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Concerns: Substance identity and SIEF formation (the role of EINECS)

Document as endorsed by CARACAL on 2 February 2010

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Please note that this document contains the views of the responsible Commission services and was endorsed by the Member States competent authorities. The Commission services and the Member States competent authorities do not accept any liability with regard to the contents of this document."

1. Introduction

This document serves as a background note for the revised Q&A pair (no. 9.5) published on ECHA's website in the FAQs section.

At the end of April 2009, ECHA submitted draft FAQ update 2.5 for written approval to REHCORN members. This update aims to complete the FAQ with a number of questions on substance identity and SIEF formation. One of the Q&A pairs proposed was FAQ no. 9.5 (RHEP entry ID 872) relating to the issue whether pre-registrants of one EINECS entry should in all cases result form one SIEF or whether different SIEFs could be formed under certain circumstances.

How is a Substance Information Exchange Forum (SIEF) formed?

The Guidance on data sharing (Section 4.5 – How and when will a SIEF be formed?) explains how and when a SIEF will be formed and covers issues such as how to determine the sameness of substances, how to facilitate communication within a SIEF and at what point in time data holders should join the SIEF.

All potential registrants and data holders for the "same" phase-in substance shall form a SIEF. However, the REACH Regulation does not define "sameness" and it does not foresee any formal role for ECHA in confirming the establishment of sameness or in the formation of a SIEF.

The assessment of the exact nature of an EINECS entry and the different substances it may cover can only be carried out by the manufacturers or importers who are best placed to assess the composition of their substances. It is, therefore, up to them to take the responsibility for defining precisely the substance(s) for which a SIEF will be formed.

In order to reach an agreement on the sameness of a substance, pre-registrants must enter into pre-SIEF discussions. As a consequence of this, a SIEF is formed when the potential registrants of a substance in the pre-registration list actually agree that they effectively manufacture or import or intend to manufacture or import a substance that is sufficiently similar to allow a valid joint submission of data.

For further information in relation to pre-SIEFs and SIEFs please refer to the *SIEF – Key Principles* document.

Within the helpdesk network no agreement could be found on the wording of the FAQ pair (more details on the consultation process can be found in Annex I). The Commission services considered that this matter is of an urgent and fundamental nature which requires discussion with the REACH Competent Authorities. Therefore, the Commission services have taken the initiative to raise this matter at the level of CARACAL. At the meeting of CARACAL on 12 October 2009, this was briefly discussed. The Competent Authorities consider clarification of this matter as a priority and requested the Commission to urgently prepare a paper for discussion in writing and for endorsement by written procedure in the weeks following the meeting. The requested paper was submitted for written comments on 11 December 2009 with a deadline for comments of 11 January 2010. This document integrates the comments received.

2. Analysis of the legal provisions and the ECHA guidance

2.1. REACH

Article 1(2) of REACH provides for that:

“This Regulation lays down provisions on substances and mixtures within the meaning of Article 3. These provisions shall apply to the manufacture, placing on the market or use of such substances on their own, in mixtures or in articles and to the placing on the market of mixtures.”
(emphasis added)

Article 3(1) of REACH defines a substance:

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

For the purpose of registration, the identity of the substance needs to be established pursuant to Article 10(a)(ii) REACH read in conjunction with section 2 of Annex VI. Section 2 of Annex VI lists several identifiers with a view to sufficiently identifying a substance. Any substance needs to be identified by the relevant identification parameters: name or other identifier (section 2.1), information related to molecular and structural formula (section 2.2) and chemical composition (section 2.3). The EINECS (the European Inventory of Existing Commercial Substances) number is only one of the identifiers listed under section 2.1. The EINECS number is listed under section 2.1.3 under the particular proviso “*if available and appropriate*” (emphasis added).

This suggests that the substance is first identified and then the EINECS entry or entries are checked to determine if the substance is covered by the EINECS entry or entries.

Annex VI Section 2 indicates the information requirements for substance identification. The Guidance for identification and naming of substances under REACH explains how this information should be interpreted and a proper and unambiguous substance name should be derived.

