



## EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

*This week, someone kindly asked me how my REACH agenda was looking these days. "Busy, hectic, overloaded": the usual adjectives came immediately to my mind. But then came the "why?"- and I paused. I could not find an answer that would make sense and summarise what I was experiencing exactly at that moment: a scattered vision of my Outlook calendar and of horses running in opposite directions.*

*REACH moves onwards, follows its intrinsic timeline, building on the 2010 or 2013 registrations (the 'R'), enthusiastically identifying and prioritizing substances of concern, maintaining our advocacy active on criteria, RMO and impacts (the 'A'). It pushes us willy-nilly along the road of further capacity building and learning on e.g. SEA, downstream users' communication, making use of information, etc.*

*There is, however, also a part of REACH that works backwards and that forces us to stop going down our "one-way" street, and even to make a U-turn. It pulls us back to our "as good as we could" submissions and forces us to dive again into things we considered - not necessarily granted, but at least - 'done'. The 'E' (Evaluation) activities of REACH demonstrate that nothing is really 'done'. The evaluation platform meeting on November 28 illustrated perfectly what can happen when the content of a dossier or our knowledge of a substance is not interpreted or assessed in the way we have in mind when writing it.*

*Evaluation is a challenge. It feels a bit like the child who has not received his teacher's blessing to leave him with his copy, but who is constantly being sent back to his desk to revise it with more questions and complexity. He is stressed - he knows that there is still a lot of other work and learning awaiting him.*

*Evaluation will keep us in the classroom for a long time to come: some of the consortia have realised that the finalisation of the evaluation of their testing proposal could easily lead them into 2020.*

*This is probably the source of our discomfort: we need to organize again, find even more ways of saving resources and energy, invest in the long term, and mourn over what is 'over and done' with REACH. Platform meetings, solidarity and exchanges among the consortia are one of the best ways to do so. With a touch of humour of course ("Humour does not diminish the pain - it makes the space around it get bigger". Allen Klein)!*

Violaine Verougstraete, EHS Director, Eurometaux

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## ECHA REACH activities: hot topics

### ECHA COMMITTEES

#### MSC-32

##### ***The first Substance Evaluation (SE) debated...***

MSC discussed the first 4 Substance Evaluations from the 2012 CoRAP listing, on which it was unable to reach agreement during the written round. The reviewed cases raised a great deal of discussion, and despite the fact that the debate focused on organic chemicals, it gave rise to very important and relevant learning lessons for the metals sector and for industry in general.

For example, MSC defined what long-term testing would have to be conducted for reproductive toxicity (2 -generations or Extended One Generation Reproductive Toxicity Study (EOGRTS), favouring the latter) while another case demonstrated how the evaluating Member State used the SE to assess whether SCC were met for the registrant of an intermediate, forcing others to upgrade their dossiers within a very strict time slot (more information: Hugo Waeterschoot).

#### ***A new Chair expected as of March 2014...***

The MSC Chair Anna-Liisa Sundquist will leave ECHA- for retirement reasons -by the end of February 2014. She will be replaced by Dr. Watze De Wolf, currently one of the Heads of Unit of the Evaluation Team. We thank Anna-Liisa for the frank and open debate she promoted at ECHA, allowing the metals sector to express its opinion and provide technical input, and hope that this open mindset will continue with the new upcoming chair (more information: Hugo Waeterschoot and Violaine Verougstraete).

#### ***5 proposed candidates for Annex XIV - none of them clear cases***

MSC reviewed the comments provided during the Public Consultation for the 5 substances listed as potential candidates for Annex XIV under the 5<sup>th</sup> priority list (3 organics and 2 Refractory Ceramic Fibres (RCFs)). Contrary to ECHA, many MSC members sympathized with industry in that the scope and prioritization of the RCF is and remains unclear and the scoring overvalued. It was recognized that an exact assessment of the boundary between substance and article would be crucial to define the scoring and relevance of maintaining RCFs on the 5<sup>th</sup> list. The first Rapporteurs' report therefore also included the option to postpone prioritization until this issue had been clarified. The December MSC discussion will therefore be crucial in defining the future of these substances (more information: Hugo Waeterschoot).

