MINUTES

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

1. **Welcome and introduction.**
   - 1.1. **Reminder on Confidentiality and Competition Law.** Participants were reminded on their obligation to comply with Confidentiality and Competition Law.
   - 1.2. **Tour de table and apologies.** The list of participants 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 (5 December 2011) – including status of action points.**
     A table with the status of the action points from the last meeting is available in Annex 2 – slide 6-7. The actions related to classification & labelling, the Eurométaux advocacy programme on Strictly Controlled Conditions (SCC), Rigorous Containment (RiCo) and exposure assessment are ongoing or have been completed and are on the agenda for discussion today. The actions related to the effects assessment and the project strategy for upgrades have been postponed to March/April 2012, because of the discussions currently ongoing at Eurométaux level on a UVCB intermediate dossier upgrade strategy. Eurométaux is holding an SCC Task Force meeting on 1 March where this strategy will be discussed by the different metal consortia. To avoid that we start working on actions where there is already some progress at Eurométaux level, it was decided to postpone these actions until after the 1 March meeting.
     No remarks on the minutes; minutes approved.

2. **Project strategy.**
   - 2.1. **Recap strategy SCC determination & dossier updates**. *(Cf. slides 9-13 in Annex 2)*
     Participants were reminded on the general approach of the Refinables project. An overview was given of the relationship between SCC and RiCo (RiCo being only a part of SCC), how SCC can be assessed for the workplace and the environment, how to determine whether a registration dossier needs to be updated or upgraded and what needs to be done in case of an update.
     For RiCo determination, RiCoG (the Rigorous Containment Guide – an Excel tool developed by EBRC) will be used. Exposure data demonstrating lack of exposure can also be used to validate the RiCo conditions of the design. While authorities do not propose a fixed Risk Characterisation Ratio (RCR) level under which residual exposure or emission levels can be considered as negligible or SCC compliant, it is clearly understood that exposure should be absolutely minimal and residual and nowhere near contribute to a risk. PMC assumes authorities will only accept significantly low levels (in the order of < 0.1). It is stressed that the use of an RCR can only be a supporting argument to demonstrate RiCo, and not a driving factor. It is further noted that the use of an RCR to validate RiCo is still under discussion with other metal consortia under the umbrella of Eurométaux. PMC seems to be the only consortium using this approach (other consortia use much more qualitative and comparative measures and arguments to demonstrate RiCo). This will be further discussed at the SCC Task Force meeting on 1 March.
     For a registration dossier update, appendix 2 and 3 need to be completed. It is remarked that many companies have been asked by local authorities to prove that the material fulfils the definition of intermediate (i.e. undergoing a chemical modification) before even looking at appendix 2. Therefore, companies are reminded that they should be able to demonstrate the intermediate status of their materials (**AP26**).
     PMC would welcome the Eurométaux SCC Task Force meeting of 1 March to focus on trying to ensure the different metal consortia / companies have the same understanding and interpretation of updates and upgrades, as there seems to be little harmony between consortia so far. This is not only due to different backgrounds (e.g. participation in previous risk

assessments under the Dangerous Substances Directive) but also due to the fact that the base dataset and knowledge level for different intermediates differs extensively and not all consortia have the same number and complexity of UVCB intermediates in scope.

2.2. Update on SCC advocacy programme of Eurométaux: outcome of ECHA review of examples. *(Cf. Annex 3 and slides 15-21 in Annex 2)*

Eurométaux originally submitted examples in October 2011, illustrating the specificities of UVCB intermediates in NFM and proving that RiCo can be achieved in different ways. In November 2011, ECHA disagreed with these examples, and CEFIC stopped the update process (and left it to the company level to interact with inspectors at the national level). In December 2011, ECHA agreed that Eurométaux would simplify their examples. Thus, Eurométaux submitted end of January the revised / simplified examples to ECHA. These focussed on process steps and illustrated 4 metal specific considerations for **SCC**:

1) Existence of large data sets on hazard info, which are used to predict the overall hazard of the intermediate and for the RiCo design, often combining several containment strategies;
2) Physical form of the intermediate (e.g. massive forms, wetted materials), associated with a low emission potential;
3) Local Exhaust Ventilation (LEV) techniques applied in metals smelting and refining are designed for particular production conditions, requiring additional exposure barriers to those applied in other industrial processes;
4) Use of Personal Protective Equipment (PPE) for activities other than sampling, cleaning and maintenance because it may be legally mandatory or because voluntarily initiated by companies as a precautionary measure (to prevent workers from being exposed during potential accidents/incidents).

The first initial reaction from ECHA (which was only received on 21 February) was not clear-cut. They indicated that not all examples would comply with SCC, but some probably do. E.g. on the issue of hazard and the physical form, ECHA seems to agree with Eurométaux (we should not forget about environmental releases though). On the issue of LEV and PPE, ECHA is not convinced yet. Their reasoning is that PPE measures are legally mandatory because the past has proven their necessity to protect the workers from exposure.

