http://echa.europa.eu

# Guidance on waste and recovered substances

**Version: 2**
**May 2010**

LEGAL NOTICE
This document contains guidance on REACH explaining the REACH obligations and how to fulfil them. However, users are reminded that the text of the REACH regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

***Guidance on waste and recovered substances***

**Reference:** ECHA-10-G-07-EN
**Publ.date:** 05/2010
**Language:** EN

© European Chemicals Agency, 2010.
Cover page © European Chemicals Agency

Reproduction is authorised provided the source is fully acknowledged in the form “Source: European Chemicals Agency, http://echa.europa.eu/”, and provided written notification is given to the ECHA Communication Unit (publications@echa.europa.eu).

If you have questions or comments in relation to this document please send them (quote the reference and issue date) using the information request form. The information request form can be accessed via the Contact ECHA page at: http://echa.europa.eu/about/contact_en.asp

**EUROPEAN CHEMICALS AGENCY**

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Annankatu 18, Helsinki, Finland

# PREFACE

This document relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006[1](hereinafter referred to as REACH) and specifically addresses the application of its Article 2(7)(d). It describes under which conditions legal entities recovering substances from waste can benefit from the exemption laid down in Article 2(7)(d) of REACH and elaborates on the obligation to share information in the supply chain as put forward in title IV of REACH, which is not contained in the exemption.

The document is part of a series of guidance documents that are aimed at helping all stakeholders with their preparation for fulfilling their obligations under REACH. These documents cover detailed guidance for a range of essential REACH processes as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under REACH.

The current guidance document was prepared by the Commission involving all stakeholders: Member States, industry and non-governmental organisations (NGOs). The document has been handed over to ECHA in the REACH CA meeting of December 2008. ECHA further developed this guidance, taking into account needs for clarification that have been identified in the discussions with experts in the course of the consultation procedure[2].

The guidance document can be obtained via the website of the European Chemicals Agency[3]. Any updates of the guidance will be drafted by ECHA and then again be subject to the consultation procedure.

[1] Corrigendum to 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); amended by Council Regulation (EC) No 1354/2007 of 15 November 2007 adapting Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) by reason of the accession of Bulgaria and Romania (OJ L 304, 22.11.2007, p. 1).
[2] http://echa.europa.eu/doc/FINAL_MB_30_2007_Consultation_procedure_on_guidance.pdf.
[3] http://echa.europa.eu/reach_en.asp.

**Document History**

| Version | Comment | Date |
|---|---|---|
| Version 1 | Draft Guidance by the European Commission (CA/24/2008 rev.1) sent for comments to members of REACH CA meeting | September 2008 |
| Version 1.1 | Draft Guidance (CA/24/2008 rev.2)<br>– article example included (aggregates could be considered articles under certain conditions) | October 2008 |
| Version 1.2 | Draft Guidance (CA/24/2008 rev.3)<br>– disclaimer adapted | April 2009 |
| Version 1.3 | – Focus the scope of the guidance on i) exemptions from registration under article 2(7)(d) and ii) corresponding duties of recovery operators to inform their customers on dangerous substances in the recovered products they place on the market.<br>o Sameness of substance already registered.<br>o Information on this substance to be available to the recovery operator.<br>o Information to be available to the recovery operator to satisfy the duties under DSD/CLP Regulation.<br>o Notification requirements under CLP<br>– Removing inconsistencies concerning sameness of substances, status of impurities and substances in mixtures.<br>– Increase consistency with the article guidance.<br>– Explain which duties a recovery operator (benefiting from the exemption) has with regard to assessing the potential hazards of the recovered material and communicating these to his customers.<br>– Links to guidance documents updated.<br>– Restructuring of the document<br>– Addition of<br>o examples<br>o a workflow<br>o a list of abbreviations and definitions | March 2010 |
| Version 2 | - Editorial changes and clarifications<br>- Increase consistency regarding the wording substance on its own, mixture and article | May 2010 |

# TABLE OF CONTENTS

1. INTRODUCTION ..... 1
2. REQUIREMENTS FOR RECOVERED SUBSTANCES UNDER REACH ..... 3
2.1. Pre-registration ..... 3
2.2. Registration ..... 4
2.2.1. Is recovery a manufacturing process under REACH? ..... 5
2.2.2. Identification of the recovered substance ..... 5
2.2.3. Distinction between substance, mixture and article ..... 6
2.2.4. Impurities ..... 8
2.3. Exemption requirements according to Article 2(7)(d) of REACH ..... 9
2.3.1. Condition 1: “Sameness” of a recovered substance and a substance already registered ..... 10
2.3.2. Condition 2: Information required ..... 11
2.4. Information to be made available to users of recovered substances ..... 13
2.4.1. Relevance and adequacy of the information ..... 13
2.4.2. Safety Data Sheets ..... 14
2.4.3. Other information: registration number and exposure scenario ..... 15
2.5. Other obligations ..... 18
2.5.1. Classification and Labelling Inventory ..... 18
2.5.2. Restrictions ..... 18
2.5.3. Authorisation ..... 18
2.6. Considerations concerning particular streams of recovered materials ..... 19
APPENDIX 1: PARTICULAR STREAMS OF RECOVERED MATERIALS ..... 21
1.1. Recovered paper ..... 21
1.2. Recovered glass ..... 21
1.3. Recovered metals ..... 22
1.4. Recovered aggregates ..... 23
1.5. Recovered polymers ..... 25
1.6. Recovered rubber ..... 26
1.7. Recovered base oils ..... 27
1.8. Recovered solvents ..... 28
APPENDIX 2: LIST OF ABBREVIATIONS AND DEFINITIONS ..... 29

# 1. INTRODUCTION

Article 2(2) of REACH provides that *"waste as defined in Directive 2006/12/EC*[4] *of the European Parliament and of the Council is not a substance, preparation or article within the meaning of Article 3 of this Regulation."* Therefore, REACH requirements for substances, mixtures and articles do not apply to waste[5].

This does not, however, mean that substances in waste are totally exempted from REACH. Manufacturers or importers of a substance as such, in mixtures or in articles (hereinafter referred to as "substance") subject to registration under REACH are obliged to take the waste life-cycle stage of the substance into account, where relevant, according to Annex I, section 5.2.2 of REACH, when undertaking the appropriate assessments under Title II, REACH[6]. In particular, according to Article 3(37) of REACH exposure scenarios are defined as *"set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or* ***used during relevant parts of its life-cycle*** *and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. […]"*. The waste, in which a substance may be contained, includes waste from manufacture of the substance, waste occurring as a consequence of the use of the substance and waste formed at the end of service life of articles in which the substance is contained.

The status of waste in the context of exposure scenarios and the interaction between REACH and waste legislation in that respect are described in section R 13.2.6 and R 18.2 of the guidance on information requirements and chemical safety assessment[7]. Exposure scenarios for the waste life- cycle stage of a substance are, therefore, not further discussed in this present guidance.

As soon as a material 'ceases to be waste', REACH requirements apply in principle in the same way as to any other material, with a number of exceptions granted conditionally. The point at which waste 'ceases to be waste' has been the subject of long debates. According to Article 6 (1) and (2) of the new Waste Framework Directive, certain specified waste shall cease to be waste when it has undergone a recovery operation and complies with specific criteria to be developed in line with certain legal conditions, in particular:

> *(a) the substance or object is commonly 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.*

Such criteria will be set for specific materials by the Commission as delegated acts under the Comitology procedure. For each waste stream different factors need to be considered.

[4] Repealed by Directive 2008/98/ECof the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (Waste Framework Directive).
[5] Further explanation on this exemption is given in the guidance on registration, http://guidance.echa.europa.eu/docs/guidance_document/registration_en.htm (section 1.6.3.4).
[6] See also the guidance on the estimation of exposure from the waste life stage http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r18_en.pdf?vers=20_08_08 .
[7] Chapter R 13.2.6 "Operational conditions and risk management measures related to the waste life stage" and chapter R 18.2 "Characterising waste streams arising from manufacture, use and subsequent life-cycle stages" of the Guidance on information requirements and chemical safety assessment (IR/CSA) http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm .

Discussion of and guidance on the end-of-waste criteria[8] for different waste streams are out of the scope of this document.

As a result of possible future Comitology Decisions[9] as well as decisions taken on end-of-waste by Member State authorities on a case to case basis in accordance with Article 6(4) of the Waste Framework Directive[10], some materials currently considered as waste might in future be considered to have ceased to be waste. This would not only mean that these materials no longer fall within the scope of waste legislation but also that they would be potentially subject to REACH requirements, unless covered by an exemption. Clarification of end-of-waste criteria is a matter for waste legislation, and the current document does not provide guidance as to when these apply and formerly discarded products cease to be waste. This guidance on waste and recovered substances intends to elaborate the obligations of establishments undertaking the recovery[11] with a view to comply with REACH, thereby contributing to the overarching objectives of the European Commission policy to sustainability and to encourage recovery and recycling.

This guidance aims to clarify the status of materials that have been recovered, that have ceased to be waste and that are subject to REACH obligations for substances, mixtures or articles. The guidance explains on the basis of which principal information a recovery operator may be able to benefit from the exemption under Article 2(7)(d) of REACH:

> *"2.7. The following shall be exempted from Titles II, V and VI:*
> *[…]*
> *(d) Substances, on their own, in mixtures or in articles, which have been registered in accordance with Title II and which are recovered in the Community if:*
>
> *(i) the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and*
> *(ii) the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery."* [12]

It is important to note that this guidance does not specify the level of detail needed for the different types of recovery streams. Appendix 1 to this guidance, however, illustrates the general obligations a recovery operator needs to fulfil in order to profit from the exemption of Article 2(7)(d) of REACH with the help of various selected examples.

[8] Information on the end-of-waste criteria developed in the context of the implementation of Directive 2008/98/EC (the "Waste Framework Directive") is available at:
http://susproc.jrc.ec.europa.eu/activities/waste/documents/Endofwastecriteriafinal.pdf
[9] http://europa.eu/scadplus/glossary/comitology_en.htm.
[10] In respect of End of Waste the revised Waste Framework Directive 98/2008EC sets out under Article 6 the following: Where (End of Waste) criteria have not been set at Community level under the procedure set out in paragraphs 1 and 2, Member States may decide case by case whether certain waste has ceased to be waste taking into account the applicable case law. They shall notify the Commission of such decisions in accordance with Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (1) where so required by that Directive.
[11] It should be noted that the terms 'recovery operator', 'establishment undertaking a recovery' and 'manufacturer of a recovered substance' are used in the document for the same actor.
[12] Article 2(7)(d) only exempts recovered substances under certain conditions. A general exemption for recovered substances through inclusion in Annex V was, therefore, not intended by the legislator.

