# Application of RIP 3.10 on "Guidance for identification and naming of substances"

## - Reaction mixtures, naming rules, phase-in criterion (a), impurities –

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**Disclaimer**

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**Application of RIP 3.10 on**
**"Guidance for identification and naming of substances"**

**- Reaction mixtures, naming rules, phase-in criterion (a), impurities -**

**WARNING**

*Every company has a responsibility to ensure that it implements REACH in accordance with the Regulation. As stated in the legal notice on RIP Guidance Documents, information contained in the guidance does not constitute legal advice and only the REACH Regulation can serve as an authentic reference. Although RIP guidance is issued by the European Chemicals Agency, the Agency does not accept liability with regard to the content.*

*As an informative tool, this paper aims to assist companies with the application of RIP 3.10. Responsibility for REACH compliance remains with a company; the authors of this paper assume no liability whatsoever for the contents or use of this document.*

**REACH implementation requires a case-by-case approach. Each company is responsible for ensuring that it is compliant with the REACH Regulation. To help companies implement REACH, Cefic is producing a number of documents that can be used in conjunction with guidance from the RIPs.**

**It is for each company to establish the most appropriate and suitable method to meet regulatory requirements. This can depend on many factors such as its products, management systems, customers, suppliers, etc. In every case, the company must check that it is meeting the requirements of the REACH Regulation.**

***This document presents Q&A on RIP 3.10 – Guidance for Identification and Naming of Substances. The issues examined relate to queries from companies on:***

***- reaction mixtures***

***- naming rules***

***- phase-in criterion (a)***

***- impurities***

## Introduction

The REACH Implementation Projects seek to explain the REACH Regulation. Methods and examples on how to meet REACH requirements are provided in the RIP Guidance Documents.

Many companies are still looking for further help to understand the complex requirements of the Regulation and follow the RIPs. Supplementary guidance from industry groups can provide a useful source of information and form of assistance.

## RIP 3.10

The European Chemicals Agency RIP 3.10 “Guidance for Identification and Naming of Substances under REACH” reviews several procedures on reporting chemical substances. In order to promote a consistent approach to implementation, this paper complements the RIP 3.10 Guidance Document by examining:

- reaction mixtures
- naming rules
- phase-in criterion (a)
- impurities

Following an analysis of information sourced from the REACH Regulation and RIP 3.10 a series of answers have been developed in response to key questions frequently asked by companies. A set of references is provided in an Appendix.

## Questions and Answers

***1. Where does the REACH Regulation describe 'multi-constituents' and 'reaction masses' and require their pre-registration or registration?***

The REACH Regulation defines "substances"[1] and "preparations"[2] and refers to "complex reaction products"[3]. It is the RIP 3.10 "Guidance for identification and naming of substances under REACH" that introduces the terms 'multi-constituent' and 'reaction mass'.

Pre-registration and registration applies to substances, even though substances comprise of multiple chemical species. As the terms 'multi-constituent substance' and 'reaction mass' do not appear in the REACH Regulation, the legislation does not specify the detailed form of the registration of such products.

The REACH Regulation establishes that "complex reaction products" may be registered as single substances if the hazard profile does not differ significantly between the different products considered as a single substance. The same rules apply for products of "unknown or variable composition" and "biological materials" within the scope of registration. This is different to preparations, where the legislation states that the individual substances of a mixture should normally be registered[4]. Nevertheless, such products may be component parts of a preparation.

In the IUCLID5 programme used for registration, a multi-constituent substance can be entered as a single entry and thereby distinguished from mixtures. Flexibility to register in the most appropriate way is therefore provided to a registrant through the combination of the REACH Regulation, the RIP 3.10 Guidance Document and IUCLID5.

It follows that the registrant must establish on a case-by-case basis whether to describe a product resulting from manufacture as:

a) *mixture of two or more substances = preparation or*
b) *single substance with impurities[5] or*
c) *UVCB substance or*
d) *reaction mass = type of multi-constituent substance in the RIP 3.10 Guidance Document*

It is important to note that most substances comprise of several constituents, regardless of which of the above categories is used as a description. In practice, descriptions will depend on how the product is manufactured, sold, used and tracked through supply chains, as well as the availability of data on substance identity and hazard. Registration requirements depend on how a registrant regards a product, as explained in the following sections.