Further investigation by ECHA of the simplified examples is planned for the coming weeks (**AP9**). If parts would comply, ECHA would consider an appropriate way forward for communicating this but there will be no update of the guidance. ECHA did indicate that the way the Eurométaux document was written up was very clear, and companies should use it when demonstrating SCC to national authorities. However, even if ECHA would accept the 4 metal specific considerations for SCC, it is stressed that it is not sufficient to prove SCC for separate process steps but that the full lifecycle of the intermediate needs compliance before SCC can be considered. Furthermore, it will be difficult to prove SCC compliance for all streams / companies / supply chains covered in one registration dossier; if one stream, registrant or user is not SCC compliant, an upgrade of the dossier will be needed.

Regarding the parallel track for **non-SCC intermediates** and dossier upgrades, ECHA invites industry for a constructive scientific discussion and recognizes a pragmatic approach on the read-across for test waiving for UVCB / Multi Constituent Substance (MCS) type intermediates is needed. ECHA stated that this could probably be conducted using a flexible approach and would not call this read-across but rather "*substance effects prediction from the known properties of the constituents*". The approach should be scientifically robust and demonstrate safe use.

Potential questions for elaboration and discussion are:

- How to best use existing constituents data sets;
- Constituents effects knowledge versus validation;
- Tools to assess hazard / risk contribution - can be part of validation (e.g. MECLAS for classification);

- Substance ID: how to handle variability in concentration versus speciation;
- Large number of streams: are the Refinables UVCB or MCS? An MCS has a previously intended composition, which is not the case for Refinables. It is suggested to organise a site visit for ECHA to make them familiar with our processes.

Eurométaux will keep track on the SCC examples (AP9) and will discuss a way forward on dossier upgrades for non-SCC intermediates with the ECHA directors and principle science advisor (AP10). A workshop / meeting on the latter is suggested at ECHA between Eurométaux and ECHA staff / scientists (possibly in parallel with the next RAC meeting in April) to demonstrate certain metal specific aspects of upgrades to ECHA: substance ID (UVCB/MCS), MECLAS, bio-elution…

For the Refinables, we are already working on the two parallel tracks (updates / upgrades). Therefore, it is suggested to go forward with developing the upgrades (exposure data collection & 'read-across' for effects file) (DP3). In anticipation of the ECHA discussion, we should:

- Demonstrate the identity of our Refinables as UVCB and as intermediate (i.e. undergoing a chemical modification based on the Eurométaux / EUromines factsheet on chemical modification) (AP26);
- Prepare examples on effects prediction from the properties of the constituents (AP32);
- Demonstrate how safe use can be demonstrated in a Tiered way.

Some PMC members are quite confident that they can demonstrate SCC compliance for their Refinables to local authorities and thus can go for **updates** (DP6). As long as the discussion with ECHA is ongoing, they want to keep the option of updates open. We should give the advocacy programme until End March / mid-April to deliver (DP2).
The arguments to go forward with developing the **upgrades** are:

- It will be difficult to prove SCC compliance for the whole lifecycle of the Refinables and for all the streams within one registration dossier, so upgrades for some Refinables / companies will most likely be needed (DP7);
- Upgrades are less likely to being challenged and provide more flexibility;
- The decision to go for updates or upgrades will not only depend on the SCC discussion, but is also a business decision and company responsibility (AP24 / DP7);
- Even if ECHA would accept the 4 metal specific considerations for SCC, ultimately the Member States (not ECHA) will be checking SCC compliance;
- It is expected that national authorities will give the registrant limited time to prepare an upgrade if they argue the SCC status;
- Upgrades may be the most cost-efficient way to go, although at this point it is not clear what the actual registration costs for an upgrade are (AP25).

By the next Refinables WG meeting we should know for which Refinables to do updates / upgrades. For some Refinables, both updates and upgrades may be necessary (some PMC Members may claim SCC compliance for one Refinable where others would not). For updates, it is decided that Appendix 2 and 3 will be prepared by the companies needing an update only (with minor supervision by PMC secretariat). DP8 / AP30

2.3. Outline of proposed approach to UVCB intermediate dossier upgrades. *(Cf. Annex 5 and slides 22-28 in Annex 2)*
A brainstorming meeting was held 19 January 2012 between Eurométaux secretariat and EPMF secretariat to outline an approach that could be followed by metals consortia to prepare dossier upgrades for their UVCB intermediates. The proposed draft approach is available in Annex 5 and will be discussed at the Eurométaux SCC Task Force meeting on 1 March 2012.

For a dossier upgrade, an exposure assessment and an effects assessment are needed to enable a risk characterisation. When preparing upgrades of their UVCB intermediate registration dossiers, registrants face the following challenges:

1) Can test waiving be applied and motivated? A classical effects assessment 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 improved safety. Alternatively, read-across from dossiers of individual constituents is proposed.
2) How to perform read-across (which tool) and how to justify it appropriately?
3) How to identify and prioritise driving constituents for the effects assessment? The effects assessment of an intermediate will depend on the effects of the individual constituents. As there are many constituents in an intermediate, a prioritisation tool will be needed to identify the driving constituents.
4) How to identify and prioritise driving constituents for the exposure assessment? The exposure assessment of an intermediate will depend on the exposure to the individual constituents. As there are many constituents in an intermediate, a prioritisation tool will be needed to identify the driving constituents.
5) How to perform the risk characterisation and propose integrated risk management measures (RMMs) and what iterations can be applied?

