CREATOR
COLLECT • PURIFY • REUSE

Deliverable report

Deliverable no./title:	D1.7 Assessment of existing legislations and regulations
Lead beneficiary:	OVM
Nature of deliverable:	Report
Dissemination level:	PU - Public
Due date:	30.11.2019

Grant Agreement number:	820477
Project acronym:	CREAToR
Project title:	Collection of raw materials, Removal of flAme reTardants and Reuse of secondary raw materials
Funding scheme:	H2020-SC5-2018-2019-2020
Coordinator:	FRAUNHOFER GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V.
Project website:	www.creatorproject.eu

TABLE OF CONTENTS

1 INTRODUCTION 3

2 APPLICABLE LEGISLATION 4

2.1 WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT DIRECTIVE (WEEE) 4
2.1.1 GENERAL OBLIGATIONS 4
2.2 END-OF LIFE VEHICLES DIRECTIVE (ELV) 4
2.2.1 GENERAL OBLIGATIONS 5
2.2.2 PARAMETERS 5
2.3 PACKAGING (WASTE) DIRECTIVE 5
2.3.1 GENERAL OBLIGATIONS 5
2.3.2 PARAMETERS 6
2.4 WASTE FRAMEWORK DIRECTIVE 6
2.4.1 GENERAL OBLIGATIONS 6
2.5 PERSISTENT ORGANIC POLLUTANTS'S REGULATION 6
2.5.1 GENERAL OBLIGATIONS 7
2.5.2 PARAMETERS 8
2.6 REACH 9
2.6.1 GENERAL OBLIGATIONS 10
2.6.2 PARAMETERS 12
2.7 CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES (CLP) 13
2.7.1 GENERAL OBLIGATIONS 14
2.8 RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES (ROHS) 16
2.8.1 GENERAL OBLIGATIONS 16
2.8.2 PARAMETERS 17
2.9 LEGISLATION ON FOOD CONTACT MATERIALS 18
2.9.1 GENERAL OBLIGATIONS 18
2.9.2 PARAMETERS 19
2.10 TOY SAFETY DIRECTIVE 19
2.10.1 PARAMETERS FEHLER! TEXTMARKE NICHT DEFINIERT.
2.11 ECOLABEL 19

3 APPLICABLE STANDARDS 21

4 EXPECTED LEGISLATION 22

5 CONCLUSIONS 23

1 INTRODUCTION

This document describes the relevant legislation and standards and identifies existing legal limitations on using the CREAToR recycled materials in new products.

Chapter 2 gives a detailed overview of these relevant legislation and identifies legal limitations on using the recycled materials in new products. Per legislation general obligations and specific parameters relevant for CREAToR are described. The latest amendment (end of 2019) to each regulation and directive has been taken into account.

A "regulation" is a binding legislative act. It must be applied in its entirety across the EU. Therefore, the general obligations and the specific parameters laid down in regulations are the same for all Member States. A "directive" is a legislative act that sets out a goal that all EU countries must achieve. However, it is up to the individual countries to devise their own laws on how to reach these goals. This means that a Member State can strengthen the general obligations and specific parameters in the directive.

Chapter 3 discusses the relevance of standards and provides an overview of standards that could be interestingfor CREAToR.

2 APPLICABLE LEGISLATION

2.1 WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT DIRECTIVE (WEEE)

Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE).

It aims to protect the environment and human health by encouraging sustainable production and consumption. It does so by:

- Preventing the creation of waste electrical and electronic equipment (WEEE);
- Promoting reuse, recycling and other ways of recovering waste from electrical and electronic equipment (EEE);
- Supporting the efficient use of resources and recovery of valuable secondary raw materials.

This directive applies to any equipment that falls under the definition of electrical and electronic equipment (EEE) as set out in article 3(1)(a). The categories of EEE can be found in Annex III of the directive. However, it does not apply to certain types of electrical and electronic equipment, notably materials for military or space purposes, filament bulbs, active implantable medical devices or means of transport.

2.1.1 GENERAL OBLIGATIONS

Member states shall ensure that all separately collected WEEE that cannot be reused, undergoes proper treatment. Proper treatment shall, as a minimum, include the removal of all fluids and a selective treatment in accordance with Annex VII of the directive. One of the removal requirements is the removal of plastics containing brominated flame retardants.

The directive does not require a separation of plastics from WEEE containing brominated flame retardants at the level of the WEEE dismantler, but the separation may also take place at a later step, e.g. after shredding in a shredder facility by means of IR or density separation processes.

This measure does not specifically target the brominated flame retardants of most concern, and penalizes the allowed brominated flame retardants. However, it is reinforced in combination with other EU legislation that restrict specific brominated flame retardants (POPs Regulation, RoHS directive, REACH.

2.2 END-OF LIFE VEHICLES DIRECTIVE (ELV)

Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (ELV).

This directive lays down measures which aim, as a first priority, at the prevention of waste from vehicles and, in addition, at the reuse, recycling and other forms of recovery of end-of-life vehicles and their components so as to reduce the disposal of waste, as well as at the improvement in the environmental performance of all of the economic operators involved in the life cycle of vehicles and especially the operators directly involved in the treatment of end-of-life vehicles.

This directive shall cover vehicles and end-of-life vehicles, including their components and materials.

