EUROMETAUX
EUROPEAN ASSOCIATION OF METALS

N°6. June 2012



EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

Please find herewith the June edition of the REACH news as well as a handful of wishes and thoughts…
To start with, we wish you a nice summer, with the possibility to run a bit less after time, to allow you to recover from the six last months and attack the next six ones with renewed energy.
The summer 'slow down' of activities usually permits to take a step back and take a critical look at the achievements and what still lays ahead. The REACH Team will definitely do this exercise, budget-wise, project-wise but even more so on a strategic level. You are more than welcome to join our brainstorming.
Overall, it can already be said that a huge amount of work has been carried out by the consortia/commodities and the REACH team since January, resulting sometimes in frustration and additional issues to solve, but most often in more knowledge, better interactions and increased credibility of the metals sector. Having a single, unified REACH Forum has significantly facilitated our communication duties but more important, the solidarity between the consortia/commodities and the commitment behind this unified group are a fantastic leverage and stimulus for the team! We really hope we can maintain this momentum in 2013!

Violaine Verougstraete, EHS director Eurometaux

ECHA REACH activities: hot topics

ECHA COMMITTEES – SURPRISING OUTCOME OF SOME TREND SETTING OPINIONS!

MSC, 4-8 June Helsinki

While the new SVHC list was adopted by written procedure, extensive discussions took place on the draft 4th priority list. The list includes again several inorganics (mostly chromates used in surface applications) but did not prioritise calcium arsenate, hydrazine, Refractory Ceramic Fibers (RCF's) and borates. The justification and reasoning for selection and non-selection was clearly much more in-depth and making full use of the Registration files. Grouping (for borates), review of the scope (for the RCF's) and low exposure potential for hydrazine supported the non-selection for this year. The calcium-arsenate discussion was also trend setting and asked for industry commitment to clarify the registration in order to avoid selection.
In view of the continued discussions on best risk management option and intermediate status for surface treatment techniques, Eurometaux proposed to organize a horizontal workshop for MSCA's, comparable to the one held last year for metal oxides in glass and ceramics. This initiative raised high appreciation by ECHA and Member States.
Following the demand of industry (the metals sector), MSC members also noted the need to revise the prioritization method for the 5th priority list, stressing that it should be more risk based.
ECHA explained its further timing on the "RAAF" project (this project documents the Read Across methods for Testing proposal, Dossier and Substance evaluation review). The metals sector requested attention for the very complex nature of read across for metals testified by the upcoming discussion on Cobalt compounds (see further).
Testing proposal review was a main priority for the MSC meeting, drawing an important conclusion on the relevance of BAL treatment of the lungs for inhalation toxicity testing of inorganics. Eurometaux will include this in its overview of manual of decisions
Finally, in follow-up of the Industry letter of early 2012, ECHA-MSC agreed to share testing proposals conclusions for substances discussed in advance of the MSC meeting so that STO can prepare the discussion while facilitating the drawing of generic learning lessons. *(More information Hugo Waeterschoot)*

RAC 21, 12-15 June Helsinki:

The discussion on the harmonized classification of GaAs for reproductive toxicity focused on the notion of secondary vs. primary effect. The hypothesis –defended among others by industry- is that the GaAs induced lung toxicity results in hypoxemia and subsequently in effects on the testes rather than directly causing effects on the testicular tissue. Industry has submitted additional studies supporting this mechanism. At stake is a classification 1B or even 2 rather than 1A.
A very interesting and final debate on the phthalates restriction proposal addressed a number of scientific concepts having also a regulatory dimension, like the meaning of a RCR that means the margin between a DNEL and LOAEL, what is a worst case, etc. (*More information Violaine Verougstraete, see also RAC highlights circulated on 18.06.2012)*

