Precious Metals Consortium

PGM TE/WG Meeting – draft minutes

Brussels, 18 October 2017 (9.30 – 16.45)

Actions	Who?	When?	Status
Pd(IV): circulate the document on Pd(IV) instability to the participants	PMC	ASAP	
Pd nitrate: check if ecotoxicity of was tested as a solid or solution	PMC	ASAP	
TAPdCl2 and Pdacac: Test TIER0 algal toxicity	PMC	Sign contract <end 2017, initiate ASAP	
PdO:			
initiate the bioelution testing	PMC	Sign contract <end 2017, initiate ASAP	
initiate the oxidizing properties testing	PMC	Sign contract <end 2017, initiate ASAP	
PdCl2: initiate the OECD 471 and 476 testing	PMC	Sign contract <end 2017, initiate ASAP	
TAPdCl2: initiate the OECD 471 testing	PMC	Sign contract <end 2017, initiate ASAP	
NaTClPd:			
check internally if the skin sensit cat1A classification of is an issue	Member Companies	<8 November	
If yes, check with members if need to test	PMC	ASAP after 8 Nov, sign contract <end 2017, initiate ASAP	
Pd RDT/Reprotox testing			
circulate the RA justification documents and organize a call to discuss	PMC	ASAP	
Generate required budget (approx. 500K €) for RDT/Repro testing	PMC	Include in 2018 budget	

inform Mgt Cttee of high importance of Pd RDT/Reprotox testing	FC	Mgt Cttee meeting X Nov	
ClPt REACH dossiers: update and circulate to the LRs for registration	PMC	registration deadline 13 Dec 2017	
Karstedt Concentrate: review bioaccumulation section	Member Companies	<6 Nov	
HHPA/2AE: circulate the updated dossier, including new phys-chem data, for review and fast-track approval	PMC	Once PC data are available	
TAPt acetate: ECHA Draft Decision			
communicate with ECHA & draft comments	PMC and Umicore	<13 Nov	
update all Pt dossiers (if and where relevant), and circulate to LR	PMC and Umicore	<end Nov	
Register/submit the Pt REACH dossiers	Umicore and PMC LRs	<13 Dec	
communicate with IPA on the dossier and status	Umicore and PMC	continuous	
PGM dermal monitoring: circulate the publication on	PMC	ASAP	
ITS matrices: circulate the most recent version	PMC	ASAP	
PtO2:			
check if and how waiving in vitro skin sensitization testing and directly testing in vivo has been applied	BASF	ASAP	
organize the required testing to update to AnnexVII	PMC	Sign contract <end 2017, initiate ASAP	
ClPt secondary poisoning: initiate literature search, do preliminary screening assessment, identify datagaps and update the dossier where needed	PMC	Sign contract <end 2017, initiate ASAP	
KC secondary poisoning: update preliminary screening assessment	PMC	ASAP	

Pt nitrate: organise a RDT / Reprotox screening study	PMC	Sign contract <end 2017, initiate ASAP	
Rh sulphate; finalise dossier and circulate for review & fast-track approval	PMC	ASAP	
Rh tris(2-ethylhexanoate)			
Mention in dossier that solvent is required to stabilize the substance	PMC	ASAP	
collect spectra for both compositions and compare to ensure substance sameness	PMC	ASAP	
finalise the phys-chem testing of the compositions	PMC	ASAP	
perform an AMES test with one composition (provided substance sameness is shown)	PMC	ASAP	
Rh2O3:			
confirm full AMES test to Covance	PMC	ASAP	
organize the required testing to update to AnnexVII	PMC	Sign contract <end 2017, initiate ASAP	
initiate the oxidizing properties testing	PMC	Sign contract <end 2017, initiate ASAP	
Rh(III) genetox: organize follow-up call with TE	PMC	November 2017	
Ru acetate: finalise the LtU with BP without the option for sub-licensing the data.	PMC	ASAP	
RuO2 : organize the required testing to update to AnnexVII	PMC	Sign contract <end 2017, initiate ASAP	
Nanomaterials: monitor the revisions of the NM definition and REACH annexes	PCM	continuous	
Pt and Pd article status: inform Mgt Cttee about advice to not co-sign this letter	FC	Nov Mgt Cttee meeting	

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 Approval of the agenda

No remarks were made. The agenda was approved.

