CALENDAR:

25 April 2017:
PMC after 2018, Brussels

18 May 2017:
PMC Management Committee, by conf call

31 May-1 June 2017:
PMC General Assembly, Pforzheim

17-19 October 2017:
PMC Autumn back to back meetings, Brussels

5-6 December 2017:
PMC General Assembly, Brussels

Dear Members,

2017 started at full speed with the finalisation of the registration of the Pd and Pd compounds and the finalisation of the Pt and Pt compounds which are now undergoing the last phase of the approval process. On the top of the preparation for registration, the first tier of the nanosilver testing for Evaluation is nearly completed and the results are now under analysis and discussion to assess the relevancy to conduct the soil fate testing.

The past months were also dedicated to improving our communication with the launch of the new EPMF-PMC website: www.epmf.be. The next steps will be to populate the members pages to ensure a smooth and efficient access to all the registration dossiers, together with the meeting documents. We also hope that this new feature will help us in the data sharing process for which activities drastically increased the past weeks.

Despite the fact that we are still in the course of the registration process, PMC needs to reflect on its future after 2018. As you all know, 2018 will not be the end of the story but only the beginning. New challenges will be in front of us: potential increase of requirements for substances between 1-10 t; moving from registration to risk management, filling the gaps identified through testing proposals etc. After the brainstomring session of October 2016, PMC will organize a meeting on 25th April to present the best option recommended by the Management Committee and prepare the Assembly of June 2017. We hope to see you there!

Enjoy the reading of PMC REACH News!

And we wish you a happy Easter break!

Best regards,

France

PMC Administration

Overview of PMC already registered substances

Name of the substance	Identification numbers		LR	Registered by LR
	CAS	EC		
Silver	7440-22-4	231-131-3	Aurubis	Nov 2010
Silver nitrate	7761-88-8	231-853-9	Ames	Nov 2010
Disilver oxide	20667-12-3	243-957-1	Ames	Oct 2010
Silver carbonate	534-16-7	208-590-3	Johnson Matthey	Mar 2012
Disilver(1+) sulphate	10294-26-5	233-653-7	Johnson Matthey	Mar 2012
Silver chloride	7783-90-6	232-033-3	Agfa Gevaert	Mar 2013
Silver bromide	7785-23-1	232-076-8	Agfa Gevaert	Mar 2013
Silver iodide	7783-96-2	232-038-0	Agfa Gevaert	Mar 2013
Gold	7440-57-5	231-165-9	C. Hafner	Apr 2016
Aurio(1+) 2,6,6-trimethylbicyclo[3.1.1]heptanethiolate	68365-87-7	269-858-3	Johnson Matthey	Jun 2016
Balsams, copaiba, sulfurized, mixed with turpentine, gold salts	68990-27-2	273-589-7	Heraeus	Apr 2016
Silver cyanide	506-64-9	208-048-6	Saxonia Edelmetalle	Nov 2016
Potassium dicyanoaurate	13967-50-5	237-748-4	Umicore Galvanotechnik GmbH	October 2016
Palladium	7440-05-3	231-115-6	Umicore NV/SA	Jan 2017
Palladium dichloride	7647-10-1	231-596-2	BASF	Jan 2017
Diamminedichloropalladium	14323-43-4	238-269-3	Heraeus	Jan 2017
Dichlorobis(triphenylphosphine)palladium	13965-03-2	237-744-2	Heraeus	Jan 2017
Palladium (II) di(4-oxopent-2-en-2-oate)	14024-61-4	237-859-8	Heraeus	Jan 2017
Palladium(II) acetate	3375-31-3	222-164-4	Heraeus	Oct 2016
Palladium monoxide	1314-08-5	215-218-3	Heraeus	Jan 2017
Tetraamminepalladium (II) nitrate	13601-08-6	237-078-2	Johnson Matthey	Jan 2017
Tetraamminepalladium(2+) dichloride	13815-17-3	237-489-7	Umicore AG&Co.KG	Mar 2017
Tetrakis(triphenylphosphine)palladium	14221-01-3	238-086-9	Umicore AG&Co.KG	Mar 2017
Disodium tetrachloropalladate	13820-53-6	237-502-6	BASF	Jan 2017
Diammonium hexachloropalladate	19168-23-1	242-854-9	Johnson Matthey	Mar 2017
Dipotassium hexachloropalladate	16919-73-6	240-974-6	C. Hafner	Feb 2017
Tetraammineplatinum dichloride	13933-32-9	237-706-5	Johnson Matthey	Feb 2017
Platinum dioxide	1314-15-4	215-223-0	Umicore AG&Co.KG	Mar 2017
Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes / Karstedt concentrate	68478-92-2	270-844-4	Heraeus	Feb 2017
Iridium	7439-88-5	231-095-9	Johnson Matthey	May 2016
Hexachloroiridic acid, Hydrogen hexachloroiridate (IV)	16941-92-7	241-012-8	Heraeus	June 2016
Diammonium hexachloroiridate	16940-92-4	241-007-0	Johnson Matthey	May 2016
Carbonyl(pentane-2,4-dionato-O,O')(triphenylphosphine)rhodium	25470-96-6	247-015-0	Johnson Matthey	Oct 2016
Carbonylhydrotris(triphenylphosphine)rhodium	17185-29-4	241-230-3	Umicore AG&Co.KG	Mar 2017
Di-μ-chloro-bis(hapto-1,5-cyclooctadiene)dirhodium(I)	12092-47-6	235-157-6	Heraeus	Sept 2016
Tris(triphenylphosphine) rhodium (I) chloride	14694-95-2	238-744-5	Umicore AG&Co.KG	Mar 2017
Tris(nitrato-O)nitrosylruthenium	34513-98-9	252-068-8	Umicore AG&Co.KG	Feb 2017
Rhenium	7440-15-5	231-124-5	KGHM Metraco	Sept 2013
Perrhenic acid (in solution)	13768-11-1	237-380-4	Heraeus	Nov 2013
Ammonium perrhenate	13598-65-7	237-075-6	Heraeus	Jul 2013
Sodium rhenate (in aq. solution)	13472-33-8	236-742-9	Climax Molybdenum	Mar 2014
Potassium perrhenate	10466-65-6	233-953-8	Heraeus	Aug 2013
Refinables (ALL)				Nov 2010

