Eurometaux European Association of Metals



N° 153 – October 2024

# **EUROMETAUX CHEMICALS MANAGEMENT NEWS**



#### Please join us in October:

- 07/10: Industrial Emissions Taskforce
- 09/10: Human Health Taskforce
- 11/10: TNO study meeting
- 24/10: iUVCB Training
- 28-29/10: ECaBaM workshop (ECHA premises)
- 13/11: PFAS Workshop

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#### Dear All,

Once upon a time, maybe.

September has been -as usual-full of meetings and hence entailed preparing long series of slide decks, on which we report below.

For most of the presentations, one could feel the efforts made by the presenters to support the dispensed information with some storytelling. With variable successes. Admittedly, it may be difficult to have a good story flow if the actors are still uncertain or unpredictable, not clearly labelled as heroes or villains. Their adventures and the landscape must still unfold. As for the other stories, those in which the roles were distributed a long time ago, even there the final episode could still entail some surprises and lead us to more or less (not) happy ends.

My youngest referred to an exercise she does with the young children in her class: she tells a story and at the end asks the 6-years-old to vote on whether it is a true story or not. Afterwards, this allows her to bring in some additional information and to stimulate them to reflect on the content, but also to anticipate the next story. These stories are a balanced mix of absurd and credible elements, facts and imagination. I immediately visualised the scene: some kids fiercely raising their hands to support the true or false possibility the instant she poses the question, and a lot of the others checking first what others do before daring to express a vote. But it seemed that my imagination got it wrong: she stated that at that age, the majority form their own opinion without consulting, and thus react spontaneously.

This left me pensive. What happened to the once kids-now adults who prefer to blindly follow a majority? When and where do we learn to bridle that spontaneity that made us believe or not that it was an ADHD knight who invented the fries by waving his sword around above a pot of boiling oil (with a squire throwing him potatoes ... of course), or that once a year it rains fish in a small village in South America (after a tropical storm)? What happens now with our gut feelings if someone tells us that once, a cat became a postman?

Some, obviously, will continue forcefully to rely on their own opinion before voting. But don't we often see adults first checking what the group does, questioning their own self-assessment and relying on the more vocal ones? And is there any possibility to turn the clock back?

The reading of my notes of the September regulatory discussions – checked to prepare this monthly update- was probably not the cleverest idea I had today. Plenty of scenarios started to pop up, all filled with data and (different) interpretations, mixing data and some more absurd claims, giving roles to actors wearing silver nitrate or talc-white coloured dresses, bravely fighting for causality and protection. I threw the power point slides in the air and reordered them randomly on my desk to change the flow and evaluate the impact this would have on the ending. I created a different way of collecting opinions, with a chair-king convoking the experts one by one to vote in a protected setting (his castle), far from the cameras and the other' 'previous interventions'. Inviting them convincingly to bond again with what they know, what they feel, with their questions at the hearing the story...

Would it change the outcomes? Difficult to know but for a moment -a precious moment of imagination- I felt connected to that belief that critical thinking is the way to go...



Violaine Verougstraete

## **COMMISSION**

#### CARACAL: comments on the IRS

On 4 September, Eurometaux submitted comments on the CARACAL Consultation on ECHA's Report from the Integrated Regulatory Strategy (IRS) workshop and considerations for the Integrated Regulatory Strategy 2024-2028. These comments raise previously stated concerns, and make proposals to further increase efficacy, cooperation, maintenance of knowledge and making the best use of resources that are becoming scarce at all levels. These proposals include increasing transparency about how Assessment of Regulatory Needs (ARNs) are used in RIME (Risk Management Experts), enabling the submission of additional information in the registration dossier and promoting the use of "use advised against" for some uses, issuing guidance on the grouping of substances for classifications, and decoupling Substances of Very High Concern (SVHC) identification from authorisation leading to a "prioritisation list" which would leave the door open to different risk management options (e.g., Occupational Exposure Limits (OELs), Environmental Quality Standards (EQS)).

The next CARACAL meeting is scheduled for 20-21 November 2024, for which no draft agenda is available yet. However, we expect some key topics on it (e.g., the Specific Concentration Limit (SCL) for cobalt metal), which may require a good preparation with the CARACAL Taskforce. An invitation to a call will follow closer to the date (more information: Ainhoa Gonzáles Pérez).

