



## PMC Management Committee

*Draft minutes, Brussels (Umicore offices, rue du Marais, 31, 1000 Brussels)*

*16 November 2017 (10:30-16:00 CET)*

*Chair: Guy Ethier (Umicore, Belgium)*

Actions	Who?	When?	Status
Ag: develop an advocacy strategy and assess the consequences of a cat 1B classification	FC	January 2018	
Pd: check with tox expert the urgency to perform the 3 OECD 422 in 2018	Holger Zitt	Before GA	
2018 budget: update the table with explanatory note and clarifications on silver	FC	November 2017	DONE
Contact CBC to create multiple accounts to protect reserves	AR	December 2017	
Cost sharing formula: update the Appendix IX to reflect the discussions on Annex III exempted substances	FC	November 2017	
Send to the PMC members a request to declare their interest to stay within the SVHC Roadmap Sub-Assembly (no reply will mean tacit consent)	AR	November 2017	DONE
Update the Articles of Association and Internal rules according to the Management Committee recommendations	K&L Gates	November 2017	
Inform FvE that the Management Committee agrees with the updated proposal regarding the nomination of the President and Vice-President of EPMF	FC	November 2017	DONE
Check Cefic and Eurometaux definition of "European"	FC	November 2017	DONE
Draft a Memo on Pt genotox testing proposal	FC	November 2017	
Contact IPA to discuss Pt genotox testing proposal	FC	November 2017	
Contact KCM to share Management Committee decision	FC	November 2017	DONE



Recommend exclusion of SFPZ to General Assembly	Mgt Cttee	December 2017	
Communicate to the Re2S7 SIEF and the new LR the decision of the Assembly to withdraw this substance from its portfolio	FC/AR	December 2017	DONE
Data sharing with SMEs: keep Management Committee informed	FC	November 2017	
Contact the two companies challenging the PMC cost sharing to propose them the agreed way forward	AR	November 2017	
Potential LoA purchasers challenging the costs: follow the procedure described in the minutes	AR	As from November 2017	
Calculate LoA costs based on real number of co-registrants and published on PMC website	AR	November 2017	
Communicate to the companies who have already bought LoA to explain them the process of reimbursement/reinvoicing which will be done over Summer 2018.	AR	November 2017	
Update LoA costs based on 2017 real expenses and updated number of co-registrants and post on website•	AR	March 2018	
Calculate the registration dossier costs based on real expenses from 2007 until 2017 included and assess the need of reimbursing/reinvoicing based on the number of co-registrants after registration deadline.	AR	Summer 2018	
Check with K&L Gates the impact of having contract with IPA governed under German law	FC	November 2017	
Communicate the outcome of the discussion to IPA	FC	November 2017	
Propose a new date for next Mgt Cttee meeting in Brussels in Q1 2018	AR	December 2017	
Inform LBMA and LPPM of the decision of the Mgt Cttee regarding Pt and Pd bars under REACH	FC	November 2017	DONE



## 1. Welcome and Introduction

Guy Ethier (Umicore, Chair of the PMC) welcomed the participants presenting the safety recommendations, reminding the anti-trust and confidentiality rules. The quorum was checked and is reached (see List of participants in Annex 1).

The agenda has been reviewed and approved. The actions of the previous conference call (23 August 2017) have been reviewed and the minutes have been approved.

## 2. Assembly preparation: 2018 PMC draft budget – reserves, new cost sharing formula and fees

France Capon presented the updated workplan for 2018. The main changes are:

- An increase of the Ag and Ag compounds draft budget due to:
  - o the addition of sediments testing to refine the PNEC and support the ongoing EQS discussion.
  - o the review of the EOGRTs budget adding a DIT cohorts. This change was needed due to recent publications increasing the risk for a reprotox classification cat 1B. The Management Committee discussed the risks related to the acceptance of the testing proposal and the different possible outcomes. Taking into account the high importance of the issue and potential impact of a reprotox cat 1B classification, the Management Committee agreed to strongly support the budget increase since the risk cannot be avoided but need to be steered. **The Management Committee requested the Secretariat to develop an advocacy strategy to support the testing proposal and a plan B understanding the consequences of a reprotox at 1B classification.**
- An increase of the Pd budget due to the need to perform 3 OECD 422 instead of 1 as originally foreseen. This proposal was made by the PGM WG. 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 to address the weakness of the current read-across approach. On the top, we can benefit of doing the 3 tests in parallel. **The Management Committee agreed to keep this budget in the proposal to the Assembly. However, it was requested to check again the urgency to perform the 3 OECD 422 in 2018 with tox experts and especially with BASF.**

