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5th Meeting of the Competent Authorities for the implementation of Regulation (EC) 1907/2006 (REACH)

25-26 September 2008

Centre A. Borschette

Rue Froissart 36,
1040 Brussels, Belgium

Concerns: **Waste and recovered substances**

Agenda item: **3**

Action requested: **Member States and observers are requested to take note of the interpretations taken and, if appropriate, provide comments at the CA meeting of 25-26 September 2008.**

1. Introduction

Article 2.2 of REACH provides that *"waste as defined in Directive 2006/12/EC 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, preparations and articles do not apply to waste[1].

This does however not mean that waste is totally exempted from REACH. In particular, according to Article 3(37) 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 its life-cycle*** *and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. […]"*. This includes considerations related to the waste stage of substances as confirmed in Annex I paragraph 5.2.2 where the life-cycle is explicitly said to cover the waste stage. In addition, Annex I paragraph 5.1.1 of REACH also makes it clear that the Risk Management Measures of an Exposure Scenario should *cover waste management measures to reduce or avoid exposure during waste disposal and/or recycling*.

As soon as a material 'ceases to be waste' in a recovery process, REACH requirements apply in principle as to any other material, with a number of exceptions (see below). Where exactly in a recovery process a waste 'ceases to be waste' has been the subject of long debates in the context of waste legislation. Most recently, work was started to elaborate end-of-waste criteria in the context of the review of the Waste Framework Directive. As a result of this work, and possible future Comitology Decisions, 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 would be outside the scope of waste legislation but also that they would be potentially subject to REACH requirements, unless covered by an exemption.

This has raised concern among some relevant industry sectors and the issue was also raised by GRIP in paper CWG/28/2007. COM replied to this paper at the CWG meeting on 19/20 June 2007 in paper CWG/30/2007. Further discussions took place at the CA meetings on 3/4 September 2007, 19/20 December 2007 and 16/17 June 2008.

The Commission services responsible for REACH and waste legislation have further discussed this matter, also with the Joint Research Centre/IPTS, which is currently elaborating a report on end-of-waste criteria. As a result of these discussions, the Commission services continue to believe that clarification of end-of-waste criteria is a matter for waste legislation and that REACH should follow the definitions and interpretations taken in waste legislation. It is therefore not appropriate to develop separate guidance on this matter in the context of REACH.

However, several questions were raised as regards the status of materials once they have been recovered and are, at least in principle, subject to REACH obligations for substances, preparations or articles. This paper aims to explain the views of the Commission services on the status of these materials with respect to the requirements for them under REACH. Where

[1] Please note that this does not mean that waste is generally exempted from REACH. Further explanation on this is given in the guidance on registration (section 1.6.3.4) and more guidance, in particular on the role of waste related risks in exposure scenarios will be given in the guidance on chemical safety assessment.

appropriate, this paper takes into account comments received from Competent Authorities and stakeholders who were consulted on a previous version of this paper (CA/24/2008).

2. Status of waste in the context of exposure scenarios

This section reacts to a series of comments submitted by the Member States on the interaction between REACH and waste legislation in the context of RIP 3.2. These issues have already been partially integrated in the version of the technical guidance document on information requirements and chemical safety assessment (TDG IR/CSA, chapters R.13 and R.18) submitted for endorsement at the meeting of the REACH CA on 16/17 June 2008.

2.1 Relationship between exposure scenarios and waste legislation

Article 3(37) defines an exposure scenario as a *"set of conditions, including operational conditions and risk management measures, 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, exposures of humans and the environment. […]"* This is further specified in Annex I, in particular section 5. In particular, section 5.2.2 specifies that *"the emission estimation shall consider the emissions during all relevant parts of the life-cycle of the substance resulting from the manufacture and each of the identified uses. The life-cycle stages resulting from the manufacture of the substance* ***cover, where relevant, the waste stage****. The life-cycle stages resulting from identified uses* ***cover, where relevant****, the service-life of articles and* ***the waste stage****. The emission estimation shall be performed under the assumption that the risk management measures and operational conditions described in the exposure scenario have been implemented."* This clarifies that, where relevant, the waste stage needs to be considered in exposure scenarios. Annex I paragraph 5.1.1 of REACH also makes it clear that the Risk Management Measures of an Exposure Scenario should cover *"the waste management measures to reduce or avoid exposure of humans and the environment to the substance during waste disposal and/or recycling".*