#### PARC project: call of Stakeholders Forum to prioritise the further activities of PARC

The PARC Stakeholders Forum (SF), which includes 15 representatives coming from NGOs and industry has been invited to express its opinion on the future activities of PARC (second half of the project). This prioritisation of 'needs' was prepared by a survey over the summer and then consolidated during a discussion on 16 September. The 5 needs that triggered the most votes from the SF relate to the following topics:

- Persistent Mobile and Toxic (PMT) and very Persistent, very Mobile (vPvM) substances (monitoring in environmental compartments and understanding the impact of new hazard classes on the procedure and methodologies to derive environmental values such as EQS)
- Monomers of polymers and biodegradable polymers (Monitor the implementation of the requirement to register polymers under REACH when it happens)
- Chemicals leaching from plastics and rubber tyres
- Characterisation of More than One Constituents (MOCs) (& aggregated exposure from mixtures)
- Benzophenones and UV filters (collection of exposure data across Europe)
- Chemicals and biodiversity (development of a next generation risk assessment, of methods to assess the effect of chemicals on biodiversity and use of monitoring data (in the absence of human biomonitoring) to inform about the exposure levels of chemicals mixtures and potential threats on ecosystem services or biodiversity)

The SF's vote will be considered by the PARC Management Board along the votes of the National Hubs and other PARC partners (more information: Violaine Verougstraete).

## **EU AGENCIES**

## **EUROPEAN CHEMICALS AGENCY (ECHA)**

### **ECHA COMMITTEES**

#### RAC-70: full meeting...

ECHA's Executive Director Sharon McGuiness opened the RAC week, congratulating the members for this 70<sup>th</sup> meeting, recalling also that RAC is a scientific committee and should avoid getting into political discussions. ECHA is aware of the challenges the new tasks will bring and is further reflecting on modalities that could help RAC to deliver in a sustainable way.

Among the highlights of the week, the discussion on a health-based value for bisphenol A as ECHA's assessment deviates from the EFSA one, namely on point of departure and toxicokinetics. Key elements are the justification and the uncertainties. Regarding classification, RAC finalised its opinion on talc, concluding finally to a 1B for carcinogenicity (on

top of the STOT RE1 for inhalation, lungs agreed on in June). The conclusion was based on the limited evidence for lung tumours in female rats and limited evidence for ovarian cancer in humans (perineal use). This classification is again for all routes, without the possibility to exclude some exposure routes (e.g., oral) as data is not available or unclear, which triggered concerns from some of the participants.

RAC also discussed silver nitrate's acute toxicity, specific target organ toxicity via single exposure (STOT-SE), skin and eye irritation/corrosion and respiratory and skin sensitisation. RAC classified silver nitrate as acutely toxic cat 2 (H302) based on available data with silver nitrate, but the quality of the data is questionable and the interlink between the observed effect and corrosivity of the substance was not fully deciphered. It was also classified as skin sensitiser cat 1, as RAC considered the weight-of-evidence from the human case studies sufficiently strong (e.g., one case with clear Ag nitrate pre-exposure and a delayed reaction to silver nitrate during the testing). The other human health endpoints will be discussed during the next RAC CLH Working Group (28-30 October) and the November plenary meeting.

The Universal PFAS restriction discussions triggered a huge participation of observers, as besides the petroleum and mining sector, RAC also debated uses of PFAS in the textiles, upholstery, leather, apparel and carpets (TULAC) sector and in food contact material and packaging. The discussions on these latter uses will continue in November. For the petroleum and the mining sector, RAC reached provisional conclusions. In general, the lack of data on the uses in the mining sector as antiwetting and flotation agents did not allow the Rapporteurs to deviate from the proposals of the 5 Member States and propose a derogation. The recommendations of RAC were further discussed by SEAC (see below). The conclusions are provisional as once all sectors have been discussed; the assessments will be checked for consistency. But also, RAC agreed to revise how PFAS emissions are calculated across different sectors with a focus on the waste stage, for example emissions from waste disposal and incineration. The revised approach emphasises the need to distinguish between PFAS particle emissions (solid) and those that leach from materials. The outcomes of this revision will also be reconsidered across the sectors. ECHA confirmed also that the uses of PFAS in the energy sector (including batteries) will be discussed in March 2025. There is no fixed date yet for the 'PFAS in equipment' issue but ECHA promised to communicate a more precise timeline as soon as they get clarity from the Dossier Submitters on when this section of the background document will become available. Please note that the learning lessons of the U-PFAS restriction for our sector will be further discussed during an Eurometaux workshop on 13 November.

Finally, RAC concluded with a long section on AfAs and discussed some possible changes in the Restriction Conformity Check procedure (more information: Violaine Verougstraete).

#### RAC-70: Drinking Water Directive Working Group

The 4<sup>th</sup> meeting of the RAC Drinking Water Directive Working Group (DWD) took place on 24 September, fully digital. ECHA presented and demonstrated live how the new IUCLID platform for DWD would work, using a fictive example of a DWD application. The DWD version of IUCLID, which will be released in April 2025, is the version that will be used for the first notification of intention to apply for the European positive lists (EUPLs) of starting substances that are allowed to come into contact with drinking water. A round of testing and feedback has been launched for RAC DWD WG members to do this by the end of October 2024.

