

N° 123 – March 2022

EUROMETAUX CHEMICALS MANAGEMENT NEWS



Please join us for next CM meetings in May:

- 10 May: MEED 2nd Workshop
- 12 May: Risk Management Taskforce
- 25 May: Chemicals Management Steering Committee

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Dear All,

You should know that by the 25^{th} of the month, Ailsa starts working on this monthly news by screening our agendas of the past weeks, filling a template with headlines, gauging the number of paragraphs she will have to chase after. This exercise immediately reveals where the pressures points were (and who will have to write a lot of paragraphs!). It also allows to have a second, retrospective look at the "CM events" of the month, compelling us to fit these in the overall picture, which helps to put the successes and (possible \bigcirc) thwarting into perspective.

Ailsa carefully follows the drafting-digestion process, encouraging, proposing here and there a phrasing to unravel the "word knots" we make, deciphering the stress and the full days, jumping from topic to topic to compile what is now number 123 of these monthly overviews.

She reminded me that 1-2-3 is also the name of a game we most probably all played when we were kids.

Remember: A player stands facing a wall, he is the leader of the game. The other players stand about 20 m from him. The player facing the wall taps three times while shouting "1, 2, 3" and when (s)he says an agreed word, (s)he turns around. During the time (s)he is not looking, the other players move forward and must stop when (s)he faces them. If one of them moves, he/she must return to the starting point. This is repeated several times, until one of the players manages to touch the wall. In this case, the latter takes the place of the leader, and the game can start again; everyone returns to the starting point (except the new leader). Interestingly, there are several variants of this game: it seems that in English the leader yells "green light, red light"; in Flemish we shouted 'piano' and in French, the last syllable of 'soleil' (sun) was the trigger to become immobile.

Ailsa asked me if this was a good allegory of the regulatory work we are doing. One could probably find an analogy with the frantic Commission activities (1-2-3 Consultation!) and the fact that the 'incentive' to move is submitted to national variations.

But what about hopscotch? I am sure you can still draw the court, that series of linear squares interspersed with blocks of two lateral squares and ending with a "safe" or "home" or "sky" base. The player tosses a marker that should land in the square without bouncing, sliding, or rolling out. The marker must be thrown in sequential numerical order completely within the square without touching the line. The player then hops through the course, skipping the marker's square, reversing his trip once he has reached the base. If, while hopping through the court in either direction, the player steps on a line, misses a square, or loses balance, his/her turn ends.

We could go on and review several of our childhood games: cat's cradle, blind man's bluff, Simon says, four squares, hide and seek...and identify some parallels with the activities summarised in these pages.

It's a good thing that we learnt to play these games without realising that one day some of these reflexes and moves would allow us to sometimes reach the green light or the base.

Never a dull moment on the regulatory side of the moon!



Violaine Verougstraete

COMMISSION

Stakeholder Workshop: Essential Use Concept (EUC) on 3 March

A full day online workshop took place, with a preparatory document circulated by Wood (the consultants in charge). The workshop consisted of plenary and breakout sessions. The plenary had about 500 participants not allowed to intervene so using the chat, and the breakouts were with about 20 active participants per group. Eurometaux was represented by France Capon (co-chair RM Taskforce) in a group also including Commission representatives and Cefic

Eurometaux's contributions were prepared based on the written response to the CARACAL paper on the reform of Authorisation & Restriction, our 8 Guiding Principles for better risk management, a draft of high-level "asks" on EUC, and the questions posed in advance by Wood.

The main learnings were:

- EUC would not apply to all chemicals, but only to "the most harmful chemicals" (definition in the CSS);
- The consultant stressed that the EUC should be seen in relation to the **end-use** of a substance (bringing the **technical function** into consideration) and not the essentiality of an article/product as such;
- However: a substance (and its technical function) *per se* cannot be essential, it becomes essential in conjunction with an article/product and what function is performed by that article/product, and how. Following this approach, the same substance (providing a specific technical function) could be essential in one article and not essential in another. Hence, the "application" in an article/product must be considered;
- EUC will go beyond REACH;
- The "Safe Use" concept and EUC are two different and distinct considerations.

To progress this topic, further discussions and interactions are planned: the REACH Open Public Consultation, Targeted Stakeholders Surveys, "Safe Use" workshop June. Eurometaux will participate in all of these.

Eurometaux, Cefic and ASMoR together submitted comments in follow up of the 3 March workshop, to emphasise our key messages, asks and recommendations. These are available, as are the draft notes from the workshop (more information: Simon Cook).

Additional REACH information requirements on uses and exposures: *Eurometaux comments on possible policy options* and workshop on 14 March

As part of the REACH review, the European Commission appointed the consultancy company RPA to study the possible introduction of additional information requirements on uses and exposures. A summary with possible policy options was presented to CARACAL and included: additional duties for REACH registrants, detailed information on volumes and more responsibilities for downstream users to provide data to ECHA and to authorities.

The document also contained a list of questions for which Eurometaux, with the support of the Registration Taskforce submitted a reply.

