CHAIRMAN: D. BOYD (CONSULTANT, UNITED KINGDOM)
SECRETARIAT: K. ROTHENBACHER (EPMF, BELGIUM) & K. ARIJS (ARCHE, BELGIUM)

14 OCTOBER 2015, 13:00 – 17:00 CET
METALS CONFERENCE CENTRE – ALUMINIUM ROOM
RUE DU DUC 100 – 1150 BRUSSELS (BELGIUM)

PGM Work Group Meeting – Minutes

AP refer to Action Points listed at the end of this document.

1 Welcome and Introduction

1.1 Reminder on Confidentiality and Competition Law

Participants were reminded on their obligation to comply with Confidentiality and Competition Law.

1.2 Tour de table and apologies

The list of participants is available in Annex 1.

1.3 Election of chair

Michael Thiel is the newly proposed PGM WG chair to replace Dave Boyd, who kindly accepted during the past months to take over the position as an interim. No objections were raised from the WG; the election was therefore approved. Michael Thiel was congratulated to his election as new chair.
Dave Boyd was thanked for his outstanding work as chair of the PGM WG and his very valuable contributions to the PGM WG. The PGM WG recommended to keep Dave Boyd' expertise in relevant fields.

1.4 Approval of the agenda

The agenda is available in Annex 2. There were no remarks / additions; the agenda was approved.

1.5 Approval of the minutes of the last meeting (25 Mar 2015) including status of action points

No remarks / additions were received on the minutes from the last meeting; the minutes were approved.
A table with the status of the action points from the last meeting is available on slides 5-7 in Annex 3. Several action items are on the agenda for discussion at this meeting.

2 Substance identification and sameness of PGMs

2.1 General approach substance sameness

PMC summarized the proposed approach for substance sameness: PMC collates information on substance identity and facilitates sameness discussions where necessary, but the ultimate decision on sameness is the responsibility of the respective registrant.

To facilitate the sameness discussion, PMC has circulated substance ID cards, as agreed previously. It is suggested to add spectral data and CoA of the reference substance to the respective ID cards, so registrants can make an informed decision on sameness

There were no objections to the above approach. It was therefore approved.

AP 1: PMC Sec to recirculate ID cards including spectra and CoA of the reference substance in Q4 2015

AP 2: PMC Sec to ask for the operating conditions under which the spectra were generated and provide them along with the spectra

The conclusions from the 29 June sameness expert meeting were presented (cf. slides 9-11 in Annex 2). No objections to the presented approach were made.

2.2 Changes in substance ID

- Rh trichloride and Ru trichloride will have to be registered as hydrated forms since the hydrated forms are substantially different from the anhydrous forms. Also, the anhydrous forms are not put on the market and are not commercially relevant. Both of these substances (i.e., the hydrates) are already pre-registered so there is an existing SIEF which we will need to join.
- The substance pre-registered as Ir tetrachloride will be registered as reaction mass of Ir tetrachloride and Ir trichloride. The new substance is not pre-registered yet. The PMC Sec together with the LR is looking into the best way forward.
- The substance pre-registered as Diammonium hexachlororuthenate will be registered as Tetraammonium decachloro-mu-oxodiruthenate, which is also pre-registered. So there is an existing SIEF which we will need to join.

2.3 ID cards

Cf. slide 14 in Annex 2. LRs/reference sample suppliers were reminded to send their CoAs and spectra (+ operating conditions) to the Secretariat by end of October, so that the spectral information can be added to the ID cards.

AP 3 Suppliers of reference substances to send CoAs and spectra to PMC sec by end Oct

2.4 Karstedt concentrate

Discussions are still ongoing with the Reconsile consortium. The original LR for Karstedt concentrate is a member of Reconsile. It was formally agreed at the 1 July meeting with Reconsile to transfer the LR role to PMC. The cooperation agreement is still under discussion.

The sameness requirements were agreed between PMC and Reconsile and the analytical work by PMC members is now completed, but it seems that only 2 of the Reconsile members sent their samples for analysis instead of the 4-5 mentioned previously.

The cooperation with Reconsile proceeds slowly and is difficult. Several options for future cooperation with Reconsile were discussed:

- Proceed without Reconsile. There is a moral constraint due to the fact that cooperation was agreed on at the 1 July meeting. Furthermore, we will not be able to submit a separate dossier with the same identifiers once Reconsile has already submitted a dossier.
- It was decided to take passive approach from now on, and wait for Reconsile to come back to us
- For the technical work, it was decided to proceed as much as possible without waiting for Reconsile. (The hydrolysis study has started. A preliminary study should be finished by end of 2015.)

Next steps:

AP 4 ID card will be finalized by PMC and sent to Reconsile.

