Eurometaux
European Association of Metals

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EUROMETAUX CHEMICALS MANAGEMENT NEWS

Please join us in December:

- **06: Chemicals Management Steering Committee**
- **12: Human Health Taskforce**
- **15: Zero Pollution Project Group**
- **16: Industrial Emissions Taskforce**
- **20: Evaluation Taskforce**

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Dear All,

The advantage of November is that the cold and darkness made me return to more intellectual inside activities, like attending RAC meetings or preparing Christmas decorations. Glögi, glossy paper and reindeer bearing socks are an integral part of these actions, providing the place with a smell of cinnamon, a tint of gold and adding a couple of additional degrees to the ambient temperature.

Now, it could be the spiced wine – or maybe all the 2022 discussions on chemicals -but all of a sudden, I started to reflect about the intrinsic properties of the activities promoted in the paragraph above (maybe irresponsibly?). What do I know in terms of classification and dose-response? And what about the potential exposure to the mixture of glitter, flavours and warmth these activities entail? Can I conclude to a 'safe use' or should I launch risk management?

Such a key concern can only be addressed by a thorough, state of the art risk assessment.
Luckily there are some guidance documents that directed me on the steps to follow. With a bit of advocacy, I could even think about submitting the document for your (and RAC's) opinion.

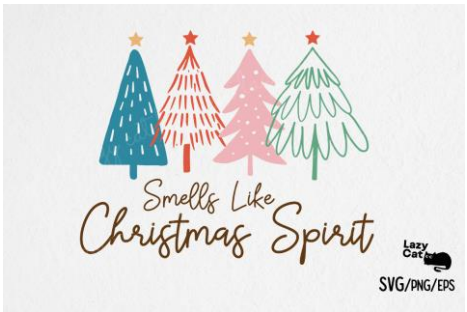
So, starting with hazard identification: I could possibly locate some human epi data to support the consideration of labelling, but from experience I know that animal data are easier to conclude upon, I left aside the possible volunteers and tested a lobster species wrapped in a silver garland, fed systematically with almonds and ginger. The identification of a threshold proved to be a challenge, even if it seemed that some kind of ice-hockey stick was implicated. The issue of variability was easily addressed by super conservative assessment factors, and I ended up with a minimal full excess risk level.

As exposure assessment has always been a passion, I was looking forward to the models and assumptions the guidance documents would prompt me to apply. However, when I looked at the outcome of the calculations that got me to the typical exposure level -based on huge amounts of game meat eaten by Christmas toddlers and unreasonable estimates of skin surface in contact with the shiny stars of the ECHA corridors- I had to wonder whether the result was un- or fairy-realistic. I proposed to climb some tiers to use measured data, but RAC expressed doubts about my detection limits and hence threw my refinements away, in a closed process.

Despite the difficulties encountered in the first two steps, I courageously started to calculate RCRs but then understood that I had to reduce the target even further by using a MIF-MAF factor. I ended in scenarios that I could not even communicate as the users would freak out.
…

I started again, closing my PC and avoiding defaults, scribbling on a simple beermat in good company and the result appeared much more convivial. True… it requires some conditions, namely 1 1⁄2cups of water, 1⁄2cup of sugar, 5 whole cloves, 1 cinnamon stick, 1 teaspoon of whole cardamom pods , 2 inches of candid orange rind, 750ml red wine , 2 tablespoons of raisins and almonds. However, putting all these ingredients together, I was rapidly able to demonstrate adequate control (with a review period to be fixed).

Violaine Verougstraete



COMMISSION

CARACAL: *16-17 November*

The first day of CARACAL was devoted to CLP, in particular to the discussion of the Delegated Act on the new hazard classes. The Commission went through the text of the Act and its annexes, presenting the changes made in follow-up of the dedicated CARACAL meeting held on 17 October and the Public Consultation. Participants were allowed to react 'on the spot' as it was announced that it was to be the last discussion. In follow-up, Commission has uploaded a revised version, which went through a dedicated session on 29 November (see below). ECHA explained the plans for updating the guidance to address the new hazard classes. They aim to publish the guidance before the end of the transition period (mid-2024). As the Act will be published in the absence of guidance, ECHA will publish some information on its website on what to do in the interim. They will have consultations with the ED/PBT expert groups and launch the PEG consultation end of summer 2023.

An update was provided on the UN GHS programme and EU's proposal for new hazard classes, as well as on the 19th and 20th (introducing and applying notes for the boron compounds). To be noted: the discussion on the 21st Adaptation to Technical Progress (ATP), which includes the Pb and Li entries, has been postponed to January 2023 (date to be confirmed). Commission concluded the CLP part by indicating that they plan to adopt the revised CLP text proposal on 19 December (the same day as the Delegated Act on new hazard classes) and start the discussion with Council/EP in January 2023.

On REACH, which was discussed the second day, Commission explained that its communication would be limited to recall that all Impact Studies performed in view of REACH 2.0 were submitted to the RSB (Regulatory Scrutiny Board), which had finalised its review at the time of the CARACAL meetings. The only REACH point that was elaborated more in detail related to the Essential Use Concept, for which the consultants gave a presentation on the outcomes of the study. The slides gave a first glimpse of the consultants' criteria and detailed recommendations on how the EUC could be assessed and implemented under REACH 2.0 and other environmental legislation. However, Commission did not allow for any discussion on the theme and repeatedly retold CARACAL that this was the consultants' views. It seems though that Commission and the consultants appeared to agree on a gradual (step-by-step) implementation of the concept.