Finance

2016 final accounts

		2016 Budget *to be spent*	2016 Budget *to be invoiced*	Expenses by 31/12/2016	Committed Expenses by 31/12/2016	TOTAL Expenses by 31/12/16 + Committed	Remaining available budget (2016 budget-Expenses-Committed)
2.1	Administrative costs	€ 618.800	€ 618.800	€ 561.665	€ 0	€ 561.665	€ 57.135
2.2	Ag-specific costs	€ 681.250	€ 689.903	€ 215.331	€ 431.983	€ 647.314	€ 33.936
2.3	Au-specific costs	€ 122.700	€ 79.550	€ 7.110	€ 96.089	€ 103.200	€ 19.500
2.4	PM CN- -specific costs	€ 388.500	€ 288.200	€ 234.829	€ 75.322	€ 310.151	€ 78.349
2.5	*PGM- horizontal costs*				*€ 360.252*	*€ 360.252*	
2.5a	*Pt-specific costs*	*€ 1.183.955*	*€ 645.102*	*€ 735.869*	*€ 256.860*	*€ 992.729*	*€ 191.226*
2.5b	*Pd-specific costs*	*€ 572.405*	*€ 622.173*	*€ 365.891*	*€ 25.000*	*€ 390.891*	*€ 181.514*
2.5c	*Rh-specific costs*	*€ 162.470*	*€ 171.217*	*€ 139.308*	*€ 88.943*	*€ 228.251*	*€ 0*
2.5d	*Ru-specific costs*	*€ 558.420*	*€ 345.956*	*€ 391.582*	*€ 214.894*	*€ 606.476*	*€ 0*
2.5e	*Ir-specific costs*	*€ 1.000*	*€ 1.000*	*€ 13.813*	*€ 0*	*€ 13.813*	*€ 0*
2.6	Re-specific costs	€ 11.400	€ 11.400	€ 3.776	€ 5.000	€ 8.776	€ 2.624
2.7	Refinables-specific costs	€ 772.550	€ 277.550	€ 23.576	€ 183.893	€ 207.469	€ 565.081
2.8	SVHC Roadmap-specific costs	€ 20.000	€ 20.000	€ 0	€ 0	€ 0	€ 20.000
2.9	Hydrazine- specific costs	€ 0	€ 0	€ 2.800	€ 0	€ 2.800	-€ 2.800
	TOTAL	€ 5.093.450	€ 3.770.851	€ 2.695.550	€ 1.738.235	€ 4.433.785	€ 1.146.567

