Chair: *Edwin Broekaert* (Umicore)
Co-Chair: *Daniela Cholakova* (Aurubis)

11 January 2011, 10:30 – 16:30
Metals Conference Centre
Rue du Duc 100, B-1150 Brussels

Minutes

1. Welcome and introduction

1.1. Confidentiality and Competition Law. Participants were reminded on their obligation of comply with Confidentiality and Competition Law.

1.2. Tour de table. The list of participants is available in slide 3 of Annex 2.

1.3. Approval of the Agenda. The Agenda (Annex 1) was approved.

1.4. Objective of the meeting. *Cf. slide 5 of Annex 2.*

2. Overview of 2010 Registrations. *Cf. slides 6 to 9 of Annex 2.*

All registration files prepared since 2007 were successfully submitted in 2010 (with the exception of gold electrolyte which requires a later registration). They were compiled in line with the approach followed by other metals consortia (with some differences) for UVCB and included key statements to demonstrate compliance with strict control as described in the February 2010 ECHA Guidance on intermediates. **AP1** All Members have received a registration number and can continue importing/manufacturing these in the EEA. Also, four Letters of Access were sold to non-Members in 2010.

3. Changes to ECHA Guidance on intermediates and overview of Members' compliance with recent interpretation of strictly controlled conditions by the group. *Cf. slides 10 to 29 of Annex 2.*

An updated version of the Guidance on intermediates was published by the ECHA in December 2010. This updated version includes a much stricter interpretation of strict control; strict control can only be demonstrated if ***all*** conditions described in Article 18.4 of REACH are met ***simultaneously*** over the ***entire life cycle*** of the intermediate. If this cannot be implemented and properly documented in-house, strict control can not be demonstrated and a full registration must be submitted.

Some participants expressed concern that Eurométaux, CEFIC, etc. had not been successful in demonstrating the unsuitability of strict control as described in the ECHA Guidance to the non-ferrous metals (NFM) streams and processes. It however seems that Member States' decision was driven by policy rather than by science or facts. Eurométaux will however continue to defend the NFM position where there is room for negotiation or change (cf. item 4 below).

It was made clear that although the ECHA Guidance is not legally binding, its content was unanimously requested, defended and approved by all Member States which are in charge of the enforcement of REACH. This means that local authorities will be referring to this Guidance (once they become aware of its release) when verifying compliance with strict control even if it does not constitute law. Local authorities will therefore expect registrants to either:

- demonstrate strict control as per the recent Guidance, or
- demonstrate that they are implementing the necessary steps and measures to comply with the recent Guidance by:

- improving their strict control measures
- updating their registration dossier

The legal consequence of not fulfilling the above expectations remains unknown and will possibly differ from one enforcing authority to the other. **AP2**

4. Impact assessment and proposed strategy to update 2010 Refinables Registration Dossiers.
Cf. slides 30 to 54 of Annex 2.

In the event a full registration is required, this means fulfilling Annexes VII-X information requirements, performing a Chemical Safety Assessment (CSA) (i.e. gathering and assessing emissions and exposure data), and generating a Chemical Safety Report (CSR)(including Exposure Scenario). The registration would however remain an intermediate registration and would as such remain exempt from Authorisation.

Performing Annexes VII-X tests for UVCB as variable and complex as PM Refinables is not deemed reasonable. Indeed the identification of one reference sample for testing is impossible and several reference samples would need to be tested to cover all possible streams. Still this would result in repeating the same test for a subset of samples, which would not tackle the full variability of refining streams and is against the principle of minimising animal testing. PMC and industry in general therefore aim at proposing alternative approaches to testing which are based on:

a) a careful characterisation of the streams covered in each Dossier,
b) a robust read-across system which would allow using: i) the hazard information on the constituents in each UVCB, and ii) data on release of soluble/potentially bio-available ionic and other metal bearing species in water/biological fluids from the UVCB to generate a hazard profile of each Refinable,
c) *de minimis* testing to support and validate the read-across approach (especially in cases where the resulting risk characterisation ratio (RCR) is borderline.

Steps a) and b) were already implemented in the 2010 registration files and step c) has been put forward as a potential condition for acceptance of the alternative approach by ECHA and Member States. These tests would not be subject to prior approval by ECHA (i.e. would not be submitted in the form of testing proposals but as a test result).