# 2. REQUIREMENTS FOR RECOVERED SUBSTANCES UNDER REACH

The stage in the processing of waste at which REACH obligations start to apply depends on when the material loses its waste status. This implies that after a material ceases to be waste, the recovery process is at an end. End-of-waste materials may from then on be processed as a substance on its own, in a mixture or in an article in a production process. Recovery processes often take place in several steps, and sometimes only the last step will result in a material that will no longer be classified as waste under the EU waste legislation. Additionally, there may be cases where only a fraction of the material resulting from the recovery process will be non-waste[13].

Therefore, all recovery steps which do not result in a non-waste material are parts of the waste treatment process which is subject to waste legislation. Moreover, pursuant to Article 2(2) of REACH, waste materials, including wastes that arise during recovery processes, are not considered as substances, mixtures or articles. 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 (see section 2.2.1).

## 2.1. Pre-registration

If applicable, the exemption from registration for recovered substances in Article 2(7)(d) of REACH relies on the condition that the same substance has been registered before. Although it is likely that most recovered substances will be registered by the time the registration obligations for phase-in substances apply, no registrations have been made by the end of the pre-registration phase[14]. It is important to note, however, that non phase-in substances which do not profit from pre-registration are subject to registration obligations as of June 2008, when Title II of the REACH Regulation entered into force. Any recovered non phase-in substance must therefore refer to these registrations in order to rely on the exemption provided in Article 2(7)(d) of REACH.

As long as the substance has not yet been registered by another actor, the conditions of Article 2(7)(d) of REACH are not fulfilled. Therefore, recovery operators manufacturing such a substance will be potentially subject to registration obligations. This means that recovery operators that have not pre-registered their substance cannot lawfully manufacture or place on the market their substance until either they or any other actor has registered the substance.

[13] Article 6(1) of the Waste Framework Directive states "Certain specified waste shall cease to be waste [...] when it has undergone a recovery, including recycling, operation [...]" and Article 6(3) of the Waste Framework Directive states "Waste which ceases to be waste in accordance with paragraphs 1 and 2, shall also cease to be waste for the purpose of the recovery and recycling targets set out in Directives 94/62/EC, 2000/53/EC, 2002/96/EC and 2006/66/EC and other relevant Community legislation when the recycling or recovery requirements of that legislation are satisfied."

[14] Pre-registration consists in providing a limited set of information (in essence the name of substance, name and address of contact person, the envisaged registration deadline and the tonnage band; for further information see http://echa.europa.eu/pre-registration_en.asp), free of charge, to ECHA. Pre-registrants must reply to requests for data (if a pre-registrant does not have such data, it is sufficient to state this in replies to such requests). Otherwise, the role of recovery operators within the SIEFs will depend on their own wishes to be involved and they can also decide not to play an active role ("dormant" participants). Such pre-registrants cannot be required to pay any SIEF costs unless they are using any information which is subject to cost sharing under REACH (for more information see guidance on data sharing). Pre-registration does not entail any obligation to register the substance.

Only pre-registration therefore provides legal security that manufacturing or placing on the market can continue until the relevant registration deadline provided that the pre-registered substance fulfils the conditions of Article 3(20) of REACH. Although the pre-registration period as well as the first deadline for late pre-registration have already passed there is still the possibility to benefit from late pre-registration for first time manufacturers and importers of recovered phase-in substances on their own or in a mixture or in the context of articles under certain conditions, as foreseen in Article 28(6) of REACH[15].

Following pre-registration, registration may not be required because the substance(s) will eventually be registered by another registrant, enabling the recovery operator to benefit from the exemption of Article 2(7)(d) of REACH. Whenever a decision is taken to modify the end-of-waste status (whether at Community or national level), it is also possible to resort to late pre-registration as explained above under Article 28(6) of REACH. Recovery operators should however evaluate whether the end-of-waste status may change the registration deadline as for some materials the volume of recovered substance may be bigger than the primary production. Hence, as a consequence of this, recovery operators may have to register prior to the primary producers.

Pre-registration may open communication with other manufacturers of the same substance. This gives recovery operators access to the contact information of other manufacturers of the substance and, if they so wish, a possibility to contribute to the SIEF discussions. Pre-registration will also allow recovery operators to participate in the discussion on the sameness of substances and to demonstrate the sameness of their substance so that they can join the SIEF. Another benefit of involvement of recovery operators in the SIEFs is that their participation facilitates the development of correct exposure scenarios for handling materials at the end-of-life stage and identification of differences and impacts (to the extent required) between primary and secondary production processes. Moreover, the SIEF may also be an opportunity to discuss access to safety information that recovery operators may need to benefit from the registration exemption and also for other obligations they may have under REACH Registration status of substances (section 2.5) and availability of information (section 2.3.2). It should be noted that pre-registering a recovered material as a UVCB (instead of single substances with impurities) may make it more difficult to benefit from the exemption under Article 2(7)(d) of REACH at a later stage (section 2.2.3).

## 2.2. Registration

In the same way as any other substance falling under the scope of REACH, recovered substances are, in principle, subject to REACH registration requirements.

The legal entity performing the final recovery should check whether the recovered substance is exempt from registration because it is listed in Annex IV or covered by Annex V of REACH. Examples of such recovered substances are mentioned in Appendix 1 of this guidance.

If such exemptions do not apply, Article 2(7)(d) of REACH provides an exemption for recovered substances under certain conditions. These provisions are further explained in section 2.3. In order to ensure compliance with these provisions, the following issues should be taken into

[15] Legal entities may pre-register after 1 December 2008 if they are:

- manufacturing or importing phase-in substances (on their own or in a mixture) after 1 December 2008 in quantities of 1 tonne or more per year and be able to prove that you are doing this for the first time; or
- producing or importing articles with an intended release of substances after 1 December 2008 in quantities of 1 tonne or more per year and are able to prove that you are doing this for the first time

If this is the case, the following deadlines for pre-registration apply:

- At the latest six months after manufacturing or importing exceeds the one-tonne threshold; and
- At least 12 months before the relevant transitional deadline for registration.

In this context, the manufacture or import 'for the first time' means for the first time after the entry into force of REACH (1 June 2007).

account with respect to the general REACH registration requirements which, in principle, also apply to the recovered substance.

### 2.2.1. Is recovery a manufacturing process under REACH?

As already discussed above, waste material after ceasing to be waste, can be considered as a substance on its own, as a mixture containing two or more substances, or as an article. Consequently, it needs to be clarified whether recovery is a continuation of the use of the originally registered substance and if this is not the case, then, secondly, whether it is "manufacturing" that transforms waste into one or several substances as such, in a mixture or in an article again.

The life-cycle and supply chain of the original substance ends with the waste stage. If waste ceases to be waste, a new life-cycle of the substances starts. The recovery process focuses on recovery of the substance from that waste. Therefore, in any event and by definition, recovery cannot be a use[16].

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, <u>all</u> 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.**

### 2.2.2. Identification of the recovered substance

To benefit from the exemption contained in Article 2(7)(d) of REACH, an identity needs to be assigned to the recovered substances. 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. Section 2 "identification of the substance" of Annex VI to REACH lists the information considered to be sufficient for correct identification and naming of the substance[17]. This information includes in principle the IUPAC name and/or any other chemical identifier, the molecular and structural formula, the composition and analytical data (including normally spectral and chromatographic data) of the substance.

Due to the variable input of the composition of the waste stream from which the substances are recovered, or due to the fact that often substances in mixtures and not substances as such are recovered from waste, it might not always be possible to produce such analytical data for each recovered substance. Whenever this is the case, it shall be clearly stated and argued which other data are sufficient to justify the identity of the recovered substance(s). Information that is

[16] Article 3(24) defines "use" as *"any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation"*.

[17] Guidance for identification and naming of substances under REACH is available at: http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.htm.

specifically relevant to the recovered substance (origin of waste, control of input material, if available spectral data, process steps that ensure that certain impurities are not present in the recovered substance on its own or in the mixture) have to be documented in order to compare the identity of the recovered substance with the original substance that was registered under Title II of REACH[18].

### 2.2.3. Distinction between substance, mixture and article

In order to assess registration requirements for recovered materials, it is essential to clearly identify whether the particular material is a substance as such, a mixture (containing 2 or more blended substances) or an article. This question is addressed below on the basis of the definitions of 'substance', 'mixture' and 'article' as per Article 3[19] of REACH. The guidance documents on substance identification and on requirements for substances in articles provide further information on how to apply these definitions.

#### 2.2.3.1. Article

The recovery process may result directly in the formation of an article, instead of a substance or a mixture such as a park bench made of plastic. This may be the case e.g. if collected and sorted polymer or metal waste is directly melted into new articles. Registration of substances in articles is only required if they are intended to be released under certain conditions as specified in Article 7(1) of REACH or if the Agency has taken a decision to require registration pursuant to Article 7(5) of REACH[20]. Only in these limited cases, there would be the need to establish whether Article 2(7)(d) applies as the recovery operator has to comply with the provisions under Article 7 of REACH regarding substances in articles. Should a recovery operator for any reason not be able to rely on Article 2(7)(d) of REACH, he may however be eventually be exempted from registration pursuant Article 7(6) of REACH if the substance has already been registered for that use.

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”*.

Based on this definition, if you can unambiguously conclude that the shape, surface or design of an object is more relevant for the function than its chemical composition, the object is an article. If the shape, surface or design is of equal or less importance than the chemical composition, it is a substance or mixture. If it is not possible to unambiguously conclude whether an object fulfils the REACH definition of an article or not, a deeper assessment is needed. For this it is recommended to consult the Guidance on requirements for substances in articles[21].

Furthermore, whenever a recovered material is supposed to undergo further chemical reaction, or a change of shape or surface (e.g. melting into a new shape), this is an indication that the material is a substance on its own or a mixture rather than an article.