AP 5 Document all interactions with Reconsile for future reference, to demonstrate our due diligence.

AP 6 Proceed with the technical work regardless of Reconsile.

2.5 PGM nano forms

Cf. slides 16-19 in Annex 2. PMC presented the status of the nano characterization programme. The programme is proceeding slower than planned, mainly due to confidentiality issues on part of the participating companies.

The results of the coordinated characterization exercise at Quantachrome have been reported, however the results of some tests could not be made available to PMC since no permission from the data owner has been granted[1]. Furthermore, two companies have been conducting the evaluation internally and the work from one company was not finalized yet.

Based on the data available, so far, only 1 material (Rh) could be considered nano.

WG members were reminded that the decision on whether or not a substance is a nanomaterial is with each registrant.

In order to allow the necessary budget assumptions for 2016, it was suggested to set a 26 October deadline to freeze the scope nano/non-nano.

It was noted that it will be a business decision to decide whether including the nano-form in the Rh registration will be worth the efforts/costs. PMC estimated the cost for inclusion of the nano-form in the registration to be 200 k€. These costs are based on read-across, T/D testing, consultancy effort, and contingency for unpredictable additional efforts.

There are many uncertainties on which exact tests will be required. Contrary to silver, there is very little data available from the literature about nano PGMs that could be used (we do have some dustiness and bio-elution data comparing bulk and nano PGMs but additional testing will be required). The situation will become clearer in December when the updated Annexes for nanomaterials and additional data requirements for nanomaterials are finalized.

It was discussed whether it will be possible to consider the PGM blacks as different substances. The group was hesitant to set a precedent for other PMC substances. A good case will be needed as to why PGM blacks should be different from the corresponding powders. A possible reason could be that blacks are not pure metals, but rather are mixtures of metals, oxides and hydroxides.

PMC pointed out that before continuing the discussion, we need to know how many PGM nanomaterials need to be registered.

AP 7 Affected WG members to inform PMC Secretariat on their nano/non-nano decision by 26th October

The issue will also be discussed with the Mgmt cttee so that all are aware of the consequences; affected WG members were invited to join the Mgmt cttee meeting on 27th October.

2.6 Final inventory / Lead Registrants

Cf. slides 21-27 in Annex 2. The final inventory was presented, updated to with the recommendations of the sameness expert group (default approach: register anhydrous forms and solids; exceptions for RhCl3 and RuCl3). By December, all LRs will be confirmed.

3 PGM testing programme/ Summary from PMG tox. experts mtg

3.1 PGM ecotoxicity testing

A short update on the ongoing ecotox testing programme was presented. (slides 30-33)

- New data from the algae test on Tetraammonium decachloro-mu-oxodiruthenate were presented. PMC is currently reviewing if any changes to the classification will be required. The PGM WG will be informed if necessary
- Karstedt Concentrate: before the main hydrolysis test can commence a preliminary test is required as method development. Very little information is available on potential degradation products and analytical methodology, making it too risky to start with main test directly

[1] Post meeting note: permission granted in the meantime, data are available to PMC now

- The Expert group recommended to read-across from rhodium trinitrate to diammonium sodium hexakis (nitrito-N) rhodate for the fish endpoint. This is a formal data gap for diammonium sodium hexakis (nitrito-N) rhodate, but fish is not the driving ecotox effect for Rh (III) compounds since algae are significantly more sensitive. Therefore, conducting a fish test on that substance would not change the assessment and thus a waiver for the fish test will be added. This was approved
- The Expert group further recommended that tetraammine platinum dichloride should not be grouped in the same group as chloroplatinates for ecotox read across. Tetraammines are structurally different and the chlorides are not covalently bound in that case. Read across from existing data on tetraammine platinum hydrogen carbonate is recommended. This was approved
- The same recommendation was made for the corresponding Pd analogues, i.e., for tetraammine palladium dichloride. This was approved too
- For this reason, a Daphnia test on tetraammine palladium dichloride, as originally recommended in slide 33, will not be necessary
- No dispersive/diffuse uses have been reported in the use questionnaires for tetraammine platinum dichloride, contrary to previous discussions. If there are no dispersive/diffuse uses then the substance can be exempted acc. Annex III of Reach and no ecotox tests will be required

AP 8: WG members to inform PMC Sec by end Oct if they have any dispersive/diffuse uses for tetraammine platinum dichloride.

