



# EUROMETAUX CHEMICALS MANAGEMENT NEWS



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Dear All,

Spending a long time in the same 'workplace' gives one a kind of a comfort zone and "patina" that will provide him/her with the gait of an old feline, moving smoothly through the agenda savanna and most of the challenges. Old "lions" or "dinosaurs" will shrug their shoulders and express that 'feeling of déjà-vu' in discussions, they will use 'information channels' they are the only ones to know and use "tricks" they are not even aware of to approach their interlocutors. They will refer to precedent-settings, Directives from the 2000s (or earlier), to workshops held in more exotic places and even to other dinosaurs of the Jurassic Park (T-rex or stegosaurus). Oldies can recycle presentations, stand up in meetings and state seriously and truly 'I was there when...'; they will (should) bear failures less "personally" knowing that issues come back with the tide.

One, younger or newer, driven by that impulse fuelled by novelty and enthusiasm, may listen politely to the tips and techniques of the 'old man' but also consider some the 'experience-sharing' in meetings as a bit of a burden and wave it gently away, in particular when the group needs to conclude and move on to the next topic of the day. No judgment here! This is how life works: everyone is wandering from sunrise to sunset.

Still, we learn from history. Or should be able to learn from it. Everyone knows the quote: "A people without the knowledge of their past history, origin and culture is like a tree without roots". Without going that far, we could acknowledge that working in our sector without considering where we come from and what has been achieved or lost, may result in a loss of time and energy. But there should probably be an appropriate framework to share this knowledge and its roots. A framework that allows to confront the old with the new, to exchange experienced and fresh perceptions of a situation and to tell and write stories.

That's the purpose of the metals academy we would like to set up. To transmit, to exchange, to learn, to realise in fine that passion is the common impetus and wisdom a tool. The idea is to invite interested persons in the sector, newcomers or 'less-recent comers', to study a series of modules that summarise a big part of the sector's learnings, combining knowledge and wisdom ('Knowledge is knowing that a tomato is a fruit. Wisdom is knowing not to put it in a fruit salad'. Brian Driscoll).



Let us know if you are interested!

Violaine Verougstraete, Chemicals Management Dinosaur Eurometaux

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## ECHA REACH & CLP Activities: hot topics

### ECHA Committees

#### **RAC-50: 50 active meetings already!**

RAC met for two weeks and had a series of very interesting restriction and classification debates. The Committee finalised its opinion in support of the restriction proposal prepared by Italy to restrict the uses of N,N-Dimethylformamide on its own or in mixtures in a concentration equal or greater than 0.3 %. On the 5 cobalt salts, RAC agreed with the proposal of the Rapporteurs to use the 'breakpoint values' of 0.5 µg/m<sup>3</sup> respirable (for carcinogenicity), 1 µg/m<sup>3</sup> inhalable (for non-carcinogenic effects) in the calculation of the excess cancer risks, to be compared with the proposal of the Dossier Submitter. RAC agreed that there is an EU-wide risk to be addressed and that an EU-wide approach is justified, but there was some debate on whether an OEL or a restriction would be the best risk management measure to address it. As the timing for the development of a cobalt OEL is still unclear, RAC agreed that a REACH restriction is currently the most appropriate EU-wide measure to address the 5 cobalt salts, however, it is recognised that with an OEL it would be possible to cover all cobalt exposure sources (including intermediates and waste). This should be confirmed in the next RAC opinion, to be circulated ahead of the last RAC discussion at RAC-51. RAC also discussed a restriction on 'sensitisers' (substances classified as Skin Sens. 1/1A/1B + 24 disperse dyes 'of concern') during which cobalt and nickel were mentioned. The reason for going for a broad restriction is to avoid regrettable substitution. The restriction proposes that such substances shall not be placed on the market for the general public at individual concentrations greater or equal than the proposed limit values (e.g. Ni compounds 110-130 mg/kg w/w, cobalt compounds 60-70 mg/kg w/w), *in any of the following articles made exclusively or partly of textile, leather, hides and furs: clothing and related accessories, articles other than clothing which come into contact with the human skin under normal or reasonably foreseeable conditions of use to an extent similar to clothing and footwear.* The restriction on microplastics was discussed as well, with some key positions taken by RAC, in particular on the definition of microplastics, defined as a material consisting of solid polymer-containing particles to which additives or other substances may have been added and where ≥1% w/w of the particles all have dimensions ≤ 5mm 15 mm for fibres). Defining a lower limit was not supported by RAC. RAC also provisionally agreed that natural non-modified polymers are not a hazard. On the other hand, the hazard was

defined as long-term irreversible, stock impossible to remove and agreed that all releases should be minimised, supporting the justification for action on a EU-wide basis.

