



## EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

Several of us have already experienced, while travelling back and forth, running in and out of meetings, jumping between calls, those brief but rather intense moments where real basic questions like “where am I?”, “what am I supposed to do here?” hit you in the middle of a corridor, an airport or a hotel room in the morning. A sudden twist of your brains, short enough to leave you perplexed but not scared. These moments are most probably the price to pay to Lady Adrenaline who keeps us delivering, multi-tasking, presenting and learning most of the time, week after week, from January to June. Needless to say that the smile received from someone realizing what you are going through at that exact moment, the question of a member bringing you back on track by asking you ‘and in practice this means?’ are priceless and essential.

Still, such flashes are also the signal that it is time to take a break and impose a wellness cure to to-do lists, calls and emails. After these heavy REACH months, the achievements of e.g. the cobalt testing proposals and selling of the read-across concept, the SVHC roadmap, the set-up of the NeRSAP, the work across consortia on common concerns like the Pb restrictions/CLH and the constructive REACH Forum meeting of last week; it is time to wish you a slowing-down, sunny and peaceful summer!

Enjoy the days and in case you really miss REACH too intensively, have a look at our summer specials: they should be sufficient to bring you back on track!

Violaine Verougstraete, EHS director Eurometaux



## ECHA REACH activities: hot topics

### ECHA COMMITTEES -

#### **RAC-25, 5-8 JUNE 2013: a last round for GaAs, a first one for Pb and Pb compounds**

RAC-25 discussed the ‘general aspects’ of the restriction on “Pb and Pb in consumer articles that can be placed in the mouths of children” like definitions, references to mouthing time, type of data/information needed to perform the exposure assessment and the risk characterisation, and possible exemptions. The key question is whether a risk can be demonstrated to justify the restriction and if yes, whether a 2-step approach (i.e. have a max. Pb content in % with the possibility to refine it with migration data) could be implemented. The consultation on the GaAs Opinion (of the RAC majority) lasted until 19 June; after that the minority view will be published as well. It is expected that the finalized Opinion will be forwarded, still in July, to the Commission. On authorisation, RAC is continuing its capacity building with e.g. a project for performing the cancer risk assessment in the context of ‘uses’ under authorisation for both Cr and As (more information: Violaine Verougstraete, see RAC highlights circulated on 10 June).

## **SEAC-19, 6-8 JUNE 2013: Pb restriction case discussion initiated**

The discussion on the Pb and Pb compounds in articles restriction case submitted by Sweden, was launched in June in parallel in RAC and SEAC. SEAC emphasized the need for additional data on analytical accuracy and costs, opened the potential for bio-elution testing, continued gathering data on Pb in recycling materials but counts on Industry to submit these data given SEAC does not expect Sweden to do so. The SEAC secretariat made specific reference to the ECI data file on Pb in Copper alloys as a very valuable source to refine the impact assessment and recommended collecting complementary data on other metal alloys/recyclables. Industry was invited to submit as much information as possible on these and other aspects by end of July to allow the SEAC Rapporteurs to evaluate its usefulness. A very important conclusion was the agreement to use “average” rather than “worst case” toxicity-effects data as a basis for the SEA analysis. This conclusion, which is clearly different than RAC’s drive for precaution, would require Industry to provide a table of embedded uncertainty covered in the Swedish proposal and RAC assessment. ILA will further the coordination, by informing the metals sector about this case and coordinating the collection of additional information (more information: Hugo Waeterschoot and Jessica Ryman, see SEAC highlights circulated on 11 June).

## **MSC-30, 11-14 JUNE 2013**

### **Update CoRAP (only) expected after the summer**

At the MSC in June Member States were briefed on the outcome of the ECHA substance evaluation workshop (see previous REACH News) and the progress with the 2014-2016 CoRAP update and extension. ECHA indicated that for the CoRAP update 70 new candidates were identified plus 20 remaining from last year, so in total 90 substances would be available. MSs now have time until 15 August, to indicate for which substances they would like to develop a substance evaluation report in 2015 or '16, or change the timing or level of concern for 2014. The updated CoRAP list is not expected to be available before mid-autumn (more information: Hugo Waeterschoot).