Moreover, the historic and legal context under which the EINECS was established is important. EINECS lists substances, which were on the Community market between 1971 and 1981 and therefore regarded as existing substances which had no obligations to be notified under Directive 67/548/EEC and hence it was rather necessary to be comprehensive but not necessarily to be very exact in the differentiation between individual substances in a single EINECS entry, as long as it was clear which substance(s) or group of substances were considered to be exempted from the notification obligations. Furthermore the reporting rules for EINECS were different from the rules which should be applied under REACH. Therefore some EINECS entries are very broad and strictly speaking cover more or even groups of substances rather than individual substances. Moreover, there are also other cases, where several EINECS entries cover one and the same substance. In those cases, such substances should be dealt with as the same substance under REACH.

In conclusion, for the purpose of substance identification and consequently SIEF formation, the relevant legal provisions in REACH are the substance definition in Article 3(1) of REACH and the identification requirements set out in Annex VI.

EINECS serves two purposes:

1. The reference to EINECS in Article 3(20) REACH is relevant in the context of the specific definition of “phase-in substance”, which, in turn, has relevance for the transitional provisions in REACH applicable for phase-in substances. The EINECS listing is thus relevant for legally determining the phase-in status of a substance and the ensuing registration deadline, as all substances covered by an EINECS entry qualify as phase-in substances.
2. EINECS in the vast majority of entries lists one substance and only in certain cases cover more than one substance. EINECS therefore assists the vast majority of registrants to efficiently identify their substance and to work with others to determine if they in fact manufacture or import the same substance.

2.2. The Guidance

The substance definition and the identification rules are further explained in the Guidance for identification and naming of substances under REACH¹ and the Guidance on data sharing². These guidance documents constitute main interpretative instruments which should be taken into account in decisions on substance identity and SIEF formation. These documents were initially developed by the Commission in close cooperation with Member States and industry stakeholders and eventually endorsed by the working group comprising competent authorities of all Member States, representative number of industry associations and NGO's. As these documents have been used as a basis for the work of SIEFs so far, any change in interpretation would likely lead to confusion and the need to revert some of the co-operation already established. The main references in the guidance to the status of EINECS in relation to substance identification and data sharing are recalled in Annex II.

3. Practical consequences and need for further work

3.1. Cross-relationship between substances, SIEFs and data sharing obligations and their relationship to EINECS numbers

Most REACH obligations apply to substances as defined in Article 3(1). REACH starts from the assumption that registrants are aware of this definition and correctly apply it (using the identification parameters set out in section 2 of Annex VI). REACH does not provide further mechanisms to determine substance identity. Failure to correctly identify substance identity affects the basis for data sharing within SIEFs and may result in preparation and submission of incomplete registration dossiers. This may violate a number of REACH provisions, which are described in more detail below.

In practice, determining substance identity often is far from straightforward and for these reasons, guidance has been elaborated on the criteria to be applied and recommending a number of steps to companies to agree on substance identity within pre-SIEFs, as a basis for data sharing. This may in certain cases lead to splitting EINECS entries into several distinct substances. As REACH foresees one SIEF per substance, this means that the pre-SIEF is split into several SIEFs.

¹ http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.pdf

² http://guidance.echa.europa.eu/docs/guidance_document/data_sharing_en.pdf

Obligatory data sharing under REACH is limited to the same substance and does not apply between different substances. Nevertheless, data sharing and read-across are also encouraged between different substances, wherever this is possible and scientifically sound. Therefore, wherever EINECS entries are split up into several SIEFs and despite the fact that data sharing is only obligatory within the SIEF, it is still advisable to consider whether data sharing and read-across could not also apply between the different substances previously covered by the same EINECS entry. As explained further in section 3.4, this may help preventing possible violations of data sharing obligations in cases of doubt and even in cases where EINECS entries have been incorrectly split.

