CALENDAR:

5-6 June 2018:
EPMF/PMC General Assemblies, Liège (Belgium)

13-15 March 2018:
PMC Spring back to back meetings, Brussels

9-11 October 2018:
PMC Autumn back to back meetings, Brussels

4-5 December 2018:
EPMF/PMC General Assembly, Brussels

Dear Members,

2017 is coming to an end… It was so quick and so intense that it is difficult to realize that 2018 and the famous final last deadline of REACH is now coming!

Fortunately, and thanks to the excellent work of the team, most of the registration dossiers have now been submitted and the few remaining ones will be submitted beginning of 2018, well ahead of the legal deadline.

In parallel, the next REACH challenges are also increasing with the review of testing proposals submitted the past years and months. This demonstrates the need to rethink our organisation to successfully address the upcoming regulatory process. There is indeed a need now to move from PMC to EPMF to have a strong and flexible structure to assist and support the members companies in the next phase of REACH but also to support them in other regulatory fields. 2018 will be a critical year to implement the restructuration that EPMF and PMC have been discussing for more than a year.

But, before that, we all deserved a nice and peaceful holidays seasons!! We wish you and your families all the best for the New Year and we look forward to seeing you all again in 2018 full of energy and ideas for a strong EPMF!

Enjoy the reading of the last issue of our 2017 REACH News!

France

PMC Administrative update

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 ***(UVCB!)***	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	Oct 2016
Palladium	7440-05-3	231-115-6	Umicore NV/SA	Jan 2017
Palladium dichloride	7647-10-1	231-596-2	BASF	Jan 2017
Dihydrogen tetrachloropalladate(2-) (in solution)	16970-55-1	241-047-9	Heraeus	May 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
Tetraamminepalladium(2+) dihydroxide	68413-68-3	270-241-6	Heraeus	May 2017
Tetrakis(triphenylphosphine)palladium	14221-01-3	238-086-9	Umicore AG&Co.KG	Mar 2017
Palladium sulphate	13566-03-5	236-957-8	Heraeus	May 2017
Tetraamminepalladium(2+) diacetate	61495-96-3	262-819-1	Umicore AG&Co.KG	Apr 2017
Disodium tetrachloropalladate	13820-53-6	237-502-6	BASF	Jan 2017
Palladium dinitrate ***(UVCB!)***	10102-05-3	233-265-8	Heraeus	Apr 2017
Palladium dihydroxide	12135-22-7	235-219-2	Umicore AG&Co.KG	Apr 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
Platinum	7440-06-4	231-116-1	Vale	Jun 2017
Hexachloroplatinic acid	16941-12-1	241-010-7	Johnson Matthey	**Ongoing**
Tetraammineplatinum dichloride	13933-32-9	237-706-5	Johnson Matthey	Feb 2017
Tetraammineplatinum dinitrate (in solution)	20634-12-2	243-929-9	Umicore AG&Co.KG	Aug 2017
Dipotassium tetrachloroplatinate	10025-99-7	233-050-9	Heraeus	**Ongoing**
Platinum dioxide	1314-15-4	215-223-0	Umicore AG&Co.KG	Mar 2017
Dipotassium hexachloroplatinate	16921-30-5	240-979-3	Heraeus	**Ongoing**
Platinum dinitrate ***(UVCB!)***	18496-40-7	242-383-9	Heraeus	Jun 2017
Platinum, 1,3-diethenyl-1,1,3,3-tetramethyldisiloxane complexes / Karstedt concentrate ***(UVCB!)***	68478-92-2	270-844-4	Heraeus	Feb 2017
Diammonium hexachloroplatinate	16919-58-7	240-973-0	Johnson Matthey	**Ongoing**
Dihydrogen hexahydroxyplatinate	51850-20-5	257-471-2	Johnson Matthey	Jun 2017