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[1] Article 3 (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.

[2] Article 3 (2): Preparation: Mixture or solution composed of two or more substances.

[3] Whereas (45): The European Inventory of Existing Commercial Chemical Substances (EINECS) included certain complex substances in a single entry. UVCB substances (substances of unknown or variable composition, complex reaction products or biological materials) may be registered as a single substance under this Regulation, despite their variable composition, provided that the hazardous properties do not differ significantly and warrant the same classification.

[4] Article 6: …any manufacturer or importer of a substance, either on its own or in one or more preparation(s), in quantities of 1 tonne or more per year shall submit a registration to the Agency.

[5] The REACH Regulation does not set concentration limits on the content of impurities.

Through registration data sets on composition and individual components of products can be submitted in a variety of ways (refer to IUCLID5). Rules for classification and labelling must always be followed, which account for composition at both substance and mixture levels. In all cases, companies must ensure that product safety can be assured under relevant legislation and that appropriate data sharing can occur. It may be that a company finds itself pre-registering substances according to the various relevant possibilities, as far as reasonably practical, e.g. based on established product management systems, to then be able to ascertain which description is most appropriate. For instance, it may be in a SIEF or joint registration consortium that consensus on descriptions are attained. Nevertheless, for the purpose of data sharing, cross-references to substances can be included in a pre-registration file – e.g. for the purposes of substance groupings.

During pre-registration, it may be that different names of substances are entered although the same reference to an EINECS listing applies. It may also be that the same name from an EINECS entry is used as a reference during pre-registration but a different naming scheme is appropriate for registration. It follows that a need to form multiple SIEF and joint registration consortia may indeed only be identified after pre-registration. Such procedures should not affect phase-in status.

### *2. How does the REACH Regulation describe a 'preparation' and distinguish it from a 'mixture'?*

The REACH Regulation defines a preparation as a "mixture or solution composed of two or more substances". This means that the terms mixture and preparation are synonymous under REACH.

The term preparation covers all types of possible mixtures of substances. In this way, the REACH Regulation neither distinguishes different origins of a preparation nor differentiates between various methods of manufacturing a preparation. A preparation can be obtained by numerous means such as: blending of substances; reactions resulting in mixtures containing substances; or extractions of substances from natural materials.

### *3. How does RIP 3.10 describe a preparation?*

The description of a preparation in the RIP 3.10 Guidance Document as an *"intentional*" mixture of substances only covers a narrow definition relevant to the specific structure and content of that guidance document. Furthermore, determining what corresponds to *"intentional"* is outside the scope of RIP 3.10, for instance, reaction mixtures of a given specification or substances with a desired level of impurities. In order to follow the legislation, the RIP 3.10 Guidance Document states that it is for each company registering a substance under REACH to establish what production and processing steps constitute 'manufacture'.

By comparison to RIP 3.10, the REACH Regulation definition of a preparation is not limited to "*intentional"* mixtures of substances and therefore includes the presence of 'unintentional' chemical species in a mixture. Fundamentally, the Regulation covers many aspects of chemical risk assessment, management and communication. For this reason, RIP 3.10 requires a company to first distinguish between what types of preparations it has by following the Regulation before applying the guidance.

### 4. *What is the difference between a reaction mass, a reaction mixture and a multi-constituent substance?*

For identifying and naming substances, the RIP 3.10 guidance provides the possibility to consider mixtures obtained by a reaction (= reaction masses) as multi-constituent substances. A reaction mass is therefore a type of reaction product that may be distinguished from reaction mixtures.

Reaction masses may be registered as single substances; although in some cases there can be the separate registration of certain constituents. By comparison, it is always appropriate to pre-register and register the separate component substances of reaction mixtures. Reaction masses are just one type of a multi-constituent substance; another example of a multi-constituent substance could be certain types of extract.

### 5. *When is it appropriate to register a mixture?*

Never. It is only appropriate to register substances. However, in some cases, a substance will comprise of several constituents. The REACH Regulation aims to maximise data sharing possibilities and minimise animal testing, so the implications of any registration procedure should be carefully considered. A mixture, whether obtained by a reaction, distillation, extraction, blending, or other means, will often be referred to as a preparation for the purposes of REACH. In these cases the separate component substances may be registered.