In addition to the IUCLID IT tool, ECHA presented the work ahead to develop a larger plan for the digitalisation of all regulatory processes at ECHA, with the development of IT tools and how the RAC DWD WG members will be able to contribute and give their feedback. ECHA then took some time to review the comments received in recent months on the Drinking Water Directive Guidance Documents (Volumes I, II, IV, V\*) and how they have been addressed. ECHA also took the opportunity to gather the views of the RAC DWD WG members on some outstanding issues related to some of the comments received. Feedback was also given on the work of the informal group on DWD toxicokinetic (this work is part of Volumes I and II of the DWD guidance).

Finally, the timing and next steps for the publication of the DWD guidance were discussed:

All guidance volumes (those drafted by ECHA) will be open for a final round of comments in October 2024. ECHA aims to publish the English versions of the guidance documents in January 2025. Later in 2025, an IUCLID manual and the translated versions of Guidance Volumes I, II and IV will be published. The next meeting of the RAC DWD WG is scheduled for December.

• Volume I: Methodologies for testing starting substances, compositions and constituents for use in the manufacture of materials or products in contact with water intended for human consumption

- Volume II: Methodologies for accepting starting substances, compositions and constituents for use in the manufacture of materials or products in contact with water intended for human consumption
- Volume III: The scope
- Volume IV: Contents of a Notification of Intention
- Volume V: Calibrants and representative samples of accepted compositions in connection to applications submitted under Commission Delegated Regulation (EU) 2024/369

(more information: Lara Van de Merckt, Federica Iaccino and Violaine Verougstraete).

#### SEAC-64: growing recognition for sustainability aspects in authorisation and focus on the U-PFAS restriction

As expected, the Universal PFAS restriction discussion dominated the ECHA SEAC meetings. As a reminder, all PFAS uses will be banned 18 months after the adoption of the restriction unless receiving a derogation. SEAC's role is to assess the robustness of information on the availability of technical and economic feasible alternatives. SEAC reviews this using a sector-by-sector approach based on available information on uses from the dossier submitter's background document and information received during the Public Consultation. Amongst others the mining sector was reviewed this time and represented at the meeting by Euromines for the specific- and Eurometaux for the generic aspects. As for metal manufacturing, which was discussed in June, the mining sector was aware of PFAS in equipment (pipes, valves,...) for corrosion protection but not of any specific PFAS uses in their reagents or solutions used for flotation or other production steps. The dossier submitters' report refers to use in mist suppressants and anti-foaming agents for which viable and feasible alternatives are available. On this basis SEAC concluded at this stage that no robust information is available to warrant a derogation on the use of PFAS in the mining sector. To note: PFAS in articles/equipment used in industry will be debated at a later stage (mid 2025?) (more information: Hugo Waeterschoot).

#### SEAC-64: growing recognition for sustainability aspects in authorisation

SEAC is currently still reviewing a long series of authorisation applications for the use of CrVI in plating for decorative, hard plating or other uses. Eurometaux as an industry observer, notes that SEAC's attention for additional aspects other than hazard substitution is increasing when such argumentation is included in the applicants' case. At the meeting, cases that required more time to implement solutions with no alternative CMR materials or materials that have less impact on the climate, were agreed upon. There was also an interesting application presented on the use of CrVI in protecting Cu foil for EV batteries. Here also a prolongation of the review period was granted given the use is critical for the decarbonisation objectives of the Green Deal. This was the first time that this argument has been raised in SEAC (more information: Hugo Waeterschoot).

#### SPI MB-75: preparation of the orientation debate in the Management Board on ECHA's future strategy

ECHA updated its mission and vision last year and published this in its strategic statement. Besides long existing objectives, they included a new pillar aiming for an improved stakeholder relationship and interaction. By the end of the year, the Management Board that steers ECHA will have to adopt its 2025-2028 Program Document that includes objectives, milestones and a long series of KPIs to implement those. Industry has always contested the multitude and number of KPIs which were often seen as being only quantitative without attention for the main objective to be reached (e.g., n° of Compliance Checks (CCH) launched by ECHA instead of the number of CCH that led to improved risk assessments in registration dossiers). During the preparatory activity (SPI) for this debate in the Management Board, the SPI agreed with industry's comments but informed participants that it is the Commission who asked for that amount of detail on launched activities given their metrics for financial support to ECHA seems built on this information. Hence, we subsequently responded by requesting a separation between these 2 overall aims of the guiding objectives and related KPIs: those for the Commission's financial needs and those relevant for the focus of ECHA's work and the performance of its activities. At the moment of the publication of this newsletter we have not yet been informed whether the MB (wherein Cefic's Director General represents industry), had recognised this in its recommendations towards ECHA's Program Document (more information: Guy Thiran and Hugo Waeterschoot).

