

**Position paper (author: Rob Versfeld, Corus Staal BV, nominated lead registrant)**

## **IS LIMITED REGISTRATION OF IRON OXIDE PELLETS UNDER REACH AN OPTION?**

**Do Iron Oxide Pellets [Einecs number 265-996-3] fall under the definition of “intermediate” under REACH Art. 3?**

The definition of intermediate in Art. 3 (no.15) is: *a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance.*

Two different types of intermediates are defined under REACH:

- Non-isolated intermediates
- Isolated intermediates
  - On-site (non transported) isolated intermediates
  - Transported isolated intermediates

Iron Oxide Pellets are consumed in a Blast Furnace or Direct Reduction Furnace and transformed into metallic iron and various impurities, resulting in the production of liquid or solid iron or direct reduced iron (= iron, furnace). Therefore Iron Oxide Pellets are clearly an isolated intermediate as described above.

### **REACH legislation and “Guidance for intermediates” about intermediates**

For on-site isolated intermediates the information requirements on physico-chemical, human health and environmental properties are limited to the data that are available to the manufacturer without any additional testing (e.g. information that it holds itself or can obtain from other sources). The registrant must therefore gather all currently available information on the physico-chemical, human health or environmental properties of the substance for which it intends to submit a REACH registration dossier.

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For transported isolated intermediates, currently available information must be submitted as for on-site isolated intermediates, in addition to which, if the annual tonnage exceeds 1,000 tonnes/year, further information has to be provided as referred to in Article 18 of the Treaty and as developed under section 2.3 of ECHA's Guidance for Intermediates and Guidance for Registration.<sup>1</sup>

The first task for the registrant is therefore to determine if the substance under investigation is an isolated intermediate manufactured and used under strictly controlled conditions.

### Strictly controlled conditions

*For isolated intermediates, the manufacturer confirms that the substance is only manufactured and used under strictly controlled conditions in that it is rigorously contained by technical means during its whole lifecycle (Article 17(3), Article 18(4)).*

Therefore, in order to benefit from the reduced registration requirements for intermediates the registrants have to first assess if their substances are handled under strictly controlled conditions on the sites of manufacture and use. When filling the IUCLID5 registration dossier the registrant must report whether or not the substance is manufactured and used under strictly controlled conditions and confirmation of this can be provided.

To establish if the intermediate is manufactured and used under strictly controlled conditions during its whole lifecycle, the registrant should determine if the following conditions, as detailed in *Article 18(4)*, are satisfied:

- (a) *the substance is rigorously contained by technical means during its whole life-cycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis; loading and unloading of equipment or vessels, waste disposal or purification and storage;*
- (b) *procedural and control technologies shall be used that minimise emission and any resulting exposure;*
- (c) *only properly trained and authorised personnel handle the substance;*
- (d) *in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;*
- (e) *in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures;*
- (f) *substance-handling procedures are well documented and strictly supervised by the site operator.*

A full explanation of the applicable strictly controlled conditions is not required in the registration dossier. However the assessment of the use(s) of any substance (or group of similar substances) as intermediate(s) should be documented within the company concerned in order to demonstrate the adequacy of the measures as the regulatory authorities may request such information which must then be made available.

The documentation may include:

- *justification for the assignment of use as an intermediate to the substance, including customers' statements if a transported isolated intermediate;*

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<sup>1</sup> See the [Library Page of the Iron Platform website](#) for the relevant documents.

- *the relevant operating conditions;*
- *the risk management measures implemented in the company and recommended to external customers;*
- *the corresponding exposure considerations; and*
- *reference or derivation of any relevant threshold value (e.g. Derived No Effect Levels (DNELs), Predicted No Effect Concentrations (PNECs)), including the relevant physico-chemical, toxicological and ecotoxicological data, including data from substance grouping where available.*

To facilitate the process for assessing whether strict control is achieved, Appendix 1 of the Guidance for Intermediates presents an indicative and non-exhaustive list of issues that could be considered. This approach is only intended as a user-friendly tool to document the process of assessing the conditions of strict control. An example of a general format to document how the substance is manufactured and used in strictly controlled conditions is also proposed in Appendix 2 of this document.

