



## EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

*It is understandable that some REACH Consortia, and their respective members, are questioning the need to still fund the Eurometaux REACH Forum. In my capacity as the chair of the Forum, allow me to provide my perspective on why this continues to make strong business sense.*

*Back in 2008/9, many companies, across many industries, believed that REACH registration would be a 2-3 year "administrative" task, which would cost money but, once completed, would, with a few exceptions, allow business to keep on doing what it was doing. Halfway through 2014, it is very clear that this belief was somewhat optimistic.*

*The metals industries are no longer able to send multiple experts, in never-ending attempts, to defend their science towards committees of Member State experts (under the old Existing Substances Regulation). Today, we are facing a well-oiled regulatory machine, powered by >600 experts both in the European Chemicals Agency in Helsinki and in the Member States. REACH implementation processes are well defined, well communicated (if you have the time to read the ECHA web portal), and operate to strict deadlines. They also have real teeth – as examples, they are resulting in more severe environmental and human health classifications, they are imposing further testing and data gathering obligations on companies, they are imposing market restrictions for certain products and they are issuing formal authorisations that will only allow you to sell your product, in a specific end-use for a limited time, until a safer alternate is available.*

*Certainly the regulators still believe that such evaluations, restrictions and authorisations will drive innovation and create jobs in the search for safer and more environmentally-friendly products – one of the core objectives behind REACH.*

*While it would be preferable to have other choices, the "legislative reality" is that THE advocate (Stakeholder Observer) for the whole non-ferrous metals industry towards ECHA is Eurometaux. This puts enormous pressure on a small group (essentially three persons) to understand the ECHA processes; to invest time in understanding your sector's needs; to be able to lobby credibly on the information, you need to provide before the mandatory deadlines; and to then communicate back to you the regulatory next steps and/or decisions.*

*The same processes also impose obligations on all of you. REACH registration dossiers are living documents that require regular updating - e.g. to reflect bigger tonnages, new end-uses, or science that identifies new environmental and/or human health concerns. While most metals' dossiers have Lead Registrants, who have the legal obligation to keep their dossiers up-to-date, all co-registrants have a shared responsibility to contribute new and relevant information, as well as to communicate effectively and consistently down the value chain.*

*Through various formal and informal interactions, we know that ECHA has a high regard for the non-ferrous metals industry and for the pro-active work done by Eurometaux (which includes the Forum). While the following examples may not mean much, to each of you individually, they do cover real successes that have helped many of your businesses in the past couple of years:*

- *Securing an 18 month delay to revise the methodologies, thus lowering the costs, for the submission of upgraded Intermediates dossiers*
- *Opening an urgent policy discussion on the severe business impacts expected from the proposed CMR classification for lead*
- *Promoting Risk Management Option analysis as a tool to define alternatives to authorisation*
- *Modifying the prioritisation processes for authorisation to better fit with metals' needs*
- *Delaying or halting the selection of some metals for authorisation*
- *Achieving recognition for bioelution tests to be used to assess the bioavailability of alloys - will be critical in future classification and labelling considerations*

All of these, and others, have been achieved through the strong spirit of cooperation that exists within the Forum - the willingness to pool financial and human resources; to fairly share data; to modify individual opinions, in order to present a uniform position to the authorities; and to share registration and evaluation experiences (good and bad) for the benefit of others.

I remain absolutely convinced that this solidarity-based and pro-active approach towards ECHA, aligned under the REACH Forum, continues to be the best way forward in ensuring that REACH implementation is as fair as we can make it for metals. We must try to limit the disadvantages we potentially face, versus competitors operating under less stringent regulatory regimes in other parts of the world, or versus organic-based alternates, such as the whole array of plastic composites. So, what recommendations can I provide and what do I ask of you?

