



Refinables Project

Strategy to update the Registration Dossiers submitted in 2010 in light of the change of interpretation of the concept of “intermediate” and “strictly controlled conditions”

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AIM

This document proposes a strategy to update the concerned Refinables’ Registration Dossiers with undue delay, in light of the change of interpretation of the concept of “intermediate” and “strictly controlled conditions” (SCC) in the December 2010 version of the ECHA Guidance on intermediates.

This strategy proposal was discussed at the 11 January 2011 Refiners WG meeting as well as at the 12 January 2011 Assembly meeting and includes adjustments done in line with the suggestions made and decisions taken at these two meetings.

BACKGROUND

Refinables are non-waste complex (UVCB) Isolated Intermediates resulting from a primary or secondary refining stream containing precious metals.

Since 2007 the Members of the Precious Metals and Rhenium Consortium (PMC) have worked together to identify, group, characterise, classify and register fourteen Refinables.

An updated version of the ECHA Guidance on intermediates was published on 16 December 2010 which clarifies that SCC is a set of conditions which apply simultaneously over the entire life cycle of the intermediate. All references to (eco-)toxicological hazard and knowledge on (eco-)toxicological properties when designing rigorous containment have been removed from this latest ECHA Guidance, which therefore results in a much stricter interpretation of strict control.

This means that Refinables which were deemed to be manufactured and imported under SCC as per ECHA Guidance of February 2010 may no longer be complying with such conditions under the updated version of the Guidance.

PMC Members must hence evaluate each Refinable and determine which Registration Dossier requires to be updated in order to comply with Registration requirements for intermediates which are not handled under SCC in accordance with the December 2010 ECHA Guidance on intermediates.

NOTA BENE

The implementation of SCC is the responsibility of each legal entity, and enforced by each National Competent Authority.

The proposed strategy requires the prompt and resourceful contribution of all PMC Members having registered one or more of these Refinables.

The update of the Registration Dossiers must be done jointly under the umbrella of the PMC for those Refinables where at least one Member of the PMC does not implement SCC as per the December 2010 ECHA Guidance.

The update of a Registration Dossier may involve a review of the identity and grouping approach in order to better distinguish different streams; this may result in further splitting of some of the largest groups of



Refinables (formed on the basis of refining process, resulting forms/species, associated classifications, etc.).

Although the information requirements for intermediates which are not handled under SCC correspond to those laid down in Annexes VII-X of the REACH Regulation (depending on the tonnage), PMC aims at:

1. Promoting the use and acceptance of non-testing approaches to comply with the objective of the REACH regulation (e.g. read-across from the information available on the constituents, etc.), and
2. Relying instead, on real workplace exposure and environmental emission/immision data (monitoring data demonstrating minimum exposure and emissions) rather than on exposure and emission modelling¹.

The below strategy may imply the revision of the cost-sharing formula that is applied on the Refinables project of the PMC.

PROPOSED STRATEGY

Several steps and sub-steps are proposed; some of these steps may occur in parallel. The complete list of associated tasks under each step will be further detailed in a specific Refinables project plan:

Inventory/re-scoping phase

1. Identification, by PMC Members, of the Refinables which are not handled under SCC in accordance with the recent version of the ECHA guidance (per Refinable and legal entity)
2. Identification, by PMC Secretariat, of the Dossiers that will require to be updated (distinguish "simple" from "complex" cases) and of priority groups in the event resources must be allocated sequentially, on the basis of the outcomes of step 1

Planning phase

3. Review of identity/sameness of streams grouped in each Dossier (considering the flexibility required for UVCB materials), review of the resulting classifications per Refinable (considering possible splitting resulting from the previous step), presentation and acceptance of the read-across/*de minimis* validation testing approach by Eurométaux and ECHA, and agreement on the final scope and execution phase of the project

Execution phase

4. Generation, evaluation and validation of effects, exposure and emission data aimed at completing the content of each Dossier considering the UVCB status of each Refinable and the robustness of the read-across/*de minimis* validation testing approach

Concluding phase

5. Update of each IUCLID 5 file and submission of updated Registration Dossier to ECHA

In the absence of further precision from ECHA and Competent Authorities on what is understood by "undue delay", PMC Secretariat aims at finalising this project in order to submit updated Registration Dossiers in December 2012. Should further precisions become available, the timeline will be adjusted. Should additional time be granted, this time will be used to improve the robustness of the underlying dataset (e.g.: generation of more emissions and exposure data points) where needed.