The Eurometaux document “Strict control for isolated intermediates to be registered under REACH – Guidance for the Metals Industry” provides a good overview of all the metal specific issues related to the interpretation of Strict Control.<sup>2</sup>

### Rigorous containment of the substance

Rigorous containment is the combination of technical and procedural measures that ensure that exposure (whether to man or the environment) is reduced so that risks are strictly controlled. It is applicable to handling of intermediates on any scale.

When hazard information is available for an intermediate, then the intermediate must be handled under appropriate conditions that ensure that any risks rising from handling of the substance are strictly managed.

### Discussion

1. The assumption for this position paper is that Iron Oxide Pellets are an isolated intermediate. The following situations can be distinguished:
  - a. production and handling of Iron Oxide Pellets at the pellet plant (e.g. pellet dust around the installations), excluding the fugitive or stack emissions of the process.
  - b. the transport from the pellet plant (including handling, storage, shipping, transshipment, etc.)
2. The advantages of registration as an isolated intermediate are clear: only currently available information has to be submitted; no CSA is required; reduced registration fee; intermediates are exempted from authorisation according to Art.2 (8).
3. The main issue what constitutes “strictly controlled conditions.”. It is stated that the intermediate should be “rigorously contained” throughout the life cycle.
  - a. **Ecotoxicology:** Would the BREF on “Production of iron and steel (for exposure in and around the pellet plant as mentioned in 1a)” and “emissions from transport” (as mentioned in 1b) fulfil this requirement? The BREFs describe the Best Available Techniques (BAT), defined in the IPPC as “the most effective and advanced stage in the development of activities and their methods of operation which indicate the practical

<sup>2</sup> See the [Library Page of the Iron Platform website](#) for the relevant documents

suitability of particular techniques for providing in principle the basis for emission limit values designed to prevent and, where that is not practicable, generally to reduce emissions and the impact on the environment as a whole”.

- b. **Toxicology:** A DNEL could be set in order to prove by monitoring of dust that the DNEL is not exceeded. But how to set a DNEL (e.g. in the Netherlands there is only a maximal acceptable concentration, which is not the same as a no effect level) and how to focus on iron oxide pellets (e.g. in the Netherlands only inert dust is measured which is not the same as the dust from iron oxide pellets)? Going down this route is in the end more or less the same as a full registration.

The above-mentioned Eurometaux guidance on Strict Control points out some other potentially problematical situations that may arise.

4. Local authorities may wish to inspect the documentation in order to assess whether strict control is in place. Whilst evaluation of the total dossier will be by ECHA, thus ensuring consistency of approach, evaluation of measures for control of isolated intermediates at local level (which is of course appropriate) may well be arbitrary and inconsistent across the EU. The advantage of full registration is that there is a level playing field across the entire EU as the same RMM's will have to be applied.
5. The perception of a fully registered substance is better than that for an intermediate.
6. Although intermediates are exempted from authorisation it is not likely that iron oxide pellets, when registered fully, will ever be subject to authorisation.

### **Conclusion:**

- Iron oxide pellets are clearly an isolated intermediate as defined in Art.3 (no. 15) of the REACH regulation, so the question is whether or not the criteria in Title II, chapter 3 are satisfied.
- It is very difficult to categorically declare that the exposure to employees is reduced such that risks are strictly controlled. There is no clear solution for this: much data gathering will be needed and measures will have to be implemented to fulfil this criterion. Besides this, it is surely preferable that what constitutes Strict Control should not be left to the determination of local authorities - the perception of a fully registered substance is better.
- This leads to the conclusion that full registration is better for iron oxide pellets. Read across to other substances (e.g. Diiron Trioxide, etc) should be proven and used whenever possible.
- Notwithstanding this, whilst it is intended to start along the “full registration route” for iron oxide pellets, the possibility of stitching to the “isolated intermediate route” will be kept under review as we move forward..

There is always the option for individual companies to register iron oxide pellets as an isolated intermediate if they feel it preferable to do so.

