PMC General Assembly Meeting

5 December 2017 (13:30-17:30)
Draft minutes - Marivaux Hotel, Bd A. Max 98, 1000 Brussels, Belgium
Chair: Guy Ethier, Umicore, Belgium | Co-Chair: Heinz-Günter Schenzel, C. Hafner, Germany

Executive Summary

The PMC Assembly:

- Approved the expulsion of SFPZ from the Ag and Refinables Sub-Assembly for default of payment
- Approved the removal from the PMC product portfolio of the Dirhenium heptasulphide
- Acknowledged the significant progresses in the registration process in preparation of May 2018 deadline
- Took note of the progresses and remaining challenges in data sharing in preparation of May 2018 deadline
- Agreed with the following way forward in the restructuration process of EPMF/PMC:
    - A company can decide to be out and transfer its membership into a LoA to have access to the data after 2018. Modalities will be explained and defined in a communication note.
    - A company can decide to stay in:
        - 15 February 2018: send written comments on Articles of Association and Internal rules
        - 15 March 2018: confirm commitment to sign/approve amended Articles of Association and Internal Rules
        - 5-6 June 2018: formal approval and signature of the amended Articles of Association and Internal Rules
        - December 2018: formal end of the PMC agreement
- Approved the PMC 2018 workplan and budget (4.289.224€) and the amount of 4.063.148€ to be invoiced.
- Approved the amended version of the Appendix IX of the PMC agreement.
- Acknowledged the progresses in the Knowledge Management tools
- Acknowledged the achievements in 2017 and challenges of 2018 of the different PMC projects.

Actions	Who?	When?	Status
Officially notify SFPZ of its expulsion for defaults of payment	FC	December 2017	
ReS7: Update the PMC product portfolio and inform the SIEF	AR	December 2017	
Send to EPMF and PMC members: a summary of the restructuration proposal including consequences of not joining	FC	December 2017	

EPMF, together with the Articles of Association and Internal rules			
Review the Articles of Association and Internal Rules	Members	15 February 2018	
Send formal commitment of joining EPMF	Members	15 March 2018	
Signature and approval of amended Articles of Association and Internal Rules by companies representative having legitimate authority	Members	5-6 June 2018	

1. Welcome and Introduction

Guy Ethier welcomed the participants to the PMC Assembly meeting and reminded the confidentiality and competition law rules. The quorum was checked and reached (>60 % - see attendance list in Annex 1).

Guy Ethier presented the agenda of the meeting organized in two ½ days: ½ day dedicated to administration and ½ day dedicated to projects. The meeting started with the administrative matters. The agenda has been approved, as the minutes of the previous meeting (June 2017). Regarding the knowledge management tool, it was highlighted that the intellectual property (IP) issues, together with the hosting contract, have been checked with our lawyer. This action is ongoing with K&L Gates and their IP expert. All other actions have been reviewed and were completed on time.

2. Membership news

2.1. Expulsion of SFPZ for default of payment

SFPZ, a company based in Morocco with an affiliate in Luxembourg, is a member of the Ag sub-Assembly and of the Refinables Sub-Assembly. Upon recommendation of the Management Committee, France Capon requested the exclusion of SFPZ for defaults of payment. Once excluded, SFPZ will keep their rights to the studies they have paid until 2016 but not for the data and work done as from 2017.

The General Assembly approves the immediate exclusion of SFPZ.

ACTION: officially notify SFPZ of its expulsion (FC, December 2017)

2.2. Withdrawal of Dirhenium heptasulphide from the Re Sub-Assembly

None of the PMC registrants have interest in this substance. Upon recommendation of the Management Committee, France Capon requested the withdrawal of Dirhenium heptasulphide (EC 234-882-5) from the Re sub-Assembly. The Re sub-Assembly had no objection.

The General Assembly approves the withdrawal of Dirhenium heptasulphide from the Rhenium Sub-Assembly.

ACTIONS:

- **Update the PMC product portfolio accordingly (AR, December 2017)**
- **Inform the SIEF (AR, December 2017)**

3. PMC Finances

France Capon presented the status of the 2017 accounts. Until October 2017, the difference between budget to be spent and the actuals seems quite significant. However, when taking into account the money which is still committed for this year (1,3 million of euros) to the actuals, we are nearly reaching the budget to be spent. The 2017 under spent, especially for Rhodium and Platinum, is due to the 25% contingency available for repeated testing and which was not used thanks for successful testing. This amount has been added to the respective reserves. EPMF external audit of the 2017 accounts will take place at the beginning of February 2018, after being reviewed by EPMF treasurer and EPMF financial controller these accounts will be presented to the PMC Assembly for approval in June 2018.