The Chairs of the Management Committee asked if the available resources are able to absorb this additional work. France Capon confirmed that this will require some reshuffling of some responsibilities especially for silver. It is also important to highlight that for such a type of studies external expertise from tox experts will be needed. This is already included in the current budget proposal.

**The draft 2018 budget has been reviewed and recommended to the Assembly for approval (under the conditions that the need for increase of Pd budget is again confirmed by the tox experts).**

The reallocation and use of the reserves have been reviewed (see preparatory document 1). **The Management Committee agreed with the proposal to invoice 4.063.148€ for a budget of 4.289.224€** and use the reserves only for the Au metal, Pt metal, Pd metal, Rh metal, Ru metal and



compounds, Ir metal, Re metal and compounds, refinables. The table will be sent to the Assembly after including an explanatory note for each column and a comment on silver metal related to the plan B for reprotox classification.

**The Management Committee recommended to contact the bank to check if multiple accounts can be created to protect the reserves in case of bank bankruptcy.**

The draft cost sharing formula circulated in preparation of the Management Committee meeting must be updated taking into consideration that a weighting factor of one will only be applied to Annex III exempted substances listed in the PMC portfolio. The SVHC Sub-Assembly will be accessible on a voluntary basis. A request will be sent to the Assembly in preparation of the next meeting to ensure that the fees presented at the Assembly will not change anymore. The Management Committee agreed that no reply will be deemed as tacit consent to stay within the SVHC Sub-Assembly in 2018.

**The updated cost sharing formula is recommended to the Assembly for approval.**

### 3. Assembly preparation: EPMF/PMC restructuration – update

France Capon presented the progresses in the EPMF/PMC restructuration. The following issues have been discussed:

- Presidency and Vice-Presidency: Proposal from FVE to add « Presidents and Chairpersons of national member associations may be elected as Presidents and Vice-Presidents of EPMF, as long as they represent at the same time a member company of EPMF. Managing Directors and Secretary Generals of national member associations are excluded to become Presidents and Vice-Presidents of EPMF ». **The Management Committee agreed with this proposal.**
- EU is defined in the Internal rules but not « European », do we need a definition? **Yes, it is recommended to check Cefic and Eurometaux definitions.**
- Article 8.1. in Internal rules requires that all the PMC LR are PMC members, which is not the case with Agfa Gevaert – do we need to amend? **Yes, add a sentence saying “otherwise decided by the Board”.**
- Article 8.2.: role of the LR must be adapted to reflect the next REACH phases. **Yes, must be broader to address the next REACH challenges. The declaration must also be checked.** The rules for LR change must be reviewed under the light of the Brexit. Indeed, the need to wait for a new LR before stepping back will only be valid for “eligible LR” but not in the case of companies which are not eligible for this role (like some of PMC LR in the future).
- Article 9.2.: Financial Controller – do we need to clarify that he cannot be a Board member? **This needs to be clarified.**
- Appendix 6: Confidentiality, Non-Use and Non-Disclosure Agreement – is it not too REACH related? **This needs to be amended.**

The next steps will be the finalization of the Articles of Association and Internal rules by December 2017. The PMC and EPMF members will be invited to review these proposals Q1 2018 and submit their comments by March 2018 at the latest to the Secretariat to ensure a smooth procedure in June 2018.