On classifications, RAC agreed with the proposal by Sweden to remove the existing specific concentration limits (SCLs, ranging from 3.1 % to 8.5 % w/w) from boric acid and several borate compounds and to assign the generic concentration limit (GCL) of 0.3 % instead, in order to ensure that mixtures and preparations are classified and labelled in line with the CLP Guidance. No specific note was added to the entry to consider the specific boric acid moiety that could be formed from the available boron calculated with reference to the total weight of the mixture. Finally, RAC agreed on a number of draft opinions on AfAs (more information: Vanessa Viegas, Sylvia Jacobi, Roger Doome and Violaine Verougstraete).

#### **SEAC-44: granules, microplastics and cobalt salts...**

SEAC adopted its opinion on granules and mulches (used as infill material in synthetic turf pitches or in loose forms on playgrounds) and agreed on a draft opinion in support of the DMF restriction proposal, concluding that it is the most appropriate EU-wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its costs. On the cobalt salts, SEAC indicated that they need more information on the cost estimates as they consider that there are uncertainties in both the dossier submitter and industry's estimates. SEAC is not clear yet whether the proposed option RO1a (10 µg Co/m<sup>3</sup>) is proportionate but noted that it provides a lower level of protection for workers than the other options assessed. RO1b (1 µg Co/m<sup>3</sup>) was considered as likely not being proportionate from a cost-benefit perspective. SEAC will agree on the 4<sup>th</sup> draft opinion at the next plenary meeting (end November) and the final RAC-SEAC opinion should be adopted in March 2020. On microplastics, the SEAC discussion focused on the Union-wide basis and EU-wide measure (scope & updates), costs, benefits, practicality and monitorability. A detailed cost-benefit analysis was presented for the cosmetics and the detergents and maintenance products sectors. The Rapporteurs will analyse additional sectors for the next meeting and consider the numerous comments submitted in the first Public Consultation. SEAC also agreed on 18 draft opinions on the AfA referring to the uses of chromium (VI) substances, coal tar pitch, high temperature and octyl- and nonylphenol ethoxylates (more information: Rohit Mistry and Violaine Verougstraete).

#### **MB-55: ECHAs workplan for 2021 and orientation debate held on 25-26 September**

ECHA substantially modified its workplan for 2021 to address both new REACH and non-REACH REFIT concerns. Key proposals made to the Management Board on REACH included for example the assessment of chemicals by groups of substances including for Restriction and Authorisation and the 4-fold increase of the number of compliance checks, so as to have 20-30% of the > 100 tons substances being evaluated by the end of 2022. Despite the high workload, ECHA proposed to maintain the high level of activities on Restrictions and Authorisations, including on substitution. Searching for new areas for SVHC substances and an efficient and consistent screening of all substances to evaluate they were properly assessed for Endocrine Disruptor concerns was also part of the proposed programme. The MB insisted on a strengthened and streamlined cooperation of ECHA with the national enforcement authorities, to minimise differences and enhance REACH implementation. All these points were expected. On the other hand, the non-REACH REFIT recommendations that ECHA proposes to include in the workplan came as a positive surprise as they referred to the attention to be paid to Circular Economy and Climate aims in order to achieve a more sustainable chemicals management. Cross links with other policy areas like the Water Framework and the Industrial Emission Directives were also mentioned. We have not yet received the formal outcome of the MB discussion but expect that the MB agreed with the directions suggested by ECHA. It is expected that a Public Consultation on ECHA's 2020-2023 workplan will soon be launched (more information: Hugo Waeterschoot).

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## **COMMISSION REACH & CLP Activities: hot topics/issues**

### **CARACAL**

#### **CARACAL-31: first CARACAL-CLP meeting under the new Delegated acts procedure:**

The Lisbon Treaty has assigned more power to the European Commission which, as specified in Regulation 2019/1243, has now been delegated to adapt a number of legal acts including Annex VI of the CLP Regulation that establishes harmonised hazardous classifications. According to the new procedure, the vote in the REACH committee is no more required. Instead, the Commission is required to consult an expert group (i.e. CARACAL-CLP) before submitting a proposal to Parliament and Council for a 2-month scrutiny. Such a procedure is supposed to give more transparency to the overall process; all documents will be publicly available and, except when closed sessions are requested by Member States, observers will be able to follow all discussions. The agenda of the first CARACAL-CLP meeting included the 14<sup>th</sup> and 15<sup>th</sup> Adaptation to Technical Progress (ATP) of CLP Annex VI. On the 14<sup>th</sup> ATP, the main discussion was on TiO<sub>2</sub>. Even though many Member States continue to disagree with the proposed classification and the request from industry to conduct an impact assessment, the European Commission plans to proceed to classify TiO<sub>2</sub> as a suspected carcinogen (cat 2.) by inhalation. On cobalt, only one country