In general, Eurometaux supports the need to have up to date use/exposure information with the contribution of the value chain to allow more representative assessments. Having accurate data is essential to avoid having regulators assessing substances based on unrealistic high exposure data, which is the case for example when conservative models instead of real data, are used to calculate exposure. The cooperation with the value chain is important to maintain updated information on volumes, but ways to facilitate this cooperation should be further thought through, drawing the lessons from previous work, like the ENES activities.

Also, to encourage maintenance of updated information, updates that do not lead to additional regulatory requirements (e.g., no changes in tonnage bands) should be considered as "administrative" updates and not lead to unnecessary full Technical Completeness Check of the dossiers.

RPA organised a follow-up workshop on 14 March where we were able to reiterate our key messages (more information: Federica laccino and Lorenzo Zullo).

Evaluation: meeting on 16 March to discuss the proposed changes (although not part of the targeted REACH reform)

The REACH review concluded that the Evaluation chapter of REACH functions well and just needs some small process improvements. In this respect, the Commission submitted a table of suggested measures to improve the evaluation process that surprisingly went significantly beyond "streamlining". Indeed, besides some expected changes like a better alignment of Testing Proposals with Compliance Checks, the paper suggests: revocation mechanisms in case of non-compliance, the introduction of a concept of being compliant "at all times", reducing the powers and scope of MSC's activities, extending the Manual Completeness Check and Technical Completeness Check to data quality, reducing the

relevance of the risk base for Substance Evaluation... all significant changes that could have a real business impact on industry.

Commission organised an ad hoc CARACAL session to review their practical suggestions, during which they emphasised that no impact assessment would be foreseen. The preparatory work done by the Eurometaux Evaluation Taskforce on 22 February and the resulting submission to CARACAL on 24 February allowed Eurometaux to actively participate in the discussions. Eurometaux stressed in particular that the better alignment and integration of the different evaluation tools (Testing Proposal Evaluations (TPE), Completeness Check (CC) and Substance Evaluation (SE)), a pragmatic approach on the concept of compliance at all times, maintaining the risk base of Substance Evaluation and the role of MSC are the most critical points for the sector (more information: Kai-Sebastian Melzer, Noömi Lombaert and Hugo Waeterschoot).

Transitional Pathways for Chemicals: second meeting on 15-16 March

The topic of transition pathways for industrial ecosystems does not appear in the Green Deal, the Chemicals Strategy for Sustainability, or the Industrial Strategy 2020. The initiative has come from the 2021 update of the Industrial Strategy, which builds on learnings from the global pandemic and aims to simultaneously strengthen resilience, deal with strategic dependencies, and accelerate the "twin transition" (green and digital) in 14 industrial ecosystems identified by the Commission as key for the recovery from the pandemic. One of the 14 ecosystems is "low carbon energy intensive industries" which includes extraction of fossil fuels, refining, and manufacturing of products with high environmental impact: plastics, **chemicals**, fertilisers, iron and steel, paper etc. Although not mentioned specifically, non-ferrous metals also sit here (related to "chemicals"), so Eurometaux attended two workshops on 15 and 16 March to discuss the 8 "building blocks" identified by the Commission as elements of the pathway for chemicals.

Of these 8 building blocks, one on "access to energy and feedstock" stimulated the greatest amount of discussion – despite being added as something of an afterthought by the Commission. In order for the chemicals ecosystem to realise the green transition it is necessary to decarbonise production processes and feedstocks. Access to zero-carbon electricity (from renewables) at an acceptable cost is critical to this. A good example of why was given by the Industrial Gases sector, which – to produce the green hydrogen that will be needed to meet Green Deal goals in 2030 – will need access to 320GW of renewable electricity to power hydrogen electrolysers (which will in turn create demand for metals). Based on considerations like this there were several calls for the Commission to take a more "holistic view" and look at all high-level goals simultaneously (Green Deal, Industrial Strategy, CSS), not just the transition pathway for chemicals.

A first draft of the pathway is due by 9 April, followed by a further stakeholder meeting on 25 April. The final draft is due to 29 April to be incorporated into the pathway for other energy intensive industries. It is expected that this topic will be presented at the next meeting of the CSS High Level Roundtable in May, but not for discussion (more information: Simon Cook).

Generic Approach to Risk Management (GRA): workshop on 21 March and written input

Still with the Impact Assessment of the REACH revision in mind, Commission organised a stakeholder workshop on the Generic Approach to Risk Management (or GRA). The main focus of the Commission is to extend the hazards covered by the so called "horizontal risk assessment approach" (Article 68(2) of REACH) from their present focus on CMR (Substances classified as Carcinogens, Mutagens or toxic to Reproduction) to other endpoints like Persistent, Bio-accumulative and Toxic Chemicals (PBT), Persistent, Mobile and Toxic (PMT), immuno-, neurotox and STOT-RE while broadening the scope from consumers to professional users. The Commission confirmed that this would be a staged extension to be spread over a period of 10 years.

The sector, represented by Kai-Sebastian Melzer, Caroline Braibant and Hugo Waeterschoot, called for "prioritisation on what matters", focusing on consumer products (articles) that are really leading to releases (exposure) to consumers or the environment and focussing on other criteria than CMR given already well covered. Many CMR metal (compounds) in consumer goods like articles made from alloys, in glass, tiles or ceramics, or in batteries are either used in strongly binding matrix forms or in closed conditions without exposure potential for the consumer, hence no need to focus on them in a GRA approach. In addition, the GRA should not be extended to professional uses given most are covered already by Occupational Safety Health (OSH).

