

Comments from the non-ferrous metals industry to

***Annex I, Table 1 (Non suitable process categories in intermediate dossiers) of ECHA letter
“Screening of registration dossiers for intermediates” dated 13 September 2012***

Date: 7 October 2012

Reasoning:

Registrants of the metals’ sector have selected PROCs in their dossiers to describe processes, for manufacture and use of substances, including intermediates. By selecting relevant, specific PROCs, the registrant describes the substance intermediate use in detail, providing a clear picture on the entire process including all process steps relevant for manufacture or use of the substance.

Our comments on the Table on “Non suitable process categories in intermediate dossiers” of ECHA refer to the following considerations:

1. Existence of “pre-transformation-steps” before the actual chemical transformation process occurs. Such steps are covered by e.g. PROC 14, 19, 21, 24.
2. Definition of PROCs not being conclusive on the level of containment, e.g. PROC 22, 26, 27.
3. Other aspects

1. **Existence of pre-transformation-steps in metal processes: PROCs and compliance with intermediate definition, as provided in Article 3(15) (e.g. PROC 14, 19, 21, 24)**

- **REACH Requirements:** The REACH regulation requires that an intermediate has to be “...consumed in or used for chemical processing in order to be transformed into another substance...”. (Article 3 (15)). The ECHA guidance, Appendix IV, page 35 further elaborates on this: “Due to the practical nature of manufacturing processes [...], one or more steps between the manufacturing of the substance (A) and its use in the manufacturing of substance (B) may be necessary to facilitate/ensure proper chemical processing.”
- **ECHA observation letter:** Most of the listed non-compatible PROCs refers to processes, which are not likely to involve a chemical transformation of the handled substance.
- **Metal sector approach:** the level of information the registrant is providing is not reduced applying the intermediate definition. For example, for transported intermediates, “packaging” or “filling” processes at the manufacturer level and “unpacking” or “emptying” processes at the user level are to be considered, respectively. Such transfer processes already indicate the practical need of “in-between-process-steps” for intermediates. Additionally, other process steps commonly used prior to chemical transformation are also applicable to intermediates. As a consequence, the reasoning as given by ECHA “*This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.*” appears somewhat incomplete. **Article 3 (15) explicitly includes any processing of the intermediate as long as the (final) purpose is the chemical transformation.** The ECHA guidance on intermediates, Appendix IV, page 35 further explains “...these steps do not alter the fact that the substance for and use in synthesis and do therefore not discredit the substance from being an intermediate.
- **Example:** Such processing could include (pre-)processes in which the physical appearance of the intermediate has to be modified (e.g. modification of particle size of a powder by milling) in order to increase the efficiency of the chemical transformation. Another example for such “pre-transformation processes” is the spraying of a solution in a spraying tower to produce crystals which are potentially the required physical form for the chemical transformation

2. Non-compliance with strictly controlled conditions as provided in Article 17 and Article 18, associated with the description of the PROC (e.g. PROC 22, 26, 27)

- **REACH requirements:** if an intermediate is used under strictly controlled conditions (SCC) (Art 17 and Art 18), the registration requirements are less. With regards to PROCs, one element of these SCC is of particular importance: rigorous containment. Only if the substance is rigorously contained during its entire life cycle, reduced information requirements shall apply.
- **ECHA observation letter:** ECHA distinguishes between (A) PROCs that are “not compatible with the requirement on strictly controlled conditions as set out in Article 17(3) and 18(4) of REACH.” and (B) PROCs that are “without adequate justification, unlikely to be compatible”.
- **Metal sector approach**
 - a) PROC that are not compatible with the requirements of SCC: some PROCs selected by industry explicitly mentioned the opportunity for exposure or direct contact (e.g. PROC4 and PROC5). It is fully agreed that these PROCs are not compatible with SCC. Where such PROCs were erroneously selected, these will be removed or replaced as appropriate.
 - b) PROCs that require adequate justification: the definition of PROCs like PROC22, are not explicit on the level of containment. For standard REACH registrations, that allowed for some flexibility as a reflection of existing differences between metal commodities and plants. Thus, the assessment of compliance with SCC should not only rely on a specific PROC definition but also on the justification provided for the associated individual process step in Appendix 3.
 - c) PROCs that require adequate justification: PROC8a, 26, 27a and 27b should be seen as PROC that “without adequate justification”, are unlikely to be compatible with SCCs, since the conditions of use or the level of containment are not mentioned in the definitions. In such cases, the assessment of SCCs should rely not only on the PROCs but also on the justification provided in Appendix 3.