For prioritisation of environmental exposure and/or effects assessment, the concentration, possibly the chemical speciation, the M-factor, the Transformation / Dissolution (T/D) data, the GHS/CLP hazard categories and the hazard values of all relevant constituents need to be considered.

For prioritisation of workplace exposure and/or human health effects assessment, the concentration, the GHS hazard categories and the DNEL (or OEL in the absence of DNEL) of all relevant constituents for each toxicity endpoint, exposure route and mode of action need to be considered.

*(**Post-meeting note:** At the 1 March 2012 Eurométaux SCC Task Force meeting, ECI agreed to make the non-confidential version of the Cu slag IUCLID 5 file available to other consortia via Eurométaux, so other consortia can learn from it. Furthermore, the upgrade strategy outlined in Annex 5 will be refined following input from EBRC and WCA, Eurométaux and ECI.)* (**AP32**)

To upgrade the Refinables' dossiers, access to information on the constituents is needed. Therefore, a common mechanism for **data-sharing** is needed. Since Refinables have a lot of constituents, access to many metal registration files would be needed. The suggested approach is to obtain access to the CSR of the driving constituents only. A central database is recommended to allow all concerned consortia to access part of the dossiers of the constituents to build their UVCB intermediate dossier upgrades. However, not all consortia are (currently) concerned and not all consortia need all files (need for consortia to list all relevant constituents). Also, the driving constituents will need to be identified first in order to channel / filter data needs and identify those consortia which need to participate in the data access / sharing.

The data access / sharing mechanism proposed by the PMC secretariat would in principle allow all (main) metal consortia secretariats to exchange CSR on relevant constituents under an *ad hoc* data-sharing / confidentiality agreement stored into a specific database. The costs of the data-sharing could either be covered by each consortium or a common "fund" could be created by Eurométaux with contributions from concerned consortia. For the administration, supervision/guardianship of Eurométaux could be instated. The legal aspects need to be further discussed once the main principles have been agreed upon at Eurométaux level. (**AP31**)

*(**Post-meeting note:** At the 1 March 2012 Eurométaux SCC Task Force meeting, all present consortia agreed that a proper data-sharing approach is urgently needed, to ensure that all consortia have the same data available for updates / upgrades. Eurométaux will work on a thought-starter for the data-*

sharing approach to be discussed at the next REACH Forum meeting on 13 March.)

3. Status hazard classification of PM Refinables. *(Cf. slides 31-50 in Annex 2)*

3.1. Impact of 2nd ATP to CLP on classification of PM Refinables.

The 2nd ATP update (implemented in MECLAS) includes the following changes:

- The sensitisation endpoint has now two additional hazard elicitation subcategories 1A and 1B for skin and respiratory sensitisation (relevant for Co and Ni compounds).
- There are new criteria and new guidance on the derivation of environmental chronic endpoint based upon chronic data is available.
- There are changes in mixtures classification category rules on sensitisation and environmental classification (addition versus summation rule) (**AP1**).

Furthermore, non-2nd ATP related updates in classification of metal constituents were taken into account to update the Refinables' classification.

In MECLAS Tier 1 assessments, the classification is based on the speciation of the constituents (and M-factors are derived from ecotoxicity and T/D data). In Tier 2 assessments, classification is refined based on T/D data of the Refinable (and M-factors are derived from ecotoxicity data only).
For Tier 1 assessments of the Refinables, the impact of the 2nd ATP is limited. A potential impact (chronic 1 to chronic 2) is expected for some companies for the classification of Residues, matte leaching (group 5.1), Gold electrolytes (group 6.2) and Flue dust (group 7).
For Tier 2 assessments of the Refinables, the impact of the 2nd ATP is mainly driven by the new mixture rules. A potential impact is expected for some companies for the classification of Doré (group 1), Matte (group 2), Borate slags (group 3) and Materials for reclaim 9.2.
PMC members agree to update all Refinables' classification profiles in light of the 2nd ATP (**AP2-7**). PMC will update the silver file with the revised M-factors. It is noted that if PM Refiners need to have the updated classification of their own Refinable streams, they will need to derive it themselves (with MECLAS or own derivation) (**AP8**).

It is proposed to change the classification of 2 groups (5.2 and 6.1) based on the new compositions reported by companies to EBRC in the workplace exposure questionnaires. ARCHE will contact the affected companies on this.

3.2. Provisional updated M-factors for Ag substances. *(Cf. slide 35)*

A chronic M-factor of 100 was derived for silver nitrate, silver chloride, silver carbonate and silver sulphate following the 2nd ATP, based on chronic ecotoxicity data. Silver and disilver oxide are poorly soluble silver compounds and following new ECHA guidance (currently out for consultation – not final yet!), provisional acute and chronic M-factors were derived by comparing the solubility demonstrated in T/D tests with acute and chronic ecotoxicity data. It was agreed to take these updated M-factors into account when reviewing the Refinables' classification profiles (**AP2**).