¹ Those PMC Members having participated in the registration of silver and silver compounds project have experienced that modelling exposure and emission often leads to risk scenarios or scenarios where risk can only be controlled by implementing unrealistic risk management measures.



PROVISIONAL TIMELINE AND BUDGET

Step	Task	Who	When	Budget per task (€)
1	a. Survey to collect preliminary feed-back from PMC Members on compliance with the latest interpretation on SCC	a. PMC Members	a. 24 Dec 2010 - 10 Jan 2011	HW: 2500 - 3750 WCA: 2000 ⁽¹⁾ TOTAL: 4500 - 5750
	b. PM Refiners WG meeting to present outcome of preliminary survey and how to interpret/check compliance with the latest interpretation on SCC	b. PMC Secretariat	b. 12 Jan 2011	
	c. Inform Eurométaux on preliminary feed-back	c. PMC Secretariat	c. 15 Jan 2011	
	d. Survey to collect final feed-back from PMC Members on compliance with the latest interpretation on SCC	d. PMC Members	d. 12 Jan - 14 Feb 2011	
2	a. Collation of responses to preliminary survey	PMC Secretariat	a. 10-12 Jan 2011	HW: 3750 - 5000 WCA: 3500 ⁽¹⁾ TOTAL: 7250 - 8500
	b. Inform Members on latest interpretation on SCC		b. 12 Jan 2011	
	c. Collation of responses to final survey		c. w/c 14 Feb 2011	
	d. Identification of the Dossiers that will require to be updated		d. End Feb 2011	
3	a. Review of identity/sameness of streams grouped in Refinables 4. Slimes and sludges; 9.1 Materials for reclaim, PM with or without support; and 9.3 Materials for reclaim, PM production by-products	a. PMC Secretariat	a. Mar - Apr 2011	HW: 7500 - 11250 EBRC: 5000 ⁽¹⁾ WCA: 5000 ⁽¹⁾ TOTAL: 17500 - 21250
	b. Presentation and advocacy of robustness of the read-across/ <i>de minimis</i> validation testing approach to ECHA	b. Eurométaux (with consortia secretariats)	b. Feb - Jun 2011	
	c. Agreement on the final scope of the project and formal commitment of concerned PMC Members	c. PMC Members	c. 30 Jun 2011	



Step	Task	Who	When	Budget per task (€)
4	a. Identify at least one reference sample per Refinable	a. PMC Members	a. Jul - Aug 2011	Manager: 150 000 HW: 40 000 EBRC: 60 000 ⁽²⁾ WCA: 60 000 ⁽²⁾ CRO: 100 000 ⁽¹⁾ Speciation: 35 000 ⁽³⁾ T/D: 35 000 ⁽⁴⁾ Bio-elution: 168 000 - 224 000 ⁽⁵⁾ Physico-chemical: 35 000 ⁽⁶⁾ TOTAL: 683 000 - 739 000 + 10% contingency TOTAL: 751 300 - 812 900 Acute & sub-chronic tests + ARCHE: 2012
	b. Gap-fill and expand existing dataset by gathering/generating elemental, speciation, T/D, bio-elution and/or physico-chemical (including dustiness) data, as relevant, for at least one reference sample per Refinable	b. PMC Members	b. Sep - Dec 2011	
	c. Gather/generate workplace exposure and emission monitoring data for each Refinable group	c. PMC Members (with support of CRO)	c. Sep - Dec 2011	
	d. Perform exposure and emission assessment (iterative exercise, two tiers foreseen)	d. WCA and EBRC	d. Tier 1: Sep - Dec 2011; Tier 2: Jan - Apr 2012	
	e. Draft a Chemical Safety Report including an Exposure Scenario (one production sector, one use sector)	e. WCA and EBRC	e. Sep 2011 - Jun 2012	
	f. Conduct/monitor acute and sub-chronic toxicity validation tests to corroborate validity of results obtained with above steps, especially in cases where the resulting risk characterisation ratio (RCR) is borderline	f. WCA and EBRC	f. 2012	
	g. Review classification of each Refinable on the basis of updated dataset	g. ARCHE	g. 2012	
5	a. Completion of Appendix 3 of December 2010 ECHA Guidance on intermediates	WCA, PMC Secretariat and Lead Registrants	Ongoing/Dec 2012	WCA: 2012
	b. Update of each Dossier and re-submit to ECHA			
GRAND TOTAL FOR 2011				780 550 - 848 400