2.2.1 GENERAL OBLIGATIONS

Member states shall take the necessary measures to ensure that hazardous materials and components shall be removed and segregated in a selective way as not to contaminate subsequent shredder waste from ELV. The minimum technical requirements for treatment can be found in Annex I of the directive. A treatment operation in order to promote recycling is the removal of large plastic components (bumpers, dashboard, fluid containers, etc.), if these materials are not segregated in the shredding process in such a way that they can be effectively recycled as materials.

The removal of plastics from ELV containing brominated flame retardants is not a minimum requirement in the ELV directive. Treatment operations for depollution of ELV only mentions the removal of batteries, liquefied gas tanks, potential explosive components, hazardous fluids and components identified as containing mercury.

2.2.2 PARAMETERS

Materials and components of vehicles put on the market after 1 July 2003 do not contain lead, mercury, cadmium or hexavalent chromium other than in cases listed in Annex II under the conditions specified therein.

2.3 PACKAGING (WASTE) DIRECTIVE

European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste.

The Packaging and Packaging Waste Directive aims to harmonize national legislations with the goal of preventing the production of packaging waste and, as additional fundamental principles, at reusing packaging, at recycling and other forms of recovering packaging waste and, therefore, at reducing the final disposal of such waste in order to contribute to the transition towards a circular economy.

This directive covers all packaging placed on the EU market and 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.

2.3.1 GENERAL OBLIGATIONS

EU countries must ensure that the packaging placed on the market meets the "Essential Requirements" contained in Annex II of the directive: In summary, these require that the packaging:

- is the minimum weight and volume adequate to maintain the necessary level of safety, hygiene and acceptance for the packed product and the consumer;
- is manufactured in such a way as to minimize the presence of 'noxious and other hazardous substances' in residues from the recovery/disposal operations;
- when intended for re-use, meets the requirements for safety in use and re-use, and is subsequently suitable for the appropriate recovery options;
- is suitable for recovery by material recycling and/or composting and/or energy recovery;

and, additionally (article 11),

- is manufactured so that the four named heavy metals are collectively within stated concentration limits.

In order to establish a common basis for assessing conformity with the "Essential Requirements" across the European Economic Area, the European Commission mandated the European standards body Comité Europeén de Normalisation (CEN) to prepare a series of standards and reports (see chapter 3).

2.3.2 PARAMETERS

The sum of concentration levels of lead, cadmium, mercury and hexavalent chromium present in packaging or packaging components shall not exceed 100 ppm by weight.

2.4 WASTE FRAMEWORK DIRECTIVE

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste (WFD).

The directive establishes a legal frameword for treating waste in the EU. It lays down measures to protect the environment and human health by preventing or reducing the generation of waste, the adverse impacts of the generation and management of waste and by reducing overall impacts of resource use and improving the efficiency of such use. This is crucial for the transition to a circular economy and for guaranteeing the Union's long-term competitiveness.

2.4.1 GENERAL OBLIGATIONS

The WFD incorporates the concept of end-of-waste (EoW), article 6 of the WFD, by setting out conditions whereby substances or objects which meet the waste definition can achieve, after undergoing a recovery operation (including recycling), an end-of-waste status and thus fall outside the scope of waste legislation.

> *"Member States shall take appropriate measures to ensure that waste which has undergone a recycling or other recovery operation is considered to have ceased to be waste if it complies with the following conditions:*
>
> *a) The substance or object is to be used for specific purposes;*
>
> *b) A market or demand exists for such a substance or object;*
>
> *c) The substance or object fulfils the technical requirements for the specific purposes and meets the existing legislation and standards applicable to products; and*
>
> *d) The use of the substance or object will not lead to overall adverse environmental or human health impacts."*

The natural or legal person who:

- Uses, for the first time, a material that has ceased to be waste and that has not been placed on the market; or
- Places a material on the market for the first time after it has ceased to be waste,

shall ensure that the material meets relevant requirements under the applicable chemical and product related legislation. The end-of-waste conditions have to be met before the legislation on chemicals and products applies to the material that has ceased to be waste.

2.5 PERSISTENT ORGANIC POLLUTANTS'S REGULATION

Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (POPs).

POPs are regulated worldwide by the Stockholm Convention and the Aarhus Protocol. These examples of legislation are implemented in the European Union by the POPs Regulation.

The POPs Regulation aims to protect human health and the environment with specific control measures that:

- Prohibit or severely restrict the production, placing on the market and use of POPs;
- Minimize the environmental release of POPs that are formed as industrial by-products;
- Make sure that stockpiles of restricted POPs are safely managed; and
- Ensure the environmentally sound disposal of waste consisting of, or contaminated by POPs.

2.5.1 GENERAL OBLIGATIONS

The manufacturing, placing on the market and use of substances listed in Annex I of the regulation, whether on their own, in mixtures or in articles, is prohibited. The prohibition does not apply to a substance present as an unintentional trace contaminant in substances, mixtures or articles. An unintentional trace contaminant (UTC) means a level of a substance that is incidentally present in a minimal amount, below which the substance cannot be meaningfully used, and above the detection limit of existing detection methods to enable control and enforcement.

With regard to wastes, producers and holders of waste are obliged to undertake measures to avoid contamination of waste with POP substances.

Waste with POPs content higher than the POP concentration limits in Annex IV of the regulation must be disposed of or recovered in such a way that the POP content is destroyed or irreversibly transformed so that the remaining waste and releases do not exhibit the characteristics of POPs. Disposal or recovery operations that may lead to recovery, recycling, reclamation or re-use on their own of the POP is prohibited.

