



PMC REACH News



Dear Members,

We hope you had a great summer and came back with recharged batteries! For the PMC team, the summer has been a good opportunity to think about improving our communication with our membership. Activities at the PMC are constantly increasing and it could become more and more difficult for you to keep track of the different issues and to have an overview of the main challenges and opportunities. Therefore, the PMC team decided to issue on a quarterly basis a newsletter summarizing our main activities in different fields: administration, technical matters or advocacy.

We hope you will enjoy this first issue. Please feel free to send us back your comments and recommendations so we can improve the next issue expected in December 2015.

We wish you a good reading!

France





PMC Administration

Outcome of the Assembly meeting (June 2015)

The main decisions of the Assembly can be summarized as follows:

Dr. Heinz-Günter Schenzel has been elected as Vice-chair of the Assembly. Due to the latest changes in the scope of the consortium, a significant overrun of the 2015 budget is expected: reserves will be used but extraordinary invoices will be issued in September 2015. To ensure stability and a better predictability for the human and financial resources, the scope of the consortium has been frozen until the next registration deadline (2018). The cost sharing formula for the consortium and the letter of access will be reviewed and updated to better reflect the current situation within the consortia and ensure a fair and equal treatment of all co-registrants. The minutes have been circulated on 11 June 2015 and can be resent upon request.

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Human resources

New Scientific Manager: the replacement of Renaud Nicolay is ongoing. Several interviews have been scheduled end of August and we hope to be able to present you the new Scientific Manager in December 2015 at the next PMC Assembly meeting and in the next issue of this newsletter.

Regulatory Affairs Manager: due to the workload in preparation of the next registration deadline and the increase of unexpected regulatory activities (e.g.: CLH proposal of silver zinc zeolite), the Assembly approved in June 2015 the appointment in 2016 of a Regulatory Affairs Manager to support PMC activities. The Job description is under approval and will be posted in September 2015. We thank you in advance for sharing this information with your network.

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Finance

2015 accounts: In June 2015, the Assembly approved a significant overrun of the 2015 budget. Here below you can find the 2nd quarterly report of 2015 including the overrun approved by the Assembly:

	2015 Budget	2015 Forecast (30/06/2015)	Expenses by 30/06/2015	Committed by 30/06/2015	Remaining available budget ¹	
2.1	Generic costs	€ 789.928	€ 902.105	346.342 €	€ 874.008	€ -84.080
2.2	Ag-specific costs	€ 241.415	€ 280.415	81.891 €	€ 134.639	€ 106.776
2.3	Au-specific costs	€ 56.650	€ 124.792	41.680 €	€ 121.610	€ -64.960
2.4	PM CN- -specific costs	€ 193.900	€ 322.790	120.457 €	€ 319.984	€ -126.084
2.5	PGM-specific costs	€ 1.168.010	€ 2.120.010	304.892 €	€ 1.608.814	€ -440.804
2.6	Re-specific costs	€ 9.450	€ 9.450	1.677 €	€ 2.600	€ 6.850
2.7	Refinables-specific costs	€ 365.824	€ 365.824	12.770 €	€ 195.582	€ 170.242
2.8	Hydrazine-specific costs	€ 78.000	€ 100.000	0 €	€ 100.000	€ -22.000
	TOTAL	€ 2.903.177	€ 4.225.386	€ 909.709	€ 3.357.237	€ -454.060

1. Remaining available budget is calculated as follows: budget 2015-committed money



The increased forecast for Au and PM CN projects will be discussed early September by the Management Committee and a recommendation will be presented to the Assembly in December 2015.

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2016 Workplan: over summer, the PMC staff met to review and update the draft 2016 WP including the draft budget which is estimated at €4,2 million. Updated detailed figures will be reviewed by the relevant working group during the back-to-back working group meetings (13-15 October 2015), presented to the Management Committee on 27 October and finally approved by the Assembly on 2 December 2015.