This raises firstly the question on the relationship between REACH and waste legislation. As a matter of principle, exposure scenarios and recommended risk management measures cannot be used to reduce any obligations arising under waste legislation. Any user of the substance for which the exposure scenario was prepared will have to comply with all requirements from waste legislation. In order to assist downstream users, exposure scenarios should as far as possible describe legal requirements under waste legislation. However, there are limits to the amount of detail which can go into exposure scenarios. It will be impossible to cover all national and local provisions as well as all possible indirect implications of waste legislation (e.g. implications of recycling targets). Moreover, requirements may change over time and it will always be challenging to keep exposure scenarios up to date.

However, this is neither required nor the purpose of exposure scenarios. Exposure scenarios should focus on the specificities of the substance and its risks during the waste stage and give recommendations on how best to control these risks. These recommendations should lead to the safe disposal or recovery of the substance and reduce the risks to human health and emissions to the environment, in addition to the requirements from waste legislation. For this purpose, the exposure scenarios may contain a number of different waste treatment options which may be applied depending on local or national conditions or legislative requirements. In cases where control of risks is provided by all waste treatment options in line with applicable waste legislation, it may also be sufficient to state this in the exposure

scenario. However, in all cases it needs to be ensured that these lead to control of risk as to be demonstrated in the CSA. If the measures suggested in the exposure scenario are in conflict with requirements set by local or national waste authorities, the inappropriateness of the measures should be communicated up the supply chain (analogue article 34 (b) of REACH). Moreover, there may also be cases where the waste stage is not relevant for the exposure scenario (e.g. if the substance is consumed during use).
In conclusion, the Commission services do not see a contradiction between the provisions on exposure scenarios and waste legislation. Rather, the interaction between substance specific risk management measures and general waste specific legislation should further increase protection of human health and the environment.

Similar considerations also apply, for example, for the interaction between exposure scenarios and the IPPC Directive.

2.2 Who has to apply risk management measures?

Section 5.2.2 of Annex I of REACH describes that the emission estimation shall consider the emissions during all relevant parts of the life-cycle resulting from the manufacture and each of the identified uses, and that the waste stage is one of the life-cycle stages to be considered. In terms of who should apply risk management measures, it is necessary to distinguish between actors receiving safety data sheets or information under Article 33 of REACH (mainly for "pre-consumer" waste) and actors who do not receive safety data sheets or information under Article 33 of REACH (mainly for "post-consumer" waste).

- "Pre-consumer" waste will cover waste from manufacturing of substances, from formulation of preparations and incorporation of substances in an article, or professional users of articles. Safety Data Sheets (SDS) are typically available for this type of waste.
- "Post-consumer" waste arises after a substance on its own, in a preparation or an article has been discarded by an actor who does not receive a safety data sheet (i.e. substances on their own, in a preparation or an article discarded by private consumers; articles discarded by professional users of an article). Thus, SDS for this type of waste are typically not available.

For "pre-consumer" waste, the manufacturer or downstream user is responsible for applying the relevant risk management measures identified in the exposure scenario in line with relevant applicable waste legislation. Whether or not the downstream user is in addition subject to waste management legislation for the management of the waste on his site is a matter for waste legislation. Therefore, this is not further specified here. Once the waste has been handed over to a waste treatment plant, the waste treatment becomes the responsibility of the waste treatment plant. However, waste treatment plants are not subject to REACH and therefore can only held liable under general contractual provisions between the downstream user and the waste treatment plant as well as under waste legislation.