The following disposal and recovery operations are permitted when applied in such a way as to ensure that the POP content is destroyed or irreversibly transformed (risk and safety statements):

- D9 : physic-chemical treatment;
- D10: incineration on land;
- R1 : use as a fuel or other means to generate energy;
- R4 : recycling/reclamation of metals and metal compounds.

Waste with a low POP content (i.e. below the concentration limits set in Annex IV of the regulation) may be otherwise disposed of or recovered.

A POP substance may be isolated from the rest of the waste, provided that it will be destroyed or irreversibly transformed.

If a "pure" POP (e.g. decaBDE) is extracted from a waste, according to article 7.2 it will have to be destroyed or irreversibly transformed. This may be in contradiction with the acceptable uses foreseen in Annex I of the regulation. However, article 7.2 leaves no room for other interpretations.

Permanent storage is only allowed for a limited list of waste. If none of the treatment methods listed above is the best option with regard to the environment for treating POP waste, the authorities can, in certain exceptional cases, grant a permit to place the waste in a landfill for hazardous waste, deep inside safe bedrock or a salt mine. If the concentration of the POP also exceeds the upper concentration limit in annex V, part 2 of the regulation, the waste can only be placed deep inside safe bedrock or a salt mine according to an exceptional procedure.

2.5.2 PARAMETERS

The manufacturing, placing on the market and use of substances listed in Annex I of the regulation, whether on their own, in mixtures or in articles, is prohibited.

SUBSTANCE	UTC	SPECIFIC EXEMPTION
TetraBDE PentaBDE HexaBDE	10mg/kg in substances for each entry 500 mg/kg in mixtures and articles for the sum of the entries	EEE within the scope of the Rohs Directive Use of articles already in use before 25 August 2010
DecaBDE		Exemptions for aircrafts, spare parts for motor vehicles and EEE within the scope of the Rohs directive Use of articles already in use before 15 July 2019
PFOS and its derivatives	10mg/kg in substances or mixtures 1000mg/kg in semi-finished products or articles	Use of articles already in use before 15 July 2019
Pentachlorobenzene	-	
Hexabromobiphenyl	-	
Hexabromocyclododecane	100mg/kg in substances, mixtures, articles or as constituents of flame-retarted articles	Use of EPS articles containing HBCD already in use in buildings before 21 February 2018 Use of XPS articles containing HBCD already in use in buildings before 23 June 2016
Polychlorinated naphthalenes		Placing on the market and use of articles already in use before 10 July 2012
Short-chain chlorinated paraffins	1% by weight in substances or mixtures 0,15% by weight in articles	Use in conveyor belts in the mining industry and dam sealants already in use before 4 Decmber 2015 Use in other articles already in use before 10 July 2012

Hexachlorobenzene	-	
Hexachloorbutadieen		Placing on the market and use of articles already in use before 10 July 2012

Waste containing or contaminated by any substance listed in Annex IV of the regulation may be otherwise disposed of or recovered in accordance with the relevant Union legislation, provided that the content of the listed substances in the waste is below the concentration limits specified in Annex IV:

SUBSTANCE	CONCENTRATION LIMIT
TetraBDE	Sum of the concentrations: 1.000 mg/kg Subject to review by the Commission not later than 16 July 2021 to lower that value to 500 mg/kg
PentaBDE	
HexaBDE	
HeptaBDE	
DecaBDE	
PFOS and its derivatives	50 mg/kg
Pentachlorobenzene	50 mg/kg
Hexabromobiphenyl	50 mg/kg
Hexabromocyclododecane	1.000 mg/kg, subject to review by the Commission by 20 April 2019
Polychlorinated naphthalenes	10 mg/kg
Short-chain chlorinated paraffins	10.000 mg/kg
Hexachlorobenzene	50 mg/kg
Hexachloorbutadieen	100 mg/kg

2.6 REACH

Regulation (EC) 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 (ECHA).

REACH aims to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances. This is done by the four processes of REACH, namely the registration, evaluation, authorization and restriction of chemicals. REACH also aims to enhance innovation and competitiveness of the EU chemicals industry.

Companies need to **register** their substances and to do this they need to work together with other companies who are registering the same substance. ECHA receives and **evaluates** individual registrations for their compliance, and the EU Member States evaluate selected substances to clarify initial concerns for human health or for the environment. Authorities and ECHA's scientific committees assess whether the risks of substances can be managed.

Authorities can ban hazardous substances if their risks are unmanageable. They can also decide to **restrict** a use or make it subject to a prior **authorisation**.

2.6.1 GENERAL OBLIGATIONS

A recycler becomes the manufacturer of substances when the material leaves the waste regime, and becomes a product again. At that point, other than some special exemptions, recyclers are subject to all the REACH obligations that apply to substance manufacturers. REACH manufacturers of chemical substances of at least one tonne per year must register the chemical substance to ECHA (the European Chemical's Agency).

Substance, mixture or article

A plastic polymer is a chemical substance within REACH. Additives to the substance that are necessary for the stability of the process, or impurities from the manufacturing process are part of the substance according to Article 3(1) in REACH.

Intentional additives added for reasons other than stabilisation which have not reacted with the polymer are considered as separate substances and are therefore not part of the polymer. Plastic granules, for example, are often regarded as a mixture of several substances.

