Chairman: *Dave Boyd* (Johnson Matthey)

16 March 2011, 10:00 – 11:30 CET

List of participants

Dave Boyd	Johnson Matthey	United Kingdom
Roland Brasch	Heraeus	Germany
Philip Copestake	BIBRA	United Kingdom
Erin Logan	WCA	United Kingdom
Adam Peters	WCA	United Kingdom
Mark Raffray	Johnson Matthey	United Kingdom
Klaus Rothenbacher	EPMF	Belgium
Mike Sheppard	Vale Inco	United Kingdom
Ed Stutt	WCA	United Kingdom
Rüdiger Thiele	Heraeus	Germany
Steven Verberckmoes	Umicore	Belgium
Paul Whitehead	WCA	United Kingdom
Roland Winde	Umicore	Germany

Minutes

1. **Welcome and introduction** ***(DB)***
   - **1.1. Approval of the Agenda**. The agenda (Annex 1) was approved. It was decided to start the discussions with points 5.2.4, 5.2.5 and 5.4 of the agenda.
   - **1.2. Approval of the minutes of the last meeting**. The minutes of the last meeting (Brussels, 08 Feb 2011) were approved.

2. **Organisational: ReachSuite (WCA)**

- The group will be using ReachSuite for communication purposes in the future
- A manual for using ReachSuite will be circulated (WCA – done)

3. **PGM project scope**
   - **3.1. Intermediates survey – update** ***(PMC)***

- PMC informed that responses from most companies have been received to date
- The status as intermediate, meeting SCC, has been confirmed for the following substances
  - Hexakis[mu-(acetato-O:O')]-µ3-oxo-triangulo-triruthenium acetate / Ruthenium acetate
  - Tris(nitrato-O)nitrosylruthenium
  - Rhodium trinitrate (in solution)

-Conflicting feedback was received on 3 substances

   - **3.2. Next steps (PMC/WCA)** **AP5**

4. **Annex III exemptions**
   - **4.1. Status update (PMC)**

- PMC informed that responses from most companies have been received to date
- The draft list contains 39 candidate substances
- The responses received to date indicate that only 1 substance may not be exempted due to potential dispersive use:
  - Tetraammineplatinum dichloride, but existing data is available to meet Annex VII requirements for this substance
- An assessment of CMR properties and PBT screening (in case organometallic ligands are involved) has been carried out by WCA and found no evidence for PBT or CMR issues

   - **4.2. Next steps and timeline (All)** **AP6**

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5. ITS

5.1. Draft data gap matrix (WCA)

- An updated data gap table had been received from WCA on the day before the meeting and circulated to the PEG
- The PEG felt that it was difficult to review the table without having an accompanying written discussion of the underlying data, why some studies have been chose over others, etc.
- BIBRA have circulated an initial "bullet point discussion" on the human health part of Ru, Rh, Ir prior to the meeting **AP7, AP8**
- Final draft ITS reports can only be prepared after having received the data from the pH measurements

5.2. Enabling information/tests

5.2.1. New data from PMC Members – update/timing (PMC)

At the previous call members were reminded to provide any new relevant data that they may have to PMC by the end of February. No new data were received.

5.2.2. pH determinations *(PMC)*

– Status update
  - A list of substances to be tested had been finalised by PMC and four member companies have been assigned for carrying out the tests (in house) on 15 Feb. 2011
- The pH testing is currently ongoing
  - Samples have been measured by 2 companies already
  - Results from other 2 companies are still outstanding
  - The companies indicated that the outstanding results will be ready by mid April
- Timing
  - Since pH data is essential to conclude on a number of endpoints of the ITS strategy, this matter was recognized to be of high priority **AP9**
  - The final ITS can only be prepared when pH data are available
  - The ITS strategy report and narrative will only be issued after completion. In the interim the PEG will work from the updateable data gap matrix and a 'bullet point' narrative giving sufficient detail to allow management of the contractors.

5.2.3. Water solubility tests)PMC)

- In view of time constraints, no in-depth discussion of this matter took place
- A short discussion was held on which analytical method to use. RT asked if AAS would be appropriate. **AP10**

5.2.4. Bio-accessibility tests – way forward *(WCA)*

- A draft document on bioavailability tests was prepared by WCA/BIBRA prior to the call
- The proposed strategy by BIBRA/WCA regarding selection of the most appropriate route of exposure is in agreement with the PEG position and no in depth discussion was necessary.
- The proposed strategy on dustiness testing was discussed under agenda point 5.2.5.

5.2.5. Dustiness tests – way forward (PMC)

- A table with an initial list of substances recommended for further PSD or dustiness testing was put together by WCA and distributed prior to the call
- The group discussed whether dustiness testing should be carried out or if PSD screening would be sufficient. It was decided to give preference to generating dustiness data since this data will be more robust and will provide important information for selecting the relevant route of exposure in repeated dose testing. This is also in line with PMC's approach in other dossiers (e.g. Silver).
- An additional advantage of generating dustiness data is that this will also inform the companies' product stewardship programmes, since it provides information on the potential of the substance for inhalative exposure.
- The list prepared by WCA had initially excluded substances with < 10% of particles having a particle size < 100 um. However, if dustiness testing is required (as opposed to PSD measurement) also substances with < 10% of particles < 100 um should be subjected to testing.