Also in the case of "post-consumer" waste, it may be appropriate for the downstream user to recommend specific measures for the waste treatment of the article after its use. This is, however, only necessary if the risks of the substance require specific measures in addition to general waste management provisions. It should also be noted that although recipients of articles will not receive safety data sheets, they may receive information on safe use of an article under Article 33 of REACH (in case the substance contains an SVHC substance

above 0.1% w/w) or similar information[2] and therefore other measures need to be applied in order to ensure the safe use of those substances in articles (including their waste stage)[3].

3. Requirements for recovered substances under REACH

In paper CWG/28/2007, the question has been raised at what stage in the recovery process REACH obligations start to apply. Recovery processes often take place in several steps, and sometimes only the last step will result in a material that will no longer be waste as a result of application of the Waste Framework Directive. Also, sometimes only a fraction of the material resulting from the recovery process will be non-waste. Therefore, all recovery steps which do not yet 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 those from recovery processes, are not considered as substances, preparations or articles. Therefore, for the purpose of REACH, recovered substances (on their own, in preparations 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.

3.1 Registration

As any other substances, recovered substances are in principle subject to REACH registration requirements. However, Article 2(7)(d) of REACH provides the following exemption:

"*Substances, on their own, in preparations 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."

This provision is further explained in the guidance on registration (section 1.6.4.5):

"*The REACH Regulation sets the following conditions which have to be respected in order to benefit from the exemption from registration:*

(1) The recovered substance must have been registered. This means that if, for some reason, the substance has not been registered at manufacturing or import stage, the recovered substance has to be registered following the recovery operation before being put to a new use.
The legal entity performing the recovery should check whether a registration exemption applies to the recovered substance. If this is the case, then that exemption can of course be invoked.

[2] For further information see guidance for downstream users (chapter 7.6.2.2.) and guidance on substances in articles (chapter 8.9).
[3] For further information see guidance on information requirements and chemical safety assessment (chapter R.13.2.5).

(2) The substance already registered must be the same, i.e. have the same chemical identity and properties, as the substance being recovered. For example, if the substance itself was modified in the recovery and the modified substance has not been registered, then the recovered substance has to be registered.
It should be noted that the sameness of the substance must be assessed according to the Guidance on substance identification.

(3) 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 obtained one of the following:

- *a safety data sheet, as required by Article 31 (1) or (3), on the registered substance,*
- *other information sufficient to enable users to take protection measures, as required by Article 31 (4), for the registered substance, or*
- *the registration number, if available, 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).*

Companies undertaking recovery operations and wishing to avail themselves from this exemption are advised to ensure as much 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, as otherwise they may have to register the recovered substance.

It is worth noting that this exemption does not require that the substance has been registered by an actor in the same supply chain. Therefore, it is sufficient that a registration was filed for the substance, either by a registrant in the same supply chain or by a registrant in another supply chain.

Note that if the recycled substance is a phase-in substance, it is recommended that the recycler pre-registers that substance in order to benefit from the transitional provisions laid down in Article 23 and eventually be later on exempted from the registration requirements if another pre-registrant registers the substance."

In addition to the above guidance, the following issues should be taken into account with respect to registration requirements and Article 2(7)(d) of REACH:

3.1.1. Is recovery a manufacturing process?

A first question for clarification is whether recovery is a manufacturing process or not. 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, fly ash, creation of methane during "feedstock recycling" of polymers) clearly fulfil this definition.

However, some recovery processes resulting in recovered substances[4] do not modify the chemical composition of substances (in particular mechanical processing or recycling, e.g. sorting and crushing materials, re-melting them without chemical modification).

Article 2(2) of REACH states that waste is not a substance, preparation or an article under REACH. However, after ceasing to be waste in a recovery chain, the recovered material will be a substance, preparation or an article under REACH. Consequently, the question arises whether recovered substances, preparations or articles can be seen as a continuation of the use of the originally manufactured substances, preparations or articles. If this is not the case, the question arises through what process if not manufacturing these materials would again become substances, preparations or articles.

