23 April 2010 (9:30 – 17:00 CET)

MINUTES

AP refers to Action Points listed at the end of this document

1. Introduction and Welcome

1.1. Confidentiality and Competition Law. All participants committed to respect Confidentiality and Competition Law.

1.2. Tour de table and apologies. The list of participants is available in Annex 1. Due to the flight interruptions caused by the eruption of the Eyjafjallajoekull volcano in Iceland, most participants were prevented from attending the meeting in person and had to participate by conference call instead. All handouts were sent by e-mail in advance of the meeting and presentations (Annex 2) were made available by GoToMeeting.

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

1.4. Revision of pending action points and approval of minutes of last face-to-face meeting (4 December 2009). *Cf. slide 4 of Annex 2.* All actions but those relative to the preparation and circulation of ID Cards were finalised. The ID Cards will be prepared in summer 2010, following the integration of the PMC Assistant to the Secretariat team. **AP1** One correction was made to the minutes of the last meeting (21 Dec 2009 replaced by 21 Dec 2010 in Table 1) and the minutes were approved by the Re WG.

2. Re Project Progress

2.1. Phase I: Literature search for Potassium perrhenate. *Cf. slides 6-7 of Annex 2.* Following the addition of Potassium perrhenate to the scope of the Re Project WCA performed a literature search to identify any existing available information on this compound. A Phase I report has been received and the invoice was sent to the concerned company.
The publication that was found indicated that K perrhenate was not toxic or irritant (i.e. not classified). It also included information on Re trichloride. Participants confirmed that this substance was not subject to Registration for any of the Members.

2.2. Phase II: Phase II report, responses from WCA on remaining questions and outcome of discussions on APR's PSD. *Cf. slides 8-9 of Annex 2.* Phase II of the Re project aimed at distributing Re substances and intermediates in categories within which read-across was deemed to be scientifically sound in order to minimise testing needs. Original categories were built on the basis of the oxidation state of the Re ion and the presence of any counter-ion which may strongly influence the (eco-)tox effect of the Re compound (e.g. ammonium).
However, the Re WG agreed to perform read-across from two key compounds: Na rhenate as a reasonable worst case and APR as an absolute worst case. Whenever possible, it is preferable to read-across from Na rhenate as the ammonium anion may have a toxic effect on its own. In the absence of information on Na rhenate, information on APR must be used instead.
Read-across from one of these two salts to (1) Re will be confirmed after the T/D test results have been obtained and (2) Perrhenic acid is not necessary as this compound is sufficiently data-rich.
WCA has updated the Phase II report with the comments made by the Re WG at the last meeting and will finalise it as soon as the remaining questions around the particle size of APR and the possibility of this material to be inhaled and/or swallowed is clarified below. **AP2**

Contact Info of the Consortium
Avenue de Broqueville, 12 – BE-1150 Brussels
Tel.: +32 2 775 63 23 **Fax:** +32 2 779 05 23 **Mobile:** +32 473 52 52 73
E-mail: braibant@epmf.be **Website:** www.epmf.be

2.3. Phase III

Update on tier 1. *Cf. slides 12-22 of Annex 2*

A first batch of tests was agreed at the last Re WG meeting, including UV visible spectroscopy, pH, water solubility and T/D, melting/freezing/boiling point analysis to be conducted by AQura in Germany. Draft reports were received for all physico-chemical analysis but for melting/freezing/boiling point for which a change of method was discussed at an *ad hoc* Re WG conference call (26 Feb 2010). **AP3**

The reports were sent to Dr Klaus Rothenbacher (Scientific Manager of PMC) and Dr Philip Mitchell (University of Reading, expert in the chemistry science of molybdates and rhenates) for consideration and both expressed concerns about the outcomes of the spectroscopy, pH and T/D tests conducted and reported by AQura (cf. Annex 3). These concerns (mainly the use of saturated solutions, the lack of filtration, and the use of buffering solutions which may have influenced the solubility of the rhenate ion) were discussed with WCA and AQura before they were reported to the Re WG Chairpersons.

