



Refinables Project

Strategy to update / upgrade the Registration Dossiers submitted in 2010 - DRAFT
Programme for 2013

AIM

The original Refinables strategy approved in January 2011 included several steps to perform sameness assessments, T/D and bio-accessibility testing, workplace exposure and environmental emission data generation/collection, validation tests and review of hazard classifications.

This document proposes a strategy to update / upgrade¹ and improve the concerned Refinables' Registration Dossiers without undue delay, in light of the latest interpretation of the concept of "intermediate" and "strictly controlled conditions" (SCC) in the December 2010 version of the ECHA Guidance on intermediates.

Following the changed guidance:

- Eurométaux started an advocacy programme with ECHA to achieve a more relevant and pragmatic interpretation of the SCC and rigorous containment conditions for UVCB intermediates by re-opening the discussions on the content of the Dec 2010 ECHA Guidance. To this end, a number of metal specific SCC examples were submitted. However, ECHA did not consider the Eurométaux examples to properly reflect SCC in the sense of the latest ECHA guidance on intermediates.
- Eurométaux and the metal consortia have been working on the development of concepts and tools to better address the assessment of complex inorganic UVCB substances. Due to the complexity of the UVCBs under assessment, plus the need to ensure consistency in approach, this process has been less straightforward than expected.
- The PM Refiners generated/collected high quality workplace exposure and environmental emission data to:
 - support SCC at company level (as the exposure analysis did not allow to support SCC on a sector-wide basis),
 - complete Appendices 2 and 3 of the Dec 2010 ECHA Guidance on intermediates for those intermediates/companies where SCC are applied and a Dossier update can be performed, and,
 - prepare the basic dataset for an exposure assessment for those intermediates where SCC are not applied and a full safety assessment is required for Dossier upgrades.

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 (the actual intermediate status) and/or the SCC until its transformation. This stresses the need to properly identify substances under REACH.

In light of the above, the PMC agreed to the following project strategy:

- (i) Demonstrate and document the substance status of the PM Refinables:
 - Waste, by-product or non-waste;
 - Substance or intermediate;
 - UVCB.
- (ii) Update preparation (if SCC): demonstrate SCC and update individual Registration Dossier by adding Appendix 3.
- (iii) Upgrade preparation (if not SCC/business decision):
 - Demonstrate due diligence;
 - Risk assessment of UVCB: contribute to Eurométaux guidance under development;
 - Upgrade joint Registration Dossiers by addressing tonnage band related information requirements via an approach alternative to testing developed by Eurométaux members with ECHA.

¹ Update: SCC can be demonstrated and documented in Appendix 3. Upgrade: Article 10 dossier (full tonnage band based-risk assessment) will be submitted because SCC cannot be demonstrated / business decision.



NOTA BENE

The timelines provided are indicative and aim at preparing improved Dossiers and Dossier updates and upgrades without undue delay. They may be adjusted from time to time depending on the development and availability of the required tools (e.g.: Eurométaux multi-metallic database, feedback from Eurométaux workshops with ECHA, etc.).

1. DEMONSTRATE AND DOCUMENT THE SUBSTANCE STATUS OF EACH PM REFINABLE

To define the scope of the 2013 work programme for the PM Refinables, it will have to be decided for each PM Refinable if it is:

1. A waste, a by-product or a non-waste (waste and by-products not placed on the market are exempted from all or some titles under REACH);
2. A substance or an intermediate (intermediates are exempt from Authorisation; intermediates under SCC benefit from reduced Registration requirements);
3. Handled and used under SCC during its entire life-cycle;
4. A unique UVCB (produced by a common manufacturing process and from a common source).

TABLE 1. PROVISIONAL TIMELINE TO DEMONSTRATE AND DOCUMENT THE SUBSTANCE STATUS OF EACH PM REFINABLE

	Task	Who	When
1.	Provide background information to Refiners WG for decision on substance status: a. Factsheets on intermediates, SCC, UVCB, Waste and Cease manufacture b. Assessment document (non-)waste, intermediate and UVCB status of PM Refinables	PMC Sec	Nov 2012
2.	Survey to assess the (non-)waste, intermediate and UVCB status of the Refinables, and to assess which Refinables are rigorously contained / handled under SCC: a. Circulate to Refiners WG b. Complete survey c. Compile answers to survey in order to define update/upgrade scope and present to Refiners WG	PMC Sec Refiners WG PMC Sec	Nov 2012 Dec 2012 Dec 2012 - Jan 2013
3.	Organise interactive 1-day intermediate workshop , addressing waste/non-waste, intermediate, UVCB status of Refinables	PMC Sec	13 Dec 2012
4.	Update ID cards of the Refinables to reflect main outcomes of survey and workshop	PMC Sec	Dec 2012 - Jan 2013
5.	Prepare input on substance identification of UVCB for January 2013 Eurométaux/ECHA workshop	Eurométaux (with PMC support)	Jul 2012 - Jan 2013