### **ECHA OTHER ACTIVITIES**

#### ECHA-Industry call: catch up post summer

The ECHA Industry call in September was the first after the summer break. ECHA provided the usual overview on the registration trends statistics which highlighted an increase in dossier submissions in June and July compared to 2023, most of which were CLP notifications (78%), followed by registrations (16%, primarily from importers and manufacturers). Overall, about 5.060 spontaneous updates were submitted to ECHA up until July 2024, with a significant

number doing it for tonnage changes and alignment with company standards, but there was still one fifth of the submissions indicating 'Other' as reason of updates. ECHA recalled that the reason for an update is important for joint submission communication (i.e. certain reasons -like changes in the CSR- trigger notifications to joint submission members, while "Other" does not, which can hinder communication with the co-registrants).

ECHA also shared an overview on the number of Product and Process Orientated Research and Development (PPORD) notifications (about 181 in the first half of 2024), which will be more deeply analysed for the next meeting. Industry shared their frustration and concerns remaining about the Russia sanctions situation and the fact that the European Commission's guidance on sanctions impacting registration dossier updates is not solving the pending questions and is still causing confusion in updating dossiers and being compliant with regulations. Industry will follow up with ECHA and European Commission on how to proceed towards an agreed solution.

Furthermore, Eurometaux raised the need to discuss the 12-year rules with ECHA (see more below) and the whole group agreed to discuss it in detail in the next October meeting, when the ECHA experts in data sharing could be involved too (more information: Federica Iaccino and Lorenzo Zullo).

## **EUROMETAUX CHEMICALS MANAGEMENT**

#### Chemicals Management Steering Committee: 3rd and important meeting

The Steering Committee met early September to get a status update on the (re)organisation of the resources following Lorenzo's departure and to anticipate Hugo's departure end 2025. Proposals for projects were discussed, including a check and possible refresh of the MERAG fact sheets, which will celebrate their 20<sup>th</sup> birthday in 2025!

This was followed by a presentation on the consequences of the EU elections for our sector, specifically focusing on chemicals management. While at DG working level no big changes are expected, the political guidelines will change. Besides an increased focus on competitiveness, Ursula von der Leyen's guidelines refer to a new chemicals industry package – "to simplify REACH and provide clarity on PFAS". The timings and status for the relevant pending files e.g., REACH & ROHS, the Export Ban, the adoption of the One Substance One Assessment (OSOA) package, the revised legislations on Water and Soil were also given. These changes at EU level need to be considered in the setting of our advocacy priorities for 2024-2029. The group agreed to further discuss the REACH priorities in the REACH Advocacy project group (see below)

A detailed update on the Water Framework revision timeline, the main issues at stake and the advocacy activities (including, the cooperation with other sectors) followed. The struggles on the prioritisation process were emphasised, recalling how the chemical and the ecological status are assessed and how the outcomes interlink (or not).

Howard Winbow (IZA) gave a status update on the Transition Pathway (TP) for metals. A consolidated draft has been produced by Commission, incorporating all written feedback received so far from the Expert Group and was presented to the Industrial Forum on 16 September (see below).

A detailed update was provided on the TNO, which led to a lively discussion on some of the data used and the assumptions made in the draft report. A follow-up discussion with TNO and the metals scope is scheduled for 11 October. The topic "risk control via exposure control" was briefly discussed in June. It was agreed to set up a small working group to reflect and design a possible roadmap focusing on exposure/risk control, considering proactivity vs reactivity, resources, uses of the data (to improve some tools or to communicate or...), link with existing databases/models, technologies, confidentiality issues etc.

The meeting ended with the updates on i) Safe & Sustainable by Design (SSbD) and advanced materials and ii) the Metals Academy (see more below in Communication).

The draft minutes were circulated to the Steering Committee members (more information: Violaine Verougstraete and Ailsa Lee).

### **CHEMICALS STRATEGY FOR SUSTAINABILITY**

#### **REACH and CLP Advocacy Project Group:** *first meeting*

The first meeting of the REACH and CLP Advocacy Project Group took place on 12 September to review the sector's priorities with regards to the REACH revision in light of the change of mandate, the shift in the political landscape and the new REACH "simplification" proposal.

The group brainstormed on how to be more targeted in our priorities and requests to the Commission, agreed on a way forward and reviewed our priorities. The CM team will now work on implementing the agreed actions and expects to hold shorter update calls according to needs and developments.

If you would like to be added to the REACH and CLP Advocacy PG distribution list, please let us know (more information: Ainhoa González Pérez).

#### IAM4EU: Innovative Advanced Materials for Europe

This is part of the Commission's ongoing activities on innovation in materials, which is linked to the CSS Strategic Research & Innovation Plan (SRIP). In February, the Commission released a communication on Advanced Materials for Industrial Leadership, which includes a proposed new EU partnership under Horizon Europe on Innovative Advanced Materials for Europe (IAM4EU). The main objective of IAM4EU is to speed up innovation on materials by addressing the current fragmentation within the EU and hence keep the EU in a leadership position, safeguard resilience and sustainability of materials value chains.