The ECHA guidelines on waste and recovered substances provide support to recyclers on how to comply with REACH. Recycled plastic material can include impurities in the form of additives that were added to the original plastic material, but serve no function in the recycled material. According to the ECHA guidance impurities of this kind, both from waste management and from original plastic material, should be regarded as a part of a substance if they do not exceed 20% (w/w). In other words, if the content of impurities is below 20% (w/w) they are considered to be part of the polymer. However, if the additives are recycled on purpose they are considered to be separate substances under REACH, and it is the same for impurities exceeding 20% (w/w). This 80/20 rule is currently being discussed further by the European Commission and the member states as there is no consensus about the interpretation.

However, it can be difficult to conclude whether a constituent of a recovered material is a substance or an impurity. There is no legal definition of an impurity in REACH.

In order to assess registration requirements for recovered materials, it is essential to clearly identify whether the particular material is a substance as such, a mixture (containing 2 or more blended substances) or an article (the shape, surface or design of an object is more relevant for the function than its chemical composition). There is no registration requirement under REACH with regard to the presence of a substance in a recovered article. Registration of substances in articles is only required if they are intended to be released under certain conditions. For an article only information requirements need to be fulfilled.

Identification of substances and impurities

The polymer recovery operator should identify all substances and impurities in the recovered material. By mechanical recycling the spectrum of impurities and their concentrations can be relatively wide. By chemical

recycling it is necessary to determine the level to which the impurities have been removed and whether or not new impurities have been formed.

Even if impurities do not have to be registered separately, they need to be:

- identified to the extent needed and allocated to the recovered substance(s) in order to facilitate the comparison with (an)other already registered substance(s); and
- identified and evaluated to the extent needed for establishing the hazard profile as well as the classification and labelling of the substance as such or in a mixture in which they occur.

In determining the status of the recovered polymeric material, information on the origin may be important in establishing which constituents may be present in the material and whether they should be seen as impurities or separate substances.

Registration

When the type of substance (substance on its own or in a mixture) and impurity of the recovered material is determined, and identified and documented the recovery operator examines whether the exemption criteria under Article Article 2(7)(d) of REACH are fulfilled.

The registration provisions under REACH do not apply to polymers, the manufacturer is required to register the monomers. For recovered polymers, the monomers and the other substances (when it is a mixture) have to be registered.

Article 27(d) means in brief that substances that result from recovery processes, if they are the same as already registered by any registrant, is exempted from registration according to REACH.

"2.7. The following shall be exempted from Titles II (Registration), V (Downstream users) and VI (Evaluation):

[…]

(d) Substances, on their own, in mixtures or in articles, which have been registered in accordance with Title II and which are recovered in the Community if:

(i) the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and

(ii) the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery."

If the REACH exemptions do not apply to the substance, then the substance or the substance in the mixture must be registered. In the registration dossier, they must identify the risks that are linked to the substances they produce and market and indicate how these risks are managed. Without registration, substances cannot be manufactured or imported into the EU ("No data no market").

Authorisation and 'Candidate list'

Substances of very high concern will be gradually identified in the 'Candidate list' and eventually included in Annex XIV of the REACH Regulation. Substances with the following hazard properties may be identified as SVHCs:

- Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1A or 1B in accordance with the CLP Regulation.
- Substances which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH Annex XIII.

- Substances on a case-by-case basis, that cause an equivalent level of concern as CMR or PBT/vPvB substances.

Substances on the candidate list can be used in mixtures and articles, but there is obligation to provide information, such as:

- Supplying a safety data sheet
- communicating on safe use
- responding to consumer requests within 45 days and
- notifying ECHA if the article they produce contains an SVHC in quantities above one tonne per producer/importer per year and if the substance is present in those articles above a concentration of 0.1% (w/w).

According to article 33 in REACH it is not compulsory to analyse or measure SVHCs in the products they market, but they are required to be able to provide information regarding SVHCs that are present in levels exceeding 0.1% (w/w).

ECHA regularly assesses the substances from the Candidate List to determine which ones should be included in the Authorisation List as a priority. The prioritisation is based on information on the intrinsic properties, wide dispersive use or high volumes that fall within the scope of the authorisation requirement. Once included in Annex XIV, they cannot be placed on the market or used after a date to be set (the so-called "sunset date") unless the company is granted an authorisation.

Restriction

Restrictions are an instrument to protect human health and the environment from unacceptable risks caused by chemicals. Restrictions are normally used to limit or to ban the manufacture, placing on the market (including imports) or use of a substance, but can impose any relevant condition, such as requiring technical measures or specific labels.

The recovery operator needs to ensure that the recovered substances comply with restrictions as set out in Annex XVII to REACH. A restriction may apply to any substance on its own, in a mixture or in an article, including those that do not require registration.

2.6.2 PARAMETERS

Authorisation

Annex XIV contains 43 substances subject to authorization, per December 2019. The most relevant substances in plastics on the authorisation list are listed table 1.