The recovery process cannot be a "use" because 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"*. All recovery processes that lead to non-waste pre-suppose that a substance, preparation or article have been generated before. Moreover, this would mean that a user of a recovered substance or preparation would automatically be a downstream user, as Article 3(13) defines a downstream user as "*any natural or legal person [...] other than the manufacturer or the importer, who uses a substance [...]*". It would, however, be impossible for such downstream users to fulfil their obligations (e.g. under Article 5 making sure that any substances they place on the market have been registered up the supply chain), as the supply chain is interrupted during the waste stage.

Article 2(7)(d) of REACH allows exemptions from registration obligations under certain conditions. This also means that REACH assumes that unless those conditions are fulfilled, recovered substances[5] would, at least in principle, be subject to registration obligations. As only manufactured substances are subject to registration obligations, this means that recovery is seen at least in principle as a manufacturing operation. This also includes cases where the substance is actually the same as the one that has been registered before, as Article 2(7)(d) of REACH implies that such substances have to be registered in cases where the information required by Articles 31 and 32 of REACH is not available to the establishment undertaking the recovery.

For all these reasons, any other interpretation than that (final) recovery (meaning recovery which leads to the material ceased to be waste) is a form of manufacturing of substances creates legal uncertainty as to the status and obligations of such recovered substances under REACH. Taking the interpretation that (final) recovery is a manufacturing process creates a more consistent and clear approach towards treatment of recovered substances and avoids such problems. **Therefore, <u>all</u> forms of recovery are in the following considered as a manufacturing process whenever, after having undergone one or several recovery steps, they result in the generation of one or several substances that have ceased to be waste.**

[4] As explained in the introductory section of chapter 3, for the purpose of REACH, recovered substances (on their own, in preparations 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.

[5] As explained in the introductory section of chapter 3, for the purpose of REACH, recovered substances (on their own, in preparations 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.

This also has the consequence that the use of a substance as a recovered substance does 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. Recipients of recovered substances that have not been registered because the exemption of Article 2(7)(d) of REACH applies will also not receive an exposure scenario from the manufacturer of the recovered substance as part of the SDS.

3.1.2. Are recovered materials substances, preparations or articles?

In order to assess registration requirements for recovered materials, it is essential to clearly identify whether the particular material is a substance, preparation or an article[6]. This question needs to be decided on the basis of the definitions of 'substance', 'preparation' and 'article'. The guidance documents on substance identification and on substances in articles provide further elements how to interpret these definitions.

3.1.2.1. Substances and preparations

According to Article 3(1), 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.*"

In the context of recovered materials, it may not always be clear whether a constituent of a recovered material is a substance or an impurity. Moreover, questions may arise whether the whole material is a substance, a preparation or an article.

Impurities

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.*"[7]

Recovered substances may contain impurities which may distinguish them from corresponding materials not deriving from 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. The content and nature of such unintended constituents may vary significantly from batch to batch (e.g. in time and location). Full knowledge of the exact composition in each such case may require substantial analytical efforts. While such constituents may have originally been intentionally added as substances to form a preparation, 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.

[6] As explained in the introductory section of chapter 3, for the purpose of REACH, recovered substances (on their own, in preparations 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.
[7] Guidance for identification and naming of substances under REACH, p.11.

Constituents present in quantities above 20%(w/w) should, however, in general not be considered as impurities but as separate substances in a preparation. Should the recovered material be intentionally selected for the presence of certain constituents, 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 softeners, it may be necessary to register these softeners, unless they have been registered before)[8].

During the mechanical separation of mixed waste it is often impossible to reach 100% purity free of alien elements. These alien elements often are 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 precise. After appropriate sorting and separation, these fractions should be present in the recovered material only in very small fractions. In this case, such elements can be considered as impurities that do not need to be registered.

