EUROMETAUX
EUROPEAN ASSOCIATION OF METALS

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Fact sheet on: "Not Chemically Modified" as it applies to minerals, ores and ore concentrates in the REACH Regulation[1].

1. Introduction

The definition of "not chemically modified" is critical for deciding if a material falls within the scope of REACh, and it is therefore critical for :

- Deciding whether or not a material needs to be Pre-Registered;
- Determining the overall costs of Registration per company;
- Determining to what extent current Material Safety Data Sheets should be modified.

a correct interpretation of the definition is also crucial for determining:

- How many similar materials can be grouped under the same Substance ID
- To what level of detail the composition of the material must be described
- If the material itself, or its individual constituents, must be Registered
- If the lighter Registration requirements for intermediates apply

This, in turn, depends on whether:

- The material is a well-defined multi-constituent substance, a UVCB[2] sub-type 2, UVCB sub-type 4 or a preparation, and
- Whether or not the exemption from Registration for naturally occurring substances (granted in Annex V.7) applies

For detailed guidance on how the definition of "not chemically modified" determines how best to *identify* your material, please refer to the separate fact sheet on "Substance ID".

This present paper aims to clarify the point at which, in the metal supply chain, naturally occurring substances have become chemically modified and the exemption in Annex V.7 of REACH no longer applies.

2. Definitions

Annex V of the REACH Regulation lists substances exempt from Registration. Section 7 reads:

- "The following substances which occur in nature, if they are not chemically modified. Minerals, ores, ore concentrates…"

With reference to the above quote, REACH provides a definition for the terms "substances which occur in nature" and "not chemically modified", but does not define minerals, ores or ore concentrates.

- "Article 3.37: Substances which occur in nature: means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by

[1] This Fact Sheet has been developed by Euromines and is supported by all EM members

[2] Substances of Unknown or Variable composition, Complex reaction products or Biological materials

steam distillation or by heating solely to remove water, or which is extracted from air by any means."

- "Article 3.38: Not chemically modified substance: means a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities."

For the purposes of this paper, it is helpful to consider the following definitions:

- "A mineral is a naturally occurring crystalline compound."
- "An ore is a naturally occurring material, composed of one or more metal-bearing minerals, of sufficient quantity and quality to be mined at profit."
- "An ore concentrate is an ore, upgraded by various means to remove minerals of no economic interest, thus leaving a higher concentration of the metal-bearing minerals."

REACH only refers to ore concentrates under the heading "substances which occur in nature, if they are not chemically modified".

Consequently, for the purpose of complying with REACH, the definition of our ore concentrates may arguably viewed as should therefore be limited in this way, although individual organisations, through custom and practice, often classify downstream chemically modified derivative materials as "concentrates".

3. An Apparent Mismatch – Removal of Impurities

- The definition of "substances which occur in nature" in Article 3.37 does not allow any chemical modification.
- However, in the definition of "not chemically modified", Article 3.38 allows for a "chemical process or treatment to remove impurities".

It may be argued that, if (i) only the impurity itself is chemically transformed and (ii) a physical process, covered by Article 3.37, is then used to separate it out, then one has not strayed outside either definition. An example would be sulphuric acid washing to remove a magnesium-bearing impurity from a zinc-bearing mineral. This seems consistent both with the spirit of the law and the juxtaposition of the two phrases.

4. An Apparent Mismatch – Synthetic Minerals

- The EChA Guidance for the identification and naming of substances (RIP3.10) states that minerals that are produced through a manufacturing process can – for the purpose of identification - be regarded to be the same as their naturally occurring equivalent, provided the composition is similar and the toxicity profile identical. An example would be the synthesis of haematite from magnetite ore.

- This implies that the legal requirements (e.g. exemptions from registration) for minerals produced through a manufacturing process and fulfilling the above mentioned conditions are also the same as those for their naturally occurring equivalent. However, no confirmation of this is currently available.

5. Options for the industry:

It is suggested/recommended that the full production chain of each material is considered on a case-by-case basis in order for the industry to decide at which point a chemical modification takes place.

In this way, industry sectors could be in a position to agree which process steps are "chemical modifications" before determining which naturally occurring minerals ores & ore concentrates might be "not chemically modified".

Mineral, Ore or Ore Concentrate Processing Step	Chemical Modification ?	
Optical/Mechanised Sorting		No
Magnetic/Electrostatic Separation		No
Gravity or Dense Medium Separation		No
Preferential Crushing, Grinding or Milling		No
Screening, Hydrocycloning or Classification		No
Agglomeration or Froth Flotation		No
Thickening & Filtration		No
Drying (or calcination that results in removal of water & impurities only)		No
Pelletising by granulation only		No
Leaching/Washing Processes to remove impurities		No
Leaching Processes to extract the value-mineral	Yes	
Pelletising with sintering	Yes	
Ion-Exchange, Solvent Extraction or Electro-winning	Yes	
Pressure Digestion in aqueous NaOH	Yes	
Sintering, Roasting & Smelting	Yes	
Calcination involving changes in the chemical structure (e.g., CO_2 release)	Yes	
Precipitation and gas precipitation	Yes	