Eurometaux was most surprised to observe that the note prepared by ECHA to estimate the number of metals and inorganics that might be covered by the GRA extended hazard criteria, included large numbers of metals with very Persistent very Bioaccumulative chemicals (vPvB) and PMT hazards. This is of great concern given it is expected that ECHA is aware that the PBT related criteria do not scientifically fit for metals in the same way they do for organics and that metals are for that reason exempted from the PBT/ vPvB criteria (REACH Annex XIII).

The comments and pragmatic input coming from the sector were much appreciated which resulted in a post-meeting invite for an exceptional written input (more information: Caroline Braibant, Kai-Sebastian Melzer and Hugo Waeterschoot).

Safe & Sustainable by Design: workshop organised by DG RTD on 22 March

Overlaps and intersections between sustainability and chemicals management

On 22 March, the Commission (DG RTD / JRC) hosted a workshop to give further insight into the extensive work they have done on Safe and Sustainable-by-Design (SSbD). Two reports were summarised in the workshop:

- JRC D2. Review of safety and sustainability dimensions, aspects, methods, indicators and tools
- JRD D3. Framework for the definition of criteria and evaluation procedure for chemicals and materials

The first is a very detailed overview of the background work that JRC has done, to look at other existing and relevant pieces of work already in existence, and from this to derive a set of considerations that should be part of the future SSbD framework under CSS. This is a very good, high quality piece of work and is very well thought-through.

The second report is a proposed framework for how the concept might work, with criteria and a five step evaluation procedure. This is also quite well thought-through, although industry has a significant concern over step 1 of the evaluation procedure. Step 1 is entitled: "Safety of chemicals and materials – hazard-based approach". In practice it is not a safety assessment at all, as it clearly will be done "independently of exposure levels or use". It is a hazard assessment. In summary, the approach defines three hazard classes:

- S1 Substances of Very High Concern (SVHC) + Most Harmful Chemicals (MHCs)
- S2 Substances of Concern (SoCs)
- S3 assorted other hazard classes, many physical/chemical in nature

Chemicals and materials that fall into class S1 are then "cut off" and cannot be considered SSbD. This is a "black and white" or pass/fail approach. There is already pressure from NGOs for chemicals and materials that fall into category S2 to be regarded in the same way e.g., cannot be considered as SSbD. For metals and metal compounds the implications of this would be significant due to the breadth of the hazard classes S1 and S2. Only chemicals and materials that do not fall into any of these three classes would be regarded as "of no concern" regarding intrinsic hazard properties. The logic of this approach is to stimulate "molecular design" (or re-design) of chemicals and materials in order to ensure that those placed on the market are inherently safe. As metals are elements, this is clearly not possible to do. Stakeholders were invited to provide written comments on report D3 in a very short time frame, so Eurometaux focussed on the concerns held (also by other industry stakeholders) about the proposed approach for Step 1 of the evaluation process (more information: Simon Cook and Kamila Slupek).

CARACAL: 44th meeting on 23-24 March

CARACAL met over two days to discuss a series of topics related to REACH and Classification Labelling and Packaging Regulation (CLP), including a common session attended by both REACH and CLP experts of the Member States.

The meeting started with a short overview of the REACH revision timelines (including the announcement of an additional workshop on 20 May on the interface GRA/EUC) before diving in a status report on issues like EUC, GRA, DMELs, Environmental Footprint and the Mixture Assessment Factor (MAF). Worrying was the discussion on "intermediates" and more specifically how the update of the related ECHA Guidance was carried out, triggering several comments from industry stakeholders concerned that it is not in line with the ruling of the European Court of Justice. Written comments were submitted in follow-up, coordinated by the REACH Alliance and co-signed by Eurometaux and SME United.

The common session addressed information requirements and New Approach Methodologies (NAMs) (via a presentation by JRC), provided a short status update on the activities of the Endocrine Disruptor (ED) CARACAL sub-group and discussed RAC's organisation, triggered by a presentation by Tim Bowmer (RAC Chair). The key message was that despite the organisation of dedicated Working Groups and a series of measures taken to increase 'efficiency', RAC is now reaching the limits of its capacity with the current number of experts. ECHA shared an update on the More than one Constituent (MOCs) issue (focusing on Persistence and Bioaccumulation) and Commission provided explanations on a study carried out by Milieu on a study on how to establish a European Audit Capacity as part of the REACH revision.

Commission kicked off the CLP session by explaining the possible procedures for the revision of the CLP and in particular the addition of new hazard classes (ordinary legislative procedure, delegated acts procedure). This presentation was followed by an update on GHS, with Commission announcing that in July they would submit a paper for discussion on potential proposals to introduce or adapt/clarify some hazard classes in the GHS according to changes with CLP and to the REACH Revisions. They will focus on PBTs, vPvB, PMT, EDs and terrestrial toxicity. Key item for our sector was the discussion on the new Adaptation to Technical Progress (ATP) and harmonised entries based on the 2021 RAC opinions. Francesco Gattiglio (Albemarle, Chair Li CLH Taskforce) and Steve Binks (ILA, Pb CLH Taskforce) made short and clear presentations on industry's main concerns with the classifications proposed by RAC. Written comments will be sent in follow-up. Key would be to have some supportive comments from MSCAs on these proposed entries to allow further consideration by Commission. Eurometaux's summary record of the meeting was circulated to the members of the CARACAL Taskforce on 2 April. Thanks also to the members and the staff who reviewed the CARACAL agenda and prepared the Eurometaux interventions on 18 March (more information: Noam El Mrabet, Hugo Waeterschoot and Violaine Verougstraete).