SUBSTANCE	FUNCTION	RELEVANT TYPES OF PLASTIC	SUNSET DATE
Bis (2-ethylhexyl) phthalate (DEHP)	Plasticiser	PVC (mainly), PMMA, ABS,..	21.02.2015
Dibutyl phthalate (DBP)	Plasticiser Catalyst	PVC PP	21.02.2015
Benzyl butyl phthalate (BBP)	Plasticiser	PVC (mainly), PMMA	21.02.2015

Diisobutyl phthalate (DIBP)	Plasticiser	PVC (mainly), PS	21.02.2015
Hexabromocyclododecane (HBCDD)	Flame retardant	EPS, XPS, HIPS, textile coating	21.08.2015
Lead chromate	Pigment	All types	21.05.2015
Lead chromate molybdate sulfate red	Pigment	All types	21.05.2015
Lead sulfochromate yellow	Pigment	All types	21.05.2015
Chromium trioxide	Catalyst	PE and other plastics	21.09.2017
2,2'-dichloro-4,4'-methylenedianiline	Curing agent, cross-linker	PU (mainly)	22/11/2017

Restrictions

Annex XVII contains 73 restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles, per December 2019. The most relevant restrictions for plastics are listed below:

- restriction 23: cadmium and its compounds
- restriction 28: substances which are classified as carcinogen category 1A or 1B
- restriction 29: substances which are classified as germ cell mutagen category 1A or 1B
- restriction 30: substances which are classified as reproductive toxicant category 1A or 1B
- restriction 45: Diphenylether, octabromo derivative
- restricition 50: Polycyclic-aromatic hydrocarbons (PAH)
- restriction 51: phthalates (DEHP, DBP, BBP, DIBP)
- restriction 52: phthalates (DINP, DIDP, DNOP)
- restriction 63: lead

2.7 CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES (CLP)

Regulation (EC) 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP).

The CLP is based on the United Nations' Globally Harmonised System (GHS) and its purpose is to ensure a high level of protection of human health and the environment. CLP is legally binding in the Member States and

directly applicable to all industrial sectors. It requires manufacturers, importers or downstream users of substances or mixtures to classify, label and package their hazardous chemicals appropriately before placing them on the market.

The hazard of a substance or mixture is the potential for that substance or mixture to cause harm. It depends on the intrinsic properties of the substance or mixture. In this context, hazard evaluation is the process by which information about the intrinsic properties of a substance or mixture is assessed to determine their potential to cause harm. It should not be confused with risk assessment, which relates a given hazard to the actual exposure of humans or the environment to the substance or mixture displaying this hazard. Nevertheless, the common denominator for both classification and risk assessment is hazard identification and hazard assessment.

2.7.1 GENERAL OBLIGATIONS

The obligations of suppliers of substances or mixtures under the CLP Regulation will mostly depend upon their role towards a substance or mixture in the supply chain. It is therefore important to identify your role under the CLP Regulation.

OBLIGATIONS	MANUFACTURER	IMPORTER	DISTRIBUTOR	FORMULATOR	PRODUCER OF AN ACTICLE	PROFESSIONAL USER	INDUSTRIAL USER
				DOWNSTREAM USER			
Classification	X	X	-	X	O	-	-
Labelling	X	X	X	X	O	-	-
Packaging	X	X	X	X	O	-	-
Notification	X	X	-	-	-	-	-
Maintain information	X	X	X	X	X	-	-

X : always applicable
O : sometimes applicable (for explosive articles)
- : does not apply

Classification

When relevant information (e.g. toxicological data) on a substance or mixture meets the classification criteria in CLP, the hazards of a substance or mixture are identified by assigning a particular hazard class and category. The hazard classes in CLP cover physical, health, environmental and additional hazards and are set out in parts 2 to 5 of Annex I to CLP.

The CLP Regulation includes provisions for two types of classification:

- Harmonized classification

- Self-classification

For a substance that already has a harmonised classification, the harmonized hazard classification is legally binding for the hazard classes and differentiations covered in the entry. The hazard classes and differentiations not covered in the entry must be evaluated and self classified, as appropriate.

The decision on classification for a partical hazard of a substance is taken at EU level. Harmonised classification normally applies to those properties of the highest concern (carcinogenicity, mutagenicity, reproductive toxicity (CMR) and respiratory sensitisers) and may also apply for other properties if there is a need for a EU-level action. Harmonised classifications of substances are included in Table 3 of Part 3 of Annex VI to CLP.

For a substance with no current Annex VI entry (i.e. the substance has no harmonized classification for any hazard class), all relevant hazard classes must be assessed by the manufacturer or importer and the self-classification must be applied to all hazard classes for which te classification criteria are fulfilled.
Mixtures must always be self-classified before being placed on the market, as they are not subject to harmonized classification and labelling.

To derive a self-classification, the classifier must gather all the available information and evaluate its adequacy and reliability. The information should then be assessed against the classification criteria and the corresponding classification has to be decided.
Classifying mixtures follows a similar process. They can be classified based on data on the mixture itself, data on similar tested mixtures, or data on the individual components in the mixture.

In order to determine the hazardous properties of a recovered material (recovered substances and mixtures), the composition must be known down to the substance/impurty level. In general substances/impurities present at 0.1 % or above should be taken into consideration, but the relevant concentration ultimately depends on the hazard class and the substance/impurity.

Labelling and packaging

Once a substance or mixture is classified, the identified hazards must be communicated to other actors in the supply chain, including consumers. Hazard labelling allows the hazard classification, with labels and safety data sheets, to be communicated to the user of a substance or mixture, to alert them about the presence of a hazard and the need to manage the associated risks.

CLP sets detailed criteria for the labelling elements: pictograms, signal words and standard statements for hazard, prevention, response, storage and disposal, for every hazard class and category.

Labelling is required when:

- The substance or mixture is classified as hazardous;
- The mixture contains one or more substances classified as hazardous above a certain threshold;
- The article has explosive properties.