3.3. Possibility / relevance of splitting some streams into several groups based on origin / process.

Following the cluster analysis, it appeared that for some Refinables, the clusters were roughly linked to processes / fluxes but there was no clear one-on-one distribution.

3.4. Cluster analysis for those Refinables that currently have classification pick-lists & resulting classification groups (Flue dust, Slags, Materials for reclaim 9.1 & 9.2, Residues, Slimes & sludges).

To update and simplify the complex hazard classification recommendations for certain Refinables (which currently have pick-lists), ARCHE conducted a cluster analysis. A stepwise

approach was followed, whereby a statistical cluster analysis (using principal component analysis) was performed on the basis of composition of the Refinables, and a manual cluster analysis interpretation was performed based on the impact of classification on several handling needs (transport & packaging, site-permits, SEVESO directive). These were used to define "hazard profile groups".

The cluster analysis results can be summarised as follows:

- Flue dust (group 7): 4 classification clusters were derived, which were partly linked to different processes;
- Slags (group 3): 4 classification clusters were derived, which were partly linked to different fluxes (borosilicate / phosphate / silicate / borate / carbonate slags) but there was no clear one-on-one distribution. The cluster analysis demonstrates that the distribution of this unique Slags group /registration in 5 Slags sub-groups / registrations would not have led to improved safety as there is no clear difference in classification;
- Materials for reclaim (group 9.1): 3 classification clusters were derived;
- Materials for reclaim (group 9.2): 3 classification clusters were derived;
- Residues cementation & reduction (group 8): 4 classification clusters were derived;
- Slimes & sludges (group 4): using principal component analysis, it was not possible to derive distinct clusters, as there were too many variables and combinations. It is recognised that slimes & sludges are especially variable and complex materials, not only across companies, but also within companies. By manual cluster analysis, 4 classification clusters were derived. PMC Members agreed to keep these clusters to demonstrate the variability of this group.

PMC Members agreed to replace the existing pick-lists in above Registration Dossiers by the classification clusters derived by ARCHE as presented (**DP1** / **AP2**). Composition cut-offs will be defined for each cluster, listing the constituents that drive the classification, so PMC Members can easily define to which cluster their Refinable belongs. Furthermore, for each cluster, some explanation will be given on how it was derived, and - to the extent possible - the link will be made with processes / fluxes.
It is noted that it is still possible for individual companies to deviate from the clusters and to list a different (usually less severe) classification in their SDS if needed / wanted (**AP8**). ARCHE tried to derive worst-case classifications in each case in order to be listed in the registration file.
It is suggested to include information on how we have derived the different Refinable groups / clusters in the IUCLID 5 files (**AP26**).

The cluster analysis is based on the 2010 classifications. There are no major changes expected on the cluster analysis following the 2nd ATP (grouping will not change). However, the new classification profiles will include the 2nd ATP and the changes for groups 5.2 and 6.1.

3.5. Overview of updated classifications.
ARCHE will prepare an overview of all updated classifications per Refinable for approval by PMC Members (**AP2-4**).

4. Rigorous Containment. *(Cf. slides 53-56 in Annex 2)*

4.1. Public version RiCoG with metal specific adaptations.
RiCoG allows identification of those Refinables that need further assessment. First, companies are invited to run RiCoG to check RiCo of their Refinables (**AP12-15**). If RiCo cannot be demonstrated with RiCoG, an exposure assessment will be run (Tiered approach: MEASE > measured data > refinements).
The updated (non-final) version of RiCoG is presented by EBRC. Feedback on the previous

version was received from Eurométaux, PMC experts and other Consortia and this was reflected in the new version. The new version also allows for checking the status of up to 10 individual process steps in 1 overview sheet.

4.2. Questions from PM Refiners on the practical use of RiCoG.

Comments / questions by PMC Members on the new version of RiCoG are listed below:

- Melting point:
  - The lowest melting point of any constituent or the melting point of the intermediate should be entered in RiCoG whatever is the lowest. Additionally, in PM refining, sometimes a substance is added to lower the generic melting point, which should be considered when selecting a figure for the melting point. This will be included and reworded in RiCoG. It is noted that the melting point is exclusively taken into account for hot processes.
  - The reference value should be 0K.
- Process steps: all existing process steps are relevant for the overall assessment, except e.g. if the intermediate comes from waste (the storing of the waste before being used in the manufacturing process is not relevant for RiCo assessment).
- Physical form:
  - Moisture content is recognised as impacting the dustiness. However, it is not foreseen to enter an exact value for moisture content in RiCoG, but, for example, 'low dusty material' could be selected as physical form (see also the RiCoG glossary) for a wetted filter-cake.
  - Crystals: there is no specific mentioning of crystals for the physical form. The glossary will be amended to reflect on the fact that crystals may be of various forms ranging from fine powders to massive objects.
- Level of contact: it is suggested to reword 'non-direct handling' to 'no dermal contact'.

EBRC will implement the suggested changes in RiCoG on melting point, physical form and dermal contact (AP11). Finalisation of RiCoG is anticipated for end of March (after approval by Eurométaux).

