



PMC Assembly Meeting

Milan, 4 June 2015 (10:00-17:00)

Executive Summary and list of actions

The following decisions have been validated by the PMC Assembly:

- Election of Dr. Heinz-Günter Schenzel, C. Hafner, as Vice-Chair of the PMC Assembly.
- Election of Dr. Nissanka Rajapakse, Johnson Matthey, as member of the PMC Management Committee.
- Development of synergies between I2A and PMC (to be formally approved by EPMF GA)
- The PMC scope is frozen until the next Registration deadline (2018), based on the tables in the presentation attached to these minutes (slides 52 to 59). The draft and update of SDS will not be included into 2015 nor 2016 workplan but some preparatory work to help companies will be included in 2017 WP.
- Recommendation to the EPMF Assembly to validate 2014 audited accounts.
- For the 2015 overspend forecast,
 - o a part of the overspend forecast (596.400€) will be invoiced following exceptional principles in Q3 2015 (exceptional contribution of concerned companies and usual costs sharing for Karstedt), the rest will be taken from the reserves
 - o a Reorganisation of HR and additional consultancy support.
- Cost Sharing
 - o Refinables: same cost sharing formula must apply than for the other substances.
 - o Nanos: due to question on legitimate driving forces, remaining uncertainties the Assembly postpone the decision but requested the Secretariat to continue working on this issue and present a proposal in due time and based on sound information.
 - o LoA: to review the LoA fee ensuring consistency with cost sharing formula in the Cs and charging only what is mandatory in the Joint Submission.
 - o Generic Costs and PGM: the cost sharing formula needs to be streamlined for the generic costs and PGM and needs to be discriminated by substance family.
- 2016 Workplan: approval of the format of 2016 WP and approval of the appointment in 2016 of one person for the new position of Regulatory Affairs Manager.
- Au project: submission of gold dossiers in Q1 2016 except the one of TCA which will be reported until Q4 2016.
- PM CN: postponement of the registration of PM CN until Q3 2016 depending on the outcome of the visit and if monitoring campaign is required.
- PGM: submission of the different PGM dossiers according to the timeline available in the presentation.



Actions	Who?	By When?	Status
Communicate to I2a final recommendation of EPMF regarding mutualization of resources	FC	5 June 2015	DONE
Check for refinables intermediates under SCC if transported or on-site	KA	End of June 2015	
SDS: add in 2017 budget and resources for extracting relevant information to draft SDS	FC	Summer 2015	
Add an extra line in the accounts presentation to show the amount of money committed	FC/AR	Summer 2015	
Cost sharing – refinables: updated wording must be sent to the Assembly with 28 days for final approval	FC	Mid-July 2015	
Cost-sharing – nanos: send suggestions to Secretariat	ALL	October 2015	
Cost-sharing – nanos: issue to be discussed again in December 2015	FC	December 2015	
Cost-sharing – LoA: update the costs as agreed by the Assembly and based on 2015 cost sharing formula (to be reviewed in 2016 if needed)	FC/AR	June 2015	
Cost-sharing – generic costs and PGM: prepare a resolution on PGM and Generic costs to be presented in preparation of a vote in December 2015 and include a simulation for the companies.	FC/AR	October 2015	
2016: Simulation for companies fee	AR	October 2015	
Circulation of DD comments to Ag producers/importers	KA	5 June 2015	DONE
Update of the DD comments according to feedback	KA	14 June 2015	
Submission of DD comments to ECHA	Heraeus	15 June 2015	
Set up a call of Ag WG to discuss EBRC comments on silver zinc zeolite CLH dossier.	KA	ASAP	
Rh: check if some compounds cannot be registered earlier	KR	Summer 2015	



4 June 2015

Minutes

1. Welcome and Introduction

Guy Ethier (Chair of the PMC Assembly) started the meeting reminding the participants on confidentiality and Competition Law. A copy of the rules was available to the participants.

Guy Ethier thanked Assomet for the good organisation of the meeting in Milan.

The meeting started by a Tour de Table. The quorum has been checked and reached: 82%. (cf. Annex I List of participants and apologies).

Guy Ethier presented the agenda. **The agenda has been approved by the Assembly.**

The actions of the previous meetings organized on 12 June 2014 and 3 December 2014 have been reviewed. All critical actions have been conducted on time. **The minutes of previous meetings have been approved.**

2. Nanomaterials: the state of play (C. Spirlet, IZA)

Christine Spirlet (International Zinc Association) kindly accepted to present the status of the discussions on nanos in different international and European bodies: OECD, EU Commission and ECHA. The last part of the presentation was dedicated to the status of the different national inventories (cf. presentation in annexe).

