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Strict control for isolated intermediates to be registered under REACH –Guidance for the metals industry

June 5, 2008

Executive summary

Isolated intermediates as defined according to Article 3 (15) b and c may benefit from reduced registration requirements, as described in Articles 17 and 18, provided that they are handled under “**strictly controlled conditions**”. The ECHA Guidance for Intermediates goes some way towards explaining the definition and application of strictly controlled conditions.

This guidance document endeavours to describe when and how the specific provisions for the registration in REACH of intermediates produced and used under strictly controlled conditions can be interpreted in the metals & inorganic sector. The document will be used in combination with the ECHA guidance and the REACH legal text and be considered as a possible template for well-informed company/commodity REACH experts with a good knowledge of REACH and RIPs to develop company specific guidance. Interpretation is, in fact, on a case-by-case basis, and is determined by company experience, state of knowledge, business strategy and by local interpretations of risk assessments.

The document outlines an approach that can be used to assess and document “strictly controlled conditions”, and provides some examples in annex. Some metal- & mineral-specific additional issues that may arise when considering what precisely is strict control are highlighted in the text.

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1. INTRODUCTION

1.1 General introduction:

The REACH Regulation¹ recognises “intermediates”, as defined in article 3 (15), as a distinct subset of substances. Within this subset of substances, the Regulation makes a distinction between non-isolated intermediates and isolated intermediates, with the latter being further subdivided into “on-site” and “transported” sub-categories.

The non-isolated intermediates, as defined in Article 3(15) (a) and outlined in Article 2 (1) c, are outside the scope of REACH altogether.

The isolated intermediates as defined according to Article 3 (15) b and c, may benefit from reduced registration requirements, as described in Articles 17 and 18, provided that they are handled under **“strictly controlled conditions”**.

1.2 Strictly controlled conditions:

Strictly controlled conditions should be seen as a combination of technical measures that are underpinned by management systems. REACH does not define “strictly controlled conditions” but describes it as “*rigorous containment by technical means during the whole lifecycle*”². The ECHA Guidance on intermediates states that: “*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*”³.

The term “strict control” only appears in REACH in the context of intermediates, while elsewhere in the Regulation⁴, the more familiar term “adequate control” is used. The term “adequate control” is also the term one finds in earlier regulations for the

¹ Regulation (EC) No 1907/2006

² REACH Article 17(3)

³ ECHA Guidance on intermediates 2.1.1

⁴ “Adequate(ly) control(led)” occurs 30 times in the REACH Regulation, whereas “strictly controlled” occurs only 3 times, all in connection with intermediates

control of hazardous chemicals. The difference between “strict control” and “adequate control” is one of the questions to be addressed.

There is a kind of underlying dilemma when considering the reduced registration requirements for intermediates ‘handled under strictly controlled conditions’. The direct consequence of having reduced registration obligations is indeed that there will be less opportunity/ data to identify potential hazards. However, the concept of adequate control is based on (a) **knowledge of the hazards** and (b) **employing sufficient risk reduction measures to ensure that the residual risk is reduced to an acceptable minimum.**

Strict control appears to be based on the premise that, taking account of less than complete hazard data, the residual risk would still be reduced to an acceptable minimum even if the substances were more hazardous than anticipated. The rules of Registration mean that in practical terms, it is the operators and employees who must satisfy themselves first and foremost about strict control; it is only then that there may be a subsequent requirement to satisfy the competent authority⁵.

The logical counterbalance to this reduced obligation is the requirement to consider “any available existing information”⁶. On the basis of a legal advice⁷ that was obtained, this comprises information on physicochemical, human health or environmental properties of the intermediate that the registrant is holding himself or that he can obtain from other sources without performing any additional testing”.

The ECHA Guidance for Intermediates⁸ goes some way towards explaining the definition and application of strictly controlled conditions. However, as evidenced by the examples cited in the ECHA Guidance on intermediates, this has been written from the standpoint of industries handling organic chemicals (viz. pharmaceuticals, petrochemicals, fine chemicals) (see also the examples used in annexes). The metals

⁵ According to section 2.1 of the ECHA Guidance: “a full explanation of the strictly controlled conditions in place is not required in the registration dossier; however the assessment of the use(s) of any substance as an intermediate should be documented within a company in order to show the adequacy of the measures as authorities may request such information which then must be made available”.