3) Other aspects

PROCs have been used as one important exposure determinant in Tier 1 exposure assessment tools. It is however commonly acknowledged that such use of PROCs is associated with varying levels of details regarding the actual exposure settings. In particular, containment measures are sometimes explicitly addressed, whereas such indications are vague or completely missing for other PROCs.. If the latter PROCs would be updated, impacts on the first tier exposure assessment tool for metals “MEASE” will be checked.

PROCs information is available in an easily accessible format, which allows ECHA ad-hoc comparisons of reported containment measures for specific sub-processes. Additionally, Information on conducted processes may help regulators to understand why certain containment measures were selected and how rigorous containment was achieved. In this respect, forcing registrants to focus only on a limited number of PROCs would reduce the level of information.

PROC	Process Categories Description	REASONING ECHA	Concerns of the non-ferrous metals industry	Example
PROC4	Use in batch and other process (synthesis) where opportunity for exposure arises	This category is not compatible with the requirement on strictly controlled conditions as set out in Article 17(3) and 18(4) of REACH.	No comment.	
PROC5	Mixing or blending in batch processes for formulation of preparations* and articles (multistage and/or significant contact)	This category is not compatible with the requirement on strictly controlled conditions as set out in Article 17(3) and 18(4) of REACH.	No comment.	
PROC6	Calendering operations	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.	It is agreed that this process is unlikely to lead to chemical transformation. However, to fulfil the intermediate definition according to Article 3 (15), it is not required that each process in which the substance is used is a chemical transformation process. It is only required that the substance is produced for the purpose of transformation and will be finally transformed into another substance.	
PROC7	Industrial spraying	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.	It is agreed that this process is unlikely to lead to chemical transformation. However, to fulfil the intermediate definition according to Article 3 (15), it is not required that each process in which the substance is used is a chemical transformation process. It is only required that the substance is produced for the purpose of transformation and will be finally transformed into another substance.	Crystallisation In the production of specific inorganic substances (aqueous) solutions are sprayed in "spray towers". The resulting crystals could then be chemically transformed.

PROC8a	Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities.	This category is, without adequate justification, unlikely to be compatible with the requirement on strictly controlled conditions as set out in Article 17(3) and 18(4) of REACH.	It is generally agreed, that justification is required for each process why it is assumed as being conducted under SCC. However, it is not clear from the "Process category description" why PROC8a should be more justified than PROC8b. The term "non-designated" does not allow concluding on the level of containment.	Multiple substances may be produced by a single manufacturer. Because of the high containment level, it may be more cost-effective to use a specific filling station (for e.g. liquids) for several substances. In such a case, the packaging station would be considered as being non-designated for a specific substance.
PROC10	Roller application or brushing	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.	No comment.	
PROC11	Non industrial spraying	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.	No comment.	
PROC12	Use of blowing agents in manufacture of foam	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.	No comment.	
PROC13	Treatment of articles by dipping and pouring	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.	No comment.	

