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IMPEL Waste management and Circular Economy Group

REACH Regulation and Circular Economy

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Introduction to IMPEL

The European Union Network for the Implementation and Enforcement of Environmental Law (IMPEL) is an international non-profit association of the environmental authorities of the EU Member States, acceding and candidate countries of the European Union and EEA countries. The association is registered in Belgium and its legal seat is in Brussels, Belgium.

IMPEL was set up in 1992 as an informal Network of European regulators and authorities concerned with the implementation and enforcement of environmental law. The Network's objective is to create the necessary impetus in the European Community to make progress on ensuring a more effective application of environmental legislation. The core of the IMPEL activities concerns awareness raising, capacity building and exchange of information and experiences on implementation, enforcement and international enforcement collaboration as well as promoting and supporting the practicability and enforceability of European environmental legislation.

During the previous years IMPEL has developed into a considerable, widely known organisation, being mentioned in a number of EU legislative and policy documents, e.g. the 7th Environment Action Programme and the Recommendation on Minimum Criteria for Environmental Inspections.

The expertise and experience of the participants within IMPEL make the network uniquely qualified to work on both technical and regulatory aspects of EU environmental legislation.

Information on the IMPEL Network is also available through its website at: www.impel.eu

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Executive Summary

REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals. REACH Regulation (EU) No 1907/2006 aims to ensure a high level of protection of human health and the environment as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. The REACH Regulation lays down three main instruments for chemicals management: registration, authorisation and restriction. The instruments are applied to chemical substances as such, in mixtures and in articles.

Materials that are considered **waste** under the EU Waste Framework Directive (2008/98/EC, WFD) are not considered substance, mixtures or articles according to REACH Regulation and are not considered in the scope of REACH. Therefore, most of the obligations deriving from REACH are not applicable to 'wastes'. However, REACH Regulation is applied to by-products or materials that have ceased to be waste. This can cause a lot of difficulties in circular economy.

By-products are not considered waste if they meet the criteria set with the WFD and will fall under the full scope of REACH if placed on the market themselves. All forms of recovery, including mechanical processing, are considered as a manufacturing process under REACH whenever they result in the generation of one or several substances as such or in a mixture or in an article that have ceased to be waste. Therefore, a REACH compliance assessment is highly relevant also for the field of

circular economy.

REACH Regulation plays an essential part of safe and sustainable chemical management. One of the main objectives of circular economy is to harness 'waste' as a resource and substitute virgin raw materials with waste-based materials. In order to promote the use of waste-based materials the concepts of 'by-product' and 'End-of-Waste' are highly relevant and a clarification about the applicability of REACH to the aforementioned is essential to promote their market and circulation. This report aims to offer guidelines for applying REACH in the circular economy. To elaborate on the theme, the report includes multiple practical examples from different Member States.

The report is divided in 6 chapters and 2 annexes:

- Chapter 1 introduces the theme and describes the most important basic concepts of REACH Regulation.
- Chapter 2 examines the scope of application of REACH Regulation and how it might apply to waste-based materials.
- Chapter 3 describes other relevant chemicals legislation which might be applied to waste-based materials. These provisions are not focused on in this report focusing on REACH Regulation.
- Chapter 4 provides guidance with practical examples to interpret and comply with the basic obligations of REACH Regulation: Registration, authorisation and restrictions.
- Chapter 5 provides guidance on applying the exemptions from the basic provisions of REACH. The chapter includes a subchapter focusing on applying recovery exemption to recycled plastics.
- Chapter 6 discusses the enforcement of REACH Regulation in recovery plants.
- Annex I contains a flowchart for REACH compliance summarizing the basic content of this report.
- Annex II sets out checklist for chemicals legislation compliance.

TABLE OF CONTENTS

1. Introduction

REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals. According to Article 1 of REACH Regulation (EU) No 1907/2006[1] it aims to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. *REACH is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle*.

REACH Regulation places the burden of proof on companies. To comply with the regulation, companies must identify and manage the risks linked to the substances they manufacture, place in the market and use in the EU. It lays down a 'No data, no market' rule that states that substances on their own, in mixtures or in articles shall not be manufactured in the EU or placed on the market unless they have been registered in accordance with the REACH Regulation.

Companies need to **register** their substances which means that they need to submit registration dossiers to the European Chemicals Agency (ECHA) before placing them on the market. The registration dossier includes a description of the uses of the substance, its physico-chemical, ecotoxicological and toxicological properties, and a hazard and risk assessment showing how the risks posed by the use of the substance are controlled. 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. The REACH registration procedure generates the majority of data on substances. Authorities can ban hazardous substances if their risks are unmanageable. Authorities can also decide to restrict a use of a substance or make it subject to a prior authorisation.

REACH impacts on a wide range of companies across many sectors, even those who may not think of themselves as being involved with chemicals[2]. Under REACH, a company may have one of the following roles: manufacturer, importer, downstream user, the only representative of a non-EU manufacturer established in the European Union.

[1] 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 (OJ L 396, 30.12.2006, p. 1–849).

[2] ECHA webpage, 'Understanding REACH' (https://echa.europa.eu/regulations/reach/understanding-reach)

The REACH Regulation lays down three main instruments for chemicals management and chemicals risk management: registration, authorisation and restriction. The instruments are applied to chemical substances as such, in mixtures and in articles.

BOX 1. Definition of substance, mixture and article in the REACH Regulation.

'**Substance**' means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

'**Mixture'** means a mixture or solution composed of two or more substances.

'**Article**' means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition

Manufacturers and importers must demonstrate how substances can be safely used, and they must communicate the risk management measures downstream, to the users. If the risks of substances cannot be managed, authorities can opt for different regulation processes. In the long run, the most hazardous substances should be substituted with less hazardous ones. [3]

Materials that are considered **waste** under the EU Waste Framework Directive (2008/98/EC[4], WFD) are not considered substance, mixtures or articles according to Article 2(2) of REACH Regulation and are not considered in the scope of REACH. Therefore, most of the obligations deriving from REACH are not applicable to 'wastes'.

Nevertheless, the waste phase has to be considered in some REACH processes and several waste-based materials may fall under the registration obligation of REACH. And if substances as such, substances in mixtures or in articles are placed on the EU market, REACH requirements have to be met. **By-products** are not considered waste if they meet the criteria set with the WFD and will fall under the full scope of REACH if placed on the market themselves[5]. All forms of recovery, including mechanical processing, are considered as a manufacturing process under REACH whenever they result in the generation of one or several substances as

[3] In 2017, the Swedish Environmental Protection Agency (Naturavårdverket) published a guidance on safe recovery that is available published on its website. Naturvårdverket 2017. Giftfria och Resurseffektiva Kretslopp – Vägledning för ökad och säker materialåtervinning. https://www.naturvardsverket.se/globalassets/vagledning/avfall-och-kretslopp/okad-och-saker-materialatervinning/vagledning-okad-saker-materialatervinning.pdf

[4] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3–30).

[5] According to Article 3(12) of REACH Regulation 'placing on the market' means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market.

such or in a mixture or in an article that have **ceased to be waste**.[6] Therefore, a REACH compliance assessment is highly relevant also for the field of circular economy.

In practice often the most difficult question is when waste ceases to be waste and at which moment REACH application should be assessed. There are three EU level End-of-Waste criteria Regulations established for iron, steel and aluminium scrap (EU) No 333/2011/EU[7], glass cullet (EU) No 1179/2012[8] and copper scrap (EU) No 715/2013[9]. The criteria for all other waste streams vary dependent on the case and practices between Member States.

The document focuses mainly on the roles of the manufacturer and importer since these roles are most relevant as regards to by-products and End-of-Waste. This is due to the fact that according to the ECHA's Guidance on waste and recovered substances "all forms of recovery, including mechanical processing, are considered as a manufacturing process whenever, after having undergone one or several recovery steps, they result in the generation of one or several substances as such or in a mixture or in an article that have ceased to be waste".[10]

This document will address in more detail: general approaches on applicability of REACH to by-products and recovered substances, practical examples and experiences of REACH, other relevant product legislation relevant for by-products and End-of-Waste and information on substances of very high concern (SVHC) and the usefulness of SCIP (Substances of Concern In articles as such or in complex objects (Products)) database and REACH enforcement in waste recovery plants. The document is complimented with Annexes I and II. Annex I provides a flowchart for REACH compliance to clarify the relation between different REACH requirements and their possible exemptions. Annex II provides a checklist for chemicals legislation compliance.

A scheme on REACH registration approach for primary substances and derived relevant waste and subsequently End-of-Waste (after a recovery process) is presented in Figure 1.

FIGURE 1. Interfaces between REACH and waste legislation (blue: REACH duties arising from the primary life cycle of the substance, responsibility lies with the primary manufacturer; red: waste phase of the substance, no

[6] ECHA 2010. Guidance on waste and recovered substances. ECHA-10-G-07-EN. https://echa.europa.eu/-/guidance-on-waste-and-recovered-substances

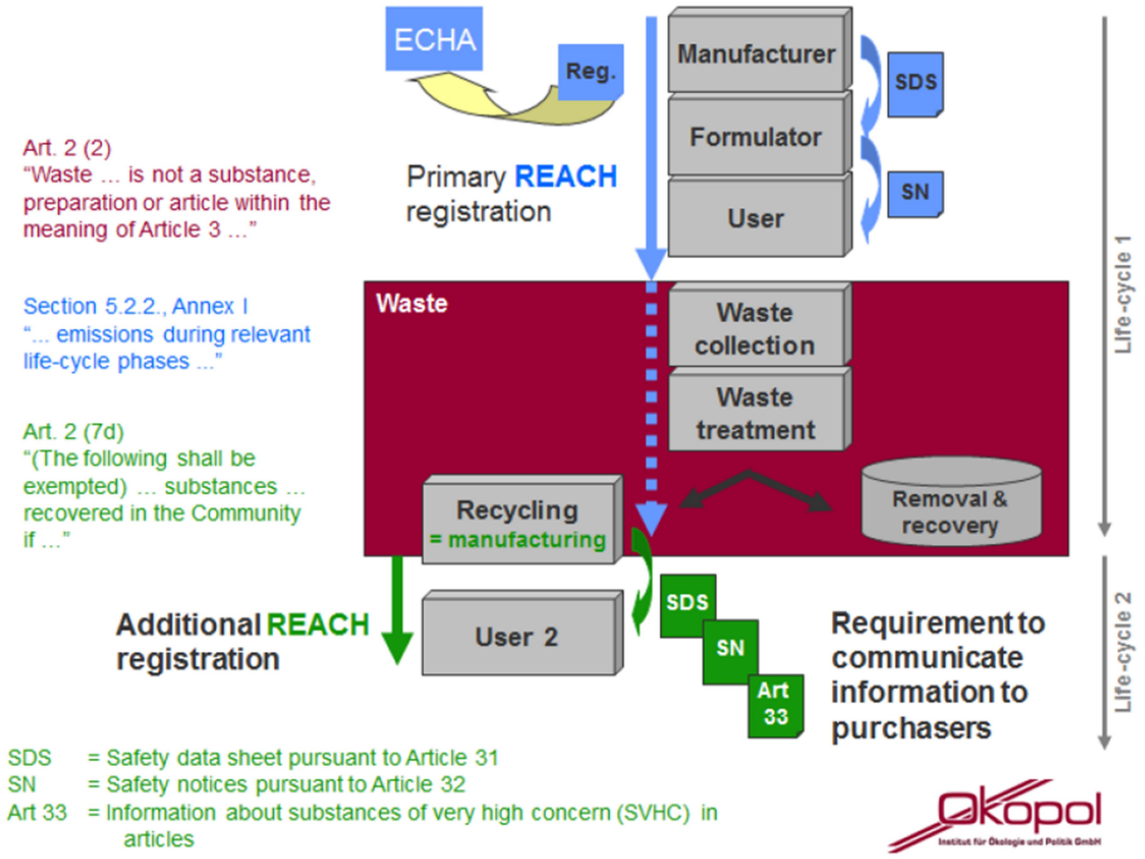
[7] Council Regulation (EU) No 333/2011 of 31 March 2011 establishing criteria determining when certain types of scrap metal cease to be waste under Directive 2008/98/EC of the European Parliament and of the Council (OJ L 94, 8.4.2011, p. 2).