SEAC, 13-15 June Helsinki: ***No proof of an EU wide risk= no restriction!***

As in RAC, the SEAC experts set an important precedent by rejecting the relevance for the restriction on 4 phthalates submitted by Denmark). SEAC concluded that any restriction requires an EU wide proven risk before any SEA should be conducted. Such proof was lacking. Moreover, doubts were raised about the efficiency of Restriction measures given alternatives could not necessarily provide a valid and cost efficient alternative. SEAC felt furthermore that on-going substitution initiatives would find their way where relevant and cost efficient.
Contrary to expectations, ECHA did not present its SEA assessment concept in preparation of the first Authorisation applications (AA's). Industry urged ECHA to make quick progress with this, given AA's are nearing soon. SEAC discussed in detail the form and possibilities of Stakeholder interaction in advance of and during AA reviews. A hearing will be organized with the Applicants and those that submitted comments under the Public Consultation at the start of the review process. From that moment on only STO will be allowed "to witness" the review of the applications. While more than originally expected, STO questioned why STO participation would not be allowed for in the first 18 months. *(More information Hugo Waeterschoot)*

WORKSHOP ON SUBSTANCE EVALUATION – 4-5 JUNE HELSINKI

Substance evaluation (SE) is the next BIG ticket item for countries' and MSC activities on REACH.
ECHA organized its first workshop on SE open to STO. The workshop was very constructive and concluded the need for early industry involvement and input when a country starts a SE dossier. Industry input will be solicited in a structural way but will have to follow strict procedures (update of registration dossier BEFORE the submission deadline of the MS) to ensure the efficiency of the system. Systematic attention will be given during the review of the SE dossiers in MSC on the underlying concepts (trends) and be noted in an Evaluation manual of decisions. Industry was invited to contribute actively to the initial phase of SE by updating the registration files in the year precedent to the review. The workshop further agreed to a more risk based selection process of substance for the CoRAP and invited industry to submit suggestions for selection approaches by the end of the summer. Member States and STOs were pleased with the announcement of ECHA to organise a SE workshop on an annual basis. *(More information Hugo Waeterschoot)*

ECHA MANAGEMENT BOARD – 21-22 JUNE HELSINKI

Guy Thiran attended the ECHA Management Board (MB) as (only) industry representative. Interesting topics on the agenda included *the multiannual work plan* (2013-2015) and the discussions on the overall low *quality of the registration dossiers* and the request from the policy level to increase *the number of compliance check levels > 5 %. The pressure is also rising to increase the number of Authorisations.* ECHA was mandated to draft a strategic note on how to encourage compliance within the required timeframe, to be discussed at the next MB meeting in September. Other items of interest included *the (level of) involvement of the stakeholders in the Authorisation debates at ECHA*, and the discussion of an external report on the review of ECHA as an organization. The latter was based on the questionnaire and interviews conducted by PWC in which Eurometaux also actively participated. Several recommendations made in the report are critical to industry like ECHA playing a more active role in contributing to the REACH/CLP regulation, developing scenario's to improve efficiency , broaden the stakeholders base to prevent disengagement with REACH and CLP, share info and data where and when possible, etc. Eurometaux will take the necessary steps over the summer to prepare for the strategic agenda items for the September meeting. *(More information Hugo Waeterschoot and Guy Thiran)*

AUTHORISATION – 3RD AND 4TH PRIORITY LIST UNDER DISCUSSION AND ECHA BRIEFING WORKSHOPS UNDER DEVELOPMENT

Eurometaux facilitated interchange and experience of the Cobalt and Chromium industry in their advocacy plans on achieving changes on the ECHA recommendations for the 3rd priority list for Annex XIV. The policy discussions are trendsetting given it is the first time the ECHA/MSC opinions was challenged successfully by Member States resulting in the need for the Commission to search for an alternative. The discussions proved that the lack of an early RMO was a clear mistake while the ECHA opinion should have searched for a more pragmatic and efficient Risk Management solution. A Commission proposal for inter service consultation is expected any day to meet the deadline for the next REACH-Article 133 meeting in September.

Industry is really looking forward to the solution the Commission will propose to break the deadlock caused by the ECHA proposal for the 3rd list. To ensure Authorisation Applicants will be best prepared for a successful Application, ECHA, Cefic and Eurometaux will organise two workshops for Consortia and Companies intending to submit Authorisation Applications for substances on the 2nd, 3rd or 4th prioritization list. The first workshop (1-2 October) will explain in detail the Authorisation Application requirements, administrative steps and process while the second (2-3 October) will zoom in on experiences Consortia confront when organising AA's and their experiences with SEA and AoA concepts. Eurometaux has invited Consortia to submit examples and cases for the workshops. Both workshops will be announced in the first week of July by ECHA. Early inscription is required due to the limited number of seats.

