

EUROMETAUX REACH PROGRAMME



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REACH Forum - Tuesday 20 June 2017 - MCC

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by sending a mail to ehsassistant@eurometaux.be

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Dear REACH Forum member,

*There is that old poem by John Godfrey Saxe talking about six blind men
"To learning much inclined,
Who went to see the Elephant
(Though all of them were blind),
That each by observation
Might satisfy its mind".*

The blind men describe the elephant; the first one saying that an elephant is long and skinny like a snake, the second one claiming it is a rope, the third one talking about a fan, contradicted by the three others who depict it respectively as a spear, a wall or a tree. Each of the men is actually touching a different part of the elephant, and due to his blindness fails to take in the elephant as a whole. And as their experience is limited to a certain part of the animal, the men assume that the elephant is (only) the part they can feel, each equally convinced that they, and only they, are right. The poem concludes that:

*"And so these men of Indostan
Disputed loud and long,
Each in his own opinion
Exceeding stiff and strong,
Though each was partly in the right,
And all were in the wrong! "*



In research, focus is often –necessarily- limited to only one small part of the elephant. Being creative even requires some kind of blindness, to start dealing with a problem that one cannot always see, exploring and experiencing the darkness progressively and daring to portray some intelligence. But then, when the time of sharing understanding and defining solutions comes, despite the fact that we are convinced we had some illumination, we often encounter certain problems of perspective. Whilst the elephant with its own six parts is often in the meeting room, taking up all the space, disorganising the agenda and throwing chairs around, researchers may still be describing either the ear, the tusk or the knee. All partly in the right and all wrong.

In some versions of John Godfrey Saxe's poem (or interpretations of it), someone passes by to tell the blind men that they need to put the parts together to see the truth, but in others there is only a sighted man passing by to tell the blind men they actually can't see. One can easily imagine the reactions of the blind men to such ascertainment. It requires really letting go and a good dose of humility to start putting together as much determination & energy in the build-up of the whole elephant perspective than as in the research that has preceded. Taking a step back from everyone's own solution to zoom out and change perception.

The energy required (to do so) may sometimes be largely available, in events like the SETAC Conferences for example, where different mind sets necessarily mix in front of the mixed audience. However, at other times it has to be generated de novo and to come on top of the efforts already consented, to some researchers' understandable frustration and convictions. The current ongoing regulatory agenda is full of these stories.

Still, it is worth the attempt: what would we be with full knowledge of the elephant's ear while it is standing with all his weight on our feet?

Violaine Verougstraete, EHS director Eurometaux

ECHA REACH Activities: hot topics

ECHA Committees

RAC-41: OELs & Restrictions

The last days of May were intensively used by RAC to debate on the development of OELs, on restriction and authorisation applications. Commission has requested RAC (via REACH Article 77(3)) to support its activities, by providing scientific advice to take action on the proposal to amend Directive 2004/37/EC (CMD). The RAC advice shall include a recommendation (on limit values) to the Advisory Committee on Safety and Health (ACSH) in line with the OSH legislative procedures. Two substances had to be dealt with by RAC before 29 May: MOCA and arsenic acid and its inorganic salts. For MOCA, the RAC formed an opinion based on the existing RAC dose-response opinion and the SCOEL OEL. For arsenic acid and its inorganic salts, as there is no SCOEL recommendation, RAC used its existing RAC opinion on the dose-response function supplemented by some additional information. The two opinions were approved by RAC and sent in due time to Commission. The next substances to be discussed include nickel and nickel compounds, benzene and acrylonitrile. Key aspects in these discussions are the consideration of a threshold and the existing categorisation used up to now by SCOEL as proposed by Bolt et Huici-Montagud (2008): e.g. category C includes genotoxic carcinogens, for which a practical threshold is supported, allowing to derive a health-based OEL. These discussions will be monitored closely. The proposed Restriction on the use of lead gunshot, or gunshots made of alloys containing > 1% lead, shooting with a shot gun within a wetland or where spent gunshot would land within a wetland, proposed by ECHA, was estimated conform and led to very interesting discussions on the actual scope and possible implementation of the EU restriction in the case for example when Member States have stricter legislation covering non-wetland areas. RAC also estimated the human health impacts were not sufficiently described, considering in particular the amount of Pb that could be concerned vs. the restriction of lead compounds in PVC stabilisers, also discussed at RAC this week. The latter discussion allowed Eurometaux to draw the attention of ECHA and RAC to the comments that were submitted by ILA in the Public Consultation on the human Health Hazard Assessment and the conclusion RAC drew some years ago that “no safe blood lead level has yet been established” in relation to negative impact of IQ in children, to be reconsidered in the light of recently published information. The discussions on the restriction of diisocyanates, aiming at preventing new cases of respiratory sensitisation to diisocyanates among workers / professionals (and indirectly exposed residents allowed further discussion on the scope of compounds to be covered and uncertainties in exposure assessment (e.g. how to address peak exposure levels). Authorisation applications on chromates and EDC were discussed as well and finally RAC got updated on the work plan for the next meetings and had a first discussion on possible longer Review Periods for Authorisation. The second part of the week (discussions on CTP-HT and TiO₂ CLH proposal will be covered in the next News as there is...a second week of RAC meetings to come) (more information: Violaine Verougstraete).

