

EUROMETAUX CHEMICALS MANAGEMENT NEWS



Please join us on:

- 14 October: MMD Demo & Training online
- 19 October: ZPAP Project Group Meeting
- 26 October: Evaluation Taskforce Meeting

Contents

COMMISSION.....	3
EU AGENCIES.....	3
EUROPEAN CHEMICALS AGENCY (ECHA)	3
ECHA COMMITTEES	3
ECHA OTHER ACTIVITIES.....	5
EUROMETAUX CHEMICALS MANAGEMENT	5
EUROMETAUX FUNCTIONING	5
CHEMICALS STRATEGY FOR SUSTAINABILITY	7
WATER	8
CLASSIFICATION.....	9
REGISTRATIONS.....	9
ENVIRONMENT.....	9
RISK MANAGEMENT.....	10
METALS & INORGANICS SECTORIAL APPROACH (MISA)	11
OUTREACH	11
OTHERS	11
CALENDAR.....	12
GENERAL INFORMATION & ACRONYMS.....	13

Dear All,

After so many months of virtual meetings, we have all now become the intrepid explorers of the lost connexion and have acquired the skill and/or the ability to multi-task in all anonymity, and thus finding ways to ensure that presentations catch our attention has become a bit of challenge. "Interaction" seems the ultimate way and we do not hesitate to return to our gaming times to trigger reactions in the webex ether: polls, votes, quizzes, emojis have taken over from the curiosity we had one year ago for the presenter's "background" ("that is nice colour for a child's room", "she seems to read a lot" ...or even: this must be the summer cottage!). We need more anchorage and not end up simply floating around.

The content of a talk or a panel may still achieve this. When it touches not only on the daily agenda and preoccupations but also on our beliefs or our drivers.

I emerged from the last chemicals management week more shaken than what I was expecting when preparing the agenda. Topics were indeed a bit provocative, speakers who joined even more so, rendering this edition of our CM week a good one...but it also presented us with some noteworthy questions.

In particular, on the "interaction".

Our job as trade association goes with "engagement", i.e., in the issues, in the debates, in the build-up of relationships. Playing the role of interface, we are expected to approach all the actors involved in the discussions, know and be known, understand the different perspectives and backgrounds and include persons or messages, or both. And along the way, because you want the interaction to be successful, you will spend some time in analysing the dynamics, you will express some empathy for other actor's views and inevitably your industry position will have already shifted a bit towards the magic consensus that will need to be found.

This of course works better if the other actors want to reach a/the same consensus.

But even when it is not the case, even when others prefer to remain with (unjustified) statements or convictions, and are not willing to move, even a little, from their beliefs, our job often pushes us to continue the debate, to not leave the scene without having at least raised a "tricky" question or having maybe even managed to shift the reticent interlocutor's view a little.

So, when David Zaruk (I would definitely recommend having a look at his blog, see below) referred to disengagement from purely hazard-based discussions as a possible way out (as it could even avoid more harm), I of course reacted intuitively, thinking this is an option we could not follow as Eurometaux. But then over the days that followed, reminiscences of series of discussions, outcomes of classification meetings, glimpses from failed interventions and unread position papers popped up with that sore stomach feeling and I started to wonder whether sometimes we are following the most efficient track? Are we not doing "too much"? How far are we willing to go to act as interface and open doors? Should we behave differently? I of course loved David's option to be able to "laugh at ridicule statements" like he is able to do but this would require on my side -besides physical meetings- a drastic change in personality as currently my laugh would probably sound like crying (and be discrete on top of that as I have that drive to honour my parents' education efforts).

As said, advocacy is content but also luck, timing and personalities. This is true, but it also requires striking the balance of how much to actively engage. To do so, one needs to carefully estimate what and who is at stake. This evaluation involves once again exploration, analysis, weighing, hence efforts and time. You cannot do that at a distance from the discussion (or only partially). Thus, a couple of days later, I came to the following conclusion: if I am anyhow 'on my way' towards the other to do this, why not try again and again to engage? Explain with the hope that something may remain.

But with less regrets or questioning? And armed with that fabulous humour that personalises David and allows him to open umbrellas even when the sun shines.



Violaine Verougstraete, Chemicals Management Director

COMMISSION

CARACAL

Endocrine Disruptors: upcoming new hazard classes in CLP

The CARACAL sub-group on Endocrine Disruptors met on 13 September to discuss the introduction in Classification Labelling and Packaging Regulation (CLP) of new hazard classes and categories for endocrine disrupting substances (i.e., ED Cat.1 / ED Cat.2). Several open points were related to the criteria to be fulfilled to determine the classification. Pictograms and signal words were also presented.

Next steps: i) sub-group members have been invited to answer a set of questions; Eurometaux is currently preparing an industry response; ii) Commission will revise the proposal and conduct an impact assessment study, including an estimation of the number of substances falling into the two categories; iii) the study will be followed by a Public Consultation. The delegated act to amend the CLP is expected for next year (more information: Marnix Vangheluwe, Violaine Verougstraete and Lorenzo Zullo).

