Chair: *A. Alderman (Johnson Matthey)*
Co-Chair: *Ken Kloska (Climax Molybdenum)*

21 June 2011, 3-3:40 pm CET

Participants

1. *A. Alderman* (Johnson Matthey, United Kingdom)
2. *C. Braibant* (EPMF, Belgium)
3. *K. Kloska* (Climax Molybdenum, United States)
4. *M.-L. Ledrich* (Traxys, Luxembourg)
5. *E. Logan* (WCA, United Kingdom)
6. *K. Rothenbacher* (EPMF, Belgium)
7. *M. Simon* (Traxys, Luxembourg)
8. *R. Thiele* (Heraeus, Germany)
9. *A. Van Meerkerk* (Climax Molybdenum, The Netherlands)
10. *P. Whitehead* (WCA, United Kingdom)

Minutes

AP refers to action points listed at the end of the minutes

1. **Discuss progress of Re project toxicity testing programme (cf. Annex 1):**
   a. **Discussion from MLA results and next step(s).** Since the MLA showed no mutagenicity, the micronucleus test must be performed. In the unlikely event that the micronucleus test reveals positive mutagenicity results *in vivo* testing must be considered. AP1
   b. **ICE at LAB (Hungary) instead of BCOP or IRE at Harlan (United Kingdom): discussion and next steps.** Because the Isolated Chicken Eye study is both ECHA- (cf. Annex 2) and OECD-approved it was recommended to choose this alternative. LAB is known for its capacities and capabilities in conducting ICE and similar studies. AP2-3
   c. **LLNA.** Pre-screening work indicates that a 25% concentration in dimethylformamide was the appropriate highest concentration for use in the assay, out of the 2 pre-assigned vehicles (DMF and 1% Pluronic L92 in distilled water). This was based on forming a suitable dosable formulation with no unacceptable irritation at 25%. *Post-meeting note: WCA has asked Harlan to evaluate the other 'standard' vehicles for the LLNA to determine whether an acceptable formulation can be obtained at higher concentrations than 25%. Although the behaviour of APR in vehicles other than DMF/water+pluronic is not fully assessed, WCA wants to ensure that the overall study design is sufficiently robust with regard to the appropriate maximum concentration to be administered. If an acceptable higher concentration can be achieved with an alternative vehicle, then the relevance of using that vehicle in comparison with DMF can be discussed. The results of the additional vehicle investigations will be available during the course of week commencing 27 June 2011. The main LLNA test will be delayed by a couple of weeks while the additional preliminary vehicle evaluations are performed at Harlan. The LLNA study will now start earlyish July 2011, with the preliminary results available around 2 weeks later.*
   d. **28d oral toxicity/Reprotoxicity screening study.** Butterworth was chosen for the method validation (not GLP but acceptable) and analyses (GLP). Although draft report not expected before Jan 2012, preliminary results (but for hystopathological ones) should be available before Dec 2011 Re WG meeting.
   e. **CSA/CSR needs.** A CSR is required for substances and non-scc intermediates registered in tonnages equal or superior to 10 t/a and for which hazard is identified/classification applies. AP4

2. **Data-sharing.** A non-Member company has recently approached PMC to request an access to the data supporting the no-classification of Re metal and APR (probably to use it in other

contexts or jurisdictions). The Re WG was invited to express their views on this request. All Re WG Members supported the possibility of sharing data with a non-Member (Members have co-ownership rights and the right to use PMC-generated data as needed) on the condition that (AP5-7):

(i) the value of the underlying data is calculated in line with costs incurred by PMC to gather or generate these

(ii) the data-sharing rules applicable under REACH are applied/respected (e.g. Fleischer 2007, CEFIC's Guidance, Eurométaux' rules, etc. – cf. Annexes 3-5)

(iii) the value and conditions that are proposed to the company are discussed with and agreed by the Re WG and the Management Committee of the PMC

3. **Next meeting.** A conference call will be held on 15 Sep 2011 (as agreed at Dec 2010 Re WG meeting) to further discuss the progress made and any relevant items. The next face-to-face meeting is scheduled on 7 Dec 2011.

Annexes

1. WCA's status of Re project toxicity testing programme
2. ECHA note on ICE
3. Fleisher, M. 2007 paper
4. CEFIC Guidance on use of published information
5. Eurométaux rules on financial valuation rules

Actions

Table 1. Actions agreed at 21 June 2011 Re WG conference call

	Action	Who?	When?
1.	Check whether *in vivo* mutagenicity test is subject to a testing proposal or whether it can be conducted upon unilateral decision of PMC.	WCA	In due course / if needed
2.	Proceed with evaluation, approval and signature of contractual terms and conditions and protocol.	WCA and PMC secretariat	Jun/Jul 2011
3.	Request Harlan to send the (~ 1 g) sample to LAB.	WCA	ASAP
4.	Check whether CSR is required on the basis of hazard or classification.	WCA and PMC secretariat	ASAP
5.	Prepare list of studies used to derive and support Re classifications.	WCA	15 Jul 2011
6.	Circulate list of studies used to derive and support Re classifications to Re WG for information.	PMC secretariat	End Jul 2011
7.	Revert to interested company with preliminary confirmation and prepare Licence to Use Agreement for discussion with/approval by Re WG.	PMC secretariat	B4 15 Sep 2011