



N° 154 – October 2024

EUROMETAUX CHEMICALS MANAGEMENT NEWS



Please join us in November for the following meetings:

- 13: Risk Management U-PFAS Workshop
- 20: REACH & CLP Project Group
- 20: Registration Compliance Taskforce
- 27: Water Taskforce

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Dear All,

Among these objects, please highlight the ones you have

| An orphan earring | More than 10 tote | A broken umbrella in | A series of |
|-----------------------|-------------------------------|---|-----------------------|
| that you keep in case | bags from | case it rains in | notebooks you never |
| the other one - lost | workshops and | Brussels (while | look at anymore |
| while traveling - | conferences you | going from the | |
| magically reappears | have been attending | metro to the Metals | |
| | | Conference Centre) | |
| | Dile -ev- Rand MINIO | | |
| A collection of dusty | A pile of paper on | Some badges | Books you promised |
| business cards | your desk that has | identifying you as | yourself to read on |
| vaguely in | not been moved for a | Dr., Senior | best practices and |
| alphabetical order | while | something, Professor, etc. | emerging topics |
| Pens that leak in | Some anti-acid | An old expense | Different coloured |
| your backpack | medication to take | ticket for a | plastic maps to |
| | before a difficult | cappuccino | organise the piles of |
| | meeting | somewhere, but | paper on your desk |
| | | Where and when? No. 15.99 RECEIVED out shaded from For LANGE TO | |

If you ticked all of these, you are a normal person working in regulatory affairs

If you ticked less than 4 items, you are too young

If you didn't tick anything at all, we won't believe you.

Violaine Verougstraete

COMMISSION

CARACAL: postponed

The CARACAL meeting initially scheduled for 20-21 November has been postponed to 18-19 December. A Taskforce call will be organised as soon as the draft agenda becomes available (more information: Ainhoa Gonzáles Pérez).

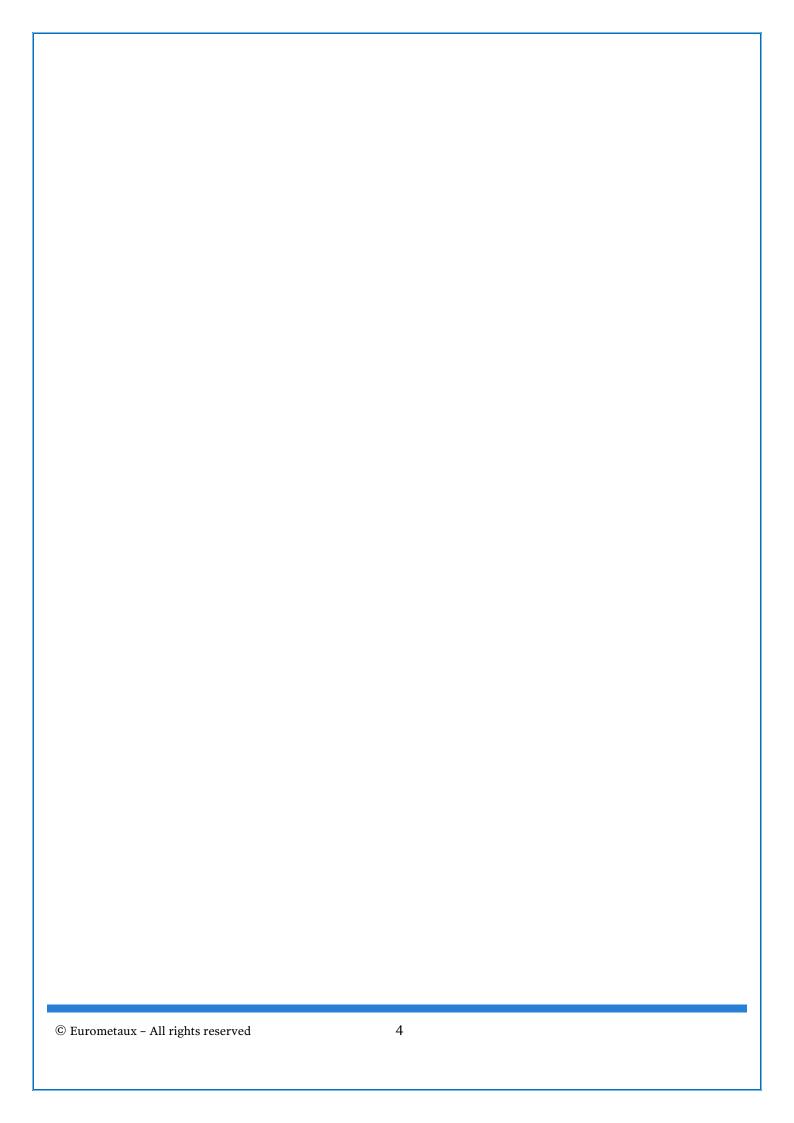
Commission workshop on Substitution: discussion on different scenario options as presented by the consultant

Waiting for REACH 2.0 to be tabled, the Commission already started on a project to rethink the way on how to promote substitution. A consultant (Logica) was appointed to draft different options for substitution scenarios towards safer chemicals, as evoked at a workshop in April. The Commission circulated the options shortly before the 1 October workshop.

The generic idea behind the suggested options is to promote more voluntary initiatives with the help of technical substitution centres, once Commission has defined the need for a chemical to be substituted. Only in the cases when industry does not take advantage of this opportunity or does not advance well, then more restrictive options (e.g., regulatory guided) or a substitution duty -as we know now under the classical restriction scheme- would apply. For this purpose, industry would be invited to form cooperation groups (like consortia but then for substitution). The role and functioning of the substitution centres are not clear yet and part of another ongoing study by Commission. Industry, in general, welcomed the tiered concept which allows first to suggest and define the potential for- and if relevant implementation of substitution. Eurometaux provided further written input highlighting that for inorganics, risk control is the main primary objective (e.g., by Occupational Safety Health (OSH) or EQS, ...) whereby substitution could be one of the options if technically and economically feasible and more efficient. Secondly, we stated that any alternative should be safer from a risk- and 3Cs concept perspective to consider the alternative as a valid one. The consultant collected all inputs and aims at producing a final report by the end of the year. It is expected that some of these aspects will be picked up under the new REACH or other product legislation, if the Member States can be convinced that voluntary initiatives should get a chance (more information: Hugo Waeterschoot).

