



Chairperson: Edwin Broekaert (Umicore)
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*Metals Conference Centre - Room Aluminium
Rue du Duc 100 - 1150 Brussels (BELGIUM)*

MINUTES

AP refer to Action 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; agenda approved.
- 1.4. **Approval of the minutes of the last meeting (26-27 September 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 7-8. All actions are either ongoing or have been completed.

No remarks on the minutes; minutes approved.

2. Recap project strategy.

2.1. Analysis update versus upgrade.

An overview is given of the relationship between Strictly Controlled Conditions (SCC) and Rigorous Containment (RiCo), 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 is the difference between both (*cf. Q&A in Annex 3 and slides 10-16 in Annex 2*).

EBRC is currently developing RiCoG (the Rigorous Containment Guide), an electronic, easy-to-use tool aimed at supporting companies to define whether or not the intermediate is rigorously contained and/or to identify areas where the situation could be improved to achieve rigorous containment. It is stressed again that the use of RiCoG by companies is voluntary; it is a supporting tool that allows self-reflection, but companies may have other means of demonstrating RiCo. PMC Members are reminded that it is their responsibility to check RiCo and SCC and to apply expert judgement in doing so.

For transported intermediates, SCC have to be demonstrated for the entire lifecycle, including users of the intermediate.

Exposure data demonstrating lack of exposure can also be used to validate the RiCo conditions of the design. 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 but RCR levels "significantly below 1" will have to be achieved to demonstrate this. Without being defined such level may be in the order of < 0.1.

For dossier upgrades, the difference between a standard substance dossier and an intermediate dossier (not under SCC) is emphasized. For intermediates, the risk characterisation is limited to the workplace and a local environmental exposure scenario for the manufacture and use of the intermediate. Furthermore, intermediates are not subject to authorisation. The PM Refiners can generate the intermediate dossiers themselves and input from users is not needed (if the exposure is modelled under reasonable worst case and demonstrating SCC as done with RiCoG). They have to provide an exposure scenario to potential downstream users.

The registration preparation cost and the registration fee is higher for upgrades than for updates, but the main cost for upgrades will be the testing cost related to the information requirements as set down in Annex VII-X (depending on tonnage level) and in case valid test waivers can't be justified. The risk characterisation derivation and Chemical Safety Report (CSR) drafting are minor cost items. Therefore, we should focus on a non-testing / read-across approach for hazard assessment and getting this approach accepted by ECHA. The costs of a read-across approach are to a large extent defined by the validation work needed. There may be cases where the read-across is very complex and several effect /



validation tests are needed. The purer the material, the less the likelihood that validation is necessary, at least in theory. 40 to 50 k€ is the estimated administration cost for an intermediate registration dossier without testing.

The aim of an **exposure assessment** for Refinables is two-fold:

- 1) it can be used to validate RiCo conditions for SCC assessment and
- 2) it is needed to perform a risk characterisation in the case of a dossier upgrade (can be modelled but preferably be based on actual monitoring data).

(Post-meeting note: *At the 16 Dec 2011 Eurométaux SCC meeting the possibility of using exposure data to demonstrate RiCo was questioned. A summary paper (Annex 5) was prepared by PMC and has been sent to all consortia and Eurométaux as a basis for discussion.)*

An overview is given of the similarities and differences between human health and environmental exposure assessment, effects assessment and risk characterisation (*cf. Q&A in Annex 3 and slides 17-27 in Annex 2*).

When using measured exposure data, it should be considered that these measured data can reflect emissions from different sources (including emissions from non-intermediates). Unless it can be proven or modelled differently, these 'combination' data have to be seen as worst-case data and should preferably only be used to demonstrate RiCo if these combined exposure levels are still low or by explicitly noting the worst-case nature of these data.