If, based on these considerations, a recovered material is considered to be an article a registration of the contained substances is only exceptionally required under Article 7(1) or Article

[18] Information resulting from the monitoring of compliance with end-of-waste criteria should ensure a certain quality of secondary raw materials, exclude hazardous properties and limit the presence of foreign materials and may help to meet the condition regarding the sameness of the recovered substance (see also section 2.3.1).
[19] Article 3(1): substance; Article 3(2): mixture; Article 3(3): article.
[20] However, the presence in the articles of substances of very high concern that are on the candidate list for inclusion in Annex XIV may trigger notification obligations according to Article 7(2) and communication obligations according Article 33 of REACH.
[21] See the Guidance on requirements for substances in articles available at http://guidance.echa.europa.eu/docs/guidance_document/articles_en.htm which is currently under revision. The latest status of the revision is available at http://guidance.echa.europa.eu/guidance4_en.htm

7(5) of REACH, from which the recovery operator may avail himself if he meets the requirements of Article 2(7)(d) of REACH, as explained before.

### 2.2.3.2. Substance on its own or in mixtures

According to Article 3(1) of REACH, a **substance** is defined as "*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.*"

Substances can be divided into two main groups:

1. 'Well defined substances': Substances with a defined qualitative and quantitative composition that can be sufficiently identified based on the identification parameters of REACH Annex VI section 2. Rules for identification and naming differ for:

- 'well defined substances' with one main constituent (in principle ≥80%) (mono-constituent substances)
- substances with more than one main constituent (in principle each constituent ≥10% and <80 %) ('multi-constituent' substances)

2. 'UVCB substances': *"Substances of Unknown or Variable composition, Complex reaction products or Biological materials, also called UVCB substances cannot be sufficiently identified by their chemical composition, because:*

- *The number of constituents is relatively large and/or*
- *The composition is, to a significant part, unknown and/or*
- *The variability of composition is relatively large or poorly predictable."*[17]

For such substances, further identifiers have to be considered such as sources of origin or type of production processes.

In particular the approaches to identify a substance as a mono-constituent or as a UVCB substance are relevant for recovered substances. In contrast, the concept of "multi-constituent substances" refers to a category of substances resulting from a specific manufacturing process (see example 3 in Appendix 1) and applies to recovered substances only in special circumstances. Whenever materials are listed in EINECS, this is an indication that they are regarded as substances, although in many cases a refinement of substance identity may be necessary.

According to Article 3(2) of REACH, a **mixture**[22] is defined as "*a preparation or solution composed of two or more substances.*" Thus, a recovered material may also be considered a mixture, containing a number of recovered substances.

In general, it has to be borne in mind that there is a clear distinction to be made between mixtures and substances, a result of which is that both terms are not interchangeable on a discretionary basis. The definitions of 'mixtures' and 'substances' need to be interpreted in a way that the term 'substance' includes reaction mass resulting from a chemical reaction. The term 'mixture' is limited to blends which are not the result of a chemical reaction.

As many recovery operations do not produce substances on their own, but rather substances in mixtures (e.g. plastics, rubber etc), the distinction between a mixture and a UVCB substance of variable composition is described hereafter.

[22] Regulation 1272/2008 of 31 December 2008 (CLP Regulation), in its Article 57 al. 11, p.30 specifies that the term "preparation" in a.o. REACH Regulation has to be replaced by "mixture".

Many recovered materials consist of two or more substances but also have typical characteristics of UVCB substances. For this reason, the alternatives to characterise the substance(s) are to a certain degree interchangeable. It is up to the manufacturer or importer to decide which of the two options best fits the characteristics of the material.

On the one hand, it will be easier to register substances with a very complex composition as UVCB substances. On the other hand, recovered materials with a complex composition will often not have corresponding original substances that have been registered as UVCB substances before. Therefore, such substances might not be able to benefit from phase-in status as there is no corresponding EINECS entry. If that is the case, there may be no other registration on which to base an Article 2(7)(d) exemption.

Nevertheless, the individual constituents of the material may already have been registered (or are exempted from registration), thus enabling the use of the exemption in Article 2(7)(d) of REACH provided that the relevant safety information is available.

A recovery may result in the generation of one or several substances as such or in a mixture. It is up to the recovery operator to consider whether the material is a substance as such or contained in a mixture. In any case he has to ensure that the individual constituents/substances have been registered before and thereby benefiting from the exemption in Article 2(7)(d) of REACH provided the relevant safety information is available (see section 2.3.2 and section 2.4.1).

### 2.2.4. Impurities

In the context of recovered materials, it may be difficult to conclude whether a constituent of a recovered material is a substance or an impurity. The guidance on substance identification defines an impurity as "*an unintended constituent present in a substance as produced. It may originate from the starting materials or be the result of secondary or incomplete reactions during the production process. While it is present in the final substance it was not intentionally added.*"[17]

Recovered substances may contain impurities which may be different from those in a substance not derived from a recovery processes. This is in particular the case when recovered materials contain unintended constituents which have no function for the recovered material and the only reason for their presence in the recovered material is that they were part of the input waste for the recovery process.

While such constituents may have originally been intentionally added as substances to form a mixture or an article, their presence in the recovered material may be unintended (depending on whether these constituents have a specific function or not) and therefore, they can be considered as impurities, which do not require separate registration on their own.

Constituents present in quantities above 20% (w/w) should, however, in general not be considered as impurities but as separate substances in a mixture. In the case that recovered material is intentionally selected for the presence of certain constituent(s), those constituents should also be considered to be separate substances, even if they are present in smaller quantities than 20% (w/w) (e.g. if PVC is selected for the presence of flame retardants, it may be necessary to register these flame retardants, unless they have been registered before).

In mechanical separation of mixed waste, it may often be impossible to derive recovered material of 100% purity (free of alien elements). These alien elements are often either extraneous to the waste stream *per se* (for example, and depending on the waste stream, stones, plastics, pieces of rubber, sand, etc.) or extraneous to the material object of the recovery but part of the final product that became waste (for example, paints, coatings, etc.), of which the composition and total amount are difficult to determine. After appropriate sorting and separation, these fractions should be present in the recovered material only in very small quantities. In this case, such

elements can be considered as impurities that do not need to be registered separately on their own.

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

- identified to the extent needed[17] and allocated to the recovered substance(s) in order to facilitate the comparison with (an)other already registered substance(s); and
- identified and evaluated to the extent needed for establishing the hazard profile as well as the classification and labelling of the substance as such or in a mixture in which they occur (see section 2.3.2).

Whenever the recovered material is considered to be a substance in a mixture, the content of this mixture has to be assigned to single substance identities. Each substance identity may include impurities[23]. This should be based on the Guidance for substance identification. Furthermore, the decision on the sameness should be based on the main constituents. Impurities may affect the hazard profile of the substance. If that is the case they should be considered with regard to the Classification and Labeling of the substance (see section 2.4.1.). Recovery operators should be aware that the concept of impurities does not apply to UVCBs. Impurities can only be considered for materials consisting of substances (on their own or in a mixture) with a well defined composition.

## 2.3. Exemption requirements according to Article 2(7)(d) of REACH

Once the type (substance on its own or in a mixture) and impurities of the recovered material have been established, identified and documented as described in section 2.2, the recovery operator is in a position to examine whether the exemption criteria under Article 2(7)(d) of REACH are fulfilled. It should be noted that companies willing to benefit from this exemption must provide the authorities (only on request) with appropriate documentation proving that their recovered substances qualify for the exemption.

Article 2(7)(d) of REACH provides the following exemption for recovered substances:

> *"2.7. The following shall be exempted from Titles II, V and VI:*
> *[…]*
> *(d) Substances, on their own, in mixtures or in articles, which have been registered in accordance with Title II and which are recovered in the Community if:*
>
> *(i) the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and*
> *(ii) the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery.*"

It should be recalled that importers of substances recovered outside the borders of the European Economic Area (EEA) cannot benefit from the exemption under Article 2(7)(d) of REACH as it only applies to recovery within the EEA. In some cases, companies may continue importing the material as waste and then recover it in the European Economic Area (e.g. after recovery, checking whether the end-of-waste criteria are fulfilled). This would ensure an efficient monitoring of the end-of-waste criteria and at the same time the substances contained in the waste can be considered as recovered within the EEA and therefore Article 2(7)(d) of REACH could apply.

[23] With regard to the requirements under REACH it should be noted that the quality of the waste may be increased by measures in the treatment-process itself. Precautions by (denial of) the acceptance of waste and exact sorting out will enhance the quality of the waste. This may reduce the impurities present in the waste and consequently make it easier complying with the obligations under REACH.

Neither can by-products benefit from the Article 2(7)(d) exemption as described in Article 5 of the Waste Framework Directive. By-products may however be exempted on the basis of Annex V on the condition that they are not imported or placed on the market themselves. Where the recovery operator cannot rely on the exemption via Article 2(7)(d) of REACH or any other exemption, he needs to register the recovered substance and must subsequently comply with all obligations that follow from the provisions under the registration title II of REACH. The subsequent two chapters describe how to fulfil the requirements of Article 2(7)(d) of REACH step by step.

### 2.3.1. Condition 1: "Sameness" of a recovered substance and a substance already registered

Article 2(7)(d)(i) of REACH provides that *the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II.* This part of the legal text comprises two requirements: The exemption relies on an existing registration and the recovered substance is the same as the substance that has been registered.

**The recovered substance must be the same as the substance already registered**

This means that if, for some reason, the same substance has not been registered at manufacturing or import stage, the recovered substance has to be registered before the recovered substance with an end-of-waste status can be imported or placed on the market.

It is worth noting that the obligations related to the life-cycle and supply chain ends with the waste stage. This also has the consequence that the uses of a recovered substance do not have to be covered in the exposure scenario of the "original" substance (i.e. the substance that became waste and which is recovered from that waste), because the life-cycle of the original substance ends when it ceases to be waste.

In order to benefit from the exemption in Article 2(7)(d) of REACH, it is sufficient that a registration was filed for the substance by any registrant. This registrant does not have to be part of the supply chain leading to the waste generation[24].

In assessing whether the recovered substance is the same as a substance that has already been registered or whether the substances are different, recovery operators need to apply the rules of the guidance on substance identification. The decision has to be based on the sameness of the main constituents. Information about the impurities does in principle not change the conclusion about the sameness[25]. In particular, it should be noted that this is an assessment that recovery operators need to make themselves using all the available information such as the Guidance for identification and naming of substances under REACH. There is no confirmation given on "sameness" by the European Chemicals Agency. Recovery operators who have pre-registered their substance can however discuss "sameness" questions with other pre-registrants of the same substance in the (pre-)SIEF. As described in the data sharing guidance, companies can also refine and if necessary correct substance identity, as long as it is clear that the pre-registration was indeed for the concerned substance.