Second Commission workshop on phasing out animal testing for chemicals safety assessments: managing change

The workshop was a follow up from the first event held in December 2023 following the Communication from the Commission on the European Citizens' Initiative (ECI) "Save cruelty-free cosmetics - Commit to a Europe without animal testing". In this communication, the Commission committed to developing a "roadmap towards ultimately phasing out animal testing for chemical safety assessments." This roadmap will outline milestones and specific actions that would be pre-requisites for a transition towards an animalfree chemical legislation. This second workshop provided a status update on the set-up of several working groups and focused on contributions from stakeholders regarding the implementation of New Approach Methodologies (NAMs) in regulatory assessments, particularly within the PARC (Partnership for the Assessment of Risks from Chemicals) framework. Presentations highlighted the potential of NAMs to drive safer and more sustainable innovations while acknowledging significant validation challenges that remain. An interesting concept that was discussed more at length in the context of change management is the 'transitional initiative'; which is any initiative contributing directly or indirectly to the replacement or reduction of animal use in regulatory assessments. Stakeholders provided several key recommendations: first, the need for coordination across sectors to improve regulatory acceptance and harmonisation, particularly given that global acceptance of NAMs varies significantly across regions and sectors. There is also a call to enhance transparency, improve data accessibility, and increase stakeholder engagement. Furthermore, securing funding and establishing progress metrics are essential for sustaining advancements and identifying existing knowledge gaps. More information on the workshop (agenda, pre-reads, presentations) can be found here. A detailed and a brief report of the workshop was circulated to the Human Health Taskforce on 4 November (more information: Tina Liesirova and Violaine Verougstraete).



EU AGENCIES

EUROPEAN CHEMICALS AGENCY (ECHA)

ECHA COMMITTEES

RAC-71 AfA Working Group: CTAC Sub application

The RAC Working Group discussed the application for authorisation for the CT_CTAC-Sub application covering 12 uses, debating selected sections of the draft opinions, namely the operational conditions (OCs) and risk management measures (RMMs) for workers and the exposure assessment for workers. They concluded that those OCs & RMMs are not appropriate and effective in limiting the risk for the workers and RAC also had minor or moderate concerns about the inhalation exposure estimates. Hence, several additional conditions for the authorisation and feasibility studies were recommended (for example: the replacement of solid Cr(VI) substances by a liquid solution, the implementation of a closed or automated system to perform the dilution of solids and bath/vessel sampling tasks, and any subsequent refilling of the baths with liquid solutions (e.g., fix-piping from the containers or mixing tanks to the baths).

The secretariat will launch RAC consultations on the draft opinions in December 2024-January 2025. Agreement on the opinions is foreseen in March (more information: Violaine Verougstraete).

RAC-71 CLH Working Group: silver nitrate discussions

Of key interest during this working group were the discussions on silver nitrate, for the muta, repro and STOT-RE endpoints. France Capon and Jelle Mertens (EPMF) kindly shared their highlights. On the proposal to go for muta cat 2, there was no consensus between RAC members. There were opposing views regarding the use of silver nano data for read-across and in the weight of evidence. There was a recommendation to go for repro 1B on fertility and developmental toxicity. The lactation endpoint still needs to be discussed as views were diverging and there were possible inconsistencies regarding the use of the data. Finally, the RAC members discussed the STOT-RE classification as cat 1 or cat 2. The use of nano data is not supported by some RAC members -and industry- since data on silver nitrate and on silver salts are available and should be given more weight in the weight of evidence approach. There was also no evidence of target toxicity in the Extended One Generation Repro toxicity study on silver acetate and some studies have a very low reliability. The finalisation of these discussions will take place at the November plenary meeting (more information: Jelle Mertens and France Capon).

MSC-87: initiative to improve the prioritisation of chemicals for announced Authorisation

Besides reviewing and adopting several new Substances of Very High Concern (SVHCs) (all organics driven by PBT, PMT or ED concerns), MSC members took note and discussed the proposal from the ECHA secretariat to review the prioritisation of chemicals as candidates for authorisation (Annex XIV). ECHA has the duty to produce such a "priority substances list" every 2 years and uses a strict scoring system, based on volume, type of hazard (e.g., PBT or CMR) and type of use (consumer, industrial, ...) for this purpose. ECHA concluded that from previous lists, either substances were selected for which authorisation was not the best or most efficient risk management option, or the prioritised substances would result in too large numbers of Applications for Authorisation (AfAs) (Cr, Pb, ...), which is not helpful. Hence, they announced an initiative to define options to improve both the selection and prioritisation. However, they stated from the start that they would not change the scoring system itself but were rather searching for parallel solutions. MSC members and stakeholders were invited to propose suggestions.

Eurometaux provided written input stating that most metals selected in the past had only a single risk to be managed (e.g., workplace) for which an OEL would have been a much better risk management option (identified in the RMOa). The fact that metals are produced in large volumes and have uses in consumer products (although risk-controlled), had led to the inappropriate selection of several metals and some metal compounds, given the scoring system assumed that these criteria are indicative for exposure. Therefore, we stated that a better exposure assessment should be used to define priorities, to refine today's proxies. This means that the scoring system should be reconsidered and changed. Finally, we indicated that metal applications are usually very broad and hence potentially result in a very high number of AfAs, which makes them almost by definition unsuitable for the authorisation scheme. Based on the comments received, ECHA

will come forward in December with ideas on how to improve the selection of priority substances for authorisation (more information: Hugo Waeterschoot).