CLP sets general packaging standards to ensure the safe supply of hazardous substances and mixtures.

Notification

The notification obligation under CLP requires manufacturers and importers to submit classification and labelling information for the substances they are placing on the market to the C&L Inventory held by ECHA. This database contains classification and labelling information on notified (CLP) and registered (REACH) substances received from manufactures and importers.

Under CLP, recovered substances and mixtures will normally have to be treated in the same way as other substances and mixtures under CLP. This means that they have to be classified in accordance with Title II of CLP and the substances have to be notified to the C&L Inventory, unless the establishment undertaking the recovery (manufacturer of the recovered substance) has already submitted a registration under REACH and included the information necessary for a notification. If the establishment undertaking the recovery can rely on the exemption from the REACH registration provisions for recovered substances pursuant to REACH Article 2(7)(d), it would still have to notify the recovered substances to the C&L Inventory, in accordance with CLP Article 39(b) and 40.

When classifying under the CLP Regulation, the establishment carrying out the recovery may take over the classification already derived in accordance with Title II of CLP by the registrant of the same substance, if this is appropriate. When notifying in such cases to ECHA, it is recommended to retrieve the classification and labelling information provided earlier by the registrant of the original substance from ECHA's Classification & Labelling Inventory and agree to it.

2.8 RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES (ROHS)

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 (RoHS).

It strengthens existing rules on the restriction of the use of hazardous substances, such as lead, cadmium and brominated flame retardants, in electrical and electronic equipment (EEE) to protect human health and the environment, in particular by enabling environmentally sound recovery and waste treatment of EEE.

Annex I of the directive sets out the categories of EEE that are covered by the legislation. These range from household appliances to information technology (IT) equipment, plus an open catch-all category. The restrictions also apply to cables and spare parts. A short list of exclusions is given for certain special cases. The restrictions do not apply to a range of items such as weapons, large-scale stationary industrial tools or photovoltaic panels.

2.8.1 GENERAL OBLIGATIONS

The directive places an obligation on manufacturers to ensure any EEE that they place on the market has been designed and produced in line with the requirements set out in the legislation. Importers must check that equipment has been approved as confirming to the required standards.

2.8.2 PARAMETERS

No more than the maximum concentration value by weight in homogeneous materials as specified in Annex II of the directive shall be tolerated.

Table 1: Restricted substances and maximum concentration values tolerated by weight in homogeneous materials

SUBSTANCE	CONCENTRATION
Lead	0,1 %
Mercury	0,1 %
Cadmium	0,01 %
Hexavalent chromium	0,1 %
Polybrominated biphenyls (PBB)	0,1 %
Polybrominated diphenyl ethers (PBDE)	0,1 %
Bis(2-ethylhexyl) phthalate (DEHP)	0,1 %
Butyl benzyl phthalate (BBP)	0,1 %
Dibutyl phthalate (DBP)	0,1 %
Diisobutyl phthalate (DIBP)	0,1 %

The POPs Regulation and REACH often refer to the RoHS directive for the maximum concentrations of certain substances in EEE.

2.9 LEGISLATION ON FOOD CONTACT MATERIALS

Framework Regulation (EC) 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intented to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

Commission Regulation (EU) 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food

Commission Regulation (EC) 282/2008 of 27 March 2008 on recycled plastic materials and articles intented to come into contact with foods and amending Regulation (EC) 2023/2006

2.9.1 GENERAL OBLIGATIONS

The Regulation 1935/2004 provides a harmonized legal EU Framework. It sets out the general principles of safety and inertness for all food contact materials.

The principles set out in this Regulation require that materials do not:

- Release their constituents into food at levels harmful to human health
- Change food composition, taste and odour in an unacceptable way

In addition to the general legislation, certain food contact materials such as plastic materials and recycled plastic materials are covered by specific EU measures.

The Regulation 10/2011 on plastic materials and articles sets out rules on the composition of plastic food contact materials, and establishes a Union List of substances that are permitted for use in the manufacture of plastic food contact materials. The Regulation also specifies restrictions on the use of these substances and sets out rules to determine the compliance of plastic materials and articles.

An important mechanism to ensure the safety of plastic materials is the use of migration limits. These limits specify the maximum amount of substances allowed to migrate to food. For the substances on the Union list the Regulation sets out '*Specific Migration Limits*' (SML). These are established by EFSA on the basis of toxicity data of each specific substance. To ensure the overall quality of the plastic, the overall migration to a food of all substances together may not exceed the Overall Migration Limit (OML) of 60mg/kg food, or 10 mg/dm^2 of the contact material.

Regulation 10/2011 sets out criteria for the composition of new plastic materials. However, after these materials have been used, they do not comply anymore to the plastic Regulation, as they may have been contaminated with other substances. Therefore, a separate Regulation exists to control the recycling processes: Commission Regulation 282/2008 on recycled plastic materials and articles intended to come into contact with foods. The materials and articles covered here are also subject to Regulation 10/2011 on plastic materials intended for food packaging.

The recycled plastic used for the manufacture of materials and articles covered by this Regulation must come from an authorised recycling process, managed according to rules set out in the Annex of Regulation (EC) 2023/2006 on good practice for materials and articles intended to come into contact with food.

