

## Strictly Controlled Conditions in the EU Non-Ferrous Metals sector

### Version 3

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One of the requirements for registering a substance as an “intermediate” and taking benefit of reduced information requirements, is the obligation to handle the substance under **strictly controlled conditions** (REACH Articles 17(2) and 18(2)).

In December 2010, ECHA issued a revised guidance on intermediates that provides additional information for Industry on what is required to demonstrate strictly controlled conditions and in particular “rigorous containment”.

This document aims to provide information on the activities undertaken by the EU non-ferrous metals sector to implement the recommendations made by ECHA in the “December 2010 guidance on intermediates”.

Many of these activities result from an *ad hoc* SCC Technical Task Force, set up under the Eurometaux umbrella, on behalf of the non-ferrous metals sector as a platform to share learning and best practice. The SCC Task Force comprises of representatives from commodity associations, REACH consortia and member companies. All have been working in re-evaluating the strategy regarding intermediates under REACH as prompted by the release of the December 2010 Guidance on Intermediates. This document outlines the activities undertaken by the SCC Task Force and the tools developed by the various consortia and/or Eurometaux.

With the action plan reported in Table 1 below, the non-ferrous metals industry demonstrates that it is aware of the latest ECHA Guidance on intermediates and is committed to adopting practical approaches that are consistent with information provided in the aforementioned guidance.

Additional formal and informal exchanges are organised with ECHA and national enforcement authorities in order to validate the proposed approaches. Where and as needed, the tentative timeline illustrated below will be adjusted.

*Table 1: Activities launched by the metals industry to address the December 2010 ECHA Guidance on intermediates*

<b>Action Plan</b>	<b>Tentative Timeline</b>
<b>1a Comparison of the 2008 and 2010 ECHA Guidance on intermediates</b> Particular attention on changes to: (1) the definition of intermediate, (2) the requirements related to REACH Art 18 (isolated, transported, >1000t/y) See also Eurometaux REACH Forum material 29 November 2010, Eurometaux guidance note December 2010	Oct 2010 – Feb 2011
<b>1b Assess potential impact of the 2010 guidance on NFM sector</b> <ul style="list-style-type: none"> <li>• Analyzing existing examples</li> <li>• Performed preliminary benchmarking across the sector</li> </ul>	Jan 2011 – March 2011
<b>1c Scope the Eurometaux priorities on SCC</b> Result: focus NFM UVCBs registered under Art 18 Note: no further work required on definition of intermediate	March 2011
<b>2 Develop tools to support Industry</b> Consortia may have prepared specific tool kits for their members but the exchanging platform at Eurometaux assured their consistency.  Tools usually contain instructions and templates such as: <ul style="list-style-type: none"> <li>○ The Eurometaux/EBRC RICO tool<sup>1</sup></li> <li>○ Supporting information: analysis of residual emissions<sup>2</sup></li> <li>○ Expert judgments/auditing visits</li> <li>○ Appendix 2 (in-house documentation) models</li> <li>○ Appendix 3 examples (see 4 NFM specific examples developed by Eurometaux<sup>3</sup>)</li> </ul>	April 2011- Dec 2012

Companies are responsible for performing in-depth compliance checks<sup>4</sup>, including consideration of the intermediate definition, of technical & legal requirements of Art 18 and consideration on today's acceptance level of the NFM interpretation.

Companies are invited to inform their respective consortia of the decision taken. In case of conclusion of SCC compliance, each concerned registrant shall complete Appendix 3 and send it to ECHA via an update of its individual dossier (on site: Appendix 2 templates shall be prepared in case of Member State enforcement visits)

### **3 Engage in advocacy activities on metal specificities**

May 2011–March 2012

Important as the 2010 ECHA Guidance does not include metals examples.

Aim: to increase confidence that NFM interpretation is accepted by ECHA and Member States. Initial discussions took place with CARACAL and some Member States (Poland, UK). A position paper was drafted.

Examples stressing NFM specificities (e.g. availability of hazard data, forms with low emission potential, LEV part of SCC, ...) were provided to ECHA in two formats. In March ECHA responded, indicating that the examples were not clear self-evident examples and referred back to the ECHA guidance for checking SCC conditions.

### **4 Address challenges related to Risk Assessment of UVCBs**

June 2011 – ongoing

In case companies determine that SCC do not apply, the registration dossier needs to be upgraded (= no longer Art 18 or 17). In such cases, a chemical safety report for the intermediate manufacturing and use stages is required (Art 10).

Eurometaux and Consortia are exploring methodologies to perform the substance identification and risk assessment of complex inorganic UVCB intermediates in a coordinated, consistent, scientifically robust and meaningful way. A preliminary brainstorming on methodologies took place in ECHA on 21 May 2012 and will be followed by a longer workshop where industry would present integrated and applied approaches for substance identification, environmental and human health effects, exposure and risk assessment, and classification of inorganic UVCBs intermediates.

A format for reporting (IUCLID, CSR, ES) and demonstrating legitimate access to the relevant data shall be defined too. Costs and timing aspects are still to be further clarified with authorities.

A multi-metallic database has been set up at Eurometaux to allow consortia to exchange data required to perform the risk assessment (ongoing).

As result of many of these activities, the SCC Technical Task Force was renamed REACH Intermediates Task Force. The new Task Force is developing inorganic-UVCB case studies to present and justify methodologies and tools used along the whole risk assessment process.

6 June 2012

A separate One-pager document reflects the activities performed by this Task Force.

<sup>1</sup> RICO: this tool is intended to provide guidance to registrants of isolated intermediates on how rigorous containment of their intermediates could be assessed and documented in line with REACH stipulations. RICO is available on request

<sup>2</sup> only in case data were available

<sup>3</sup> Examples were used for Eurometaux advocacy activities

<sup>4</sup> Exercise may be repeated regularly, pending outcome of acceptance activities

The REACH Forum at Eurometaux is kept up to date about the above tasks on a regular basis.

Companies having difficulties in demonstrating SCC during REACH inspections are invited to inform their Competent Authorities about on-going efforts by the industry outlined above.

### **FINAL MESSAGE**

Companies are responsible to duly update their REACH dossier for substances used under SCC.

Concerned registrants shall:

- Complete Appendix 3 and send it to ECHA via an update of the individual REACH Dossier;
- Complete Appendix 2, as 'on-site' documentation. Appendix 2 does not have to be attached to the REACH Dossier, but has to be ready in case of a Member State enforcement visit.

Please, keep up to date communication with the respective consortia!

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