REACH IT AND IUCLID

ECHA put in place an Industry User group to discuss the current status and future developments of some of the REACH related IT-Tools (IUCLID, REACH-IT and the C&L inventory and platform) and the dissemination of data, among others from the registration files and the C&L notifications to the general public. Cefic, Concawe, Eurometaux and the downstream users platform (DUCC) participate in this group. At the first meeting of this group on 15 June, the huge modifications to IUCLID in the most recent version 5.4 (released beginning of June) and the upcoming modifications to REACH-IT (mid July 2012) and to the dissemination of data (November 2012) were discussed. Detailed information can be found in the one-pager on IUCLID and REACH-IT and the slides of the last Eurometaux REACH Forum meeting. In order to provide feedback to ECHA on the IT-Tools and to, at the request of several members, revive the REACH registration group set up in 2010 to prepare 2013 registrations, the Secretariat proposes to create one new expert group to cover these two topics.
Members who are interested in joining this group, are invited to contact the Secretariat *(More information Inneke Claes)*

REACH activities at Commission Level

CARACAL

The 11th meeting of CARCAL foreseen for 26-28 June 2012 in Brussels was cancelled and replaced by a one-day ad hoc meeting on 28 June in Helsinki. The morning session, only open to representatives of the MS' competent authorities, was used to discuss risk management option analysis – to choose between authorisation and restriction as best legal instrument for risk management for the use of SVHC. The afternoon open session included discussions on DU obligations, where MS voiced their high expectations for ENES to help improving the quality of ES and SDS; on nano materials, where it was pointed out that the potential overlap between the work of the ECHA Working Group on nanomaterials and the CARACAL subgroup on nanomaterials needed to be addressed; and on lessons from four recent restriction cases and the need to go in the direction of focussed restrictions. Further topics on which information was given included: status of applications for authorisation (none received so far); "substances in substances" important for the classification of substances with impurities, multi-constituent and UVCB substances; and the extended one-generation reproductive toxicity test. The next meeting of CARCAL is foreseen for 27-29 November 2012 in Brussels. *(More information Inneke Claes)*

EUROMETAUX REACH activities: hot topics/issues

SCC TASKFORCE BECOMES TASKFORCE ON REACH INTERMEDIATES

In the framework of intermediate registration dossiers, companies need to confirm whether they intend to update or to upgrade their registration dossiers and inform their consortia. Several tools are available, such as RICOG, decision schemes ECI, weight of evidence approach of Metallochimique. Upgrading intermediate dossiers involves a number of challenges with regard to substance identification and assessment. Methodologies and approaches shall be developed as well as the appropriate format to report back to ECHA. The SCC taskforce agreed to prepare a guidance on how to assess metallic UVCBs, using practical examples. A first meeting will take place on July 6. It was also agreed to have a one day workshop between ECHA and industry to present the developed approaches (timing to be defined). In this context, the multi-metallic database is a useful tool to collect and update data. Data collection has not finished yet, but is promising. More discussions are envisaged to finalise data sharing process and solve possible legal issues. *(More information Federica Iaccino*)

EUROMETAUX REACH FORUM MEETING - JUNE 19

The most important topics discussed at the last Eurometaux REACH Forum meeting were related to prioritisation for authorisation and restrictions, classification, the priority lists and the applications for authorisation. Members discussed how to exchange information, experiences and learning lessons between the different metals/consortia and to harmonise views across metals on topics of importance for authorisation/restriction. This resulted in several initiatives. The following workshops will be organised: a multi-metallic read-across workshop, a technical horizontal sectorial workshop on surface techniques, an authorisation platform meeting (August 1). Together with zinc, the Secretariat will follow-up the RIVM activities on the link between risk characterisation and SEA. The Secretariat will also follow-up on the SubSPORT, a new project where information on existing restrictions is given and which aims a substituting hazardous chemicals. The sharing of data between the metals consortia and with authorities (EU or other parts of the world) was discussed. A status report was given on the multimetallic database to share information between the consortia and of major importance for complex UVCB/mixture assessment/combined exposure. Further on, the agenda addressed nanomaterials and the role of customs authorities in in REACH enforcement. A detailed report of the meeting and the agreed actions table were circulated to members on 28 June. The next meeting of the Eurometaux REACH Forum will be held on 16 October *2012 (More information Inneke Claes)*