⁶ The precise meaning of “any existing available information” is outside the scope of this guidance.

⁷ Eurometaux legal advice December 2007

⁸ Published by European Chemicals Agency (ECHA) in June 2007

industry has encountered some difficulties when seeking to interpret the available guidance for its inorganic materials and, in particular, the meaning of the term “strict control”.

1.3 Purpose of this guidance document:

This guidance document endeavours to describe when and how the specific provisions for the registration in REACH of intermediates produced and used under strictly controlled conditions can be interpreted in our sector.

It has been designed to provide pointers as to what one might reasonably expect to find in circumstances where “strict control” is in place and it provides a number of examples from the metals industry to illustrate some of the underlying principles.

It shall, however, be realised that there are no simple universal answers to the question of whether or not “strictly controlled conditions exist”. **Each situation must be judged case by case.**

This document is only relevant to substances which have been identified as intermediates⁹ and which require Registration. For information on the categories of intermediates, their definitions and possible exemptions from Registration, we refer to the Eurometaux Fact Sheet on Intermediates (<http://www.reach-metals.eu/>).

This guidance document does not apply to substances outside the scope of REACH, such as non-isolated intermediates and wastes¹⁰.

Please note that this document endeavours to:

- supplement but certainly not replace the ECHA guidance document on intermediates, from which the structure outlined in appendix 2 has been taken over (i.e. recommended format to document the decisions taken by a company). This document shall be used in combination with the ECHA guidance and the REACH legal text

⁹ As per the definition in REACH Article 3(15)(a); some companies describe materials internally as intermediates although they do not meet this definition. It is important that, for external purposes, companies should be careful only to use nomenclature compatible with REACH.

¹⁰ Some wastes in mid-treatment would meet the definition of an intermediate if they were deemed to have ceased to be waste and hence came within the scope of REACH. The important issue of whether a given substance is a waste or non-waste is way outside the scope of this guidance.

- serve as a template for well-informed company/commodity REACH experts, with a good knowledge on REACH and RIPs, to develop company specific guidance. Interpretation is indeed case by case and determined by the company experience, state of knowledge, business strategy and by local interpretations of risk assessments.

The document outlines an approach that can be used to assess and document “strictly controlled conditions”. Some additional issues that may arise when considering what precisely is strict control are highlighted. Examples are provided in Annex.

2. A ‘GENERIC APPROACH’ FOR DOCUMENTING PRODUCTION/USE OF INTERMEDIATES UNDER “STRICTLY CONTROLLED CONDITIONS”

Note: The format used below follows the structure of appendix 2 of the Guidance for intermediates for documenting information on strictly controlled conditions of isolated intermediates. This format can be used by the registrant of an isolated intermediate (M/I) and the user of the intermediate to confirm to the registrant that his use takes place under strictly controlled conditions. Metal-relevant issues requiring further discussion are highlighted and presented in a framework under each item:

Comment

The issue at stake is the *successful management of risk* both for the environment and for workers during the lifecycle of the substance. This requires performing: a) the **knowledge** (building) of the conditions of use/production, of exposure and hazard properties of the intermediate as well as of the risk management measures in place, b) a **compliance check** in terms of containment of the substance versus existing reference values to demonstrate “controlled conditions”.

As a general principle, it is proposed to use as far as possible existing information, registers, etc...and what has been documented in the context of existing legislation. For example, the NFM BREF note could be used and referred to. Any information on processes produced for the purpose of other pieces of legislation (e.g. worker protection legislation, ISO 14001 and/or OHSAS 18001 quality standard accreditation of their management systems, IPPC) could be used. Existing risk assessments shall be used as well.

2.1 Description of technological process used in manufacture and 2. description of the uses of the substance:

The objective is to describe the conditions of manufacture and uses of the intermediate (i.e. to describe its life-cycle including storage, processing, synthesis) to be able at the next step to identify where exposure (risk) may take place.

An Excel sheet is provided in Annex I and constitutes an attempt to collect information on life-cycle and processes in a user-friendly way. This sheet has also been used in the examples provided in Annex II.

