

EUROMETAUX CHEMICALS MANAGEMENT NEWS



One last meeting before the summer break: on 3 July Environment Taskforce & Rapid Removal EM Silicon Room: Avenue de Tervueren 168 – 8th Floor

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Dear All,

Transition, (non-)toxic and transparency were some of the key words used repeatedly during the high-level EU Chemicals Policy 2030 Conference held in Brussels last week. But also transforming, trusting, tracking and today (to give it a sense of urgency). We are in a world that needs to transmute, translate words into work and that screams for transparency at all levels. Interestingly, trans-actors' cooperation, transboundary and tools for increasing knowledge were mentioned as well.

Until the end of this year, due to the change in EU authorities and the associated (re-)profiling games, the Brexit and overall global uncertainties, all players will try and find the spot where they can best target their goals and protect their assets.

This is true for our sector as well! We have a high potential for being the best in the class for circularity but will remain under high scrutiny due to our toxicity and the volumes we handle. We are recognised as essential to help in reaching some EU policy objectives, but still suffer from the competition outside the EU. We are not the popular 'lad' when it comes to talking green chemistry or successful alternative-seeking but more the weirdo of the group who has the complex science and the smaller numbers (of substances!). We are good candidates for grouping, less for funding projects. We are present at all levels of the chemicals' lifecycle, more or less bioavailable, will remain for years, are measurable but hard to get rid of.

We won't have a lot of other choices than work more, document and explain. To ensure our specificities are not forgotten in the dynamism everyone will now deploy to implement the Council's and Fitness conclusions. To benefit from the efforts that will be consented to discuss with society the trade-offs on 'needed' chemicals. To incorporate in the capacity-building exercise that will be launched a story about metals, rather than be considered as a second-tier player with 'nasty stuff'.

How? We know that being a step ahead requires resources, being right on time entails organisation and coordination, and defending is energy-draining. We will need to identify where our plusses are and build on those. Be stronger in knowing and sharing our understanding. And also, as the coming months will most probably be about each one's narratives and building relationships, be ahead in translating the authorities 'urges' and 'calls' into "concrete" actions and more palpable outcomes. The credibility may help to compensate the lack of visibility!

The summer months come at the right time to take a little step back and reflect on our strengths -encompassing our creativity, verve and humour, often acknowledged by our partners- in a transforming regulatory world. And this is also why this edition comes with the new 'chems on the beach' -to keep a touch of lightness and recharge the batteries! Enjoy the summer!

Violaine Verougstraete, Chemicals Management director Eurometaux

ECHA REACH & CLP Activities: hot topics

ECHA Committees

RAC-49: discussed cobalt salts, microplastics and skin sensitisers restrictions

During its first week of meetings, RAC discussed a couple of very relevant restriction dossiers, like the cobalt salts but also microplastics and skin sensitisers in textiles. On the cobalt salts, the debate focused primarily on hazard and the proposal of the Rapporteurs to have a mechanism of action-based threshold (MoA). A nice comparison exercise between the available cobalt data and the nickel data used for the binding occupational exposure limit (BOEL) derivation in 2017-2018 was made, but RAC concluded that due to the lack of quantitative in vivo data on local genotoxicity vs. inflammation for cobalt, they cannot conclude to a real MoA- based threshold. Several RAC members were concerned about the (predictive) value of inflammation as pre-carcinogenic effect (does it occur first? at what level?) but also by the severity of the effects in the 2-year animal study. Indeed, RAC proposed to use animals as starting point for the derivation of the 'value' to achieve, as they had some difficulties to evaluate the available human data on cobalt (salts) considered as not thoroughly presented in the Annex XV prepared by the Dossier Submitter. Industry thus proposed to prepare an overview of the epidemiological data that was submitted before the end of the Public Consultation. An important achievement was that RAC agreed with the Rapporteur's proposal not to use the lung cancer dose-response to account for upper respiratory tract or systemic cancers. The discussion on the hazard section is not over yet, as it was agreed that the Rapporteurs and ECHA secretariat will prepare a text regarding the "conclusion" reached at RAC and circulate a text to the RAC members over summer. The RAC members will have some time to comment on the approach and the final discussion will take place at the September meeting. It is important to note in this context that the RAC followed the new appendix to the ECHA Guidance R.8, on the definition of OELs. The exposure section of the restriction was also discussed but more briefly, and in follow-up to this the CoRC/CI submitted further

