Factsheet
REACH & intermediates

Note: the objective of this factsheet is to clarify the circumstances under which a substance may or may not be regarded as an intermediate under REACH.
For the specific conditions that need to be fulfilled by registrants in order to make use of the specific registration requirements covered by Articles 17 and 18 of the REACH Regulation, please refer to the factsheet on SCC.

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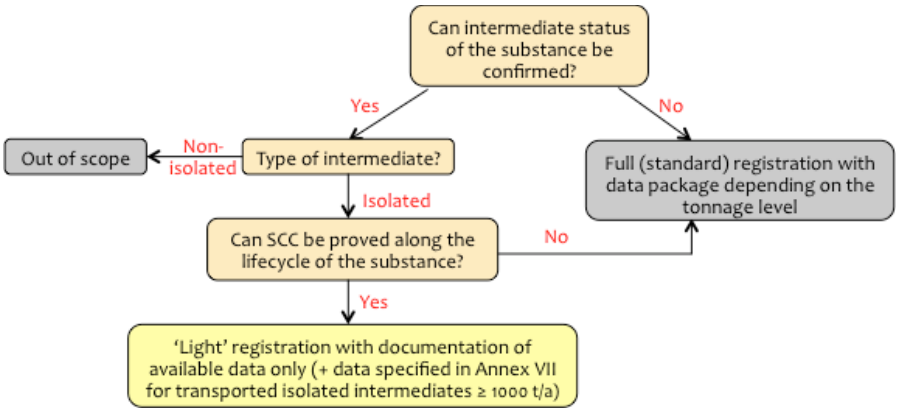
1. Intermediates under REACH: how are they regulated?

- Intermediates are a class of substances for which specific provisions have been laid down under REACH for reasons of workability and because of their special nature (recital 41).

- REACH distinguishes between non-isolated and isolated intermediates:
  - REACH Regulation does not apply to non-isolated intermediates.
  - Isolated intermediates are ruled under REACH but benefit from **reduced Registration requirements**, provided their manufacture and use take place under the conditions set in Article 17 and 18 (strictly controlled conditions or SCC). Moreover a reduced fee will apply for the Registration of an intermediate under SCC.



  - For *on-site* isolated intermediates used under SCC, neither dossier nor substance evaluation apply (Article 49). However, where the MSCA considers that a risk to human health or the environment, equivalent to the one triggering listing under Authorisation, arises from the use of an on-site isolated intermediate and that risk is not properly controlled, it may require more information and risk management measures. Dossier and substance evaluation do apply to *transported* isolated intermediates.
  - (*On-site* and *transported*) isolated intermediates are exempt from Authorisation (Article 2(8)). For *on-site* isolated intermediates, the provisions on introducing new and amending current restrictions (Article 68(1)) do not apply.

- Should a substance be no longer used by a registrant as an intermediate only and/or the registrant can no longer confirm that the substance is manufactured and used under SCC, the registration dossier will need to be updated according to Article 22(1) without undue delay to include, depending on the tonnage band within which the substance is registered, all the information required by Articles 10 and 12.

- For the proper implementation of the REACH Regulation, the status of a substance as to whether it is an isolated intermediate or not should be **unequivocal**.

2. How is an intermediate defined under REACH?

2.1. Aim is to be chemically transformed (intended process)

- REACH 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**". Intermediates should therefore not be present in the final manufactured substance (except possibly as an impurity). It is stressed that an intermediate must be manufactured **for the purpose of** being chemically transformed into another substance in a subsequent step. The substance should effectively be used (i.e. transformed into another substance) in such a subsequent step, in order to be regarded as an intermediate.

- The lifecycle of an isolated intermediate begins with its manufacture and ends with the use of the substance in the synthesis process for the manufacture of another substance (with its own lifecycle).

- Examples (underlined substances are intermediates):
  - Substance A -> Substance B -> Substance C
  - Substance A containing Substance C -> Substance B containing Substance C -> Substance C

- The status of a substance as an intermediate is not specific to its chemical nature but to how it is used. In this respect, this identification is strongly linked to the definition of an **intermediate use of a substance**: for each substance considered as intermediate, only the quantity of that substance that is consumed in or used for chemical processing in order to be transformed into another substance is regarded as intermediate. Any other quantity of the same substance is not regarded as an intermediate. In the new IUCLID 5.4, released 5 June 2012, it is possible to better allocate uses and tonnages. In section 3.2, the registrant has to report the tonnage for own use (including both uses as an intermediate and as a non-intermediate), the tonnage manufactured for use as on-site intermediate under SCC and the tonnage manufactured / imported for use as transported isolated intermediate under SCC. This way, the quantity of a substance used as intermediate under SCC will be easily identifiable.

