



## EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

We hope you are all doing fine.

As you will read below, the somewhat quieter REACH rhythm we were experiencing at the time of the July REACH news has accelerated again to become allegro (even scherzo) over the last weeks of August.

Some metals are now faced with a workload that will be testing and stretching agendas and also resistance in the forthcoming months. At Eurometaux, we will definitely do our best to support you all as much as we can.

However, the concerns and capacity needs due to the SVHC list, the authorisation, restriction and evaluation programmes, the UVCB work, the testing proposals etc., are now very generic, with possible multi-metallic implications. Therefore, the coming months shall also be devoted to further defining and organising altogether metal sector responses and strategies.

The proposals of technical projects for 2013 that will be circulated shortly are part of the response. Organising a metal-focused exchange and communication exercise with our REACH authorities on e.g. Risk Management Options may be another piece of the musical score. In any case, the best music will be the one played altogether!

Violine Verougstraete, EHS director Eurometaux

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## ECHA REACH activities: Hot topics

### **ECHA-COMMISSION ACTIVITY - ROI ANNOUNCEMENT FOR 38 NEW POTENTIAL SVHC CANDIDATES INCLUDING 21 LEAD COMPOUNDS**

Mid-August ECHA received a proposal from the Commission for a series of potential SVHC candidates including 21 lead compounds. ILA, Eurometaux and the battery sector released press releases on the proposal, questioning the relevancy and efficacy of proposing the Authorisation regime for these substances as they are indeed well regulated and manufactured and used under strict risk management control. Industry further regretted the lack of any preliminary discussion with industry and complete lack of RMO assessment for these compounds which could have demonstrated that such an initiative would be very burdensome for all parties while not creating value in respect to reduced risk management. Eurometaux encouraged its members and potentially affected downstream user sectors to react in an organised and systemic way to the public consultation given this was already opened in August (More information: Aggie Kotze & Hugo Waeterschoot).

### **INTERMEDIATES AND STRICTLY CONTROLLED CONDITIONS**

#### **REACH TASK FORCE ON INTERMEDIATES- WORK ON DATA-SHARING AND SUBSTANCE IDENTIFICATION**

A meeting of the REACH Intermediate Taskforce took place on 23 August and aimed at sharing work done by specific subgroups of the Task Force on technical aspects related to substance identification and on legal aspects of data-sharing.

A third meeting will follow in October and will aim at taking decisions on common data-sharing modalities, consolidate substance identification guidance and discuss risk assessment options. The different pieces of work will be

brought together in a guidance note for internal use explaining how to perform risk assessment of inorganic UVCBs. Discussions will take place with ECHA to assess whether a first meeting devoted to substance identification issues could be organised in the short future to help members with dossiers updates, IUCLID 5.4 changes and inquiries. In order to finalise a common data-sharing agreement an exercise is on-going in order to map out the context of data-sharing changes, comparing previous mono- and multi-constituent substance registrations versus data-sharing for UVCB registrations. Further information will follow at the next REACH Forum meeting on 16 October. (More information: Federica Iaccino)

## **ECHA MEETINGS**

### **READ-ACROSS: PLANNING FOR A WORKSHOP WITH THE MEMBER STATES**

Eurometaux responded to the request of the Cobalt sector and ECHA to plan for a briefing workshop for the Member States to ensure that the complexity of metals read-across techniques and methods is fully grasped by the reviewers of Testing Plans and REACH Compliance Checks when providing opinions or making decisions on metal files. This workshop is now planned for 1 October in Helsinki back-to-back with the ECHA workshop on read-across techniques (RAAF). Eurometaux collected examples for the briefing meeting and invited ECHA, Member States and Commission to participate (More information: Violaine Verougstraete & Hugo Waeterschoot)

### **WORKSHOP ON REACH AND CHEMICALS AT THE WORKPLACE**

The European Commission's DG Employment, Social Affairs and Inclusion and ECHA will organise a workshop on Chemicals at the Workplace on 3 October in Helsinki. The aim of the workshop is to create a better understanding of how the REACH Regulation and Occupational Safety and Health Directives can reinforce each other in terms of their respective and common goals. The synergies between REACH and worker protection legislation will be considered and the opportunities to improve standards and avoid duplication of work. Another topic of discussion will be the relation between limits established under REACH and those established under CAD/CMD and how these can be put into practice.