4. 2017 PMC Workplan: timeline and registration status

France Capon presented the status of the 2017 Workplan, as the remaining challenges.

Up till now, 66 substances have been registered, not including the refinables. Still 12 substances need to be registered or updated by the May 2018 registration deadline.

- The Tetrachloroauric acid dossier submission is expected in January 2018.
- The Potassium dicyanoargentate dossier should be submitted in December 2017.
- Pt dossiers: updates of the Tetraammineplatinum dichloride and dinitrate dossiers are ongoing due to the recent review of the testing proposals in Umicore's Tetraammineplatinum compounds dossiers. The updated dossiers need to be submitted by 13 December 2017.
- Chloroplatinates dossiers are currently updated for the same reasons and will be submitted in December 2017.
- HHPA-2 aminoethanol dossier is under approval by the members, submission expected in January 2018.
- Diammineplatinum (II) nitrite dossier should be submitted in December 2017.
- Karstedt: due to a change in classification (becoming reptrotox cat 1B), the dossier has been updated and should be submitted in January 2018.
- Rh tris(2-ethylhexanoate): due to a late change in the registration strategy (from solid to solution), additional phys-chem testing is still running. Dossier submission is expected in March 2018.
- The Ru acetate and Ru trihydroxide dossiers should be submitted in December 2017.

Overall registration is on time and finalized well before the 2018 registration deadline.

5. REACH LoA status

Audrey Rondepierrre presented the status of data sharing. Since 2010, 59 LoA's have been sold, mainly for the Ag sub-Assembly. The total costs of the sold LoA's is evaluated at more than 2,5 million of euros. All LoA sold in 2012 and 2013 have been reimbursed to members (827 000 euros). As from 2013 money received from the sold LoA has been added to the reserves. A detailed overview of all sold LoAs can be found on slide 21.

In 2016, due to the Implementing Act on Data sharing, the cost sharing formula has been review and efforts have been conducted by the secretariat to provide itemisation and justification of the costs. Despite all the efforts done, the cost-sharing formula is still challenged by potential co-registrants. This communication exercise justifying the fairness, transparency and non-discrimination of the system in place is extremely time consuming and resource demanding.

In 2018, the challenge will be to deal with a pic of requests in March/April before the registration deadline and potential increase of questions related to the cost sharing formula used.

6. PMC after 2018: update and next steps

France Capon presented the status of the restructuration of PMC and EPMF. The objective is to have a very flexible structure, taking into account the REACH and non-REACH topics but also the diversity of the different groups of metals covered by the association. In this new structure there will be two possible types of memberships: Members A (companies only) could decide to contribute to REACH and non-REACH platforms, while members B (national or international associations) could only contribute to the non-REACH platforms. This difference of access will ensure high level data protection and will avoid free riders.

More information on the term of references of the new structure is given on slide 24. It was highlighted that at Assembly level, the voting rights will be based on vested interests. If for example you do not contribute to the silver platform, you will not be able to vote on silver related topics.

The Assembly asked how many members will be represented in the new structure. At the moment we do not know precisely how many members will join the new structure. The aim is to maintain the same membership and have a full transfer of PMC members to the new structure. It was reminded that there is no new entity created. EPMF will be kept but the existing by-laws will be amended.

In June 2018, PMC members (who are not EPMF members) will be invited to sign the amended by-laws of the EPMF to become EPMF. The EPMF members will have to approve the amended by-laws. The consortium will not exist anymore as such as from end 2018. There will be only one association (EPMF) representing REACH and non-REACH interests. In the future we will have a much more agile and effective organisation based on a menu driven approach to address in a more efficient way the future challenges.

Three key documents have been circulated:

- The summary of the proposal
- The Articles of Association
- The Internal rules

It is worth to note that the Articles of the Association and the Internal Rules is legal documents. These documents and especially the Internal Rules reflect to a large extent the content of current PMC Consortium Agreement to ensure a smoother process avoiding unnecessary changes. It is important at this stage since all the principles are now agreed that companies request internally a legal review of the documents to ensure a smooth approval process in June 2018.

The new structure is presented on slide 25. France Capon explained that on an operational basis, there won't be a meeting for each of the proposed platforms (i.e. for Pt, Pd, Rh, RU, Ir platforms will be grouped in one meeting). This structure is meant for organisation purposes (voting and cost sharing)

but not for operational purpose. F. Capon explained that the list presented on slide 25 is not exhaustive and must remain flexible to allow enough reactivity to address emerging challenges.