Authorisation

NeRSAP: 6th Meeting took place in Helsinki

The 6th meeting of NeRSAP, the Network of REACH Socio Economic Assessment and Analysis of Alternatives Practitioners took place in Helsinki on 18-19 May, bringing together more than 50 practitioners for exchanges and learnings. The first session headed by industry (Eurometaux) was focused on the Man via the Environment scenario, more specifically how the assessment can be improved to better fit the needs for AfAs and Restrictions. The learnings from the Eurometaux seminar (January 2017) were debated, and useful suggestions were made. Many NeRSAP attendees (consultants and Member States) are directly involved in the Man via the Environment scenario drafting, which made the debate interesting. An update of the IUCLID model and specific guidance on inorganics were reconfirmed as relevant needs. The second theme of the meeting related to the promotion of Alternatives and what could be done to stimulate better assessments on technical and economic feasibility and awareness raising. This session was headed by Professor Joël Ticker from the US and appointed by ECHA to help them develop such a policy. This theme is certainly most relevant to monitor closely given it may have an impact on industry's business models for substances and applications requiring to search for alternatives (more information: Hugo Waeterschoot).

Others

Bioelution: webinar with Bioelution Expert Group

In follow-up of the meeting held in Helsinki on 26-27 April, a webinar was set up to allow the Member States and ECHA representatives of the group to receive a step-by-step explanation of the proposed alloys classification schemes and to make first comments. This webinar took place on 23 May and was very well attended. Comments made highlighted once more that to obtain acceptance of the bioelution concept and translate it into a refinement of the current CLP rules to consider the alloys' specific properties, we will need a simple but also very coherent system when it comes to testing and information duties both on industry and authorities sides. The Expert Group can send comments until 2 June and afterwards the schemes will be

refined before they can be submitted to CARACAL for discussion on 28-29 June, as an annex of the report this group will produce (more information: Adriana Oller and Violaine Verougstraete).

Nanos: meeting mid-May in Helsinki of the Nano Materials Expert Group

The ECHA Nano Materials Working Group has changed its name to Nano Materials Expert Group to align with the Biocides and Endocrine Disruptors expert groups. It has a dedicated webpage on the ECHA website and the agenda/minutes will now be publicly available. The group will meet twice a year (next meeting is 7-8 November). The experts/representatives are nominated for 2 years. JRC's most recent project was presented: - NanoComput-Computational approaches in the safety assessment of nanomaterials - Investigation of the availability of Quantitative structure-activity relationship (QSAR) models and grouping approaches for nanoparticles, and assessment of their applicability under REACH. Participants were provided with a presentation on the ProSafe review of the OECD Technical Guidance documents, and the OECD work programme. The focus is definitely on fate and effects but also on TG 110 (particle size distribution) and a new guidance being developed on dispersion stability of nanos in simulated environmental media. Also of importance, the revision of TG 412 and 413 on subacute and subchronic inhalation toxicity. A dedicated presentation was provided by ECHA on how to report nanomaterials SID in IUCLID6, and an example on Calcium Carbonate registration was given by IMA (more information: Christine Spirlet).

ENES (Exchange Network on Exposure Scenarios): Work programme 2010-2020

In July 2013 the CSR/ES Roadmap was published for the first time, accompanied by a charter signed by ECHA, various industry associations (including Eurometaux) and Member States. During 2016 the programme underwent an evaluation, confirming the usefulness of ENES and the tools that were developed (e.g. use maps, SpERCs, SWEDs, ECom, SUMIs etc.), and highlighted the need to intensify the efforts made to promote the use of the tools to a broader audience. The industry organisations and the Member States who signed the Charter have agreed to carry out a four year follow-up programme in support of further improving the generation and communication of information related to uses, conditions of (safe) use and the corresponding exposure estimates. The draft programme, circulated for comments to the CSR/ES Roadmap Coordination Group, focuses on the three following goals: a) the quality of exposure scenario information for substances and mixtures has improved and is practically useful for the management of chemical risks with regard to products and processes, b) a significant number of leading companies have implemented (plan to implement) the ECom package and c) information on use and exposure in the REACH registration database has improved, in particular the information used by authorities to prioritise and deprioritise substances for regulatory scrutiny. Eurometaux has commented on some actions of the programme (e.g. SpERCs, mass flow analyses) to make those somewhat more concrete but also to make sure that the efforts made regarding ENES fit in with the 2020 objectives and this in order to avoid duplication of the work (more information: Lorenzo Zullo, Violaine Verougstraete).