## ANNEX

### Article 10 of the REACH Regulation

#### Information to be submitted for general registration purposes

A registration required by Article 6 or by Article 7(1) or (5) shall include all the following information:

(a) a technical dossier including:

- (i) the identity of the manufacturer(s) or importer(s) as specified in section 1 of Annex VI;
- (ii) the identity of the substance as specified in section 2 of Annex VI;
- (iii) information on the manufacture and use(s) of the substance as specified in section 3 of Annex VI; this information shall represent all the registrant's identified use(s).

This information may include, if the registrant deems appropriate, the relevant use and exposure categories;

- (iv) the classification and labelling of the substance as specified in section 4 of Annex VI;
- (v) guidance on safe use of the substance as specified in Section 5 of Annex VI;
- (vi) study summaries of the information derived from the application of Annexes VII to XI;
- (vii) robust study summaries of the information derived from the application of Annexes VII to XI, if required under Annex I;
- (viii) an indication as to which of the information submitted under (iii), (iv), (vi), (vii) or subparagraph (b) has been reviewed by an assessor chosen by the manufacturer or importer and having appropriate experience;
- (ix) proposals for testing where listed in Annexes IX and X;
- (x) for substances in quantities of 1 to 10 tonnes, exposure information as specified in section 6 of Annex VI;
- (xi) a request as to which of the information in Article 119(2) the manufacturer or importer considers should not be made available on the Internet in accordance with Article 77(2)(e), including a justification as to why publication could be harmful for his or any other concerned party's commercial interests.

Except in cases covered under Article 25(3), Article 27(6) or Article 30(3), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (vi) and (vii) for the purpose of registration; L 136/24 EN Official Journal of the European Union 29.5.2007

(b) a chemical safety report

when required under Article 14, in the format specified in Annex I. The relevant sections of this report may include, if the registrant considers appropriate, the relevant use and exposure categories.

### Article 17 of the REACH Regulation

#### Registration of on-site isolated intermediates

1. Any manufacturer of an on-site isolated intermediate in quantities of one tonne or more per year shall submit a registration to the Agency for the on-site isolated intermediate.
2. A registration for an on-site isolated intermediate shall include all the following information, to the extent that the manufacturer is able to submit it without any additional testing:
  - (a) the identity of the manufacturer as specified in Section 1 of Annex VI;
  - (b) the identity of the intermediate as specified in Sections 2.1 to 2.3.4 of Annex VI;
  - (c) the classification of the intermediate as specified in Section 4 of Annex VI;
  - (d) any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted;
  - (e) a brief general description of the use, as specified in Section 3.5 of Annex VI;

- (f) details of the risk management measures applied. Except in cases covered under Article 25(3), Article 27(6) or Article 30(3), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (d) for the purpose of registration.

The registration shall be accompanied by the fee required in accordance with Title IX.

- 3. Paragraph 2 shall apply only to on-site isolated intermediates if the manufacturer confirms that the substance is only manufactured and used under strictly controlled conditions in that it is rigorously contained by technical means during its whole lifecycle. Control and procedural technologies shall be used to minimise emission and any resulting exposure.

If these conditions are not fulfilled, the registration shall include the information specified in Article 10.

# ANNEX VI of the REACH Regulation

## INFORMATION REQUIREMENTS REFERRED TO IN ARTICLE 10

### GUIDANCE NOTE ON FULFILLING THE REQUIREMENTS OF ANNEXES VI TO XI

Annexes VI to XI specify the information that shall be submitted for registration and evaluation purposes according to Articles 10, 12, 13, 40, 41 and 46. For the lowest tonnage level, the standard requirements are in Annex VII, and every time a new tonnage level is reached, the requirements of the corresponding Annex have to be added. For each registration the precise information requirements will differ, according to tonnage, use and exposure.

The Annexes shall thus be considered as a whole, and in conjunction with the overall requirements of registration, evaluation and the duty of care.