### **Substance evaluation complemented by dossier evaluation**

A novelty is that ECHA will conduct full Dossier Compliance Checks (DCCs) for substances on the CoRAP list from 2015 onwards to check the quality and completeness of the registration dossiers. The check will in principle include both the LR’s submission as well as those from the other registrants. Given the timing to complete such assessments for 2014 substances is too short, ECHA will conduct DCCs only for the SID’s (Substance Identity) section of the Registration files; 2013 substances will not undergo any screening in advance. Eurometaux will share DCCs experience with the members at the joint Evaluation platform meetings with Cefic (more information: Hugo Waeterschoot).

### **Approved next SVHC list and proposal for a 5<sup>th</sup> prioritisation list for Annex XIV**

In June, MSC approved amongst others, Cd and CdO as SVHCs for their CMR and their Equivalent Concern properties. Osteoporosis and renal dysfunction hazards were recognized as fitting the criteria for equivalent concern (57 (f)), thereby setting a first precedent for a substance classified as STOT-RE. However, it was recognized that STOT-RE 1 or 2 classified substances should not enter the Candidate List as such, albeit requiring a case by case assessment to check the seriousness of the effect (more information: Hugo Waeterschoot and Violaine Verougstraete).

### **5<sup>th</sup> prioritisation list for Annex XIV in Public Consultation**

MSC achieved agreement on the prioritisation proposal from ECHA to propose 6 substances for the next update of the Annex XIV list. The list contains only 6 substances this year including 2 Refractory Fibers widely used in the metals sector and a substance (Decabromo) that in parallel will be submitted for the POP’s convention. A Public Consultation was launched on 24 June for a period of 2 years. The Eurometaux Authorisation and Restriction platform will follow this activity (see further). (More information: Hugo Waeterschoot)

### **First metals Read Across case for Testing Proposals adopted**

MSC set an important milestone and precedence by agreeing with the Testing Proposal for Cobalt compounds. The extensive discussions and interaction with the Cobalt sector and Eurometaux over the last 6 months gave recognition to the relevancy of Bio-elution tests to define grouping, read across hypothesis formulation and testing proposal selection. However, the Cobalt sector will have to prove the validity of the read across hypothesis when they deliver and submit the outcome of the testing program to ECHA or take corrective measures or suggest additional testing. A first debrief was provided to the Eurometaux REACH Forum and a more detailed debriefing to assess the consequences for other Consortia will be scheduled after the summer (more information: Violaine Verougstraete, Hugo Waeterschoot and Steven Verberckmoes).

## **ECHA MEETINGS**

### **Formatting issues (IUCLID, CSR, Chesar) in UVCB and metals dossiers: *how to further improve?***

On 3 June, a small delegation from Eurometaux met experts from the Computational and Evaluation units of ECHA to discuss formatting issues in the metals and inorganic UVCB dossiers. More specifically, the participants highlighted the issues encountered when using the available IUCLID/CSR templates and the possible solutions to improve reporting and understanding in case of complex dossiers and metal specificities not covered by default. The discussion also included an exchange on metal-specific aspects to address before being able to fully use Chesar for metal dossiers and the possible links between metal tools like SPERCs and MEASE. It has been agreed to explore -on both sides- the possibility to develop a test case using a 'complex inorganic dossier', which would allow identifying further changes needed and/or recommendations. This was further discussed at the meeting of the REACH Intermediates taskforce meeting on 28 June (more information: Federica Iaccino and Violaine Verougstraete).

### **PEG on PBT and vPvB: *PEG considered organo-metal definition***

A Partner Expert Group (PEG) including a representative from Eurometaux reviewed the updated REACH guidance section on PBT and vPvB. Two years of experience with the PBT, vPvB identification for SVHC listing demonstrated a clear need to clarify and update this guidance section. The guidance now includes a definition of an "organo-metal", exempting simple organo-metal compounds that dissociate easily in water. While the guidance is not directly applicable to metals and inorganic metal compounds it provides a direction on how these criteria should be applied to metals in the future. Eurometaux will suggest that the Eurometaux GEHS working group anticipate this challenge in its 2014 work plan (more information: Hugo Waeterschoot).