Other stated objectives include substitution of critical raw materials (CRMs) and implementation of Safe and Sustainableby-Design (SSbD) as an innovation approach. From the point of view of metals, these goals appear conflicting.

The Strategic Innovation Agenda (SRIA) for IAM4EU was presented in a validation workshop on 19 September, which confirmed these three objectives. The drive to substitute CRMs is supported by some specific downstream sectors: hydrogen, where platinum group metals are widely used in catalysts; and magnets, which depend on rare earth elements. SSbD advanced materials were also covered, although it was clear that there are no case studies yet carried out and the practical difficulties likely to be encountered in applying SSbD to advanced materials innovations are not at all well understood.

The industry contribution to the IAM4EU partnership will be covered by a new association, IAM-I. Membership is open to all stakeholders, including other industry associations including Eurometaux (for a nominal fee).

On 16 September there was a separate but related stakeholder workshop on a possible Important Project of Common European Interest (IPCEI) on advanced materials. If implemented this would be complementary to IAM4EU (more information: Simon Cook).

### **CLASSIFICATION**

#### Li CLH Taskforce: update call

The Li Taskforce had a post-summer call on 5 September to get status updates on the Li salts classification process, on the Round Table of experts to be set up in the UK and the industry RMOa and then discuss next steps on Li and EQS setting. The participants asked to have an AOB item on the TNO study that also includes Li and for which a draft report had been circulated to the Eurometaux Chemicals Management Steering Committee. At the time of the call the final Li opinion had not been posted on the ECHA website but it is now accessible <u>here</u>. The final opinion will be analysed in detail to identify possible advocacy needs at CARACAL level but also vs. countries outside the EU. ILiA explained that some progress has been made with the Round Table concept, clearly elaborated now in a concept note. The Round Table will discuss both development & fertility.

Regarding the industry RMOa, it was announced that the latest draft received by Apeiron will be discussed with the dedicated ILiA Working Group and that it may be opportune to inform the French ANSES (developing its regulatory RMOa) on the updated timetable.

Then, the Taskforce discussed the technical and advocacy actions set up to react to the proposals of EQS by some Member States. A core group has been working on a scientific paper that could be the basis to proactively reach out to authorities. However, considering the relative paucity of data on Li, the possibility to do additional studies to be able perform a Species Sensitivity Distribution has to be discussed as well. A follow-up ILiA meeting on this topic has taken place on 10 September. Supporting arguments for the studies are the clear interest of the EU and Members States for Li but also the comment by the French ANSES that the environmental part of the REACH dossier is a "bit light". Draft minutes of the Taskforce call were circulated on 9 September.

Note: at the Eurometaux Science Forum meeting, Martin Wieske (representative at the Working Group Chemicals) informed the members on the ongoing exercise to prioritise substances for which an OEL should be derived in the coming years. Li is part of the list and feedback from the Li Taskforce is sought on whether to push for the derivation of a Li health-based value in 2025 or 2026 (more information: Violaine Verougstraete and Francesco Gattiglio).

### **REACH REGISTRATIONS**

#### **REACH** Dossier updates under Russia Sanctions: Industry seeks further clarifications

Despite the release of the <u>updated FAQ in July 2024</u> by the European Commission regarding the handling of REACH dossier updates under Russia sanctions, several unresolved issues continue to pose significant challenges for REACH consortia. The primary concerns focus on two key areas: identifying sanctioned companies and determining the appropriate actions to take toward co-registrants impacted by sanctions.

Eurometaux is calling for clearer guidance on how lead registrants should proceed, particularly when co-registrants fail to confirm their status regarding sanctions. Additionally, clarification is needed on the competition law implications of requesting sanctioned co-registrants to cease operations, as outlined in the updated FAQ.

A letter addressing these concerns is being finalised, with the goal of sending it to the European Commission and ECHA, along with a request to organise a meeting promptly. This meeting would provide a forum for further discussion to resolve the current barriers preventing dossier updates.

Eurometaux remains committed to working with other industry organisations and regulators to ensure that REACH compliance can continue without disruption (more information: Federica Iaccino or Lorenzo Zullo).

#### Registration Compliance Taskforce Webcall: '12-year-old data sharing rule' (04.09.2024)

On 4 September, the Registration Compliance Taskforce organised a 2-hour dedicated call to discuss best practices concerning the application of the 12-year-old data sharing rule stipulated in REACH, i.e., compensation payments for data only for a 12-year period after submission in a registration dossier in Europe (REACH Article 25(3)).