The first step in the human health exposure assessment is to identify a 'decisive DNEL' for each exposure pathway (inhalation/dermal) based on the individual DNEL of the Refinable constituents and their concentration in the Refinable. The DNEL with the highest rank is designated as decisive DNEL. The decisive DNEL approach is used to define the most important risk driver and prioritize the occupational exposure assessment. For dossier upgrades, the Consortium will first do a company-specific assessment and then possibility for grouping will be considered. It is noted that the majority of the Chemical Safety Reports (CSRs) is generic, but you can include different conditions (e.g. for different tonnages). For dossier updates, in principle a company-specific exposure assessment and company-specific determination of the decisive DNEL will be needed.

For the testing requirements for an upgrade, 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 improve safety. Alternatively, read-across from dossiers of individual constituents is proposed.

As for exposure assessment, the approach for effects assessment will be different for health and the environment. The environmental effects assessment can be based on the effects data of the constituting metal ions, the environmental classification obtained through MECLAS - as MECLAS is regularly updated with the most up to date Ecotoxicity Reference Values (ERVs) - and TDP tests on the Refinable. The environmental effects assessment should be a reasonably small exercise unless there are no TDP tests available for certain reference samples. A validation can be relevant in case a check for mixture effects is required (e.g. MECLAS demonstrating borderline classification due to accumulative effects). The main issue is to collect all ERVs / PNECs (for all environmental compartments - i.e. not just water!), a task currently ongoing by Eurométaux. Letters of Access will be needed for this and it was suggested that a "quid pro quo" approach should be promoted if possible. We will also need partition coefficients for all the constituents that we are modelling, via a Letter of Access. Also, while mainly the most relevant and vulnerable endpoint, MECLAS



only covers aquatic endpoints; there are also terrestrial and sediment endpoints to fulfil at these tonnages. **AP1**

The human health effects assessment can also to some extent be based on the effects data of the constituents but fundamentally different as for the environment, recognising speciation! The human health classification obtained through MECLAS can be used - as MECLAS is regularly updated with the most up to date Toxicity Reference Values (TRVs) - and selected bio-elution tests on the Refinable to reduce the bioavailability assumption, otherwise driven by an RCR assuming 100% bioavailability. The decisive DNEL could also be used to identify the constituent of concern as read-across source. The concerns with this approach are that 1) potentially access will be needed to a lot of registration dossiers of individual constituents, and 2) this is a worst-case approach assuming 100% bioavailability. Bio-elution tests might be needed for refinement (demonstration of “partial bioavailability”) and if so, we will need (a) representative sample(s). It is suggested to use the same representative sample as was used for the original registration (i.e. Lead Registrant's + another registrant's sample to cover relevant forms, compositions or endpoints).

The approach including the use and role of the decisive DNEL approach and the classification derived by MECLAS should be best demonstrated in a pilot case.

PMC members agree to use the precious metals refining flue dust as typical metal flue dust to demonstrate by means of a pilot study, the read-across approach and to present to Eurométaux / ECHA. **AP3 & AP20**

Others are welcome to provide examples too.

2.2. Questions & Answers.

Following the last PM Refiners WG meeting, a Q&A was drafted to address questions that arise at these meetings (*cf. Q&A in Annex 3*). This is a working document that will be updated as needed.

One of the actions from the last PM Refiners WG meeting was to find out (practical and legal) consequences for PMC Members if one or several of the constituents of their UVCB intermediates is listed on the candidate list and/or prioritised for listing under Annex XIV. Therefore, an authorisation strategy document was drafted and presented at the meeting (*cf. slides 28-32 in Annex 2*).

Points to be clarified / added in the document (**AP4**):

- 1) ‘constituent of PM Refinable’ should be replaced by ‘substance used for PM refining’;
- 2) how to submit an authorisation application;
- 3) clarification on whether Pb oxide can be regarded as a natural component;
- 4) authorisation is legal-entity specific;
- 5) importance of timeline: once a substance is on the prioritisation list, you have 2 to 2,5 years to prepare your authorisation application and you have to start immediately;
- 6) a “ball park figure” for the cost of an “analysis of alternatives” (AoA) (about 250.000 euro) / socio-economic analysis (SEA) (100.000 euro per use). However, these costs depend significantly on availability of existing information and number of uses to be covered.

