CALENDAR:

1-3 April 2019:

Spring Back-to-Back meetings, Brussels

5-6 June 2019:

EPMF General Assembly, Bordeaux

8-10 October 2019:

Autumn Back-to-Back meetings

3 December 2019:

EPMF General Assembly and event, Brussels

Acronyms

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

Dear Members,

This is the last PMC REACH News since PMC is living its last days! A new format will be proposed next year to ensure a good communication and to allow you to use it internally.

For this last issue, the technical and scientific agenda is still very dense in the different metals group.

I would like to especially highlight the excellent outcome of the Ag Evaluation, with the conclusions of this Evaluation published on the ECHA website and confirming that nanosilver is not more toxic than silver compounds.

The end of the year was also busy with the first EPMF event celebrating the merger of EPMF and PMC. For more information: https://www.epmf.be/event/

We take this opportunity to thank you for the work done the past years with your support which is paramount to have a strong federation in the future.

We would like to particularly thank Guy Ethier who chaired the PMC Assembly and Management Committee since 2011, for his tremendous support, dedication and leadership.

We wish you and your family a Merry Christmas and Happy New Year!!

Enjoy the reading!

France

PMC Technical update

Ag and compounds

Substance Evaluation (SEv) of Ag metal (nano): The Conclusion document has now been published on the ECHA website (https://echa.europa.eu/documents/10162/c6597a4b-a88f-9bc9-1a23-b8a41772302c) and this ends the SEv process. Based on the information we submitted, the eMSCA has concluded that he concern that ionic silver may not be a proper 'worst case' in the risk assessment regarding toxicity of the silver nanoforms covered under REACH is now removed. Consequently, no further information is required at this point.

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 zeolite and silver copper zeolite (including a Repr Cat 2 classification) and for silver sodium hydrogen zirconium phoshpate (no Repr classification) has not started yet but they are on the preliminary planning for discussion at the June 2019 RAC meeting. In addition, KemI is in the process of deciding on CLH proposals for silver nitrate and elemental silver, 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, we have requested a joint meeting between the involved stakeholders (EMPF and ESTF) and regulators (ECHA and KemI). ECHA has been in contact with KemI to see how the various processes under REACH, BPR and CLP can be coordinated and KemI is currently considering the way forward.

Furthermore, EPMF and ESTF developed a strategy to strengthen their respective read-across approaches and work following a tiered approach is currently ongoing. A meeting with the Tox Experts from both sides is planned on 19 December.

Extended one-generation reproductive toxicity study (EOGRTS) testing proposal (TP) on silver acetate: EPMF has updated the TP early April and is still waiting for the Draft Decision which should be sent soon. After receiving the draft decision, a 30-day commenting period will start during which we should also have the opportunity to have an informal call with ECHA.

EPMF is currently conducting enabling work on the effects of silver on the gut biome, to support argumentation used in the TP. Since the overall balance of evidence on silver reprotoxicity shifted adversely over the last two years, EPMF has also developed a strategy in case of a 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 still under discussion in a substance-specific sub-group and EPMF is contributing to these discussions but the European Commission is currently looking for a new MS lead for this group.

For the chronic freshwater PNEC, EPMF 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. This assessment confirms the previously used chronic freshwater PNEC value on an improved scientific basis. These data have also been used by EPMF for commenting on a recent Swedish national consultation on EQSs. As a result, the Ag EQS setting in Sweden has been postponed.

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.

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Au

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

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PMCN

To bring the testing proposal on genotoxicity of potassium dicyanoargentate in line with the other compounds in EPMF, a second opinion on the genotoxicity testing strategy was requested. Based on the expert opinion of David Krikland, the COMET assay will be proposed as the most suitable *in vivo* genotoxicity study and the testing proposal will be updated accordingly.

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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.

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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.

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Refinables

In MISA the discussion on iUVCBs will start as from 2019. To start the discussions the focus will be first on substance identity and Eurometaux will be share the most recent draft iUVCB SID guidance by end of this year. This SID guidance is currently already being implemented in the updates of the intermediate dossiers by the different metal concortia, including EPMF. ECHA will review this guidance document and feedback is expected end January 2019 which will serve as a starting point for the discussions.

During the refinables WG meeting in October, the new lead registrants for the splitted dossiers were approved.

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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.

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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.

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SVHC Roadmap

The Assembly decided to create a Pb/PbO platform to properly address the next challenges related to Pb and PbO RMM. An EPMF strategy has been developed and approved by the platform. A summary has been shared with ILA to ensure consistency in advocacy activities and avoid duplication of efforts.

The end of the year was also dedicated to the finalisation by REACHLaw of the analysis of the SIS/SIM CARACAL paper and the development of an advocacy strategy to manage the impact on recycling of precious metals.

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