



PMC General Assembly Meeting

5 June 2018 (13:30-17:00)

Draft minutes

Chair: Guy Ethier, Umicore, Belgium | Co-Chair: Heinz-Günter Schenzel, C. Hafner, Germany

Actions	Who?	When?	Status
Ag EQS: prepare an advocacy plan to address the concerns related to EQS proposal and the next steps. This will allow us to have clear decisions steps.	KA/FC	September 2018	
Refinables: Take stock of achievements the past 10 years and assess what to do more at political level	EPMF Board	December 2018	
Review of the calculation of the minimum reserves needed	EPMF Board	December 2018	
Calculate the costs of a registration dossier in summer 2018	AR	August 2018	
Assess the need to reimburse or invoice LoA purchasers	EPMF Board	September 2018	
Review the LoA costs sharing of admin costs	PMC Cost sharing WG	November 2018	
Calculation of 2019 LoA costs	AR	March 2019	
Draft WP on exposure scenarios improvements and updates	JM/ME,	October 2018	

Executive summary

The Assembly:

- Recommends to the EPMF Assembly to approve the 2017 audited accounts
- Approves the termination of the PMC agreement in December 2018
- Gives a mandate to the Management Committee to take all the necessary measure for the termination of the agreement.
- Approves the signature of the MISA Framework of cooperation and involvement of PMC via EPMF in the MISA from 2018 until 2020.



1. Welcome and Introduction

Guy Ethier welcomed the participants and started the meeting by congratulating the team and especially the Scientific team for compliance in due time of the REACH registration deadline which is now over. This is a major accomplishment for the team and for the PMC members.

He reminded the participants that we operate under confidentiality terms and competition law. The quorum was checked and reached (>60% - see attendance list in Annex 1)

The agenda was approved, as the minutes of the previous meeting after review of the actions.

2. Update on PMC Projects

2.1 Ag Project

The Ag WG elected a new chair: Clémence Siret (SAFT) and a new co-chair: Rob Garrett (Ames Goldsmith).

Substance Evaluation: all actions have been conducted in due time and now we are waiting for the conclusions of the eMS. They have until July 2018 to provide their conclusions (see slides 10-12).

Ag EQS: JRC published a watch list report and silver is not listed but this leave the door open to have silver on the priority list. Further monitoring data have been requested to MS and a sub-group has been created to further work on silver. This group is led by Sweden and PMC is one of the active members. Several actions have been taken to highlight the discrepancies between SSD dataset of PMC and Sweden and fill in existing gaps (e.g.: additional ecotox testing is ongoing). (see slides 13-17). If the timing is unclear at EU level, EQS setting continues at MS level: Sweden launched recently a consultation on national EQS and PMC will contribute.

Some clarifications were requested on the discussions with Sweden and the process to set up the EQS value. Sweden is leading the sub-group. For the different substances on the short list, EC requested some MS to take the lead. Sweden volunteered to lead the one on silver but there is no clear mandate nor timeline related to this work. Regarding the value, if SSD approach is used, the value should be very close to PMC PNEC value. The main discussion point will be to defend the SSD approach and also the AF which will be used. Indeed, MS uses often a conservative AF of 10 while PMC used an AF of 3.

ACTION: prepare an advocacy plan to address the concerns related to EQS proposal and the next steps. This will allow us to have clear decisions steps.. (September 2018, KA)

Ag EOGRTs: Katrien Arijs updated the Assembly on the last developments related to the EOGRTs testing proposal. This proposal has been updated in agreement with ECHA to reflect the latest information available. Enabling work will be carried out on gut microbiome and should start in the coming weeks. The DD is expected soon. (see slides 18-21).

It is unlikely that the full EOGRTs work is performed this year, therefore, the available budget will be carried over in 2019.

It is worth to remind that this is a long term project and that the outcome is still very uncertain regarding the classification of silver as reprotox.

2.2 Refinables Project



Vincent Dunon updated the Assembly on the status of the refinables project (see slides 22-26) focusing on the substance id discussion which is still ongoing with the ECHA. Some of the criteria have been clarified:

- Detailed manufacturing process
- Explain source of variability
- Clarify origin and variability source materials
- Provide a typical set of data

There are still some pending issues which will be discussed internally at EM level but also under the MISA (Metals and Inorganics Sectorial Approach) project.

In parallel, PMC continues to work on the regrouping of some of the refinables and the updates of the registration dossiers.