3.2 PGM acute/repeated dose testing

Karstedt Concentrate

New proprietary studies from Reconsile have become available for Karstedt Concentrate. The studies are confidential, so no details can be shared. Bibra have reviewed the studies on a confidential basis; a detailed discussion of this took place at the Expert group meeting. The recommendations are that

- The Reconsile data will be useable for acute oral, skin irritation and eye irritation.
- Sensitisation: 5 studies are available and the study results range from no effect to Cat. 1A. No detailed description of the test material was provided in the test reports (e.g., no CoA) so it was not possible for the Expert Group to come to a conclusion. PMC will request this information and further discuss this with the expert group

AP 9: PMC Sec to request CoAs from proprietary Karstedt Concentrate studies from Reconsile.

- Further, PMC will challenge Reconsile on the following points
  - If Sens Cat 1A results are real, why is this not reflected in the CLP inventory?
  - Why was no TSCA8(e) notification filed?
- If Karstedt Concentrate should indeed be a sensitizer, this would have a significant impact on Karstedt Concentrate's uses since many Karstedt applications require biocompatibility

AP 10: PMC Sec to discuss classification of Karstedt Concentrate with Reconsile.

HHPA-2AE compound: testing approach RDT

After reconsideration the expert group proposed a revised testing strategy:

- Submit a testing proposal (TP) for an in vitro MN (OECD 474)
- An OECD 422 study should be started immediately

The reason for reconsidering was that

- We need to be able to derive a DNEL at an earlier stage (TP will only be submitted together with final dossier)
- A combined OECD 422/ in vitro MN study is combining 3 separate studies. Separate studies will make this practically easier to manage and increase likelihood of success.

No objections were raised

Other

- Initial data from an LLNA test on Tetraammonium decachloro-mu-oxodiruthenate indicate potential sensitizing effects. A TSCA 8 (e) notification may be required. It was discussed whether a TSCA notification is needed in case of intermediates that are not put on the market. It was concluded that this may be relevant for the US and a notification should be filed.

- An action point form the previous meeting was to review if a classification for reprotox will be required for Diammonium hexachloroplatinate based on the results from the recent OECD 421 study. The Expert group concluded that no classification will be required. No objections were raised

3.3 PGM nanomaterials – impact on ITS

This point was discussed under agenda point 2.5. No further discussion was required

4 Current status of PNEC and DNEL derivation

4.1 PNEC derivation

WCA gave an update on the status of the PNEC derivation. This is summarized on slide 38 in Annex 2.

4.2 DNEL derivation

Bibra gave an update on the status of the DNEL derivation. This is summarized on slide 39-41 in Annex 2. The approach for acute DNELs was discussed: it was agreed to develop qualitative statements/approach for RMMs in these cases

4.2.1 DN(M)EL derivation chloroplatinates

- PMC informed the group that it is proposed to consult with an external expert for this topic. A thorough assessment will be required to make sure data available from IPA will be fully accounted in the DNEL derivation.
- There was general agreement to contract an external expert.
- The Expert group has indicated that they are interested in following this process closely. It was proposed to set up a dedicated steering group for this project.

AP 11 Members to indicate to PMC their representatives for the steering group on DN(M)EL derivation for chloroplatinates.

5 Exposure Scenarios (uses / env.)

Life cycle trees have been drafted for all Pd and Pt substances and will be circulated to the WG. An example was provided on slides 44-46.

AP 12 PMC sec to circulate LCT of Pd- and Pt substances

5.1 Identified uses Rh and Ru

All use questionnaires have been received and responses were collated by WCA. WCA will directly follow up with companies in case of questions. The use titles will be circulated with the meeting documents.

AP 13: WG members to review use titles and highlight any missing uses.

5.2 Site-specific PGM monitoring programme

- Six companies are part of the monitoring programme: 4 companies are participating in the coordinated exercise and 2 companies are performing in-house monitoring.
- The programme is at its final stage. The last samples had been taken at the day of the meeting.
- Site specific risk assessments will be now be refined. Results are expected by end 2015/ early 2016

5.3 STP monitoring programme

WCA gave an update on the status of the STP monitoring programme. This is summarized on slides 53-55.

5.4 Emissions questionnaire Pt, Rh & Ru substances

The information has been collected and no new env. exposure questionnaires were received. WCA pointed out that only very little data on air emissions has been received. WCA plan to apply the SpERCs in that case and are currently putting together a justification for using them.

6 Occupational exposure

6.1 Occupational questionnaires Pt substances

- EBRC is currently implementing the 'workplace-specific approach' agreed at the previous meeting. This has been delayed due to the late availability of the data by IPA
- A test run with 2 member companies is planned in October and the full survey will be started in November
- Format: rather than issuing yet another questionnaire, EBRC proposed to conduct the survey in dedicated interactive sessions directly online with each participant. The PGM WG welcomed the approach

6.2 PGM workplace exposure monitoring exercise

- A workplace monitoring campaign will be organised in 2016 for several PMC substances. It was proposed to add PGMs to the scope. This will save time and costs, and will make sure that the data are available when needed.
  This was agreed.

