



# PMC Management Committee

Minutes, Brussels, 15 March 2017

Chair: Guy Ethier (Umicore, Belgium)

Actions	Who?	When?	Status
Check the sum of total column (expenses / committed) and update the presentation	AR	15/03/2017	DONE
Reserves - Review companies which are in PGMs and which Sub-Assembly	FC	22/03/2017	DONE
Reserves - WG needs to assess the remaining needs for each Sub-Assembly to complete registration or other ongoing work and the associated risks	FC	22/03/2017	DONE
Reserves - A summary note should be sent to the Management Committee on outcome of the two previous actions	FC	22/03/2017	DONE
New approval process – Launch written approval by the Assembly	FC	March 2017	DONE
KPIs2017 - Prepare for the Management Committee and Assembly an approval calendar	AR	March 2017	DONE
KPI's 2017 - Update the LR to do list according to the approved KPI's	Secretariat	March 2017	DONE
IPA agreement - comments on the draft agreement can be sent to the Secretariat	Management Committee	17/03/2107	DONE
IPA – genetox proposal - Assessment of the risks and opportunities reviewed by the WG and come back with a recommendation to the Management Committee	FC,	22/03/2017 COB	DONE
Calculate the difference of costs between funding members and new members since 2007	AR	2017	
LtU biocides agreement - to be amended	K&L Gates	April 2017	DONE
Organize a discussion with EPMF Presidents asap	FC	April 2017	DONE



Organize a call or meeting between Mngt and Board in May in preparation of the Assembly meetings	FC	May 2017	DONE
EPMF/PMC new structure - Develop an action plan and draft statutes	FC	April 2017	DONE
Send a communication to the Assembly on this new project and request for volunteers in the Knowledge Management Task Force.	FC	March 2017	DONE
Website - Check if password can be changed regularly to increase security.	AR	16 March 2017	DONE
Website - Add a location in the members' pages to have access to the Eurometaux REACH news and some important ECHA information.	FC	March 2017	DONE
Brexit - Suggest to Eurometaux to create a REACH Brexit Task Force	FC	March 2017	DONE
Brexit - Send to the Secretariat information on Brexit and REACH when available	UK based companies	Continuous	ONGOING

## 1. Welcome and Introduction

Guy Ethier welcomed the participants reminding the competition law and confidentiality duties.

The agenda has been approved adding a discussion on IPA request related to genotox work.

The actions of the previous conference call have been conducted on time and the minutes of the previous conference call have been approved.

## 2. Finance

### 1. 2016 accounts and audit

France Capon presented the accounts 2016 as audited in February 2017. The variations between the budget and expenses/commitments have been reviewed and discussed (see presentation slide 10).

**ACTION: Check the sum of total column (expenses / committed) and update the presentation (AR, 15/03/2017)**

**The Management Committee recommends the PMC Assembly to recommend the EPMF Assembly to approve the audited accounts.**

### 2. 2017 invoicing

France Capon presented the status of the cash flow and reserves by December 2016 (cf. slide 11). The available reserves are higher than expected due to:



- the change in the product portfolios of some members
- the new membership of Cri Criterion
- the savings in Pt and Pd projects as described on previous slide
- the reallocation of the PGMs reserves based on real figures (Pt and Pd projects are nearly finalized)

The Management Committee discussed the possibility to invoice less in 2017. However, the work is far to be finalized and changing now the invoicing could be a risk. On the other hand, so important reserves need to be clearly justified if the invoicing is pursued as foreseen. It is suggested to ask the WG review the reserves for each project and to justify the need to keep high reserves depending on the risks. When doing the exercise on what is still needed to complete the ongoing tasks and potential related risks, it is also important to make a distinction between the “minimum reserves” (what needs to be kept for the good management of organization) and the reserves needed based on risks. This is the delta between the “minimum reserves” and the actual reserves which needs to be discussed and justified. It is necessary to highlight here that the reserves are the value of the flexibility and capacity to work and quickly react to unexpected situations.

The Management Committee agreed that for 2018 budget, we need to review all the aspects related to budget and reserves.

