Minutes

AP refers to action points listed at the end of this document

1. Welcome and Introduction

1.1. Confidentiality and Competition Law (reminder). Participants (Annex 1) were reminded on their obligation to comply with Confidentiality and Competition Law.

1.2. Approval of the Agenda. The Agenda (Annex 1) was approved. The slides presented at the meeting are provided in Annex 2.

1.3. Actions from last Assembly meeting – Slide 4 of Annex 2. All actions are in progress and will be achieved on-time for the next Plenary meeting.

1.4. Chairmanship of the MC – Slide 5 of Annex 2. According to Article 4.2.1.2 the Chairman of the Management Committee must be elected every two years. It was proposed for A. Griffiths to remain Chairman until Dec 2010 when a new Chairman would be proposed. The Management Committee (MC) accepted this proposal. **AP1**

2. Scope of activity of the PMC: recent changes, final changes – Slides 6-10 of Annex 2.

Following the closure of the scope of the PM & Re Consortium (PMC) in September 2009 additional requests for changes were received in December 2009. C. Braibant discussed the potential impact of these changes with the consultants and invited the relevant Work Groups (WG), including the Technical Advisory Panel (TAP), to support or reject the proposed changes of scope. All changes were supported with the condition that cost implications are carefully considered and allocated to the Members having requested these changes. The Management Committee (MC) accepted this proposal.

2.1. Disilver oxide and other changes. Slide 7 summarises the changes that have been proposed. In general, all these changes simplify the projects. The MC agreed that no additional change would be accepted in 2010. **AP2** It was agreed to continue developing the Disilver oxide dossier as if it was subject to the first registration deadline.

2.2. Cost implications and agreed approach. Although no *ad hoc* work has been done on any of the removed materials and hence, no reimbursement must be obtained from the concerned Members (collected information can be used for read-across), past work to be performed on newly added substances and intermediates (only related to Phase I, i.e. literature search) will be charged to the Members having added these materials to the scope. **AP3**

2.3. Follow-up on nanosilver provisional position. The provisional position proposed and approved by the Assembly on 3 December 2009 remains unchanged. Experience with the REACH Implementation Project group on Nanomaterials (RIP-oN1)'s indicates an overall acceptance of the Consortium's view that silver and nanosilver can be registered separately.

3. Progress of PMC projects.

A weekly update of each project plan is foreseen as from March 2010. All project plans will be made available in a centralised database (REACHsuite or EPMF website). **AP4**

3.1. Ag – Slides 12-24 of Annex 2. Phases I-IId have been successfully finalised, Phase III is on track, and Phases IV-V are running slightly behind schedule.

Two tests must be repeated (oxidising properties and sensitisation, pending ECHA's reponse on a PMC inquiry) and a number of human health tests may be prevented by purchasing (if relevant) data generated under the EU Biocides Directive (BPD).

The PNEC and DNEL derivation are on track. The generation of exposure scenarios (ES) has been delayed by the late receipt of responses to the questionnaire on uses, exposure and emissions, amongst others. An ES meeting will be held on the first week of March to determine whether sufficient information has been received to date or not, to accelerate the process of ES building, and to allow the official transfer of this specific task to H. Waeterschoot. **AP5**

The project has been slightly delayed but remains on track; however, the remaining time between today and the registration deadline (1 Dec 2010) does not allow to refine the risk

characterisation if this was necessary. This means that Members may need to implement more restrictive risk management measures temporarily, until the risk characterisation is updated with the generation of additional data, and the Dossier is updated. This would mean unnecessary costs to Members and should be avoided. Although it is clear that the CSR must be compiled with representative data, the possibility of using "any" data collected to date in order to prepare a complete CSR on-time for the registration deadline was considered.
It was recently brought to the attention of the PMC that the Classification, Labelling and Packaging (CLP/GHS) Directive requires the generation of physico-chemical data where no data exists. **AP6**