In both sessions, Commission made a presentation on the strategic research and innovation plan & sustainable by design themes. A Commission Recommendation should be adopted in the following weeks. After the adoption of the framework, Commission will launch a phase to test the framework and collect comments to ensure its operability. Eurometaux volunteered to be involved, to provide feedback, e.g., on the implications of too hazard-driven steps.

Eurometaux's summary record was circulated to the CARACAL Taskforce on 19 November (more information: Hugo Waeterschoot and Violaine Verougstraete).

CARACAL ad-hoc meeting: *last discussion on the introduction on new hazard classes in CLP*

An ad-hoc CARACAL meeting with focus on the introduction of new hazard classes in CLP took place on 29 November. The new proposed hazard classes are: Endocrine Disruptors (EDs) and the following, that are not applicable to metals: PBT, vPvB, PMT, vPvM. The meeting was intended to provide an overview of the state of play of the proposed Delegated Act. It was reported that, during World Trade Organisation/ Technical Barriers to Trade Committee (WTO/TBT) notification, US and China questioned the misalignment with the UN GHS classification system. The Commission plans to reply to those comments by re-confirming the need to move ahead without changing the legal text. The only changes introduced were minor aesthetic adjustments for legally improving the text.

The proposal for amending CLP will now need agreement from Parliament and Council; in parallel, it will be shared at UN level to prepare the discussion for amending the GHS. The Commission stated that it is optimistic about reaching an alignment while continuing its route to protect Human Health and Environment (for more information: Lorenzo Zullo and Violaine Verougstraete).

Titanium Dioxide (TiO2): *EU Court of Justice ruled against the Commission on the classification of TiO2 in powder form as carcinogenic*

The EU Court of Justice has recently concluded that the European Commission committed a "manifest error of assessment on the harmonised classification and labelling of TiO2 as a carcinogenic substance by inhalation in certain powder forms". The withdrawal of the classification is not immediate. The European Commission has two months to appeal. Until then, or afterwards during the appeal, the classification will remain. It is still not clear whether the

Commission will appeal or how, meanwhile, new submitted classification dossiers - based on the same principles used for TiO2 - will be handled (for more information: Lorenzo Zullo and Violaine Verougstraete).

EU AGENCIES

EUROPEAN CHEMICALS AGENCY (ECHA)

ECHA COMMITTEES

RAC-63: *plenary discussions on cobalt, PAHs and LEVs*

RAC has held its last plenary meeting of the year, in face-to-face mode for members and regular stakeholders but remotely for occasional stakeholders and experts, which deprived the latter from the Finnish end-of the-year sweets and snow.

The RAC group warmed up by having a final discussion on the cobalt and the PAH (Polycyclic aromatic hydrocarbons) 'Exposure Risk Relationship'. For cobalt, a study on diamond polishers was used as key study to derive a proposed value of 1 µg/m³ for the inhalable fraction (i.e., to protect against a reduction in lung function), and the National Toxicology Program (NTP) rodent study with Co sulphate used to derive a proposed value of 0.5 µg/m³ for the respirable fraction (i.e., to protect against lung carcinogenicity). The respirable fraction is associated with excess cancer risks, as RAC concluded that there were still uncertainties regarding the genotoxicity of Co substances, and declined to give Co a mode-of-action based threshold (industry evoked testing proposals submitted 3 years ago). No Biological Limit Value was proposed -in line with the Nickel Occupational Exposure Limit (OEL) assessment but Biological Guidance Values are identified (2 and 0.7 µg Co/L in urine for females and males respectively). A Derived No-Effect Level (DNEL) was identified for reproductive toxicity effects (4 µg Co/m³ respirable) occurring at higher levels than the values indicating lung effects. Industry continues to question the use of the key study for lung effects, which is cross-sectional and for which co-exposure to diamond dust as well as other abrasion products was reported, in a large database of alternative high quality cobalt epidemiology studies. Also, this study reports indications of a restrictive effect, whereas Co exposure has consistently been shown to be associated with an obstructive effect and refers to total dust and not to the inhalable fraction. Industry also continues to question the lack of consideration of human epidemiology data in supporting a less conservative cancer dose-response for cobalt. The values proposed by RAC are for cobalt and all inorganic cobalt compounds, without distinction for the poorly soluble compounds and compounds included in complex substances. RAC's reasoning is that no toxicity data is available to discriminate these compounds (industry recalled that testing proposals were submitted 4 years ago) and that in most exposure settings, workers are exposed to mixtures of cobalt compounds. The available data do not allow to discriminate workplaces where the only exposure is to poor soluble compounds. Industry also suggested -for reproductive toxicity- the use of a specific biokinetic model that demonstrates that the distribution of cobalt to the tests differs between animals and humans but RAC sticked to its generic derivation. RAC's opinion, when ready, will be forwarded to Commission for the tripartite discussions under Occupational Safety Health (OSH). The learning lessons of the Co OEL will be presented to the Human Health Taskforce on 12 December.

On PAHs, the Exposure-Risk Relationship (ERR) proposed is based on Benzo-a-Pyrene as exposure indicator and lung cancer. The uncertainties of the approach are acknowledged: the ERR is derived for lung cancer only, skin cancer was not considered due to the lack of quantitative data; a definite health-based OEL for effects on reproduction/development for the respirable fraction cannot be fixed due to lacking data. As PAHs are non-threshold carcinogens, no health-based Biological Limit Value (BLV) can be defined.

