



EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

We hope you have all been able to enjoy the first "Spring-is-back" signals over the last weeks, even in Helsinki...The birds and first flowers, the increasing daylight took out of hibernation a number of REACH-issues and discussions as attested by the "bouquet" of emails we have sent you over the last month.

This March News will recall the main highlights of those past weeks and allows us as well to wish you an excellent Easter break!! Take a deep sunny breath!

Violaine Verougstraete, EHS director Eurometaux



And where is my egg may I ask?

ECHA REACH activities: hot topics

ECHA COMMITTEES

RAC - GALLIUM ARSENIDE AND PHTHALATES

The 20th meeting of the Risk Assessment Committee provided Geert Dancet, ECHA Executive Director, the opportunity to stress, amongst others, ECHA's intention to serve as the hub for capacity building and to address scientific challenges. We will definitely further use this opening when relevant! On harmonized classification, a way forward was found with ECHA and the Commission to consider the additional information on GaAs reprotoxicity, as submitted by industry/Eurometaux before Christmas. In the meantime, the Rapporteur already made a first assessment and evoked the possibility of an indirect effect, following lung toxicity. A collateral outcome from all the tribulations on GaAs over the last months is that ECHA made a proposal to improve the transparency and efficiency of the CLH process; it will however further limit the input of industry during the Public Consultation periods! On restrictions, the RAC discussion on phthalates addresses a number of crucial REACH-related concepts like assessment factors, exposure defaults, data quality. It also generated a discussion on the significance of the identified risk versus uncertainties in the exposure assessment (when for example worst case assumptions are used): a learning case! (For more information, please see RAC highlights circulated on March 15).

ECHA - MANAGEMENT BOARD

The ECHA management board meeting took place on March 22-23 and CEFIC's input in the discussion was prepared via a cross-industry sectors call (CEFIC, CONCAWE, Eurometaux, FECC, IMA). Interesting topics were for example the follow-up by the board on the requests from STOs for more attention for STO's involvement in the ECHA Committees (see REACH news February) and the proposal for a new compliance check strategy which will support the long term strategic aim to increase the future quality of registration and ensure the interlink with other REACH processes (substance evaluation, risk management processes, etc.).

Feedback on the outcomes shall become available soon. The next ECHA management board will be attended by Guy Thiran.

SEAC - STARTED DISCUSSING HOW TO ADDRESS THE SEA PART OF AUTHORISATION APPLICATIONS

The last SEAC meeting (Helsinki 13-15 March) was very much focused on a review of the experience with restrictions so far and the precedent setting case on the SEA assessment of Phthalates. The experience with 4 restriction cases including Pb in jewellery provided recommendations on how both process and content could improve. Main action points are with the Member States and ECHA will foresee a training program to increase the capacity level. The SEA of the new restriction case on 4 phthalates compounds is reviewed in detail (much more in depth than in the past, demonstrating experience gains by member state experts). Moreover it sets an important precedent in respect to the methods and concepts used for the assessment of combined exposure/effects cases as is often the case for metals. The discussions on the balance between benefits and costs are reviewed from the perspective of effectiveness and proportionality which in their turn are trend setting. It is obvious that SEAC discussions achieve higher levels of interest now that Authorisation applications are nearing. (For more information, please see RAC highlights circulated on March 20).

INTERMEDIATES AND STRICTLY CONTROLLED CONDITIONS – REPLY FROM ECHA TO OUR EXAMPLES

ECHA examined the simplified examples on SCC we sent in January, highlighting a number of metal-specific issues like the availability of hazard data, the physical form associated with low emission potential (massive, wet cake) considered when designing rigorous containment, as well as the existence of LEVs and PPE but concluded unfortunately that they 'still do not have clear self-evident examples of SCCs for the circumstances that industry raised with us'. The Eurometaux SCC taskforce has been made aware of this outcome. Those metal-specificities were raised again in a presentation CEFIC made at the recent EPG meeting.

ENES – A SECOND WORKSHOP OF THE EXCHANGE NETWORK ON EXPOSURE SCENARIOS SCHEDULED FOR MAY

The Exchange Network on Exposure Scenarios is preparing its second workshop scheduled for 21-22 May. This time, emphasis will be on the often overly precautionary RMM measures and conflicting Exposure Scenarios proposed by manufacturers and how DUs can effectively deal with these. Focus will be on the setting of environmental ES, as ECHA noted this as being the area with the highest needs. The workshop aims for discussing with representatives of DUs and manufacturers how challenges can be resolved in a pragmatic but sound way. The challenges for DUs to apply the mixture ruling will certainly also surface. The coordination team recognized the specific concerns of the metals sector and one of the breakout groups planned for aims to discuss this. The invitations will be forwarded to the Consortia as soon as we receive them.