It was clarified that silver and nano silver are currently covered by the same platform since both are part of the same registration dossier and that a mechanism (specific weighting factor) can be activated to ensure faire cost sharing if needed.

Regarding non-REACH platforms, and in addition to the already existing SVHC Roadmap and Ag EQS, the Board of the EPMF and the PMC Management committee would like to propose the following platforms: Chemicals/waste/products Roadmap, Risk Register (centralised point where all regulatory threats will be listed), occupational health, WFD and PGMs, responsible sourcing, taxes, communication and advocacy, food contact materials). In 2018, only the Aq EQS and the SVHC one will exist.

In June 2018, the current EPMF members will have to approve the amended EPMF articles of association and internal rules. In addition, the PMC members will have to sign the EPMF articles of association and internal rules.

The Assembly asked what would happen if a PMC member doesn't want to join the EPMF and what would be the consequences. France Capon explained that the concerned member can withdraw his membership and buy a Letter of Access for access to future work after 2018.

ACTIONS:

- **PMC secretariat to send to PMC and EPMF members a summary of the proposal including consequences of not joining EPMF, together with the Articles of Association (see Annex 3) and Internal rules (Annex 4) (FC, December 2017)**
- **PMC members to review internally and comment the EPMF Articles of Association and the EPMF Internal Rules (Members, 15/02/2018)**
- **Commitment of joining EPMF/approving amended Articles of Association (Members, 15/03/2018)**
- **05-06 June 2018: Members sign/approve the EPMF Articles of Association and Internal Rules in front of the notary. The person who will represent his/her company and sign the by-laws will need to have the legitimate authority to do so.**

7. 2018 PMC Workplan and budget: a transition year

France Capon presented PMC 2018 Workplan, as the associated budget. As from 2018 we will follow the new structure with the different platforms. The workplan has been developed based on the Opportunites For Improvement (OFI) tracker and the prioritisation criteria used by ECHA for further regulatory actions. 2018 will be focused on the development of new data to fill in the gaps. Potential updates of the dossiers will only be done in 2019-2020.

For all plaforms there is a budget for literature review, IUCLID hosting, updated of uses and exposure scenarios.

France Capon presented the highlights of the 2018 workplan on slides 35-36 (see also detailed Workplan in Annex 5). The Ag project will be very important in 2018. During the CLH process on silver active substances, important data gap has been identified regarding reprotox endpoint. An EORGTS testing proposal was submitted two years ago and is under review by ECHA, which means that this

testing will be able to start in 2018. A large budget has been foreseen for next year to cover this activity. The Assembly was reminded that the existing data gap and the available literature on this issue could trigger a classification reprotox cat 1B of silver. This classification would be extremely detrimental to the precious metals industry since triggering a restriction on consumer uses. Therefore, it is critical to ensure that robust scientific data are available before starting the classification discussions. However, the outcome of the testing being uncertain, this is worth to not that this will not ensure a no classification.

Another major change in the budget 2018 (in comparison with June 2017) is the increase of Pd compounds budget (700.000e to conduct 3 OECD 422) due to the need to reinforce the read-across strategy. This needs has been prioritized and identified as an urgency due to the experience and feedback on read-across received from ECHA for the Pt compounds.

The table summarizing the 2018 accounts and reserves is available on Annex 6 and has been reviewed and explained in details. The footnotes in the table clarifies the content of each column.

France Capon confirmed that for silver, in 2018, we are not building reserves for potential next challenges and we invoice only what is really needed to cover the 2018 workplan.

A trend of budget level for the last three years can be found on slide 42.

The General Assembly asked if it was not possible to send the budget one or two months earlier so that companies can better forecast for the next year. France Capon explained that we had this year three budget exercises (June, September and November) to increase predictability but we cannot do more due to the fact that unexpected events can happen (e.g.: TP review of Pt or new literature sources which influences the EOGRTs design).

The General Assembly approves the 2018 budget of 4 289 224 euros and the amount of 4 063 148 euros to be invoiced (slide 37-41).

8. PMC agreement: updated Annex IX (Cost sharing)

France Capon presented the updated Appendix IX of the PMC agreement including the new cost sharing formula:

- Admin costs: there will be an equal share for all members. For members only interested in 1 or 2 platforms there will be an annual fixed fee for the contribution to the admin costs.
- Non-REACH platforms: equal share of the costs as a starting point but this could be reviewed in thefuture.
- REACH platforms: share of the costs based on the requirements (tonnage band, intermediate under SCC and annex III exempted substances as listed in PMC online inventory)

In 2018 we will still have two separate budgets EPMF and PMC. Next year we will only have Ag EQS and SVHC roadmap as non-REACH platforms and both platforms can be joined on a voluntary basis. For 2018, the membership of these platforms is now fixed.

