



EUROMETAUX CHEMICALS MANAGEMENT NEWS



Authorisation Platform Workshop & REACH Forum & EHS/REACH Steering Committee
 Back to back at the MCC Brussels
18 – 19 – 20 September

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Dear REACH Forum member,

It is difficult to believe we are already in September... Yesterday, I was walking light-headed in the hot and luminous summer, today I am crawling through a full calendar and multi-tasking in a conference. Looking at the faces around me in rainy Brussels, it appears that I am not the only one who seems a bit 'lost' in space and rhythm... you can still see the sea in the eyes of your neighbour on the tram, others contemplating pictures on their phones or what remains of their tan, some still walking with the bounce in their step you use to visit beautiful postcard places.

I know -from experience- that the reoccurrence of the to do lists and the traffic jams can be a strong encouragement to book a next break, but this September, I must admit I was rather impatient to go back to 'school'. I caught myself sharpening my colour pencils and looking for a new notebook before the end of my holidays.

The main reason is that the holiday season kept its promises, making me still feel like a happy penguin (see news July), as indeed the summer saw the concretisation of several projects or the beginning of some initiatives that are very close to Eurometaux's heart. For example:

- *Take MISA: 2 years were needed to define its scope and modalities but the participation rate to date and the horizontal learnings from the self-assessment tool make these efforts worthwhile. The exchanges with consortia, the continuously increasing support and trust from ECHA make way for a promising horizon.*
- *There was also that idea to organise a small bioelution exchange in the middle of the break to discuss some technical aspects: we expected 10 people but ended up with 40 workshop participants and memorable discussions, thus fully justifying but also further encouraging to follow the quote of E.H. Land "Do not undertake the program unless the goal is manifestly important and its achievement nearly impossible."*
- *The retirement of some of our "walking metals encyclopaedias" triggered the idea of creating a 'Metals Academy' to save the knowledge and provide newcomers in the industry with a toolbox and the first reactions to this 'dream' were numerous and enthusiastic.*
- *The restructuring of EHS and REACH towards a 'Chemicals Management' department and all the input received - demonstrating at least the intensity and vitality of the interactions with our members*

This is not an exhaustive list: as you will read in this edition there have been further interactions with Canada and a toxicologists' conference....Reasons enough to share with you the generated enthusiasm and thank you all for your contributions that made it a great summertime.

Let's now move -as serenely as possible -into autumn and the meetings' agendas, trying to preserve a bit of the magic of a sunny summer day!

Violaine Verougstraete, EHS director Eurometaux

ECHA REACH & CLP Activities: hot topics

ECHA Committees

RAC, SEAC and MSC surveys: *annual survey for stakeholders*

As regular sectorial stakeholder, Eurometaux has been invited to complete ECHA's annual survey on the functioning of the three ECHA Committees (RAC, SEAC, MSC). Members of the Committees (Member States or experts) are completing this survey as well. The questionnaire provides a good opportunity to raise comments and suggestions on how the meetings are run and prepared by ECHA's staff, evaluate the dynamics (including on the stakeholders' engagement) and assess the chairing of the sessions. Additionally we may make process improvement proposals. Eurometaux reiterated for example its concern on the too limited environmental classification expertise in RAC and asked to restore the annual meetings between the chairs of the three committees and the regular stakeholders, so as to further increase consistency between the committees and avoid -as much as possible- overlapping processes. Moreover at that meeting, we would especially like to raise the possibility for further commenting once we could study the draft CLH proposals. The surveys are analysed by ECHA's staff and outcomes presented to the Committees (more information: Hugo Waeterschoot and Violaine Verougstraete).