2.2. Is the substance rigorously contained during the manufacturing and its uses?

The objective is to describe **the process and technical means to contain the substance**, to identify the **potential emissions to the workplace and environment**, to **report data (modelled, monitoring) on exposure** and document the **procedure and systems in place to comply with existing health, safety and environmental legislation**.

This can be done partly by using the Excel sheet referred to above.

This 'Flow sheet' may be used for each individual intermediate or by process/combination of processes. It is essential for a good description to accompany the flow sheet setting out the reasoning and arguments used!!

Several metal-specific items shall be addressed and will be reported where relevant: e.g.

- *Reality is a complex mix of metals and compounds within the boundaries set for the assessment*
- *Storage*
- *Strict control during transport of intermediates*
- *Non-threshold substances*
- *Personal Protective Equipment*
- *Fugitive emissions*

2.2.1 Environment:

▪ *Identification of potential emissions*

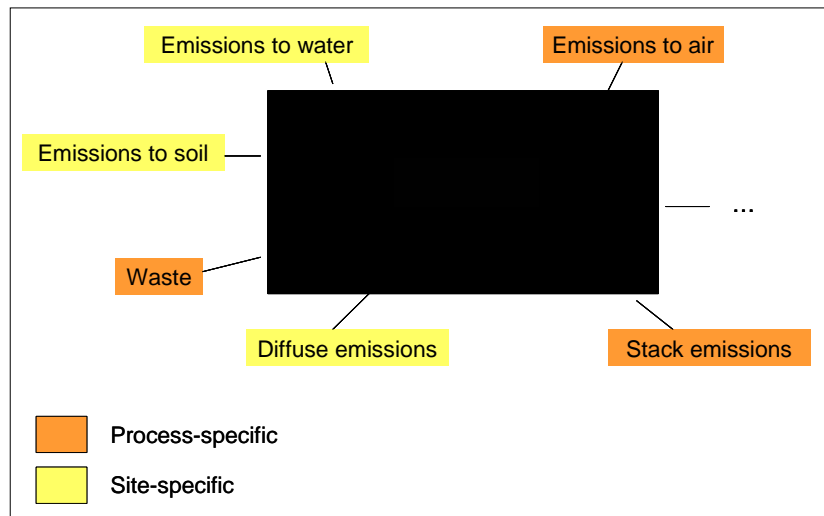
The idea is to consider the plant as a ‘unit’, considering the emissions of the *entire* site. Relevant evaluation parameters (e.g. Pb for the group of Pb compounds) should be selected and measured/modelled and should be compared to existing ELVs:

- If you can demonstrate that the operations comply with existing limit values (ELVs), the intermediates used/produced in these operations should be considered, as such, in strictly controlled conditions.
- If no ELV is available, emissions have to be compared to the PNECs for the different compartments. If the comparison exposure versus PNEC is satisfactory, then it can be concluded that the intermediates are produced/used in a way that does not affect the environment

Limitations: This approach considers the processes performed at one plant altogether and all intermediates produced/used as a ‘whole’. However:

- not all intermediates involved in site processes are responsible for (hazardous) emissions. One intermediate may also drive the emissions and require specific consideration
- this approach may work for the water and soil/sediment compartment where there is one point of (discharge)/measurement, but emissions to air and waste could require a more refined approach, as they are more specifically linked to processes and have several measurement points

Consequently, this ‘unit’ approach should be considered as **Tier 1** of a tiered approach. The next step will consist of evaluating the emissions per process. The **refined Tier 2** may enable a driving intermediate to be identified, but will be more difficult to apply in the case of site-specific emissions (e.g. to water)



This approach requires emission data. In cases where no exposure data are available, exposure modelling should be applied. Example of models can be found in the guidance for performing the CSA/CSR. Models can also help to avoid the errors induced by the influence of historical pollution on monitoring data, but can be stringent and limited to “default” or “worst-case scenario” values.

- *Modelling estimations or available monitoring data if needed*

In the metals sector, clear preference is given to measured data over modelled data as available models generally overestimate exposure levels, in particular for occupational & consumer exposure. In case no measured data are available, it should be referred to models (EUSES, EASE, ...). Examples of models for performing exposure modelling are referred to in the guidance on how to perform the CSA/CSR (RIP 3.2-2) for example. As all models have limitations, one should be aware of those as well as of their strengths when using them.