- **As soon as the main aim of the chemical process is not to transform a substance (A) into another substance (B), or when substance (A) is not used for this main aim but to achieve another function, substance (A) used for this activity should not be regarded as an intermediate under REACH.** It is therefore key in the definition of an intermediate that the manufacturer of the intermediate is certain that a customer of the intermediate is a manufacturer of another substance using the intermediate for chemical processing (synthesis) into that other substance. In case the customer is using the substance for other processes than for synthesising another substance, the substance is not considered to be an isolated intermediate.
  - **Reactants** are not intermediates unless they (partially or fully) transform into the resulting substance, product of the reaction.
  - **Catalysts** (used to change the rate of chemical reactions) are not intermediates because they are not used to be themselves converted into the manufactured substance.
  - **Processing agents** aimed at optimising the physico-chemical environment of the reaction medium (e.g. dispersing agents, pH-regulating agents, viscosity modifiers, lubricants and lubricant additives, antistatic agents, fluxes) are not intermediates because they are not used to be themselves converted into another substance. This applies even if they end up as impurities in the manufactured substance.
  - Following technical functions are incompatible with the technical function of an intermediate: agents adsorbing and absorbing gases or liquids, binding agents, colouring agents, pigments, bleaching agents, fertilisers, fillers, flame retardants, flotation agents, and tanning agents.

- In case of **remainders** of the isolated intermediate:
  - when they are not transformed into another substance in a manufacturing process, they will typically be discarded or disposed of as **waste** (waste management) or recycled as a non-isolated or isolated intermediate. Consequently, they may or not fall in the scope of REACH.
  - where they are found in the synthesised substance, they are covered (as an **impurity**) by the registration and evaluation of that other substance.

- In Appendix 4 of the 2010 ECHA Guidance on intermediates, some examples can be found on intermediates.

2.2. Chemical modification must be demonstrated

The full production chain of each material should be considered on a case-by-case basis in order for registrants to decide when chemical modification takes place.

An overview of processes applied to minerals, ores and ore concentrates and whether they cause chemical modification is given in the below table (source: Eurométaux Fact sheet 2008, adjusted for the PM sector), for general guidance.

Mineral, Ore, Ore Concentrate Processing Step	Chemical modification?		Oxidation / Reduction
Optical/Mechanised Sorting		No	Can be oxidation ('impurity removal')
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		No
Pelletising with sintering	Yes		No
Ion-exchange, solvent extraction or electro-winning, electro-refining	Yes		No
Pressure Digestion in aqueous NaOH	Yes		No
Sintering, Roasting & Smelting	Yes		Oxidation
Calcination involving changes in the chemical structure (e.g., CO_2 release)	Yes		Oxidation
Cementation and reduction, precipitation and gas precipitation	Yes		Reduction
Distillation	Yes		Can be oxidation (Ru/Os)

In September 2012, ECHA conducted an IT-based screening to check whether REACH intermediate registration dossiers contain information that put into question the transformation of the substance during chemical processing and/or the SCC until its transformation. The tool screens the use descriptors (PROCs and ERCs) applied for the intermediate dossier submissions.

After clarification by Eurométaux with ECHA regarding the technical aspects related to metal PROCs and their compatibility with the intermediate definition / SCC, the following use descriptors have been identified as not compatible with the definition of an intermediate under REACH, as they are not expected in the context of chemical processing (synthesis):