information on e.g. the MEASE input parameters, the use of analogous data etc. The last part of the debate focused on effectiveness and enforceability, with a short discussion of the advice provided by the Enforcement Forum and its concerns on monitorability and practicability of the Dossier Submitter proposal. Some comments were also raised on the existence of background levels/essentiality and how achievable the proposed reference exposure value (REV) would be if approaching the background levels. This will be further discussed in September. To note: the recommendation by the trade unions to use the REV value proposed by the Dossier Submitter as BOEL and have REV and BOEL implemented in parallel to cover all cobalt compounds. Also, it was stressed that the information submitted during the public consultation shall be in included in the updated registration dossier without undue delay. This requirement is part of the Evaluation Action Plan worked out by Commission and ECHA and that was supported by ECHA's Management board (see below). Another debate that triggered a lot of attention from stakeholders that week is the proposed restriction on microplastics. ECHA has submitted a restriction proposal for microplastic particles that are intentionally added to mixtures used by consumers or professionals, which was considered as being in conformity at the March RAC meeting. This time, as the first draft opinion was to be discussed, all involved stakeholders were invited to provide an opening statement (including Fauna and Flora International). The debate focused on hazard, the proposed risk assessment approach and very importantly, the scope of the restriction proposal. Provisional views of RAC is that they agree that there is a concern to be addressed and that a non-threshold approach should be followed. However, this discussion will be continued in September as there were several comments on the difficulties to identify the targeted compartment (terrestrial and marine), the hazard (extreme persistence vs. biodegradability raised by the NGOs), secondary vs. primary materials, and the definition of microplastics to start with. Finally, the proposal to restrict skin sensitising substances in textiles and footwear was estimated as conform and ECHA has launched in follow-up the Public Consultation (PC) that will last until December 2019. This restriction aims to reduce the risk caused by the skin sensitising substances in clothing and related accessories, articles-others-than-clothing that come into contact with the human skin under normal or reasonably foreseeable conditions of use and to some extent are similar to clothing and footwear (e.g. finished textiles, leather, hide and fur articles). The proposal covers the substances which are classified as skin sensitisers in Category 1 or 1A or 1B in Annex VI to CLP, as well as a list of disperse dyes that are indicated as having skin sensitising properties. The restriction proposal refers to nickel and cobalt compounds. More specifically: the articles or parts of articles, shall, at point of sale, not contain the following substances above concentrations specified below: nickel compounds in concentration greater than 130 mg/kg w/w in textile and 110 mg/kg in leather, hides and furs and cobalt compounds in concentration greater than 70 mg/kg w/w in textile and 60 mg/kg w/w in leather, hides and furs. The PC and restriction proposal can be found here: <u>https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/23405/term</u> (more information: Violaine Verougstraete).

SEAC-43: Cobalt salts restriction: the alternative SEA assessment prepared by industry taken very seriously

The cobalt sector submitted an alternative socio-economic and proportionality assessment under the PC on the cobalt salts restriction proposal. The industry assessment demonstrated that the costs for compliance are much larger than estimated by the Dossier Submitter (DS) (due to there being more companies and a larger variability in existing risk management measures) while on the other hand, the benefits for society will be lower resulting in an even more disproportionate conclusion to proceed with the 0.01 µg Co/m³ Reference Exposure Value (REV) proposed by the DS (ECHA). Especially the fact that this input was presented as an integrated, transparent and well documented report resulted in the SEAC Rapporteur making direct reference to it when presenting the second draft opinion at the SEAC meeting mid-June. Whilst the Rapporteur concluded that an EUwide basis for a relevant Risk Management Measure on the cobalt salts was justified, he also confirmed that the costs for industry are underestimated and announced they would use the evidence provided by industry as a "sensitivity assessment" to demonstrate the reasons for and the extent of the under-estimation. Furthermore, the Rapporteur confirmed that the monetised benefits as presented by the DS are overestimated. However, they asked industry to further substantiate the underlying assumptions for the alternative benefits impact assessment, which industry confirmed was already submitted before the end of the PC deadline. Based on all this and given that the Enforcement Forum also guestioned the relevancy of an additional workplace exposure standard system (OEL and REV), the Rapporteur could only conclude that the proposal was non-proportionate by several orders of magnitude. There seems to be broad support for this view by SEAC members but on the other hand, unexpectedly some NGOs remain supportive. A third and final opinion for discussion in November is now being prepared by the Rapporteur. This high-profile restriction case demonstrates that adequate planning and targeted input could be very effective. Furthermore, the Rapporteur challenged industry by asking if they can come forward with a qualitative benefits/cost comparison between the OEL and the REV approach. Responding to this could even raise recognition for the input (more information: Rohit Mistry and Hugo Waeterschoot).

SEAC-43: the lead chromate court case continues to send shock waves to AfA holders

SEAC was informed by ECHA's legal unit on the status of the recent court case on lead chromates whereby the Court, in first order, annulled a granted authorisation claiming inappropriate assessment of the availability of alternatives and the way that outstanding uncertainties in the application were used to define the Review Period... which the Court said should not be done that way. The legal service confirmed the Commission would appeal the Court's outcome but only on selective provisions. ECHA further explained the activities they planned to respond to the court case conclusions. One of the most important suggestions for change would be the request that the applicants list both "generic alternatives" and "specific alternatives"; the latter focussed on the use niches covered and on which a technical and economic feasibility would be required. Eurometaux intervened, stating that industry requires certainty to continue business during the granted authorisation period and invited ECHA to clarify the challenges posed by the Court in respect to the conditions for the Review Period and what would be understood by (or the different forms of) "uncertainty". Eurometaux supported by the other industry representations in SEAC requested a dialogue on the consequences and stated that an update of the Application for Authorisation (AfA) guidance was relevant (more information: Hugo Waeterschoot).

MSC-65: it's all about the increase of the number of evaluations

MSC-65 took place from 24 to 27 of June in parallel with ECHA and Commission adopting the new Evaluation Action Plan. This plan includes clear targets and actions to accelerate the data generation and identification for substances of "concern". By the end of 2019, it will clarify for which priority substances of concern a check will be conducted by the end of 2020 for high- and by 2027 for low- volume substances. This will evidently result in a sharp increase of compliance checks to minimum 20% or most probably 30% of the substances screened. To be representative for all substances registered, ECHA will develop in the months to come a comprehensive grouping strategy (a first proposal was presented at the MSC meeting) complemented with a more streamlined compliance check process. Eurometaux asked to pay attention to the specific properties of metals when developing the grouping approach, whereby ECHA indicated that for metals, MISA would be instrumental to achieve the new policy target. One such option for ECHA for dossier and substance evaluations is to make much more use of the written adoption procedure as already tested during this MSC meeting. From the 11 dossiers and 4 substance evaluation proposals, only one of each appeared at MSC; the rest was handled by written approval. This saves time but does not allow for industry interactions and learnings. ECHA compensates this by pre-meeting briefing sessions for regular stakeholders to ensure interactions concerning cases that were adopted in written procedure. The debrief this time included for example the decision on the Testing Proposal on Ag (EOGRTS) (more information: Hugo Waeterschoot).