1.4 Approval of the minutes of the last meeting (22 March 2017) and status of action points

No remarks were made. The minutes of the previous meeting of 22 March 2017 were approved. All action points identified during previous meeting have appropriately been addressed, or will be discussed in this meeting.

2 Palladium and compounds

2.1 Status (ongoing) registration dossiers

An update was given on the registration status of the Pd dossiers. All dossiers have been registered by the lead registrants.

2.2 Review of the OFI tracker and setting priorities for urgent work under current budget

The layout of the OFI tracker is shown. The OFI tracker will be included in the PMC Knowledge Management system (cfr. specific discussion point under AOB).

The PMC Secretariat has identified from the OFI tracker most urgent issues that can be **tackled under the current budget**. Note that proposals that are not prioritized, are kept in the OFI tracker for future consideration (as is the case for those entries not proposed below).

Pd PNEC refinement

Pd PNEC refinement has been identified before as urgent (today: generic PNEC, rely on DDP as reference substance). Acute ecotox data are available for other Pd compounds than DDP. Data confirm algal toxicity as the most sensitive endpoint.
In earlier discussions with the PGM Tox Experts, it is agreed:

- -Pd(IV) is unstable
- -Cl-coordinated compounds are most potent
- -TAPd compounds are different from Cl-coordinated compounds.

The participants agree with the proposed grouping:

Group 1 = Cl-coordinated Pd(II/IV) compounds incl DDP
Group 2 = Pd(II) tetraammine compounds
Group 3 = uncomplexed Pd(II) compounds

PdCl2 is included in group 3 (different molecular structure than Cl-coordinated Pd cmpds). DDP is included in group 1 (cfr molecular structure and comparable ecotox thresholds). The triphenylphosphine Pd compounds are considered stable in water (as long as the solution is not boiled). Testing a PMC substance considered appropriate in case of rejection of the read-across by ECHA. If Pd nitrate is used as test substance in TIER1, it is reasonable to test a solution (dissolution is required for testing and solution is considered more potent than the solid).

The participants agree to

-include the triphenylphosphine Pd compounds in group 2
-**test a PMC TAPd substance for group2, and therefore start at TIER0 with algal toxicity to TAPdCl2.**
-test as TIER0 the algal toxicity to Pdacac for group3. Once finalised, a decision will be taken with the group to do further TIER1/2 testing with Pd nitrate or Pdacac.

ACTIONS:

- **PMC secretariat to circulate the document on Pd(IV) instability to the participants**
- **PMC secretariat to check if ecotoxicity of Pd nitrate was tested as a solid or solution**
- **PMC secretariat to initiate the TIER0 testing, inform the group of the results, and decide afterwards on the test substance for the TIER1 testing**

PdO dossier update

PdO is registered as Annex VII dossier. Generating bioelution data (gastric and perspiration) will strengthen the dossier (acute tox, irritancy endpoints and skin sensitization.
The participants agree to test PbO bioelution (gastric & perspiration artificial fluids).

The physico-chemical endpoint 'Oxidising properties' is currently waived based on expert judgement but PtO2 and RuO2 are both classified as Oxid Solid.
The participants agree to test Oxidising properties PdO.

ACTION:

- **PMC secretariat to initiate the bioelution and oxidizing properties testing with PdO.**

PdCl2: additional genotox testing

PdCl2 is reference compound for genotoxicity in the RA group '*uncomplexed Pd(II) compounds*'. The PdCl2 AMES test misses a critical strain, and the OECD476 endpoint contains a WoE argumentation.
BASF received in the past Compliance Checks from ECHA for dossiers (non-PMC substances!) that contained old, non-compliant test data, and ECHA requested new and compliant data.
The participants agree to perform a OECD 471 and 476 study with PdCl2.

