



EUROMETAUX CHEMICALS MANAGEMENT NEWS



Please join us in March:

- 04: LVIC BREF Working Group (online)
- 08: CARACAL Taskforce (online)
- 18-21: Chemicals Management Spring Week
- 26: Registration Compliance Taskforce

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Dear All,

Mark Twain said it once: "Facts are stubborn, but statistics are more pliable". I also like this one: "Most people use statistics like a drunk man uses a lamppost; more for support than illumination" (A. Langman). There is a lot to learn from the type of statistics applied, what they tell, and how what they tell is then applied. This thought popped up in my mind once again while reading a recent opinion on a metal, where a series of statistical terms and results from the handling of the data led the assessor to a firm conclusion.

But I also think it requires some courage to dive into statistics.

Let's imagine the scene: you have been offered a ticket to access a site where data says it all. You enter the place, naively, just equipped with your beliefs. Most probably you did not bring a suitcase with you as it looked like an easy couple-of-hours activity. When, only a minute later, the door by which you entered bangs, you realise you are locked in a room whose walls are covered by a multitude of datapoints. The data floats with no apparent coherent pattern. Some points are flickering, others playing it discrete, some collating into a cloud, whilst others seem to prefer the outer confines of the group. And when you (do) catch a datapoint -to grasp what it means- you understand that there is some missing accompanying information on the variable. That's probably why there are so many cupboards around you. But which one to open first? Is there a key or a sequence that helps comprehend the meaning? You are tempted to knock on the door but before you can start grumbling, a supernatural voice communicates quietly that you are expected to deliver an assessment to get out. What?

It takes a moment to calm your heartbeat. You try to reassure yourself. You know numerous people managed data, so why not you? This task cannot be that difficult to perform that no one wins. But you should not have left that pack of cookies in the cloakroom. This is the moment when some sweet comfort is needed.

Despite the absence of sugar, you decide to go into 'attack mode'. First by organising this mess of data! You try to fit them in distributions, make them enter boxplots or histograms you draw on a board that has appeared. A small piece of parchment under the carpet suggests that you replace each variable x with a $\log(x)$ to arrive at a nice bell shape. Luckily, the transformation works thanks to your phone (but by now the battery is empty). By opening all the drawers, you find some characteristics that illustrate the variables you have in front of you. But the search also reveals that there may be missing data. After an intense and unsuccessful search (you have even been driven to lifting the floorboards), you decide to write down that there may be some errors here.

And, miracle, as soon as you recognise the possible error, a door - invisible up to now- opens a little! Without waiting, you squeeze yourself through the gap, into the next room. It is completely empty except for a barely lit notebook and an instruction in bold letters: "write down your hypothesis".

You hesitate a bit. How to best formulate it, how to demonstrate it? How will you be able to decide whether your hypothesis is true or false, what is significant? The thought of the cookies in your jacket makes you take a decision: $p < 0.05$ it will be!

This is sufficient for a parade to suddenly start taking place in front of you: different models appear, smiling, showing their attributes, making promises about results, asking you to select the most beautiful one. The choice is difficult, not helped by the fact that the limitations are not visible. Should you go for the t-test that looks authentic and simple, paired or not? Or for its more exotic Chi square cousin? For the seducing ANOVA, or the multiple linear regression that seems so complex but has it all? Unable to choose you propose combinations, using them all, claiming you will be transparent when reporting.

The day has come to an end, but you cannot stop overnight. You need to get to your assessment. Exhausted you fall asleep a couple of seconds, enough to have a dream that warns you that you have completely ignored the epidemiological data sitting in a dark corner, and that you may fail if these do not receive the appropriate treatment. This is sufficient to wake you up and frenetically, you build odds ratios and relative risks to serve to the epidemiology, playing it humble, interspersed with confidence intervals.

Time passes...

But you get it -or you think you get it! You generate results, use Greek letters, you compare and plan to even come back to your hypothesis. You fight against the curse of uncertainty by recycling the confidence intervals, renaming them standard errors, draw criteria for their acceptability.

Actually, the exit door has been open for a while. But you did not pay attention to it...

You did not hear the supernatural voice again, but you do not need it anymore.

You have your assessment: it is clear, structured, scribbled... it is yours!

Is it clear enough to be understood, transparent as you promised it would be?

Are you ready to share it with the external world via a peer-review?

But you are not sure anymore that outsiders deserve the whole epic.

You wonder if a table of results in supplementary material is not sufficient? Or even a statement at the end of an opinion, signed 'expert judgment'?