*If you are part of a Consortium staff:*

- Be active in the REACH Forum - input the highest priorities of your Consortium and its members, contribute your time and expertise into the various working groups and send one representative to each Forum meeting (3\*year)
- Ensure your members are aware of the key activities and achievements of the Forum. One simple way is to circulate the monthly REACH News highlighting, if necessary, those items of particular importance and benefit to your members
- Go to the ECHA website, for generic REACH information, and Eurometaux's KnowMe database, for more specific metals info, before asking Eurometaux staff for historical information
- Focus your inputs and requests to Eurometaux staff on outward looking REACH issues. Avoid unnecessary administrative requests

*If you are a REACH registrant (producer, importer, only representative):*

- Ensure that appropriate senior management are fully aware of your company's obligations
- Be sure you have robust business processes in place to maintain/update your registration(s)
- Appoint named individuals (have more than one) whose responsibility is to regularly check your REACH IT inbox and respond in a timely manner, if necessary, after consulting your co-registrants. Failures to reply in time have resulted in additional obligations and/or financial penalties
- Guide, and be prepared to fund, well-defined and rigorously prioritised activities, monitored on an annual basis, within your own Consortium
- Support your Consortium remaining active in, as well as sharing in the funding of, the Eurometaux Forum under the same conditions as above

*It is clear that all of the above requires continued solidarity and funding. It is also clear that nobody, who pays their fair share, wants to see free riders, or those who try to find ways around the system.*

*The cost scrutiny being directed at all Associations and Consortia, by their members, is a clear recognition of the challenging economic situation that exists across Europe. However, compliance with chemicals management is not an option.*

*Therefore, you have my personal commitment that future Forum budgets will be kept to the minimum relevant level by being transparent and rigorously prioritised on horizontal activities that benefit all Consortia. While we have looked at models, which have fixed and variable components, driven by individual Consortium needs, they risk becoming extremely complex and open to interpretation on what does X or Y actually cost. We therefore propose to stay with the current, three category model for next year.*

*Thank you for taking the time to read this. If you have any comments/suggestions, please send them to Violaine, at verougstraete@eurometaux.be, with a cc to me at john.schonemberger@copperalliance.eu.*

*Sincerely,*

*John Schonemberger  
Chief Executive, European Copper Institute  
Chairman, Eurometaux REACH Forum*

# ECHA REACH activities: hot topics

## ECHA COMMITTEES

### **RAC-30: draft opinions now available and to be discussed in September.**

ECHA is actively preparing the next RAC and SEAC sessions (8-12 September), releasing new or revised versions of draft opinions for the restrictions on Cd in paints, Cd in artist paints and copper compounds classification. With regard to CLH part of the meeting, copper compounds (human health) will be an opportunity to test the new fast-track procedure proposed by the RAC Secretariat in June. It means that after adequate scrutiny by the Rapporteur and the RAC secretariat, selected hazard classes are proposed for agreement in plenary, via a list, without further debate. This should allow sparing some time in plenary that could then be devoted to more complex endpoints/discussions. This procedure should apply to a number of hazard classes for the copper compounds. On the other hand, ECHA will organise an evening session to inform the RAC members on the environmental classification of the copper compounds, and in particular on the removal from the water column, so as to prepare the December discussions. This session is the response to several requests from Eurometaux and ECI to be able to explain to the RAC experts the work that has been done to integrate the outcomes of modelling and data in a picture that makes sense and considers metal specificities. Katrien Delbeke, Chad Hammerschmidt (Wright State University), Steve Loft (Centre for Ecology & Hydrology) will accompany Eurometaux as STO experts (more information: Hugo Waeterschoot, Katrien Delbeke and Violaine Verougstraete).

