MINUTES

AP refer to Action Points listed at the end of this document.

1. Welcome & Introduction

1.1. Reminder on Confidentiality and Competition Law.

Participants were reminded on their obligation to comply with confidentiality and Competition Law rules.

1.2. Tour de table and apologies

The list of participants and apologies is available in Annex 1.

1.3. Approval of the agenda

The agenda is available in Annex 1. No remarks/additions; agenda approved.

1.4. Approval of the minutes of the last meeting (6 February 2014) – including status of action points

The minutes of the meeting were approved. The status of actions is reported in slides 5-6 of Annex 2.

2. Substance identity (SID) of PM Refinables *(Cf. slides 7-18 in Annex 2)*

2.1. Feedback from ECHA

- As indicated at the last PM Ref WG meeting, ECHA has requested improved SID for existing UVCB registrations. In the meantime, ECHA has conducted a plant visit, which has been really helpful in making them understand the complexity of how these substances are produced. They indicated the guidance foresees a degree of flexibility in defining the key identifiers for the source and process descriptions (see also Annex 5).
- ECHA's main priority is to have all upgraded dossiers submitted by the agreed deadline of 30 April and they realize that the SID part of the dossiers can thus only be of a certain standard and will have to be improved through further updates. It is stressed that we will need to properly justify the variability of the Refinables and the way we have currently grouped/splitted them.

  *(**Post-meeting note**: ECHA requested another call with Eurométaux members on Friday 4 April to discuss SID of inorganic UVCB in more detail (see also Annex 6), and proposed to use four examples of the PM industry: matte, slimes and sludges, residues from cementation and reduction, and flue dust. ECHA indicated that perhaps we should not have enlarged 'residues from cementation' to 'residues from cementation and reduction'. They also immediately asked why slimes from electrolysis processes were grouped with sludges from other hydro-metallurgical processes. They generally understood that flue dust cannot be separated out per source and process.*
  ECHA grasped the difficulty in working on possible grouping refinements to better fulfill regulatory requirements while remaining realistic. They understood that the intrinsic variability of PM UVCB was due to the variability of the sources used, but they made it very explicit that the variability of each Refinable, and the possible approaches to decreasing the variability by splitting some dossiers after April 2014 would need to be described in detail in each CSR. After the call, the PMC secretariat has hence done this for each Refinable, in section 2.1 of each CSR. Due to time constraints, it was not possible to get the PM Ref WG's approval on these final CSR additions before submission of the dossiers but Lead Registrants (LRs) were asked to check them and correct/add where needed without reducing the level of detail.)

- ECHA clarified that one can update all parts of a dossier without having to re-pay a registration fee, except SID. When you change SID, this is considered a new registration implying a new registration fee. However, the ECHA SID unit is currently setting a process to allow a change in identifiers (backed up by a good justification) for a service cost only (instead of a new fee) but this will take some time.
- ECHA invited Eurométaux to submit an 'SID plan' describing the current status of the SID part of the inorganic UVCB dossiers, indicating which registrations will be kept, merged or split with the corresponding supporting rationale (see Annex 5). PMC has contributed to this SID plan after consulting the Refinables WG. As 1) the SID reasoning cannot be applied consistently across all Refinables and reflected in time for the April deadline, and 2) ECHA cannot confirm that adapting the SID of certain UVCB by splitting the registrations will not result in duplicate registration fees for some companies, the Refinables WG agreed not to further split any registration dossiers for this update but to keep the same identifiers as for 2010 registration. **AP1**
- From the 14 Refinables registered as SCC intermediates in 2010, 1 is now considered REACH exempt (waste/by-product route), 2 remain an SCC intermediate and 11 are considered non-SCC intermediates, requiring an 'upgrade' to an Article 10 dossier.