#### 4. Outcome of the informal meeting with ECHA on Pt genotox testing proposals

Umicore has received a draft decision for a testing proposal for in vivo genotoxicity on TAPt diacetate. Another testing proposal on TAPt hydrogen carbonate is now under consultation (also for in vivo genotoxicity) and the draft decision is expected in the coming weeks. During the conference call organized with ECHA on the draft decision for TAPt diacetate, Umicore explained the read-across and grouping approach for the tetraaminePt compounds. Umicore highlighted the fact that this testing proposal is currently handled in isolation while it is part of a grouping approach and a more comprehensive testing strategy. ECHA confirmed informally that such a grouping approach is acceptable to them (if you can support with the appropriate justification and data), and that they prefer to have a clear overview of the read-across and testing strategy for sake of consistency and efficiency. They recommended Umicore to raise this issue formally in their written comments which were submitted by 13 November 2017 but also to have all the relevant dossiers updated/submitted and aligned by 13<sup>th</sup> December 2017.

In the meantime, Claudio Carlon (ECHA Head of Unit of Evaluation responsible for the Testing Proposal review and CCH planning) proposed to Eurometaux to organize in the context of the Metals Sectorial Approach an informal meeting with PMC to discuss the testing proposals in the various Pt dossiers that are already submitted or planned for submission, and the grouping strategy. The initial idea of ECHA is to use this as an example for the Metals Sectorial Approach and demonstrate the need to work more in a horizontal and holistic way, rather than in silos (cf. current experience with the TAPt dossiers). A first informal chat was organized on 13 November 2017 to explore the possibilities. France Capon met with Hannu Braunschweiler, Claudio Carlon and discussed a preparatory note requested by ECHA shortly before the meeting. ECHA highlighted the legal constraints that they have regarding the NONs substances registered by Umicore. However, ECHA would like to find a solution staying within the legal framework to ensure a review of the different genotox testing proposals submitted for Pt compounds by PMC. The registration/update timing has been shared with ECHA and does not seem to be a major hurdle. This could ensure a comprehensive review of the different proposals and an alignment of the timing. It is worth to note that this meeting was **informal** and **do not engage ECHA or the industry** to embark into this exercise. Rather, it must be seen more as an exploratory meeting on how to improve the Dossier Evaluation process and PMC is now invited to follow-up updating/submitting the relevant dossiers and following-up with ECHA.

Nissanka Rajapakse expressed the following concerns:

- On the process: the preparatory document for the meeting was not shared with the members. France Capon confirmed that only an email with the outline of the discussion and the overall aim was shared due to late request from ECHA to receive this note. The note was circulated to the Pt Sub-Assembly and the Management Committee immediately after and includes only information already available in the dossier or on PMC website in a summary way.
- On the fact that the different groups could be now reviewed and especially the CIPTs. It was indeed decided by PMC to postpone as much as possible the submission of the dossier to avoid premature screening of these files. The ongoing discussions could have a negative impact since ECHA could decide to extend the review from genotox testing proposals to broader concerns like the OELs (now that RAC will be in charge of this task for the Commission). France Capon confirmed that indeed there could be a risk for the CIPTs dossiers. However, PMC already agreed to submit these dossiers in December 2017 to ensure a smooth



registration process. The discussion with ECHA will not influence this. If we look at the overall timing and based on the current knowledge of the ACROSS system, it was expected to have the CIPts screened 2nd half of 2018 and put on the PACT for further actions due to the respiratory sensitization classification. Now, there is indeed a risk that the CIPts could be prioritized earlier in 1st half 2018 which means 6 months earlier than expected. However, the risk at this stage seems limited due to the fact the two different units are involved in these processes: we are in discussion with the Evaluation (compliance unit) while the prioritisation is done at the level of the Risk Management Unit. Moreover, before going to the stage of a RAC discussion on potential OELs for CIPts this should require different steps: a high priority defined in the context of OHS (which does not seem the case so far) or a review via the PACT (and then, we are prepared having already available a shadow RMOAs and an AoA available internally). Therefore, overall, if the risk exists it seems quite limited.

**The Management Committee requested that a memo is drafted and shared with Pt Sub-Assembly and with IPA (since this process can influence the timing of IPA ongoing activities on Pt genotox) but welcomed this constructive approach with ECHA.**

**The Management Committee agreed to update the PMC dossiers to ensure consistency with ongoing TPs discussions and to use the fast track procedure to ensure no delay in the submission time.**

## 5. KCM request to transfer PMC membership into LoA

The Management Committee considered the requests of KCM regarding a transfer of membership to LoA and the reimbursement mechanisms.