STEP 1 — GATHER AND SHARE EXISTING INFORMATION

STEP 2 — CONSIDER INFORMATION NEEDS

STEP 3 — IDENTIFY INFORMATION GAPS

STEP 4 — GENERATE NEW DATA/PROPOSE TESTING STRATEGY

## INFORMATION REFERRED TO IN ARTICLE 10(a) (i) TO (v)

### 1. GENERAL REGISTRANT INFORMATION

#### 1.1. Registrant

1.1.1. Name, address, telephone number, fax number and e-mail address

1.1.2. Contact person

1.1.3. Location of the registrant's production and own use site(s), as appropriate

1.2. Joint submission of data

Articles 11 or 19 foresee that parts of the registration may be submitted by a lead registrant on behalf of other registrants.

In this case, the lead registrant shall identify the other registrants specifying:

— their name, address, telephone number, fax number and e-mail address,

— parts of the present registration which apply to other registrants.

Mention the number(s) given in this Annex or Annexes VII to X, as appropriate.

Any other registrant shall identify the lead registrant submitting on his behalf specifying:

— his name, address, telephone number, fax number and e-mail address,

— parts of the registration which are submitted by the lead registrant.

Mention the number(s) given in this Annex or Annexes VII to X, as appropriate.

1.3 Third party appointed under Article 4

1.3.1. Name, address, telephone number, fax number and e-mail address

1.3.2. Contact person

### 2. IDENTIFICATION OF THE SUBSTANCE

For each substance, the information given in this section shall be sufficient to enable each substance to be identified.

If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items below, the reasons shall be clearly stated.

2.1. *Name or other identifier of each substance*

2.1.1. Name(s) in the IUPAC nomenclature or other international chemical name(s)

2.1.2. Other names (usual name, trade name, abbreviation)

2.1.3. EINECS or ELINCS number (if available and appropriate)

2.1.4. CAS name and CAS number (if available)

2.1.5. Other identity code (if available)

2.2. Information related to molecular and structural formula of each substance

2.2.1. Molecular and structural formula (including SMILES notation, if available)

- 2.2.2. Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)
- 2.2.3. Molecular weight or molecular weight range
- 2.3. *Composition of each substance*
- 2.3.1. Degree of purity ( %)
- 2.3.2. Nature of impurities, including isomers and by-products
- 2.3.3. Percentage of (significant) main impurities
- 2.3.4. Nature and order of magnitude (... ppm, ... %) of any additives (e.g. stabilising agents or inhibitors)

### **3. INFORMATION ON MANUFACTURE AND USE(S) OF THE SUBSTANCE(S)**

- 3.5. Brief general description of the identified use(s)

### **4. CLASSIFICATION AND LABELLING**

4.1. The hazard classification of the substance(s), resulting from the application of Articles 4 and 6 of Directive 67/548/EEC.

In addition, for each entry, the reasons why no classification is given for an endpoint should be provided (i.e. if data are lacking, inconclusive, or conclusive but not sufficient for classification).

4.2. The resulting hazard label for the substance(s), resulting from the application of Articles 23, 24 and 25 of Directive 67/548/EEC.

4.3. Specific concentration limits, where applicable, resulting from the application of Article 4(4) of Directive 67/548/EEC and Articles 4 to 7 of Directive 1999/45/EC.

### **5. GUIDANCE ON SAFE USE CONCERNING:**

This information shall be consistent with that in the Safety Data Sheet, where such a Safety Data Sheet is required according to Article 31.

- 5.1. First-aid measures (Safety Data Sheet heading 4)
- 5.2. Fire-fighting measures (Safety Data Sheet heading 5)
- 5.3. Accidental release measures (Safety Data Sheet heading 6)
- 5.4. Handling and storage (Safety Data Sheet heading 7)
- 5.5. Transport information (Safety Data Sheet heading 14)

Where a Chemical Safety Report is not required, the following additional information is required:

- 5.6. Exposure controls/personal protection (Safety Data Sheet heading 8)
- 5.7. Stability and reactivity (Safety Data Sheet heading 10)
- 5.8. Disposal considerations
- 5.8.1. Disposal considerations (Safety Data Sheet heading 13)
- 5.8.2. Information on recycling and methods of disposal for industry
- 5.8.3. Information on recycling and methods of disposal for the public.