commented, requesting to follow RAC's opinion on the Specific Concentration Limit. However, it seems likely that the Commission will proceed with the proposed classification "Carc 1B" with the Generic Concentration Limit" (GCL). Eurometaux informed CARACAL that industry is investigating the possibility of conducting an oral carcinogenicity study to fill this 'knowledge gap' and asked the Commission to consider providing more guidance around the CLP regulatory text to reconsider the use of 'relevant data' such as epidemiology data, to allow the relevant routes of exposure to be reflected in the classification, rather than 'all routes' by default. On the 15<sup>th</sup> ATP, which covers substances for which RAC delivered an opinion in 2018, the major debate was on the lead environmental classification. Several Member States supported the concerns previously raised by EM/ILA and in particular: i) the need to split the powder/massive classifications, ii) the importance of following the EU guidance on metals classification, iii) the need to adopt a pH-banded approach and iv) the importance of waiting for the results of the ongoing snail test. Commission mentioned that they will consider the comments before putting forward the classification for lead metal as suggested by RAC. An update will be provided at the next CARACAL meeting scheduled on 6-7 November. The draft minutes of the CARACAL meeting will be circulated soon (more information: Lorenzo Zullo).

## REACH COMMITTEE

### **REACH Committee: target for registration dossier compliance check raised from 5 to 20%**

During the last REACH Committee meeting, Member States agreed unanimously to increase the compliance check target of registration dossiers in REACH from 5% to 20%. This decision is part of the [Evaluation Action Plan](#) developed by the EU Commission and ECHA as a consequence of the fact that, in general, about 1/3 of the dossiers checked so far by ECHA did not meet the requirements specified in REACH. Compliance checks will be comprehensive and evaluate the substance identity description, safety information related to human health and the environment. ECHA aims to check 20% of dossiers for substances registered in high volumes (> 100 tonnes per year) by 2022, complemented by 20% of dossiers for substances registered in lower volumes by 2027. This increased screening target together with the grouping approach that will be implemented means that most dossiers will be evaluated in the years to come. This decision further stresses the importance for companies to regularly review/update their registration dossiers. MISA anticipated this by promoting the updates through workplans so as to minimise the trigger for Compliance Checks (more information: Lorenzo Zullo and Hugo Waeterschoot).

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# EUROMETAUX CHEMICALS MANAGEMENT Activities

## Meetings and activities to respond to Chemicals Management challenges

### **Chemicals Management Steering Committee: 5 September**

The Steering Committee met for a lively meeting, starting with a review of the functioning of the department and groups (including the budget and projects for 2020), moving on to a brainstorming on how industry should (re)act towards the 2030 Chemicals Policy announced by Commission, the June Council conclusions on a Sustainable Chemicals Policy Strategy and the 'Zero-Pollution' concept promoted by Ursula von der Leyen. This was complemented by an update on the actions carried out by Eurometaux towards Parliament and Commission in follow-up of the elections and a discussion on the communication efforts that have been made to promote the consideration by regulators of the interaction between climate, circularity and chemicals management goals. An update on the IED Evaluation and Air Quality, on the waste database developed by ECHA and on the preparation of the Eurometaux General Assembly and Conference ("The global raw material race: Ensuring Europe can supply its climate transition" <https://eurometaux.eu/event-landing-page/>) on 17 October, was provided as well. Sandro Starita was nominated as co-chair of the Regulatory Forum, perfectly in time for the Chemicals Management week (see below). Draft minutes of the meeting -including a series of agreed actions- were circulated on 1 October (more information: Violaine Verougstraete).

### **Registration Taskforce Meeting (16 September): update of REACH Registration dossiers will keep us busy**

As part of the restructuring of the Eurometaux Chemicals Management Department, the former Taskforces on Exposure Scenarios and Data Sharing have now merged into the new Registration Maintenance Taskforce. The kick-off meeting, chaired by Caroline Braibant and Frank Van Assche, was held on 16 September. One of the hot topics of the meeting was the upcoming Implementing Regulation on the duty to update the REACH registration dossiers which, by setting very short timeframes for updating the registration dossiers, seems to omit a proper consideration of the complex reality of the joint submissions and the interconnection/interdependency between different parts of the registration dossiers. The taskforce

considered appropriate for Eurometaux to reiterate these concerns and evaluate possible cross-industry advocacy actions, also involving national authorities which might be consulted in the REACH Committee in Q1 2020. The agenda also included a discussion on the amendments of REACH Annexes that are intended to improve clarity and consistency of REACH information requirements (Annex VI to XI) and to define data needed to assess endocrine disrupting properties. The launch of two new dedicated CARACAL sub-groups was recently announced and Eurometaux asked for a seat. Regarding the nano-related amendments already introduced by the Commission Regulation (EU) 2018/1881, the deadline to comply with the new data requirements is the 1<sup>st</sup> of January 2020. Industry is concerned by this deadline as currently, there are only draft guidance documents available. The secretariat is planning to organise a workshop/webinar to share available information and experiences of consortia. The next meeting of the Registration taskforce will be organised in Q1-Q2 2020. Considering the number of topics on the agenda, an interim exchange via web-conference might be organised in Q4 2019 (more information: Caroline Braibant, Frank Van Assche and Lorenzo Zullo).

