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EUROMETAUX CHEMICALS MANAGEMENT NEWS



<u>ERRATUM</u>

Dear All,

We apologise for having – in our previous edition - wrongly located our dear fellow members of the Frits and Inorganic Pigments Consortia. They are based in **Castellón de la Plana**. So indeed Valencia, but the region and not the town.

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Dear all,

My youngest, who is studying to become a primary school teacher, returned from 24 hours of teaching in front of a class of kids she barely knew, with their "evaluation report". The children had been tasked to score her on a number of 'traits' and capacities, which included in the absolute top three of the "qualities to have" -after friendliness and interest -: 'a good sense of humour'. Being able to crack a joke -which was how the kids understood "sense of humour"- even overruled clarity of presentations and instructions. Surprising? Hardly, when considering that humour has been around for as long as there has been humanity (or even longer if you think about Judy in Daktari). Not really, when thinking that human beings typically search for pleasure and avoid pain. The pursuit of humour and pleasure influences many of our daily decisions from what we read or watch to the people we talk to (or not). Humour may thus be one of the most important qualities of all!

Humour is ubiquitous and impacts all life-stages, it appears to help people's psychological and physical well-being. Laughter has even been shown to have physical benefits, with positive effects on blood circulation, lungs and muscles (including those in the abdomen area). It is well known that funny people receive attention and admiration and that having a GSOH (good sense of humour) in your profile will influence who wants to date, mate or befriend you. Humour seems to boost creativity and can (often) smooth potential awkward social and cultural interactions. Humour may thus be one of the most (public health) topics of all!

Yet, the amount of research done on the topic is still too limited, as is also evident from the International Society for Humor Studies website (http://www.humorstudies.org/). Scientists always want to make sure their work is respectable, and to be doing research on humour is not seen as respectable enough. Still, researching how humour works ...or not, would deserve a bit of academic rigour. Because while successful humour leads to a myriad of benefits, a failed one can be destructive. If we can better figure out what makes things funny, we will end up far better equipped to handle it when we or our audience don't get the joke. Does this not make (non)sense?

Solet's start immediately: this edition of the News includes 5 attempts of joke. Did you spot them, did you laugh, or did we fail? Feedback welcomed at www.chemicals_management_with_a_laugh.eurometaux.

Violaine Verougstraete, Chemicals Management director Eurometaux

ECHA REACH & CLP Activities: hot topics

ECHA Committees

RAC-48-Week 1: increasing workload driving the dynamics

Important restriction cases were debated during the first week of RAC, i.e. on rubber crumb, Dimethylformamide and cobalt salts. As the number of restriction cases will further increase in 2019, ECHA and RAC members reflect about possible solutions to streamline the process. One proposal is that stakeholders will be strongly encouraged to send information and comments by month 4 of the Public Consultation (PC) to ensure they can be duly discussed in plenary. ECHA will further improve the guidance for the Public Consultation and provide some examples of accurate submissions. Also, the PC will be used to alleviate uncertainty and if there is no meaningful input, RAC will go for the more conservative approach. With regard to the restriction on cobalt salts, RAC focused primarily on hazard and exposure. Important was the discussion of a possible breakpoint in the dose-response (threshold) to be considered to base the hazard on rather than the default dose-response proposed by the Dossier Submitter (ECHA). Some RAC members acknowledged the conservatism of ECHA's approach and the likelihood of a threshold, but have not yet committed to any of the proposals made by the Rapporteur. On the other hand, agreement was reached that the lung tumour dose-response should not be extrapolated to systemic tumours, thus consistent with the RAC opinion of 2016. The discussion whether inhalable or respirable dust should be used will be finalised at the June meeting. Industry was asked to help identify the critical uses of the 5 Co salts (leading to the highest exposures and highest excess cancer risks?). The cobalt discussion was attended by Vanessa Viegas (CoRC/CI) and Sylvia Jacobi (on behalf of Catalysts Europe). The restriction on DMF proposes that manufacturers, importers and downstream users of the substance, used on its own or in mixtures, at a concentration equal or greater than 0.3%, shall use in their CSRs worker based harmonised DNELs for long-term inhalation and dermal exposure. RAC discussed among others the aspects of biomonitoring, the starting point for the derivation of the DNELs and the representativity of the exposure data. Here as well, it was mentioned that the PC should provide further data to address the pending questions. A significant increase in workload is also expected on

Authorisation. In addition to extending the 4 RAC meetings/year to two weeks each, a working group will be set up and meet in between two meetings to support the Rapporteurs. A first meeting will take place mid-April. This working group will function like RAC with the same access for regular stakeholders. A short update was also provided on the ECHA Guidance Appendix to R.8-17 'Guidance for proposing Occupational Exposure Limits'. Industry, including Eurometaux and its members, have submitted comments on the draft earlier this year after the PEG meeting. The draft is now going for RAC consultation for 4 weeks and CARACAL will be consulted in June/July. It is expected that ECHA will publish the finalised guidance by August/September 2019, in time for the first discussions on the Pb and diisocyanates OELs that will be developed by RAC. In this context, some SCOEL members have now been nominated as co-opted RAC members. ECHA should also launch a call for evidence on the Pb OEL (scientific aspects/data) in the coming weeks (more information: Violaine Verougstraete).

RAC-48-Week 2: quick discussions on Cu & Ni compounds with different outcomes

RAC debated 2 classification and labelling dossiers of interest for the metals sector. The first on previously classified copper compounds considered the consequences of the recently defined Chronic Ecotoxicity Reference Value (ERV) for Copper granulates on the M-factor setting for those compounds. While the proposal from the rapporteurs was to a great extent in line with industry's views of, industry regretted that a non-normalised ERV was used as a reference for this assessment. Industry considers this as a non-optimal use of the extensive database on copper. Most importantly the case proves that recent classification for the environment may impact previous compounds for the same element. The second case related to the acute classification of trinickel subsulfide based on an Annex XV submitted by industry. RAC disagreed with the proposal for an acute category 4 and suggested a category 3 based on a different interpretation of the data set. RAC concluded that the female rats in the key study were more sensitive, while the variability of the sensitivity of these data was within the boundaries of the one of the males. Moreover, RAC used some sub-chronic evidence to support this. Industry was surprised about this way of interpreting data which they felt was not in line with the guidance (more information: Mike Taylor, Carol Mackie and Hugo Waeterschoot).

SEAC-42: focus on restrictions including cobalt salts

As for RAC, the scheduled agenda for the last half of 2019 and further years to come will increase significantly, mainly due to new and returning (expired) authorisation applications and a tripling of the number of restrictions. SEAC debated how they could become more streamlined and efficient to manage this workload. A first content discussion took place on the restriction proposal on the 5 cobalt salts. The debate remained limited to a detailed explanation of the proposal and identification of key issues. The new concepts based on Reference Exposure Values and "risk equity" raised many questions but the meeting did not discuss their relevancy at this stage. One of the reasons is that SEAC begins its cost/benefit impact assessment based on the RAC toxicity impact. RAC may still change the latter significantly. The Rapporteur further indicated that they recently received significant contributions from industry and indicated they would review and consider them for the 2nd draft opinion. A second large restriction proposal that drew lots of attention was the proposed restriction on microplastics. The case is large and may have a price ticket of close to 10 bio ϵ /y. SEAC concluded the completeness check, meaning that a public consultation for 6 months will be opened soon, and the Rapporteur can start drafting a first opinion (more information: Hugo Waeterschoot).

SEAC and RAC: the European Court annulled a granted authorisation case, T-837/16 Sweden versus Commission

A last point of attention of relevance for both RAC and SEAC, was the outcome of the recent European Court case on Lead chromates whereby the court annulled, for the first time, a granted authorisation. The main argument was that *the Commission had not checked if the RAC/SEAC opinion was still relevant* after new information on the Alternatives became available. The court felt it was the duty of the Commission to do so. Moreover, the court concluded that conditions and the length of the review period may not be used to mitigate for shortcomings of the application. The case raised extensive debate in RAC and especially SEAC on the required motivation on the assessment of alternatives and how to ensure this information remains updated during the opinion forming. This clearly has a direct impact on the applicant given its users see their granted use annulled. Moreover, the case sets a precedent demonstrating that a granted authorisation can be challenged in court and a follow-up of the AoA, beyond the submission date, may be needed by the applicant (more information: Kai -Sebastian Melzer and Hugo Waeterschoot).

Management Board-53: a new representative for industry and an agenda focussed on the BoA activities and increasing the number of compliance check evaluations

So far Peter Smith (Cefic) represented industry in the ECHA Management Board. Peter left Cefic and Marco Mensink (Director General of Cefic) will, in agreement with Eurometaux, replace him for the remaining part of his mandate. The main agenda items of the MB-53 were the approval of the 2018 ECHA general report, the review on the BoA activities and the increase in evaluation activity. The 2018 report informs about the achievements in 2018 using objective performance indicators. The report also includes the updated *vision and mission of ECHA* whereby the science-hub role is replaced by a contribution to a sustainable chemicals management in the EU! The report is much crispier in its format and includes for the first time some cross-links between REACH and other EU policies like the Circular Economy and Waste. While industry appreciates this

broadening attention, we were surprised that the report does not refer to any of the sectorial approaches such as MISA; a point that Cefic will raise at the MB meeting. Eurometaux will circulate the report as soon as it becomes formally available. The second main item related to the report given by the BoA chairperson who reached the end of her term. The MB appreciated the BoA's excellent track record, whereby it has demonstrated its value in the correct implementation of the REACH regulation, by providing legal certainty for REACH actors and consistent approaches to the most difficult aspects of REACH. Stakeholders recognise the importance of BoA's work for the regulatory system but all confirmed that the BoA can be a vulnerable body. The BoA chair therefore requested that the MB and Commission ensure the stability and autonomy of the BoA by appointing a new chairperson as soon as possible. Thirdly and most importantly is the MB's agreement to boost the evaluation activities of the agency more than 4-fold, aiming for assessing 30 to 40 % of all dossiers in the years to come. The MB agreed to re-allocate the resources to the evaluation unit to support this primary goal for at least the next two years. This will clearly impact other ECHA activities. Eurometaux requested Cefic to raise attention for the sectorial approaches given one of their aims is to improve the dossiers and hence decrease the need for evaluations (more information: Guy Thiran and Hugo Waeterschoot).

CoRAP: Member States will evaluate 31 substances in 2019 while Consortia will be informed on the draft decision on the 2018 substance Evaluations on the 18th of April

At the start of the spring, ECHA published the updated Community Rolling Action Plan (CoRAP) 2019-2021 for substance evaluation, with a 100 substances listed to be evaluated in 2019-2021. Besides the introduction of a limited number of new substances, Member States postponed a long series of substances on the previous list including Cr₃+ by France, mostly with one year's delay to take care of the outcome of the parallel running Compliance Checks on the other endpoints than are being covered by the Substance Evaluations. The new list News release | 2019-2021 CoRAP list contains no new metal substances which may probably be one of the side effects of MISA. ECHA also informed Eurometaux recently on the release date for the Substance Evaluations conducted in 2018. By 18 April, ECHA will mail out the draft decisions for those substance evaluations which include the antimony compounds. Industry has subsequently 30 days to provide ECHA with a coordinated review and response allowing the evaluating Member States to prepare a decision to be reviewed by the MSCAs. (more information: Hugo Waeterschoot).

COMMISSION REACH & CLP Activities: hot topics/issues

CARACAL

CARACAL REACH session: REACH Review ongoing - Implementing Acts and enhanced institutional and regulatory synergies on the table

The REACH session of CARACAL was held on 19 March. The REACH Review remains an important topic in the agenda. With regards to Action 3 on "extended SDS", Commission indicated that they need more time to digest the outcome of the 18/3 workshop which included discussions on minimum requirements for ES and methods for communicating information on mixtures. Commission is planning to circulate an interim report ahead of the next CARACAL meeting (July) and to organise another workshop in September.

On Actions 8-9, related to the restriction procedure and related public consultation process, feedback from the dedicated Restriction Taskforce was provided. They have organised so far two meetings to discuss the cooperation with MSs to define how to report information on risks when preparing a restriction proposal, how to conduct socio-economic analysis and possible ways to simplify the overall procedure. This should result in an ECHA good-practice paper which could also explain how to best deal with restrictions for industrial and professional uses. Commission suggested that stakeholders should submit comments at early stages of the consultation process to ensure that authorities have more time to analyse them; such a proposal was not fully supported since industry also needs proper time to prepare its input and all comments submitted before the deadlines should be equally treated.

Another topic discussed was on how to deal with changes in authorisation conditions (e.g. volumes and uses). It was clarified that enforcement authorities shall verify that the authorisation conditions are fulfilled and, if necessary, the authorisation holder must submit a review report. The Commission also announced the discontinuation of the preparation of the nickel guideline due to significant diverging views regarding which articles shall be in or out of the scope of the restriction. Instead, Commission asked ECHA to prepare a REACH Annex XV dossier to review the restriction and to evaluate whether it is necessary to modify the reference to prolonged/repetitive contact; an Annex XV dossier is expected in 2020. The head of the cleaning department concluded the meeting by announcing the new dressing code rules: future meetings will be held without shoes to help maintain the premises clean. Eurometaux thinks it is a great idea and will think of also implementing it in its new premises. The minutes of this CARACAL meeting will be circulated soon (more information: Lorenzo Zullo).

CARACAL CLP session: lead metal, granulated copper and bioelution

The CLP session of CARACAL's agenda was held on 20 March. The update of the ATPs to CLP was a particularly important topic for Eurometaux. The Commission presented an overview of the opinion delivered by RAC in 2018, containing a classification proposal for lead metal and granulated copper.

On lead metal, Eurometaux reiterated its concerns regarding the inconsistency of the environmental classification proposal with recommendations and common practices for data-rich substances, the CLP guidance for metals and the recent metal cases discussed in RAC. Specifically: i) despite the fact that the registration dossier contains good quality data to prove different releases and dual classification entries for powder and massive forms, such data was not used, ii) the benefits of having large data sets have been ignored/discarded by using the lowest toxicity value instead of a weight-of-evidence approach for data treatment of a data-rich substance for ERV derivation, and iii) the opinion for lead is not consistent with how other metals were classified in the EU and how the GHS criteria are applied outside the EU. Whilst not directly relevant to CLP classification, Eurometaux underlined that the impact on downstream user legislation would be very considerable given the classification cut-off for mixtures in the massive form, such as alloys for example, would be as low as 0.025%. This is close to background values in main metal streams, hampering the recycling but also making the use of millions of tons of metal slags in safe building applications close to impossible. Moreover, the lack of a split entry between powder and massive, will unnecessarily bring many metal processing and using sites into the SEVESO. Eurometaux invited the European Commission and CARACAL members to read carefully Eurometaux's position paper, submitted as follow up to the meeting. Concerning granulated copper, at the previous meeting Sweden challenged the RAC proposal, which in line with the classification assigned in the framework of the Biocidal Product Regulation, suggested to assign three different hazard classifications to granulated copper depending on the physical form. Eurometaux supported the need to remain consistent with the BPR and indicated that, being a political rather than technical issue, a legal opinion should be requested before any amendment is proposed. Furthermore, it also pointed out that there are additional cases for which the concept of classification splitting might not be limited to massive/powder (e.g. nano-forms) and that more reflection on the subject might be needed in the future. Eurometaux will keep monitoring the follow-up comments to understand the position of MSs on these topics. More information on how Commission is planning to proceed with the 2018 RAC opinions might be provided at

the next meeting that will be held in July 2019.

Regarding the **bioelution method**, Commission explained that the European Centre for the Validation of Alternative Testing Methods (ECVAM) is planning to meet at the beginning of May and a final opinion is expected in June. If ECVAM validate the method, more discussions will be needed on how it might be used in CLP (more information: Lorenzo Zullo).

OTHERS

REACH Committee: 14th ATP does not progress

The REACH Committee met on 7 -8 March and re-discussed the Draft ATP (Adaptation to Technical Progress) to the CLP that includes among others the entries for cobalt metal (CMR with a temporary Generic Concentration Limit of 0.1%) and the classification of TiO2 as carcinogen by inhalation. Again no agreement could be found. A new attempt to get the ATP through will take place at the next REACH Committee, scheduled for 11-12 April. Also the international community is following closely the activities around this ATP: in comments to the WTO, the US, concerned that products containing the substance (e.g. paints, cosmetics and plastics) will have to be reformulated or labelled as containing a carcinogen, called for a clarification on why titanium dioxide, which is labelled as 'low toxicity' in RAC's opinion, was classified as a category 2 carcinogen. The US also commented on the proposed cobalt classification, mainly because of the possible impacts on the US exports of medical products and food processing equipment to the EU, since stainless steel may contain 2-3% cobalt (more information: Hugo Waeterschoot and Violaine Verougstraete).

REACH-Committee: approval of CTAC application and debate on next (Annex XIV) authorisation list

The REACH Committee agreed to grant the upstream CTAC application on several chromates uses, several years after the sunset date (SSD) for the chemical. To compensate for the large uncertainties caused by the upstream and broad nature of the application, the granting was restricted to short review periods and a long series of conditions. It is expected that the tough and expensive conditions will encourage downstream user groups of the chemical to apply for a use-specific application. While this case demonstrates that upstream applications are "feasible" it also demonstrates that a more refined split of uses would a better way forward. This may be further stimulated by the recently launched debate in the European Parliament challenging the granted application for sodium chromates. The REACH Committee also agreed on a proposal for the next Annex XIV. The proposed list contains 2 perborates whose uses are close to elimination, but more importantly it proposed to handle the risk management of the 4 listed lead compounds used in lead-batteries to the development of an updated binding-OEL in line with industry's request. It is expected that the list will be supported by an absolute majority of Member States (more information: Hugo Waeterschoot)

Classification of silver nitrate: discussing regulatory efficiency with the EU Commission

On 13 March, Industry met representatives from the Commission (DG ENVI, DG Santé, DG Grow) to discuss their concerns on ongoing processes in the REACH/CLP and BPR areas and the overlap between a classification proposal submitted by Sweden and a testing proposal evaluated under REACH applicable to the same silver compound. In a nutshell, industry identified a data gap on reprotoxicity and in 2015 submitted a Testing Proposal (TP) for an EOGRTS (OECD TG 443). This TP was then updated in 2018 to reflect the latest scientific information available and include the DIT cohort. Industry proposed to use silver acetate as test substance and that the outcome of the study would then be applicable to all silver compounds, as effects are assumed to be associated with the silver ion. ECHA's draft decision on the TP was received in December and so far, ECHA accepted the test design/test substance meaning that the TP is now going through the next steps of the process. The results should become available in 2021. However, without waiting for the outcomes of the testing. Sweden proposes to classify silver nitrate toxic for reproduction category 1B, raising questions about the relevance of the testing. Commission agreed to further discuss this with ECHA but asked industry to clarify in a table format what would be the added value of the EOGRTS vs. existing data used by Sweden. This table has now been submitted to Commission and it is hoped that a way forward can be found to ensure that the test results will be considered by authorities (more information: France Capon, Katrien Arijs and Violaine Verougstraete).

EUROMETAUX CHEMICALS MANAGEMENT Activities

Resource mapping to respond to Chemicals Management challenges

UPDATE distribution lists of the different Eurometaux groups: thanks for completing the survey

In view of the new Chemicals Management structure and in order to update our Chemicals Management Department's mailing lists, we would like to remind you to provide us, **before 15 April 2019**, by following this link: <u>https://www.research.net/r/872PWRG</u> with the names/e-mails of those you wish to be included in the distribution lists of the different CM groups .

- This survey should be filled in by:
- •Eurometaux Company Members
- •Eurometaux Commodities
- •Eurometaux National Federations
- •Eurometaux Associate Members

•For the consortia who are now Eurometaux Associate Members, may we please ask the secretariats to nominate their representatives in the taskforces/committees? Experts from companies that are not direct members of Eurometaux, but members of the consortium should be nominated by their secretariat.

We remain at your disposal for any further information (more information: Ailsa Lee and Sofiana Dokou).

Chemicals Management Steering Committee meeting: 4 meetings/year to discuss coherence and steering

The Steering Committee, which exerts an umbrella function in the new Chemicals Management department by steering the functioning of the department and making the links with the Eurometaux statutory bodies and the other Eurometaux departments met on 15 March. The agenda included topics like the presentation of the Roadmap that explains the new structure and the related activities, the preparation of the Executive Committee that will take place in Helsinki on 3-4 April, but also provided some updates on key developments on Industrial Emissions & Air Quality, Water and the Chemicals/Products/Waste issues. Maika Fohrenbach (AMCHAM) kindly participated in the meeting to present their outreach strategy and how it is prepared and implemented. Her presentation was an additional input in the key debate that marked the day: how to best/better communicate on chemicals management and avoid the feeling that it is a 'black box'? The upcoming EU elections and the reference to the UNEP and OECD Global material resources outlook documents were also discussed in the context of a disconnect between EU policies on decarbonisation (without CO₂ emissions), Circular Economy (without waste) and Chemicals Management (without hazardous substances). We will need to show (non-defensively) that all three objectives will hardly be achieved together without trade-offs. The draft minutes will be circulated to the Committee members. Please note that this Committee is composed of all the Chairs of all the Chemicals Management groups (Committee, Forums, Taskforces) + 1 representative per member (companies, commodities, associate members, national federations) that does not hold a chairmanship (see also update distribution lists above) (more information: Veronique Steukers and Violaine Verougstraete).

Chemicals Management: Science Forum: a first successful meeting

The Science Forum met for the first time in its new format on the 25-26 March. The scene was set by reminding participants that the forum meetings aim at providing information and favour discussions so as to ensure capacity building of the members. Both the environment and human health technical sessions were structured to look at the learnings from the past and dossiers from the present in order to prepare the future. The environmental part of the session focussed on the classification experience with lead metal, drawing learning lessons for other metals that classify massive metal differently from powders. The progress with the Rapid Removal concept is the key cornerstone of the current discussions with ECHA. The environmental session ended by looking forward to the upcoming challenges. Members confirmed that the IUCLID update, QICARs to complement data-poor files and improving the ecological relevance of chemicals management risk assessment for metals are real and relevant challenges to be prepared for. The human health part started from the cobalt metal classification learnings, which now require a pro-active view from the metals sector to progress towards a reasonable solution on the potency debate. Nipera and the NI kindly presented their ideas including a template to improve the readacross justifications in the dossiers. The upcoming OELs on a series of metals drew a lot of attention from participants confirming that this activity has increased a lot at RAC and WPC level. The meeting included more horizontal briefing aspects, especially on the second day, like on the how consortia deal with combined exposure, the status of the classification mapping tool and the new features of MeClas to help predict the impact of changing classifications. Richard Meads from the European Risk Forum provided an inspiring speech on the conflict of interest and bias in scientific decision-making. And many, many other things... like the recipe to bake Brussels waffles were discussed. All together a comprehensive while generic briefing pack for members (more information: Hugo Waeterschoot and Violaine Verougstraete).

Chemicals Management: Regulatory Forum: excellent kick-off

The second part of the Spring Chemicals Management Week was dedicated to the Regulatory Forum (27 – 28 March). This was the first occasion for the Forum to meet after its creation as part of the Eurometaux restructuring. The aim was to provide a general overview of the major activities ongoing within the various Eurometaux taskforces, ranging from industrial emissions, air quality, OSH legislation, supply chain communication (exposure scenarios and SDS), risk management policies (RMM, RMOa, Authorisation, OELs) and RoHS. The meeting was sparked by the presence of several external speakers from the European Commission. Veronica Manfredi, Director of the "Quality of Life" unit of DG Environment, opened the meeting with an overview of the ongoing REFIT activities, underlining the importance of spirit of cooperation and responsibility; she stressed on the need to have a medium/long-term thinking/vision on sustainable development.

Cosmin Codrea and Ian Hodgson (DG ENV unit C4 "Industrial emission and safety") presented an outline of the evaluation of the Industrial Emissions Directive, while Helen Clayton and Lourdes Alvarellos (DG ENV Unit C1 "Clean Water") explained current Commission activities on water policy. Katrin Schutte, Commission Policy Officer at DG Environment, gave some insights on the upcoming Commission Implementing Regulation on Dossier Updates: the drafting of a text proposal is still ongoing and a presentation to the REACH Committee for discussion is expected in April 2019 without previous stakeholder consultation. We also had the opportunity to greet Alick Morris, Commission Policy Officer from DG Employment, who explained the Commission's perspective on the good management of risks at the workplace and future related activities including: i) scientific evaluations in support of future OELs to be carried out by ECHA RAC, ii) 5th list of IOELVs under Chemical Agents Directive (CAD) to be presented for adoption by the MSs later this year, iii) Evaluation on how best to regulate reprotoxic chemicals, iv) development of guidance on the use of biomonitoring at the workplace, and v) actions arising from the 2017 REACH Review with regards to REACH/OSH interface. A report of the two days Regulatory Forum meeting will be circulated in the coming weeks. The next meeting will be held in autumn (more information: Nathalie Kowalski, Lorenzo Zullo).

Authorisation and Restriction Platform: interactive sessions on scoping the new Taskforce and improving Chemicals Management Risk Management

The Authorisation and Restriction (A&R) Platform met for the last time in its present form on 19 March. The platform debated how it could best complement the scope of its broader focus of activities when changing into the Risk Management Taskforce. RoHS would be one of the legislations that would be followed by the TF in the future, for the multi-metallic aspects. A call for participants for the TF has been launched (see also item update of distribution lists). It was confirmed that consultants working for the metals sector remain welcome. The A&R reviewed and elaborated further on the thought-starter paper on the "10 recommendations to improve the RMM on chemicals in the EU" by collecting suggestions in interactive breakout sessions. Once finalised, the paper will be presented to the Commission and ECHA to promote both the efficiency and efficacity of the RMM system. The A&R platform took stock of the intense restriction activity in SEAC whereby CoRC explained the status of the debate, as well as how they aligned the downstream user sectors for a Binding-OEL approach as a common alternative for the newly developed concepts of Reference Exposure value and "risk equity". In contrast the lead compounds case seems to be evolving well at the level of the REACH Committee, going in the direction of an update of the Binding-OEL. An outstanding large challenge in the weeks to come could potentially be the proposal by MSC and ECHA to prioritise Pb metal, Cd metals, Cd oxide and hydroxide for authorisation, given these substances occur regularly as impurities

or minor constituents in UVCBs and specific alloys. The recent outcome of the EC court case on sodium chromates, rejecting the granted authorisation was noted by the platform as a potential important challenge for the future of authorisation in the EU. It would consequently require a more in-depth review to increase the understanding of its impact (more information: France Capon, Klaus Kamps, Hugo Waeterschoot).

CARACAL and REACH Alliance: Eurometaux's participation challenged by part of the glass sector

Since a number of years, the REACH Alliance has had one seat in CARACAL, which is most regularly occupied by Eurometaux and IMA, the two most active sectors when it comes to the CARACAL agenda. The REACH Alliance was set up in 2005 -before the entry into force of the REACH Regulation- to coordinate and align the input/advocacy of the metals/inorganics sector into the REACH legislation drafting debates. When 'CARACAL' started its activities in 2009, Roger Doome (IMA) was identified as primary contact point for the REACH Alliance. However, before that, Eurometaux, Eurofer and IMA had, for some years, occupied several 'seats' and participated actively in the Competent Authorities' meetings. Over time, the issues addressed by CARACAL triggered diverging and variable interests among the members of the REACH Alliance, resulting in different needs and the willingness to attend the CARACAL discussions and provide input. Eurometaux also took over the task -with IMA- to regularly inform its inorganic partners and coordinate the activities of the REACH Alliance on CARACAL related matters. The conference calls, the annotated agenda and minutes were exclusively prepared by the Eurometaux and IMA secretariats. Considering resources, but also the divergence in interests (e.g. on topics like Authorisation, REACH exemptions, bioelution etc.), Eurometaux asked whether a seat at CARACAL could be assigned to Eurometaux, as representative of the metal sector. The Glass sector did not support the proposal and unilaterally decided to contact the European Commission, triggering an analysis of the current seats' situation. The European Commission noted that the REACH Alliance was not listed in the transparency register and therefore decided to suspend its seat in CARACAL. Contacts with Commission are ongoing and Eurometaux hopes to have this issue solved by the next meeting. Eurometaux has meanwhile also announced that it would leave the REACH Alliance to clarify the situation/representation (more information: Lorenzo Zullo and Violaine Verougstraete).

Update of the REACH Registration dossiers: proposal for complementary measures to the upcoming EU Implementing Regulation.

On 10 January, during the "Stakeholder consultation for Implementing Regulation on Registration updates" organised by the European Commission, ECHA expressed its interest in finding smooth solutions to support dossier updates, as complementary measures to the clarifications that the upcoming Implementing Regulation is expected to bring. To this purpose, the former Eurometaux Data-Sharing Taskforce, elaborated some possible ideas that could be implemented to stimulate joint REACH Registration Dossier updates by all member registrants. In particular, three options were put on the table:

- OPTION 1 Joint Submission Object (JSO) membership expires upon submission of qualified update, and member registrants need to 're-join' it with a new token security number granted by the LR
- OPTION 2 Specific JSO are produced for qualified updates, and member registrants need to join new JSO with new token security numbers granted by LR
- OPTION 3 Lead Registrant 'selects' member registrants having the right to refer to qualified update

The options, submitted to both ECHA and Commission, were described in a power point presentation which contained also a list of conditions for success, including a proper definition of 'qualified update', the introduction of an 'on hold' status for member registrants not having obtained permission to refer to updated information and, more transparency on the dossier updates on the ECHA dissemination website.

Commission and ECHA confirmed the reception of the document and thanked Eurometaux for the input. For the time being they are still collecting input and will come back as soon as further progress is made (more information: Caroline Braibant, France Capon, Lorenzo Zullo).

Metal-specific REACH application tools and concepts

Exchanges with other industry sectors on UVCB guidance

Inorganic UVCBs approach is part of the MISA priorities for 2019. With the refinement of the Eurometaux guidance document that is currently ongoing, some exchanges with other sectors are taking place to identify similarities in approaches and comparable issues. The need to exchange regularly on different types of UVCBs had become apparent at the time of the SID discussions, where exchanges with the Inorganic Pigments and Frits Consortia highlighted the importance of having coherent approaches. This is also very important when coming to classifications of UVCB constituents: changes should be communicated in due time to allow appropriate UVCB classification updates. One of the best and efficient ways identified during the exchanges with other inorganics was the use of pigeons to convey the information, although it is recommended to send them to the consortia to avoid the mail dropping in the furnaces. Also, other non-metal, non-inorganic sectors are interested to exchange on the risk assessments modalities of the UVCBs, in particular on how to address combined

exposure/combined toxicity. A session in SETAC will bring the different sectors together to present their methodologies around these themes (more information: Federica laccino and Violaine Verougstraete).

Metals Sectorial Approach

MISA: learnings and report

In follow-up of the 7 February workshop on the information requirements/adaptations for the environmental hazard, MISA participants were expected to submit their workplan for this endpoint by end of March. 25 key learnings to promote a good quality dossier for this endpoint and a detailed report of the workshop were circulated to the MISA community, after their revision and discussion with ECHA. Their aim is to facilitate the drafting of the workplans, which should indicate to ECHA how and by when consortia will improve their dossiers in line with the learnings taken from the workshop, through updates or submissions of testing plans where relevant. Eurometaux also proposed to discuss with the consortia the Self-Assessment Tools that were completed ahead of the workshop. Such discussions were held with several consortia. Also, in March, ECHA circulated a progress report on MISA to CARACAL, which is important to assure Member States that work on the dossiers is ongoing and as a result potentially reduce the selection for compliance checks. The paper also specifies the next steps: a) continue work on the industry guide on reporting inorganic UVCBs, carry on the discussion on the application of the Rapid Removal concept for the environmental classification, continue raising interest for joining MISA with industry and industry associations that are not yet participating, conduct a review of the first year of MISA based on agreed performance indicators and consider the need for updating the "MISA rolling action plan" and finally further specify, plan and start work on the remaining priority topics. The MISA workshop was organised back to back with a debate on the Rapid Removal concept. Here as well, a detailed report was prepared and extensively discussed with ECHA. A timeline has been defined for the next steps, among others a briefing meeting with RAC members in June. Eurometaux's environmental classification taskforce also started working on the replies to provide to the questions identified on 8 February. It is aimed at having an exchange moment with ECHA in the margins of the SETAC conference in May and to anticipate the further debate in RAC and CARACAL (more information: Federica laccino, Hugo Waeterschoot and Violaine Verougstraete).

Water

Water Framework Directive REFIT: Eurometaux's position and answer to the public & stakeholder consultation –on 7 March, Brussels

Eurometaux's answer to the public & stakeholder questionnaire for the evaluation of the water legislation - the Water Framework Directive (WFD), the Environmental Quality Standards Directive (EQSD) and the Groundwater Directive (GWD) – was delivered online and enriched by a position document.

The main recommendations conveyed in Eurometaux's position are the following:

- The updated CIS Guidance nr. 27, and the new CIS Guidance on Implementing Metals EQS, should be widely used as this will greatly enhance the quality and consistency of metals assessment under the WFD.
- Assessment of metal bioavailability and natural metal background should be compulsory in compliance assessment; results of compliance should be reported as exceedance ratios.
- Regulators should apply robust criteria when considering "EU-wide risk"

- Socio-economic impacts should be better taken into consideration and properly addressed when implementing the WFD. (more information: Annalisa Bortoluzzi, Nathalie Kinga Kowalski).

EEA: EIONET Consultation on the 2016 Reporting Guidance elements – Eurometaux's answer on 22 March

As member of the CIS WG DIS (Data and Information Sharing) and selected stakeholder by the EEA, Eurometaux was invited to answer to EIONET's consultation on the WFD-2016 reporting guidance in order to prepare for the 2022 reporting on the 3rd RBMPs (review of the WFD-2022 reporting process). Eurometaux's comments were related to the guidance chapter 7 and 9, reporting 'Schema elements' related to background concentrations and bioavailability, and to the riverine load approach. We suggested that Member States should indicate whether natural background concentrations for metals and their compounds are taken into consideration where such concentrations affect compliance with the relevant EQS and whether the relevant tiered approach methodology for implementing bioavailability was applied (ref. CIS Guidance on Implementing Metals EQS) (more information: Annalisa Bortoluzzi and Nathalie Kinga Kowalski).

Industrial Emissions and Water

EEA report on "Industrial waste water treatment – pressures on Europe's environment": published 20 March

The latest report published by the EEA on industrial emissions deserves much attention from Eurometaux – as well as other industry associations' side, given the critical analysis reported of industrial emissions by mass and eco-toxicity. The EEA

analyses and reporting related to metals emissions in water is one of the three main priorities for the water taskforce in 2019. In fact, an attentive work on the E-PRTR data - in collaboration with the Industrial Emissions taskforce – will be needed and possibly formulation of a metals' industry 'story-telling' on metals emissions to water and related eco-toxicity. A specific attention to the use of the USEtox model will also be further required (more information: Annalisa Bortoluzzi, Nathalie Kinga Kowalski).

Industrial Emissions

Smitheries and Foundries BREF

Last year the European IPPC Bureau kicked-off the review on the SF BREF by creating the Technical Working Group (TWG) where Eurometaux is represented by four experts (including the secretariat). Following this, at the beginning of the year the Bureau called for the initial position on their proposed scope and way-forward for the review. Eurometaux developed not only its own position but also submitted a shared document with Eurofer, the Steel and Iron Industry association. Our arguments focus on Scope definition and Key Environmental Issues (KEIs) proposals. In general, we support the proposal not to extend the scope but remain as it currently is. However, the wording used in the proposed document doesn't specifically exclude (aluminium) casting processes which are already regulated by the NFM BREF. To undermine our position, we also submitted a background document explaining the technical understanding of "casthouses" and related processes. Further we disagree with proposed KEIs on consumption levels of water, energy, oil or foundry chemicals since we believe such limitations can be only decided based on a case-by-case analysis. Eurometaux submitted all documents by the deadline of 15th March 2019 and will analyse the answers submitted by the other TWG members. The Kick-of-Meeting is planned for the end of September/ beginning of October (more information: Nathalie Kinga Kowalski).

Nanos

REACH Amendments for Nanomaterials

End of 2018, Eurometaux nominated three experts for the needed guidance's' updates on substance identification, Human Health and environmental & physico-chemical endpoints. As reported, a prior preparatory workshop has been held in Helsinki back-to-back with NMEG meeting beginning of November, but in January the consultation on the Guidance updates for the human health and environmental endpoints has been postponed until further notice.

However, the writing of the new Appendix to the Guidance on Registration and substance identification is ongoing, after a comment collection and clarification call with ECHA; the Partner Expert Group (PEG) will meet on 9 April.

Finally, after a consultation between ECHA and DG Environment regarding the tight timeline until the January 2020 deadline, ECHA informed of the decision that the new REACH amendments for nanomaterials will enter into force only in January 2025, and not in 2020 as previously planned (more information: Nathalie Kinga Kowalski).

FURTHER OUTREACH OF REACH

OECD

OECD: slides on Rapid Removal submitted to the Test Guidelines Group

The OECD secretariat of the OECD Testing Guidelines Programme Working Group (WNT) has invited Eurometaux to submit a couple of slides explaining the extension of the existing Transformation/Dissolution Protocol (T/DP) (OECD Guidance Document N° 29) to assess the metal removal from the water column. Metals that rapidly remove are classified in a lower ecotoxicity category, given their exposure is much shorter. Such change reduces the impact of downstream legislation like impacts, alloys classifications or permits. The existing T/DP determines the rate and extent at which a metal, sparingly soluble metal compound, or complex inorganic material may release metal ions to an aqueous environmental medium with standardised composition. However, it is not sufficient to evaluate the (subsequent) removal of the metal ions from the water column, not at least because it does not contain any substrate. The extension of this test, called extended Transformation/Dissolution protocol (T/DP-E), was developed in follow-up of the 'ECHA Rapid Removal workshop in 2012' to measure the rate and extent of metal removal and irreversibility of the removal when bringing the metal in contact with substrate. The T/DP-E protocol, was carefully built to ensure that the test could be conducted under standardised conditions, be repeatable and have a measurable outcome, but also to allow comparability among metals and represent some key removal processes in a conservative way. It can discern variations in removal rates related to varying particle affinity of different metals and the type of frog species present in the Erlenmeyer. The protocol has been built as a potential extension of the existing OECD 29 T/DP to be useable at GHS as well as at CLP level. The slides summarising the history of the Rapid Removal concept and the main features of the T/DP-E will be circulated for information to the WNT, so as to prepare the

potential next steps of the validation of this extension. (more information: Emily Garman, Stijn Baken, Violaine Verougstraete and Hugo Waeterschoot).

COMMUNICATION

Pb as a key enabler in the EU: meeting with ETN Socrates

Socrates is a programme of EU scientists that promote good quality factual evidence by publishing briefings on themes relevant for policy decision-making. Several Belgian authors from the KU Leuven and Professor Markus Reuter, Director of the Helmholtz Institute Freiberg for Resource Technology (Germany) published recently an excellent briefing note on the role of Pb as a key element in the recycling of especially precious metals (<u>https://kuleuven.sim2.be/wp-content/uploads/2019/02/SOCRATES-Policy-Brief-2019-Lead.pdf</u>). Under, the auspices of Metallo Belgium, representatives of the metals sector met some of the authors providing them with the regulatory background on the Pb metal risk management in the EU at this moment. This strengthened the view of all for the urgent need of clear, factual and scientific communication on the role of Pb in recycling processes. The briefing note was in this respect recently complemented by an informative communication message which we will circulate soon and suggest sectors circulate widely to draw attention for the importance this metal plays in the Circular Economy (more information: Inge Maes, Lisa Allen, France Capon and Hugo Waeterschoot).

Chemwatch Conference on the future of Authorisation: an effective way to convey messages to a large audience

The metals sector conducted several projects over the last 2 years related to the REACH Authorisation scheme like the legal reviews on SIDs and SIM, views on RMOa, etc. However, communication of those recommendations is always a challenge. We therefore contacted Chemical Watch which resulted in a study day on 18 March on the future of Authorisation. Aim of the day was a free discussion on suggestions to help improve and focus the authorisation system in the EU to keep it efficient and relevant. The theme was much appreciated given close to a 100 people attended from industry but also regulators as well as NGOs. Commission and ECHA provided updates on review programmes while industry focussed on tools like improving the RMOas, a more transparent RIME and attention for a more balanced substitution programme that recognises other EU policies like decarbonisation and circular economy and the outcome of the legal reviews on Art. 58 (2) and SIDs/SIM. It is the first time we use this way of communicating which turned out to be efficient (more information: France Capon, Steve Binks and Hugo Waeterschoot).

CALENDAR

- 3 April: Joint Industry Association Meeting, with consultants of WFD evaluation (Brussels)
- 4-5 April: WFD CIS WG Chemicals; workshop on Emissions permitting and non-deterioration (Brussels)
- 9-10 April: WFD CIS WG Data and Information Sharing (EEA's premises, Copenhagen)
- 13-17 May: MSC-64 ECHA (Helsinki)
- 21 May: Authorisation & Restriction Platform MCC (Brussels)
- 21 May: Workshop on implementing metals' EQSs and BLMs use with Italian national and regional authorities (Rome)
- 15 May: WFD CIS Strategic Coordination Group (TBC; Brussels)
- 23-24 May: Helsinki Chemicals Forum (Helsinki)
- 25-29 May: SETAC Europe (Helsinki)
- 3-7 June: RAC-49 (A) ECHA (Helsinki)
- 4 June: Evaluation Platform –MCC (Brussels)
- 10-14 June: RAC-49 (B) ECHA (Helsinki)
- 10-14 June: SEAC-43 ECHA (Helsinki)
- 19-20 June: MB-54 ECHA (Helsinki)
- 20 June: Chemicals Management Steering Committee MCC (Brussels)
- 25-28 June: MSC- 65 (B)- ECHA (Helsinki)

<u>ACRONYMS</u>

AoA: Assessment of Alternatives (REACH)	MS: Member States
ATP: Adaptation to Technical Progress	MSCA: Member States Competent Authorities
BoA: Board of Appeal	NFM: Non-Ferrous Metals
BPR: Biocidal Products Regulation	OECD: Organisation of Economic Cooperation and Development
BREF: Best available technology Reference document	OEL: Occupational Exposure Limit
CAD: Chemicals Agents at work Directive (EU)	OSH: Occupational Safety Health
CARACAL: Competent Authorities for REACH and CLP	PC: Public Consultation
CIS: Common Implementation Strategy	PEG: Partner Expert Group
CLP: Classification, Labelling and Packaging Regulation	QICAR: quantitative ion characteristics-activity relationship
	model
CM: Chemicals Management	RAC: Risk Assessment Committee
CMR: Carcinogens, Mutagens or toxic to Reproduction	RBMP: River Basin Management Plan
CoRAP: Community Action Rolling Plan	REFIT: Regulatory Fitness & Performance Programme (EU)
CSR: Chemical Safety Report	RMM: Risk Management Measures
CTAC: Chromium Trioxide Authorisation Consortium	RMOa: Risk Management Option analysis
DIS: Data and Information Sharing	RoHS: Restriction of Hazardous Substances
DIT: Developmental Immunotoxicity	SDS: Safety Data Sheet
DMF: Dimethylformamide	SCOEL: Scientific Committee on Occupational Exposure Limits
	(EU)
DNEL: Derived No Effect Level	SEAC: Socio-Economic Analysis Committee (ECHA)
EAA: European Environmental Agency	SETAC: Society of Environmental Toxicology and Chemistry
ECVAM: European Centre for the Validation of Alternative	SEVESO (Directive): Technological Disaster Risk Reduction
Testing Methods	
EIONET: European Environment Information and	CID. Cultateners Islanditu
Observation Network	SID: Substance identity
EOGRTS: Extended One Generation Reproductive Toxicity	SIM: Substances in Mixtures
Study	
E-PRTR: European Pollutants Release and Transfer Register	SIS: Substances in Substances
ERV: Ecotoxicity Reference Value	SSD: Sunset Date
ES: Exposure Scenarios	TDp: Transformation Dissolution protocol
EQS: Environmental Quality Standards	TF: Taskforce
EQSD: Environmental Quality Standards Directive	TP: Testing Proposal
GHS: Globally Harmonised System	TWG: Technical Working Group
GWD: Groundwater Directive	UNEP: United Nations Environment Programme
IPPC: Integrated Pollution Prevention and Control (Directive	UVCB: Unknown or Variable Composition, Complex Reaction
96/61/EC)	Products and Biological Materials
I-OELV: Indicative Occupational Exposure Limit Value	WFD: Water Framework Directive
IUCLID: International Uniform Chemicals Information	WPC: Working party Chemicals
Database	
KEI: Key Environmental Issues	WTO: World Trade Organisation
MB: Management Board	
MeCLAS: Metals Classification Tool	
MISA: Metals & Inorganics Sectorial Approach	