#### ***CoRAP: speeding-up and extending the list, but limited new issues for metals***

ECHA published the draft CoRAP on November 4, thereby doubling the number of substances under planning and review for SE during 2014-2016 (from 69 to 125). With Be, Ag, ZnPO<sub>4</sub>, GaAs and SiO<sub>2</sub> already being listed, the update did not bring any new major surprises for metals this time. Only AlCl<sub>3</sub> will be added to the CoRAP list for 2016 by France, for the same reasons as AlSO<sub>4</sub> last year (potentially CMR and PBT). The draft CoRAP was published much earlier than usual, and is still up for review and approval by MSC by February 2014, but the procedure does not include any Public Consultation. Eurometaux will check the consequences of the 2 Al compounds being listed, as some of its members manufacture them (consortia covered by Cefic). Eurometaux registrants with substances on the CoRAP list for 2014 and 2015 noted Compliance Check (CC) activities by ECHA, a standard practice that will be conducted on each listed substance the year before the SE is scheduled (more information: Hugo Waeterschoot).

#### ***Prioritisation for Annex XIV: new criteria under development may improve the situation for metals***

MSC welcomed ECHA's proposal to review the prioritisation system to identify substances from the Candidate List to be included first in Annex XIV. MSC-32 concluded that the new proposal was in line with the recommendations of the workshop on this subject (see September REACH News). The most important changes include: 1) equal weighting for intrinsic properties, volume and wide dispersive use (WDU); 2) PBT receiving a maximal scoring for intrinsic properties; CMR a minimal scoring -in line with the REACH text; 3) more volume categories; and 4) WDU being defined by the "type of use" (industrial, professional or consumer) instead of by number of workers and sites. A volume/use correction could be applied IF this information is available from a materials flow analysis from the Registration file. While the proposed system includes a number of improvements that may lead to a less discriminatory system for metals and inorganics, Eurometaux feels that it could still be further refined significantly, e.g. by deprioritizing substances used in consumer articles in an embedded form (e.g. CMR substances enclosed in batteries) and substances used in alloys. Many Member States support this view, but ECHA maintained its resistance, given that these additional criteria cannot be automated (more information: Hugo Waeterschoot).

## **SEAC**

#### ***Alarming impact of the Pb restriction case on Cu recycling reported to ECHA***

A narrowed scope and the recognition of bio-elution as a potential tool to demonstrate that articles are safe may limit the potential impact of the Pb restriction case. ECHA-SEAC took note of the data submitted on testing costs for the proposed restriction (up to 84 million/year). A general surprise for both industry and the Member States is the fact that the restriction would have a very significant impact on the Cu recycling sector (probably 140 million euros/year) if the limit was to remain at 0.05 % of Pb content in brass and if no exemptions were to be granted. ECI made calculations and informed ECHA that this cost would decrease to less than 20 million euros if SEAC were to accept the outcome of the bio-elution work and if all exemptions were to be granted. Alternatively, ECI proposed an alignment of the Pb content in brass in line with a recommendation for drinking water supply materials. Eurometaux will raise these comments at the upcoming SEAC meeting in December, hoping that SEAC will consider the consequences of this collateral damage of the Pb restriction case (more information: Steve Binks, Katrien Delbeke and Hugo Waeterschoot).

## Commission REACH activities: hot topics/issues

### ***European Commission consults industry on the impacts of modifications to REACH annexes for nanos***

On 12 November, representatives of DG ENV and DG ENT met with representatives from some industry sectors to exchange views and information on some of the options under discussion to adapt the REACH Annexes, in order to better accommodate the information requirements for nanomaterials. The European Commission was particularly interested in an estimate of the cost implications for the individual registrants. These are somewhat difficult to estimate, as they will depend on current 'routine' practices: on how the nanomaterials are defined and grouped in the registration dossiers (generic nanoform, nanoform or product grade), or on the tests currently already carried out for the characterisation of the materials, depending on the specific nanomaterial. As a result of the meeting, the general understanding of the issues was improved and industry was invited to give a presentation at the CARACAL meeting (more information: Inneke Claes).