Interesting discussions took place on some of the Applications for Authorisation (AfAs), related to the presence of a continuous control system for the functioning of Local Exhaust Ventilations (LEVs) (whether this should be translated in a soft or hard recommendation) and the high risk levels in some AfA opinions that are now rejected by some members of the REACH Committee (more information: Vanessa Viegas, Martin Wieske and Violaine Verougstraete).

RAC-63: *copper environmental classification: no classification for the massive form!*

RAC discussed in plenary the outcomes of the RAC CLH Working Group discussions (held in October) and concluded that a split classification between the massive and powder form is justified for copper metal. The powder is much more soluble and therefore will be classified for the environment as Acute 1 (M=10) and Chronic 1 (M=1), whereas the massive will not receive any environmental hazard classification. This time, the science and data prevailed, and the CLP guidance was mostly followed correctly. In particular, the classification recognised a pH banding approach and a normalisation of the effects data for the two most relevant parameters that influence the bioavailable fraction, i.e., pH and DOC. This is

almost the opposite of the approach followed by RAC on Pb one year ago. Moreover, the Rapporteur -supported by RAC- went a step further by expressing the copper release per unit surface area, which brings the hazard classification even closer to reality as it considers the shape of the substance. However, some concerning issues remain, e.g., the extrapolation of the transformation-dissolution data to pH 5.5 and the lack of recognition for a high-quality dataset on rapid environmental transformation. Finally, RAC did not comment on any changes to existing entries for copper flakes and for granulated copper, specifying that this is up to the EU Commission to decide. Eurometaux and the copper industry experts who attended the meeting acknowledged the quality and thoroughness of the review conducted by the Rapporteur (more information: Carol Mackie, Stijn Baken and Hugo Waeterschoot).

RAC-63 & SEAC: *restriction on lead in ammunition*

The European Ombudsman took into account comments submitted by industry, which stressed that crucial information -impacting the outcomes of the Pb restriction in ammunition case- had not been made available to stakeholders while it was used by the ECHA SEAC Rapporteur. This triggered a reopening of the case (via article 77(3) request), including a new Public Consultation used by the sector to provide detailed information aiming at improving the risk calculations (related to the Pb intake via game meat).

RAC and SEAC debated the new evidence and while the conclusions were not significantly different, the case sets an important precedent. If Commission follows the opinions, the use of Pb in ammunition for civilian applications in open air as well as the use of Pb in fishing tackle will now be banned in the EU, although in a phased way. One of the exemptions agreed by RAC/SEAC allows the use of Pb in Cu brass in concentrations higher that the restriction trigger of 1 % (up to 3 %). This exemption is however proposed to be conditional to a review on how the Pb in brass content can be reduced over time (more information: Hugo Waeterschoot).

SEAC-57: *Eurometaux reported on NeRSAP and the on the workshop on chromates plating*

The last SEAC meeting of the year was a very busy one with several restrictions (including the one on Pb, see above) and many Authorisation Applications (AfAs) to be discussed, most related to the use of chrome plating on metals like steel, aluminium and nickel.

In the debates of the AfAs, some SEAC members expressed the importance to consider the conclusions of the milestone-setting workshop on the potential regrettable substitution of CrVI by CrIII held in October (see CM news of October). Both the ECHA secretariat as well as Eurometaux had been invited to report on the outcomes of this workshop, which emphasise that not considering how CrIII is produced and used in the plating process could even lead to a higher potential exposure of the workers (instead of the aimed elimination). The report triggered the attention of the SEAC members, and some rapporteurs started to use the conclusions in their assessments of new AfAs. However, some SEAC members would still like to stick to the current substitution approach. This means that we will need to continue to stress that for metals and inorganics, a full life cycle perspective is crucial to ensure industry does not invest in substituting technologies that do not improve the situation for workers and the environment.

Eurometaux was also invited to report on the main outcomes of the 10th NeRSAP meeting, which debated important themes like how a RMOa can integrate risk management in a 3Cs concept (Chemicals, Climate and Circularity), the development of new Willingness to Pay studies coordinated by the OECD, etc… (see CM News of October). NeRSAP is a network that brings together consultants, industry organisations, Commission, ECHA and SEAC members in a learning network. The added value of NeRSAP was confirmed by several SEAC members (more information: Hugo Waeterschoot).

ECHA OTHER ACTIVITIES

REACH-Processes and IT & Evaluation Meeting: *with ECHA, Cefic, Concawe, Eurometaux*

On Wednesday 30 November, ECHA and industry met to exchange and discuss on several REACH and IT processes and changes. ECHA explained their internal changes to face the upcoming need to develop -in the next 3-8 years- a new centralised user interface, where there will be better integration of the IT landscape, more cost-efficient maintenance, centralised backlog management, user support and communication. This medium/long term work is foreseen to change and improve the entire IT systems at ECHA to better communicate to all users, i.e., involved in REACH, BPR, PPP, PIC,… The new portal is tentatively expected in 2026 and exchanges with stakeholders (via collaboration with industry groups) will start soon: in the meantime, a paper on the future of ECHA's submission systems will be published in mid-2023.