ECHA OTHER ACTIVITIES

ECABAM: second capacity-building workshop

ECABAM is a program launched by Eurometaux to facilitate exchanges with ECHA on its tasks for the implementation of the new EU Battery Regulation and substance restrictions, with the active involvement of stakeholders along the whole battery value chain. The aim is to build capacity and share technical expertise for all actors, both on the batteries' science and regulatory aspects. A first workshop was held in April at Eurometaux, where the role of ECHA and Commission under the Batteries Regulation but also the information needs to inform ECHA's mapping and substance of concern list under the Regulation were discussed. The technology trends and critical material challenges were also presented. The participants helped to refine a survey aiming at collecting the data over summer.

The second workshop was hosted by the European Chemicals Agency and discussed the outcomes of this data-gathering survey but also the future challenges. Breakout groups discussed prioritisation, waste and recycling and socio-economic aspects. The group also delved into the key issues that battery producers and OEMs are facing, alongside the roles of inorganic and organic materials. The workshop confirmed the importance of collaboration in expertise development and the early submission of relevant information. A draft report is in the making (more information: Ainhoa González Pérez).





ECHA: Eurometaux reapproval in SEAC and MSC

Every year the contribution, activity and adherence to the ECHA committees code of conduct is evaluated by the Committees in follow-up of a personal interview with the Chair. Eurometaux's active contribution was evaluated as positive and of added value, hence our position as representative for the metals and to some extent also the larger inorganics sector was prolonged for a year by MSC and SEAC.

During such interviews, the Chairs discuss Eurometaux's contributions in general whilst also allowing the stakeholders to raise points. We mentioned that in general, we appreciate the transparency of the ECHA processes but feel that the increased use of written procedures in MSC challenges this. Providing more attention to the Manual of Decisions helps but cannot be a substitute for transparency. The MSC Chair indicated that they would maintain the debriefing sessions at the end of each MSC meeting to help industry pick up precedents and learning lessons. The systematic info sessions on the status of court cases, their main learnings and the SEAC openness to exchange with stakeholders were underlined as positive points by industry.

Both Committees were also informed that Hugo will be leaving by the end of the year and agreed that those replacing him (Vio for MSC and Simon for SEAC) will be allowed to attend the sessions in parallel to promote a smooth transfer (more information: Hugo Waeterschoot).

ECHA Industry: monthly call (18.10.2024)

During the regular ECHA Industry Call, ECHA provided **updates on the registration trends** after summer reporting that the overall submission numbers for the year are slightly below forecast (2% drop in initial submissions and 12% drop in updates), largely due to a low submission rate during the August holiday season. In September submissions increased again (by 25% compared to August) even if they remained slightly under the expected numbers.

For **CLP notifications**, submissions are robust, reaching almost 7.000 by the end of September 2023, i.e. a 56% increase from the same period in 2022. Generally, the large number of notifications received were not updates related to new hazardous classes, but rather new notifications.

As shared in the previous newsletter, ECHA is closely following up on how industry reports rationales for dossiers update, the communication across the joint submission and checking if it is correct and efficient. A big challenge identified by industry was posed by the frequent updates, such as annual revisions worked cat category rather than rather at substance level. That typically leads to the reason being marked as "Other", thus there is a lack in details about what was changed in the dossier and making it difficult for joint submission members to identify important updates, unless they manually check REACH-IT. ECHA further clarified that companies can always select multiple update reasons, assuming that would help their choice. The group also discussed about enhancing the email notification system to include more specific information in REACH-IT about the reasons for updates and the substance name, but it was acknowledged that upgrades to REACH-IT are now limited due to ECHA's focus on developing the new Submission Portal and that these suggestions will be relayed to the relevant team working on that initiative.

On the 12-year data sharing rule and the implication with regards to Article 26 and 27, ECHA replied to Eurometaux's questions on how to manage studies older than 12 years in REACH-IT and how data requests for read-across purposes are handled at ECHA. In a nutshell, ECHA clarified that when it provides data older than 12 years, this is based solely on the first submission date, and that any updates or modifications made to the studies after the initial submission do not affect this determination. Follow up question on REACH-IT functioning was further exchanged with the relevant ECHA Unit after the meeting and these replies and details will also be shared at the upcoming Registration Compliance Taskforce meeting on 20 November 2024.

Lastly, Salla Gynther, team leader of the **PIC** team at ECHA provided an update on the upcoming changes to the PIC processes. ECHA processed approximately 9.720 export notifications in 2024, with 1.800 already submitted for 2025 (70-80% of 2025 export notifications are expected in the next 2-3 months). The next amendment to the PIC regulation will be effective from 1st March 2025 and will include the addition of 40 new substances or groups (35 pesticides and 5 industrial chemicals) (more details: Federica Iaccino and Lorenzo Zullo).

EUROPEAN ENVIRONMENT AGENCY (EEA)

EEA State of Water report

The EEA launched their Status of Water report last Tuesday. The full report is available following this <u>link</u>. For the launch, EEA held a short online event to present the main outcomes (the replay of the event is on YouTube <u>here</u>). DG ENVI Veronica Manfredi also gave a speech following the presentation. The results were alarming, with water status not on track to achieve good status by the 2027 deadline (only 29% of surface waters are in good chemical status).

The results of the comparison of the chemical status of this third River Basin Management Plan (RBMP) and the previous one, include the ubiquitous PBTs (mainly brominated flame retardants and mercury). As the status is assessed on a one out-all out basis, it is difficult to show real progress. It should also be noted that the EEA has not assessed the same number of water bodies in this RBMP as in the last one, affecting the robustness of the comparison. For the metals, we do not know which Member States have used bioavailability modelling or not, rendering it even more difficult to get a concrete picture of the reality.

