



CALENDAR:

6-7 December 2016:
PMC General
Assembly, Brussels

21-23 March 2017:
PMC Spring back to
back meetings,
Brussels

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

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

Dear Members,

PMC Secretariat is really happy to announce that a significant number of dossiers have been finalized over summer and are ready for submission. Overall the workplan is on track. However, I would like to draw your attention on the fact that the overall timing is still very tight and that due diligence from companies is really important when reviewing the different parts of the registration dossiers in preparation of the final approval process. A timely input is really needed to avoid that critical changes would be required at the last stage of the approval process, jeopardizing the overall timeline and requested a new round of approvals. To help companies to plan and better understand the different steps, a processed description of the different phases of the preparation of the remaining registration dossiers will be available in the coming weeks. This will be presented at the next Assembly meeting to smooth the finalisation and submission of the 35 remaining dossiers.

Thanks again for all the support and timely contribution!



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 Deutschland GmbH and Co. KG	Apr 2016
Silver cyanide	506-64-9	208-048-6	Saxonia Edelmetalle GmbH	Ongoing
Potassium dicyanoaurate	13967-50-5	237-748-4	Umicore Galvanotechnik GmbH	Oct 2016
Palladium	7440-05-3	231-115-6	Umicore NV/SA	Approved
Palladium dichloride	7647-10-1	231-596-2	BASF	Approved
Dihydrogen tetrachloropalladate(2-) (in solution)	16970-55-1	241-047-9	Heraeus	Approved
Diamminedichloropalladium	14323-43-4	238-269-3	Heraeus	Approved
Dichlorobis(triphenylphosphine)palladium	13965-03-2	237-744-2	Heraeus	Approved
Palladium (II) di(4-oxopent-2-en-2-oate)	14024-61-4	237-859-8	Heraeus	Approved
Palladium(II) acetate	3375-31-3	222-164-4	Heraeus	Oct 2016
Palladium monoxide	1314-08-5	215-218-3	Heraeus	Approved
Tetraamminepalladium (II) nitrate	13601-08-6	237-078-2	Johnson Matthey	Ongoing
Tetraamminepalladium(2+) dichloride	13815-17-3	237-489-7	Umicore AG&Co.KG	Approved
Tetraamminepalladium(2+) dihydroxide	68413-68-3	270-241-6	Heraeus	Approved
Tetrakis(triphenylphosphine)palladium	14221-01-3	238-086-9	Umicore AG&Co.KG	Ongoing
Disodium tetrachloropalladate	13820-53-6	237-502-6	BASF	Approved
Diammonium hexachloropalladate	19168-23-1	242-854-9	Johnson Matthey	Approved
Dipotassium hexachloropalladate	16919-73-6	240-974-6	C. Hafner	Approved
Tetraammineplatinum dichloride	13933-32-9	237-706-5	Johnson Matthey	Oct 2016
Platinum dioxide	1314-15-4	215-223-0	Umicore AG&Co.KG	Ongoing
Iridium	7439-88-5	231-095-9	Johnson Matthey	May 2016
Hexachloroiridic acid, Hydrogen hexachloroiridate (IV)	16941-92-7	241-012-8	Heraeus Deutschland GmbH and Co. KG	Jun 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	Ongoing
Di-μ-chloro-bis(hapto-1,5-cyclooctadiene)dirhodium(I)	12092-47-6	235-157-6	Heraeus	Sep 2016
Tris(triphenylphosphine) rhodium (I) chloride	14694-95-2	238-744-5	Umicore AG&Co.KG	Ongoing
Tris(nitrato-O)nitrosylruthenium	34513-98-9	252-068-8	Umicore AG&Co.KG	Ongoing
Rhenium	7440-15-5	231-124-5	KGHM Metraco	Sept 2013
Perrhenic acid (in solution)	13768-11-1	237-380-4	Heraeus Deutschland GmbH and Co. KG	Nov 2013
Ammonium perrhenate	13598-65-7	237-075-6	Heraeus Deutschland GmbH and Co. KG	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 Deutschland GmbH and Co. KG	Aug 2013
Refinables (ALL)				Nov 2010



Finance

2016 Accounts

Overall cash flow situation is good and the reserves are satisfactory but tight, especially for certain projects like Au and some PGMs. This explains that in the 2017 budget proposal significant figures for building reserves are included. A specific attention is required for Au Sub-Assembly: the reimbursement from Covance on TCA testing has still not been received. Pressure is put on the laboratory to ensure that money will be available as soon as possible.

