



7 of September 2010  
10:30 - 16:30

Chairman: E. Broekaert (Umicore)

*Metals Conference Centre: Nickel/Zinc room  
Rue du Duc 100 - 1150 Brussels (BELGIUM)*

## MINUTES

### 1. Introduction

- 1.1. **Confidentiality and European Competition Law provisions.** Participants were reminded to comply with confidentiality and Competition Law obligations.
- 1.2. **Tour de table.** The list of participants is available in Annex 1.
- 1.3. **Objective of the day and approval of the Agenda.** (cf. slides 4-5 of Annex 2) The meeting aimed at clarifying any open question PM Refiners WG members had on the overall project scope, methods, schedule and expected deliverables. The Agenda (Annex 1) was approved.

### 2. Recap on status of PM Refinables project. (cf. slides 6-11 of Annex 2)

It was clarified that the registration deadlines indicated in slide 8 are based on tonnage only (REACH registration deadlines are also influenced by classification) and are therefore subject to a change once the classification(s) derived for each refinable are presented on 11-12 October.

Also, it was made clear that Annex VII testing requirements applicable to transported isolated intermediates manufactured and/or imported in > 1000 t/a will be fulfilled by applying a non-testing approach, on the basis of the characterisation and classification method applied by the PMC.

#### AP1

As regards the flow chart, it was confirmed that sludge can be generated in Pb metallurgy (one of PMC's Members had questioned whether having Slimes and sludges in the Pb metallurgy was sound) and that materials for reclaim (9.1, 9.2 and 9.3) can both be generated during PM refining as well as be fed into PM refining from secondary sources.

### 3. Preparation for Registration: LR versus non-LR files. (cf. slides 12-15 of Annex 2)

The basis for Registration preparation can be found in the REACH text (Articles 17 to 19 for intermediates), in ECHA guidance and industry guidance. Slides 12 to 14 provide the legal basis to be used as reference to prepare for Registration.

As regards strict control, as interpretation from industry, authorities and ECHA diverge in some cases, it is recommended to apply the legal text and properly document the evidence of such strict control internally. In 2011 an updated ECHA Guidance may be released which may force industry to update its intermediate dossiers into substance dossiers<sup>1</sup>. This would mean that all REACH Annexes would be required (tonnage-based) as well as a Chemical Safety Assessment for all hazardous Refinables manufactured in volumes equal or superior to 10 tonnes/year. As regards REACH Annexes, PMC's non-testing approach may need to be revisited and completed for higher tier testing requirements. (AP2)

Slide 15 presents a summary of the information that needs to be submitted by LR and non-LR registrants and an indication on where the information will be provided by PMC and where it must be generated by each registering entity.

### 4. Minimum substance identification analytical requirements for PM Refinables and how to obtain a representative sample for testing. (cf. slides 16-18 of Annex 2)

<sup>1</sup> **Post-meeting note:** An e-mail from Eurométaux providing an update on the changes made to the ECHA guidance on intermediates is available in Annex 5.



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Several PMC Members had requested PMC to generate a specific recommendation on minimum substance identification analytical requirements that would be relevant for solid, liquid, and complex PM materials. It was clarified that the selection of the type and number of methods used to characterise a substance or intermediate is the responsibility of each registrant. PMC recommends as a minimum, an elemental analysis and an IR or Raman spectrum (Raman for liquid materials).

Granulometry data is relevant for materials that are dusty in order to show the presence or absence of inhalation risk (especially if intermediate files had to be updated in substance files requiring a Chemical Safety Assessment).

N-BET data is relevant for materials which are classified in the form of powder (materials are usually tested in the form of powders even when they are manufactured or imported in massive forms) but should not be classified in more massive forms.

A question was raised on how sampling should be performed to obtain one or more representative samples per UVCB Refinable. It was recommended to use a tiered approach where historic analytical data is used to proof the identity of the PM Refinables and analysis are only performed on an *ad hoc* basis on new or exceptional streams, or when requested by authorities in the event of a compliance-check.

**5. Overview of IUCLID 5 for UVCB Refinables - live access to IUCLID 5 & Q&A.** (cf. slides 19-40 of Annex 2).

Participants were taken through IUCLID 5 in order to be familiarised with the software and understand the format in which the information will be entered and delivered to the ECHA. The only information that must be prepared by registrants is the contact information of the contact person. The rest should be provided by PMC.

It was explained that where the name or description of the Refinable in the EC inventory is not fully correct, a special field "Reference substance" in **section 1.1** can be completed with the name and description agreed at PMC level. Following registration, EU authorities are then responsible for generating the associated EC number, in the event a new or different number is required.

In **section 1.2** an *ad hoc* "composition box" can be created for each composition profile or grade. Each composition box will have a unique "composition ID" that can be linked to an associated classification in section 2. It was recommended to list all constituents of each Refinable as constituents and to leave sections on Impurities and Additives empty.

Although **section 1.3** is not mandatory, it is useful to create a link between the pre-registration and registration performed by each legal entity, even if they were not necessarily done under the same EC number.

Although **section 1.4** is not mandatory for intermediates, the elemental analysis and characterisation results performed on the reference samples will be uploaded and described in this section, to serve as a reference for identification and sameness checks. Non-LR are free to add their own analytical information or not.

**Section 2** is foreseen to contain the classification proposal(s) for each Refinable. Two sub-sections (DSD/DPD and CLP/GHS) must be completed. The work performed by ARCHE and the results obtained with the tests performed at Harlan will be uploaded by WCA to section 2, which should be left blank in all non-LR files.