Even if impurities do not have to be registered separately, they may be relevant for the hazard profile as well as the classification and labelling of the substance or preparation in which they occur. Relevant risk management measures may need to be recommended in safety data sheets or information according to Article 32. These risk management measures can consist e.g. in further purification steps to eliminate impurities or measures to ensure the safe handling of the substance with the impurities in it.

Preparations versus UVCB substances

According to Article 3(2), a preparation is defined as "*a mixture or solution composed of two or more substances.*"

The guidance on substance identification describes UVCB substances as follows: *"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." [9]

Many recovered materials consist of two or more substances but also have typical characteristics of UVCB substances[10]. For this reason, the two possible ways 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 fit better to 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, in certain cases, mixtures of recovered materials with a complex composition will often not have corresponding new materials that have been

[8] The '20% rule' as explained applies to constituents/impurities in substances. It is not to be understood that, in the case of preparations, unintended components of a recovered preparation present in a concentration below 20% can be disregarded for the purposes of registration.
[9] Guidance for identification and naming of substances under REACH, http://reach.jrc.it/docs/guidance_document/substance_id_en.htm, p.29.
[10] The guidance for identification and naming of substances also uses the category of "multi-constituent substances". However, this concept refers to a very specific category of substances, which are normally the result of putting substances in a reactor. This normally does not apply to recovered substances and therefore this category is not further considered here.

registered as UVCB substances before. Therefore, such substances might not be able to benefit from phase-in status as there is no such EINECS entry. Nevertheless, the individual constituents of the material may have already 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.

In such cases, while both options are in principle acceptable, it may therefore be easier for the manufacturer or importer to consider the material as preparation in which the individual constituents/substances have been registered before and therefore benefit from the exemption in Article 2(7)(d) (provided the relevant safety information is available).

"Sameness" of substances with substances originally registered

As indicated in the registration guidance, "*it is worth noting that [the exemption in Article 2(7)(d)] does not require that the substance has been registered by an actor in the same supply chain. Therefore, it is sufficient that a registration was filed for the substance, either by a registrant in the same supply chain or by a registrant in another supply chain."*[11] There is also no requirement that this other supply chain is in any way linked to the waste material and the recovered substance. This applies both to substances which correspond to substances that also exist as virgin or synthesised materials (e.g. recovered copper, which corresponds to copper produced from ores) and to substances which do not have a non-recovered equivalent (e.g. fly ash). Therefore, for example recovered copper does not have to be registered if copper has been registered before and fly ash does not have to be registered if someone else has registered fly ash before, as long as the copper/fly ash is the same substance as the copper/fly ash that has been registered.

In assessing whether the recovered substance is the same as a substance that has already been registered or whether the substances are different, recovery installations need to apply the rules of the guidance on substance identification and the guidance on data sharing. In particular, it should be noted that this is an assessment that recovery installations need to make themselves. There is no confirmation given on "sameness" by the European Chemicals Agency. Recovery installations who have pre-registered their substance can however discuss "sameness" questions with other pre-registrants of the same substance in the (pre-)SIEF[12]. 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.

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 data sharing, *"for substances with a well-defined composition (i.e. mono-constituent and multi-constituents substances) the sameness of the naming is in principle sufficient to be able to share data even though certain impurities might lead to a different classification/hazard profile. Only in cases where all data is clearly not suitable for the other substance these substances can be regarded as different (e.g. in case of very different physical properties which have essential impact on the hazard properties, like water solubility).*

[11] Guidance on registration, http://reach.jrc.it/docs/guidance_document/registration_en.htm, p.37.
[12] According to REACH, the exchange of information for the purpose of data sharing takes place for all those potential registrants and others who have submitted information to ECHA for the (same) substance in a Substance Information Exchange Forum (SIEF). Therefore, the data sharing guidance recommends first having discussions on the sameness in a pre-SIEF, before the SIEF is formed.

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."[13]

3.1.2.2. Articles

Article 3(3) of REACH defines articles as *"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"*. This has further been elaborated in the guidance on substances in articles[14].