The EEA also identified the main pressures on surface water and groundwater:

For surface water, the main pressures are diffuse air pollution (most Hg comes from atmospheric deposition from coal burning) - 52%, changes to the physical characteristics and natural flow of rivers (hydromorphology) - 51%, diffuse agricultural pollution - 29% and 18% from point sources. Member States also report that agriculture is the most important pressure on both surface water and groundwater (from diffuse pollution to agricultural practices).

The EEA proposes 3 pillars to work on to tackle the pressures and achieve water resilience: reducing water consumption and preventing pollution, reusing water to improve water cycles (here the involvement of industry was very much highlighted) and nature-based solutions (restoring rivers, wetlands...).

The European Commission will also publish its own reports assessing the 3rd River Basin Management Plans (RBMPs), emphasising country-specific analysis and the need for better policy implementation.

It should be noted that both the EEA report and the forthcoming Commission report use essentially the same data reported by the Member States. The difference is that the EEA was stricter in terms of deadlines for submission and only those Member States that submitted electronically were included. This means that the EC report will be more complete (it will include all late submitters and those that did not submit electronically).

A full analysis of the results of the EEA report, with a focus on metals, will be given at the next Water Taskforce meeting (more information: Lara van de Merckt).

EUROMETAUX CHEMICALS MANAGEMENT

Chemicals Management Autumn Week: successful Regulatory and Science Forum discussions

The Regulatory Forum – chaired by Lisa Allen (ILA) and Karine Van de Velde (As consortium, IMAT) kicked off with a presentation by Aaron McLoughlin (Fleishmann Hillard) on the possible priorities for the new Commission, Parliament and Council, for chemicals. Key highlights from the Draghi report but also what a 'simpler' regulatory environment for industry may mean were discussed. An important learning is that the work on zero pollution will continue, subject only to the bandwidth of the administrative state.

Jože Roth (Ricardo) recapped the novelties on IED 2.0 and discussed the interplay of this revised Directive and the water ones. Changes in the water legislative landscape (EQS-, Groundwater-, Urban Wastewater- and Water Framework Directive) potentially affect the setting of Emission Limit Values in the IED permits. Cynthia Mestanza (Euromines) explained that mining is now within the scope of the IED 2.0 and sketched the possible impacts and the possible contradiction between robust IED 2.0 with strict BREF requirements and permits causing insecurity for investments in European mines vs the objectives of the CRM Act. Key will be to avoid red tape, ensure policy coherence and simplification.

Raji Kaur (Recharge) concluded this first day of the Chemicals Management week by explaining that manufacture of batteries, other than exclusively assembling, with a production capacity of 15 000 tonnes of battery cells (cathode, anode, electrolyte, separator, capsule) or more per year will also fall under the scope of IED 2.0. She stressed the importance to engage early to be able to influence policy and stay ahead of regulations but also to coordinate strategic advocacy to ensure that the sector's unique challenges & innovations are recognised in the BREF.

The second day kicked off with a discussion on innovation in water management. Franck Ganne from Veolia started from the water challenges in the metals industry, highlighting best practices and developments to optimise water usage considering potential shortages and local conditions. Techniques to facilitate the use and valorisation of industrial by-products and implementation of the air quality legislation were also evoked.

Titas Anuskevicius (DG GROW) recalled that Transition Pathways (TP) (including the one for metals) identify the actions needed to achieve the twin transition, giving a better understanding of the scale, benefits and conditions required. He presented the history, building blocks of the TP for metals and the timeline which should culminate with a publication before the end of the year.

The rest of the morning was devoted to biodiversity with interesting and stimulating case studies presented by Bauke Lenaerts (Natuurpunt) and Sergej Osipov (Atlantic Copper). The importance of conceiving a design and management plan, of considering native species and ensuring the cooperation with the local community were highlighted.

The Science Forum meetings chaired by David Boyle (Cobalt Institute) and Irene Cañas Sierra (Vanadium Consortium) started with Stijn Baken (ICA) giving the state of play on the Endocrine Disruptors (EDs). The CLP guidance on ED is to be published imminently but the final draft presents a big challenge for implementation by industry. Eurometaux will organise a workshop in January 2025, and ahead of time will also prepare a brief simplified guidance for companies. Daniel Koske (EBRC) presented the assessment for an insoluble substance (TiO2), focusing on the literature search and the challenges posed by handling large numbers of studies that can be of variable quality.

Rodger Battersby (EBRC) starting from the TiO2and talc dossier, highlighted the importance to monitor regulatory activities on particles and support the activities of the cross-industry platform, insisting on the need for thorough documentation if lung overload is suspected.

Arne Burzlaff (EBRC) provided a state of play on the update of the mutagenicity guidance, highlighting the difficulties both in the dynamics and the contents of the revised guidance where ECHA sneaks in elements that are not supported. A letter was sent to ECHA asking for a second round of comments or an additional PEG meeting.

Adriana Oller (Oller Consulting) concluded the first day of the Science Forum by reporting on the latest developments on bioelution (see more under Human Health Taskforce).

On the last day of the chemicals management week, Martin Wieske (WVM) gave his bi-annual overview on OELs and the work done by the Working Party Chemicals (WPC) on the different update waves of the OSH

Directives. Key aspects of these updates were highlighted as well as work done in parallel by the WPC. The guidance on biomonitoring is close to finalisation, publication is expected end 2024/Ql 2025. Finally, we learned about the priorities for 2025, which include PSLTs, combined exposure, and potentially lithium and toluene.