#### **Risk Management Taskforce Meeting (17 September): *agreement on how to progress on the I-RMO guidance and learnings from the cobalt salts' restriction case***

The Risk Management Taskforce agreed with the recommendations on how to update the Industry- Risk Management Option analysis guidance to also consider Circular Economy and other EU environmental policies in the assessment. Additionally, the members agreed to have two RMOas-levels: *a simple one* for anticipating upcoming regulatory RMOas and a *more integrated one* aiming for providing strategic guidance for companies on potential risk management. The RM Taskforce further agreed to launch a web-based version of the new guidance to facilitate its use. The second main theme of the meeting covered "*learnings from the Co-salts SEA case*". Eftec (Rohit Mistry), supporting the cobalt sector, presented the non-proportionality of the case, how they refined both the benefits and the costs aspects and the relevancy for considering alternative risk management Options (e.g. OEL) as more efficient. ILA provided an update on its advocacy strategy to prevent lead metal to further progress towards authorisation. It was agreed to continue promoting the update of the existing B-OEL for lead (driven by the 4 lead compounds considered for Annex XIV update), as a positive precedent for lead metal. The metals sector expects lead metal to be prioritised by MSC and ECHA as a substance candidate for Annex XIV listing Q1 2021. Also, Cd and CdO may be prioritised, with the first ECHA proposal being visible by early 2020. RoHS was discussed as well. The last main agenda item of this intense taskforce meeting related to the discussion, update and approval of "*the advocacy plan on the 10 recommendations of the metals sector for improving the risk management policy*". A revised version will be presented for written approval to the Chemicals Management Steering Committee while in parallel some communication actions will already be triggered (more information: France Capon and Hugo Waeterschoot).

## **Chemicals Management Autumn Week**

#### **Science Forum (23-24 September): *update on science-related issues and insights in new upcoming challenges***

The second meeting of the Science Forum was characterised by a broad and diverse agenda of metal science-related issues. The reporting on the bioelution activities, the disappointing outcomes of the Rapid Removal workshop held with RAC/MSA experts and on recent OSH-OEL activities triggered the attention of the participants. ECVAM's probable green light on the gastric bioelution test protocol and the supportive comments made by several Member States on the principle issues, associated with the proposed environmental classification for lead metal, were presented as the direct results of collaborative of Eurometaux and its members' persistent action. The case study on an elaborated "man via the environment scenario for Pb" provided an excellent benchmark for other metals on how EUSES can be updated making it relevant for metals. On IT-related aspects, Eurometaux informed the Science Forum on the latest progress with the Classification mapping tool, covering almost 60 downstream legislations that can be triggered by a harmonised classification. The update of the Multi-Metallic database, which is a critical information source for UVCB assessment, is progressing well and the sector may have a beta version available for the UVCB MISA workshop planned for 5 November. Two guest speakers also entertained the participants: Annamaria Carusi (Stonehaven Consulting), who explained what Adverse Outcomes Pathways are and are not before having a debate with the participants on their possible added value and Professor Ronny Blust (University of Antwerp) who explained how two new major scientific trends (Toxicogenetics and Endocrine Disruption) are developing fast and have the potential to affect the metals sector for Chemicals Management as well as other EHS areas like EQS setting. Finally the meeting also covered the forward looking agenda point on the upcoming "Zero-Pollution concept", explaining that materials flow and diffuse sources assessment as well as (bio)monitoring data could help demonstrating a "Risk Controlled use of metals and its compounds over the life cycle"(more information: Violaine Verougstraete & Hugo Waeterschoot).

#### **Regulatory Forum (25-26/9/2019): *taking stock of ongoing and emerging regulatory challenges***

The first day of the Regulatory Forum started with a presentation of a new tool developed by Eurometaux to help its members keep track of ongoing institutional activities (i.e. CARACAL, RAC, SEAC, MSC, etc..) and catch medium-term expectations in chemicals management. Participants then had the opportunity to follow an interesting panel discussion on the upcoming Implementing Regulation on dossier updates, which, as it stands now, includes unprecedented challenges for the consortia.

France Capon (EPMF Secretary General), Steven Van de Broeck (Cefic Director REACH & Chemicals Policy) and Sarah Hottenroth (Manager Regulatory Affairs at Umicore) explained their concerns and views in terms of implications for the industry and possible actions that can be taken to mitigate the impacts. Presentations and debates around the communication in the supply chain animated the afternoon session. Mari Järvikivi, product stewardship specialist at Norilsk Nickel, kindly provided an overview of the outcome of the second Workshop on REACH Review Action 3 "Improving the workability and quality of eSDS". The presentation on the ChemChain Project, a blockchain platform to track & trace chemicals along the value chain, raised particular interest; the discussion will proceed on possible pilot cases dealing with mass flow analysis and tracking/transfer of REACH Authorisation numbers. The first day also covered upcoming activities in CARACAL sub-groups mandated to amend REACH Annexes and the cross-industry activities on RoHS exemption methodology and legislative review. The day ended with a presentation given by the secretariat on "How to prepare for impact assessments for future broad classifications?"

