EUROMETAUX
EUROPEAN ASSOCIATION OF METALS

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Fact Sheet on Identification of Materials for REACH

1. Introduction

Correct identification of a substance within the context of REACH is necessary for;

- **Pre-Registration** [as per Annex VI Sections 2 to 2.1.5]
- **Light Registration as an intermediate** [as per Annex VI Sections 2 to 2.3.4]
- **Full Registration** [as per Annex VI Sections 2 to 2.3.7]
- **Notification of Substances in Articles** [as per Annex VI Sections 2 to 2.3.4]
- Reporting separate **Chemical Safety Reports for a Substance** [as per Annex VI Sections 2 to 2.3.4]
- Inquiring about the identity of **"new" substances** [as per Annex VI Sections 2 to 2.3.7]
- Notification for **Classification & Labelling** [as per Annex VI Sections 2 to 2.3.4]
- Applying for **Authorisation** of use(s) [as per Annex VI Sections 2 to 2.3.7]

2. Key Questions

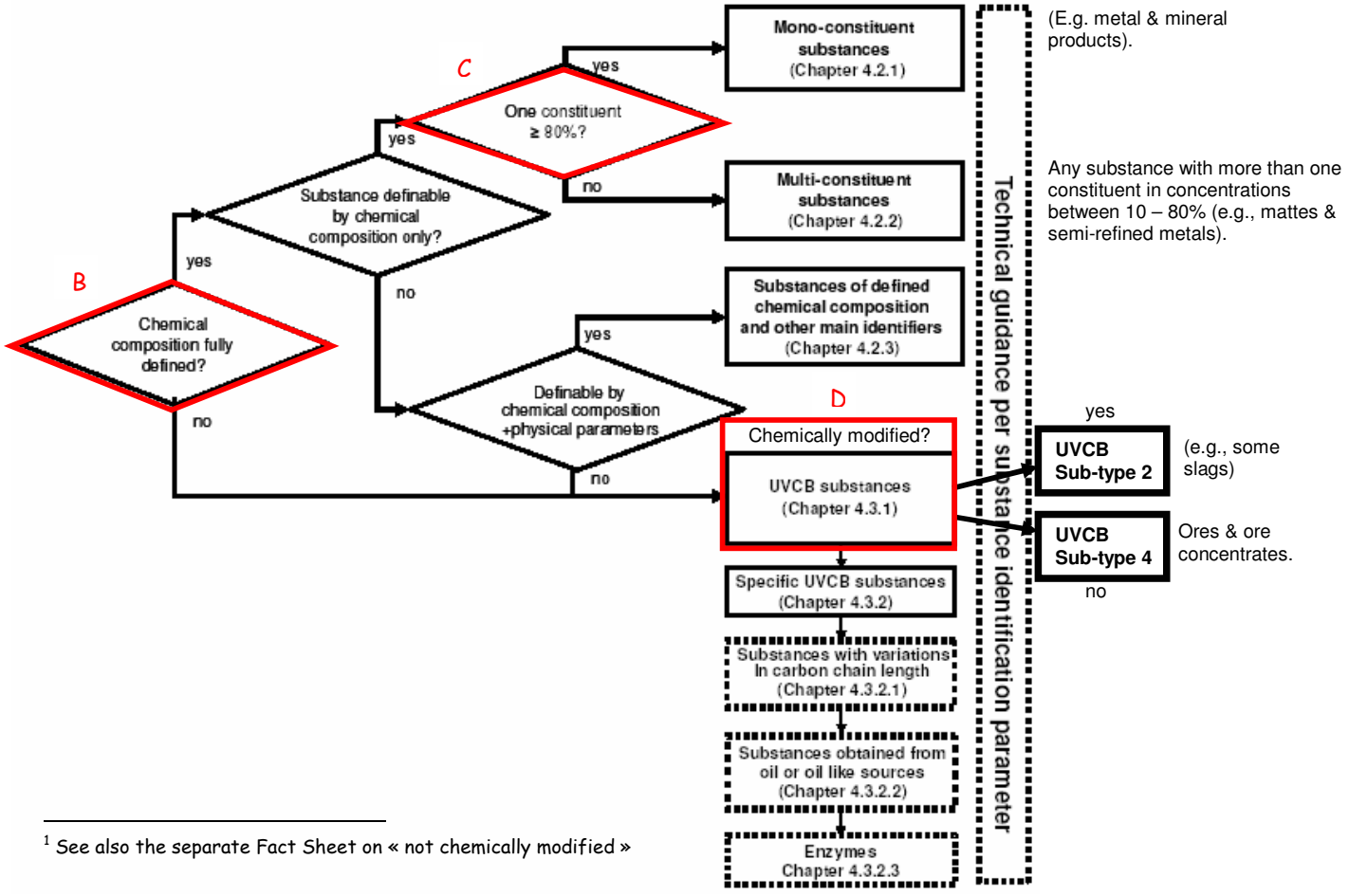
When identifying inorganic materials in the metals sector, the four key questions to ask are;

A. Is the material an individual substance or a mixture of substances, i.e. a preparation or special preparation?

B. Can the chemical composition be fully defined with relevant & accessible data which exist?

C. Is one constituent substance present in concentrations greater than 80%?

D. Is the material the result of a process-step, which is considered to be a "chemical modification"? If yes, has the process-step changed the chemical structure of the material?[1]