EU AGENCIES

EUROPEAN CHEMICALS AGENCY (ECHA)

ECHA COMMITTEES

RAC-60: plenary meeting

Addressing RAC in the context of its 60th meeting, both ECHA's Executive Director (Bjorn Hansen) and RAC's Chair (Tim Bowmer) took a step back and praised the RAC experts for their achievements, raising concerns about the continuously increasing workload and the importance of having enough capacity (and Rapporteurs) to deal with classification, restrictions, Applications for Authorisation (AfA) and Occupational Exposure Limits (OELs).

Two OELs were discussed by RAC (isoprene and 1,4 dioxane) before diving in the first CLH discussion on glyphosate. For this substance, exceptionally and considering the overall policy/political contexts, stakeholders were allowed to contribute to a suite of short presentations after the Dossier Submitter had explained why a CLH dossier had been submitted. The current opinion on the classification and labelling of glyphosate was adopted in 2017 but the current approval of glyphosate for use in plant protection products expires in December 2022. A decision on renewal of approval requires an assessment made in accordance with the requirements set out in Regulation (EC) No 1107/2009 and associated legislation and this includes classification. The Rapporteurs gave a first overview on all endpoints, allowing the chair to conclude that this will be a major CLH dossier with small amounts of new data, new insights in some hazard classes, to be carefully looked at by the RAC members.

Eurometaux monitored very closely the CLH discussions on sulfur and on silver. On sulfur, RAC finalised its debates proposing a classification for irritation category 2, no classification for eye irritation and no classification for Specific Target Organ Toxicity-Single Exposure (STOT-SE) due to data not sufficient for classification.

On silver, RAC re-discussed in depth the STOT-RE (Repeated Exposure), mutagenicity and carcinogenicity endpoints. The discussion on STOT-RE will be finalised at the next CLH Working Group as further information was required from 90-day studies and argyria cases. On mutagenicity, the Rapporteur had reassessed the quality of the *in vivo* data. EPMF had provided a useful white paper, describing their reliability assessment of all available studies. RAC agreed to recommend no classification for mutagenicity due to inconclusive data. Two RAC members will propose a minority position as they could not support the conclusion. One recurrent issue in the silver discussion is the physical form (nanos, bulk) and how representative the data collected on nano silver are for the bulk form (for which less or no data are available). RAC is divided on the possibility to have a split classification, whilst we may have e.g., for mutagenicity, different mechanisms of actions at stake.

On carcinogenicity, RAC agreed to provisionally recommend no classification due to inconclusive data. However, here as well, one RAC member would like to submit further comments.

The next episode in the silver saga will be the discussion of the reproductive toxicity. This is planned for 25 April.

One restriction of interest related to the Restriction of Pb in hunting, shooting and fishing. Only the latter was discussed, due to the extensive comments received under the Public Consultation for the hunting and shooting section, requiring more time to be processed. RAC agreed on the restriction and substitution of Pb in fishing sinkers based on proven concerns for birds (ingesting small sinkers) and humans that prepare the fishing sinkers using home casting practices (more information: Hugo Waeterschoot and Violaine Verougstraete).

SEAC-54: focus on authorisations on plating and the restriction on Pb in fishing sinkers

SEAC-54 covered a long series of Authorisation cases including several on decorative plating with Cr6. It was the first time that an applicant raised the issue that Cr3+ might not be such a good alternative given Cr6+ is being used in the manufacturing and equally some borates. So the concept of safer alternatives and hence the way to demonstrate monetisable benefits could be questioned. Surprisingly SEAC did not put much emphasis on this and still focussed on old

concepts and methods as applied in previous cases. Eurometaux intends to follow up on this case given lifecycle thinking and comparative risks should be part of alternatives assessments.

SEAC further finalised the Pb restriction case on the use of lead in fishing sinkers which was not a difficult one given alternatives are widely at hand and not more costly. Moreover substituting this use could prevent home casting practices of such sinkers which is an unacceptable use for that metal. The use of lead in hunting and sport shooting is postposed to the next meeting due to the extensive comments received under the Public Consultation (more information: Hugo Waeterschoot).

MB-65: last meeting of Bjorn Hansen (Executive Director of ECHA) and presentation of view of court of auditors

The first ECHA-MB meeting of the year traditionally focuses on financial aspects and the adoption of the Committee's working report of last year. The former did not include any surprises except the amount of resources that ECHA had to engage in Chemicals Strategy for Sustainability (CSS) related projects in support of the Commission, which clearly drained senior staff resources. An interesting background document summarised the challenges especially for RAC and to a lesser extent for SEAC in respect to potential new tasks coming from the CSS implementation. Some balancing with MSC was suggested and a call for extending the number and organisational structures and working procedures for RAC (and SEAC) were debated.