(1) Ball-park figure based on estimated days of work

(2) Assuming 4 days/refinable and 14 refinables

(3) Assuming full characterisation (including particle size and surface area), 5000 €/test item, and 7 test items

(4) Assuming only 24h screening tests, 5000 €/test item and 7 test items

(5) Assuming four synthetic media (artificial sweat, artificial gastric fluid, artificial interstitial fluid, and artificial lysosomal fluid), 12000 - 16000 €/test item, and 14 test items

(6) Assuming minimum test package (granulometry, melting point, boiling point, relative density, oxidising properties, self-ignition), 5000 €/test item, and 7 test items



An indication of who will be involved in each step and how long each step may take is provided in each case:

- PMC Members means: All Members having declared at least one Refinable to PMC
- PMC Secretariat means: Caroline Braibant and, in her absence, Hugo Waeterschoot

Where consultants are assigned a specific task, this is done in full cooperation with PMC Secretariat and PMC Members.

POTENTIAL BOTTLE NECKS

If the following tasks are not accomplished effectively, it may jeopardise the overall success of the PM Refinables update strategy:

- Concurrent agreement and participation of all concerned PMC Members (late comers should not be accepted)
- Update of MEASE/SPERCS (lead by by Eurométaux)
- Acceptance of read across approach by ECHA (promoted by Eurométaux)
- Finalisation of bio-accessibility round robin test (promoted by Eurométaux)
- Generation of effects data (linked to sample availability and test houses capacity)
- Generation of emission and exposure data (PMC Member involvement/feed-back and CRO availability/adequacy)

KEY MILESTONES

	Key Milestone/Decision point	Justification	When?
a.	Agreement on "sameness"	Impacts design of execution phase	April 2011
b.	Acceptance of Read Across approach by ECHA and exposure collection needs by PMC Members	Impacts design of execution phase	June 2011
c.	Finalisation of effects, emission and exposure data collection (two tiers)	Delay could strongly paralyse/delay CSA and subsequent drafting/validation	Late Q1/Early Q2 2012
d.	Finalisation of Appendix 3 and updated Registration file	Key for successful submission	Dec 2012

RESULTING TIMELINE AND ASSOCIATED MEETING AND CONFERENCE CALLS

A recap of the resulting timeline and preliminary meeting and conference call periods is available below:

M1: 12 January 2011 - presentation of Dec 2010 ECHA Guidance and PMC strategy

M2: April 2011 - feed-back on final compliance survey, collection of data on operational conditions, overall progress and sameness check of groups 4. Slimes and sludges; 9.1 Materials for reclaim, PM with or without support; and 9.3 Materials for reclaim, PM production by-products

M3: June 2011 - agreement on sameness of groups 4., 9.1 and 9.3, and agreement on execution phase

M4: July 2011 - evaluation of data on operational conditions and training in preparation of emission and exposure data generation

M5: December 2011 - first tier of CSA and determination of preliminary validation needs

M6: April 2012 - second tier of CSA, first ES drafts and confirmation of validation needs

M7: June 2012 - revised ES drafts and follow-up of validation step

M8: September 2012 - review of final CSA/CSR, ES and validation test results, review of draft Appendices 3 and review of classification

M9: November 2012 - review of updated dossiers and preparation for dossier update



Step	2011												2012											
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
1 a	M1																							
1 b																								
1 c																								
1 d		C1																						
2 a																								
2 b																								
2 c																								
2 d		C1																						
3 a				M2																				
3 b																								
3 c						M3																		
4 a							M4																	
4 b								C2																
4 c									C3															
4 d										M5						M6								
4 e																	M7							
4 f																								
4 g																				M8				
5																							M9	