[1] See also the separate Fact Sheet on « not chemically modified »

3. Definition of Preparation

- Article 3.2: Preparation: means a mixture or solution composed of two or more substances.
- Definition in GHS: "Mixture means a mixture or solution of two or more substances which do not react (Mixture and preparation are synonymous)"
- ECHA Guidance for substance identification and naming: Preparations are intentional mixtures of two or more substances without an intended chemical reaction.
- Special preparation: means a mixture in which the properties of the constituent substances are modulated by their inclusion within the chemical matrix[2]
- REACH does not explicitly define **minerals, ores & ore concentrates**. Annex V.7 implies they are all **substances** which occur in nature, i.e. they are substances and not preparations.
- The flowchart on the previous page is only applying to substances

4. Defining Chemical Composition

- For well-defined substances, the following are known; Degree of purity (%), Nature of impurities, including isomers and by-products, Percentage of (significant) main impurities.
- Variability for well defined substances is specified by the upper and lower limit of the concentration range(s) of the main constituent(s).
- If the material cannot be sufficiently identified by the above items, it should be identified as a UVCB. This would be the case, e.g., when the number of constituents is relatively large and/**or** the composition is, to a significant part, unknown and/**or** the variability of composition is relatively large or poorly predictable.

Options for Reaction Products with <80% purity

Options	Main Requirements	Pros	Cons
Consider material as **Preparation**	Chemical Safety Assessment per Component (plus possibly Socio-Economic Assessment for Authorisation per CMR)	Can share costs with manufacturers/importers of the component substances.	**Contradicts guidance** in RIP3.10 because an intended chemical reaction has taken place.
Consider material as **UVCB**	Chemical Safety Assessment if not an intermediate (plus Socio-Economic Assessment for Authorisation if not an intermediate and classified CMR)	Follows RIP3.10 guidance.	Only possible when the composition is **insufficiently known** or variability is large.
Consider material as **Multi-Constituent Substance**		Maintains Phase-In status provided all constituents have an EINECS entry.	Requires 100% identification of constituents. Allows less sharing of costs.

5. The 80% Rule

Multi-constituent substances are distinguished from mono-constituent substances by application of the 80% rule, that indicates that the main constituent needs to be present in ratios of at least 80% (w/w). However, a deviation from this 80% rule can be justified. Possible examples for a justified deviation are:

- If the main constituent is < 80% but the substance can be shown to have similar physicochemical properties and the same hazard profile as other mono-constituent substances with the same identity that fulfil the 80% rule.

[2] see also EM/EIMAG guidance document on special preparations

- The range of concentrations for the main constituent and the impurities overlap the 80% criterion and the main constituent is only occasionally ≤ 80%..

6. Chemical Modification or Intended Chemical Reactions

The definition of "not chemically modified" is critical for deciding how many similar materials can be grouped under the same Substance ID for the purposes of REACH. Well-defined multi-constituent substances are generally considered to be reaction products and are therefore normally subject to Registration. UVCBs can either be reaction products or naturally occurring substances, which are exempt from Registration. The separate Fact Sheet on "Not Chemically Modified" suggests which process steps should be considered "chemical modifications" for the purposes of REACH.

7. Describing Composition

Although mineral speciation is more accurate, currently available data is generally limited to chemical species. It should be possible to develop generic Substance IDs for materials in the metals sector by describing the full range of major constituents (chemical), minor constituents (chemical) ***and*** predominant minerals. e.g.,

Name	Copper concentrate obtained from crushed copper ore by conventional mineral processing (e.g., flotation)
Source	Copper ore obtained from natural deposits of of chalcopyrite, bornite,…, chalcocite and their oxidised zones by mining.
Process	Crushing and flotation of mined copper ore to separate valuable minerals from low-grade materials, typically increasing their concentration by a factor of up to one-hundred.
Composition	Typically contains X% Arsenic compounds in the following mineral forms,… etc. etc.

Annex VI Substance ID Item		Required for,…	Relevance to UVCBs
2.1	**Name or other identifier of each substance**	**All Provisions**	**To include source and most relevant process steps in generic terms. Processes are identified by the type of refinement step e.g., extraction, fractioning, concentration or the type of chemical reaction. Any concentration step shall be specified together with the generic composition of the resulting substance in comparison to the starting material.**
2.1.1	**Name(s) in the IUPAC nomenclature**		**For constituents present in concentrations >10% if available.**
2.1.2	**Other names (usual name, trade name, abbreviation)**		**For UVCBs any one (or more) of these alternative identifiers can be provided.**
2.1.3	**EINECS or ELINCS number**		
2.1.4	**CAS name and CAS number**		
2.1.5	**Other identity code**		
2.2	Information related to molecular and structural formula	For Classification & Labelling, Full Registration or	Not relevant to inorganic UVCBs

2.3	**Composition of each substance**	Authorisation	**To be provided in a generic way, with typical concentrations and concentration ranges of known & classified constituents.**
2.3.1	Degree of purity		Not Relevant to UVCBs
2.3.2	Nature of impurities		
2.3.3	Percentage of (significant) main impurities		
2.3.4	**Nature and order of magnitude of any additives**		**Relevant**
2.3.5	Spectral data	Only for Full Registration or Authorisation	Not Relevant to UVCBs
2.3.6	High-pressure liquid chromatogram, gas chromatogram		
2.3.7	Description of the analytical methods		