You are now a happy but lonesome statistician, walking towards the sunset, with a pack of -now old- cookies

Violaine Verougstraete

COMMISSION

CARACAL next meeting: 20-21 March and preparatory call

The next CARACAL (51st) meeting is scheduled for 20-21 March. The latest version of the agenda includes relevant discussions for the sector, including an update on the ECHA Basic Regulation and the updated Restrictions Roadmap, as well as discussions on the restriction on Chromium (VI) substances and the outcomes of the Substitution workshop. Finally, on harmonised classifications, a final consideration is envisaged on the amendments of the Annex VI draft Delegated Regulation for 2022 RAC opinions (including Cu & Ag) and a discussion on the upcoming 23rd ATP.

To prepare for the 51st CARACAL, a CARACAL Taskforce call will take place online on Friday 08 March 2024, 10:00-11:30 CET (more information: Ainhoa González Pérez).

EU AGENCIES

EUROPEAN CHEMICALS AGENCY (ECHA)

ECHA COMMITTEES

MSC-85: clarified when a substance already undergoing RM can be prioritised for Authorisation

MSC-85 was a(n) (remote) interim session without important new topics for discussion and conclusion setting. One relevant item related to the (new) 12th priority list for Authorisation on which a Public Consultation is presently running. MSC agreed to add an additional substance on the list that was not withheld by ECHA because of the intention to risk manage the substance under a restriction (on Brominated Flame Retardants). MSC agreed that a substance can be excluded from prioritisation or have its score recalculated (lowered) excluding the risk managed volume, IF the intention for regulatory Risk Management is materialising (e.g., the drafting of an Annex XV started by a Member State or ECHA) and not just an intention (on PACT or call for evidence to scope a potential restriction). This is an important clarification and even MSC was stricter than ECHA. To note, if this ruling had been applied to previous lists, it would have excluded Pb metal from the 11th priority list.

At the first MSC of the year, the legal service always provides a summary overview of key legal (BoA and ECJ) cases related to evaluation/risk management activities. This year's overview focussed as expected on the annulment of the ChemService CrVI granted grouping application for authorisation and the 3 cases in which the BoA rejected the Learning and Memory test demand by ECHA under Compliance checks. Lastly, Commission updated MSC on its New Approach Methodologies (NAM) strategy plan with emphasis on the outcome of a recent workshop to prepare for the NAM implementation. The strategy aims for a phase-out of classical animal testing (where feasible) by the end of 2025 for all chemicals legislation. MSC was informed what that could mean for them. EM indicated that while recognising NAMs can be most useful, they need to be robust and validated. Moreover, EM noted that in the context of the water quality monitoring discussed at the OECD CBC meeting it was suggested extending animal testing, and hence there is a need for consistency in policies (more information: Hugo Waeterschoot).

SPI-MB: an insight on the annual report on ECHA's activities in 2023

The ECHA Strategy, Planning and Innovation group prepares the meetings of the ECHA Management Board and provides advice. The SPI met on 27 February during which Guy Thiran represented the EU industry in this ECHA high-level group. The main agenda point related to the review and adoption of the Annual Report 2023, which always provides an interesting insight into ECHA's external and internal activities and deliveries. The progress performance on the planned outputs for 2023 were assessed based on pre-agreed Key Performance Indicators (KPIs). Industry welcomed the transparency and comprehensiveness of the draft annual report but insisted that both the planned outputs and KPIs should become more indicative of the quality of the work rather than exclusively focusing on the quantity of work conducted. An example, quoted in this respect related to evaluations, were the KPI "how many were handled by ECHA", while industry is often faced with very long and unpredictable timings of these reviews, which can impact test programs and registration updates. In follow-up of the meeting, we sent them written comments on the interventions we made as well as some specific recommendations for improving further Annual Reports (more information: Guy Thiran and Hugo Waeterschoot).

ECHA OTHER ACTIVITIES

ECHA-Industry call: discussions between ECHA and industry representatives regarding the TCC releases with IUCLID updates

On 1 December, a first ECHA Industry meeting took place to primarily discuss IUCLID updates. Subsequently, on 16 February, ECHA and industry further engaged to discuss the implementation timelines for the technical completeness check (TCC) rules. During these discussions, industry representatives reiterated the sentiments expressed in a joint letter submitted to ECHA with Cefic and Concawe back in November 2023. It was emphasised that while there is a general acceptance and understanding of the TCC rules as a tool to ensure dossier completeness and alignment with REACH requirements, the implementation of new TCC rules poses challenges for the industry. These challenges include the need to update dossiers and the consequent issues arising from the updated IUCLID versions, such as installation errors, bugs, and the time required for updates due to work around solutions. To address these concerns, industry proposed a 4-5 month period between IUCLID releases and new TCC implementations.