On the ongoing Assessment of Regulatory Needs (ARNs) work, ECHA explained that they process an average of 70 groups/year, but more are still published as about 50 groups are in the backlog from the past activities. ECHA explained that the ARNs is not a formal legal process and that they use it to identify where more action is needed on their side: chemical similarity and manageable group size are parameters used by ECHA to set up these substances' groups. To run quicker searches, it is recommended to export the available list and then filter through it and check the status information

to identify if the process is concluded, still under development or whether follow up action appears on the list. ECHA recognised that a webinar would help in exchanging with industry and clarify pending questions. This might be organised in the coming months.
The new Unknown or Variable Composition, Complex Reaction Products and Biological Materials (UVCBs) grouping guidance was discussed and industry expressed several concerns to ECHA's approach. Because of the very specific questions raised by industry, it was proposed to further discuss this topic in a dedicated meeting and, on behalf of the NFM industry, Eurometaux proposed to the group to explain the sameness exercise we run and the way we proceeded with the full assessment approach. The reason to bring up our inorganic UVCB case there, is especially to reach out to other experts in ECHA and to possibly have more official recognition. We will follow up this item closely (for more information: Federica Iaccino).

ECHA guidance document on REACH Data Sharing: *new version released*

The European Chemicals Agency has published an updated version of the guidance document on data sharing. The objective of the Guidance is to provide advice on the sharing of data and cost as required under REACH between multiple registrants of the same substance. The document also describes Confidential Business Information, Intellectual Property Rights and Competition Law issues in the context of data sharing.
The new version takes into account the end of the phase-in scheme on 31 May 2018 and the applicability of Articles 26 and 27 of REACH to all substances alike. Obsolete information has been deleted, namely references to phase in substances, pre-registration and Substance Information Exchange Forum (SIEFs).
The update includes: i) the inquiry process under Article 26 REACH and related data sharing obligations before submitting a registration, ii) data sharing among existing registrants: as a result of dossier or substance evaluation decisions, or in case of tonnage upgrade; iii) data sharing for read-across purposes; iv) clarification of other legal obligations.
The guidance document can be downloaded for ECHA website: https://echa.europa.eu/guidance-documents/guidance-on-reach

EUROMETAUX CHEMICALS MANAGEMENT

Human Health Taskforce: *catch up call*

The meeting started by taking stock on the Extended One-Generation Reproductive Toxicity Studies (EOGRTS) item, with a short status update on ECHA's evaluation work followed by the sharing of the learning lessons on the EPMF EOGRTS studies (thanks Anissa Alami). A series of welcomed recommendations were formulated and discussed by the participants. The group was also informed about a Cefic call scheduled for 22 November which aimed at discussing critical parameters in the EOGRTS in reply to ECHA, based on a parallel analysis of 8 studies. In follow-up, the Taskforce received a summary of the main outcomes of the discussions that focused on the relevance of the measurement of TSH in various age groups, the external sex determination and achievement of sexual maturation and when to suspect an endocrine disturbance, the high dose setting in reproductive studies. Next steps on this topic are to analyse ECHA's final report when made available Q1 2023 and participate in the workshop they will set up.
Marco Vallini (Nickel Institute) followed with a presentation on the call for evidence on skin sensitisers in consumers mixtures. This was being followed closely by NI and NiPERA as it could be a preliminary step for later REACH Restrictions.
Adriana Oller (NiPERA) gave an update on the bioelution testing "saga", concentrating on the OECD track. In résumé, since the last Taskforce call, there has been a commenting round on the Test Guideline and a couple of meetings of the OECD Bioelution Expert Group that led up to preparing a Response to Comments (RCOM) and a revised Guideline. A testing proposal aiming at assessing the influence of particle size on metal release is currently being discussed with the

NL. Unfortunately, over the summer, Canada sent in a series of comments - also complaining about the transparency of the process- that are difficult to address as they question elements already agreed upon with the Expert Group. To note: for now, the activities of the CASG Bio group expected to decide on how to use bioelution data for classification, are put on hold, due to the heavy CLP agenda but also to wait for further progress on the OECD Test Guideline.
Eurometaux explained the outcomes of a webinar on human biomonitoring and e-Waste, with some interesting results on Pb and Cd and a follow-up study in PARC that will involve other metals.
On welding, it was recalled that ECHA had been mandated by the Commission to prepare a scoping report, which is now available and will be circulated to the Taskforce soon. It was questioned whether the position paper developed by Eurofer & Eurometaux and EWA (2010) to provide guidance on safe use for downstream users with regard to fume and gases generated during welding of metals and alloys should now be updated in view of the current discussions.
The meeting ended by recalling that the OECD Guidance on Grouping Chemicals from 2014 is currently being updated and that EM & NiPERA received a mandate to provide an updated text by the end of the year.
The full minutes of the meeting were circulated to the Taskforce members on 14 November (more information: Ailsa Lee and Violaine Verougstraete).