Authorisation

ECHA meeting with CTP-HT suppliers: *relevance of the substitute clarified*

Eurometaux was invited -as observer- to an exchange between ECHA and the CTP-HT suppliers and non-metal sector users. Given the LAD for CTP-HT and Anthracene is quickly approaching (March 2019), ECHA was keen to understand the status of the AfA preparatory activities in industry, the suppliers' involvement and address outstanding questions. Eurometaux was invited to make a presentation on the outcomes of the assessment of the intermediate status of CTP uses, allowing ECHA to re-confirm the outcomes, with one outstanding question on their use in specific applications like sliding gates and the mixing to manufacture bricks... This is to be followed up by the concerned sectors. Most interesting was ECHA's interpretation of the outcome of the Acrylamide court case on the secondary function of Annex XIV substances and the recognition of the preheated CTP as a legally valid alternative, as soon as some administrative hurdles have been cleared. However, ECHA could not guarantee that a Member State would not trigger SVHC status on this substance in future, considering its hazard properties. They also indicated that the CMD would still require an investigation on potential substitutes. Finally the suppliers clarified that they are preparing applications for 3 uses including CTP-HT use in ramming paste on which the interest of the metals sector was requested (more information: Hugo Waeterschoot).

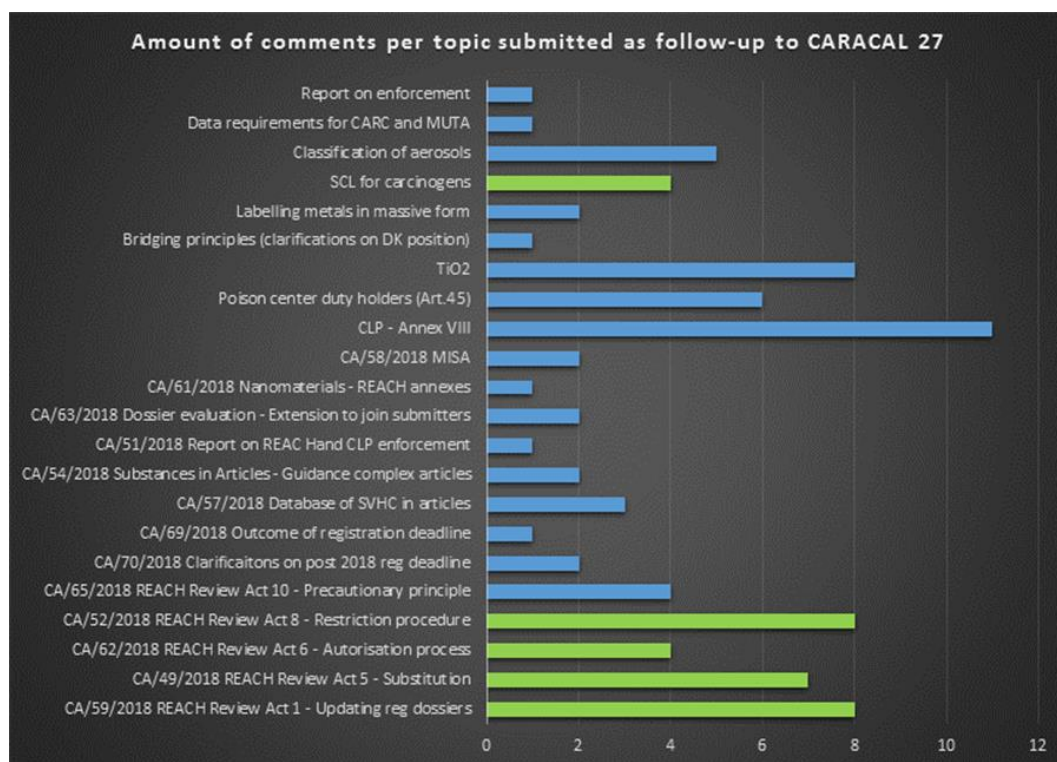
COMMISSION REACH & CLP Activities: hot topics/issues

CARACAL

CARACAL 27: a lot of comments submitted following the June meeting

The agenda of the last CARACAL meeting was (as usual) full of important REACH and CLP related topics. CARACAL members had the possibility to submit follow up comments.

The below chart provides an overview of the amount of comments submitted on the various topics; it is a generic indicator of the levels of interest among CARACAL members. The topics commented by Eurometaux are marked in green. We are currently analysing all the comments. Specifically on the REACH Review actions, a general overview of "who commented what" will be presented by Eurometaux on the 19th of September at the REACH Forum meeting; this should give a general idea of how/where future discussions and actions might focus on (more information: Lorenzo Zullo).