While ECHA demonstrated a high level of understanding and willingness to find workable solutions, technical constraints were acknowledged as well. Specifically, ECHA explained that IUCLID and TCC are developed in tandem, making it technically infeasible to update IUCLID but keep it paired with the old TCC rules linked to the previous IUCLID version. During the call, various scenarios were explored, but it was not possible to agree on a definitive path forward. Considering that the upcoming April IUCLID release will not include new TCC rules, it was decided to use this 'simpler' release to further gather and analyse industry feedback on new IUCLID installations and proceed with an additional dedicated meeting to discuss this feedback, after which a decision will be made on the best approach for future IUCLID and TCC releases (more information: Federica Iaccino).

ECHA workshop on the Integrated Regulatory Strategy: preparation of industry input

On 6-7 March, ECHA is organising a workshop to review the implementation of its Integrated Regulatory Strategy (IRS) and align it with ECHA's future priorities and strategic focus, also taking into consideration elements like the one substance, one assessment (OSOA) initiative and new tasks to be re-attributed to ECHA (Batteries, Drinking Water, Cross-border Health threats etc.). Stakeholders (industry, NGOs) are invited to participate in the open sessions on 6 March and to provide presentations on a) the experience with the current IRS implementation and b) perspectives on how to move towards more impactful coordinated risk management (of groups) of substances. Breakout sessions will address key questions related to successes and challenges of the IRS, how did the grouping work, key priorities and enhancements needed to move towards a more coordinated risk management, and how to improve communication and cooperation in the years to come.

The accredited stakeholders invited to the workshop were asked to go for joint presentations, as far as possible. Two calls have taken place in February with a.o. Cefic, Concawe, FuelsEurope, FECC, SMEUnited, AISE, DUCC, IFRA to identify the common industry messages, both on the current successes and shortcomings but also on how an IRS 2.0 could be more cooperative and efficient. The outcomes of the workshop will be reported in the next News and at the Regulatory Forum meeting (more information: Violaine Verougstraete).

ECHA High-Level Conference: 'Shaping Tomorrow'

On 28 February, Eurometaux attended the European Chemicals Agency's conference 'Shaping Tomorrow' at ECHA in Helsinki. The conference centred on the future of chemicals legislation, focusing on implementation and innovation. During the conference it was possible to meet and have one-to-one sessions with ECHA's experts to learn about their work and address specific topics or issues.

The discussions focused on three main areas: Collaboration, Science and Knowledge. The green and digital transition and regulatory coherence were highlighted as key components in tomorrow's chemical landscape. Initiatives that are being developed to support businesses in the green and digital transition were discussed. Looking forward, one of the regulators' main priorities will be fostering chemical safety through research and bridging the gap between science and regulation. It was underscored that scientific research should address regulatory challenges also through alternative methods and international collaboration. It was highlighted that an important challenge to achieve this would be overcoming the regulatory barriers to data sharing, standardising chemical data, and leveraging the evolving potential of AI in chemical regulation.

Among the panel speakers were Commission Officials, ECHA's Directors, representatives from the OECD and the EEA, Academia, NGOs and Industry (more information: Lorenzo Marotti).

EUROMETAUX CHEMICALS MANAGEMENT

Chemicals Management Steering Committee: 1st meeting of 2024

One of the key items on the agenda was the discussion of the main outcomes of the Denton strategic survey and how to build on the recommendations, in particular developing a longer-term vision. To feed the discussion, short presentations were made on e.g., the recent [Antwerp Declaration](#) asking for an EU Industrial Deal, ECHA's Strategy Statement for 2024-2028 and the international policy trends. Over the last years, Eurometaux has developed several sustainability messages (from the Sustainable Metals Concept, 3Cs, 4 Cs etc.) the secretariat explained how these could be articulated within the 8 Building Blocks of the Transition Pathway (TP) for metals that is currently being worked on.

Eurometaux will lose Hugo's expertise in 2025 and several scenarios were presented to try to maintain the level of current chemicals management activities and Eurometaux's knowledge & credibility. These scenarios will be presented to the Eurometaux Management Committee.

The Eurometaux secretariat gave the key takeaways of a meeting held at the Commission with Aurel Ciobanu-Dordea (Director Circular Economy) as well as an interesting overview of Sustainable Finance and EU Taxonomy and the challenges still to be addressed.

The meeting ended with an update on the TNO study that is a critical piece of information to demonstrate safe use of metals under the Green Deal growth scenarios, and whose robustness depends on entering key information that is to be supplied by members in the coming week.

The potential precedent settings of the ZnO nano Substance Evaluation were highlighted to the participants. Eurometaux will monitor the case carefully and provide strategic advice where it can. The draft minutes of the meeting will be circulated in the coming days (more information: Violaine Verougstraete and Ailsa Lee).

Human Health Taskforce: call to discuss welding

The European Welding Association (EWA) has -over the last year- updated the "REACH & welding of metals and alloys" document, which was initially circulated in 2010 in view of the REACH Registration deadline. The document discusses welding processes, health hazards of welding, existing risk management of welding and includes a proposal for risk assessment and risk management measures of "welding processes+" and compliance with REACH.