Discussion

A question was raised on OECD programme on silver: was the programme conducted in collaboration with the NL and ECHA? Unfortunately, there is no link between the OECD programme and the current ongoing Evaluation. However, this issue could be raised in the comments on the DD (see below discussion under point 7).

Has IZA used OECD guidelines? In the case of ZnO₂, there were so many existing literature that no study has to be conducted to fulfil REACH obligations and draft the registration dossier. However, this will be evaluated in 2016 by Germany in the context of the Substance evaluation.

Was the OECD programme focusing on methodology or on testing results? The OECD programme was focused on the methodology and on the validity or the need to update the guidelines. However, some of the results can still be important e.g.: depending on the method that you use you can have different results. Therefore, the results could play an important role in the overall discussion and should be checked carefully.

Regarding the nano definition and the characterisation, there is an issue related to the proof that a material is not a nano. In theory, it does not mean that you have always to prove that you don't have nano but in some cases and due to the nature of the definition, some of the companies who are not intentionally producing nanos could be faced to this issue.



3. PMC membership news

PMC MC and Assembly Chairmanship

Guy Ethier introduced the changes in the Consortia Management Committee and in the consortia membership with Mark Raffray leaving Johnson Matthey. He welcomed Nissanka Rajapakse as new JM representative in the PMC. He warmly thanked Mark Raffray for outstanding work and dedication to the Precious Metals and Rhenium Consortia during the past years.

The Management Committee has elected Heinz-Günter Schenzel (C. Hafner) as Vice-Chair of the Management. The Management Committee recommends to the Assembly to elect him as vice-Chair of the Assembly.

The Assembly approved the election of Heinz-Günter Schenzel as Vice-Chair of the PMC Assembly.

Guy Ethier wish to step down from his positions of Chair of the PMC Assembly and Chair of the PMC Management Committee as of June 2016 and a procedure will start Q1 2016. Candidatures are welcomed and can be sent to the Secretariat.

Nissanka Rajapakse is candidate to replace Mark Raffray as a member of the Management Committee.

The Assembly approved the election of Nissanka Rajapakse as member of the Management Committee.

Legal WG Chairmanship

Alain Palmers left his position as PMC legal counsel and as Chair of the Legal Work Group for the Consortia. The position of Chair of the Legal WG is open and discussions are ongoing with potential candidates and new candidates are welcome.

A budget is included in 2016 draft budget to outsource his task of legal counsel.

Guy Ethier warmly thanked Alain Palmers for his support during the past years as PMC legal counsel.

Staff reorganisation

France Capon presented a summary of the staff reorganisation which is currently ongoing due to the leave of Renaud Nicolay and the understaffed identified in the PMC team (cf. presentation). In addition to the replacement of Renaud Nicolay and the recruitment of a person for a new position of Regulatory affairs manager, France Capon presented a proposal to mutualize efforts and resources with another small association located in the same building, I2a (International Antimony Association). (cf. presentation).

Heinz-Günter Schenzel underlined the importance to have different competences in the staff but also in the membership at management level to ensure that the right expertise will be available at the right moment. Guy Ethier supported this proposal as a great opportunity for both associations and to fulfil the need to have resources available in an efficient way.



It is worth to insist on the fact that this is not a merger of two organisations but a share of resources in a strict and well thought legal framework allowing the review or cease of the deal when and if needed.

The Assembly approved to develop the synergies between I2A and PMC and recommends this to the EPMF Assembly.

It is worth to underline that this mutualisation of resources will not be possible without the recruitment of a Regulatory affairs manager (cf. below section 6)

ACTION: communication of the decision after EPMF meeting on 5 June 2015 (FC)

PMC Scope freezing of the scope

France Capon presented the recommendation of the Management Committee to the Assembly to freeze the scope of the PMC work until 2018 (cf. presentation).

Discussion

What will happen if a tonnage is increasing near the deadline? Since tonnage band is based on 3 years average, companies should have now a good sense of what will be the tonnage band in 2018. As soon as a company sees that the trend in the production/import of one of the substances in the scope will increase, this company is invited to communicate this to the Secretariat to ensure that this information can be taken into account in due time in the PMC rolling plan.

What will happen if a change is requested due to an authority request? Hopefully, there will be soon a moratorium on existing REACH guidance to avoid to be confronted to “last minutes changes”. However, and only if the change in the PMC scope is imposed by the authorities, the situation will be analysed on a case-by-case basis.