EUROMETAUX REACH, CLP & EHS Activities: hot topics

Resource mapping to respond to REACH / ECHA challenges

SPERCs Quality Criteria: a revised version will soon be shared with ECHA/Member States

The cross-industry SPERCs taskforce has been active over the summer and proceeded with the work on the SPERCs Quality Criteria (QC) as follow-up to the workshop organised in June with ECHA and Member States' representatives. The draft QC have been revised to give more focus on the SPERCs elements that are considered to be of most relevance, such as the description of the scope (process/product-types) and the key conditions of use that are driving environmental releases. An introductory text has also been integrated to the document containing the QC, giving the background and purpose of the QC and some explanatory notes for certain criteria. The draft QC is expected to be shared with ECHA and MSs in the coming weeks. The minutes of the workshop held in June have also been prepared and are currently being checked for approval by the participants; the final version is expected to be made available in September (more information: Frederik Verdonck and Lorenzo Zullo).

Classification

Cobalt CLH call: follow-up

During the last Taskforce call (July), it had been agreed to further reflect about the possible arguments to use in favour of a split of the concentration limit according to the physical form of cobalt (i.e. use the 0.1% GCL for the massive form, the 0.01% SCL for the powder form), in line with the precedent set by the lead metal classification. The split concentration limit could be a back-up plan in case the REACH Committee does not support the setup of the expert group on the potency and the use of the GCL ad interim in the ATP. A call was held on 2 August to further discuss the arguments to have at hand. Regulators will be keen to be assured that for example a massive alloy containing cobalt metal will not generate fine dust under reasonably expected conditions of use. Bioelution data will also play a role in this discussion, so as to support a difference in release between the difference physical forms of cobalt. In parallel, further technical work has been done on the 'T25 issue' and the applicability of the methodology used in CLP to derive the carcinogenic potency. Several commodities, as well as contracted consultants have reviewed the T25 calculations prepared by Cobalt Institute/Nipera and Eurometaux, yielding some interesting findings. It is expected that the Commission inter-service consultation on the ATP proposal will be launched early September, which will be the opportunity to take stock on the advocacy and technical activities and needs. The next call is scheduled for 7 September, 15:00 (more information: Brigitte Amoruso, Ruth Danzeisen, Jenny Poulter, Hugo Waeterschoot and Violaine Verougstraete).

Preparing for the RAC debate on Lead metal: an upcoming challenge!

The lead sector received insight in the Rapporteurs proposal for the upcoming RAC meeting. The proposed draft opinion is disappointing given it did not respond to our legitimate questions to split the classification in a massive and a powder entry based on available data. Other aspects that were not taken forward include a focus on standard species and a better recognition of the data richness of the lead file. In response the lead sector, supported by Eurometaux, prepared a response providing further evidence why the requests from industry are supported by data, the CLP guidance and previous practices on metals. The lead metal case will be discussed at the RAC meeting on 13 September and the lead sector will defend the case in person together with Eurometaux (more information: Jasim Chowdhury and Hugo Waeterschoot).

Metal-specific REACH application tools and concepts

Bioelution Workshop: 10 August

While the workshop was initially set up to discuss technical aspects related to the use of bioelution for the classification of UVCBs, the large participation it triggered resulted in a reshuffling of the scope and objectives, which proved to be useful to ensure all would have the same information and understanding of the status and progress made on the use of bioelution data for classification. Other objectives of the workshop were to be able to make progress on technical questions raised by ECVAM in the context of the validation of the gastric protocol and identify whether additional guidance should be prepared for companies who want to use bioelution testing for classification and communicating in the SDS. Very interesting input was provided by the participants on the SOP and other questions posed by ECVAM and a number of follow-up actions were identified. The objective now is to update the documents submitted to ECVAM in February to consider the input and further data. It was also agreed that the use of bioaccessibility data for UVCBs requires further work: it was proposed to reflect collectively on the different approaches that are proposed, also looking at the legal and the scientific aspects. ECI kindly volunteered to organise a workshop to further debate this with all interested experts. A workshop report was circulated to the participants mid-August and is available on request (more information: Adriana Oller and Violaine Verougstraete).

