Chairman: *Dave Boyd* (Johnson Matthey)

11April 2011, 10:00 – 11:00 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
Ed Stutt	WCA	United Kingdom
Paul Whitehead	WCA	United Kingdom
Roland Winde	Umicore	Germany

Minutes

1. **Welcome and introduction** *(DB)*
   - **1.1.** Approval of the Agenda
   - **1.2.** Approval of the minutes of the last meeting (Brussels, 16 March 2011)

2. **PGM project scope**
   - **2.1. Intermediates survey** *(PMC)* **AP14**

The revised inventory document was presented, further to a survey by PMC on SCC. In some cases the tonnage had to be revised since some substances did not qualify for SCC and thus need a full substances dossier. This resulted in an increase tonnage band for Diamminedichloropalladium
The tonnage bands for other substances was revised downwards, e.g., for Diammonium hexachloroplatinate and Tetraammonium decachloro-mu-oxodiruthenate(4)
There were no objections to the revised scope by the participants.

   - **2.2. Annex III exemptions (WCA) AP15**

A final Annex III report was received from WCA and provided as background document to the meeting. As expected, all listed substances except Tetraammineplatinum dichloride will be able to benefit from reduced data requirements according to Annex III.
Due to the reduction in tonnage of Tetraammonium decachloro-mu-oxodiruthenate this substance might also qualify for an Annex III derogation.

3. **ITS**
   - **3.1. Draft data gap matrix (WCA)**

An updated data gap matrix has been received from WCA and was provided as background document to the call. This matrix will be discussed in-depth at the next face-to-face meeting on 5/6 May in conjunction with the accompanying reports. No detailed discussion took place at the conference call.

   - **3.2. Data gap matrix support documents AP16**

Bullet point narratives on the env./human health/phys.chem part were received from WCA and BIBRA. These documents are currently under discussion between PMC and WCA.
It was agreed that WCA/BIBRA will provide 3 documents for the 5/6 May meeting:
- updated data gap matrix
- narrative to data gap matrix
- document with underlying rationale

There was some misunderstand on part of WCA as to what exactly is required for the 5/6 May meeting. A bilateral call between PMC and WCA was agreed to discuss what exactly will be provided/expected. PMC to inform the PEG accordingly.

   - **3.3. Enabling information/tests AP17**
     - **3.3.1.** pH determinations *(PMC)*

The pH determinations are required in order to allow WCA and BIBRA to finalise the draft ITS assessment. So far, only partial data were received; still outstanding are data on 4

substances from one company and data on 6 substances from another company. Both companies have indicated to PMC that the data can be ready by 15 April.
The subject of the pH measurements was raised at the recent MC call and the acting MC chair agreed to raise this directly with the concerned companies if no resolution can be found.

3.3.2. Water solubility tests)PMC) **AP18**
The water solubility tests are currently ongoing. Results are expected by the end of April.

3.3.3. Bio-accessibility tests
No discussion took place on this point.

3.3.4. Dustiness tests – way forward *(PMC)*
- *Agree final scope*

PMC has proposed a final scope for dustiness testing in a communication on 5 April 2011. This proposal is based on an initial table by WCA, with the following modifications:
- Include coarse substances (granulometry)
- Excludes substances with full PSD data from TD tests (4) **AP19**
  - *Exception: propose add. dustiness test for PdO for product stewardship reasons*
- 1 substance is exclude since it is not available (PdO2)
- Suggestion not to test chloroplatinates (3 substances) since inhalation exposure is strictly avoided already
- Total: 14 substances

Regarding the proposal not to test chloroplatinate, a question was raised whether we can justify not testing when at the same time we cannot guarantee SCC. There was agreement to confirm that full PSD data are available for the concerned substances and use this as a basis (if available) instead of additional dustiness testing **AP20**

Apart from the above question on chloroplatinates, no objections to the proposed scope were raised. **AP21**

- *Time line*

PMC is in contact with a specialized CRO that can carry out the required tests (DMT, Germany). This is the same CRO that also carried out our dustiness tests for Ag. The cost per test will be around 800 Euros. The timing will depend on the exact number of substances and needs to be confirmed with the lab.

Due to their long experience with handling and testing potentially toxic dusts (mainly from mining activities) DMT is in a position to implement strict containment of the samples. All testing will be carried out under a closed fume hood. Operators will wear respiratory protection, overalls, goggles and gloves.
In a personal conversation DMT was confident to be able to handle our PGM materials, but requested to see the respective MSDS' before making a final judgement.

3.3.5. Toxicokinetics (TK)
BIBRA has carried out a specific literature survey on TK properties. PMC informed WCA/BIBRA that we will take the evaluation of the detected references upon itself.

4. AOB, next meeting and closing remarks

4.1. Agreed actions/timeline

The following timing was agreed:
- 15 April: PMC/WCA to finalise open points on bullet point summaries
- 15 April: all pH data available
- 21 April: WCA/BIBRA to issue initial ITS
- end April: water solubility data available

- 5/6 May: PEG face-to-face meeting: discuss and agree ITS

4.2. Next meeting (face to face mtg in 5/6 May 2011) AP22-23

The timing of the meeting was confirmed, with a start at lunchtime, allowing participants to travel to Brussels in the morning. The meeting will continue to next day, as long as is necessary to resolve the issues. It was agreed to invite an RSA representative to meeting.

Table 1. Actions agreed at 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
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

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	Action	Who?	When?
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
13.	Agree on study monitor via written procedure by end of the week (18 March). PMC to facilitate decision making.	PEG	18 March
14.	Confirm final scope/tonnages to WCA/BIBRA	PMC	Done
15.	PMC to confirm necessary data (CMR, dispersive use, etc) with manufacturers of T and confirm to WCA WCA to update Annex III report accordingly	PMC/WCA	
16.	Bilateral call to discuss what exactly will be provided/expected for the PEG meeting on 5/6 May. PMC to inform the PEG accordingly.	PMC/WCA	
17.	Report back to PEG in case pH data are not received	PMC	15 April
18.	Water solubility tests: confirm exact date with concerned companies	PMC	
19.	Advise if PSD data from TD tests are sufficient to calculate the necessary parameter, e.g., MMAD.	WCA	
20.	Check if robust PSD data are available for chloroplatinates	PMC/WCA	
21.	Inform PGM WG on final proposed scope, with a deadline for objections	PMC	15 April
22.	Advise on recommended participants from RSA for PEG meeting 5/6 May	WCA	
23.	Issue invitation for face-to-face PEG meeting 5/6 May (done)	PMC	Done

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