The General Assembly approves the updated Appendix IX of the Consortium agreement

9. Knowledge Management System

Cathy Martin presented the status of the development of the new Knowledge Management System. The system will allow us to archive data like scientific studies, scientific publications, REACH registration dossiers, regulatory actions, meeting documents etc. The access will be given by

representatives of members companies and will be limited to data related to substances in portfolio. Two ways of searching will be made available: by typing key words or directly by navigating through the substances via the buttons. The uploading of the documents onto the tool will start in 2018. A demo is to be organised during the Q1 2018. This system will not totally replace the members' pages on our website but is to be considered as a complementary tool. (e.g.: the minutes of our meetings will certainly remain on the members pages on our website since the way of archiving is more user friendly in this case).

10. Brexit: status, consequences and scenarios for EPMF

France Capon presented an update on Brexit and potential consequences on EPMF/PMC. At the moment it is still difficult to predict what will happen and all options are still open (see slide 55). So far the threats that have been identified for PMC are the 26 substances with UK Lead Registrants and the IUCLID hosting in the UK. Due to the all uncertainties, it was agreed at the Management Committee to finish first the REACH registration and then to understand the UK companies strategy. To find the latest news regarding the Brexit, a list of useful websites is available on slide 56.

11. A.O.B.

France Capon updated the Assembly regarding the status of the Metals Sectorial Approach. The project will start by a Workshop with ECHA in Brussels on 24 January 2018.

France Capon updated the Assembly regarding the status of the SEA project. The project has been delayed due to data gathering issues. This phase is now nearly finalised. For some compounds we have obtained a 100 % coverage, but for the metals it is more difficult to obtain a good coverage. The processing of the data and the outcome of the exercise is scheduled in Q1 2018.

12. Closing remarks

Guy Ethier closed the 1st day of the Assembly meeting giving the floor to Heinz-Günter Schenzel to summarize the next steps for the restructuration of EPMF-PMC: the company will have to choose to be in or out. He reminded also the importance to comply with the following schedule:

- 15/02/2018: send comments on legal documents (Articles of Association and Internal Rules)
- 15/03/2018: formal commitments to join EPMF
- 5-6 June 2018: empowered representative of companies to approve/sign amended Articles of Association and Internal Rules.

If a member decide to leave, this member will keep access to the data until 2018 included but will have to buy a LoA to have access to the data generated after 2018.

PMC General Assembly Meeting

6 December 2017 (09:00-12:15)
Draft minutes – Marivaux Hotel, Bd A. Max 68, 1000 Brussels, Belgium
Chair: Guy Ethier, Umicore, Belgium | Co-Chair: Heinz-Günter Schenzel, C. Hafner, Germany

1. Welcome and Introduction

Guy Ethier welcomed the participants to the PMC Assembly meeting and reminded the confidentiality and competition law rules. The quorum was checked and reached (>60 % - see attendance list in Annex 1).

Guy Ethier presented the agenda of the meeting organized in two ½ days: ½ day dedicated to administration and ½ day dedicated to projects. The second day was dedicated to an update on the projects in details. Each project manager will go through all items.

2. Update on PMC Projects – For info

2.1 Ag Project

Katrien Arijs started by updating the members about the main achievements of 2017:

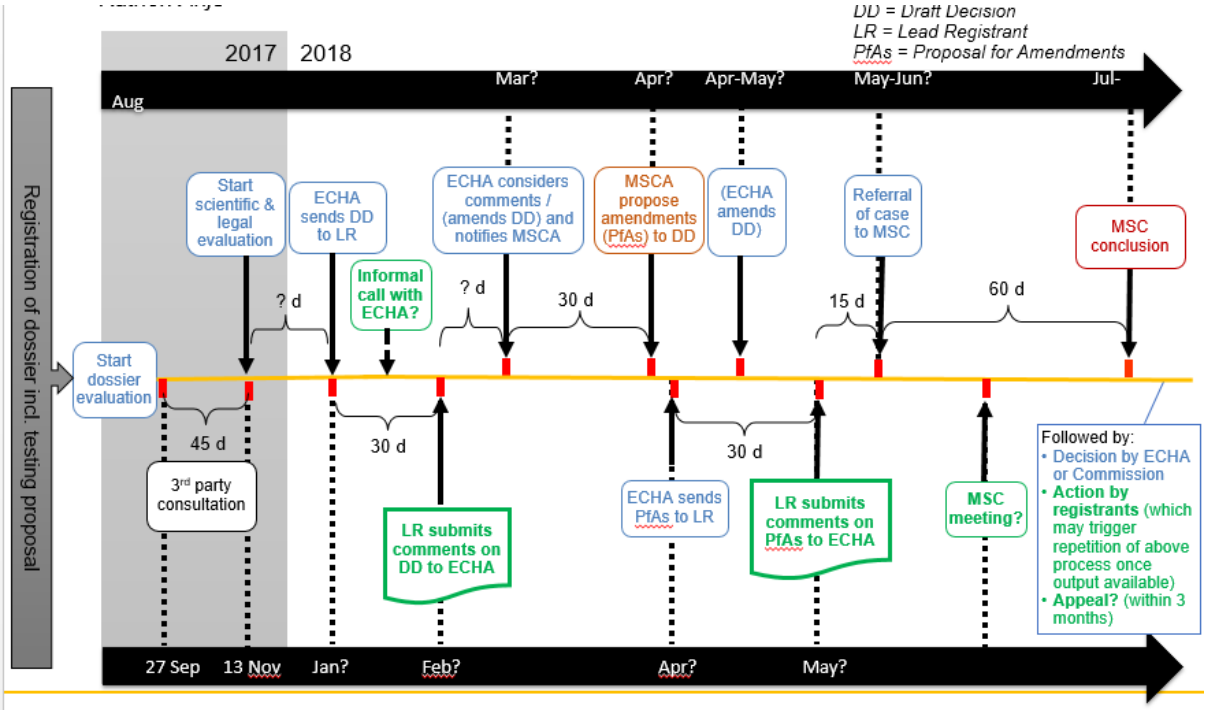
- **The finalisation of the 1st tier of the Substance Evaluation of nanosilver** with an update of the dossier submitted in July 2017. The outcome was positive: ecotoxicity of nanosilver is not higher than for silver. (cf. Slides 66- 68). The e-MS has until July 2018 to review and conclude on the udpated silver dossier. Two options: no further work will be needed or the second tier must be conducted. At this stage, no feedback has been received.
- **The progresses in the discussion on silver EQS under the WFD** (cf. Slides 69-70). Internal scientific review is ongoing since new data have been generated since the PNEC was derived. This triggered the recommendation to conduct additional ecotox testing to have a suitable study to derive PNEC derivation. The risk is high that Sweden does not agree with our PNEC derivation, therefore this study has been included in 2018 budget. This work will probably trigger further update of the silver dossier. A WG has been dedicated to silver and is led by Sweden, PMC is deeply involved in the technical discussions looking at the full dataset for silver. The timing remains still unclear.
- **CLH process under BPR** (cf. Slide 71): three CLH proposals have been submitted by Kemi for silver active substances. Public consultation (extended from 45 to 60 days) will start in the coming weeks but no clear timing so far. PMC will reiterate former comments on reprotox classification but also on environmental part.

Katrien Arijs presented the 2018 challenges:

- All platforms
    - Literature review
    - Update of uses and exposure scenarios
    - Update of PNECs / additional tests
    - Dossier evaluation: EOGRTS

- Silver metal
  - o CLH proposals
  - o Substance evaluation conclusion?

The main challenge will be the EOGRTS TP, the best timing estimation is as follows:



Ag reprotox: there was a shift in position over the last 2 years:

- SCAS CLH outcome: ECHA RAC precedent → classification of SZZ Repr Cat. 2; RAC mainly attribute effects to Ag^+
- More data emerging on SCAS (further 2-gen reprotox study data; developmental effects a focal point)
- New data (2016/17) on Ag^+, incl. new developmental immunotoxicity (DIT) data
- Overall balance of evidence: shifted adversely

Defense of TP will be key to sector but TP now outdated and will become a **complex EOGRTS** taking into account the latest information on immunotox**.** This is the main reason of the budget increase. The updated TP is under preparation, as some preparatory work. A meeting was organized in November 2017 with an expert in immunotox to ensure the robustness of the proposal. And another expert will be consulted on gut microbiome.

Heinz-Günter Schenzel highlighted again the importance of this project and the need to allocate the right level of resources due to the potential huge impact on the PM industry of a reprotox classification of silver. This work is also very important in the context of the CLH discussion under BRP and the position of Sweden regarding existing studies on silver salts.

Steven Verberckmoes warned the GA that doing the test is one step but that it does not guaranty the non-classification but at least that the classification will be based on sound science and on data. This predicts tough discussions with regulators. France Capon confirmed this and informed the GA that the Management Committee requested to draft a strategy to support the TP but also to ensure that a good strategy is in place in case of negative outcome for the industry.