SEA WORKSHOP, LONDON 29 MARCH - EXCELLENT NETWORKING OPPORTUNITY WITH SEA EXPERTS -SEAC STAFF

Eurometaux and several Consortia involved in SEA activities attended a workshop of the UK Royal Academy of Chemistry on exchanging experiences with SEAs under REACH Authorisation. The workshop was well attended by experts as well as by SEAC members, ECHA and Commission, and allowed for taking stock of experiences from industry including Cr and Ni. The short breakouts reviewed key aspects like the deepness required on the Assessment of Alternatives (AoA), the process of Authorisation Applications (AA) and others. Important "take home" messages from the workshop included a) the need to first conduct a screening AOA before launching in depth SEA activity and b) the confirmation that monetarisation of the cost benefits is not often needed to compare different alternatives with the baseline assumptions. It was further recognized that indirect effects often have a prominent role in the SEA assessment and that the role and importance of the AoA should not be underestimated.

REACH activities at COMMISSION LEVEL: hot topics

AUTHORISATION – 3RD PRIORITY LIST AT POLITICAL DISCUSSION LEVEL

The recommendation of ECHA on the substances proposed for Annex XIV inclusion (series of CrVI and Co compounds) are presently reviewed by the Commission and Eurometaux provided guidance, support and input to the sectors concerned on how to achieve the best outcome on this more political part of the approval procedure. It is expected that a draft proposal from the Commission will be presented at the REACH Committee on April 19. This is a quite exceptional procedure, which may indicate that the Commission proposal may deviate from the ECHA opinion, hopefully in the direction requested by industry.

CARACAL : SLOW PROGRESS ON SERIES OF REACH AND CLP ISSUES

The 10th CARACAL meeting took place on 21-23 March. One of the key discussions was the test design of the EOGRTS. A political decision is still pending as Commission is awaiting a final scientific opinion from RAC on the usability of the EOGRTS data for Classification purposes. On another topic, some Member States commented the ES they had seen as being of low quality and “useless” for downstream users. They warned that on-going activities on ES and DU communication do not pre-empt to comply with legal obligations. On the how to adapt the CLP Annex VI to the new CLP criteria, CARACAL did not come to an agreement on how to proceed. Discussions will be continued in a CARACAL subgroup on the 4th ATP to CLP in April 2012. (For more information, please see the CARACAL meeting report circulated on March 26).

DG ENT EPG - A REVIEW OF THE AUTHORISATION PROCESS EXPERIENCE BY THE METALS SECTOR

The Consortia and Eurometaux conducted a review of learning lessons after 3 years of experience with the different steps of the authorisation procedure. This review resulted in 10 concrete recommendations which were, together with examples, presented to the newly formed DG ENT EPG meeting on REACH. This meeting of Industry ministry executives tries to provide a balance with CARACAL, which is more attended by executives from environmental ministries. The presentation that covered the selection for the ROI, SVHC setting, RMO phase as well as the prioritization phase, was very well received by the committee and Industry was solicited to present further detail in exchanges with DG ENT in the weeks to come.

EUROMETAUX REACH activities: hot topics/issues

AUTHORISATION MEETINGS -7/8 MARCH METALS CONSORTIA EXCHANGE EXPERIENCE ON AUTHORISATION STEPS

Metals Consortia exchanged experience on the different steps of the authorisation process. In this context, the metals sector is often not only a manufacturer of such substances but also a user, pushing metals Consortia into authorisation programs they did not schedule for. Ways to improve the priority screening, and in particular to encourage proper RMO assessment at the earliest step possible were identified and included in the presentation for the DG ENT EPG (see above). The meeting further requested Eurometaux to launch a program to raise attention on the discriminative nature of the priority scoring criteria for annex XIV listing towards metals and to identify how these could be improved. The second day of the authorisation meetings offered an exchange moment between industry and ECHA on the authorisation application phase. ECHA explained the critical steps and points of attention for industry to submit successful applications. Eurometaux requested attention for the early recognition of the threshold nature of many metals to safeguard the adequate control route, a point that was recognized by ECHA and taken forward.