These concerns were reinstated by Dr Mitchell and Dr Rothenbacher as well as by the chairpersons of the Re WG, who decided to discontinue its collaboration with AQura. **AP4**
A. Alderman indicated that Johnson Matthey could perform some of these tests should the Re WG sample providers agree to send their samples to a competitor. **AP5**

Eco-tox tests were also approved and launched with Evonik in Germany. One report has been received (Respiration inhibition) which shows that APR is not likely to be toxic to activated sludge or waste water micro-organisms (even in presence of high quantities of phosphates). No report have been received for the tests commissioned on algae, *Daphnia* and fish but preliminary results obtained by WCA show that the APR and Na rhenate have a moderate effect on algae and no effect on *Daphnia* or fish. **AP6**

Preparation of tier 2 tests + CLP testing requirements *Cf. slides 23-33 of Annex 2* and Annex 4

As per CLP requirements, a classification notification must be prepared for all Re materials in scope by 3 Jan 2011. Although (eco-)tox information is not mandatory under CLP, physico-chemical hazards must be reported; if the information does not exist, it must be generated before 3 Jan 2011. Five physico-chemical hazards must be assessed for all Re materials (substances and intermediates, no matter the tonnage): flammability, explosive properties, self-ignition, oxidising properties and corrosivity to metals. These tests can be waived on the basis of melting and/or boiling point (cf. Annex 5) which means that where no information exists on these two parameters, any CLP test should be preceded by the determination of a melting and/or boiling point.

The relevance of certain of these five hazards is dependent on the composition and form of the material. In order to waive any of the required tests, the Re WG and WCA need to know:

- The composition of each Re material: the presence of certain groups can trigger the need to conduct or the possibility to waive a given test
- The likely solubility or non-solubility of each Re material: insoluble or sparingly soluble forms need to undergo a T/D test in order to avoid a default Ecotox classification Cat. 4
- In which form(s) each Re material is manufactured and/or imported: anhydrous solid, hydrated solid, or solution (and the medium) (e.g.: it is assumed that a hydrated powder will not be flammable)
- On which basis and facts the Re industry experts can or not affirm that a given material is or not oxidising, flammable, corrosive, etc. **AP7**, **AP8**, **AP9**

Contact Info of the Consortium
Avenue de Broqueville, 12 – BE-1150 Brussels
Tel.: +32 2 775 63 23 **Fax:** +32 2 779 05 23 **Mobile:** +32 473 52 52 73
E-mail: braibant@epmf.be **Website:** www.epmf.be

Tox tests have also been proposed by WCA on APR (as per Annex VII and VIII requirements). In some cases the route of administration to be used in the test requires clarification on the size and shape of the APR powder particles before the test can be launched. At the 26 Feb 2010 *ad hoc* Re WG conference call WCA suggested to determine the PSD and the MMAD of the APR of the LR, if the latter was deemed to be representative of the APR usually manufactured and/or imported into the EEA, in order to determine whether APR powder could be easily inhaled. J. Schlessmann (LR representative of APR) reported the results of these analysis at the meeting; these showed that the APR is unlikely to be inhaled. Since dermal exposure is not relevant and a LD50oral exists, the acute toxicity testing on APR could be waived. **AP10** The short-term repeated dose toxicity test by oral route on APR remains necessary to derive a NO(A)EL for APR.

2.4. Phase IV: Uses, exposure and emissions questionnaire for ammonium perrhenate. *Cf. slides 34-36 of Annex 2.* The PMC Secretariat has received a draft questionnaire from WCA, to which several comments were made to transform it into a more user-friendly tool. The Re WG recommended to have two questionnaires: one for manufacturers and one for downstream users. The latter should ideally be shorter. This would make it easier for manufacturers and downstream users to complete the questionnaire in a shorter timeframe (e.g.: one month).
The Re WG agreed that it was too premature to start circulating a questionnaire to gather monitoring data on Re. The experience gathered with the Ag project showed that this exercise is very time-consuming for the Members, the Secretariat and the Consultants and that it cannot be precipitated, especially if monitoring data on Re materials is not likely be readily available.
It was agreed to:

- Launch a monitoring data request inviting all Re Members to start monitoring the exposure to and emissions of Re on their sites (AP17)
- Discuss the most appropriate timeline for exposure and emissions data collection at the next Re WG
- Circulate a questionnaire to collect all generated monitoring data not before 2011, after careful planning of the Re project Phase IV and the availability of the tier 1 and tier 2 effects data (to be used in the derivation of the DNEL and PNEC[1])

2.5. Phase V: IUCLID 5 Hosting System. *Cf. slides 37-38 of Annex 2.* The remaining questions on the IUCLID 5 Hosting System proposed by WCA have been solved and the Mgmt Cttee of the PMC has authorised C. Braibant to purchase this service on behalf of the PMC. WCA has subsequently launched the set-up of the system and will soon provide usernames and passwords to the PMC Secretariat and LR so they can follow the preparation of their IUCLID 5.2 files "live" in a centralised system. LR will however have "read-only" access only. **AP11**

2.6. Project timeline towards registration deadlines. *Cf. slides 39-40 of Annex 2.* The overall Re project timeline is delayed by the following issues:

- Delay in tier 1 tests due to the deferred sample arrival
- Delay in tier 1 tests due to the need to change testing houses and repeat some tests
- Need to generate monitoring data before the uses, exposure and emissions questionnaire can be circulated

