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Legislative Mapping: Phthalates and Hexamoll® DINCH

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Summary Document

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1 Introduction

This document provides a summary of the legislative status of Phthalates and Hexamoll® DINCH 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 Phthalates Legislation

The below table summarises the legislation which affects phthalates.

Table 2-1: Simplified Summary Phthalates

Substance Name	CAS No.	Rotterdam Convention / PIC Regulation	REACH	CLP	PACT	CoRAP	Signs at Work Directive	CAD	Young Workers Directive	Pregnant & Breastfeeding Workers Directive	Cosmetic Products Regulation	Plastic Food Contact Materials Regulation	Recycled Plastic Food contact Materials Regulation	Medical Devices Regulation	In Vitro Medical Devices Regulation	RoHS Directive	Tobacco Directive	Waste Framework Directive	Water Framework Directive	Environmental Quality Standards Directive	Industrial Emissions Directive
DEHP	117-81-7		Y	Y	Y						Y	Y	Y			Y			Y	Y	Y
BBzP	85-68-7	Y	Y	Y	Y						Y	Y	Y								
DnBP	84-74-2		Y	Y	Y		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y			
DiBP	84-69-5	Y	Y	Y	Y		Y	Y	Y	Y	Y			Y	Y	Y	Y	Y			
DEP	84-66-2		Y		Y	Y					Y										
DiNP	28553-12-0		Y	Y	Y						Y	Y	Y								
DiNP	68515-48-0		Y	Y	Y			Y			Y	Y	Y					Y			
DnOP	117-84-0		Y																		
DiDP	26761-40-0		Y					Y				Y	Y					Y			
DiDP	68515-49-1		Y									Y	Y								

DMP	131-11-3		Y								Y									
DnPeP	131-18-0		Y		Y						Y									
DCHP	84-61-7		Y	Y	Y	Y														
DPHP	53306-54-0		Y		Y	Y														
Hexamoll DINCH	166412-78-8											Y	Y							
DiPeP	605-50-5		Y		Y						Y									
DHNUP	68515-42-4		Y	Y	Y						Y									
DnHP	84-75-3		Y	Y	Y															
DMEP	117-82-8		Y	Y	Y						Y									

3 International Conventions and Implementing EU Legislation

3.1 Rotterdam Convention & PIC

Legislative act: Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals

This Regulation implements the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. It aims to promote shared responsibility and cooperative efforts in international movement of hazardous substances in order to protect human health and the environment. This Regulation applies to certain hazardous chemicals that are subject to the prior informed consent under the Rotterdam Convention and certain hazardous chemicals that are banned or severely restricted within the Union or a Member State. Annex I provides the list of chemicals that are subject to the export notification procedure, the list of chemicals that qualify for PIC notification, and the list of chemicals subject to the PIC procedure. Annex V provides the list of chemicals and articles that are subject to the export ban referred to in Article 15.

Table 3-1 below indicates which phthalates are regulated under international conventions.

Table 3-1: International Conventions

Cat.	Substance Name	CAS No.	PIC Status
A	BBzP	85-68-7	Y
A	DiBP	84-69-5	Y

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]

4.2 CoRAP

The Community Rolling Action Plan (CoRAP) identifies the substances which shall be evaluated by Member States in the next three years and it is updated annually in March. Substance evaluation aims to clarify the initial concern that the manufacture and/or use of the substances could pose a risk to human health or the environment. These initial concerns tend to relate to potential persistency, bioaccumulation, toxicity (PBT), endocrine disruption, carcinogenicity, mutagenicity or reprotoxicity (CMR), in combination with wide dispersive use or consumer use of the substance.

Member States may focus their evaluation on the area of initial concern, but this does not have to be limit of the scope of the evaluation. Following evaluation, if additional data is required to clarify a suspected risk then further information may be requested from registrants of the substance, or it may be concluded that the substance does not constitute a risk and no further data is required.

Table 4-1 below indicates which phthalates are regulated under cross regulation activities.

