



## CALENDAR:

**14 March 2016:**  
PMC Management  
Committee, Brussels

**17 March 2016:**  
EM REACH Forum,  
Brussels

**17-18 March 2016:**  
EM Authorisation &  
Restriction Platform,  
Brussels

**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

**6-7 December 2016:**  
PMC General  
Assembly, Brussels

## Welcome and Introduction

Dear Members,

We are glad to send you the second issue of our PMC REACH News!

The last quarter of 2015 was very challenging at administrative but also project level: testing programs are running at full speed for PGMs substances, outcome of nanos characterisation of PGMs blacks is key for future work of the PMC, Gold dossiers (except TCA) are nearly finalized and exposure programs started in different projects.

Q4 2015 was also an opportunity for PMC to operate a „facelift“ with the creation of a new logo and the revamp of our templates, including this newsletter.

We hope you will enjoy the reading of this second issue. Please feel free to send us back your comments and recommendations so we can improve the next issue expected in April 2016.

We take this opportunity to wish you already a Merry Christmas and a Happy New Year 2016! And we hope to see you again in 2016 full of energy to address the upcoming challenges!

France





## PMC Administration

### Outcome of the Assembly meeting (December 2015)

A series of Lead Registrants have been elected which means that now all the substances included in the PMC scope have a Lead Registrant. Thanks to the companies which accepted to volunteer for this task!

The Assembly validated the withdrawal of UIT (January 2016), Dragstsvetmet (January 2016) and Lonmin (February 2016). An amended version of the Consortium Agreement was approved, including a new cost sharing formula. The Silver Sub-Assembly approved a specific cost sharing formula taking into account nano requirements for 2016. This formula will be reviewed on an annual basis. Based on the new cost sharing formula, LoA fees will be updated for all substances of the PMC in Q1 2016.

Finally, the Assembly approved the 2016 workplan and the budget of 5.023.050€ (to be spent) and 3.770.851€ (to be invoiced).

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### Human resources

Welcome to Marie Gorkem, EPMF Regulatory Affairs Manager and Jelle Mertens, EPMF Scientific Manager. Both have a valuable experience in REACH and chemicals management in general and will be a great asset for the Precious Metals Consortium. They will start on 1<sup>st</sup> January 2016. Their coordinates and responsibilities will be communicated in January 2016.

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### Finance

#### 2015 Accounts

The accounts until October 2015 have been finalized and are presented here below:

		2015 Budget	2015 Forecast (30/06/2015)	Expenses by 30/10/2015	Committed by 30/10/2015	Remaining available budget (2015 budget- Committed- Expenses)
2.1	Generic costs	€ 789.928	€ 902.105	585.736 €	€ 288.272	€ -84.080
2.2	Ag-specific costs	€ 241.415	€ 280.415	110.956 €	€ 110.000	€ 20.459
2.3	Au-specific costs	€ 56.650	€ 124.792	51.091 €	€ 65.499	-€ 59.940
2.4	PM CN- -specific costs	€ 193.900	€ 322.790	158.501 €	€ 307.774	-€ 272.375
2.5	PGM-specific costs	€ 1.168.010	€ 2.120.010	474.347 €	€ 1.876.857	-€ 1.183.194
2.6	Re-specific costs	€ 9.450	€ 9.450	3.621 €	€ 0	€ 5.829
2.7	Refinables-specific costs	€ 365.824	€ 365.824	17.021 €	€ 178.893	€ 169.910
2.8	Hydrazine-specific costs	€ 78.000	€ 100.000	45.750 €	€ 500	€ 31.750
	<b>TOTAL</b>	<b>€ 2.903.177</b>	<b>€ 4.225.386</b>	<b>€ 1.447.023</b>	<b>€ 2.827.795</b>	<b>€ -1.371.641</b>



## PMC Technical matters

### Ag and compounds

**Substance Evaluation of Ag metal (nano):** Following submission of PMC's comments on the silver draft decision mid-June 2015, registrants have updated their silver dossier by 1 November 2015 to allow better identification of nanosilver registrants and to include recent information. In January 2016, the e-MS will send the (possibly adjusted) draft decision to ECHA and the MSCAs for proposals for amendment (PfAs). From 26 February to 29 March 2016, PMC will be able to submit comments on the PfAs. Discussion of the silver draft decision at MSC level is planned for the MSC meeting of 25-29 April 2016, at which PMC can send an expert. Although testing related to the substance evaluation cannot start until the final decision is issued, PMC is preparing for the testing.

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**CLH of silver zinc zeolite:** The CLH dossier of silver zinc zeolite proposing a classification of *inter alia* carcinogen cat. 2, STOT RE cat. 2 and reprotox cat. 1B has been discussed at the RAC meeting 2-3 December 2015. RAC agreed on no classification for carcinogenicity and STOT RE and reprotox classification cat. 2. Industry's comments (including PMC's) helped steer the discussions into the right direction.