This update was timely as there is ongoing work on welding in different forums: ECHA has carried out a scoping study, the ACSH has issued an opinion on how to introduce "work involving exposure to fumes from welding processes containing substances that meet the criteria for CMR category 1A/1B set out in the CLP into Annex I of the Carcinogens, Mutagens, Reprotoxic Directive (CMRD)".

Several comments were made on the revised draft when circulated to the Human Health Taskforce, leading to a dedicated call on 20 February. An updated version, considering the suggestions of the participants, is currently under preparation and will be circulated to the Human Health Taskforce, Eurofer and EWA for approval and finalisation (more information: Violaine Verougstraete).

CHEMICALS STRATEGY FOR SUSTAINABILITY

Chemicals Strategy for Sustainability: meeting with DG ENV

On 12 February, Eurometaux met Aurel Ciobanu-Dordea, Director for Circular Economy in DG Environment as well as other officers from DG Environment working on Safe and Sustainable by Design (SSbD), REACH & CLP, batteries, ESPR and waste.

The meeting was a continuation of the dialogue on chemicals management and Critical Raw Materials (CRM) established in 2023 and extended it to the next policy cycle on wider topics such as waste and products policy. Eurometaux asked for clarifications and provided actionable solutions and priorities for the next Commission's mandate on substances, products, waste, and emphasised the need to have an Industrial Deal.

The Commission indicated that the REACH revision will most probably come as a package and not in separate pieces for comitology and OLP. Nevertheless, it is uncertain how much Commission will push for

the REACH revision since it is currently focusing on improving risk management within the current legal framework. Regarding industry's concerns that ESPR would be used as a backdoor for restrictions in the absence of a revised REACH, the Commission noted that ESPR should be complementary and not a surrogate for REACH restrictions and have clear boundaries, with ideally REACH remaining the basis for restrictions for safety reasons and ESPR addressing concerns related to sustainability and especially recyclability of a material. In this context, incorporating the Substances of Concern (SoC) definition under REACH is not foreseen. The tracking of SoC under ESPR can nevertheless be used under REACH to identify concerns in articles to then initiate restrictions.

Finally, the Commission is discussing with ECHA the consequence of waste not being covered in REACH and welcomed Eurometaux's views on this. The participants concluded that 2024 will be the year to fix the borders between substance-products-waste regulations and that the legislative agenda in the next years will be determined by what was agreed under the Green Deal, and work will have to focus on implementing measures. Participants agreed to continue the dialogue (more information: Ainhoa González Pérez & Simon Cook).

Expert Group on One Substance One Assessment: *meeting expert group*

The Expert Working Group on One Substance, One Assessment (OSOA) met on 21-22 February 2024 to present and discuss the recently adopted package of proposals on the re-attribution of scientific and technical tasks among agencies, the reattribution of tasks to ECHA on the RoHS directive, and on the establishment of a common data platform on chemicals. The meeting aimed at presenting extensively the new proposals and coordinating initiatives on safety assessments of chemicals across chemical legislation between Commission services, EU agencies and Member States. Despite being held behind closed doors, the meeting documents provide extensive explanations of the proposals and are publicly available. The ECHA basic regulation proposal is still in the pipeline but has not been presented yet.

The deadline to provide comments to the Commission proposals is the 3rd of April. The Belgian Presidency has created an Ad Hoc Working Party on One Substance One Assessment to work on the texts under the leadership of the Council's environment group, with reporting to the representatives of the Agriculture, Health, Technical Harmonisation and Competitiveness sectors, with the objective to cover all the transversal aspects of these legislations.

While the Council is expected to progress on the formation of its opinion, the time constrains make it practically impossible for the EP to work on this file within this mandate. Nevertheless, the files have already been allocated to the ENVI committee and it is expected to be led by an EPP rapporteur, pending final decision on the referral. MEP Maria Spyraiki (EL, EPP) is meant to lead one of the proposals. The current Parliament may decide to leave the opinion-making to the new Parliament, which will start to work in Q3 2024 (contact Ainhoa González Pérez for access to the documents).

ZERO POLLUTION ACTION PLAN

Ambient Air Quality Directive: *update*

On 5 February, the Eurometaux Air Quality Taskforce held an update call to discuss the latest development relative to the AAQD Review process. An overview of the process, actions and information available was presented. A discussion with input by members followed. It was agreed to continue monitoring the process by keeping in contact with Council. The group will have another update call following the publication of the compromise agreement text to discuss its content.

On 20 February, the Commission, Council and Parliament during their last trilogue reached a compromise agreement on the new Ambient Air Quality Directive, aiming for stricter pollution limits by 2030 for key pollutants.