**The Management Committee agreed with a payment holidays for Re in 2017.**

**ACTIONS:**

- **Review companies which are in PGMs and which Sub-Assembly (FC, 22/03/2017)**
- **WG needs to assess the remaining needs for each Sub-Assembly to complete registration or other ongoing work and the associated risks (PMC Secretariat, 22/03/2017)**
- **A summary note should be sent to the Management Committee on outcome of the two previous actions (FC, 22/03/2017)**

### 3. PMC approval process: review and streamlining

The Management Committee agreed to submit to the Assembly the proposal to streamline the approval process. The new approval process will be as follows for dossiers where we have more than two registrants:





In the consortium agreement, no decision has to be taken at unanimity. The reason was to avoid that one company could block the entire system. It is therefore suggested to apply the same decision rules by a qualified majority of 2/3.

**ACTIONS:**

- **Written approval by the Assembly (FC, March 2017)**

Nissanka Rajapakse raised some concerns about the speed of the approval process and the need to have enough time to review the dossiers since this is not always guaranteed that the WG did a proper review. It was agreed that due to the approaching deadline a tight approval process must be kept but that on an informal basis some extension and changes in the deadlines can be requested.

#### 4. 2017 KPIs proposal

France Capon reviewed the 2017 KPI's (see presentation slides 20-25).

**The Management Committee approved the KPIs' for 2017.**

**ACTIONS:**

- **Prepare for the Management Committee and Assembly an approval calendar (AR, March 2017)**
- **Update the LR to do list according to the approved KPI's (PMC Secretariat, March 2017)**

#### 5. Data sharing

##### 1. Data ownership of existing studies: status

France Capon updated the Management Committee on the status of the use of existing data: all PMC members signed the agreement except Cendres & Métaux; none of the contacted non-PMC members replied so far. The Secretariat will follow-up with these companies.

**Regarding the lists of studies provided by the companies, the Management Committee agreed to share it with SIEF members but not outside the SIEF.**

##### 2. K-REACH

France Capon presented the status of the data sharing with Korea. Overall, the process is going well and is not too time consuming at this stage.

It is worth to note that the updated version of the LtU agreement includes a clause ensuring that the PMC members who co-own the data are not obliged to pay again for these studies in Korea.

The proposal sent to the companies in Korea is only related to the PMC studies and not the studies owned by individual companies.

##### 3. IPA updated draft agreement

The Management Committee agreed with the following main changes proposed:

- The parties of the contract are IPA and EPMF and not anymore PMC and STF (since no legal entities)



- Clarification of the scope: only for advocacy purpose – no rights for IPA members to use the data for other purposes without proper LoA or LtU
- Add a clause to allow the co-sponsorship of the studies
- A more detailed list of scientific information to be shared

**ACTION: comments on the draft agreement can be sent to the Secretariat (Members, 17<sup>th</sup> March 2017)**

IPA would like to run an *in vivo* testing on Pt on genotoxicity to check potential for mutagenic effects. IPA does not want to wait for the REACH process and the submission of a testing proposal as currently foreseen in the Pt registration dossiers. IPA requests PMC to put on hold the submission of the Pt dossiers, time for IPA to run a mutagenicity testing in the US. The dossiers could be submitted after the completion of the study including the results. IPA is willing to pay for the study.

Issue to be explored:

- What is the risk of manual completeness check impact if submission of these dossiers is done at the last moment (January 2018 at the latest)?
- What is the impact on the registration dossier if the study is positive and requires a change in classification? Would we have time to amend the dossiers?
- The cost of the study is 350.000/500.000€, how PMC will have right to use and sub-license?
- Do we have an insurance/risks of the acceptance of the data?

**ACTIONS:**

- **Assessment of the risks and opportunities reviewed by the WG and come back with a recommendation to the Management Committee (FC, 22/03/2017 COB)**

#### 4. 2017 LoA costs

**The Management Committee approved the 2017 LoA costs (see in presentation slide 30).**

**ACTION: Difference of costs between funding members and new members since 2007 (AR, 2017)**

#### 5. Umicore request to use tetraammineplatinum dinitrate and tetraammineplatinum dichloride for ELINCS registration

Umicore request the access to this data to update existing ELINCS. It is important at this stage to pay attention to not update the ELINCS dossiers with the testing proposal on Pt until a decision is taken by the Management Committee.