Commission Workshop on Air Quality: review in the air

The new Air Quality Directive is to be reviewed by the Commission, following the new air quality standards released by WHO. The new WHO Global Air Quality Guidelines (AQGs) were released on 22 September. These guidelines recommend new air quality levels to protect the health of populations, tightening the standards for particulate matter (PM₁₀, PM_{2.5}), ozone (O₃), nitrogen dioxide (NO₂) sulfur dioxide (SO₂) and carbon monoxide (CO).

On 23 September, Commission held a stakeholder meeting organised in the context of the Revision of EU rules on Air Quality. As part of the European Green Deal, the EU is revising Air Quality standards, to align them more closely with the recommendations of the World Health Organization. A public consultation was launched on 23 September to 16 December. This will be further discussed during the Zero Pollution Action Plan (ZPAP) Project Group meeting to be held on 19 October (more information: Lorenzo Marotti and Noam El Mrabet)

EU AGENCIES

EUROPEAN CHEMICALS AGENCY (ECHA)

ECHA COMMITTEES

RAC-58: RAC opinion for lead metal in massive form fails to recognise available evidence and has severe consequences for many sectors

In September, RAC finalised its opinion on the environmental classification of Lead metal. Unlike for previously reviewed metals they did not recommend a split classification between the “massive” and the “powder” forms and introduced several new criteria and a new classification scheme that has implications for the sector. RAC concluded a single environmental classification entry of Lead metal as Very Toxic for the Aquatic Environment Acute 1, M factor 10 and Chronic 1; factor 1000. This means in practice that lead metal and all mixtures or alloys that contain more than 0,00025 % Pb will be classified and has severe consequences for downstream legislation including transport of dangerous goods and Seveso status of manufacturing sites. Such low concentrations would even do away with concepts such as “lead-free” typically triggering at 0.1%! Although not of great help, RAC will include an indication of what the classification would have been if the massive form would have been classified separately to powder (this will result in a lower M-factor but would still result in classification as very toxic to the aquatic environment). At RAC plenary meetings IND raised repeatedly the divergence of the opinion with the present metals CLP guidance, the precedent established in previous metals harmonised classifications and even the Commission posed some questions on this. It is relevant that two other metals are presently in the pipeline for RAC environmental classification review (Ag and Cu both in the metal form) raising concerns that they will also be assessed following the new methodology adopted in the lead case.

On 9 November, ILA and Eurometaux will therefore organise an extensive debrief and advocacy planning session to take up the challenge for Lead and consider actions that need to be taken to defend general principles for metals in massive form. All metal commodities are welcome including downstream representatives (more information: Steve Binks, Jasim Chowdhury and Hugo Waeterschoot).

RAC-58: *Li but also interesting restriction cases*

RAC finalised its debate on the classification of the three lithium compounds (chloride, hydroxide, carbonate) successively addressing the read-across of the classification to the hydroxide (considering its corrosive properties), the analysis of the human data for developmental toxicity and the lactation endpoint. These three items had been prepared during a meeting of the RAC working group on classification in July with two follow-up actions: setting up an ad hoc group (no industry participation allowed) to examine the “read-across” to the hydroxide and a targeted consultation on a 2021 paper on lactation effects. Industry prepared contributions submitted over summer. A classification for fertility (as category 1B) was agreed on in the last RAC plenary meeting (June) and was not reopened. RAC supported the proposed read-across between the three lithium substances based on the “analogue approach” and the consideration that LiOH has a similar intrinsic property to the other two lithium salts with respect to reproductive toxicity due to the lithium ion. On developmental toxicity, the Rapporteurs started by presenting a short summary of the animal studies, concluding that the weight of evidence of the animal data would support a classification, although the evidence was admittedly feeble. RAC concluded that in a weight of evidence assessment, epidemiological studies show evidence of increase in rare cardiac malformations in infants exposed to lithium during the first trimester of pregnancy. Although the association was acknowledged as being weak, it was considered as reliable for classification as cardiac malformations are serious, rare and that there is a limited number of pregnancies where lithium has been used during the first trimester. RAC followed the proposal to go for category 1A for developmental toxicity. RAC also agreed that a classification for effects on or via lactation with H362 is justified by the presence of lithium in human breast milk and infant serum, and the potential for a slower excretion of lithium in infants due to immature excretory system, so as to address the concern for the health of children breast-fed to mothers on lithium therapy. Industry expressed serious concerns on how weight of evidence had been applied, including on the use of low-quality studies, leaving aside the results of the REACH study carried out for the carbonate compound. The opinion will now be finalised by the Rapporteurs supported by the ECHA RAC secretariat and forwarded to Commission. RAC also debated SO₂ and more specifically read-across, STOT-SE, respiratory and skin sensitisation. The discussions will be continued in the RAC CLH Working Group meeting scheduled for end of October. With regard to restrictions, ECHA made an interesting presentation on the Article 69(2) restrictions, that complement authorisation by addressing articles. Aims of Article 69(2) are to ensure that any uses leading to a risk are prevented, guarantee a level playing field for EU producers of similar articles based on alternative substances or technologies and prevent new uses of the SVHC. RAC discussed a simplified procedure for preparing such dossiers. It should be noted that 69(2) is the only restriction process where ECHA can mandate itself to put the Annex XV dossiers together. The level of assessment/detail in the Annex XV report is intended to be ‘fit-for-purpose’ and depends on both the Application for Authorisation (AfA) status and available information. A Public Consultation on the Annex XV restriction proposal is used to verify the assumptions in the report. Following this presentation, the conformity of the ECHA dossier on 2,4 dinitrotoluene was assessed. Although estimated conform, several uncertainties were identified. The learnings from this restrictions debate were presented to the Risk Management Taskforce on 21 September. Also to note, RAC concluded discussions on the proposal submitted by France to restrict hazardous substances that may be present in single-use baby diapers (more information: Violaine Verougstraete).