CHEMICALS STRATEGY FOR SUSTAINABILITY

Strategic Research & Innovation Plan (SRIP) for Safe & Sustainable Chemicals: *"Materials 2030 Roadmap"*

The SRIP was published on 26 October. Its purpose is to identify Research & Innovation (R&I) needs crucial for boosting the transition to chemicals and materials that are safe and sustainable. It was written in 2022 by the Commission and was the subject of two stakeholder surveys, both of which Eurometaux participated in.
At the same time as the SRIP was published, the Commission also publicised a draft "Materials 2030 Roadmap". The purpose of this is to build on the "Materials 2030 Manifesto" from February 2022, which underlines 4 challenges (circularity, zero pollution, climate contribution, traceability) and highlights opportunities for further research on advanced materials. (Eurometaux referenced the "Materials 2030 Manifesto" in survey input on SRIP.)
The 103 page "Materials 2030 Roadmap" was created by the signatories to the Materials 2030 Manifesto, working with four major European Technology Platforms (EMIRI, EuMAT, MANUFUTURE and SUSCHEM). It appears well-written, detailed and thorough. There is a strong focus on improving overall sustainability (e.g., greater circularity, longer-lasting products), and reducing time to market for new innovations. Nine materials innovation markets are identified: health; construction; new energies; transport; home & personal care; packaging; textiles; agriculture; and electronic appliance.
Coherence is lacking, however - chemicals management considerations are largely absent. The policy support section does not mention the CSS or the new concepts of Most Hazardous Chemicals (MHCs) and Substances of Concern (SoCs) – the use of both will be needed to deliver the objectives of the roadmap.
Eurometaux has signed up to AMi2030, the group developing the roadmap – with the objective of contributing to the work stream on policy support and improving coherence between chemicals management and innovation objectives (more information: Simon Cook).

Safe & Sustainable by Design: *OECD webinar*

On 3 November, several representatives of OECD's Chemicals and Biotechnology Committee gave a webinar to showcase their work on a "safer and sustainable innovation approach" (SSIA) applied to (nano) advanced materials. SSIA started in 2018 and combines the concepts of Safe and Sustainable-by-Design (SSbD) and Regulatory Preparedness (RP) in order to identify and minimise the possible health and environmental risks, and sustainability impacts of innovative materials, products, applications, and processes in a timely manner during the innovation process.
SSIA addresses regulatory requirements for safety and sustainability, including any necessary adaptations to cover the specific properties of materials or technologies. SSIA thus relies on dialogue between industry and regulators and, as appropriate, other stakeholders. This dialogue ideally starts at an early stage of the innovation process and is facilitated by a so-called Trusted Environment (TE).
The European Commission has more recently done their own work on SSbD and published their framework report in July 2022. It is expected that this will be adopted in the next few weeks, with a two-year testing process starting at the same time. The Commission will support the testing process by providing methodological guidance and collecting feedback on the experience gained in the framework application.
The OECD work on SSIA goes far beyond SSbD however. Additionally, it considers how to incentivise and unblock the innovation process from a regulatory point of view (RP), and also how to create an environment involving all relevant stakeholders (a TE) that will support the innovation process along entire value chains. RP and TE are both of high importance: RP because materials innovation is such a fast-moving field that regulators are generally not aware of at all,

or not aware early enough in the process to act accordingly; TE because it can be used (for example) to protect intellectual property and confidential business information (more information: Simon Cook).

Cefic/DUCC: *workshop on Supply Chain Communication*

In a joint effort to improve supply chain communication on chemicals, Cefic and DUCC (Downstream Users of Chemicals Coordination group) organised a workshop in the context of Cefic's program of cross-industry exchanges on different aspects of the CSS. Meeting objectives were to: identify minimum data needs for supply chain communication; support greater digital flow of information; ensure use of work done in the past; and set out a workplan to deal with key issues, and next steps. Participants included: DUCC and Cefic experts on supply chain communication/Safety Data Sheets (SDS); IT experts providing commercial supply chain communication solutions.

This is not a new topic and the workshop started by reviewing the work done over the last 10 years or so. Agreements on workable systems still need to be reached. The subject is relevant for the CSS, the REACH revision, safe use etc., and new topics need to be raised with the various stakeholders e.g., digitalisation. The group should aim to put practical solutions on the table in the coming years. There were two main areas of discussion:

1) What should be the scope of the group – should it be limited to Safety Data Sheets, or widened to cover other information flows that need to happen in the value chain – both up and down (for example; the Digital Product Passport – DPP, lifecycle assessment information - LCA)?

2) If electronic SDSs become mandatory, what is the best format? Is it possible to use Extensible Markup Language (XML) only, or will portable document format (PDF) also be needed? How can we stop typing data in systems?

On point 1 there was no clear consensus, but the group felt that the work program should be such that meaningful output was possible in a reasonable time. It was concluded that the first focus should be on information related to ensure chemical safe use (i.e., SDS) while keeping an eye on other supply chain communication issues such as DPP-related information. Cefic will coordinate with other existing industry groups to support a synergistic approach towards supply chain communication..

On point 2 it was agreed that both formats will be needed as some stakeholders will always require PDF. A mandatory eSDS could actually help with standardisation, as this would create a "pull" from software providers and a "push" from chemicals companies – with funding. Further discussion will take place, in which multiple actors along the supply chain will need to be involved e.g., REACH registrants, formulators, distributors, professional and industrial end users, as well as authorities (inspectorates)(more information: Simon Cook and Lorenzo Zullo).

ZERO POLLUTION ACTION PLAN

Air Quality: Public Consultation and project

End of October, the new Air Quality Directive Proposal was published, and an Open Public Consultation (OPC) was launched (deadline: 25 January 2023). Eurometaux carried out an in-depth technical analysis of the Air Quality Directive proposal, which was circulated to the members. Discussions will take place during the next Zero Pollution Action Plan Project Group (ZPAP PG) meeting to define Eurometaux's input.

On 1 December, the Air Quality Expert Group (Commission and Member States) will have a meeting (behind closed doors) discussing the implementation of the Air Quality Directive and the new Proposal. The Commission's Third Clean Air Outlook is foreseen to be published before the end of the year.