Professor Ronny Blust (University Antwerp) provided an overview of the main biodiversity loss drivers with the key message that each cannot be tackled independently, and a more holistic approach is needed. He outlined some metrics being used to assess biodiversity and introduced the concept of ecosystem services (and what those do for us) as equally important to consider as species numbers in environmental management strategies. The EU regulatory thinking is changing in this direction, and this is positive since EQS for metals are often not ecologically relevant and are conservative.

Violaine Verougstraete (Eurometaux) then updated the participants on PARC and KARC, respectively a huge EU project and an ECHA document aiming to inspire PARC developing research on regulatory relevance. Several regulatory challenges identified by ECHA and relevant for PARC or linked to some of the PARC projects were presented.

And finally, Lígia da Silva Lima (ARCHE Consulting) concluded the Science Forum meeting by explaining how lifecycle assessment (LCA) can be used to identify process improvements at company level. It is a rapidly developing area of science with new methodologies developed to characterise additional impact categories e.g., biodiversity and ecosystem services. Authorities are increasingly using LCA in policy e.g., the batteries regulation - the metals sector including those in chemicals management needs to monitor further developments closely.

The minutes of the meetings will be circulated shortly and the dates of the Spring CM Week communicated as soon as possible (more information: Violaine Verougstraete and Hugo Waeterschoot).

TRANSITION PATHWAY

TNO study: draft report under review by reported metals

In September, TNO presented its draft conclusions of study: metals in the Twin Transition-Regional emissions in EU metal technology pathways. The report assessed the potential additional contribution loads of indicative metals (Ga, Ni, Cu, Zn, Li) to European surface waters based on the estimated raising volumes and capacities to be built to match the EU Green Deal objectives on decarbonisation and digitalisation. The study was set up to respond to the policy questions on expected increased impacts and will be supporting the Transition Pathway.

The metals under its scope requested to further work on the contextualisation of the findings and to review of some of their emission factors. Eurometaux with the help of ARCHE conducted contextualisation work, using the MEED reference backgrounds and TNO emission volumes, concluding that for the base metals the additional contribution for the 5 key transitional supply chains is negligeable (<1%) despite significantly increased use volumes and relative worst-case assumptions on release estimates. A metal under the scope requested that these very low contributions would be further refined, given monitoring evidence on EU mining activity could confirm lower emissions and therefore allow to overrule the LCI-based emission factor used in the draft report. Only for Li the added concentration would be somewhat higher due to the use of default estimates, given emission monitoring data are lacking in the EU. The Ga impact is also very low and regional and of no relevance given lacking any environmental toxicity.

A meeting with the TNO researchers was held on 11 October. In follow-up, TNO and Eurometaux are updating the report aiming to use these very positive conclusions for the entire sector as soon as we can (more information: Violaine Verougstraete, Hugo Waeterschoot and Simon Cook).

CLASSIFICATION

Li Taskforce call: ANSES RMOA and discussion with Commission

The French ANSES has issued its draft RMOA that entails a series of recommendations, ranging from monitoring to REACH risk management measures. The long document, prepared since 2022, started from the harmonised classification of the Li salts but went beyond to tackle the following objectives: evaluate Li salts on Endocrine Disruption and aquatic hazard properties, ensure the adequacy of worker protection measures, assess data on potential risks for human health related to (low) environmental exposures and on

potential risks for environmental species related to environmental exposure (EQS, Li in water), identify the risks expected from the growing amount of lithium used in Europe and from mining activities in the EU. Comments can be submitted until 5 December (the initial deadline of 5 November has been extended).

The Li Taskforce was called together to discuss the outcomes of the French document and compare these with the results of the Industry RMOA (that should be finalised by end of the year). Possible actions were agreed on and a position paper will be circulated soon, cross industry sectors. The Taskforce was also updated on the experts Round Table to be organised in Ql 2025 and that might be looked at now from an additional perspective, namely evaluate the data available to derive/refine a DNEL (Derived No-Effect Level) and an OEL (Occupational Exposure Limit). An update was provided on the water-related activities and the set-up of SSD testing to inform the Predicted No-Effect Concentration (PNEC) and Environmental Quality Standards (EQS) derivations.

A meeting has taken place with the Commission (DG GROW/DG ENV) to discuss industry's analysis of the French RMOA and provide Commission with a state of play on some of the proposed measures. The notes of the meeting with the Commission will be circulated shortly to the Li Classification Taskforce (more information: Francesco Gattiglio, Roland Chavasse, Joeri Leenaers and Violaine Verougstraete).

RISK MANAGEMENT

PFAS concerns: rising due to the EU-restriction discussions

During the Universal PFAS discussions at ECHA, sector by sector are being screened by their formal review Committees (RAC and SEAC). The Committees check -in essence- if the generic ban as proposed, could be implemented, or if temporary derogations can be justified to assure technical and economical feasible alternatives could be developed in time. These sector reviews also impact the metal mining, manufacturing and downstream user sectors raising existing but often unknown uses by industry. Hence this results in lacking the capacity to assess or adequately respond to the suggested generic ban or the need for a derogation of their specific or generic use. Sectors reviewed by ECHA (e.g., mining, metals plating, ...), received training and background information, to be prepared to follow the ECHA screening activities. Given upcoming review sessions will affect major metal users' sectors (construction, energy, batteries, electronics), Eurometaux decided to organise a more generic briefing session on 13 November, to learn from experience so far hoping to help sectors with upcoming reviews (more information: Violaine Verougstraete and Hugo Waeterschoot).