COMMISSION REACH Activities: hot topics/issues

CARACAL

Getting ready for the next CARACAL meeting: follow-up

As follow-up to the last CARACAL meeting (March 2017), Eurometaux submitted, on behalf of the REACH Alliance/REACH Forum, comments on the study commissioned by the European Commission to evaluate the impacts of introducing new testing requirements for substances in the 1-10 tonnage band. The high costs for compliance as well as the difficulties to manage new testing requirements after the 2018 registration deadline were highlighted. The REACH Alliance/REACH Forum proposed to develop a substance prioritisation process as a base to define targeted testing programmes, instead of a horizontal approach applicable to all substances. In May, Eurometaux analysed the comments received from other stakeholders. On this topic, France was the country that submitted the most detailed comments; they did not take a clear position on the best approach but constructively criticised the way in which the impact assessment was conducted. The topic has not been introduced (yet) in the agenda of the next CARACAL meeting which will be held on the 28-29 June and which will cover, among others, several important topics: bioelution (background document from ECHA Expert Group expected in June), bridging principles, metals in massive form, risk management in the supply chain and the follow-up to the workshop on ECHA's integrated regulatory strategy. In preparation of the meeting, a phone conference to discuss the agenda with the REACH Forum/REACH Alliance will be organised on 23 June when more working documents should be available (more information Lorenzo Zullo, Hugo Waeterschoot)

Consultation Waste/Chemicals/Products: call and useful input to refine the questionnaire

A first brainstorming on the input to provide on the Commission consultation on the interface Chemicals/Products/Waste was held on 17 May. It was suggested that the secretariat identify a first set of messages for each of the 4 sections of the

consultation (1. Insufficient information about substances of concern in products and waste, 2. Presence of substances of concern in recycled materials (and in articles made thereof, including imported articles), 3. Uncertainties about how materials can cease to be waste and 4. Difficulties in the application of EU waste classification methodologies and impacts on the recyclability of materials, based on the discussions with DG ENV in February and held at the EHS/SUS meeting on 5 April. The secretariat has circulated a draft template including a summary of Commission's evaluation, a potential Eurometaux story and some specific questions on those four items, with the kind request that members provide some input by 6 June. Members were also invited to reflect about possible case studies that could be provided. On 13 June, the Secretariat will circulate a consolidated input based on the responses received, with a conference call planned for 19 June (more information: Kamila Slupek, Annalisa Bortoluzzi, Chris Heron and Violaine Verougstraete).

Update on nanos: *ongoing activities*

The CASG nano meeting took place on 14-15 March with as main objectives to discuss the EU nano observatory and the "non-paper" on REACH revision of the annexes. An EU inventory with registration would be too costly and thus the Commission opted for the Observatory and delegated the project to ECHA. First release is planned for 14 June. The following segments will be part of the launch in June: General info, safety, regulatory info, products/uses, workers, substances, research. Links with eNanoMapper (already includes NanoREG data) and NanoDATA and inclusion of the national inventories are done. This initiative is highly contested by MSs who would have preferred an EU inventory initiative and also by all NGOs as they believe the observatory is not sufficient. Industry mainly focuses on the quality of the visible data as ECHA has confirmed they have no possibility to validate those data. Sweden will move on to set up their own inventory with possible 1st registration in February 2019. The revision of the REACH annexes was the centre of attention as they are critical for good coverage of the nano specific information and assessment. Absence of provisions may lead to additional BoA cases (cf. TiO₂). Work is still ongoing. In the meantime, ECHA has published five documents that will help registrants in preparing dossiers that cover nano forms ahead of the 2018 registration deadline, as the REACH provisions are still missing. The Commission touched upon the definition of nano: following the inter-service consultation, a revision was considered appropriate and another draft recommendation (including recitals) was prepared. A public consultation will follow and adoption by the Commission is planned for the second half of 2018 together with a guidance by JRC on how to implement that definition. The definition will be based on materials (not products or components) and only on sizing (50% by number as the only threshold). The Volume Specific Surface Area (VSSA) is left as supporting evidence to demonstrate either nano or non-nano status (more information: Christine Spirlet and Nathalie Kinga Kowalski).

EUROMETAUX REACH Activities: hot topics/issues

Authorisation

Intermediate status clarification workshop with ECHA (15 May): *a successful start of the second round*

The Eurometaux intermediates programme aims at clarifying the status of the uses of substances that are (potential) candidates for Authorisation, so as to achieve an aligned view with ECHA and Commission, improve the prioritisation process and clarify what uses or steps could become authorisable. The first round of the programme ran in 2015 and was recently concluded by ECHA. ECHA suggested to include some examples in their update of the ECHA intermediates examples manual, and will further debate this with the concerned sectors (batteries, inorganic pigments/frits and some CTP users). They expect to publish those by the end of the year. The main part of the 15 May meeting was devoted to the presentations and a fruitful and open debate on a number of uses of inorganic metal salts including the catalyst sector and the use of PbO as a scavenger in the precious metals recycling sector. An additional case on the use of CTP in the steel sector was also presented. The concerned sectors took note of the suggestions made and these could help them to update their views and improve their argumentation where relevant. As a follow-up, Eurometaux will set up sectorial calls. The sectors were further invited by the chair (France Capon) to prepare a draft internal guidance that could serve as basis for a second discussion round in autumn. It is hoped that this second series of uses could moreover successfully result in internal industry guidance and that ECHA could also select here some examples to further illustrate the ECHA intermediates examples manual (more information: France Capon and Hugo Waeterschoot).

Authorisation & Restriction Platform Meeting (A&R platform): *a lot of learnings from ongoing cases*

The A&R platform met on 16 May for a busy but most interesting meeting. Updates on the status of the RMOa project (training and improved guidance), the Recycling and Authorisation project (update on the legal case on intermediate status), the outcome of the first session of the second round of the intermediates programme (see above), and the experience of the Cd

sector with the Eurometaux AfA preparation strategy support programme were reported and possible next steps debated. Special attention was devoted to the challenging upcoming debate on the interpretation of Article 58 (2) that allows exemptions from authorisation based on the availability of substance specific RMM legislation. This is a crucial issue for the Pb sector. All these issues have a broad and precedent-setting nature covering a wide scope of metal(s) (compounds) fitting the SVHC criteria. These debates were complemented by a reporting session on the planning of ECHA A&R initiatives like the horizontal Fast-Track restriction on textiles, the listing of Ni compounds on the PACT list, and learning lessons from the chromates AfAs. The cross sectorial learning lessons from running restrictions were most interesting and indicated alternative ways of thinking, such as how a voluntary and/or a regulatory exposure reduction programme by industry could possibly substitute for a restriction. Finally the meeting took note of the planning on the upcoming priority lists and the restriction cases like Pb in shot, which is the first environmental metal restriction case (more information: France Capon, Klaus Kamps, Violaine Verougstraete and Hugo Waeterschoot).

Authorisation & Restriction Platform meeting: a suggestion launched for pilot cases for an A&R expertise centre

The increase in number and scope of Authorisation and Restriction activities challenges companies, consortia and Eurometaux. Indeed the necessary specific expertise level may not be available when it is needed and the time pressure does not help either in ensuring the most effective outcome for the Authorisation challenge for metal uses. Moreover, authorisations may also affect companies in a collateral way, affecting the use of substances that are not related to the main production process (e.g. process chemicals, ...). This triggered a discussion on a metals A&R expertise centre to help the sector to respond as effectively as possible to these resources and expertise needs. The A&R debated a proposal to collect, educate and train a group of experts, who would then be asked to provide such service/support on demand. An organisational model as well as the proposal to search for pilot cases to test this out in practice were agreed by the A&R and will be presented to the REACH Forum for information (more information: France Capon, Klaus Kamps, Violaine Verougstraete and Hugo Waeterschoot).

Evaluation

Evaluation Platform Meeting: took place on 17 May

The Evaluation Platform started by reviewing the learning lessons from the recent Member States Committee meetings on testing proposals, Dossier and Substance evaluation, several related to the EOGRTs study and its conditions (e.g. DIT, DNT cohorts, possible waiving). An interesting case also highlighted that a respiratory sensitiser can be identified as SVHC and listed although all uses are intermediate ones (meaning that the substance can never be prioritised for Authorisation). MSC concluded that this substance can be listed to stimulate substitution. Consortia shared their recent experiences on Dossier and Substance Evaluation, with among others some very interesting learnings on the cobalt compounds where MSC finally agreed unanimously to test CoCl₂ for the 2nd species PNDT. A recent update was provided on the zinc oxide and antimony compound substance evaluations, as well as on ECHA's Collaborative Approach. Finally, the recent legal cases on TiO₂ and octocilene were discussed, again with the aim to extract useful precedents. The next meeting will take place on 22 November 2017 and will include a session on nanos, where all nanos-evaluation and information requirements-related topics will be reviewed. Draft minutes were circulated on 19 May (more information: Violaine Verougstraete and Hugo Waeterschoot).

Resource mapping to respond to REACH / ECHA challenges

Cd AfA Workshop: very useful discussions

Eurometaux and ICdA organised an intensive strategy discussion on AfA preparation for the Cd manufacturing and user sectors on 4 May. Goal was to identify what strategic decisions and information needs are required for a successful AfA preparation, if needed at some point in time. Quite unique was that ICdA engaged almost all its users for this reflection, motivating all actors along the supply chain to define common targets (DMEL setting, ...) and individual contributions (workers exposure and local Man via the Environment assessment). This pro-active discussion helped the sector to be prepared in due time for a RMM process and to define initiatives for alternative RMM (Article 58 (2), EU-wide OEL, ...) (more information: Patrick de Metz, Christian Canoo and Hugo Waeterschoot).