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**Testing proposal extended one-generation reproductive toxicity study (EOGRTS):** Given the data gap on reproductive toxicity for silver and the regulatory context with different harmonized classification ongoing for silver compounds under biocides, the Ag WG has submitted a testing proposal for an EOGRTS together with the dossier update related to the Substance Evaluation.

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### Au and compounds

The testing program for tetrachloroauric acid (TCA) is almost completed. Currently we are awaiting the last final reports of the toxicity testing and additional physicochemical testing of the hydrate will be scheduled in January-February 2016. Problems with the formulation of TCA was brought under our attention for the OECD 422 and OECD 474 studies. We are currently investigating together with the CRO how to proceed to this should not impact timing nor budget.

The life cycle trees have been generated for all gold substances and the environmental exposure scenarios are expected to be finalized end of 2015. For TCA a site visit might be required early 2016 to ensure that safe use can be demonstrated in the registration dossier to be submitted by Q3 2016.

The dossiers of Aurio and Balsams will be made available for review beginning of January 2016 and the dossier of the gold metal will follow soon after. Registration for the 3 gold substances, not requiring occupational exposure assessment, are scheduled for Q1 2016 as foreseen.

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## Ir and compounds

The nano-characterization exercise of PGM blacks has now been completed. No nanomaterials have been identified for Iridium.

The technical work for the registration dossiers of Ir and compounds has been finalized by the agreed deadline. However, the dossiers cannot be submitted yet, since PMC Secretariat is still waiting for the necessary spectra from the Lead Registrant. The finalization of the dossiers is on hold until the required spectra are available. Spectra for Hexachloroiridic acid and Diammonium hexachloroiridate are expected in the coming days, spectra for the Ir-chlorides will not be available before Q1 2016 due to analytical challenges encountered by the LR.

All above substances must be registered asap once the required spectra are available. No additional resources in 2016 will be required, except some human resources. For the Iridium chlorides, only one company is affected.

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## Pd and compounds

The nano-characterization exercise of PGM blacks has now been completed. No nanomaterials have been identified for Palladium. Some changes in LR have been approved by the Sub-Assembly in December and are recorded in the minutes.

The DNEL derivation is ongoing and will be completed by the end of 2015. On the exposure side, life-cycle trees have been developed for all substances and an environmental emissions monitoring campaign will be completed by end of 2015.

Early 2016, an occupational monitoring campaign will be conducted and exposure scenarios will be developed once final DNELs are available. All dossiers will be finalised by Q3 2016.

The PGM Sub-Assembly decided to register all Pd dossiers in Q3 2016 except the dossiers of chloropalladates. These dossiers will be ready by Q3 2016 as well, but registered in Q4 2017 due to their classification as skin sensitizers with adverse effects, which could be considered as "equivalent concern" under Authorisation.

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## PM CN

Testing program for potassium dicyanoaurate and silver cyanide is completed and awaiting the last final reports.

The life cycle trees have been generated for all PM CN substances and a preliminary occupational exposure assessment has been drafted. This preliminary occupational assessment indicated that further refinements or data will be needed to prove safe use of the PM CN compounds. The environmental exposure assessments are expected to be finalized end of 2015.

For potassium dicyanoargentate, the repeated dose and gentox tests are being scheduled in January 2016. The submission of these dossiers (except potassium dicyanoargentate) is still scheduled by Q3 2016.

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## Pt and compounds

The nano-characterization exercise of PGM blacks has now been completed. No nanomaterials have been identified for Platinum. Some changes in LR have been approved by the Sub-Assembly in December and are recorded in the minutes.

The testing program, in which several substances were undergoing extensive testing on ecotoxicity and mammalian toxicity (e.g. irritation, corrosion, sensitization, genotoxicity, repeated dose, repro-screen, etc.), has been completed as planned. On the exposure side, life-cycle trees have been developed for all substances and an environmental emissions monitoring campaign will be completed by end of 2015.

The ecotoxicity and mammalian toxicity testing on Dihydrogen hexahydroxyplatinate, compound with 2-aminoethanol (CAS 68133-90-4, HHPA-2AE) is ongoing. The testing strategy has been reviewed during the last WG meeting and one of the testing (OECD 422, repeated dose/ reprotox screen - the longest-duration test) will be conducted in 2016.

Testing on Karstedt concentrate is on hold until open questions on sensitization are clarified. Inconsistent data have been received from the Reconsile consortium. PMC Secretariat requested more detailed information from Reconsile to be able to resolve the issue. We keep following up on this as a matter of priority to prevent any delay in the registration of this compound.

2016 will be mainly dedicated to completing the ongoing testing, PNEC and DNEL derivation, occupational exposure monitoring and finalisation of exposure scenarios, in preparation of the registration scheduled by Q1 2017.