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PMC Technical matters

Ag and compounds

Substance Evaluation of Ag metal (nano): PMC comments on the draft decision on silver metal (nano) have been successfully submitted mid-June 2015. The comments are focused on generic principles (e.g.: proportionality of the decision, lack of clarity in the use of certain wording, request for the extension of the deadline to comply with the decision, identification of nanosilver registrants); on the methodology proposed for phys-chem testing and characterisation of nanosilver and finally on the experimental design for the soil fate testing. The e-MS has given us the possibility to update the silver dossier by 1 November 2015 to allow better identification of nanosilver registrants and to include recent information. Feedback from the e-MS on our comments is not expected before end of 2015.

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CLH of silver zinc zeolite: PMC comments on the CLH dossier of silver zinc zeolite proposing a classification of carcinogen cat. 2 and reprotox cat. 1B (the latter based on silver ion) have been successfully submitted on 28 July 2015 and are publicly available on the ECHA website. The next important step will be the discussion of the dossier at the RAC meeting end of November 2015. Some advocacy activities will be conducted in coordination with the ESTF (European Silver Task Force). Given the data gap on reproductive toxicity for silver, the Ag WG has decided to submit a testing proposal for an EOGRTS together with the dossier update related to the Substance Evaluation.

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Au and compounds

Status REACH dossier: Testing of the gold substances is in the final phase and we are awaiting the last reports shortly. Uses have been identified and compiled and the work on the exposure scenarios will start in the coming weeks.

Physical forms tetrachloroauric acid (TCA): It was brought under our attention that TCA is not only produced as an aqueous solution but also as a hydrate. Therefore the pure hydrated form of TCA will be registered and



the solution will be considered as a mixture. Due to the change in registration of the physical form of TCA, additional physicochemical endpoints have to be included in the dossier for which extra testing might be needed.

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Ir and compounds

Ir and compounds will be registered by end of 2015. Uses have been collected and outstanding physical-chemical properties have been determined. The substance identification is now finalized. Iridium tetrachloride is now identified as a 'Reaction mass of iridium tetrachloride and iridium trichloride'. This change could slightly delay the registration of this substance until early 2016 due to additional work needed. A second change is foreseen: Iridium trichloride will be registered as hydrated form only. The practical implications of these changes are under assessment.

Over summer, Iridium blacks have been characterized to determine whether or not these materials meet the definition for nanomaterials. The Secretariat is currently evaluating the data together with the respective registrants.

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Pd and compounds

Pd and compounds will be registered by Q3 2016. Testing is finalized, as the PNECs derivation. The DNEL derivation is ongoing. Exposure scenarios will be developed early 2016 when final DNELs will be available and the environmental emissions monitoring campaign will be completed.

Over summer, Palladium blacks have been characterized to determine whether or not these materials meet the definition for nanomaterials. The Secretariat is currently evaluating the data together with the respective registrants.

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PM CN

GHS classification update Potassium dicyanoargentate: Recent testing of Potassium dicyanoargentate has revealed that it causes skin corrosion. Due to these test results skin corrosion 1A will be added to the GHS classification of Potassium dicyanoargentate.

Status REACH dossier: Testing of Silver cyanide and Potassium dicyanoaurate are in the final phase and we are awaiting the last reports shortly. Uses have been identified and compiled and the work on the exposure scenarios will start in the coming weeks. For Potassium dicyanoargentate, the repeated dose and genotox tests are being scheduled in the beginning of 2016.

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Pt and compounds

Registration preparation: New testing required due to tonnage increases have been initiated on Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol and on Karstedt Concentrate. An agreement with the Reconcile consortium has been reached: PMC is in charge of the dossier preparation and Heraeus will be the lead registrant.

Over summer, Platinum blacks have been characterized to determine whether or not these materials meet the definition for nanomaterials. The Secretariat is currently evaluating the data together with the respective registrants.

Due to the classification of chloroplatinates as respiratory sensitizers (see also next point), special attention will be required for the DNELs /DMELs derivation for these substances. An expert group has been formed and will work in close collaboration with IPA, which has been compiling relevant epidemiology data over the past years.

