



CALENDAR:

4-6 October 2016:
PMC Autumn back to
back meetings,
Brussels

6 October 2016 AM:
PMC Management
Committee

6 October 2016 PM:
Brainstorming session
on PMC after 2018

6-7 December 2016:
PMC General
Assembly, Brussels

Welcome and Introduction

Dear Members,

The second quarter of 2016 has been full of challenges, events and surprises! Indeed, after 22nd of March 2016, Brussels tried to get back to normal; the UK voted for the Brexit and the Euro cup 2016 is bringing back some fun in this strange period! In parallel, REACH is running at full speed with a high level of activities at Secretariat level but also soliciting more and more the input of the companies. The latter is of course critical to ensure that the work can be done in a smooth way, on time and of good quality. The team fully realizes that the pressure is continuously increasing on the companies and especially on the leading ones but I would like to remind you that without your timely input the work cannot progress and the overall workplan and strategy including the final deliverables will be put at risk. I would like therefore to ask you to provide the missing information and requested input in due time and to ensure good back up plans during your holidays!

I wish you a good and relaxing holiday!! And hope to see you all back full of brilliant ideas, energies and motivation!



France



PMC Administration

Assembly meeting in Wroclaw (June 2016)

The Assembly meeting of the PMC has been organized on 1 and 2 June 2016 in Wroclaw. The meeting was split into two sessions: one dedicated to the update on the progress of the different projects, another one was focused on administrative issues (approval of 2015 audited accounts, status of 2016 accounts, forecast for 2017 as discussions on potential impact of the Data Sharing Implementing Act on PMC). For more details please consult the minutes circulated in June 2016.

For more info: france.capon@epmf.be

Finance

2016 Accounts

Overall cash flow situation is good and the reserves are satisfactory but tight and especially for certain projects like Au and some PGMs. This means that reserves must be built in the future to maintain the agreed 5-7% reserves depending on the project. At the General Assembly, key messages were focused on TCA, PGMs transitional period and the consequence of the postponement of Iridium submission with 5 months delay (no money has been carried over in 2016 budget but this money is available in "the committed").

Attention has been raised on the status of the Au project budget. Indeed, due to the need of repeating the OECD 422 test on TCA, the forecast for 2016 is above budget. However, thanks to the reimbursement of the testing and some related costs (sample costs) by Covance the situation will significantly improve.

		2016 Budget to be spent	2016 Budget to be invoiced	2016 Forecast	Expenses by 30/04/2016	Committed	Remaining available budget (2016 budget- Expenses- Committed)
2.1	Administrative costs	€618.800	€618.800	€618.800	€152.540	€286.558	€179.702
2.2	Ag-specific costs	€681.250	€689.903	€681.250	€53.213	€146.407	€481.630
2.3	Au-specific costs	€122.700	€79.550	€307.450	€38.139	€68.565	€15.996
2.4	PM CN- -specific costs	€388.500	€288.200	€388.500	€53.421	€200.418	€134.661
2.5	PGM-specific costs	€2.478.250	€1.785.448	€2.479.608	€347.895	€1.651.745	€478.610
2.5	PGM- horizontal costs					€ 486.902	€ -486.902
2.5a	Pt-specific costs	€ 1.183.955	€ 645.102	€ 1.183.955	€ 97.252	€ 582.656	€ 504.047
2.5b	Pd-specific costs	€ 572.405	€ 622.173	€ 572.405	€ 166.083	€ 11.714	€ 394.608
2.5c	Rh-specific costs	€ 162.470	€ 171.217	€ 162.470	€ 23.935	€ 73.011	€ 65.524
2.5d	Ru-specific costs	€ 558.420	€ 345.956	€ 558.420	€ 50.933	€ 496.104	€ 11.383
2.5e	Ir-specific costs	€ 1.000	€ 1.000	€ 2.358	€ 9.692	€ 1.358	€ -10.050
2.6	Re-specific costs	€11.400	€11.400	€11.400	€936	€5.000	€5.464
2.7	Refinables-specific costs	€772.550	€277.550	€772.550	€3.986	€246.065	€522.499
2.8	SVHC Roadmap-specific costs	€20.000	€20.000	€0	€0	€0	€20.000
	TOTAL	€5.093.450	€3.770.851	€5.259.558	€650.130	€2.604.758	€1.838.562