The main reason for the physical nature of the meeting was that it was Bjorn's last session as ECHA's Executive Director. He was praised for his guidance of the agency through difficult times.

The MB had also invited the author of the court of EU auditors who wrote a report on the functioning and management of the different agencies. The report -more than the presentation made at the meeting- provided interesting directions on how the Management Board can be made more effective and influential (more information: Hugo Waeterschoot and Guy Thiran).

ECHA OTHER ACTIVITIES

PEG meeting-Guidance update on Appendix R7-1 for nanoforms: evidence on the metals sector is not recognised

ECHA organised a Partner Expert Group (PEG) meeting on the physico-chemistry guidance section of the nano guidance. Eurometaux previously submitted extensive comments on the water solubility testing section as a new non-validated testing strategy was proposed for nanos (TG 318, dispersion stability test), including non-relevant ecological conditions, instead of the validated Transformation Dissolution test (OECD TG 29) widely used for metals and inorganics. Our comments on the relevance of the dispersion stability test were however not withheld because results for our test case ZnO were not considered as relevant for all nanomaterials. Eurometaux represented by Koen Oorts (Arche Consulting) contested this approach stating that the usefulness of the dispersion stability test for risk assessment is not demonstrated nor validated by results on nanos at all. Moreover, ECHA is sticking to the point that only the 24h part of the T/Dp test is useful for nanomaterials and hence T/Dp cannot be used for the analysis of the dispersion rate resulting in the need for extensive and expensive testing with the TG 318 for nanos in metallic form if this Guidance is to be implemented. In conclusion: this was a very unsatisfactory outcome requiring consideration on how to follow up on this (more information: Koen Oorts and Hugo Waeterschoot).

EUROMETAUX CHEMICALS MANAGEMENT

CHEMICALS MANAGEMENT WEEK

Science Forum: Human Health & Environment

The Chemicals Management week was held between 21 and 24 march, starting with two days of Science Forum meetings. The discussions, very efficiently chaired by Martin Wieske (WVM) and David Boyle (CI) allowed to address a range of topics, from (developmental) neurotoxicity and New Approach Methodologies (NAMs) to a qualitative approach for risk assessment, diffuse sources and advanced materials. We also benefited from Martin's popular update on ongoing and future Occupational Safety Health (OSH) work and Jelle Mertens (EPMF) -in duet with Hugo Waeterschoot- gave a high level overview on the running environmental classification discussions. The Forum meetings aim at providing updates on issues appearing on the horizon and/or that deserve to be given a different perspective. Detailed follow-up discussions on these issues will take place in Eurometaux Taskforces. For example, Alleyn and Overy gave us a useful presentation on what the precautionary principle entails and how its elements are often evaluated in the context of court cases. This presentation was the kick-off for a possible project aiming at drafting a legal analysis/memo and a paper on how the precautionary principle should be interpreted in the context of the CLP. This project will be further discussed with the Pb (and Li) classification taskforces. NAMs, and the possible resulting monitoring and actions by the sector, will be further debated in the Human Health and Environment Taskforces. The draft minutes and slides will be circulated soon. A big thanks to the speakers, the chairs and of course the participants who helped us to make a success from this hybrid version of the CM week meetings (more information: Hugo Waeterschoot and Violaine Verougstraete).

Regulatory Forum: CSS & Zero Pollution

The Chemicals Management Week's Regulatory Forum was held on 23 and 24 March. The discussions were chaired by Sandro Starita (EA) and Lisa Allen (ILA), the latter chairing the Forum for the first time – congratulations! Their excellent chairmanship guided the Forum through a series of topics: on the first day, we had presentations on the EU soil health (Piotr Wojda, Panos Panagos, JRC), an update on water pollution (Lara Van de Merckt, Eurometaux), a picture on air quality in Europe (Catherine Ganzleben, EEA), a panel discussion with Hélène Duguy (Client Earth), Dunja Drmac (Cefic), Hugo Waeterschoot (Eurometaux), and an overview on how to prepare Council Presidencies (Robert Weibel, CENAD). On the second day, we discussed ECHA's Integrated Regulatory Strategy (IRS) and Grouping (Chrystele Tissier, ECHA), the state of play on the REACH Revision (Otto Linher, DG GROW), and the role and issues of the industrial gases Industry (Philippe Cornille, EIGA).

The Regulatory Forum offered the opportunity to have high-level discussions on the latest developments regarding chemicals policy at EU level (and beyond), whilst providing a unique occasion to receive a different perspective, learn more and further reflect on such topics. Follow-up discussions on these issues will take place in Eurometaux's Taskforces. The draft minutes and slides will be circulated soon. Many thanks to the speakers, chairs, and all participants who helped us to make a success from this hybrid version of the Eurometaux CM Week meetings (more information: Lara Van de Merckt, Noam El Mrabet and Lorenzo Marotti).