The Management Committee questioned on the precedent setting of approving the use of data for a substance that we do not know since it could impact the read-across strategy developed in PMC registration dossiers.

It was agreed that in this case since Umicore is well aware of this strategy that the risk is limited. In the future, such a type of decision must be made on a case-by-case basis.

**The Management Committee approved the use of the data of tetraammineplatinum dinitrate and tetraammineplatinum dichloride by Umicore for ELINCS updates.**

#### 6. Requested changes in LoA agreement:

##### 6.1. Reconcile – toll manufacturing and enforceability



Reconcile requested two changes in the LoA agreement:

- Consideration of a toll manufacturer as an affiliate
- The enforceability clause must be reciprocal

**Based on the legal advice of K&L Gates, the Management Committee rejected Reconcile requests.**

What are the risks now for the data sharing?

- Option 1: Reconcile accepts the decision and the process continues
- Option 2: Reconcile rejects the decision and decides to launch a data sharing dispute but they have little ground due to the fact that the requests are not standard requests.
- Option 3: Reconcile considers to opt out and submit separately the information, but there is again here no ground for this.

In summary, the risk is therefore very low.

#### 6.2. Clariant – change of Legal entity

Clariant proposed to have a clause related to the transfer of rights in case of fusion, merger of acquisition. **The Management Committee agreed with the proposal but prefers at this stage to do a side agreement with Clariant instead of having this in the LoA agreement now.** The agreements will be updated later on in 2018 when invoicing for the finalisation of the registration will be done.

#### 7. Request for costs itemisation since 2007 and overall application of Implementing Act to the letter of the law

Some potential registrants request a higher level of itemisation of the PMC costs as other detailed questions on PMC functioning, data sharing, content of the dossiers etc.

**Comparing the requested efforts with the risks and taking into account our main objectives and the time and resources constraints, the Management Committee agreed to stick with the current strategy of data sharing.**

The Management Committee agreed to review and try to increase the level of details in the itemisation of the costs progressively and especially for post-2018 work.

#### 8. ESTF - Biocides: request to sub-license the studies

The Management Committee agreed to give a sub-licensing right to ESTF for the licensed data. The Management Committee agreed to leave the costs as proposed but requested to suggest a system of royalties in case of sub-licensing. Each time that ESTF will sub-license the data, ESTF will pay PMC back 1 000€.

**ACTION: amend the license agreement (K&L Gates, April 2017) and contact ESTF**

#### 9. Tarn-Pure – Biocides: request to receive a copy of full IUCLID of silver

Tarn-Pure must register an active substance containing silver under BPR. They want to use the PMC registration dossier for sake of consistency. France Capon presented different proposals and based on the fact that the main objectives for the PMC is that same data are used under the two regulations, the following option has been chosen: 25% of the costs of one silver dossier under PMC + 25% for admin



and propose a system of royalties in case of sub-licensing. It will be important to clarify with Tarn Pure that this does not include the potential updates nor the EOGRTs which is under a testing proposal.

A royalties system could present a risk if the company is not trustable but the list of biocides registrants is publicly available and can be checked by PMC.

## 6. Future of PMC

### 1. Outcome of the meeting between EPMF Board and PMC Chairs and preparation of the meeting on future of PMC (25 April 2017)

France Capon presented the outcome of the meeting between EPMF Board and PMC Chairs (see presentation slide 40) and the new business proposal for EPMF/PMC (see presentation slides 41-43).

The Management Committee supports the business proposal and agreed to move that way developing an action plan especially on legal aspects and drafting status to be discussed at the EPMF and PMC Assembly meetings.

Some clarifications were requested on the scope:

- When mentioning global overview, the Secretariat meant wholesome overview of the regulatory impacts on REACH registration dossiers. There is no intention at this stage to extend the scope to international issues already covered by other associations.
- Which expertise or lack in resources can an association cover? Some smaller companies do not have all the expertise needed in chemicals management (e.g.: tox, ecotox etc.) and see a benefit in the mutualisation of such a type of resources. It is also important that the association focus on issues which benefit of a common work (as it was the case for REACH). It is a way to leverage companies' resources together in the regulatory context in the most cost effective way.