PROC14	Production of preparations or articles by tableting, compression, extrusion, pelletisation	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.	It is agreed that this process is unlikely to lead to chemical transformation. However, to fulfil the intermediate definition according to Article 3 (15), it is not required that each process in which the substance is used is a chemical transformation process. It is only required that the substance is produced for the purpose of transformation and will be finally transformed into another substance.	Sintering In sintering processes, metal powders (of high melting points) are exposed to high temperatures (below their melting point). Due to the high temperature, the input materials begins to "overlap" and thereby forming a new substance (e.g. metal carbide). Prior to sintering it is sometimes required that the input powders are "pressed" into specific "furnace pans". Forming processes Substances may be brought into specific shapes for the ease of their further use. Such forming processes may include "tableting", "compression", "extrusion" and pelletisation.
PROC16	Using material as fuel sources, limited exposure to unburned product to be expected	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.	No comment.	
PROC17	Lubrication at high energy conditions and in partly open process	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.	No comment.	
PROC18	Greasing at high energy conditions	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.	No comment.	

PROC19	Hand-mixing with intimate contact and only PPE available	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.	Agreed, although "mixing" may be required prior to chemical transformation. This PROC seems to be incompatible with SCC requirements.	
PROC 20	Heat and pressure transfer fluids in dispersive, professional use but closed systems	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH	No comment.	
PROC 21	Low energy manipulation of substances bound in materials and/or articles	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.	It is agreed that this process is unlikely to lead to chemical transformation. However, to fulfil the intermediate definition according to Article 3 (15), it is not required that each process in which the substance is used is a chemical transformation process. It is only required that the substance is produced for the purpose of transformation and will be finally transformed into another substance.	Transfer of massive objects Massive objects may be used in chemical transformation processes. The transport of these objects prior to any chemical transformation may be referred to as "low energy manipulation".
PROC22	Potentially closed processing operations with minerals/metals at elevated temperature Industrial setting	This category is not compatible with the requirement on strictly controlled conditions as set out in Article 17(3) and 18(4) of REACH.	PROC22 and PROC23 are commonly used as being "hot-metallurgical" processes. With PROC23 designated to "open processing" (in particular casting), PROC22 is considered as being the appropriate PROC to describe processes conducted in closed furnaces. In its unspecific meaning, the term "potentially closed" should not be used as a trigger for SCC compliance. PROCs 8b and 9 do also not infer on the level of containment but are assumed by ECHA as being "SCC-compatible".	

PROC23	Open processing and transfer operations with minerals/metals at elevated temperature	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.	No comment.	
PROC24	High (mechanical) energy work-up of substances bound in materials and/or articles	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.	It is agreed that this process is unlikely to lead to chemical transformation. However, to fulfil the intermediate definition according to Article 3 (15), it is not required that each process in which the substance is used is a chemical transformation process. It is only required that the substance is produced for the purpose of transformation and will be finally transformed into another substance.	Forming processes Substances may be brought into specific shapes for the ease of their further use. Such forming processes may include rolling, milling, etc.
PROC25	Other hot work operations with metals	This process category is not expected in the context of chemical processing (synthesis), and hence it is not compatible with the definition of an intermediate under REACH.	No comment.	
PROC26	Handling of solid inorganic substances at ambient temperature.	This category is, without adequate justification, unlikely to be compatible with the requirement on strictly controlled conditions. as set out in Article 17(3) and 18(4) of REACH.	It is generally agreed, that justification is required for each process why it is assumed as being conducted under SCC. However, it is not clear from the "Process category description" why PROC26 should be more justified than PROC8b. Both PROC definitions do not infer on the level of containment.	Handling of metal powders Handling of metal powders is often described as PROC26.

PROC27a	Production of metal powders (hot processes)	This category is, without adequate justification, unlikely to be compatible with the requirement on strictly controlled conditions as set out in Article 17(3) and 18(4) of REACH.	It is generally agreed, that justification is required for each process why it is assumed as being conducted under SCC. However, it is not clear from the "Process category description" why PROC27a should be more justified than PROC8b. Both PROC definitions do not infer on the level of containment.	
PROC27b	Production of metal powders (wet processes)	This category is, without adequate justification, unlikely to be compatible with the requirement on strictly controlled conditions as set out in Article 17(3) and 18(4) of REACH.	It is generally agreed, that justification is required for each process why it is assumed as being conducted under SCC. However, it is not clear from the "Process category description" why PROC27b should be more justified than PROC8b. Both PROC definitions do not infer on the level of containment.	