CHEMICALS STRATEGY FOR SUSTAINABILITY

Chemicals Strategy for Sustainability: Project Group meeting held on 9 March

The group met with a new chair (Howard Winbow – International Zinc Association) who started the meeting by giving the group a timely and useful reminder of where we started from early last year, how we have got to where we are today, and the progress made in efficiently dealing with and managing many complex work streams. The purpose of the meeting was to discuss recent updates including transition pathways and the Essential Use workshop (please see previous sections), high-level messaging, the Sustainable Products Initiative, and the lack of a "value chain approach" in the Commission's thought processes. The main item was however to prepare for the next meeting of the High-Level Roundtable (HLRT) in May. In that meeting, two innovation-related discussion topics will be covered as one:

- The Strategic Research & Innovation Plan (SRIP) for Chemicals and Materials in the Green Deal Era
- Safe and Sustainable-by-Design (SSbD)

These topics were both addressed in the Commission's background paper entitled "Research and innovation for the transition to safe and sustainable chemicals and materials". This paper should have been released by the end of February, hence the timing of the CSS PG meeting to give the group time to review the document and the questions posed by the Commission in it. In fact, the background document was released only a few days before the CSS PG meeting so there was no time for review, instead the Eurometaux CM team drafted a set of "principles" on SSbD, taking into account Eurometaux's Sustainable Metals Concept, and useful and good quality work done on SSbD by Cefic and OECD. These "principles" were later used to draft answers to the four questions posed by the Commission in the background document. The group also reviewed one NGO position on SSbD, which has the following concerning aspects from the metals point of view:

- Pushback on the "full lifecycle" approach to assessing the overall value of a substance to achieving societal goals and overall sustainability because it is too difficult to do
- Focus on the production phase of chemicals because it is easier to do (metals are energy-intensive)
- Definition of "safe" = no hazard Hazardous chemicals are a direct threat to human health and the environment and can therefore never be identified as safe and sustainable

During subsequent discussions in the contact of the HLRT Sherpas, it became clear that the main area of disagreement on SSbD is whether the "safety assessment" should include considerations of risk and exposure. Industry supports this, NGOs are totally against, and the academic community are roughly 50:50 split. This will be the main area of contention for the next joint report of the HLRT (more information: Simon Cook).

REACH OPC 2nd Workshop: *Registration, Evaluation, Risk Management and Enforcement parts of the questionnaire discussed on 28 March.*

Members were invited to participate in a second cross-taskforces debate on the input to provide to the REACH Open Public Consultation (OPC). After a brief catch-up presentation on the most recent developments, members were divided in breakout groups to discuss the Registration, Evaluation and Risk Management/enforcement elements of the REACH revision. A draft completed questionnaire was circulated ahead of the workshop. The discussions -in hybrid!- allowed to agree on a series of guiding principles, to refine the draft replies and start compiling a Eurometaux draft position paper. A revised questionnaire as well as a draft position paper were circulated on 1 April. The minutes of the workshop - including the guiding principles- were circulated on 30 March. Further comments will be integrated in final versions that will be submitted by 15 April. A big thank you to all the members who helped us to further improve the messages we would like to share, and to identify what to submit in this more high-level OPC vs ongoing consultations and targeted surveys with the Commission consultants (more information: Violaine Verougstraete).

ZPAP

Air Quality

The 2nd Air Quality Project sponsorship meeting was held on 31 March. The aim of the call was to have a meeting with the members interested to sponsor the Air Quality Project in order to discuss the progress of the pre-study (launched to gather preliminary data and information and asses their relevance against the deliverables of the project), and to address all the questions raised during this exercise.

As a next step, Eurometaux and Arche will further reflect on how to integrate the comments and concerns raised, and have a refocused proposal that serves the overall objective and allows to get to the dataset needed to calculate the Burden of Disease (BoD). The minutes were circulated via the Zero Pollution Action Plan Project Group.

The Commission has launched an (ongoing) infringement procedure against Belgium (INFR(2016)2005) for having persistently failed to meet the binding air quality limit values for nitrogen dioxide (NO2), to which a question for written answer E-000838/2022/rev.1 was submitted to the Commission by Sara Matthieu (Verts/ALE). Air quality measurements by citizen movement Recht op Lucht show new exceedances in 2021 of NO2 limit values in Antwerp. After slight improvements due to COVID-19 lockdown measures in 2020, the latest data shows a new increase in NO2 values (more information: Lorenzo Ceccherini, Lighea Speziale, Lorenzo Marotti and Violaine Verougstraete).

Soil sub-group: 1st meeting

The first meeting of this soil sub-group took place on 11 March. The sub-group's main goal is to deal with soil and its scope in the Green Deal (GD). Soil is a component of the Zero Pollution Action Plan (ZPAP), with goals such as – by 2030 restoring degraded land & soil, striving to achieve a land degradation neutral world and reaching good ecological and chemical status in surface and groundwaters. And, by 2050 reach "no net land take" (to be defined) and reducing soil pollution levels. The main instrument to deal with this is the Soil Health Law (by 2023).

The Clean Soil Outlook (CSO) was presented by Koen Oorts (Arche expert). Its purpose amongst others is to analyse synergies and trade-offs between different EU policies; help to translate early warnings into recommendations; analyse data and environmental landscape following the R-DPSIR (Driver, Pressure, State, Impact, Response) approach, provide projections; identify the knowledge gaps and ways to close them. It is developed in synergy with the Soil Monitoring Report and based only on the JRC input and the LUCAS database.