During the call, participants shared their approaches and the main issues they face in setting and updating data sharing agreements. Some points requiring further investigation were raised and directly brought to the attention of the ECHA during the ECHA/industry monthly call that took place in September.

During the Eurometaux call, it was agreed to discuss the topic thoroughly with the ECHA experts on data sharing during the next ECHA/industry call, in order to: i) better understand how the REACH IT tool deals with highlighting data older than 12 years and ii) clarify ECHA's approach to inquiries received from new potential registrants that may lead to such data sharing (particularly in relation with read-across situations). More information will be shared after the call planned on Friday 18 October (more information: Lorenzo Zullo and Federica Iaccino).

### WATER

#### Update

Following the publication of the EU <u>Commission's proposal</u> to amend the Water Framework Directive (WFD) and the List of Priority Substances (PS) in October 2022, the European Parliament (EP) published its <u>opinion</u> in September 2023. The Council of the EU voted on its <u>general approach</u> to the file on 19 June 2024.

Eurometaux drafted and circulated an advocacy paper on the file, which was co-signed by Eurofer. As a result of this outreach, several meetings with EU regulators have been secured for the month of October.

There are no known dates for the start of the trilogues, which are not expected before the end of October at the earliest. In the meantime, EM is continuing its outreach to secure further meetings and to spread our message (more information: Lara Van de Merckt).

## TOOLS

#### Metal release: meeting in Ispra with JRC

In April, the OECD project aiming at drafting a Test Guideline to measure metal release in gastric fluid has been withdrawn by the Leads (Commission), four years after its acceptance into the Testing Guidelines Group program. This followed a lengthy submission of critiques by Canada and UK, without possible ways forward. This was reported in detail in the April News. At that time, Canada and UK indicated that they would write their concerns and submit them for publication (as the OECD WNT documents are not publicly available). End of August, we became coincidentally aware that a letter to the Regulatory Toxicology & Pharmacology Editors (RTP) purportedly concerning the Henderson et al. (2014) round robin paper had been published online. RTP did not notify R. Henderson (corresponding author) about this letter and in addition, the content of the letter was only tangentially related to the original paper. The main aim was rather to complain about the OECD discussions and reiterate their concerns. We are currently preparing with the JRC a rebuttal to this letter as it states at the end "Based on concerns raised by OECD member countries, the European Commission discontinued leading the 0.032 M HCl TG project in April 2024. However, confusion will continue to arise in future, whenever the diluted protocol of Henderson et al. is referenced in regulatory or scientific literature as a gastric assay. To minimise such confusion, a statement is needed to clarify that the weakened Henderson et al. SOP does not simulate gastric solubility, nor does it generate bioaccessibility values appropriate for regulatory use". This statement is not just targeting Henderson et al. but aiming to prevent any future use of a protocol based on the draft OECD Test Guideline. What is not coherent with the request of Canada and UK is that they refuse that the OECD papers are declassified, thus preventing their accessibility to e.g., readers of RTP. This will be highlighted in our rebuttal, which will also include some statistical analyses to address one of the concerns raised.

In parallel, we are also preparing a paper describing the results from alloy particle effects on metal release and the %RMC approach to alloy classification. This initiative and the concept of %RMC for classification of alloys is even more pressing as the latest ECHA report on carcinogen potency stresses that it would be justified to associate cobalt metal with a SCL of 0.01% or lower. In such a scenario, testing the metal release to have a %RMC based classification (rather than simply on content of cobalt) will be key.

The letter to the editor, the alloys manuscript and further possible actions to pursue the work towards the acceptance of metal release data to support read-across and classification were discussed in-depth with the JRC ECVAM in September, in an intensive but very encouraging meeting (more information: Adriana Oller, Kate Heim and Violaine Verougstraete).

## **METALS ENVIRONMENT EXPOSURE DATA PROGRAM (MEED)**

#### MEED program: Canada MEED Workshop

On Monday 9 September, an extensive MEED sponsors delegation met with the Canadian Environmental authorities (ECCC Environment and Climate Canada). The meeting was set up by the Canadian metals and mining sector, making the most of the ETAP meetings being organised in Canada this year. We met more than 15 government representatives (half online) and provided a review on the status of MEED, in particular the metals-mixture and metals-organics mixture literature review and further test work. As anticipated, ECCC was very interested given they are following the MAF activity in the EU and are considering how to apply the mixtures toxicity for environmental permitting setting. The key message from our sector was that the concentration addition is more than protective hence no need for additional safety factors. As a result of these informal contacts, ECCC and Climate Canada also presented a paper on U-PFAS and the Canadian mining sector (more information: Hugo Waeterschoot).