The 2016 PMC accounts have been audited in February 2017 and are currently under review by the Treasurer and the Financial Controller. PMC expenses (actuals and committed) are **20% below budget to be spent.** The main reasons are:

- Administrative costs: we have an underspent in travels and meetings due to a cost efficient Assembly in June 2016, in legal costs (no major issues with data sharing yet) and in salaries due to a non-indexation of the salaries, and the bonus which have been paid in 2017.
- Ag costs: cost efficient solution has been found for the literature review and the budget for the silver Evaluation was prepared before having received the final decision allowing a tiered approach.
- Au costs: the reimbursement of TCA testing and sample by Covance gives the impression of an underspent but overall, we are on budget.
- PM CN costs: the underspent is linked to the fact that one of the additional testing required took some time to be designed and the contract was only signed in February 2017. Therefore, a part of the left amount will be used in 2017 but is not included in the committed expenses by 31 December 2016.
- Pt and Pd costs: the significant underspent is due to the contingency added throughout the project as the budget foreseen in case of repeated testing needed. It is worth to note that if for Pd, we won't need to use this contingency anymore, there is still a risk for some Pt substances (HHPA) for which testing is still ongoing. In the case of Pt, we also save some money in the development of exposure scenarios and also in a change of strategy for Karstedt (waiving of a part of the ecotox test).

- Refinables costs: the project is lagging behind due to the significant delays in the discussions with ECHA regarding the IDs of UVCBs which delayed the program and the risk to be obliged to update the dossiers and perform additional ecotox testing.
- Hydrazine costs: a small overspent is recorded due to unexpected activities related to hydrazine in the context of the SVHC Roadmap project.

The 2016 audited accounts will be presented to the Assembly in June 2017 for validation.

PMC Technical matters

Ag and compounds

Substance Evaluation of Ag metal (nano): The ecotoxicity testing and physico-chemical characterisation of the smallest silver nanoform covered by the REACH registration dossier is ongoing and available testing results have been presented / discussed at the 23 March Ag WG meeting. All test reports should be available in April-May and a meeting / call with the eMSCA will be organised in May to discuss test results and clarify next steps / need for further fate testing (only in case any of the ecotoxicity tests show higher toxicity for nanosilver as compared to ionic silver, further fate testing will have to be undertaken). PMC is also finalising the data collection on the uses for the two silver nanoforms that are covered by the REACH registration dossier. If no further fate testing is needed, the dossier must be completed, approved and registered by 13 July 2017 (deadline set in the final decision by the authorities).

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

CLH of silver containing active substances (SCAS) under BPR: PMC had the opportunity to meet with Kemi in January, and to present the scope of the silver REACH dossier and the importance of consistency in data sets and methodologies used under REACH and the BPR. It is expected that the commenting period for the CLH proposals for silver zeolite, silver copper zeolite and silver sodium hydrogen zirconium phosphate will start around June-July 2017. The CLH proposal for elemental silver has been postponed and will probably be available for commenting after summer 2017. For silver copper zeolite, PMC is considering joint commenting with ECI.

