



PMC Management Committee

Minutes, Conference call, 23 August 2017 (10:00-12:00 CET)

Chair: Guy Ethier (Umicore, Belgium)

Actions	Who?	When?	Status
Update 2018 budget accordingly and send invoices allocation estimation to members	AR	By 1st September 2017	DONE
Challenge the Ag WG to demonstrate the need to have a second budget included for EOGRTs on nanosilver in 2018 budget.	Management Cttee	October 2017	DONE
Organize a Cost sharing WG meeting/conf call to discuss new proposals in cost sharing formula	FC	September 2017	DONE
Forecast minimum reserves to be kept in house end of 2018	AR/FC	August 2017	DONE
Forecast impact of potential holiday payment on 2018 reserves	AR/FC	August 2017	DONE
Compare 2018 forecast reserves and minimum reserves to be kept in house	AR/FC	August 2017	DONE
New holiday payment proposal	AR/FC	August 2017	DONE
Update Articles of Associations and Internal rules based on the recommendations of the Management Committee	K&L Gates	August 2017	DONE
Opt out by a SIEF member from silver registration: continue the dialog, assess the consequences of the opt out and propose a potential compromise	FC	September 2017	ONGOING

1. Welcome and Introduction

Guy Ethier (Umicore, Chair of the PMC) welcomed the participants 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 meeting (18th May 2017) have been reviewed (only the draft of the different options for data sharing outside REACH has been postponed to the next meeting upon recommendation of the PMC chairs) and the minutes have been approved.



2. 2018 PMC draft budget – reserves, new cost sharing formula and fees

Guy Ethier introduced the topic reminding the outcome of the Assembly regarding the 2018 budget and the reserves. The Assembly concluded that due to uncertainties related to some further potential regulatory actions on some substances and the lack of clarity regarding the number of LoA which will be sold, it is premature to discuss payment holidays for 2018. The aim of the exercise today is to conduct a first assessment of the 2017 reserves in preparation of the 2018 deadline. The Assembly agreed that the change in the reserves policy could only be conducted after May 2018, when the full picture will be available.

1. 2018 PMC revised draft budget

France Capon reminded the process to draft and approve the annual budget of PMC: in June, a first draft is presented to the Assembly after discussion and review by the relevant WG and Management Committee. Over summer, the staff reviews the budget based on the most recent information available. The refined budget is then discussed with the relevant WG and the Management Committee in preparation of the final approval by the Assembly in December.

France Capon went through the workplan highlighting the following changes and refinements since June 2017:

- Ag metal:
 - The budget foreseen for the 2nd tier of the Substance Evaluation has been removed since the 1st tier of the program was sufficient and an updated version of the registration dossier of silver has been submitted in July 2017.
 - The remaining budget includes mainly the 2 EOGRTs foreseen on silver bulk and nanosilver as recommended by the WG in March 2017. The Secretariat review again the proposal to include a budget for 2 EOGRTs and expressed some pending questions regarding the relevancy to have these budgets available in 2018. Indeed, based on internal discussions but also with Eurometaux experts, it is unlikely that both studies on bulk and nanos have to be conducted in parallel. The following options are more likely to happen:
 - Testing proposal is accepted as submitted and the testing will be done only on bulk => need only the budget for one EOGRTs
 - Testing proposal is not accepted as such since ECHA wants to have the most sensitive species tested (nanosilver) and recommends to extrapolate from nanosilver to silver bulk to avoid animal testing. It is indeed questionable that ECHA would accept two animal testing at the same time on the “same substance” => need only for one EOGRT.
 - If the outcome of the nanosilver testing is positive and if we can argue that an EOGRT is needed on silver bulk => need to a second budget for EOGRTs but not before 2020 at the earliest.

Based on this, the Management Committee recommended at unanimity to:

- **Remove the budget for the EOGRTs on nanosilver from the 2018 budget**
- **Request to the Ag WG to consider the above questions and answer them if the Ag WG wants to have the budget for a 2nd EOGRTs included again in the 2018 budget.**



ACTIONS:

- **Update 2018 budget accordingly and send invoices allocation estimation to members (AR, by 1st September 2017)**
- **Challenge the WG to demonstrate the need to have a second budget included for EOGRTs on nanosilver in 2018 budget.**
- Au metal, PGMs metals: inclusion of a budget to further investigate on nanos following a recommendation of the PMC members involved in an ad-hoc meeting on nanos (Pforzheim, June 2017).
- PGM compounds: The review of the “must” and “nice to have” as requested by the Assembly allowed to slightly decrease the budget of some PGMs platforms
- Overall: Some costs have been reduced considering the potentials to internalise some tasks like the study monitoring for phys-chem and ecotox testing. It is important to highlight that for study monitoring of studies related to HH and especially reprotox, budget has been kept for allowing the support of toxicologists.

Regarding the budget to be spent, it is difficult at this stage to estimate it. In principle, since the registration projects are coming to an end, the Secretariat would like to reduce to a maximum the “carry over” from 2017 and 2018 but there is a risk that a few amount will still be carried over for the projects which will be finalized end of 2017. An estimation will be presented at the next Management Committee in November 2017.