In the case of the refinables some changes are under discussions (e.g.: split of existing dossiers) but these potential changes have been already budgeted and taken into account into the actual workplan. For the record and publication on the PMC website, it is important to check again for refinable the status substance, intermediates under SCC (on-site or transported).

ACTION: check refinables intermediates under SCC if they are transported or on-site (KA, End of June 2015)

The PMC Assembly approved the freezing of the scope of the PMC until 2018, based on the tables available in the presentation.

PMC scope: SDS

France Capon presented the current status of SDS in the PMC scope (cf. presentation).



Due to the difficulty to extract from the Registration dossiers, the information to draft an SDS, Aurubis suggested that the Secretariat extracts from the registration files the relevant information and provide it to the members for each substance.

The PMC Assembly approved the Secretariat proposal to not include in 2015-2016 SDS work into WP but to include some preparatory work to facilitate the work of the company in 2017 PMC WP.

4. PMC Finances

2014 accounts

France Capon presented the audited 2014 accounts. The Assembly recommends to the EPMF Assembly to approve 2014 audited accounts.

2015 forecast

France Capon presented the 2015 forecast (cf. presentation and cf. preparatory document to the Assembly).

Discussion

Guy Ethier and Heinz-Günter Schenzel reiterated the fact that end of 2015 the reserves will be limited for some critical projects (e.g.: PGM) and for the generic costs. Therefore, it will be critical to rebuild the reserves in 2016 and beyond. This is the reason why PGM reserves have not been used to cover all the overspend but only a part of it. This was very important to secure the minimum of reserves needed.

Regarding Karstedt, it was clarified that PMC will prepare full dossier and hopefully will be able to recover a part of the costs via the selling of letters of access. If Reconsile is not responding or not respecting the One Substance One Registration rule, it is advisable to contact ECHA in a short notice.

ACTION: Add a line on how much is committed for next financial report (FC, Summer 2015)

The Assembly approved the Management Committee recommendation:

- **A part of the overspend forecast (596.400€) will be invoiced following the above principles in Q3 2015 (exceptional contribution of concerned companies and usual costs sharing for Karstedt), the rest will be taken from the reserves**
- **Reorganisation of HR and additional consultancy staff support are approved.**

PMC cost sharing

France Capon presented the reasons of reviewing the cost sharing formula as the main recommendations of the Cost Sharing formula WG. She reminded that the approval of the principles and the change of the wording must be approved with a majority of 2/3.



1. Refinables: Interim agreement in 2011 – we say now that there is no exception anymore. **The Assembly agrees that the refinables are treated like other substances acknowledging the possible to have intermediates under SCC.**

ACTION: adapt the wording and start a written procedure within 28 days for final approval.

2. Nanos: There will be limited work performed on nano in the context of Evaluation in 2015 and if any, this work will be related to characterisation and charged to the relevant companies. Regarding the principle, it is a question of fairness but this is also a question of principle related to One Substance One Registration and until now nanos are not different substances than the massive forms... **Due to question on legitimate driving forces, remaining uncertainties the Assembly postpone the decision but requested the Secretariat to continue working on this issue and present a proposal in due time and based on sound information.**

ACTION:

- **send to Secretariat ideas and recommendations (ALL) by October 2015**
- **to be discussed in December 2015 (next GA)**

3. LoA: what will happen if a company does not pay the additional invoice? First of all, this company will not have access to the additional data needed generated. Additionally, they will be in breach with the signed contract and could be suit for this. How predictability for SME will be ensured? This question is key and is already relevant now. The PMC should work on this if SME requests come. Would it be feasible to have some recognition in the LoA fee for the work done by the company members of the Cs? This must be investigated carefully to ensure that the fairness and transparency are still respected.

The Assembly approved the principle to review the LoA fee ensuring consistency with cost sharing formula in the Cs and charging only what is mandatory in the Joint Submission.

5. Generic principle related to generic costs and PMG WG: the **Assembly agreed that cost sharing formula needs to be streamlined for the generic costs and PGM and needs to be discriminated by substance family as from 2016.**

ACTION: prepare a resolution on PGM and Generic costs to be presented in preparation of a vote in December 2015 and include a simulation for the companies.

6. PMC 2016 Workplan

France Capon presented the new PMC 2016 Workplan, draft budget and human resources.

Lipmann Walton & Co requested to pay particular attention to Generic costs which increased significantly since 2008. The Secretariat explained that this is due to the staff increase from 1 to 6 persons needed to achieve the tremendous work to do in preparation of 2018 deadline.

ACTION: simulation will be sent to the members of the Assembly in preparation of the next Assembly meeting in December 2015.