ARCHE's final report on the Air Quality Project was circulated to members mid-November for feedback and approval. The results of the study arrive in time to support our advocacy activities on the new Air Quality Proposal. An abstract of the study was submitted to SETAC Europe 33rd Annual Meeting (Dublin, 30 April - 4 May 2023). In addition, Eurometaux will present the methodology of the study to the 15th International Pollutants Release and Transfer Register (PRTR) Coordinating Group organised by the UNECE (OECD, Paris, 25-27 January).

The next meeting of the Zero Pollution Project Group is scheduled for 15 December (more information: Lorenzo Marotti).

CLASSIFICATION

Environmental Classification guidance: *Eurometaux contributed to the PEG on this critical CLP guidance*

ECHA is preparing an update of its CLP guidance document on environmental classification to integrate recent experiences and address items identified as requiring further clarifications. This guidance update includes the extensive section on the metal environmental classification, which forms the basis of the discussions of the metals under review for potential CLP Annex VI listing, like Pb, Ag and most recently Cu. This justifies a careful review and check of ECHA's proposed changes. A PEG was set up and a first series of comments were compiled by Eurometaux (thanks to all members

who provided input). The metals sector's input focuses on key aspects like the preferred use of high-quality standard species data (instead of all potential evidence), (still) allowing to use the Environmental Transformation concept to improve the classification of metals on the basis of case specific evidence. Eurometaux expects that the discussion on these points will be difficult given several Member States push for more precaution to be included in the classification system. The most recent experience like the interpretation of the normal handling and use for massive metals (cfr Pb discussion) is not yet included in this guidance update, as the Commission discussions on the environmental classification outcomes of Pb are still pending. This would be addressed in the next update scheduled for 2024 (more information: Stijn Baken, Jelle Mertens and Hugo Waeterschoot).

Li: *status update on activities in November*

On 14 November, an industry delegation met the cabinet of Commissioner Breton to reiterate their concerns regarding the proposed classification of the three lithium salts, highlighting the impacts on international competitiveness and security of supply for the EU vs. other systems that are unlikely to adopt the same classification. The overall uncertainty the classification may generate (in particular regarding some possible restrictions to the market etc.) and the stigmatisation effect (on mining, products) were explained in detail by the industry delegates. Commission asked to have more details on the remediation measures the industry is planning to adopt if the classification were to be adopted, and what would be the benefit for the industry in getting a delay of the decision if RAC is asked to re-assess its opinion? Both Commission and industry reiterated the importance of having science-based decisions, and in industry's views a re-assessment by RAC would allow reaching a more solid classification.
Li was not discussed in the CARACAL meeting of 17-18 November: the discussions on the 21st Adaptation to Technical Progress (ATP) are expected to take place in January.
The International Lithium Association had a call with the French ANSES to discuss the Risk Management Option analysis (RMOa) they have launched on the three Li salts and Li metal. This RMOa is expected to give suggestions on which risk management measures should be implemented to manage the risks connected to Li exposure. This French initiative, selected because of the importance of Li was started mid-2022 and should be finalised during the first half of 2023. An update was circulated to the Li Taskforce on 22 November (more information: Francesco Gattiglio, Chris Heron and Violaine Verougstraete).

RISK MANAGEMENT

Risk Management Taskforce: *reporting on recent activities*

The Risk Management Taskforce met on 24 November ahead of its originally scheduled date. The main focus was to debrief on a long series of Risk Management related activities that have taken place since the summer in order "to clean the sheet". This will allow us to fully concentrate on the first information related to REACH 2.0, and especially on the publication of the CSS study reports and on the RSB report. The outcome of the EUC study presented at the CARACAL by Wood was reviewed and discussed during the meeting. It gave an insight on the views of the consultants on the criteria and ways of how the EUC can be introduced for REACH and other ENV legislation in the EU. The main message is a strong promotion of a step-by-step approach.
Another important topic was a status reporting on the 11th priority recommendation by ECHA and MSC on substances for potential Annex XIV inclusion, that includes Pb metal. The ECHA-MSC meeting from early December would be crucial to check if further advocacy would be needed to prevent the listing of Pb metal. The RMTF encouraged ILA to organise a debrief and action workshop, including the DUs, as soon as this ECHA opinion is out. The RMTF meeting included further debriefs on NeRSAP and the Chromates workshop as discussed above in this Newsletter. 2023 will certainly be a very active year for the RMTF related to the 11th recommendation and especially to the Risk Management recommendations under the REACH 2.0 expected mid-2023. The Taskforce aligned its meeting schedule accordingly (more information: France Capon, Klaus Kamps and Hugo Waeterschoot).

INDUSTRIAL EMISSIONS

Industrial Emissions: *opinions on the Commission proposal*

Early November, the European Parliament ENVI and ITRE Draft Opinions on the Commission's Proposal for the new Industrial Emissions Directive (IED) were published.
The ENVI Draft Opinion is rather supportive of industry and includes clarifications and amendments addressing the concerns raised by the stakeholders. The Rapporteur's approach is to propose a compromise on the disputed parts of the legislative proposal and to look for solutions for legitimate concerns, while keeping in place the increased ambition

proposed by the Commission. In its Draft Opinion, the Rapporteur picked up amendments proposed by several industrial associations, including key suggestions from Eurometaux. The Draft Opinion still has the potential to be additionally improved in our favour. Further advocacy work is needed to ensure this. Eurometaux carried out an analysis of ENVI's Draft Opinion and worked on fresh amendments to submit to more MEPs.
The Final Opinion may be amended even substantially in the next steps of the co-legislation process.