The Management Committee supported the updated budget 2018 (to be invoiced) as discussed above to send an estimation to support the companies busy with their internal budgeting exercise.

2. New cost sharing formula as proposed at the June GA

France Capon presented the new cost sharing formula has discussed by the Assembly in June 2017:

- **Admin. Costs:**
 - Basic principle for all: equal share
 - For companies and associations only interested into 1 or 2 platforms: fixed fee of 5000€/year for the contribution to the administrative costs.
- **Non-REACH** (non-related to registration dossiers): an equal share is recommended as a starting point but could be reviewed in case of the fairness principle could be challenged. In this case, an ad hoc cost sharing formula could be approved by the Board.
- **REACH** (related to registration dossiers): based on requirements (tonnage band, intermediate under SCC or nanos) similar to the current PMC agreement

Following a request from a SIEF member, the possibility to take into account the Annex III exempted substances specific requirements in the weighting factors have been assessed by the Secretariat.

There are two options:

- apply a weighting factor of 1 (as intermediates under SCC) to all companies having an Annex III exempted substance recognized by PMC



- apply a weighting factor of 1 (as intermediates under SCC) to all companies following a declaration that they can rely on Annex III exemption

The Secretariat recommended to apply a weighting factor of 1 to all companies having an Annex III exempted substance recognized by PMC.

Nissanka Rajapakse challenged the fairness of the procedure. Guy Ethier asked if it is possible to put in place a mechanism to allow an implementation of the other option.

The Management Committee recommended to the Cost Sharing WG to assess again the fairness of the proposal but also to ensure the development of a relevant process to implement this proposal.

ACTION: organize a Cost sharing WG meeting/conf call to discuss new proposals in cost sharing formula (FC, September 2017).

Following the preparation of the simulation for the 2018 fees, the following questions arose:

- **Relevancy of weighting factor of 5000 for the nanos?** In 2018, the ratio between overall budget and nanos budget changed significantly. This must be taken into account and a different weighting factor must be applied

The Management Committee agreed that this question is not relevant anymore since there is no nanosilver specific budget in 2018 proposal but agreed that this has to be kept in mind for potential future nanosilver work.

- For platform with only 1 substance, **relevancy for “applicable costs” of the two weighted approach** (50% based on number of substances and 50% based on requirements)?

Recommendation of the secretariat: if there is only 1 substance in the platform, 100% of the applicable costs are shared following the requirements (weighting factor linked to tonnage bands, SCC, etc.)

The Management Committee agreed with the recommendation but asked the Cost sharing WG to review it before inclusion in the new draft Appendix 9 of the PMC agreement.

3. Reallocation proposal of the reserves based on the new structure

France Capon presented the 2017 reserves forecast based on the current structure. However, due to the new structure to be implemented in 2018, the reserves need to be reallocated.

The following proposal has been validated by the H.G. Schenzel (Chair of the Cost sharing WG):

- We take the contribution of the members to each substance in the past. We know the number of members per substance and in each tonnage band which allows us to calculate their contribution to each substance.
- We allocate these amounts to the correct platforms.
- Based on that, we calculate the proportion of the contribution between the platform
- We apply the same proportion for the allocation of the reserves to the right platforms

This proposal is based on the principle that the reallocation must take into account the contributions of the members in the past and who will benefit of the reserves in the future in the context of the new structure.



The Management Committee agreed to recommend to the Assembly to approve the reallocation of the reserves as proposed above.

4. 2018 fees

Based on the 2017 forecast reserves, the Secretariat suggested potential holiday payments, mainly for the platforms dedicated to the metals (excepted silver) and for the refinables.

The Management Committee is not in a position to make a recommendation regarding potential holiday payments and requested the Secretariat to provide the following missing information:

- Minimum reserves to be kept in house by end of 2018 (based on the current system for reserve calculation)
- Impact of the proposed holiday payments on the 2018 reserves
- Comparison of the 2018 reserves forecast and of the minimum reserves to be kept in house by end of 2018 and updated proposal on holiday payments (considering also % to be used from reserves and % to be invoiced)

The Management Committee recommended to communicate to the Assembly 2018 fees simulation based on:

- Updated 2018 draft budget
- New cost sharing formula including the weighting factor for annex III exempted substances and the “one weighted” (only based on requirements) instead of “two weighted” approach for platforms including only 1 substance.

The message to the Assembly must include some warning regarding the ongoing discussions on EOGRTs for nanosilver and the additional assessment of the reserves. However, at this stage, this is the best estimation that we can give to the companies for their internal budgeting exercise.

ACTIONS:

- **Forecast minimum reserves to be kept in house end of 2018 (AR/FC, August 2017)**
- **Forecast impact of potential holiday payments on 2018 reserves (AR/FC, August 2017)**
- **Comparison of 2018 forecast reserves and minimum reserves to be kept in house (AR/FC, August 2017)**
- **New holiday payments proposal (AR/FC, August 2017)**

3. EPMF/PMC restructuring: status and overview of the amended documents

France Capon summarized the content of the updated Articles of the Association and Internal rules based on the outcome of the EPMF/PMC Assemblies.