Taking into account that KCM always paid their dues and have already registered their substances, the Management Committee recommends the following approach:

- KCM keeps the co-ownership rights and right to refer for the data generated under their official withdrawal.
- Penalty for leaving: no reimbursement will be made since signing the contract is considered as a commitment to PMC.
- KCM will have to pay for the administrative costs related to the transfer from PMC membership to LoA.
- After that date, if KCM wants to benefit of the dossiers updates, they will have to buy a LoA (costs will be calculated based on the work done as of the withdrawal dates).
- Regarding the communication, KCM will be treated as all the other SIEF members.

The Secretariat will go back to KCM to share the Management Committee decision. The withdrawal procedure will only start when an official request will be received from KCM.

## 6. PMC 2017 fee: non-payment by SFPZ – expulsion procedure

**The Management Committee agreed to recommend to the Assembly to proceed with SFPZ expulsion.** SFPZ (and affiliates) will keep their rights until 2016 but not to the data and work done after that date due to the payment default in 2017. If SFPZ wants to have access to the subsequent updates



they will have to buy LoA. No legal actions will be undertaken against SFPZ at this stage taking into account the costs benefits.

It is worth to note that at this stage there is no mechanism at ECHA level to make a difference between the co-registrants who have contributed financially to the updates or not since all are part of the joint submission. This is an ongoing discussion with ECHA and this issue has been spotted as an important barrier to update the dossiers. The Management Committee agreed to continue to advocate with ECHA/Commission that a system has to be put in place in the interest of the dossiers maintenance.

## 7. Change in PMC portfolio: removal of Re2S7?

Taking into account that there is no strategic interest to keep this substance in the PMC portfolio, **the Management Committee recommends to the Assembly to withdraw this substance from the PMC portfolio.** It was also agreed to not enter with the new LR/Consortium taking care of this substance into a data sharing process taking into account the low added value in comparison to the resources needed to do so.

## 8. Data sharing

### 1. Outside REACH: options to be assessed and published on PMC website after legal review

The Management Committee reviewed the different options laid down by the Secretariat and agreed to use this document as an internal guidance in case of data sharing request outside REACH. The Management Committee recommended to promote the data sharing outside REACH on the PMC website but to not make this document publicly available to keep some room of manoeuvre depending on potential new situations and to make the calculation of the costs related to an option when the request comes.

### 2. Data sharing issues with SMEs

The Management Committee took note of the proposal of ECHA to the DCG to allow free access to the data for SMEs but does not support this proposal, nor the proposal to put in place a payment instalment. The Management Committee is not willing to implement it at this stage due to the legal concerns raised by Eurometaux. The next DCG meeting will be organized on 27<sup>th</sup> November 2017. This is very likely that this proposal will be accepted except by Eurometaux. The Secretariat will keep the Management Committee informed.

### 3. SIEF members challenging LoA costs

The Management Committee reviewed the different options proposed by the Secretariat to address questions/concerns from some SIEF members regarding the costs of LoA.

The Management Committee agreed with the following suggested way forward:

- Keep PMC cost sharing formula unchanged in 2017 and apply in 2018 new cost sharing based on the new structure (except for administrative costs).



- Use immediately in 2017 the LoA costs taking into account the real number of co-registrants and propose this new fee to co-registrants
- Do not start case-by-case basis approach
- If companies still refuse to pay these updated costs, accept the opt out and propose the token access for 1 250€.

The next steps will be

- Calculate LoA costs based on real number of co-registrants and published on PMC website
- Communicate to the companies who bought already LoA to explain them the process of reimbursement/reinvoicing which will be done over Summer 2018.
- In March 2018, update LoA costs based on 2017 real expenses and updated number of co-registrants
- In Summer 2018, calculate the registration dossier costs based on real expenses from 2007 until 2017 included and assess the need of reimbursing/reinvoicing based on the number of co-registrants after registration deadline.