5. Workplace exposure assessment programme. *(Cf. slides 57-72 in Annex 2)*

The availability to the PMC of other metal DNELs is limited. Some DNELs are available from the ECHA dissemination website but underlying data are very limited, which is critical for the development of the decisive DNEL tool. Furthermore, the hazard profile is not yet available for all substances.

For the data-sharing approach, it is suggested to get the necessary data through the consultants instead of through the individual data-holders. The underlying data for the DNELs would be in the CSR, so access to (the hazard part of) the CSR (excluding the exposure scenario) should be sufficient. (AP31)

5.1. Summary of received questionnaires.

The questionnaires to gather workplace exposure data resulted in 100% participation with very heterogeneous feedback. A total of 49 questionnaires were returned, with 301 individual process steps reported for 14 Refinables. Two companies will send further information.

5.2. Grouping of workplaces.

A first grouping of workplaces was identified based on similarities in process title, process description, PROCs, process temperature, enclosure and physical forms of input/output/re-feed materials. All 301 process steps were manually assigned and the assignment was checked based on measured data. A beta-version of this grouping is presented in Annex 2 – slide 60. An updated version will be circulated for PMC Members to check / comment on (AP17). 9 process types were identified.

Identified issues include:

- Inconsistencies: e.g. the process is nominated with PROC 1 (closed process with no potential for exposure), but 'not fully enclosed' was selected.
- Definition of process step:
  - May have to be divided in more steps: e.g. powder handling, furnace operation, leaching, precipitation nominated in one step may be divided into 4 single steps.
  - May have to be aggregated further as similarities are potentially 'underestimated'.
- Different input, output, re-feed materials:
  - The compositions are poorly defined in some cases (it is assumed that some companies have varying concentrations of the same Refinable in different streams).
  - The physical forms have to be further grouped; it is suggested to use the same categories as in MEASE.
  - One Refinable can appear in different physical forms in one process step (e.g. massive and powder or fume).

Based on these first impressions, grouping is feasible in most cases, but there are heterogeneous operational conditions and RMMs in some cases (e.g. exposure duration varies from <15 min >240 min within process groups). It is very important to specify / group physical forms for each process type. MEASE was not used yet because of issues with physical forms and the non-availability of DNELs and their expected low levels. Further grouping will be needed based on measured data, and inhalation monitoring data will be screened first (AP17).

5.3. Identification of potential exposure hotspots.

To identify potential exposure hotspots, further work on the grouping of workplaces and identification of critical steps is first required.

5.4. Summary measured inhalation exposure data.

All companies are encouraged to submit monitoring data, as pooling of monitoring data will help to close data gaps and will allow read-across across sites where equal/equivalent operational conditions exist. Furthermore, monitoring data could support RiCo demonstration, and the assumptions behind the decisive DNEL.

Inhalation monitoring data were received from 7 companies and some minor issues are to be solved with 2 or 3 companies. Additional data deliveries are expected / indicated (AP16). All data are included in the relational database (also containing the questionnaire results).

In total, 710 measurements were received, of which 269 were personal, inhalable, full shift representative and assigned to 1 workplace. These 269 measurements could be attributed to 7 different process categories.

The inhalation monitoring data need to be further analysed and corrected for physical form and concentration (AP17).

For the workplace exposure assessment, next steps suggested are:

1) RiCoG will be run by companies (DP4 / AP12-15).
2) For those Refinables for which RiCo cannot be demonstrated with RiCoG and company specific evidence/expert judgement, an exposure assessment will be run. Qualitative information may be sufficient to demonstrate RiCo (DP5).
3) DNELs from other metal consortia will be gathered by PMC / Eurométaux secretariat. Some can be collected from the ECHA dissemination website but not all information is there (quality of available DNELs is unsure and some DNELS are missing). For some compounds there is no DNEL available at all. Furthermore, some DNELs are under revision. It is suggested to launch a survey among other consortia to gather DNELs of presumable driving endpoints and to launch a survey among PMC members / companies to check which value they are using (national / regional OEL). Maybe we can use the OEL if the DNEL is still lacking (might be the case for As) (it is noted that we have to be careful when using OELs; an OEL is not necessarily more stringent than a DNEL, and vice versa). (AP20)

4) Once DNELs (or OELs) are available, the driving constituents will be identified (approach/tool to be determined) (**AP21-22**).
5) Following the assessment of exposure data, the RCR will be calculated for the driving constituents to demonstrate whether the (residual) exposure is significantly higher or lower than the relevant DNEL or OEL (**AP23**).

These steps would allow judging whether an update or an upgrade is needed. It is noted that we do not need to have all quantitative details for the updates (for updates, exposure data are supporting info); for the upgrades, quantitative details are needed. Therefore, refinement may be needed for upgrades, to get rid of the uncertainty.

5.5. Dermal exposure.

Dermal exposure should potentially be considered in exposure scenarios, but is currently not expected to be relevant if rigorous containment is ensured.

The IOM ingestion study will generate dermal exposure data as well. Two companies have indicated their willingness to participate in the IOM study and contact has been made between IOM and these companies.