Metals Sectorial Approach

MISA Exchange with ECHA: 30-31 August

Eurometaux and ECHA met on 30-31 August to prepare the next steps of the MISA programme, mainly the signature event and the first workshops on Information requirements/adaptations/weight-of-evidence. This was the opportunity to inform ECHA on the current MISA participation and to compare it with their list of registered metals, so as to evaluate the coverage and assess where further efforts should be made to increase participation. Follow-up actions were agreed upon, both for Eurometaux and ECHA, but ECHA acknowledged that the participation from the metals under the EM umbrella is already satisfactory. Ideas were exchanged on how MISA's commitments could be formalised before the first workshop scheduled for 2 October, as the workshop shall only be accessible to MISA participants, but still including a stimulating and original 'touch'. Communication aspects (i.e. MISA page on ECHA website, MISA newsletter, information towards Member States) were discussed as well. Possible criteria to assess the progress with MISA (overall or on specific activities) were debated as well as some 'indicators' that will be needed for ECHA's Management Board, Commission and Member States to justify and support ECHA's resources but also to encourage Member States refraining -as much as possible from regulatory activities- on substances included in the MISA programme. Important to know is that ECHA has now mobilised a team that will actively/consistently participate in MISA. This was immediately visible when drafting the agenda of the 2 October workshop: ECHA had prepared some cases that could be presented and extracted a number of learnings to share. The learning lessons and questions extracted from the completed SAT-HH were very useful in that regard as well (thanks a lot to all those who sent us a completed template) as they allowed to identify 'horizontal' themes to be discussed in breakout format to ensure a maximum of interactivity and agreements. Further actions were identified with regard to e.g. the consortium workplan template that was circulated to the Forum end of August and on the other MISA activities (e.g. UVCBs, Environmental Classification and Rapid Removal). A complete update on the exchanges with ECHA and reached agreements will be provided at the REACH Forum meeting on 19 September. After the formalisation of the 'MISA commitment' (signature event), steering, governance and updates will be handed over to the "MISA community", including participants from industry and ECHA (more information: Hugo Waeterschoot, Lorenzo Zullo and Violaine Verougstraete).

FURTHER OUTREACH OF REACH

ICMM-CMWG meeting: good debate on how to ensure an efficient input in OECD chemicals management activities

The ICMM Chemicals Management working group chaired by Ilse Schoeters met back-to-back with the ETAP meeting (see further) providing updates on Chemicals Management of minerals and metal issues of global relevance. Claudine Albersammer - ICMM-secretariat's contact point for the CMWG activities- , informed the working group of the revised structure, ICMM's management organisation as well as the budget for the CMWG for 2019. The link with the ETAP meeting allowed to define communication and advocacy needs, building on the science developed through ETAP projects. The Rapid Removal concept was one of those whereby a Taskforce was created at worldwide level to promote regulatory acceptance. A key objective of ICMM's CMWG is to ensure better coordination of chemical management activities at global level. To this extent, Claudine gave an overview of technical and policy developments at UN level. Regional updates were provided for the US (NAMC), Canada (Scott Thurlow) and the EU (by Eurometaux) allowing the identification of common issues and concerns such as the exchange of effects data sets. The need for succinct briefing notes was identified on important developments (e.g. bioelution) to increase the awareness of members in different regions. The issue of impurities management was raised by Eurometaux and reactions demonstrated a broader geographic interest. It was agreed that the sector needs to investigate how material flows of impurities could be affected by restrictive regulatory measures. Another fruitful discussion was held on better coordination and preparation of input regarding chemicals management in OECD meetings. Going forward, "agenda input and review calls" will be organised shortly before the OECD joint meeting on chemicals. Such calls will allow briefing industry in an efficient way of important developments, whilst helping define sectorial positions in advance of the meetings. The latter will help Kai-Sebastian Melzer (ICMM's representative) to raise them at the BIAC level and subsequently at the OECD Joint meeting level (more information: Ilse Schoeters, Kai-Sebastian Melzer and Hugo Waeterschoot).

