



CALENDAR:

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

4 December 2018, PM:
PMC last General Assembly, Brussels

5 December 2018, AM:
EPMF General Assembly, Brussels

5 December 2018, PM:
EPMF event: "Conflict and Opportunity: Chemical Management, the Circular Economy, & Precious Metals", Brussels

5-6 June 2019:
EPMF General Assembly, Bordeaux

Dear Members,

In June 2018, an important step has been taken with the integration of REACH and Chemicals Management into EPMF. The PMC assembly approved the termination of the agreement in December 2018. As of 2019, EPMF will become the main and unique body representing the European Precious Metals industry.

During the past years, a tremendous amount of data has been generated. In 2017, the Management Committee mandated the Secretariat to develop a Knowledge Management System (KMS) to ensure a secured and organized access to the PMC database. I am glad to announce that this system is now live! You should have received on 26 June an invitation by email to join the KMS. The upload of the documents is ongoing and is a continuous process. However, this first milestone is already a major achievement for the PMC team and especially for Audrey and Cathy.

Please do not hesitate to share with us your experience and feedback on this new KMS!

In parallel, the technical work continues in the different projects to improve registration dossiers but also address the upcoming regulatory challenges.

To know more, please look at the PMC News below!

Enjoy the reading!

France

.... We wish you a happy





PMC Technical update

Ag and compounds

Substance Evaluation of Ag metal (nano): No feedback from the eMSCA has been received yet following the 2017 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 so we expect to receive their opinion soon.

CLH of silver containing active substances (SCAS) under BPR: The 60-day public commenting period for the 3 CLH proposals submitted by Kemi (Sweden) on SCAS has not started yet. PMC has a meeting planned with the European Silver Task Force (ESTF) on 5 July to discuss the CLH proposals and other topics of joint interest.

Extended one-generation reproductive toxicity study (EOGRTS) testing proposal (TP) on silver acetate: PMC has updated the TP early April and has recently contacted ECHA to check when the draft decision will be sent. After receiving the draft decision, a commenting period of 30 days will start during which we should also have the opportunity to have an informal call with ECHA.

In addition to updating the TP, PMC has started enabling work, with the input of a number of experts to ensure a robust proposal. Since the overall balance of evidence on silver reprotoxicity shifted adversely over the last two years, PMC has also developed a strategy in case of a negative outcome for the industry (i.e. Repr Cat. 1B classification for silver).

Potential prioritisation of silver under the Water Framework Directive (WFD): A final decision on the relevance of silver for the PS shortlist will be made based on a confirmed PNEC/EQS. Silver EQSs are currently still being discussed in a substance-specific sub-group led by Sweden. The aim is to agree on EQSs 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).

For the chronic freshwater PNEC, PMC has re-assessed the previously used dataset and has performed further ecotoxicity tests to strengthen the dataset and allow a probabilistic (SSD) derivation of the PNEC. These further tests largely confirm the previously used chronic freshwater PNEC value, but have significantly improved its scientific basis. These data have also been used by PMC as a basis for commenting on a recent Swedish national consultation on EQSs.

The chronic sediment PNEC has not been discussed yet with the silver sub-group, but the Ag WG recognised that the current available studies are not suitable for PNEC derivation and agreed to perform well-designed sediment tests if the REACH sediment PNEC is challenged by the sub-group.

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



Pd and compounds

The agreed additional testing (cfr. minutes PMC autumn BtB meetings) has been started. The dose range-finding tests from the three repeated dose toxicity&reproduction/developmental toxicity screening tests with palladium dichloride, Pd(acac) and disodium tetrachloropalladate are completed. Dose setting for the full tests will be decided soon. Next to these assays, the *in vitro* genotox assays for palladium dichloride and tetraamminepalladium dichloride, and the *in vivo* skin sensitisation (Local Lymph Node Assay) assay with disodium tetrachloropalladate are also running. The bioelution assays and test for oxidising properties with Pd monoxide will be started as soon as the test material has been produced and received by the contracted testing lab.