### 6. *What does this mean in practise for the pre-registration / registration requirements regarding the manufacturing of substances?*

Each manufacturer and importer must define its products in terms of the component substances on the basis of the REACH Regulation, the RIP 3.10 Guidance Document, scientific references and expert judgement. Care must be taken to ensure compliance with the REACH Regulation otherwise a company may be challenged by competitors or enforcement officers.

There are four fundamental categories of product:

a) mixture of two or more substances = preparation: the pre-registration and subsequent registration of each single substance according to its mass fraction of the total mass of the preparation; the tonnage of each substance across the manufacturer or importer's product portfolio must be aggregated.

b) 'UVCB substance' (unknown or variable composition, complex reaction products or biological materials) = complex product: a single pre-registration and registration according to the total mass of that product (or category of product meeting the same UVCB substance definition).

c) single substance with impurities: a single pre-registration and registration according to tonnage of the substance across products. The impurities and their content in the substance need to be specified in the registration dossier[6]. The substance can contain more than one constituent, but still be considered as a mono-constituent substance following RIP 3.10 guidance[7].

[6] Note that the REACH Regulation does not require impurities >10 % to be considered as constituents and it does not give any concentration limits with regard to the actual content.

[7] The REACH Regulation establishes that a substance can comprise of multiple constituents. RIP 3.10 uses the term mono-constituent substance to refer to single substance registrations. However, RIP 3.10 contains

d) reaction mass = multi-constituent substance: a single registration. Data from each constituent can however be used for the purpose of registration. As a deviation from a single registration, individual constituents can be registered separately to account for missing data, if justifiable. In this case the information requirements should be established based on the highest possible requirements of that constituent, as detailed in RIP 3.10. For a single registration, levels of data requirements should be based on the summation of the tonnage for each individual constituent across products.

**Examples:**

**(i)** A company manufactures substances C and D through the following manufacturing process:

1. A + B → [C+D+A+X] 16 t/a
   X = by-product and A = unreacted starting material impurities)
2. [C+D+A+X] is purified in subsequent processing steps
   → substance C and substance D are obtained separately, each at 5 t/a
   (A and X are removed = e.g. waste, recycling)

As the company manufacturers substances C and D, only these two substances have to be pre-registered and subsequently registered in accordance to their actual production volume (< 10 t/a). There is no mandatory requirement to pre-register and register the reaction mixture [C+D+A+X] as further manufacturing occurs.

**(ii)** A company produces a reaction product containing the substances C, D, A, and X. The total volume of the product is 16 t/a. There are no purification steps that separate the substances. Part of the resulting product is the used in further chemical reactions and part is placed on the market without processing:

For the purpose of pre-registration and registration, the manufacturer may regard the reaction product as:

a) *mixture of four substances* - A preparation following the definition of preparation under REACH Regulation and application of Article 6. Substances C, D, X, A must then be registered according to their actual volume in the preparation. (Note that A might already be registered as a starting material.) or

b) *complex reaction product* - A single registration as UVCB substance in accordance with the definition of a substance in the REACH Regulation as possibly comprising of multiple chemical compounds and following the legal preamble and application of Article 6. (Note that data on main constituents of a UVCB can still be submitted as part of a registration, if appropriate.) or

c) *substance C with impurities D, A, X* - The registration of C would be required (16 t/a) and the impurities must be accounted for in the registration dossier and any testing/ test data relevant to the substance. (Note that data on more than one constituent can be submitted as part of registration.) or

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examples of how a mono-constituent substance may contain more that one constituent and explains that the main constituent may be present in a range of different percentages of the mass fraction. The registration dossier should account for such variations and relating constituent composition.

d) *complex reaction product with known composition* - In accordance with the RIP 3.10 Guidance Document and following the legal preamble, the manufactured product could be viewed as a single reaction mass. A registration as a multi-constituent substance would then be possible. If data on the substance prove insufficient, but other sources of data are available on the constituents, the constituents can be registered separately to account for the data gaps, following RIP 3.10. Nevertheless, a registration of a complex reaction product can itself include data on some constituents.)

***7. How can phase-in status be managed for different substances that fall under the same EINECS entry?***

Meeting Article 3 definition 20 criterion (a) of phase-in clearly requires reference to an EINECS listing[8][9]. However, many substances can be part of a single EINECS entry – e.g. reaction mixtures or derivatives of naturally occurring substances. In such cases, there is just the need to refer to the EINECS entry relevant to the substance or the substance constituents. Reference to EINECS relates to the entry and not the name.