Several comments were made by the members on the CSO, stressing the importance to contribute with our expertise on background values for metals, thresholds, bioavailability. Comments were compiled in follow-up and will be submitted to JRC by 15 April.

As last point of the 11 March meeting, the possibility of having a Watch List & Priority Substances (PSs) list as presented by the JRC was debated.

Interesting to note in this context was the participation of JRC to the Regulatory Forum meeting end of March (minutes will be circulated soon).

Eurometaux also attended the SOILver project (info: <u>http://www.soilver.eu/development/</u>) The next meeting of the Soil Pollution Technical Working Group is scheduled for 27 April, to discuss the latest version/contributions of the CSO. The soil sub-group will be reconvened soon to catch up on the developments (more information: Lara van de Merck)

CLASSIFICATION

Environmental classification proposal on Pb metal: discussed in CARACAL, advocacy actions are launched

CARACAL discussed the list of possible entries in the upcoming Adaptation to Technical Progress (ATP) of the Classification Labelling and Packaging Regulation (CLP), based on the opinions issued by RAC in 2021 (see also above). This list included lead in massive form, referring to the 2 options in the final RAC opinion (one single entry for powder and massive (supported by RAC) or 2 separate entries and classifications (not supported)). The Commission's note made further reference to some aspects of the classification of the massive form being more political than scientific inviting Member States to comment on their choice of option with argumentation by 25 April. The proposal to classify the massive in the same way as the ultra-fine powder is of great importance for the metals sector who rejects this concept forcefully given contrary to the scientific evidence presented in the REACH files on dissolution and the justification by RAC based on a minute amount of releases from articles including massive lead.

ILA and Eurometaux hence organised a special briefing session to launch the advocacy phase to promote that several countries would reply in writing contesting the technical, legal and proportionality of the RAC proposal. The relevance of such action is supported by the outcome of a SEA exercise conducted by Eurometaux clarifying that half of the alloy manufacturing sites using lead would come into the Seveso permitting regime and many of them may even need to move given located in a zone where no such activity is allowed.

ILA and Eurometaux prepared in follow-up an advocacy package encouraging national federations, commodities and local companies to organise national advocacy to contest the proposal. Industry proposes to postpone the lead discussion until the Ag and Cu environmental classification opinions of RAC are available so that a common and level playing field approach can be assured (more information: Steve Binks and Hugo Waeterschoot)

INDUSTRIAL EMISSIONS

On 2 March, Eurometaux (Lorenzo Marotti) delivered a presentation at the 14th CEM (Conference and exhibition on Emissions Monitoring) on emissions to Air Ambient Air Quality Directives Review: Strengthening of Air Quality Monitoring, Modelling and Plans

The EIPPC Bureau issued the call for Initial Positions for the Large Volume Inorganic Chemicals (LVIC) BREF (feedback from members of the Technical Working Group is accepted from 18 February until 22 April 2022). In March, Eurometaux's Working Group (WG) on LVIC BREF has already provided preliminary inputs for the questionnaire template. The draft questionnaire was circulated to the Industrial Emissions Taskforce and with the WG, including a summary of the main messages that Eurometaux would like to submit to the EIPPC Bureau. These documents will be finalised in a virtual meeting of the WG on LVIC BREF that will be held in April. Any comments and additional contributions to the questionnaire and the background document are very welcome.

On 29 March, Eurometaux received a leaked version of the reviewed text of the IED, to be published by the European Commission on 5 April 2022. This was circulated to the Industrial Emissions Taskforce (together with a preliminary analysis). This version shows significant modifications to the text of the Directive and reflects some of the most ambitious policy options that the Consultants have analysed during the impact assessment period. The new IED will be discussed in a dedicated meeting with the Industrial Emissions Taskforce in April and an advocacy plan for the sector will follow (more information: Lighea Speziale, Lorenzo Ceccherini and Lorenzo Marotti)

WATER

Water: Impact Assessment, tight deadlines and procedural concerns

The final version of the Commission document on the deselection of existing priority substances (PS) was published on CIRCABC with the note "...that the document is circulated for information only and no further commenting is envisaged". The document was expected to include comments made during the last call for feedback in autumn 2021 but it seems

that it also contains new sections of text not discussed by the Working Group Chemicals members, who raised this during the 2nd Impact Assessment (IA) workshop on 18 March.

The overall purpose of the IA workshop was to present the background document prepared by Commission for the Impact Assessment, circulated two days before the meeting. Discussions focussed mainly on pesticides and pharmaceuticals.

However, metals were addressed during the breakout session on Surface Water : the Commission consultants (WOOD/Trinomics) presented the concepts of "Dynamic Baseline" and "Distance to target", which quantifies the existing state (based on Environmental Quality Standards (EQS) dossiers and monitoring data) against a desired state (i.e., good chemicals status). In follow-up, possible measures were identified, and a (preliminary) cost-benefit assessment was presented. For silver, the results look rather promising (it should be noted here that the JRC is trying to find a date for the Ag expert sub-group to discuss the SCHEER opinion, following EMPF's repeated requests). For nickel, as the dossier is currently under review by the JRC, it is not known which EQS they have used for their analysis; the distance to target is qualified as medium.