3.2. Criteria to be applied in case of doubt

Determining the sameness of a substance is a very critical step. The criteria to be applied are described in the guidance on identification and naming of substances (see above). ECHA has received several dossiers where the substance identity is not sufficiently elaborated, for example when splitting one EINECS entry into several substances, the substance identity in cases of varying composition of UVCB substances, e.g. EINECS entries for extracts covering tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues which have due to refinement steps different compositions, or merging of several EINECS entries into one substance, e.g. Amines, C12-18-alkyl (EINECS number 268-953-7) with Amines, hydrogenated tallow alkyl (EINECS number 262-976-6). However, this will require more analysis and cannot be done within the scope of this paper. This will therefore be done in a separate document.

Registrants should in a first step assess whether there is a clear reason to split up EINECS entries. This is in particular the case where an EINECS entry covers different chemical identities under one and the same EINECS entry. UVCB substances, in particular, are often defined very broadly though the individual substances which are covered by such an entry may be different because of the different production processes are used or the different substances are much more narrow in definition.

However, quantitative variations of impurities or quantitative variations of the fractions of the main constituents of defined substances within certain limitations do not lead to a different substance identity, even though the resulting substance properties might differ and these differences need to be documented in the registration dossier. In such cases, it is essential that the information provided is sufficient to cover the properties of all variants of the substance (i.e. testing should be done on the most hazardous variants or in a way to allow a sufficiently robust extrapolation on properties to be expected in case of variation of composition of substances).

Wherever an EINECS entry has been split up into several substances, it is strongly recommended to provide clear documentation giving a scientifically-based justification why this has been done. On the other hand, in cases where there can be doubts on substance identity, it is also necessary to justify why an EINECS entry has not been split, to avoid problems in the further assessment of the dossier.

3.3. Specific considerations for recovered substances

Also, in many cases recovered substances have a different impurity profile than substances manufactured from primary materials. This does not necessarily mean that they are different

substances for the purpose of REACH. More information can be found in the Commission document on REACH and waste and recovered substances³.

3.4. What happens if EINECS entries have been incorrectly split into several substances

There have been reports that companies within pre-SIEFs have used a very narrow interpretation of the substance definition to keep other companies and in particular SMEs out of the data sharing process, thereby making it very difficult and costly for these companies to prepare their own registration dossiers. This may violate REACH and Community legislation in various ways.

On the one hand, this practice violates data sharing obligations with potentially serious consequences under REACH. In particular, it should be understood that, in line with Article 30(3), refusal to provide data which involves testing on vertebrate animals on request results in inability to register substances and therefore in the extreme case the inability to continue manufacturing or importing the substance. Article 30(6) specifically requires the penalisation in accordance with Article 126 of the owner of the study who has refused to provide either proof of the cost or the study itself, i.e. the need for penalisation is emphasised in case of this particular breach.

On the other hand, such a practice – whether the relevant substance involves testing on vertebrate animals or not – may, if it has the object or effect of excluding other companies from the relevant market as established in accordance with the Community legislation in the field of competition, constitute a violation of EU competition law and may therefore be prohibited and give rise to fines imposed under the EU competition rules.

Companies facing doubts on whether they can or should split up EINECS entries should therefore take a cautious approach with respect to data sharing. On the one hand, substance identification criteria should be analysed very carefully and splitting up EINECS entries should be avoided where this is not justified. On the other hand, wherever it is concluded that splitting up EINECS entries is necessary, it may be scientifically appropriate to apply data sharing and read-across nevertheless to the entire group of substances, which will also help to avoid violation of data sharing obligations in case a mistake has been made, and it is found later on by authorities that the EINECS entry should not have been split.

Companies facing situations where other companies manufacturing or importing the same substance refuse access to data with the argument that their substance is different are strongly recommended to formally request those data in line with Article 30(1) REACH. If the owner of the data refuses to provide the data, this has as a consequence that, provided it involves vertebrate animal testing, the data owner cannot register the substance and that, the company who is refused access to the data can proceed to register the substance without fulfilling the relevant information requirement. (The Agency may decide within 12 months of the date of such registration, if the owner of the information has not provided access to the requestor, that the test must be repeated by them.)

³ http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/waste_paper_ca_090403_en.pdf

However, such situations should be avoided as far as possible. Therefore, it is recommended that companies take a cautious approach with regard to data sharing obligations. If conflicts on the scope of data sharing on the basis of different interpretation of substance identity appear unavoidable, it may be useful that concerned companies contact ECHA with a view of resolving this conflict before submission of registration dossiers.