- **New Rules Overview:** set stricter 2030 limits and target values, compared to current rules, for several pollutants including particulate matter (PM_{2.5}, PM₁₀), NO₂ (nitrogen dioxide) and SO₂ (sulphur dioxide). For PM_{2.5} and NO₂, the annual limit values are to be more than halved from 25 µg/m³ to 10 µg/m³ and from 40 µg/m³ to 20 µg/m³ respectively. It also mandates an increase in air quality sampling points in cities and requires national and local actions to comply with these standards.

- **Monitoring & Planning Enhancements:** the directive strengthens air quality monitoring and modelling, improves air quality plans, and mandates air quality roadmaps by 31 December 2028 for EU countries, to detail measures to meet the new limits.
- **Review Clause:** a review of the air quality standards is scheduled for 31 December 2030 and every five years thereafter, with additional reviews if new scientific findings emerge, e.g., revised WHO guidelines.
- **Requirements for Exceedances:** if pollutant levels exceed or risk exceeding set values, Member States must establish air quality roadmaps, plans, and short-term action plans with emergency measures to mitigate health risks.
- **Compliance and Postponement:** Member States can request a deadline postponement for meeting air quality limits under specific conditions until 2040 or 2035, with required air quality roadmaps showing plans to minimise exceedance durations.
- **Access to Justice and Compensation:** the directive provides for access to justice and compensation for health damages due to intentional or negligent violations, calling out for Member States to establish penalties for infringements. The Directive also sets out provisions to ensure access to justice for those who want to challenge its implementation, including public health and environmental NGOs.
- **Institutional Statements:** Commissioner Virginijus Sinkevičius highlighted the agreement as a milestone for zero pollution and a step towards cleaner air, benefiting vulnerable groups and moving towards a pollution-free Europe. European Parliament ENVI Committee Rapporteur Javi López emphasised the agreement's role in updating EU air quality standards and improving monitoring and protection for sensitive populations. Alain Maron, Minister of the Brussels-Capital Region and representative of the Council Presidency, remarked on the EU's prioritisation of citizen health and the agreement's contribution to reducing air pollution and achieving the EU's zero-pollution ambition by 2050.

Next Steps: the European Parliament and the Council will now formally have to adopt the revised Directive before it can enter into force 20 days after its publication in the Official Journal of the EU. EU countries will then have two years to apply the new rules.

The European Parliament scheduled a plenary vote to adopt the AAQD on 22 April (TBC) (more information: Lorenzo Marotti).

CLASSIFICATION

Li classification: further actions

ECHA's Risk Assessment Committee will most probably finalise the revision of its opinion on the Li classification at its plenary session on 11 March. The Li toxicologists and Eurometaux provided a last input to RAC, including the publication by Smith & Payne. This study aims at demonstrating that pregnant bipolar patients are a unique patient population experiencing numerous co-morbidities who have reported risk factors for congenital heart defects of the same or larger magnitude than the reported risks attributed to lithium. At the time of the Public Consultation, it was only available as a manuscript submitted for publication and hence could hardly be quoted in the RAC opinion.

Several members of the Eurometaux Li Taskforce/ILiA have a seat in the European Round Table of Industrialists (ERT) that brings together the CEOs of 60 major European companies. The organisation was invited to submit examples of overregulation or incoherent regulation impacting industry's competitiveness to the team of Mr Draghi, in charge of preparing a report on European Competitiveness at the request of Ursula Von Der Leyen. Input was prepared, circulated to the Taskforce and submitted. It explains the issues but also details what the impacts on the competitiveness are (in particular the regulatory uncertainty and higher costs, going against the targets included in the Critical Raw Materials Act).

Finally, a sub-group of the Li Taskforce had a discussion on the possible scope/focus of an expert round table to be organised in the UK. The UK still needs to deliver its final opinion on the Li classification, and it is hoped that the UK HSE would be interested to have an expert discussion on the data supporting the developmental toxicity classification (more information: Violaine Verougstraete).

RISK MANAGEMENT

Risk Management Taskforce: *focus on updating the industry-RMOa guidance and preparing for the Commission Substitution Workshop*

The Risk Management Taskforce met on 28 February with most participants attending via remote access. The lack of information on the new risk management section of the REACH review allowed to focus attention on the update of the Industry-RMOa aiming to include “criticality as a substance, or a use” in considering the best risk management option. The Taskforce agreed on the scenario presented by Michel Vander Straeten as how this could be implemented in practical terms. He will now prepare the guidance text for the second half of April.

The second key point of attention related to preparing for the upcoming Commission Substitution workshop, scheduled for 1 March. The key messages on substitution as presented by Eurometaux under the REACH review were recalled and re-agreed. The secretariat also presented a series of historical examples covering positive and negative learning lessons that could be used during the Commission workshop to demonstrate how successful use specific, non-regrettable substitution could work as part of a risk control toolbox.