# OUTREACH

### OECD

#### OECD Working Party and Chemicals Management: workshop on substitution, going beyond safety

The annual meeting of the OECD Working Party on Risk Management took place in Paris from 23-26 September. The first two days were entirely dedicated to a most interesting workshop on additional attributes beyond safer for selection and substitution of chemicals. Whilst the OECD definition of safer alternatives already includes hazard and risk considerations, the workshop focused on what additional sustainability aspects should be considered when searching for the substitution of chemicals. Climate and circularity were quoted as the main ones, but critical uses/materials were also noted as key to consider, while recognising that simple metrics to include those are not yet clear but under consideration in several initiatives. One such initiative presented at the workshop by Eurometaux was the Industry RMOa that now considers a 4C approach (chemicals, climate, circularity and criticality), that was felt most relevant in this respect. The World Wrought Copper Council presented their R&D program in searching for technical well-performing alternatives for Pb in copper alloys, concluding that even if some of them have no or a lower toxicity performance, they are problematic from the recycling, climate and criticality perspective (e.g., Bi in Cu alloys). The workshop participants also seemed conscious of the fact that solutions for organics and inorganics could differ. E.g., the metals build further on the RMOa, given that their point of departure is Risk Management, whilst the organic sector starts from the Safe and Sustainable by Design given that the substitution of substances is often feasible for them. Many EU countries, the Commission and ECHA attended the workshop and hence picked up these key messages.

The annual Working Party meeting filled the second part of this annual Chemicals Risk Management week. The focus was very much on reporting on OECD projects on Risk Management like the Willingness to Pay project that aims to define monetary values for the impact of diseases or environmental damage, and reporting on country/regional specific programs. On the latter point it was surprising to note in how many countries outside the EU, regulators are active on

reviewing restrictions on uses of PFAS as is presently under consideration in the EU. It is therefore expected that a worldwide ban in the use of such substances can be expected in the years to come (more information: Hugo Waeterschoot).

## **OTHERS**

#### Ecotox Chemicals Management – REACH: conference in Bratislava

Eurometaux supports the organisation of the "2024 Chemicals Management – REACH" conference organised yearly by Ecotox in Bratislava, on 14-16 October.

Eurometaux will be presenting on several topics, including substances in batteries (14 October) as well as the challenges to cope with the multitude of different legislations from the metals industry perspective (16 October). The agenda includes relevant presentations and panel discussions on the future of EU chemicals legislation, the transition towards new requirements for chemicals and products, chemicals management beyond REACH or Enforcement. This event is an opportunity to reach different audiences, with authorities from Central and Eastern European countries attending as well as local industry. Speakers include ECHA, the European Commission and Industry.

You can sign up for the batteries session <u>here</u>. You can sign up for the rest of the REACH conference <u>here</u>.

This is a paying conference to cover the logistical costs, but Eurometaux members can benefit from a discounted rate in the last step of the check out by introducing the following code: **RC2024em@** (more information: Ainhoa González Pérez).

#### Jadar Project: invitation to visit

Eurometaux was invited to visit Rio Tinto's Jadar Project in Serbia on 19-20 September. Together with other invited agencies and associations, Eurometaux had the chance to engage in a deep dive of the project that showcased the work that has been done so far to ensure that the project adheres to high Environmental Social & Governance (ESG) standards (actions on community engagement, biodiversity, water, waste, emissions, etc).

Once greenlighted, Jadar will produce three products in powder form: borates, lithium carbonate and sodium sulfate, with applications ranging from agriculture and digital technologies to the manufacture of batteries for electric vehicles and solar panels (more information: Ainhoa González Pérez).

#### International Lead and Zinc Study Group: 69th edition in Lisbon

The International Lead and Zinc Study Group (ILZSG) held its 69<sup>th</sup> Session on 26 and 27 September 2024 in Lisbon. Eurometaux was invited to provide an overview of EU chemical and emission regulations related to minerals and metals during the Economic and Environment Committee. The presentation focused on the relevance of these regulations for a company's license to operate and market access, providing a review of current legislation as well as the challenges arising from the reviews triggered by the Green Deal and Zero Pollution Action Plan, including policy coherence concerns. The session concluded with a summary of the different actions that the sector is taking to deal with these challenges, including the soon to be published Transition Pathway for Metals. This constituted an opportunity to present the "Spaghetti Slide" showcasing the complex and intricate patchwork of interconnected policy and legislative initiatives that have an impact on the sector, to a more governmental and international focused audience which showed great interest in receiving more information on the topic.

Eurometaux also attended the Joint Study Groups' Seminar "Critical Mineral Strategies and Initiatives", which included presentations from the US Department of Commerce, the British Geological Survey, the International Energy Agency, the Cobalt Institute, and the Extractive Industries Transparency Initiative (more information: Ainhoa González Pérez).