The additional ecotoxicity tests are ongoing; the two algae toxicity tests have been finalised, and the chronic Daphnia tests and Active Sludge Respiratory Inhibition Test (ASRIT) will be initiated soon. These tests will allow refinement of the Pd PNEC for the different palladium groups instead of the current generic PNEC value for all palladium substances.

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

Pt and compounds

The agreed additional testing (cfr. minutes PMC autumn BtB meetings) has been started. The dose range-finding test from the repeated dose toxicity&reproduction/developmental toxicity screening test with platinum dinitrate is completed. Dose setting for the full test will be decided soon. Next to this assay, the assays for *in vivo* skin sensitisation (Local Lymph Node Assay) and *in vitro* genotox for PtO₂ are also running.

The testing proposals (TP) for *in vivo* genotoxicity testing have been included in all relevant Pt dossiers (including platinum dinitrate) and have successfully been submitted to ECHA. Some of them have already been published for public consultation while for others publication is expected soon. ECHA has also informally contacted some Lead Registrants of proposed test substances to clarify questions on substance identity.

Once all these substance identity issues have been clarified, and the TP for *in vivo* genotoxicity testing have passed the public consultation, ECHA will prepare all the draft decisions in parallel to ensure a consolidated review of the TPs by the MSC (Member State Committee). ECHA will try to issue all the final decisions at once. PMC aims to test the substances in a tiered testing approach (i.e. sequential testing to optimise the testing protocol based on the learning lessons from the previous assays) to eventually avoid the need to test all 5 groups (in most optimistic case!).

Further discussions with the PGM WG and Tox Experts are required to fine tune and agree on the testing approach, as well as with ECHA staff to defend our approach and formally agree on it. Our best guess for initiating the testing is Q2 2019.

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



Refinables

Some progress has been made on the SID discussion with ECHA. Recently some inquiries for iUVCB dossiers has been accepted and the template used for describing the SID was well received. During the intermediates TF meeting the implementation of this SID template for the dossier updates will be further discussed.

New tonnage band declarations have been sent out to define the scope of the different refinable dossiers. Also invitations were sent out to member companies for taking up the lead registrant position of the new 'splitted' refinable dossiers. Further preparations are being made for updating the exposure scenarios and an external consultant will be assigned in the coming weeks.

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

Rh and compounds

The dossiers of all rhodium substances have been successfully registered by the LR's within the 2018 REACH deadline.

The additional AMES assays for poorly water soluble Rh(III) compounds (cfr. decision spring 2016 BtB meeting) have been finalised, and all confirm absence of mutagenic potential. This information strengthens the hypothesis of Rh(III) genotox being driven by soluble Rh(III) ionic species, and triggers further discussion with the tox experts about the testing proposal for *in vivo* genotox to be included in the dossiers of the relevant Rh(III) REACH dossiers.

The agreed additional testing with dirhodium trioxide (cfr. minutes PMC autumn BtB meetings) will be initiated as soon as the test material has been produced and received by the testing labs.

For more info: jelle.mertens@epmf.be

Ru and compounds

The agreed additional testing for Ru(IV) oxide (cfr. minutes PMC autumn BtB meetings) has been started: *in vitro* skin irritation/corrosion, *in vivo* skin sensitisation and *in vitro* genotoxicity.

For more info: jelle.mertens@epmf.be

SVHC Roadmap

Pb metal has been approved at unanimity by the MSC to be included in the Candidate List which will be updated in the coming days. The inclusion in the Candidate List triggers some communication obligations (e.g. article 33). The prioritization process could start already in 2019 with a public consultation organised in September. This means that the SSD could be 2024. An advocacy strategy will be discussed at Eurometaux level regarding the potential prioritisation as the relationship or potential alignment with the prioritisation of the PbO (and other Pb compounds) which is ongoing.

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