		2016 Budget to be spent	2016 Budget to be invoiced	2016 Forecast	Expenses by 31/09/2016	Committed	Remaining available budget (2016 budget- Expenses- Committed)
2.1	Administrative costs	€618.800	€618.800	€618.800	€330.554	€135.000	€153.246
2.2	Ag-specific costs	€681.250	€689.903	€400.000	€102.023	€398.373	€180.855
2.3	Au-specific costs	€122.700	€79.550	€307.450	€78.582	€224.989	€-180.871
2.4	PM CN- specific costs	€388.500	€288.200	€388.500	€216.760	€77.432	€94.308
2.5	PGM-specific costs	€2.478.250	€1.785.448	€2.488.250	€1.138.449	€1.682.808	€-343.007
2.5	PGM- horizontal costs					€486.902	€-486.902
2.5a	Pt-specific costs	€1.183.955	€645.102	€1.183.955	€496.403	€520.879	€166.673
2.5b	Pd-specific costs	€572.405	€622.173	€572.405	€305.526	€51.548	€215.331
2.5c	Rh-specific costs	€162.470	€171.217	€162.470	€122.876	€150.410	€-110.816
2.5d	Ru-specific costs	€558.420	€345.956	€558.420	€200.441	€473.069	€-115.090
2.5e	Ir-specific costs	€1.000	€1.000	€11.000	€13.203	€0	€-12.203
2.6	Re-specific costs	€11.400	€11.400	€11.400	€1.177	€5.000	€5.223
2.7	Refinables-specific costs	€772.550	€277.550	€772.550	€14.940	€235.352	€522.258
2.8	SVHC Roadmap-specific costs	€20.000	€20.000	€0	€0	€0	€20.000
	TOTAL	€5.093.450	€3.770.851	€4.986.950	€1.882.485	€2.758.953	€452.012

ECHA Sectorial initiative: impact on PMC

In August, PMC representatives together with Eurometaux and other REACH consortia representatives, attended a workshop with a large and high-level European Chemicals Agency (ECHA) delegation, to discuss their ideas for streamlining the EU's chemicals management strategy after 2018.

Main technical challenges from the REACH Regulation and other EU Chemicals policy, plus solutions for resolving them and recognising the unique characteristics of metals has been discussed. ECHA showed willingness to tackle these together with Eurometaux on a priority basis, putting us in a strong position to further implement and improve sound chemicals management.

This was also an opportunity for ECHA to present their sectorial initiative. Indeed, until now, the REACH Regulation has mainly focussed on the registration and evaluation of chemicals. With last registrations due by June 2018, regulators are focussing more and more on how to manage risks from the use of hazardous substances. To ensure an efficient system, ECHA suggest to set-up "sectorial approaches", including for the metals and inorganic sector. This could involve substances being set aside when their uses are of low priority or their risk is proven to be managed. PMC, as the other Consortia, are invited to reflect on the following questions:

- Which registered substances are covered by Eurometaux? What about other registered metals?



- How have our dossiers been built and substances grouped?
- How well do our supply chains coordinate and share information?
- What is the availability and quality of hazard information?
- What are key barriers to updating our dossiers?
- Do they have the key information for prioritising or deprioritising a substance?

This issue has been discussed at the Brainstorming session on the Future of PMC on 6th October 2016. The outcome will be communicated in the next REACH News.



PMC Technical matters

Ag and compounds

Substance Evaluation of Ag metal (nano): Silver registrants received the final decision in July 2016 and are requested to 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. 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 has initiated the testing requested in the decision and will soon start the data collection on the uses.

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 **tetrachloroauric acid** is foreseen for Q3 2017.

Testing status of TCA: Physicochemical analysis have been finalized. The **OECD 422** is initiated and a draft report is expected by April 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 successfully registered by the LR. The co-registrants can complete their individual registrations.

For more info: jelle.mertens@epmf.be

Pd and compounds

Three dossiers have been finalised, and are in the process of registration by the lead registrant. Twelve other dossiers are in the final approval stages by the respective sub-assembly (deadline 3 October), and will be made available for submission by the lead-registrants soon after.

Four dossiers are still pending due to missing information. For three of these dossiers, the required phys-chem testing is currently running. For the fourth dossier, further exposure and risk assessment needs to be performed, and the PMC Secretariat is currently informing with consultants on the financial and timing aspects. As it stands, these four pending Pd dossiers will be registered by the end of 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 almost completed and the final reports are expected to be received by the end of the year.

Registration: The registration dossiers of **silver cyanide** and **potassium dicyanoaurate** have been finalized and sent to the lead registrant for submission.

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

Pt and compounds

Two dossiers have been finalised, and are in the process of registration by the lead registrant. Six other dossiers are currently being finalised by the consultants and the PMC secretariat. The review process will be initiated first half of October 2016.

For three dossiers, testing is still running:

°**Platinum dinitrate:** additional phys.-chem. testing is running, and the dossier will be ready for registration as foreseen.

°**Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol:** the ecotoxicity testing is completed. The mammalian toxicity testing is proceeding on schedule: the dose range finder for the repeated dose toxicity test has been finalised. The dosing for the full test will be agreed upon w/c 3 October, and the full test will be initiated w/c 28 November.

°**Karstedt concentrate:** An additional water solubility pre-experiment is currently running prior to initiating the final ecotoxicity testing. The exotoxicity testing will be finalised by the end of 2016. The OECD422 testing is in its in-life fase, and is running as scheduled. Based on the genetox expert review (cfr. next paragraph), it was decided to directly include an in vivo micronucleus assay with TK assessment in this OECD422 test. This does not affect the general timing for finalisation of this dossier. All other testings have finalised, or are in their reporting phase.

