Chairperson: A. Alderman (Johnson Matthey)
Secretariat: C. Braibant (EPMF)

4 December 2012, 14:00 – 18:00 CET
Metals Conference Centre – Copper Room
Rue du Duc 100 – 1150 Brussels (BELGIUM)

MINUTES

1. Welcome and Introduction

a. **Confidentiality and Competition law.** Participants were reminded on their obligation to comply with confidentiality and Competition Law rules.

b. **Tour de table and apologies.** The list of participants is available in Annex 1.

c. **Approval of the agenda.** The Agenda was approved. The slides presented at the meeting are available in Annex 2.

d. **Review of actions agreed at and approval of minutes of the last meeting (28 Sep 2012 Re WG conference call).** All actions except two are done or in progress. The circulation of ID Cards and launch of the SIEF communication was delayed due to the fact that the format of the ID Cards is developed for all projects in parallel, where each project has a different complexity and pace. The pending actions (generation of analytical data and note to inform registrants on possible consequences of late or individual registration) will be actioned in the coming months.

2. Finalisation of APR testing programme and classification/CSR+ES needs.

Finalisation of testing programme

The last test of the Re project was the OECD 422 test on APR. This test is now finalised and a draft report has been received and is being reviewed for comment by WCA. This review will also entail comparing the results of this test on APR with the historical data on e.g. thyroid weight changes available to the test house.

P. Whitehead presented the effects observed in the three dose groups (high with 1000 mg/kg/day dose; intermediate with 330 mg/kg/day dose; and low with 110 mg/kg/day dose) and explained how these are not sufficiently unequivocal to lead to either a STOT RE 2 or a reprotoxicity classification. As in many toxicology tests it is difficult to distinguish the potentially confounding effects resulting from the general toxicity and the reproductive toxicity. The interpretation of the results require a degree of toxicology expert judgement:

- The effects in the pituitary and thyroid glands cannot be associated to a specific mechanism of toxicity and are considered reversible effects. Though this assumption would have been more precisely confirmed if the test had included a recovery group, such a group is not foreseen in a normal OECD 422 protocol and was not deemed to be necessary for APR considering the outcome of the dose-range finding study and the objective of minimising the use of test animals.
- 1 Out of 10 litter is normally lost in a OED 422 test control group. In the APR test 2 litter losses were observed but according to historical data available, this number of litter losses has also been observed in control groups.
- The decrease of viability observed in the intermediate groups could be explained by the size of the litter in which the decrease of viability was observed: 20 pups instead of a normal litter of 13-15 pups. Whereas in the control group the damn with a litter of 20 pups lost 4 and in the intermediate dose group the 20 pups litter lost 7, this is not sufficient to demonstrate an unequivocal effect of APR on litter losses.

The limited data resulting from a screening study such as the OECD 422 one, and the general lack of data on APR and Re toxicity in general makes it difficult to put the results into context. The assessment is hence limited to addressing REACH and CLP compliance needs rather than intending to understand the mechanism which lead to the observed effects. If the Re WG wanted to investigate the effects via further testing, this would not be authorised unless a testing proposal is

filed and ECHA approves this testing proposal.

Classification/CSR+ES needs
The low dose of 110 mg/kg/day will be used as No Observed Adverse Effect Level (NOAEL) for APR. It was agreed that the observed effects were not indications of potential STOT or reprotoxic activity of APR or rhenate and that no further testing was needed and no classification implemented on APR. This also means that no extended CSR with Exposure Scenarios are required but that a complete MSDS should be sufficient to ensure the safe handling of APR in industrial settings.
The above will be properly documented both in the report as well as in the IUCLID 5 file.

Read-across strategy
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3. **Live demonstration of IUCLID 5 completion (including uses)**

4. **Finalisation of ID Cards, SIEF communication and sameness check**

5. **Next steps including:**
    a. Timeline for Dossiers submission
    b. 2013 budget/membership fees

6. **AOB, next meetings/calls and closing remarks**