3. Update on advocacy programme of Eurométaux: examples, information requirements UVCBs. (*Cf. slides 34-40 in Annex 2*)

Several industry representatives met with high level delegates from ECHA on 26 August 2011 to discuss the challenges and difficulties created by the stricter interpretation of SCC in the Dec 2010 ECHA Guidance on intermediates. ECHA asked for industry's cooperation in terms of specific case examples demonstrating that current guidance leaves room for interpretation, especially regarding HIRST 2 conditions. Eurométaux submitted end of September four examples to ECHA,

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illustrating the specificities of UVCB intermediates in NFM and proving that RiCo can be achieved in different ways. CEFIC also submitted (more focused and less detailed) examples; CONCAWE did not provide any examples given they assume that most of their process intermediates either are clearly SCC or will be updated).

Informal discussions were held between ECHA, Eurométaux and CEFIC early November to report on the SCC intermediates example development. In general, ECHA felt that the examples are a significant step forward but still require further technical update, with more focus on proving how hazard knowledge was used to design the installations for SCC, and what measures beyond LEV and respect of national standards were applied to comply with SCC. Eurométaux proposed to review and focus the examples a last time according to the request of ECHA (AP5). It was understood that CEFIC will stop working on their examples and focus on national training of inspectors.

The exchange with ECHA (re)confirmed the need for a pragmatic approach on the read-across for test waiving for UVCB type intermediates. ECHA stated that this could probably be conducted using a flexible approach and would even not call this read-across but rather “*substance effects prediction from the known properties of the ingredients*”. Such assessment could waive testing based on a weight of evidence approach and eventually include a couple of validation assessments (bio-elution, lower TIER toxicity tests). ECHA suggested Eurométaux to come forward with a proposal and discuss it with ECHA in an “*exchange of thoughts and opinions*”. As indicated above, PMC members are happy to prepare a precious metals refining flue dust pilot study aiming at demonstrating such read-across approach and to present to Eurométaux / ECHA. **AP3 & AP20**

There will be a large inspection programme on intermediates end of 2012 coordinated by the Forum (Member States), meaning that good progress should be made with the intermediates programme and remaining steps are clear and planned for. It is stressed again that each company should decide for themselves whether they are SCC compliant using the tools available and their own expert judgement, but the whole lifecycle of the intermediate has to be considered! Two examples were given where a national member state inspection judged that the intermediates did not comply with SCC: 1) RiCo was demonstrated for workers but not for local storage; 2) SCC were not demonstrated for users. **(Post-meeting note: At the 20 Dec 2011 Eurométaux REACH Forum the Zinc sector informed other NFM sectors that inspectors may look at whether a material fulfils the definition of intermediate before even looking at whether it is handled under SCC.)**

It is concluded that Eurométaux will give the examples a last try (ideally, a meeting will be organised with ECHA including a technical expert for each example) by end of January and include a first discussion on the “read-across” for test waiving for UVCB’s. The PM Refiners WG will decide on a strategy for update or upgrade of the registration dossiers based on the outcome of this last try.

4. Workplace exposure assessment programme.

4.1. Proposed general approach & tools.

(Cf. slide 43 in Annex 2)

4.2. Updated version RiCoG with metal specific adaptations.

(Cf. slides 44-46 in Annex 2)

The updated version of RiCoG is presented by EBRC. Internal and external comments of varying extent were received on the previous version and metal specific issues were



reflected in the updated version. The physical form, containment strategies, process steps, etc. are now better considered. The new version is not available for download yet as the glossary and terminology still need to be updated. It was proposed that it would create value for companies if a webinar to explain how to use RiCoG could be organised once fully ready, but this might not be necessary if the glossary is sufficiently explanatory.