INDUSTRIAL EMISSIONS

Industrial Emissions: Taskforce call

On Monday 7th October 2024 Eurometaux's IED Task Force meeting took place. A general update on IED and related topics was given, and further actions were planned. On 25th October 2024 Eurometaux provided comments to the "orientation document on the BREF Guidance" which was circulated among Art. 13 Forum members by DG Environment asking for views and comments. On 15th October 2024 the INCITE platform was officially launched to submit and consult information on innovative techniques. On 22-23 October Eurometaux attended online the "9th meeting of the OECD Expert Group on Best Available Techniques". New activities for Phase IV (2025-2027) which includes "the role of BAT in new energy sources: H2 production" and "the role of BAT in sustainable resources and waste management (including battery sector)" were presented to discuss and further develop their scope. The deadline to send comments is 18th of December. On Monday 2nd of December 2024, Eurometaux will participate in a workshop coorganised by DG GROW and IOGP Europe dedicated to improving interoperability and digitalisation in permitting processes. If you would like to share some highlights/input please contact Violaine Verougstraete or Eleonora Tosi.

Industrial Emissions: NFM BREF

As concerns NFM BREF, Eurometaux will soon launch a survey to assess how NFM BAT Conclusions have been implemented within EM's membership. It aims to understand the compliance of the installations with BATs and the readiness of the sector for the future NFM BREF review.

An updated list of NFM plants was circulated to EM's members to be reviewed by end of October and the draft questionnaire will be shared with members for feedback. (more information: Violaine Verougstraete and Eleonora Tosi)

Industrial Emissions: ongoing BREFs

For the LVIC BREF, the EU-BRITE is planning to organise the first Data Assessment Workshop in the form of a web-based meeting early December 2024 (tentatively). The EU-BRITE team is working on the drawing up of the Draft 1 of the BREF which will be issued tentatively the first quarter of 2025. For MIN BREF, the kick-off meeting is planned for the 1st week of December 2024. For the new Battery (PBG) and Landfill (LAN) BREFs, the frontload work should start by the end of 2024 and the kick-off work is planned for 2025. (more information: Violaine Verougstraete and Eleonora Tosi)

Ambient Air Quality Directive: adoption by the Council

On Monday 14th October the Council formally adopted the revised directive setting updated air quality standards across the EU. It prioritises the health of EU citizens setting new standard to be reached by 2030 which are more aligned with the WHO air quality guidelines. The revised directive mandates early action, with air quality roadmaps that need to be prepared ahead of 2030 if there is a risk that new standards will not be attained by that time. By 2030, the Commission will review the air quality standards and every 5 years thereafter according to latest scientific evidence (more information: Violaine Verougstraete and Eleonora Tosi).

National Emission Reduction Commitments Directive (NEC): consultations

The Commission has opened in parallel an <u>Open Public Consultation</u> and a <u>Targeted Stakeholder Consultation</u> from 3 September to 26 November. Eurometaux attended the related stakeholder workshop hosted by **DG Environment** in Brussels on Monday <u>14th October</u> (more information: Violaine Verougstraete and <u>Eleonora Tosi</u>).

HUMAN HEALTH

Welding Guidance: update call

In 2010, the European Welding Association, Eurofer and Eurometaux published a note in view of the first REACH Registration deadline, discussing welding processes, health hazards and making a proposal for risk assessment and risk management measures of welding processes and compliance with REACH. An update was prepared in 2023 considering more recent regulatory activities on welding (scoping study ECHA, discussions in the Occupational Safety Health (OSH) context) but also the changes in REACH since 2010. The purpose of the document is both to assist in ensuring workers' health during welding processes and to facilitate compliance with the associated legal requirements for registrants and downstream users under REACH. It will also discuss communication tools like use maps and exposure scenarios. A final version will become available before end of the year and circulated to the membership (more information: Violaine Verougstraete).

Human Health Taskforce: update call

This well-attended meeting was held on 9 October and chaired by Kate Heim (NiPERA) & Vanessa Viegas (Cobalt Institute). It kicked off with an update of the 3 projects that are funded by the HeTAP budget, i.e., the work on particle issues and follow-up of the activities of the cross-industry platform, the dermal exposure database, Endocrine Disruptors (EDs) for human health.

ECHA's carcinogenicity potency draft report was also presented, recalling its history. The report is based on the work of the ECHA Expert Group and consultants who reviewed this work. The ECHA report concludes for cobalt, a low SCL is justified, without giving it some context (e.g., the fact that the approach followed could not assess site of contacts carcinogens). Eurometaux submitted some comments but the follow-up discussions in CARACAL will have to be monitored closely. To this effect it was agreed to revive the Co CLH Taskforce.

Kate and Adriana Oller (Oller Consulting) gave an update on the bioelution/metal release project, reminding participants that Canada & the UK managed to stop the progress of the Draft Test Guideline at

OECD level. However, a very constructive meeting took place with JRC ECVAM in September and it seems that there is clear willingness from Commission to pursue the project as an EU-recommended protocol. Several immediate actions have been identified and are being put in place, including papers to be published and testing, for which members' contributions were requested.

Vanessa Viegas (CI) presented the cobalt testing programme and the CI's considerations. The identified key hurdles include finding a good laboratory and ensuring the study design considers all regulatory concerns, working on the short-term & long-term issues and keeping stakeholders informed. The lessons learned ensure the read-across approaches are well communicated, REACH dossiers are up to date. Finally, a short status update was given on the Welding Paper (see above). Under AOB, Noömi Lombaert (IZA) mentioned the second ECHA Workshop on moving away from animal testing and Steven Verpaele (NI) asked for volunteers to collect exposure data for metals and metalloids in the workplace. The minutes will be circulated shortly (more information: Kate Heim, Vanessa Viegas, Daniel Vetter and Violaine Verougstraete).

WATER

Working Group (WG) Chemicals meeting (24/10/2024): highlights from a fully digital meeting

The last WG Chemicals was held on 24 October. The 5th Watch List (WL), originally planned to be adopted before summer, has been amended and it is now awaiting adoption by the Article 21 Committee. The European Environmental Agency (EEA) presented their State of Water Report related to the monitoring from the 3rd River Basins Management Plan (RBMP) (more information is provided below). They introduced the online dashboards, and a workshop has been scheduled to train Member States (26 November). The EEA also updated the participants on the activities of their Working Group on antimicrobial resistance (AMR), for which a report is expected in Ql 2025. The Commission and JRC plan to examine AMR in more detail within the framework of the Urban Wastewater Treatment Directive (UWWTD) next year.

