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,

The summer was full of administration challenges: recalculation of the LoA costs and of the reserves, implementation of the new structure etc. which will be presented at the next GA meeting in December. Overall, most of the PMC members moved to EPMF and we are just waiting for the responses of three more companies.

This summer was also the opportunity to reflect on the first EPMF event which will be organized on 5th December 2018, and build an attractive and original program to face the "Brussels events competition". If you have not yet register, please do so!

As usual, the technical work continued in an intense mode for the PGMs and Silver groups.

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

Enjoy the reading!

France

PMC Technical update

Ag and compounds

Substance Evaluation of Ag metal (nano): We have informal news from the eMSCA that, based on the information we submitted, they concluded that no further information is required. The conclusion document should be finalized soon and will then be published on ECHA's website. This should then end the ongoing Substance Evaluation process.

CLH of silver containing active substances (SCAS) under BPR: The 60-day public commenting period for the CLH proposals already submitted by KemI (Sweden) for silver sodium hydrogen zirconium phoshpate and silver copper zeolite (including a Repr Cat 2 classification) has not started yet but they are on the preliminary planning for discussion at the June 2019 RAC meeting. PMC had a meeting with the European Silver Task Force (ESTF) on 5 July to update each other on the ongoing regulatory processes under REACH and the BPR. ESTF informed us of KemI's intentions to prepare CLH proposals for silver nitrate and silver metal, possibly including a Repr Cat 1B classification. This is concerning news and we would prefer that the additional reprotox testing for which we have submitted a testing proposal (see next point) can proceed before a decision by RAC on the CLH is made. Therefore, through Eurométaux, we have requested a joint meeting between ESTF / PMC / ECHA / Kemi in order to explain the importance of the interaction between the different legislations applying to Ag / Ag substances. We are awaiting a reply from ECHA.

Furthermore, while discussing PMC's / ESTF's bioelution / read-across approach with PMC's Ag Tox Experts, we recognized that further work in this area will be needed and we will need to put a plan in place for read-across / bioavailability. This is being further discussed internally and with ESTF.

Extended one-generation reproductive toxicity study (EOGRTS) testing proposal (TP) on silver acetate: PMC has updated the TP early April. We have not received the Draft Decision yet but the ECHA Evaluation Unit informed us that they are in the final stages of processing our TP and the draft decision should be sent soon (they anticipated still in September all going well). 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

Au

The human health literature study for gold and nano-gold has been initiated and currenlty being performed by an external consultant.

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

Pd and compounds

The agreed additional testing (cfr. minutes PMC 2017 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* genetox 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 2017 autumn BtB meetings) is ongoing. The dose range-finding test from the repeated dose toxicity&reproduction/developmental toxicity screening test with platinum dinitrate is completed. The testing is put on hold until we have clarity on substance ID (cfr next paragraph). The *in vitro* genetox assay for platinum dioxide shows absence of genotoxic potential. The i*n vivo* skin sensitisation assay (Local Lymph Node Assay) is running.

The testing proposals (TP) for *in vivo* genotoxicity testing have been published for public consultation, except for dihydrogen hexahydroxoplatinate, compound with 2-aminoethanol ('HHPA-2AE) and platinum dinitate. This delay is related to substance ID questions raised by ECHA (cfr next paragraph).

ECHA has also informally contacted the Lead Registrants ('LR') of proposed test substances HHPA-2AE and Platinum dinitrate to clarify questions on substance identity ('SID'). For HHPA-2AE the dossier has been resubmitted by the LR with the requested information before summer, and ECHA has informally confirmed the update is acceptable. The work for Platinum dinitrate is still ongoing. For this substance, we have initiated new analytical testing:

- in a first tier ^{195}Pt NMR will be used on solutions, solid and redissolved solid to confirm substance sameness and further clarify SID.

- depending on the outcome of the ^{195}Pt NMR testing, in a second tier, XANES/EXAFS analysis might be required.

This ongoing work will obviously delay the public consultation for the TP of Platinum dinitrate. ECHA has been informed about this.

Once TPs for *in vivo* genotoxicity testing have passed the public consultation, ECHA will prepare a draft decision. As the ongoing SID questions have delayed the public consultations for the TPs of the HHPA group (with HHPA-2AE as proposed test substance) and Platinum dinitrate, it is unlikely that all draft decisions will be prepared in parallel. Rather, they will be prepared per group, or for a few groups together, and as such be reviewed by the MSC (Member State Committee). Taking into consideration the properties of the proposed test substances in the different TP, this potential delay of the TP for the HHPA group and Platinum dinitrate has no influence on our internal testing strategy. Further discussions with the PGM WG and Tox Experts are required to finetune the testing, as well as with ECHA staff to defend our approach and formally agree on it. Our best guess for intiating the testing is Q2-3 2019.

Also Karstedt Concentrate has been subject to a substance ID check for the EOGRTS TP. For this substance no analytical testing was required and the requested additional information will be provided by the LR in the next month.

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

Refinables

Tonnage band declarations have been collected and the scope for the refinable dossiers has been set. Accordingly the SIP of the different dossiers have been revised. Lead registrants for the new splitted dossiers have been assigned and approval will take place during the upcoming refinables working group meeting.

A consultant was assigned to update the environmental and occupational exposure scenarios and this task is currently ongoing.

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

Rh and compounds

The additional AMES assays for poorly water soluble Rh(III) compounds (dirhodium trioxide, rhodium trihydroxide, rhodium tris(2-ethylhexanoate); (cfr. decision spring 2016 BtB meeting) have been finalised, and all confirm absence of mutagenic potential. The testing proposal for *in vivo* genotoxicity and the read-across justification document is under development. Once finalised, this will be included in the dossier of dirhodium trisulphate (the agreed test substance for further testing).

The additional testing with dirhodium trioxide (acute oral toxicity, eye irritation, skin irritation, *in vivo* skin sensitisation; cfr. minutes PMC autumn BtB meetings) has been initiated.

For more info: jelle.mertens@epmf.be

Ru and compounds

The agreed additional testing for Ru(IV) oxide (cfr. minutes PMC 2017 autumn BtB meetings) is ongoing. The *in vitro* genotoxicity assay showed absence of mutagenic potential. The *in vitro* skin irritation assay showed no irritating properties. The *in vivo* skin sensitisation assay is ongoing.

For more info: jelle.mertens@epmf.be

SVHC Roadmap

Following the listing of Pb metal in the Candidate List, EPMF met with ILA and other sectors impacted by this new regulatory action on Pb to discuss the advocacy strategy. ILA confirmed that they are happy to take the umbrella/coordination role but that they will only invest time in the development of strategy, advocacy and data for batteries and that they will not invest time in other uses. Based on this decision and taking into account the importance of Pb/PbO in the Precious Metals refining, the Board recommended to create a specific platform on Pb/PbO. If you are interest in joining this platform, please confirm this by email. A draft strategy will be discussed at the next SVHC Roadmap WG meeting.

Over summer, Eurometaux conducted a study to assess the CARACAL document related to the status of substance in substance/substance in mixture in the context of the Authorisation. A Workshop was organized on 18th September to discuss the first findings as a strategy to address this major threats for the metals industry. A summary will be presented at the next SVHC Roadmap WG.

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