ETAP panel met in New York: population dynamic models seems a new important avenue to improve the ecological relevance of metals risk assessments

The ETAP panel advises the metals industry (mainly represented by metal commodities) on critical ecotox issues that need a scientific opinion/solution as well as providing early signs on emerging more long-term environmental toxicity issues. Eurometaux attends the meeting as an observer to enable taking these scientific issues forward to the EU technical/policy discussions. This year the ETAP panel provided a view and a way forward on 4 key issues: 1. *Mercury standards, fate and environmental effects*, concluding the suggested EU limit for secondary poisoning set at 20 µg/kg being scientifically robust and reasonable while suggesting some field work to complement and validate the laboratory conclusions; 2. *Providing clear*

support for the development of Mechanistic-based population models given their high relevance for metals ecotoxicology and risk assessment; 3. Searching an explanation for the *high sensitivity of Lymnaea stagnalis* (snail) given that it's driving many metals hazard and risk assessments (seems the food source may be part of the problem) and 4. The potential *impact of time trends like climate change on Metals in Waters, Sediments, and Soils*, noted as indeed having an impact on the bioavailability levels due to physico-chemical changes in these compartments. Each of those themes resulted in recommendations for white papers, test work or workshops to progress further. Prof. Karel De Schampelaere (Ghent University) gave as a guest speaker a superb key note presentation on theme 2 explaining why and how Dynamic Energy Budgets (DEB) which are common for all organisms, combined with Individual Based Models (IBMs) which keep track of how each individual in the population can progress ecological risk assessment for metals. In addition to these 4 themes, the panel members provided a series of potential emerging issues which will be evaluated by industry on their importance and relevance. The ETAP meeting remains an interesting forum to explore novel solutions for environmental challenges for the metals sector and an important base source of information to provide solutions for regulatory challenges. While still effective, the sponsors suggested that some changes to the format of the meeting could maintain and further develop the efficiency of the panel for the future (more information: Jelle Mertens, Ilse Schoeters and Hugo Waeterschoot).

Meeting with Environmental Canada: *discussions on Rapid Removal and MISA*

On 24 August the metals sector (represented by Stijn Baken, Emily Garman and Hugo Waeterschoot) and Justyna Laurie-Lean from the Mining Association of Canada, met in Ottawa with Environmental Canada for an exchange on relevant issues for metal chemicals' assessment. ENV. Canada explained the status of their CEPA/CMP programme that will review a long series of metals in the near future (2018-2019: Zn, Cu, talc and for 2019-2021: amongst many others, Al, Ag, Mn, ...).

Upcoming assessments: CMP3 Rolling Work Plan for Inorganics

- Latest published update, December 2017.

Year 2 Jan - Mar 2018	Year 3 Apr - Sept 2018	Year 3 Oct 2018 - March 2019	Years 4-5 Apr 2019 - March 2021
Cyanides Draft Screening Assessment	Update to the Approach for a Subset of Substances Prioritized during Categorization That Have Already Been Addressed	A subset of inorganic substances with low concern for human health and the environment Draft Screening Assessment	Silver Draft Screening Assessment
	Science Approach Document for the Ecological Risk Classification of Inorganic Substances	Zinc and its compounds Draft Screening Assessment	Thallium Draft Screening Assessment
	Antimony Draft Screening Assessment	Copper and its compounds Draft Screening Assessment	Manganese Draft Screening Assessment
		Talc Draft Screening Assessment	Acids and Bases Draft Screening Assessment
			Aluminum Draft Screening Assessment



Environment and
Climate Change Canada

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Canada

ENV. Canada confirmed that the contribution from the metals sector including REACH data sets were always most appreciated and reiterated their interest in data exchange agreements with concerned Consortia. A template they recently developed could be used for communication with the metals covered by the 2019-2021 round, so as to frame the exchange of data. They also acknowledged the challenge of assessing data-poor metals and the potential QICAR approach to fill such gaps raised interests from Canada.

But most of the meeting was spent discussing the history and status of the development of a concept and tool to measure the Rapid Removal of metals. This was triggered by the critical input from Canada at a past ECHA workshop. CANMET explained the extended Transformation Dissolution protocol and showed with convincing data that according to its aims, the protocol works to demonstrate Rapid Removal and lack of Resuspension. The following debate focussed on the selection and loading of the particles in line with comments received from regulators during the SETAC workshop on this theme. Industry confirmed that it was working on this issue and invited ENV. Canada to support further debate at the OECD and UN-GHS in the future. Industry further underlined the critical and appreciated work done by CANMET and expressed hopes for its continuation. ENV. Canada confirmed their interest in following the further steps of this project (e.g. including the EU debate). The ongoing MISA project was the last item discussed. ENV. Canada had picked this up and was most interested to hear more about it. Eurometaux explained the aims, objectives and challenges as well as the two planned parallel tracks. It was obvious from the informal talks after the meeting that Canada is most interested in following the MISA experience and results given both tracks may provide valid input for their national chemicals programme (more information: Stijn Baken, Emily Garman and Hugo Waeterschoot).