RAC-58/SEAC-52: *Pb Restriction on ammunition and fishing*

Both Committees progressed with the lead restriction case on limiting the use of lead for use in ammunition and fishing. The restriction case is for many reasons precedent setting for industry and the metals sector in particular, in that it takes into account for the first time how the metals impact on groundwater contamination and the contribution via food -as consequence of the use of lead- can be assessed and it contains an extensive mix of different risk management measures applied in one restriction (banning, restricted use, communication, risk abatement and recycling targets). Moreover, it uses a motivation based on the biodiversity convention (for birds).

RAC concluded in a quantitative way on some classical health endpoints and the impact on birds but for many other endpoints only a qualitative impact assessment based on severity and probability was able to be defined. The Rapporteurs therefore developed a new “*qualitative risk assessment concept*” whereby the assessments can be conducted in a comparative way for very distinctive endpoints (Man via the Environment, groundwater impact, ...) and they can be assessed in an additive way to estimate the potential qualitative impact.

But while this resolves the RAC challenge this creates a significant problem to develop a decent monetisation and probability assessment by SEAC. The latter Committee took note of this new suggestion proposed by RAC and considered several options on how to deal with it. This new quantitative Risk

Assessment (RA) approach requires the metals sector's careful attention given it is expected that RAC will use it more and more to deal with risks that cannot easily be quantified.

The restriction case is in another way also peculiar in that RAC asked the dossier submitter (ECHA) to present less precautionary assessments (for lead uptake via shot in game meat). This resulted in the use of a distribution of exposures instead of a worst-case value which is a first (more information: Lisa Allen and Hugo Waeterschoot).

MB-63: strong discussions on the role and extent of ECHA's involvement in the CSS

The ECHA Management Board (MB) meeting built on the input from the Strategic Planning Group that Eurometaux attended (see report last month). An expected point of discussion related to the involvement of ECHA in the CSS. At present many of them relate to the launch of a series of impact studies for the CSS. However, this stretches ECHA's resources due to the fact that more than 10 senior members of staff are working for the CSS to advise the Commission. As a consequence, programmes like the grouping approach or support for industry programmes such as MISA, guidance development and others are reduced. Moreover, Member States and ECHA had questions on the separation of responsibilities given ECHA should not be involved in policy aspects. The Management Board further provided some advice to the Commission in respect to the replacement of Björn Hansen as Executive Director of ECHA in March 2022. They emphasised, in particular, the need for good skills on building bridges and strategic opinion forming given the upcoming challenges of the CSS and new REACH.

Lastly, but not unimportantly, the MB discussed the financial challenges caused by the decreasing income from fees (from registration and authorisations). We are aware that a draft proposal on the review of the funding mechanism for fees is circulating between ECHA, Commission and the Member States but have so far not had any insight in it due to its confidential status. A significant review of the fee requirements may however be expected for 2022 whereby it would reflect more on the workload/activities that are involved. The further conclusions of the MB meeting are not yet known at this moment given Cefic has not yet reported them (Marco Mensink, Executive Director of Cefic represents industry in the ECHA MB) (more information: Hugo Waeterschoot).

ECHA OTHER ACTIVITIES

Monthly update: ECHA announces the launch of IUCLID 6.6 and the upcoming webinar on CSR completeness check

The last monthly call on registration updates between ECHA and industry representatives was held on the 17 September. ECHA announced two important dates: a) IUCLID 6.6 will be launched on 27 October and will contain the new completeness check rules, as well as quality warning on reporting uses; b) on the 12 November they will organise a webinar on Chemical Safety Report (CSR) completeness check, which will include practical advice based on frequent reasons for incompleteness and suggestions on how to improve reporting of uses and exposure assessments.

ECHA also took the opportunity to inform that there are still some technical issues, not related to security, within their dissemination website. A project to improve the website has been postponed and the current IT infrastructure is expected to be reviewed. ECHA invited industry to keep reporting any issues that they spotted. The next ECHA-industry representatives' call is scheduled on the 29 October (more information: Lorenzo Zullo, Federica Iaccino and Violaine Verougstraete).