In addition the Taskforce took note of the progress of several ongoing Risk Management activities like the U-PFAS restriction (besides ruling on representation, no further news given SEAC and RAC meetings are scheduled for March), the status of the 12th ECHA priority list for Annex XIV (including a call to industry to check if they use any of the listed substances and if so then participate in the running Public Consultation), the dates and potential theme for the next NeRSAP meeting and the planning for the next RMTF meetings.

Finally, we also shortly discussed the Commission's publication of the Advanced Materials Communication, which has a focus on CRM substitution and that we will further explore (more information: France Capon, Klaus Kamps, Ainhua Gonzáles Pérez and Hugo Waeterschoot).

EVALUATION

Substance Evaluations: *ZnO received a request from DE for further testing instead of a closure document on the previous one*

The ZnO sector recently received a new draft Substance Evaluation request from Germany (DE), demanding extensive further testing on their nano forms. This draft decision (DD) is remarkable and precedent setting in many ways! Indeed, contrary to the expected closure document on the previous Substance Evaluation on ZnO nano forms launched by DE, they now request additional further test work to cover for risk-based concerns on reprotoxicity and cardiotoxicity. Industry feels that existing information on the soluble forms is more than protective given the previous work demonstrated that all nanomaterial dissolved quickly in lung fluid. The proposal is further remarkable given that it is demanding that 9 EOGRTS tests be carried out on 7 different nano forms and 2 reference substances + Learning and Memory (L&M) tests and additional measurements in complement. This proposal is in the view of the sector “over the edge” and contrary to a strategy to minimise animal testing as well as the Board of Appeal (BoA) decision on the need for clear risk-based triggers before L&M testing can be requested. EM has therefore supported the sector by providing strategic insight and setting up a briefing call for other metal sectors who have nano materials as part of their registration dossier. It is evident that this DD will require extensive review input from the sector (deadline 20 March), and that debates with ECHA staff will be solicited. before the MSC discussion that is expected in the months to come (more information: Christine Spirlet, Noömi Lombaert and Hugo Waeterschoot).

INDUSTRIAL EMISSIONS

Industrial Emissions Directive: *small update*

The co-legislators reached a provisional political agreement during the last trilogue on 28 November. The provisional agreement resulting from interinstitutional negotiations was adopted in ENVI on 11 January. Coreper endorsed the agreement on 15 December 2023 and the file will now have to be formally adopted by a Council configuration..

Next Steps: European Parliament Plenary Vote: 11 March 2024 (more information: Lorenzo Marotti).

Large Volume Inorganic Chemicals: *data collection is ongoing*

The plant-specific data collection is ongoing and progressing and the EIPPCB uploaded on BATIS documents related to the information collection.

The EIPPCB has already started to outline the draft of the new LVIC BREF. As a starting point, the Bureau is using the existing LVIC-AAF (**Ammonia, Acids and Fertilisers**) and LVIC-S (Solids & Others) BREFs documents which contain the descriptive sections, applied processes and techniques on production processes. Eurometaux has drafted a document with its contribution related to the descriptive section for the H₂SO₄ process complemented with relevant comments for the production of sulphuric acid specifically from NFM installations. This document was shared with the members of the WG for feedback and input.

Next Steps: The next LVIC Working Group meeting will be held online on 4 March to discuss progress on data collection, the draft Eurometaux sulphuric acid descriptive sections for bulk information collection, the new candidate BAT-BAYQIK and AOB (more information: Lorenzo Ceccherini, Lighea Speciale, Lorenzo Marotti and Violaine Verougstraete).

WATER

1) The water framework directive (WFD) revision: *state of play, advocacy & next steps*

As you may recall, the EU Commission published [its proposal](#) to amend the WFD/EQSD([Water Framework Directive/ Environmental Quality Standards Directive](#)) in October 2022. It passed through the hands of the European Parliament, who voted [on its opinion](#) in September 2023.

The dossier has been under discussion in the EU Council since last autumn. During the Spanish Presidency, several meetings of the Working Party on the Environment (WPE) were held, which produced a first compromise text. Neither the Spanish nor the Belgian Presidencies have made it a priority. The latter has not communicated any firm dates for reaching a general approach on the dossier. However, now that the trilogues on the Urban Wastewater Treatment Directive (UWWTD) are over, it is more likely that they will have more time to devote to the file and that a general approach may be reached at the Environment Council on 17 June. Trilogues are expected to run during the Hungarian Presidency.

The first WPE meeting of 2024 to discuss the file took place on 27 February, with monthly meetings thereafter until June.