The same EINECS and CAS numbers for substances are an indicator for the sameness of substance. It should be noted 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. According to the guidance on identification and naming of substances, "*No differentiation is made between technical, pure or analytical grades of the substances. The "same" substance may have all grades of any production process with different amounts of different impurities. […].*

[24] Guidance on registration, http://guidance.echa.europa.eu/docs/guidance_document/registration_en.htm .
[25] Information about the impurities must be taken into account for issues such as Classification and Labelling and drafting of SDSs.

*Where the impurity profile of a well-defined substance from different manufacturing sources differs markedly, expert judgement will need to be applied to decide if these differences affect whether test data generated on one substance can be shared with other SIEF members.*"[17] Moreover, the guidance on data sharing explains that: *"For UVCB substances also – in general - the name is leading to determine the 'sameness'. If the name is the same, the substance is regarded the same, unless available data shows the contrary."* [26]

**Registration status of substances**

The exemption from registration for recovered substances in Article 2(7)(d) of REACH relies on the condition that the same substance has been registered before. To find out if this condition is fulfilled for a certain substance, several information channels can be used.

The main sources of information on substances are the data exchanged within the Substance Information Exchange Fora (SIEFs). The recovery operators having pre-registered the recovered substances will automatically be part of the pre-SIEF. As soon as the sameness of substance identity has been agreed between the pre-SIEF members, the SIEF is officially formed. Because recovery operators may have limited interest in registering the substance, it may happen that they will not actively participate in the SIEF communication. However, they should ensure that they will be informed about the registration status of the substance. Once the substance is registered, the conditions of Article 2(7)(d) of REACH may apply.

A second source of information will be the dissemination website from ECHA[27] as described in Article 77(2)(e) of REACH Regulation. Information on registered substances will be made publicly available under the provisions of Article 119 of REACH. This includes for example the name of the registered substance – for substances listed on EINECS – and its classification and labelling. For substances not listed on EINECS, the name of the substance may not be available via this source due to registrants' claims to not make this information available on the Internet[28]. As a consequence this information source alone may not be sufficient to conclude on the sameness. Also, information on impurity levels in the registered substance impacting on classification may not be available via this source due to registrants' requests to treat certain data confidential.

Other channels of information depend on the recovery operators' or their associations' own initiative to contact manufacturers or importers of the substance in question. The documents recovery operators use to provide evidence for the "sameness" and for the safety information can be provided in the form of standardised information prepared by their associations. Such standard documents should cover all relevant aspects for those materials which comply with end-of-waste criteria[29]. This may create synergies as the manufacturer/importer needs information on waste quantities and composition of waste for his registration dossier, whereas the recovery operator requires safety information on the registered substance to benefit from the Article 2(7)(d) exemption.

### 2.3.2. Condition 2: Information required

Article 2 (7)(d)(ii) of REACH provides that *"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"*.

[26] Guidance on data sharing, http://guidance.echa.europa.eu/docs/guidance_document/data_sharing_en.htm , p.35.
[27] http://apps.echa.europa.eu/registered/registered-sub.aspx
[28] Article 119(2)(f) and Article 119(2)(g) of REACH.
[29] The Commission representatives recommended this approach in the discussion with the metal recycling sector in October 2009. See JRC report on iron and steel scrap, p. 41 and 43 available at http://susproc.jrc.ec.europa.eu/activities/waste/documents/Endofwastecriteriafinal.pdf .

The legal entity that did the recovery must ensure that information on the registered substance is available to it, and that information must comply with the rules on information provision in the supply chain.

This means that the legal entity who undertook the recovery must have available one of the following, depending on the case:

- a Safety Data Sheet (SDS) as required by Article 31(1) or Article 31(3) of REACH, on the registered substance, with the annexed exposure scenarios, if applicable, for the registered substance;
- other information sufficient to enable users to take protection measures, as required by Article 31 (4) of REACH, for the registered substance in case no SDS is required; or
- the registration number, if available[30], the status of the substance under the authorisation part of REACH, details of any applicable restrictions under REACH and information necessary to allow appropriate risk management measures to be identified and applied, as required in accordance with Article 32 (1) of REACH.

With exception of the first bullet point (SDS), the form in which this information has to be available to the company carrying out the recovery is not further specified in this provision but this provision aims at allowing recovery operators to comply with their duties under Title IV of REACH. Such information only needs to be available for substances including their impurities. Information does not have to be available for the impurity on its own (see also section 2.2.4).

**Availability of the information**

Recovery operators will normally not receive an SDS[31] or other safety information in the framework of Title IV of REACH. In order to benefit from the registration exemption under Article 2(7)(d) of REACH, the required information must however be available to them. Furthermore, whenever required, they need to either prepare SDSs themselves or agree with owners of existing SDSs on using those SDSs. As there are no further legal provisions on this, this is a matter for the manufacturer of the recovered substance. The recovery operator can use any available information, starting with the information on the ECHA website and published in accordance with Article 119 of REACH, but must make sure that he does not violate any property rights. When using an existing SDS, he should, therefore, make sure that he has legitimate access to the information, and that the hazard profile of his recovered substance is adequately covered by this existing SDS (see section 2.4.2). The same applies to other safety information, if required. Discussions on the use of such information can, for example, take place within the SIEF, if the recovery operator has pre-registered the substance. Provisions can be made in the SIEF agreement on how the necessary information can be provided to the recovery operator without violating property rights. The activities within SIEFs are outside the remit of ECHA, and recovery operators are advised to contact the relevant industry associations which could play an important role in preparing standard information for their members.

Companies undertaking recovery operations and wishing to avail themselves of this exemption are advised to ensure as insofar as possible that the information on the registered substance, which was put together to comply with the REACH Regulation, is available to them as well in order to properly document that they can rely on the exemption via Article 2(7)(d) of REACH. In case a recovery operator is unable to access the relevant information on the same substance already registered, he cannot rely on the exemption under Article 2(7)(d) of REACH and has to register the recovered substance.

[30] The registration number should be provided only under the conditions of Article 32 (1) (b-d) of REACH. However, as explained in this guidance, the recovery operator usually does not receive any SDS as he is not acting as a downstream user of the original material.
[31] The information required for the preparation of a SDS is outlined in Article 31 and Annex II of REACH.

## 2.4. Information to be made available to users of recovered substances

Assuming that the recovery operator has established the identity of the recovered substance(s) as such, in a mixture or in an article (see section 2.2.3), he should then have available the corresponding safety information for the same already registered substance(s). This information should be relevant and adequate. Suppliers of substances as such or in mixtures have to provide the recipient with safety information that is sufficient to allow safe use of the recovered substance. This requirement applies to any recovered substance, irrespective whether or not the exemption from registration under Article 2(7)(d) of REACH applies. For certain substances as such and in mixtures, safety information has to be provided in the form of Safety Data Sheets (SDSs). Even if a SDS is not required there may still be an obligation to communicate information in the supply chain. These issues are explained hereafter.

### 2.4.1. Relevance and adequacy of the information

In order to assess whether this information is relevant and adequate to the recovered substance(s) and their foreseen use, he is advised to check the following:

- Which fraction of a recovered substance in a mixture can be referred to the same substances already registered? In order to meet his own duties regarding communication of safety information to customers, the recovery operator should take into account all components at > 0.1%[32] in the recovered substance in a mixture[33].
- To what extent may the impurity profile of the recovered substance(s) differ from that of the same registered substance, and may these differences (if any) lead to differences in the hazard profiles of the substances? In case the hazard profiles are different although they can still benefit from the earlier registration of the same substance, the information related to the already registered substance is potentially not adequate for the recovered substance. Consequently, these other hazards need to be described, classified and communicated to the customers of the recovery operator.
- Could the foreseen uses of the recovered substance(s) lead to exposure not covered in the exposure scenarios of the same substances already registered? If this is the case, the recovery operator needs to assess whether the substance information available to him covers the anticipated additional uses[34]. This could mean for example that if the information available for the same already registered substance does not include a DNEL for consumer exposure and also no exposure scenarios for consumer uses, the recovery operator may conclude that it would be inappropriate to use the recovered substance in applications leading to consumer exposure.

Wherever neither the registered substance nor the recovered substance(s) meet the criteria for classification as being dangerous or PBT/vPvB and a substance is not on the candidate list and not subject to restrictions, it is not required that according to Article 31 of REACH an SDS will be automatically provided. However the Article 32 obligation to provide information on the safe use of the substance will remain applicable.

[32] This is based on the lowest of the concentration limits in Directive 1999/45/EC or in Annex VI to Regulation (EC) No 1272/2008 (CLP-Regulation) so that the preparation would not have to be classified as dangerous; and the 0,1 % (weight by weight) threshold for PBTs, vPvBs and substances of equivalent concern for which classification rules do not apply. Please note that there are some cases with concentration limits below 0.1%.

[33] Please note that "impurities" on their own are not addressed in the exemption under Article 2(7)(d) of REACH. They are considered part of the substance as such or the substances in the mixture. For more information please refer to impurities in section 2.2.4.

[34] The recovery operator must provide enough information to allow safe use of the recovered substance based on Article 31 or Article 32 of REACH. As Article 2(7)(d) of REACH exempts the recovery operator from completing a CSA and providing a CSR, he is not obliged to provide an exposure scenarios on the basis of Article 31(7) of REACH.

How to establish the composition of the recovered material is the responsibility of the recovery operator. It may be based for example on the following non-exhaustive information sources:

- Representative chemical analysis of the waste and recovery stream through sector organisation initiative made available to the single companies involved in a particular type of recovery operations. The same information can possibly also be derived from literature;
- Good communication with the suppliers of the already registered substance or with producers of mixtures or articles to identify product compositions before entering into the waste life stage;
- Quality classes of secondary raw material which often contain limits for impurities and information on the rough composition of the material;
- Information resulting from the monitoring of compliance with end-of-waste criteria ensuring a certain quality of secondary raw material, excluding hazardous properties and limiting the presence of foreign materials.

A case by case analytical assessment of recovered material need only be carried out if all other information sources fail to provide sufficient information.

### 2.4.2. Safety Data Sheets

For certain substances, safety information has to be provided in the form of Safety Data Sheets (SDSs) in accordance with Article 31 of REACH, including where relevant the annexed exposure scenarios[34]. If SDSs are not needed, safety information according to Article 32 has to be provided, as applicable[35]. There may according to Article 33 of REACH also be a duty to communicate information on substances in articles to allow safe use if the articles contain substances of very high concern that are on the 'candidate list'. These obligations are further explained in the Guidance on requirements for substances in articles.