2.2. **UVCB identification rules: decision tree for SID**

A decision tree for SID of the Refinables is currently under development and will take into account:

- Origin or source
- Process / type of refinement step
- Reality of PM refining (e.g. flue dusts collected from several PM refining steps are collected, captured and treated together and hence considered the same substance)
- Speciation and composition (for validation purposes)
    - Should be given as far as known
    - Justification will be needed if ranges broad
- Classification (for validation purposes)

AP2-3

2.3. **Updated ID cards** *(Cf. Annex 4)*

- The Refinables ID cards have been updated with:
    - Updated generic compositions (across industry) as agreed at the last PM Ref WG meeting. The updated compositions also take into account new/updated information received from some companies and exclude those companies that are no longer registering.
    - Speciations have been checked/updated and are based on information available to registrants and/or mineralogical analysis (if available).
    - Updated classifications and classification-related compositions.
- Two ID cards were produced for the PM slags following the splitting that was agreed in November 2013 but these will be registered together for the April deadline as 2 grades of the same substance, with separate classifications (explanatory note has been added to the ID cards).
- For the PM slimes & sludges one ID card was produced given the recent objections to the splitting.
- The updated ID cards were circulated to the Refinables WG on 26 March. Remarks/additions:
    - Some of the concentration ranges in the ID cards will have to be enlarged to cover all registrants. **AP4**
    - Under analytical methods for identification of the substance, XRD and SEM should be listed as recommended methods and Raman spectroscopy should be listed under methods for molecular analysis. **AP5**
    - Registrants are advised to enter their LE specific composition as elemental concentrations and specify the speciation where available. **AP6**
    - It is suggested to collect the latest LE specific compositions once all registrants have submitted their updated dossier, in order to further refine SID. **AP7**
    - Speciation of the generic compositions will be further checked/refined. **AP8**

2.4. **Splitting of PM slags and PM slimes & sludges: way forward**

- The intention is to split the PM slags dossier in the previously agreed groups (2) once we have clarity from ECHA regarding procedure/fees to split. The WG agrees to leave both groups in one dossier as long as ECHA does not provide any flexibility on the registration fees. **AP10-11**
- For the PM slimes and sludges, the splitting will be re-considered using the decision tree and using updated process/source information collected during the previous splitting exercise. **AP3**

*(**Post-meeting note**: At the 4 April ECHA/Eurométaux call on SID of inorganic UVCB (see also Annex 6), ECHA listed the PM slimes and sludges specifically as an example of extreme/doubtful variability and spontaneously asked why we had grouped slimes from electrolysis processes with sludges from hydro-metallurgical processes. ECHA stated electrolysis is a separate process justifying separate UVCB registrations. The PMC secretariat explained that these processes were grouped in 2010 because in the BREF they are described as hydro-metallurgical processes overall and explained that the 2014 version of the dossier would still include the three sub-groups of slimes and sludges (from Ag electrolysis / Au electrolysis / hydro-metallurgical processes) but that we are aiming to refine SID after that. During the call, ECHA insisted on putting the detailed explanations on variability/splitting in the CSR. The PMC secretariat has hence done this. The LR has subsequently edited the CSR with some useful corrections, but also removed all reference to splitting electrolysis processes from other hydro-metallurgical processes, diluting the message ECHA expected to read.*
As per instructions of the PMC management committee, the PMC secretariat prepared an ad hoc clarification letter to ECHA providing the additional information that was missing in the latest version of the CSR prepared with the LR's expertise. However, given the objections from the PM Ref WG, it was decided not to send the letter but continue to investigate refinement of SID and tighten up our SID approach.)

3. **Updated classifications PM Refinables** *(Cf. slides 20-22 in Annex 2)*
Classifications of the PM Refinables were updated taking into account:
- New information/changes in MeClas since the last classification update (June 2012). This includes the update of the specific concentration limits (SCL) for STOT classification of Pb compounds voluntarily proposed by ILA. Aurubis has asked ILA to reconsider this SCL as it has consequences on the human health classification and is pushing to remove it from MeClas.
- Updated composition information received from some companies (and excluding those companies that are no longer registering). This meant that some previous classification clusters became obsolete.
- The new cluster analysis for PM slimes and sludges using the recent composition information received through the splitting exercise.