EBRC will finalise RiCoG and circulate to comment providers for trial / last commenting round as soon as possible (with the approval of Eurométaux). EBRC should suggest what the current weak points are and where supporting evidence is needed from PM Refinables WG members. [AP6-8](#)

4.3. Status of occupational exposure assessment - questionnaires.

(Cf. slides 47-49 in Annex 2)

A total of 24 occupational exposure questionnaires were returned. Inhalation monitoring data were received from 7 companies and biomonitoring data were available as well at some companies. Dermal exposure data were not available at all. EBRC is still waiting for further information from some companies. [AP9](#)

4.4. Feasibility pilot case for flue dust streams declared by Johnson Matthey.

EBRC presented the status of the flue dust pilot study *(Cf. slides 50-63 in Annex 2)*. The flue dust streams declared by Johnson Matthey showed a large variation of concentrations of constituents (depending on input materials), which had implications for the application of the decisive DNEL approach. Since not all DNELs are available yet, OELs were used instead for the flue dust pilot study. One of the critical DNELs/OELs is for Platinum, so monitoring was predominantly aimed at compliance checking for Platinum, but the Platinum content varied significantly between different flue dusts.

Four process steps were identified. Furnaces are sealed during operation, and furnaces are loaded when cooled down. The dustiness of the flue dusts, and not the process temperature, is the exposure driver. Therefore, dustiness testing is strongly suggested.

When using RiCoG to check RiCo during the manual sealing of the drums, it is noted that RiCo is not achieved. Expert judgement is needed to decide on update or upgrade (RiCoG will help you identify the weakest link). RiCoG is still subject to some level of expert judgement, which is a company responsibility.

Challenges to be evaluated in the pilot case:

- High importance dustiness check on Refinables (NB: it is a company's responsibility to make sure they have the correct composition of their Refinables). Particle size distribution is not sufficient to define the dustiness potential. If DNELs/OELs are extremely low, there is a possibility that dustiness tests could be waived. (default categorisation as highly dusty material). [AP10](#)
- If DNELs are not available, we should use available OELs. [AP11](#)
- EBRC to elaborate how to better reflect automated process steps in RiCoG. [AP6](#)
- Dermal exposure is not yet considered. EBRC notes that IOM is currently performing a dermal exposure assessment campaign. Volunteers should indicate their interest in participating in this study as soon as possible to EBRC. [AP13-14](#)

5. Environmental emissions assessment programme.

5.1. Proposed general approach & tools.

(Cf. slides 67-78 in Annex 2)

5.2. Status of environmental emissions assessment - questionnaires.

(Cf. slides 79-90 in Annex 2)



WCA presented the status of the environmental emissions assessment. A total of 12 questionnaires were returned, with 9 containing a 'reasonable' amount of information. All PM Refiners are requested to send their missing data as soon as possible. **AP9**
A provisional Generic Exposure Scenario (GES) was developed based on the 6 sites providing the most complete datasets. As more data come in, more statistically robust Emission Factors (EFs) will be calculated and a decision on whether to retain or assess outliers separately can be made. Where possible, for each metal component, total produced / used and emitted to the environment due to Refinable processing is needed. Also, information on site total input per metal is needed if other activities on site are using these substances. An initial site-specific modelling was undertaken but additional parameter values are still required.

The way how to assess the mixture toxicity issue for UVCB's will have to be resolved.

6. Strategy to review the MECLAS derived hazard classifications of Refinables.

6.1. Cluster analysis pilot case for flue dust streams.

(Cf. slides 94-122 in Annex 2)

Companies questioned if the complex hazard classification recommendations for certain intermediate groups (which currently have pick-lists) could not be updated and simplified. It was in this respect that a cluster analysis pilot project was launched with ARCHE on the flue dust Refinables group to check if a scientific relevant and statistical robust technique could be used to achieve this goal.

ARCHE presented the status of the classification cluster analysis pilot case on flue dusts. A stepwise approach was followed, whereby a statistical cluster analysis was performed on the basis of composition of the flue dusts, and a manual cluster analysis interpretation was performed based on impact classification. These were used to define "hazard profile groups".

A range of statistical multivariate techniques (such as hierarchical and partition-based cluster analysis, principal component analysis and decision tree analysis) was considered, as these techniques should be seen as diagnostic techniques, each with their statistical focus and their strengths and weaknesses. These various methods gave quite similar results for limited number of clusters (1 to 3) but fewer similarities when higher cluster numbers (>3) were derived. Therefore, 3-4 clusters is considered the maximum for a robust assessment in this case. To cover for the variability in concentrations in composition, the cluster analysis was conducted for two scenarios: the arithmetic mean of the composition range and maximum elemental concentration. A prerequisite for a robust assessment is that the number of samples/streams should always be larger than the number of investigated parameters. Therefore, elements driving classification was selected (for flue dusts, As, Ni and Pb were the most important drivers for health classification and Ag amongst other metals was driving environmental classification).

