EUROMETAUX
EUROPEAN ASSOCIATION OF METALS

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Fact sheet on Intermediates under REACH

1. Introduction

The REACh Regulation recognises "intermediates" as a distinct subset of substances that may either be able to benefit from a reduced registration regime or are totally exempted from the scope of the Regulation. The scope of this fact sheet is to outline how to correctly identify intermediate substances and to determine:

- if the substance falls under the Scope of REACH at all [Art. 2§1(c)]
- which Registration requirements apply [Art. 2§8]
- if the substance can be liable to Evaluation [Art. 49]
- if the substance can be liable to Authorisation [Art. 2§8]
- if the substance can be liable to Restriction [Art. 68§1]

A more detailed general overview of the requirements related to intermediates on Classification, evaluation and authorisation can be found in Annex II.

2. Definitions

Article 3 (15) defines an ***intermediate*** as "a *substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance(s)"* Intermediates should therefore not be present in the final manufactured substance (except possibly as an impurity).

While in a conventional organic or inorganic synthesis, this matches the typical reaction sequence:

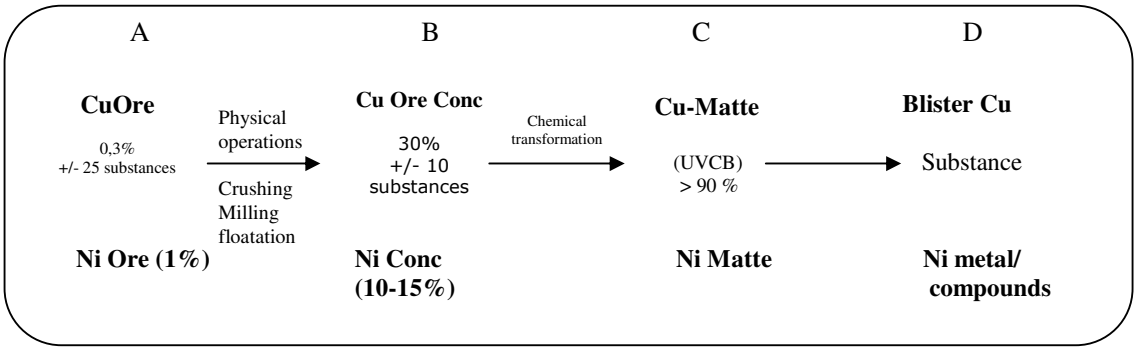
Substance A → Substance B (intermediate)→ Substance C

The conventional sequence is extended in REACh to cover the following case:

Substance A containing Substance D → Substance B containing Substance D

→ Substance C containing Substance D → Substance D

Where the process goes on to produce Substance D in a pure form and Substances A, B and C are intermediate. Translating this into a metals example could give the following cases, where A, B and C can be considered as intermediates:



The interpretation of any substance as an intermediate is linked to its fate. If it is transformed into another substance, it might be an intermediate. To determine the final obligations under REACh, however, a further distinction needs to be made between three sub-categories of intermediates:

√ A ***"non-isolated intermediate*** as defined in article 3 §15 c: means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process, as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step,…"

According to Article 2 § 1 c, non-isolated intermediates are fully exempted from the scope of REACh !!!

√ *A*n ***"On-site isolated intermediate",*** as outlined in Article 3 § 15 b, means an intermediate […] where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities; The special requirements that apply to this type of intermediates are further discussed in Section 3.

√ A "***transported isolated intermediate",*** as defined in Article 3 §15 c, means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites; The special requirements that apply to this type of intermediates are further discussed in Section 3.

If a substance is used directly on its own, in a preparation or in an article for another purpose, this substance cannot be an intermediate and will be subject to the normal registration requirements.

3. **The case of Registration and data requirements**

Manufacturers of on-site isolated intermediates and manufacturers or importers of transported isolated intermediates in quantities of 1 tonne or more per year need to submit a registration dossier unless otherwise exempted.

In line with Articles 17 § 2 and 18 § 2, manufacturers or importers of intermediates requiring registration can provide ***reduced registration information*****,** comprising**:**

a) the identity of the manufacturer or importer as specified in Section 1 of Annex VI;
b) the identity of the intermediate as specified in Sections 2.1 to 2.3.4 of Annex VI;
c) the classification of the intermediate as specified in Section 4 of Annex VI;
d) any available existing information on the physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted;
e) a brief general description of the use, as specified in Section 3.5 of Annex VI;
f) information on risk management measures applied and recommended to the user in accordance with paragraph 4.