We have been meeting with Permanent Representatives since last autumn. From these meetings, what we can say is that most [article 16](#) of the WFD has been back-entered in the compromised text prepared by the Spanish Presidency. Most Member States are not up for delegated acts for the prioritisation process and for the review of Environmental Quality Standards (EQSs), this will be further discussed in the upcoming WPE meetings. Discussions on the non-deterioration principle are expected, with an initiative coming specifically from a few Member States (NL, SE, FI,...).

2) The Blue Deal initiative: *and the postponement of Water resilience*

a. The EU Blue Deal:

The [EU blue deal](#) is a proposal drafted by the European Economic and Social Committee (EESC) in 2023, which has been taken up by the EU Parliament due to the work of the Water Group and now also by the Committee of the Regions (CoR), who is drafting an opinion on the subject to be adopted in June.

It puts water at the heart of the next mandate of the European Commission, noting that water issues lack harmonisation, governance and ambition in all EU legislations.

From the meetings of both the EESC and the CoR, where the EU Commission was present, it seems that the EU Commission (EC) is responding to this call by encouraging Member States to implement the tools already available in the Water Framework Directive, being a rather ambitious directive that addresses the issues related to water, although EC agrees that there are still gaps and room for improvement, which is why they are working on the Water Resilience Initiative. Please note that MEP Pernille Weiss, a member of the Parliament's Water Group, will be presenting the EU Blue Deal and how our industry fits into this initiative at the **next Chemicals Management Week** in March.

b. The Water Resilience initiative:

During the last Working Group (WG) Chemicals, the Water Resilience Initiative was announced as a kind of "bridge", a guideline for the next EU Commission to work on water. It was expected to focus more on the

gaps, the quantity/scarcity of water, the costs and the social aspect. This initiative was due to be presented early March, but the EC has announced that it will be postponed, with no new date set. The reason for this is still unclear, although at the last CoR meeting the Commissioner present explained that the EC wanted to focus more on its Climate Risks Initiative. To be noted, the next EU Green Week will focus on water (more information: Lara Van de Merckt).

SOIL

Update

a. European Parliament

The Committee on the Environment, Public Health and Food Safety (ENVI) is still discussing its opinion, whilst the Committee on Agriculture and Rural Development (AGRI) adopted its opinion in February. It seems that the content of the ENVI opinion has changed quite significantly since the first draft was published in November, giving more flexibility to Member States on several points of the original EC proposal. The ENVI Committee is preparing to vote on its opinion on 11 March and the EP plenary is scheduled for 10 April.

b. EU Council

In parallel, the EU Council is also working on the Soil Monitoring Directive, and the BE Presidency often schedules WPE meetings to discuss it with the Permanent Representatives and their experts. The Spanish Presidency has already produced a first compromise text (published [here](#)). Amongst other things, this text includes consideration of natural background concentrations, an alternative with 3 different classes to the "one out all out" principle in the definition of soil health (which is also in the EP opinion, as you know, but with 5 classes and based on ecological status), and the importance of developing site-specific criteria and assessment (more information: Lara Van de Merckt).

METALS ENVIRONMENT EXPOSURE DATA PROGRAM (MEED)

MEED program: outreach with Canada

Through Eurometaux Members, the Mining Association of Canada solicited us to support a briefing session on Mixture Toxicity Assessment on metals, for the Authorities of Canada. In follow-up a webinar engaging close to 15 Environment and Climate Canada representatives, took place on Wednesday 21 February. The main content covered the MEED objectives, the findings so far and further scheduled activities. Eurometaux, supported by ARCHE, demonstrated that a blanket Mixture Assessment Factor (MAF) approach would not work for metals (not even at natural background level), emphasising the need to develop a more scientific approach. As an alternative, the sector is working on the Mixture Interaction Factor that leans towards independent mixture action rather than concentration addition or synergistic action. The authorities were impressed by the scientific work done so far and most interested in learning from the further outcomes. This is now already the second non-EU jurisdiction who seems to be considering mixture assessment strategies. Eurometaux will consider, together with the sponsors, on how the knowledge developed in the EU can potentially create added value for sponsors in other jurisdictions where they operate (more information: Hugo Waeterschoot, Charlotte Nys and Marnix Vangheluwe).

OUTREACH

OECD

OECD Guidance on grouping: accomplishment of the final draft

Two years ago, the OECD started to update its Guidance on grouping chemicals. The process has been very exhaustive as it aimed to augment the existing text with experience and examples encountered in the OECD Integrated Approaches for Testing and Assessment (IATA) Case Studies Project, the OECD's Working Party on Manufactured Nanomaterials (WPMN) but also e.g., in the EU ToxRisk Project, the tripartite Accelerating the Pace of Chemical Risk Assessment (APCRA) Project, European Food Safety Authority (EFSA) and EU REACH discussions.

This third edition of the guidance, initially published in 2007 also introduces new or revised guidance on nanomaterials, and discusses the utility of New Approach Methodologies/Methods (NAMs) in developing groups and substantiating similarity. The metals sector has been part of the drafting group and updated the sections on inorganic UVCBs and metals.