### **PEG for the Guidance on Downstream Users: *scaling and measured data***

On behalf of Eurometaux, Frederik Verdonck attended the PEG meeting for the Guidance for Downstream Users where the issue of scaling and the information to provide on mixtures were further discussed. The discussion highlighted some issues where there is still no consensus among Industry and ECHA. ECHA considers that the DU has to implement and recommend ES that include as a minimum the conditions included in the supplier's ES, the DU RCR shall be lower than the supplier's ES RCR. No agreement was achieved on the applicability of scaling to the environment. The main disagreement was related to the possibility to include dilution into scalable parameters for the municipal waste water treatment plant that receives discharge from the DU's site. These issues will be further followed up by the Eurometaux Exposure Scenario taskforce after the summer (more information: Frederik Verdonck and Violaine Verougstraete).

## **AUTHORISATION**

### **ECHA's 4<sup>th</sup> Authorisation Application (AA) training and first Authorisation Application received**

ECHA organized together with CEFIC and Eurometaux a 4<sup>th</sup> training session on AAs. Eurometaux's contribution included presentations on the SEA-AoA-CSR interaction, and joint versus individual AA submissions. EM also chaired one of the two questioning sessions. The training workshop clearly shifted in that direction and questions that previously focused on the AA process, shifted to tools (SEA-AoA) and the ECHA committee decision processes. ECHA announced at the workshop that they received a first and early AA for a phthalate substance on which a group authorisation request is also expected. The submission by a DU took Industry by surprise and confirmed that AAs are clearly in a different league with different rulings (more information: Hugo Waeterschoot and Sandro Starita).

## **OTHERS**

### **Substance-specific support**

Besides ensuring the STO roles in Pb and Co discussions (see RAC, SEAC, MSC), EM also provided support to GaAs (substance evaluation) and Cd (Authorisation) (more information: Violaine Verougstraete and Hugo Waeterschoot).

## Commission REACH activities

### **REACH Review event on 27 June**

The European Commission held an event to discuss the upcoming REACH Review with stakeholders; Vice-president Tajani invited stakeholders ("those having day-to-day experience" with REACH) to provide their views on the review of REACH. Throughout the day, SMEs received a lot of attention, with discussions on the simplification of tools and guidance and even the possibility of a "REACH-light" for 2018; questions about the fairness of costs for data-sharing in SIEFs and consortia and letters of access; lack of expertise in SMEs and the possibility of a certification system for consultants helping them against a reduced fee; the need for novel ways to reach SMEs and communicate with them; and mentorship from large companies. ECHA stated that companies should consider their REACH registration dossiers as assets which can be used for communication purposes and for company internal assessments. ECHA will focus its actions related to the registration dossiers according to the following lines: improvement of the quality, communication in the supply chain and dissemination of the information. Eurometaux gave a presentation on the quality of registration dossiers, what can be done to further improve them in the future and gave input for the Review of REACH based on the Eurometaux-Eurofer position paper released on 24 June 2013.

Downstream users mentioned the complexity of the supply chain and their dependence on the actions of registrants (manufacturers or importers); the difficulties in managing all the SDS and information from the ES; the need to have warning long enough in advance when SVHC are identified and have been prioritised for authorisation. The proposed actions from the ECHA CSR/ES roadmap which will be published mid July 2013, should provide some solutions. There was general support for the Commission Roadmap for the SVHC, including an early RMO analysis covering all possible policy options to address the risk of certain uses of chemicals of concern. ECHA and the Commission are working on an implementation plan which is expected for the end of the year.

The presentations and recordings will be available from the Commission's website by mid July 2013 ([http://ec.europa.eu/enterprise/sectors/chemicals/reach/events/index\\_en.htm#h2-1](http://ec.europa.eu/enterprise/sectors/chemicals/reach/events/index_en.htm#h2-1)) (more information: Inneke Claes).