- A similar list for dustiness testing was prepared by BIBRA in the scope of the discussion document on bioavailability testing. The BIBRA list contained a slightly different scope of substances **AP11**

- Preferred testing lab for dustiness testing
  - UK HSL cannot do the tests since it lacks the appropriate containment for hazardous samples.
  - DMT in Germany would be an option. This company was also used to carry out the dustiness tests for PMC's silver dossiers. **AP12**
- WCA indicated that they are in a position to do the necessary data manipulations of the data generated by the dustiness tests, e.g., MPPD calculations.

5.2.6. Toxicokinetics – update on literature search *(WCA/BIBRA)*

In view of time constraints, no in-depth discussion of this matter took place

5.3. Assessment of read-across potential from out-of-scope substances *(DB)*

- Feedback from PEG

-At the previous call members were invited to raise comments or objections to the read across strategy presented. In view of time constraints, no in-depth discussion of this matter took place. But since no comments or objections have been received, the proposed strategy is considered approved.

5.4. Route of exposure in repeated dose testing (PMC)

In view of time constraints, no in-depth discussion of the PMC discussion paper was possible. However it is noted that the discussion paper on bioaccessibility by BIBRA (Agenda point 5.4) is in agreement with PMC's position, so no need for further discussions is seen.

6. Testing programme – study monitoring

6.1. Update on possible options *(PMC)*

In view of time constraints, no in-depth discussion of this matter took place **AP13**

7. AOB, next meeting and closing remarks

7.1. Agreed actions/timeline: See below table of actions

7.2. Next meeting (face to face mtg in April)

- Due to a delay in the pH tests, the draft ITS will not be ready by end March. The next face to face meeting was therefore postponed 5/6 May 2011.
- A conference call will be held on 11th April for 1.5 hours.

Table 1. Actions agreed at 10 Jan 2011, 8 Feb 2011 and 16 March 2011 PGM Experts Group conference calls

	Action	Who?	When?
1.	Finalise PGM project scope – Revert with feed-back on invitation to confirm intermediate status, SCC as per Dec 2010 ECHA Guidance, tonnage as on-site, tonnage as transported (including two 100-1000 t/a Pt and Pd intermediates)	PMC (CB)	End Feb 2011
2.	Expand original Phase I and II reports to make sure: - Proprietary data on out of scope compounds is reviewed, Klimisch ranked and considered, and - Toxicokinetics associated with dermal exposure-based waiving has been fully considered/explored	WCA BIBRA	End Mar 2011
3.	Finalise Annex III assessment and reasonable worst case data gap matrices including: - Revisit traffic light code to distinguish between definitive data gaps and situations where data is available/gap can be filled without (additional) testing (distinguish between data available, read-across, and adaptations) - LD50, classification, etc. provided/triggered by the available data	WCA	(End Mar 2011) - data gap matrix depending on pH data; delayed to mid April

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	Action	Who?	When?
4.	PGM EG meeting to discuss progress of above action points and address following actions: - Formulate an enabling testing programme proposal (bio-accessibility, dustiness) to support likely read-across proposals - Formulate an initial test proposal (including CRO+Study Monitor options) to start with eye+skin irritation/corrosion test programme on potential reference substances - as a starting package for early gap filling; relatively inexpensive, in line with avoidance of animal testing, could inform the next steps of ITS - Address skin sensitisation on a more targeted fashion, using D. Basketter's expertise as needed - Further develop which conditions should be met for inhalation tests to be considered - in addition to whether or not there is potential for inhalation exposure (to be confirmed via dustiness test and respiratory tract deposition modelling (MPPD)), it is possible to generate a stable test atmosphere, there were signs of toxicity in the oral acute test, among others. - Address mutagenicity on a more targeted fashion (e.g.: Rh 3+ programme to be designed differently from other groups) - Generate decision tree to select most relevant route of exposure	PGM EG	10/11 Apr 2011 Meeting postponed to 5/6 May
5.	Discuss with concerned member companies directly to confirm SCC/ final intermediate status of substances with conflicting feedback. Some of these substances fall into a high tonnage band (100-1000tpa), so this may have important implications for members. Final proposed scope to be discussed with the PGM WG	PMC	End March
6.	Provide written report with final Annex III exempted substances, including a discussion of CMR and PBT screening	WCA	End March
7.	Provide bullet point discussion of the human health parts of Pd, Pt	BIBRA	End March
8.	Provide bullet point discussion on environment and phys.-chem. part	WCA	End March
9.	Remind the 2 companies to prioritize the pH measurements	PMC	Done
10.	PMC to check and advise Heraeus	PMC	End March
11.	Propose final draft proposal of substances for dustiness testing, reconciling WCA and BIBRA lists, and excluding substances < 10 tpa and intermediates	WCA/BIBRA	End March
12.	Discuss with DMT if they can ensure the appropriate safety/containment measures in dustiness testing (for non chloroplatinates substances – additional discussion may be needed on chloroplatinates)	PMC	End March

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	Action	Who?	When?
13.	Agree on study monitor via written procedure by end of the week (18 March). PMC to facilitate decision making.	PEG	18 March

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