



CALENDAR:

19-21 April 2016:
PMC Spring back to
back meetings,
Brussels

1-2 June 2016:
PMC General
Assembly, Wroclaw

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

6 October 2016 PM:
PMC Management
Committee

7 October 2016 AM:
Brainstorming session
on PMC after 2018

6-7 December 2016:
PMC General
Assembly, Brussels

Welcome and Introduction

Dear Members,

We hope you enjoyed a good and peaceful Easter break, as good Belgian chocolate eggs!



2016 will be an important step for PMC deliverables: Ir, Au, PM CN and very soon Pd and some Rh dossiers are nearly ready for registration! It is time to maintain high level of energy for the PMC Secretariat and the membership to start this long run marathon bringing us to May 2018.

In parallel, other regulatory challenges are ahead of us with the CLH of silver biocides dossiers and the silver Evaluation. It is worth also to keep an eye on the SVHC roadmap activities and the potential prioritization of key substances for the precious metals industry like borates, Pb compounds or hydrazine.

We hope this 3rd edition of the REACH News will help you to keep up with all the PMC activities. We wish you a nice reading and we are looking forward to fruitful discussions at our next back-to-back meetings in April 2016!

France



PMC Administration

Human resources

Klaus Rothenbacher decided to terminate his contract as consultant with the Precious Metals Consortium after 7 years of collaboration. I would like to take this opportunity to thank him for his work and excellent scientific advice during the past years and to wish him the best for the future, in his new career. Klaus will leave us on 30th April 2016.

Jelle Mertens will ensure the secretariat and overall coordination of the PGMs project. Due to the nature of the remaining work to be done (finalization of some ongoing testing, derivation of PNECs and DNELs, exposure assessment), ARCHE (Maxime Eliat Eliat and relevant back office) will support Jelle Mertens in his new assignment. Klaus Rothenbacher will stop his activities for PMC on 30th April 2016.

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Finance

2015 Accounts

2015 accounts have been closed and audited early March 2016. The table below include an overview of the budget and expenses as the money committed until 2015 (and not yet invoiced, to be used from the reserves):

		2015 Budget	Expenses by 31/12/2015	Committed by 31/12/2015
2.1	Generic costs	€ 789.928	800.410 €	0 €
2.2	Ag-specific costs	€ 241.415	167.485 €	€ 67.000
2.3	Au-specific costs	€ 56.650	68.528 €	€ 63.500
2.4	PM CN- -specific costs	€ 193.900	213.883 €	€ 295.500
2.5	PGM-specific costs	€ 1.168.010	699.018 €	€ 1.854.185
2.6	Re-specific costs	€ 9.450	4.292 €	€ 0
2.7	Refinables-specific costs	€ 365.824	17.685 €	€ 178.893
2.8	Hydrazine-specific costs	€ 78.000	46.249 €	€ 0
	TOTAL	€ 2.903.177	€ 2.017.550	€ 2.459.078



2016 Accounts

2016 budget has been approved at the Assembly in December 2015. The table below summarizes the situation of the PMC accounts after the audit in March 2016.

		2016 Budget	Available cash flow by 31/12/2015	Committed reserves by 31/12/2015	Carry over to 2016	Reserves
2.1	Administrative costs	618.800	254.855	0	0	254.855
2.2	Ag-specific costs	689.902	338.521	0	0	338.521
2.3	Au-specific costs	79.550	68.385	0	30.150	38.235
2.4	PM CN- -specific costs	288.200	177.589	0	87.300	90.289
2.5	PGM-specific costs	-	2.056.963	1.134.600	706.400	215.963
2.5a	<i>Pt-specific costs</i>	645.102	514.241	414.600	383.800	-284.159
2.5b	<i>Pd-specific costs</i>	622.173	719.937	270.000	50.000	399.937
2.5c	<i>Rh-specific costs</i>	171.217	411.393	210.000	0	201.393
2.5d	<i>Ru-specific costs</i>	345.956	308.545	190.000	262.600	-144.055
2.5e	<i>Ir-specific costs</i>	1.000	102.848	50.000	10.000	42.848
2.6	Re-specific costs	11.400	189.468	0	0	189.468
2.7	Refinables-specific costs	277.550	641.403	169.000	326.000	146.403
2.8	SVHC Roadmap-specific costs	20.000	0	0	0	0
	<i>Hydrazine-specific costs</i>	0	86.208	0	0	86.208
	TOTAL	3.770.850	3.727.184	1.303.600	1.149.850	1.273.734



PMC Technical matters

Ag and compounds

Substance Evaluation of Ag metal (nano): ECHA sent the Proposals for Amendments (PfAs) on the silver metal Substance Evaluation draft decision to the relevant registrants on 26 February, together with the amended draft decision. Several (but not all) of PMC's original comments to the draft decision have been taken into account by the e-MS in the amended draft decision. PfAs are limited to comments from ECHA on the physico-chemical testing requirements (to be better justified or removed from decision), the number of nano forms to be tested for ecotox/fate testing and a number of more general comments (definition of form, request for clearer response to some of PMC's comments ...). PMC Secretariat has submitted comments to the PfAs on 29 March and will participate to the next MSC meeting on 25-29 April 2016 where the silver draft decision will be discussed. Although testing related to the Substance Evaluation cannot start until the final decision is issued, PMC Secretariat is preparing for the testing.