EINECS listings do not specify impurities or concentration limits. Therefore, some substances originally reported under EINECS may contain more than 10 or 20 % impurities. A company seeking to register a phase-in multi-constituent substance through separate registration of its constituents following RIP 3.10 must therefore consider whether constituents previously considered as impurities have phase-in status. It may be that a company finds itself limited to following the EINECS reporting rules and registering a substance as a single mono-constituent substance (perhaps with more than one main component) rather being able to register it as a multi-constituent substance following the RIP 3.10 Guidance Document if it wants to maintain phase-in status.

***8. How should reaction products be named as a result of variations in the concentration of reaction materials and/or constituents? For instance:***

***I. Would there be a need to rename the substance for a change of concentration?***

***II. How can CBI be protected if a substance must be renamed?***

***III. Does a change in reaction conditions/ constituent concentrations imply a need to register immediately?***

I. Naming rules for substances follow IUPAC or other international chemical naming schemes. It is for the registrant(s) to determine the most suitable method of naming for the purpose of SIEF formation and data sharing.

II. The selection of the most suitable naming method should avoid the potential for divulging confidential business information. For instance, a substance or multi-constituent substance can be named and the relevant IUCLID5 / registration file can cover a wide range of different percentage of composition. In such cases, variations in composition do not require renaming.

III. If a change in reaction conditions or constituent concentrations or impurities is outside those detailed in the relevant IUCLID5/ registration file, then this must be sent to the Agency as an update following Article 22.

[8] Note that phase-in status (a) by reference to an EINECS entry is just one method of demonstrating phase-in status. There is also phase-in criteria (b) and (c) in Article 3 of the REACH Regulation.

[9] Article 3 – definition 20 (a): it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS).

***9. What are the consequences of changing any naming schemes with regards to other legislation?***

Other legislation especially classification labelling, often refers to substance definition in chemical legislation and the respective naming of substances according to IUPAC or other international chemical names. Therefore changes in naming schemes used can impact the practical aspects of implementing corresponding legislation.

References to EINECS or CAS numbers instead of or in addition to cited chemical names reduces potential effects arising from changes in chemical naming. It is for companies to establish whether or not a substance meets the relevant substance definition referred to in other legislation. On a case-by-case basis it may be necessary to revise other legislation to account for changes to naming or substance definition.

***10. How do a manage difference in impurities or composition in a substance?***

Impurities and changes in composition can fall within the definition of any given substance. Therefore a single substance for the purpose of registration under REACH can have different impurity or composition profiles. For the purpose of registration, some information on impurities and composition must be included in the IUCLID5/ registration file. Therefore, a single registration can cover a range of different percentage of composition and/ or impurities. However, if the purity or composition differences result in significant differences to managing the registration process and completing testing, as well as corresponding risk management and communication, then the substances must be distinguished accordingly. An update to the registration file must then be submitted.

## Appendix – References and Analysis

For background reference purposes[10], this Appendix summarises information sourced from the REACH Regulation, RIP 3.10 and current practice on:
(1) Reaction mixtures; (2) Naming rules; (3) Phase-in criterion (a) - EINECS listing; (4) Impurities.

### 1. Reaction Mixtures

| | REACH Regulation | RIP 3.10 | Current Practice |
|---|---|---|---|
| **Summary** | 1) The REACH Regulation defines a preparation to include various forms of mixtures; a reaction mixture meets the definition of a preparation. (Note that a preparation in the legal text can even include a mixture that is to react.)<br>2) Registration applies at the substance level, but a manufacturer can produce a mixture[11] directly not only by mixing of separate substances.<br>3) Complex products such as UVCB (unknown or variable composition, complex reaction products, or biological materials) 'may' be registered as substances rather than managed as mixtures, if appropriate. REACH extends the definition of UVCB to include any EINECS entry considered as a complex substance. | 1) Introduces a new term 'reaction mass' and does not provide guidance on mixtures. Requires complex rules for multi-constituent substances that are reaction masses but differ to mixtures.<br>2) States that registration applies at substance level and that it is for a company to determine what stages of a production and processing constitute manufacture.<br>3) Provides separate guidance on complex reaction products under the UVCB category. | 1) A reaction mixture refers to a mixture after a reaction has occurred.<br>2) Substances in reaction mixtures can be considered as EINECS listed if the starting materials are EINECS listed. Otherwise EINECS listing depends on the separate EINECS listing of the substance in the reaction mixture.<br>3) Many reaction mixtures were EINECS reported as substances - e.g. dichlorbenzene, carbon, titaniumdioxide, xylole. A few were reported as a 'reaction mixture substance' and others as mixtures without limitation on the level of impurities.<br>4) It is a case-by-case decision to use one of the different options (reaction mixture = preparation, or reaction mixture = substance). |