Iridium	7439-88-5	231-095-9	Johnson Matthey	May 2016
Hexachloroiridic acid, Hydrogen hexachloroiridate (IV) ***(UVCB!)***	16941-92-7	241-012-8	Heraeus	June 2016
Diammonium hexachloroiridate	16940-92-4	241-007-0	Johnson Matthey	May 2016
Rhodium	7440-16-6	231-125-0	Johnson Matthey	Nov 2017
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
Dicarbonyl(pentane-2,4-dionato-O,O')rhodium	14874-82-9	238-947-9	Umicore AG&Co.KG	Sep 2017
Rhodium trichloride, hydrate	20765-98-4	606-630-8	Heraeus	Sep 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
Rhodium triiodide	15492-38-3	239-521-5	Umicore AG&Co.KG	July 2017
Dirhodium trisulphate	10489-46-0	234-014-5	Umicore AG&Co.KG	**Ongoing**
Dirhodium trioxide	12036-35-0	234-846-9	Umicore AG&Co.KG	July 2017
Rhodium (III) acetate ***(UVCB!)***	42204-14-8	255-707-9	Umicore AG&Co.KG	July 2017
Rhodium trinitrate ***(UVCB!)***	10139-58-9	233-397-6	Johnson Matthey	Nov 2017
Rhodium trihydroxide	21656-02-0	244-508-2	Heraeus	July 2017
Triammonium hexachlororhodate	15336-18-2	239-364-2	Vale	July 2017
Diammonium sodium hexakis(nitrito-N)rhodate	64164-17-6	264-713-0	Vale	July 2017
Ruthenium	7440-18-8	231-127-1	Heraeus	Nov 2017
Ruthenium trichloride, hydrate	14898-67-0	604-667-4	Heraeus	Nov 2017
Ruthenium (IV) oxide	12036-10-1	234-840-6	Heraeus	Nov 2017
Tris(nitrato-O)nitrosylruthenium	34513-98-9	252-068-8	Umicore AG&Co.KG	Feb 2017
Hexakis[mu-(acetato-O:O')]-μ3-oxo-triangulo-triruthenium acetate / Ruthenium acetate	55466-76-7	259-653-7	Johnson Matthey	**Ongoing**
Tetraammonium decachloro-mu-oxodiruthenate(4-)	85392-65-0	286-924-7	Heraeus	Nov 2017
Ruthenium trihydroxide	12135-42-1	235-221-3	Umicore NV/SA	**Ongoing**
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

PMC Technical update

Ag and compounds

Substance Evaluation of Ag metal (nano): No feedback from the eMSCA has been received yet following the July silver REACH dossier update, in which PMC concluded that the nanoform of silver is less toxic than ionic silver and therefore further fate testing is currently not needed. The eMSCA has until July 2018 to evaluate the new information and they will conclude either that no further data is needed or they will draft a new decision indicating that further information is still needed to address the concern.

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

CLH of silver containing active substances (SCAS) under BPR: The 60-day public commenting period for the 3 CLH proposals submitted by Kemi (Sweden) for silver zeolite (SZ), silver copper zeolite (SCZ) and silver sodium zirconium hydrogen phosphate (SSZHP) has not started yet. PMC is already preparing comments specifically on the Repr classifications of SZ and SCZ, and in this respect, will refer to their submitted testing proposal for the EOGRTS (see also below).

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

Extended one-generation reproductive toxicity study (EOGRTS) testing proposal on silver acetate: The third party consultation on the EOGRTS on silver acetate ended 13 November 2017 and a scientific and legal evaluation is currently ongoing. PMC expects that the draft decision will be sent to the registrant (so far only to the LR) in January 2018. A commenting period of 30 days will then start during which we should also have the opportunity to have an informal call with ECHA. At this point, PMC will inform ECHA that the testing proposal is outdated since it was submitted in 2015 and new data on the reprotoxicity of ionic silver and SCAS has emerged since then, and a complex EOGRTS test design (including all cohorts) is now assumed. PMC is currently preparing an update of the testing proposal and possible enabling work, with the input of a number of experts to ensure a robust proposal. It is important to note that the overall balance of evidence on silver reprotoxicity shifted adversely over the last two years, and PMC will need to strategise in case of a negative outcome for the industry (i.e. Repr Cat. 1B classification for silver).

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Potential prioritisation of silver under the Water Framework Directive (WFD): Silver is currently not proposed for the Watch List (WL). Additional silver monitoring data have been received and JRC calculated a new STE score which is now < 1.8 (cut-off value for Priority Substances (PS) shortlist). A final decision on the relevance of silver for the PS shortlist will be made based on a confirmed PNEC/EQS. EQSs are currently being discussed in substance-specific sub-groups and the silver sub-group is being led by Sweden. Both PMC and Eurométaux are participating to this sub-group, and MS participation is limited to Germany, France, Latvia and Denmark. The aim is to agree on EQSs early 2018 for all matrices that could be of relevance, including sediment. There will be no revision of the PS list in the short term, but MSs will be encouraged to take into account shortlisted substances and their harmonised EQS for the third River Basin Management Plan (RBMP).

In the meantime, the PMC Secretariat has (re-)assessed its ecotox dataset for the Ag REACH PNECs. For the chronic freshwater PNEC, the report will be circulated to the Ag WG for internal PMC review shortly. For the chronic sediment PNEC, the Ag WG recognised that the current available studies are not suitabel for PNEC derivation and agreed to perform well-designed sediment tests if the REACH sediment PNEC is challenged.

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

Au and compounds

Status of TCA: The registration dossier has been finalised and approval process currently ongoing. Submission of the TCA dossier is estimated for end January 2018.

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 Lead Registrants, and co-registrants are kindly invided to register as soon as possible.

For more info: jelle.mertens@epmf.be

Pd and compounds

The REACH registration dossiers for Palladium metal and all Palladium compounds have been successfully registered by the Lead Registrants, and co-registrants are kindly invided to register as soon as possible.