3.2. **Au + PM CN- - Slides 25-28 of Annex 2.** As approved by the Assembly on 3 Dec 2009, these two projects were allocated to WCA, who is now mandated to continue the work initiated by Dr Knoell Consult (DKC). Both Phase I reports have been sent to WCA who has identified additional references that were omitted by DKC, particularly on the Au compounds. DKC has invoiced PMC for additional Phase I, Phase II and Phase V work (although invoices for Phase I have already been paid) but PMC has indicated that these invoices will only be paid upon receipt of the deliverables resulting from the work performed, including the literature references purchased on behalf of the PMC under Phase I. As soon as these are received they will be transferred to WCA. A teleconference with WCA is scheduled on 26 February to discuss the overall progress of these two projects and particularly the set-up of Phase II. As per previous experience with the Ag project it is highly recommended to launch the ES work as soon as possible. **AP6** A WG meeting will be set-up in April 2010. The project is on track (earliest registration in Q1 2012).

3.3. **PGM – Slides 29-34 Annex 2.** The inclusion of one intermediate to the PGM scope requires the update of the Phase I report of the PGM project. The Phase II report has been delayed due to repeated changes of scope and due to the need to clarify the registration strategy of anhydrous/hydrated forms of certain PGM. T/D testing recommendations have been received already and a timeslot has been secured in April 2010 with CANMET. A tiered testing strategy will be implemented as soon as the Phase II report is received, which also implies the need to identify sample providers and hence, Lead Registrant candidates. As per previous experience with the Ag project it is highly recommended to launch the ES work as soon as possible. **AP6** The project is on track (earliest registration in Q1 2012).

3.4. **Re – Slides 35-39 of Annex 2.** The inclusion of one intermediate to the Re scope requires the update of the Phase I report of the Re project. Testing recommendations (Phase II) have been received in a tiered approach, thereby triggering a tiered testing programme (Phase III) which started in December 2009 with physico-chemical, T/D, and ecotox tests. The next Re WG meeting will take place on 23 April 2010 and will aim at agreeing on next testing tiers, the circulation of the questionnaire for ES building, and the classification notification. **AP6** The project is on track (earliest registration in Q1 2012).

3.5. **Refinables – Slides 40-49 of Annex 2.** A significant progress has been achieved between 20 January and today, thanks amongst others to the input provided by H. Waeterschoot. A testing and classification strategy is being devised, starting with chemical and mineralogical characterisation (at Outotec) and 24 T/D pretests (at ECTX). The next meeting is scheduled on 21 April 2010 and will aim at evaluating the first test results, confirming the grouped approach, deriving provisional classifications and identifying further testing needs. The project is on track (registration deadline 2010).

4. **Lead Registrants: official designation, commitment, and duties – Slides 50-51 of Annex 2.** So far Lead Registrants for some materials have been elected by the PMC but these have not officially committed to accomplish this role as provided in the Consortium Agreement. It is proposed to attach the document provided at the end of Annex 3 to the Consortium Agreement (as Appendix 10 of the Agreement).

5. **Revision of Consortium Agreement – Slides 52-59 of Annex 2.** It was proposed to use a different colour for those changes requiring a discussion/vote by the Assembly and those changes that have already been approved by the Assembly and to prepare a summary of the changes made to guide

the Members in their evaluation of the third version of the PMC Consortium Agreement. **AP7**

5.1. Integration of addendum, clarifications and other *ad hoc* notices. This was done in the attached version (Annex 3).

5.2. Strengthen Members' commitments after Registration. This was done by strengthening the Preamble and Article 3.5 of the Consortium Agreement (Annex 3). It was agreed that budget predictions should be used to provide PMC Members with an indication of the annual amount they would be required to pay after Registration submission (for dossier maintenance *et al.*). **AP8**

5.3. Appendix 5: Clarification of working structure and decision-making. Done, see attached Agreement (Annex 3).

5.4. Inclusion of intermediates to cost-sharing formula. The reasons to include intermediates in the cost-sharing formula are provided in Annex 4. The MC approved the proposal of including intermediates in f3 of the cost-sharing formula only, with a weight of 1.