EUROMETAUX CHEMICALS MANAGEMENT

EUROMETAUX FUNCTIONING

Chemicals Management Autumn Week-Regulatory Forum: reflecting on the past to better prepare for the future

You are seeing leaves falling from trees, you are taking out your favourite knitwear from your wardrobe, and you've started adding spiced cinnamon to your latte? This means Autumn has arrived, and with it our bi-annual chemicals management week! For this edition, we decided to dedicate the first two days to the Regulatory Forum. Under the "**Chemicals Strategy for Sustainability (CSS) theme**", we discussed our vision for the future "**Safe and Sustainable by Design**" concept applied to metals and how to better integrate

climate and circularity to chemicals management (what we now call the “3Cs”). Our guest speaker for this session, Professor Raabe of the Max Planck Institute, gave us some great insights on the trends in uses and applications for non-ferrous metals. After that, we discussed the future of risk management (authorisations & restrictions) for the upcoming **REACH revision** with our precious Chair of the Risk Management Taskforce, EPMF’s France Capon. After a presentation of the latest developments regarding ‘**One Substance – One Assessment**’, it was decided to bring the issue to the CSS Project Group for potential future advocacy. Also on the agenda was a panel discussion on the **essential use concept (EUC)** with none other than Professor Ian Cousins from Stockholm University (considered by many as “the” father of the EUC), Frida Hök, Deputy Director of the NGO ChemSec, and Lisa Allen from ILA bringing the multi-metallic perspective. Professor Cousins, whose work has been largely focussing on organic chemistry and PFAS (Per- and polyfluoroalkyl Substances), said that getting the metals perspective for essential uses was “eye opening”. Under the “**Zero Pollution Action Plan (ZPAP) theme**”, we discussed the latest developments on **Air Quality**, most notably the release of the WHO air quality recommendations, more than 15 years after their previous publication, and we announced that this policy area would be further discussed under the ZPAP Project Group. Finally, it was time to dive into the “**Industrial Emissions (IED) theme**”, addressing the possible conflict (and/or synergies?) between pollution criteria developed under taxonomy and the IED revision with Mik Gilles from IZA, Mukund Bhagwat and Laura Fazio Bellacchio from Eurometaux. Finally, Lighea Speciale (Seeds Consulting) took us for a mind mapping tour, exploring links between the three pillars of the Zero Pollution Ambition, i.e., CSS, Zero Pollution Action Plan and revision of the IED. Did you miss this edition of the Regulatory Forum? Fear not, as detailed minutes will be shared with you soon! (more information: Lara Van de Merckt, Lorenzo Marotti, & Noam El Mrabet)

Chemicals Management Autumn Week: Science Forum - Human Health

The second part of our CM Autumn Week, the Science Forum meetings got off to an exciting start with “The Risk-Monger” aka David Zaruk who defied our principles, challenged our perceptions with his views on Precautionaria, the disease related to the Precautionary Principle, which is not part of the Risk Management process but an uncertainty management tool. His lecture confirmed that precautionary logic differs from scientific logic and that not being right is not the same as being wrong. For more info: <https://risk-monger.com/2021/09/24/precautionaria-an-affluent-disease-spread-by-fear-and-ignorance/>

We will certainly follow up on all the learnings!

To pursue on this intrepid presentation, Adriana, Emily & Chris from NiPERA kindly provided some examples of how science enabled them to sometimes overrule the precautionary principle the nickel way and gave participants some important take-away messages, supported by Kenny Rogers.

Then, one of the Science Forum co-chairs, Martin Wieske (WVM) took the online floor to give his now traditional overview of Occupational Exposure Limits (OEL) developments. He recalled the objectives of the EU Strategic Framework on Health & Safety at Work and gave a complete update of the Working Party Chemicals activities/agenda. He also explained in detail what is at stake for the lead OEL and introduced nicely the presentation made by Vanessa Viegas (Cobalt Institute) on the upcoming EU-wide OEL Co and inorganic Co compounds. After recalling the long history of risk management of cobalt in the EU, Vanessa explained how the CI members prepare for the OEL setting process, which has started with a call for evidence (deadline: 19 November). The CI will organise an information webinar end of October for downstream users and interested parties, to highlight their scientific position and advocacy plan.

Sylvie Lemoine (Cefic) gave a most interesting talk about animal testing and the New Approach Methodologies (NAMs), and how those are at stake in the context of the CSS. Cefic is working with Cruelty-Free Europe and MEPs to ensure alternatives to animal testing are fully considered as well, and invited Eurometaux members to support their activities. To end the first Science Forum day, Lorenzo Zullo (EM) gave an update on the Human Biomonitoring for Europe project that is being finalised in 2021 and will be followed by PARC (also see [OTHERS](#)). Draft minutes of the Science Forum will be sent soon (more information: Ailsa Lee, Hugo Waeterschoot and Violaine Verougstraete).

Chemicals Management Autumn Week: Science Forum - Environment

The last day of the Forum meetings was focused on the Environmental science aspects.

The outcome of the debate in RAC on the Environmental Classification of lead metal was of course a headliner (see above RAC-58) ending with an invitation to participate in the debriefing and advocacy planning session of 9 November.

The meeting welcomed the attendance of Luis Carretero Sánchez from DG ENV who provided a short overview on the CSS reference on the Environmental Footprint challenge. However, he was unable to

provide any further indication on the direction the discussion on this criterion might take (a proposal will be developed in the next 10 months. 3 workshops will be organized to seek input)

Stephanie Bopp from the JRC was the second guest speaker who gave a very nice overview on the IPCHEM <https://ipchem.jrc.ec.europa.eu/> database -screened for their quality- designed to store exposure data sets in a transparent and uniform way. In complement ARCHE (Karel Viaene) provided some first experiences with this new standard data storage tool, concluding that *IPCHEM forms a good and quick overview of existing EU databases on environmental exposure with attention for quality, location of the sampling and trends information*. It was therefore recommended that industry explores how it can store its new information in IPCHEM format to promote its accessibility. Some attendees reacted that IPCHEM may be suitable to store ENV data, but probably less suitable to store workers exposure data. Eurometaux then provided a short update on the status of the Multi-Metallic Database (MMD) which is now close to being released and a training/demo for users will take place on 14 October.