The updated classifications were circulated 26 March. Comments:
- The Doré classification should be reviewed as Doré contains metallic Pb/Cu and not Pb/Cu oxides. According to the speciation analysis of Doré, metallic silver encloses copper selenium silver tellurides, copper oxides and tellurium-bearing copper lead oxides which also fill the interstices of metallic silver. Therefore these intermetallic species shall be considered as inclusion and not as available compounds. Furthermore the sample tested for speciation was prepared by drilling/sawing, which might have caused some oxidation. **AP12-13**

Apart from the Doré classification, all PM Refinables classifications were approved by the WG.
*(**Post-meeting note**: Annex 3 contains all updated classifications, including the post-meeting update of the Doré classification.)*

For the purpose of classification, the compositions of the PM Refinables are defined by means of formulas. The WG agrees to change these formulas into elemental compositions (max of typical) where possible for a future update. **AP14**

4. **CSR generic and intro sections** *(Cf. slides 24-28 in Annex 2)*
A number of introduction sections are being generated by the PMC secretariat and Eurométaux and will be added manually to the CSR. See slides 24-28 in Annex 2 (**AP15**). Comments:
- For the manufacture and uses section, the PM Ref WG agrees to provide the full list of PROCs in the CSR (i.e. for manufacture/use under SCC and manufacture/use not under SCC). Registrants are then advised to check/edit the PROCs in their own company-specific IUCLID file and make sure they only report the PROCs appropriate to their use. Since the current risk assessment is restricted to the list of mentioned PROCs, it is only possible for registrants to delete PROCs, whereas additional PROCs are not to be included without amending the risk assessment. **AP16-17**
- The MeClas output sheets have been generated using a representative sample for each cluster. These output sheets will be attached to the LR IUCLID files in section 13. In addition, companies are free to attach their own company-specific MeClas output in section 13.

5. **CSR human health and occupational sections** *(Cf. slides 30-56 in Annex 2)*
Final occupational exposure scenarios (ESs) have been sent to companies 24 March 2014 (generic + company-specific).

Generic occupational ES (describing methodology)
- The overview DNEL table will be further updated according to the status of the data-sharing agreements. If we have no official data access (yet), the DNEL is being used in calculations but is not reported as such for copyright reasons. ECHA indicated that they understand data sharing is a complex issue when working on a constituent-specific basis and they do not expect to see all DNELS reported in the current updates. The reason why we have no official data access for some constituents is mainly related to delayed responsiveness and legal changes required to the data-sharing agreement. **AP19**
- Extrapolation factors for assessment of inhalation exposure were included. For the extrapolation to different RMMs, default RMM efficiencies were taken from a publication by Fransman et al. (2008). The generic exposure assessment (GEA) table with inhalation exposure estimates is available in Appendix 1 of the generic occupational ES.
- For blood Pb data, estimates were derived for 3 distinct exposure settings:
    - handling of materials with Pb content <1%,
    - handling of materials with Pb content >1%,
    - handling in completely closed processes with no potential for exposure.
- Dermal exposure estimates were derived from MEASE.

- An uncertainty analysis was included upon the specific request of ECHA.
- A section on combined toxicity was included.

Company-specific occupational ES

- The company-specific occupational ESs contain as much company-specific information as possible.
- Available inhalation monitoring data were pooled for all companies.
- The upper limit concentration of the elements in the overall content listed under conditions of use is used to determine the exposure estimates and for extrapolation.
- Full shift exposure estimates, peak exposure estimates and estimates for combined exposure are provided (or a data gap is indicated).
- If no DNEL is available, a qualitative assessment is done or a surrogate value is used.
- The RC tables exclude DNELs/exposure routes where no hazard is identified.
- The prescribed OCs and RMMs are to be seen as minimum requirements under REACH. Higher protection is always possible and national regulation is to be respected in parallel.
- It is noted that RPE should be seen as a last resort. Local authorities may ask for the company-specific occupational ES upon inspection.
- If companies have (new) monitoring data, no update of their ES is needed right away if companies can prove compliance with the current ES with their monitoring data.
- The CSR and generic ESs will be submitted by the LR only. Companies are strongly advised to attach their site-specific occupational ES to their dossier (IUCLID section 13) as the 'Generic' occupational ES only described the methodology used and refers to the site-specific report for the actual ES. A confidentiality claim is not needed when submitting the site-specific ES, as this information will not be disseminated by ECHA. Should this change in future, registrants can then still decide whether a confidentiality claim is needed.
  AP20-23