6. Environmental emissions assessment programme. *(Cf. slides 76-95 in Annex 2)*

6.1. Proposed general approach & tools.

A questionnaire was launched to gather information on Refinable composition, tonnage, potential emissions, RMMs, monitoring data, local receiving environment characteristics and confounding factors. The environmental emission assessment and risk characterisation focuses on those Refinable constituents that have an environmental classification under DSD and/or CLP/GHS (Ag, As, B, Cd, Cr, Cu, Ni, Pb, Zn). Each constituent is modelled separately and local environmental concentrations are estimated according to R16 guidance and using a Tiered approach:

1) In Tier 1, an overall Generic Exposure Scenario (GES) is developed and applied to each constituent; exposure concentration in environmental compartments will be estimated using tonnage and exposure parameters for each constituent. This is a 'reasonable worst case scenario' using maximum or 90th percentile tonnage (from all sites), typical RMMs, emission characteristics and default emission factors (EFs). These GES are used for all Refinables. If the aquatic RCR is nearing 1 for any constituent, we move to Tier 2.
2) In Tier 2, emission estimates are refined using refined SPERC values (Kd-adjusted emission factor for emissions to water for each component). If the aquatic RCR is nearing 1 for any constituent, we move to Tier 3.
3) In Tier 3, emission estimates are further refined using site-specific data to undertake individual risk assessment for each constituent. These assessments will be confidential and only shared with the respective companies, and will identify those sites which can demonstrate safe use, and those sites which need additional refinement to demonstrate safe use (i.e. more information or monitoring).

Air, freshwater (with and without further treatment at a municipal STP) and marine waters are considered as receiving environment. Regional background is not considered at this stage.

*(**Post-meeting note:** RCR should be as low as possible as a general principle and hence all possible refinements (e.g.: dilution factor, calculation of contribution of the Refinable to the emission, etc.) should be assessed for potential application. This is especially important for the Refinables project where the RCR are calculated for each constituent. Indeed, authorities may expect/request the individual RCR to be summed up to arrive at a total RCR for the Refinable and in doing so, in order to address combined toxicity/antagonism/synergism, there is a tendency to apply a correction factor for combined effects ensuring that none of the components would contribute more than 0,2 RCR to the overall risk).*

6.2. Summary of received questionnaires.

12 questionnaires were received in total, of which 9 contained a good amount of useful information. These data will be the basis of the GES *(**Post-meeting note:** Those companies who*

have not provided data will not contribute to the GES; they should however be aware that they may need a site-specific assessment to document their local situation). A good level of information on wastewater output (and receiving environment) was available, slightly less information was available on stack emissions but just enough to work with. The deadline to receive questionnaires has now closed so this is the final working dataset for environmental exposure and risk assessment. However, WCA may get in touch with some companies to request additional data or clarification for site-specific risk assessment (especially on stack emissions) (**AP16**).

6.3. Status of environmental emissions assessment.

3 scenarios are required for discharge to the aquatic environment: freshwater with / without STP and marine environment. A provisional GES was developed, primarily based on the 9 sites providing the most complete datasets. Regarding the emission days, it is proposed to use the median since all companies provided data. It is noted that for some companies, there may be a discrepancy in the number of emission days for water and air due to batch processes (no daily emission to air, but daily emission to water because of continuous water treatment).

The emission factor (EF: ratio annual amount discharged / annual tonnage used or produced) is a very important parameter for the GES. SPERCs (metal specific ERCs) have been produced detailing EFs for various sectors of the metals industry. The emission factors calculated from data provided by the Refinables member companies was generally in good agreement with the ARCHE metal SPERCs. The relationship between the solid-water partitioning coefficient for suspended matter (Kd) and the EF to water needs to be checked in more detail (**AP19**). It was therefore provisionally proposed to use the ARCHE metal SPERCs as these are based on a much larger dataset (data from the Refinables sector will be used as supporting evidence to justify application of the metal SpERCs).

Soluble boron became recently a concern given its environmental classification under DSD. It is however suggested to treat boron as a 'special case' (i.e. exclude it from the main Refinables constituents datasets for Tier 1 and Tier 2 assessments using GES) as no reliable prediction can be made by using metal SPERCs given standard water treatment systems for metals are unable to handle boron. It is therefore suggested to treat boron separately and measure emissions for sites using borates as a flux agent (**AP18**) and conduct immediately a Tier 3 assessment using the added risk approach (due to the high background).

In general WCA is comparing Refinables output and total site emissions, which is acknowledged to be a conservative approach.

Additional parameter values from the metal constituents are still required in order to conduct the final modelling (Kd, STP removal rate, PNECs and DNELs). This was already discussed further during point 2.3 of the meeting. GES parameters have been revised based on additional data, and latest provisional Tier 1 results indicate that Tier 3 (site specific modelling) may be required (**AP19**).

The issue of the overall toxicity of the whole Refinables was discussed. The Eurométaux / EPMF brainstorming had suggested that the Toxic Unit approach is followed – this would be equivalent to summing the individual RCR and demonstrating that the total RCR was still below 1. This needs to be further discussed in accordance with approaches developed by other Consortia (**AP33**). This can be further improved by definable stream specific assessments if such information can be generated or estimated.