The following questions have been raised by the lawyers/Secretariat:

- One or two representatives of Members B eligible to the **Board**?

The Management Committee recommends to leave open the number of Members B eligible to the Board. The Assembly will vote to elect 9 representatives maximum amongst the candidates from all Members.



- Are **President, Vice-President and Treasurer** positions only open to Members A or to all Members?

The Management Committee recommended to restrict the position of President and Vice-President to Members A and leave the other positions open to all Members.

- **Data ownership:** do we keep co-ownership or do the members transfer ownership to the Association keeping a perpetual license to Use in all jurisdictions (as it is already the case)?

The Management Committee agreed to consider this proposal but do not see any urgency to address it. It is recommended to keep so far the “co-ownership” principle of the data generated by PMC.

- In case of **resignation/expulsion of a member:** members are deprived of all the rights attached to membership except otherwise stipulated in the internal rules (same clause than in the PMC agreement but there it is mentioned « otherwise decided by the Management Committee » - in the internal rules, we added « The suspended, terminated or resigning Member A who was also member of REACH Related Platform(s), shall have the right to refer to the concerned Registration Dossier(s) as it (they) was (were) at the date of its suspension, termination or resignation. In case the suspended, terminated or resigning Member A wishes to refer to updates of the Registration Dossier(s) generated after the date of its suspension, termination or resignation, it must obtain the necessary authorisation pursuant to Article 10.2.2 of these Internal Rules” - **do we include this?**

The Management Committee recommended to use in the Internal rules a similar wording than in the current PMC agreement: all resigned or expelled members are deprived of all the rights attached to membership except otherwise stipulated by the Board.

The updated versions of the Articles of the Association and of the Internal rules will be circulated to the Assembly in October, well in advanced to the December meeting but after the EPMF Board meeting.

4. A.O.B. and closure of the meeting

1. Brief update data sharing - K-REACH

France Capon informed the Management Committee that one of the Korean stakeholders bought a LtU for studies on potassium dicyanoaurate following the original conditions (50% of the costs of the study + 25% admin costs and sub-licensing rights triggering reporting obligations). An amount of 20.000 euros has been recovered. Other discussions are still ongoing.

2. Potential change in Management Committee membership – Heraeus reorganisation

Internal restructuring is ongoing at Heraeus. Heraeus could appoint a new representative (Dorothea Steiger) in the PMC but so far no formal application has been received by the Secretariat. The Management Committee will review the issue when formal application has been received.

3. LoA silver 1-10t – request from a SIEF member to opt out

A SIEF member informed the Secretariat that they plan to opt out from the JS of silver taking into account the LoA costs using the article 11.3.(a): “A registrant may submit the information referred to in



Article 10(a)(iv), (vi), (vii) or (ix) separately if it would be disproportionately costly for him to submit this information jointly”.

The Secretariat would like to check with the Management Committee if the position is still to avoid any negotiation and leave the company to opt out. The Secretariat expressed some concerns related to this position for the following reasons:

- An opt out still require the LR to provide a token to the company which opts out but the rules are unclear
- An opt out could draw attention on the dossier of the company opting out but also of the LR dossier
- There is also the risk to have divergent information available to ECHA on the same substance.
- The assessment given by the legal counsel on the silver LoA costs for 1-10t (see Management Committee of June 2017)

The Management Committee agreed:

- To continue the dialog with the company clarifying which opt out criteria they will use (disproportional costs)
- To analyse further the consequences of this opt out (depending on the nature of the opt out)
- To assess options to propose another costs (e.g.: based on updated calculation taking into account the new number of co-registrants)
- To be careful before making a proposal (if any) to the SIEF member to set up clear principles and reasoning since this will set a precedent for the future.

Nissanka Rajapakse expressed some concerns setting such a type of precedent especially knowing that if the company is ready to rely only on handbook information it is unlikely that we will never be able to propose an “acceptable cost” for them for this dossier.

ACTION: continue the dialog, assess the consequences of the opt out and propose a potential compromise (FC, September 2017).

4. Next meeting of the MC: 16 November 2017

Due to works at the Metals conference centre, Guy Ethier kindly proposed to host the meeting at Umicore Offices. Practical information will be sent to the participants in September. Guy Ethier closed the meeting thanking the participants and the Secretariat for the good preparation of the meeting.



Annex 1: Participants

Francisco Boo, Metalor (Switzerland)
France Capon, EPMF (Belgium)
Rudolf Eller, Heraeus (Germany)
Guy Ethier, Umicore (Belgium)
Nissanka Rajapakse, Johnson Matthey (UK)
Audrey Rondepierre, EPMF (Belgium)
Heinz-Günter Schenzel, C. Hafner (Germany)
Holger Zitt, BASF (Germany)

Apologies

Joern Muehlenfeld, Aurubis (Germany)