Table 4-1: PACT List and CoRAP entries

Cat.	Substance Name	CAS No.	PACT List	CoRAP
A	DEHP	117-81-7	Y	
A	BBzP	85-68-7	Y	
A	DnBP	84-74-2	Y	
A	DiBP	84-69-5	Y	
A	DEP	84-66-2	Y	Y
A	DiNP	28553-12-0	Y	

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

A	DiNP	68515-48-0	Y	
B	DnPeP	131-18-0	Y	
B	DCHP	84-61-7	Y	Y
B	DPHP	53306-54-0	Y	Y
B	Hexamoll DINCH	166412-78-8		
C	DiPeP	605-50-5	Y	
C	DHNUP	68515-42-4	Y	
C	DnHP	84-75-3	Y	
C	DMEP	117-82-8	Y	

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 which phthalates are registered under REACH and its registered uses.

Table 5-1: REACH Registration

Cat.	Substance Name	CAS No.	FULL REACH Registration	Intermediate REACH Registration	Information on REACH registered uses
A	DEHP	117-81-7	Y	Y	Y
A	BBzP	85-68-7	Y		Y
A	DnBP	84-74-2	Y	Y	Y
A	DiBP	84-69-5	Y	Y	Y
A	DEP	84-66-2	Y	Y	Y
A	DiNP	28553-12-0	Y		Y
A	DiNP	68515-48-0	Y		Y
B	DiDP	68515-49-1	Y		Y
B	DMP	131-11-3	Y		Y
B	DCHP	84-61-7	Y		Y
B	DPHP	53306-54-0	Y		Y
C	DiPeP	605-50-5	Y		Y

Table 5-2: REACH Registered uses									
Cat.	Substance Name	CAS No.	Consumer uses	Article services life	Widespread uses by workworn	Formulation or repackaging	Uses at industrial sites	Manufacture	Intermediate only
A	DiNP	68515-48-0	Y		Y	Y			
B	DMP	131-11-3		Y	Y	Y	Y	**Y**	
B	DCHP	84-61-7			Y	Y	Y	**Y**	
B	DPHP	53306-54-0		Y	Y	Y	Y	**Y**	
C	DiPeP	605-50-5	Y		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 below indicate which phthalates are restricted and authorised under REACH.

Table 5-3: REACH Restriction

Cat.	Substance Name	CAS No.	Restriction list (annex XVII)	Registry of restriction intentions
A	DEHP	117-81-7	Y	Y
A	BBzP	85-68-7	Y	Y
A	DnBP	84-74-2	Y	Y
A	DiBP	84-69-5	Y	Y
A	DiNP	28553-12-0	Y	
A	DiNP	68515-48-0	Y	
B	DnOP	117-84-0	Y	
B	DiDP	26761-40-0	Y	
B	DiDP	68515-49-1	Y	

Table 5-4: REACH Authorisations

Cat.	Substance Name	CAS No.	Authorisation list	Candidate list	Candidate list: substances in articles	Registry of SVHC intentions
A	DEHP	117-81-7	Y	Y	Y	Y
A	BBzP	85-68-7	Y	Y	Y	Y
A	DnBP	84-74-2	Y	Y	Y	Y
A	DiBP	84-69-5	Y	Y	Y	Y
B	DnPeP	131-18-0	Y	Y	Y	Y
B	DCHP	84-61-7	Y	Y	Y	Y
C	DiPeP	605-50-5	Y	Y	Y	Y
C	DHNUP	68515-42-4	Y	Y	Y	Y
C	DnHP	84-75-3	Y	Y	Y	Y
C	DMEP	117-82-8	Y	Y	Y	Y

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 which phthalates are regulated under CLP regulation.

Table 6-1: Harmonised Classification

Cat.	Substance Name	CAS No.	Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	ATP inserted/ATP Updated
A	DEHP	117-81-7	Y	Y	Y	Y	Y
A	BBzP	85-68-7	Y	Y	Y	Y	Y
A	DnBP	84-74-2	Y	Y	Y	Y	Y
A	DiBP	84-69-5	Y	Y	Y	Y	Y
B	DCHP	84-61-7	Y	Y	Y	Y	Y
C	DHNUP	68515-42-4	Y	Y		Y	Y
C	DnHP	84-75-3	Y	Y	Y	Y	Y
C	DMEP	117-82-8	Y	Y	Y	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.