[10] The contents of the Appendix are not intended to be used as guidance.
[11] The original Commission proposal for the REACH Regulation did not include manufacturers of preparations – see Article 5(1)

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| **Refs** | 1)Article 3 – definitions<br>2)Article 6 - registration<br>3) Preamble 45 - UVCB | 1) RIP 3.10: p.14 and p.27-28<br>2) RIP 3.10: p.26<br>3) RIP 3.10: p.30-46 | 1) EINECS Reporting: Ch. 2, Criterion 20<br>2) EINECS Reporting: Ch. 2, Criterion 20<br>3) MoD – p.26, p.27, p.53 |
| **Impact** | - To improve workability, the REACH Regulation was revised from the original Commission draft (previously Article 5(1)) to ensure that manufacturers can register substances in mixtures rather than only as substances on their own. This allows better data sharing through One Substance, One Registration (OSOR).<br>- OSOR aims to reduce animal testing and facilitate implementation, esp. for SMEs.<br>- Allowing the registration of complex reaction products as single substances aims to reduce multiple registrations when this is not necessary, for instance as it is unlikely that the component substances are manufactured on their own. | -Considering reaction mixtures as reaction masses would not be enforceable with regards to imported products.<br>- Considering reaction mixtures as reaction masses would increase number of registrations and is very likely to result in increased animal testing.<br>- RIP 3.10 guidance requires a case-by-case approach to defining manufacture and deviating from RIP 3.10 rules that can result in inconsistent REACH implementation if reaction mixtures are considered as reaction masses.<br>- UVCB categories are narrowly defined resulting in potential increase of registration and possible unintended increase in animal testing. | - Only 56 reaction mixtures have been entered in EINECS as a single entry. In most cases, the starting materials or products were considered. Continuing current practice should therefore facilitate REACH implementation.<br>- In the MoD regarding EINECS and NONS, whether or not the constituents of a reaction mixture are EINECS listed was always considered when establishing if the reaction mixture should be managed as a 'reaction mixture substance' or a mixture. |

**Conclusions:**

- A reaction mixture should not be considered as a reaction mass under RIP 3.10.
- Registration of substances must be managed by a company in a way that ensures maximum potential for avoiding animal testing.

**2. Naming rules**

| | REACH Regulation | RIP 3.10 | Current Practice |
|---|---|---|---|
| **Summary** | 1) The REACH Regulation does not prescribe naming rules<br>2) REACH refers only to the IUPAC naming system or other international chemicals names.<br>3) User names (usual name, trade name, abbreviation) ore other identity codes are to be added. | 1) Guidance developed under RIP 3.10 introduces new naming rules apart from IUPAC / CAS or other chemical code systems in the scientific literature and practice.<br>2) Introduces a specific naming scheme for 'reaction mass' and does not provide guidance on other types of multi-constituent substance.<br>3) States that EINECS naming rules "should be regarded as a common base for identifying and naming a substance and thus finding a potential co-registrant of this particular substance". | 1) Naming rules vary according to case-specifics; however, a standard set of naming rules was used for EINECS reporting under the ESR (IUCLID Data Sets), for classification and labelling and other European chemicals legislation.<br>2) IUPAC naming is normally used if there is no CAS-name or other international code name.<br>3) When using CAS, the CA STN index name are often used whenever available (i.e. 8ci or 9ci)<br>4) Many international standards relate names according to codes for flavours or fragrances, international colour index, INCI codes for cosmetic ingredients. |
| **Refs** | 1) REACH - Article 28 & Annex VI<br>2) Annex VI - Section 2.1.1 & 2.1.2<br>3) e.g. Annex XVII - Restrictions | 1) RIP 3.10: e.g. Appendix 1<br>2) RIP 3.10<br>3) RIP 3.10: p.47 | 1) e.g. ESR RARs<br>2) e.g. Dir. 67/548 Annex I and Dir. 76/769<br>3) as (1) and (2)<br>4) e.g. Dir. 76/768 (cosmetics), Reg. 1935/2004 (food contact) |