During the back-to-back meeting in October, the members agreed to improve several Pd dossiers. The main improvements are:

- PNEC refinement for the Pd substances,
- additional repeated dose toxicity and repro/developmental toxicity screening tests for 3 Pd compounds.

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

PM CN

Status of $KAg(CN)_2$: The registration dossier is finalised and approved. Submission of the dossier by the LR is foreseen for December 2017.

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

Pt and compounds

The REACH registration dossiers of Platinum metal and 6 Platinum compounds have been successfully registered by the LR and co-registrants are kindly invided to register as soon as possible.

The dossiers of the four Chloroplatinates will be submitted by the Lead Registrants by end of 2017 to anticipate potential regulatory follow-up actions.

The dossier for diammineplatinum (II) nitrite has been approved and will be sent to the LR for registration before end 2017.

The registration dossier for dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol has been sent out for approval. The data of the ongoing phys-chem testing and reviewed testing proposal for in vivo genotoxity testing will be included once available, and circulated for review and approval via the fast track procedure. The dossier is expected to be available for registration Jan/Feb 2018.

The updated dossier for Karstedt Concentrate has been sent out for approval. An update was required to (mainly) reflect the Repro2 classification, the inclusion of exposure scenarios and inclusion of a testing proposal for an Extended 1-generation Reproductive Toxicity Study. Re-submission of the updated REACH dossier is foreseen beginning of 2018.

During the back-to-back meeting in October, the members agreed to improve several Pt dossiers. The main improvements are:

- update platinum dioxide dossier from AnnexIII exempted dossier to an AnnexVII dossier, implying further mammalian testing,
- perform a repeated dose toxicity and repro/developmental toxicity screening tests for Platinum nitrate.

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

Re and compounds

At its recent meeting, the PMC General Assembly has approved the withdrawal of Dirhenium heptasulphide (EC 234-882-5) from the Rhenium Sub-Assembly, since none of the PMC registrants have interest in this substance anymore.

The 2017 literature review for Re and Re compounds is currently ongoing.

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

Refinables

Discussions with the SID unit of ECHA have not resulted in clear recommendations on how to overcome problems with the SID of iUVsCBs. Possibly, recommendations regarding SID could be incorporated in the sectorial acpproach. Currently we are also in discussion with the compentation unit of ECHA on how to increase transparancy of the intermediate dossiers in IUCLID using assessment entities.

Updates of the refinable dossiers are foreseen for 2018. To define the scope of the refinable dossiers the proposed dossier splits and SIPs will be reviewed and finalised according to the recommendations of the intermediates TF. A work plan will be enrolled together with the WG.

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

Rh and compounds

The dossiers of Rhodium metal and 13 Rhodium compounds have been successfully registered by the LR. Co-registrants are kindly invided to register as soon as possible.

The dossier of dirhodium trisulphate has been approved and send to the LR for registration.

One dossier is still under development: rhodium tris(2-ethylhexanoate). The required phys-chem testing is running. The dossier is expected to be ready for fast-track approval early 2018, and registration by the LR is expected for Feb/March 2018.

The members agreed to further improve some Rh dossiers in 2018. Main actions are:

- update dirhodium trioxide dossier from AnnexIII exempted dossier to an AnnexVII dossier, implying further mammalian testing.
- further develop the grouping approach for Rh(III) genotoxicity to differentiate between water soluble and poorly water soluble Rh(III) compounds, via chemistry testing and additional in vitro genotoxicity testing.
- include a testing proposal for in vivo genotoxicity in the dossiers of the water soluble Rh(III) compounds.

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Ru and compounds

The dossiers for Ruthenium metal and 4 Ruthenium compounds successfully registered by the LR. Co-registrants are kindly invided to register as soon as possible.

The dossiers of ruthenium acetate and ruthenium trihydroxide have been approved and sent to the LR for registration.

The members agreed to further improve the dossier for Ruthenium(IV) dioxide in 2018, implying further mammalian testing.

For more info: jelle.mertens@epmf.be

SVHC Roadmap

- **Chemycal monitoring tool**: the WG decided that quaterly report will be sent to the companies. This report will be based on the list of substances of interest for each company. The first issue will be sent before Christmas. Please note that as of 2018, this quaterly report will only be sent to the companies part of the SVHC WG Sub-Assembly. In case of emergency on a substance of interest, an email alert will be sent to the SVHC Roadmap WG.
- **Intermediate guidance on the use of PbO in precious metals industry**: as you probably remember, ECHA, Cefic and Eurometaux launched in Spring a new technical project to assess the intermediate use of substances in complex matrices. The internal guidance has been sent to ECHA and already refined based on ECHA comments. It is unlikely that a follow-up meeting will be needed with ECHA but we are waiting for their final feedback.

For more info: france.capon@epmf.be or jelle.mertens@epmf.be

Acronyms

http://www.epmf.be/members-area/#382-list-of-acronyms