- *Procedure and systems in place to comply with existing environmental legislation*

List all the measures that are in place:

- IPPC and BAT (as IPCC plants have been evaluated by authorities)
- Measures taken at all process stages: e.g. ISO14001 environmental aspects, workplace evaluation, etc
- Management system: e.g. ISO 14001, EMAS, procedures for control, training, accidents, etc.

Example:

- determine the *substances* (metals, metal compounds, other relevant elements, ...) that are fed into each process, including handling and storage
- determine the *relevant parameters* to be measured: Pb for all Pb compounds, ...
- sample and analyse the discharge water
- ELV's for water are derived from the water EQS under the Water Framework Directive

Comment: Reality is a complex mix of metals and compounds within the boundaries set for the assessment

It should be realised that, in practice, both workers and environment are not exposed to a single substance (intermediate) but to a mix of metals, minerals and metal compounds, resulting from the presence of different substances in the same exposure area or the existence of different processes for a substance/intermediate. It has therefore been proposed to approach the definition of strictly controlled conditions by considering the process as a unit rather than a substance and to focus on the assessment of the whole process with all inputs and outputs. To do this, a clear definition of the system boundaries will be required in the description of the exposure.

Comment: fugitive emissions

The actual presence or absence of fugitive emissions in the life cycle of the intermediate has to be assessed. If present, the risks of these fugitive emissions has to be determined, and risk reduction measures should be applied if required.

This aspect is very much case-specific and in most cases, real measured ambient¹¹ data will be the result of many different sources of (fugitive) emissions (including emissions caused by other intermediate or non-intermediate substances). Compliance with emission and/or ambient concentration standards (if they are available and applicable) around a site (e.g., a surface water EQS) should prove that fugitive emissions of all individual sources are strictly controlled.

¹¹ often translated to « *immissions* » in German

2.2.2 Workplace

- *Identification of potential emissions*

The suggestion is to consider exposure control on a “logical process unit” basis and per job description/category (melting/smelting, mechanical handling, raw material handling, drying, etc.). The logical process unit groups grouping several related functions and operations (‘same breathed air area’) that create one common exposure area.).

- *Modelling estimations or available monitoring data if needed*

The next step is then to select the relevant evaluation parameters (e.g. Cu for Cu compounds), to measure/estimate exposure and compare the exposure values against reference values such as OELs, when available, or DNELs. If the reference values are exceeded, there is a need to go for a more refined approach to assess which measures shall be put in place

Comment: Reality is a complex mix of metals and compounds within the boundaries set for the assessment

It should be realised that, in practice, both workers and environment are not exposed to a single substance (intermediate) but to a mix of metals, minerals and metal compounds, resulting from the presence of different substances in the same exposure area or the existence of different processes for a substance/intermediate. It has therefore been proposed to approach the definition of strictly controlled conditions by considering the process as a unit rather than a substance and to focus on the assessment of the whole process with all inputs and outputs. To do this, a clear definition of the system boundaries will be required in the description of the exposure.

- *Procedure and systems in place to comply with existing health and safety legislation*

Lists what is in place to:

- show that protection hierarchy is observed
- describe measures taken at all process stages
- ensure that the management system is in place: e.g. OSHAS18001, procedures for training, risk assessment, accidents,...

Example:

Description of workplace: (e.g. tapping floor of blast furnace)

- sub-processes: tapping of lead
 - casting of lead in final form
 - tapping of matte
 - tapping of poor slags
- functions: furnace operators
 - fork-lift truck drivers
- *Measurements:* stationary measurements (Pb, Cu, Cd, ...) and portable measurements (Pb, Cu, Cd, ...)
- When measurements do *not comply* with TLV, MAC, ...:
 - use of PPE
 - definition of improvement actions
 - regular auditing & recording (operational control)

Comment: role of personal protective equipment

The ECHA Guidance notes that “it should be kept in mind that the use of personal protective equipment (PPE) should not have a prime role when determining whether workplace exposures to an intermediate are strictly controlled as the use of such measures alone generally cannot equate to strictly controlled conditions. It is recognised that PPE should be recommended and used especially in relation to sampling, maintenance and repair”¹².