6. Letter of Access – Slides 60-69 of Annex 2.

6.1. LoA calculation method. The principles and assumptions made to calculate a fair and non-discriminatory cost for the Letter of Access is provided in Annex 5. The PMC cost-sharing formula and a survey on registration intentions circulated through REACHsuite have been used as a basis to calculate the cost of a LoA aiming at obtaining a similar cost for PMC Members and non-Members.

6.2. Budget/Expenses predictions: administrative support. Budget predictions were made for the Generic costs and each project separately. The MC agreed to apply an inflation rate of 3% and a 20% contingency to these budget predictions so as to cover for other Members' and PMC and/or uncertain costs.

6.3. LoA prices. Cost prices are proposed on page 4 of Annex 5. These will be presented to the Assembly for discussion and approval at the next Plenary Meeting (Hamburg, 18 June 2010). Once approved, the legal frame will be made available to all SIEFs through REACHsuite, which will also enable an online signature of the LoA agreement. Monies recovered through the selling of LoA will limit the amount invoiced to Members annually and any excess will be kept in an *ad hoc* fund and reused in risk assessment-related activities only under the supervision of the EPMF and subject to the approval of the PM & Re Consortium concerned (Sub-)Assembly.

7. IUCLID 5 Hosting System – Slides 70-74 od Annex 2. All security and software questions were addressed and resolved by WCA. The MC agreed to sign a contract with WCA to implement one instance per project. **AP9**

8. AOB, next meetings, closing remarks

8.1. AOB. No other business was raised.

8.2. Next meetings

- **8.2.1.** Re WG teleconference: 26 February 2010, 3 pm CET
- **8.2.2.** Exposure Scenario meeting: Brussels, 2 March 2010
- **8.2.3.** TAP+Ag WG meeting with EBRC: Brussels, 18 March 2010
- **8.2.4.** TAP+Ag WG meeting with WCA: Brussels, 6 April 2010
- **8.2.5.** Exposure scenario workshop: Brussels, 7-8 April 2010
- **8.2.6.** PM Refiners WG meeting: Brussels, 21 April 2010
- **8.2.7.** PGM WG: Brussels, 22 April 2010
- **8.2.8.** Re WG meeting: Brussels, 23 April 2010
- **8.2.9.** MC teleconference: tbd
- **8.2.10.** PMC Plenary Meeting: Hamburg, 18 June 2010
- **8.2.11.** MC meeting: Brussels, September 2010 (registration readiness)

8.3. Closing remarks

Annexes

1. Agenda and list of participants
2. Slides presented of the meeting
3. Consortium Agreement dd 26 February 2010
4. Adjustment of cost-sharing formula to include intermediates
5. Calculation of LoA cost (+ Annex 5.1)

Table 1. Actions agreed at Management Committee meeting – Brussels, 24 February 2010

	What?	Who?	When?
1.	Re-elect A. Griffiths as Chairman of the PMC until Dec 2010	Members	18 June 2010
2.	Inform all Members (and consultants) on new scope and on MC's decision to reject any further changes (in 2010)	C. Braibant	Mar 2010
3.	Inform all concerned Members on costs associated to inclusion of new intermediates	C. Braibant	Mar 2010
4.	Add two budget columns (foreseen versus spent) and task numbers to all project plans Implement a centralised database to allow Members to access weekly updates of all project plans	T. Hird	Mar 2010
5.	Circulate a list of uses (and associated PROC and SU codes) identified for silver, disilver oxide and silver nitrate to the Members for review	T. Hird	Mar 2010
6.	Devise an *ad hoc* testing strategy for classification notification for all materials in scope	PMC Officers and WG	Mar 2010
7.	Adjust colour code of the Consortium Agreement to and prepare a summary of the changes made	C. Braibant & A. Palmers	Mar 2010
8.	Calculate annual amount to be paid by each Member after Registration submission (as per PMC project plans)	C. Braibant	Mar 2010
9.	Inform WCA on MC's decision to implement the IUCLID 5 Hosting System	C. Braibant	Mar 2010