7 Financial update / Project Planning

7.1 Financial update

- It is proposed that the 2016 budget will include 2 columns: a budget to be spent and a budget to be invoiced (proposal to be approved by the Mgmt Cttee). The budget to be spent will include amounts invoiced already in 2015 but to be spent only in 2016 (because of late invoices, postponed items, studies running over several years …).
- Several updates will be required due to the decisions at this meeting:
  - Rh: budget for fish study can be removed
  - Nano Rh budget will have to be reviewed following discussions under agenda point 2.5. 150 k€ may not be sufficient for the worst case scenario

- HHPA: since the RDT study will be carried out asap, some of the 2018 budget will have to be moved to the 2016 budget.
- Increased scope for mammalian tests (separate OECD 407 + 421, dietary exposure) to be reflected in Ru budget.

AP 14 PMC to update budgets with the above changes, for consideration by the MC
AP 15 PMC to refine the nano budget for consideration by the MC (done)

7.2 Time line

The timelines for the different PGM projects were reviewed:

- Pt and Pt compounds: the timing for HHPA-2AE will need to be updated since time for conducting the RDT study has to be taken into account
- Ru/Rh and Ru/Rh compounds: more time will be required for the testing on Ru due to the increased scope. The internal deadline will be postponed to Q1 2017.
- Ru/Rh and Ru/Rh compounds: there is a pending action for PMC to check if some of the Rh substances can be registered earlier. PMC will make a proposal at the next meeting

AP 16 PMC to update time lines and present updates at the next PGM WG meeting

8 AOB, next meetings/calls and closing remarks

- PGM uses: it is suggested to put the identified (non-confidential) uses of all PMC substances on the PMC website and to link each use to the relevant ES. No objections were raised, the suggestion was approved.
- Next meetings: the next PGM WG meetings will be held in April and October 2016 at the Metals Conference Centre in Brussels. It was suggested to hold the Expert Group and WG meetings on different days, and switch the Authorisation WG meeting with the Expert Group meeting
- TSCA 8(e) notifications: in the past PMC would file notifications on behalf of its members. However, the last submission was considered as "FYI" due to the fact that the submission was done by a non-US party. The Secretariat is concerned that previous submissions were not fully covering the companies in the US. Johnson Matthey kindly offered to double check before the Management Committee on 27 Oct 2015 where the issue will be discussed.
  AP PMC to forward background of discussions to Nissanka; Nissanka to review situation.
  AP PMC Sec to check if feedback from US EPA on TSCA notifications was distributed to PMC members
  It was suggested that it would be useful to have an independent person in between PMC and companies to decide if there are reporting requirements.

The next PGM WG meetings will be held 19-20 April 2016 and 5-6 October 2016 at the Metals Conference Centre in Brussels.

9 Actions

Table 1. Actions agreed at the 14 October PGM Work Group meeting in Brussels

	What?	Who?	When?	Status
Substance identification and sameness				
1.	Recirculate ID cards including spectra and CoA of the reference substance	PMC Sec	in Q4 2015	
2.	Ask for the operating conditions under which the spectra were generated and provide them along with the spectra	PMC Sec	asap	
3.	Send CoAs and spectra to PMC sec	Suppliers of reference substances	end Oct.	
4.	Finalise ID card for Karstedt Concentrate and sent to Reconsile	PMC Sec	end Oct	
5.	Document all interactions with Reconsile for future reference, to demonstrate our due diligence.	PMC Sec	continuously	
6.	Proceed with the technical work regardless of Reconsile.	PMC Sec	continuously	
7.	Inform PMC Secretariat on their nano/non-nano decision by	WG members	26th October	
8.	Inform PMC Sec if they have any dispersive/diffuse uses for tetraammine platinum dichloride.	WG members	end Oct.	
9.	Request CoAs from proprietary Karstedt Concentrate studies from Reconsile	PMC Sec	Asap	done
10.	Discuss classification of Karstedt Concentrate with Reconsile.	PMC Sec	Asap	done
11.	Indicate to PMC their representatives for the steering group for DNEL derivation of chloroplatinates	WG members	Asap	
12.	Circulate LCTs of Pd- and Pt substances	PMC sec	end Nov.	
13.	Review use titles and highlight any missing uses	WG members	end Nov.	
14.	Update budgets with discussed changes in scope, for consideration by the MC	PMC sec	Asap	done
15.	Refine the nano budget for consideration by the MC	PMC sec	Asap	done
16.	Update time lines and present updates at the next PGM WG meeting	PMC sec	continuously	

Annexes

1. Agenda & list of participants
2. Slides presented at the meeting
3. Use titles Rh- and Ru compounds