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| **Impact** | - In order to facilitate implementation, the Regulation does not mandate specific naming rules. Substances can be named according to IUPAC or other international names. | - RIP 3.10 does not give guidance on when to use different naming rules.<br>- Naming rules do not alter Sameness of Substance checks for SIEF formation.<br>- The new naming rules complicate the coming together in a pre SIEF. | - As most substances that must be registered under REACH relate to EINECS entries, EINECS reporting rules would facilitate REACH implementation<br>- IUPAC naming requires specific expertise, therefore, such resources are best shared within a SIEF. Therefore, companies should use available naming schemes for pre-registration.<br>-Company experts should be aware of what naming is most appropriate. This naming must be appropriate for the identity of the substance and the efficient functioning of SIEF and joint registrations. Often selecting the naming system will require advice from procurement, sales and marketing staff together with scientists. |

**Conclusions:**

- EINECS naming rules should be followed as closely as possible.
- CAS names may prove equally if not more relevant than EINECS for the purpose of pre-registration and SIEF formation; CAS names are readily available for all chemicals with CAS numbers.
- Where more than one name appears particularly relevant, it should be considered as good practice to include more than one name in (pre-) registration.
- Establishing IUPAC names and the relevance of IUPAC naming may need to occur in a SIEF, especially as following IUPAC nomenclature can require particular expertise which can be shared within a SIEF.

### 3. Phase-in criterion (a) - EINECS listing

| | REACH Regulation | RIP 3.10 | Current Practice |
|---|---|---|---|
| **Summary** | 1) The REACH Regulation refers to EINECS entries, where a substance must meet the criteria of being 'listed in EINECS';<br><br>All EINECS-Substances regardless of their constituents, impurities, additives etc. are phase-in substances (except the EINECS description or the corresponding CAS description to the CAS number limits the impurities or other constituents in a substance). For instance, a chemical derivative of an extract will not contain the same constituents as the parent extract.<br><br>2) Under REACH the derivative may be regarded as a different substance but covered under the same listing of the EINECS inventory because extracts from different processes, different solvents and even physical or chemical derivates were often covered by a single entry. | 1) RIP 3.10 recommends that a registrant should "indicate to which EINECS entry the substance belongs" for the purpose of phase-in criterion (a). Substances considered as multi-constituent substances and named following the format of "reaction mass of …" would qualify as phase-in substances if all individual constituents were listed on EINECS. An example is given for a reactions mass that should be regarded as a phase-in substance under REACH, even though the product does not have an EC number because the substance was covered by the EINECS entries for the constituents. | 1) Although EINECS is a 'closed list', it has been subject to revisions and corrections. With regards to its status under REACH, the RIP 3.10 Technical Guidance Document "the registration process allows for corrections to EINECS to be made".<br><br>2) When examining the EINECS list, it is important to note that some substances in EINECS appear on the list because they were transferred directly from other compendia. In other words, some EINECS listed substances did not need to have to be EINECS reported in the first place and may be exempt from registration under REACH. Therefore when considering phase-in status, understanding the types of substances that needed to be reported to EINECS should not always be based on actual entries to EINECS but on the entries valid at the time, when EINECS was published.<br><br>3) Mixtures can be reported in terms of starting materials or the components.<br><br>4) An EINECS entry may not distinguish between physical and chemical processing of the same type of material. Similarly, extraction methods carried out at different temperatures do not necessarily result in different EINECS entries, even when composition varies. |