The JRC reported delays in the Effect-Based Methods (EBM) activities. Meetings are planned in November with participants from the interlaboratory exercises on EBM - oestrogenicity and EBM - mutagenicity/carcinogenicity (the latter involves cadmium).

Also, the EU Commission reviewed comments received from the Member States on the CIS Work Programme 2025-2027. Future cooperation between the WG Chemicals and ECHA was discussed, as ECHA will handle prioritisation and EQS derivation. Groundwater pollutant assessment will be discussed (with a possible shift to a risk-based approach from a hazard-based approach). Also under the CIS programme, a new taskforce on exemptions is added and the Commission noted Eurometaux's interest in joining this new group.

The copper harmonised EQS was also discussed: as a brief reminder, Cu was originally proposed as a Watch List substance (4th WL), but based on the monitoring data, JRC indicated that there was sufficient data to carry out a risk assessment, which concluded that exceedances were occurring. Cu is a candidate for harmonisation of its EQS as a river basin specific pollutant and likely to be proposed as a candidate for priority substances in the next round. As soon as the JRC will be ready with the draft EQS dossier, an expert group (involving Member States, stakeholders, JRC and ECHA) will be set up. The dossier will be sent to SCHEER (Scientific Committee on Health, Environmental and Emerging Risks) for its opinion. As the proposal to amend the WFD/EQSD is still not published, the prioritisation/EQS derivation cannot be formally transferred to ECHA (no formal budget for it etc.), hence the Cu EQS will follow the current procedure. Commission emphasised that this does not mean that Cu is officially a candidate Priority Substance: it means that JRC/EC is preparing an EQS dossier for Cu to be used first in the harmonisation of Cu EQS as RBSPs, but this dossier will be used if Cu is shortlisted as a candidate PS in the next review.

Finally, it was mentioned that Trilogues on the Water Framework Directive/Environmental Quality Standards Directive (WFD/EQSD) are not expected until January 2025. The next meeting will be held in March 2025, it should be hybrid and is planned in Brussels, with the autumn meeting potentially in Helsinki (more information: Lara Van de Merckt).

Drinking Water Directive

ECHA tasks:

- A last round of comment on the Guidance volumes (I, II, II and IV) was launched during the month of October. The comments will now be processed, and the final versions of the Guidance volumes are expected to be published by January 2025.
- ECHA will host a webinar on "Looking towards the future of the Drinking Water Applications" on 27 November from 10:00 to 12:00 (CET). The webinar will focus on the process of submitting DWD applications, providing insight into the information requirements for DWD notifications of intention and applications and how to navigate through these requirements. It will also discuss how ECHA will support future applicants throughout this process. The webinar is open to all, no registration is required. If you are interested, please add the event to your calendar using the link here.

EU Commission DWD:

- During EU Commission's Working Group Chemicals meeting this week, EU Commission announced that the EU Commission will start the review of Annex I and II of the DWD in 2026. Annex I deals with

the parameters and parametric values*, which are very important to us (it sets parametric values for a wide range of elements including Pb, Cd, Cu, Al, Ni, Se, Fe, Mn, U, Cr...).

EFSA call for data

EFSA has launched a call for data on the determination of natural background concentrations of essential metals (Co, Cu, I, Mn, Mo, Se and Zn) in water, sediment and soil. This will be used by EFSA for a report on the safety of feed additives to the Commission. The deadline for data submission is 23 January 2025.

Prior to this, there will be an ad hoc meeting with stakeholders on 6 November 2024 (from 15:00 to 16:00) to discuss the data request (registration for the meeting is required by 4 November 2024). More details and registration available here (more information: Lara Van de Merckt).

SOIL

Update

The trilogues on the Soil Monitoring Law (SML) started on 22 October. Eurometaux has sent the sector's position to the EU regulators in advance of the discussions, and we have a meeting with DG ENV on 8 November to discuss the file (more information: Lara Van de Merckt).

TOOLS

Inorganic UVCBs (iUVCBs): Platform training session

Following up on the iUVCB Platform activities addressing ECHA's concerns on complex inorganic materials assessment in the NFM industry, harmonising the dossiers assessment strategy and reporting with a transparent approach throughout all risk assessment steps, the Platform organised a training day combining theory and a practical testing phase to allow registrants and consortia managers preparing and navigating through the iUVCB dossiers, to understand the effects of updated hazard information (classification, PNECs/DNELs) and enabling them to effectively communicate with their REACH team for any future handover of the dossiers.

The training provided participants with comprehensive explanation on how to build and manage the technical dossiers, whilst also enabling more experienced team members to track the status of existing dossiers and to identify necessary updates. A series of accompanying materials have been circulated, including a refined version of the existing Eurometaux iUVCB Guidance, a concise 'How to conduct an inorganic UVCB assessment' document and 'How to report an inorganic UVCB REACH dossier' document which were developed as a series of a one-pager per assessment / reporting milestone. Additionally, a user-friendly screening tool designed to help assessing dossier status and update requirements was shared and explained as a checklist tool: in the form of an Excel file, the tool outlines all necessary steps for preparing/managing technical dossiers, including SIP, boundary composition, classification, and PNEC&DNEL considerations. Following this October session, a recorded version of the training will be circulated with all the Platform participants, together with the finalised screening tool. Furthermore, the Platform team is happy to announce that they will be working on a publication to share the developed assessment strategy for inorganic UVCBs, to provide valuable insights and guidance to enhance understanding and implementation of these risk assessment strategies and reporting under REACH (more information: Federica Iaccino).