### **Consultation on review of Annexes of REACH with technical provisions for nanomaterials**

The objective of the consultation is to collect feedback on how nanomaterials are addressed and safety demonstrated in registration dossiers. Feedback is asked on several policy packages, including technical modifications to the Annexes of REACH. Eurometaux will prepare input for the consultation (deadline for replies is 13 September 2013). The questionnaire is available from this web page: [http://ec.europa.eu/environment/consultations/nanomaterials\\_2013\\_en.htm](http://ec.europa.eu/environment/consultations/nanomaterials_2013_en.htm) (more information: Inneke Claes).

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## EUROMETAUX REACH activities: hot topics/issues

### **REACH FORUM MEETING: Meeting on 20 June 2013**

There was an excellent turnout for the meeting on 20 June with lively discussions among the participants. Topics on the agenda included, among others, agreements on data-sharing, an update on the KnowMe database, a discussion on Evaluation (CoRAP update, feedback on the evaluation workshops, outcomes from the MSC discussions on the Cobalt compounds testing plan) and authorisation aspects. An initial discussion on the work plan for the REACH Forum for 2014-2015 based on input received from some consortia and work programme was presented. Your comments are still utmost welcome! A draft work plan with budget estimates will be presented at the September REACH Forum meeting. Draft minutes will be circulated soon. The next meetings will take place on 17 September and 17 December 2013 (more information: Inneke Claes).

### **INTERMEDIATES TASKFORCE: Taskforce meeting on 28 June 2013**

The taskforce discussed the status of the ongoing work to finalise the inorganic UVCBs assessment strategy. Methodology and tools used to assess UVCBs classification will be discussed 3 October at ECHA. Industry will explain the principles and the use of the MeClas tool in the context of complex substances classification. In July, experts will refine examples and notes to prepare the meeting. The task force will receive preparatory material by mid-August and will decide on what to share with ECHA ahead of the meeting. Details on risk assessment methodology were discussed and in summary UVCBs risk assessment is based on classified constituents assessment. Principles and explanations will be summarised in a note that will be finally

included in the Internal Guidance. On the data sharing agreements developed to allow data exchange between consortia, the taskforce agreed on the principles and recognized the value of free sharing, without breaching any former legal agreements. Supporting documents will be sent to the REACH Forum, to ensure good understanding and boost collaboration (more information: Federica Iaccino).

## **AUTHORISATION**

### **Recycled substances and REACH Authorisation: *announcement of a brainstorming Session on 3 September 2013***

End of May 2013, the EM Waste and End-of-Life WG discussed the possibility that waste and recycling might be dragged into the REACH Authorisation process, way beyond the provision of information required for the Chemical Safety Report. Recycling flows might be threatened by the need to have an authorisation for some substances. The REACH Forum on 20 June received a presentation on the possible concerns. An investigation project was outlined, the result of which will be presented at a brainstorming session to be held on Tuesday 3 September 2013 at Eurometaux/MCC. The legal texts and the interpretations given by the Commission and some Member States will be matched with the industrial reality in terms of material types, flows and processes. The aim of the brainstorming is to agree on a clear Industry view on how the current uncertainties should be addressed (more information: Michel Vander Straeten).

### **Authorisation and Restriction (A&R) Platform meeting: *a fully charged agenda***

The Eurometaux A&R Platform met on 21 June evaluating the outcome of the MSC meeting and the progress made with the SVHC implementation Road Map. Important items that were discussed included how to contribute/anticipate the Public Consultation on the RCF's in close cooperation with representatives of the manufacturing sector, the planning of the pilot cases on the waste/recycling materials and authorisation project in preparation of a debriefing session in September, a policy initiative to provide DU stakeholders with more voice during the SVHC identification and follow-up and most importantly a review of the main principles of the proposed new prioritisation method for defining the order of selecting chemicals from the candidate list for Annex XIV listing. It was agreed on the latter to submit written comments to ECHA by 5 July (more information: France Capon and Hugo Waeterschoot).