All the revisions were discussed in calls, meetings coordinated by the OECD secretariat supported by Penman Consulting.

The final draft should be circulated for comments to the OECD Working Parties on Hazard and Exposure Assessment before Easter, and it is hoped that the guidance will be declassified (published) before the end of the year. The final draft will be circulated to the Human Health and Environment Taskforces (more information: Violaine Verougstraete).

BIAC & OECD CBC: *the annual high-level planning session on chemicals at OECD level*

Every 10 months, OECD holds its high-level chemicals meeting (called CBC) to discuss progress, planning and budgeting status of its overall chemicals program. The last meeting took place in Paris on 6-8 February and was attended by a long series of countries including 22 European countries, Commission and ECHA. It's obvious that after Covid, these planning meetings are once again proving to be attractive. Eurometaux attended part of the session of direct relevance for the EU activities in complement of ICMM who attended the whole week. Aspects of relevance for the EU sector covered the OECD activities to speeding up and simplifying the validation of testing guidelines, accelerating innovation in water quality monitoring by adding new bio-analytical tools, the overall renewal of the mandate of the CBC and its subsidiarity bodies (Working Parties), the future of the e-Chem portal and a half-day workshop on the potential use of Artificial Intelligence for the sound management of chemicals (a session built on examples on different areas and jurisdictions). The outcome of the session will be reported to the relevant Eurometaux groups (more information: Hugo Waeterschoot).

KAMILA'S SUSTAINABLE CORNER

Battery black mass: *as hazardous waste*

Following number of requests from the industry and NGO (WWF, Transport & Environment) community, the European Commission is running the process of updating the European List of Waste (LoW) with the new hazardous waste codes for waste Li-ion batteries & their black mass. Given the lack, or even diverging waste codes, the situation is far from harmonised at the Member States level.

The purpose of the new waste codes is to:

- harmonise conditions for the intra-EU shipment;
- facilitate proper management, tracing & reporting of the battery-related waste;
- discourage outflow of these relevant waste streams from the EU to boost the circularity, resilience and competitiveness.

This work is being carried out since early 2023. Last year the JRC, assisting the European Commission, collected a substantial feedback from the stakeholders and Member States Waste Experts via workshops or bilateral meetings and data collection. According to the timeline, the draft proposal to amend the EU List of Waste should be available in 1Q 2024. However, a small delay is expected. Once the EU list is amended, the Member States have to follow up, by adding those new waste codes to their national lists to secure a full harmonisation across the EU (more information: Kamila Slupek).

COMMUNICATION

Metals Academy 3: *looking good*

In view of the Metals Academy 3 that will take place from 23 to 26 April; invoices have been sent to confirm the numerous registrations, then based on payments received (to confirm registration) a final list will be established mid-March.

The Organising Committee has met to discuss the final touches to be made to the agenda and organise the three Modules that will all be held on the final morning.
More information will be provided to participants regarding organisational issues end of March (more information: Ailsa Lee).

CALENDAR

Please find here below a non-exhaustive list of the meetings that are already planned for Q1 & Q2 2024.

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](#)

- 04/03: RAC-68 REST Working Group
 - 04/03: LVIC BREF Working Group (online only)
 - 6-7/03: ECHA IRS Workshop
 - 08/03: CARACAL Taskforce (online only)
 - 11-14/03: RAC-68 Plenary
 - 12-15/03: SEAC-62
 - 14-15/03: RAC-68 DWD Working Group
 - 18-21/03: Chemicals Management Spring Week
 - 20-21/03: CARACAL (TBC)
 - 21-23/03: ECHA MB-73
 - 26/03: Registration Compliance Taskforce
 - 10-11/04: [Helsinki Chemicals Forum](#)
 - 16-17/04: Batteries Workshop
 - 19/04: MEED Progress Webinar (sponsors only)
 - 23-25/04: RAC-69 CLH Working Group
 - 23-26/04: Metals Academy 3
 - 29/04: Human Health Taskforce
 - 05-09/05: [SETAC 2024](#)
 - 07-08/05: RAC-69 AfA Working Group
 - 21-22/05 RAC-69 DWD Working Group
 - 27-28/05: RAC-69 REST Working Group
 - 03-07/06: RAC-69 Plenary
 - 03-07/06: SEAC-63
 - 10-14/06: SEAC-63
 - 10 -14/06: MSC-86 (TBC)
 - 18-19/06: ECHA MB-74
 - 18/06: Risk Management Taskforce
 - 24-25/06: NeRSAP
 - 27/06: Chemicals Management Steering Committee
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GENERAL INFORMATION & ACRONYMS

Follow the logo and check out our Metals Gateway website.



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

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