Eurometaux will be represented at the workshop by Martin Wieske (Wirtschaftsvereinigung metalle).

### **ECHA'S SECOND LEAD REGISTRANT WORKSHOP**

The European Chemicals Agency organises its second workshop for Lead Registrants preparing for the 2013 REACH registration deadline from 11 to 12 October 2012 in Helsinki. Participation is limited to Lead Registrants who have notified ECHA of their role. Several presentations aim at helping the Leads with the preparation of the 2013 registration deadline and participants will also be able to book 20 minute one-to-one sessions with ECHA staff. Eurometaux will share with the workshop participants its experiences on information requirements in order to fulfil compliance checks. Dossier evaluation is a first critical step in the ECHA review process.

Companies, who have not yet informed ECHA of their Lead Registrant status, can still do so via <https://comments.echa.europa.eu/comments/cms/LeadRegistrantNotification.aspx> and will subsequently receive an invitation for the workshop.

### **ECHA AUTHORISATION AND SEA-AOA WORKSHOPS DESIGNED IN CLOSE COOPERATION WITH EUROMETAUX**

As an active partner in the Steering Committee Eurometaux helped design and organise the ECHA-Industry workshops (Helsinki 1-3 October) to brief industry on how to best organise/prepare for Authorisation Applications and share some best practices on the organisation and management of Socio-Economic Assessments (SEA) and Assessment of Alternatives (AoA). Consortia involved in the different steps of the Authorisation process were solicited to contribute to the panel debates (More information: Hugo Waeterschoot).

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# EUROMETAUX REACH activities: hot topics/issues

## AUTHORISATION

### **REACH AUTHORISATION PLATFORM MEETING - A REVIEW OF THE DIFFERENT STEPS IN THE PRIORITISATION OF METALS FOR THE AUTHORISATION LIST**

The Eurometaux REACH Authorisation Platform met on 1 August and handled a very busy ECHA agenda and Consortia initiatives related to this increasingly important REACH pillar. Most important items included: a Eurometaux analysis of experiences with the authorisation process so far and further communication activity on this, reviewing the status of the 3<sup>rd</sup> priority list for Annex XIV listing including how the advocacy activities for cobalt and chromium could be supported, a review of the prioritisation process for the 4<sup>th</sup> Annex XIV list taking note of those substances not selected and the way to make prioritisation criteria less discriminatory for metals and a review of the aims and planning for the sectorial workshop on metal compounds used for surface treatment. Consortia confirmed the need for the Authorisation Platform to continue functioning as an exchange forum on advocacy activities and experiences. (More information: Hugo Waeterschoot).

### **RISK MANAGEMENT OPTION: A FIRST EXAMPLE DISCUSSED BY THE AUTHORISATION PLATFORM MEMBERS**

ILA presented an in-depth experience with RMO analysis for Pb oxide. The experience demonstrated the type of information and effort required to influence the selection process for the most appropriate risk management option, very early in the SVHC selection process. The Platform exchanged the data collection template used for this and concluded that voluntary RMO work for Consortia would be a potential and effective tool to avoid unnecessary selection of CMR substances for authorisation. It was further agreed to develop an advocacy campaign to increase regulatory recognition for the RMO tool, starting with a workshop early 2013.

## REGISTRATION

### **PRACTICAL RECOMMENDATIONS FOR REGISTRATION DOSSIERS - PBT ASSESSMENT**

With the new version 5.4 of IUCLID launched in July of this year, it is mandatory to include the PBT assessment - overall result in section 2.3 of the IUCLID file for dossiers where a Chemical Safety Report is required. If this field is not filled in, the dossier (new or updated) will fail the business rules. The section "Justification" only needs to be filled in if "PBT assessment does not apply" is chosen in the PBT assessment field. The section "Likely route of exposure" is not mandatory yet. See for more information the "Data Submission Manual Part 04 - How to Pass Business Rule Verification ("Enforce Rules")" and the "Data Submission Manual Part 05 - How to complete a technical dossier for registrations and PPORD notifications" available from the ECHA website. (More information: Inneke Claes).

### **DISSEMINATION OF DATA FROM REGISTRATION DOSSIERS**

As of November 2012, ECHA will disseminate more information from the submitted registration dossiers than is currently the case (see also REACH News - June 2012). This new information includes (but is not limited to): the name of the registrant, the registration number, the tonnage band, the trade name and the PBT assessment outcome.

