Chairman: *Dave Boyd* (Johnson Matthey)

8 February 2011, 10:00 – 11:30 CET

List of participants

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

Minutes

1. **Welcome and introduction**.The list of participants is available in Annex 1.

   1.1. Approval of the Agenda. The agenda (Annex 1) was approved.

   1.2. Approval of the minutes. The minutes of the last meeting (Brussels, 10 Jan 2011) were approved.

2. **Organisational: WCA changed responsibilities re PGM project**
   - PW informed the group (PEG) that WCA have changed responsibilities. An organigram provided by WCA is attached to the minutes (Annex 2).
   - It was agreed to use Reach suite for further technical discussions wherever possible. PMC will organise a web seminar to introduce the system. **AP17**

3. **PGM project scope**

   3.1. Intermediates survey – update from PMC
   PMC informed WCA/BIBRA that some member companies will only be able to provide feedback on the intermediate status by the end of February. This may have implications on the time line (see next point).

   3.2. Proposed way forward regarding ITS preparation
   - The PGM expert group indicated that most intermediates will not be eligible for SCC exemptions and that they thus will have to be treated as substances for the purpose of Reach.
   - Information on the substance status is required for the preparation of the ITS. In order not to delay this, it was agreed to proceed with developing an ITS on a worst-case basis, assuming substance status for all intermediates.

4. **Annex III exemptions**

   4.1. List of Annex III candidate substances *(WCA)*
   An initial list with substances that might potentially qualify for Annex III exemption had been circulated with the background documents to this call. Until their status is finally confirmed, this list also includes intermediates as if they were substances.

   4.2. Expected feed-back from PMC
   Feedback is required from PMC members on the substances listed on the draft Annex III list: **AP10**
   - whether or not the substances are used in wide, dispersive or diffuse use
   - industry knowledge/understanding on likely hazards (pH, CMR, PBT, vPvB)

Specific requests were sent to individual companies on 07 Feb.2011

- If no specific information is supplied by the members, it will be assumed that the applications are not wide, dispersive or diffuse. The final list will be subject to approval by PMC members anyway
- PBT assessment: this is only needed on the organometallic substances (9). WCA will consider available data plus, if necessary, surrogate information on the organic components. **AP11**

4.3. Next steps and associated timeline

- A deadline for feedback from member companies had already been agreed for end Feb.
- A draft final draft assessment of Annex III exemptions will be provided by WCA by end March
- Since the Annex III assessment has a time critical impact, it is important to get feedback from member companies asap, so that WCA can finalise the assessment.

5. ITS

5.1. Draft data gap matrix – example for discussion **AP2**

- A data gap matrix was circulated for Rh on 3 Feb 2011. This will serve as a model for the data gap matrices on the other substances. WCA will circulate data gap matrices on the other PGMs by the end of the week.
- The assessment was done on a worst case basis, and will be used as a starting point for ITS development. In case more than one study was available for an endpoint, all studies have been mentioned.
- The PEG was happy with the overall format of the matrix and there were no objections
- The matrices will have to be updated at a later stage once the Annex III derogations have been finalised.
- Practicalities: to facilitate communication, the documents will be uploaded to Reachsuite

5.2. Enabling information/tests

5.2.1. Newly generated (test) data from PMC Members **AP12**

The members were reminded to provide any new relevant data that they may have to PMC by the end of February, so that the data can be considered in the ITS.

5.2.2. pH determinations

List of substances to be tested AP3, AP6, AP13

- An initial list of substances that require testing was circulated on 2 Feb 2011. The list also includes intermediates until their final status is confirmed.
- A discussion of the list indicated that some changes to the scope have to be made (eg., no need to test metals, some substances may hydrolyse, etc)

Practical testing: protocol, test houses, timeline AP14

As agreed at the 10 January meeting, the pH tests will be carried out in-house by Johnson-Matthey, Umicore and Heraeus.

- Ideally, all tests should be done from the same batch. In particular pH can vary considerably from batch to batch. The group felt that this approach would be ideal but practically not feasible. As a pragmatic solution it was agreed to retain a sample from each batch to retest the pH if required

A discussion of the further testing strategy, e.g., on likely *in vitro* irritation tests was postponed to the next meeting (16 March 2011).

