

SPECIAL PREPARATIONS

Pre-registration

Overview

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Pre- registration in case of special preparations

Legal basis for pre-registration:

Art.28: duty to pre-register phase-in substances:

- name of the substance (EINECS, CAS or other identity codes)
- name and address of the legal entity (+ contact person)
- envisaged deadline and tonnage band



Pre-registration in case of special preparations

Legal entities check

A legal entity is a "natural or legal person" established within the Community (EEA) in the capacity of:

- manufacturer
- importer
- downstream user
- distributor
- only representative (non-EEA manufacturers)

ONLY MANUFACTURERS, IMPORTERS AND OR do register.

- concept of "legal entity" is a national issue, depending upon the law of establishment
- several production sites may be involved within the same group because different legal entities

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Who is the manufacturer? (1)

Art. 3.8: a manufacturing process means producing or extracting a substance in the natural state

- the ownership of the substance is irrelevant
- the responsibility falls on the entity which is actually engaged in the physical production or extraction of the substance

with  out tolling?

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Who is the manufacturer? (2)

Tolling is basically **a service**. In these circumstances, who is the responsible manufacturer?

- REACH addresses safety (to both the environment and the human health)
- since the ownership of the substance is irrelevant, the burden falls on the entities engaged in the production process, **hence the toll smelter (the customer only places on the market)**
- **however, the nature of the tolling process should be considered: "new" substance because of a chemical reaction or mixing/blending operations?**

case  case approach

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Who is the importer?

Art 3.10: import means the physical introduction of the material into the EU (EEA)

HOWEVER: the criteria of "responsible for physical introduction" depends on many factors and on the contractual situation

- the customs clearance might not be either the decisive factor

cd  case approach

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What to do when the manufacturer is outside the EU (EEA)? (1)

- the non-EU manufacturer (NEM) is NOT as such covered by REACH
- however, if he wants to keep importing into the EU (EEA), he has a choice:
 - Either let his **EU importer** to register the substance
 - Or appoint an **only representative** (OR)

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What to do when the manufacturer is outside the EU (EEA)? (2)

-the OR option might be the best choice because:

- it avoids disclosing potentially sensitive information to customers/importers in the EU
- EU customers are relieved from registration obligations: in this case, importers become **downstream users**

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Who can be an OR (only representative)?

- Must have a "sufficient background" in the practical handling of substances and have the related information to them
- Must be a legal entity established in the EU (EEA)
- May be a party external to the company/group: law firm, consultant etc...

 Important to identify within the supply chain who is responsible for what

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Definitions relevant for (pre-)registration:

Alloy means (Art. 3. 39): a metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they can not be readily separated by mechanical means.

Preparation means: a mixture or solution composed of two or more substances;

Multi-constituent substance means: a substance, defined by its quantitative composition, in which more than one main constituent is present in a concentration $> 10\%$ (w/w) and $< 80\%$ (w/w).

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Definitions relevant for **assessment**:

Annex I 0.11 When assessing the risk of the use of one or more substances incorporated into a **special preparation** (for instance alloys), the way the constituent substances are bonded in the chemical matrix shall be taken into account.

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What to (pre-)register (1)?

Article 6, Paragraph 1 (Registration):

Save where this Regulation provides otherwise, any manufacturer or importer of a substance, **either on its own or in one or more preparation(s)**, in quantities of 1 ton or more per year shall submit a registration to the Agency.

Commission (DG ENT): an alloy made of ores by a process which chemically modifies the raw materials implies that the constituents of the alloy must be registered, because, by this process, new substances are placed on the market (strict interpretation of Art. 6).

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What to (pre-)register (2)?

	Smelted Alloys (*)	Melted Alloys(**)
EEA manufacturers	Registration of constituents or MCS	No registration (downstream use) if constituents have been already registered by the M and/or importer
Importers	Registration of constituents or MCS	Registration of constituents

NO REGISTRATION OF IMPURITIES

(*) *chemical transformation: Heating and alumino-carbo-silico thermic reduction of ores/concentrates*

(**) *no chemical transformation: blending, mixing, ...*

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What to (pre-)register (3)?

It appears that the need for **a chemical reaction is core to:**

- the possible options opened to alloys in terms of (pre)-registration: only alloys produced by a chemical reaction can be **(pre)registered as MCS**
- on the contrary, melted alloys (without a chemical reaction) can never be (pre)registered as MCS
- smelted alloys are NEVER a downstream use of their constituents
- in parallel, a **tolling** smelter becomes a manufacturer responsible for REACH if the tolling process implies a chemical reaction creating a « new substance »