MSC-65: the selection of chemicals towards Authorisation progressing slowly but progressively

The SVHC identification focused until now primarily on CMR chemicals. Member States are now expanding the search basis for SVHCs, whereby they become "creative" in developing new combinations of hazard categories that could produce suitable SVHC candidates under the legal provision of Equivalent Concern (EloC). One of the proposed combinations covers very Mobile, Persistent (vMP) substances that do not bind and thus remain bioavailable in water bodies. The reaction of the MSC on this criterion was evaluated using an organic fluor-based chemical used by metal articles manufacturers to collate Teflon on aluminium and steel structures like cooking equipment. MSC agreed on the SVHC status of this substance based on vMP grounds with the abstention of several countries. This debate is important for metals given they are seen as persistent and some as being mobile in groundwater. We therefore supported the view that over time bioavailability would be recognised for non-selection of specific metals. MSC also debated the next step in the authorisation selection process, namely the prioritisation for authorisation, by debating the outcome of the PC on the 18 substances proposed, including 7 Pb stabilisers. Two of the seven Pb-stabilisers have no production in the EU but are included for their potential inter-substitutability. The third one, a Pb sulphate oxide, is not inter-substitutable so cannot be included. ECHA however, defended the selection based on historical information from registration files. The Pb manufacturing and concerned user sectors stated their disagreement in writing. The next MSC, the 3rd week of October, will come to a conclusion on this opinion, triggering the next step at the level of the Commission and the start of the 10th priority list on which lead may appear (more information Hugo Waeterschoot).

MB-54: the outcome of the REACH review drives the strategic direction for ECHA

A major objective of the ECHA Management Board (MB) is to ensure progress with and to implement action on the REACH Review conclusions. The 2 key actions the MB is working on for 2019 and that are of direct relevance to industry are a), the Evaluation Action Plan and b) improving the Authorisation Applications scheme in respect to the identification of relevant substitutes. The MB agreed with the proposed Evaluation Action Plan as it would speed up the compliance by industry (see above and below) but recognised it would draw extensive resources from ECHA. It was therefore agreed to allocate, at least for 2 years, staff from other units to this project and to restrict the list of priorities ECHA would preferentially work on in the next 2 years to the following areas: grouping of substances for REACH, CLP and BPR, Compliance Checks, Restrictions and Applications for authorisation, BPR active substance review programme and lastly as a new task: setting Occupational Exposure Limits. The MB was informed about the appeal of the Commission on the lead chromate case and ECHA's management plan to deal with the outstanding consequences of the court case. Cefic, representing the EU-wide industry at this level, requested certainty to be ensured for industry and that a clear guidance would allow applications, when well-motivated, to pass. The MB held a workshop on a separate day for the last main agenda item: assessing if the organisational structure and composition of the MB is still up to date. Several suggestions to improve this were listed but the outcome of the debate is at this stage unknown to industry given part of the debated happened behind closed doors (more information: Hugo Waeterschoot).

COMMISSION Chemicals Management activities:

CARACAL

CARACAL: all set to provide input on a lot of important topics on the agenda of the 1-2 July meeting

The CARACAL-30 meeting will be held in Brussels on 1-2 July. Eurometaux has analysed the large set of available working documents and prepared an annotated agenda defining the positions and interventions to be made on the various items that will be discussed. This annotated agenda was sent for comments to the CARACAL Group, recently established as part of Eurometaux's restructuring. Some topics are considered particularly important as they could have a significant impact on our activities in the future such as: the REACH Evaluation Action plan and the recent court case that would make substitution plans obligatory for almost all applications for authorisations. The discussion will also cover the implementing regulation on dossier updates recently drafted by the European Commission. Based on a first analysis, it seems that it does not clarify some of the issues that industry raised repeatedly with regard to free riders and time constraints for joint submissions managed by consortia. Detailed comments will be submitted in written form in August. REACH requirements for nanomaterials will also be debated since the lack of updated guidance documents and standardised methods represent a challenge for the practical implementation of the updated annexes. Metals are impacted by these nano requirements and we will stress that metal specificities should be considered when developing standardised methods and guidance. Discussions on CLP-related items are scheduled for the second day of the comments. Written comments have already been submitted on the lead metal environmental classification and the need to consider different entries for the massive and powder form. In an oral intervention, Eurometaux will stress the need to include in the discussion the different options contained in the RAC opinion (more information: Lorenzo Zullo).