ACTION:

- **PMC secretariat to initiate the OECD 471 and 476 studies with PdCl2**

TAPdCl2: additional genotox testing

The AMES assays used in the RA group '*TAPd(II) compounds*' are not compliant with today's standards.
The participants agree to perform a compliant OECD 471 study with TAPdCl2.

ACTION:

- **PMC secretariat to initiate the OECD 471 study with TAPdCl2**

NaTCPd: skin sensitization testing

Disodium tetrachloroPd is part of the RA group '*tetrachloroPd(II) compounds*'. The substance is classified as Skin Sens 1A via read-across from dihydrogen tetrachloroPd despite negative substance specific test data (GPMT, pre-GLP).
For metals, in vitro skin sensitization testing is less applicable (QSAR not relevant, DPRA results not accepted if negative). If no conclusive negative in vitro results are shown, in vivo follow-up testing is required (cfr. decide about categorization).
The participants agreed that each company needs to check internally if the skin sensit cat1A is an issue for them:

-If no, the classification as Skin Sensit cat1A will be maintained

-If yes, reference is made to the testing approach for PtO2 (cfr section 3.5).

ACTIONS:

- **PMC member companies to check internally if the classification of disodium tetrachloropalladate as Skin Sensit cat1A is an issue and inform the PMC Secretariat before 8 November.**
- **PMC secretariat to go back to the PMG WG with the member input and decide on a need to initiate the testing.**

Additional RDT/Reprotox screening assays

During the review of the Pd RA approach, it was concluded that the RA for the endpoints RDT and Reprotox were not sustainable for the '*Tetrachloropalladates',* '*uncomplexed Pd(II) compounds*', and for Pdacac. The testing is considered urgent (cfr. responsible care)

The participants agreed that

-test data need to be generated for the three groups (data gaps and/or serious doubts on data quality)

-the testing is of high importance, but the RA need to be rechecked to decide on a testing strategy / source substance / prioritization.

-the budget (approx. 500K €) needs to be generated (via 2017 budget and alternatively via 2018 budget).

-the signal of 'high priority testing' needs to be given to the Mgt Ctte.

ACTIONS:

- **PMC secretariat to circulate the RA justification documents to the PGM Tox Experts and organize a call to discuss this RDT/Reprotox screening testing**
- **PMC secretariat to generate the required budget (500 k€) via the remaining 2017 budget, or the 2018 budget.**
- **FC to inform the Mgt Cttee of the high importance to fill these data gaps.**

2.3 Review of the OFI tracker and setting priorities for urgent work

The additional RDT/Reprotox testing discussed under 2.2 are identified as priority. The budget needs to be generated via the 2018 budget, and testing needs to be organized.

3 Platinum and compounds

3.1 Status (ongoing) registration dossiers

Seven Pt dossiers have already been registered by the LR.

The 4 Chloroplatinate dossiers are ready and approved, but submission is postponed to avoid being picked up by ECHA's automated screening. However, following receipt of a Draft Decision on the TP for in vivo genetox testing for TAPt diacetate by Umicore (cfr. section 3.4), update and submission of these dossiers by the LRs is recommended before 13 December to ensure consistency with the TAPt group.

The participants agree with the recommendation to check the 4 chloroplatinate dossiers for consistency and register by the LRs before end November 2017.

POST-MEETING NOTE: during discussions with Umicore, PMC and the consultants, it is considered feasible that the ClPt dossiers will be updated and available for registration <13 December. However, a review and approval period for the PMC members needs to be included, so the dossiers will most likely be available for registration early December (and not end of November). PMC secretariat will clearly communicate on expected actions by the members.

The dossier of diammineplatinum nitrite is ready for review and fast-track approval. The dossier will be circulated soon together with the dossiers for rhodium trisulphate and ruthenium trihydroxide.

ACTION:

- **PMC secretariat to circulate the 4 chloroplatinates REACH dossiers to the lead registrants for registration.**

3.2 Karstedt Concentrate: leaching data and dossier update

The exposure scenarios for KC (Karstedt Concentrate) are drafted and reviewed by the members. A TP (Testing Proposal) for an EOGRTS study will be included in the dossier, following the observations in the OECD422 study and the decision to classify as Repr2.

PMC Secretariat received from Reconsile:

-input on KC phys-chem properties and bioaccumulation; input has been considered and included in the dossier where required. The secretariat requests to members to review the bioaccumulation section.

-study results about KC leaching from silicones; data are confidential and can not be shared. Pt leaching was below detection limits, and supports the assumptions made in the exposure scenarios. Some weaknesses were identified in the study.

The participants agree to not repeat the leaching study, and reconsider the need once the EOGRTS results are available.

ACTION:

- **PMC members to review the bioaccumulation section with care**

3.3 HHPA/2AE: status and remaining work

The in-life phase of the OECD422 study with HHPA/2AE, the DNEL derivation and development of exposure scenarios is completed and the dossier is ready for review and approval.

Based on recent experiences with ECHAs manual completeness check, additional testing for some phys-chem endpoints is still running. Results for these assays are expected end Dec 2017.

The participants agree with the proposed way-forwards regarding dossier review and approval:

-send the dossier for review and approval (process expected to be finalised in Dec)

-once available, include newly generated phys-chem data in the dossier, and send out for review and fast-track approval.

-once approved, the dossier can be registered by the LR (expected early 2018).

ACTION:

- **PMC to circulate the updated dossier of HHPA/2AE, including newly developed phys-chem data, once available for review and fast-track approval**

3.4 Pt genetox: status

A recap of the Pt genetox work was given.

Recently, Umicore (as LR) received a draft decision on the in vivo genetox TP for Tetraammineplatinum (TAPt) diacetate (registered as non-phase-in substance). This registration dossier is not registered via PMC, but the substance data are considered in the tetraammineplatinum read-across group. The registration dossiers of all TAPt dossiers were aligned before registration. The Umicore dossier was however reviewed by ECHA in isolation (no other TAPt dossiers considered by ECHA). In the draft decision, ECHA expressed concerns mainly about the read-across justification and the design of the proposed genetox assay. There will be an informal call with ECHA (23 Oct '17). Written comments will be formally provided by Umicore (deadline 13 Nov '17) and all relevant Pt dossiers need to be updated by the LRs before 13 Dec '17.

Umicore will prepare comments together with PMC and its consultants, and update the dossiers to strengthen the read-across (improve justification), include all available data, and update the design of the TP in line with ECHA's comments (eg add liver and glandular stomach as target tissues). The earlier agreed approach for the TAPt dossiers (grouping, TAPt dichloride as source substance, in vivo Comet/MN assay with TK assessment) will be kept.

In this respect, it was also proposed to submit the chloroplatinates REACH dossiers end Nov, and update the other Pt dossiers as required, as the in vivo genetox testing is part of a generic testing plan, covering the various Pt RA groups.

The ECHA Draft Decision was also discussed during the IPA STF meeting. The STF will start an extended in vivo genetox testing program as from 2018 to investigate and assess the genetox potential of Pt substances. Priority test substances are defined based on IPA's recent work on DPRA reactivity of Pt compounds, which led to the hypothesis that the Pt genetox potential is related protein reactivity via a bell-shaped relationship. PMC secretariat stresses that under REACH, no in vivo genetox testing can be initiated without submitting a TP and receiving a final decision from ECHA on this TP. In this respect, and due to the ongoing review of the Umicore testing proposals, PMC recommended to IPA to align the in vivo genetox testing timing with the ongoing discussions with ECHA and the reception of the final decision by Umicore in 2018.

POST MEETING NOTE: ECHA has launched a public consultation end Oct 2017 for the in vivo TP for TAPt hydrogen carbonate, another TAPt dossier outside PMC scope and submitted by Umicore (deadline for commenting 11 Dec 2017). This dossier is part of the TAPt read-across group, and was foreseen to be updated following the ongoing activities on TAPt acetate.

ACTIONS:

- **Umicore and PMC to communicate with ECHA, draft comments on ECHA's DD (<13 Nov) and update the REACH dossiers where required**
- **Umicore and PMC to update all Pt dossiers (if and where relevant), and circulate end November to LR for registration <13 Dec**
- **Umicore and the other LR to register/submit the REACH dossiers for the TAPt compounds (<13 Dec) and other Pt compounds (where required – deadline will be communicated)**
- **Umicore and PMC secretariat to communicate with IPA on the dossier status, and IPA to consider the REACH framework and timing when developing the test plans**

3.5 Review of the OFI tracker and setting priorities for urgent work under current budget

The Pt entries in the OFI tracker were clarified.

ACTION:

- **PMC secretariat to circulate the publication on PGM dermal monitoring**

The PMC Secretariat has identified from the OFI tracker most urgent issues that can be **tackled under the current budget**. Note that proposals that are not prioritized, are kept in the OFI tracker for future consideration (as is the case for those entries not proposed below).

Update PtO2 dossier to Annex VII dossier

The PtO2 dossier is registered as AnnexIII exempted dossier, but this is considered not sustainable vs its uses.
The participants agreed to update the REACH dossier to an AnnexVII dossier. For skin sensitization, it was proposed to waive in vitro skin sensitization and directly test in vivo. BASF will check internally if and how this approach has been applied.

ACTIONS:

- **BASF to check internally if and how they applied waiving in vitro skin sensitization testing and directly testing in vivo (on non PMC dossiers)**
- **PMC secretariat to organize the required testing and develop an AnnexVII compliant dossier (considering BASF input)**
- **PMC secretariat to circulate the most recent ITS matrices**

ClPt secondary poisoning

The chloroplatinates are classified as STOT-RE1, so a secondary poisoning assessment is required. However, this assessment is waived (intermediate use, stringent workplace controls, limited ENV exposure), and this is considered not sustainable.
The participants agreed to investigate the bioaccumulation potential of ClPt's / Pt via a literature study.
The need for a TIER2 will be decided after the bioaccumulation literature study has been conducted.

ACTION:

- **PMC to initiate a literature search, preliminary screening assessment and identify data gaps, and update the dossiers where needed**

Karstedt Concentrate secondary poisoning

KC is classified as Repr2, so waiving based on no toxicity was not possible anymore. A screening assessment has been performed using a measured BCF and 2 estimates (TGD default and QSAR value). Only the over-conservative QSAR value resulted in a risk in the formulation scenario (RCR=1.18). In the meantime changes to the bioaccumulation section were introduced and secondary poisoning is now waived based on no bioaccumulation.
The participants agreed to focus on the measured BCF, and remove the assessment with the over-conservative estimate.

ACTION:

- **PMC to update the screening assessment, but not include in the dossier at this stage.**

TK refinement (inhalation and dermal)

During DNEL derivation, the driving NOAEC value is derived from a study with oral administration. As such, the value needs to be recalculated for inhalation and dermal exposure. For platinum, this implies a correction with conservative inhalation and dermal absorption values versus a measured oral absorption value. This results in a very conservative corrected NOAECs. The situation can be improved by performing a toxicokinetics (TK)study and experimentally deriving the inhalation and dermal absorption values.
The participants do not consider this proposal as high priority, as all exposure scenarios show safe use.

Pt nitrate RDT/Reprotox screening

Waivers are included in the dossier for RDT, Reprotox and in vivo genetox based on corrosivity. However, it was agreed earlier that corrosivity/low pH is no valid reason to waive testing, and the test design needs to be adjusted to anticipate these effects (eg via feeding study).
The participants agreed to perform a RDT / Reprotox screening study with Pt nitrate.

For in vivo genetox, a tiered testing approach is agreed, and the inclusion of a TP for Pt nitrate is postponed (waiver is currently included for in vivo genetox) until further in vivo evidence on the genetox potential of other Pt compounds gets available.

ACTION:

- **PMC to organise a RDT / Reprotox screening study with Pt nitrate.**

Chronic Daphnia ecotoxicity study of Pt(IV)

The chronic study included for Pt(IV) PNEC derivation is not fully compliant with today's standards. Following an expert review, the study is considered 'sufficiently reliable' and the threshold value (assessed as EC16 / 2) can be used as surrogate NOEC.
The participants do not consider this proposal as high priority.

3.6 Review of the OFI tracker and setting priorities for urgent work

Following topics are considered important, but are not covered under current budget:

-in vivo TP for Pt dossiers – cfr IPA testing plans

-EOGRTS: TP will be included in KC REACH dossier (update expected effective end 2017 or early 2018). The test is expected to be initiated in 2019-20.

4 Rhodium and compounds

4.1 Status (ongoing) registration dossiers

An update was given on the registration / preparation status and timing of the Rh dossiers.

Twelve rhodium substances have already been registered by the LR. The registrations for rhodium metal and rhodium nitrate are ongoing.

The rhodium sulphate dossier is almost ready; only missing information is a water solubility test report, and this is expected soon. The dossier will be circulated soon together with the dossiers for diammineplatinum nitrite and ruthenium trihydroxide.

Rhodium tris(2-ethylhexanoate) will be registered as solution. Heraeus is the new LR. Phys-chem testing is ongoing for the compound with 2-ethylhexanol as solvent. During discussions with registrants,

it became evident that also 2-ethylhexanoic acid is possible as solvent. The solvent is required to stabilize the substance. Spectra of both compositions need to be generated and compared to ensure sameness.

The participants agree to include

-both forms in a single dossier (mono-constituent) with 2 compositions.

-the solvents as impurities (cfr approach of other PMC substances in solution)

-a different classification for each composition, following the classification of the solvent.

For the second composition, some phys-chem testing needs to be organized soon.

ACTIONS:

- **PMC to finalise the Rh sulphate dossier and circulate for review & fast-track approval**
- **PMC to clearly mention in the Rh tris(2-ethylhexanoate) dossier that the solvent is required to stabilize the substance.**
- **PMC to collect spectra for both Rh tris(2-ethylhexanoate) compositions and compare to ensure substance sameness.**
- **PMC to finalise the phys-chem testing of the two Rh tris(2-ethylhexanoate) compositions, and circulate the dossier afterwards for review and fast-track approval**

4.2 Rh(III) genetox: testing status & further actions

A brief recap on the earlier Rh(III) discussions was given.

The AMES test of Rh(OH)3 is finalised (no genetox activity), and the Dose-Range finding experiment with Rh2O3 is available (tested at Covance) showing a similar pattern as Rh(OH)3. Confirmation of a final test is still pending.

The bioelution testing is finalised, but not all draft reports are received yet. The results support the grouping in water soluble and moderately water soluble Rh(III) cmpds (95-100% dissolution) vs poorly water soluble Rh(III) cmpds (<=0.3% dissolution).

The participants agreed to

-confirm the full AMES test with Rh2O3 to Covance

-perform an AMES test with one Rh tris(2-ethylhexanoate) composition (provided substance sameness is shown – cfr action point in 4.1)

-no further bioelution testing is required.

For RhI3, performing an AMES test with water as solvent is not sufficient as counter-evidence for the positive response in the older RhI3 AMES with DMSO as solvent. Some solubility testing of RhI3 in

water vs DMSO and comparison of the spectra is suggested. It is suggested to check the mutagenic potential of DMSO (and especially its behavior in AMES test) and the chemistry of RhI3 in DMSO (and the potential quenching effect of DMSO on Rh(III)).

The participants agreed that

-further actions regarding the RhI3 AMES test in DMSO need to be discussed in a follow-up call with the Tox Experts

-the need for an additional in vitro MN assay to clarify clastogenic activity of RhCl3 (before including an in vivo TP) is questioned (cfr. conclusion of TE meeting 14 Jan 2016), and needs to be verified with Mark Raffray during the follow-up call with the Tox Experts.

ACTIONS:

- **PMC to confirm full AMES test Rh2O3**
- **PMC to perform AMES test with 1 Rh tris(2-ethylhexanoate) composition (if substance sameness is shown!)**
- **A follow-up call on Rh(III) genetox needs to be organized to discuss further RhI3 testing (AMES, solubility) and in vitro genetox assays**

4.3 Review of the OFI tracker and setting priorities for urgent work under current budget

The PMC Secretariat has identified from the OFI tracker most urgent issues that can be **tackled under the current budget**. Note that proposals that are not prioritized, are kept in the OFI tracker for future consideration (as is the case for those entries not proposed below).

Update Rh2O3 dossier to Annex VII dossier

The Rh2O3 dossier is registered as AnnexIII exempted dossier, but this is considered not sustainable vs its uses.

The participants agreed to update the REACH dossier to an AnnexVII dossier. For skin sensitization testing, reference is made to the approach in the PtO2 dossier (cfr. section 3.5).. The AMES data are generated under point 4.2

ACTION:

- **PMC secretariat to organize the required testing and develop an AnnexVII compliant dossier**

Rh2O3 oxidising properties

The phyisico-chemical endpoint 'Oxidising properties' is currently waived based on expert judgement but PtO2 and RuO2 are both classified as Oxid Solid.
The participants agree to test Oxidising properties Rh2O3.

ACTION:

- **PMC secretariat to initiate the oxidizing properties testing with Rh2O3.**

4.4 Review of the OFI tracker and setting priorities for urgent work

The in vivo genetox testing proposal(s) (still to be discussed during follow-up meeting) is the only identified priority for future work.

5 Ruthenium and compounds

5.1 Status (ongoing) registration dossiers

An update was given on the registration / preparation status and timing of the Ru dossiers.

One Ru dossier has already been registered, and five have been reviewed and approved by the members. They will be send to the LR for registration shortly.

The dossier of ruthenium trihydroxide is ready for review and fast-track approval. The dossier will be circulated soon together with the dossiers for rhodium trisulphate and diammineplatinum nitrite.

In the Ru acetate dossier, BP owned data are included (for the 3 acute ecotox endpoints). These data are not used in other Ru dossiers. The dossier can only be registered by the LR once the LtU agreement is signed.

The participants agree that sublicensing of these data to co-registrants is not expected.

ACTION:

- **PMC to finalise the LtU agreement for the acute ecotox data for Ru acetate with BP without further discussions to have the option for sub-licensing the data included.**

5.2 Review of the OFI tracker and setting priorities for urgent work under current budget

The PMC Secretariat has identified from the OFI tracker most urgent issues that can be **tackled under the current budget**. Note that proposals that are not prioritized, are kept in the OFI tracker for future consideration (as is the case for those entries not proposed below).

Update RuO2 dossier to Annex VII dossier

The RuO2 dossier is registered as AnnexIII exempted dossier, but this is considered not sustainable vs its uses.

The participants agreed to update the REACH dossier to an AnnexVII dossier. For skin sensitization testing, reference is made to the approach in the PtO2 dossier (cfr. section 3.5)..

ACTION:

- **PMC secretariat to organize the required testing and develop an AnnexVII compliant dossier**

5.3 Review of the OFI tracker and setting priorities for urgent work

Besides usual maintenance, no immediate concerns have been identified.

6 PGM nanos: next steps?

A literature review for nanoAu and nanoPGMs is included in the 2018 workplan.

PMC monitors the EU COMM activities to revise the nanomaterial (NM) definition via Eurometaux. Future sector specific commenting is considered.

A consultation is ongoing on changing the REACH annexes for nanos. This is being followed-up closely via Eurometaux, and an internal review is ongoing. Many unclarities have been identified e.g. on additional testing requirements and tonnage (aggregated or nano-specific). Once the REACH annexes have been updated, this might have serious consequences on the PMC Workplan.

ACTION:

- **PMC secretariat to closely monitor the revisions of the NM definition and REACH annexes.**

7 Pt and Pd bars: article status?

LBMA/LPPM assessed the status of the import of Good Delivery (GD) platinum and palladium plates and ingots under REACH. As a basis, they took the assessment conducted on Au GD bars. They extrapolated from there concluding that GD Pt and Pd plates and ingots can be considered ‘articles’ under REACH..This means that they are not subject to registration and can be excluded for tonnage band calculations. The WG shared its experience with investment bars and expressed doubts about

the “only investment” use since a lot of bars are going back to IND for further use, which is not the case for Au bars.

The participants agreed

--that the GD Au bars concepts is not applicable to GD Pt and Pd plates and ingots.

-that the LBMA/LPPM request it difficult to defend

-to not co-sign this letter.

ACTION:

- **FC to inform the Mgt Cttee about the PGM WG advice to not co-sign this letter**

8 Workplan and budget

Cfr actions identified in previous sections.

There is budget included to review 2 Pd and 4 Pt dossiers in 2018. Suggested consultants are DHI, Arcadis and Anthesis.

PMC secretariat proposes for **future meetings**:

-Spring: define priority project(s) for next year, project proposals by the PMC members

-Autumn: status update + confirm priority project(s)

The 2017 expenses (expenses status 31/8 vs budget to be spent) and 2018 draft budget for Ir, Pt, Pd, Rh and Ru are shown.

9 AOB, next meetings/calls and closing remarks

Some screenshots from the knowledge management tool are presented. The system is expected to be available end 2017. A live demo will be given during the GA meeting in December. In 2018, the system can be fed with the PMC documents, and it is expected to be fully available end 2018.

A question was raised about the companies’ representation during the WG meetings as important decisions are made. It is anticipated that this will get better with the new platforms as it are mostly companies only registering the metals who are not present and most issues do not concern them directly.

Dates for next meetings:

2017 PMC General Assembly:

5-6 December, Brussels (*Marivaux Hotel Congress & Seminar Centre – Boulevard A. Max 98 – 1000 Bruxelles*)

2018 PMC BtB meetings:

Spring: 13-15 March, Brussels (PGM WG 14/03)

Autumn: 9-11 October, Brussels (PGM WG 10/10)

Annexes:

1. Agenda & List of participants
2. Slides presented at the meeting

Annex I: Agenda & List of participants

Angela Alderman, Johnson Matthey (United Kingdom) – via conference call

Bodo BERKNER, Ferro (Germany)

Roland BRASCH, Heraeus (Germany)

Arno BUTHE, Heraeus (Germany) – via conference call

France Capon, EPMF (Belgium)

Maxime ELIAT, consultant for EPMF (Arche, Belgium)

Herbert FUCHS, Heraeus (Germany)

Mark HOSFORD, Johnson Matthey (United Kingdom) – via conference call

Michael HUBER, C. Hafner (Germany)

Mari JÄRVIKIVI, Norilsk Nickel (Finland) – via conference call

Simona LAI, Varinor (Switzerland)

Marie-Laure LEDRICH, Consultant for Traxys (Luxembourg) – via conference call

Olga LEMKE, BASF (Germany)

Jelle MERTENS, EPMF (Belgium)

Nissanka RAJAPAKSE, Johnson Matthey (United Kingdom) – via conference call

Christoph ROELICH, Heraeus (Germany)

Mike SHEPHERD, Vale (United Kingdom)

Hege STUBBERUD, Glencore (Norway)

Michael THIEL, BASF (Germany)

Steven VERBERCKMOES, Umicore (Belgium)

Annex II: Slides presented at the meeting

To be included