The Refinables WG highlighted the importance of the interfaces between Circular Economy and REACH and especially for the refinables. This issue will be broaden up and an event on that topic will be organized in December back-to-back with EPMF Assembly meeting.

ACTION: take stock of achievements and assess what to do more at political level (EPMF Board, December 2018)

2.3 Au Project

Vincent Dunon updated the Assembly on the status of the Au dossiers (see slides 27-29).

2.4 PM CN Project

Vincent Dunon updated the Assembly on the status of the PM CN dossiers (see slides 30-31). A second opinion will be requested on the TP genotox on Silver dicyanoargentate to align it on the other PMC substances.

2.5 Ir Project

The PGMs WG elected a new chair: M. Thiel and a new co-chair: A. Büthe.

Jelle Mertens updated the Assembly on the status of the Ir dossiers (see slides 34-35). The main challenge will be related to the upgrade of Annex III exempted dossier to Annex VII dossier now that the phase-in period is over.

2.6 Pd Project

Maxime Eliat updated the Assembly on the status of the Pd dossiers (see slides 36-40). A series of testing are ongoing to strengthen or reshuffle the read-across. The outcome of the testing will also trigger a review of the DNELs and PNECs which will have an impact on the CSA and exposure scenarios.

Clarifications were requested on what the basis are to carry out the update of this dossier. During the preparation of the dossiers, we realize that some of the read across were over-grouped. It was too late for the registration deadline to adapt it, but the WG decided to do it quickly after the registration. Regarding the upgrade from annex III exempted to Annex VII, the read-across can still be used there is no need to have a full dataset for each substance.



2.7 Pt Project

Maxime Eliat updated the Assembly on the status of the Pt dossiers (see slides 41-46).

Pt group is under regulatory pressure due to the ongoing review of the Pt genotox testing proposals and the EOGRTs on Karstedt Concentrate.

A series of testing are ongoing to strengthen or reshuffle the read-across. The outcome of the testing will also trigger a review of the DNELs and PNECs which will have an impact on the CSA and exposure scenarios.

Some clarifications were requested on why PMC submitted testing proposals. The *in vitro* data set results to be positive, which means that we need to make further *in vivo* testing based on the regulatory requirements. Without *in vivo* data, which can be only generated via a testing proposal, we could be obliged to classify the substance following the precautionary approach. .

Regarding Karstedt, the Chair expressed some concerns regarding the ongoing discussions with Reconcile on the content of the dossier. The Secretariat confirmed that we need to be vigilant to avoid being again trapped in resource intensive process with Reconcile but this should be manageable.

2.8 Rh Project

Jelle Mertens updated the Assembly on the status of the Rh dossiers (see slides 47-50). A TPs on genotox will be included in the water soluble Rh III group dossiers and will increase the regulatory pressure on the Rh dossiers.

A series of testing are ongoing to strengthen or reshuffle the read-across. The outcome of the testing will also trigger a review of the DNELs and PNECs which will have an impact on the CSA and exposure scenarios.

2.9 Ru Project

Jelle Mertens updated the Assembly on the status of the Ru dossiers (see slides 51-53).

Main challenge will be related to the upgrade from Annex III exempted to Annex VII dossiers. Some additional testing is ongoing on mammalian tox. This will be reflected into the next dossiers updates.

2.10 Re Project

Katrien Arijs updated the Assembly on the status of the Re dossiers (see 54-55).

Registration of these dossiers was done in 2013 and 2014. ECHA is required to do registration updates on a regular basis and especially on the tonnages manufactured and imported. How this will impact the Re dossiers? The obligations related to dossiers updates are broader than tonnages and should be done as soon as new information on the substance is available. In 2018, the Re dossiers will be updated with phys-chem data (additional testing is ongoing) and upgraded to IUCLID 6.

The maintenance of the dossiers is discussed at Commission, ECHA and MS level. If the MS wants to have periodic mandatory updates (e.g.: every 3 years), the industry is defending a position that updates must be done on certain prioritisation criteria and only if the new information influence the risk assessment and the risk management. However, companies are invited in the individual files to keep an eye more specifically on the tonnage and uses information.



2.11 SVHC Roadmap project

France Capon updated the Assembly on the status and next challenges related to the SVHC WG (see slides 56-57);

A company confirmed that the impurities or substances in substances issue is of growing concerns since the Dutch authorities have started a survey to understand which SVHC (or potential SVHC) are present in substance and mixture.

This issue will be the topic of the 1st event organized on 5th December 2018 by EPMF, back-to-back with its GA.