Classification Mapping Tool: upcoming activities to update content and scope

Eurometaux's Classification Mapping Tool has become an essential resource for members, providing a comprehensive overview of regulatory impacts associated with the (re)classification of hazardous substances. By identifying connections between hazardous classifications and legislative provisions—spanning approximately 60 EU directives and regulations across areas like workers' safety, consumer protection, environmental standards, and transport—the tool helps members anticipate and understand both current and future regulatory impacts across the supply chain.

With the recent introduction of new hazard classes under CLP and a growing focus on sustainability initiatives such as ESPR, CSRD, and taxonomy regulations, updates to the tool's content and scope are necessary to ensure it continues delivering valuable insights. Recognising its wide usage and importance

| for our members, we are actively working to implement these enhancements as soon as possible. More information on next steps and timing will follow shortly. For further details or to gain access to the tool, please contact Diana Dobre or Lorenzo Zullo. |
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METALS ENVIRONMENT EXPOSURE DATA PROGRAM (MEED)

MEED program: annual progress meeting scheduled for 18-19 November in Ostend and SETAC special session request

MEED sponsors received an invitation for the upcoming annual progress meeting in Ostend (18-19 November 2024). While 2022 and 2023 were years of literature review, identification of data gaps and defining testing schemes, 2024 was characterised by testing the identified metal-metal and metal-organic mixture knowledge gaps and the analysis and assessment of the new data generated. While not fully finalised, these results will be presented at the meeting together with an initial discussion on how a Mixture Allocation Factor (MAF) could (hopefully) be adjusted by better science. Secondly an overview will be provided on the progress and further planning of the Ecorelevance project on which the researchers obtained supportive funding. A draft science communication plan on proposed publications on the outcomes of MEED and external presentations/posters will be presented too. The MEED organisers also submitted a request for a special session at the SETAC Vienna meeting. The conference organisers appreciated the theme but suggested to merge it with a related special session suggested by ECHA, EFSA and the European Commission. Discussions on this are still ongoing (Marnix Vangheluwe and Hugo Waeterschoot).

OUTREACH

OTHERS

Chemicals management briefings by Eurometaux and Cefic: for East - and Southeast European countries.

Ekotox, a consultancy in Bratislava with an extended network in the former eastern-bloc countries, has a now longstanding tradition to provide REACH and CLP briefings for companies based in that part of Europe. Attendance is moving towards national chemicals authorities and web briefing, hence raising Cefic and Eurometaux's interest to reach this network that is rarely accessible to us.

This year's briefing took place in Bratislava on 22 and 23 October and was followed by close to 50 national authorities from 8 Eastern EU countries mainly via webinar. Eurometaux and Cefic provided updates including some industry policy messages on aspects, like on how companies are dealing with the new CLP endpoints, REACH risk management (restriction and authorisation), the implementation of the Chemicals Strategy for Sustainability (CSS), the Ecodesign for Sustainable Products Regulation (ESPR), the Battery Regulation on the One Substance One Assessment (OSOA) approach. Each session ended with a panel debate to restate key messages towards the attendance. Especially and a bit surprisingly the OSOA and ESPR themes raised questions from authorities, probably given that the consequences, risks and benefits do not seem very clear to them (more information: Ainhoa González Pérez and Hugo Waeterschoot).

Battery Regulation session in Bratislava: information

Back-to-back with the REACH conference (see above) Eurometaux organised a briefing session on the Batteries Regulation for regional authorities. After an introduction on the challenges by Eurometaux, ECHA explained the main regulatory aspects of the new regulation in detail, as well as the timeline. The background on the regulation allowed the battery sector (by Recharge) and the Recycling sector (by Botree Europe) to explain their perspectives.

Finally, this was complemented by a presentation of ECaBaM by Eurometaux and a challenging panel debate with all presenters. Almost 50 regulators from Southeastern Europe countries attended the session mostly by webinar, underlining the need and relevance for local communications to reach them effectively (more information Ainhoa González Pérez and Hugo Waeterschoot).

COMMUNICATION

New member of the Chemicals Management team: Andrea Pellini

We are pleased to announce the arrival on 4 November of (Italian) Andrea Pellini, an Industrial Chemist with expertise in Material Engineering, Industrial R&D, Sustainability and Recycling.



He will be a much-welcomed new addition to our Chemicals Management Team and will work on several topics alongside his new colleagues. We look forward to introducing Andrea to you during our November meetings.

CALENDAR

Please find here below a non-exhaustive list of the meetings planned until 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

- 6/ll: ChemWatch conference Asia: Chemicals management challenges for the metals sector in the EU
- 13/11: RMTF workshop on restriction of U-PFAS learnings and further anticipation
- 14/11: IUCLID 6 Service release webinar https://echa.europa.eu/fr/-/iuclid-6-october-service-release
- 15/11: MeClas Steering Committee Meeting
- 18-19/11: RAC-71 REST Working Group
- 18-19/11: MEED Annual Workshop (Ostend) (Sponsors only)
- 20/11: REACH & CLP Project Group
- 20/11: Registration Compliance Taskforce
- 21/11: Introduction to ECHA's guidance on new CLP hazard classes https://echa.europa.eu/fr/-/introduction-to-echa-s-guidance-on-new-clp-hazard-classes
- 25-29/11: RAC-71 Plenary
- 25-29/11: SEAC-65 including PFAS discussion on metals coatings in construction applications
- 27/11: Water Taskforce
- 27/11: Future of drinking water applications https://echa.europa.eu/fr/-/looking-towards-the-future-of-drinking-water-applications
- 2-5/12: SEAC-65
- 10-13/12: MSC-88 including new prioritisation strategy for authorisation 10-11/12: RAC-72 DWD Working Group
- 18/12: Risk Management Taskforce including training on restriction process
- 19/12: Chemicals Management Steering Committee
- 18-19/12: CARACAL
- 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

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