Finally, Eurometaux ended the 4-day session with a teaser on how the sector will be confronted with the biodiversity targets and objectives under the Green Deal and the ZPAP. While not easy to demonstrate the contribution from metals, it may be a good way to demonstrate that the metals environmental impact on biodiversity is negligible contrary to other sources and stressors like agriculture and traffic. The presentation concluded that *while the biodiversity targets need to be reached in 2030, starting to assess how to demonstrate low or no impact is a task that it would be better to start sooner than later*, hence it is included in the MEED programme (more information: Hugo Waeterschoot and Violaine Verougstraete).

CHEMICALS STRATEGY FOR SUSTAINABILITY

Chemicals Strategy for Sustainability (CSS) Project Group: *preparing for next meeting of the High Level Roundtable (HLRT)*

The Commission has set the date for the 2nd meeting of the HLRT as 25 November. The discussion topic will be “strengthening enforcement” and the HLRT members will prepare a joint report to be discussed and adopted in the meeting. To start the preparation process, the Commission released a background document in early September. This document highlights two main areas of concern with respect to non-compliance with current EU legislation and regulations – imported products, and online sales. The industry view on the background document was discussed and refined by a cross industry group including many companies and industry associations, and will be used by Cefic to create a “joint statement”. The first meaningful exchange by all HLRT participant organisations followed, in a workshop on 17 September organised by the Commission and facilitated using a “toolbox dialogue” tool (Michigan State University, US) which stimulated discussion without confrontation, with the goal of highlighted convergences and divergences of opinion. This proved to be a productive approach, and there was much common ground to be found – in addition to divergences when drilling down more deeply. For example – there is broad agreement that improvements in both enforcement and enforceability of existing legislation are needed, but disagreements on how this could be achieved e.g., the balance between the “carrot and stick” approach (penalties for non-compliance vs incentives to improve compliance). The output from this workshop will be taken forward into a final preparatory workshop on 14 October, from which the first draft of a joint report on enforcement will be prepared by a professional writer. This draft will then be reviewed over the following few weeks to produce a final draft to be presented in the second HLRT.

On 17 September, the HLRT Sherpas also discussed the Rules of Procedure, revised by the Commission to take into account comments made in July. Disagreements still exist, including the number of meetings to be held per year, with industry favouring at least 3 face-to-face, but the Commission preferring at least two for reasons of resources. Comments on the list of discussion topics for future HLRT meetings were also provided in July, but a revised list has so far not been released by the Commission (despite requests for it) (more information: Simon Cook).

CSS Cross Industry meeting on Sustainable Product Initiative (SPI): *Overlaps and intersections between sustainability and chemicals management*

The CSS calls for more transparency in value chains regarding the use of Substances of Concern (SoCs) in products. This is a key objective of the SPI, with the ultimate goal of boosting the circular economy by facilitating greater recycling of complex products. One vehicle for passing information on SoCs along the value chain is the Digital Product Passport (DPP), which may contain (for example) a list of substances used in a particular product.

The Cross Industry group met for a useful exchange on the DPP. In summary, there is broad support for the SPI and DPP as ways to improve circularity moving forward. However - there are questions over a “one size fits all” DPP – to be successful the DPP must cover the whole value chain, if not then information will not arrive with waste operators at the end of the chain. “One size fits all” is not likely to be efficient given the diverse nature of products on the market - a pencil sharpener should not be regarded in the same way as an aircraft. Concerns over information requirements in the DPP generally increase moving along the value chain – and are very strong from producers of highly complex products which contain an enormous number of substances. As well as volume of information, issues relating to Confidential Business Information and Intellectual Property are also clearly present. A possible approach could be to create “clusters” of products, which are families based on similar characteristics / complexity / lifespan. There is an ongoing project in Germany involving product manufacturers and waste operators, which has four different product clusters and is giving some promising results. The project is considering: what are the problems that need to be solved to facilitate circularity; which can be solved by information; if they can be solved, what type of information and how should it be provided; if they cannot be solved by information flow then what are other possible solutions.

The group agreed to continue this type of information exchange and sharing (more information: Kamila Slupek and Simon Cook).

WATER

Public Consultation of the Water Framework Directive Refit

The Open Public Consultation and Expert Consultation for the Impact Assessment of the Water Framework Directive (WFD) Refit were launched on 27 July. We have submitted our response for the expert consultation where we focused on silver and nickel. In addition, we have attached a more general concerns letter drafted that was co-signed by the JAM members. The deadline for the more generic, public consultation, to which we will also respond, is 1 November.

Prioritisation Process

Silver has been shortlisted as a priority substance under the Water Framework Directive and the Environmental Quality Standards Directive. The draft EQS dossier was forwarded by the European Commission (EC) to the Scientific Committee on Health, Environment and Emerging Risks (SCHEER) for opinion in February 2021. SCHEER's opinion on silver was published by the EC in September. While SCHEER recognises the importance of considering metal specificities in setting an environmental quality standard (EQS), its comments on the draft EQS for silver and its compounds neglected the actual scientific knowledge and omitted areas where consideration of metal specificities is critical, as well as existing high-quality data sets (e.g., no consideration of bioavailability).