3.5. Incorrect submission of dossiers covering several substances

On the other hand, where splitting up of EINECS entries into several substances is justified on the basis of the substance identification criteria, failure to do so can also have serious consequences, because REACH foresees that one registration is made per substance.

If a registration dossier incorrectly covers several substances, the registration can be considered as valid at most for one of those substances or if it is unclear which of the substances is covered, the registration may be considered as invalid for all substances it was intended for. In this case, manufacturing and importing of all substances which are not covered may have to be stopped (except where the relevant registration deadline has not yet expired), new registration dossiers must be submitted and a (new) fee must be paid for each of those substances.

The background to these considerations and their underlying provisions in REACH is that the hazards and risks of substances should in all cases be properly assessed and controlled. This is not the case if only one of several substances covered by an EINECS entry (or one of several variants of the same substance) is tested and where extrapolation of data is not sufficiently robust. Therefore, while it is recommended that in case of doubt rather several separate dossiers are submitted than one dossier that is too broad, it should in all cases and even in cases where EINECS entries are not split up be taken care that the submitted data cover all substances or variants of the same substance. In case of serious doubts on the approach to follow, ECHA should be contacted to resolve problems before submission of the dossier.

Further details on what happens upon submission of dossiers with unclear and/or insufficiently addressed substance identity still need to be elaborated and will be addressed separately in a planned paper.

3.6. What can companies do in case of doubt?

As described above, incorrect definition of substance identity can have serious consequences. Refusal to share data within SIEFs upon a request based on Article 30(1), if it concerns data involving testing on vertebrate animals, may lead to inability to register the substance for the owner of that data. Failure to split EINECS numbers into several substances may result in invalid registrations, the need to prepare and re-submit registration dossiers for all concerned substances and to pay the registration fee again. Therefore, in case of doubt, it is recommended to share data as widely as possible within the group of companies having pre-registered with the same EINECS entry (even if this is not strictly required by REACH) and, at the same time, to interpret the substance definition narrowly, i.e. to rather submit several separate dossiers. Wherever a decision is taken not to split EINECS entries, care should be taken that the data submitted are adequate for all variants and forms of the substance. In case of major problems, it is advised to contact ECHA to seek clarification.

4. Conclusions

The identity of the substance under REACH needs to be established on the basis of Article 3(1) definition using the identifiers enumerated in section 2 of Annex VI REACH. These provisions are further interpreted in the Guidance on substance identification. This guidance refers to the EINECS reporting rules as a basis for identification and naming of substances. As in most cases, the EINECS reporting rules should be correctly reflected in EINECS, one EINECS entry should in those cases correspond to one substance under REACH. Also, a different impurity or hazard profile due to other reasons than those determining substance identity does not necessarily mean that identities of substances are different.

In accordance with the REACH legal text and the Guidance on substance identification the EINECS number is an identifier for substance identification, but it does not alone determine substance identity, as other identifiers have to be taken into account. Therefore, one EINECS entry may correspond to two or more different substances. In those cases different SIEFs should be formed and joint submissions must be submitted for more precisely defined substances. Although this is more likely to occur for UVCB substances, this in principle applies also to ‘well-defined’ substances, as the substance definition in REACH does not distinguish between these two substance types. There can also be cases where several EINECS entries may correspond to one and the same substance for the purpose of REACH.

In REACH, the EINECS listing is relevant mainly for determining the phase-in status of a substance (Article 3(20)). In cases where one EINECS entry corresponds to two or more different substances, all substances previously covered by that entry qualify as phase-in substances.

In the process of data sharing, the first step of SIEF formation will be the establishment of the sameness of the substance within the SIEF. This is a process which takes place among the potential registrants, and there is at this stage no confirmation or rejection by ECHA or the Commission. In establishing the sameness, the potential registrants must respect the substance identity rules as established by REACH. These rules are further interpreted in the substance identification guidance, which should be used as the main interpretative tool. Companies should be aware that any decisions on sameness which are not in line with REACH requirements may be challenged by the authorities.