The Ag and Ag compounds budgets on REACH evaluation covers only the EOGRTS and related work.

2.2 Refinables Project

Vincent Dunon updated the Assembly on the main achievements in 2017:

- Ongoing and endless SIDs discussions and continuous review of the dossiers to improve the SIDs of PMC dossiers
- Ongoing discussions with the ECHA computational unit to Use Assessment Entities (AEs) to:
    - Increase transparency dossiers: a real challenge taking into account the internal difficulties on characterising UVCBs
    - Show consistency of our approach in the metals industry

He updated the Assembly on the main challenges for 2018:

- Substance identification (SID):
    - Finalisation SID
    - PMC will ensure relevant input into the discussions between Eurométaux / ECHA
- Effects assessment and classification:
    - Classification review following SID review
    - T/D testing & phys-chem testing for splitted dossiers
    - Validation testing if needed
- Exposure and risk assessment:
    - MvE assessment, combined toxicity, update exposure & risk assessment
- Compilation of IUCLID 6 files & Registration Dossiers

The Metals Sectorial approach will be used to address these next challenges and ensure a smooth process with a buy in of the authorities.

2.3 Au Project

Vincent Dunon updated the Assembly on the main achievement in 2017 which is the finalisation of the TCA dossier which will be submitted early 2018.

The main challenges for 2018 are limited:

- Gold metal:
    - General updates
    - Literature review nano-Au
- Gold compounds:
    - General updates

2.4 PM CN Project

Vincent Dunon updated the Assembly on the main achievement in 2017: the finalisation of the Kag(CN)2, the dossier was slightly delayed due to further analytics studies requested.

The main challenges for 2018:

- $AgCN$ & $KAg(CN)_2$:
  - General updates
- $KAu(CN)_2$:
  - General updates
  - Testing proposal: *in vivo* genetic toxicity

2.5 Ir Project

All Ir dossiers have been submitted in 2016 and no specific work has been needed in 2017.

The main challenges for 2018 remains:

- Co-registrants invited to register well ahead of ECHA deadline (May 2018)
- Requests coming from LoA buyers (e.g.: composition, uses, etc.)
- Some literature review is foreseen
- Upgrade of the dossiers from IUCLID 5 to IUCLID 6

2.6 Pd Project

Maxime Eliat updated the Assembly about the main achievements in 2017:

- all Pd substances in the PMC scope have been registered by the LR
- Pd registrations learnt us a lot about the ECHA manual completeness check

The main challenges in 2018 will be:

- General maintenance
  - Literature review (including PGM nanos)
  - Expert review of the dossiers to get a second opinion
  - Small updates/improvements based on the OFI tracker
- REACH registrations:
  - Co-registrants invited to register well ahead of ECHA deadline (May 2018)
  - Requests coming from LoA buyers (e.g.: composition, uses, etc.)
- Updates for 2018:
  - PNEC refinement: perform additional ecotox testing and derive a PNEC for three Pd groups (↔ current generic Pd PNEC)
  - PdO dossier improvement: perform additional bio-elution testing and test for oxidising properties
  - Pd genotox: perform 3 in vitro genetox testings to replace weak studies ($PdCl_2$ & $TAPdCl_2$)
  - Skin sensitisation NaTClPd: perform substance specific in vivo skin sensitisation test
  - Data gap filling RDT/Reprotox screening: perform 3 repeated dose toxicity and reprotox screening studies to get rid of weak read-across
  - Uncomplexed & partially-complexed Pd(II) Salts (3 PMC substances): $PdCl_2$ as test substance
  - TetraClPd RA group (3 PMC substances): NaTClPd as test substance Pdacac

The most urgent work has started in 2017 under existing budget. The budget for Pd was increased to cover 3 OECD 422 testing to support the read-across. This program will be a one year project with an update of the dossiers in 2019.