This interpretation of PPE appears to be subject to some variations. Some Member States appear to assume that any observed wearing of PPE is evidence of an absence of strict control. In the UK, the Control of Substances Hazardous to Health Regulations 2002 (as amended) are in force. Paragraph 71 of L5, the corresponding Approved Code of Practice and Guidance document reads as follows: “In deciding what measures are needed to control exposure, employers should only use personal protective equipment (PPE) so far as is reasonably practicable after all other measures have been taken. Employers may use PPE as secondary protection in combination with other control methods such as local exhaust ventilation, if those other control measures do not adequately control exposure by themselves. However, there may be circumstances where an employer considers it prudent to issue personal protective equipment such as clothing, face shields, gloves etc, not because other control measures are inadequate on their own, but to provide employees with additional protection should any of those measures fail.”

Thus PPE is the last in the hierarchy of measures to be applied to minimise exposure and over-reliance on it would make it difficult to demonstrate strict control.

Finally, there may be cases where the wearing of PPE may not be related at all to the handling of a given isolated intermediate under strict control but may rather be a general requirement in a facility to protect against one or more other hazardous operations taking place there.

Comment: non-threshold substances

The strict control dilemma also arises in a somewhat different context where tests have been carried out and indicate the presence of a non-threshold hazard, for which there is no designated safe level of

¹² ECHA Guidance 2.1

exposure. Examples include the presence of a carcinogen, mutagen or reprotoxic substance (CMR)¹³, a not uncommon occurrence when manufacturing metals from both primary and secondary sources.

The REACH Recitals, which express the spirit of the Regulation, appear to acknowledge that such substances can be handled safely. Recital 70 refers to substances “for which it is not possible to establish a safe level of exposure” when talking of identifying measures to ensure adequate control in the Chemical Safety Report, whereas Recital 71 recognises the possibility of the Commission establishing thresholds for carcinogenic and mutagenic substances.

There is a need to display a sense of proportion when determining what is strict control for non-threshold substances. Clearly, although they will have a similar classification, there is a world of difference between safe handling of (a) a refining intermediate such as nickel oxide, which is pure 100% Class 1 carcinogen, and (b) an intermediate containing one thousand times less of this substance at the 0.1% level. Case (a) needs to be virtually non-isolated, whereas case (b) needs good but not necessarily perfect containment.

2.3 If emissions have been identified on sites of manufacture or uses, are there procedural and control technologies to minimise emission and resulting exposure?

See under 2.2.

2.4. Is the substance handled by trained and authorised personnel?

- *Is the personnel provided with safety data sheets (SDS) of the substances handled?*
- *Is there sufficient training and information on appropriate precautions and working procedures (proper labelling of specific working places) at workplace?*

To complete if not covered under 2.2.

¹³ This only refers to CMR Classes 1 and 2 (Classes 1a and 1b under GHS, the Globally Harmonised System for Classification and Labelling of Chemicals, being implemented in EU hand in hand with REACH).

Comment: Strict Control during Transport of Intermediates

REACH Article 18(4) states that reduced registration requirements shall only apply to transported intermediates “if the manufacturer or importer confirms himself or states that he has received confirmation from the user that the synthesis of (an)other substance(s) from that intermediate takes place on other sites under the following strictly controlled conditions:

- (a) The substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal, or purification and storage...”

Clearly, there is no issue with materials transported in sealed containers.

However, in the metals industry, metallurgical intermediates may be transported in quantities of greater than 1000 tonnes loose in the hold of a bulk carrier. Furthermore loading and unloading may be carried out on the quayside by a third party. Whilst acknowledging that such operations will be covered by other legislation, how does REACH, which in general does not cover transport, regard such operations in the context of Article 18(4)?

Assume first that the unloading is carried out by the downstream user at a quayside on his own property. Article 18(4) only refers to synthesis and not to transport. Furthermore the conditions in subsection (a), whilst referring to the “whole lifecycle”, then offer no hint of the transport operations being considered here. Indeed REACH Recital 10 indicates that “the carriage of dangerous substances and of dangerous preparations by rail, road, inland waterways, sea and air” should be excluded from scope. Hence it seems reasonable to regard transport as being outside the letter of the law. But is this consistent with the spirit of the law?