Two common cluster techniques, the principal component and cluster analysis, gave similar clusters. At a more detailed level and depending on the method used, a few (outlying) flue dust types (companies) can be allocated to different clusters. The rank-transformation (where all metal concentrations are normalised to the same scale) gives a more robust assessment than the untransformed scenario. Results are not much different for typical versus maximum scenarios.

With the manual cluster analysis interpretation based on impact classification, it was relatively 'easy' to define relevant classification clusters for flue dust. The clusters were more or less the same as for the composition driven analysis, but there was more differentiation in the 'metal-poor' cluster and less differentiation in the 'metal-rich' cluster. It was concluded that a cluster analysis based on elemental concentrations divided by their classification cut-off should be applied for flue dusts.



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Based on this positive experience, PMC members agreed to extend the Cluster analysis to other Refinable groups that currently have pick-lists. However, PMC members proposed to reduce the number of cluster analysis methods and focus on the principal component analysis. Boundaries will have to be defined for each cluster, so members can easily define in which cluster their Refinable belongs. An additional identifier might be origin or process from which the Refinable results. [AP15-16](#)

ARCHE also presented the update of MECLAS to reflect the changes in mixtures classification category rules adopted by the 2nd ATP:

- 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 is new guidance on derivation of environmental chronic endpoint based upon chronic data.

The 2nd ATP adaptations are developed and implemented in a beta version of MECLAS (which includes the new chronic environment category) now also accessible to all users. [AP17](#)

6.2. Classification in registration dossier vs. SDS.

One of the actions from the last PM Refiners WG meeting was to check whether registrants are allowed / obliged to put the worst-case classification in the MSDS equally to the generic worst-case classification in the registration dossier; or if each manufacturers can define the classification and categorisation level for his/her own Refinable based on documented evidence (see individual MECLAS runs). Therefore, a question was formulated that will be submitted to the ECHA helpdesk (*Cf. slide 124 in Annex 2*). PMC members are asked to provide comments to the question as soon as possible.

Post-meeting note: *It seems one of the PMC Members had raised a similar question in October 2010 already, where the ECHA helpdesk had replied the following:*

"The classification presented in the SDS should be consistent with the information on the label and reflect the real composition and therefore the toxicity of the [material] supplied. For a UVCB substance, for registration purposes (as for C&L notification) different classifications can be linked to the same substance due to varying composition. Also in the CSA the possible range of concentrations and classifications of the UVCB substance can be reflected.

A UVCB substance can have a concentration range for which the classification of the substance is more severe at higher concentrations than at lower ones. Even if the lead registrant gives the more severe classification in the registration dossier, it is possible for another supplier of the substance with concentrations giving rise to the less severe classification, to place that classification in his SDS. He can also add the severe one (as agreed in the consortium) as additional information with justifications in section 16, as long as the classification in section 2 is consistent with that on the label."

This response will be validated with Eurométaux before it is formally accepted and circulated. This will influence the number of classification profiles that are grouped by ARCHE via the above cluster analysis.

7. AOB, next calls, meetings, and closing remarks.

Cost-sharing: the cost-sharing formula is not to be changed for now. If there is a really clear-cut situation regarding updates/upgrades, the cost-sharing formula should be changed. [AP21](#)

It is noted that not only Pb Oxide but also aluminium and zirconium refractory ceramics fibres (RCF's) were selected by MSC as SVHC substances (candidate list). These are widely used in the



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Aluminium industry. PM refiners should check if they are used in PM refining. A substitution should be feasible. **AP22**

It is suggested to organise an informal session with ECHA about UVCB assessment techniques in general, including tools like decisive DNEL. This would be done via Eurométaux, with the support of the consortia, after the tools have been discussed and reviewed with interested consortia. **AP19**