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## Re and compounds

The registration dossiers for all but one Re compounds in scope were submitted in 2013-2014. Literature search updates were carried out in 2015 and there were no relevant results returned for the environment or for human health (i.e. nothing requiring update of the dossiers). The remaining dossier (dirhenium heptasulphide) will be submitted in 2016 now that registration interest is confirmed.

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## Refinables

PMC is following ongoing UVCB substance identity (SID) discussions between ECHA and Eurométaux and checking SID determination for each one of the Refinables. Update of the dossiers is foreseen for end 2016.

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## Rh and compounds

The nano-characterization exercise of PGM blacks has now been completed. No nanomaterials have been identified for Rhodium. Some changes in LR have been approved by the Sub-Assembly in December and are recorded in the minutes.



The scheduled ecotoxicity and mammalian toxicity testing program has been completed. The issue of Rh(III) genotoxicity is under discussion at the PGM WG.

On the exposure side, uses have been collected for all substances and an environmental emissions monitoring campaign will be completed by end of 2015. An occupational monitoring campaign will be conducted early 2016.

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## Ru and compounds

The nano-characterization exercise of PGM blacks has now been completed. No nanomaterials have been identified for Ruthenium. Some changes in LR have been approved by the Sub-Assembly in December and are recorded in the minutes.

The ecotoxicity and mammalian toxicity testing program is ongoing for Tetraammonium decachloro-mu-oxidiruthenate (CAS 85392-65-0). The tests have been delayed because of substance identification issues but there will be no impact on the overall registration time line.

On the exposure side, uses have been collected for all substances and an environmental emissions monitoring campaign will be completed by end of 2015. An occupational monitoring campaign will be conducted in early 2016.

The ecotoxicity and mammalian toxicity testing on Ruthenium trichloride hydrate (CAS 14898-67-0) is ongoing.

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## SVHC Roadmap

The SVHC Roadmap Working Group has been launched in October 2015. The mandate of this Working Group is to monitor activities related to SVHC Roadmap (Screening of substances for CoRAP, RMOs, etc.); to contribute to public consultations for critical substances for the PM industry and to contribute to advocacy activities related to SVHC Roadmap (e.g.: RMO, recycling...) to help preventing and mitigating Authorisation impact on PM industry. It is important to highlight the fact that PM substances potentially impacted by SVHC Roadmap are excluded because handled by the relevant WG (e.g.: chloroplatinates are handled under the PMG/Pt project).

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## Hydrazine

The final report on the occupational exposure assessment to hydrazine has been issued in November 2015. Occupational exposure to hydrazine was measured during the execution of various tasks in the manufacturing plants and laboratories of PMC member companies during the summer 2015. In general, hydrazine is well-controlled with the use of dry-break couplings, fume cupboards and appropriate personal protective equipment. Some recommendations have been included in the report to maintain and even improve the already very low exposure level.

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## Miscellaneous

### Upgrade of IUCLID in 2016

In summer 2016, a new version of IUCLID, the tool used to compile regulatory data on chemicals, will be released. This new version will include many improvements and will be based on an **entirely new technical platform**. On the 20th of November ECHA has released a new beta version of IUCLID 6 that will allow you to prepare for the update. If you use IUCLID from your company server, it is particularly important to know what is going to change and how to **prepare your company's IT environment** for IUCLID 6, warn your IT department about the upcoming changes if they are not yet aware of them. Experience from testers has revealed that the switch from Tomcat to Glassfish as the application server can be challenging and take some time in complex IT systems.

If you're using the stand alone (desktop) version of IUCLID the IT changes are probably less relevant and you should be glad to hear that IUCLID 6 will come with one installer installing all the required software. No need to install different pieces of software before being able to install IUCLID.

The final release of IUCLID 6 is expected for the last week of April but will only be suitable to submit dossiers once REACH-IT has been upgraded from REACH-IT 2 to REACH-IT 3 (expected the last week of May). It is highly recommended to install the final version IUCLID 6 as soon as it's available. Also try out the migration function to see if your dossiers encounter issues while being migrated from IUCLID 5 to IUCLID 6. But you will need to continue using IUCLID 5 until REACH-IT 3 has been released. This means that there will be a period where you will have both systems running in parallel and you should be careful that in the end all the latest data will be on the IUCLID 6 system.

For more information, ECHA released an interesting newsletter in the past:

[http://newsletter.echa.europa.eu/home/-/newsletter/entry/2\\_15\\_get-ready-for-iuclid-6](http://newsletter.echa.europa.eu/home/-/newsletter/entry/2_15_get-ready-for-iuclid-6)

The IUCLID 6 website is also online now: <https://iuclid6.echa.europa.eu/>



## 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  
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  
STOT RE: Specific Target Organ Toxicity – Repeated Exposure  
SVHC: Substance of Very High Concern  
TCA: Tetrachloroauric Acid  
WG: Working Group