2. UPDATE PREPARATION

For those Refinables where SCC are met, a dossier update will be made. Documentation of the SCC in place needs to be reported in an Appendix 2 (to be kept in-house) and Appendix 3 (for inclusion in registration dossier).

Following the ECHA screening of REACH intermediate registration dossiers, Eurométaux has started a dialogue with ECHA to clarify which (metal) PROCs can be compatible with SCC. ECHA expects entities having SCC intermediates to justify the selection of each PROC and document its applicability for each step of the intermediate's production and life-cycle in the Appendix 3 they include in their registration dossier.



TABLE 2. PROVISIONAL TIMELINE FOR DOSSIER UPDATES

	Task	Who	When
1.	Document SCC supporting evidence in Appendix 2 and 3	PMC Members	ASAP
2.	Justify PROCs for each step of the intermediate's production or life-cycle on the basis of the Eurométaux and EBRC document entitled 'Comments from the NFM industry to Annex I, Table 1 of ECHA letters dated 13 Sep 2012' dated 7 Oct 2012 in the Appendix 3 of each and every SCC intermediate	PMC Members	ASAP
3.	Update individual IUCLID 5 file with Appendix 3 and reviewed and/or justified PROCs	PMC Members	ASAP and at the latest by end Mar 2013

3. UPGRADE PREPARATION

If all the SCC criteria are not met or are borderline (will always be subject to some level of interpretation by the registrant and/or local authorities), an upgrade to a full intermediate dossier will be required. This would require an effects assessment, an exposure assessment (limited to the workplace and local environmental scenario for the manufacture and use of the intermediate) and a risk assessment demonstrating Risk Characterisation Ratios (RCR) below 1.

A classical effects assessment for > 1000 t materials is scientifically not appropriate for UVCBs, due to the difficulty to collect a representative sample for testing; performing the battery of REACH tests on a UVCB sample would certainly not lead to improve safety. The alternative is to perform read-across from the hazard and exposure information on the individual constituents.

The PMC is participating in the Eurométaux Task Force on REACH intermediates (including representatives from several metal consortia), which is preparing guidance on how to assess metallic UVCBs, using practical examples, illustrating the constituent-based approach.

TABLE 2. PROVISIONAL TIMELINE FOR DOSSIER UPGRADES

	Task	Who	When
1.	Eurométaux Task Force on REACH intermediates:		
	a. Finalise the multi-metallic (E-)TRV database for use in risk assessment of UVCB under REACH	Eurométaux	Dec 2012 - Jan 2013
	b. Prepare data-sharing agreement format outlining: background, purpose, access restriction and compensation mechanism to be formally approved by all data providers	Eurométaux (with PMC support)	Jan-Feb 2013
	c. Continue development of guidance to risk assess inorganic UVCB under REACH, including test cases to demonstrate applicability of the developed approaches	Eurométaux (with PMC support)	Oct 2012 - summer 2013
2.	Human health exposure assessment:		
	a. Describe and test approach towards preparation of sector-wide and company-specific Exposure Scenarios	EBRC	Oct 2012 - Apr 2013
	b. Once TRV are compiled in the Eurométaux multi-metallic (E-)TRV database, continue preparation of sector-wide Exposure Scenarios	EBRC	Jan-May 2013
	c. Develop site-specific Exposure Scenarios	EBRC	Jun-Aug 2013
3.	Environmental exposure assessment:		
	a. Once ERV are compiled in the Eurométaux multi-metallic (E-)TRV database, prepare generic Exposure Scenario	WCA	Jan-May 2013
	b. Consider need for site-specific Exposure Scenarios	All	Jun-Aug 2013
4.	Submission Article 10 dossiers		Aug-Oct 2013