Combined exposure/toxicity

- The combined exposure assessment for systemic long-term effects (CSL) was done per element by summing up the inhalation systemic long-term (ISL) RCR and the dermal systemic long-term (DSL) RCR (both RWC).
- The combined effects assessment for all elements with DNELS for a specific route is based on typical exposure estimates, and results in summed up RCRs < 1.
- It is noted that assessment factors are used for every DNEL, this may be considered as highly conservative in assessment of combined toxicity.
- The current combined toxicity approach has not been presented to ECHA yet.

Uncertainty analysis

- 3 types of uncertainty are considered:
  - Uncertainty related to the conducted hazard and exposure assessment and resulting risk characterisation conducted as for any other (standard) substance;
  - Uncertainty related to the variability of / missing knowledge on the composition of the UVCB;
  - Uncertainty related to the specific approach followed in this risk assessment for inorganic UVCBs.
- Plausibility considerations are used as much as possible.

Further updates

- It is noted that the current dossier update has been a learning curve and further updates will be needed. The next update is suggested for end 2014.
- EBRC has already identified a number of changes/additions for the next update. **AP24**
- As mentioned at the last PM Ref WG meeting, Eurométaux has sent a roadmap of actions with short, medium and long-term actions to ECHA.

Exposure of man via the environment (MvE)

- Eurométaux previously suggested waiving of the MvE assessment claiming this is already covered by the relevant constituent registration dossiers. However, this justification can only be used for the regional assessment, and a local assessment still needs to be performed. Further data access is thus needed to the CSR of the individual constituents.
- EBRC has developed a placeholder statement on MvE assessment in the generic occupational ES. **AP25**

CSR/IUCLID human health

- Summaries of LoA substances were included in IUCLID files if provided by 20 March.
- Several constituents (e.g. Hg, CrO3, H2SO4) are not present in the Refinables as such but may be present in workplaces. Registrants should indicate if they need to have them included.
  - It is noted data sharing for Hg is free.
  - For H2SO4 it is suggested to use the SCOEL recommendation. Some Refinables WG members are also H2SO4 registrants.
  - P2O5 was assumed for speciation of Slags but this may be a worst case assessment.
  - For HCl and HNO3 a species questionnaire would need to be issued.
- RCF may be present in spent catalysts (Refinable 9.1) and an assessment may thus be needed.
  AP26

6. CSR environmental sections *(Cf. slides 58-70 in Annex 2)*

Exposure assessment - methodology

- Focusing on selected constituents for environmental hazard/exposure ('driving constituents': Ag, As, Cd, Cu, Ni, Pb and Zn) assessed separately without consideration of additivity.
  - B: only discharged in the form of borates, which have no environmental classification.
  - Cr: only Cr(III), which has no environmental classification.
- EUSES modelling to estimate PECs.

Generic Exposure Scenario (GES)

- Includes 2 environmental ESs: discharge to freshwater or marine waters via STP (ES1) and direct discharge (to freshwater and marine) (ES2).
- Several refinements to the GES were made since the last PM Ref WG meeting: see slides 61-62 in Annex 2.
- The selection of driving constituents for environmental exposure assessment was re-assessed based on the following criteria:
  - Classified as hazardous to the environment;
  - Availability of PNEC for risk characterisation;
  - Availability of monitoring data to enable exposure assessment.