Intermediates Task Force Meeting (12 May): catch up

On 12 May, the Eurometaux Intermediates Task Force met to catch up with the inorganic UVCB dossiers submitted in 2014 and get updated on progress made on SID, combined toxicity and Man via the Environment assessment. The goal of the meeting was to define together an action plan: (1) On SID: the update on SID will be run in a couple of steps to allow consortia secretariats to gather all the necessary information to prepare the Substance Identity Profile (SIP) and to ensure Legal Entities (LE) specific details are appropriately reported. While some exchanges are still ongoing with ECHA, a web training is foreseen in June to share the main structure of the SIP template/SID reporting. (2) On IUCLID: IUCLID Dossiers will need to be compliant with IUCLID 6 requirements. To smoothen this task, whilst ensuring that specific metal dossiers are correctly updated in IUCLID 6, EM is working on pilot cases for UVCB in IUCLID 6 and will further discuss details with the ECHA

Computational Unit. The scope of this interaction is to develop a guidance for registrants who will use the AE. (3) Combined toxicity and Man via the Environment assessments have gone through several discussions, seminars, exchanges and tiers testing. These efforts and results already obtained will need to be included/documentated in the UVCB dossiers update. Where inorganic UVCB (i.e. non-substance specific) concept will need to be explained, EM will prepare a generic text to be included in the dossiers (more information: Nathalie Dom, Federica Iaccino, Violaine Verougstraete).

Cross Industry Initiative (CII) activities: *panel debate in Berlin & video conference with KEMI*

In a panel debate at a conference in Berlin, DG GROW took the position that REACH Candidate Listing and Authorisation ensure better protection at the workplace than OSH and OELs do. However, it is also acknowledged that in some cases OSH may be sufficient. DG GROW did not commit to putting forward criteria when that may be the case. The CII, in its presentation at the workshop, recalled that the Member States in the REFIT Platform had suggested that criteria should be established. At a Conference in Prague, DG ENV indicated that the forthcoming Common Understanding Paper should include some clarifications on when OSH / Authorisation are relevant options when conducting an RMOa. Substantive discussions with the Member States on a draft Common Understanding Paper will take place in CARACAL after summer. The CII continues its outreach to Member States. A delegation of the CII (Brigitte Amoruso and Kai Melzer, with the support from Michael Gillen, IBEC) met with the Irish MSCA, which is also responsible for OSH. In-depth substantive discussions -on OSH and possible weaknesses of OSH that may need to be addressed- were held. Another delegation of the CII (Lorenzo Zullo, Heinz Wimmer and Kai Melzer) held a video conference with the REACH-MSCA of Sweden (KEMI). KEMI appreciated the information provided at the meeting and recognised that OSH should be considered as an option during RMOas. It suggested that the criteria that the CII developed for choosing OSH as RMO are relevant and should be shared broadly with Member States for their consideration. They do not agree with the CII that such criteria should be set forth in a Guidance, as KEMI is of the view that Member States should be able to choose their own approach when being in charge of an RMOa for substances. The evolvement of the CII position based on input received from various stakeholders was appreciated by KEMI (more information: Kai-Sebastian Melzer and Lorenzo Zullo).

Classification

Granulated Copper CLH: *Eurometaux submitted comments under Public Consultation*

Eurometaux exceptionally submitted comments during the Public Consultation on the classification proposal for Granulated Copper. The contribution of Eurometaux focused on the many conceptual aspects related to the proposal for the environmental classification for this substance. Most are in support of the proposal prepared by France, like the focus on standard species, given the large data set available. Eurometaux supported the comments of the Cu sector on the statistical treatment of the toxicity data indicating that splitting the data set into pH categories without appropriate statistical treatment of the data results in the data set becoming more uncertain. Alternatively Eurometaux reminded RAC of the possibility to normalise the toxicity data set using available BLM models which allows using all toxicity evidence for the assessment of the environmental classification (more information: Stijn Baken and Hugo Waeterschoot).

Metal-specific REACH application tools and concepts

Bioelution: *a work plan*

At the last Risk Assessment & Classification taskforce and EHS Steering Committee meetings, it was recommended to prepare an action plan on bioelution to clarify actions, timings and responsibilities in order to get some support on the 5 following tracks of activities: the achievement of a validated bioelution protocol, an agreement on how to use bioelution results in classification, the political acceptance of the concept, the drafting of guidance to industry and the accumulation of experience and knowledge (e.g. by setting up a database of bioelution results and publishing). There is still a lot of work ahead of us to achieve the buy-in from regulators and industry, but progress is noticeable. Besides the call for volunteers, members were also invited to a webinar on 8 June, to get a step-by-step explanation of the proposed alloys classification schemes, currently reviewed by the ECHA Bioelution Expert Group (more information: Adriana Oller and Violaine Verougstraete).