The Assembly welcomed the new PMC Workplan format and agreed with the appointment of one person for the new position of Regulatory Affairs Manager.

7. Update on PMC Registration Projects

Ag project

Katrien Arijs presented the status of the Ag project mainly focused on Evaluation of silver metal (nanoform) and on the current ongoing harmonization of classification of silver zinc zeolite which could have an important impact on silver and silver compounds.

Substance Evaluation - discussion

- What is the definition of form? This is one of the comments to be submitted.
- Do we know if eMSCA is happy with the information provided by the companies to demonstrate they don't have nano? This is unclear. We can assume it but there is no clear confirmation in the DD and the usual data provided, could not always be seen as sufficient.
- Legal advice could be seek for the issue related to the identification of the addressees but also on the overall DD. However, due to a lack of time, this will not be feasible. Some aspects will be reviewed by external consultant.
- Cost-sharing? Who will bear the costs? This is not yet decided (see discussion under section 5)
- At the last SETAC conference, there were several presentation related to silver nanoparticle and related to soil. What the NL is asking is studied since years now and is still not solved by scientists.
- The DD and comments are mixing scientific and political discussions. There is indeed some difficult scientific requests made by the NL under an unrealistic timeline. However, this is not just a question of ticking the boxes since there is a possibility for the NL to reject the outcome if it does not address properly the identified concerns. It is therefore critical to go for a compromise and to be balanced without accepting everything.
- It will be important to mention in the comments the ongoing OECD studies, this could be an argument to slightly postpone the overall Evaluation.

ACTIONS:

- **The DD comments will be circulated on June 5 2015 to Ag producers (KA)**
- **Update of the DD comments according to feedback (14 June 2015) (KA)**
- **Submission of DD comments by Heraeus (15 June 2015)**

Biocides - Discussion



Need to ensure that the Ag Working Group can review EBRC comments before the meeting with the Silver Task Force in charge of the biocides dossiers.

ACTION: set up ASAP a call of Ag WG to discuss EBRC comments on silver zinc zeolite CLH dossier.

Au project

Maxime Eliat presented the status of the preparation of the registration of Au and Au compounds. (see presentation)

It was reminded that due to workload and tight deadline it is very important to have all the information needed (e.g.: uses, data...) on time.

The Assembly decided to submit gold dossiers in Q1 2016 except the one of TCA which will be reported until Q4 2016.

PMC CN project

Maxime Eliat presented the status of the preparation of the registration of PM CN and PM CN compounds. (cf. presentation)

It was reminded that due to workload and tight deadline it is very important to have all the information needed (e.g.: uses, data...) on time.

The Assembly decided to postpone the registration of PM CN until Q3 2016 depending on the outcome of the visit.

Refinables Project

Katrien Arijs presented the status of the update of the Refinables dossiers based on further work related to Substance identification.

It was confirmed that no additional testing will be conducted on these substances unless formally requested by ECHA.

PGM Project

Klaus Rothenbacher presented the status of the preparation of the registration of PGM including a detailed timeline for registration waves.

It was reminded that due to workload and tight deadline it is very important to have all the information needed (e.g.: uses, data...) on time.

Regarding Karstedt, this is not a change in tonnage band but a change of responsibility which trigger the update of PMC workplan.



The timeline presented is the one that the team will work on but in case of testing issues, there is small room of manoeuvre and some registration can be slightly postponed.

It is recommended to check if some Rh compounds cannot be submitted earlier. For Platinates, there is limited latitude for repeated any work, need to make the good choice in the lab. (LPT will be chosen).

Re Project

Katrien Arijs presented the status of the post-registration Re project (cf. presentation).

8. Authorisation

Hydrazine

France Capon presented the status of the project of Occupational Exposure Assessment (cf. presentation).

RMO on chloroplatinates

France Capon presented the status of the shadow Risk Management Option Analysis which is under preparation. (cf. presentation).

9. A.O.B., next meeting and closing remarks

No other business has been raised during the meeting.

Guy Ethier closed the meeting thanking again Assomet for the good organization of the meetings. He thanked the Secretariat for the good work and the preparation of a loaded agenda which is proportionate to the challenges of the PMC consortia.

Next meeting: 2 December 2015 (Brussels)

Post meeting proposal: it is proposed to organize on December 1 (PM) the session dedicated to projects review to ensure that time enough is available to review them. The Administration will be discussed on December 2. Please book both dates in your calendar.



List of annexes:

Annex 1: Agenda

Annex 2: List of Participants and apologies

Annex 3: Slides presented at the meeting

Annex 4: Preparatory document Finances

Annex 5: 2016 draft Workplan