The second day was split in three major topics: the future von der Leyen Commission's environmental programme, the Industrial Emissions Directive and Water related regulation. The future EU Chemicals Policy will go towards "a Zero-Pollution" environment – being a young, yet non-developed term, Eurometaux aims to contribute to the discussion at an early stage. This is grounded on building up Eurometaux's status as a constructive stakeholder. A second panel with a representative from the Environmental Department of the Flemish Government (Tom Boonen). BusinessEurope's spokesperson (Eva Blixt) and the European Environmental Bureau (Christian Schaible) focused on the ongoing IED Evaluation. The discussion showed that the different stakeholders agree that the IED text is robust, however the implementation, especially when it comes to the Seville process, needs further improvement. The improvement measures caused an (amicable) divergence of views between the panelists – e.g. the EEB representative underlined the need for a more integrated energy policy in the IED. Tom Boonen explained that the Member States requested that new practices of the BREF processes should be updated in the Guidance document. While Eva Blixt underlined the need to ensure that the given BREF guidance is respected. Afterwards, guest speaker Lighea Speziale (CEWEP) presented ongoing efforts by the Waste-to-Energy industry to inform those who release permits about the problem with measurement uncertainty that exceeds given BAT-AELs ranges. A technical issue which has been worsened by using different calibration methods and thus causing non-compliance with emission regulation. The Forum's discussions were finalised by the overviews of the Water Directives' REFIT activities, USEtox projects by Chris Cooper (IZA) and activities on the support of the implementation of bioavailability-based metal EQS by Chris Schlekot (NiPERA). The latter pointed out the importance of technical workshops with the regional authorities of Member States to give them better access to the use of the bio-met tool and calculation of natural background concentration. All in all, a successful forum with several guests who enjoyed participating in the Chemicals Management Autumn week (more information Nathalie Kinga Kowalski and Lorenzo Zullo).

## Classification

### **The environmental classification of lead metal: *Eurometaux provided support on Commission's and Member States' advocacy***

Eurometaux actively supported the advocacy activities on the proposed environmental classification for lead metal, which is currently under discussion at Commission and in CARACAL. The main reason is that the challenges raised by the proposal are ones of principle, hence applicable to all metals with ecotoxic ions. More precisely, the lack of a split in the classification of the massive and powder forms, the non-application of the metals CLP guidance and last but not least, the use of non-standardised test, all not in line with the existing metals classification system. Eurometaux and ILA produced advocacy material aiming at convincing the Commission to wait for relevant new evidence that could demonstrate that the RAC's assessment was not appropriate. Eurometaux and ILA further asked to redraw the classification proposal as it stands from the draft 15<sup>th</sup> ATP to prevent extensive costs and damage to the metals and alloys sectors at large, until the case has been reviewed. Given the importance and urgency Eurometaux also supported ILA in national advocacy activities. ILA, Eurometaux and its members were therefore pleased to note that several Member States picked up the concerns of the metal sector on the proposed classification, commenting either verbally at the CARACAL meeting mid-September (see hereabove) or in writing (more information: Steve Binks, Jasim Chowdhury and Hugo Waeterschoot).

### **Cobalt CLH taskforce: *a call, advocacy and the CARACAL CLP outcomes***

The Cobalt CLH Taskforce had a call on 4 September to catch up on the activities of the Expert Group set up by ECHA/Commission that will assess whether the current CLP methodology to derive "potency" (and thus define the SCLs) presents applicability issues when it comes to inorganics/inhalation carcinogens. This expert group, which includes RAC members, Member States experts, industry representatives and two consultants, had the opportunity to comment on the current approach and propose changes, to be discussed in a webinar held on 23 September. The Taskforce was also updated on bioelution activities (see below) and discussed how to best organise outreach to the Member States before the CARACAL CLP meeting of 18 September. A Briefing Document re-iterating the sector's requests and suggesting adding some details as footnotes to the ATP was circulated to the advocacy teams. Key points in this note include: a) the support of the sector for

the replacement of the SCL by the GCL, b) the request to consider bioavailability for cobalt contained in matrix form and the request for further reflection on how to resolve the (regulatory) defaulting to the 'all routes' notation when the risk from routes other than inhalation is not relevant to workplace chemicals. The latter issue is relevant for all substances that do not have the demonstration at hand to prove that they do not constitute a hazard by the oral and dermal route at the time of the classification. Eurometaux made a statement on this issue at CARACAL, requesting that the EU consider providing more guidance around the CLP regulatory text to reconsider the use of 'relevant data' such as epidemiology data, to allow the relevant routes of exposure to be reflected in the classification, rather than 'by default'. The Member States, except France, did not comment on the cobalt classification during the CARACAL meeting. the 14<sup>th</sup> ATP, including the cobalt metal entry as Carcinogen 1B all routes, Muta 2 and Repro 1B will now undergo scrutiny by the European Parliament and the Council before being published. This was the last Taskforce call led by Brigitte Amoruso, who we would like to thank for all her energy and devotion to this complex dossier! (more information: Adam Mc Carthy, Ruth Danzeisen, Hugo Waeterschoot, Lorenzo Zullo and Violaine Verougstraete)