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CLH of silver containing active substances (SCAS) under BPR: PMC further followed up on the CLH dossier of silver zinc zeolite and, together with Eurométaux, raised a number of issues on the environmental classification (which was based on inappropriate methodology) at European Commission level. Furthermore, PMC Secretariat is following CLH proposals of other SCAS.

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Au and compounds

Registration: Review process of the registration dossiers for **gold** and **balsams, copaiba, sulfurized, mixed with turpentine, gold salts** are finalized and submission by the lead and co-registrant is currently ongoing. For **aurio(1+) 2,6,6-trimethylbicyclo[3.1.1]heptanethiolate** the reviewing process is initiated and registration is foreseen mid May.

Testing status of TCA: Additional physchem testing is started and should be finalized in May. Currently we are also discussing with Covance on a way forward on the OECD 422 and 474 studies. A final decision on the acceptance of the OECD 422 will be taken during the WG meeting on the 19th of April.

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

Ir and compounds

Registration: Review process of the registration dossiers of Iridium metal and Diammonium hexachloroiridate has been initiated and the final approval by the Assembly must be received by end of April 2016.

Spectra for Hexachloroiridic acid have been received in March but require further discussion with the LR, who is also the only registrant in the PMC.



Iridium trichloride and “Reaction mass of iridium tetrachloride and iridium trichloride” will not be registered since the LR (who was the only registrant) withdrew support for these compounds.

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Pd and compounds

A couple of additional phys.-chem. parameters need to be determined on four Pd compounds (Palladium sulphate, -nitrate, Tetramminepalladium(2+) diacetate, and -dihydroxide). They have previously been included in the PMC inventory as solutions only but the PGM expert group concluded that they are also available on the EU market as solids, requiring additional data (e.g., melting point, PSD, etc.). Testing can be done on short notice and will not have an impact on the overall timing.

DNELs have been finalised on 12 Feb. 2016 and the occupational exposure assessment is ongoing and will be finalized early April. The draft REACH dossiers will be ready by mid-April and will be discussed at the next PGM WG meeting on 20th April.

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PM CN

Testing status of KAg(CN)₂: The second phase of the toxicity testing is ongoing as scheduled. The key studies, dose range finding and combined repeated dose toxicity, have been initiated.

Registration: Currently chemical safety reports and exposure scenarios for AgCN and KAu(CN)₂ are being drafted. The reviewing process for the registration dossiers of AgCN and KAu(CN)₂ will start in May and registration will be initiated in July-August.

For more info: vincent.dunon@arche-consulting.be or maxime.eliat@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 repeated dose toxicity test - the longest-duration test – has been started.

Platinum dinitrate: a couple of additional phys.-chem. parameters need to be determined. It has previously been included in the PMC inventory as solution only but the PGM expert group concluded that it is also available on the EU market as a solid. Testing can be done on short notice and will not have an impact on the overall timing.

Karstedt concentrate: the substance ID card has been finalised. Reconsile confirmed sameness of the substance. The cooperation agreement between PMC and Reconsile is under finalization. The testing program on Karstedt concentrate has started due to the impossibility to use the existing incomplete data shared by



Reconcile. Barring any unforeseen events, the tests will be completed in November this year and the draft dossier can be finalised by end 2016.

Chloroplatinates: in February 2016, the PGM WG approved to conduct a qualitative approach for the occupational exposure for the respiratory sensitization. The PGM sector guideline value was considered not to be the optimal approach for REACH dossiers. A technical steering sub-group has been formed to manage and input into the qualitative assessment. The occupational exposure assessment is ongoing on that basis.

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Re and compounds

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

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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.

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Rh and compounds

The testing program for Rhodium and compounds has been finalised. The REACH registration of this group of substances will be split in time to spread the workload for the PMC members and Secretariat: five Rh(I) compounds (1-10 tpa tonnage class) will be ready for registration end of 2016, whereas the REACH dossiers of the remaining Rh substances will be prepared for Q2 2017.

The discussion on the potential genotoxicity classification of the Rh(III)-group members is ongoing. PMC secretariat is currently gathering further information, and aims to agree on the way-forward during the coming BtB meetings (19-20 April).

For more info: jelle.mertens@epmf.be

Ru and compounds

The ecotox and tox testing program is ongoing for RuCl₃ and TetradoRu (10-100 tpa substances) according to the agreed timeline. The REACH registration dossiers are scheduled to be finalised Q3 2017.

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SVHC Roadmap

Public consultation on lead monoxide (ECHA's draft 7th Recommendation for REACH Authorisation):

PMC submitted a contribution to the public consultation on lead monoxide in the context of ECHA's draft 7th Recommendation for new substances to be included in REACH Authorisation. Lead monoxide being already part of ECHA's previous Recommendation (the „6th list“), only information not available yet to ECHA was to be submitted. In this context, PMC identified the need to provide further clarification on the use of lead monoxide as laboratory reagent in fire assaying. On this point, PMC insisted on the criticality of this use and on the absence of alternatives to lead monoxide. Furthermore, and in line with ILA, PMC advocated for the exemption of this use from REACH Authorisation on the basis of Article 58.2 of REACH due to the binding OEL for lead and lead compounds which already ensures proper risk management. ECHA's final 7th Recommendation list is expected in June.

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Acronyms

Afa: Application for Authorisation
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