PMC Technical matters

Ag and compounds

Substance Evaluation of Ag metal (nano): PMC Secretariat participated to the Member State Committee (MSC) meeting on 25-29 April 2016 where the silver draft decision was discussed. After PMC's intervention, MSC agreed that the registrants should perform physico-chemical characterisation and ecotoxicity testing (on algae, long term toxicity on aquatic invertebrates and on soil microorganisms) only on the smallest nano form with the highest specific surface area that is covered by the REACH registration dossier, and only in case any of the ecotoxicity tests show higher toxicity for nano silver as compared to ionic silver, further fate testing will have to be undertaken. Furthermore, information on the uses for each individual nano form is still requested. PMC is pleased with the outcome of the meeting and will assess the impact on the silver workplan and budget and initiate the requested testing when the final decision is received.

For more info: katrien.arijs@arche-consulting.be

CLH of silver containing active substances (SCAS) under BPR: New CLH proposals of SCAS are not expected before the end of 2016.

For more info: katrien.arijs@arche-consulting.be or marie.gorkem@epmf.be

Au and compounds

Registration: The registration of **gold, balsams, copaiba, sulfurized, mixed with turpentine, gold salts and aurio(1+) 2,6,6-trimethylbicyclo[3.1.1]heptanethiolate** have been finalized.

Testing status of TCA: An agreement with Covance was found to reimburse the **OECD 422 and 474 studies** with TCA. A retest of the combined repeated dose toxicity study is initiated with LPT and the testing will start in August-September.

For more info: vincent.dunon@arche-consulting.be

Ir and compounds

The REACH registration dossiers for Iridium metal, Diammonium hexachloroiridate and Hexachloroiridic acid have been successfully registered by the LR. The co-registrants who have not yet submitted the dossiers will be able to do so in the coming weeks when the upgraded version (from IUCLID 5 to IUCLID 6) of the Ir dossiers will be available.

For more info: jelle.mertens@epmf.be

Pd and compounds

A couple of additional phys.-chem. tests are required for 2 Pd compounds. Setting up the contracts with the labs has taken more time than anticipated and isolating/providing the samples is still ongoing. As a consequence, the registration of these 2 Pd compounds might be slightly delayed.



For all Pd dossiers, the exposure scenarios have been finalised, the IUCLID files are being completed and the last pieces of information are being requested and prepared. The review of these registration dossiers is expected to start early July. Registration by the LR is expected in September 2016

For more info: maxime.eliat@arche-consulting.be

PM CN

Testing status of KAg(CN)₂: The second phase of the toxicity testing is progressing as scheduled. The key combined repeated dose toxicity study is ongoing and a first draft is anticipated in September.

Registration: The reviewing process for the registration dossiers of **silver cyanide** and **potassium dicyanoaurate** has been initiated and registration by the lead registrant is expected in August-September.

For more info: vincent.dunon@arche-consulting.be

Pt and compounds

Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol: the ecotoxicity and mammalian toxicity testing is proceeding on schedule. The testing on irritation is completed and the dose range finder for the repeated dose toxicity test - the longest-duration test – will be initiated soon.

Platinum dinitrate: a couple of additional phys.-chem. parameters need to be determined. The contact with the lab has been signed and test sample requested.

Karstedt concentrate: The cooperation agreement between PMC and Reconcile has been signed. The testing program on Karstedt concentrate is progressing on schedule. Barring any unforeseen events, the tests will be completed in November this year and the draft dossier can be finalised by end 2016.

Chloroplatinates: On the 25th of May 2016, the Chloroplatinates WG has brainstormed and decided on a qualitative approach for the occupational exposure assessment for the respiratory sensitizing Pt compounds. The occupational exposure assessment is ongoing on that basis and a first draft is expected on the 21st of June 2016.

The DNEL reports for all Pt compounds requiring a Chemical Safety Assessment have been drafted and reviewed while the PNECs are expected to be drafted by the 30th of June.