2.12 SEA data gathering exercise

Maxime Eliat updated the Assembly on the SEA data gathering exercise (see slides 58-64)

The Chair highlighted the importance of this exercise especially knowing that SEA becomes very important in the next steps of REACH. To improve the results of the exercise the following actions have been suggested:

- A Sector analysis with expert market analysts
- The organisation of a workshop under attorney privilege rules to discuss and improve the outcome of the current exercise.

We have definitely a challenge with this exercise: data are needed and must be maintained but also ensure full compliance with confidentiality and competition law.

ACTION: Organize a workshop focused on one or two metals (Ag, Pt) clarifying upfront what is required from the companies and present the outcome at the next GA meeting (FC/ME, December 2018).

3. Closure of the meeting

Conclusions: all substances have been registered but work goes on!



PMC General Assembly Meeting

6 June 2018 (09:00-12:00)

Draft agenda – Hôtel des Comtes de Méans, rue du Mont St-Martin 11, 4000 Liège, Belgique

Chair: Guy Ethier, Umicore, Belgium | Co-Chair: Heinz-Günter Schenzel, C. Hafner, Germany

4. Welcome and Introduction (9:00-9:05)

Guy Ethier welcomed the participants reminding the competition and confidentiality rules. He introduced the meeting reviewing the agenda which will be focused on administrative matters on this second day. The quorum was reached (> 60%, see annex 1).

5. PMC Finances

- 2017 audited accounts

France Capon presented the 2017 audited accounts, reviewed by an external auditor, the Treasurer and the Financial controller, which are overall on track. The 2017 overspent and underspent are explained on slide 74.

The PMC Assembly recommends to the EPMF Assembly to approve the 2017 PMC accounts.

An overview of the reserves available at the end of 2017 can be found on slide 75 (6 768 569 euros), as well as an estimation of the reserves at the end of 2018.

An assessment of the estimation of the reserves by end of 2019 have been conducted to assess the potential use of these reserves in 2019 (see annexes 3 & 4).

ACTION: Review of the calculation of the minimum reserves needed (EPMF Board, December 2018)

- 2018 status - For info

The status of the 2018 accounts at the end of the first trimester can be found on slide 78. The expenses and committed are aligned with the forecast.

6. PMC Workplan 2018: status

The highlights of the 2018 workplan summarizing the presentations of the 5th June 2018 can be found on slides 80-81.

7. Data Sharing status: REACH LoA

Audrey Rondepierre presented an update of the LoA project. PMC sold a total of 40 LoAs in 2018 (slide 83). A couple of LoA's to be sold are still in the pipeline. A full overview of all LoA sold between 2010 and 2018 can be found on slide 84. Over the last 8 years the Consortium has sold 88 LoAs for a total of 3.8 million of euros by mid-May 2018.

During summer, the secretariat will recalculate the LoA costs taking into account all co-registrants. The aim is to assess the need to reimburse (via credit note on the future work to be conducted) or reinvoice



the LoA purchasers. The latter decision will be taken by the EPMF Board in September 2018. The allocation of the administrative costs (which can not be equally shared in the context of a LoA) will be reviewed by the Cost-sharing WG and the EPMF Board in Q3 2018. In Q1 2019 the 2019 LoA costs will be calculated taking into account the 2018 real costs and the outcome of the Board regarding the administrative costs.

ACTIONS:

- Calculate the costs of a registration dossier in summer 2018 (AR, August 2018)
- Assess the need to reimburse or invoice LoA purchasers (EPMF Board, September 2018)
- Review the LoA costs sharing of admin costs (PMC Cost sharing WG, November 2018)
- Calculation of 2019 LoA costs (AR, March 2019)

8. Termination of PMC agreement in December 2018

The members of the PMC duly represented at the Assembly approved the termination of the PMC agreement in December 2018 at unanimity. The PMC will be in transition period up till the next Assembly in December. The Assembly mandates the Management Committee to undertake all the necessary measures for the termination of the agreement in December 2018.

9. EPMF 2019 Workplan: focus on the REACH platforms

France Capon presented the 2019 workplan of the administrative costs (674 200 euros) and REACH platforms (3 604 991 euros) (slides 90-114). The total of the 2019 draft budget is evaluated at 4 351 491 euros including the non-REACH platforms. The estimated resources needed are of 5,93 full time equivalent. A first simulation of the membership fee has been sent to the Assembly in preparation of the meeting. It is worth to note that this simulation only includes the confirmed EPMF members and not the PMC members who have not yet decided to join EPMF.