## **COMMUNICATION ACTIVITIES**

### ***Pb 2013, 18<sup>th</sup> International Conference, Prague 19-21 June 2013***

Eurometaux gave a presentation on "Overall trends and drivers in EU regulation: just a threat or will there be opportunities?". The presentation started with the observation that the EU regulatory scene on chemicals management and OSH is a patchwork of legislative pieces assembled over the last 5 decades, involving many players from different leagues; rendering thereby timely, precise and relevant input a challenge. The presentation aimed at taking a step back and identifying the trends and the drivers of the EU policy scene, both for today and tomorrow. While the inherent complexity can most probably not be solved in the short-term, Industry can prepare itself for what will be the main topics to be addressed, and use possible opportunities, by e.g. making the best use of existing data and knowledge, alleviating implementation efforts by ensuring consistent approaches of regulators and supporting the move to risk-based management of concerns rather than hazard based (more information: Violaine Verougstraete and Hugo Waeterschoot).

### ***REACH: legal implications & supply chain strategies Conference***

In the context of the REACH legal implications & supply chain strategies 2013 conference, Eurometaux made a presentation on CLP-related issues: CLP notifications in 2010, the existing C&L inventory and progress to harmonisation. The presentation summarised the experience with the ECHA C&L inventory and the platform (many thanks Sandra and Sue for your helpful input!), and highlighted the concern that Industry may wait for «data mining» initiatives from authorities in the C&L inventory before reacting. Other aspects covered in the presentation included the preparation of the 2015 deadline for mixtures and how MeCLAS can help for inorganic complex materials, global harmonisation and briefly, the importance to understand the downstream consequences of CLP (more information: Violaine Verougstraete).

# Further outreach of REACH

## OECD

### **BIAC meeting 10 June 2013**

Eurometaux attended the Business and Industry Advisory Committee to the OECD meeting on 10 June, whose main objective was to prepare the interventions of Industry for the OECD Joint Meeting, taking place a couple of days later. Interventions were prepared on a range of topics, including nanomaterials, substitution, test guidelines and UVCB. Eurometaux drew participants' attention to the issues the metals sector related to the OECD guidance on the grouping of chemicals and the demand to have environmental assessment guidance for metals drafted in the context of the CoCAM activities. BIAC noted that the metals sector prepared first contributions for review by CoCAM under the voluntary collaboration programme and that it is expected that other metals/inorganics will follow. With regard to PRTR, it was noted that the metals sector had informed the OECD that they have scheduled work on a voluntary programme on metals diffuse sources releases inventory to complement the Nordic initiative (more information: Violaine Verougstraete and Benjamin Davies).

### **OECD for Hazard Assessment Taskforce meeting: 25-26 June 2013**

The OECD Hazard assessment taskforce meeting end of June addressed a number of interesting and relevant topics for the metals/inorganic sector. China, US, Canada, Australia, Japan and the EU presented a status of their latest Chemical Management activities. Also a number of technical issues were debated, like the characterisation of UVCBs (using the example of oleochemicals), combined exposure to multiple chemicals, the outcomes of a comparison exercise of GHS classifications, grouping and read-across, endocrine disruptors etc. The meeting also discussed -and endorsed- the proposal by Eurometaux and ICMC to have a guidance drafted on metal specificities in environmental assessment. Highlights of the meeting will be circulated soon, as discussions evidenced a number of trends and interactions that will influence our work plan (more information: Violaine Verougstraete, Hugo Waeterschoot and Benjamin Davies).

### **UN Subcommittee GHS - Eurometaux submitted updated environmental Classification Guidance on metals**

The UN-GHS was one of the first legislations that included specific guidance on how to assess the hazards of metals and metal compounds, being restricted so far to the environmental endpoint. In this respect the GHS contains a section on classification strategy (section 9) and the transformation dissolution protocol (Annex 10) which were subsequently introduced in the CLP. However, the implementation of the environmental chronic endpoint (3<sup>rd</sup> UN-GHS update) and the new CLP guidance made the UN guidance on metal outdated. ECHA and COM requested alignment and Eurometaux- in agreement with the UN- prepared working documents for the update of both UN-GHS guidances which will be presented at the UN-GHS meeting early July (more information: Hugo Waeterschoot, Benjamin Davies and Violaine Verougstraete).