#### 4. IPA agreement

The Management Committee reviewed IPA comments and agreed with most of the them except:

- Article 5.2.: it is important for each Party to keep some freedom of using the data in case of co-funding studies. Especially taking into account that in the case of PMC, this is not EPMF/PMC which is the owner but each member. Therefore, it is proposed to rephrased the clause saying that each Party must inform the other one which has a right to refuse the use of the data within a strict timeframe. It is important to solve this issue since two projects could be co-founded in a near future by PMC and IPA: the genotox Pt testing and the genotox Rh testing.
- Article 14: the Management Committee wants to keep a clause on governing law and disputes. The Secretariat will check with PMC legal counsel the consequence of accepting the Munich Court of justice instead of Brussels to see if a compromise is acceptable on this point.

#### 9. Status of Pt and Pd bars under REACH

The Management Committee reviewed LBMA/LPPM proposal to co-sign an advice related to import of Pt and Pd GD bars. Taking into account the WG recommendation and the hurdles to clearly define GD bars for Pt and Pd, **the Management Committee does not support that PMC co-signs LBMA document.**

#### 10. Brexit: status

The Management Committee agreed that this could have a huge impact on PMC and especially on the LR positions in the future but it is premature at this stage to take any actions due to the political uncertainties and the need first for British companies to agree on their own strategy. It was agreed that



the topic will be discussed again in June 2018. British companies are invited to keep the Secretariat informed as soon as possible about their strategy related to their LR roles and registration.

## 11. A.O.B. and closure of the meeting

France Capon reviewed the registration status and the remaining substances to register:

- **Gold**
  - o TCA: dossier sent to the WG for review – submission of the dossier is expected in January 2018.
- **PM CN**
  - o KCN Ag: dossier will be approved this week and should be submitted in December 2017.
- **Pt**
  - o Tetraammineplatinum dichloride and dinitrate dossiers: updates are ongoing to address ECHA comments on read-across approach and testing proposal. Updated dossiers need to be submitted <13 December 2017 (cf. comments to ECHA).
  - o Chloroplatinates dossiers: dossiers are currently being updated to address ECHA comments for TAPt dossiers on read-across approach and testing proposal. Dossiers to be submitted in December 2017.
  - o HHPA-2 aminoethanol dossier under approval: submission of the dossier is expected in January 2018.
  - o Diammineplatinum (II) nitrite: under review by WG and approval by fast-track procedure will follow. The dossier should be registered in December 2017.
- Karstedt: updated dossiers under approval – two LoA with Reconsile members are under finalisation.**Rh**
  - o Rh metal: registration is ongoing by LR and was just finalized during the meeting.
  - o Rh trinitrate: registration is ongoing by LR and was just finalized during the meeting.
  - o Rh tris(2-ethylhexanoate): additional phys-chem testing is running (due to change in registration strategy from solid to solution). Finalisation and submission of the dossier is expected in March 2018.
  - o Dirhodium trisulphate: under review by WG and approval by fast-track procedure will follow. The dossier should be registered in December 2017.
- **Ru**
  - o Ru, Ru trichloride, Ru oxide and Tetraammonium decachloro-mu-oxodiruthenate: registration is ongoing by LR
  - o Ru acetate: dossier is ready for submission by LR but data sharing finalisation is needed with one data holder. Dossier should be submitted in December 2017.
  - o Ru trihydroxide: under review by WG and approval by fast-track procedure will follow. The dossier should be registered in December 2017.

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

**Next meeting of the MC: 27 February 2018 is not suitable anymore and another date will be proposed in the coming weeks.**



## Annex 1: Participants

Francisco Boo, Metalor (Switzerland)

France Capon, EPMF (Belgium)

Guy Ethier, Umicore (Belgium)

Joern Muehlenfeld, Aurubis (Germany)

Nissanka Rajapakse, Johnson Matthey (UK)

Audrey Rondepierre, EPMF (Belgium)

Heinz-Günter Schenzel, C. Hafner (Germany)

Dorothea Annette Steiger, Heraeus (Germany)

Holger Zitt, BASF (Germany)

### **Apologies**

Juha Parkkinen, Norilsk Nickel (Finland)