5.2.3. Water solubility tests – update/reminder *(KR)*

Requests for sample materials have been sent on 25 January 2011 but no material has been received by the testing lab yet. The participants were reminded of the urgency of providing the materials.

5.2.4. Bio-accessibility tests – way forward *(KR + MR)* **AP18**

A discussion of the further testing strategy was postponed to the next meeting.

5.2.5. Dustiness tests – way forward *(KR)*

WCA/BIBRA will prepare a discussion document for the next meeting, on substances recommended for testing for bioaccessibility and for dustiness

5.2.6. Toxicokinetics – update on literature search *(WCA/BIBRA)* AP4, AP16

This is work in progress. BIBRA has scheduled this work for February and will report back by next meeting.
Note PMC: previous work done for Ag can be shared with WCA/BIBRA on a confidential basis as an example. But it has to be acknowledged that the reports involved work by other consultants.

5.3. Assessment of read-across potential from out-of-scope substances *(DB)* AP15, AP20

A list of proprietary studies on out-of-scope substance was circulated on 3 Feb. 2011. This list includes initial comments by the chair on potential read across options. PEG was invited to review the list and let PMC know if there are any comments or objections.

5.4. Route to route extrapolation AP7, AP 19

Further to internal discussions, PMC have drafted a thought starter on how to proceed with repeated dose testing. This will be further discussed at the next meeting.

6. Testing programme – study monitoring

6.1. Update on possible options *(WCA)* AP5

WCA experienced a delay in receiving a proposal for study monitoring by Martin Richards and is currently pursuing a second option.

7. AOB, next meeting and closing remarks

The next conference call will take place on 16 March 2011 at 10.00am CET.

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Table 1. Priority 1 actions agreed at 10 Jan 2011 and 8 Feb 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.	- Circulate remaining data gap matrices - EL to update the matrices to include intermediates, until their final status is confirmed.	WCA	By 11 Feb
3.	pH testing: Circulate revised testing scope	PMC	Done
4.	Confirm timing of written report for toxicokinetics literature search	WCA/BIBRA	By 11 Feb
5.	Circulate proposal for study monitoring	WCA	By 11 Feb 2011
6.	pH testing: PMC to finalise scope based on feedback received	PMC	Week 14 Feb
7.	Circulate discussion paper on how to proceed with repeated dose testing.	PMC	By 18 Feb 2011
8.	Gather data from PMC Members: ☞ newly generated (test) data ☞ wide/dispersive use for Annex III substances ☞ existing/estimated solubility data for all substances ☞ existing + generated pH data for all substances	PMC (KR)	End Feb 2011
9.	Launch remaining solubility tests	PMC (KR) + JMTC (DB)	End Feb 2011
10.	Annex III exemptions: Provide feedback on dispersive or diffuse use and potential CMR properties to PMC.	Members	end February
11.	Annex III exemptions: Provide data on organic ligands, if available	Members	end February
12.	Proprietary data: Provide any new relevant data to PMC by the end of February, so that the data can be considered in the ITS	Members	end February
13.	pH testing: PEG to provide final feedback/approval of revised testing scope by the end of the week	PEG	By 13 Feb
14.	pH testing: Organise sample provision and practical testing directly with the above companies Recirculate proposed method for testing (Young et al paper) (done)	PMC	end February
15.	Proprietary data: Review the list and comment back to PMC if there are any comments or objections to the proposed read across options	PEG	end February
16.	PMC to consider sharing previous work done for Ag as an example how to proceed with TK work.	PMC	end February
17.	- Organise a Web seminar to introduce Reachsuite - Recirculate passwords - WCA and PMC to discuss practicalities: how to upload documents, at which time intervals to update them, etc., and report back to PEG at the next call	PMC/WCA	16 March 2011
18.	Bio-accessibility tests: Draft initial proposal as a basis for discussion at the next call	WCA/BIBRA	16 March 2011
19.	Table repeated dose paper (route to route extrapolation) for discussion at the next call	PMC	16 March 2011
20.	Validate potentially relevant proprietary studies	WCA/BIBRA	By end March
21.	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

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	Action	Who?	When?
22.	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
23.	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

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