### ***CARACAL***

The CARACAL meeting of 26-27-28 November was characterised by a very heavy agenda with many preparatory documents made available just before the meeting. This resulted in very little actual discussion during the meeting itself; even requests to send in written comments after the meeting were not always taken up by the Commission or ECHA. For next year, there could well be three full CARACAL meetings, as has been the case in the past. Some of the topics of relevance for the Eurometaux membership included the following:

- C&L Inventory: ECHA will set up a working group (including representatives from stakeholder organisations) to discuss possible solutions to improve the contents of the inventory
- A proposal from the Commission on post-natal exposure and developmental effects under the hazard class 'toxic for reproduction': an update will be given at the next CARACAL meeting
- EOGRTS: the Commission proposes to make the EOGRTS the default test instead of the two-generation test
- ECHA's proposal for the definition of prolonged contact with skin for the restriction on nickel in certain articles
- A Eurometaux presentation on the plans to update the UN GHS Annexes 9 and 10 on the environmental classification of metals and metal compounds

More information will be circulated shortly (more information: Inneke Claes).

### ***Workshop on the links between REACH and other pieces of legislation***

On 8 November, a workshop for the Commission, Member States Competent Authorities and ECHA took place to discuss the links between REACH and RoHS, OSH, POPs and Toys legislation. Stakeholders were not allowed to participate. The aim is to draft four common understanding papers. The ones for REACH and RoHS and REACH and POPs have already been submitted to CARACAL, and the two remaining papers are expected for early 2014.

A summary of the meeting and the presentations are available on this link: [http://ec.europa.eu/enterprise/sectors/chemicals/reach/events/index\\_en.htm#h2-3](http://ec.europa.eu/enterprise/sectors/chemicals/reach/events/index_en.htm#h2-3) (more information: Inneke Claes).

### ***Workshop on the SVHC Roadmap***

Back-to-back with the CARACAL meeting on 28 November, the Commission organised a workshop on the implementation of the roadmap for the SVHC. The 'Roadmap Implementation Plan' (RIP) was adopted by CARACAL during its closed session. Even though an RMO analysis is to be carried out on a voluntary basis by Member States, ECHA and the Commission emphasised that the aim of the RIP was to increase transparency, provide early warning, and allow for early involvement of stakeholders in the RMO process. ECHA will launch a special section on its website on the SVHC roadmap in early December. This will contain the Roadmap, the RIP, information on the screening for SVHC for regulatory risk management and the public conclusions of the RMO analysis. Information on certain substance-specific activities will be communicated via the new Public Activities Coordination Tool (PACT) in the third quarter of 2014. The presentations made at the workshop and a live recording are available on this link: [http://ec.europa.eu/enterprise/sectors/chemicals/reach/events/index\\_en.htm#h2-2](http://ec.europa.eu/enterprise/sectors/chemicals/reach/events/index_en.htm#h2-2) (more information: Inneke Claes).

# EUROMETAUX REACH activities: hot topics/issues

## AUTHORISATION

### ***Q4 meeting of the Authorisation/Restriction Platform***

The Eurometaux Authorisation/Restriction platform met on 21 November for a meeting dedicated to the theme of “learning experiences”. The platform discussed the progress made with the prioritization criteria for Annex XIV and recommended further advocacy targets. The status of the 5<sup>th</sup> priority list, especially the RCF case, was also presented. The main part of the meeting focused on learning cases, however, i.e. a) a theoretical study on environmental hazard impact assessment concepts/techniques, demonstrating how far Member States have got with these types of tool; b) a review of the Cd court case demonstrating that a restriction lacking proof of an EU-wide risk can be challenged; c) the first metals authorisation case on As<sub>2</sub>O<sub>3</sub> providing insights into the challenges/approaches for authorisation applications; d) the Pb restriction case illustrating how sectors other than manufacturing and use could be impacted (i.e. recycling); and e) the challenge of Cobalt balancing between the risk of being covered by a Restriction or by an Authorisation. The platform also defined its main objectives for 2014 and work programme headlines for 2014 (more information: France Capon, Aggie Kotze and Hugo Waeterschoot).

## CLH

### ***Borates CLH***

Eurometaux met representatives of the borates consortium to prepare the forthcoming borates CLH discussions at RAC. The Polish authorities have submitted an Annex XV proposing the reclassification of boric acid as Category 2 reproductive toxicant under CLP. The Public Consultation has taken place, and the substance is expected to be tabled on the RAC 28 meeting agenda (March). These discussions are of high interest to the metals community/Eurometaux, as they raise a number of critical issues such as the use of human data versus animal data in classification, new evidence on mechanism of action, use of hazard and exposure data in classification, and comparison of exposure levels between humans and animals when setting an effect level (more information: Borates Consortium, Hugo Waeterschoot and Violaine Verougstraete).

## EVALUATION

### ***Evaluation Platform Kick-Off Meeting***

The first meeting of the Eurometaux Evaluation platform was organized on November 28, with the aim of getting acquainted with Dossier and Substance Evaluation processes; sharing current experience from the members on DE and SE; and agreeing on the Terms of Reference of the Platform, with special focus on 2014 activities. Caroline Braibant kindly agreed to endorse the chairmanship☺. The meeting also provided a good opportunity –by using practical cases- to illustrate the importance of drawing horizontal learning lessons and precedent settings, so as to enable industry to better anticipate evaluation activities. The next meetings will be scheduled in line with the CoRAP process, and most probably back-to-back with other Eurometaux REACH meetings, with a tentative schedule of April and November 2014 (more information: Hugo Waeterschoot and Violaine Verougstraete).

## INTERMEDIATES

### ***Communication ongoing with ECHA***

On January 22 2014, a delegation from the EM REACH Intermediate Task Force will visit ECHA to explain the approach for a realistic and scientific-based chemical safety assessment of inorganic UVCBs. The meeting is perceived as the conclusion of our exchanges with ECHA during the current year on SID and classification. By 22 April 2014, at the clear request of ECHA, companies are expected to submit their inorganic UVCBs Article 10 dossiers. Meeting documents and presentations will be prepared and shared with the task force for feedback before being submitted to ECHA (more information: Federica Iaccino).

## MAPPING TO RESPOND TO REACH / ECHA CHALLENGES

### ***Re-organisation for a more balanced workload***

Eurometaux has started to reflect on a possible reorganisation of REACH activities to better deal with the long-term challenges (workload, efficiency, costs) that REACH has in store for us. A SWOT analysis of organisational capacities, a benchmarking exercise and the identification of poles of expertise were used as starting-points. The objective is to further work out a concrete proposal to be discussed with the REACH Forum chairs and members in early 2014 (more information: Violaine Verougstraete and Hugo Waeterschoot).

## METAL-SPECIFIC REACH APPLICATION TOOLS AND CONCEPTS

### ***Chesar and IUCLID - compatibility with metals***

Eurometaux, EBRC and ARCHE are discussing with ECHA the possibility of making the next version of Chesar more “metals-friendly”. The limitations of the current version for the assessment of metals (e.g. no possibility to edit the removal efficiency rate of the municipal sewage treatment plant, no possibility to edit the regional releases), and the technical steps and resources that would be required to overcome the latter, are currently listed and will be further discussed with the ECHA experts in January 2014. Further exchanges on the format of IUCLID for the UVCB dossiers will also take place. IUCLID 6.1 and Chesar 3.0 will be released in Q1 2016. Please note that ECHA has clarified that, until the release of such updated tools, IUCLID 3.7 data will not be subject to TCC, thus not being mandatory (more information: Violaine Verougstraete and Federica Iaccino).

## COMMUNICATION ACTIVITIES

### ***ENES 5 meeting and SCEDs workshop***

Eurometaux, DUCC, Cefic and Concawe jointly funded the 5<sup>th</sup> meeting of the Exchange Network on Exposure Scenarios, which took place on November 21-22 in Brussels. Important topics on the agenda were the CSR/ES roadmap that several industry sectors committed to sign last summer (progress and next steps), further efforts to harmonise and standardise ES (short titles, Specific Exposure Determinants, updating of Guidance R12, ECom, etc.), and methodologies to assess the safe use of mixtures. Eurometaux also attended a workshop organised by AISE and DUCC on Specific Exposure Determinants (SCEDs) aimed at obtaining more realistic and transparent data for assessing consumers' uses in different sectors, which should serve to standardise & harmonise the communication of safe use information in the supply chain. Both meetings involved Member States Competent Authorities, ECHA and industry. Notes summarising the main outcomes have been circulated to the Exposure Scenarios Task Force (more information: Federica Iaccino and Violaine Verougstraete).