[8] Commission Regulation (EU) No 1179/2012 of 10 December 2012 establishing criteria determining when glass cullet ceases to be waste under Directive 2008/98/EC of the European Parliament and of the Council (OJ L 337, 11.12.2012 p. 31).

[9] Commission Regulation (EU) No 715/2013 of 25 July 2013 establishing criteria determining when copper scrap ceases to be waste under Directive 2008/98/EC of the European Parliament and of the Council (OJ L 201, 26.7.2013 p. 14).

[10] ECHA 2010. Guidance on waste and recovered substances. ECHA-10-G-07-EN. https://echa.europa.eu/-/guidance-on-waste-and-recovered-substances

direct REACH duties, green: REACH duties arising from the secondary life cycle of the substance lies with the secondary manufacturer = recycler)



The figure uses the term 'preparations' that has been substituted later with a term 'mixtures'. In addition, it should be taken into account that both manufacturers and formulators can provide SDS and SN. (Figure 1 is extracted from from UBA 2012[11]).

[11] UBA 2012. Reach and the recycling of plastics – Reference manual for an appropriate implementation of the REACH requirements for the operators of recycling plants. http://www.uba.de/uba-info-medien-e/4263.html

2. Understanding by-products and End-of-Waste and the applicability of REACH Regulation

REACH Regulation plays an essential part of safe and sustainable chemical management. Although its main instruments are not applied to 'waste' as defined in Article 3(1) of WFD, the specific legislation on waste aims at promoting a sound management of waste ensuring limited environmental and sanitary impacts. One of the main objectives of circular economy is to harness 'waste' as a resource and substitute virgin raw materials with waste-based materials. In order to promote the use of waste-based materials the concepts of 'by-product' and 'End-of-Waste' are highly relevant and a clarification about the applicability of REACH to the aforementioned is essential to promote their market and circulation across the borders. However, there are no expressed definitions of by-products and End-of-Waste in the REACH Regulation, so it's necessary to go through the definitions set up by the WFD.

BOX 2. By-product criteria of the WFD

Article 5 WFD states that Member States shall take appropriate measures to ensure that a substance or object resulting from a production process the primary aim of which is not the production of that substance or object is considered not to be waste, but to be a by-product if the following conditions are met:

(a) further use of the substance or object is certain,
(b) the substance or object can be used directly without any further processing other than normal industrial practice,
(c) the substance or object is produced as an integral part of a production process, and
(d) further use is lawful, i.e. the substance or object fulfils all relevant product, environmental and health protection requirements for the specific use and will not lead to overall adverse environmental or human health impacts.

BOX 3. End-of-Waste criteria of the WFD

Article 6 WFD states that 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:

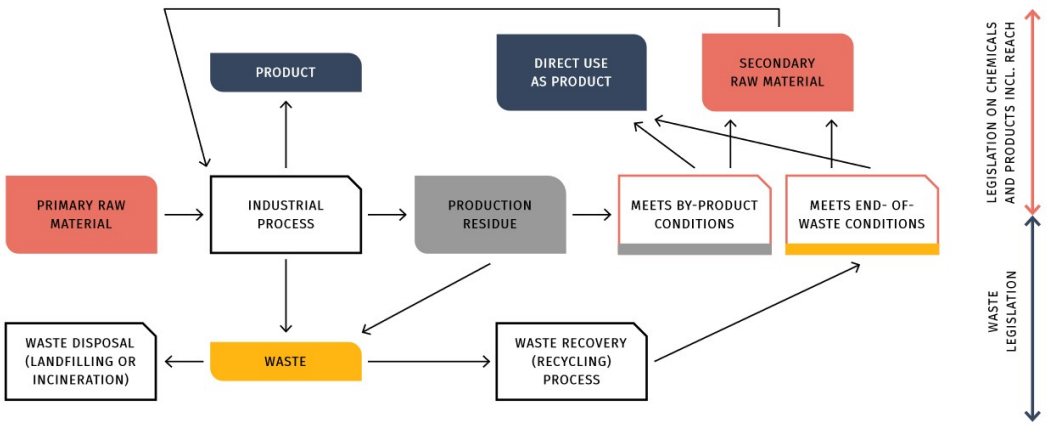
(a) the substance or object is to be used for specific purposes,
(b) a market or demand exists for such a substance or object,
(c) the substance or object fulfils the technical requirements for the specific purposes and meets the existing legislation and standards applicable to products, and
(d) the use of the substance or object will not lead to overall adverse environmental or human health impacts.

One of the criteria in the WFD for by-product and End-of-Waste status is that the further use of the material is lawful, in other words that its use is in accordance with all legislation applicable on products. This means that the chemical content of the by-product or End-of-Waste material should be analysed and all substances should be identified according to REACH requirements in order to identify the scope of REACH to the by-product or End-of-Waste material. Before the material is placed on the market basic requirements of REACH have to be fulfilled. This has been emphasized in the latest amendment of the WFD ((EU) 2018/851[12]): Article 6(5) states that the natural or legal person who a) uses, for the first time, a material that has ceased to be waste and that has not been placed on the market; or b) 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.

As by-products and End-of-Waste materials are not considered waste, they can be defined as substances, mixtures or articles according to REACH Regulation. Following that the rules of registration, authorisation and restrictions may be applied to them. There are exemptions from the basic obligations of the REACH Regulation that are discussed in Chapter 5 this document.

The following figure illustrates how the waste legislation and legislation on chemicals and products has been separated. Simply put, the waste legislation is applied to materials that are considered waste and the chemicals and products legislation is applied to materials that are instead considered End-of-Waste or by-product (not waste).

FIGURE 2. Application of waste and product and chemicals legislation



[12] Directive (EU) 2018/851 of the European Parliament and of the Council of 30 May 2018 amending Directive 2008/98/EC on waste (OJ L 150, 14.6.2018, p. 109–140).

The ECHA published in 2010 a specific "Guidance on waste and recovered substances"[13], which contains useful information both in terms of the general approach (BOX 4) to evaluate the REACH Regulation compliance for End-of-Waste and practical examples.

By-products and End-of-Waste materials are both concepts that are regulated with the WFD. If the conditions of the WFD are met so that waste legislation requirements no longer apply to them, relevant chemical and product legislation requirements have to be met. That would mean that the REACH Regulation would be applied to the materials. Legally the procedures of REACH Regulation (registration, authorisation, etc.) and WFD (assessment of by-product or End-of-Waste status) run in parallel. Although the REACH Regulation is not applied to 'waste', there are no control mechanisms in REACH Regulation for assessing whether substance or object is waste or not. On the other hand, registration under REACH Regulation is not required for substances to be classified as by-product or End-of-Waste although the registration obligation would normally apply to the substance as it is manufactured or placed on the market.

In practice, each recovery operator is a potential registrant who should follow the basic REACH obligations steps on what requirements would apply to them. So, designing the recovery process and implementing everything necessary from the WFD side should already be accompanied with mapping the data requirements of REACH in parallel. **The fact that a substance is registered under REACH does not automatically mean that it has ceased to be waste**.

For example, in the Netherlands a non-binding governmental declaratory opinion[14] regarding the End-of-Waste status of recovered material is prepared and the need for registration or authorisation is checked by looking at the technical data of the substance(s) in question. The by-product or the End-of-Waste status then is declared on the condition that the registration or authorisation will be completed. In Estonia, all by-product and End-of-Waste criteria are discussed in the context of a permit as all waste operators' activities need to be authorised. As the REACH Regulation places responsibility on companies, the authorities will not dictate any REACH conditions on permits related to by-products or End-of-Waste. First the by-product or End-of-Waste status is established, than REACH applies. However, the applicant of a permit will have to describe their activities in detail, identify their waste streams, substances if necessary, future use categories and more dependent on specific cases in order to conclude if by-product conditions are met or waste will cease to be waste. This information is also used in REACH inspections.

Many recovery operations produce mixtures (e.g. plastics, rubber) and UVCB substances instead of single substances on their own. The Swedish "Recovered substances" project has drawn some relevant practical conclusions summarised in BOX 5 which is based on REACH enforcement experience.

[13] ECHA 2010. Guidance on waste and recovered substances. ECHA-10-G-07-EN. https://echa.europa.eu/-/guidance-on-waste-and-recovered-substances

[14] The legal opinions are published on following web site: https://www.afvalcirculair.nl/onderwerpen/afval/toetsing-afval/

BOX 4. Relevant statements included in the ECHA "Guidance on Waste and Recovered substances"[15].

1. For the purpose of REACH, recovered substances should only be understood as substances that, after having been part of waste materials, have ceased to be waste according to the Waste Framework Directive. The constituents of the recovered substance may have been present as such in the waste stream or have been obtained from the waste stream through chemical modification during the recovery process.
2. Article 3(8) of REACH defines manufacturing as "production or extraction of substances in the natural state". Substances that have undergone a chemical modification during the waste and recovery process (e.g. certain slags such as steel slag that is weathered, fly ash, creation of methane during "feedstock recycling" of polymers) clearly fulfil this definition. Some recovery processes resulting in recovered substances however do not modify the chemical composition of substances (in particular mechanical processing or recycling, e.g. sorting, separation, de-pollution, homogenisation and treatment to modify the macro structure of the material such as crushing (aggregates), cutting, shredding (metal scrap), granulating (plastic waste) and grinding materials, re-melting them without chemical modification). For the sake of consistency and enforceability of the approach, all forms of recovery, including mechanical processing, are considered as a manufacturing process whenever, after having undergone one or several recovery steps, they result in the generation of one or several substances as such or in a mixture or in an article that have ceased to be waste.
3. In the same way as for other substances subject to registration under REACH, the name and corresponding data that sufficiently identify a recovered substance need to be available.

BOX 5. Some relevant conclusions included in the KEMI report on recovered substances[16].

Some conclusions derived from the practical experience during the project "Recovered substances", carried out by Swedish EPA and Chemical Agency are below reported.

1. Chemicals legislation "works well" for:
   a. **Well-defined waste streams**, where there is no major contamination or mixing with other substances. In these cases, it is relatively easy for companies to comply with the regulations that exist. The easiest scenario is where the entire stream is a closed cycle.
   b. **Chemical recovery**. Where an advanced chemical process is for recovery, the actual manufacturing process of the recovered substance is highly controlled. Where the inspected companies used chemical

[15] ECHA 2010. Guidance on waste and recovered substances. ECHA-10-G-07-EN. https://echa.europa.eu/-/guidance-on-waste-and-recovered-substances

[16] KEMI 2016. Recovered Substances – Report on an enforcement project 2016 Enforcement 13/16. https://www.kemi.se/en/publications/enforcement-reports/2016/enforcement-13-16-recovered-substances

processes for recovery, they performed extensive chemical and physical analyses of the recovered substance, and substance identification had often already been determined.

c. **Recovery directly to an article**. Where the waste can be directly used for manufacturing an article without first passing the step of chemical product, the requirements of the chemical's legislation are much less extensive. Here, the companies can concentrate on identifying and checking the substances that are regulated for the article, for example, particularly dangerous substances included on the REACH Candidate List.

2. The **main issues** encountered during the inspection were following.

a. **Losses in the information flow when waste is created.** The waste that is used as input material is often mixed and of complex composition. The recovery operator therefore needs to collect relevant information for the recovered substances from several different sources, e.g.. safety data sheets. Indeed, there is no obligation to pass on this type of information to the waste recipient. Correspondingly, for articles, the obligation to provide information on the content of particularly dangerous substances only applies until the end user and thus excludes waste stage.

b. **Inadequate quality of waste**. The recovery companies find it difficult to ensure that the waste they receive maintains a high quality. The quality of waste not only affects physical properties but also the opportunity to determine the substance identity of the recovered material. If incoming waste fractions become purer, this will make it easier for the recovery operator to meet the requirements of the chemical legislation.

c. **Recovered polymers**. The registration requirement under REACH does not apply to polymers but monomers are subjected to REACH Regulation. In order to ensure that the recovered polymer does not contain any substances regulated in the chemical's legislation, it is important to avoid material streams that contain particularly dangerous substances included on the REACH Candidate List. One way to do this is to avoid PVC plastic being recovered together with other plastics. It is above all in PVC products that the Swedish Chemicals Agency's enforcement of plastic articles has found particularly dangerous substances.

d. **Recovered oils**. Recovered base oils are normally UVCB substances. UVCB substances cannot be identified solely by means of their chemical composition. This is because the number of constituents is relatively large or a significant part of the composition is unknown, varies greatly or is difficult to predict. Determining the substance identity of recovered UVCB substances therefore involves particular challenges. Recovery of base oils that do not come from a simple stream requires a relatively sophisticated recovery process if the aim is to recover the substances for the same purpose. It is not certain that it is possible to find a registered petrochemical substance with a description and substance identity corresponding to the recovered product. The next step is then to try to find a combination of several petrochemical substances that, when they are mixed, would have the same physical and chemical properties as the recovered base oil. The project has shown that it takes quite a lot of work to be able to verify the substance identity. Knowledge and advice have proven difficult to be obtained despite contacts with industry associations and consultants. However, ECHA's statement to CONCAWE[17] might be helpful.

[17] Letter of ECHA to CONCAWE (07-05-2008/IN/je D(2008)/719) that all products produced within a refinery are substances (mainly UVCBs) (e.g. petrol produced in a refinery is a substance but petrol produced outside a refinery is mixture).

3. Other relevant chemicals legislation for by-products and End-of-Waste.

Besides REACH Regulation many different provisions are relevant for chemicals management and ensuring that the waste-based materials are fit for purpose and do not cause adverse human health or environmental impacts when they are classified as by-products or End-of-Waste. This document focuses on REACH Regulation but also provides short introductions to CLP Regulation (EC) No 1272/2008[18], Regulation (EU) 2019/1021[19] on persistent organic pollutants (POPs) and RoHS Directive 2011/65/EU[20].

The document will not address product group specific provisions as their application is dependent on the product group in question. In circular economy, the main rule currently is that materials that are considered waste are regulated under the legislative regime for waste and materials that are not considered waste (including waste-based materials such as by-products and End-of-Waste) are regulated under the regime of applicable product and chemicals regulation. The picture[21] (Figure 3) elaborates on the distinction.

CLP Regulation lays down rules for classification, labelling and packaging (CLP) of chemicals (substances and mixtures). The Regulation aims at ensuring a high level of protection of health and the environment, as well as the free movement of substances, mixtures and articles. It is based on the United Nations' Globally Harmonised System (GHS)[22]. CLP Regulation 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. One of the objectives of the regulation is to determine whether a substance or mixture displays properties that lead to a hazardous classification. According to CLP Regulation substances and mixtures are identified by assigning a certain hazard class and category based on the relevant information (e.g. toxicological data) on a substance or mixture and the classification criteria in CLP. Once a substance or mixture is classified, the identified hazards must be communicated to other actors in the supply chain, including consumers, by hazard labelling and safety data sheets. Hazard labelling allows the hazard classification 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. The requirements for safety data sheets are established with the REACH Regulation. It's clear that a by-product originated from a production process where substances and mixtures are used may be

[18] Regulation of the European Parliament and of the Council on the 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 (OJ L 353, 31.12.2008, p. 1–1355).

[19] Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45–77).

[20] Directive 2011/65/EU of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88–110).

[21] Kauppi, S. et al. (2019). Safe and sustainable circular economy. Policy Brief 17/2019. Government's Analysis, Assessment and Research Activities.

[22] Globally Harmonised System of Classification and Labelling of Chemicals (GHS). Eighth revised edition. United Nations 2019.

labelled as hazardous and the same for an End-of-Waste originated from a recovery process of hazardous waste: such by-products and End-of-Waste have to be labelled and managed compliant with CLP Regulation.

Irrespective of the quantity both End-of-Waste and by-products will have to be notified to ECHA's classification and labelling inventory in case they are placed on the market and classified as hazardous or contained in a hazardous mixture above a relevant concentration limit, which results in the classification of the mixture as hazardous.

POP (Persistent Organic Pollutants) Regulation bans or restricts the manufacturing, placing on the market, and use of POPs in both chemical products and articles, with the exception of their presence as unintentional trace contaminants (UTCs). In its Annex IV, the Regulation lays down a concentration limit for each POP substance in waste. Wastes that contain POP substances above the Annex IV concentration limit (referred to also as 'POP waste') are to be treated in a manner in which the POP substances are destroyed or irreversibly transformed into substances that do not exhibit similar characteristics.

The appropriate waste management measures for POP waste are listed in Annex V of the Regulation. Other waste management options may be used for waste that do not exceed the Annex IV concentration limit, in accordance with the EU waste legislation. According to Annex V, POP waste exceeding the Annex IV concentration limit can only be managed in the following ways:

- **D9**[23] **- Physico-chemical treatment**
- **D10 - Incineration on land**
- **R1**[24] **- Use principally as a fuel** or other means to generate energy, excluding waste containing PCBs
- **R4 - Recycling/reclamation of metals and metal compounds**, under the following conditions: The operations are restricted to residues from iron- and steel-making processes such as dusts or sludges from gas treatment or mill scale or zinc-containing filter dusts from steelworks, dusts from gas cleaning systems of copper smelters and similar wastes and lead-containing leaching residues of the non-ferrous metal production. Waste containing PCBs is excluded. The operations are restricted to processes for the recovery of iron and iron alloys (blast furnace, shaft furnace and hearth furnace) and non-ferrous metals (Waelz rotary kiln process, bath melting processes using vertical or horizontal furnaces), provided the facilities meet as minimum requirements the emission limit values for PCDDs and PCDFs laid down in accordance with Directive 2010/75/EU, whether or not the processes are subject to that Directive and without prejudice to the other provisions of the Directive

Other waste management option are open for wastes that do not exceed the low-POP threshold (the Annex IV concentration limit).

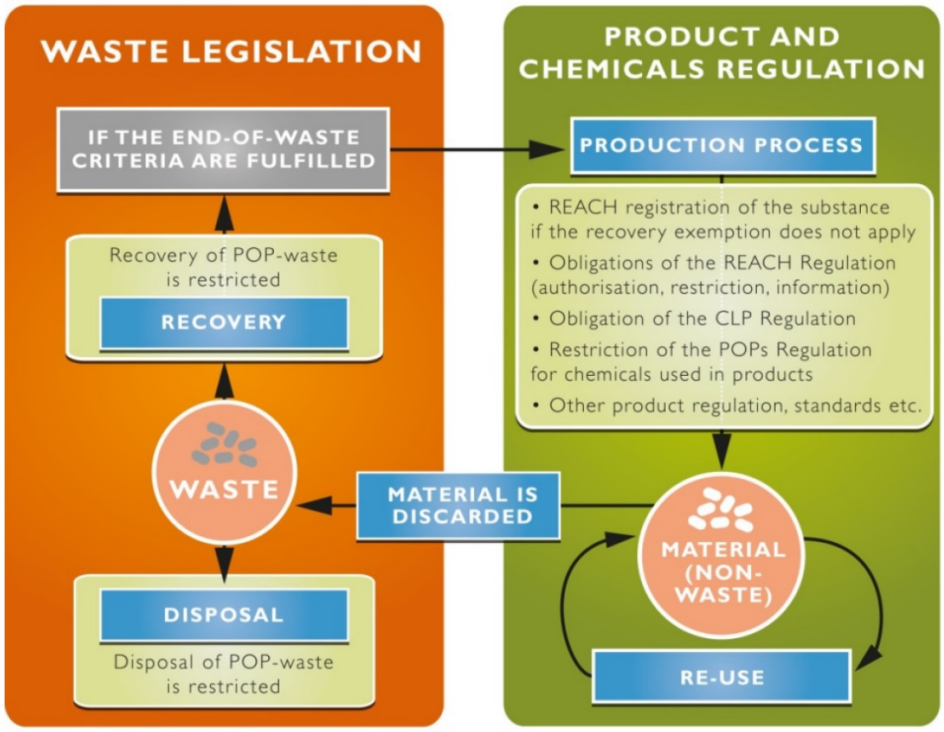
Annex V allows for pre-treatment of POP waste prior to its destruction or irreversible transformation if the POP substances are isolated from the waste in the pre-treatment process and handled according to Annex V of the

[23] Annex I WFD: List of disposal operations.
[24] Annex II WFD: List of recovery operations.

Regulation. This also applies to a situation where only a part of the waste contains POPs. Intentional diluting of POP wastes is not considered environmentally sound.[25]

In addition to POP thresholds laid down for waste, the POP Regulation sets limit values for POP substances in substances, mixtures or articles that are manufactured, placed on the market and used in the EU (Annex I limit values for UTCs). Additionally, new products produced from recycled materials, such as recycled plastics that have reached End-of-Waste status, must fulfil the UTC concentration requirements for POP substances in products set in Annex I of the POP Regulation. Products not complying with the requirements of the POP Regulation cannot be put on the market.

FIGURE 3. Regulatory framework for management of chemicals during the life cycle of the product



[25] UNEP 2019a. General technical guidelines on the environmentally sound management of wastes consisting of, containing or contaminated with persistent organic pollutants. Conference of the Parties to the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, Fourteenth meeting Geneva, 29 April–10 May 2019. UNEP/CHW.14/7/Add.1/Rev.1.

Directive 2011/65/EU on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic equipment (EEE) (**the RoHS Directive**) limits the use of hazardous substances in electrical and electronic equipment. Its aim is to contribute to the protection of human health and the environmentally sound recovery and disposal of waste electrical and electronic equipment (WEEE). The RoHS directive applies for electrical and electronic equipment put on the market in EU (with certain exemptions), both imported and domestically manufactured products. Substances restricted under RoHS are Pb (0, 1 %), Cd (0,01 %), Hg (0,1 %), Cr VI (0,1 %), PBB (0,1 %), PBDE (0,1 %), DEHP (0,1 %), BBP (0,1 %), DBP (0,1 %), DIBP (0,1 %). One rationale of the Directive is to support the circular economy and to prevent adverse effects in the waste management stage. In particular, for recycled metals and plastics, the maximum concentration values and exemptions play a crucial role for secondary material streams intended to be reused in EEE. The RoHS directive influences the possibilities to use recycled materials in production of electrical and electronic equipment since it makes it necessary to know what is in the waste. For example, plastic recyclers may have problems with identifying all possible substances present in plastics. As many substances restrictions under POPs and REACH contain scope exclusions for EEE, the RoHS restrictions are applicable and their derogations can be relevant: Articles 4(4) and 4(5) lay down several derogations from the substance restrictions which reflect the 'repair as produced' principle. The aim of these derogations is to facilitate the repair and reuse of EEE and therefore contribute to the EU's resource efficiency and circular economy objectives. Article 4(6) of the Directive allows time-limited and application-specific exemptions for applications listed in Annexes III and IV, to which the substance restrictions do not apply.[26]

BOX 6. An Italian example of REACH and POPs Regulations compliance: Plastic's End-of-Waste recovered from WEEE.

An application for a case-by-case End-of-Waste assessment for plastic obtained from shredded and sorted electrical and electronic waste devices was submitted to the Competent Authority in Italy. No EU wide or national criteria are at the present available. The plant's technology will allow to separate different plastic polymers (such as PP, ABS, PS) by different physical sorting procedures.

Plastics constituting electrical and electronic Equipment (EEE) may contain brominated flame retardants, some of which are included in POPs Regulation. More specifically the current Regulation includes limits for following compounds: PBDE, HBDE and HBCD. The compliance with such limits was set up as environmental standard

[26] If you need further information, there are two recent support studies on the RoHS Directive available: European Commission, Directorate-General for Environment, Support for the evaluation of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment : final report, Publications Office, 2021, https://data.europa.eu/doi/10.2779/89335; European Commission, Directorate-General for Environment, Gustavsson, N., Bruijne, E., Berlinghof, T., et al., Study to support the assessment of impacts associated with the general review of Directive 2011/65/EU (RoHS Directive) : final report, Publications Office of the European Union, 2023, https://data.europa.eu/doi/10.2779/809625.

(Condition of Article 6 WFD) in the binding technical opinion drafted by the Competent Regional EPA in favor of the Permitting Authority.

The operator presented a study in order to evaluate the need to register the product according to the REACH Regulation. More specifically the operator evaluated the possible application of Article 2(7) d exemption. By chemical analysis the sameness of the monomers contained in the recovered plastics with the common plastic's raw material, already registered and used for EEE production, was demonstrated. Furthermore, the operator demonstrated that the information required by Articles 31 and 32 of the REACH Regulation were available by the recovery installation and proposed to draft safety sheets for each plastic recovered polymer.

4. Basic requirements of REACH Regulation

4.1. Registration under REACH Regulation

4.1.1. The registration

Manufacturers[27] **and importers** will need to obtain information on the substances they manufacture or import and use this information to assess the risks arising from the manufacture and use of the substances and to ensure that these risks are controlled.

For substances manufactured or imported in quantities of one tonne or more per year, per company, the information and the assessment must be demonstrated in a registration dossier submitted to the ECHA. This obligation applies to substances on their own, in mixtures or in articles where the substance is intended to be released under normal or reasonably foreseeable conditions of use.

The registration aims to define and characterise the identity of the substance, identify the hazardous properties for hazard communication, identify and quantify the hazardous properties for risk assessment as well as to obtain parameters necessary for exposure assessment and risk characterization. The registration is carried out with a dossier that is submitted electronically by the registrant and consists of two main parts: 1) a technical dossier and 2) chemical safety report (CSR). The technical dossier is obligatory for all substances subjected to the registration obligation whereas the CSR is only required if the registrant manufactures or imports a substance in quantities of 10 tonnes or more per year.

[27] ECHA 2010, p. 10: For the sake of consistency and enforceability of the approach, all forms of recovery, including mechanical processing, are considered as a manufacturing process whenever, after having undergone one or several recovery steps, they result in the generation of one or several substances as such or in a mixture or in an article that have ceased to be waste.

4.1.2. What is a substance?

The substances under registration can roughly be divided in two categories: well-defined substances and substances of unknown or variable composition, complex reaction products or biological materials (UVCB)[28]. The first category refers to substances with composition that can be quantitatively and qualitatively defined and the registrant is able to provide a chemical specification of the constituents.

The registrant will be able to identify all the constituents, covering the composition up to 100%. To decide whether it should be considered as mono-constituent or instead as multi-constituent the so-called "80%- 20%" and "80%-10%" rules are applied. If one constituent is present at a concentration of at least 80% (w/w) and the impurities make up no more than 20% (w/w), the substance will be considered as mono-constituent. If more than one main constituent is present in a concentration between 10% and 80% (w/w) the substance is considered as a multi-constituent substance.

UVCB substances have high number of constituents or the composition is to a significant extent unknown, or the variability of composition is a large or unpredictable. In these cases, a clear identification based on the chemical composition only is not possible. Various types of substances can be grouped under the UVCB umbrella. Typically, they should be identified by considering the origin material of the substance, the most relevant steps during the manufacturing process and other relevant parameters specific to the case in question (in addition to what is known about their chemical composition). It is recognised that there will be borderline cases between well-defined and UVCB substances; e.g. substances which are produced by means of reactions between many constituents, each within a broad range, or reaction products with variable and poorly predictable composition.[29]

In addition to substances, there are also mixtures and articles that need to be taken in the account in the registration process. According to article 3(2) of REACH, a mixture is defined as "a mixture or solution composed of two or more substances." Mixtures are not registered as such but as they are composed of two or more substances, the substances in the mixture will have to be registered.

Article 3(3) of REACH defines "article" as "an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition. Like mixtures, articles are not registered as such. However, the substances that are included in the article shall be registered when the substance is intended to be released during normal and reasonably foreseeable conditions of use of the article in the quantities above 1 tonne per year.

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[28] UVCB is not a term in the legislation text, but mentioned in the Annexes and guidance documents.

[29] ECHA 2017. Guidance for identification and naming of substances under REACH and CLP. ECHA-16-B-37.1-EN https://echa.europa.eu/view-article/-/journal_content/title/guidance-for-identification-and-naming-of-substances-under-reach-and-clp

According to Article 7(2) REACH Regulation any producers and importers have to notify to ECHA the substances listed on the Candidate list for eventual inclusion in Annex XIV (List of substances subject to authorisation) which are present in their articles, if: 1) the substance is present in these relevant articles in quantities totaling over one tonne per year and 2) the substance is present in their relevant articles above a concentration of 0.1% weight by weight.

Companies have to notify no later than six months after the inclusion of the substance in the Candidate List. This notification is not required when: 1) the producer or importer of an article can exclude the exposure of humans and the environment to the substance during normal or reasonably foreseeable conditions of use of the article, including its disposal (In these cases, the producers and importers will give appropriate instructions to the recipient of the article) and 2) the substance has already been registered by a manufacturer or importer in the EU for that use.

4.1.3. The duties of the registrant

REACH Regulation requires that each substance that is being manufactured inside EEA or imported into the EEA in quantities of 1 tonne or more needs to be registered. In the process leading up to REACH registration, the manufacturers and importers will need to obtain information on the substances they manufacture or import and use this information to assess the risks arising from the manufacture and use of the substances and to ensure that these risks are controlled.

Before registering, the potential registrant has a duty to prepare and submit an inquiry to ECHA to verify whether a registration has already been submitted for the same substance. When preparing the inquiry, specific attention should be paid to the substance identity information which must contain information specified in section 2 of Annex VI of REACH. The precise information requirements may differ depending on the available information on intrinsic properties as well as on tonnage, use and exposure. This information must be complete and clearly describe the manufactured or imported substance. If the same substance has previously not been registered, the ECHA informs the potential registrant accordingly. If the same substance has previously been registered, the ECHA informs the potential registrant of the contact information of the previous registrants and of the relevant summaries or robust study summaries already submitted by them. Studies involving vertebrate animals shall not be repeated and must be shared with the potential registrant under agreed conditions. For such cases a substance information exchange forum (SIEF) may exist. Once the contact is made with the SIEF, the new registrant needs to establish substance sameness between the new substance and the already registered one. ECHA has published guidance[30] on data-sharing under REACH Regulation.

[30] ECHA 2022. Guidance on data-sharing. ECHA-22-H-16-EN. https://echa.europa.eu/regulations/reach/registration/data-sharing

When a registration dossier has been submitted and if information is missing, the registrant will need to resubmit a complete dossier within a specified timeframe. The registrant is responsible to keep the registration up-to date. This is necessary e.g. when the registrant changes the composition of the substance, increases the production volume or receives additional information related to the classification and labelling of the substance.

BOX 7. Example of UVCB substances and registration

Many recovery operations produce mixtures (e.g. plastics, rubber) and UVCB substances instead of single substances on their own. For example, shale oil is a UVCB substance and is registered under REACH with a joint registration dossier. One of the joint registrants wanted to add tyre chips to the shale oil production process. A PPORD notification was submitted to ECHA. As regards to the REACH registration dossier of the already registered shale oil, the input substances changed and the necessity to update the dossier was assessed. The evaluation concluded that alterations to the shale oil composition resulting from adding tyre chips were within the limits of variability allowed for UVCB substances. The hazard profile of the shale oil didn't change and it was not necessary to update the dossier. However, the registrants of the joint registration dossier in parallel came to a conclusion that the substances are no longer the same, since more conditions were taken into account when assessing the sameness of a UVCB substance amongst the registrants of the joint dossier.

4.2. Authorisations under REACH Regulation

In some cases, secondary raw materials may require a REACH authorisation allowing only certain specific uses of the material. The authorization requirement must ensure that the risks from substances of very high concern (SVHCs) are properly controlled and that those substances are progressively replaced by suitable alternative substances or technologies. Substances subject to authorisation are listed in Annex XIV to the REACH Regulation. Once included in this Annex, a substance cannot be placed on the market for a use or used after a given date (the so-called 'sunset date') unless the companies concerned are granted an authorisation for the specific use(s) or an exemption applies according to Article 56 of the REACH Regulation. Authorisations are granted by the Commission, after obtaining the opinion of the Committee for Risk Assessment and the Committee for Socio-economic Analysis of the ECHA. Applications for authorisation can be made by the manufacturer(s), importer(s) and/or downstream user(s) of the substance, covering one or more uses and/or one substance or a group of substances. In addition, applications can be made by separate legal entities or group of legal entities.

An authorisation can be granted on two bases: 1) the risk to human health or the environment from the use of a substance is adequately controlled or 2) it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. The authorisation on basis of socio-economic benefits may not be granted when suitable alternatives are available for the applicant. The applicant must explain why he considers that there are

no suitable alternatives and list the actions, including timelines that would be required to transfer to alternative substance or techniques, should suitable alternatives be available on the market but not yet ready for an immediate substitution.

BOX 8. Example of REACH Authorisation

Authorisation decision C(2014) 5551 final. Rolls-Royce plc was granted an authorization to use Bis(2-ethylhexyl) phthalate (DEHP, EC No: 204-211-0, CAS No: 117-81-7) on the basis that the risk is adequately controlled in accordance with Article 60(2) REACH. In addition, Commission stated that "(t)here are no suitable alternatives at present and search for technically feasible alternatives is ongoing under a 5-10 year research programme". The authorization was granted on 7th August 2014 and was set to expire 21st February 2022. The decision granted the authorization for DEHP to be used in processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades.

Authorisation decision C(2017) 3454. Arlanxeo Netherlands B.V. was granted an authrosation to use Sodium dichromate (EC No. 234-190-3, CAS No. 7789-12-0 10588-01-9) on the socio-economic basis. Commission stated that "the socio-economic benefits outweigh the risk to human health arising from the use of the substance and there are no suitable alternative substances or technologies in terms of their economic feasibility". The authorization was granted on 19th May 2017 and was set to expire 21st September 2029. The decision granted the authorization for use of sodium dichromate as corrosion inhibitor in ammonia absorption deep cooling systems.

4.3. Restrictions under REACH Regulation

REACH restrictions are an instrument to protect human health and the environment from unacceptable risks posed by chemicals. They are normally used to limit or 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. A restriction may also apply to any substance that do not require registration, for example, substances manufactured or imported below one tonne per year or certain polymers. On-site isolated intermediates, substances used in SR&D, and substances only posing risks to human health from their use in cosmetics are exempted from REACH restriction. Annex XVII to REACH Regulation includes all the restrictions adopted in the framework of REACH and the previous legislation, Directive 76/769/EEC. Each entry of the Annex shows a substance or a group of substances or a substance in a mixture, and the consequent restriction conditions.

REACH Regulation sets restrictions on certain substances that are allowed in recovered materials (Article 67-73). E.g. a restriction on Cd-content in plastic is in force. The allowed cadmium content in recycled plastic (0,1%) is higher than in new plastic (0,01%). A similar restriction of lead (Pb) is underway.

BOX 9. Dutch example of restrictions assessment issuing a PVC granulate End-of-Waste legal judgment**.**

The Ministry of Infrastructure and Water Management has issued legal judgments in which, in a specific case, the Ministry of Infrastructure and the Environment has given its opinion as to whether or not a material is waste. The legal judgment is intended to support assessments and decisions by the governing body that is the competent authority for the company's activities. The legal judgment is not a decision within the meaning of the General Administrative Law Act and only applies to the situation and the company that requested the legal judgment. A legal judgment on PVC granulate End-of-Waste was published in 31 January 2018. An operator produces PVC recyclate, which is obtained from various hard PVC waste and is afterward used as raw material for the production of three-layer tubes for indoor and outdoor drainage. Compliance with REACH was assessed, due to the cadmium and lead content in the PVC granulate. For cadmium restrictions are set up in Annex XVII of REACH. A general ban is stated to use cadmium "*in mixtures and articles, produced from the following synthetic organic polymers […] polymers or copolymers of vinyl chloride (PVC)*". As derogation such ban shouldn't be applied to "*mixtures and articles containing recovered PVC if their concentration of cadmium (expressed as Cd metal) does not exceed 0,1 % by weight of the plastic material in the following rigid PVC applications […] pipes for non-drinking water if the recovered PVC is used in the middle layer of a multilayer pipe and is entirely covered with a layer of newly produced PVC".* The PVC granulate End-of-Waste was compliant with the cadmium's limit of 0,1%. For lead in PVC there was no legal limit stated in REACH Regulation at that time. The limit value of lead in products proposed by ECHA of recycled PVC was 1 % and the PVC granulate End-of-Waste was compliant with this limit.

4.4. Information on SVHCs and the SCIP database

Substances of Very High Concern (SVHCs) are chemicals that have serious effects on human health or the environment. SVHCs include for example substances that are carcinogenic, mutagenic, toxic for reproduction or persistent, bio-accumulative and toxic or have endocrine disruptive properties.

Based on criteria specified in the REACH Regulation a Candidate List is established for SVHC substances and published by the ECHA. Once a substance is added to the Candidate List, REACH imposes immediate obligations on manufacturers and importers of articles to declare the substances if present. Article 33(1) states that manufacturers and importers of articles (products) are required to notify their customers of the presence of SVHCs in their products exceeding 0.1% by weight and provide instructions on safe use of the product.

In 2018 the WFD was amended and a new Article 9(1)(i) was introduced that requires all suppliers of articles to notify ECHA if their articles contain any SVHC more than 0.1% weight by weight. Here it is relevant to point out that articles remain articles when they are incorporated into so-called 'complex objects' and that the obligation to notify applies to all actors in the supply chain, not only to manufacturers and importers. For example, in a bicycle, a single bolt is considered an article and therefore if that single bolt contains any SVHC more than 0.1% weight by weight, its suppliers are required to notify to ECHA.

The data is to be gathered to so-called SCIP (Substances of Concern In articles as such or in complex objects (Products)) database, with the purpose of providing information on the presence of SVHC substances to waste treatment operators and consumers. ECHA publishes the information as received on its website. Hence, the usefulness and accuracy are mostly up to the companies to submit data in a transparent manner in their SCIP notifications. Moreover, the SCIP notification only help to identify SVHC substances, which constitute a small proportion of substances of concern. Information can be searched from SCIP database based on the following search categories: article identity, article category, material & mixture category, SVHC(s), concern/reason for inclusion and SCIP number.

The improved availability of the data in the SCIP database helps to ensure safer material cycles but as such does not set out any legal obligations for the reduction of chemical risks in products. These obligations are laid down in other legislation. However, the SCIP ensures that the information on articles containing Candidate List substances is available throughout the whole lifecycle of products and materials, including at the waste stage. The information in the database is then made available to waste operators and consumers. The database is a web-based tool on the ECHA website: https://echa.europa.eu/scip-database.

5. Exemptions from basic obligations of REACH Regulation

5.1. By-product exemption

An object considered as by-product under the WFD is in principle subject to REACH Regulation, since the exclusion provisions of Article 2(2) REACH apply to 'waste' only and by-products within the meaning of the WFD are not waste. According to article 2(7)(b) and Annex V of the REACH regulation by-products are exempted from the obligation to register unless they are imported or placed on the market themselves, due to the fact that registration is deemed inappropriate or unnecessary. It should be noted that even though Annex V includes an exemption from the registration obligation concerning 'by-products', the term 'by-products' is defined in Article 5 of the WFD and not REACH Regulation. As by-products that are imported or placed on market themselves are subjects to REACH registration, mostly by-products are treated in a similar manner to 'normal' substances from the perspective of REACH Regulation. Therefore, only by-products that are either not placed on the market, or are further processed into (a) different substance(s) before placing on the market, are exempted from the registration.

BOX 10. By-products exemption included in REACH Regulation.

Article. 2 (7)(b)

2. This Regulation shall not apply to: [...]

7. The following shall be exempted from Titles II, V and VI: [...]

(b) substances covered by Annex V, as registration is deemed inappropriate or unnecessary for these substances and their exemption from these Titles does not prejudice the objectives of this Regulation.

ANNEX V. Exemptions from the obligation to register in accordance with Article 2(7)(b)

[...]

5. By-products, unless they are imported or placed on the market themselves.

The by-products exemption may be in practice considered when a by-product is directly used in the same production process or when it's delivered to another production process without a its marketing. However, the legal application of this exemption should be evaluated on a case-by-case basis. "Placing on the market" according to REACH (Art. 3(12)) "means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market." Therefore, a payment is not needed to be considered that something is placed on the market. The key factor here is to determine if the by-product is going to be delivered to a third party or not.

Even if the by-product is exempted from the obligation to registered under REACH Regulation, this does not exempt it from other provisions of chemical legislation. For example, they can be subjected to authorisation and restrictions under REACH Regulation as well as the obligations laid down in the CLP Regulation.

BOX 11. Examples of by-product exemption

Finland. The sandy crust separated from the processing of the solids-containing waters of the sawmill yard and the cleaning crust of the yard, i.e. bark sand, are classified as a by-product of the production process in the environmental permit. This bark sand has a well-established use as a soil conditioner when it meets the quality requirements set for soil conditioners in the Finnish national fertilizer regulation. Bark sand is suitable as mulch or for preparing soil. Bark sand is generated as an essential part of the permitted production process and, as a whole, does not cause adverse environmental impacts. It therefore fulfills the waste legislation's criteria for classification as a by-product (Section 5 a of the national Waste Act). Bark sand is alternatively suitable for energy production. According to the REACH Regulation, by-products are exempt from registration, unless they themselves are imported or placed on the market. Regulation defines 'placing on the market' as follows: supplying or making available, whether in return for payment or free of charge, to a third party. If the bark sand is used for energy production in the company's own operations, it does not need to be registered. If bark sand is delivered for use as a soil conditioner, it must meet the requirements of the REACH regulation and

fertilizer legislation as it is placed on market as such. REACH Regulation also includes an exemption for substances that occur in nature if they are not chemically modified (Annex V, para 8). Although this exemption was not considered in the example case, this kind of approach could be considered in a similar case.

Slovenia. EAF-C slag (Electric Furnace Slag) is produced in the electric arc furnace during the production of carbon non-alloyed steels. It is also called "black steel slag". It is used as an aggregate in asphalt wear layers. In the production process the electric arc furnace is filled with steel or iron waste and where the waste comes to contact with graphite electrodes and heat. Then additives such as lime and oxygen that bind impurities into the slag are added to the furnace. From each ton of steel waste obtained 120 to 150 kg of slag is produced. After the slag is poured from the furnace, it is cooled down and aged in specific manner to achieve high toughness and long-term roughness as well as appropriate volumetric stability of the slag. The aggregate from slag is obtained through crushing, sieving and magnetic separation. The Slovenian company producing this slag has registered it under REACH Regulation together with Consortium for steel industry in Europe. If the slag is considered a by-product (according to Article 5 of Waste Directive) placed on the market as such, it must be registered under REACH Regulation for a specific purpose of use. Moreover, if the slag is intended for use in the construction industry, it must also meet the requirements arising from the legislation on construction products. The slag can be used in road construction – as gravel, as additive in cement production, as concrete and other hydraulic binders, for stabilisation and solidification, etc.

5.2. Recovery exemption

According to Article 2(7)(d) (the so-called recovery-exemption), no registration is required for substances recovered in the EU-EEA, if the substance that results from the recovery process is the same as a substance that has already been registered and 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. This refers to the concept of End-of-Waste as defined in Article 6 of the WFD. Materials that are recovered but are still waste are not considered substances, mixtures and articles under REACH and thus are outside the scope of application. The legal entity performing the final recovery should check whether the recovered substance is exempt from registration.

There are two conditions for the “recovery exemption”: 1) the “**sameness”** between the recovered substance and the already registered substance and 2) the **availability of the information** regarding that substance, which was already registered by another company. If both conditions are fulfilled the recovery operator is not required to: 1) make an exposure scenario for the use of the recovered substance, 2) register the recovered substance or 3) notify the use of the recovered substance. ECHA highlights in its guidance on registration that

"if, for some reason, the same substance has not been registered at the manufacturing or import stage, the recovered substance must be registered".[31]

The assessment of the "sameness" is in the hands of the recovery operator and the sameness is not confirmed or verified by the ECHA. In the assessment, the recovery operators need to identify the substances. As a general rule, any manufacturer of End-of-Waste shall consider himself to be a potential registrant (until otherwise is proven) and therefore they would have a duty to inquire from ECHA whether a registration has already been submitted for the same substance (Article 26 of REACH Regulation). If the recovery operator can be sure about the identity of the substance and it can be confirmed that the substance has been registered before, no inquiry with ECHA would be necessary. Nonetheless, inquiry with ECHA is an opportunity that can be used to connect the recovery operator with the SIEF or the consortium of the registration dossier, if the sameness between the recovered and registered substance is not clear or it is difficult to connect to the lead registrant for example, if they are not in the same country. In practice the inspector might have to assess the information on substance identity and decide whether sameness with an already registered substance is proven. However, it should not be the task of the inspector to prove the sameness, but it is the responsibility of the recovery operator to make sure all necessary information is available to prove sameness and also the legal (proprietary) right to use data for already registered substances

The decision must be based on the sameness of the main constituents: information about the impurities does not in principle affect the sameness. The sameness of the substance must be assessed according to the criteria laid down in ECHA's guidance[32] for identification and naming of substances under REACH and CLP. If the substance is modified in the recovery and the modified substance has not been registered, the recovery exemption cannot be applied.[33] The same EINECS[34] and CAS[35] numbers for substances are an indicator for the sameness of substance but do not determine the sameness between the substances. It should also be recognised that variations in the composition and the impurity profile, including a variation in the percentage of impurities, do not necessarily mean that substances are different. This is even more complicated for UVCB substances (e.g. recovered substances from waste oil) as they are generally identified by their chemical composition, their source (or origin) and the most relevant steps taken during processing: Source materials of

[31] ECHA 2021: Guidance on registration. ECHA-21-G-05-EN, p. 32. https://echa.europa.eu/documents/10162/2324906/registration_en.pdf/de54853d-e19e-4528-9b34-8680944372f2

[32] ECHA 2017. Guidance for identification and naming of substances under REACH and CLP. ECHA-16-B-37.1-EN. https://echa.europa.eu/documents/10162/2324906/substance_id_en.pdf/ee696bad-49f6-4fec-b8b7-2c3706113c7d?t=1525879053278

[33] ECHA 2021: Guidance on registration. ECHA-21-G-05-EN, p. 32. https://echa.europa.eu/documents/10162/2324906/registration_en.pdf/de54853d-e19e-4528-9b34-8680944372f2

[34] European INventory of Existing Commercial chemical Substances.

[35] A unique numerical identifier assigned by the Chemical Abstracts Service (CAS) to every chemical substance.

recovered substances are, by definition, different from virgin material and in many cases the recovery process is different from the original production process as well.[36]

In addition, the recovery operator must ensure that information on the registered substance is available, and that information must comply with the rules on information provision in the supply chain: for example, a Safety Data Sheet (SDS) (with the annexed exposure scenarios, if applicable). The ECHA guidance document on registration states that in order to apply the recovery exemption the recovery operator must have available: "the information that is contained in a safety data sheet - - -, or if the substance is supplied to the general public, sufficient information to enable users to take the necessary protection measures, or if a safety data sheet is not required, the information on any authorisation or restriction on the substance and other relevant information necessary to identify and apply risk management measures, as applicable.[37] Obtaining the information on the registered substance often requires that the recovery operator pays the original producer of the data. The REACH Regulation nor ECHA guidance documents do not specify the form in which this information has to be available to the company carrying out the recovery.

Although the recovery exemption required that there is an already registered substance that is considered "same" enough with the recovery material, the recovery exemption is not tied to volume or the purposes of use of the original registration. Therefore, a recoverer who places a recovered substance of concern on the market using the recovery exemption, for a use not identified in the original registration(s), cannot demonstrate by means of a chemical safety assessment that the risks from the use of the substance are controlled.

It is important to underline that those who recover and are exempt from registration can use the substance for a use other than that registered but must provide the information for safe use. The recovery operator should take account of the existing information and has to provide appropriate risk management measures in the SDS, if needed, or if SDS is not needed, to provide sufficient information on the safe use of the recovered substance.

Recipients of recovered substances that have been subject to the recovery exemption of Article 2(7)(d) will generally not receive: a registration number or an exposure scenario for the subsequent downstream uses within the new life cycle chain after the recovery has taken place from the manufacturer of the recovered substance as part of the SDS.

General exemptions are also applicable to End-of-Waste:

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[36] ECHA Forum 2022. Report on the pilot project on recovered substances exempted from REACH registration. ECHA-22-R-07-EN.

[37] ECHA 2021: Guidance on registration. ECHA-21-G-05-EN, p. 32–33. https://echa.europa.eu/documents/10162/2324906/registration_en.pdf/de54853d-e19e-4528-9b34-8680944372f2

1) According to art. 2(7)(a) "*substances specifically named in Annex IV, as sufficient information is known about the intrinsic properties of these substances that they are considered to cause minimum risk*". For instance, Cellulose pulp (EINECs n. 265-995-8) is included in the list
2) According to art. 2(7)(b) "*substances covered by Annex V, as registration is deemed inappropriate or unnecessary for these substances and their exemption from these Titles does not prejudice the objectives of this Regulation*". For instance, "*the following substances which occur in nature if they are not chemically modified: minerals, ores, ore concentrates, raw and processed natural gas, crude oil, coal*",[38] or compost and biogas.[39]

BOX 12. Some examples of REACH compliance assessment in the ECHA guidance waste and recovered substances[40].

A short summary of the REACH compliance assessment for some End-of-Waste is reported below.

1. **Recovered paper**. Recovered paper mainly consists of cellulose pulp, that is listed in Annex V. Recovered paper consisting exclusively of cellulose pulp with impurities without specific function in the material will therefore be exempt from registration, downstream user and evaluation obligations.
2. **Recovered glass**. Certain types of glass are exempted through inclusion into Annex V, entry 11. Recycled glass may contain other components such as paper, glue, paint or alien elements such as plastics, rubbers, sand, metals, stones, ceramics. If their presence in the recovered material is unintended, they have no specific function in the material and they are below 20 %, then they can be considered as **impurities**. Recovered glass consisting exclusively of types of glass complying with the exemption requirements of Annex V with impurities, will therefore be exempted from registration, downstream user and evaluation obligations.
3. **Recovered metals**. There isn't a unique way to assess how recovered metals can comply with REACH registration requirements. For instance, a mixed metal alloy scrap can be viewed as a substance with impurities (if the purpose of recovery is only to reclaim one main metal) or a special mixture, for which several substances have to be evaluated. Article 2(7)(d) exemption may be relevant, as well as other exemptions (e.g. Art. 2(5), 2(6), Annex V). Recovered metals may also go directly into article production

[38] Article 3(39) of REACH defined that a "substance which occur in nature" means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means.

[39] For more detailed information, see ECHA 2012. Guidance for Annex V Exemptions from the obligation to register. ECHA-10-G-02-EN. https://echa.europa.eu/documents/10162/2324906/annex_v_en.pdf/8db56598-f7b7-41ba-91df-c55f9f626545

[40] ECHA 2010. Guidance on waste and recovered substances. ECHA-10-G-07-EN. https://echa.europa.eu/-/guidance-on-waste-and-recovered-substances

under certain conditions, if fulfilling the applicable End-of-Waste criteria. No further registration requirements then apply unless the substance is intended to be released.

4. **Recovered base oils**. The recovered base oils are typically UVCB substances. No exemption other than that addressed in Article 2(7)(d) of REACH potentially applies, so the recovery operator should have access to the necessary information. However, the identified uses of recovered base oils are not always the same as those referred to in the original registrations. Depending on the recovery process applied, these recovered base oils may still be used for the same purpose or, if they lose their lube oil properties, they may be used as fuels. In the last situation Article 2(7)d exemption may also be applied if the necessary information is accessible to the operator.

Some further indications on the possible procedure to apply exemption of Article 2(7)(d) REACH is reported in Appendix II of the Swedish KEMI report[41].

BOX 13. Guidance for the registration exception for recycled (translation from Swedish to English).

The proposed procedure is following.

1. Identify which substances are included in the recycled material.
    a. This can be done by mapping the waste stream and the chemical content by: compiling information from the manufacturer of the original product and others available sources.
    b. If the waste flow is complicated, has unknown content or undergoes an advanced recycling process, the above-mentioned information may need to be completed with analyses to support the assumptions and conclusions drawn.
2. Identify the pollutants contained in the recycled material. A contamination may be applied to the originating material but be something that does not affect the function of recycled material, for example a pigment. Gravel, oil and similar material not added intentionally can also be a contamination. Please note that contamination may affect the classification of a substance or mixture.
3. Check if the recovered substance has been registered. This can be done by searching the ECHA database of registered topics: https://echa.europa.eu/information-on-chemicals/registered-substances.
4. Obtain product information for the recycled substance. For substances that are classified as hazardous, safety data sheets and possible exposure scenarios already exist. For substances that are not classified as hazardous, the registration number for the substance is usually enough. Please note that a safety data sheet for the original mixture or polymer is not sufficient. Also make sure that you have the right to use the information. Do not forget to document what you do so that it is available under supervision!

[41] KEMI 2016. Återvunna ämnen – Rapport från ett tillsynsprojekt 2016. Tillsyn 10/16. https://www.kemi.se/en/publications/enforcement-reports/2016/enforcement-13-16-recovered-substances. The Appenxes only availble in the swedish language version.

BOX 14. Examples of recovery exemption in the case of End-of-Waste

Netherlands. In the first case, pyrolysis oil from waste car tyres is a recovered substance from a recovery process of waste car tyres. The substance had not been registered before. Thus Article 2(7)(d) was not applicable and the first manufacturer had to register this recovered substance in accordance with Title II. The wording of Article 2(7)(d), leads to the conclusion that from now on, for other manufacturers of this recovered substance it fulfills the requirements to be exempted from registration: because now it has been registered "before". Later, in another case concerning the registration of pyrolysis oil from waste car tyres, the other manufacturers of the same recovered substance can now claim exemption from registration based on Article 2(7)(d). According to the 'Guidance on waste and recovered substances' the use of a recovered substance is not limited to the identified uses of the "original" substance.[42] This means other manufacturers are not limited to the use of this substance as an intermediate.

Finland. The company produces recycled oil from ships' bilge water. Bilge waters are a mixture of oil and water, which originate from e.g. separation of heavy or light fuel oil used as ship fuel, tank washing, engine leaks and condensate. Bilge water can contain e.g. hydraulic oils and lubricating oils. Due to the metal particles coming off the motors and bearings, the raw material also contains e.g. nickel, zinc and vanadium. Raw material quality varies a lot and the oil content of the incoming bilge water varies by estimate between 5% and 45%. In the recovery process, the bilge water is separated, so that the oil, water and solid matter are separated. The composition of the recycled oil was determined using the same analyses used to determine the substance identity of similar virgin oils. The composition of the recycled oil was compared to the substance identity of heavy fuel oil (CAS 270-675-6) determined in the registration procedure according to the REACH Regulation. In the comparison, it was found that the substances are similar in terms of their chemical composition and the recycled oil is considered 'the same substance' as the already registered heavy fuel oil (Article 2 (7)(d) REACH regulation). When the recycled oil ceases to be waste according to the End-of-Waste criteria, the safety data according to Article 31 of the REACH Regulation (safety data sheet and exposure scenarios) is obtained for the product and an exemption according to Article 2(7)(d) can be applied. If preferred, the recovered substance can be registered. Any substance-specific or other restrictions of the REACH regulation must also be taken into account when using the substance. In the environmental permit, the End-of-Waste status of the recovered oil was approved so that the recovered oil can be used in cement and lime kilns as well as in thermal drying of sludge and thermal treatment of contaminated land. The End-of-Waste status was not approved for use as fuel for asphalt stations or as bunker oil, e.g. due to the fact that the recovered oil was not similar in terms of technical characteristics with the heavy fuel oil on the market and the use of recycled oil would cause more air emissions than similar fuels, based on the oil quality data. Thus, when looking at the End-of-Waste criteria, the intended use of the substance and the environmental and health impacts of the use must also be taken into account, despite the fact that the chemical similarity of the

[42] ECHA 2010. Guidance on waste and recovered substances. ECHA-10-G-07-EN. https://echa.europa.eu/-/guidance-on-waste-and-recovered-substances

substance to the already registered, virgin substance has been demonstrated. Thus, the permitted purpose(s) of use of the recovered (End-of-Waste) substance may be different from the similar substance that has already been REACH registered.

5.3. Recovery exemption and recycled plastics

The recovery exemption has been considered from the point of view of recycled plastics. **In ECHA's Guidance on Waste and Recovered substances**[43] following indications are given: The polymer recovery operator should also identify any intended substances in the recovered material (e.g. substances added to adjust or improve the appearance and/or the physicochemical properties of polymeric material). Intentionally recovered substances cannot be treated as impurities but have to be considered as a substance for which one has to check whether one can rely on the exemption via Article 2(7)(d) of REACH. For this reason, it is recommended to regard the recovered material as a substance in a mixture (e.g. in the case of selective recycling of soft PVC, it may be necessary to register the relevant softeners, unless they have been registered before). Any other unintentional "impurity" present in the recovered polymer substance (e.g. pigments which any longer don't have the intended function in the recovered material or impurities that are introduced after polymer manufacturing) can be considered as impurities, unless present in quantities above 20%. There is also the option of handling recovered polymers as UVCBs, if the composition is unknown.

In the Swedish KEMI Report on recovered substances also addressed the recovery of plastics.[44] In the report **f**ollowing indications are given: For recovered polymers, the monomers and other substances in the polymer must have been registered in order for it to be possible to make use of the exemption in REACH. In order to ensure that the recovered polymer does not contain any substances regulated in the chemicals legislation, it is important to avoid material streams that contain particularly dangerous substances included on the REACH Candidate List. One way to do this is to avoid PVC plastic being recovered together with other plastics. It is above all in PVC products that the Swedish Chemicals Agency's enforcement of plastic articles has found particularly dangerous substances.

[43] ECHA 2010. Guidance on waste and recovered substances. ECHA-10-G-07-EN. https://echa.europa.eu/-/guidance-on-waste-and-recovered-substances

[44] KEMI 2016. Recovered Substances – Report on an enforcement project 2016 Enforcement 13/16. https://www.kemi.se/en/publications/enforcement-reports/2016/enforcement-13-16-recovered-substances

The German Environmental Ministry (UBA) drafted a guidance in order to evaluate the REACH compliance for recovered plastic[45]. The guidance highlights that applying the recovery exemption under Article 2 (7)(d), does not exempt recyclers from the other information requirements under REACH and other statutory substance-relevant regulations. The basis for all further information requirements (classification, labelling, providing information to customers etc) is knowledge about **the hazard profile of the substances manufactured/marketed**. In order to be able to meet further requirements with regard to classification, labelling and customer information, recyclers must know the hazard profile of the substances manufactured by them. This means that recyclers have to determine whether the substances manufactured by them (including any impurities) have hazardous properties (e.g. corrosive, acutely toxic, chronically toxic, carcinogenic etc). Substances and substance groups that possess hazardous properties and thus may trigger relevant classification/labelling ('problem substances') is relevant in this context. In principle, recyclers have two options for obtaining information about the constituents of substances:

a) **Complete (laboratory) analysis of the constituents**: this option is often difficult to apply due to necessity to know beforehand what constituents should be investigated and due to the high costs of an exhaustive analysis.

b) **Accessing available knowledge about the composition**. When only mechanical processes are applied to incoming waste in the recovery activity (for instance in the case of plastic recovery) the starting point is the fact that normally at the end of the recycling process, nothing can be contained in a recycled product (End-of-Waste) that was not contained previously in the waste input or was added deliberately during recycling.

In principle, knowledge can be available in two different respects:

i) There exists 'positive' knowledge about the fact that a substance (or group of substances) is not contained.

ii) There exists 'positive' knowledge about the fact that a substance (or group of substances) is contained.

Such 'positive' knowledge should be distinguished clearly from 'negative' or non-knowledge, manifested in such statements as e.g.: "*Nobody has told me that my input material contains hazardous substances, therefore I will assume that they are not contained in my recyclates*". If it is known 'positively' that substances (groups) are not present in the input material (case i)), in quality-assured processes their absence in the output, in the secondary plastic, can be assumed also. If, in contrast, the presence of substances (groups) is known in principle (case ii)), the recycler should be clear about of the order of magnitude of such content. Moreover, it is necessary to know whether the content changes during the recycling process.

[45] UBA 2012. Reach and the recycling of plastics – Reference manual for an appropriate implementation of the REACH requirements for the operators of recycling plants. http://www.uba.de/uba-info-medien-e/4263.html

5.4. SR&D and PPORD exemptions

In addition to the by-product and recovery exemptions, there is an exemption for **product and process orientated research and development (PPORD).** The PPORD exemption is available under Article 9 of REACH Regulation. Article 9 contains an exemption from the obligation to register for a period of 5 years for substances manufactured or imported at tonnages >1 tonne/year when they are used in product and process orientated research and development (PPORD) or imported for the purpose of PPORD. A notification to ECHA is necessary. A PPORD exemption can be prolonged under conditions set in Article 9(7) of REACH.

Product and process orientated research and development (**PPORD**) is any scientific development related to product or process development and/or application of a new or already existing substance, irrespective of the tonnage, in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance. The notifier may only start the manufacture or import (of the substance or mixture) or production (of an article) upon the confirmation of the completeness by ECHA or two weeks after the notification, unless he receives an indication to the contrary from ECHA.[46] The PPORD notification exempts the quantities above 1 tonne imported or manufactured for the purpose of PPORD only from the obligation to register; an authorisation may be required and restrictions may apply. The PPORD exemption is not an exemption from REACH authorisation or restriction schemes as default. However, there are exempted (categories) of uses in Annex XIV for REACH authorisation that can apply to PPORD.

In addition to the PPORD exemption, there is an **exemption applicable for a substance manufactured in scientific research and development**. **Scientific research and development (SR&D, Article 3(23) of REACH Regulation**) is any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume <1 tonne/year. Because SR&D exemption only applies to quantities of substance less than 1 tonne/year, it would not be subject to REACH registration even normally. However, if for purposes of SR&D the substances used are also not subject to authorization obligation or the restrictions laid down in the REACH Regulation.

BOX 15. Estonian examples of exemptions using the PPORD notification.

Tyre pyrolysis is a thermo chemical conversion process in which an irreversible chemical change is caused to end-of-life tyres by the action of heat in absence of oxygen. The result is fuel, carbon black and gas. An Estonian company made a PPORD notification for an exemption of REACH registration in order to assess final product and its market. They succeeded and could market their product. The Environmental Board in Estonia issued a temporary permit for 1-year period to evaluate if the process and the plans have worked.

[46] ECHA has produced a guidance on this issue where it is further explained: ECHA 2017. Guidance on Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD). ECHA-17-G-24-EN https://echa.europa.eu/regulations/reach/registration/research-and-development

Another Estonian company collects waste oils with the aim to recover the fuel component and has submitted PPORD notifications for 3 fractions. One PPORD notification was selected to ECHA assessment and was concluded that it didn't meet necessary requirements. ECHA sent the company additional questions but has not received replies. As the company's PPORD notifications are expiring, registrations of the 3 fractions should follow. However, the company submitted PPORD notifications for processes that in practice were stable long term uniform processes with supporting testing data. No innovative activities or product or process orientated scientific research was detected during inspections. Local authorities are of the opinion that the activities of that specific company cannot be considered research and development applicable for PPORDs. A PPORD would not apply to processes where the end product is certain, the conditions of the process are uniform and already set and testing data shows no variability.

6. REACH enforcement in recovery plants: the experience of ECHA forum

A Pilot project on recovered substances exempted for REACH Registration was carried out by the ECHA´s Forum for Exchange of Information on Enforcement (Forum). This Project was the first one of the ECHA Forum dealing with the interface between REACH and the WFD, thus the results within will contribute to clarify and improve compliance with REACH of substances, mixtures in the circular economy. It focuses on the exemption that the recycling sector has from registering substances that they have recovered from waste. It targets recovered substances that fulfil the End-of-Waste criteria. The report[47] of the project is based on an EU enforcement project inspecting 107 products during 2021 in 11 EEA countries. In the project, the inspectors targeted waste operators and checked whether the substances recovered from their processes that were put on the market, applied the recovery exemption of Article 2(7)(d) REACH.

The project assessed the application of the recovery exemption. This exercise was performed in 46 cases. In 63 % of the cases, there were no issues regarding the assessment of the first condition of the exemptions (sameness of recovered and registered substance). However, inspectors found a clear breach of this condition in 23 % of cases and could not conclude on compliance in 11 % of cases. The second condition for exemption (availability of information) was fulfilled in 96 % of cases.

The project showed significant problems in the application of the recovery exemption. Therefore, the report listed multiple overall and targeted recommendations. Firstly, the overall recommendation is to strengthen cooperation and understanding between national authorities enforcing REACH and national waste authorities. Secondly, the REACH and waste authorities were encouraged to organise joint inspections as a learning

[47] REF

opportunity for both and strengthening the cooperation, aiming for more efficient enforcement activities in the Member States.

The report also lays down targeted recommendations for e.g. waste operators (recoverer), national REACH and waste enforcement authorities as well as for the Member States. The recommendations are the following:

To waste operators:

- Ask your customers about the real uses of the recovered substance they place on the market to be able to update their safety data sheets.
- Ask the competent authorities or national helpdesks for advice and guidance.
- Collect or produce more and better evidence to prove sameness of a recovered substance to a registered substance.
- Strive to learn more about registration duties for recovered substances, with special attention to UVCB substances.

REACH national enforcement authorities

- The working group recommends that inspection bodies make more use of national databases of End-of-Waste (EoW) decisions. The results show that it was somewhat difficult for the inspectors to identify the waste operators placing EoW material on the market. Use of the aforementioned databases and cooperation with waste inspectors may help in targeting companies for inspections.
- Inspectors are recommended to monitor the situation of recovered substances placed on the market given the high percentage of non-compliance found in this project.

Waste enforcement authorities

- Put more effort in the assessment of EoW and confirmation of the EoW status of recovered substances.

Member States

- Promote close cooperation between REACH and waste inspectors to ensure that recovered substances placed on the market meet requirements of all EU chemicals legislation.
- Raise awareness between waste operators of their obligations regarding chemicals legislation.

BOX 16. Example of REACH enforcement at ammonium sulphate recovery from a leachate treatment plant (Italy)

Recovered ammonium sulphate is marketed in aqueous solution or in granular form. Its main uses are as fertilizer or as a catalyst in the polymerisation of urea resins in the production of chipboard panels. It is not listed in Annex IV or Annex V of REACH Regulation and therefore is not subject to general exemptions. The facility disposes of non-hazardous waste by landfilling and treats its own leachate. If untreated, the leachate would be disposed of as waste (EWC code 19 07 03). Leachate typically contains ammonia nitrogen, organic

nitrogen, volatile acids, sulphates, chlorides and metals, which can contaminate the recovered product. The leachate treatment process involves:

- 2-stage vacuum condensation (concentrate to disposal)
- condensation
- pH control with soda dosage
- ammonia stripping
- absorption of the ammonia current in counter-current with a sulphuric acid solution.

The product obtained is a 30-33% solution of ammonium sulphate (CAS 7783-20-2). The ammonium sulphate is sold to a third company that resells it, without further treatment. The recoverer had the duty to register the ammonium sulphate pursuant to Article 6 of REACH. The substance is obtained by absorption in a sulphuric acid solution of the ammonia effluents from leachate treatment. Deadline for registration was 31/5/2013. During the inspection, evidence was acquired of:

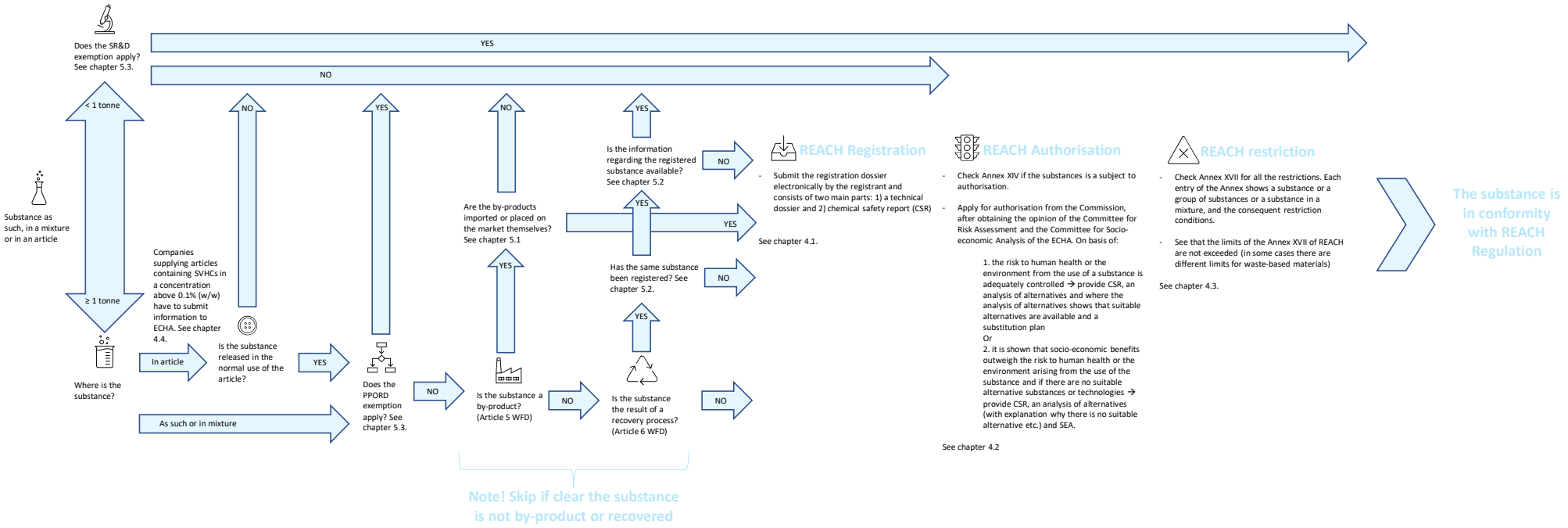
- pre-registration of the product as reaction mass of sulphuric acid and ammonium sulphate (Pre-Registration Submission Report)
- successive pre-registration of the product as ammonium sulphate (Late Pre-registration Submission Report). This late pre-registration was necessary in order to join the SIEF of the recovered substance.
- chemical analyses carried out by the recoverer were initially limited to just a few parameters, which were extended at the request of the inspection team to all the parameters that, on the basis of the characteristics of the incoming leachate and the process, could be present in the mixture originating from the process (pH, density, dry residue @105°C, elemental analysis, determination of metals, anions, cations, organic compounds)
- Letter of Access from manufacturer to the ammonium sulphate registration dossier (100 - 1000 t/year) prepared by the FARM Consortium, for the preparation of its own registration dossier.
- Joint Submission Registration Report of ammonium sulphate (the substance has already been registered)
- C&L Notification Submission Report, ammonium sulphate.

Inspection was completed on 20.02.2013. The company had registered the substance within the applicable deadline (31/5/2013), Joint Submission.

In conclusion, for the recoverers, the identification of REACH and CLP obligations appears critical. A survey of facilities authorised to recover chemicals from waste and on compliance with REACH requirements is desirable. Identity assignment to the substance is critical for the identification of possible risks from exposure to the substance as well as the statement of sameness. Analytical checks on substance identity are desirable. Regarding the compliance with C&L inventory notification obligations, the congruence with the documentation proving the date of first placing on the market (invoices, transport documents, ...) can be checked.

Annexes

Annex I. Flowchart for REACH compliance



Annex II. Checklist for chemicals legislation compliance

POPs-REACH-CLP FULFILLMENTS for End-of-Waste:				
n.	**Fulfillments**	**References / notes**	**Reg.**	**(Synthetic) outcome of company assessments**
FULFILLMENTS POPs				
1	Are substances included in Annex IV of Regulation (EU) 2019/1021 and subsequent amendments present in the waste (substances, mixtures or articles) intended to go through a recovery operation aimed at becoming End-of-Waste?	art. 4 (4), art. 7 (2) art 7 (3), art. 7 (4) a), art. 7 (4) b), art. 7 (6), Annex IV-V POPs. A collection of information and / or analysis by the waste producer is necessary in order to decide which recovery operation could be applied for the relevant waste stream. If Annex IV concentration limits are exceeded, only limited recovery operations are allowed and no End-of Waste is possible. For the articles you need to have the information from the manufacturers (for example for flame retardants). In addition, Member States shall take the necessary measures to ensure the control and traceability of waste containing or contaminated by a substance listed in Annex IV to this Regulation.	**POPs**	

POPs-REACH-CLP FULFILLMENTS for End-of-Waste:				
n.	**Fulfillments**	**References / notes**	**Reg.**	**(Synthetic) outcome of company assessments**
2	Are the quantities of POP substances identified in the waste stream intended to go through a recovery operation aimed at becoming End-of-Waste lower than the limits set out in Annex IV?	art 7 (4) a) If they are below the limits set out in Annex IV they can be recovered or disposed of in accordance with European legislation If they are above the limits set out in Annex IV, the WASTE MUST BE disposed of and / or recovered ONLY according to the indications of Annex V part 1 or part 2	**POPs**	
3	Are there any traces in the final End-of-Waste (substance, mixture or article)?	art. 3, art 4 b). Annex I-II. If there are traces, they must comply with what is indicated in Annex I and II of the POP Regulation. There are exemptions and unintentional trace contaminant limit values. However, the limit values do not apply to a substance present in articles already in use before or on the date on which this Regulation (EU) 2019/1021 or Regulation (EC) No 850/2004[48] became applicable to that substance, whichever came first	**POPs**	
IDENTITY'				

[48] Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC. No longer in force. Repealed with Regulation (EU) 2019/2021.

POPs-REACH-CLP FULFILLMENTS for End-of-Waste:				
n.	**Fulfillments**	**References / notes**	**Reg.**	**(Synthetic) outcome of company assessments**
1	Identify whether the recovered material is a substance, mixture or article	*art. 3 (1), art.3 (2) art. 3 (3) REACH, art.2 (7), art. 2 (8) CLP* *Check if you are in the presence of a substance, mixture, article and if substance, define its type:* • *mono-constituent* • *multi-constituent* • *UVCB* *ECHA Guidance for the identification and naming of substances under REACH and CLP*[49] *ECHA Guidance on waste and recovered substances*[50]	REACH-CLP	
REGISTRATION - CHEMICAL SAFETY ASSESSMENT				
2	Registration	Art. 6 (1) ECHA ECHA Guidance on registration[51]	REACH	

[49] ECHA 2017. Guidance for identification and naming of substances under REACH and CLP. ECHA-16-B-37.1-EN https://echa.europa.eu/view-article/-/journal_content/title/guidance-for-identification-and-naming-of-substances-under-reach-and-clp

[50] ECHA 2010. Guidance on waste and recovered substances. ECHA-10-G-07-EN. https://echa.europa.eu/-/guidance-on-waste-and-recovered-substances

[51] ECHA 2021: Guidance on registration. ECHA-21-G-05-EN, p. 32. https://echa.europa.eu/documents/10162/2324906/registration_en.pdf/de54853d-e19e-4528-9b34-8680944372f2

POPs-REACH-CLP FULFILLMENTS for End-of-Waste:				
n.	**Fulfillments**	**References / notes**	**Reg.**	**(Synthetic) outcome of company assessments**
		ECHA Guidance on waste and recovered substances[52]		
3	Exemption from registration	Art. 2 (7) (a) Annex IV Art. 2 (7) (b) Annex V Art. 2 (7) (d) *ECHA Guidance on waste and recovered substances*[53] The supporting documentation (available in the company) must give objective evidence	REACH	
4	Chemical Safety Assessment (CSA / CSR)	Art. 14	REACH	
5	PBT or vPvB assessment	Annex XIII	REACH	
CLASSIFICATION, LABELING AND PACKAGING				
6	CLP classification	Annex XIII	CLP	

[52] ECHA 2010. Guidance on waste and recovered substances. ECHA-10-G-07-EN. https://echa.europa.eu/-/guidance-on-waste-and-recovered-substances

[53] ECHA 2010. Guidance on waste and recovered substances. ECHA-10-G-07-EN. https://echa.europa.eu/-/guidance-on-waste-and-recovered-substances

POPs-REACH-CLP FULFILLMENTS for End-of-Waste:				
n.	**Fulfillments**	**References / notes**	**Reg.**	**(Synthetic) outcome of company assessments**
7	Labelling	Annex I parte 2 – 5, all. Annex VI	CLP	
8	Packaging	Art 35	CLP	
SAFETY DATA SHEETS				
Obligation to provide an SDS according to REACH				
9	a) if a substance or mixture meets the criteria for classification as dangerous according to CLP	Art. 31 a)	REACH	
10	b) when a substance is persistent, bioaccumulative and toxic (PBT), i.e. very persistent and very bioaccumulative (vPvB) based on the criteria set out in Annex XIII of REACH;	Art.31 b)	REACH	

POPs-REACH-CLP FULFILLMENTS for End-of-Waste:				
n.	**Fulfillments**	**References / notes**	**Reg.**	**(Synthetic) outcome of company assessments**
11	c) when a substance is included in the list established pursuant to Article 59, par. 1 (candidate list) for reasons other than those referred to in letters a) and b).	Art. 31 c)	REACH	
Obligation to provide an SDS upon request according to Annex II REACH Regulation				
the supplier transmits to the recipient, on request, an SDS of a non-hazardous mixture according to CLP, but which contains:				
12	(a) in an individual concentration ≥ 1% by weight for non-gaseous mixtures and in an individual concentration ≥ 0.2% by volume for gaseous mixtures, at least one substance presenting a risk to human health or the environment; or	Art. 31 (3)	REACH	

POPs-REACH-CLP FULFILLMENTS for End-of-Waste:				
n.	**Fulfillments**	**References / notes**	**Reg.**	**(Synthetic) outcome of company assessments**
13	b) in an individual concentration ≥ 0.1% by weight for non-gaseous mixtures, at least one substance which is category 2 carcinogen or category 1A, 1B and 2 toxic for reproduction, category 1 skin sensitizer, category 1 respiratory sensitizer or has effects on breastfeeding or through breastfeeding is persistent, bioaccumulative and toxic (PBT) very persistent and very bioaccumulative (vPvB);	Art. 31 (3)	REACH	

POPs-REACH-CLP FULFILLMENTS for End-of-Waste:				
n.	**Fulfillments**	**References / notes**	**Reg.**	**(Synthetic) outcome of company assessments**
14	c) a substance for which Community legislation sets workplace exposure limits.	Art. 31 (3)	REACH	
Obligation to provide an SDS upon request according to the CLP Regulations				
Mixtures not intended for "sale to the public", it is required that the sentence EUH210 "Safety Data Sheet available on request" be placed on the label for mixtures not classified as dangerous, but which contain:				
15	a) ≥ 0,1 % of a substance classified as skin sensitiser category 1, 1B, espiratory sensitiser category 1, 1B, or carcinogenic category 2,	Annex II 2.10	CLP	
16	b) ≥ 0,01 % of a substance classified as skin sensitiser category 1A, respiratory sensitiser category 1A	Annex II 2.10	CLP	

POPs-REACH-CLP FULFILLMENTS for End-of-Waste:				
n.	**Fulfillments**	**References / notes**	**Reg.**	**(Synthetic) outcome of company assessments**
17	c) ≥ one tenth of the specific concentration limit for a substance classified as skin sensitiser or respiratory sensitiser with a specific concentration limit,	Annex II 2.10	CLP	
18	d) ≥ 0,1 % of a substance classified as toxic to reproduction categories 1A, 1B or 2, or with effects on or via lactation,	Annex II 2.10	CLP	

POPs-REACH-CLP FULFILLMENTS for End-of-Waste:				
n.	**Fulfillments**	**References / notes**	**Reg.**	**(Synthetic) outcome of company assessments**
19	e) at least one substance in an individual concentration of ≥ 1 % by weight for non-gaseous mixtures and ≥ 0,2 % by volume for gaseous mixtures either: classified with other health or environmental hazards; or for which there are Community workplace exposure limits	Annex II 2.10	CLP	
20	f) ≥ 0,1 % of a substance classified as endocrine disruptor for human health category 2,	Annex II 2.10, in force after 20.4.2023		
21	g) ≥ 0,1 % of a substance classified as endocrine disruptor for the environment category 2.	Annex II 2.10, in force after 20.4.2023		
VERIFICATION OF SVHC SUBSTANCES - RESTRICTIONS - AUTHORIZATIONS - NOTIFICATIONS				

POPs-REACH-CLP FULFILLMENTS for End-of-Waste:				
n.	**Fulfillments**	**References / notes**	**Reg.**	**(Synthetic) outcome of company assessments**
22	SVHC substances≥0.1%	Art. 59 (10) https://echa.europa.eu/it/candidate-list-table	REACH	
23	Substances included in Annex XIV (Authorization)	Art.58 https://echa.europa.eu/it/authorisation-list	REACH	
24	Substances included in Annex XVII (Restrictions)	Art.67 https://echa.europa.eu/it/substances-restricted-under-reach	REACH	
25	Notification of SVHC substances present in the article	Art. 7 (2) https://echa.europa.eu/it/regulations/reach/candidate-list-substances-in-articles/notification-of-substances-in-articles	REACH	
NOTIFICATIONS TO ECHA and to the appointed national body				
26	Notification to the C&L database of the classification	Art.39,40	CLP	
27	Notification to the appointed national body	Art.45	CLP	

POPs-REACH-CLP FULFILLMENTS for End-of-Waste:				
n.	**Fulfillments**	**References / notes**	**Reg.**	**(Synthetic) outcome of company assessments**
268	Notification to the EU database Poison Control Center PCN (Poison Center Notification)	https://poisoncentres.echa.europa.eu/it/echa-submission-portal	CLP	
29	UFI (Unique Formula Identifier)	Annex VIII https://poisoncentres.echa.europa.eu/it/ufi-generator	CLP	
OBLIGATION TO STORE INFORMATION				
30	Obligation to keep information and requests for information	Art.36 The retention of the verification information of REACH compliance is mandatory for at least 10 years from the production of the last supply	REACH	
31	Obligation to keep information and requests for information	Art.49 The retention of the verification information of CLP compliance is mandatory for at least 10 years from the production of the last supply	CLP	
NOTIFICATION UNDER THE WASTE DIRECTIVE (WFD)				
32	SCIP Database	Directive 851/2018 art. 9 (1) and 9 (2) From 5 January 2021 https://echa.europa.eu/it/scip-database	WFD	