HARMONISED CLASSIFICATION AND LABELLING - UWM WORKSHOP REPORT PUBLISHED REQUESTING FOR FURTHER EXPERT REVIEW

Almost parallel with the new CLP guidance on metals classification, ECHA published the report of the UWM workshop on metals degradation, a critical concept to ensure equal footing with the degradation concept of organics. ECHA noted areas for further clarification and proposed to organize an expert team to review the concept and propose guidance. Eurometaux organized in follow-up a conference call of the UWM project team reviewing the additional information needs and defining a strategic plan to meet them. Crucial in this respect are the outcomes of the UWM assessment of series of metals as conducted by Mutch Associates and the work planned by ARCHE on the boundary conditions. All this will be reviewed at a "technical review session" end of August allowing the metals sector for appropriate input when the expert panel will be established by ECHA early autumn. Some recommendations on how to comply with the 2nd ATP in due time –even if the UWM debate is not closed- as well as the training package will be circulated soon. *(More information Hugo Waeterschoot or Katrien Delbeke)*

TESTING PROPOSAL REVIEWS BY ECHA - DEFINED THE NEED FOR AN EXPLANATORY WORKSHOP ON READ ACROSS CONCEPTS FOR METALS

ECHA was recently challenged with the first integrated and complex testing proposal and read across program for a metal group, in casu Cobalt compounds. Eurometaux organized a review session with the Cobalt sector and ECHA allowing a constructive dialogue on read across concepts for REACH Annexes 9 and 10 requirements. Besides raising understanding by ECHA about the methods applied, the meeting concluded the relevancy for organizing an informative workshop on metal read-across concepts for test waiving, read across and grouping, for MSCA's to ensure a proper understanding and recognition of this complex issue before they would set a precedent setting conclusion in the Cobalt case. Eurometaux and the Cobalt Consortium organized a quick consultation of interested Consortia to contribute to the workshop to be organized in September.

COMMUNICATION ACTIVITIES

NI WORKSHOP ON AUTHORISATION: *MORE AND EARLY FOCUS ON RMO AND TARGETED SEA MAY HELP INDUSTRY*

Eurometaux provided on June 12 a review of experiences of the metals sector on all steps of the Authorisation (selection) process. The role and importance of an early and comprehensive RMO analysis to define the scope of Risk Management activity, to ensure the selection of the right and most effective risk management tool is certainly an issue that requires more attention from industries involved in the manufacturing and use of CMR metal compounds. Eurometaux further stressed the need for focus on SEA and AoA through defining the most critical parameters that would make the real difference (80/20 rule). Finally, Eurometaux invited Consortia to exchange their experiences on organizational, SEA and AoA aspects, recognizing that all CMR materials for given applications (surface treatment, use in catalysts, …) will pass the review of the MSC committee in the next 5 years . The presentation provided to the NI is available on request

REACH Conference on Legal Implications and Supply Chain Strategies 2012

The conference provided an opportunity for Eurometaux to present, in front of ECHA, Member States and Commission staff, its overall perspective and experience on the concepts -and possibilities for industry-with regard to the selection of substances for Authorizations, as well as the assessment of Restriction cases. The Commission confirmed in reply the validity of the request of Eurometaux for an early and in-depth assessment of RMO preferably before countries submit an Annex XV.The Commission also noted the increasing quality and refinement of restriction dossiers. The conference allowed Eurometaux staff to review and discuss the progress made in other jurisdictions with REACH look-a-likes.