Further discussions on the ENVI and ITRE Draft Opinions are taking place in the context of the IEA (Industrial Emissions Alliance) and in the Alliance's steering sub-group for strategy and advocacy (which includes Eurometaux) to agree and align on priority amendments to submit to additional MEPs (deadline: 5 December for ITRE and 7 December for ENVI). Continued advocacy is ongoing at Parliament level also via the Alliance, and in cooperation with other Industrial Associations.

Industrial Emissions: *industry activities*
Eurometaux attended the high-level roundtable on the IED hosted by the European Energy Forum. Participants included MEP Radan Kaven (Rapporteur ENVI), MEP Michal Wiezik (Shadow Rapporteur, ENVI), MEP Ondrej Knotek and Stefan Leiner (new HoU, DG ENV, IED unit) and Christopher Allen (DG ENV, IED unit).
Regular meetings of the Industrial Emission Alliance are organised to exchange information and share intelligence on the ongoing IED review. Meetings took place on 7 November (hosted by Glass for Europe) and on 28 November (hosted by Industrial Minerals Europe). An IEA steering sub-group was set up to design the group's advocacy strategy and actions, in which Eurometaux participates.

Industrial Emissions: *other related activities*
Eurometaux is in contact with ECHA regarding their workshop on Chemicals Management Systems (CMS) and on the methodology to prioritise chemicals in the IED-context (mid-February 2023, exact date to be confirmed, remote). Some members expressed interest in contributing actively to the workshop and coordination with them is ongoing.

Also, on 24-25 November, Eurometaux participated in the United Nations 9th meeting of the Working Group of the Parties to the Protocol on PRTRs (Geneva, Switzerland/hybrid meeting). The Working Group considered a number of subjects, including the development of the Protocol and the progress in implementing the work programme and financial matters, the promotion and coordination on compliance and reporting mechanisms. Furthermore, subregional and national activities were discussed including potential needs and challenges for capacity building. The Parties, other Member States and stakeholders had the opportunity to share their experiences in implementing pollutant release and transfer registers.

The next meeting of Eurometaux's Industrial Emissions Taskforce is scheduled for 16 December. The draft agenda and the calendar invitation were sent out to members (more information: Lorenzo Ceccherini, Lighea Speziale and Lorenzo Marotti).

LVIC BREF: *Sevilla …and follow up*
Eurometaux participated in a Large Volume Inorganic Chemicals (LVIC) BREF post-Kick-off Meeting (KoM) meeting (hosted by Cefic) to coordinate and align on key issues individuated during the discussions in Sevilla.
Eurometaux shared with the Eurometaux LVIC Working Group a first draft of the questionnaire sheet dedicated to sulphuric acid production and a draft list of "well-performing plants". The final list will be decided on by the whole Technical Working Group (TWG) and the selected plants will participate in the data collection (i.e., their data will be used to derive BAT conclusions and Best Available Techniques -Associated Emission Levels (BAT-AELs)). Based on the received input, Eurometaux will finalise these two documents and send them to the EIPPC Bureau as Eurometaux's contribution to the first draft of the questionnaire template for the LVIC BREF (expected by the end of February 2023).
The EIPPCB is currently drafting the KoM report that was announced to be circulated for comments by end of November (tentative) and will be given sufficient time to comment on it. Site visits will probably be organised for March 2023. In addition to this, a number of web-based workshops are planned for the next few months:

- January 2023 TBC - 'Relevant contextual information and key data features for the questionnaire development (including a session on energy)'.
- TBD - 'Questionnaire development'. A workshop for finalising the questionnaire template to be used for the data collection exercise.
- TBD - 'EU Hydrogen production'. A series of workshops to identify and track advances on H2 projects (scope, size, technology maturity and relevant key environmental aspects). The first workshop foreseen for this topic will be organised by Cefic during Spring 2023, in close collaboration with the EIPPCB.

The next meeting of the LVIC Working Group is scheduled for 16 December and will focus on the development of a questionnaire template for sulphuric acid production (more information: Lorenzo Ceccherini, Lighea Speziale and Lorenzo Marotti).

WATER

End of October, the Commission has presented a "Proposal for a Directive amending the Water Framework Directive, the Groundwater Directive and the Environmental Quality Standards Directive", as part of the Zero Pollution Package, which also included the proposal for a recast Urban Waste Water Treatment Directive (UWWTD) and the proposal for the Ambient Air Quality Revision. The European Parliament (ENVI and AGRI Committee) and the Council (Working Party on the Environment) will now scrutinise the European Commission's proposal in order to come up with a final text. The inter-institutional negotiation of the proposal is expected to take place between Q1 and Q4 2023 with entry into force in Q1/Q2 2024. A more detailed analysis of the changes was circulated to the Water Taskforce. Several important elements require reactions, including on the Priority Substances List.
Commission has opened a feedback period until 29 January. This is an opportunity to reiterate our concerns on the process followed over the last years and make some recommendations, building upon the hook included in the Commission's proposal that ECHA would be charged with a responsibility role in the derivation of Environmental Quality Standards (EQS).
The concerns of the sector and the possibility of a joint letter to be included in the Consultation package but also directly to Commission, ECHA and the Secretary General were discussed with other industry sectors in a JAM meeting on 29 November and an exchange with Cefic on 16 November. It is hoped to get a united industry front to make it clear that the process can be improved.
The Water Taskforce will be updated in more detail before the break on the recent developments, also on specific EQS and on events like the workshop organised by JRC on "Effect-based Method (EBM) Trigger Values for Chemical Status" (more information: Chris Cooper, Marco Vallini and Violaine Verougstraete).