  Based on these criteria, Se, Te, Co and Sn should be added to the list of driving constituents. The potential risk of these constituents is currently addressed by a qualitative assessment (i.e. assessment of other constituents present at higher concentrations, and with lower PNEC). For the next update, waste-water monitoring data for these constituents will need to be collected.
- Monitoring data for PGMs will also need to be collected. PGMs are not yet registered under REACH, but are or will be classified for environmental hazard following generation of test data (many will have low PNECs, which might be a problem for the detection limit).
  AP27

Combined exposure/toxicity

- A placeholder statement prepared by Eurométaux has been included, summarizing current thinking and ongoing research/approaches under development in the metals sector. Testing is already ongoing for several metals.
  AP27

CSR changes

- Generic sections have been added at start of Sections 4 and 7.
- General approach for UVCBs and selection of driving constituents has been added for each Refinable.
- Constituent data have been moved to a separate annex of the CSR to improve readability.
- Data access has now been agreed for all constituents covered in the environmental assessment – maybe data access for additional constituents will be needed for future updates.

IUCLID

- The LE specific composition in section 1.2 should be the average over years and should match the analytical data in section 1.4.
- Co-registrants should not enter any information in IUCLID section 2. This section is only completed in the LR file. Hence the composition is not linked to a classification in the co-registrant IUCLID file.

Site specific risk assessments (SSRAs)
- The SSRAs have been updated to remove MvE and environmental exposure assessment of B and Cr(III) as no longer driving constituents.
  AP28

7. Submission upgraded PM Refinables dossiers

7.1. **Status data-sharing agreements**
Cf. slide 72 in Annex 2.

7.2. **Status phys-chem testing**
Cf. slides 73-74 in Annex 2. Some physico-chemical tests are still ongoing and results may not be available in time for the April submissions. A holding statement has been included in the IUCLID files and results will be included when they become available.
AP29-31

7.3. **Timing & procedure submission**
Cf. slides 75-77 in Annex 2. Timing:
- 8 April: CSRs/IUCLIDs to be finalised & circulated
- 21 April: Deadline for LRs to submit updated dossier
- 30 April: Deadline for co-registrants to submit updated dossier

AP32-35

7.4. **Updates foreseen after April 2014**
Cf. slide 78 in Annex 2. The next update is foreseen for end 2014. **AP18**

8. Next steps, AOB, next meetings/calls and closing remarks
A date for a next meeting will be communicated in due time.

Annexes
1. Agenda & list of participants
2. Slides presented at the meeting
3. Overview Human Health and Environmental classification of PM Refinables (ARCHE, 7 Apr 2014)
4. Refinables ID cards without Ag and Au electrolyte (no upgrade) (PMC, 10 Apr 2014)
5. ECHA mail on registration of metal UVCBs: follow up to discussions on 4 March (ECHA, 9 Mar 2014)
6. Eurométaux feedback to the REACH Intermediates Taskforce on recent exchanges with ECHA (Eurométaux, 7 Apr 2014)

Actions

Table 1. Actions resulting from the 1 April 2014 PM Refiners WG meeting in Brussels

	Action	Who?	Timeline
Substance identification (SID)			
1.	Follow-up registration fee issue for splitted dossiers with ECHA	PMC Sec / EM	Wait for feedback ECHA
2.	Develop decision tree to be used to define Refinable dossier scope / substance ID including source, process, composition and classification (with the two latter ones serving validation purposes and not substance ID definition ones)	PMC Sec; review by PM Ref WG	By end Jun 2014
3.	Check all Refinables using the decision tree and the possibility/need for further splitting	PM Ref WG	By end Sep 2014
4.	Check if concentration ranges in ID cards cover LE specific composition and inform PMC Sec if concentration ranges have to be enlarged	PM Ref WG	Done
5.	Update analytical methods in ID cards	PMC Sec	Done
6.	Enter LE specific composition (elemental + speciation if available) in IUCLID section 1.2 so that it matches the analytical information entered in section 1.4	All PM Ref registrants	Done
7.	Collect updated LE specific compositions to further refine SID (composition + speciation)	PMC Sec	Q2-Q3 2014
8.	Perform further speciation analysis where needed	PMC Sec	Q3 2014
9.	Update ID cards and IUCLID files following refinement SID	PMC Sec	By end 2014

