

Position paper on impurities

Overview and definitions

“Impurity” is not defined in the REACH Regulation. A definition of impurity is included in the Guidance Document for “identification and naming of substances” (see Chapter 2.2)¹:

Impurity: *An unintended constituent present in a substance as manufactured. It may originate from the starting materials or be the result of secondary or incomplete reactions during the manufacture process. While it is present in the final substance it was not intentionally added.*

The definition of “substance” (see Art 3 of the REACH Regulation)² includes a reference to impurities:

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*

According to the above definition, a substance has to be considered together with the associated impurities. Because only substances (either on their own or included in preparations or articles) need to be registered, there is no obligation to register impurities as separate substances.

This provision is further developed in the Guidance Document for identification and naming of substances as of May 2017, where a convention to distinguish between “**mono-constituent**” and “**multi-constituent**” substances is elaborated on the basis of the contents of “main constituents” and “impurities”. This reads as follows:

¹ https://echa.europa.eu/documents/10162/2324906/substance_id_en.pdf/ee696bad-49f6-4fec-b8b7-2c3706113c7d?t=1525879053278

² <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410>

Mono-constituent substance: As a general rule, a substance, defined by its composition, in which one main constituent is present to at least 80% (w/w).

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

Impurities in metal alloys

Metallic alloys do not conform to either the definition of a substance or preparation. REACH recognises steels and other metallic alloys as ‘special mixture’ [see Art. 3 (41) and Annex I point 0.11]³.

Alloy means a metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means.

Steel alloys, according to the different steel grades, contain substances as alloying elements that play a specific function in the material and need to be present in certain percentages to give the material the needed properties. These alloying elements are intentionally added or controlled in the manufacturing process.

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

For these reasons these substances even if they might be present in very small percentages, can not be treated as impurities, and, if totalling more than 1 ton per year, need to be properly registered by manufacturers or importers.

Nevertheless, metals and alloys can contain substances that can originate from source material (ores, coal, recovered scrap, etc.) or generated during the process, which are not intentionally added and not needed (i.e. according to the specific steel grade) but still present in very low percentages in the manufactured or imported material.

These substances can be treated as impurities and therefore, regardless of their total quantity per year involved in manufacturing or importing, they are not subject to registration.

In some cases, impurities might be relevant for the hazard profile of a substance in which they occur and therefore should be properly considered in the information to be included in the registration dossier for that single metal or substance concerned.

Commented [PK1]: Alloy means a metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means

³<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410>

Impurities in recovered waste

On the assumption that the following provisions of Article 2(7)(d) are fulfilled, the recovered substances from the waste (*whether it be imported or produced in the EU*) would be exempted from registration:

- the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and
- the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery.

Recovered waste may contain some impurities which are unintended constituents that have no function for the recycled material and do not change the chemical identity of the substances selected for recycling. The only reason for their presence in the material is that they were part of the input waste for the recycling process. Waste sorting can never reach 100% purity free of alien elements and it's unavoidable that some small fractions of these elements are still present in the recovered waste.

Such elements have to be considered impurities that do not need to be registered and, most important, do not affect the sameness of substances required by Article 2(7)d.

This document was updated according to current legislation in force.

"Important Notice: This position paper is intended as a supplement to the REACH Regulation and the official REACH Technical Guidance Documents published by the European Chemicals Agency (ECHA). It is provided as an advisory document and, as such, has no legal standing. Therefore, in conjunction with this position paper, users are advised to consult Regulation EC 1907/2006 (for the legally binding requirements of REACH) and the official REACH Technical Guidance Documents (for detailed information on REACH implementation). It may also be appropriate to seek independent legal advice on matters related to pre-registration and registration. While every effort has been made to ensure the accuracy of this document, neither EUROFER nor the authors of this document accept liability for its content or for the use which might be made of the information herein."