As usual, this is a first draft of the workplan and this will be refined over summer by the team and with the relevant WG in October before the final approval of the budget at the EPMF GA meeting in December 2018.

France Capon reminded the Assembly that the basis of the EPMF income is the membership fees based on the budget. The LoA and LtU fees are additional income based on real costs. It is worth to note that only a part of these costs (e.g.: what is mandatory for the Joint submission and data sharing process under REACH) can be charged to the LoA buyers.

Clarifications were requested on the data sharing per substance: the platforms have been grouped based mainly with read-across or similarities in regulatory requirements in order to avoid to have to manage as many platforms than substances included in the PMC product portfolio. Within a platform with several substance (e.g.: Ag compounds), weighting factors are applied to take into account the number of substances and tonnage band of a company.

The secretariat was asked whether a sheet with Exposure Scenarios should not be added in the workplan template since a new use, PNEC etc could trigger an update of the dossier.

An important topic is missing in the draft workplan, the update and workability of the exposure scenario. It is requested to assess the need to create a new platform on this issue or at least to make it more visible under each relevant platform. Indeed, exposure scenarios are key for the communication within



the supply chain, the improvements during the past years were not sufficient to ensure that this tool can achieve its primary goals. Now that the registration is over, this must be taken as a high priority. This is not a precious metals specific issue, therefore, the work must be done at two levels: Eurometaux and Precious metals for the implementation.

ACTION: draft WP on exposure scenarios improvements and updates (JM/ME, October 2018)

10. MISA: Metals Sectorial Approach: status and next steps

France Capon presented an update of the MISA and reminded the importance of the project due to the political and regulatory pressure on chemicals management in and outside the EU. MISA will help companies to address the increasing importance of Chemical Management in corporate values. The resources invested in the past 10 years need to be maintained, improved, used and valorised and MISA is a way to do so. It is also critical to be part of an open and collaborative dialog with ECHA (and MS) which proofed already its efficiency and efficacy (e.g.: Pt genotox, Ag evaluation, Ag testing proposal)

Following comments have been raised:

- MISA is an opportunity but could become a threat if ECHA comes with unmanageable expectations and this will be important for industry to manage this risk and keep the balance.
- Is there a clause on dispute resolution in the MISA framework of cooperation? It was decided to reduce to the minimum the legal aspects of this document and to build on trust. It is worth to underline that if disagreements should arise between parties, ECHA will go back to the official legal track (like compliance check) to address it.
- What will be the governance of this project? It is foreseen to keep an Eurometaux Steering Committee (as for the development of the project) communicating and managing directly the project with ECHA. EPMF is an active member of this committee.
- What will be the consequences on the resources of EPMF? The MISA Rolling plan has been drafted in collaboration of the different commodities including EPMF. The priorities set match with EPMF priorities already included in 2018 and 2019 workplan. Therefore, the decision to join MISA will not impact the WP. Regarding the participation to the different MISA activities, this will have no impact on the available resources since these activities will replace some of the ones currently ongoing at EM level (e.g.: technical WS of MISA will be handled under the Evaluation platforms). In summary, with or without MISA, this work on read-across, UVCB or genotox has to be done.

The General Assembly approves the signature of the MISA Framework of cooperation and involvement of PMC via EPMF in the MISA from 2018 until 2020.

11. Communication: Knowledge Management System

Cathy Martin presented the "Knowledge management System" tool which will go live by the end of June 2018. Aim of the tool is to archive data for the PMC secretariat and for the members (studies, supporting documents, minutes etc). Up till now, around 300 documents have already been uploaded, principally test reports and newsletters. The members will receive a mail with their password to access to the tool in the coming weeks. They were inviting to read the user start up guide which will be made available and to give their feedback. The Chair thanked the team for this work which will be of high added value for the industry.



12. Closing remarks

The Chair thanked the members for their participation and involvement and reminded them that even if the registration phase of REACH is over, the Authorisation and Evaluation just start as the maintenance of the dossiers.

The last PMC General Assembly meeting will take place on 4 December afternoon, back to back with the new format of the EPMF General Assembly which will take place on 5 December in Brussels (morning will be dedicated to the admin and an event on “Chemicals Management versus Circular Economy” will be organised in the afternoon, this event will also be open to non-members).

List of annexes:

Annex 1 – Final attendance list

Annex 2 – Slides presented at the meeting

Annex 3 – Use of the reserves in 2019 budget

Annex 4 - Estimation of the reserves end 2019

Annexe 5 – Draft 2019 Workplan