It is also possible that the recovery process results directly in an article, instead of a substance or preparation. This may be the case e.g. if collected and sorted polymer waste is directly melted in new articles. In this case, registration is only required if the article contains a substance with an intended release under certain conditions or if the Agency has taken a decision to require registration pursuant to Article 7(5). A notification is required for substances of very high concern identified in the candidate list for inclusion in Annex XIV under certain conditions.

3.1.3. In what form does information required under Article 2(7)(d), second indent have to be provided in order to benefit from the exemption from registration?

Article 2 (7)(d) 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"*. How this information is obtained is not further specified in this provision. Such information only needs to be available for substances. Impurities are part of substances and the information therefore does not have to be available for the impurity on its own[15].

Recovery installations will normally not receive SDS 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), the required information must be, however, available to them. Furthermore, whenever required, they need to either prepare SDS themselves or agree with owners of existing SDS on using those SDS. As there are no further legal provisions on this, this is a matter for the manufacturer of the recovered substance. The manufacturer can use any available information 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. The same applies to other safety information, if required. Discussions on the use of such information can, for example, take place within the SIEF, whenever the recovery installation has pre-registered the substance. Also, industry associations could play an important role in preparing standard information for their members.

3.1.4. Should recovered substances generally be exempt through inclusion into Annex V?

Article 2(7)(d) **only** exempts recovered substances **under certain conditions**. Therefore, the Commission services consider that a general exemption for recovered substances under Annex V is incompatible with Article 2(7)(d). A solution for potential problems for

[13] Guidance on data sharing, http://reach.jrc.it/docs/guidance_document/data_sharing_en.htm, p.35.
[14] http://reach.jrc.it/docs/guidance_document/articles_en.htm
[15] For more information please refer to last paragraph of the section on impurities.

recovered materials should consequently rather be sought through clarification on the status and obligations for manufacturers of recovered materials. This does however not affect cases where recovered substances are exempted from registration on the basis that the substance as such is listed on Annex IV or V or is covered by any other relevant exemption in REACH.

3.1.5. Considerations concerning particular streams of recovered materials

3.1.5.1. Recovered metals

Under REACH, pure metal (even if containing a certain amount of impurities) is considered as a substance. Recovered pure metal (even if containing a certain amount of impurities) is also a substance. Registration requirements for the substance will depend on whether the substance has been registered before and the relevant safety information is available (see Article 2 (7)(d)) of REACH[16].

Alloys are considered as (special) preparations and the substances in those preparations are subject to registration. Recovered metal made from mixed alloy metal scrap will normally be a preparation 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 seen as impurities). In general, all components which have been intentionally selected for recovery and which have a main function in the recovered material should be seen as separate substances (e.g. steel will next to iron normally always contain manganese; the recycled steel is therefore a preparation). 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 seen as impurities (e.g. molybdenum may occur in certain types of steel but not in others).

3.1.5.2. Recovered aggregates

Recovered aggregates[17] should be understood in this paper as materials recovered from mixed construction waste (i.e. recovered mineral aggregates) or recovered material that can be used as aggregate. These include recovered construction materials, stones, certain slags, fly ash, etc.

Recovered aggregates will normally be either substances or preparations but not articles until further processing. Article 3.3 of REACH defines an article to mean 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"*. This is considered to be the case where the individual item has a very clearly defined shape, surface or design (e.g. a whole brick) but not where the material consists of a large number of grains with varying shape or surface, even if they are sorted for a particular grain size or overall shape (round, sharp etc.). Materials like gravel of a particular grain size are therefore not considered as articles.

[16] Wherever the substance does not meet the criteria for classification as dangerous, is not a PBT/vPvB or a substance on the candidate list and not subject to restrictions, it is unlikely that relevant safety information will be required.

[17] As explained in the introductory section of chapter 3, for the purpose of REACH, recovered substances (on their own, in preparations 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, preparations or articles under REACH. They are subject to waste legislation but not to obligations for substances, preparations or articles under REACH.