The European Precious Metals Federation (EPMF) has prepared a detailed document on the SCHEER opinion for the EC, based on which we are also submitting a response in support of EPMF's opinion.

Deselection of existing Priority Substances

Progress on the revision of the deselection criteria was presented and discussed at the 29 April meeting of the Working Group (WG) Chemicals. The updated document was prepared by the Joint Research Centre (JRC) and sent to WG Chemicals for comments (deadline 11 October). After this deadline, an updated document will be sent to SCHEER for feedback. Again, the JRC's approach towards deselection is not evidence/science based. We are drafting comments on this document, which we will submit to the Commission. In doing so, we will draw on the recent WCA paper on criteria for deselection of priority existing substances.

Diffuse sources

The Working Group on improving emissions to water (i.e., diffuse sources) gathered as planned on 15 September, during which the draft factsheets for the different emission pathways were discussed. This diffuse emission project is coming to an end, we submitted our comments on the factsheets and these should be presented during an upcoming WG Chemicals meeting. We have expressed our interest to be involved in further activities of the sub-group on improving emissions to water. Note that during the September meeting, the European Environment Agency (EEA) mentioned the importance of the diffuse emission project regarding the Zero Pollution Action Plan (ZPAP) and the work done by Professor Sean Comber has played a significant role in the overall project which is quite encouraging for the future.

The next Working Group Chemicals meeting is scheduled on 21 October (more information: Lara Van de Merckt).

CLASSIFICATION

Lithium CLH Taskforce call: *taking stock of RAC*

ECHA's Risk Assessment Committee (RAC) had its final discussion on the classification of the Li compounds (chloride, hydroxide, carbonate) on 13 September and concluded to a classification as Repro 1A, H360 FD, Lactation H362. The Lithium CLH Taskforce was invited to discuss the RAC outcomes and consider the next steps, i.e., towards Commission and Member States (CARACAL). An estimated timeline was presented (tbc): Commission may start preparing entries for the next Adaptation to Technical Progress (ATP) considering all classifications proposed by RAC this year in Q1 2022. These entries will be proposed to CARACAL end of Q1 with possibilities to comment (for MSCAs and stakeholders), and a decision by Commission may be taken end of autumn, which will be submitted to scrutiny by the European Parliament and the Council in autumn 2022.

Interesting to mention is that the UK is also looking at lithium and may come up with a different view as the conclusions heavily rely on interpretation/consideration of studies and weight of evidence. The sector will ensure that all the information made available to RAC (including the recent publication of Van Deun et al., 2021) will also be made available to the UK authorities.

Next steps are to map the impacted sectors and invite them to describe the impacts and prepare advocacy. It was also proposed to start reflecting about risk management options. The minutes of the call were circulated on 28 September and the chairs/secretariat will come back to the Taskforce with a concrete action plan in the coming weeks (more information: Jennifer Diggins, Bob Miller, Sylvia Jacobi, Werner Köhl, Hugo Waeterschoot and Violaine Verougstraete)

REGISTRATIONS

REACH Review: *what would be the impact of possible additional data requirements for low tonnage substances?*

Among other measures that are part of the REACH Review, the European Commission might consider adding more REACH information requirements for low tonnage substances.

The issue is particularly important and the impact could be very significant depending on how Commission will shape its proposal. It is expected that significant testing will be required to identify CMR (Substances classified as Carcinogens, Mutagens or toxic to Reproduction) (or other hazardous properties: EDs (Endocrine Disruptors), PBT (Persistent, Bio-accumulative and Toxic Chemicals), etc..) for 1-10 ton substances. Low tonnage substances are also more likely to be registered by fewer registrants, leading to higher impacts on individual companies compared to high volume substances. Inclusion of environmental hazard testing might also lead to unbearable costs. Prioritisation based on exposure could also be a possible approach that industry is currently reflecting on. Eurometaux, besides maintaining an active dialogue with other industries, has initiated to map potentially impacted substances and related uses; the topic will be further discussed at the next Registration and Maintenance Taskforce meeting to be held in the first half of November (more information: Lorenzo Zullo).

Implementation of REACH Art. 22 duties on dossier updates: *ECHA campaign on SVHCs*

Following the interest expressed by Member States (MSs) on whether the Implementing Regulation on dossier updates is working, ECHA decided to initiate a campaign targeting Substances of Very High Concern (SVHCs) with full registration dossiers (no intermediates).

A letter was sent to individual registrants (lead- and co-registrants) as a form of awareness campaign asking to provide information within a specific deadline on the status of their dossiers. Particular focus is given on the uses, for which authorisation has not been renewed (are your registered uses still up to date?). More letters to be sent are in the pipeline and ECHA is also following up by phone. The responses collected from the registrants will be compiled and shared with MSs for further consideration. Some results are expected to be communicated at the beginning of next year; the campaign could then be expanded to other groups of substances (more information: Lorenzo Zullo and Violaine Verougstraete).