The safety data of the registered substance the recovery operator received in order to fulfil the exemption requirements under article 2(7)(d) of REACH, can be used as a basis for providing the required information for the recovered substance. However, due care must be taken that the data received is indeed adequate for the recovered substance. A difference in the impurity profile may lead to a different hazard profile and therefore to distinct information to be provided to the recipient of the recovered substance. Providing inappropriate SDSs could potentially make recovery operators subject to liability issues as the hazards of the recovered substance may not be sufficiently communicated. Such a scenario could be foreseeable e.g. when the presence of impurities as a consequence of the service life or mixing of wastes has an impact on the hazard profile or where the original producer of the substance was not obliged to make a SDS but the recovery operator is due to the presence of impurities that change the hazard profile of the recovered substance.

Article 31(1) of REACH states; *"the supplier of a substance or a mixture shall provide the recipient of the substance or mixture with a safety data sheet compiled in accordance with Annex II:*
*(a) where a substance or mixture meets the criteria for classification as dangerous in accordance with Directives 67/548/EEC or 1999/45/EC; or*
*(b) where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII; or*
*(c) where a substance is included in the list established in accordance with Article 59(1) for reasons other than those referred to in points (a) and (b)."*

[35] Article 32 of REACH obliges the supplier to share only information on authorisation, restriction and information necessary for risk management, especially in case of waving. It does not contain a general information requirement for all substances or mixtures regardless of their hazardous properties.

Note that Directive 67/548/EEC (Dangerous Substances Directive, DSD) and Directive 1999/45/EC (Dangerous Preparations Directive, DPD) will be repealed by the Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) on the 1st of June 2015. The CLP Regulation applies to substances as of 01 December 2010[36] and to mixtures (= preparations) as of 01 June 2015[37].

Article 31(3) of REACH provides that *"the supplier shall provide the recipient at his request with a safety data sheet compiled in accordance with Annex II, where a mixture does not meet the criteria for classification as dangerous in accordance with Articles 5, 6 and 7 of Directive 1999/45/EC, but contains:*
*(a) in an individual concentration of ≥ 1 % by weight for nongaseous mixtures and ≥ 0,2 % by volume for gaseous mixtures at least one substance posing human health or environmental hazards; or*
*(b) in an individual concentration of ≥ 0,1 % by weight for non-gaseous mixtures at least one substance that is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or has been included for reasons other than those referred to in point (a) in the list established in accordance with Article 59(1); or*
*(c) a substance for which there are Community workplace exposure limits."*

If the above criteria are fulfilled, these provisions apply to all recovered substances (including those that are exempted from registration, downstream user obligations and evaluation under Article 2(7)(d) of REACH) except those that are exempted from Title IV of REACH. The impurity profile must be taken into account both in the classification and labelling of the substance and in the risk management measures that might have to be recommended to the downstream users of the recovered substance. For recovered substances containing impurities that are classified and contribute to the classification, the impurities have to be indicated.

It is worth noting that the presence of impurities above the legal cut-of values[32] should be addressed in the communication via a SDS or safe use information communicated towards customers. Furthermore, according to Article 31(1) of REACH recovery operators are only required to provide a SDS if the substance which they recover requires a SDS. Impurities as such cannot create the need for a SDS under Article 31(1) as this may only be triggered by the obligations under Article 31(2) of REACH. Figure 1 provides a decision tree[38] that may be used to determine whether a SDS is required.

### 2.4.3. Other information: registration number and exposure scenario

The recovery operator benefiting from the exemption under Article 2(7)(d) of REACH will often not have a registration number. When placing a recovered substance on the market, a recovery operator does not have to indicate a registration number, as he is exempted from the provisions of title II of REACH. However, under certain conditions as specified under Article 32(1) of REACH it may be required, if available, to provide a registration number free of charge:

*(b) if the substance is subject to authorisation and details of any authorisation granted or denied under Title VII in this supply chain;*
*(c) details of any restriction imposed under Title VIII;*

[36] Article 61 of the CLP Regulation ((EC) No 1272/2008).
[37] Article 59(2) (a) and (b) of the CLP Regulation ((EC) No 1272/2008) amend Article 31(1) and (3) of REACH to align it with the requirements for classification and labelling of mixtures as from 1 June 2015. The CLP Regulation sets out a transitional period for the SDS. The transition refers to the requirements when to provide the CLP classifications in parallel to the DSD/DPD classification in the Safety Data Sheet. See section 4 of Module 1 of the guidance.
[38] Taken from "Draft guidance for the provision of Information in the Supply Chain and Safety Data Sheets for Recovered Substances and Preparations" prepared by Waste Recovery Industry Chain (WRIC).

*(d) any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied including specific conditions resulting from the application of section 3 of Annex XI.*

According to Article 14(1) of REACH, a chemical safety assessment shall be performed and a chemical safety report shall be completed for all substances subject to registration for quantities of 10 tonnes or more per year and per registrant. Recovery operators that can rely on the Article 2(7)(d) of REACH are exempted from registration and consequently do not need to perform a chemical safety assessment or complete a chemical safety report of the recovered substance.

The recovery operator that has the required information available for the same substance and therefore can rely on Article 2(7)(d) of REACH even if the use of a recovered substance is not covered by the registration of the same substance, is not required to:

- make an exposure scenario for the use of the recovered substance;
- register the recovered substance;
- notify the use of the recovered substance.

However he should take account of the existing information and has to provide appropriate risk management measures in the SDS, if needed, or to provide sufficient information on the safe use of the recovered substance in case no SDS is needed.

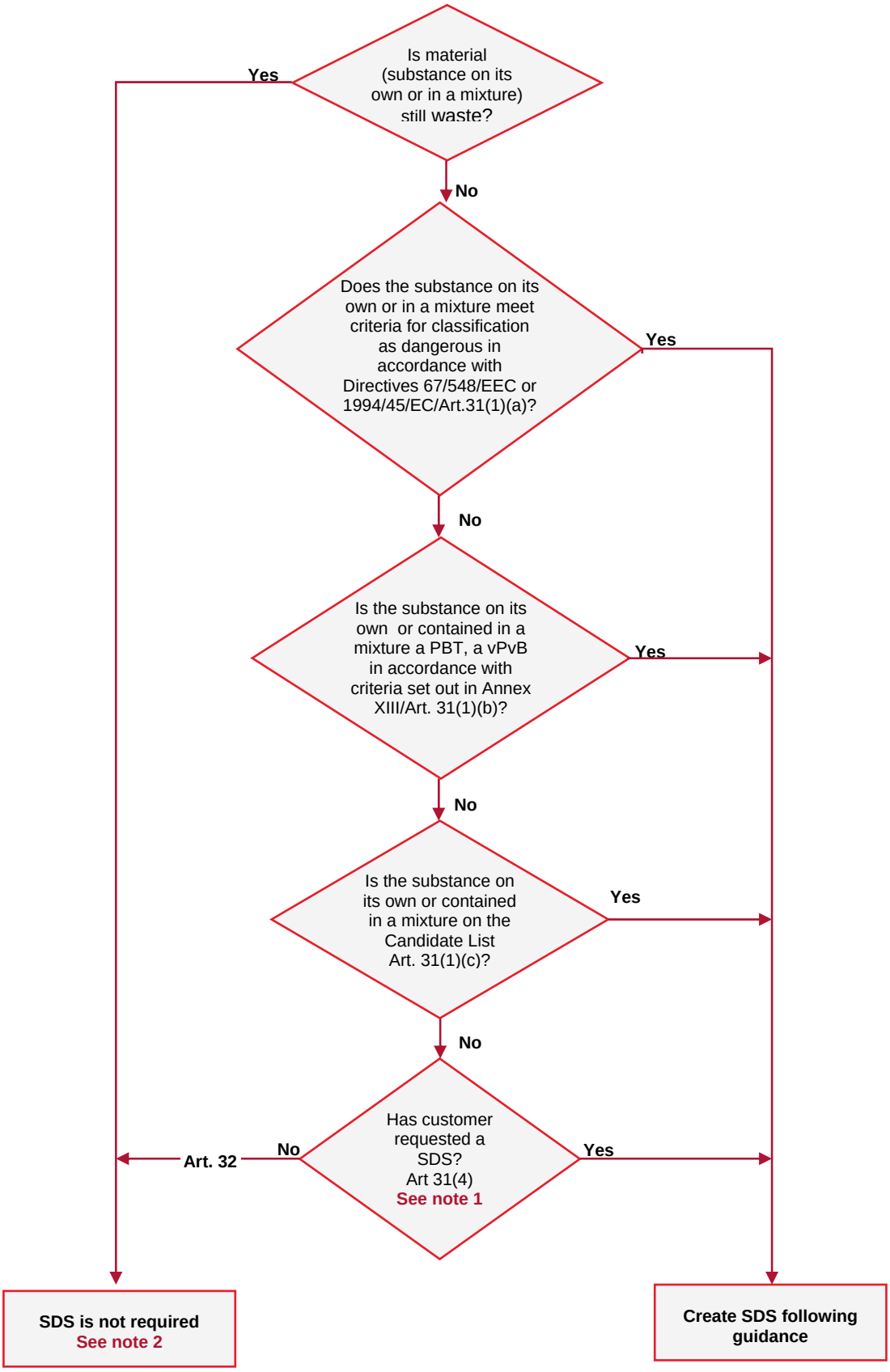
Therefore, recipients of recovered substances that have not been registered by the recovery operator because the exemption of Article 2(7)(d) of REACH applies will generally not receive:

- a registration number;
- 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[39].

[39] This section may need to be modified after Annex II (Safety Data Sheet format and content) of REACH has been revised and adopted via the Comitology procedure.

**Figure 1**: Decision tree to confirm the necessity for a SDS for a recovered substance under REACH




**Source**: "Draft Guidance for the provision of Information in the Supply Chain and Safety Data Sheets for Recovered Substances and Preparations" prepared by Waste Recovery Industry Chain (WRIC).

Some processes, such as metal refining, are capable of removing or destroying certain constituents.
The recovery operator has no obligation to attach an exposure scenario to the SDS.

**Note 1:** For commercial reasons a manufacturer may choose to produce a SDS at the request of a customer, even if he is not legally obliged to do so.

**Note 2:** SDS need not be supplied if a dangerous substance or mixture is offered or sold to the general public and provided with sufficient information (Art 31(4)) i.e. SDS are only for professional users.