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).

In case 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 preparation) or as constituents of one complex UVCB substance. As outlined in section 3.1.2.1., the two interpretations are to a certain degree interchangeable and it is up to the manufacturer of the recovered material to decide which interpretation is more appropriate in the individual case.

In determining the status of the recovered aggregates, information on the origin may be important to know which constituents may be present in the material and whether they should be seen as impurity or separate substance. An analysis of the waste material will only be necessary in so far as constituents may in normal cases occur in quantities above 20%[18] (or are intended – however, in this case the recovery installation should know about their presence). Moreover, if impurities are relevant for the hazard profile of the material or might be subject to restrictions under REACH, further analysis may be necessary.

Materials such as aggregates from mixed construction waste could be seen both as UVCB substances and as preparations[19]. Materials sometimes used as aggregates, 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 substance 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).

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[20]. Such substances can benefit from the staggered registration deadlines.

3.1.5.3. Recovered glass

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 identifies glass as follows: *Glass, nonoxide, 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)*[21].

Glass can therefore also benefit from the staggered registration deadlines. The same considerations also apply to recycled glass. Depending on when the exact status of end of

[18] 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.

[19] For more practical considerations on this question, see section 3.1.2.1.

[20] See guidance documents on substance identification and on data sharing.

[21] 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.

waste is reached (this is a matter for waste legislation), recovered glass may therefore also have to be considered as a UVCB substance, or if is at the end-of waste stage already in a specific shape, an article. As glass will normally have been registered and relevant safety information is unlikely to be required, it is expected that it can benefit from the exemption provided for in Article 2 (7)(d).

It should also be noted that the Commission has proposed to exempt certain types of glass from registration, downstream user and evaluation obligations as part of the ongoing review of Annex V. The proposal is currently undergoing the process for adoption under the regulatory procedure with scrutiny[22].

3.1.5.4. 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[23]. Recovered paper consisting exclusively of cellulose pulp with impurities will therefore be exempt from registration, downstream user and evaluation obligations.

3.1.5.5. Recovered polymers

Polymer recovery installations are exempted from the obligation to register the monomer(s) or any other substance(s) meeting the criteria of Article 6(3) in the recovered polymer, provided that these substance(s) from which the polymer is derived have been registered (Article 2(7)(d)). Moreover, the recovery installation must have the safety information required by Article 31 or 32 on the recovered polymer substance or on a recovered preparation containing a polymer substance. For that purpose, all available information on the components of the recovered material needs to be taken into consideration.

Should the polymer recovery also include the recovery of other intended substances (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, as it may be the case for selective recovery, it is recommended to regard the recovered material as a preparation (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).

Whenever the presence of other chemicals are derived from substances originally present in the polymeric material that was recovered is not intentional, these chemicals can however be regarded as impurities of the recovered polymer substance (e.g. pigments which have no more intended function in the recovered material can be considered as impurities), unless the

[22] For more information see http://echa.europa.eu/reach/legislation_en.asp; Annex V, new point 11.
[23] On the conditions to be met, see section above on impurities.

chemical constituent is present in quantities above 20% (in this case, the constituent should be seen as a substance in a preparation, even if its presence is non-intentional).

In determining the status of the recovered polymeric material, information on the origin may be important to know which constituents may be present in the material and whether they should be seen as impurity or separate substance. An analysis of the waste material will only be necessary in so far as constituents may in normal cases occur in quantities above 20% (or are intended). Moreover, if impurities are relevant for the hazard profile of the material or might be subject to restrictions under REACH, further analysis may be necessary.

However, this 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) and in some cases, it may be possible to characterise the recovered polymeric product sufficiently without considering the origin.

If the recovery process directly results in articles (i.e. if the first non-waste product in the recovery chain is an article and neither a substance or a preparation), any polymer substance present in the recovered articles is, in any case, exempted from the registration requirements under REACH with regard to this substance.

