



PMC Management Committee

Minutes, Conference call, 13 May 2016 (10:00-12:00)

Chair: Guy Ethier, Umicore, Belgium

Actions	Who?	When?	Status
TCA - Discuss with Metalor legal counsel the TCA dossier	Francisco Boo	End of May 2016	DONE
TCA - Send a formal letter to Covance requesting reimbursement	FC	End of May 2016	DONE
TCA) Investigate with relevant legal counsel further actions against Covance to recover damages costs	FC	End of June 2016	DONE
TCA - Check with accountant the status of reimbursement of costs and damages by Covance and how to book it.	AR	End of May 2016	DONE
Ag Evaluation budget – review impact of the updated requirements	FC	End of June 2016	DONE
Assembly – update agenda before circulation	AR	13 May 2016	DONE
Data sharing – draft LtU agreement between Ag and PM CN Sub-Assemblies	FC	6 October 2016	DONE
ESTF data sharing request – prepare an offer to share the requested data of Ag	FC/AR	End of May 2016	DONE
Reelection of the Management Committee – current members are invited to be ready to make a statement in June 2016	MC members	1st June 2016	DONE



1. Welcome and Introduction

Guy Ethier welcomed the participants reminding the anti-trust guidelines. The quorum has been checked and is reached (cf. list of participants in Annex I).

The agenda has been approved, adding under A.O.B. a discussion related to Substance Evaluation of silver, a request for data sharing received from the European Silver Task Force, data sharing guidance under development (affiliates versus companies approach).

The actions of the meeting of 14th March 2016 have been conducted. The Management Committee approved the minutes of this meeting.

2. Q1 2016: financial report

France Capon presented the status of 2016 accounts with a focus on: TCA, PGMs transitional period and the consequence of the postponement of Iridium submission (see Annexes 2 and 5). Guy Ethier asked some clarifications about the availability of the cash flow for Iridium remaining work. The Secretariat confirmed that money is available but was not booked as committed money to be spent in 2016 since the work should have been finalized by end of 2015.

Regarding the TCA issue, **the Management Committee approved the Secretariat proposal (option B – cf. Annexes 2 and 5, slide 10) to use available cash flow and make the balance for Au project in 2017.** The Management Committee recommends that a formal letter should be sent as soon as possible to Covance asking for reimbursement and that some investigation is done to see how we can recover damages costs (costs related to monitoring, sample etc.). Metalor is invited to send to the Secretariat some recommendation of Swiss lawyer since K&L Gates (PMC legal counsel) cannot take this case due to a conflict of interest and the contract is done under Swiss law. K&L Gates recommended already some law firm in Switzerland.

Nissanka Rajapakse highlighted the fact that WCA, as monitor of the study, could have identified the issue earlier and has a part of the responsibility. The Secretariat agreed but cannot prove it. Guy Ethier asked if everything has already been paid to Covance. The Secretariat confirmed. The Management Committee recommends to check with the accountant the status of the money which will be reimbursed and how to book it.

The Management Committee agrees with the way of presented the PGMs accounts during the transitional period (cf. Annex 5, slides 8 and 10).

Regarding 2016 accounts, Roland Brasch asked if the potential impact of the updated requirements under silver evaluation has already been reflected. The Secretariat confirmed that this has not yet been done since the final decision has not yet been received. Based on the informal outcome received so far, it was premature to assess the financial impact and the available information was not sufficient to make a quantitative assessment. This will be done as soon as the final decision will be available. If the budget decreases, how this will be handled? The Secretariat suggested to adapt 2017 silver Evaluation budget accordingly but this will be reassessed when a quantitative assessment will be available.



3. Status of 2016 Workplan and timelines

1. TCA

The need to repeat OECD 422 testing on TCA will impact the overall timeline. All Au substances will have been submitted in 2016 except TCA which will be submitted Q2-Q3 2017.

2. Early registration of Annex III exempted substances

Due to imminent changes in IUCLID and the publication of an Annex III substances list by ECHA, as to split again the registration workload of the companies, the Secretariat proposes to submit the dossiers for the Annex III exempted substances listed in Annex 5, slide 13 before 21 June 2016 (official switch from IUCLID 5 to IUCLID 6).

The Management Committee fully supports the idea. If all registrations are not possible by then, they could still be done later on since the upgrade of all PMC dossiers from IUCLID 5 to 6 will be done over summer.

3. Phys-chem testing for some Pd compounds

The Management Committee took note of the potential delay in the registration of 3 palladium compounds due to additional phys-chem testing requested. The impact should be minimum (one month maximum).

4. Draft agenda for June 2016 Assembly meeting

The Management Committee approved the suggested agenda (cf. annex 3) and suggested to add two issues:

- Under data sharing a specific session dedicated to the Implementing Act on Data Sharing and the ECHA guidance which is under review (status, actions taken and potential impact).
- Under membership news, include the announcement of the reelection of the Management Committee at the December 2016 Assembly meeting.