The Re project plan will be adjusted as soon as WCA has reverted with a proposal for tier 1 and tier 2 tests and the PMC Secretariat has launched a proper monitoring data request. **AP12**

[1] Derived No Effect Level (DNEL) and Predicted No Effect Concentration (PNEC) are necessary to calculate the Risk Characterisation Ratio (RCR) which indicates whether or not a certain use or site is at risk and therefore, likely to be prohibited under REACH unless the risk is reduced by more careful monitoring and the implementation of risk management measures. Monitoring data is necessary to derive the actual exposure and emission levels (PEC) that is compared with the DNEL and PNEC, respectively, when determining the RCR. RCR = Exposure/DNEL for human health risk characterisation and RCR = PEC/PNEC for environmental risk characterisation. If RCR > 1 there is a risk; if RCR < 1 there is no risk.

Contact Info of the Consortium
Avenue de Broqueville, 12 – BE-1150 Brussels
Tel.: +32 2 775 63 23 **Fax:** +32 2 779 05 23 **Mobile:** +32 473 52 52 73
E-mail: braibant@epmf.be **Website:** www.epmf.be

3. AOB, next meeting, and closing remarks

3.1. 2010 Re WG meetings. *Cf. slide 42 of Annex 2.* 15 June 3 pm (conference call), 23 September full day (ftf mtg in Brussels (tbc)) and 3 December full day (ftf mtg in Brussels (tbc))

3.2. Assembly meetings. *Cf. slides 43 and 48 of Annex 2.* 18 June and 2 December. Participants were informed on the key topics that will be discussed at the next PMC Plenary meeting in Hamburg. All background documents will be circulated one month prior to the meeting in order to allow Members (whether present at the Plenary meeting or not) to provide their comments and questions on the proposals to the PMC Secretariat.
Two items were of particular interest to the participants, namely:

- *Review of Consortium Agreement to make clarify rights and obligations of Members after Registration submission:* it was clarified that the changes made aimed at ensuring a proper continuation of the Consortium without imposing any excessive financial or administrative burden on the PMC Members. This will be supported by a budget prediction whereby Members will be informed on the likely amounts that will be charged to PMC Members after Registration submission, to ensure dossier maintenance.
- *Letters of Access for classification information:* it was clarified that classifications derived at Consortium level would be shared with other NFM consortia created under the umbrella of Eurométaux and with all PMC Members for free. The data supporting such classification would however not be shared unless a Letter of Access is signed and paid for by the party wishing to see and/or use this data. There will be no Letters of Access mechanism for classification since:
  - It is in the interest of the industry to promote a harmonised classification (different classification, especially if not justified by the presence of specific impurities, triggers prioritisation for Dossier evaluation)
  - REACH-IT allows any notifier under CLP or REACH registrant to simply "agree" with the classification notification proposed (by the LR) and there is hence no way of imposing any kind of compensation on any company wishing to agree with the proposed classification

Participants were invited to authorise other PMC Members to represent them at the Plenary meeting if they cannot participate personally in order to reach the minimum quorum and avoid a last minute re-scheduling of the Plenary meeting.

3.3. IUCLID 5.2. *Cf. slides 44-47 of Annex 2* and Annex 6. A three hours training was provided by C. Braibant to the attendees on sections 1.1, 1.3, 1.4 and 1.5 of IUCLID 5.2. The aim of this training was to allow participants to "discover" the software that future REACH Registrants and/or CLP notifiers need to use to submit their Registration Dossier and/or CLP notification. The submission of a REACH Dossier or a CLP notification will follow the steps summarised in Table 1 below.

During the training, C. Braibant responded to the questions raised by the participants and took note of these in order to complete the guidance that will be proposed to the PMC Assembly in Hamburg. The questions that could not be answered are (**AP13**):

- Can a IUCLID 5 file created by a registrant by the time of pre-registration still be used for registration? Is there any risk of information loss or incompatibility with the more recent IUCLID 5 versions?
- Is it possible to copy-paste sections from the PMC IUCLID 5.2 file to a company-specific IUCLID 5.2 file (e.g.: when the registrant had created its IUCLID 5.2 file for pre-registration)
- When does a confidentiality flag (request to keep given information confidential) trigger an

Contact Info of the Consortium
Avenue de Broqueville, 12 – BE-1150 Brussels
Tel.: +32 2 775 63 23 **Fax:** +32 2 779 05 23 **Mobile:** +32 473 52 52 73
E-mail: braibant@epmf.be **Website:** www.epmf.be

additional cost (invoiced by ECHA as part of Registration cost)?