SETAC Europe: *27th Meeting - Brussels*

The SETAC Conference brought together more than 2000 participants on the theme "Environmental Quality Through Transdisciplinary Collaboration". 81 sessions, 1188 poster presentations and 564 platform presentations animated The Square between 7-11 May, in an outstanding event chaired by Ilse Schoeters and Karel De Schamphelaere. The metal sector was quite involved in the organisation of the Conference, contributing to its scientific content (presentations, posters, chairing of sessions) but also more concretely in its set up by participating in the Scientific and Local Organising Committees. Eurometaux has been instrumental in bringing in Geert Dancet (Executive Director ECHA) as a keynote speaker, reflecting on the main achievements of the REACH Regulation and identifying further scientific (environmental) challenges and research needs. Mr Dancet insisted on the importance of having regulators and the research community working together to solve knowledge

gaps and develop improved methods and approaches in an anticipative way. More integrated approaches between human health and environmental effects, using mechanistic knowledge for human health to gain more insight into mechanisms of action in ecotoxicology, could facilitate grouping and read-across approaches to predict properties of substances. Eurometaux also co-chaired an interesting session bringing together OECD, ECHA, Canada, RIVM and industry on the environmental assessment of complex composition substances and mixtures (UVCBs). Koen Oorts (ARCHE) took the opportunity to present a very clear status update on the approach followed in the UVCB dossiers to address the challenge of combined toxicity for the environment demonstrating the advanced nature of the metals UVCB assessment scheme. A lunch session on measuring the metal removal from the water column (set up by NiPERA and Eurometaux) attracted several regulators and scientists from academies and industry. Finally, the Metal Interest Group gathering, over welcomed drinks and snacks, allowed the participants to exchange on the recent developments related to bioavailability, the soil PNEC calculator, the soil screening values used in the UK for ecological risk assessments on metals and issues like mercury,. The metals sector was involved in a series of posters, many dealing with the upcoming issue of combined toxicity and read-across. The posters in general confirmed that combined toxicity assessment and endocrine disruptor hazards are a further growing theme in SETAC. The next SETAC Europe Conference will be organised in Rome (13-17 May 2018). In the meantime have a look at the platform presentations available from <https://brussels.setac.org/> (more information: Violaine Verougstraete & Hugo Waeterschoot).

Classification mapping tool and new MeClas functionalities: *the work is on track*

The work of the Classification Mapping TF is on track. The classification mapping tool, which is expected to be completed by the end of 2017, will allow to identify provisions and industry requirements associated to specific hazardous classes in a broad range of legislations including workers' protection, environment, transport and consumer products. It will be an efficient tool to identify consequences and impacts of substance reclassifications. A preliminary test of the beta version of the tool was conducted on 23 May by comparing the legislative pressure of substances/mixtures classified as Carcinogenicity category 2 vs. Carcinogenicity category 1B; the preliminary results were very satisfactory. The focus of the taskforce in the coming months will be on the expansion of the legislative perimeter and the development of a suitable interface to make the tool intuitive and user friendly. Regarding the newly proposed MeClas functionalities to automatically identify how the reclassification of an individual substance could trigger the classification of a mixture, the MeClas Steering committee was asked to provide his 'green light'. Once the proposal is approved, it might take a couple of months to have the new functionalities implemented (more information: Lorenzo Zullo).

Cu-Alloys: *an open debate with the alloy user sector on the classification scheme for alloys*

ECl organised on 30 May an assessment session with their alloy sector to take stock of the status and assess the consequences of the proposed classification scheme for Cu-alloys. Eurometaux developed together with the Consortia draft decision schemes and guidance to define the environmental and Human Health (HH) classification for alloys based on the mixture rules and the use of Transformation dissolution respectively the Gastric bioelution test to assess the matrix (alloy) effects. The HH assessment scheme for systemic endpoints is presently under review by an ECHA led technical Task Force including Member States and a small delegation from industry. Adriana informed the audience how difficult the discussions have been as they focussed on the need for proof (by data) rather than on expert judgement, which explained the simplification of the decision schemes and the focus on the bioelution tests. The Cu sector indicated that testing "every alloy" for bioelution could become a burdensome and complex task for the Cu-alloy sector due to the more than a hundred different copper alloys, some of which are custom-made. On the other hand, understanding was raised for the context of the regulatory discussion. Eurometaux indicated that major efficiencies could be gained by applying the assessment concept in a grouping approach using also the bridging classification technique. The meeting concluded to further explore this potential for grouping and to gather data that could help improve the assessment scheme even more (more information: Adriana Oller, Stijn Baken and Hugo Waeterschoot).

