EUROMETAUX
EUROPEAN ASSOCIATION OF METALS

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EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

September is now over, kids are used to the school rhythm again, Brussels looks pretty wet and we are fully 'dancing' in REACH tempo again. The SVHC list end of August announced a pretty busy end of 2012, and the ECHA and Commission activities during this last month seem to confirm that this hyperactive trend will last during 2013. This will only add to the 2013 registration and 2010 update duties of several consortia. More than ever it will be crucial to take occasional breaks in your overloaded days to assess what can be learnt from each other and to ensure some consistency between the metals. This consistency is of course key to companies involved in several consortia but also a key defense tool in our discussions with authorities. It may also help to spare some energy that can be re-invested in the quality and completeness (hot topics in all authorities' communications) of the deliverables to be provided.

Having been 'off' for two weeks this month and measuring the additional burden this generated for the rest of the REACH team, I would definitely like to make a plea for keeping an eye on resources and a 'margin of safety for health' in your consortia: we need to protect the essentials here!

Thanks to all for your very kind messages over the last weeks and a big thank you to Hugo, Inneke, Ailsa and Fè for having taken over so well my "REACH duties" these last weeks

Violaine Verougstraete, EHS director Eurometaux

ECHA REACH activities: hot topics

ECHA MEETINGS – RAC

A NEW CHAIR AND GaAs SCIENCE DISCUSSION CLOSED

RAC22 met in Helsinki from 11 to 14 September. The new RAC chair Tim Bower immediately gave the meeting a different and dynamic momentum while carefully balancing the different scientific opinions. The Reprotoxicity assessment of GaAs was a main headline point and resulted in animated discussions. The Rapporteur proposed Repro 2, justified by the effects on the male reproductive organs as secondary and being caused by the impact of overloading the lungs of test animals with particles. While there was clear recognition for the principle of lung overload, RAC members unanimously felt that this would require more proof demonstrating that the noted effects were not caused by any direct toxicity effect on the reproductive organs therefore agreeing on Repro 1b. This case sets important precedence for the metals sector given lung overload cases appear in many different cases. Series of other classification reviews discussed contained quite important precedence for metals including the balance between animal and Human health data to conclude category 1B, how extensive workers exposure data sets could be used in classification decisions and others, … The GaAs case and the learning lessons will therefore be further analysed in the Eurometaux Classification and Labelling group. (More info: V. Verougstraete and H. Waeterschoot)

ECHA MEETINGS – SEAC

THE CHROMIUM RESTRICTION CASE SETTING PRECEDENCE FOR SEA ASSESSMENT FOR CONTACT SENSITIZERS

SEAC 16 met in parallel with RAC (see above) and focused mainly on restriction cases and preparatory activity for the proper handling of Authorisation Application (AA) cases. The meeting established a clear reasoning and concept for the SEA part of the restriction case on Cr6 in leather, an impact assessment methodology that would be trend setting for materials in contact with consumers that cause sensitization. ECHA made no real progress with its paper on assessment criteria for the evaluation of "the economic feasibility criterion" for AA's. However they clarified comments and questions industry and SEAC members had on the concept. The main learning lessons from this debate will be discussed at the next Eurometaux SEA-platform. (More info: H. Waeterschoot)

ECHA MEETINGS – COMBINED RAC – SEAC MEETING

COMMITTEES REACT POSITIVELY ON ASSESSING DNELS AND THRESHOLDS FOR AAS

Making the right choice between the Risk based or SEA based route when applying for authorisations is a critical decision action for the applicant based on the threshold nature of the CMR effect. Additionally ECHA committees fear that AAs will submit for the same substance applications by different routes and using different DNEL's. The ECHA secretariat therefore raised a paper suggesting that RAC would evaluate the "threshold nature" and additionally provide an opinion on "recommended DNEL's" so that more harmony could be achieved. Most Committee members supported the idea to streamline the threshold and DNEL derivation, while industry noted that leaving this decision to authorities is against the spirit of REACH. Indeed while the RAC opinions would only be recommendations they could be opposite to industry's view and information. Eurometaux will therefore submit a written reaction to ECHA in October. (More info: V. Verougstraete and H. Waeterschoot)

ECHA MEETINGS – MSC

THE CANDIDATE LIST MAY SOON BE FURTHER EXPANDED WITH RESPIRATORY SENSITIZERS

The **25th MSC** meeting took place from 18-21 Sept. in Helsinki. and a series of new NGO organizations (ETUC, EEB, Client-earth) and a representative of the"OR" organization attended for the first time. Main headlines included:

- the speeding up of the Testing Proposals (TP's) review program given all TP's need to be launched before the end of the year. Metals TP's seem on hold, waiting for the outcome of the Eurometaux metals Read Across workshop (Oct. 1).
- MS's, Industry and NGO's all criticized the recent initiative of the Commission to list 37 potential SVHC's including 21 metals because of lacking preliminary RMO assessments (see further).
- MS's evaluated a proposal to consider Respiratory and selective Skin sensitizers, as substances of equivalent concern
- The CoRAP updating program will include > 100 new substances on the list, thereby doubling the figures for the 2 years to come. The list and justification will be made public by the end of the autumn.