ENVIRONMENT

New outreaching MEED programme: *to keep ahead of future challenges*

Eurometaux, in collaboration with the consortia, commodities, associations and companies designed a comprehensive "environmental exposure gathering programme" called MEED (Metals Environment

Exposure Data). The objectives of this initiative are to comply with the outstanding MISA priorities on exposure but also more broadly with the Zero Pollution Ambition and biodiversity objectives, while making the best use of resources available in the sector.

MEED is composed of 2 data gathering packs, composed of 6 projects, driven by the following regulatory concerns: the Mixture Assessment Factor (MAF) proposed under REACH by the CSS and, the Zero Pollution Action Plan /MISA/REACH and it will run for a duration of three years. The aim of the programme is to demonstrate a good understanding of today's exposures, risks, and their control, complemented by knowledge and management of expected future emissions and/or trends. A detailed overview of the project should already be in your inbox alongside a survey <https://www.surveymonkey.com/r/FZVNFB5> that allows you to send in your views and suggestions. For any additional information or clarification, please write us an email at dobre@eurometaux.be

RISK MANAGEMENT

Risk Management Taskforce: no clarity yet on Pb metal prioritisation, so more time for a strategic discussion on Risk Management

The Taskforce met on 21 September in remote. Due to the delay on the posting of the scoring table of substances on the candidate list to identify the next priority list of substances for Authorisation, the group had more time to discuss some strategic forward-looking aspects on Risk Management under the CSS. The Taskforce took note of the comments submitted by Eurometaux to CARACAL under the Restriction Roadmap for the period 2022-2025/27. Most importantly, it was underlined that any specific restriction in the EU should run under Article 69 (2) and hence remain risk based and be based on a carefully considered Risk Management Option analysis (RMOa). In addition, grouping for Risk Management should be use-specific and not mainly driven by collecting as many substances as possible together in one group. The Taskforce confirmed that these points are actually also the critical issues to be defended for the period after 2025/27 under the REACH Review. Indeed some more recent comments from Commission on the generic restrictions under REACH indicate a move towards a hazard based approach. A round table discussion on the future of authorisation under the REACH Review indicated that not all Consortia had formed an opinion on what option suggested by the Commission to CARACAL would be the best way forward to balance both industry's and societal views. Most Consortia seem to lean towards the Commission's suggestion to always use restriction as a basis whereby industry sectors could request/submit for alternative Risk Management measures and individual companies apply for exemptions under the form of an "authorisation new style". Until further clarifications on the Commission's views, Eurometaux will not elaborate in detail on the preliminary options presented at CARACAL at this stage, but will continue explaining to the Commission and Member States what the key principles should be to inspire the future EU Risk Management policy (more information: France Capon, Klaus Kamps, Michel Vander Straeten and Hugo Waeterschoot).

OECD Working party on Risk Management: Eurometaux's presentation on RMOa welcomed by OECD

The OECD held its first meeting of its new Working Party on the Risk Management of Chemicals (WPRM), in parallel with the Eurometaux Regulatory and Science Forum meetings. This Working Party was created to coordinate and better integrate all of the OECD's existing RM activities, given the rising membership interest. This was testified by the large and impressive attendance at the meeting with more than 50 attendees covering all continents). Kai-Sebastian Melzer (NI) as BIAC-vice chair and Hugo Waeterschoot for Eurometaux attended this meeting for the metals sector. Given it was the first meeting, it was mainly focused on defining the scope of activity and discussions on ongoing projects. Before the Member States were invited to explain regional activities on RM, Eurometaux was invited to present its Industry RMOa tool. We were able to explain the concept and present our experience with the tool, that certainly drew some attention from blocks other than the EU as well as from the OECD, thus a more than worthwhile investment. One of the projects the OECD secretariat presented was the launch of the development (in 2022) of a compendium of successful tools and approaches to Risk Management whereby Eurometaux was invited to include the RMOa tool it developed. To note was that besides EM's input there was none coming from other industry sectors (more information: Kai-Sebastian Melzer and Hugo Waeterschoot)

Restriction Roadmap: Eurometaux's contribution submitted to CARACAL

Mid-September, Eurometaux submitted its contribution to CARACAL on the Restriction Roadmap proposal. Given the aim to attain more efficiency, effectiveness and transparency, in its comments Eurometaux underlined its support for the principles behind the review of the Restriction process for the

period 2022-2025/'27, until the new REACH will be implemented. An earlier announcement of intentions and a rolling list of substances and risk-based concerns could indeed improve the transparency and predictability of Restrictions. Eurometaux recommended in particular that a restriction should always remain based on Art. 69 (1) of REACH, requiring a risk-based concern requiring action at EU level. The RMOa is therefore critical to define the need, extent and scope of the risk to define the most optimal tool to further control the risk. Eurometaux further emphasised two major points of attention in respect to the Roadmap draft: i) the announced grouping of substances to speed up restrictions which should not be an aim in itself given it is *their use* that leads to exposure and ii) the need to ensure attention for the 3Cs (Climate, Circularity and Chemicals) in a balanced way when defining the best Risk Management options. Finally, Eurometaux asked for clarification on how the present lists -of suggested restrictions and substances for which a restriction could be defined for- were composed given lacking clarity and transparency. Series of organizations posted comments so it would be most interesting to see how Commission draws learnings from this stakeholder input at the next CARACAL in November (more information: Hugo Waeterschoot).