SCC TECHNICAL TASKFORCE MEETING- OPENNESS FOR A DISCUSSION ON UVCB EFFECTS ASSESSMENT

Interesting and intense discussions took place at the SCC taskforce meeting on March 1 where consortia strategies, tools and methodologies for ‘upgrades of the UVCB intermediate dossiers’ to full dossiers were discussed. One important follow-up action is a discussion with ECHA representatives planned for May 21, where first ideas on UVCB effects assessment and substance identification will be exchanged. The possibility to have a longer, ‘real’ workshop with ECHA on these topics will be addressed as well. This discussion will be prepared with the taskforce (more information in the emails circulated on March 16).

RISK FORUM MEETING : AUTHORISATION AND TESTING PROPOSAL REVIEW CAUSING ACCELERATED ACTIVITY

The Risk Forum meeting of March 13 was again an opportunity to exchange on a number of REACH-related advocacy issues. The growing relevance of Authorisation and Testing Proposal related aspects and the increased activities from ECHA were notable. Important discussions took place on the classification and labelling inventory as well as on substance identity. A number of one-pagers were circulated for comments by the consortia. (For more information, please see RAC highlights circulated on March 20). The meeting also gave the opportunity to clarify ‘who will do what on REACH’ in the Eurometaux staff, to welcome Federica and thank Joeri for his work over the last years.

RISK ASSESSMENT & CLASSIFICATION WORKING GROUP

A number of technical issues, related to REACH and CLP, covering both human health and environment have been intensively discussed on March 28 with the Risk Assessment and Classification Working Groups. These groups are also overseeing the progress & potential issues on the projects covered by the REACH financing 2012 and the Eurometaux EHS budget.

COMMUNICATION ACTIVITIES – COMMENTS PROVIDED ON A PRACTICAL GUIDE FOR THE DOWNSTREAM USER & ON PEG GUIDANCE FOR PHYS-CHEM

Comments have been provided to ECHA on the two updated drafts circulated last month by ECHA, i.e. the Practical Guide for the DU, which also addresses the issue of scaling, and the updated Chapter *R.7.1: Physico-chemical properties* part of the Information Requirements for the CSA/CSR guidance. We would like to thank here in particular Mari Järvikivi, ARCHE, EBRC and Johnson Matthey who helped us manage to provide a timely response.

Further outreach of REACH

NANOMATERIALS SAFETY CONFERENCE

On March 8-9, the Dutch Ministry of infrastructure and environment organised a policy conference attended by about 50 participants (Member States, European Parliament and Commission, Industry and NGOs), to discuss choices to be made to move towards a proper risk assessment for Nano-materials. The different stakeholders made presentations on the current state of play, recent evolutions in some Member States (e.g. France), possible options to address this challenge in the current legal framework and the potential to use alternatives to legislation (e.g. voluntary initiatives). At the end of the meeting there was a broad support from authorities and the NGO side that it is now time to act on nano-materials through legislation, through reporting on uses and the proper assessment of the potential risks and preferably at EU level.

However, Member States also stated that if the EU Commission continues to be unwilling to act, they would not hesitate to take action at national level.

Calendar

- **17-18-19 April:** Back to Back Meetings – MCC Conference Centre
- **23-27 April:** MSC 23 – Helsinki
- **21 May:** UVCB assessment and substance identification *exploratory* discussion with ECHA
- **21-22 May:** ENES Workshop-Helsinki
- **23 May:** 7th Stakeholders' Day-Helsinki
- **4-8 June:** MSC 24 - Helsinki
- **4-5 June:** Workshop on Substance Evaluation – ECHA Conference Centre
- **11-15 June:** RAC & SEAC Helsinki
- **25-29 June:** ECHA Forum – Helsinki
- **October 2:** next REACH Forum meeting

Acronyms

CARACAL: Competent Authorities for REACH and CLP
CLH: Harmonised Classification and Labelling
CLP: Classification, Labelling and Packaging
CSA/CSR: Chemical Safety Assessment/Chemicals Safety Report
DG ENT EPG: DG Enterprise Policy Group
DU: Downstream User
ENES: Exchange Network on Exposure Scenarios
EOGRTS: Extended One generation Reproductive Toxicity Study
ES: Exposure Scenario
LEV: Local Exhaust Ventilation

PPE: personal protective equipment
RAC: ECHA Risk Assessment Committee
RMM: Risk Management Measures
ROI: Registry of Intentions
RMO: Risk Management options
SEA: Socio-economic Analysis
SEAC: ECHA Socio Economic Committee
SCC: Strictly Controlled Conditions
SVHC: Substance of Very High Concern
UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials

Guess I found it... Happy Easter to you all