For more info: katrien.arijs@arche-consulting.be or france.capon@epmf.be

Potential prioritisation of silver under the Water Framework Directive (WFD): During the review of the Priority Substances (PS) list for the WFD, silver has been shortlisted as a potential candidate for prioritisation / EQS derivation. JRC has drafted an EQS dossier for silver, with a proposed EQS that is 4 times lower than the REACH PNEC. The legislative process for review of the PS list has been postponed but it is expected that by the end of 2017, JRC will re-assess the relevance of substances to be included in the Watch List or PS list and need for EQS derivation. PMC will contribute to this process through Eurométaux and is currently building a robust, up to date silver ecotoxicity dataset to assess the need for a PNEC revision.

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

Au and compounds

Testing status of TCA: The **OECD 422** is ongoing and a draft report is expected by May 2017.

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 registered by the Lead Registrant, and co-registrants are kindly invided to register ASAP.

For more info: jelle.mertens@epmf.be

Pd and compounds

All dossiers have now been finalised; 13 are already registered by the Lead Registrant ('LR') and 4 are waiting registration by Lead Registrant. Co-registrants are kindly invided to register ASAP after registration by the LR.

Two dossiers were rejected by the manual completeness check from ECHA. The issues are being addressed and the dossiers will be resubmitted before the summer.

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

PM CN

Status of $KAg(CN)_2$: The occupational exposure scenarios have been drafted and commented. Due to additional analytics that are being performed in the OECD 422 testing, supporting exposure, the final report will be issued in June 2017. The registration of $KAg(CN)_2$ is still foreseen for Q3 2017.

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

Pt and compounds

Three dossiers have been finalised and registered by the Lead Registrant.

Eight dossiers are currently being approved by the Pt Sub Assembly and will be send out for registration by the Lead Registrant in April, except the Cplts dossiers which will be submitted by end of the year for regulatory reasons.

For two dossiers, testing is still running:

Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol: the main study for repeated dose toxicity has been initiated 5 December. The in-life phase is completed and the draft report is expected in June. The PMC internal timing for registration of this substance is Q4 2017.

Karstedt concentrate: The in-life phase of the repeated dose toxicity study, combined with an in vivo micronucleus assay, has been completed, and the final draft report is expected end of March. As approved by

the registrants and Management Committee, the dossier (including all available data) has been registered in February 2017 as foreseen by the PMC workplan and the agreement with Reconsile. An update is planned once the final report of the OECD 422 is available and the classification for this substance has been defined.

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

Analysis of Alternatives to Chloroplatinates: an interedimate report has been finalized by the consultants on 29 March 2017 and is under reviewed by the Secretariat. The relevant parts of the report will be shared with the companies which sent input to ensure that all the confidential information has been aggregated or removed before circulation ot the entire group. The final report is expected by end of April 2017 or beginning of May 2017.

For more info: france.capon@epmf.be

Re and compounds

The literature review from end 2016 returned no results requiring an immediate update of the Re / Re compounds dossiers. **Dirhenium heptasulphide dossier** will be submitted if requested by the LR.

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. A workshop with ECHA on substance identification will take place on 31 March to find a workable and acceptable solution for the industry and ECHA.

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

Rh and compounds

Four dossiers have been finalised and registered by the Lead Registrant.

The remaining 12 dossiers are in preparation:

-the drafting of the Annex VII and 2 Annex VIII dossiers is progressing as scheduled, and

-draft Annex III justification reports for the other 9 dossiers are available.

PNECs have been derived for diammonium sodium hexakis (nitrito-N) rhodate (only Rh substance requiring exposure scenarios).

The Rh(III) genetox data have been reviewed internally, and the PMC members decided on a way-forward. The AMES assay for the poorly water soluble Rh trihydroxide is negative (no reverse mutation activity detected).

Two Rh compounds (Rhodium tris(2-ethylhexanoate) and Rhodium sulphate) need additional phys-chem testing, and their registration will be delayed compared to the other Rh compounds (but still well ahead of the May 2018 deadline).

The Rh substance ID cards are currently under review by the registrants, except for one where company input is pending.

The REACH registrations (except those requiring additional phys-chem testing) are scheduled Q2 2017.

For more info: jelle.mertens@epmf.be

Ru and compounds

One dossier has been finalised and registered by the Lead Registrant.