TOOLS

MeClas Steering Committee: *achievements and priorities*

The MeClas Steering Committee had its annual call on 23 November, to review the progress made in 2022 on the priorities that were agreed on last year and to decide on further improvements of the tool in 2023. The integration of the Multi-Metallic and the MeClas databases was discussed at some length, with the recommendation from the Steering Committee members to include a quality step for data to be included that would not be backed up by registrations or a quality check (e.g., notifications on the Classification & Labelling (C&L) inventory). This quality step is essential to avoid jeopardising the reliability and credibility of the tools. Other updates of the tool relate to mixture rules and MARPOL. Also a short video, prepared to raise awareness about the MeClas tool and promote it was presented to the Steering Committee. All members and MeClas users are encouraged to share it: https://we.tl/t-FYA0LIWRdk
There are two outstanding issues in the 2022 program, related to the Rapid Environmental Transformation (RET) and the split massive/powder aspects. It had indeed been agreed last year to wait for the outcomes of the Ag, Pb, Cu environmental classifications in RAC before making proposals for these issues in MeClas. Now that these discussions have progressed, it is proposed to circulate a self-assessment form to be completed by the consortia/associations on the justifications they use for RET and the split massive/powder based on the results and work out possible solutions in MeClas that would allow users to have a possible access to these justifications. A clear warning was given that we should balance the further expansion of the tool vs. user-friendliness and ease to use.
A status update was provided on the finances of the tools, and it was proposed to the Steering Committee to reduce the annual fee.
Priorities proposed for 2023 include: add a chronic 4 warning drawing the users' attention to its possible meaning, have a systematic check of the ERVs included in the database to ensure their quality and reliability, split the environmental and human health assessments in Tier 2, etc.
The minutes of the call were circulated on 1 December for approval by the committee (more information: Frederik Verdonck, Hugo Waeterschoot and Violaine Verougstraete).

METALS ENVIRONMENT EXPOSURE DATA PROGRAM (MEED)

MEED program: *expert review session on 22 November and several SETAC posters submissions*

Ensuring the credibility and transparency of the MEED program, its assessments and outcomes is crucial. To support this, the sponsors had recommended to set up an external expert review panel to review key milestones steps. A first session was held on 22 November, to review the determination of the test work for the metals' mixtures project of the program. Eurometaux started by presenting the program and the progress made on the projects. After that, ARCHE (Charlotte Nijs) presented in extenso the approach followed to define the smart test design for the metals-mixtures project, with specific attention for the scientific justifications. The review by the external scientists was very helpful and supportive, and clear suggestions were made. The feedback also included some warnings (like on the relevancy of testing Cr). The recommendations will be considered in the test program. The MEED team will organise a second session of this external expert team as soon as the design of the metals-organics mixture program is available (spring).

Series of abstracts were also prepared by the program contributors (University of Ghent, ARCHE and Eurometaux) on the different MEED projects, status and outcomes, for the upcoming SETAC Dublin meeting (May 2023). More information will be provided to the sponsors of the MEED program (Marnix Vangheluwe, Violaine Verougstraete, Diana Dobre and Hugo Waeterschoot).

COMMUNICATION

Ainhoa joined the Eurometaux Chemicals Management team in November 2022 as Policy Officer, where she will focus on the Chemicals Strategy for Sustainability, CARACAL and Risk Management dossiers. She previously worked in a public affairs consultancy, and in regional government representation to the EU, covering environmental and chemicals policies and providing strategic advice on how to engage with EU institutions and key stakeholders. Her files included REACH and CLP revisions, GRA and Essential Uses, MAF, OSOA, as well as specific substance restrictions.

Ainhoa holds a BA in International Relations and a MA in EU International Relations and Diplomacy studies, with a focus on EU environmental and energy policy.

Born in Spain, Ainhoa is fluent in English and Basque, speaks French and Turkish, and has notions of Chinese.

And if that was not sufficient to become an EM star…Ainhoa has some experience in TV, as she acted in several Turkish TV programs during her exchange year in Istanbul!!

CALENDAR

Please find here below a non-exhaustive list of the meetings that are planned for end of year 2022.

For meetings at Eurometaux

Most of our meetings will now be held as hybrid meetings, and **our members will be informed ahead of the meetings** (links to join will be sent ahead of the meetings).

For meetings at ECHA: this information is published on ECHA's website

- 05-09 December: ECHA SEAC-57
- 06 December: Chemicals Management Steering Committee
- 12-16 December: ECHA MSC-80
- 12 December: Human Health Taskforce
- 15 December: Zero Pollution Project Group
- 16 December: Industrial Emissions Taskforce
- 15-16 December: ECHA MB
- 20 December: Evaluation Taskforce

An 2023 calendar will be included in next month's issue.

GENERAL INFORMATION & ACRONYMS

Follow the logo and check out our Metals Gateway website.

This website is a one stop information source for regulators & risk assessors dealing with metals/metal compounds and is tailored to the specific needs of the metals industry sector.

A continuously updated list of acronyms is available under the Reach Metals Gateway (RMG)