No CSR were submitted with the 2010 registrations. The CSA/CSR must be performed taking account of the fact that each Refinable contains several toxicity drivers (e.g.: Pb, Ni, As, etc.) for which more than one exposure route may be relevant. **AP3** The preparation of CSA/CSR and the Exposure Scenario for each Refinable will therefore be much more complex than what was done for mono-constituent substances registered in 2010 (e.g. silver, silver nitrate and disilver oxide). Although a tiered approach is proposed (starting with modelled emission and exposure), it is expected that only measured emission and exposure data will be able to demonstrate safe use (and strict control). When updating the Refinables files CSA/CSR may be required for both Refinables manufactured/imported > 10 tonnes/year and below.

PMC Members were requested to complete a preliminary survey on compliance with the latest interpretation of strict control and return this survey by 10 January 2011. **AP4** It was acknowledged that this survey aimed at gathering preliminary feed-back only and that it would require confirmation after the meeting. The answers to the preliminary survey indicated that for each Refinable at least two companies (except for those Refinables where only one Member is interested) could no longer satisfy strict control as per the recent ECHA Guidance. This means that all dossiers require to be updated. Confirmation of this preliminary feed-back will

be required by 15 February 2011. **AP5**

Considering some Refinables as wastes instead of products/substances was agreed to be a decision to be taken by each company in accordance with its local legislation and competent authorities.

A strategy to update the files was presented and discussed with the participants. The strategy includes four main phases, an associated timeline (including key milestones and bottle necks) and a budget (which was updated at the PMC Assembly meeting on 12 Jan 2011). The objective is to update the files to meet the requirements of a full registration (including exposure assessment and risk characterization), and improve the existing hazard part of the dossiers in terms of characterization, refinement of classification, IUCLID file completion, etc. It was recognised that more work/resources will be required in 2011 and 2012 to update the files, than what was required over 2007-2010. **AP6**

An updated version is attached as Annex 3. **AP7** The budget provides worst case estimation of testing and related cost. The exact testing scope for every Refinable stream will be justified and agreed by PMC Members in April. It was agreed that sameness would only be revised for 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. **AP8**

The current cost-sharing formula to allocate the PM Refinables project budget among PMC Members assumes the same amount of work is needed for all Refinable files and all tonnages and therefore assigns a unique weight of 1 to all Refinables declared by PMC Members. In light of the type of work that is required to update the files and the fact that all files will likely require to be updated, it was agreed to leave the cost-sharing formula unchanged. This decision will be re-considered in due course, in the event the work becomes tonnage-dependant.

5. AOB, next meeting and closing remarks

5.1. Agreed actions/timeline (including feed-back to Eurométaux). Cf. table 1 below.

5.2. Next conference calls/meetings. Cf. Annex 3

Annexes:

1. Agenda
2. Slides presented at the meeting
3. Strategy to update the 14 PM Refinables files
4. Final survey on SCC compliance
5. Feed-back from Eurométaux on efforts invested in revision of ECHA Guidance

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Table 1. Actions agreed at 11 Jan 2011 PM Refiners WG meeting

	Action	**Who?**	**When?**
1.	Circulate full Refinables IUCLID 5 files to PMC Members	WCA & CB	ASAP
2.	Carefully follow review of REACH text and particularly changes suggested to those articles having a direct or indirect impact on REACH requirements for intermediates	Eurométaux & PMC	Ongoing
3.	Request Eurométaux to collect PNEC and DNEL values for all metal and metal compounds in preparation of CSA needs	CB	Done
4.	Inform Eurométaux on preliminary feed-back received from PMC Members on compliance with Dec 2010 ECHA Guidance on intermediates	CB	Done
5.	Complete final SCC compliance survey (Annex 4) and return to CB	PMC Members	By 15 Feb 2011
6.	Invite Eurométaux to use strategy proposals and associated milestones and bottle necks such as PMC' to demonstrate the need for a minimum of 2,5 years to update the UVCB intermediate registration files submitted in 2010	HW	ASAP
7.	Translate the PM Refinables strategy to update the 14 PM Refinables files into a specific project plan	CB	By 15 Feb 2011
8.	Use data provided by Members to derive the company-specific MeClas classifications to review the 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 to consider need to split each group on the basis of speciation and associated process	HW	Before 15 Feb 2011

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