2.7 Pt Project

Maxime Eliat updated the Assembly on the achievements of 2017:

- Four chloroplatinates dossiers will still be registered by LR < end 2017
- Diammineplatinum dinitrite:
  - Annex III exempted dossier
  - Review & approval currently ongoing
  - Available for registration by LR before end 2017
- HHPA-2AE
  - Mammalian toxicity testing finalised, DNELs derived and ES created
  - Dossier completed except for
    - some phys-chem endpoints (additional testing required – cf. PMCs experience with ECHA Manual Completeness Check)
    - TP for in vivo genotoxicity (under discussion by PGM Tox Experts)
  - Partial review & approval currently ongoing
  - Fast track approval for the missing parts in January 2018
- Karstedt Concentrate:
  - Registration in line with agreed deadline Reconsile
  - Update of KC due to classification as Repro tox Cat 2:
  - Main changes: generation ES & inclusion TP for Extended One Generation Reproductive Toxicity assay
  - Update finalised and reviewed by the WG
  - Approval process ongoing
  - First LoA signed by Reconsile member company
  - Review by Reconsile?
  - TP for in vivo genotoxicity of platinum dossiers: first discussions with ECHA following the draft decision on the TAPt diacetate dossier (outside PMC scope)

The main challenges for 2018 will be:

- General maintenance
  - Literature review (incl PGM nanos)
  - Expert review of the dossiers to get a second opinion
  - Small updates/improvements based on the OFI tracker
- REACH registrations:
  - Have registration dossier HHPA-2AE available for LR registration in January 2018
  - Co-registrants invited to register well ahead of ECHA deadline (May 2018)
  - Requests coming from LoA buyers (e.g.: composition, uses, etc.)
- Discussions with ECHA on in vivo TP
  - ECHA has reviewed the TP for some TAPt compounds, dossiers updated accordingly
  - Try to have the TP for all Pt compounds considered together by ECHA (and not in isolation per group)

  - Updates for 2018:
- PtO_2: update dossier from Annex III to Annex VII which will requires some mammalian toxicity testing: skin sensitisation and AMES
- Secondary poisoning ClPts: literature search
- Data gap filling RDT/Reprotox screening: perform a repeated dose toxicity and reprotox screening study with Pt dinitrate to replace waiver

The most urgent work has started in 2017 under existing budget. A budget has been foreseen in 2018 for Authorisation to cover potential activities related to the Clpts in case of selection of these substances by ECHA in 2018.

2.8 Rh Project

Jelle Mertens updated the Assembly on the main achievements in 2017:

- Rh metal: submitted as Annex VII dossier (1-10 tpa), Annex VIII draft available
- Diammonium sodium hexakis (nitrito-N) rhodate:
  - Annex VIII dossier (10-100 tpa)
  - DNELs & PNECs derived
  - Exposure scenarios generated
- Dirhodium trisulphate:
  - Annex III exempted dossier
  - All required phys-chem testing finalised
  - Review & approval currently ongoing
  - Available for registration by LR by end 2017
- Rhodium tris(2-ethylhexanoate)
  - Registration 1-10 tpa (Annex III)
  - Dossier delayed due to change in registration strategy moving from solid to solution and requiring additional phys-chem testing.
  - Aim: have registration dossier available Feb-March 2018
- Rh(III) genotoxicity:
  - AMES testing:
    - Rh trihydroxide tested, no genotoxic activity
    - Rh trioxide: DRF finalised, full test put on hold
    - Rh tris(2-ethylhexanoate): on hold
  - Internal review document drafted
  - Bioelution testing:
    - Solution mimicking human gastric solution
    - Results confirmed PMC grouping:
    - Water soluble Rh(III) cmpds – dissolve ± completely
    - Non water soluble Rh(III) cmpds – dissolve much less

- The PMC Tox Experts Group is now discussing the next steps.

The main challenges in 2018 are:

- REACH registrations:
  - Have registration dossier Rh tris(2-ethylhexanoate) available for LR registration in Feb/March 2018
  - Co-registrants invited to register well ahead of ECHA deadline (May 2018)
  - Requests coming from LoA buyers (e.g.: composition, uses, etc.)
- Rh(III) genotox:
  - AMES: finalise testing Rh trioxide and Rh tris(2-ethylhexanoate)
  - Water soluble Rh(III) compounds: include testing proposal for in vivo genetox testing
  - Poorly water soluble Rh(III) compounds: develop WoE argumentation to support grouping and absence of genotoxic potency via:
    - further chemistry testing with Rh triiodide
    - desktop research
- Rh trioxide:
  - Update dossier from Annex III to Annex VII which means that mammalian tox testing will be needed: acute toxicity (oral), skin irritation/ corrosion, eye irritation/corrosion, skin sensitisation
  - Phys-Chem properties: test for oxidising properties (to replace waiver)
- General maintenance
  - Literature review (including PGM nanos)
  - Small updates/improvements based on the OFI tracker

The most urgent work has started in 2017 under existing budget. Regarding the Annex III exemption, it was clarified that we need to wait for ECHA/Commission input before upgrading the dossiers. We will do this in a tiered approach and start already now with the most urgent ones since not fitting anymore with the Annex III exemption criteria. Discussions are ongoing at Commission level and with MS and more information should be available in March 2018.