Such challenges may have serious consequences for the legality of registration dossiers. If EINECS entries are incorrectly split up and data sharing is refused on this basis after a request for data on the basis of Article 30(1) has been made, this results, in case it involves testing on vertebrate animals, in the inability of the registrant who refuses data sharing to register the substance. In any case, the refusal to provide studies on request should be penalised. On the other hand, incorrect registration dossiers covering several substances may be considered non-compliant and companies may have to prepare and submit new registration dossiers for each substance and pay the fee again. A possible way out in case of doubt is to interpret the substance identity narrowly, i.e. in case of doubt rather prepare several registration dossiers but nevertheless apply the data sharing obligations widely, i.e. to share data and apply read-across within the entire group of companies which pre-registered with this EINECS entry. In case of doubt, it is also recommended to contact ECHA in order to avoid problems after submission of the dossier.

Based on these conclusions, the Commission services propose to rephrase the Q&A pair in question as follows:

How is a Substance Information Exchange Forum (SIEF) formed and what is the role of EINECS in defining substance identity?

The Guidance on data sharing (Section 4.5 – How and when will a SIEF be formed?) explains principles on how and when a SIEF will be formed and how to determine the sameness of substances (i.e. whether the quantitative and qualitative composition of a substance leads to the conclusion that it needs to be considered as one and the same substance with one name for the purpose of REACH) and therefore whether they should be considered together in one SIEF. The Guidance also explains how to facilitate communication within a SIEF and at what point in time data holders should join the SIEF.

All potential registrants for the same phase-in substance shall form a SIEF on the basis of the rules laid down in REACH and further explained in the Guidance for identification and naming of substances under REACH. Wherever a phase-in substance has an EINECS number, this will normally mean that one SIEF will be formed for one EINECS entry. However, one EINECS entry may also correspond to several substances or several EINECS entries may correspond to one and the same substance. Establishing substance identity and determining whether substances should be considered the “same” substance and join the same SIEF is the matter for “sameness” discussions which should take place before a SIEF is formed. It should be noted that the REACH Regulation does not define "sameness" and it does not foresee at this stage any formal role for ECHA in confirming the establishment of sameness or in the formation of a SIEF.

In order to reach an agreement on the sameness of a substance, pre-registrants must enter into pre-SIEF discussions. As a consequence of this, a SIEF is formed when the potential registrants of a substance in the list of pre-registered substances actually agree that they effectively manufacture or import or intend to manufacture or import the same substance to allow a valid joint submission of data.

Any decision on the substance' identity and substance name should be carefully examined to ensure that they are in line with the REACH substance identity rules explained in the Guidance for identification and naming of substances. Refusal to share data within SIEFs may under certain circumstances lead to inability to register the substance. Failure to split one EINECS entry into several substances, where necessary, may result in invalid registrations, the need to prepare and re-submit registration dossiers for all concerned substances and to pay the registration fee again. Therefore, in case of doubt, it is recommended to share data as widely as possible within one EINECS entry (even if this is not strictly required by REACH) and, at the same time, to interpret the substance definition narrowly, i.e. to rather submit several separate dossiers. Wherever a decision is taken not to split EINECS entries, care should be taken that the data submitted are adequate for all variants and forms of the substance.

In case of major problems, it is advised to contact ECHA to seek clarification.

For further information in relation to pre-SIEFs and SIEFs please refer to the *SIEF – Key Principles* document and to document CA/74/2009 rev.2 (available on http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/substance_identity_sief_formation_en.pdf).

Annex I: Details of the consultation procedure in the helpdesk network

In the written procedure (2nd step) launched on 9 June 2009, ECHA summarized the comments received on this Q&A pair. In essence, PL and AT agreed, SK, BE proposed redrafting, and DE proposed to delete the pair. ECHA proposed to discuss this Q&A pair at the next REHCORN meeting.