## Metal-specific REACH application tools and concepts

### **Bioelution: industry submitted a new package of information**

Industry has submitted a new package of information to address the questions posed by the ECVAM experts on the gastric bioelution test protocol. This package included replies to the experts' questions (including on the composition of the gastric fluid), a summary of additional tests carried out over summer, the design for a repository and a revised SOP. The experts' group discussed this submission on 25-26 September, with industry being invited for a 2-hour webinars to provide further explanations and address possible pending questions. A number of actions -including carrying out some additional tests- were identified along this call and should be carried out before the protocol can be submitted to the OECD (deadline 15 November). The experts are indeed trying to identify all possible uncertainties before the project is discussed by the OECD Testing Guidelines Group to give it a maximal chance to pass through (more information: Adriana Oller and Violaine Verougstraete).

## Metals Sectorial Approach

### **MISA organisation: meeting with ECHA on 3 September**

ECHA and Eurometaux spent one day in Helsinki to discuss the organisation of the upcoming MISA activities, namely the UVCB workshop to be held on 5 November and the Exposure-related activities that should lead to a workshop in February-March 2020. This was also an opportunity to debrief on the webinar held on 30 August with the MISA community, to discuss the KPIs to be used by ECHA in communication with the Commission and Member States and the reporting to RIME and CARACAL (mid-October and early November). Part of the discussion also addressed how to best support the MISA consortia/associations with their planned updates (in addition to the manual compliance check issues). It was agreed to explore the possibilities to have a MISA 1-2 taking-stock support workshop early 2020. The aim would be to evaluate progress made with the updates, the alignment with metals guidance and learnings from environmental information requirements & classification/human health information requirements/compliance checks reviews. More information will be circulated soon, as well as on the Exposure & Supply-Chain communication activities. Finally, the Rapid Removal issue was discussed with an exchange of views and what could/will be the next steps. In follow-up of the meeting with ECHA, the updated sectorial rolling action plan and the KPI template were circulated to the MISA community for last comments before publication (more information: Hugo Waeterschoot, Federica Iaccino and Violaine Verougstraete).

### **MISA UVCB Workshop: preparation meeting with ECHA**

The 3<sup>rd</sup> MISA workshop on inorganic UVCB (iUVCB) assessment is planned for 5 November in Brussels. During the month of September, several exchanges were held with ECHA to prepare at best for the workshop. The goal of the workshop is to provide participants with clear guidelines on "how to prepare the REACH iUVCB Dossiers, from SID to Risk Assessment demonstrating safe use". Eurometaux shared with ECHA the intention to use this day to clarify how to define and report SID in a joint submission, how to perform classification and hazard assessment, how to run the combined toxicity assessment, how to demonstrate safe use AND how to report the entire assessment in the dossier (IUCLID/CSR). In the meantime, parallel discussions are ongoing between EM and ECHA about the IUCLID reporting issues for iUVCB dossiers (i.e. iUVCB constituents' assessment is performed accessing constituents' effects' assessment summary data and not importing all their robust study summaries). The IUCLID 6 dossier of a test case provided by EPMF has been shared with ECHA, together with an explanatory presentation to guide the regulators through this practical example. Eurometaux expects to discuss the IUCLID reporting during the first weeks of October and to agree with ECHA on a workable solution, so that the iUVCB workshop will focus more on the assessment strategy for iUVCB (i.e. via the presentation of the EPMF test case) and only partially on the reporting. The agenda and further information on the workshop will follow in October (more information: Federica Iaccino).

## Industrial Emissions

### **Industrial Emissions Directive: Evaluation process**

Over the summer, the Commission opened the public and targeted consultation in regards of the ongoing IED Evaluation and beginning of the month, Eurometaux submitted its contribution. The public consultation only aimed for a very broad understanding, unlike the targeted consultation which included over 52 specific questions. Eurometaux added a statement paper where it was highlighted that the IED as such is seen as a successful regulation which continuously contributes to industry's improvement of the environmental performance. It is also pointed out that the implementation lacks some efficiency and consistency: e.g. the integrated approach needs to be well considered when discussing BATs, high-quality data is needed to develop robust BAT-AELs, hence, the methodology to do so needs to be defined. Furthermore, it was stressed that the IED can contribute but shall not be misused for the achievement for other overall environmental goals, as Energy or Circular Economy policies. Requests to the contractor Ricardo to schedule an interview have been not approved till date. The next stakeholder meeting on the IED Evaluation was confirmed for the 17<sup>th</sup> December 2019 (more information: Nathalie Kinga Kowalski).