- Can an importer leave some IUCLID 5.2 fields that are more relevant for manufacturers empty and still pass the Business Rules and TCC?
- How to report information on waste from production and use? As total waste? As metal concentration in waste/typical metal loss? As a recovery efficiency?
- What fields are absolutely required for substances and intermediates in a joint registration, as per the TCC?

Table 1. Steps to submit REACH Registration Dossier and/or CLP notification

	REACH Registration	CLP notification
Preparation of the Dossier or Notification	By WCA and PMC Secretariat: all generic fields will be pre-populated to the maximum level in order to minimise the work left for the actual registrants; content will be presented to and approved by concerned registrants or notifiers	
Work left for Lead Registrant (with support of PMC Secretariat)	☐ Complete company-specific information in section 1.1 of "joint IUCLID 5.2 file" provided by WCA and PMC Secretariat ☐ Create REACH Dossier ☐ Pass Business Rules and Technical Completeness Check (TCC) ☐ Submit Dossier, obtain Registration number and pay invoice to ECHA ☐ Send copy of submitted Dossier to PMC Secretariat	Not applicable, each manufacturer or importer must submit a classification notification individually through REACH-IT
Work left for individual companies	☐ Complete company-specific information in section 1.1 of "individual IUCLID 5.2 file" provided by PMC Secretariat ☐ Create REACH Dossier ☐ Pass Business Rules and TCC ☐ Submit Dossier, obtain Registration number and pay invoice to ECHA	☐ Complete company-specific information in pre-populated file provided by PMC Secretariat ☐ Create CLP notification ☐ Submit notification

Annexes:

1. Agenda and list of participants
2. Slides presented at the meeting
3. Dr Philip Mitchell's reports
4. Recap of Re project tiered testing strategy
5. Tiered approach for CLP physico-chemical testing
6. Print-screens of relevant IUCLID 5.2 sections

Table 2. Actions agreed at the 23 April Re WG meeting in Brussels

	What?	Who?	By when?
1.	To prepare ID Cards for each in-scope Re material	CB	Summer 2010
2.	To adjust category approach/read-across strategy of Re project	WCA	Release of final Phase II report – see below
3.	Obtain UV visible spectrum for potassium perrhenate from existing literature and confirm that the rhenate ion is the Re species in solution	WCA	ASAP
4.	To inform AQura on the decision of the Re WG to discontinue its work with this testing house, settle the remaining practical and administrative details, and identify other testing houses where these tests can be conducted/repeated (e.g.: ECTX Consult for T/D) unless AQura accepts to repeat these tests successfully and at no additional cost for the PMC	WCA (with support of KR)	ASAP

Contact Info of the Consortium
Avenue de Broqueville, 12 – BE-1150 Brussels
Tel.: +32 2 775 63 23 **Fax:** +32 2 779 05 23 **Mobile:** +32 473 52 52 73
E-mail: braibant@epmf.be **Website:** www.epmf.be

5.	To prepare formal offer to conduct water solubility tests on Re substances (including detailed testing protocol + clarification on testing method(s) that may "change" the nature of the Re substance + list of substances with solubility > 10 mg/l)	AA	ASAP
6.	To inform CB on progress of remaining eco-tox tests of the Re project	WCA	ASAP
7.	Prepare a report on the likely potential of each in-scope Re material to be corrosive to metals	Dr P. Mitchell	ASAP
8.	Confirm CLP testing recommendations for each Re material based on the composition/presence of specific groups, form of the material as manufactured/placed on the EEA, and ECHA waivers (cf. Phase II report, slide 27 of Annex 2 and Dr Mitchell report on corrosivity to metals – see AP above)	WCA	ASAP + include in Phase II report - see below
9.	Obtain quotes from available (GLP-compliant) testing houses to start CLP tests on all Re materials (and maybe also on PGM, Au and PM CN-materials) in July 2010	WCA	Mid Jun 2010
10.	Confirm Acute toxicity test can be waived on the basis of PSD and MMAD results for APR and adjust testing recommendation in draft Phase II report	WCA	ASAP + include in Phase II report – see below
11.	Provide usernames and passwords for PMC Secretariat and LR to access the IUCLID 5.2 Hosting System	WCA	Next Re WG meeting
12.	Prepare and circulate Re monitoring data request to all Re Members (to be announced at PMC Plenary Meeting)	TH + AA	Mid May 2010
13.	Obtain responses to pending questions and include these in the final PMC Registration guidance	CB	Mid May 2010

Contact Info of the Consortium
Avenue de Broqueville, 12 – BE-1150 Brussels
Tel.: +32 2 775 63 23 **Fax:** +32 2 779 05 23 **Mobile:** +32 473 52 52 73
E-mail: braibant@epmf.be **Website:** www.epmf.be