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| **Refs** | Article 3 – definitions | 1) RIP 3.10: p.17, p.35<br>2) RIP 3.10: p.26, p.56 | 1) e.g. EINECS Corrections 03/ 2007; RIP 3.10 p.16<br>2) e.g. EINECS Reporting: Chapter 3.<br>3) EINECS Reporting: Chapter 2, Criterion 20.<br>4) MoD: p.30 |
| **Impact** | The REACH Regulation defines criterion (a) for phase-in to cover all substances that were considered as 'existing' and therefore reportable under the EINECS reporting rules. This allows for maximum potential of creating a level playing field and enabling OSOR. | The RIP 3.10 guidance may raise legal uncertainties for compliance and enforcement of pre-registrations. This is because it could be interpreted as saying that substances with names that differ to the names that appear in EINECS do not qualify as phase-in substances under criterion (a). As written, the guidance is creating confusion for companies that are not familiar with EINECS reporting rules and their relationship with the REACH Regulation. | EINECS reporting rules are complex but must nevertheless be followed to establish phase-in status. Following EINECS reporting rules allows companies that are familiar with EINECS to confirm phase-in status with minimal effort. |

**Conclusions:**

- Many substances can be part of a single EINECS entry – e.g. reaction mixtures, derivatives and extracts of naturally occurring substances.
- For phase-in status, there is just the need to refer to the relevant EINECS entry/entries. This should be clearly communicated to companies.

## 4. Impurities

| | REACH Regulation | RIP 3.10 | Current Practice |
|---|---|---|---|
| **Summary** | 1) The REACH Regulation includes impurities within the definition of a substance and does not give any indication to maximum levels of any impurity.<br>2) The Regulation does not specify how to identify whether or not a substance is the same for the purpose of a SIEF and registration. | 1) RIP 3.10 states that an impurity should generally be considered as a constituent, if its concentration in a multi-constituent substance is above 10%. However, an impurity cannot be considered as a main constituent.<br>2) Some examples are given where impurities are above 20% for a mono-constituent substance especially with regard to water. Generally for a mono-constituent substance, impurities could not exceed 20% because the man constituent should be above 80%.<br>3) RIP 3.10 does not cover Sameness of Substance check – it refers to RIP 3.4 instead. In turn, RIP 3.4 asserts that the principles of sameness should be based on criteria from RIP 3.10 but does not specify how to use the criteria or make use of combinations of criteria. The practical elements of SIEF and joint registration consortia formation are left to industry. | 1) Impurities are distinguished from components of a substance or mixture<br>2) EINECS reporting rules do not require the reporting of impurities<br>3) For notified substances, testing should be carried out on the substance with impurities<br>4) For ESR RARs, studies may be available for the substance with different impurities, from which the implication of impurities must be deduced<br>5) Classification and labelling must include impurities only if the are dangerous. |
| **Refs** | 1) Article 3 - definitions<br>2) Article 29 - SIEF | 1) RIP 3.10: p.12<br>2) RIP 3.10: p.25<br>3) RIP 3.10: p.47 | 1) EINECS Reporting Rules, MoD<br>2) EINECS Reporting Rules<br>3) MoD, p.47<br>4) e.g. ESR RARs<br>5) MoD; p.47; Dir. 1999/45 |

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| **Impact** | - The REACH Regulation allows a case-by-case approach to managing impurities and establishing Sameness of Substance | - The RIP Guidance potentially limits flexibility for companies to decide that certain constituents may be regarded as an impurity.<br>- Although the RIP allows for companies to deviate from the guidance, the guidance is rather confusing. For instance, a mono-constituent substance can have more than one main constituent. Without further clarification, following the RIP 3.10 guidance could complicate SIEF formation and data exchange.<br>- If not carefully implemented, RIP 3.10 could result in companies revealing information on the composition of substances without consideration as to whether this is necessary for safety or disclosure is in the general public interest (e.g. if the constituents in the name of the reaction mass are published in the ECHA data bank, regardless as to whether or not these are dangerous). | - Following EINECS and ESR, consideration must be given to impurities but reporting and testing must not necessarily include the impurities. Applying this approach to REACH will facilitate SIEF formation and data exchange. It remains a case-by-case decision of expert scientific judgement to establish whether an impurity profile results in the same or a different substance.<br>- Following notification rules for testing on substances with impurities would require an excess number of registrations and animal test studies to be performed. Notification rules are not suitable for 'existing substances'.<br>- |

**Conclusions:**

- Impurities can be present at any % in a substance.
- Impurities present at above 10% can be considered as constituents in multi-constituent substances that are not reaction masses but this is optional. The data set needed for a multi-constituent substance that is not a reaction mass can refer to a different purity profile of the main constituent substance(s).
- Managing impurities must be accounted for during SIEF formation, data exchange, joint registration, Classification and Labelling, as well as risk management measures.