Future of CARACAL: consequences of the applicability of Article 290 of the Treaty on the functioning of the EU on the CLP regulation

In preparation for CARACAL-30, the European Commission has circulated an informative note presenting the changes triggered by the entry into force of the Treaty on the Functioning of the European Union (TFEU). While the regulatory procedure will remain applicable to REACH, in CLP it is replaced with an adoption via delegated acts. These changes impact the procedure to be followed in the future to amend CLP annexes I to VIII. One of the major changes is that the REACH Committee will not be competent to deal with most CLP matters any more. Consultations on delegated acts will take place in the framework of CARACAL instead of the REACH Committee. CARACAL will be considered as an expert group to assist the Commission in the preparation of delegated acts. For this purpose, the Rules of Procedure ("RoP") will be amended via a written procedure to be launched soon. The different categories of observers and their roles would remain broadly unchanged. However, considering their important contribution in the new process, the Commission is planning to launch a new public call for applications, and aiming at having the new list of observers fixed by the CARACAL meeting of November. Eurometaux is planning to respond to the call to ensure that the metal sector will have the possibility to provide input to the drafting of the delegated act and to ensure continuity with the work done on metals in the ECHA Committees where we have a regular stakeholder seat (more information: Violaine Verougstraete).

Chemicals Policy

Commission: outcomes Fitness Check chemicals legislations excluding REACH

The findings of the 'Fitness Check' of the most relevant chemicals legislation regulating chemical substances (excluding REACH), whose target was to assess whether the legislation was fit for purpose and delivered as intended, was published on 25 June. The 'Fitness Check' (available here: http://ec.europa.eu/transparency/regdoc/rep/1/2019/EN/COM-2019-264-F1-EN-MAIN-PART-1.PDF) concludes that, overall, the EU chemicals legislation delivered results as intended. However, it also identifies a number of important issues and weaknesses that are holding the EU chemicals legislation back from delivering its full potential and also limit its ability to achieve its objectives and be fit-for-purpose. These challenges are also based on the extensive study carried out by RPA, Milieu, Ökopol and Ricardo -AEA (https://publications.europa.eu/en/publication-detail//publication/7e26e205-18f9-11e7-808e-01aa75ed71a1). Some of the challenges relate to specific pieces of legislation, others are more generic like the ones related to implementation and enforcement (e.g. the cutbacks in, and variations between, the capacity, resources and expertise of Member States competent authorities); the duplication/burdens and pace of procedures (it mentions that Commission has started to work with ECHA and EFSA to better ensure the convergence of conclusions, but that there are additional opportunities for simplifying the current set-up and streamlining the risk assessment processes among all relevant EU assessment bodies; the communication of hazard and safety information to consumers); consistency of risk management measures; the challenges in keeping up with science when it comes to risk assessment and

knowledge gaps; global competitiveness/innovation and sustainability. The text concludes that the 'Fitness Check' is a further step in the reflection process on the EU chemicals legislation. It is intended to provide a common understanding of the challenges and to invite all interested parties to become involved (more information: Violaine Verougstraete).

Council: towards a Sustainable Chemicals Policy Strategy of the Union

On 26 June, the EU Council adopted the Conclusions on the future of the EU's chemicals strategy. The text can be found here http://data.consilium.europa.eu/doc/document/ST-10713-2019-INIT/en/pdf. The Council's conclusions emphasise the need to protect human health and the environment through sound management of chemicals and the importance of improving and mainstreaming the chemical risk assessment and management of chemicals across EU legislation, so as to increase the coherence and effectiveness of EU chemicals-related legislation. But the conclusions also outline more detailed actions and requests on endocrine disruptors, vulnerable groups, the CPW interface and highlight the importance of exposure and biomonitoring. Overall, the reactions from the Member States for the proposed text were supportive. Several Member States stressed the need to ensure that ECHA would have the necessary human and financial capital within a long-term perspective. A majority of Member States has also evoked the urgency and need for Commission to issue a Non-Toxic Environment Strategy, as foreseen by the 7th Environment Action Programme. Commissioner Karmenu Vella confirmed that this will be a task for the incoming European Commission. Interesting to note among the reactions of the Member States, are the references to trade agreements - and the importance to ensure that those guarantee a high level of protection of human and natural environment, particularly for consumers. France made a plea for consistency in the EU's environmental objectives and its trade policy, as it could act as leverage on environmental standards. In their comments, the UK stressed interestingly that phase-outs based on hazard properties alone would likely lead to their substitutes being newer but equally problematic substances. They also strongly supported close collaboration at an EU and international level and were in favour of staying loyal to the commitments made in the 7th Environment Action Programme. The Council conclusions and the Fitness check will be further looked at by Eurometaux's staff to propose further actions after the summer (more information: Violaine Verougstraete).

High-level Conference on EU Chemicals Policy 2030: 27-28 June

Commission and Denmark's environment ministry co-hosted a two-day high-level conference bringing together representatives from EU and national governments, NGOs, businesses and the academic world to collect their visions for EU chemicals policy over the next decade. The conference started with speeches from Karmenu Vella Commissioner ENV, Elżbieta Bieńkowska, GROW and a representative from the Danish Ministry; before moving towards a mix of panel discussions and thematic sessions organised along the world-café format. Eurometaux was invited -along with other stakeholders like Client Earth, EURIC and FEAD to provide its vision (in one background document, one slide and a one- minute speech) during the thematic session on Chemicals and the Circular Economy: safe management of chemicals in products and waste and

contribution to resource efficiency. The participants attending the thematic sessions were invited to propose and vote on a vision for 2030, objectives and related actions. The outcomes of these sessions were used to feed the subsequent panel discussions. Recurrent messages were the calls for a better implementation and enforcement of chemicals legislation, more harmonisation, safety by design, transparency and quality of the data, knowledge building, the necessity to protect vulnerable groups and the possibility of an "early warning system". A report with findings from the conference will be presented to the new Commission and will be used as a "basis for further decisions", along with the other Evaluations such as the



REACH review and the Fitness Check. A report on the conference will soon be circulated by Eurometaux's staff (more information: Chris Heron, Hugo Waeterschoot and Violaine Verougstraete).

OSH

OSH: ACSH opinions on benzene, nickel and acrylonitrile and publication 3rd wave of the CMD

The Advisory Committee on Safety and Health (ACSH) adopted opinions on benzene, nickel and acrylonitrile during its plenary meeting on 4 June 2019. These substances had been previously discussed by the ECHA Risk Assessment Committee in 2017-2018. The RAC's opinions had been submitted to Commission who has consulted the Working Party Chemicals (WPC) of the tripartite ACSH, which is an expert group, composed of employers, trade unions and government representatives. ACSH's task is to consider the scientific opinions as well as socio-economic implications and the technical feasibility of possible OELVs and provide a recommendation to the Commission. The socio-economic implications (cost and health benefits of introducing EU-binding OELVs) had been investigated by a consortium of external contractors (RPA, FoBiG, COWI). The final ACSH Opinion on nickel compounds recommends the following values: 0.01 mg/m³ and 0.05 mg/m³ for the respirable and inhalable fractions respectively and both shall apply from January 2025 onwards. Also to note in June, the publication of the third wave of OELs amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to

carcinogens or mutagens at work. It includes arsenic, beryllium and cadmium and can be found here: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=uriserv:OJ.L .2019.164.01.0023.01.ENG</u> (more information: Martin Wieske and Violaine Verougstraete).

EUROMETAUX CHEMICALS MANAGEMENT Activities

Resource mapping to respond to Chemicals Management challenges

Evaluation Taskforce Meeting new format: Nano registration requirements, ECHA's Compliance Check boost and MISA follow-up activity

The Evaluation Taskforce, in its new format, is a merger of the previous Evaluation platform and Nano Taskforce. A logical step given most nano cases are handled under evaluations or testing proposals. The first meeting took place on 18 June, focussing to a great extent on the recent nano substance evaluation experience. The deadline for registration of nanomaterials is fast approaching: 1 January 2020. Although several activities around the new legal requirements in REACH are still ongoing, there are several pending questions regarding testing guidelines and registration approaches. Currently only the ECHA substance identification guidance is being updated with the nanomaterials' relevant guestions. Regarding human health, environmental & physico-chemical endpoints the work was stopped until further notice. Several testing guidelines are being initiated at OECD level by European Member States, however, these certainly will not be ready by the end of the year. Additionally, some seem to overlap with ongoing projects or 'overlook' already existing (non-nano specific) guidelines which could reduce new workload. The Taskforce nano session's core was composed by the experiences some members encountered during the undergoing substance evaluation of nano zinc oxide and Community Rolling Action Plan (CoRAP) discussions on titanium dioxide. Overall, it became clear that it will be important to clarify necessities to include nanomaterials in substance dossiers and take on board those first cases' learning lessons for everyone. A more in-depth webinar on registration requirements was suggested and a possible agenda is currently being identified by the Eurometaux secretariat. The Evaluation Taskforce was also informed and took note of the proposed ECHA Evaluation Action Plan and its proposed deadlines. Eurometaux presented and explained the 15 concrete action points, evaluating in short what they could mean for the metal sector. Action 15 on industry taking on the compliance challenge refers to the sectorial approaches including MISA. ECHA explained that the good functioning of these programmes would help facilitate the progress of the Evaluation Action plan. The Evaluation Taskforce ended with an action point resulting from the MISA-2 workshop (February 2019) to develop a common view on the counter-ion impact on ecotoxicity tests and read-across to promote a common motivation note. A draft prepared by Stijn Baken, Jelle Mertens and Bill Stubblefield will be circulated for final comments before being sent to ECHA for informal input and provided with a recommendation to the MISA consortia to include it as a motivation note when they update the environmental section of their registration file (more information: Hugo Waeterschoot and Nathalie Kinga Kowalski).

Chemicals Management Steering Committee: met on the 20 June with a varied agenda

The Chemical Management Steering Committee (CMSC) met on 20 June to discuss an agenda ranging from an update on the new Chemicals Management department structure and membership, the outcomes of the Circular Economy Mission and a status on the EU elections to recent developments in OECD. It also addressed risk management aspects (RoHS, 10 risk management measures improvement plan, communication on chemicals management), the ongoing evaluations on Air, Water and Industrial Emissions, the CPW interface and topics like USEtox and the E-PRTR. In view of the number of matters to be addressed during the meeting and their variety, and also to ensure the Committee can best exert its *steering* function, it is proposed from now on, to send ahead of the meeting, a document summarizing the possible issues/discussions points handled by the different taskforces for which direction is needed from the CMSC. This should help the CMSC to understand the background of the topic and directly input in the debate. This will be particularly important for the next meetings of the CMSC where high-level communication/advocacy on metals chemicals management will be discussed and validated. The minutes of the 19 June meeting will be circulated soon. It is reminded here that the CMSC brings together all the chairs of the department and 1 representative by member not having a chairmanship (commodities, companies, federations, associate members) (more information: Violaine Verougstraete).

Chemicals Management Communication: brainstorming exercise

On 21 June, representatives from several commodities and the WVM came together to brainstorm on how to best coordinate activities and resources to address the disconnect between the EU's chemicals legislation and low-carbon/circular economy goals. The meeting was moderated by James Stevens (Rud Petersen) and a lot of good suggestions were raised by the group to overcome silo-working, mobilise stakeholders and promote the links between circularity, climate and chemicals management policies. These suggestions will be considered this summer by EM's staff to prepare and share a workplan to be

carried out in the coming months, making the best use of the existing resources and the political context (more information: Chris Heron and Violaine Verougstraete).

Metal-specific REACH application tools and concepts

Bioelution: discussion with animal welfare

Eurometaux has been exchanging on the topic of bioelution testing with Cruelty Free International. Eurometaux provided some documentation like a note on how bioelution testing fits with the 3Rs (Replacement, Reduction and Refinement) objective and a note explaining how it can be applied for grouping and classification of complex materials. Also, part of the package was an overview of cases currently/recently discussed in the regulatory arena where bioelution plays/has played a role. The role of bioelution data in grouping and read-across debates was of particular interest in this context. We have also explained where, from industry's perspective, the difficulties are when it comes to acceptance (more information: Adriana Oller, Hugo Waeterschoot and Violaine Verougstraete).

SPERCs quality criteria: green light from ECHA and presentation to OECD

After several interactions with ECHA and Member States, the SPERCs Quality Criteria draft proposed by the SPERCs crossindustry Taskforce (chaired by Eurometaux) can now be considered as final. The document explaining these criteria was shared with ECHA and the Member States for a final review in June and was presented at the 3rd Meeting of the OECD Working Party on Exposure Assessment (see below). The agreement on the criteria and the interest the document triggered at the WPEA are good signals, showing how the hard work done on the SPERCs has progressively increased their visibility and recognition, including outside the EU. The various industry sectors will now proceed with the review of their respective SPERCs. The review is expected to be conducted also via external reviewers. The modalities (and a mapping of ongoing initiatives like the Nordic project) will be discussed by the SPERCs Taskforce, ECHA and Member States in the coming months (more information: Frederik Verdonck, Lorenzo Zullo).

Metals Sectorial Approach

Preparatory meeting for the MISA UVCB Workshop: planned for end of summer

Since the last environmental MISA workshop in February, several meetings and exchanges occurred on inorganic UVCBs, on issues when reporting hazard in IUCLID and on the need to have consistency in these dossiers' preparation. Overall, there has been a big interest from regulators and industry to ensure consistent approaches in the UVCB assessment and reporting. As ECHA is looking at the topic without making a difference between the UVCB's affiliation to a specific consortium, (because it is not always obvious to which consortium it is associated due to the variability of its constituents) we have been reflecting on the possibility to consider the inorganic UVCBs as a single product portfolio. Thus, in order to handle these updates in the most efficient way and, we could create a multi-metallic UVCBs platform that would handle all the UVCBs in a coordinated way with the support of the technical expertise coming from the consortia and their consultants in charge of the dossiers, rather than being assessed separately by each consortia. Such a platform will help share the different expertise developed by the different consortia but will also facilitate the data-sharing, allowing a better use of some tools like the multi-metallic database and MeClas. To discuss this possibility in depth and to prepare for the upcoming MISA UVCB workshop on 5 November, UVCB registrants have being invited for a face to face meeting on 29August: the agenda focuses on discussing the set-up of the UVCB Platform as well as the organisation of the workshop, agreeing on how to efficiently present the risk assessment approach (from SID to documentation) to ECHA and MSs. The goal of the workshop is of course to have a standardized approach for the inorganic UVCBs assessment, which is understood and accepted by regulators. To get there, we will need to show ECHA how the UVCBs are assessed and are hence currently investigating the best approach, as experts from several ECHA units and Member States will be present. The most efficient way would be to select a specific substance and take them through the assessment with explanations across the entire Chemicals Safety Assessment and IUCLID reporting. As the UVCBs are complex by definition, each substance will have different specificities in the assessment and we will have to ensure that these can be presented at the meeting, again through practical responses to ECHA's questions. By the end of July, all participants will receive the entire UVCB Guidance (i.e. follow-up of the SID Guidance and Annexes developed by December 2018) and the UVCB SATs to ensure a good understanding of the status of the UVCBs under MISA (more information: Federica laccino and Frederik Verdonck).

Water

Workshop Fitness Check Water Framework Directive: meeting 3rd June

On the 3rd June 2019 the Commission invited Member States and stakeholders to the final stakeholder workshop on the Water Directives' Fitness Check. The Commission, represented by Hans Stielstra (Clean Water Deputy, DG ENV), highlighted the

satisfaction with the contractors work and concluded that coherence issues especially need to be taken care of more in-depth. A weakness of the evaluation exercise was that there was not a given baseline of what the situation was/would be without the Water Directives. Despite the contractors concluding that the WFD, having yet not fully achieved all its objectives, is going in the right direction. Most problematic are the differences in monitoring practise between countries (or even regions). The workshop participants picked up mostly on the use of the one-out-all-out principle, which disallows a realistic view on progress made, but also the very critical view of the contractors on the exemption's numbers - the high number was misleading since it did not show that these are mostly only time exemptions and not objective exemptions. Even though the participants asked for more in-depth discussions on the importance of the Weser-ruling, they were not considered.

The final report of the contractors still hasn't been shared with the stakeholders, though it was promised to be finalised shortly after the meeting. Once the report is available, an analysis will be done, and it will be decided if further advocacy actions are needed. The final staff working documents of the Commission are expected in autumn, one will be on the Waste Water Treatment Directive and the other on the Water & Flood Framework Directives (more information: Nathalie Kinga Kowalski).

Industrial Emissions

Industrial Emissions Taskforce Meeting: first meeting following the new structure

On the 19th June, the Industrial Emissions Taskforce met for the first time, outside of the "old" EHS Weeks, following the new structure of Eurometaux's Chemicals Management team. The meeting had two parts: In the morning the taskforce was informed about and discussed EM's different activities within the different BREF reviews and the overall strategy, Air Policy and other needed advocacy work, e.g. in the view of monitoring data reports of the EEA. The taskforce is preparing for the Kick-off-Meeting of the Smitheries and Foundries (SF) BREF, which will take place mid-September and will require good advocacy to secure the non-overlapping regarding the scope of the SF and the NFM BREFs.

The afternoon was dedicated to the beginning of the IED Evaluation process. The Commission opened the "open public consultation (OPC)" end of May for answering by 4th September. Unfortunately, the targeted questionnaire hasn't been shared yet, but should be received soon, especially as it was promised by mid-June. The taskforce worked successfully on important messages for the questionnaires, but also on the specific answers to be given in the OPC in a two-group focused session. Eurometaux will work on delivering positive messages on the success of the IED. The draft minutes of the meeting and OPC answers draft (to be forwarded to NFM companies for their own input) will soon be circulated within the taskforce (more information: Nathalie Kinga Kowalski).

Other

ENES coordination group: preparation for next ENES event on 21 November 2019 in Brussels

The Exchange Network on Exposure Scenarios (ENES), bringing together ECHA, Member States and sector organisations like Cefic, Concawe, Eurometaux, Fecc, and DUCC is now preparing the next ENES event. It will take place in Brussels on 21 November. The goal of the 12th ENES is to inform companies who are manufacturing, formulating and using chemicals about approaches and tools that can make supply chain communication more structured and efficient; demonstrate how the tools work and the benefits of using them; and increase understanding of the practical value of information included in the extended safety data sheet for ensuring safe work places and products. Participants will be invited to discuss what the uptake of the ENES approaches/tools (e.g. SpERCs, use maps etc.) has been so far, and how the use of the tools could improve the quality of the registration dossiers with regard to realistic use conditions of the substance, efficiency in communicating relevant safety information to the users of chemicals and safe use of chemicals in terms of providing the information in a format and terminology that will meet the needs and enhance the experience of the user audience. Eurometaux will lead a session on how the approaches/tools help in getting prepared for the post-registration processes under REACH, i.e. risk management. The announcement and link for registration will be published at: https://echa.europa.eu/news-and-events/events. Registration will be open early July until end of September, or until all places are filled (the number of delegates is limited to 150) (more information: Lorenzo Zullo and Violaine Verougstraete).

FURTHER OUTREACH

OECD

OECD Working Party Exposure Assessment: Paris, 13-14 June

Eurometaux participated in the OECD Working Party on Exposure Assessment meeting on 13 and 14 June. Eurometaux made a presentation on behalf of the SpERCs cross-industry taskforce, jointly with ECHA. The presentation triggered interest from several countries that would be keen to participate in the external review process of the SpERCs now that the quality criteria have been finalised. The meeting also discussed a series of interesting topics like Emission Scenario Documents (Japan reported on the ESD "smelting and disposal of metals" that covers emissions from smelting and disposal phase of metals used in electrical and electronic products, mainly focused on incineration and emissions to air), biomonitoring databases and derivation of biomarker DNELs, tracking and exposure to chemicals in products, and dermal exposure. The Working Party is asked to comment on a series of documents and next steps like the mid-term strategy of the WPEA but also exposure of susceptible populations (incorporating gender in exposure assessment). Highlights have been circulated to the Science Forum and key messages/proposed actions also shared with the ICMM Chemicals Management Working Group that met on 26 June (more information: Violaine Verougstraete).

OECD Working Party Hazard Assessment: 17-18 June

Eurometaux also participated in the meeting of the Working Party on Hazard Assessment (WPHA). Eurometaux explained the MISA project and in particular the two MISA tracks, i.e. work on the registration data and the potential outcomes on technical/scientific aspects of interest when performing risk assessment and management of metals and inorganics. The presentation was supported by the comments made by the EU Commission and ECHA. The WPHA has asked to remain posted. We believe it was important to highlight the cooperative MISA efforts in these times where there are more and more questions from authorities on the quality and limitations of the data, in particular on uses and exposures. The meeting also discussed further projects like the APCRA (Accelerating the Pace of Chemical Risk Assessment) one, that brings together governmental entities engaged in the development of new hazard, exposure, and risk assessment methods and approaches for their chemical evaluation activities and/or the initiative led by Canada to collate best practices in setting priorities for risk assessment. But also, topics like New Approaches methodologies (NAM), combined toxicity, weight-of-evidence and grouping were discussed. As for the WPEA, highlights have been circulated to the Science Forum and key messages/proposed actions also shared with the ICMM Chemicals Management Working Group that met on 26 June (more information: Violaine Verougstraete).

COMMUNICATION

Summer meetings

Due to work in progress at the Metal Conference Centre, all summer meetings will take place (unless specified otherwise) at our new address: Avenue de Tervueren 168 – 1150 Brussels. Please consult our meeting calendar here below for more details about these summer meetings (more information: Ailsa Lee, Sofiana Dokou).