## 2.5. Other obligations

Recovered substances are generally not exempted from notification obligations for the classification and labelling inventory of CLP. Moreover, they are not exempted from the authorisation and restrictions under REACH.

### 2.5.1. Classification and Labelling Inventory

Pursuant to Article 39(a) and 39(b) of the CLP Regulation, also recovered substances meeting the classification criteria as hazardous and being placed on the market either on their own or in a mixture (if present in a mixture above specified concentration limits) have to be notified to the C&L Inventory under the conditions set out in Article 40 of the CLP Regulation by the recovery operator. This notification obligation applies also to cases where the recovery operator relies on the exemption from the REACH registration provisions for recovered substances pursuant to Article 2(7)(d) of REACH. When notifying in such cases to ECHA, the recovery operator could retrieve the classification and labelling information provided earlier by the registrant of the original substance from ECHA's classification and labelling inventory and agree to it. This also means the recovery operator accepts a notified classification and thus, also accepts the responsibility for the result[40]. However, impurities could change the hazard profile of a substance and consequently its classification, which should be borne in mind by recovery operators when notifying to the C&L Inventory. For notification the identification of the substance needs to be supplied only to the extent of sections 2.1 to 2.3.4 of Annex VI of REACH[41]. No spectral data is required. Further information on the CLP Regulation is provided in the introductory guidance on the CLP Regulation and in the CLP-FAQ[42].

### 2.5.2. Restrictions

The recovery operator needs to ensure that the recovered substances comply with restrictions as set out in Annex XVII to REACH. These obligations are to a large extent similar to the obligations under previous Directive 76/769/EEC on the restrictions on marketing and use of certain dangerous substances and preparations.

### 2.5.3. Authorisation

The recovery operator needs to ensure that the recovered substances comply with the authorisation requirement in Title VII. In addition, the communication obligations concerning substances in articles according to Article 33 of REACH, and the notification obligations as mentioned in Article 7(2) for substances included in the 'candidate list' and present in articles may apply.

[40] The notification to the C&L inventory should be done until 3.1.2011. Only in some cases the information is provided earlier by the registrant.
[41] See Article 40(1)(b) of the CLP Regulation.
[42] Available on ECHA's website at http://guidance.echa.europa.eu/docs/guidance_document/clp_introductory_en.pdf

## 2.6. Considerations concerning particular streams of recovered materials

Specific examples of streams of recovered materials are described in Appendix 1. The principles explained in the previous chapter are applied to the examples described in this Appendix. For all waste streams four basic assessments need to be carried out:

- Establish the identity of the substance(s) in the recovered material, including characterisation and assignment of impurities to one or more of these substances:
    - Is the recovered substance a substance as such, or a substance in a mixture?
    - What is the identity of the recovered substance(s)?
    - What are typical impurities? What are typical concentrations of the impurities? To which substance(s) may these impurities be assigned?

- Check if other exemptions[43] (e.g. Article 2(5), Article 2(6), Annex IV or Annex V of REACH) or limited registration requirements (for articles) apply:
    - Is the Article 2(7)(d) exemption relevant and potentially applicable to the recovered material? Do exemptions other than that mentioned in Article 2(7)(d) of REACH apply? Is the substance e.g. listed in Annex IV or Annex V of REACH?
    - Does the recovery of the substance from waste lead directly to an article? Do therefore only limited registration requirements apply?

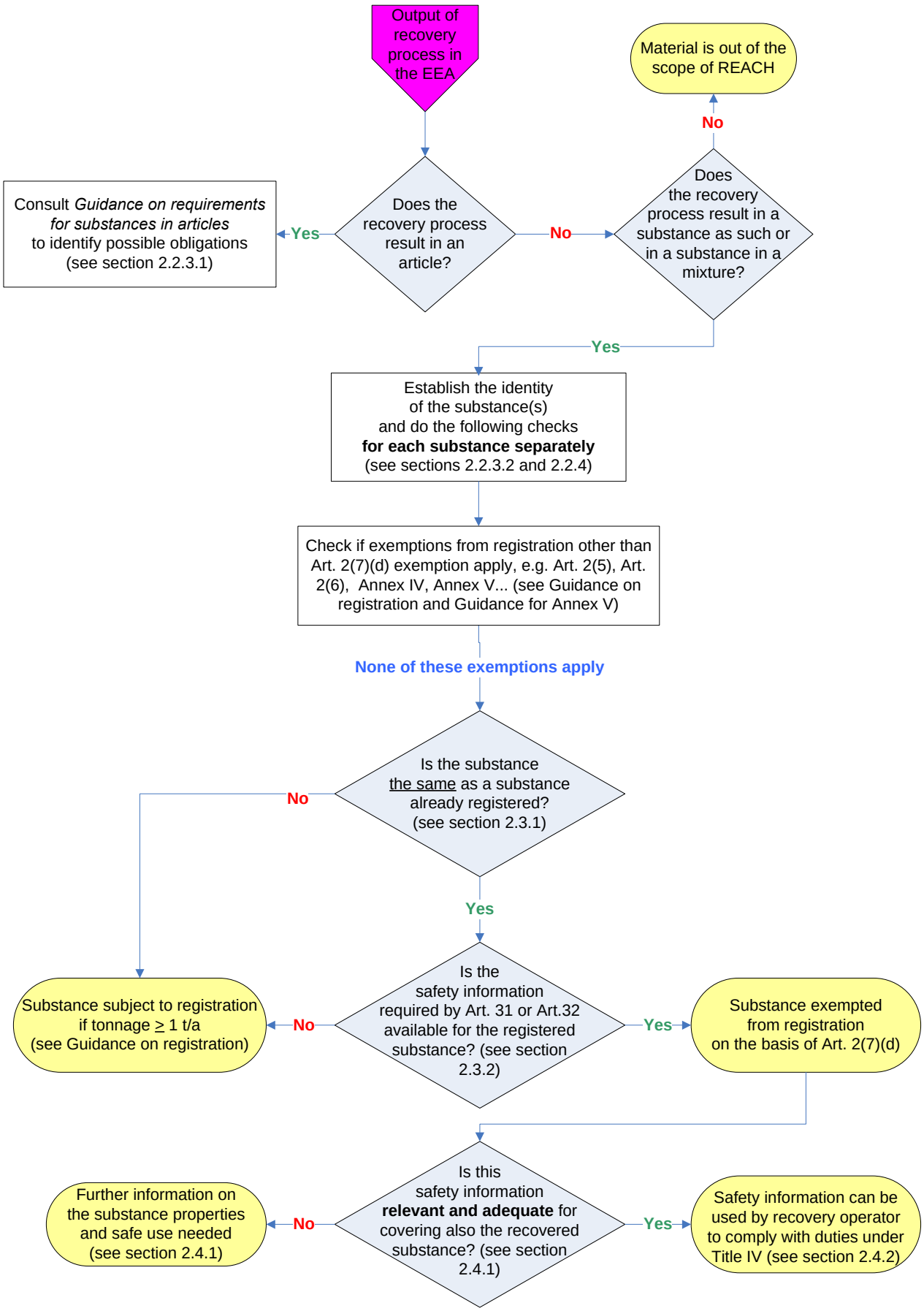
- Identify whether the same substance(s) have already been registered:
    - Establish the sameness of the recovered substance with a substance that has been/will be registered. Is the relevant information according to Article 2 (7)(d) of REACH available for these substances?

- Check adequacy and relevance of the available safety information of the registered same substance for covering the properties of the recovered substance(s). Compile the classification, labelling and other relevant safety information for the recovered substance(s) and the foreseen uses:
    - Is the available safety information on the registered same substance relevant and adequate for covering the properties of the recovered substance(s)?
    - Do the identified uses for the recovered substance(s) correspond to the uses of the same substance(s) already registered so that the available safety information is relevant and appropriate? If not, is further information on substance properties and safe use needed?

Detailed waste stream specific interpretations of these assessments will not be given in the present guidance. However, a general assessment of whether one could rely on the exemption via Article 2(7)(d) of REACH regarding the recovered material can be based on the aforementioned approach. A workflow for checking whether a recovery operator can rely on Article 2(7)(d) of REACH and the related obligations that may apply, has been given in Figure 2. The examples in Appendix 1 have been handled according to this workflow.

[43] More information on other exemptions is available in the Guidance on registration and the Guidance for Annex V.

**Figure 2**: Workflow for checking whether a recovery operator can rely on Article 2(7)(d) of REACH and the related obligations



# APPENDIX 1: PARTICULAR STREAMS OF RECOVERED MATERIALS

The examples hereafter deal with materials that meet the end-of-waste criteria and/or that have ceased to be waste under national legislation. Materials fulfilling these conditions are to be considered as recovered substances in the context of the Guidance on waste and recovered substances.

## 1.1. Recovered paper

Recovered paper mainly consists of cellulose pulp. EINECS identifies cellulose pulp as follows: *"The fibrous substances obtained from the treatment of lignocellulosic substances (wood or other agricultural fiber sources) with one or more aqueous solutions of pulping and/or bleaching chemicals. Composed of cellulose, hemi-cellulose, lignin, and other minor components. The relative amounts of these components depend on the extent of the pulping and bleaching processes."* (EINECS number 265-995-8).

Cellulose pulp is listed in Annex IV, and consequently, exempted from registration, downstream user and evaluation obligations. Recovered paper may contain other constituents such as pigments, inks, glues, fillers etc. Regarding the recovery and recycling process, constituents that have no specific function in the material (cellulose pulp), can therefore be considered as impurities (see section 2.2.4). 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.

## 1.2. Recovered glass

According to the scientific literature glass is the state of a substance rather than a substance as such. For legislative purposes, it can best be defined through its starting materials and production process, similar to many other UVCB substances. EINECS has several entries for glasses as follows: *Glass, monoxide, chemicals (EC: 295-731-7), Glass, oxide, calcium magnesium potassium sodium phosphosilicate (EC: 305-415-3), Glass, oxide, calcium magnesium sodium phosphosilicate (EC: 305-416-9) and Glass, oxide, chemicals (EC: 266-046-0)*[44].

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 (see section 2.2.4). 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.

[44] Please note that the description following the heading in the EINECS listing of these substances is part of the substance entry and in most cases it is most decisive for substance identification.

## 1.3. Recovered metals

Under REACH pure metals obtained from ores, ore concentrates or secondary sources, even if containing a certain amount of impurities are considered as substances. Registration requirements for the substances will depend on whether the substances have been registered before and whether the relevant safety information is available.