PROC / ERC nr	Name of PROC/ERC incompatible with intermediate definition
PROC10	Roller application or brushing
PROC11	Non industrial spraying
PROC12	Use of blowing agents in manufacture of foam
PROC13	Treatment of articles by dipping & pouring
PROC16	Using material as fuel sources, limited exposure to unburned product to be expected
PROC17	Lubrication at high energy conditions & in partly open process
PROC18	Greasing at high energy conditions
PROC20	Heat & pressure transfer fluids in dispersive, professional use but closed systems
PROC23	Open processing & transfer operations with minerals/metals at elevated temperature
PROC25	Other hot work operations with metals
ERC3	Formulation in materials
ERC4	Industrial use of processing aids in processes & products, not becoming part of articles
ERC5	Industrial use resulting in inclusion into or onto a matrix
ERC6b	Industrial use of reactive processing aids
ERC6c	Industrial use of monomers for manufacture of thermo-plastics
ERC7	Industrial use of substances in closed systems
ERC8a	Wide dispersive indoor use of processing aids in open systems
ERC8b	Wide dispersive indoor use of reactive substances in open systems
ERC8c	Wide dispersive indoor use resulting in inclusion into or onto a matrix
ERC8d	Wide dispersive outdoor use of processing aids in open systems
ERC8e	Wide dispersive outdoor use of reactive substances in open systems
ERC8f	Wide dispersive outdoor use resulting in inclusion into or onto a matrix
ERC9a	Wide dispersive indoor use of substances in closed systems
ERC9b	Wide dispersive outdoor use of substances in closed systems
ERC10a	Wide dispersive outdoor use of long-life articles & materials with low release
ERC10b	Wide dispersive outdoor use of long-life articles & materials with high or intended release (incl. abrasive processing)
ERC11a	Wide dispersive indoor use of long-life articles & materials with low release
ERC11b	Wide dispersive indoor use of long-life articles & materials with high or intended release (incl. abrasive processing)
ERC12a	Industrial processing of articles with abrasive techniques (low release)
ERC12b	Industrial processing of articles with abrasive techniques (high release)

Note that wide dispersive uses (uses outside of industrial sites) are generally incompatible with the intermediate status. Intermediates are always used within industrial processes.

Below use descriptors can be compatible with the definition of an intermediate under REACH, **but adequate justification should be provided in Appendix 3** (linking the use descriptors with the appropriate handling/processing steps), explaining these use descriptors apply to pre-transformation / post-transformation steps of the intermediate and not to the chemical transformation process itself:

PROC number	Name of PROC compatible with intermediate definition if appropriately justified in Appendix 3
PROC6	Calendering operations
PROC7	Industrial spraying
PROC14	Production of preparations or articles by tabletting, compression, extrusion, pelletisation
PROC19	Hand-mixing with intimate contact and only PPE available
PROC21	Low energy manipulation of substances bound in materials and/or articles
PROC24	High (mechanical) energy work-up of substances bound in materials and/or articles

In addition to above use descriptors, there are some PROCs that ECHA considers not compatible with the requirement on SCC or that require particular explanation on the applied technical process in order to justify that SCC can be met (cf. factsheet on SCC).

3. How to prepare for inspections on intermediate status?

If a substance is identified as an intermediate, it is important to provide evidence and extensive documentation on this choice. **To demonstrate the intermediate status of their substance, registrants should have a full description of the synthesis route of the manufacture of the intermediate and of each substance manufactured from the intermediate** (e.g. in the form of a chemical reaction scheme).

This includes (for all the processes covered by the registration in which the intermediate is transformed into another substance):

i. A description of the **relevant chemical reactions** taking place when the intermediate is used to manufacture another substance. Ensure that all relevant activities (unit operations) are covered in this description, such as synthesis, purification steps, cleaning and maintenance, sampling and analysis, loading and unloading, storage and waste treatment;
ii. A description of the **technical role** in the process for which the intermediate is used in the manufacturing process of the other substance. The description shall include:
    - Justifications as to why the substances cannot be manufactured without the intermediate and;
    - Justifications as to why the presence of any reaction product from the intermediate is essential to the composition of the manufactured substance;
iii. The chemical identity of the **substance manufactured from the intermediate**;
iv. Whether the substance manufactured from the intermediate is:
    - A substance on its own or;
    - A substance in a mixture;
v. Whether the substance manufactured from the intermediate is subject to registration requirements under the REACH Regulation and if not: the reason why;
vi. If the isolated intermediate is **transported** to the site(s) of downstream user(s) (DUs):
    - A detailed description of the synthesis route of each substance manufactured by the DU(s) from the intermediate, including the information in sections i-v above, or;
    - Any relevant documentary evidence that the transformation of the intermediate into substance(s) manufactured by each DU was certain (e.g. a letter from the DU(s) confirming that the substance is used as an intermediate as defined in Article 3(15) of the REACH Regulation or a letter to the DU(s) restricting the use of the substance to intermediate use as defined in Article 3(15) of the REACH Regulation).

It is important to note that ECHA and MS act jointly: following ECHA inquiries, there has been on-site verification by MS. Ideally, registrants should have all above information available at their premises for consultation by ECHA / MS upon inspections.

If the intermediate status of their substance cannot be demonstrated and the substance is not covered by the waste legislation (cf. factsheet on waste), registrants will need to update their registration dossier without undue delay to include, depending on the tonnage band within which the substance is registered, all the information required by Articles 10 and 12.