Authorisation may be granted if recycling processes comply with the following:

- The input must be quality controlled;
- The input must originate from plastic materials made in accordance with EU legislation on plastic materials and articles intended for contact with food;

- The process must guarantee that there is no risk of contamination or that it is at a level posing no risk to health;
- The finished article must not release components into food in a quantity likely to endanger human health or cause an unacceptable change in the composition of the food, or a deterioration in its appearance, smell or texture.

The whereas of Regulation 282/2008 mentions in (6) plastic waste can be treated mechanically to produce recycled materials and articles or it can be broken down to monomers and oligomers by chemical depolymerisation. Monomers and oligomers resulting from chemical depolymerisation should not be treated differently from monomers manufactured by chemical synthesis. Therefore, they are covered by the authorisation of monomers and additives in Directive 2002/72/EC and they should comply with the specifications and purity criteria established therein. Therefore, they should not be covered by this Regulation. There or no specific guidelines for materials resulting from other chemical recycling technologies.

2.9.2 PARAMETERS

The Regulation 10/2011 lists the substances that may be intentionally used in the manufacture of plastic materials and articles. The list includes 1069 substances: monomers, additives, polymer production aids and macromolecules obtained from microbial fermentation. The Regulation's annexes set out the conditions of use for authorized substances and migration limits. All plastic materials and articles must comply with specific migration limits and overall migration limits.

2.10 TOY SAFETY DIRECTIVE

Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys.

It sets out the safety requirements that toys made available in the EU must meet. These requirements are designed to provide a high level of health and safety, to protect the public and the environment and to guarantee free movement of toys in the EU.

2.10.1 PARAMETERS

The toy safety directive puts in place strict requirements for chemicals:

- chemicals that are susceptible to cause cancer, change genetic information, harm fertility or harm an unborn child (so-called CMR substances) are no longer allowed in the accessible parts of toys beyond the concentration limits set in the CLP Regulation, or unless they are considered safe following a rigorous scientific evaluation.
- 19 so-called 'heavy elements' like mercury and cadmium are not allowed in toy parts accessible to children beyond the limits laid down in the toy safety directive.
- 55 allergenic fragrances have been banned. However, some of them, and another 11, may be used in certain toys provided that they are indicated on the label and comply with additional requirements.

2.11 ECOLABEL

Regulation (EC) 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel

This Regulation lays down rules for the establishment and application of the voluntary EU Ecolabel scheme.

The EU Ecolabel may be awarded to products and services which have a lower environmental impact than other product in the same group. The label criteria were devised using scientific data on the whole of a product's life cycle, from product development to disposal. The label may be awarded to all goods or services distributed, consumed or used on the EU market whether in return for payment or free of charge, on condition that the ecological criteria have been clearly established.

The label cannot be awarded to products containing substances meeting the criteria for classification by CLP as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR), nor to goods containing substances referred to in Article 57 of REACH.

For a product that has an ecolabel only plastic recyclate can be used that does not contain any of the above mentioned substances. The recycler must be able to guarantee this.

3 APPLICABLE STANDARDS

Standards and other standardisation publications are voluntary guidelines providing technical specifications for products, services, and processes. Standards are developed by private standardization organisations usually on the initiative of stakeholders who see a need to apply a standard.

European standards are adopted by one of the 3 European standardisation organisations: European Committee for Standardisation (CEN), European Committee for Electrotechnical Standardisation (Cenelec) and European Telecommunications Standards Institute (ETSI).

At national level, standardisation is managed by national standardisation bodies who adopt and publish national standards. The national standardisation bodies also transpose all European standards as identical national standards and withdraw any conflicting national standards.

Harmonised standards

Harmonised standards are a specific category of European standards following a request, known as a 'mandate', from the European Commission. Technical requirements given in EU legislation are mandatory, while the use of harmonized standards is usually voluntary. Harmonised standards establish technical specifications which are considered suitable or sufficient in order to comply with the technical requirements given in EU legislation.

In most cases, using harmonized standards is voluntary. A manufacturer can choose another technical solution to fulfill the legal requirements. In some cases, standards are referenced in legislation as a preferred way or even as a mandatory requirement to comply with specific laws.

Links to summary lists of possible relevant harmonised standards for CREATOR can be found below:

- **Under Toy safety directive**
- **For construction products**
- **Under RoHs directive**
- **Under Ecodesign and Energy labelling directives**
- **Under Packaging (waste) directive**
- **Standards on WEEE treatment**

Standards on plastics's recyclates

The following series of standards is aiming at the management and the characterisation of plastics's recyclates:

- EN15342:2007 Characterisation of polystyrene (PS) recyclates
- EN15343:2007 Plastics recycling traceability and assessment of conformity and recycled content
- EN15344:2007 Characterisation of polyethylene (PE) recyclates
- EN15345:2007 Characterisation of polypropylene (PP) recyclates
- EN15346:2007 Characterisation of polyvinylchloride (PVC) recyclates
- EN15347:2007 Characterisation of plastic waste
- EN15348:2007 Characterisation of polyethylene terephthalate (PET) recyclates

A detailed view of the standards relevant for the project will be included in the follow-up report (D1.8).

4 EXPECTED LEGISLATION

REACH Article 138(2) provides for an ongoing review of the 'risks posed' by polymers, with a view to identifying those that display equivalent levels of concern to other substances. The article also states that a report must be published on the need, if any, to register certain types of polymers, taking into account the impact on competitiveness and innovation.

The European Commission is currently working on a proposal for polymer REACH registration. The objective is to finalise this proposal by 2022.

This report will be updated as soon as new regulations, with relevance for the project, are published.

5 CONCLUSIONS

When demonstrating the end-of-waste status article 6 of the **Waste Frame Directive** is of special significance for recyclers. Only waste that has undergone a recovery, including recycling, operation can be checked against the conditions for end-of-waste.

Specific waste legislation imposes obligations whereby:

- plastic that contains brominated flame retardants should be removed from WEEE (**WEEE directive**) or
- plastic with a POPs content higher than the POP concentration limits in **Annex IV** of the POPs Regulation must be disposed of or recovered in such a way that the POP content is destroyed or irreversibly transformed so that the remaining waste and releases do not exhibit the characteristics of POPs (**POPs Regulation**).

The recovery operation must comply with these obligations.

Article 6 of the Waste Frame Directive:

"Member States shall take appropriate measures to ensure that waste which has undergone a recycling or other recovery operation is considered to have ceased to be waste if it complies with the following conditions:

a) The substance or object is to be used for specific purposes;
b) A market or demand exists for such a substance or object;
These first two conditions are related. Compliance with these two criteria can be indicated by: e.g. the material goes to a plastic converter, the existence of firmly established market conditions related to supply and demand,…

c) The substance or object fulfils the technical requirements for the specific purposes and meets the existing legislation and standards applicable to products; and
Compliance with this criterion can be indicated by compliance with established relevant technical specifications or technical standards that are used for virgin materials for the same purpose. The material should be ready for final use and no additional waste treatment steps should be needed.

d) The use of the substance or object will not lead to overall adverse environmental or human health impacts.
Compliance with this criterion can be indicated by comparing the use of the material under the relevant product legislation with the use of the same material under waste legislation. The following questions are also relevant: Is the product legislation sufficient to adequately minimise the environmental or human health impacts? Would releasing the material from the waste regime lead to higher environmental or health risks?

A recovered material can leave the waste status in different forms: as a recyclate (substance/mixture) or as a plastic item (article). It means a big difference in terms of general obligations in chemical legislation (REACH, CLP). The administrative obligations for articles are much more limited. Whether the first not-waste material is a substance/mixture or an article it must always be demonstrated that the material meets the relevant requierements under the applicable product legislation (POPs regulation annex I, RoHS, REACH restrictions, Food contact materials, Toys safety,…. Therefor the end use must be known."

Figure 1 gives an overview.

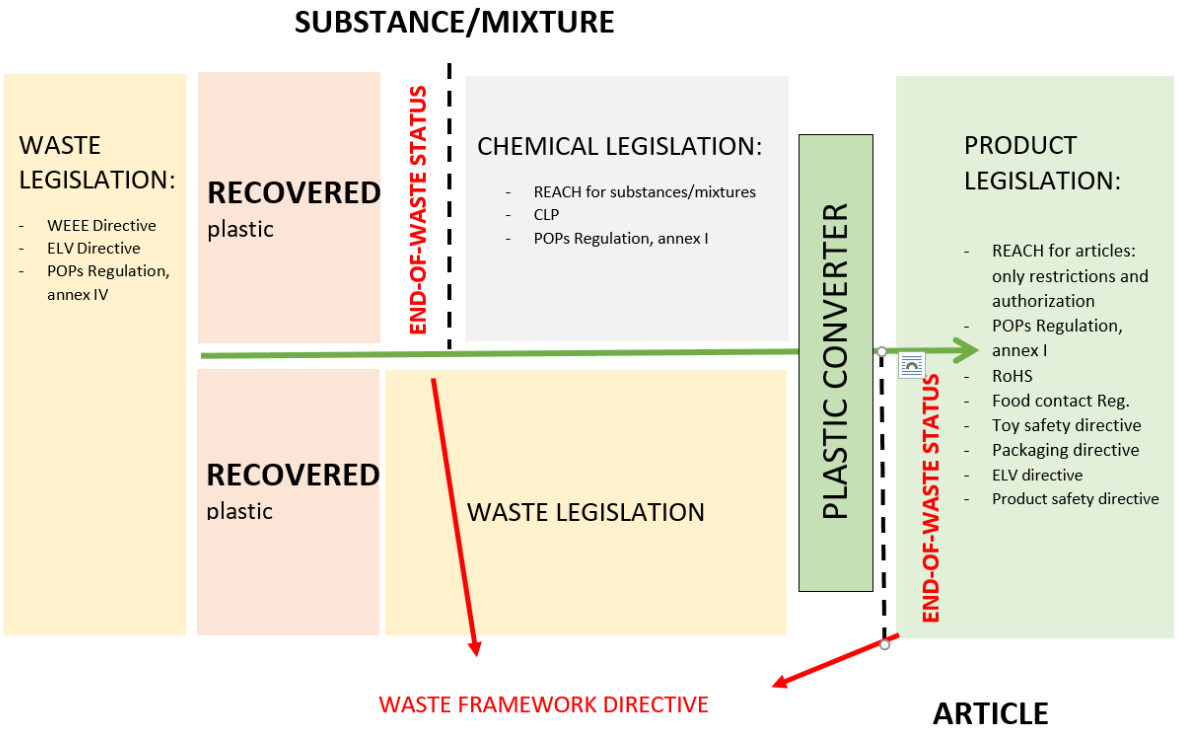

Figure 1 Overview of the applicable legislation when the end-of-waste material is a substance/mixture or an article