During the PGM BtB meetings, it was agreed to have the Pt genotox database reviewed by an external consultant in order to advice on an intelligent in vivo testing proposal strategy. Prof David Kirkland has been contracted, and the final report is expected at the end of August 2016.

For more info: maxime.eliat@arche-consulting.be

Launch of AoA to Chloroplatinates: Further to PMC shadow RMOA on chloroplatines, PMC decided to conduct this year an Assessment of Alternatives (AoA) in order to further substantiate the RMOA conclusions as regards uses and alternatives assessment.

The project was launched at a meeting on 22 June in presence of appointed consultants, Jens Torslov from DHI and two independant experts: Dr Martin Lok for catalysts and Dr Hubert Schmidbaur for refining and plating. The aims of the meeting were to ensure a common understanding on the general approach and scope



of the project. At the same time, it also revealed information gaps as regards certain uses which will have to be filled in the course of the project. It was agreed to have a first interim report end October and another meeting mid-November.

For more info: marie.gorkem@epmf.be

Re and compounds

Dirhenium heptasulphide dossier will be submitted in 2016 once the LR has provided the necessary information.

For more info: katrien.arijs@arche-consulting.be

Refinables

PMC Secretariat is following ongoing UVCB substance identity (SID) discussions between ECHA and Eurométaux and checking SID determination for each one of the Refinables. Refined SID sheets have been developed for the Refinables following the approach proposed by Eurométaux. Further information from the registrants has been requested. Those registrants that have not provided input yet, are requested to do so as soon as possible.

For more info: katrien.arijs@arche-consulting.be

Rh and compounds

During the PGM WG meetings in April, it was agreed to:

- classify the water soluble Rh(III) compounds (Rh trichloride, -trinitrate, -sulphate, -acetate and triammonium hexachlororhodate) as Muta2
- classify diammonium sodium hexakis(nitrito-N)rhodate as Muta2 (precautionary basis)
- not classify Rh metal.

For the poorly water soluble Rh(III) compounds (Rh trioxide, -trihydroxide, -tris(3-ethylhexanoate) and -triiodide), it is not possible to decide on their mutagenic potential. It was decided to:

- perform AMES tests on the 3 compounds lacking this information
- develop a good strategy for further in vivo testing (included in REACH dossiers via testing proposals) after considering the chemistry & speciation of the compounds and an internal review of the available data.

For Rhodium tris(2-ethylhexanoate), a couple of additional phys-chem parameters need to be determined. The contact with the lab has been signed and test sample requested.

The REACH registration dossiers are scheduled to be finalised Q2 2017.

For more info: jelle.mertens@epmf.be



Ru and compounds

The testing program is ongoing for:

-RuCl₃: the dose-range finders for ecotox are finalised, and the main experiments will follow soon. For mammalian tox, the DRF study for repeated dose toxicity (RDT) is finalised, and the main study (OECD407) will be initiated early July. Based on this testing, a reproduction/developmental tox screening test (OECD 421) will be performed afterwards.

-Tetraammonium decachloro-mu-oxodiruthenate(4-) (TetradoRu): the DRF study for RDT is finalised, and the main combined RDT study with reproduction/developmental toxicity screening (OECD422) is scheduled to start in September.

The REACH registration dossiers are scheduled to be finalised Q3 2017.

For more info: jelle.mertens@epmf.be

SVHC Roadmap

30 PMC-relevant substances in the current SVHC Roadmap: PMC conducted a review of all substances currently addressed under the SVHC Roadmap in order to have a clear picture of what it contains and to identify critical substances for the precious metals sector. The outcome of this exercise, which requested members' feedback about over 1000 substances, led to the identification of 30 substances of interest for PMC. PMC-relevant substances are spread accross all SVHC Roadmap processes, from Substance Evaluation to Authorisation, and are used or present in various precious metals related processes, as shown in the below table. Regulatory developments in relation to these substances are being closely monitored.