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Shadow RMOA on chloroplatinates: The chloroplatinates carry a respiratory sensitizer harmonized classification. This put these substances at risk in the context of the SVHC Roadmap and the related regulatory pressure. Proactively, the PMC decided to conduct a shadow RMOA on chloroplatinates. The aim is to prepare for the eventuality of some regulatory actions that would initiate an EU MS or ECHA (on behalf of the EC) in the context of the SVHC Roadmap. The objectives are exploring all possible RMO that may potentially apply to chloroplatinates, from both an industry and a regulator perspective; discover, through a series of selection steps and substantiating argumentations, the most adequate and proportionate RMO applicable to chloroplatinates and finally identify the knowledge and data gaps to be addressed by industry to make a convincing contribution to an official RMO exercise. A first draft of the RMOA will be presented and discussed on 25 August between PMC members, IPA and the consultant in charge (Michel Vander Straeten). The final RMOA is expected by October 2015.

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Re and compounds

The registration dossiers for all Re compounds in scope were submitted in 2013-2014. Literature search updates were recently carried out and there were no relevant results returned for the environment or for human health (i.e. nothing requiring update of the dossiers).

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Refinables

PMC is currently checking substance identity (SID) determination for each one of the Refinables in line with the newly proposed ECHA methodology. An SID decision tree has been developed mentioning the Refinables per process, supplemented with a document with definitions for all refining processes. The structural representation of all Refinables is currently ongoing.

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Rh and compounds

Rh and compounds will be registered by Q3 2016. Testing is proceeding as planned. Uses have been identified. The Secretariat is assessing the possibility to register earlier some Rh compounds.

Over summer, Rhodium blacks have been characterized to determine whether or not these materials meet the definition for nanomaterials. The Secretariat is currently evaluating the data together with the respective registrants.

The substance identification is now finalized. Rhodium trichloride will require registration as hydrated form only. The practical implications of this change are under assessment.

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Ru and compounds

Ru and compounds will be registered by mid-2017. New testing required due to the tonnage increase of Ruthenium trichloride hydrate have been initiated. Uses have been identified. Pending testing on Tetraammonium decachloro-mu-oxodiruthenate has also started, following the clarification of substance ID (change from Diammonium hexachlororuthenate). The substance identification is now finalized. Ruthenium trichloride will require registration as hydrated form only.

Over summer, Ruthenium blacks have been characterized to determine whether or not these materials meet the definition for nanomaterials. The Secretariat is currently evaluating the data together with the respective registrants. The practical implications of the latest changes are under assessment.

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Hydrazine

Over summer the second phase of the Occupational exposure assessment project has been conducted. Sites visits and monitoring campaign have been conducted by WES (consultant in charge of the project) to demonstrate that exposure to hydrazine in the precious metals industry is minimum and compliant with the most stringent standards. A draft report will be available in September 2015 and will be used in case of prioritization of hydrazine for Authorisation.

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Miscellaneous

Data Sharing Implementing act

In June 2015, the CARACAL discussed an updated version of the Data Sharing Implementing Act to be implemented by the industry in preparation of the 2018 deadline. Major concerns have been raised by Eurometaux and written comments have been submitted by mid-July 2015. These concerns are mainly related to certain requirements related to data sharing to be applied retroactively to existing agreements. The adoption is foreseen in Q4 2015.

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Calendar

- **3 September:** Eurometaux Authorisation & Restriction platform meeting
- **7 September:** PMC Cost sharing WG meeting
- **9 September:** PMC Management Committee conference call
- **23 September:** Eurometaux REACH Forum meeting
- **13 October:** PM CN WG and Au WG meetings
- **14 October:** PGM experts WG and PGM WG meetings
- **15 October:** Ag WG and Refinables WG meetings
- **27 October (AM):** PMC cost sharing WG meeting
- **27 October (PM):** PMC Management Committee meeting
- **17 November:** ECHA/Commission workshop on AfA simplification
- **1 December (PM)-2 December:** PMC Assembly meeting

Acronyms

Afa: Application for Authorisation
CARACAL: Competent Authorities for REACH and CLP
CLH: Classification & Labelling Harmonization
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
e-MS: Evaluating Member State
EOGRTS: Extended One-Generation ReproToxicity Study
ESTF: European Silver Task Force
IPA: International Platinum Association
MSC: Member States Committee
PMC: Precious Metals & Rhenium Consortium
RAC: Risk Assessment Committee
RMM: Risk Management Measure
RMOA: Risk Management Option Analysis
SVHC: Substance of Very High Concern
WG: Working Group