CALENDAR

- 10-14 September: RAC-46 – ECHA (Helsinki)
- 10-14 September: SEAC-40 – ECHA (Helsinki)
- 12-13 September: Scientific Workshop on Grouping of Nanomaterials - NanoReg2/ Gracious – OECD (Paris)
- 18 September: Authorisation & Restriction Platform (Impurities issues) – MCC (Brussels)
- 19 September: REACH Forum – MCC (Brussels)
- 20 September: EHS/REACH Steering Committee – MCC (Brussels)
- 24-27 September: EHS Autumn Week – MCC (Brussels)
- 27-28 September: Management Board-51 – ECHA (Helsinki)
- 2 October: MISA Workshop – MCC (Brussels)
- 8-12 October: MSC-61 – ECHA (Helsinki)
- 11-12 October: MSC-RAC workshop – ECHA (Helsinki)
- 16 October: Nanos Taskforce – MCC (Brussels)
- 17 October: Evaluation Platform – MCC (Brussels)
- 28 October-31 October: RAC-47 – ECHA (Helsinki)
- 6-7 November: NMEG12 – ECHA (Helsinki)
- 7 (PM) November: NeRSAP/Substitution Workshop – (To be confirmed)
- 8(PM)-9(AM) November: NeRSAP Workshop – UA (Antwerp)
- 8-9 November: WS Implementation REACH Info Requirements for Nanomaterials – ECHA (Helsinki)
- 19-23 November: RAC-48 (A)– ECHA (Helsinki)
- 26-30 November: RAC-48 (B)– ECHA (Helsinki)
- 26-30 November: SEAC-41 – ECHA (Helsinki)
- 4 December: ChemWatch Conference “The future of Authorisations” (tbc) - Brussels
- 10-14 December: MSC-62 – ECHA (Helsinki)
- 13-14 December: ECHA Management Board-52 – ECHA (Helsinki)
- 17 December: Authorisation & Restriction Platform (RMOa update/MFA) – MCC (Brussels)
- 18 December: REACH Forum - MCC (Brussels)

ACRONYMS

AfA: Application for Authorisation	MISA: Metals & Inorganics Sectorial Approach
ATP: Adaptation to Technical Progress	MSC: Member State Committee
CanMET: Natural Resources Canada	NAMC: North American Metals Council
CARACAL: Competent Authorities for REACH and CLP	OECD: Organisation of Economic Cooperation and Development
CEPA: Canadian Environmental Protection Act	QC: Quality Criteria
CLH: Harmonised Classification and Labelling process	QICAR: Quantitative Ion Character Activity Relationships
CLP: Classification, Labelling and Packaging Regulation	RAC: Risk Assessment Committee
CMD: Carcinogens and Mutagens Directive	REFIT: Regulatory Fitness & Performance Programme (EU)
CMP: Chemicals Management Plan	SAT-HH: Self-Assessment Template – Human Health
CMWG: Chemicals Management Working Group	SCL: Specific Concentration Limit
	SDS: Safety Data Sheet
CTP-HT: Coal Tar Pitch High Temperature	SEAC: Socio-economic Analysis Committee
DEB: Dynamic Energy Budgets	SETAC: Society of Environmental Toxicology and Chemistry
ECVAM: European Centre for the Validation of Alternative Testing Methods	SOP: Standard Operating Procedure
ETAP: Environmental Toxicology Advisory Panel	SPERC: Specific Environmental Release Category
GCL: Generic Concentration Limit	SVHC: Substance of very High Concern
GHS: Globally Harmonized System	TDp: Transformation Dissolution protocol
IBM: Individual Based Models	UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials
LAD: Latest Application Date	