10.	PM Slags CSR: reword section on reason for registering the 2 sub-groups together for this April 2014 version of the registration (i.e. remove reference to fees)	PMC Sec	Done
11.	PM Slags dossier: split once we have clarity from ECHA regarding procedure/fees	PMC Sec	After AP1
Classification			
12.	Review Doré composition/classification to reflect presence of metallic Pb/Cu	ARCHE	Done; cf. Annex 3
13.	Perform 28d TDP test on Doré to refine the classification	PMC Sec	Q2-Q3 2014
14.	Change the formulas in the classification-related compositions into elemental compositions (max of typical) where possible and update IUCLID files	ARCHE	By end 2014
CSR – generic sections			
15.	Provide input to CSR sections 2.1 (Manufacture) and 2.3 (this will be a manually added section entitled 'Manufacture and use of PM Refinables')	LRs	Done
16.	Merge the PROCs for manufacture/use under SCC and manufacture/use not under SCC	WCA	Done
17.	Make sure only appropriate PROCs are reported in company-specific IUCLID file	All registrants	Before dossier submission
18.	Draft strategy/checklist for next update	PMC Sec with EBRC & WCA	Q2 2014
CSR – human health and occupational sections			
19.	Update DNEL table in generic occupational ES according to status data-sharing agreements	EBRC	Done
20.	Inform EBRC if inconsistencies are found in the company-specific RC tables	All registrants with company-specific ES	ASAP
21.	Inform EBRC/the PMC secretariat if new monitoring data are available	All registrants	As appropriate
22.	Attach site-specific occupational ES to the dossier	All registrants with company-specific ES	Upon dossier submission
23.	Provide comments to site-specific occupational ES	Heraeus	By 2 April COB
24.	Changes/additions for the next update: • Include additional activity class (AC4) for some companies • Close current data gaps (data access, exposure estimates, DNELs) and issue questionnaires if needed (e.g. species refinement) • Include additional PROCs (4 and 27b) for some ACs • Correct RC tables where needed • Include additional information on assessment of typical dermal exposure levels in methodology paper • Check OCs and RMMs for Pb • Improve/extend uncertainty analysis • Improve/extend consideration of combined toxicity • Include MvE assessment	EBRC	By end 2014
25.	Send statement on MvE assessment to WCA for inclusion in site-specific environmental risk assessment	EBRC	Done
26.	Inform EBRC/the PMC secretariat if additional compounds need to be taken into account for occupational assessment	All registrants	As appropriate
CSR – environmental sections			
27.	Changes/additions for the next update: • Collect waste-water monitoring data for Se, Te, Co, Sn and PGMs to include in environmental risk assessment • Collect monitoring data of stack emissions • Improve/extend consideration of combined toxicity	WCA	By end 2014
28.	Add secondary poisoning consideration to SSRAs	WCA	Done
Phys-chem testing			
29.	Follow-up ongoing phys-chem testing	WCA	As appropriate
30.	Check for which substances TDP testing may be needed	PMC Sec	Q2 2014
31.	Have TDP tests conducted at ECTX for Flue dust and other Refinables identified in AP30	WCA	By end 2014
Submission of upgrades			
32.	Finalisation of CSRs and IUCLID files	WCA, EBRC & PMC Sec	Done

33.	Develop guidance for dossier submission	PMC Sec	Done
34.	Submission of dossier upgrades by LRs	LRs	Done
35.	Submission of dossier upgrades by co-registrants	Co-registrants	Done
36.	Once the dossiers have been finalized, review the LoA price to reflect the additional work done since the first submission in 2010	PMC Sec	After Apr 2014
37.	After the separate dossiers have been submitted, inform the SIEF, together with the LoA Agreement/price announcement	PMC Sec	After Apr 2014
38.	Check schedule of dossier updates with other metal consortia for dossiers where the use phase of the ES is in another dossier (e.g. Cu electrolytic slimes & sludges used in the production of Doré) to align update frequency and strive towards parallel updates	PMC Sec with EM	Q2-Q3 2014
39.	Update dossiers for Ag and Au electrolytes (SCC intermediates) as needed (for a transported SCC intermediate >1000 tonnes, the data requirements on the substance's intrinsic properties as specified in Annex VII must be included)	PMC Sec with WCA and EBRC	After Apr 2014