On 19 June 2009, DE replied that it still has substantial concerns with this Q&A pair. It argued that a SIEF is not formed when the potential registrants of a substance in the pre-registration list actually agree that they effectively manufacture or import or intend to manufacture or import a substance that is sufficiently similar to allow a valid joint submission of data but that a SIEF is formed if the substances are identical. At the next level the companies of the same substances have then to decide whether a test conducted with a substance with a specific composition (impurity profile, purity) can be used for the same substances however having different impurity profiles and purities. DE proposed to discuss this matter at the October REHCORN meeting.

In further comments sent on 30 June 2009, reacting to a UK example on orange extract, DE further specified its considerations, underlining that according to its opinion one EINECS entry defines only one SIEF. It considers that this principle is laid down in the ECHA guidance on substance identification and applies both to well defined and UVCB⁴ substances.

ECHA replied to the DE on 30 June 2009, underlining that the REACH substance definition does not contain a reference to EINECS, and that both the guidance on substance identification and the guidance on data sharing clearly mention that a substance as defined by an EINECS entry is not necessarily identical to a substance under REACH.

In a further reply of 5 August 2009, DE accepted the possibility that the rule ‘one EINECS number = one substance’ may not be applied to some UVCB substances as these substances are more complex but insisted that the rule ‘one EINECS number = one substance = one SIEF’ should apply to all substances with a well defined composition, regardless whether they are mono-constituent or defined multi-constituent substances (in the latter case substances can also be defined by the EINECS numbers of their main constituents).

Following this exchange of e-mails, the Commission services have suggested raising this matter at the level of CARACAL.

⁴ Substances of Unknown or Variable composition, Complex reaction products or Biological materials

Annex II: Main references in the guidance to the status of EINECS in relation to substance identification and data sharing

1. Guidance for identification and naming of substances under REACH (Guidance on substance identification)

1.1. Rules for all types of substances

The guidance confirms that the checking of the sameness of the substance is based on EINECS reporting rules but at the same time clearly refers to the possibility to divert from the EINECS listing in certain justified cases.

[The EINECS reporting rules] “which were applied for establishing EINECS [Manual of Decisions, Criteria for reporting substances for EINECS, ECB web-site; Geiss et al. 1992, Vollmer et al. 1998, Rasmussen et al. 1999] should be regarded as a common base for identifying and naming a substance and thus finding a potential co-registrant of this particular substance. In the following paragraphs guidance for identifying and naming substances is given. Substances which are not regarded as the same may, however, be regarded as structurally related by application of expert judgement. Data sharing might, nevertheless, be possible for these substances if scientifically justified. However, this is not subject of this TGD, is addressed in RIP 3.4 Data Sharing.” (section 5, p. 46)

The guidance also confirms:

“A substance is completely identified by its chemical composition, the chemical identity and the content of each constituent in the substance. Although such straight-forward identification may be possible for most substances, for certain substances it is not feasible or not adequate within the scope of REACH. In those cases, other or additional substance identification information is required.” (section 4.1, p. 18).

It should be noted that, in interpreting the substance definition and the identification rules, the guidance refers to the EINECS reporting rules as a basis for identification and naming of substances but not to the EC list as such. Even though in many cases the result of applying these rules will be the same (and it will be useful not to reopen discussions unless there is a major reason to do so), there may be cases where the result of a refined analysis or new information may be to define substances differently than in the EC list.

On the nature of EC lists, the guidance confirms their limited role, related to the phase-in vs. non phase-in status of the substance, as follows:

“The EC Inventory can be used as a tool for manufacturers and importers to decide whether a substance is a phase-in substance or a non-phase-in substance. Thus, the EC Inventory will help manufacturers and importers to find out when the registration of a substance will be required, and if a pre-registration or an inquiry is necessary.” (section 3.2.1, p. 15)

The possibility of different substance identification, compared to EINECS, under the new REACH inventory to be created by ECHA, after entry into force of REACH is referred to:

“The registration process allows the new inventory of registered substances to “correct” the current EINECS, where “mistakes” were made.” (section 3.2.2, p. 15-16)

The guidance subsequently describes the possibility of imprecision of certain broad EINECS entries:

“Sometimes the description of a substance in EINECS is relatively broad. In these cases, the potential registrant is invited to describe the substance in question more precisely (e.g. via the IUPAC name or other identifiers). To benefit from the phase-in rules, the registrant should

nevertheless indicate to which EINECS entry the substance belongs. In such cases, the European Chemicals Agency will decide whether or not it is appropriate to allocate a new EC number to the substance in question.” (section 3.2.2, p. 16)

In its mail of 19 June, DE also argued that “*a SIEF is formed if the substances are identical. At the next level the companies of the identical substances have then to decide whether a test conducted with a substance with a specific composition (impurity profile, purity) can be used for the identical substances with different impurity profiles and purities. This system was already successfully applied under NONS, and in our view the only possible way to handle the tremendous amount of substances under REACH*”.

In this context, the guidance states:

“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. However, well-defined substances should normally contain the main constituent(s) and the only impurities allowed are those derived from the production process (for details see Chapter 4.2) and additives which are necessary to stabilize the substance. 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. (see section 5, p.46)”

1.2. Substances of defined chemical composition

It is obvious that substances of well defined quantitative chemical composition, and in particular mono-constituent substances, will be most straightforward to identify and therefore there should be little reasons to deviate from the EC list. Nevertheless, it should be noted that the guidance on substance identification does not explicitly state that for such substances the EC list is the basis for substance identification nor does it explicitly exclude the possibility for deviations. This would also be difficult to justify as the substance definition in REACH does not distinguish between well-defined and UVCB substances and therefore in principle the same rules apply to all types of substances.

Mono-constituent substances

For most mono-constituent substances, it will not make sense to deviate from the EC list. However, such deviations could be useful for some substances (e.g. silicon dioxide (EC number: 231-545-4), as silicon dioxide exists in different modifications and different forms which qualifies them as different substances).

Multi-constituent substances

For defined multi-constituent substances, the situation is specific, as the practice in EINECS listing differed to a large extent from the recommendations in REACH guidance. REACH requires the registration of substances, as manufactured or imported. The specifics of multi-constituent substances in this respect have been further interpreted in the Guidance for identification and naming of substances under REACH. Multi-constituent substances could not be reported for EINECS but were covered by EINECS if all individual constituents were listed on EINECS (see section 4.2.2, p. 25 and section 5, p. 49). This means that a defined

multi-constituent substance generally does not have its own EINECS number, but often is covered by several EINECS entries corresponding to its constituents.

The guidance offers an example of a mixture of isomers (reaction mass of isomers), which should be registered as a multi-constituent substance under REACH, whilst it was covered by two or more entries of the individual isomers reported for EINECS. The guidance also emphasizes in this context that, in the registration dossier, reference should be made to the EINECS entries of the individual isomers to demonstrate the phase-in status (see section 7.3, p. 54).

1.3. UVCB substances

For UVCB substances (substances of unknown or variable composition, complex reaction products or biological materials), and in particular for extracts specific identification rules are provided for:

“As a chemical derivate of an extract will not contain the same constituents as the parent extract, it shall be regarded as a different substance. This rule may have as a consequence that the identification by name and description deviates from the earlier EINECS name and description. At the time of the setting up of the EINECS inventory, extracts from different processes, different solvents and even physical or chemical derivatives were often covered under one single entry. These substances may be registered as a single substance under REACH, provided that the hazardous properties do not differ and warrant the same classification. However, there may be reasons, e.g. broad substance description in EINECS, to identify several different substances under one EINECS number.” (section 4.3.1.2, p. 34).

The guidance further specifies in this respect that, for such UVCB substances, where the source is biological and the process is refinement, the differentiation of further processed extracts may have the consequence that the new name and description will differ from those in EINECS. At the time of setting up the inventory, such a differentiation has not been made and all types of extracts with different solvents and further process steps might have been covered under a single entry (see section 4.3.1.2, p. 36).

For specific types of UVCB substances – enzymes, again, a specific need is envisaged in the guidance to identify them differently compared to the old EINECS entries. In EINECS, the main identifier for enzymes is the catalytic activity. Enzymes are listed as generic entries without further specification or with specific entries indicating the source organism or the substrate. The guidance suggests identifying enzymes in a more systematic way according to the international system for enzyme nomenclature IUBMB (International Union of Biochemistry and Molecular Biology) (see section 4.3.2.3, p. 41-45).