### **Smitheries & Foundries BREF: Kick-off-Meeting - 17-21 September**

A bit shorter, but definitely not less intense, the week spent in Seville. Eurometaux, represented by Nathalie K. Kowalski and Eva Tormo from European Aluminium, participated in the Kick-Off Meeting of the review process of the Smitheries and Foundries BREF to ensure a solid scoping where activities of the NFM BREF are clearly excluded. The confusion was caused as a member of European Aluminium was approached by a Member State for their current permit under SF BREF. Reading the background paper, it showed that in the reference to IED Annex I 2.5 b it was not made clear enough which processes would be included under SF BREF. We succeeded in obtaining a clearer border line and during the meeting it was also interesting to observe the KEI decision process. Most importantly it became clear that the EIPPC Bureau strongly supports the inclusion of energy consumption BAT-AEPLs – a highly controversial approach to address energy efficiency in the BREF process (more information: Nathalie Kinga Kowalski).

## Nanos

The European Commission announced on 3 December 2018, that it adopted amendments to several REACH Annexes to clarify the information requirements for nanomaterials. The amended requirements will apply beginning 1 January 2020. On 12 November 2019, the European Chemicals Agency (ECHA) will hold a webinar on the amended information requirements for nanoforms under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation. ECHA states that the updated Annexes introduce new concepts: nanoform and a set of similar nanoforms. The updated REACH Annex VI also defines specific characterisation parameters for the nanoforms of substances. The first part of the 12 November webinar will explain what a nanoform is and how to build a set of similar nanoforms. It will also explain how to fulfil data requirements for the characterisation of nanoforms. The second part will introduce new International Uniform Chemical Information Database (IUCLID) fields for reporting the characterisation parameters of nanoforms and give some practical examples on how to use the different fields. Attendees will also have the chance to ask questions to ECHA's experts (more information: Christine Spirlet, Federica Iaccino and Lorenzo Zullo).

## Others

### **RoHS: new consultation launched**

A new stakeholder consultation has been launched by Öko-Institut as part of the "Study for the review of the list of restricted substances and to assess a new exemption request under Directive 2011/65/EU (RoHS 2) – Pack 15". This consultation is related to the [Substance Review](#) and the [Substance Inventory](#) parts of the study. For the [Substance Review](#), 7 substances are to be assessed in the course of the study with a view on the review and amendment of the RoHS Annex II list of restricted substances. The current consultation aims at collecting comments on four of the seven substances that have been assessed: Indium phosphide, Beryllium and its compounds, Nickel sulphate and nickel sulfamate and Cobalt dichloride and cobalt sulphate. A consultation on the remaining three substances shall be launched in the fourth quarter of 2019. With regard to the [Substance Inventory](#), the revised inventory is being consulted with as aim to collect information for its updating and for the final determination of the substances to be subjected to the prioritisation review. The consultation is online and shall be held for six weeks from today 26 September 2019 and until 07 November 2019 (<https://rohs.exemptions.oeko.info/index.php?id=331>). Non-confidential information submitted during the consultation will be posted on the [EU CIRCABC website](#). The "Revised Manual Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II) under the RoHS 2 Directive" has also been published online and can be viewed here:

[https://rohs.exemptions.oeko.info/fileadmin/user\\_upload/RoHS\\_Pack\\_15/4th\\_Consultation/Pack\\_15\\_Substance\\_Review\\_Draft\\_Manual\\_Methodology\\_second\\_version\\_20190926.pdf](https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation/Pack_15_Substance_Review_Draft_Manual_Methodology_second_version_20190926.pdf).

Please note as well, the still ongoing consultation on the RoHS Evaluation (deadline 6 December), available here: [https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2018-3106007/public-consultation\\_en](https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2018-3106007/public-consultation_en)

As agreed during the Risk Management Taskforce, Eurometaux will prepare a draft response that will be circulated for comments in the coming weeks (more information: Caroline Braibant and Hugo Waeterschoot).

#### **Re-authorisation of chromates for the Aerospace and Defence (A&D) Sector: *managing business risks***

Critical uses of eight chromates throughout the entire A&D supply chain are at risk, requiring REACH authorisation. This impacts all A&D actors from formulators to downstream users manufacturing chromate-containing parts or components to OEMs to all airline and defence MRO operations. The Aerospace and Defence Chromates Reauthorisation (ADCR) consortium was formally launched in Brussels on 20 September 2019. The ADCR REACH chromates re-authorisations will be developed specifically for and by the A&D sector and all A&D stakeholders throughout the supply chain are welcome to become members of the Consortium. UK authorisation post-Brexit is also included in the scope. Any A&D sector business needs to be actively involved in the ADCR, to make sure their uses are included. Conditions of use being imposed on current REACH Authorisation applications are far more limiting than originally expected. The involvement of all A&D sector users is vital to ensure their remaining uses, which must be narrower in scope, and will continue to be authorised (more information see: <https://www.adcr-consortium.eu> or contact: [ADCR-info@rpaltd.co.uk](mailto:ADCR-info@rpaltd.co.uk)).