CALENDAR

- 1-2 July: CARACAL Brussels
- 3 July: Rapid Removal: Outcome of EU regulatory workshop Avenue de Tervueren 168 (Brussels)
- 29 August: MISA UVCB Workshop Preparatory Meeting Avenue de Tervueren 168 (Brussels)
- 30 August: Human Health Taskforce Avenue de Tervueren 168 (Brussels)
- 5 September: Chemicals Management Steering Committee MCC (Brussels)
- 09-13 September: RAC-50 (A) ECHA (Helsinki)
- 09-13 September: SEAC-44 ECHA (Helsinki)
- 16-20 September: RAC-50 (B) ECHA (Helsinki)
- 17 September: Risk Management Taskforce MCC (Brussels)

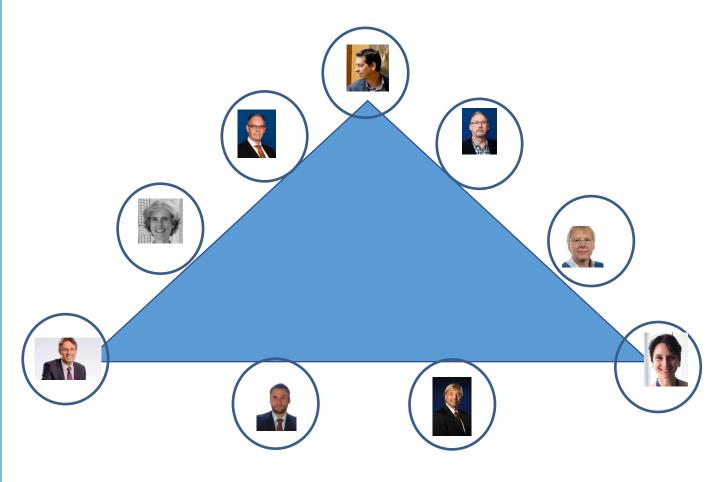
- 17-20 September: Smitheries and Foundries BREF Kick-off-Meeting JRC/ EIPPCB (Seville)
- 23-26 September: Chemicals Management Autumn Week MCC (Brussels)
- 24-25 September: WFD CIS Strategic Coordination Group (TBC; Brussels)
- 26-27: NeRSAP 8 FRAM (Gothenburg, Sweden)
- 26-27 December: MB-55 ECHA (Helsinki)
- 21-25 October: MSC-66 ECHA (Helsinki)
- 22-23 October: WFD Working Group Chemicals (TBD, Brussels)
- 5 November: MISA UVCB Workshop (TBC; Brussels)
- 12-13 November: WFD CIS Strategic Coordination Group (TBC; Brussels)
- 14 November: Evaluation Platform –MCC (Brussels)
- 25-29 November: RAC-51 (A) ECHA (Helsinki)
- 25-29 November: SEAC-45 ECHA (Helsinki)
- 2-6 December: RAC-51 (B) ECHA (Helsinki)
- 9-13 December: MSC-67 ECHA (Helsinki)
- 12 December: 2nd stakeholder workshop Industrial Emissions Directive Evaluation (TBC; Brussels)
- 16 December: Risk Management Taskforce MCC (Brussels)
- 17 December: Chemicals Management Steering Committee MCC (Brussels)
- 16-17 December: MB-56 ECHA (Helsinki)

ACRONYMS

3 Rs: Replacement, Reduction and Refinement	NGO: Non-Governmental Organisation
ACSH: Advisory Committee on Safety and Health at workplace	OECD: Organisation of Economic Cooperation and Development
AfA: Application for Authorisation	OEL: Occupational Exposure Limit
BOEL: Binding Occupational Exposure Limit	OELV: Occupational Exposure Limit Value
BPR: Biocidal Products Regulation	OSH: Occupational Safety Health
BREF: Best available technology Reference document	PC: Public Consultation
CARACAL: Competent Authorities for REACH and CLP	PC: Public Consultation
CLP: Classification, Labelling and Packaging Regulation	RAC: Risk Assessment Committee
CMD: Carcinogens and Mutagens Directive	REV: Reference Exposure Value
CMSC: Chemicals Management Steering Committee	RMM: Risk Management Measures
CoRAP: Community Action Rolling Plan	RoHS: Restriction of Hazardous Substances
CPW: Chemicals, Products, Waste	SEA: Socio-Economic Assessment/Analysis
DNEL: Derived No Effect Level	SEAC: Socio-Economic Analysis Committee (ECHA)
EEA: European Economic Area	SF: Smitheries & Foundries
ECVAM: European Centre for the Validation of Alternative	SID: Substance Identity
Testing Methods	
ENES: Exchange Network on Exposure Scenarios	SPERC: Specific Environmental Release Category
E-PRTR: European Pollutants Release and Transfer Register	SVHC: Substance of very High Concern
ESD: Exposure Scenario Document	USE-tox: scientific consensus model endorsed by the UNEP/SETAC Life Cycle Initiative for characterising human and ecotoxicological impacts of chemicals
IED: Industrial Emissions Directive	UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials
IUCLID: International Uniform Chemicals Information Database	WFD: Water Framework Directive
MISA: Metals And Inorganics Sectorial Approach	WPC: Working Party Chemicals
MoA: Mode of Action	WPEA: Working Party on Exposure Assessment
MSC: Member States Committee (ECHA)	WPHA: Working Party on Hazard Assessment



<u>REGULATOR SUDOKU</u>: Please insert the numbers **1** – **9** so that **each side** adds up to **17 industry people**



More tricky: Connect all 9 policy dots with 4 straight connecting lines