With the dissemination plug-in for IUCLID 5.4, companies can check which parts of their registration dossier will be disseminated.

It is recommended that companies assess if for their already submitted registration dossiers, confidentiality claims are necessary and if so, to submit an update of their dossier to ECHA.

For more detailed information please see the "Data Submission Manual Part 15 – Dissemination" and the "Data Submission Manual Part 16 - Confidentiality Claims: How to make confidentiality claims, and how to write Art 119(2) confidentiality claim justifications" available from the ECHA website (More information: Inneke Claes).

### **ON-GOING DIFFICULTIES WITH INQUIRIES**

Companies from the metals sector and the chemicals sector reported problems with the inquiry procedure. Under this procedure, companies which did not pre-register a substance for the 2010 registration deadline and now need to register it, have to submit an inquiry for this substance to ECHA. ECHA then checks if this substance has already been registered (compares substance identities) and if so, brings the company in contact with the Lead Registrant of the joint registration. The problem which some companies encountered is that ECHA requires very extensive information on the substance

identity, sometimes more than the information submitted in the initial registration. As long as ECHA is not satisfied with the information submitted by the inquiring company, no inquiry number is issued and the company cannot register the substance, thus preventing the access to the market. Industry feels that potential problems with substance identification should be solved during the evaluation of the registration dossier and not during the inquiry process. Discussions with ECHA are on-going and companies which encountered such problems are invited to inform the Eurometaux Secretariat. (More information: Inneke Claes).

## **CLP**

### **THE SCIENCE ON THE UNIT WORLD MODEL SUMMARISED AND ADVOCACY PLANNED**

The metals sector globally supported the development of the Unit World Model as a tool to assess the removal of the water column equivalent to the degradation criterion for organics. Once adopted, this model would provide the sector with a level playing field on environmental hazard assessment with the organic sector and is therefore a critical tool for amending the CLP guidance for metals. For interested Consortia, Eurometaux organised a combined data collection program and other follow-up activities to respond to the questions and concerns raised by the Member States at the UWM workshop at ECHA earlier this year. This resulted in an overview report presently under review by the Consortia and the design of a stepwise advocacy and communication program for 2012 and 2013 to increase the acceptance of the model by the EU and UN. The overview report was used to design a reply to the Member States concerns and turned into a proposed set of modelling parameters. (More information: Katrien Delbeke & Hugo Waeterschoot).

### **MECLAS STEERING TEAM PROPOSED MAKING IT FREELY AVAILABLE FROM 2013 ONWARDS**

MECLAS, the special web based program to assess the hazard classification of complex inorganic materials has proven very successful for the registration and notification of complex intermediates, metal UVCBs and other inorganic materials. ECHA and OECD raised interest but cannot recommend it given the tool is propriety based. Moreover, DUs may raise interest for MECLAS in the coming months due to their duties while the MECLAS tool will also be complemented with an alloy assessment tool. At its annual meeting the MECLAS Steering Team therefore proposed a change in the business model providing generic Eurometaux/Consortia sponsorship for 2013 -'14 to make the updated MECLAS tool freely available upon registration of the users. Other priorities for 2013 included a MECLAS update on alloys, including the most recent ERVs from the REACH files, the new criteria for Specific Concentration Limits for CMRs as soon as adopted and a check to see if the model could be used to identify hazardous waste criteria (More information: Violaine Verougstraete & Hugo Waeterschoot).

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## **Further outreach of REACH**

### **THE KNOWME DATABASE IS ENTERING ITS TESTING PHASE**

In order to ensure consistent and transparent transfer of knowledge and regular update on decisions' rationale and on-going discussions at different ECHA Committees, an ad hoc metals database has been developed and named the KnowMe database. The KnowMe database aims at being a flexible, user-friendly living tool to collect and store the most relevant key messages and information. The database is structured according to levels and with increasing details in the provided information, thereby allowing Consortia/Commodity associations to select the level that best suits their specific needs. All of the information is collected, stored and organised following a list of regularly updated keywords (e.g. Risk Assessment, Assessment of Alternatives ...) and applicability domains (restriction, authorisation,...). The KnowMe learning lessons database has now entered its testing phase. (More information: Federica Iaccino).