In follow-up of the workshop, Eurometaux sent comments on the IA discussions to convey the sector's key messages to the IA consultants. Thanks for the very efficient teamwork!

Also, Eurometaux had a meeting with other associations (JAM group), during which it was agreed to send a letter highlighting the procedural concerns with the overall IA/prioritisation process, stressing the importance of drawing learnings from the current process and how this could be done better in a cooperative way. While it is not expected that Commission will provide a detailed response to this letter, we hope to be able to use the content and proposals outlined in this letter for informal advocacy with other Commission DGs (DG GROW, DG SANTE, ...), Member States and MEPs. The battle is indeed mostly over for the technical part of this prioritisation process, but the political one is not. This joint action could also have an impact on how the next prioritisation process is handled.

Finally, the Water Taskforce will ask the Commission to publish the technical guidance document on implementing EQS for metals on the Commission's public website (and not only on CIRCABC, as is the case now) to allow easier access for interested parties.

The next Working Group Chemicals is scheduled for 4 May. The date for the next Water Taskforce will be communicated soon (more information: Lara Van de Merckt).

METALS ENVIRONMENT EXPOSURE DATA PROGRAM (MEED)

MEED program: report on 2nd MAF study concluded and I-PCS identified

ARCHE updated the 2nd Mixture Assessment Factor (MAF) pilot report on metals and inorganics, based on the outcome of the workshop held on 1 February. The MAF 2 report provided the scientific base to select the metals/inorganics that contribute the most Inorganic Priority contributing Substances (I-PCS) to the overall potential for combined risk in European waters and soil. This study was based on a very extensive comparison of hundreds of thousands of monitoring data points across the EU and the aquatic and soil effects levels (HC5 and PNECs) reported in the metals registration files. The report also identified the potential impact of bioavailability correction, or the application of the added risk approach. While it somewhat changed the order of the I-PCS, it did not really modify the selection of I-PCS. To the contrary, the lack of refinement of the effects assessment on some metals/inorganics had a large effect meaning that if those metals would update their effects session with some chronic environmental effects data, they would most probably disappear from the I-PCS listing.

In complement to the MAF 2 report, ARCHE and Eurometaux developed a paper summarising the recommendations of the I-PCS, a selection that is critical for the launch of the next steps of the MEED program. This paper includes, besides the recommendations of the MAF 2 report, other lines of evidence like the recommended priority substances under the Water Framework Directive and substances listed frequently on national soil priority lists. Both documents will be circulated early April to the sponsors of the MEED program including an invite for the 2nd MEED workshop scheduled for 10 May (external venue to be communicated) (more information: Diana Dobre, Violaine Verougstraete, Marnix Vangheluwe and Hugo Waeterschoot).

COMMUNICATION

Helsinki Chemicals Forum 2022 Conference: 8-9 June 2022

A few weeks ago the programme of the Conference was published and the registration for live and online participants opened. The programme is attractive and comprehensive and will start with the joined Green



MEET US! 8–9 June 2022 Join the discussion on global chemical safety management issues in the 13^m Helsinki Chemicals Forum PAR

Economy Business Summit. The organisers hope that we can find time to join live or follow the conference online during

the event. For that purpose please **register for free** by using this link <u>https://visit.messukeskus.com/registration/Registration/Login?id=457-22278-1302</u>.

Ekotox Slovakia: series of webinars

Please note that Ekotox Slovakia will organise a series of webinars on the REACH revision changes.

The first one, scheduled for 26 April, will address new information requirements in the REACH registration process, more information requirements on uses and exposure and the Mixture Assessment Factor.

There is a good participation from Commission, Cefic and Eurometaux. More information can be found here: <u>https://ekotoxtraining.com/events/eu-reach-registration-changes-covering/</u>

We would encourage the consortia/commodities to participate in these webinars as their outline and (large) attendance are quite interesting and relevant!

CALENDAR

Please find here below a non-exhaustive list of the meetings that are planned for Q1 - Q2 2022.

For meetings at Eurometaux

The MCC has been opened to allow hybrid meetings, we will inform our members if our meetings will be held as hybrid or online only (links to join will be sent ahead of the meetings). For those travelling to Brussels: more details on https://www.info-coronavirus.be/en/

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 <u>website</u>

Further information on the COVID-19 situation information can be found on the ECDC website

- 19-22 April: ECHA RAC-61 CLH WG
- 25 April: 2nd Zero Pollution Stakeholder Platform
- 25-29 April: ECHA RAC-61 AfA WG
- 04-05 May: ECHA RAC-61 REST WG
- 04-06 May: Metals Academy
- 10 May: 2nd MEED Workshop
- 12 May: Risk Management Taskforce
- 16-19 May: SETAC 32 (Copenhagen)
- 18 May: CSS High-Level Roundtable
- 25 May: Chemicals Management Steering Committee
- 30 May-03 June: ECHA RAC-61 Plenary (reserve) & SEAC-55
- 06/07-10 June: ECHA RAC-61 Plenary & SEAC-55
- 08-09 June: Helsinki Chemicals Forum
- 13-17 June: ECHA MSC-78
- 15-16 June: ECHA MB

- 21 June: Risk Management Taskforce
- 22 June: 3rd MEED Workshop

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)