Further outreach of REACH

OECD HAZARD ASSESSMENT TASKFORCE MEETING - 12-13 JUNE, PARIS

The OECD hazard assessment taskforce meeting discussed a number of issues which are also of relevance for the REACH work carried out in the EU. Examples are substance identification of UVCBs, read-across and categorisation, submission of REACH effects datasets in the context of the CoCAM programme, a global GHS list of classifications etc. Ilse Schoeters kindly attended the meeting on behalf of Eurometaux/ICMM and made a presentation on differences in GHS classifications throughout different jurisdictions.
To follow up: further to the workshop on metals specificities in environmental assessment held in September 2011, Canada has submitted a proposal for grouping of organometallic and organic metal salts. This proposal is tying in to a number of conclusions from the workshop such as developing a decision scheme for further guidance of grouping. Eurometaux and ICMM will comment on the final proposal to stress the need for consistency if relevant. Finally, it was announced that eChem Portal will increase its scope of information to also include GHS classifications. ECHA will submit all information that is published on their website whether it is the CLP inventory, testing proposal or the CoRAP list.

Calendar

- **6 July**: Task Force on REACH Intermediates - MCC
- **9 July (a.m.)**: ICMM REACH Seminar – MCC
- **1 August**: 3rd Authorisation Platform Meeting - MCC
- **5-6 September:** European Chemicals Policy-REACH – Barcelona
- **24 September:** Stakeholder Event on the review of REACH
- **25-27 September**: Eurometaux B2B Autumn Meetings - Brussels
- **1-3 October**: Workshop for Authorisation Applicants– Helsinki
- **3 October**: CE (DG EMPL) – ECHA Workshop Occupational Health (tbc) - Brussels
- **3-4 October**: ECHA-MSC discussion on Testing Proposal issues & Read-across WS CEFIC LRI-Helsinki
- **16 October**: Eurometaux REACH Forum meeting – MCC
- **27-29 November**: CARACAL - Brussels
- **19 December**: Eurometaux REACH Forum Meeting – MCC

Acronyms

AOA: Assessment of Alternatives	**MSCA:** Member States Competent Authorities
CARACAL: Competent Authorities for REACH and CLP	**RIVM:** Dutch National Institute for Public Health & the Environment
CLP: Classification, Labelling and Packaging Regulation	**RMO**: Risk Management Options
CoCAM: Cooperative Chemicals Assessment Meeting	**SCC**: Strictly Controlled Conditions
CoRAP: Community Action Rolling Plan	**SDS**: Safety datasheets
DUCC: Downstream Users of Chemicals Co-ordination group	**SEA**: Socio-Economic Assessment
ENES: Exchange Network on Exposure Scenarios	**SEAC**: Socio-Economic Committee
ES: Exposure Scenarios	**SVHC**: Substances of very high concern
GaAs: Gallium Arsenide	**STO**: Stakeholder Organisation (Industry, NGOs & Labour Unions)
MS: Member State	**UVCB**: Unknown or Variable Composition, Complex Reaction Products and Biological Materials
MSC: Member States Committee	**UWM**: Unit World Model

Have fun and a lovely summer to you all
And enjoy our game

REACH on the BEACH

E T X G E F S H A O O A B A F Q O
S N N O U R T B C A F D S O H K T
H C A N I E A O X T Y V O I D D P
T L V S N E T J G R R V O D L V C
S A C I R E D E F I E G O L Z F W
E S E K O J N A Y C A I Z M E F M
N S R H S Z O R A R C L S S O W L
R I N I K N I S L E H E Y S Y G A
R F S N O I T A U L A V E O O C L
A I L S A A C I K A N V K P B D R
E C Q T A W I N R X A N T K H L B
S A U T H O R I S A T I O N N K N
A T A T C P T D M T M A N T Q P E
C I L O E G S Q A I E F N N Y U S
M O I I G P E A S O A Z E E E I E
E N T P A U R M R N E T W O R K D
C P Y O E K H O G P N N S S E F E

Please find the following words back:

- AILSA
- AUTHORISATION
- CLASSIFICATION
- DOSSIER
- EVALUATION
- ECHA
- FEDERICA
- FUN
- HELSINKI
- HUGO
- INNEKE
- NETWORK
- OPTIMISM
- QUALITY
- REACH
- RELAXATION
- RESTRICTION
- VIO