METALS & INORGANICS SECTORIAL APPROACH (MISA)

MISA: discussion about finalisation of the programme

Eurometaux had a call with ECHA on 10 September on the next steps of the MISA programme. As a reminder, it was agreed during autumn last year to extend the MISA timeline, initially scheduled for 2018-2020, by one year to allow for the finalisation of some technical discussions and related updates on the Unknown or Variable Composition, Complex Reaction Products and Biological Materials (UVCBs) and have enough time for in-depth discussions on exposure. ECHA did a thorough check of the “update activities/workplans” end 2020 and prepared a communication/report to CARACAL to support/justify this extension of the cooperation. However, the prolongation was only for one year, which now means that we are nearing the end of MISA. It is understood that some updates/data generation will only take place after the December limit, because of some remaining open discussions (see below) but formally the “framework” will be stopped. ECHA and the metals sector will need to communicate about the programme and its learnings to the authorities and the ECHA Management Board. This needs to be prepared, to add to the Key Performance Indicators (KPIs) -agreed at the start of the programme- what are the less visible but as important achievements of the programme (e.g., multi-metallic work and technical discussions). The MISA community has been invited to share its learnings.

ECHA and Eurometaux also discussed what to do about the last priority, i.e., the work on minor constituents/impurities & supply chain communication. This activity fits in a broader context than REACH compliance only, considering for example the ‘non-toxic material cycles’ driver in the Circular Economy and Sustainable Chemicals discussions. It was agreed that the set-up of MISA 5 requires some reflection and time and will not fit in the remaining months. However, a specific cooperation might be set up in 2022. It was proposed to start by identifying a couple of examples, to reflect about the questions to be addressed and use these to design a possible work programme (including links with REACH registrations, risk management, CE, other legislations (Occupational Safety Health (OSH), Industrial Emissions Directive (IED), etc.) and other sectors.

Another call was held with ECHA exposure experts on some open actions on exposure from the MISA 4 exposure workshop as ECHA also needs to prioritise its work. Agreement was made on where consultants/Eurometaux could support the ECHA actions. We used this opportunity to inform ECHA on the environmental exposure projects (MEED) as they have seen the drafted placeholders included in the MISA dossiers.

Finally, ECHA proposed to have bilateral meetings with MISA consortia to discuss their workplans and updates if interested (more information: Federica Iaccino, Hugo Waeterschoot and Violaine Verougstraete).

OUTREACH

OTHERS

HBM4EU: is reaching an end, opening the door to the 400M euro PARC project

The 5-years [Human Biomonitoring for Europe project \(HBM4EU\)](#) will be completed at the end of 2021. The overall project focused on i) coordinating and advancing human biomonitoring in EU, ii) generation of

human exposure evidences and iii) support policy makers in Europe and beyond. Among various deliverables, a list of prioritised substances was recently released and included: “trace/heavy metals”, “flame retardants”, “mercury” and “metals in batteries”. Such a prioritised list will be used as input for an huge upcoming project, called “PARC” whose objective is to “*consolidate and strengthen the EU’s research and innovation capacity for chemical risk assessment to protect human health and the environment and contribute to a non-toxic environment and circular economy*”. For the PARC project, a budget of 400 million euro is expected to be allocated, half of which financed by the European Commission. It will involve 28 countries, three agencies (EEA, EFSA, ECHA), the Joint Research Centre, five EU Commission Directorate Generals and 200 public institutions, universities and laboratories. If finally approved, this project is expected to be kicked-off around March-May 2022. A stakeholders group, including industry, will also be established (more information: Lorenzo Zullo).

CALENDAR

**Here below a non-exhaustive list of the meetings that are planned so far for after the summer 2021.
Please save the dates for the meetings of interest for you.**

For meetings at Eurometaux

The meetings at Eurometaux will be held online until end of September.

The MCC is planned to open on **1 October 2021**, thus from then on meetings will be held in a hybrid manner, both in attendance for those who can attend and according to the limitations in numbers (Covid safety measures) and online for those who are unable to attend in person.

For meetings at ECHA

ECHA meetings, including those of formal ECHA bodies, **will be held remotely until further notice.**

ECHA will keep the situation under review and will provide any further information as appropriate.

This information is published on ECHA’s [website](#)

Further information on the COVID-19 situation information can be found on the [ECDC website](#)

- 11-15 October: ECHA MSC-75 Meeting
 - 14 October: MMD Demo/Training
 - 19 October: ZPAP Project Group Meeting
 - 21 October: Working Group Chemicals Meeting
 - 26 October: Evaluation TF Meeting
 - 28 October: MeClas Steering Committee Meeting
 - 10 November: CARACAL TF Meeting
 - 18 November: Water TF Meeting
 - 17-18 November: CARACAL-41 TBC
 - 22-26 November: ECHA RAC-59 & SEAC-53 Meetings
 - 29 November-3 December: ECHA RAC-59 & SEAC-53 Meetings
 - 08 December: Chemicals Management Steering Committee Meeting
 - 07-08 December: ECHA Committee Meeting (TBC)
 - 13-17 December: ECHA MSC-76 Meeting
 - 15-16 December: ECHA MB-64 Meeting
 - 21 December: Risk Management Taskforce Meeting
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GENERAL INFORMATION & ACRONYMS

Follow the logo to 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)