### ***REACH-IT news and end-of-year ECHA business opening hours***

Eurometaux, together with other industry sectors, attended a meeting on 28 November 2013 at the Cefic premises, where ECHA presented the future plans for REACH-IT. The main messages were that Version 2.7 of REACH-IT (to be released in 2014) is still the only channel used by ECHA to communicate with legal entities, that users are requested to be aware of the legal implications of the terms and conditions, and that it is recommended to log in regularly to ensure correct follow-up. A few specific key features, such as a quick automated reply from ECHA acknowledging receipt of a dossier update and introducing an action flag to attract a user's attention were presented, together with a more detailed REACH-IT 3.0 high-level plan for the coming years (release foreseen in 2016). Detailed presentations will be made available by ECHA and circulated to the members, together with a report on the meeting (more information: Federica Iaccino). Please note that ECHA will be closed for the holidays at the end of the year, which means that also REACH-IT will close on 23 December 2013 at 13h00 and open again for normal service on 2 January 2014 at 10h00.

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## Further outreach of REACH

## OECD

### ***Meetings of the TFEA and TF-PRTR: Eurometaux in Geneva***

The Task Force on Exposure Assessment (TFEA) and the PRTR Task Force (TF PRTR) both held their annual meetings, bringing together representatives from the OECD countries to discuss topics ranging from consumer exposure methodologies to emission scenarios. Eurometaux -like BIAC- made a presentation on the diffuse sources project at both meetings. The PRTR Task Force welcomed the presentation and the proposed work aimed at increasing the quality of the data and a better understanding of diffuse sources. The metals sector is invited to forward the project drafts (i.e. a “template format” to document scope, relevance & data quality and horizontal factsheets by release category for a series of metals) when available, for review and input by the members, and to make a presentation at the next meeting on the peer review publication that should summarise new conceptual experience and data (more information: Hugo Waeterschoot and Violaine Verougstraete).

## OECD Guidance on Grouping Chemicals

A re-worked version of the metals section of the updated OECD guidance on grouping chemicals has been submitted to the OECD Secretariat, aimed at addressing some comments made by OECD countries on the structure and terminology ... in the hopes that this version will be accepted and published in the coming months (more information: Violaine Verougstraete).

## Calendar

### 2013

- 2-5 December: RAC-27 ECHA (Helsinki)
- 9-11 December: SEAC-21 ECHA (Helsinki)
- 9-13 December: MSC-33 ECHA (Helsinki)
- 17 December: REACH Forum – MCC (Brussels)

### 2014

- 1 April: REACH Forum – MCC (Brussels)
- 28-29 April : ECHA Seminar on the basics of AfA (for beginners)
- 29-30 April : ECHA Workshop on lessons learned of AfA
- 25 September: REACH Forum – MCC (Brussels)
- 17 December: REACH Forum – MCC (Brussels)

## Acronyms

AISE : Association for Soaps, Detergents and Maintenance Products	PBT: Persistent Bio-accumulative Toxic Substances
BIAC : Business and Industry Advisory Committee to the OECD	Pb : lead
CARACAL: Competent Authorities on REACH and the CLP Regulations	POPs : Persistent Organic Pollutants
CLH: Harmonised Classification & Labelling process	RCF : Refractory Ceramic Fibres
CLP: Classification Labelling & Packaging Regulation	RIP : REACH Implementation Project
CMR : Substances classified as Carcinogens, Mutagens or toxic to Reproduction	RMO : Risk Management Option
CoRAP : Community Action Rolling Plan	SCC : Strictly Controlled Conditions
CSR: Chemical Safety Report	SCED: Specific Consumer Exposure Determinants
Cu : Copper	SEA : Socio-Economic Analysis
DE : Denmark	SE : Sweden
DUCC : Downstream Users of Chemicals Co-ordination	SEAC: ECHA Socio-Economic Committee
ECHA : European Chemicals Agency	SID: Substance Identification
ECI: European Copper Institute	SVHC: Substance of Very High Concern
ENES: Exchange Network on Exposure Scenarios	SWOT : Strengths Weaknesses Opportunities Threats analysis
ES: Exposure Scenarios	TCC : Technical Compliance Check
EOGRTS : Extended One Generation Reproductive Toxicity Study	TFEA : Task Force on Exposure Assessment
MSC: Member States Committee	TF PRTR : Task Force on Pollutants Release and Transfer Register
OSH : Occupational Safety Health	UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials
OECD : Organisation of Economic Cooperation and Development	WDU: Wide Dispersive Use
PACT : Public Activities Coordination Tool	