# REACH International

## EUROMETAUX ACTIVELY PARTICIPATED IN THE ICMM-COMMODITIES EXCHANGE ON CHEMICALS MANAGEMENT AGENDA POINTS

Eurometaux participated and actively contributed to the Chemicals Management Review session of the ICMM-Commodities meeting in Aberdeen this month. Eurometaux provided an overview of international chemicals management drivers, organised a review session on the UWM model including the advocacy plan to raise the acceptance level and several REACH related activities that required broader support from the metal Commodities and their research organisation (e.g. read-across workshop, Combined toxicity assessment, ...). In turn, the meeting provided Eurometaux REACH staff with an opportunity to learn more on other regional and global initiatives to ensure that trends can be picked up and anticipated and therefore avoid overlap. (More information: Violaine Verougstraete & Hugo Waeterschoot).

## OECD/NORDIC INITIATIVE ON PRODUCT RELEASE FACTORS COULD SERIOUSLY IMPACT REGIONAL ASSESSMENTS UNDER REACH

The Nordic PRTR Council submitted product release estimates from brake pads for Cu, Cr, Pb, Ni and Zn under a pilot program from the OECD-PRTR program to develop Release Estimate Fact Sheets for a series of product applications. The Nordic and OECD initiative aims at adopting these release estimates at OECD level and using them for regional PRTR and consumer release modelling (including REACH). The first pilot case demonstrated a significant lack of critical review of the literature and proposed release estimates not in line with more extensive and recent knowledge on the metals (Cu) sector. Eurometaux therefore wrote a letter to the Nordic Council and the OECD secretariat to request a more diligent approach, allowing the experiences of the metal sector to be reported when new fact sheets are developed. Fact sheets for releases from tyres and building applications are planned and Eurometaux and the Consortia thought about how this could best be anticipated in order to avoid irrelevant release estimates that would have to be used for the regional REACH risk characterisations. (More information: Violaine Verougstraete & Hugo Waeterschoot).

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## Calendar

- **5-6 September:** European Chemicals Policy-REACH – Barcelona
  - **6 September:** ECHA Lead Registrant Webinar on dissemination and confidentiality claims
  - **12 September:** Sherpas' Telephone Conference
  - **20 September:** Bio-Elution Discussion – MCC
  - **21 September:** Directors' Contact Group – Brussels & Helsinki
  - **24 September:** Stakeholder Event on the review of REACH
  - **25-27 September:** Eurometaux B2B Autumn Meetings - Brussels
  - **1-2 October:** Workshop for Authorisation Applicants with EM Presentation – Helsinki
  - **2-3 October:** ECHA Workshop on SEA – Helsinki
  - **3 October:** European Commission (DG EMPL) & ECHA Workshop on Chemicals at the Workplace - Helsinki
  - **3-4 October:** ECHA-MSD discussion on Testing Proposal issues—& Read-across Workshop CEFIC LRI-Helsinki
  - **5 October:** ECHA webinar on substance evaluation Registration for the webinar is required at:  
<http://www.echa.europa.eu/web/guest/support/training-material/webinars>
  - **11-12 October:** ECHA Lead Registrants Workshop with EM Presentation – Helsinki
  - **16 October:** Eurometaux REACH Forum meeting – MCC
  - **19 October:** ECHA Lead Registrant Webinar on General principles of dossier preparation and submission
  - **20-21 November:** ENES III – Brussels
  - **27-29 November:** CARACAL - Brussels
  - **19 December:** Eurometaux REACH Forum Meeting – MCC
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# Acronyms

**AOA:** Assessment of Alternatives

**CAD/CMD:** Chemicals Agent Directive / Carcinogens Mutagens Directive

**CMR:** Carcinogen Mutagen Reprotoxicant

**DU:** Downstream Users

**ERV:** Ecotoxicological Reference Value

**IUCLID:** International uniform chemicals information database

**MECLAS:** Metals Classification Tool

**MSC:** Member States' Committee

**OECD:** Organisation for Economic Cooperation and Assessment Development

**PBT:** Persistent bio accumulative toxic chemical

**PPORD:** Product and process orientated research and development

**PRTR:** Pollutant Release and Transfer Register

**RAAF:** Read-Across Assessment Framework

**ROI:** Registry of Intentions

**RMO:** Risk Management Options

**SCC:** Strictly Controlled Conditions

**SEA:** Socio-economic Analysis

**SVHC:** Substance of Very High Concern

**TF:** Task Force

**UN:** United Nations

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