7. Overall timing of the project & implementation of the new ECHA guidance on intermediates without undue delay. *(Cf. slides 98-106 in Annex 2)*

The Refinables work plan is embedded into the wider work plan of the metals industry. PMC is therefore implementing the Dec 2010 ECHA Guidance on intermediates without undue delay, and can demonstrate this by regular participation in Eurométaux meetings, regular organisation of PM Refiners WG meetings and involvement of several experts. PMC members are reminded that the execution of the Refinables project also depends on their timely input and response to questionnaires within the defined deadlines.

Project Manager Katrien Arijs will be on maternity leave from 5 March to 20 June included. She will be replaced by Federica Iaccino (ARCHE) for the PM Refinables project during this time.

8. **Refinables project budget for 2012: proposed way forward.** *(Cf. slide 108 in Annex 2)*
The 2012 budget for the PM Refinables project will be of 250 000 €. The cost-sharing of the PM Refinables project will remain unchanged (one share per Member and Refinable). The budget and cost-sharing will be reviewed in the second half of 2012 according to the outcomes of the ongoing work on RiCo demonstration and upgrade preparation. **DP9-10** / **AP34**

9. **AOB, next calls, meetings, and closing remarks.**
Currently there is no meeting foreseen before summer to allow Eurométaux and EBRC 3-6 months to come up with concrete results. It is suggested to have a conference call after the ECHA discussions are closed end of March / mid April. An e-mail will be sent around in due time to inform PMC Members on progress.

Annexes
1. Agenda & list of participants
2. Slides presented at the meeting
3. Examples SCC submitted to ECHA
4. Eurométaux / EUromines factsheet on chemical modification
5. Draft upgrade strategy UVCB intermediates
6. Summary of the minutes of the 22 February 2012 PM Refiners WG meeting in Brussels

Decisions

Table 1. Decisions made at the 22 February 2012 PM Refiners WG meeting in Brussels

Classification & labelling	
1.	PMC Members agreed to replace the existing pick-lists in some of the Registration Dossiers by the classification profiles derived by ARCHE by cluster analysis.
Eurométaux advocacy programme on SCC / upgrade strategy with ECHA	
2.	Despite the recent feedback from ECHA, PMC Members agreed to give the ongoing advocacy programme by Eurométaux a chance to deliver before quitting on it.
3.	PMC Members agreed to go forward with developing an upgrade strategy following an approach agreed by Eurométaux and ECHA.
Rigorous containment	
4.	Companies will run RiCoG as a first Tier to demonstrate RiCo.
Exposure assessment	
5.	For those Refinables for which RiCo cannot be demonstrated with RiCoG and expert judgement, an exposure assessment will be run and an RCR will be calculated to further support RiCo/SCC demonstration.
Updates versus upgrades	
6.	Dossier updates will be done if SCC can be demonstrated for all streams covered in 1 Registration Dossier by a given registrant for the entire lifecycle and supply chain of the Refinable.
7.	Dossier upgrades will be done if requested by registrant because: 1) SCC cannot be demonstrated for all streams covered in 1 Registration Dossier by a given registrant for the entire lifecycle and supply chain of the Refinable; 2) Business decision by the registrant.
8.	Appendix 2 and 3 will be prepared by the companies needing an update only (with minor supervision

	by PMC secretariat).
Budget and cost-sharing	
9.	The 2012 budget for the PM Refinables project will be 250 000 €.
10.	The cost-sharing of the PM Refinables project will remain unchanged (one share per Member and Refinable).

Actions

Table 2. Actions agreed at the 22 February 2012 PM Refiners WG meeting in Brussels

	What?	Who?	When?
Classification & labelling			
1.	Clarify and streamline mixtures classification category rules on sensitisation and environmental classification between the consortia.	Eurométaux	Mar
2.	Update classifications: • Replace existing classification pick-lists in some of the Registration Dossiers by the classification profiles derived by cluster analysis. • Update all classification profiles of all Refinables in light of the 2nd ATP to CLP (changes in sensitisation categories and M-factors for Ag). • Re-evaluate environmental classification of Matte to see if refinement is possible. • Prepare an overview of all updated classifications per Refinable for approval by PMC Members.	ARCHE	Mar
3.	Check updated classification overview before circulation to PMC Members.	CB & WCA	Mar
4.	Circulate updated classification overview for comments to all PMC Members (give 1 month for response), collect responses, update classifications with comments received (liaise with ARCHE, HW & CB if needed), re-circulate for approval and send approved version to WCA.	FI*	Mar-Apr
5.	After updated classifications are approved, update all IUCLID 5 files of all Refinables for re-submission to ECHA by LR and implementation by all concerned companies before Dec 2012.	WCA	May
6.	Check IUCLID 5 files for each Refinable to make sure it reflects the latest information and send each LR the relevant IUCLID 5 files for submission to ECHA.	FI*	May-Jun
7.	Submit updated classification to the Registration Dossiers where needed.	LR	Jun
8.	Derive own company-specific classification (with MECLAS or own derivation) if needed / wanted.	PM Ref WG	As needed
Eurométaux advocacy programme on SCC / upgrade strategy with ECHA			
9.	Report ECHA feedback on SCC examples to PMC members.	Eurométaux / PMC sec	End-Mar / mid-Apr
10.	Discuss way forward on dossier upgrades with ECHA.	Eurométaux	Apr
Rigorous containment			
11.	Reflect comments of PMC Members and finalise RiCoG for "public release" and use for RiCo assessment programme.	EBRC	End-Mar
12.	Circulate final RiCoG to PM Refiners WG for first tier RiCo determination. Together with RiCoG and papers mentioned in AP26, circulate **first survey** inviting PM Refiners WG to summarise:	FI* (CB will prepare survey)	Apr

