or part of a river basin district that lies within their territory. This should include their concentrations in sediment and biota, as appropriate. The reference period for this inventory should be one year between 2008 and 2010.

10.3 Groundwater Directive

Legislative Act: [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](#)

This Directive establishes the specific measures as provided for in the Water Framework Directive in order to prevent and control groundwater pollution. It sets out the criteria for good groundwater chemical status and the criteria for the identification and reversal of significant and sustained upward trends and for the definition of starting points for trend reversals. Annex I contains the groundwater quality standards. Member States have to consider establishing threshold values for 10 substances.

10.4 Drinking Water Directive

Legislative Act: [Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption](#)

This Directive aims to protect human health from the adverse effects of any contamination of water that is intended for human consumption by laying out the requirements to ensure that it is clean. One of the requirements is for Member States to set quality standard values for the parameters that are

set in Annex I, be that microbial or chemical. Regular monitoring is a requirement of this Directive, as is remedial action.

10.5 Industrial Emissions Directive

Legislative Act: [Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions \(integrated pollution prevention and control\)](#)

The IED lays down the rules on integrated prevention and control of pollution that arises from industrial activities. It aims to prevent, or where this is not possible, to reduce emissions to air, water and land and to prevent the generation of waste. This Directive applies to industrial activities that are referred to in Chapters II to VI, which are listed in Annex I. Annex II provides a list of polluting substances for air and water.

10.6 Ambient air quality Directive

Legislative act: [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](#)

This Directive outlines the measures that should contribute to:

- Defining and establishing objectives for ambient air quality designed to avoid, prevent or reduce harmful effects on human health or the environment;
- Assessing the ambient air quality in Member States using a common method and criteria;
- Obtaining information on ambient air quality in order to help combat air pollution and to monitor long-term trends and improvements that may result from national and Community measures;
- Ensuring that information on ambient air quality is made available to the public;
- Maintaining air quality where it is good and improving it where is not;
- Promoting increased cooperation between the Member States to reduce air pollution.

Upper and lower thresholds exist for a number of substances in Annex II.

10.7 National Emissions Ceilings Directive

Legislative Act: [Directive \(EU\) 2016/2284 of the European Parliament and of the Council of 14 December 2016 on the reduction of national emissions of certain atmospheric pollutants](#)

The National Emissions Ceilings Directive sets 2020 and 2030 emission reduction commitments for five main air pollutants. The new directive introduces a number of new reporting requirements for Member States. These are defined in Annex I of the directive and include annual information on emissions of a number of pollutants:

- the five main air pollutants NO_x, NMVOCs, SO₂, NH₃ and PM_{2.5} as well as carbon monoxide (CO);
- in addition to PM_{2.5}, also PM₁₀ particulate matter and, if available, black carbon (BC) and total suspended particulate matter (TSP);
- heavy metals cadmium (Cd), lead (Pb) and mercury (Hg) and, if available, the additional heavy metals arsenic, chromium, copper, nickel, selenium and zinc); and

- persistent organic pollutants (POPs) including selected polycyclic aromatic hydrocarbons (PAHs), dioxins and furans, polychlorinated biphenyls (PCBs) and hexachlorobenzene (HCB).

Table 10-1 below indicates how lead is regulated by environmental legislation.

Table 10-1: Applicable Environmental Legislation									
Cat.	Substance Name	CAS No.	Water framework Directive	Environmental quality standards	Groundwater directive	Drinking Water Directive	Industrial emissions directive	Ambient air quality Directive	National Emissions Ceilings Directive
B	Lead	7439-92-1	Y	Y	Y	Y	Y	Y	Y



RPA Europe
Via Turati Filippo 8, 20121 Milan (Italy)