2. Guidance on data sharing

The Guidance on data sharing in general does not introduce new or different rules on substance identification but refers to the rules in the Guidance on substance identification in every instance where the issue of substance identification is tackled in the context of pre-registration, formation of SIEFs, involving of data holders etc. (see in particular p. 13, 17, 25, 26, 35, 39). Rather, the Guidance on data sharing complements the Guidance on substance identification by focusing on data sharing mechanisms for phase-in and non phase-in

substances under REACH. In case of phase-in substances, the aim of this guidance is also to describe the process of the formation of SIEFs and ensuing data sharing in more detail.

In the similar vein as the Guidance on substance identification, the Guidance on data sharing confirms that:

“The substance identity often corresponds to an existing EINECS or CAS entry or similar identification code but there are also cases where one EINECS entry covers several substances or where several EINECS entries correspond to one substance.” (section 3.9, p. 25).

In the context of pre-registration, the guidance states:

“However, the submission of the identifiers does not include information on the actual composition of the substance. In some cases this could lead to the fact that, although several Potential Registrants have pre-registered the same identifiers (e.g. the same EINECS number), this does not mean that they will be registering the "same" substance (because the EINECS entry describes several substances).

Mono-constituent substances and UVCB substances can be registered using the EINECS number as the proper identifier. In cases of errors in the EINECS entries, sufficient information to properly identify the substance can be given at pre-registration. In some cases the EINECS entries of UVCB substances are defined very broadly. Also in these cases it is recommended to provide additional information (e.g. IUBMB number for enzymes) to improve the process steps following pre-registration (i.e. SIEF formation and Joint submission).”(section 3.9, p. 26).

The precondition of forming a SIEF is a discussion on the sameness of the substance among manufacturers and importers. Once agreement on the sameness of the substance has been found, SIEFs will be formed.

“The assessment of the exact nature of an EINECS entry and the different substances it may cover can only be carried out by the manufacturers or importers who should be aware of the composition of the substance. It is, therefore, up to them to take the responsibility of defining precisely the substance for which a SIEF will be formed.”

In order to reach an agreement on the sameness of a substance, Pre-Registrants must enter into pre-SIEF discussions. As a consequence of this, a SIEF is formed when the Potential Registrants of a substance in the pre-registration list, actually agree that they effectively manufacture, intend to manufacture or import a substance that is sufficiently similar to allow a valid joint submission of data.” (section 4.5, p. 34)

For substances with a well-defined composition the guidance confirms the line in the Guidance on substance identification that different impurities do not necessarily lead to different substances (even if the classification and labelling and thus the toxicological and eco-toxicological profile is different) but that at the same time there may also be cases where such substances should be considered to be different:

“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.” (section 4.5.1, p. 35).

For UVCB substances, the guidance confirms that, in most of the cases, the substances that have been pre-registered under the same entry in EINECS will be identified by potential registrants as the same substance and the joint submission of data for registration will follow. However, the guidance explains that, in certain cases, the exact nature of the substance

covered by an EINECS entry will have to be scrutinised in order to ascertain whether it can be covered by the same joint submission of data and that the relevant hazard data can be purposefully exchanged. This reasoning is based on REACH recital (45). Typically, this may happen in the following situations:

“The description in EINECS given for a substance can be very broad to the extent that the physical-chemical and (eco)toxicological properties of the different substances covered by this one entry are not sufficiently similar to use the same data to describe it. This may particularly be the case for UVCBs.” (section 4.5.1, p. 35).

This course of action for potential registrants in cases, where one EINECS entry covers different substances, is again restated in another place in the guidance (see the same section, p. 37)

It is equally important to stress that REACH does not envisage any role for ECHA to participate in the discussion on the sameness of the substance nor to confirm or reject the creation of a SIEF. Although decision on the sameness is finally result of an agreement among the respective manufacturers or importers, they have to follow REACH substance identification rules, as outlined above.