#### **ACTIONS:**

- **Organize a discussion with EPMF Presidents asap (FC, April 2017)**
- **Develop an action plan and draft statutes (FC, April 2017)**
- **Organize a call or meeting between Mngt and Board in May in preparation of the Assembly meetings (May 2017)**

Based on the current business proposal, BASF could reconsider to join EPMF which becomes more attractive for a big company.

## 7. Knowledge Management tool: first proposals

France Capon presented a draft structure and offers received for the Knowledge Management system to be put in place (see presentation slides 45-50). **The Management Committee supports the first draft structure and proposal to appoint 9O'Clock and start the work following the proposed timeline. The Management Committee agreed to use the reserves (37.000€) for this project.**

It was highlighted that knowledge protection must be taken care off and guarantees must be brought by 9 O'Clock or the hosting partner. Rudolf Eller raised also some concerns regarding the workload for



Secretariat and company but it was confirmed that, for the Secretariat, most of the workload will be in 2018 when filling in the system.

**ACTION: send a communication to the Assembly on this new project and request for volunteers in the Knowledge Management Task Force (FC, March 2017)**

## 8. PMC website: new member's pages

The revamp version of the EPMF and PMC website will include now members pages for PMC as agreed in 2016.

Overall, the Management Committee agreed with the structure, available information and congratulated the staff for this achievement.

The public pages must be available by end of March. A communication will be sent to the Assembly but also to all relevant stakeholders (like the SIEF) to ensure a smooth access to important information like how the data sharing is working. The member' pages will be available later and will be filled in gradually with the relevant information.

### **ACTIONS:**

- **Check if password can be changed regularly to increase security? (AR, 16 March 2017)**
- **Add a location in the members' pages to have access to the Eurometaux REACH news and some important ECHA information. (FC, March 2017)**

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

- Potential new member: Varinor

The Management took note of the possibility to have a new member.

- Consequences of the Brexit on PMC: Lead Registrants, data sharing etc.

The Secretariat started to assess the potential consequences of the Brexit on REACH and on the PMC (data sharing, LR, review of the RA removing UK data etc.). It is difficult at this stage to have a clear picture of the situation but the discussions must be followed closely to ensure a proper management of the situation at PMC level.

### **ACTIONS:**

- **Suggest to Eurometaux to create a REACH Brexit Task Force (FC, March 2017)**
- **Send to the Secretariat information on Brexit and REACH when available (UK based companies)**
- Next meeting: conference call early May to prepare PMC Assembly (31 May-1 June 2017)

The Secretariat will send a doodle with the minutes of the meeting.

- Ag EQS update

15 members confirmed their participation to the Sub-Assembly. Further process is unclear: Prioritisation exercise postponed? Same time as overall WFD review + more holistic approach? What will happen to EQS dossier / silver factsheet? How will these documents be used?



The Commission wants to delay the process while some Member States want to stick to it. If process is delayed, some Member States consider to set up national EQS. A meeting with the European Commission has requested to clarify overall process / timing in order to better contribute – no response yet.

Nevertheless, the internal work must continue in preparation of the next steps and the workplan and strategy will be presented next week at the Ag WG.

List of annexes:

Annex 1 Participants list

Annex 2: Slides



## Annex 1: Participants

Francisco Boo, Metalor (Switzerland), will be bit late

France Capon, EPMF (Belgium)

Rudolf Eller, Heraeus (Germany)

Guy Ethier, Umicore (Belgium) until 14:30.

Nissanka Rajapakse, Johnson Matthey (UK)

Audrey Rondepierre, EPMF (Belgium)

Heinz-Günter Schenzel, C. Hafner (Germany)

Holger Zitt, BASF (Germany)

### Apologies

Joern Muehlenfeld, Aurubis (Germany)

Juha Parkkinen, Norilsk (Finland) - proxy was given to Nissanka Rajapakse