NEW Metals Sectorial Approach

ECHA and Eurometaux are further exchanging on the possible modalities of the metal sectorial approach, using the opportunity of the meetings taking place in Helsinki to make more tangible the next steps agreed on with the Steering Committee early April, e.g. the formal invitation of ECHA to embark on a sectorial approach and the draft baseline report. The latter should be sent to the Steering Committee and then to the consortia, so as to have an informed discussion at the next REACH Forum meeting (20 June) (more information: Hugo Waeterschoot and Violaine Verougstraete).

FURTHER OUTREACH OF REACH

OECD

OECD-BIAC: *OECD Chemicals Joint Meeting - Focus on the revision of Council Acts and Recommendations*

BIAC the industry representation in the OECD met on 29 May the day before the OECD Joint Chemicals Committee. The latter is responsible for providing policy, strategy and oversight on the different and growing chemicals management activities of the OECD. This Joint Meeting was exceptionally heavily focussed on the revision of Council Acts and Recommendations related to chemicals management and therefore of a more strategic nature than usual. OECD Council Acts and Recommendations (CA&R's) provide the frame and outline for the Task Force duties and activities. Many of them were somewhat outdated and did not fit any longer with the actual activities and/or the expectations and demands of the OECD countries. Amongst others the following relevant CA&Rs are under revision: PRTR (defining the emission and product release assessment and reporting requirements), Co-operative investigation and Risk reduction of existing Substances (defining the programs of the Hazard and Exposure assessment task Force and MAD), Testing and Assessment of Nanomaterials. Eurometaux provided comments on some of them, which were agreed by BIAC and forwarded to the OECD secretariat. The Joint Meeting's agenda also included a special session to reconcile IATAs with the OECD MAD status/agreement. IATAs include assessment techniques like QSARs, Genomics and others. It is BIAC's opinion that the crown jewel of the OECD chemicals programme (the MAD agreement and Test guideline programme) should not be watered down as it is the benchmark for reliable high quality fact-based toxicity information the basis for the global exchange and a recognition of toxicity references (more information: Violaine Verougstraete, Kai Melzer and Hugo Waeterschoot)

BIAC Chemicals Committee: *Benjamin Davies resigns as vice-chair*

Benjamin Davies from ICMM resigned as vice-chair of BIAC's Chemicals Committee. Benjamin has decided to take on a new challenge for his career and will become Product Stewardship manager of Anglo American. Eurometaux would like to explicitly thank Benjamin for his contributions to the Committee by continuously putting the minerals and metals agenda and points of concern on BIAC's and OECD's Chemicals Management agenda. The BIAC bureau asked the metals sector to consider appointing a new vice-chair for the Committee. In order to maintain a good balance, the candidate should preferably be European, from the metals sector, have industrial experience and a clear interest in OECD's chemicals management policy. ICMM and Eurometaux promised to consider suggesting a candidate for this vice-chairmanship in the weeks to come (more information: Violaine Verougstraete and Hugo Waeterschoot).

COMMUNICATION

REACH Conference Pruhonice: *active contribution*

The metals sector participated actively in the annual REACH Forum conference co-hosted by the Czech MSCA and other new Member States. Speakers from Member States, ECHA and the Commission explained several aspects of REACH with lots of focus on the REACH and CLP REFIT (by RPA). Most interesting were the views of Commission on the future of OEL-setting, who indicated that this will depend a lot on the outcome of the pilot cases on MOCA and Arsenic Acid. France Capon provided a perspective on the potential role and tasks of Consortia > 2018 and Clémence Siret demonstrated how the Eurometaux Intermediates programme helped them clarify the status of battery products under REACH. Hugo Waeterschoot chaired the session on REACH and CLP > 2018 and presented a summary of industry's experiences with the preparation and assessments of AfAs (more information: France Capon, Clémence Siret and Hugo Waeterschoot).

RMOa training: *the present training package provides sectors with the tool to conduct an effective self-assessment*

The industry-RMOa tool as prepared by Eurometaux was recently updated and a new version was released early May. The tool starts now with a pre-assessment including materials flow and if relevant a diffuse release assessment to define the potential priorities for RMM needs. A training session with the new guidance was organised by Eurometaux as part of its project "outreach planning" requested by its members. The session was organised back to back with the REACH Conference in Pruhonice given the high interest of local authorities and sectors. More than 20 participants attended the interactive training session that included an instructive role play demonstrating how the RMO tool could create value for industry (manufacturers and users) as well as for authorities. Attendees appreciated more specifically the strategic reflection that took into account wider considerations than the exposure caused by the direct use (more information: Michel Vander Straeten, France Capon and Hugo Waeterschoot).