There is as yet no definitive answer to this question or the case of third party involvement¹⁴. However one must never forget that the overriding consideration must as always in such matters be to ensure that there is no risk to human health or the natural environment.

Comment: interpretation issue on ‘storage’:

Note that, in defining non-isolated intermediates, Article 3(15)(a) includes intermediates in “pipework for transfer from one vessel to another for the purpose of the next reaction step”. However it excludes intermediates “stored in tanks or other vessels after their manufacture” from being classified as non-isolated, irrespective of how well they are contained. This definition has been written in the language of organics, with their characteristics clearly in mind. How does this translate into the reality of the metals industry? For example, consider the case of a pyrometallurgical flowsheet, where a solid intermediate, manufactured in one unit operation, continuously passes through a crusher onto a conveyor belt, which transfers the crushed material into a feed hopper above a furnace, where it undergoes “synthesis”¹⁵. It seems logical to regard the furnace as a “vessel” but is there an implied containment requirement for the conveyor belt to be considered to be “pipework”? Does REACH

¹⁴ Note that off-loading the intermediate at the downstream user’s processing facility would unquestionably be liable to the same strict control considerations as its subsequent treatment in order to take advantage of the benefits of such control.

¹⁵ As defined in REACH Article 3(15)

really regard the material which is continuously fed and briefly held in the feed hopper, in order to facilitate its semi-continuous discharge into the furnace below, as being “stored” (and hence “isolated”) even if there is rigorous containment (as described below)?

Since the obligation to register a particular intermediate depends inter alia on whether or not it is deemed to be isolated, such decisions should be carefully documented within a company, together with their technical, legal and scientific justifications.

3.ANNEXES

Annex II: Examples

TYPE OF REACTION VESSEL producing the intermediate: blast furnace	NAME OF INTERMEDIATE: Pb bullion from blast furnace	DESCRIPTION OF LIFE CYCLE				
		1. transfer	2.casting	3. storage	4.loading in refining furnace	5.actual refining
physical form		liquid	massive	massive	massive	liquid
1. WORKPLACE						
EXPOSURE						
exposure possible/form of exposure		yes/fumes	yes/fumes	no	yes/fumes	yes/fumes
risk reduction measures*		extraction hood / respirator during opening of furnace	extraction hood	no	extraction hood	extraction on refining vessels/ventilation of the workplace
exposure data available?		example: 32 µg/dl				
MANAGEMENT SYSTEMS	OSHAS 18001					
HAZARD						
DNELs		40 µg/dl				
RISK CHARACTERISATION						
if exposure/DNEL < 1= no risk		NO		not applicable		
2. ENVIRONMENT						
EXPOSURE						
exposure possible/compartment		yes/air				
risk reduction measures*		bagfilters				
emission data available?						
fugitive emissions?						
risk reduction measures*						
MANAGEMENT SYSTEMS						
HAZARD						
PNEC						
RISK CHARACTERISATION						

TYPE OF REACTION VESSEL producing the intermediate: electro refiner	NAME OF INTERMEDIATE: spent Cu anodes	DESCRIPTION OF LIFE CYCLE				
		1. transfer	2.casting	3. storage	4.loading in converter furnace	5.conversion into blister Cu
physical form		massive	not applicable	massive	massive	liquid
1. WORKPLACE						
EXPOSURE						
exposure possible/form of exposure		yes/fumes			yes/fumes	yes/fumes
risk reduction measures*		extraction hood / PPE during handling		no	extraction hood	extraction hood
exposure data available?						
MANAGEMENT SYSTEMS						
HAZARD						
DNELs						
RISK CHARACTERISATION						
if exposure/DNEL < 1= no risk						
2. ENVIRONMENT						
EXPOSURE						
exposure possible/compartiment		yes/air		yes/water		yes/air
risk reduction measures*		bagfilters		WWTP		bagfilters
emission data available?						
fugitive emissions?						
risk reduction measures*						
MANAGEMENT SYSTEMS						
HAZARD						
PNEC						
RISK CHARACTERISATION						