The next **MSC (**22-24 Oct) will include the following topics of interest for the metals sector: the new list of SVHC's and the new criteria for respiratory and skin sensitizers, PBT and Endocrine disruptors, the draft opinion for the 4th priority list, the updated CoRAP list and justification for the selected substances, a discussion on RAAF Read Across manual (incl. report on the metals Read Across workshop outcome) and the planning for the start of the Substance Evaluation discussions in MSC. (More info: H. Waeterschoot)

PARTICIPATION OF INDUSTRY STAKEHOLDERS AND EXPERTS IN ECHA COMMITTEES: 2 PROPOSALS TO RESTRICT INPUT OF INDUSTRY

Two proposals were tabled last month to restrict industry stakeholder participation in ECHA Committees. The first proposed to restrain industry STO (like Eurometaux or CEFIC) from attending the Authorisation Application reviews by MSC. An intervention at ECHA Management Board level by G. Thiran and a letter from industry achieved a balanced solution whereby industry can attend the introductory discussions if the applicant did not request confidentiality, whilst industry will have to abstain from the final discussions. As for testing proposals an Authorisation Hearing Officer will brief the sectorial STO on the generic outcome of all cases. The second proposal aimed at improving the speed and quality of the decision taking in Classification dossiers by excluding any industry expert attendance during RAC meetings and requesting them to then use Public Consultation period for this purpose. While recognizing the need for assuring all experts understand the CLP and RAC procedures, STO reacted very critically as well as RAC members requiring ECHA to review its policy. (More info: H. Waeterschoot and V. Verougstraete)

ECHA MEETINGS – MANAGEMENT BOARD (MB)

FOCUS ON THE LONG TERM PLANNING PROCESS

The ECHA management Board met in Bucharest on 27-28 Sept and was attended by G. Thiran as industry representative. The main focus was on the 2013 work plan and the launch of the Longer Term ECHA objectives and 5 year work scheme (2014-2018). ECHA's planning demonstrated high activity in 2013 due to the increasing importance of the Substance Evaluation and Authorisation Application review and the speeding up of the Compliance checks. However the 5y's work scheme will highly depend on budget considerations. The Board further agreed with the request for providing STO access to Testing proposals and Compliance check reviews so they could prepare this and better report back to their home base. This response was a result of the combined Industry letter to ECHA in June. The MB also elected a new chair Ms. Nina Cromnier, Executive Director of KEMI (Sweden).

ECHA WORKSHOPS

ECHA-INDUSTRY WORKSHOPS ON AUTHORISATION APPLICATIONS AND SEA-AOFA EXPERIENCE: AN OPEN DEBATE BETWEEN INDUSTRY AND ECHA

ECHA, Cefic and Eurometaux organized two workshops in Helsinki for companies soon involved in Authorisation Applications (AA's) aiming to best prepare industry for good quality applications. Both workshops were attended by number of metal company and sector representatives. The first workshop provided a detailed briefing on the AA process steps, timing and ECHA committee review processes, as well as "firsthand" experience and recommendations from industry (including Eurometaux). The second workshop focused on increasing the understanding of industry on the scoping of Socio-economic Assessments (SEA's) and Assessments of Alternatives (AoA's) so that industry's delivery on those would fit the expectations of ECHA and the SEAC-RAC committees to promote the success rate. The open and frank exchange demonstrated the limited experience on REACH related SEA's and AoA's by industry (and other stakeholders). It also highlighted the importance of conducting feasibility studies and examining interaction between SEA and AofA to limit and focus the scope before the full assessment phase of both reporting requirements. A general level of uncertainty was expressed by industry on how both ECHA committees will interpret the REACH Authorisation assessment principle that the "*benefits of maintaining the use for the substance should outweigh its risk*". The metals sector presented several cases and overviews including: a collection of experiences with organizing AA Consortia, planning and timing (C. Braibant), SEA for a building construction application for Pb sheet (S. Binks) and experiences with integrated first tier SEA-AofA assessment to define scoping and focus of full assessments (H. Waeterschoot). All presentations are available on request. The overall impression gained from the workshops is that the development of SEA and AOA still remains somewhat of an academic exercise and that the standard required by ECHA for such analysis will only become clear once the first substances have been submitted for authorization. (More info: H. Waeterschoot)

OTHER ECHA NEWS

TARGETED COMPLIANCE CHECK REGISTRATION DOSSIERS

In addition to the full compliance checks which ECHA needs to carry out for 5% of the submitted registration dossiers, ECHA is now also carrying out targeted compliance checks. Using IT-tools and expert judgement, ECHA checks "areas of concern" related to the safe use of a substance and endpoints which matter for human health (PBT, CMR and sensitising properties) and the environment. As a consequence of the targeted compliance check, a registrant might receive several draft decisions at different moments in time for the same registration dossier. For more information please see the ECHA press release (http://echa.europa.eu/view-article/-/journal_content/1a87ce8e-6286-4d1b-9dc2-b2d10d6f1d79) and the Q&A on targeted compliance check (http://echa.europa.eu/support/faqs/qa-on-targeted-compliance-checks) (More info: I. Claes)

INQUIRY PROCESS: TWO-WEEK INTERRUPTION END OF NOVEMBER 2012 BEFORE THE LAUNCH OF A NEW VERSION OF REACH-IT

ECHA is currently automating the process to handle inquiries submitted through REACH-IT. A new functionality will allow a legal entity which submitted an inquiry, to access directly through REACH-IT the contact details of the co-registrants of that substance. This will however only be visible to the inquirer after ECHA has checked the substance identity and issued an inquiry number. The substance ID check will still be carried out manually as is currently the case.

UPDATED C&L INVENTORY AND PLATFORM

The updated C&L inventory available went live at the end of September. The C&L inventory contains all substances for which at least one notification classifying the substance as hazardous was submitted. In the updated version, the "non-classifications" of these substances are also shown, e.g. from the registration dossiers. With this update, ECHA addresses a major concern from industry as the inventory now gives a more complete picture of all the classification information related to substances. ECHA will launch the classification and labelling platform in January 2013. This web-based discussion tool will allow companies to enter into contact with other companies to discuss the possibly different self-classifications for the same substance and if necessary streamline the classifications. The tool is voluntary and streamlining the classifications is also voluntary, but industry and ECHA hope that this tool will lead to a consolidation of the classifications. (More info: I. Claes)

DISSEMINATION OF "SDS" INFORMATION FROM REGISTRATION DOSSIERS

As of November 2012, ECHA will disseminate more information from the registration dossiers as was the case up to now (please see REACH newsletter from June 2012 and links below). Companies have until the end of October 2012 to check their already submitted registration dossiers with the dissemination plugin and file confidentiality claims if necessary (subject to a fee!). As one needs to use IUCLID 5.4 to submit an update to a registration dossier, the new mandatory information in IUCLID 5.4 as the outcome of the PBT assessment needs to be filled-in in order to claim information as confidential. Information which in the past could be claimed as confidential without any additional fee (eg name of registrant or registration number) will now give rise to a confidentiality fee. ECHA press release on dissemination SDS information: http://echa.europa.eu/en/view-article/-/journal_content/77a6455a-c28f-4183-91ca-a854f5c3a176
Q&A on dissemination and confidentiality claims of SDS information in IUCLID 5.4:
http://echa.europa.eu/documents/10162/13651/questions_and_answers_sds_info_dissemination_en.pdf
Data submission manual 16 on submitting confidentiality claims: http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals (More info: I. Claes)

These new functionalities will be implemented though a new version of REACH-IT which is to be launched at the end of November 2012. Due to the major changes in the process flow, ECHA will suspend the processing of the inquiries two weeks prior to the launch of the new version of REACH-IT. Inquiries can be submitted, but they will not be processed.
Further details including updates of Q&As and manuals will follow later. (More info: I. Claes)

COMMISSION

SVHC ROI LISTING OF 21 PB COMPOUNDS: PB SECTOR AND EUROMETAUX MET THE COMMISSION

The Commission confirmed the proposed listing was inspired by the political commitment of the Commissioners to list 136 CMR substances by the end of 2012 and all relevant CMR's and Equivalent concern substances (> 1000) by 2020. In practice this would require Commission proposing more than 50 substances a year to complement the proposals from member states. While not contesting that the proposed compounds meet the SVHC criteria, industry confirmed its disappointment given the decision was taken without any RMO considerations or dialogue with industry. The Pb DU sectors demonstrated appropriate risk management control for all applications within the scope of REACH. The Commission further announced they would develop a Road Map before the end of the year to meet the 2012 target together with the Member states. The promise was made that both for the present proposals as for future listings, RMO would continue playing an important role in deciding the relevance for Restriction or Authorisation. Eurometaux will develop a response to the Commission Road Map and plan a strategic session with Consortia covering CMR or substances of equivalent concern. (More info: H. Waeterschoot)

EUROMETAUX REACH activities: hot topics/issues

COMMUNICATION ACTIVITIES -

INFORMA: EUROMETAUX PRESENTED ITS EXPERIENCES WITH SVHC AND AUTHORISATION LISTING

At the INFORMA meeting in Barcelona Eurometaux presented its view and experience with the SVHC and Authorisation listing process and called publicly for a more transparent and balanced system for Metals. The meeting allowed for open discussions with ECHA staff and MSCA's to increase the understanding of each other's objectives and concerns.
The Eurometaux presentation can be obtained on simple request. (More info: H. Waeterschoot)

Further outreach of REACH

OECD

Costs and practicalities for two new OECD guidelines on Extended One-Generation Reproductive Toxicity Test and Transgenic Rodent Somatic and Germ Cell Mutation Assay

The report on the "Survey of Worldwide Contract Research Organisations: Costs and Practicalities of Two New OECD Guidelines for Testing Chemical Substances OECD 443, Extended One-Generation Reproductive Toxicity Study, and OECD 488, Transgenic Rodent Somatic and Germ Cell Mutation Assay" which was commissioned by ECHA was published at the beginning of September 2012. These two new OECD test guidelines are important because for example, the extended one-generation reproductive toxicity study (EOGRTS) will, under certain conditions, fulfil the current information requirements for a "two-generation reproductive toxicity study" under REACH. The consultants conclude that at this relatively early stage after the release of the OECD guidelines, the new OECD test methods are more expensive than the previous "standard" tests and the test house capacity to undertake them is still limited, in particular for the Transgenic Rodent Somatic and Germ Cell Mutation Assay. For more information, please see the ECHA website (report: http://www.echa.europa.eu/documents/10162/13628/survey_report_worldwide_cros_en.pdf and ECHA press releases ECHA/NA/12/39 and ECHA/NA/12/02). (More info: I. Claes)

RTR: the metals sector invited the OECD for an exchange on Product release factors

Eurometaux forwarded early September a letter to the OECD PRTR secretariat criticizing the lack of scientific rigidity in reviewing product release factors. The program run by the Nordic Council provided first cases for releases from break paths which were not corresponding to industry's best knowledge. The Nordics are further preparing release factors on (metal) releases from tyres, building products and others. Most problematic is the lack of potential for early input and critical review, leaving almost no opportunity to correct the recommendations which are used for many applications including REACH consumer scenarios. ICMM, Eurometaux and the Consortia therefore proposed a more pro-active approach suggesting that a "technical exchange workshop on product releases for metals, best science and data sets" be held to improve the starting base for further assessments. The OECD PRTR meeting reacted positively to this suggestion. (More info: H. Waeterschoot or B. Davies (ICMM))

Calendar

- **11-12 October**: ECHA Lead Registrants Workshop with EM Presentation – Helsinki
- **16 October**: Eurometaux REACH Forum meeting – MCC
- **17 October**: Strategic planning session on the SVHC policy of the Commission
- **19 October**: ECHA Lead Registrant Webinar on General principles of dossier preparation and submission
- **12-13 November**: Industry Authorisation Application briefing meeting
- **20-21 November**: ENES III – Brussels
- **27-29 November**: CARACAL - Brussels
- **19 December**: Eurometaux REACH Forum Meeting – MCC

Acronyms

AA: Authorisation Application	**OECD**: Organisation for Economic Cooperation and Assessment Development
C&L: Classification & Labelling	**OR**: Only Representative
CMR: Carcinogen Mutagen Reprotoxicant	**PBT**: Persistent bio accumulative toxic chemical
CoRAP: Community Rolling Action Plan	**PRTR**: Product Releases Transfer Registry
DNEL: Derived no effect level	**RAAF:** Read-Across Assessment Framework
DU: Downstream User	**SEA:** Socio-economic assessment
EOGRTS: Extended One-Generation Reproductive Toxicity Test	**STO:** recognized Stakeholder Observers, for industry represented by Cefic, Ecetoc and Eurometaux
GaAs: Gallium Arsenide	**SVHC:** Substance of very high concern
MB: Management board	**TP:** Testing Proposal