1st International Zinc Conference Europe: *can REACH be explained in a (not frightening) nutshell?*

Eurometaux was kindly invited to the Zinc Conference Europe to explain Eurometaux's perspectives on addressing the EU REACH challenges. Starting from REACH's objectives and Eurometaux's tasks in this context, the presentation evoked subsequently the future of chemicals management in the EU (e.g. mapping of the chemicals universe, the Non-Toxic Environment) and at a more global scale (e.g. Sustainable Development Goals 2030), stressing the essentiality of cooperation, a key element to face the challenges and use the opportunities. This presentation was nicely followed by an overview of the more specifically-related zinc legislative challenges presented by IZA (more information: Frank Van Assche and Violaine Verougstraete).

CALENDAR

- **29 May-2 June:** RAC-41 – ECHA (Helsinki)
- **7 June:** 10 years REACH celebration – ECHA (Helsinki)
- **8-9 June:** RAC-41 – ECHA (Helsinki)
- **5-9 June:** SEAC-35 – ECHA (Helsinki)
- **12-16 June:** SEAC-35 + MSC-54 – ECHA (Helsinki)
- **12-13 June:** OECD Working Party on Hazard Assessment (Paris)
- **13-14 June:** OECD Working Party on Exposure Assessment (Paris)
- **20 June:** REACH Forum – MCC (Brussels)
- **20-21 June:** ECHA Management Board – ECHA (Helsinki)
- **27-28 June:** Chromates AfA Review Workshop – EM & ECHA – MCC (Brussels)
- **28-29 June:** CARACAL 24 – Commission (Brussels)
- **28-29 June:** OECD Working Party on PRTR (Washington)
- **30-31 August:** OECD SEA Methodology Workshop (Ottawa)
- **1 September:** OECD WTP Workshop (Ottawa)
- **4-8 September:** RAC-42 – ECHA (Helsinki)
- **11-15 September:** SEAC-36 + MSC-55 – ECHA (Helsinki)
- **18-22 September:** RAC-42 + SEAC-36 – ECHA (Helsinki)
- **26 September:** A&R Platform meeting – MCC (Brussels)
- **27 September:** REACH Forum – MCC (Brussels)
- **28-29 September:** ECHA Management Board – ECHA (Helsinki)

NB: Please note that RAC/MS/SEAC dates are all tentative and can be subject to change

ACRONYMS

ACSH: Advisory Committee on Safety and Health	NeRSAP: Network of REACH Socio-Economic and Assessment of Alternative Practitioners
AfA: Application for Authorisation	OECD: Organisation of Economic Cooperation and Development
BIAC: Business and Industry Advisory Committee to the OECD	OEL: Occupational Exposure Limit
BLM: Biotic Ligand Model	OSH: Occupational Safety Health
BoA: Board of Appeal	PACT: Public Activities Coordination Tool
CA & Rs: Council Acts & Recommendations (OECD)	PNDT: Pre-Natal Development Test
CARACAL: Competent Authorities for REACH and CLP	PRTR: Pollutants release and Transfer Register
CII: Cross Industry Initiative	PVC: Polyvinyl Chloride
CLH: Harmonised Classification and Labelling process	QSAR: Quantitative Structure-Activity Relationship (models to predict toxicity)
CLP: Classification, Labelling and Packaging Regulation	RAC: Risk Assessment Committee
CSR: Chemical Safety Report	REFIT: Regulatory Fitness & Performance Programme (EU)
CTP-HT: Coal Tar Pitch High Temperature	RMM: Risk Management Measures
DMEL: Derived Minimal Effect Level	RMOa: Risk Management Option analysis
EDC: Endocrine Disrupting Chemicals	SETAC: Society of Environmental Toxicology and Chemistry

ENES: Exchange Network on Exposure Scenarios	SCOEL: Scientific Committee on Occupational Exposure Limits (EU)
EOGRTS: Extended One-Generation Reproductive Toxicity Study	SEA: Socio-Economic Assessment/Analysis
ES: Exposure Scenarios	SEAC: Socio-Economic Analysis Committee (ECHA)
HH: Human Health	SETAC: Society of Environmental Toxicology and Chemistry
IATA: Integrated Approaches to Testing and Assessment	SID: Substance Identity
IUCLID: International Uniform Chemicals Information Database	SIP: Substance Identity Profile
JRC: Joint Research Centre	SpERC: Specific Environmental Release Category
LE: Legal Entities	SUMI: Safe Use Mixture Information
MAD: Mutual Acceptance of Data (OECD)	SVHC: Substance of very High Concern
MeClas: Metals Classification Tool	SWED: Sector specific Worker Exposure Description
MOCA: 4,4'-Methylenedibis(2-chloroaniline)	UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials
MSC: Member States Committee (ECHA)	VSSA: Volume Specific Surface Area
MvE: Man via the Environment	