2.9 Ru Project

Jelle Mertens updated the Assembly on the main achievements in 2017:

- Ru metal: registered as Annex VIII dossier (10-100 tpa)
- Ru trichloride,hydrate and Tetraammonium decachloro-mu-oxodiruthenate
  - Registered as Annex VIII dossiers (10-100 tpa)
  - Environmental and mammalian tox testing finalised
  - PNEC and DNEL derived
  - Exposure scenarios drafted
- Ruthenium trihydroxide:
  - Annex III exempted dossier
  - All required phys-chem testing finalised
  - Review & approval currently ongoing
  - Available for registration by LR by end 2017

- Ruthenium acetate:
    - Dossier reviewed and approved
    - Submission by LR pending :
    - Company owned data included (non-PMC member)
    - Discussions with company on data-sharing / LtU ongoing since mid-2017
    - Process in final steps, expected to be finalised by end 2017

Main challenges for 2018:

- REACH registrations:
    - Co-registrants invited to register well ahead of ECHA deadline (May 2018)
    - Requests coming from LoA buyers (e.g.: composition, uses, etc.)
- Ru(IV) oxide:
    - update dossier from Annex III to Annex VII which means that mammalian tox testing will be required: skin irritation/corrosion, skin sensitisation, AMES
- General maintenance
    - Literature review (including PGM nanos)
    - Small updates/improvements based on the OFI tracker

2.10 Re Project

Katrien Arijs updated the Assembly about the achievements in 2017: Literature review ongoing (WCA/Bibra).

The main challenges for 2018:

- Literature review
- Phys-chem testing due to lack of robustness of some waivers.
- Improvements / updates of CSR and IUCLID

2.11 SVHC Roadmap project

France Capon updated the Assembly about the achievements in 2017:

- **SVHC monitoring tool** is now in place: Chemycal
    - Companies specific report will be sent 4 times/year
    - Email alerts will be used in case of urgency
- **PbO** - Intermediate guidance:
    - Aim: clarify the regulatory status of PbO in precious metals refining
    - Conclusions:
        - Case 1: PbO used in order to produce a PM Lead alloy (UVCB): intermediate use
        - Case 2.1: Pb(PbO) as carrier metal in the refining of PM (and non-PM) – Pb/PbO present in input material: this is not a use of Pb/PbO, and not relevant for the intermediate discussion
        - Case 2.2: Pb(PbO) as carrier metal in the refining of PM (and non-PM) – Pb/PbO added to form a slag: intermediate use
        - Case 3: PbO used in fire assay: NOT an intermediate use
    - Status: final Industry guidance under review by ECHA

- Next steps: meeting with ECHA and publication of the guidance

- **Article 58(2)** interpretation
  - Background: Prioritisation of Pb compounds into Authorisation – exemption could be granted under article 58(2) (substances and uses already regulated under other EU legislation)
  - ECHA recommendation to Commission requested some legal review
  - Co-funded project was conduct and the outcome will be used for next advocacy steps
  - Critical issue due to precedent setting

The next challenges in 2018 are:

- Inclusion of Pb into PACT – potential listing into Candidate list
- Increasing activities on Substitution at EU and MS level
- High risk of prioritisation of PbO into Authorisation
- Continuous scrutiny on RCFs and Borates but unclear timing
- Memorandum of understanding still expected on REACH and OHS

Regarding Hydrazine, there is a high chance that the substance in not prioritize in the next list (9th) but more information will be available mid-December 2017 during the MSC meeting.

3. A.O.B. next meetings and closing remarks

Guy Ethier thanked the staff for the very well structured reporting and the excellent work done at work group levels.

He reminded the importance of the restructuration especially under the light of the next challenges identified and the fact that registration is only the first step of a longer journey. This will require an organisation that can sustain this and ensure an appropriate and efficient advocacy. We are also building a very credible and agile association which will be able to defend and support the precious metals industry.

Next steps of restructuration:

- By 15/02/2018: Members send comments on EPMF Articles of Association and EPMF Internal Rules
- By 15/03/2018: Members confirm their intention of joining the EPMF
- 05-06 June 2018: sign the EPMF Articles of Association and Internal Rules in front of the notary. The person who will represent his/her company and sign the by-laws should have the legitimate authority to do so.

Next meetings:

- **5-6 June 2018 in Liège (Belgium)**
- **4-5 December 2018 in Brussels (Belgium)**

List of annexes:

1. Agenda
2. Final attendance list
3. Slides presented at the meeting
4. 2018 Workplan and budget
5. 2018 accounts and reserves table