#### ETAP 2024: focus on the Triple Planetary crisis

The annual meeting of ETAP took this year place in Montreal at the Rio Tinto offices (one of the key sponsors) and was well attended by many Commodity sponsors, Rio Tinto and The Canadian metals and Mining sector, ICMM and Eurometaux as observers. As a reminder, ETAP was created 29 years ago and aims to provide industry with external proactive advice from independent scientists on environmental science challenges and emerging issues. While several themes were on the agenda, the main one was clearly the challenge posed by the Triple Planetary Crisis and its links with Metals Pollution and Biodiversity. The presenting scientists showed the need for and the evidence that climate, biodiversity and chemical pollution challenges are intertwined and impacting each other, hence the need to understand

and tackle all 3 in a coherent way. In practice they provided us with some way forward on biodiversity assessment metrics to extend industry's knowledge beyond the classical chemicals impact assessment. Eric Van Genderen who co-headed ETAP for several years will be replaced by a new industry co-head and was thanked for his contributions. (more information: Jelle Mertens, Hugo Waeterschoot).

# KAMILA'S SUSTAINABLE CORNER

#### **Implementing the Batteries Regulation**

Subsequent implementing elements from the Batteries Regulation are being worked on. Just recently the European Commission has published for feedback the draft delegated act for recycling efficiency and recovery of materials. There are selected battery metals to recover:

- Co, Cu, Pb and Ni: 90% by end 2027 and 95% by end of 2031
- Li: 50% by the end 2027 and 80% by end 2031

Major battery chemistries will have to be recycled according to the efficiency levels of:

• 75% for Pb-acid batteries (80% in 2030)

- 65% for Li-based batteries (70% in 2030)
- 80% for Ni-Cd batteries
- 50% for other waste batteries

Eurometaux is consulting its members to prepare the input to the consultation by 18/10

See: <u>https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14265-Calculation-and-verification-methodology-of-rates-for-recycling-efficiency-and-recovery-of-materials-of-waste-batteries\_en</u>

On the other hand, the draft delegated act for calculating carbon footprint of the EV batteries has been delayed and the discussions are stuck due to divergent views on how to address the electricity modelling issue. There is the expectation that the way to move forward with this guidance will be sought once the new European Commission is in place.

Approval-wise, delegated acts once approved by the European Commission are now going for a 2-month scrutiny period by the European Parliament and the Council who give a "Yes/No" opinion to the proposed act. If the verdict is positive the act goes for publication in the EU Official Journal (more information: Kamila Slupek).

## COMMUNICATION

#### Metals Academy: programme on its way for the 4<sup>th</sup> edition in 2025

The Organising Committee met beginning September after the closure of the very successful survey. The interest from our members is very high, be it from newcomers (to the Metals Academy and/or to the industry) or from those who participated in the previous edition(s).

In the coming weeks, we will closely examine the survey results and build a programme best adapted to respond to the needs of all.

To note is that there will be a first afternoon (Monday 5 May) dedicated to the newcomers, who will be joined by the rest of the group for an introductory evening, followed by two days of modules given to all (Tuesday 6 & Wednesday 7 May) and the 2025 edition of the Metals Academy will end on the Thursday 8 May with a choice of 3 Modules, from which participants will be able to follow 2.

We will send out the programme to all our members and those who pre-registered in the survey, with a JotForm to be filled in that will be considered as a firmer commitment; so that we can establish the final list of participants (maximum 30), based on first come-first served, whilst maintaining a level playing field.

If you have any questions in the meantime, please contact Ailsa at <u>lee@eurometaux.be</u> (more information: Ailsa Lee and Violaine Verougstraete).

## CALENDAR

#### Please find here below a non-exhaustive list of the meetings until the end of the year.

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

- 30/09-02/10: Chemicals Management Autumn Week
- 07/10: Industrial Emissions Taskforce
- 07-11/10: MSC-87
- 08-10/10: RAC-71 AfA Working Group
- 09/10: Human Health Taskforce
- 11/10: TNO Study Meeting
- 24/10: iUVCB Training
- 28-29/10: ECaBaM workshop (ECHA premises)
- 28-30/10: RAC-71 CLH Working Group
- 30-31/10: EPAA NAM workshop (Helsinki)
- 13/11: RM Taskforce workshop on restriction of U-PFAS learnings and further anticipation
- 18-19/11: MEED Annual Workshop (Ostend) (Sponsors only)
- 18-19/11: RAC-71 REST Working Group Cancelled
- 20/11: Registration Compliance Taskforce
- 20-21/11: CARACAL (TBC)
- 25-29/11: RAC-71 Plenary
- 25-29/11: SEAC-65
- 27/11: Water Taskforce
- 2-5/12: SEAC-65
- 9-13/12: MSC-88 (TBC)
- 10-11/12: RAC-72 DWD Working Group
- 18/12: Risk Management Taskforce
- 19/12: Chemicals Management Steering Committee
- 19-20/12: ECHA MB-76

## **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)