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**Section 3.5** is aimed at describing the use of the Refinable (intermediate) through specific PROC, ERC, PC, SU, AC and other codes. **AP3**

**Section 11** is the last section to be submitted to the ECHA. Its content should be generic but as close as possible to reality (i.e. conditions guarantying strict control). **AP4**

A meeting is planned with WCA on the last week of September to check the completeness of all Refinable files so they can be finalised shortly after the 11-12 October meeting. The secretariat was recommended to action the joint submission as soon as possible as although it is a simple exercise, it may be time-consuming (**AP5**). In order to avoid last minute registrations, as soon as the LR file has been submitted (whether or not it has been accepted), the PMC secretariat should give the concerned co-registrants a greenlight to proceed with co-registration. Once the LR file is accepted, all related co-registrations should in principle be accepted too.

**6. Approach towards classification of PM Refinables - DSD+DPD vs CLP, ERV and TRV, cutt-off limits, introduction to MECLAS & Q&A.** (cf. slides 41-45 of Annex 2 and Annex 3)

Basic questions relative to classification regulations, reference values and cutt-off limits (**AP6**) were raised by participants and are addressed in slides 41-45 of Annex 2. Once the REACH dossiers are submitted, classifications and the associated SDS generation, labelling and packaging obligations must be implemented as soon as possible (legally speaking by 3 Jan 2011 but participants recognised this is technically impossible to achieve).

F. Verdonck introduced participants to MECLAS (Annex 3) which is a web-based system to derive classifications of complex materials (UVCB and mixtures or preparations). MECLAS has been created with the input of several consortia and associations and has been subject to several quality-checks to guarantee the quality of the scientific values that support the resulting classification.

It is composed of a tiered system:

- Tier 0: elemental data only - all constituents are assumed to behave as their most soluble form (e.g.: sulphate or oxide)
- Tier 1: speciation data added - constituents are associated to a specific form and distribution
- Tier 2: T/D or bio-elution data added - whatever the form in which the constituents exist in the material it is their potential for release which is considered (no release = no influence in resulting classification; release = influence in resulting classification considered in light of cutt-off limit)
- Tier 3: test data added - this tier is not applied for PM Refinables and usually of importance for substances or mixtures

The classification of all reference samples used in the testing programme of the PM Refinables project (including characterisation, T/D, CLP, etc.) as well as each individual stream reported by each PMC Member to the PMC secretariat is derived by using the same tool. The more extensive dataset generated around the reference samples is used to complete tiers 1 and 2 for the companies' individual streams (i.e. it is assumed that the same species exist, in a same distribution, resulting in comparable environmental releasing rates).

The tool has been presented to ECHA in summer 2010; ECHA appreciated the science-basis and usefulness of MECLAS (**AP7**<sup>2</sup>).

<sup>2</sup> **Post-meeting note:** ECHA has not reverted with any official acceptance or rejection of the MECLAS tool. A brief summary of the presentation made to ECHA is available in Annex 6 page 5.



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The final classification of each reference sample will be uploaded on the online MECLAS tool allowing each company to compare its own stream(s) with the reference one. As regards the individual streams already declared to the PMC, ARCHE is currently generating a classification for each stream and comparing this with the classification of the reference sample to determine whether one classification or more classification clusters should be generated for each Refinable group (AP8). This will be reported in more detail on 11-12 October.

## 7. AOB, next meetings and concluding remarks

### 7.1. Next meeting/conference call: Brussels, 11-12 October 2010

#### Annexes:

1. Agenda and list of participants
2. Slides presented at the meeting
3. Slides on MECLAS tool
4. One-pager on cutt-off limits
5. E-mail from Eurométaux on changes proposed to ECHA guidance on intermediates
6. Minutes of workshop where MeClas was presented to ECHA

**Table 1.** Actions agreed at 7 Sep PM Refiners WG brainstorming meeting

	Action	Who?	When?
1.	Inform WCA on approach followed by Cu Consortium to complete sections 4 to 7 of IUCLID 5	CB + DC	End Sep
2.	Request updated Guidance on strict control and date of workshop to Eurométaux	CB	Done <sup>3</sup>
3.	Check what is the minimum number of fields in section 3.5 that must be completed for an intermediate file to pass the TCC	CB	End Sep
4.	Check what is the minimum number of fields in section 11 that must be completed for an intermediate file to pass the TCC	CB	End Sep
5.	Circulate guidance inviting LR to create joint submission object and generate token number for each Refinable on REACH-IT	CB	ASAP
6.	Provide one-pager on method applied to calculate cutt-off limits	ARCHE	Done <sup>4</sup>
7.	Obtain minutes or "compte-rendu" of meeting between Eurométaux and ECHA in summer 2010	CB	Done <sup>5</sup>
8.	Clarify with Eurométaux whether the classifications derived with MECLAS should consider the available classification (e.g.: reported in Annex VI of CLP) or the classification resulting from the REACH work (self-classification until picked up for harmonisation and approved at EU level)	CB	ASAP

<sup>3</sup> **Post-meeting note:** According to Eurométaux the EM guidance on intermediates will only be revised after the 20 Sep PEG meeting (see Annex 5), following which a workshop date should be proposed.

<sup>4</sup> **Post-meeting note:** See Annex 4

<sup>5</sup> **Post-meeting note:** See Annex 6