5. 2017 Workplan: 1st draft

France Capon summarizes the main activities and the related costs discussed at PMC team level and at WG levels (cf. Annex 4). This is a first draft which needs to be reviewed and updated over summer, reflecting particularly the new information related to Silver Evaluation and the decision related to TCA.

The Management Committee recommended to present this first draft to the Assembly.

6. Data sharing

1. Between Ag and PM CN sub-Assembly



The Management Committee agreed with the proposal to have a data sharing agreement between Ag and PM CN sub-assembly including a cost sharing dimension to formalize the use of silver data in the dicyanoargentate dossier. A draft agreement and a cost sharing proposal will be prepared and submitted to the Management Committee for discussion at the next meeting (6 October 2016).

2. Agfa Gevaert

Agfa Gevaert declined the proposal to become a PMC member. An updated LoA agreement, as an invoice for the work done between 2014-2016 have been sent. **Regarding the current cooperation agreement, the Management Committee recommended to leave it as it is and reconsider the need to clarify certain areas if and when needed.**

3. Reconsile

The cooperation agreement has been signed end of April and received back from Reconsile on 12 May 2016. This formalizes the cooperation between Reconsile and PMC and will allow the new LR to proceed with creation of the Joint Submission.

4. European Silver Task Force (ESTF) request to use a study on silver

PMC Secretariat received a request from the ESTF to use a study owned by PMC members of the Silver Sub-Assembly to support their read-across approach used in the silver nitrate biocide dossier. The Management Committee agreed to share this data with ESTF since this is in the benefit of all to use same and good quality data. For the cost, it is suggested to review the cost of the study and for the costs related to administration to apply 25% of the study cost.

7. Approval process: standard and exceptions (one registrant, Annex III)

To ensure the respect of the approval procedure included in the Consortium agreement but ensure also some efficiency and pragmatism in the registration dossiers approval process, **the Management Committee approved the recommendation of the Secretariat that for Annex III exempted substances and the substances for which there is only one registrant, a “fast track procedure”** applies, sending at once the dossiers for approval to the WG, the Management Committee and the Sub-Assembly and to proceed with the registration as soon as approval of the Management Committee and the relevant registrants from the Sub-Assembly has been received.

8. A.O.B and closure of the call

1. Reelection of the Management Committee 2017-2019

Following the Consortium agreement, the Management Committee must be reelected every 3 years. The next elections by the Assembly will take place in December 2016. Guy Ethier requested that this topic will be included in the June 2016 Assembly agenda and that current members of the Management



Committee will be ready to make a statement in June regarding their willingness to continue or not as Management Committee member. France Capon underlined the need at this critical point of the process (so close to the registration deadline) and after so many changes in the PMC staff to ensure a maximum stability at Management Committee level.

2. Data Sharing updated guidance

The update of the data sharing guidance is ongoing to reflect the recently published Implementing Act on data sharing. Nissanka Rajapakse highlighted the fact that ECHA and the Commission are not in favor of a data sharing system which is not done by Legal Entity. This could have an important impact on the current data sharing system applies at PMC level. The Secretariat confirmed indeed that the ongoing update of the guidance (and especially this point) could have consequences on the PMC data sharing principles and therefore, the Secretariat is deeply involved with Eurometaux into the PEG (Partner Experts Group) discussions. Guy Ethier suggested that a summary of the issue, ongoing actions and potential consequences are presented to the Assembly in June.

3. Silver: Substance Evaluation

The Ag WG requested the Secretariat to investigate the possibility to lodge an appeal on Ag Evaluation. K&L Gates prepared a note based on the current available information and focused mainly on the concept of proportionality. **Due to the positive outcome of the MSC (Member State Committee), the Management Committee recommends to not lodge an appeal on Silver Evaluation** and stop investigating this for sake of resources. However, in a broader context, the Management Committee supports the need to conduct advocacy activities to ensure that the proportionality principle is taken into account when requiring additional information on nanos. The issue will be discussed with the Ag WG when the Final Decision will be available.

List of annexes:

Annex 1: Participants list as listed below

Annex 2: Preparatory document on Finances

Annex 3: Draft agenda of June 2016 GA

Annex 4: Draft Workplan 2017

Annex 5: Slides presented at the meeting



Annex 1: Participants

Francisco Boo, Metalor (Switzerland)

Roland Brasch on behalf of Markus Willeke, Heraeus (Germany)

France Capon, EPMF (Belgium)

Guy Ethier, Umicore (Belgium)

Nissanka Rajapakse, Johnson Matthey (UK)

Audrey Rondepierre, EPMF (Belgium)

Holger Zitt, BASF (Germany)

Apologies:

Michael Herman, Ames (United States)

Jörn Mühlenfeld, Aurubis (Germany)

Juha Parkkinen, Norilsk Nickel (Finland)

Heinz-Günter Schenzel, C. Hafner (Germany)

Markus Willeke, Heraeus (Germany)