It is proposed to have the next PM Refiners WG meeting end of January / early February. An e-mail will be sent around to check which time is best for all. The updated project strategy is to be presented at the next meeting. **AP18**

Post-meeting note: *The meeting will be held around mid February to enable the consultants to present significant progress.*

Annexes

1. Agenda & list of participants
2. Slides presented at the meeting
3. Questions & Answers (Q&A)
4. Strategy Authorisation - will be circulated by mid Jan 2012
5. PMC Summary paper on the use of RCR for upgrades and updates

Actions

Table 1. Actions agreed at the 5 December 2011 PM Refiners WG meeting in Brussels

	What?	Who?	When?
1.	Agree on efficient data-sharing (e.g. swapping, LoA) approach among metal consortia to formalise use of PNEC, DNEL and supporting rationale in PM Refinables Dossiers	CB	Q1 2012
2.	Add information on the difference between streams and groups and what is used where (MECLAS, exposure assessment etc.) to Q&A	KA	End Jan 2012
3.	Elaborate flue dust pilot study to demonstrate the read-across approach for effects assessment	EBRC / WCA	Mid/End-Feb 2012
4.	Update the authorisation strategy document following input from the meeting	KA	Mid-Jan 2012
5.	Fine-tune metal-specific examples of SCC for a last presentation to and discussion with ECHA	Eurométaux	Jan 2012
6.	Finalise RiCoG (including a better reflection of automated process steps) and circulate to comment providers for trial/last commenting round	EBRC	End-Jan 2012
7.	Finalise RiCoG for “public release” and use for RiCo assessment programme	EBRC	Mid-Feb 2012
8.	Start RiCo assessment for all PM Refinables and revert to PMC with indication of which Refinables fail/pass RiCoG	PM Refiners WG	End-Feb 2012
9.	Revert with missing data (all constituents, tonnages, etc.) in workplace and environmental questionnaires to EBRC and WCA, respectively	PM Refiners WG	27 Jan 2012
10.	Explore needs for dustiness work on Refinables and agree on timeslot to perform such work (including how to address sensitisers: find laboratory performing dustiness test on	EBRC	Mid-Feb 2012



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	sensitisers + default categorisation as highly dusty material)		
11.	Map available OEL, indicative OEL and SCOEL recommendations for each Refinable constituent (to be used for exposure assessment in the absence of DNEL)	KA / EBRC / Eurométaux	End-Jan 2012
12.	Explore needs for further characterisation/speciation work on Refinables and agree on timeslot to perform such work	EBRC	Mid-Feb 2012
13.	Explore relevance of dermal exposure and propose way forward	EBRC	Mid-Feb 2012
14.	Indicate interest in participating in IOM monitoring study to EBRC	PM Refiners WG	End-Jan 2011
15.	Check “composition/process” information in EBRC’s database to determine possibility/relevance of splitting some streams into several groups - based on origin (Ag, Au or PGM refining) or process (smelting, refining) - before implementing cluster analysis to arrive at classification groups	ARCHE	Early-Jan 2012
16.	Present classification groups for remaining PM Refinables for discussion and approval	ARCHE	End-Jan 2012
17.	Check impact of 2 nd ATP on classification of different PM Refinables	ARCHE	End-Jan 2012
18.	Finalise PM Refinables Project Plan/Strategy including way forward, milestones, timeline and budget for updates and upgrades and circulate to PM Refiners WG	KA	End-Jan 2012
19.	Compare general approaches towards demonstrating RiCo, preparing updates and upgrades, and deriving classification groups with other metal consortia	CB+HW+KA	Mid-Jan 2012
20.	Present pilot case studies to illustrate applicability of RiCoG, Decisive DNEL, Cluster Analysis, and other UVCB-specific tools to Eurométaux Members and ECHA	All	Q1 2012
21.	Discuss need to adjust cost-sharing formula of PMC for PM Refinables project	CB	End-Jan 2012
22.	Circulate minutes of glass, frits, etc. meeting to PM Refiners WG for information	HW	End 2011