Except in cases covered under Article 25 §3, Article 27 §6 or Article 30 §3, the registrant shall be in legitimate possession of, or have permission to refer to, the full study report summarised under (d) for the purpose of registration.

The provisions outlined above however only apply if the following requirements are met:

√ *For on-site isolated intermediates*

The manufacturer needs to confirm that the substance is only manufactured and used under **strictly controlled conditions** in that it is rigorously contained by technical means during its whole lifecycle (Article 17 §3). The information requirements relative to the substance's intrinsic properties (physicochemical, human health and environment properties) are reduced to already available data

(e.g. information that he holds himself or that he can obtain from other sources), and only study summaries have to be submitted if a full study report is available (Article 17)[1].

√ *For transported isolated intermediates*

The manufacturer or importer himself confirms or states that he has received confirmation from the user (inside or outside the EU) that the manufacturing and use takes place on other sites under strictly controlled conditions (Article18 §4)[1].

If the annual production/ import volume of the substance is ***less than 1000 tonnes***, the information requirements relative to the substance's intrinsic properties (physicochemical, human health and environment properties) are reduced to **available data** as outlined above (Article 18 §2).

When the substance is manufactured/ imported and used under strictly controlled conditions and the ***annual quantity of the substance is 1000 tonnes or more*****,** the data requirements on the substance's intrinsic properties (physicochemical, human health and environment properties) as specified in Annex VII (i. e. data requirements for substance ≥1 and ≤ 10 tonnes) must be included in addition to the information required for isolated intermediates.

If the manufacturer or importer of a substance manufactures or imports *the substance not exclusively for the use as an intermediate*, or if the manufacture or use(s) are not under strictly controlled conditions, then the manufacturer or importer needs to submit a "standard" registration dossier according to the requirements of *Article 10*.

If only part of the tonnage manufactured or imported is for use as intermediate under strictly controlled conditions, this tonnage will not need to be taken into account for the information requirements of the full registration dossier. Nevertheless, use as an intermediate should be documented in the registration dossier, including the volume manufactured or imported for that purpose. ***A separate reduced registration dossier for use as an intermediate under strictly controlled conditions is <u>not</u> required.***

Annex I of this document includes a flow chart that in combination with the aspect highlighted can assist you in determining if your material is an intermediate and if yes, determine which provision will apply to your case.

4. <u>How to define strictly controlled conditions</u>

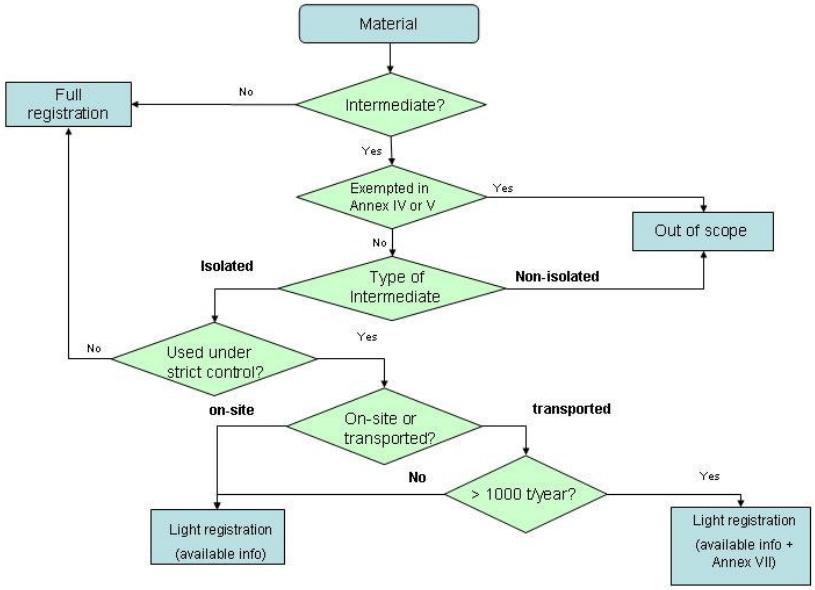
Overall, strictly controlled conditions should be seen as a combination of technical measures that are underpinned by management systems. Article 18(4) states that, in order to assess whether the intermediate is manufactured and used under strictly controlled conditions during its whole lifecycle, the registrant should evaluate whether the following conditions are met:

(a) the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage;
(b) procedural and control technologies shall be used that <u>minimise</u> emission and any resulting exposure;
(c) only properly trained and authorised personnel handle the substance;
(d) in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;
(e) in cases of accident and where waste is generated, procedural and/or control technologies are used to <u>minimise</u> emissions and the resulting exposure during purification or cleaning and maintenance procedures
(f) substance-handling procedures are well documented and strictly supervised by the site operator.

[1] Further information can be found in the ECHA guidance document on intermediates

Guidance on strictly controlled conditions is available in the ECHA guidelines on intermediates. The metals industry has, however, encountered some difficulties when seeking to interpret the available guidance for its inorganic needs, and in particular with regard to the interpretation of the term 'strict control'. Consequently, a Metals industry guidance to be used in combination with the updated ECHA guidance document on intermediates published in February 2008 has been developed.

Annex I – schematic overview



Annex II Summary of obligations for isolated intermediates

On-site isolated intermediates

Registration

Article 2 (7) exempts intermediates listed in Annex IV or V from the general obligation to register substances (e.g., O&C).

Article 2 (8) exempts intermediates from the general obligation to register substances.

A manufacturer of an on-site isolated intermediate has to register his substance in quantities of 1 tonne or more per year, as specified in Chapter 3 of Title II of REACH.

Classification

The manufacturer must notify to the Agency the information related to its classification and labelling if (cf. Art 113);

- he puts the substance on the market (i.e. he makes it available to another legal entity on the same site), and
- he has not already submitted a registration.

Timing:

- before 1st December 2010 for substances already on the market at that date or,
- for substances that were not yet on the market on 1st December 2010, as soon as the substance is put on the market
- If registered before 1 Dec 2010, the C &L is included in the registration dossier and no separate notification is required

Evaluation

Dossier and substance evaluation do not apply for on-site isolated intermediates used under strictly controlled conditions (Art 49)

However, ***the Member State Competent Authority (MSCA***) where the manufacturing site is located may request additional information if it considers that:

- there is a risk to human health or the environment equivalent to the level of concern arising from the use of a substance of very high concern (cf. Art 57); and
- that risk is not properly controlled (cf. Art 49)

Authorisation

All Intermediates are exempted from authorisation (i.e. Title VII)

Any manufacturer/ importer or downstream user must check whether an intermediate is covered by any **restrictions** in Annex XVII of REACH

Transported isolated intermediate

Registration

Article 2 (7) exempts intermediates listed in Annex IV or V from the general obligation to register substances (e.g., O&C).

Article 2 (8) exempts intermediates from the general obligation to register substances.

A manufacturer of a transported isolated intermediate has to register his substance in quantities of 1 tonne or more per year, as specified in Chapter 3 of this guidance.

If a notification under Dir. 67/548/EC covering the relevant use has already been submitted by the manufacturer/ importer, no registration is required.

Classification

The manufacturer/ importer of a phase in substance must notify to the Agency, the information related to its classification and labelling if (cf. Art 113):

- he puts the substance on the market (i.e. he makes it available to another legal entity on the same site or on another site), and
- he has not already submitted a registration.

Timing:

- before 1st December 2010 for substances already on the market at that date or,
- for substances that were not yet on the market on 1st December 2010, as soon as the substance is put on the market
- If registered before 1 Dec 2010, the C &L is included in the registration dossier and no separate notification is required

Evaluation

Dossier and substance evaluation apply to transported isolated intermediates. Unless exempted from evaluation via art 2 (7), e.g. O & C that are not chemically modified.

If there is no agreement between MSCA and the Commission, the Agency may request additional information when it is conducting an evaluation.

The request must be met within the set deadlines.

Authorisation

Intermediates are not subject to authorisation (i.e. Title VII – Authorisation - does not apply).

Any manufacturer/ importer or downstream user must check whether an intermediate is covered by **any restrictions** in Annex XVII of REACH (cf. Art 67)