Process at stake	Substances (non exhaustive)	PM-related uses
Authorisation	Chromium trioxide	Refinables
	Diarsenic trioxide	Refinables
Recommended for Authorisation	Borates	Analytics, electroplating, soldering fluxes
	RCFs	Insulation, catalysts
	Lead dinitrate	Catalysts, gold cyanidation, electroplating
SVHC	Hydrazine	Reducing agent
	Lead monoxide, Lead oxide sulfate, Lead diacetate	Refining, frits production, analytics, catalysts, Electroplating
	Cadmium, Cadmium chloride, Cadmium oxide	Refinables, analytics
RMOA	Formaldehyde	Catalysts, refining
CoRAP	Carbon black, Cerium dioxide, Zinc oxide, Titanium dioxide, Silicon dioxide	Refining, refinables, catalysts, contact materials
CLH	Lead metal, nitric acid	Refining

For more info: marie.gorkem@epmf.be

Use mapping exercise for Pb/Pb compounds in Precious Metals Refining: In a draft recommendation issued early this year (the so-called ECHA's draft 7th list), ECHA proposed the inclusion of four lead compounds, including lead monoxide, in REACH Authorisation. While lead monoxide may intentionally be used as such in precious metals refining, the other lead compounds may be present in refinables.



A meeting was organised on 22 June in order to clarify the possible uses and occurrences of these four compounds as well as of lead and other lead compounds in the precious metals industry since the lead substance group in general figures high on the Authorisation agenda.

During the meeting, an initial assessment from an Authorisation standpoint has been conducted to see which uses may fall within the scope of Authorisation or may be excluded/exempted. A strong exemption possibility remains the existence of a binding OEL for workplace uses of lead substances. However, this is still under discussion within ECHA and the Member States. PMC will contribute to the advocacy effort up to the final decision by the European Commission in order to support such an exemption. In parallel, it was agreed to develop a position paper on intermediate uses in precious metals refining and to discuss it if needed with ECHA within the Eurometaux/Cefic-ECHA Intermediate platform. Further discussions on ECHA's 7th draft list will take place at the Member State Committee Meeting in September. An update of the Authorisation list is not expected before 1Q2017.

For more info: marie.gorkem@epmf.be

REACH review: The European Commission is set to issue a report by 1 June 2017 reviewing REACH implementation over the past five years. Ahead of this report, Member States and ECHA have already submitted their assessment and recommendations. A public consultation will be organised later this year in order to collect input from all stakeholders including industry. PMC contributed to the development of an Eurometaux position, which contains five main recommendations:

- 1) REACH should become the reference dataset for other legislations
- 2) Substance screening, prioritisation should be driven by risk, not hazard
- 3) RMOAs should be used systematically and according to an harmonised methodology prior to any regulatory measure
- 4) It should be possible to apply Authorisation to certain uses of a substance only, instead of having to apply for authorisation for all uses
- 5) Overlaps and inconsistencies with other legislation (e.g. OSH) should be avoided

Remarkably, there seems to be a consensus on the fact that REACH text should not be reopened due to the high risk of entering a new legislative process in the European Parliament and Council. It is therefore already expected that further improvement as regards REACH will have to take place within the boundaries of the current text via better implementation.

For more info: marie.gorkem@epmf.be



Acronyms

Afa: Application for Authorisation
BPR: Biocidal Products Regulation
CARACAL: Competent Authorities for REACH and CLP
CLH: Classification & Labelling Harmonization
CoRAP: Community Action Rolling Plan
CRO: Contract Research Organization
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
ILA: International Lead Association
LoA: Letter of Access
LR: Lead Registrant
MSC: Member States Committee
MSCA: Member State Competent Authority
PfA: Proposal for Amendment
PNEC: Predicted No-Effect Concentration
PMC: Precious Metals & Rhenium Consortium
RAC: Risk Assessment Committee
RMM: Risk Management Measure
RMOA: Risk Management Option Analysis
SCAS: Silver Containing Active Substances
STOT RE: Specific Target Organ Toxicity – Repeated Exposure
SVHC: Substance of Very High Concern
TCA: Tetrachloroauric Acid
UVCB: substance of Unknown or Variable composition, Complex reaction products or Biological materials
WG: Work Group