The Pt genetox database has been reviewed by prof. David Kirkland. After the expert review and discussion with the members, it was decided to intelligently group the Pt substances that require registration. It was proposed to do one additional in vitro assay for tetraammine Pt dichloride (mouse lymphoma TK assay) before finalising this dossier - in case of a solid negative outcome, this allows waiving further in vivo testing for this substance and its read-across group member substances. For 4 other groups, a testing proposal for in vivo testing (Comet/TK assays) will be included in the registration dossier.

The occupational exposure assessment for chloroplatinates have been revised by the PMC Secretariat and is under review by PMG WG. It was decided to apply a qualitative approach, and include a benchmark value for the inhalation exposure (chronic,systemic).

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

Analysis of Alternatives to Chloroplatinates: The project is ongoing with the launch early July of a use survey among interested members aimed at identifying possible alternatives to uses of chloroplatinates in



1/refining and production of Pt, 2/catalysts and 3/surface treatment. DHI, the consultant in charge of the project, is currently reviewing the input received. Additional contributions would be welcome. The outcome of this first phase of the analysis – identification of possible alternatives – will be compiled in a draft interim report to be issued end October and discussed at the project interim meeting on 21 November. Substances or processes identified as possible alternatives will then be further assessed from a technical, economic and hazard reduction standpoint. The project is expected to be completed by February 2017.

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, and examples have been sent to ECHA to demonstrate the approach.

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

Rh and compounds

Four dossiers have been finalised, and are in the process of registration by the lead registrant.

The AMES tests for two poorly water soluble Rh(III) compounds (Rh trioxide, Rh trihydroxide) are currently running. For Rhodium tris(2-ethylhexanoate), the sample for testing has not yet been delivered.

For two substances (Rhodium tris(2-ethylhexanoate) and dirhodium trisulfate), additional phys-chem testing is still required, but the samples for testing have not yet been delivered.

The internal Rh genotox review is currently being drafted by the PMC secretariat. Similar to the Pt dossiers, this review should assist in clarifying the genotox profiles, and in developing a good strategy for potential further in vivo testing (included in REACH dossiers via testing proposals).

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

For more info: jelle.mertens@epmf.be

Ru and compounds

One dossier has been finalised, and is in the process of registration by the lead registrant.

The testing program is ongoing for:



-RuCl₃: the ecotox testing is finalised, and the test reports are being drafted. For mammalian tox, the in-life phase of the 28-day repeated dose toxicity assay is finalised. Pathology results are due end October, and the draft report end November 2016. The Reproduction/developmental toxicity screening test is currently at the in-life phase, and the draft report is due mid January 2017.

-Tetraammonium decachloro-mu-oxodiruthenate(4-) (TetradoRu): The dosing for the reproduction/developmental toxicity screening is agreed and the in-life phase will start mid October 2016.

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

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SVHC Roadmap

Update on the possible inclusion of PbO in REACH Authorisation: Last month, the Member States Committee (MSC) of ECHA supported ECHA's proposal in its "7th list" to include PbO as well as three other Pb compounds (orange Pb and two Pb sulphates) in REACH Authorisation list. Remarkably, several members of the MSC abstained or did not support this decision. In line with industry's arguments, these MSC members were of the view that Pb compounds are already well regulated via various regulatory instruments, and that REACH Authorisation would be disproportionate. The European Commission will now have to work on a compromise position in order to gain enough support on its legislative proposal in the REACH Committee, whose approval is the next and final step before new substances can be subject to Authorisation. The exemption of certain uses on the basis of already existing risk management measures (Article 58.2 of REACH) will be the key bargaining instrument. Eurometaux, with the support of PMC, will continue to advocate for an exemption of all industrial uses of PbO covered by the binding OEL for Pb and its compounds. The inclusion in Authorisation might set a negative precedent for other metals, including PMs, covered by the OSH legislation. Furthermore, it should be noted that the MSC, for the first time, confirmed the intermediate status for several uses including the use in frits. As revealed by an internal analysis of PMC, a few members may nonetheless have to submit AfAs for other uses. As things stand, AfAs would have to be submitted at the latest 30 months after the inclusion of PbO in Authorisation, i.e. by 2020.

For more info: marie.gorkem@epmf.be

Next Authorisation list update: The European Commission has launched a one month consultation (until end October) on the list of substances to be part of the 2016 update of the REACH Authorisation list. CTP is listed. Nonetheless, and most importantly, the borates, RCFs are not part of the list. The inclusion of borates has been postponed due to workload concerns. As for RCFs, the Commission underlines the very limited scope of uses that would fall in the scope of Authorisation.

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Miscellaneous

Silver and the Water Framework Directive (WFD): Technical discussions are ongoing at Joint Research Center (JRC) level on the WFD prioritization. A monitoring-based exercise has been conducted for the identification of potential priority substances by ranking, and silver has been identified as a potential candidate. EPMF has raised several concerns about the assessment of silver data and is following up this issue to ensure that the best available information on silver is used as well as the correct methodology.

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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