3.1.5.6. Other recovered substances

For reasons of timing, no new examples have been integrated in this paper. Further examples illustrating the practical application of the principles outlined in this document may be included, once ECHA has decided how to integrate the current paper into the relevant guidance documents.

3.2. 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 for most recovered substances this will be the case by the time registration obligations for phase-in substances apply, there is no certainty that registrations would have already been made by the end of the pre-registration phase. [24]

As long as the substance has not yet been registered by another actor, the conditions of Article 2(7)(d) are not fulfilled and therefore recovery installations manufacturing such a substance will be subject to registration obligations. This will mean that recovery installations 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 and that a downstream user of the recovery installation cannot legally use the substance.

[24] Pre-registration consists in providing a limited set of information (in essence the name of substance, name and address of contact person 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 installations 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.

Pre-registration will therefore provide legal security that manufacturing, placing on the market and using the substance can continue until the relevant registration deadline. It is possible that pre-registration of recovered substances may result in multiple pre-registration of the same substance in different stages of the recovery chain (unless it is known that the substance has already been registered). It is expected that in most cases, further steps will not be required because the materials will sooner or later be registered and the recovery installation will be able to benefit from the exemption of Article 2(7)(d) of REACH. Whenever a decision is taken to modify the end-of-waste stage (whether at Community or national level), it is also possible to resort to Article 28(6) for a 6 months period to pre-register after manufacturing or importing a substance for the first time (assuming that the material is manufactured or imported for the first time as non-waste).

Recovery installations should note that in cases where the substance has not yet been registered, only pre-registration will give them the legal security that they can legally manufacture and place on the market their substance and that their downstream users (both in their own country and in other EU Member States) can legally use their substance. Moreover, pre-registration gives the chance to communicate with other manufacturers of the same substance. This gives recovery installations access to the contacts to other manufacturers of the substance and, if they wish so, a possibility to contribute to the SIEF discussions. Pre-registration will also allow recovery installations to participate in the discussion on the sameness of substances. Moreover, the SIEF may also be an opportunity to discuss access to safety information, which recovery installations may need to benefit from the registration exemption but also for other obligations they may have under REACH. 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 from article 2(7)(d) at a later stage.

3.3. Information requirements

Article 31(1) provides that *"the supplier of a substance or a preparation shall provide the recipient of the substance or preparation with a safety data sheet compiled in accordance with Annex II:*
(a) where a substance or preparation 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)."

Article 31(3) provides that *"the supplier shall provide the recipient at his request with a safety data sheet compiled in accordance with Annex II, where a preparation 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 preparations and ≥ 0,2 % by volume for gaseous preparations at least one substance posing human health or environmental hazards; or
(b) in an individual concentration of ≥ 0,1 % by weight for non-gaseous preparations 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 and preparations (including those who are exempted from registration, downstream user obligations and evaluation under Article 2(7)(d)) except those that are exempted from Title IV of REACH. However, safety data sheets do not need to be provided for impurities. The impurity profile must however be taken into account both in the classification and labelling of the substance or preparation and in the risk management measures that might have to be recommended to the downstream users of the substance.

The way safety data sheets have to be established for recovered substances is not further specified in REACH and therefore a matter for the manufacturers of the recovered substances. The Commission services have been approached by several of the concerned industry sectors to provide further guidance on this matter as part of the guidance on chemical safety assessments. The Commission services are open to discuss this matter further with all concerned recovery sectors. ECHA has been asked for advice how to best organise such a discussion.

3.4. Other obligations

Recovered substances are in general not exempted from authorisation, restrictions and notification obligations for the classification and labelling inventory. For further information on these obligations, the relevant guidance documents should be consulted in so far as they are available.

4. Conclusions and next steps

Member States and observers are requested to take note of the interpretations taken and, if appropriate, provide comments at the CA meeting of 25/26 September 2008. The Commission services will then finalise the paper, publish it on its website and hand it over to ECHA for incorporating the interpretations into future updates of the relevant guidance documents.