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## Calendar

- 1-3 July 2013: Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals meeting – Geneva (UN)
- 3 September 2013: Brainstorming Session on Recycled substances and REACH Authorisation – MCC (Brussels)
- 17 September 2013: REACH Forum – MCC (Brussels)
- 23 September 2013: Exposure Scenario Meeting – MCC (Brussels)
- 12 November 2013: Authorisation & Platform Meeting – MCC (Brussels)
- 17 December 2013: REACH Forum – MCC (Brussels)

**Webinars** <http://echa.europa.eu/support/training-material/webinars>

- 11 September 2013: : [ECHA webinar "How to bring your registration dossier in compliance with REACH - Tips and hints, part 4"](#)
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## Acronyms

|                                                                              |                                                                                           |
|------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| AA: Authorisation Application                                                | LR: Lead Registrant                                                                       |
| AoA: Assessment of Alternatives                                              | NeRSAP: Network of REACH Socio-Economic and Assessment of Alternative Practitioners       |
| A&R: Authorisation & Restriction                                             | OECD: Organisation of Economic Cooperation and Development                                |
| BIAC: Business and Industry Advisory Committee to the OECD                   | OSH: Occupational Safety Health                                                           |
| CHESAR: Chemical Safety Assessment & Reporting Tool                          | PBT: Persistent, Bio-accumulative and Toxic Chemicals                                     |
| C&L: Classification & Labelling                                              | PEG: Partner Expert Group                                                                 |
| CLP: Classification Labelling & Packaging Regulation (EU)                    | POP: Persistent Organic Pollutants                                                        |
| CMR: Substances classified as Carcinogens, Mutagens or toxic to Reproduction | PRTR: Pollutants Release and Transfer Register                                            |
| CoCAM: Cooperative chemicals assessment meeting                              | RCR: Risk Characterisation Ratio                                                          |
| CoRAP: Community Rolling Action Plan                                         | RMO : Risk Management Option analysis                                                     |
| CSR: Chemical Safety Report                                                  | SDS: Safety Data Sheet                                                                    |
| DCCs: Dossier Compliance Checks                                              | SEA: Socio-Economic Assessment                                                            |
| DU: Downstream User                                                          | SID: Substance Identity                                                                   |
| ES: Exposure Scenarios                                                       | SIEF: Substance Information Exchange Forum                                                |
| GaAs: Gallium Arsenide                                                       | SME: Small and Medium-Sized Enterprise                                                    |
| GHS: Global Harmonised System                                                | SPERC: Specific Environmental Release Category                                            |
| IUCLID: International Uniform Chemicals Information Database                 | STO: Stakeholder Observer                                                                 |
| MeCLAS: Metals Classification (Tool)                                         | STOT-RE: Specific Target Organ Toxicity (classification endpoint) Repeated                |
| MEASE: Occupational Exposure Assessment Tool for REACH                       | SVHC: Substance of Very High Concern                                                      |
| MS: Member State                                                             | UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials |
|                                                                              | vPvB: Very Persistent, very Bio-accumulative chemicals                                    |

## Summer Special

Find the following words ...

- BEACH
- BOOKS
- COCKTAIL
- DISCONNECTED
- HAPPINESS
- LAZY
- NOTHING
- REACHNEWS
- REFLECT
- RELAX
- RESOLUTIONS
- SLEEP
- SPORT
- SUN
- TIME
- WALK
- ZEN



And find the word that does not make sense in the list: .....



Train your **storyteller skills**: make a max 10 line story with the following words: Once upon a time – mignonette – corridor-  
authorisation – anarchist – REACH – opportunity – reindeer – happy end and send your stories back to [EHSAssistant@eurometaux.be](mailto:EHSAssistant@eurometaux.be)

The best story will be published in the next REACH News (and the author gets a special award!)