



EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

We hope you are well. The first snow has made its appearance, although it was more successful in giving the 'Christmas' feeling to Helsinki than to Brussels. REACH activities are definitely not being slowed down by decreasing temperatures: the month of November has been full of meetings, events, workshops, reflections on authorization and RMO.

The REACH financing exercise for 2013 is also slowly coming to a conclusion, and we are very grateful for your support and for all the constructive suggestions! A last couple of confirmations and the train will be able to leave the station on its journey through 2013! This also made us realize even more just how essential it is to explain the efforts and achievements of the REACH team and the metals' family! Please do not hesitate, therefore, to circulate the REACH news to the members of your consortium. This REACH news is your tool!

We wish you some warming-up weeks to come, with the possibility to enjoy those end-of-the year moments, in between rushing to meetings. Please take a deep breath as well if you are taking some days off: 2013 has been announced as a year of glitter, work and metals !!

Violaine Verougstraete, EHS director Eurometaux

ECHA REACH activities: hot topics

ECHA MEETINGS - RAC

CAPACITY BUILDING

RAC-23 discussed for the last time this year a series of harmonized classifications, interesting cases for restrictions and ...Gallium Arsenide! Regarding the latter, we expect RAC to finalize its opinion at the next meeting, in the spring of 2013. RAC is definitely reflecting on how to further build up capacity for authorizations/restrictions and providing the right expertise to deal not only with hazard, but also exposure and risk aspects. Somewhat intense and "full-of-useful-learning-lessons" discussions are taking place on the use and place of human data (epidemiological and monitoring data), expert judgment, DNEL derivation; highlighting once more that when we deviate from the ECHA guidance our justifications must be complete and transparent to avoid our approaches being discarded (more information: Violaine Verougstraete).

DNEL-AND THRESHOLD REVUE BY ECHA FOR SUBSTANCES ON CANDIDATE LIST: EUROMETAUX CHALLENGED RAC PROPOSAL

In order to help potential Authorization Applicants (AA), RAC suggested to conduct a preliminary assessment of the DNELs/DMELs and potential threshold nature for substances on the candidate list. RAC hereby aims at streamlining the AA submissions by providing guidance to the potential applicants. In response Eurometaux submitted last month a letter indicating that such preliminary review should only be conducted on demand of industry. Indeed it is expected that RAC may challenge the DNEL/DMEL derivation or apply only the generic assessment factors foreseen in REACH which would not be in favour of data rich substances and Consortia that spend extensive resources in the DNEL derivation. CEFIC joined the position and co-signed the letter. How these industry comments will be considered was not further discussed at RAC 23. (more information: Hugo Waeterschoot and Violaine Verougstraete).

ECHA MEETINGS

MSC PROPOSES TO CONSIDER SENSITIZERS AS SUBSTANCES OF EQUIVALENT CONCERN UNDER THE AUTHORIZATION PROCESS

MSC recommended respiratory sensitizers category 1a and some skin sensitizers to be recognized as substances of equivalent concern. Eurometaux reacted in writing last month on this proposal stating that the concern must be serious and the effects irreversible while aspects such as potency, sensitive populations and others should be considered carefully before

adding any sensitizer to the SVHC list. Eurometaux contested further the assumed automatic link between skin and respiratory sensitizers indicating that the scientific proof for such statement is lacking. (more information: Hugo Waeterschoot and Violaine Verougstraete).

REACH ENFORCEMENT FORUM OPEN SESSION

Together with representatives from Cefic, IMA-Europe and the plastic convertors, Eurometaux attended the open session of the REACH Enforcement Forum in Helsinki on 29 November 2012. The following topics were discussed: actions towards SMEs; assistance to recyclers in the plastics chain, highlighting in particular the issues they are facing regarding authorisation in particular for recycled substances exempt from registration but not from authorisation; the current enforcement project focussing on DU obligations, SDS, CLP notification, pre-registration and registration; and the upcoming project on enforcement which will look at registration obligations (manufactures and importers) and which will be carried out in close cooperation with Customs. The identification of importers will be a particular point of attention. Further points on the agenda related to communication in the supply chain and a project to identify analytical methods to check restrictions (more information: Inneke Claes).

ECHA WORKSHOPS

UPCOMING SEMINARS FOR FUTURE APPLICANTS FOR AUTHORIZATION

On 11 and 12 February 2013, ECHA will host a seminar on applications for authorization specifically designed for future applicants. The aim is to raise the overall understanding of the authorization application procedure via presentations, discussions and feedback from the industry. Due to space constraints, participants will be selected through an application process which will open on 10 December 2012. Priority will be given to future applicants not having had a chance to participate in the seminar held on 1 and 2 October 2012. A similar seminar is also planned to take place sometime during June 2013.

3RD MEETING OF THE EXCHANGE NETWORK ON EXPOSURE SCENARIOS (ENES) ON 21-22 NOVEMBER:

More than 110 people attended this meeting, including authorities from 11 Member States, NGOs and many ECHA representatives. The event was jointly organized by Cefic, Concawe, DUCC, FECC and Eurometaux. Presentations in plenary sessions and breakout discussions focused on information on mixtures to be provided along the supply chain and the most useful format (as ES or in the body of the eSDS?), further improvements in Exposure Scenarios communication in general (follow-up from the last ENES meeting in May), and increased efficiency in developing CSA. Regarding mixtures more specifically, several organic sectors explained their methods of consolidating/aggregating substance information for mixtures and generating outputs. ECHA has also drafted a kind of 'decision tree' that will be put to practical experience. The participants were also given an update on SPERCs and the recently created Specific Consumer Exposure Determinants (SCEDs). The possibility of using 'scaling' was further debated, and while progress was made on acceptance, the possibility of using measured data in the context of scaling to demonstrate safe use still needs further confirmation. Eurometaux and ARCHE are following this up! The meeting concluded with agreement to develop a cross-stakeholder Roadmap for the long-term improvement of the CSA/CSR/ES processes. The material from this 3rd meeting will shortly be published on the ECHA website. Information from previous ENES meetings can be found here: <http://echa.europa.eu/en/about-us/exchange-network-on-exposure-scenarios>

ECHA PLANS SEDIMENTS SCIENCE WORKSHOP IN 2013: UPDATE OF REACH GUIDANCE FOR METALS EXPECTED

The efforts of the Nickel sector to further unravel the bioavailability of metals sediments and their long-term fate was the key driver behind the recently announced scientific work programme of ECHA on sediments assessments for Chemicals Management purposes. ECHA has set up a scientific committee including members from the metals sector (Chris Schlekot and Hugo Waeterschoot), who are helping it to organise a Sediments Science Workshop in May 2013 with the ultimate aim of improving the guidance for sediments risk assessment, including bioavailability considerations with considerable focus on metals. The GEHS members will be informed of the progress of the workshop (more information: Hugo Waeterschoot and Chris Schlekot).

ECHA OTHER ACTIVITIES

REGISTRATION NUMBERS AND LEGAL ENTITY NAMES AVAILABLE FROM ECHA'S DISSEMINATION WEBSITE

As of the end of November, ECHA made new information available on registered substances on its dissemination page: the registration numbers and the names of the registrants (unless the latter claimed confidentiality). At the same time, the search functionality has been extended. The data can now be accessed via a search on e.g. classification endpoint, tonnage band, registration number, name of registrant, etc. As of December and the first quarter of 2013, ECHA foresees the publication of the PBT/vPvB assessment results, DNEL and PNEC assessment factors per endpoint, details of contact persons

and some further registration numbers and registrants' names as the dossiers are processed for e.g. confidentiality claims. ECHA has also launched a survey to improve its dissemination portal. The survey will be available until 20 December via this link: <http://surveys.eworx.gr/index.php?sid=81639&lang=en> (more information: Inneke Claes).

CO-REGISTRANTS' PLATFORM

The new version of REACH-IT released at the end of November of 2012 introduced the co-registrants page. Through this page in REACH-IT, co-registrants and inquirers who have received an inquiry number have direct access to each other's contact details. This will help companies to submit joint registration dossiers and fulfil their data-sharing requirements. At the same time, the inquiry process has been integrated into REACH-IT (similar process to the submission of registration dossiers), but the substance identity check will still be performed manually by ECHA. More information, a webinar and updated guidance are available from the ECHA website (more information: Inneke Claes).

ECHA LAUNCHES C&L PLATFORM IN JANUARY 2013

ECHA will launch the C&L platform at the end of January 2013. Via the platform, notifiers of the classification and labelling of a substance or registrants will be able to enter into contact with other notifiers of a classification or registrants of the same substance (same EC number) in order to arrive at an agreed classification. To protect confidentiality and avoid misuse, access to the platform will be restricted using a REACH-IT. Aliases can be assigned to the legal entities entering the platform if they so wish (more information: Inneke Claes).

Commission REACH activities

REACH-COMMITTEE MEETING: COBALT'S AUTHORIZATION THREAT ELIMINATED WHILE CR GETS MORE TIME

Eurometaux provided input to support the CDI and Chromates in their advocacy activities in preparation of a decisive REACH Committee meeting in November that de-listed 5 Cobalt salts and gave Chromates an extra 14 months in which to submit Applications. Eurometaux was also contacted by several MSCAs in this respect for more background information. The case demonstrates that ECHA's opinions are not always followed by the Commission, and furnishes a good series of reasons as to why this precedent-setting decision was taken (more information: Hugo Waeterschoot or Brigitte Amoruso).

12TH CARACAL MEETING

The 12th meeting of CARACAL was held on 28-29 November. Eurometaux attended on 28 November on behalf on the REACH Alliance, and IMA-Europe attended on the second day. The following issues of interest to the non-ferrous metals industry were discussed: poison centres; a proposal from the European Commission to stop using the DSD classification in proposals for CLH as of January 2013; status and timing of the 4th and 5th ATPs to the CLP; proposals to streamline the process of submitting and handling CLH dossiers; nanomaterials; and an update on the status of dossier and substance evaluation. The Commission's plans for a roadmap for SVHC assessment and REACH risk management measures were discussed during a closed session of CARACAL exclusively with the Member State Competent Authorities. It is understood that the ideas for the roadmap include the fact that that RMO analysis is the preferred tool for identifying the most appropriate risk management route for SVHCs under REACH. The MS supported the idea of a roadmap, and the Commission hopes to publish a draft by the end of the year (more information: Inneke Claes).

CARACAL SUBGROUP ON NANOMATERIALS

Eurometaux attended the meeting of the CARACAL subgroup on nanomaterials in Brussels on 20 November 2012. The Commission presented the staff working paper on nanomaterials that accompanied the Communication on the 2nd regulatory review on nanomaterials. Ways of practically implementing the definition of "nanomaterial" were discussed. IMA-Europe presented some first ideas on this, with a plea to adopt a pragmatic approach through a first-tier screening to eliminate coarse materials. The division of the workload between the various groups active in the filed of nanomaterials was discussed: the CARACAL subgroup on nanomaterials (regulatory and policy issues), the new ECHA WG on nanomaterials (technical and scientific issues) and GAARN (already registered nanomaterials). A final draft of the impact study on different policy options for handling nano-materials, conducted by BiPro for the European Commission, was presented. These results, together with the results of a further impact study which is to be launched by the Commission to fill in remaining data gaps, will provide the basis for proposals on how to handle nanomaterials under REACH, possibly including modifications to the REACH Annexes (more information: Inneke Claes).

EUROMETAUX REACH activities: hot topics/issues

5 YEARS OF EXPERIENCE WITH RESTRICTIONS UNDER REACH: A STRATEGIC REVIEW

A subset group of the Eurometaux Platform reviewed the metal sector's experience with the selection and priority setting of substances. Eurometaux supplemented this with experience from the Restriction programmes and turned this into a 5-year experience review including recommendations for structural improvements to reduce the impact for metals, while at the same time ensuring more balance and less discriminative handling of metals. The review will be presented to the REACH Forum in December for approval and implementation (more info: Hugo Waeterschoot and Violaine Verougstraete).

EUROMETAUX'S PRESS RELEASE ON RMO: ANTICIPATING THE EU ROAD MAP INITIATIVE ON INCREASED SVHC IDENTIFICATION

Building on the experience with Cobalt Salts and the 5-year REACH review, the Eurometaux REACH Platform recommended that early Risk Management option analysis be promoted. This would enable the best Risk Management Measures to be selected when necessary, while at the same time reducing the selection potential. Eurometaux published a press release on this issue on November 28, raising immediate attention from the Commission, ECHA and other industry sectors. The aim of this press release was to impact the thinking of countries, ECHA and Commission on the development of a Road Map to speed up the identification and selection of substances for the candidate list and subsequent Annex XIV, and to highlight the crucial role of RMO as early in the process as possible in this respect (more information: Hugo Waeterschoot and France Capon).

INTERMEDIATES

Following the ECHA annotation letters challenging intermediates registration dossiers, EM reacted on behalf of the NFM sector. A letter was sent out explaining the ongoing work and listing the consortia that are actively working on meeting regulatory requirements, while at the same time having to face time constraints to ensure consistency in submitting relevant information. The ECHA experts agreed that the NFM sector has some specificities, including in its use and definition of metal PROCs. PROCs do not have to be changed in the updated dossiers. Registrants who go for updates of their intermediates dossiers are expected to send in their appendices 3 should not remove the metal PROCs that define their intermediate process but add a justification of SCC (Appendix 3) that is consistent with the PROCs. Regarding the UVCB Guidance, the Risk Assessment Subgroup met in November: principles on human health approaches have been shared and are being included in the guidance. The Substance Identification chapter has been further improved and it is ready to be used as basis for a workshop at ECHA. This workshop will take place on January 8 and will focus on substance ID and how to duly explain and report information e.g. in the IUCLID. The next meeting of the TF is on December 7: the agenda is especially built around the upcoming workshop and the feedback on the annotation letters received from ECHA. Finally, the multi-metallic database (MMD) will be presented (thanks for all your efforts!) (more information : Federica Iaccino).

EXPOSURE SCENARIOS

The Exposure Scenarios Task Force met on November 9 to discuss the outcomes of the Hazardous Waste study carried out by ARCHE. The objectives of the study were to provide industry with a basis for assessing the risks of metals present in hazardous waste in a realistic way by updating and/or replacing the defaults given by the ECHA guidance. Based on the exercise of data collection and refinement, safe use could be demonstrated for the 6 metals participating in the study, for all compartments. An update on SPERCs, scaling and the CHESAR tool was also provided. The task force agreed to now go into "hibernation mode" until next spring, when some further issues on Exposure Scenarios may well crop up (e.g. ES for mixtures, feedback from downstream users). This will not prevent further background work on validation of the Tier 1 tools, of MEASE in particular, on the scaling issue and the issue of measured data; and making the links between CHESAR and our metal tools (MEASE, SPERCs) (more information : Violaine Verougstraete).

WORKSHOP ON CHROMATES AND SURFACE TREATMENT: A FIRST SECTORIAL LEARNING CASE ON AUTHORIZATION

Together with CEFIC and ECHA, Eurometaux organized a first sectorial workshop on Applications on 12-13 November following more informative ECHA briefings. The entire chromates supply chain, from importers, to the surface treatment sector, right up to the article manufacturers, collected practical questions on scoping and organizing Consortia, on how to group uses, and practical aspects related to the preparation of Authorization Applications. This extensive learning experience resulted in a series of "Myths" related to authorization, as well as an extensive Q&A screened by ECHA, relevant for all metal sectors, particularly non-ferrous metals, delivering to the surface treatment supply chain. Both will be published by

Eurometaux as a follow-up and guidance for the metal sectors involved in Applications (more information: Hugo Waeterschoot and Inneke Claes).

SECTORIAL DISCUSSION WITH THE GLASS SECTOR: THE BOUNDARIES OF THE INTERMEDIATE USE OF METAL OXIDES

ECHA's draft response challenging the glass sector's claim for intermediates status and the listing of Arsenic acid on the next prioritization list triggered an urgent multimetallic exchange with the glass and crystal sector to define the consequences of these proposals. Metal Consortia assessed the consequences for the use of metal oxides for these uses and defined common advocacy messages and positions that Eurometaux will defend at the upcoming ECHA-MSM meetings (more information: Hugo Waeterschoot and Inneke Claes).

METAL-SPECIFIC REACH APPLICATION TOOLS AND CONCEPTS

MECLAS: THE REVIEWED CONCEPT WILL MAKE THE TOOL FREELY AVAILABLE TO DOWNSTREAM USERS (www.meclas.eu)

Eurometaux and ARCHE have published a new concept for MECLAS aimed at making it freely available for downstream users such as the alloy and other metal-using sectors, and to increase regulatory recognition. MECLAS is an automated metals classification tool allowing hazard assessment under CLP for complex metal materials such as ores and concentrates, UVCB's complex intermediates, etc., making use of metal-specific guidance and (eco)toxicity data sets. The sponsor Consortia agreed to make this tool freely available so as to promote the use of best quality hazard data and assessment approaches for these complex materials and to strive for harmonized Classification recommendations for complex metal component-containing materials. The sponsoring Consortia will form a steering group to determine priorities for further development and to promote further regulatory use of the tool (more information: Hugo Waeterschoot, Violaine Verougstraete, Patrick Van Sprang and Frederik Verdonck).

UWM MODEL : EUROMETAUX BRIEFS ECHA ON RECENT PROGRESS

The UWM model constitutes a critical new tool to assess metals behaviour in the aquatic system, assessing the fate properties used for Hazard ID and Classification and Labelling under CLP and GHS. Eurometaux, supported by ECI, prepared a status update for ECHA aiming for further support and encouraging a scientific debate at ECHA level to promote regulatory acceptance. This is important, if not downright critical, in order to arrive at equal treatment between organics and inorganics to ensure that elimination from the water column for metals is recognised as equal to the degradation of organics. The acid test on the acceptance of the model and the conditions proposed by industry will come when Cu and Cu compounds are assessed for environmental classification in 2013 (more information: Hugo Waeterschoot and Katrien Delbeke).

Other news

REACH REVIEW: LOOKING AHEAD AT 2013 AND 2018: EURACTIV EVENT SPONSORED BY THE NICKEL INSTITUTE

Eurometaux attended a Euractiv event sponsored by the Nickel Institute on the Review of REACH that took place on 27 November 2012. The round table debate was well-attended by representatives from the European Commission, ENGOs and industry. The Commission explained that, following a broad assessment of different aspects of REACH carried out over the past 2 years, a Communication on the Review of REACH would be published at the beginning of 2013. The Nickel Institute pointed out that it was still too early for a major revision of the legal text, but that some improvements could be made through updated guidance or procedures. Even though authorisation is new, some improvements have been identified from first experiences with the prioritisation of SVHC, e.g. early RMO analysis (see also articles on "5 years of experience with Authorisation & Restrictions under REACH" and the EM press release on RMO). Eurometaux supported these comments and mentioned 2 other examples where the existing REACH framework was used successfully to bring improvements: nano-materials with an update of the REACH guidance documents, and the on-going evaluation of registration dossiers and upcoming substance evaluation by ECHA (more information: France Capon and Inneke Claes).

INDUSTRY DU USER GUIDE ON AUTHORISATION PUBLISHED

Cefic, ACEA and ASD have issued a guidance paper on authorisation for DU. Eurometaux contributed to this document, as did several other sector organisations. The intention of this document is to clarify the process and give some tips and recommendations to downstream users (DUs) dealing with substances of very high concern as defined in the framework of the REACH Regulation. It can be downloaded from the Cefic website

(<http://www.cefic.org/Documents/IndustrySupport/REACH%20Implementation/REACH-Authorisation-Guidance-for-Downstream-Users.pdf>), and will also be posted on the REACH Metals Gateway.

Further outreach of REACH

OECD

BIAC MEETING AT OECD: ECHA OUTSOURCES WORKLOADS TO OECD

In advance of the OECD-Chemicals Joint Meeting, BIAC (Industry representation at OECD level) met the equivalent of the Caracal at OECD. This strategic meeting provided an insight into OECD chemicals management activities for the next 2 years. Notable points included increased interest and working activities in respect of the development of Exposure Scenarios and exposure emission ratios on diffuse sources and releases from products. The list includes several metals and metal-containing materials. The increased collaboration of ECHA and the EU Commission in this extensive OECD programme area is a clear EU strategy to outsource some of its workloads to worldwide level (e.g. IUCLID). Eurometaux and ICMC contributed to BIAC's overview of activities and identified priorities and comments from the metals sector (available on request) (more info: Hugo Waeterschoot and Katrien Delbeke).

Calendar

- 7 and 19 December : Eurometaux webinar on authorisation
- 7 December : Eurometaux Task Force on Reach Intermediates
- 11 December : Directors' Contact Group Meeting
- 10-14 December 2012 : MSC review the CoRAP update and decide on next priority list
- 14-15 December: ECHA Management Board meeting
- 19 December 2012 : Eurometaux REACH Forum Meeting
- 8 January: UVCB SID meeting (Helsinki)
- 15 January 2013 : ECHA Workshop for MSCA and accredited stakeholders on the C&L Inventory, Helsinki
- 16 January 2013 : ECHA Workshop for MSCA and accredited stakeholders on developing a CLH dossier, Helsinki
- 21-22 January 2013 : 2nd GAARN meeting on already registered nano-materials, Helsinki
- 23 January 2013 : 1st meeting of the ECHA Working Group on nano-materials, Helsinki
- 23 January 2013 : ECHA/European aerospace/aeronautics Workshop, Cologne
- 11-12 February 2013 : ECHA's 3rd Application seminar to inform potential applicants, Helsinki
- 14 February 2013 : Commission Workshop on the review of REACH
- 26 March 2013 : ECHA Stakeholders day, Helsinki

Acronyms

AA: Authorisation Application	IUCLID: International Uniform Chemicals Information Database
ACEA : European Automobile Manufacturer's Association	MECLAS : Metals Classification Tool
ASD : Aerospace and Defense Industries	MMD : Multi-Metallic Database
ATP : Adaptation to Technical Progress	MSC: Member State Committee
CARACAL: Competent Authorities for REACH and CLP	NFM: Non-ferrous metals Industry
CEFIC : European Chemical Industry Council	NGO : Non-Governmental Organisation
CHESAR: Chemical Safety Assessment and Reporting Tool	OECD: Organisation for Economic Cooperation and Assessment Development
CLH : Harmonised Classification	PBT : Persistent Bioaccumulative and Toxic
CLP : Classification, Labelling and Packaging Regulation	PNEC :
CSA : Chemical Safety Assessment	PROCs: Process Codes
CoRAP: Community Rolling Action Plan	RAC : Risk Assessment Committee
CSR: Chemical Safety Report	RMO: Risk Management Options
DMEL : Derived Minimal Effect Level	SEAC: ECHA Socio-Economic Committee
DNEL : Derived No Effect Level	SCEDs : Specific Consumer Exposure Determinants
DSD : Dangerous Substances Directive	SCC: Strictly Controlled Conditions
ENES : Exchange Network on Exposure Scenarios	SPERCs: Specific Environmental Release Factors
ENGO : Environmental Non Governmental Organisation	SMEs : Small and Medium Enterprises
ES : Exposure Scenario	SVHC: Substance of very high concern
eSDS : Extended Safety Data Sheet	UWM : Unit World Model
GEHS: Group on Environment & Health Sciences of Metals (EM)	UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials
IMA : Industrial Minerals Association	vPvB : very Persistent, very Bioaccumulative