	• for which Refinables / process steps RiCo can be demonstrated by RiCoG and those where further (exposure assessment) work is needed; • for which Refinables the intermediate status can be justified (cf. also AP26); • for which Refinables the UVCB status can be justified (cf. also AP26).		
13.	Run RiCoG formally for all PM Refinables in order to confirm for which Refinables RiCo can be demonstrated.	PM Ref WG	Apr
14.	Return first survey (RiCoG failed / passed + intermediate / UVCB status) to PMC secretariat.	PM Ref WG	Mid-May
15.	Compile answers to first survey in order to list Refinables: • for which RiCo is demonstrated; • for which RiCo has not been shown yet (and exposure assessment is needed) • for which an upgrade will definitely be required (if PMC Members have already provided such indication).	FI*	Mid-Jun
Exposure assessment			
16.	Send additional inhalation monitoring data to EBRC and – if requested - send additional data or clarification on environmental emission data to WCA.	PM Ref WG	Mar
17.	Further analysis of inhalation monitoring data and correction for physical form and concentration. Use these data for further grouping of workplaces. Circulate updated version of workplace grouping for PMC Members to check / comment on.	EBRC	Mar-May
18.	Measure total versus soluble boron emissions in aquatic effluents for those sites using borates as a flux agent.	PM Ref WG	Q2 2012
19.	Check the relationship between the Kd and the EF in more detail. Progress environmental modelling as far as possible bearing in mind that additional modelling parameters are required from sources outside the PM Ref WG before this can be finalised.	WCA	Mar-Jun (depending on AP20)
20.	Gather DNELs/OELs/PNECs: • From the ECHA dissemination website; • From other consortia; • From PMC members / companies (national / regional OEL).	Eurométaux (FI* will follow up)	Mar-Apr
21.	Agree on approach to identify driving constituents (MECLAS and/or the decisive DNEL approach).	PM Ref WG	Apr-May
22.	Identify driving constituents.	EBRC	May (depending on AP20)
23.	Calculate the RCR for the driving constituents to demonstrate whether the (residual) exposure is significantly higher or lower than the relevant DNEL/OEL.	EBRC	May-Jun (depending on AP20 + 22)
Updates versus upgrades			
24.	Prepare a list of aspects to be considered by registrants when making business decision to go for updates / upgrades.	FI*	Mar
25.	Check registration cost of an intermediate dossier upgrade.	Eurométaux	Mar
26.	Document intermediate (i.e. undergoing a chemical modification: make sure intermediate results from or undergoes one of the processes listed	PM Ref WG (FI* will	Mar-May

	in red in the table at the end of Annex 4 – factsheet chemical modification) and UVCB (large variability in composition) status of each Refinable to attach to each relevant IUCLID 5 file. Detail description of each Refinable, the processes they undergo, and how we have derived the different Refinable groups / clusters.	prepare short papers on criteria intermediate / UVCB)	
27.	Circulate **second survey** to PM Refiners WG inviting them to summarise for which Refinables SCC compliance can be demonstrated for an update, and those where upgrading of the files is necessary.	KA (CB will prepare survey)	Jul
28.	Return second survey (update / upgrade) to PMC secretariat.	PM Ref WG	Aug
29.	Compile answers to second survey in order to list Refinables for which an update will be needed and for which an upgrade will be needed.	KA	Sep
30.	Prepare Appendix 2 & 3 with minor supervision by PMC secretariat.	PM Ref needing update	Q3 2012
31.	Agree on efficient data-sharing approach among metal consortia to formalise use of PNEC, DNEL and supporting rationale (cf. also AP20).	Eurométaux / CB	Mar-Apr
32.	Once (E-)TRV and the Cu slag Dossier are available, organise meeting(s)/call(s) with EBRC and WCA, EM and ECI, to refine upgrade approach in preparation of presentation to ECHA (ideally develop examples testing the approach).	FI*	Apr-May
Risk Characterisation			
33.	Clarify at Eurométaux level on when and how to apply the Toxic Unit ruling for assessing the combined effect for an individual intermediate.	Eurométaux	Q2 2012
Budget and cost-sharing			
34.	Review the budget and cost-sharing according to the outcomes of the ongoing work on RiCo demonstration and upgrade preparation.	PMC sec / PM Ref WG	Q3 2012

* FI = Federica Iaccino, replacing Katrien Arijs during her maternity leave