### **MSC-37: compliance checks on complex substances: move to more complex cases**

The upcoming MSC agenda lists a compliance check (dossier evaluation) of a Ni-Sb-Ti compound manufactured by a company belonging to the organic sector. While Ni and Sb are not involved in the dossier, the outcome may affect the way how complex materials like this are assessed in the future. The manufacturer did not make use of the "classical metals toolbox" (like the transformation dissolution for the environmental, or bioelution for the health, endpoints) to justify read across as proposed in the metals UVCB strategy but proposes classical testing. Eurometaux and the sectors involved considered a response strategy aiming to ensure that the metals complex substance assessment approaches could be maintained and ensured (more information: Irene Cañas Sierra, Karin Van de Velde and Hugo Waeterschoot)

### **MSC-37: 6<sup>th</sup> priority list for Annex XIV: preparing for the launch of the Public Consultations (PC) in the first week of Sept.**

Following industry's request, in June MSC decided to postpone the Public Consultation on the draft 6<sup>th</sup> priority list for authorisation (Annex XIV) to after the summer period. It is expected that the consultation will start in the first week of September for a 2 months period. MSC recommended further to list at present more than 20 substances (including several borates, Pb-compounds, hydrazine, Coal Tar Pitch,...), using the responses on the PC to reduce the list to an expected number or 10-12 substances. In parallel using a separate PC-template, ECHA will collect socio-economic information for the substances listed which it will hand over to the Commission to help support the proportionality assessment of the ECHA-MSO opinion on the 6<sup>th</sup> list. Eurometaux will keep its members posted on the launch of the PC and encourage manufacturers and users to respond to both consultations (more information: Hugo Waeterschoot).

## OTHER WORKSHOPS

### **SID and sameness: a workshop in October and a presentation by Eurometaux**

ECHA is organizing on 6-7 October a workshop on Substance Identification and Substance Sameness. The objective is to discuss specific challenging areas of substance identification under REACH and CLP and to develop solutions and criteria to assist both industry and regulators adopt a consistent approach. 2 representatives by country or organization can attend this event that will include both presentations in plenary and breakout sessions. ECHA has invited Eurometaux to make a presentation on its experience with inorganic UVCBs. Aspects that will be discussed include how sameness was assessed in SIEFs/consortia, how EINECs numbers have been used and how information/expert judgment was used to reflect the variability of our UVCBs but also the primary/secondary sources of input material, the known composition etc. The presentation –currently in the make- will be circulated to the UVCB taskforce. Katia Lacasse and Katrien Arijis will represent Eurometaux, ECI and EMPF, as accredited stakeholders (more information: Katia Lacasse, Katrien Arijis, Violaine Verougstraete).

### **Read-across assessment framework (RAAF): workshop on 2-3 October, to follow up**

The RAAF aims at facilitating the consistent assessment of read-across (human health) cases by ECHA experts. This framework has been built on discussions that took place at a first workshop held in October 2012 for Member States and STOs. The RAAF specifically targets cases where read-across has been used in the context of Annex XI of the REACH Regulation ("General rules for adaptations of the standard testing regime set out in Annexes VII to X"). The acceptance of a read-across case depends on making scientific judgments and regulatory considerations. An internal ECHA tool was deemed necessary to ensure consistency and coherence in the assessment of the read-across justification provided by the registrants. It consists of a tiered approach and scenarios, associated with an evaluation of critical assessments elements and scores,

whose combination should help the evaluator to determine if the case is acceptable or not Metals are not immediately visible in the examples that have been given up to now in the RAAF background documents but the scenarios should remain flexible enough to be compatible with main components of our 'read-across approach' like bioavailability of the ion, speciation, particle aspects, etc. Eurometaux has provided comments stressing these aspects and will attend the next RAAF workshop that will take place on 2-3 October (more information: Violaine Verougstraete).

## CSR/ES ROADMAP

### **Preparation of ENES 7: workshop in November**

The 7th meeting of the Exchange Network on Exposure Scenarios (ENES7) should take place in Brussels on 18-19 November 2014. These meetings are prepared by regular calls, led by ECHA and attended by the CSR/ES Steering Group where Eurometaux has a seat. The programme of ENES7 is currently discussed: it will focus on the extended use maps, improvements of the structures of ES (short titles and standard phrases) but also allow downstream users to have more interaction on the downstream user CSR and possible interactive tools. If you are interested in attending, please let us know (more information: Irene Cañas Sierra, Violaine Verougstraete).

---

## EUROMETAUX REACH activities: hot topics/issues

### REACH SEMINAR

#### **Preparatory call: a very energetic start**

A first call took place on 19 August 19 with the members of the REACH Forum who kindly volunteered to help us organize the REACH Seminar on 21-22 October. Diving immediately into the essentials (key messages, target audience, questions to address), the group gave a strong impulse to the organization. A 'save the date' was circulated and a final programme will be available soon. Please do not hesitate to circulate the information! The target of the first half-day (immediately after EM's General Assembly) is to pass the message to the executive management level that REACH allows resource-efficient compliance with chemicals management. Day 2 will discuss REACH in the overall context of chemicals management and SAICM 2020, how to cost-effectively integrate chemicals management into mainstream business processes and reflect on the roles of Eurometaux, Consortia and Companies with respect to REACH compliance. The targeted audience is the REACH managers at company, consortia and commodity levels (more information: Hugo Waeterschoot and Violaine Verougstraete).

### AUTHORISATION AND RESTRICTION

#### **Designing for a more relevant "Authorisation strategy": first thoughts collected**

Eurometaux launched a detailed review of experience with the different steps of the Authorisation procedure applying a "Cradle to Grave" approach. Learning lessons were defined, based on cases for each of the steps of the selection process: *RMO assessment, SVHC identification, prioritisation and authorisation application*; assessing the effectiveness and proportionality of the measures taken. The aim is to define a limited number of effective recommendations for regulators, as well as for the metals sector, on how to improve the Authorisation system, limiting its damage and defining and promoting alternative Risk management Options other than Authorisation and Restrictions. All this will be compiled in a concise strategy paper of the sector for the next Authorisation and Restriction platform meeting on 26 September (more information: Aggie Kotze, France Capon and Hugo Waeterschoot).

#### **RMO on Ni compounds: a high class RMO: France opens a public consultation (PC) at national level**

After several years of assessment France opened a public consultation on two Risk Management Option analyses they prepared for respectively NiSO<sub>4</sub> and NiO, while other Ni compounds will follow later. The PC will run until the end of October and can be consulted from <https://www.anses.fr/fr/search/site/nickel?iso1=fr&iso2=en&tri=1>. France proposes a binding OEL for nickel compounds using the SCOEL recommendation as the best RMO, justified on the need for risk management focus for the workplace while ensuring exposure from intermediates or compounds are handled equally. The setting of an EU-wide OEL for nickel compounds is currently under discussion by DG Employment. Alternatively, in case a harmonized OEL would not be an achievable target, or the agreed OEL value is higher than the SCOEL recommendation, the French authorities will consider other RMO possibilities including Restriction or Authorisation. This alternative "third RMO approach" (OEL based) is a crucial new pathway in line with the strategic recommendations of Eurometaux towards a more effective RMM approach in the EU. It will certainly raise great attention and the interest of the entire metal sector given it will be setting an important precedent. It is evident that a harmonized OEL can also affect the industry given Ni and its compounds are widely used in many alloy applications or available as impurities during the refining process. It is therefore strongly recommended to participate in the national public consultation opened by France (more information: Hugo Waeterschoot or Irene Cañas Sierra).

## EXPOSURE SCENARIOS

### **Working session on 7 August: testing communication tools**

A small subgroup of the Exposure Scenarios taskforce came together early August to test the new format of extended use maps, aimed at facilitating communication along the supply chain. This format is currently tested by a number of sectors, downstream users and registrants, in an exercise coordinated by ECHA and DUCC. We also used the opportunity to test the new 'Short Titles' for ES, as promoted by the CSE/ES roadmap project. Our drivers were the following questions: does the template help registrants to better communicate with DUs and for DUs to understand what registrants do/propose and is the format tuned to the reality of our sector. While the overall exercise was estimated useful, it seems that the current proposed format misses some important aspects like RMMs, physical form to be a useful communication add-on for the metals consortia that tested it. The subgroup will however further reflect on what could be of use and report the 'lessons' to the Exposure Scenarios Working Group. Thanks a lot to Irene, Kate, Laia and Frank for their presence and active involvement in this testing (more information: Frank Van Assche, Violaine Verougstraete).

### **Chemical entity meeting: is it a useful approach?**

On 27 August, industry at large and ECHA met in the metals conference centre to discuss a possible "technical facilitator", namely the chemical entity, which is a way to better structure information in IUCLID and the CSR for complex cases. Eurometaux was particularly interested in this approach and organized the meeting as our sector has been struggling over the last year to produce workable and understandable IUCLIDs for its complex inorganic UVCBs, where the relevant constituents driving toxicity shall be assessed. While the UVCB dossiers are now submitted, the idea of a facilitator linking the different pieces of information –facilitating the reading- when parallel assessments are conducted is worthwhile to explore. A possible application could be that the chemical entity (or 'assessment entity') would enable to set links between hazard, exposure and uses and possibly avoid false positives in selecting/prioritisation of substances by authorities purely based on hazard information (in case an impurity would trigger a CMR classification or SVHC status). Other possible applications could be cases where you have several forms [or several compositions] with different (fate)/hazard profiles ending up in different uses or substances undergoing transformation on use or in the environment. Industry and ECHA have agreed that the idea might be useful; it shall now be tested with practical cases so as to define the specifications required to use it in IUCLID/CSA (more information: Violaine Verougstraete)

## METAL-SPECIFIC REACH APPLICATION TOOLS AND CONCEPTS

### **ICMM-Eurometaux MERAG project: a first review of the updated MERAG fact sheets**

The MERAG fact sheet series is under review in anticipation of the OECD and ECHA-REACH Environmental Guidance Updates scheduled for 2015. Selected MERAG fact sheets were updated by ARCHE based on input from Commodities, Eurometaux and Consortia as well as new scientific evidence. The main suggestions to complement and update the fact sheets were presented in Toronto at the combined ICMM-Eurometaux MERAG review session, commented by Eurometaux and soliciting further suggestions from the Commodities and Consortia attending. Suggestions were provided on what and how new scientific aspects should be included and members were invited to submit comments in writing by 19 September at the latest to ensure ARCHE can prepare a new version in time for a second commenting round. ICMM ensured that a peer review session organised by the UK DEFRA is now scheduled before the end of the year (more information: Marnix Vangheluwe, Hugo Waeterschoot or Benjamin Davies).

### **Environmental Toxicologist Panel: Eurometaux attended the session that handled many issues of high importance for REACH & CLP**

The Environmental Toxicology panel (ETAP) sponsored by metal Commodities and companies, met in Toronto mid-August. The panel consists of a series of independent scientific experts of different expertise that provide guidance to the industry on challenging and emerging environmental science issues, raised by industry. Amongst others, two issues where in this respect of particular and direct importance for Eurometaux activities on REACH and CLP namely 1) *how relevant are Species Sensitivity Distributions and PNECS derived for the temperate zone for other climate zone (boreal, Mediterranean,...)* and 2) *how can degradation be measured in an empirical way under standard conditions in the laboratory in line with GHS and CLP criteria*. Eurometaux will therefore participate in the follow-up of those aiming to translate the scientific guidance into practical recommendations for the REACH Consortia (more information: Ilse Schoeters and Hugo Waeterschoot).

## COMMUNICATION ACTIVITIES

### **Korea REACH: Eurometaux met Korean Technical Institute and government**

Alongside the OECD meeting and the training session with Japanese authorities on MERAG principles, Eurometaux met with KTR a major technical institute in Korea helping industry, including importers, to comply with the new K-REACH ruling. Besides data protection needs for the transfer of REACH registration data, Eurometaux suggested that KTR and the Korean government consider the relevance of MECLAS, MERAG and HERAG when drafting the specific hazard and risk assessment guidance in 2015. Different than under REACH, Korea had so far not considered developing specific guidance for metals and

inorganics. Eurometaux therefore suggested that Korea actively follow the OECD activities on environmental guidance development inspired by the MERAG update as well as checking the usefulness of MECLAS for the assessment of complex metal mixtures and materials to ensure global consistency. KTR and other groups will organize a briefing session in Brussels on 17 Oct, to inform the Eurometaux and Consortia memberships on data registration and other chemical management requirements in Korea (more information: Hugo Waeterschoot).

## Further outreach of REACH

### Meeting with Canada: *Eurometaux meeting the Canadian authorities*

Along the ICMM Chemicals Management Working Group meeting in Toronto, Eurometaux had the opportunity to meet the Canadian authorities responsible for Chemicals Management. Besides an explanation by Eurometaux on its comments and suggestions on the Organometals guidance Canada wrote for the OECD (see July newsletter), the briefing session focussed on the potential relevance of MECLAS, MERAG OECD update as well as the review report on diffuse sources, for Canada. The introduction of the GHS in the country (by 1 June for all substances and mixtures) and a very challenging program on metals risk assessment (DSL) for the 5 years to come would make these tools most relevant. On the latter Canada plans to review more than 10 metals and their compounds and invited Eurometaux to co-organise a webinar to inform the concerned European REACH Consortia and to solicit interest for data sharing agreements as successfully done for Cobalt. Canada further informed the metals sector that they will release the Cobalt case in autumn as the first in a series of metals risk assessments (more information: Hugo Waeterschoot).

## Calendar

- **8-12 September:** RAC-30 (Helsinki)
- **15-19 September:** MSC-37 (Helsinki)
- **25 September:** REACH Forum – MCC (Brussels)
- **26 September:** Authorisation & Restriction Platform – MCC (Brussels)
- **1 October:** Director's Contact Group (Brussels)
- **2-3 October:** RAAF (Read-Across Assessment Framework) - ECHA (Helsinki)
- **6-7 October:** SID workshop-ECHA (Helsinki)
- **17 October:** K-REACH Meeting – MCC (Brussels)
- **21-22 October :** REACH Seminar - Square (Brussels)
- **27-31 October:** MSC-38 (Helsinki)
- **24-28 November:** RAC-31 (Helsinki)
- **1-5 December:** RAC-32 (Helsinki)
- **8-12 December:** MSC-39 (Helsinki)
- **16 December:** Authorisation & Restriction Platform – MCC (Brussels)
- **17 December:** REACH Forum – MCC (Brussels)

## Acronyms

CLH: Harmonised Classification	OEL: Occupational Exposure Limits
CLP: Classification, Labelling & Packaging Regulation	PC: Public Consultation
CMR: Substances classified as Carcinogens, Mutagens or toxic to Reproduction	PNEC: Predicted No-Effect Concentration
CSR: Chemical Safety Report	RAC: ECHA Risk Assessment Committee
DU: Downstream User	RAAF: Read-Across Assessment Framework
ECHA : European Chemicals Agency	RMM: Risk Management Measures
EINECS: European Inventory of Existing Commercial Chemical Substances	RMO: Risk Management Options
ENES: Exchange Network on Exposure Scenarios	SAICM: Strategic Approach to International Chemicals Management
ES: Exposure Scenarios	SCOEL: Scientific Committee on Occupational Exposure Limits
ETAP: Environmental Technology Action Plan	SEAC: ECHA Socio-Economic Committee
GHS: Global Harmonised System / Standard	SID: Substance Identity
HERAG: Health Risk Assessment Guidance for metals	SIEF: Substance Information Exchange Forum
IUCLID: International Uniform Chemicals Information Database	STO: Stakeholder Observer
MECLAS: Metals Classification Tool	SVHC: Substances of Very High Concern

MERAG : Metals Environmental Risk Assessment Guide

UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials

MSC: Member States Committee

UK-DEFRA: UK – Department for Environment Food & Rural Affairs

OECD: Organisation of Economic Cooperation and Development