Alloys are considered as special mixtures and the substances in those special mixtures are subject to registration. Recovered metals made from mixed alloy metal scrap meeting the end-of-waste criteria will normally be special mixtures but it could in certain cases also be a substance with impurities (e.g. when the purpose of recovery is only to reclaim one main metal and all other constituents can be regarded as impurities). This should also be the case for those metals for which the concentration in the final alloy is variable, or even strictly limited, and which concentration is unknown from the either waste or the end-of-waste scrap. In these cases their concentration is initially considered as an impurity. All components which have been intentionally selected for recovery (e.g. Cr or Ni) and which have a main function in the recovered material should be regarded as separate substances. Constituents which only occasionally occur in parts of the waste from which the recovered metal originates or which do not have a particular function in the recovered material can be regarded as impurities (e.g. molybdenum may occur in certain types of steel but not in others).

As the majority of metals are produced both from primary and secondary resources, the exemption of Article 2.7(d) of REACH is relevant for metals, while other exemptions that may be applicable are:

- non-isolated intermediates resulting from the recovery of metals from complex articles containing multiple metals;
- Article 2(5) and Article 2(6) exemptions such as metals and metal compounds used in medicinal products used for human and veterinary use within the scope of Regulation 726/2004 and Directive 2001/82/EC and Directive 2001/83/EC as laid down in the provisions of Article 2(5)(a) and Article 2(6)(a);
- Annex V.

Recovered metals may go directly into article production 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.

Some metals are recovered from simple and rather pure materials (Al, Cu, Pb, Zn from e.g. construction products, pre-consumer scrap) and sometimes pure metals are recovered from very complex materials (electronic scrap containing e.g. Cu, precious metals) into pure metals. Other metals (Mo, Cr, Ni e.g. present in steel products) are not recovered into the pure metals and used for the production of new metal alloys because of their target metal content, resulting in special mixtures. Certain metal compounds (e.g. antimony trioxide, Pb- and Cd-based stabilizers in plastics) are directly recovered from plastics master batches. Knowing these differences, end-of-waste criteria may be different[45].

The impurities may vary as the metals that are recovered and refined from scrap materials meeting the end-of-waste criteria into pure metals depend on several factors, such as the available (refining) technology, the amounts present in the scrap meeting the end-of-waste criteria, value of the materials versus cost to recover. While recovered metals may be directly incorporated into other special mixtures, the presence of a certain metal may in one case be

[45] Further discussions take place under the Waste Framework Directive (see section 1).

considered as an impurity and in another case be a constituent depending also on the potential end-application.

The manufacturers of recovered metals should also have information to the extent needed on the identity and quantities in which hazardous minor constituents or impurities are present in the recovered metal or alloy as described in the section on impurities (section 2.2.4).

For metals several tools are available in order to analyse in a relatively easy way the composition of the material according to Good Laboratory Practice (GLP) in order to check the sameness (e.g. ASTM or ISO standards).

Recovered metals can be used for the same purposes as primary metals because the recovering process usually takes place without deterioration of the material properties. Therefore the uses are assumed to be the same. If that is the case, the safety information of the registered substance may be relevant and appropriate for the use of the recovered substance.

## 1.4. Recovered aggregates

Recovered aggregates[46] should be understood in this paper as covering aggregates resulting from the processing of inorganic material previously used in construction (e.g. concrete, stones), as well as certain aggregates of mineral origin resulting from an industrial process involving thermal or other modification (e.g. unprocessed slag[47], waste from processing of slag[48], fly ash).

The question was raised whether such recovered aggregates can be seen as articles or whether they are substances on their own or in a mixture.

Recovered aggregates from construction consist of concrete, natural stones, masonry, ceramics (e.g., roofing tiles) and/or asphalt, either alone or in certain cases mixed. They can have diverse applications, such as in civil engineering works, in roads and as railway ballast. The main function of this application is to provide stability and resistance to degradation/fragmentation. If for this function the shape, surface or design is more important than the chemical composition, the recovered aggregates would be considered as articles. By definition, this would however only be the case if the shape, surface or design of the material has been deliberately determined and given during its production (e.g. in order to meet certain recognised aggregate standards such as EN 12620, 13043 or 13242). If for this function the shape, surface or design does not determine the function of the material to a greater degree than its chemical composition, then the aggregate would not be in line with the article definition, and should thus be seen as a substance on its own or in a mixture. Examples of different recovered aggregates are given below:

**Aggregates from construction and demolition waste**
Particles from aggregates from construction and demolition waste are produced with specific shape and surface characteristics depending on their application, like e.g. in asphalt pavements. The shape of such a particle is described using the ratio of the longest and smallest dimension of the particle. EN Standards 933-3 and 933-4, for instance, describe methods to determine the shape of such particles. The surface of such a particle is defined by its micro- and macrorugosity (i.e. variations in the height of a surface at different scales), which are measured as described by the EN Standards 1097-8 and 933-5 respectively. Shape and surface of a particle from

[46] As explained in the introductory section of chapter 3, for the purpose of REACH, recovered substances (on their own, in mixtures or in articles) should be only understood as substances that, after having been part of waste materials, have ceased to be waste according to the Waste Framework Directive. Aggregates which have undergone certain recovery stages and which are still waste, are not considered as substances, mixtures or articles under REACH. They are subject to waste legislation but not to obligations for substances, mixtures or articles under REACH.
[47] Waste code number: 100202.
[48] Waste code number: 100201.

aggregates from construction and demolition waste determine its function to a greater degree than the chemical composition of the particle. The essential chemical properties are restricted to a maximum of allowed solubility - if the aggregate is soluble it cannot fulfil its function – and are less important than the shape and surface. These particles are therefore considered to be articles according to the article definition under REACH.

**Ferrous slags**

Most of the slags produced by the iron and steel industry throughout Europe will be registered as UVCB substances and are used in applications such as the production of cements and concrete products. It is the hydraulic properties of the slag that is important to these applications. Thus, the chemical composition of the slag is clearly more important. As a result, ferrous slag is to be considered as a substance. By analogy, slags from other metallurgic processes should be considered as substances as well.

**Fly ash**

Fly ash is a heterogeneous mixture of constituents consisting of amorphous and crystalline silicon dioxide ($SiO_2$), aluminium oxide ($Al_2O_3$), iron oxide, calcium oxide and carbon. It has various uses such as in the production of cement, cement clinker and grout, embankments and structural fill, stabilization of soft soils, road subbase and as a mineral filler in asphaltic concrete. For its use the chemical composition is more important than the shape, surface or design of particles. Therefore fly ash is considered to be a UVCB substance.

For recovered aggregates that are substances on their own or in a mixture it will be necessary to determine the exact status of the material under REACH and to verify whether the conditions of Article 2(7)(d) apply. If the substance as such or in a mixture is not exempted from registration, late pre-registration - provided that all conditions under Article 28(6) are fulfilled - or decreasing the volume below 1 tonne/year until the substance has been registered (by any actor) are possible alternatives for potential registrants.

In determining the exact status of the recovered aggregates, the following considerations should also be taken into account:

a) Some of these materials, such as certain slags and residues of various melting or metallurgic processes, will normally be UVCB substances. There may however also be cases where such substances are multi-constituent substances (e.g. when the substance is the result of a chemical reaction during recovery and consists of a limited number of constituents).
b) Some recovered aggregates may consist of materials which are exempted from registration, evaluation and downstream user obligations under other REACH provisions, in particular Annex V. Examples include minerals which are not chemically modified (e.g. natural stones) or substances occurring in nature which are not chemically modified and do not meet the criteria for classification as dangerous (e.g. wood).
c) In the case where recovered aggregates consist of one main constituent (possibly with impurities), they will be a mono-constituent substance. In case they consist of several constituents, those constituents may either be seen as separate substances (i.e. then the recovered aggregate will be a mixture) or as constituents of one complex UVCB substance. As outlined in section 2.2.3, it is up to the manufacturer of the recovered material to decide whether the recovery operation resulted in a substance (mono-constituent, multi-constituent or UVCB) as such or in a mixture.

In determining the registration status of the recovered aggregates, information on the origin may be important in order to establish which constituents may be present in the material and whether they should be seen as impurity or separate substance. To identify the substances, that in principle, are subject to registration an analysis of the waste material will only be necessary

insofar as constituents may in normal cases occur in quantities above 20%[49] (or are intended to be present in the recovered material – however, in this case the recovery operator should know about their presence).

The manufacturers of recovered aggregates should also have information on the identity and quantities in which hazardous minor constituents or impurities are present in the recovered aggregate to the extent needed as described in the section on impurities (chapter 2.2.3).

## 1.5. Recovered polymers

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) originally present in the polymeric material that was recovered. This may happen in case of selective recovery. Intentionally recovered substances can not 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).

The spectrum of impurities and their concentrations is relatively wide. Impurities originating from substances originally present in the polymeric material to be recovered do not need to be registered, as their presence is covered by the registration of the monomer substance(s). Any other unintentional “impurity” present in the recovered polymer substance (e.g. pigments which have not any longer 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%. If that is the case, the constituent should be seen as a substance in a mixture, even if its presence is non-intentional.

In determining the status of the recovered polymeric material, information on the origin may be important in establishing which constituents may be present in the material and whether they should be seen as impurities or separate substances. Impurities are part of the substances and do not need to be registered (see section 2.2.4).

However, manufacturers of recovered polymers should have information on the identity and quantities in which hazardous minor constituents or impurities are present in the recovered polymer to the extent needed as described in the section on impurities (see section 2.2.4).

An analysis is not required in certain cases where no significant impurities are expected (e.g. if the recovery occurs from a polymer used in its pure form). Also in some cases it may be possible to characterise the recovered polymeric product sufficiently without considering the origin. However, in the case of polymers, and with the idea to help recovery operators in identifying the materials in various plastic items, plastic identification code numbers 1-6 have been assigned to six common kinds of recyclable plastic resins, with the number 7 indicating any other kind of plastic, whether recyclable or not. Standardized symbols are available incorporating each of these codes. As there are six commonly recycled polymers it would be helpful to give such

[49] In cases where such constituents are regularly close to this limit, it is recommended to take a safe approach and consider the constituent as a separate substance. Where constituents exceed 20% only in rare, individual batches which cannot be realistically expected under normal conditions, those constituents do not have to be considered as separate substances. It is also not necessary to examine each individual batch of waste material for the presence of such constituents.

information on which monomers have been used for the manufacturing of the polymer. There is also the option of handling recovered polymers as UVCBs, if the composition is unknown.

In a first step it may be assessed whether the recovery process results directly in an article (i.e. if the first non-waste material in the recovery chain is an article and neither a substance as such nor in a mixture). There is no registration requirement under REACH with regard to the presence of a polymer substance in a recovered article[50].

Following the approach provided in section 2.6, the recovery operator should than assess, whether substances in the recovered polymers are exempted under Annex IV or Annex V of REACH or whether any other exemption criteria under REACH apply.

Although the registration provisions under REACH do not apply to polymers, the manufacturer or an importer of polymer is required to register the monomers and other substances used to manufacture the polymer under certain conditions in accordance with Article 6(3) of REACH. Similarly, for recovered polymers, the monomers and the other substances have to be registered in order to be able to rely on the exemption of Article 2.7(d) of REACH. The impurities in the monomer need to be identified and evaluated to the extent needed for establishing the hazard profile as well as the classification and labelling of the recovered monomer.

In most cases the waste polymer is collected from the EU market,, then the polymer recovery operators are exempted from the obligation to register the monomer(s) or any other substance(s) meeting the criteria of Article 6(3) of REACH in the recovered polymer, provided that these substance(s) from which the polymer is derived ha(s)(ve) been registered. Moreover, the recovery operator must have the safety information required by Article 31 or Article 32 of REACH concerning the monomer as the monomer is subject to registration requirements. For that purpose, all available information on the components of the recovered material needs to be taken into consideration.

## 1.6. Recovered rubber

In general, besides polymers such as SBR (styrene butadiene rubber) and natural rubber, recovered rubber may also contain substances which still have a function such as fillers (carbon black, silica…). Other components/constituents present in the recovered rubber which are not intended to be recovered such as pigments, additives, oils, shall be considered as impurities if present in a concentration below 20% of the main constituent fraction[51].

The manufacturers of recovered rubber should also have information on the identity and quantities in which hazardous minor constituents or impurities are present in the recovered material to the extent needed as described in the section on impurities (section 2.2.4).

Recovered rubber may result from mechanical and/or chemical treatment of the original rubber article in order to transform it into a material intended to be used in a new process. The substances intended to be recovered are mainly polymers such as SBR and natural rubber. Therefore information on recovered polymers provided in the previous section is also applicable to recovered rubber.

[50] See the guidance on polymers available at http://guidance.echa.europa.eu/docs/guidance_document/polymers_en.htm

[51] Specifically for rubber recovered from tyres, a detailed representative list of substances intended to be recovered, or potentially exceeding the 20% impurity threshold, is provided by industry , accessible via the European Tyre and Rubber Manufacturers Association in the “Guidelines for Recovered Rubber” (www.etrma.org) which includes references to publicly available documents that could help in estimating concentrations of recovered substances and impurities.

Rubber waste may go directly into article production when it is added to primary rubber and cast into an article. No further registration requirements then apply unless the substance is intended to be released (see section 2.2.3.1). Should the rubber in the article meet the definition of a polymer, then there is no registration requirement whatsoever. Following the approach provided in section 2.6, the recovery operator should then assess whether any other exemption under REACH applies.

For other substances that were added to the rubber such as fillers (carbon black, silica…) documentation has to demonstrate that they fulfil the exemption requirements of Article 2(7)(d) of REACH.

A recovery operator should make sure that the use of a recovered substance is covered by the registration of the original substance, which is often the case for recovered rubber. If that is the case the available safety information on the registered same substance may be relevant and adequate for the recovered rubber. The same may not be applicable to impurities (i.e. pigments, additives, etc.) since the Chemical Safety Assessment of the original substance may cover only specific applications. Recovery operators need to generate information on the composition of the recovered material, in order to identify potential hazards and to conclude whether the safety information obtained for the registered substance is applicable for the recovered substance.

## 1.7. Recovered base oils

The recovered base oils[52] are typically UVCB substances according to the Guidance for identification and naming of substances under REACH. The industry sector dealing with base oils are following this practice. These substances are commonly referred to as “base oils” identified by relevant EINECS numbers if applicable.

Intentionally recovered base oils 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. Base oils cannot benefit from the exemptions listed in the Annexes IV or V of REACH. This type of recovery does usually not lead to an article. No exemption other than that addressed in Article 2(7)(d) of REACH potentially applies. They are described by the relevant EINECS entries if their properties, as referred to UVCB substances, coincide with the substance identity (see section 2.2.3.2).

Recovery of base oils requires a relatively sophisticated recovery process if one is willing to recover the substances for the same purpose. Under these conditions, there are no constituents that do not originate from the base oil itself due to the recovery process used. If there are any such constituents, they are at a level far below 20%[53]. The resulting recovered base oils are very similar to the original base oils and the sameness of the recovered substance may be established and they can rely on Article 2(7)(d) of REACH provided that the recovery operator has access to the necessary information.

Less advanced recovery processes will result in recovered substances that, although the main impurities have been removed, fall below the quality criteria of the original substance. This is due to the presence of impurities such as polyaromatic hydrocarbons. It may be difficult to establish the sameness of the recovered base oils with the registered substances if less sophisticated recovery processes are applied due to evaporative and combustion processes that may result in substantial losses or addition of new substances during the use of the original substance. In

[52] The term “base oils” also includes “lubricating oils”. The latter should not be confused with the term “lubricants”. The term “lubricating oils” refers to mixtures made out of base oils and additives. The wording “lubricating oils” is also used for “highly refined base oils” and “lubricant base oils” (see CONCAWE Products Dossier 97/108 for a list of base oils).

[53] It should be noted that contamination of base oils by poly-chlorinated biphenyls (PCBs) or other severe contamination may occur. In that case, even if these constituents are far below 20%, recovery or (re)use is not allowed (e.g. legal level for PCB= 50 ppm).

principle it is still possible that such recovered substances could still benefit from the exemption under Article 2(7)(d) of REACH on the condition that the recovery operator can establish the sameness and has access to the necessary information.

In summary, 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.

## 1.8. Recovered solvents

The recovered or recycled solvents should be named exclusively as single or UVCB substances according to the Guidance for identification and naming of substances under REACH. The industry sectors dealing with the primary manufacture of these solvents are following this practice.

In this context recovered solvents means those materials in the common classes of hydrocarbons, oxygenated hydrocarbons and halogenated hydrocarbons originally used in industrial applications. In this classification many solvents are single chemical substances e.g. acetone or toluene, though there are a number of UVCB substances including a range of petroleum distillates.

Article 2(7)(d) of REACH is both relevant and applicable to most recovered solvents according to the most common EINECS numbers used for pre-registering these substances. Potentially no exemption other than that addressed in Article 2(7)(d) of REACH may apply. Solvents cannot always benefit from the exemptions listed in the Annexes IV or V of REACH. This type of recovery does usually not lead to an article.

The sameness of the recovered substance with the registered substance is well established for a wide range of solvents. Normally there are no constituents that do not originate from the solvent itself due to the recovery processes used. If there are any such constituents they are at a level far below 20%. It is however possible to recover mixed substances together where the individual substances are well defined for sameness purposes and if this is the case the result is considered to be a mixture.

The identified uses for solvents are normally the same as those referred to in the original registrations of the substance but there may be restrictions on certain reuses, for example in the pharmaceutical industry.

# APPENDIX 2: LIST OF ABBREVIATIONS AND DEFINITIONS

| | |
|---|---|
| Annex XIII | Criteria for the identification of PBTs and vPvBs |
| Annex XIV | List of Substances subject to Authorisation |
| Annex XVII | Restrictions on the manufacturing, placing on the market and use of certain dangerous substances |
| Article | 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. |
| 'candidate list' | Candidate List of Substances of Very High Concern for Authorisation (SVHCs) |
| CAS number | Chemical Abstracts Services registry number |
| CMR | Carcinogenic, mutagenic and toxic to reproduction. |
| CSA | Chemical Safety Assessment. |
| CSR | Chemical Safety Report. |
| Downstream User | Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user |
| EC-Inventory/EC-number | The three European lists of substances from the previous EU chemicals regulatory framework, EINECS, ELINCS and the NLP-list, in combination are called the EC Inventory. The EC Inventory is the source for the EC Number as an identifier of substances |
| EEA | European Economic Area. It allows the EEA EFTA States (Norway, Iceland and Liechtenstein) to participate in the Internal Market on the basis of their application of Internal Market relevant acquis. All new relevant Community legislation is dynamically incorporated into the Agreement and thus applies throughout the EEA, ensuring the homogeneity of the internal market. |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| ELINCS | European List of Notified Chemical Substances |
| Exposure scenario | The set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposure of humans and the environment. Exposure scenarios may cover one specific process or several processes or uses as appropriate. |
| Importer | Any natural or legal person established within the Community who is responsible for import |
| IUPAC | International Union of Pure and Applied Chemistry |
| Manufacturer | Any natural or legal person established within the Community who manufactures a substance within the Community. |
| Non-phase-in substance | A substance requiring registration which does not benefit from the |

| | |
|---|---|
| | transitional regime provided for phase-in substances under REACH. |
| PBT | A persistent, bioaccumulative and toxic as defined in Annex XIII. |
| Phase-in substance* | A substance which meets at least one of the following criteria:<br>(a) It is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);<br>(b) It was manufactured in the Community, or in the countries acceding to the European Union on 1 May 2004, but not placed on the market by the manufacturer or importer, at least once before the entry into force of the REACH regulation;<br>(c) It was placed on the market in the Community, or in the countries acceding to the European Union on 1 May 2004, and between 18 September 1981 and 31 October 1993 inclusive it was also placed on the market by the manufacturer or importer and was considered as having been notified in accordance with the first indent of Article 8 (1) of Directive 67/548/EEC, as amended by Directive 79/831/EEC, but does not meet the definition of a polymer set out in Directive 67/548/EEC, as amended by Directive 92/32/EEC; provided there is documentary evidence of this. |
| Preparation | Mixture or solution composed of two or more substances. |
| PCB | poly-chlorinated biphenyls |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| Restriction | Any condition for or prohibition of the manufacture, use or placing on the market. |
| Substance | 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. |
| SVHC | Substance of Very High Concern meeting the criteria of Art. 57 |
| vPvB | Very persistent and very bioaccumulative as defined in Annex XIII. |

**European Chemicals Agency**
P.O. Box 400, FI-00121 Helsinki
http://echa.europa.eu