The remaining 6 dossiers are in preparation:

-RuCl3: PNECs have been derived. The final report for the 28-day repeated-dose toxicity assay is available. The full draft report for the reproductive toxicity screening assay is expected end March-early April.

-tetraammonium decachloro-mu-oxodiruthenate(4-) (TetradoRu): PNECs have been derived. A first draft report for the 28-day repeated-dose toxicity assay combined with reproductive/developmental toxicity screening is available.

The uses and SID cards have been reviewed by the PMC members.

The REACH registration dossiers are scheduled Q3 2017.

For more info: jelle.mertens@epmf.be

SVHC Roadmap

The recommendation of the 7th list including Pb compounds including PbO is now on the desk of the Commission of final review and approval. The REACH Committee could discuss it at the earliest in April 2017 but it is a high risk (or chance!) to not have the majority needed to pursue with the prioritisation of Pb compounds. In the ECHA recommendation, the interpretation of the article 58(2) has been overstretched, the SVHC Roadmap WG agreed to contirnbute to a collective effort to performa legal review in preparation of further advocacy.

The first indications related to the 8th list are encouraging since hydrazine will not be selected due to the willingness of ECHA to oblige the Commission to decide on all the draft priority substances like Co compounds, B or RCFs. This means that the 8th list could still trigger the need for further advocacy for PMC.

Lastly, to ensure a more efficient monitoring of the critical substances for the Precious Metals industry, the Secretariat is investigating different monitoring tool which could facilitate this exercise.

For more info: france.capon@epmf.be

Miscellaneous

Hot topic at CARACAL meeting in March 2017: extension of the obligations for substances between 1-10 t

The Commission commissioned a third study under the review requirement of Art 138(3) on information requirements of 1 – 10 t substances (previous studies in 2012 and 2015). It also considers the review requirement of Art 138(1) on extension of the CSA/CSR requirement to CMR1A/B substances (previous report on this subject from 2014). As per article Study on information requirements of 1 – 10 t substances, including extension of requirements for CMR 1A 1B. The aim is to consider the following series of changes in the annexes:

Annex III

- Deletion of diffuse & dispersive use criterion (for all substances expected to be classified full Annex VII information would be required)
- Complete deletion of Annex III (for all substances full Annex VII (or VII+ or VII++) information would be required)

Annex VII+

Additional information requirements:

- Screening and assessment for PBT/vPvB properties
- 9.1 Aquatic Toxicity – a third test is required (on fish)

Annex VII++

Additional information requirements:

- Screening and assessment for PBT/vPvB properties
- 9.1 Aquatic Toxicity – a third test is required (on fish)
- 8.4 Mutagenicity – an extension to two test battery, additional screening test for cytogenicity
- 8.5 Acute Toxicity – dermal or inhalation toxicity studies added as in Annex VIII
- 8.6 Repeated Dose Toxicity as in Annex VIII already to be included in Annex VII

Combinations of the above amendments have been assessed in form of five different options as follows:

Table 1: Final combinations of options for analysis in Phase 3

Annex III Options	Information Options		
	Current Annex VII	Annex VII+	Annex VII++
Do nothing	**Baseline**	**Option A**	
Remove diffuse/dispersive use criterion (ND)		**Option D**	**Option B**
Remove all criteria		**Option C**	**Option E**

Overall the study indicates higher benefits vs costs (for all scenarios) in amending the annexes. According to it, amendments would give further support (scientific evidences) to MS and COM to identify risks and propose restrictions. There were no evidences of disproportionate impact on SMEs. The outcome of this discussion will have an important impact on the PMc work since 34 substances are registered between 1-10 t benefitting from the current possible exemption. The changes will not occur before 2018 registration deadline but timing is still unclear.

The next steps will be to comment on the study (deadline is 24th April 2017) and assess internally the impact on PMC workplan of the different scenarios.

For more info: france.capon@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
OEL: Occupational Exposure Limite
OHS: Occupational Health and Safety
PfA: Proposal for Amendement
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