Table 7-1 below indicates which phthalates are regulated under OSH legislation.

Table 7-1: Relevant OSH legislation

Cat.	Substance Name	CAS No.	Signs at work	CAD	Young Workers	Pregnant & breastfeeding workers
A	DnBP	84-74-2	Y	Y	Y	Y
A	DiBP	84-69-5	Y	Y	Y	Y
A	DiNP	68515-48-0		Y		
B	DiDP	26761-40-0/68515-49-1		Y		

8 Professional and Consumer Legislation

8.1 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.

8.2 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.

8.2.1 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.

8.2.2 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.

8.3 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.

8.4 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.

8.5 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.

8.6 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.

Tables 8-1 and 8-2 below indicate which phthalates are regulated under professional and consumer legislation.

Table 8-1: Relevant Professional and consumer legislation

Cat.	Substance Name	CAS No.	Cosmetic products	Plastic Food Contact Materials	Recycled Plastic Food Contact Materials	Medical Devices
A	DEHP	117-81-7	Y	Y	Y	
A	BBzP	85-68-7	Y	Y	Y	
A	DnBP	84-74-2	Y	Y	Y	Y
A	DiBP	84-69-5	Y			Y
A	DEP	84-66-2	Y			
A	DiNP	28553-12-0	Y	Y	Y	
A	DiNP	68515-48-0	Y	Y	Y	
B	DiDP	26761-40-0		Y	Y	
B	DiDP	68515-49-1		Y	Y	
B	DMP	131-11-3	Y			
B	DnPeP	131-18-0	Y			
B	Hexamoll DINCH	166412-78-8		Y	Y	
C	DiPeP	605-50-5	Y			
C	DHNUP	68515-42-4	Y			
C	DMEP	117-82-8	Y			

Table 8-2: Relevant Professional and consumer legislation

Cat.	Substance Name	CAS No.	In Vitro Medical Devices	RoHS	Tobacco
A	DEHP	117-81-7		Y	
A	DnBP	84-74-2	Y	Y	Y
A	DiBP	84-69-5	Y	Y	Y

Note from EU Policy Board regarding setting of TDI for food contaminants:

"EFSA is currently working on the phthalates as a broad category… DEHP, DBP, BBP, DINP, DIDP: opinion adopted and to be published very soon (this week), cannot disclosed outcome until publication."

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.

Table 9-1 below indicates which phthalates are regulated under waste legislation.

Table 9-1: Applicable Waste Legislation

Cat.	Substance Name	CAS No.	Waste Framework Directive
A	DnBP	84-74-2	Y
A	DiBP	84-69-5	Y
A	DiNP	68515-48-0	Y
B	DiDP	26761-40-0/68515-49-1	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

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 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.

10.4 Import and Export of Hazardous Chemicals

Legislative act: Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals

This Regulation implements the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. It aims to promote shared responsibility and cooperative efforts in international movement of hazardous substances in order to protect human health and the environment. This Regulation applies to certain hazardous chemicals

that are subject to the prior informed consent under the Rotterdam Convention and certain hazardous chemicals that are banned or severely restricted within the Union or a Member State. Annex I provides the list of chemicals that are subject to the export notification procedure, the list of chemicals that qualify for PIC notification, and the list of chemicals subject to the PIC procedure. Annex V provides the list of chemicals and articles that are subject to the export ban referred to in Article 15.

Table 10-1 below indicates which phthalates are regulated under environmental legislation.

Table 10-1: Applicable Environmental Legislation

Cat.	Substance Name	CAS No.	Water Framework Directive	Environmental Quality Standards	Industrial Emissions Directive	Import and Export of Hazardous Chemicals
A	DEHP	117-81-7	Y	Y	Y	
A	BBzP	85-68-7				Y
A	DiBP	84-69-5				Y

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