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## **FURTHER OUTREACH OF REACH**

#### **REACH Conference: Slovakia, Bratislava, 5 & 6 September**

This annual non-commercial conference allows the sector to interact and communicate with regulators and companies of the Visegrad countries. Especially the panel sessions on learnings from the authorisation and restriction risk management schemes allowed extensive debate posing rather fundamental questions on how to improve their efficiency. On this Risk Management theme, Eurometaux presented its proposal for a more “sustainability”-focussed contribution when it comes to ECHA’s substitution policy, by balancing the risk management measures with Circular Economy and Climate objectives. On a panel debating restrictions, Eurometaux made a plea for fit-for-purpose restriction proposals that should always be risk-based and proportional in their application. This seminar allowed for several interesting contacts with country representatives of that region who showed an interest for metals (more information: Hugo Waeterschoot).

#### **NeRSAP: Sweden, 26 & 27 September**

The 9th session of the Network of REACH, Socio-economics and SEA Assessment Practitioners took place in Göteborg, Sweden. More than 50 consultants, ECHA, Commission and Industry experts met to exchange and learn from new cases and provide suggestions for smoother and better-quality Authorisation and Restrictions. The Netherlands presented the outcome of the CLEAR project that evaluated the need for and how impurities can best be managed. Paul Ylioja from Johnson Matthey presented the objectives and main improvements of the metals industry RMOa project which raised quite some attention from some SEAC members as well as from ECHA. It was in this respect suggested that the guidance should be presented to RIME as soon as the update to include Circular Economy objectives was concluded. The metals sector provided a second input, this time together with ECHA, on how the whole industry-ECHA interaction from PSIS over Public Consultation and Trialogues as well as substance specific seminars can be improved to identify the best quality application, eventual relevant substitution possibilities, or whether the use would fall out of the scope of the authorisation scheme. NeRSAP attendees presented several items, from substitution programmes, to OECD SEA support activities on willingness to pay and many other interesting issues for the metals sector. Really new were the multiple presentations on price-based instruments in the field of chemicals safety, a well-known technique in climate and some water emission control systems. The main outcomes of this NeRSAP meeting will be presented at the next Risk management Taskforce in December (more information: Hugo Waeterschoot).

# CALENDAR

- 21-25 October: MSC-66 – ECHA (Helsinki)
- 5 November: MISA UVCB Workshop (The Office; Brussels)
- 5 November: Enforcement Forum (Helsinki)
- 6-7 November: CARACAL-32 (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)
- 16 December: Risk Management Taskforce – MCC (Brussels)
- 17 December: Chemicals Management Steering Committee – MCC (Brussels)
- 16-17 December: MB-56 – ECHA (Helsinki)

# ACRONYMS

A&D: Aerospace & Defence	MB: Management Board
ADCR: Aerospace and Defence Chromates Reauthorisation	MISA: Metals and Inorganics Sectorial Approach
ATP: Adaptation to Technical Progress	MSC: Member States Committee (ECHA)
BAT: Best Available Technique	OEL: Occupational Exposure Limit
BAT-AEL: BAT-Associated Emission Level	OSH: Occupational Safety Health
BAT-AEPL: BAT-Associated Environmental Performance Level	PSIS: Pre-Submission Information Sessions (Authorisation Process)
BREF: Best available technology Reference document	RAC: Risk Assessment Committee
CLEAR Project: Project enabling Consumers to Learn about, Engage with and Adopt Renewable energy technologies	REFIT: Regulatory Fitness & Performance Programme (EU)
CLP: Classification, Labelling and Packaging Regulation	RIME: Risk Management Experts
CSR: Chemical Safety Report	RM: Risk Management
DMF: Dimethylformamide	RMM: Risk Management Measures
ECVAM: European Centre for the Validation of Alternative Testing Methods	RMOa: Risk Management Option analysis
eSDS: Extended Safety Data Sheets	RoHS: Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment
EQS: Environmental Quality Standards	SCL: Specific Concentration Limit
EUSES: European Union System for the Evaluation of Substances	SEA: Socio-Economic Assessment/Analysis
GCL: Generic Concentration Limit	SEAC: Socio-Economic Analysis Committee (ECHA)
IED: Industrial Emissions Directive	SF: Smitheries & Foundries
IUCLID: International Uniform Chemicals Information Database	SID: Substance Identification
iUVCB: inorganic Unknown or Variable Composition, Complex Reaction Products and Biological Materials	SOP: Standard Operating Procedure
KEI: Key Environmental Issues	USEtox: Scientific consensus model endorsed by the UNEP/SETAC Life Cycle Initiative for characterising human and ecotoxicological impacts of chemicals
KPI: Key Performance Indicators	UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials