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EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

Today is the second important REACH milestone in terms of registration. A number of metals consortia, companies and consultants once again experienced those particular pre-deadline weeks where changes in use descriptors, IT fantasies and communication disturbances are immediately translated into additional working hours (and decreasing sleeping ones). Congratulations to all of you for managing this again!



Now, please take a deep breath...4, 3, 2, 1...

All of you know now that registration is only the first of the REACH efforts, and that the REACH acronym has much more in reserve. Keeping track of the changes in guidance but also in regulatory trends to reflect those in updated REACH dossiers and to go 'informed' to ECHA Committee meetings; defending in a sensible way what has been submitted and recycling the huge investments made; give consideration on how to translate the REACH objectives in quality information or something sensible that can actually be used; exploring the lifecycle to identify others concerned by a substance are key priorities that have been identified by several consortia secretariats and the REACH team.

Further exchanging on how to put these priorities in practice will be even more 'key' in the coming years to remain all in 'tone' and visible as a sector. We have started -pushed by some of you- to explore additional 'tools' to facilitate -or make more attractive- learning and circulation of information. So a REACH blog and "role plays" will now become part of the arsenal we would like to offer as REACH team to the consortia. And any additional ideas to continue surfing this wave are of course most welcome

1, 2, 3, 4...Let's all go for a deep creative inspiration! ☺

Violaine Verougstraete, EHS Director Eurometaux

ECHA REACH activities: hot topics

ECHA COMMITTEES

RAC: PUBLIC CONSULTATIONS ON GALLIUM ARSENIDE AND PB COMPOUNDS:

GaAs: end of the CLH story

ECHA has launched on 29 May the Public Consultation on the RAC draft opinion regarding the reprotoxicity classification of gallium arsenide (GaAs). This consultation is part of the mandate of a REACH article 77 (3) request made by ECHA's Executive Director for the RAC to re-examine the substance's reprotoxicity based on new evidence. This consultation ends the GaAs discussions in RAC on carcinogenicity and reprotoxicity, where several key concepts of relevance for the metals like read-across, the notions of secondary effects, the impact of physical form and bioavailability were -heavily- debated. Both the GaAs industry and Eurometaux have come a long way in the familiarisation with the RAC and CLH processes, the assessment of the impacts of classifications on other pieces of legislation and the toxicology of this semi-conductor mainly used in high tech electronic products. The comments received during the 21-day, public consultation will be considered by the RAC in its final opinion. Separately, evaluation of gallium arsenide under the Community Rolling Action Plan (CoRAP) will begin next February (more information: Violaine Verougstraete and Hugo Waeterschoot).

Pb restriction: preparing for RAC and SEAC reviews

The first versions of the Draft Opinions on the restriction proposal on Pb compounds in articles were received in parallel with the on-going Public Consultation (PC). The Pb sector has submitted comments as well as other impacted user sectors. Eurometaux provided process support. Eurometaux and ILA are reviewing the Draft Opinions and already submitted input in preparation of the upcoming RAC and SEAC meetings where the first content discussions will take place. The case is of a conceptual importance for the metals sector at large on how restrictions for metal (compounds) in articles would be scoped and assessed especially from the SEA perspective (more information: Hugo Waeterschoot and Violaine Verougstraete).

ECHA MEETINGS

Sediment workshop 7-8 May: metals hazard and risk evaluation at the core of the debate

Building on the demand of Ni Institute and Eurometaux, ECHA organized its first topical science workshop on the theme of sediments hazard and risk assessment in May, in Helsinki. More than a 100 international scientists participated actively, including experts from the metals community. The workshop reviewed recent progress in sediment assessments and provided an excellent basis for the development of an updated ECHA guidance. Eurometaux thanked ECHA for this event as it also demonstrated their willingness and efforts to achieve the strategic objective of becoming a scientific hub, at the top of the International regulatory science development (more information: Hugo Waeterschoot and Chris Schlekot).

Substance Evaluation workshop 23-24 May: a first review of experience

Eurometaux participated and made a presentation at a recent ECHA-Member States Workshop on Substance Evaluation (SE). The meeting aimed at reviewing the first years of experience with the SE part of REACH, which is a very large and vast programme, still ramping up and aiming at a cruising speed of 50 Substance Evaluations/year. The first year proved SEs to be of good quality but often overlapping with the objectives of dossier evaluations (DE). A plan to pre-empt SEs by Dossier Compliance Checks has therefore been set up, meaning that all listed CoRAP substances from 2015 onwards will have undergone full Compliance Check. The key demands in Eurometaux's presentation were to focus on 1) methods and concepts to improve substances reviews, rather than going for corrective actions only and 2) SE should strive for a process that creates a spontaneous learning curve to improve registration files on generic aspects and not have CoRAP becoming another blacklist (more information: Hugo Waeterschoot).

ENES 4 workshop 16-17 May

The fourth meeting of the ECHA-Stakeholder Exchange Network on Exposure Scenarios brought together representatives from industry, Member States and ECHA to discuss several topics linked to Exposure Scenarios, their use and communication. A draft Roadmap including concrete actions on what improvements can be made on exposure scenarios, how this could be done and the priorities was presented as well as the outcome of an exemplification exercise on the harmonisation of short titles for ES and the table of content for the eSDS annex. This meeting was attended by Irene Canas Sierra (Nickel Institute) and Inneke Claes. Status and progress on the tools for communicating ES information or generate Specific Consumer Exposure Determinants (SCEDs) were also reported. A report including some suggestions for further follow-up will shortly be circulated to the Eurometaux ES Taskforce. The next ENES meeting will take place in the autumn and reflect on ways on how to further improve the implementation of ES and an effective communication, including on mixtures (more information: Irene Canas Sierra or Violaine Verougstraete).

ECHA OTHERS

ECHA guidance review: Environmental hazard and risk assessment section planned for 2014

ECHA indicated they would like to review and update the environmental Effects, Exposure and Risk Assessment guidance documents in 2014, based on the experience they gained with the Registration, Restrictions, and Dossier/Substance Evaluation processes. While no details on timings and modalities are available at this stage, it is beyond doubt that such activities will be a high priority for the metals sector. Some of the existing sections of the guidance (e. g. sediments risk characterisation, secondary poisoning assessment, ...) should emphasise or include more metal specific aspects. Eurometaux will therefore propose to the Risk Assessment Working Group and the REACH Forum to design a program to anticipate and follow up on this guidance update (more information: Hugo Waeterschoot and Violaine Verougstraete).

Guidance on PBT-vPvB assessment: PEG meeting on 4 June

ECHA released a draft update of its PBT and vPvB guidance, aiming at upgrading its REACH hazard assessment guidance and extending it to SVHC identification. Eurometaux participated in the technical review process focusing its efforts on the generic concepts and aspects, and on the definitions of relevance for organo-metal compounds, in view of the upcoming challenge to develop an equivalent assessment scheme for inorganics. A key issue for discussion is to know which metal compounds

would qualify as having an “organo-metal” status. A formal Partner Expert Group meeting is foreseen for 4 June and will be attended by Eurometaux (more information: Hugo Waeterschoot).

Registration: ticking boxes for jointly submitted information by the Lead on behalf of co-registrants

When Lead Registrants create and submit their dossier (new or updated), it is recommended that they check that they did not erroneously tick the box to indicate that the Lead submits the “Chemical Safety Report” or the “Guidance of safe use” or the “Review by an assessor” on behalf of the co-registrants, if the individual registrants submit that information themselves. This can only be corrected by ECHA through a resource and time-consuming procedure: ECHA needs to get a written declaration from all of the co-registrants in the joint submission that they indeed agree with the individual submission of the information (more information: Karine Van de Velde).

Registration: Opt-out information

Several consortia reported issues with potential joint registrants who refuse to pay the costs for the shared data in the joint dossier. They either claim that the costs are disproportionate, or that they have their own data available or that the data are freely available on the internet and that they have the right to use these data for free. Some have indicated that they will submit their own registration dossier outside the joint submission. These are very difficult situations to solve and unfortunately, following the feedback received from ECHA outlined below, the burden is put on the companies to straighten out these situations:

- Opting-out is possible for one or more endpoints, but it is not possible to opt-out from an entire dossier
- Not agreeing on cost sharing, is a valid reason for opting out, but the potential registrant has to show that every effort has been made to come to an agreement and that his claims regarding the costs for data sharing being too high, can actually be substantiated
- A company that opts-out, remains (or should become) a member of the joint submission
- The Lead Registrant is not obliged to give a token for the joint submission to a potential co-registrant who wants to go for an opt-out of the (full) dossier
- If the potential co-registrant submits an own registration dossier outside the joint submission, he is in breach of REACH. However and unfortunately, ECHA said that they will not prohibit the submission of such registration dossiers and will issue a registration number.

ECHA explained that they cannot take any action as REACH enforcement is in the hands of the Member States. It is for industry to monitor such situations and to take actions by alerting the enforcement authorities in the Member State where the company that submitted a dossier violating copyright, data protection or legitimate access to data provisions is based and to initiate a case before the competent national courts. These actions are only possible once proof can be obtained that the company submitted the registration dossier from e.g. the information published on the dissemination website. For the dossiers submitted by the 2013 registration deadline, it could take ECHA up to the end of 2013 to disseminate the data. ECHA intends to solve this situation only in time for the 2018 registration deadline. This is very unfortunate, as the costs for actions to redress such situations will need to be borne by the companies which in the first place correctly applied REACH (more information: Inneke Claes).

Commission REACH activities: hot topics/issues

REACH Review: discussions in the European Parliament and Commission event

The REACH Review is still high on the political agenda. On 29 May, Geert Dancet (ECHA), Allen Seatter (Deputy Director General DG ENV) and Graham Wilmott (Head of the REACH Unit DG ENT) exchanged views with the members of the ENVI Committee of the European Parliament. Commission and ECHA confirmed the main lines for the Review and MEPs raised concerns regarding the quality of the data from the registration dossiers, support for SMEs, alternatives to animal testing), SVHC (PBTs and endocrine disruptors in particular) and substitution, compliance and nanomaterials. Further, in the European Parliament, on 4 June a meeting on “REACH: Ensuring environmental protection and European competitiveness” will be organised by MEP Pavel Poc. An exchange of views is foreseen between the Commission, MEPs and stakeholders from NGOs, industry and civil society.

On 27 June 2013, the European Commission will hold a technical workshop on the review of REACH, with a focus on the quality of the registration dossiers, challenges for SMEs and the role of DU. Eurometaux will give a presentation at the workshop (more information: Inneke Claes).

Please note as well that the Eurometaux REACH Forum of March requested the secretariat to develop a position paper on the REACH review in anticipation of this workshop. The paper reviews in short the 5 years’ experience of the sector with the different REACH tools and proposes 4 recommendations to make the REACH process more relevant, efficient and propor-

tionate from the perspective of the metal sector. The paper will be distributed early June and reviewed by the REACH Forum (more information: Hugo Waeterschoot and John Schonenberger).

Wrapping up activities Directors' Contact Group and sherpas for 2013 registration deadline

During the last telephone conference of the sherpas of the Directors' Contact Group (DCG) on 23 May the following topics were discussed and agreed:

- Actions to clean-up the C&L inventory: ECHA will investigate possibilities to contact non-responsive notifiers and a paper with recommendations to clean-up the inventory will be further developed
- Activities from DCG leading up to the 2013 deadline: no major issues were reported and ECHA reopened the DCG solutions from the 2010 registration deadline to help registrants experiencing problems to provide certain information in time for the registration deadline. The "achievements document from DCG 2" will be finalised and presented to CARACAL and the ECHA Management Board
- Future of the DCG: it was preferred to keep the DCG in place, even if it is expected that activities might only be needed closer to the 2018 registration deadline. The Commission will work on a proposal on how to practically organise this, linking to initiatives from the DCG remit also mentioned in the REACH review (DCG to continue to monitor processes, support for DU and for authorisation applications) (more information: Inneke Claes).

EUROMETAUX REACH activities: hot topics/issues

AUTHORISATION

Refractory Ceramic Fibers (RCFs): potential candidates for the next Annex XIV priority list?

Recognizing that RCFs are widely used throughout the entire metals sector, Eurometaux responded to a request of the RCF to review the potential for appearing on the 5th priority list for authorisation and what could still be done to prevent formal listing. In turn, Eurometaux indicated a wide interest of the metals sector for collaboration in case RCFs should be selected and suggested that the sector attend the upcoming Authorisation/Restriction platform meeting in June to exchange on combined advocacy anticipating the Public Consultation (more information: Hugo Waeterschoot and Violaine Verougstraete).

EVALUATION

Cefic-Eurometaux Evaluation workshop on May 13

A workshop co-organised by Cefic and Eurometaux and attended by Wim De Coen (ECHA Head of Evaluation Unit 1) took place mid-May in order to take stock of the ECHA Evaluation report and the experiences with Dossier and Substance Evaluation. Representatives from industry and ECHA discussed and exchanged views on processes and ECHA/industry experiences but also on technical issues like Substance Identity, read-across and justifications, UVCBs and grouping, exposure based adaptation of information requirements etc. It was recalled that Evaluation is a system put in place to assess quality, not a system of approval of registration dossiers. It is binding (REACH regulation) and the strict timelines have to be respected, but there are several windows of opportunities, communication systems put in place to encourage exchanges on possible concerns with ECHA. A report will shortly be circulated to the participants and main learning presented at the next REACH forum meeting (more information: Violaine Verougstraete and Hugo Waeterschoot).

Testing proposals: Eurometaux organized an MSC training review

A series of Cobalt compounds will be assessed by MSC in June under the Testing Proposal program. The sector conducted extensive efforts in developing a robust read-across concept that in the eyes of ECHA would become a model reference for metals testing proposals and waiving obligations and set further guidance for RAAF. The upcoming MSC meeting is therefore of great importance for both the Cobalt sector and the metal sector at large. Eurometaux prepared a "mock-up" training session to prepare the industry and their consultants for MSC review. Several experts from other Consortia participated in the training meeting. The relevance of such training sessions will be discussed further at the REACH Forum meeting. Such sessions may be organised on a regular basis, adapted to the specific needs of the Consortia and of the REACH programs of concern (more information: Violaine Verougstraete and Hugo Waeterschoot).

Preparing for Substance Evaluation sessions: GaAs meets the Substance Review country Latvia

GaAs is the first metal meeting its Substance Review country (31 May). The results of this discussion were not yet available when this monthly report was drafted and will be reported in next month's report. It is Eurometaux' intention to draw horizontal learning lessons from the preparatory session so that other Consortia preparing for such a meeting (Ag, Zn, ...) could

benefit from it. An exchange meeting will be organised in the weeks to come to promote the learning experience (more information: Hugo Waeterschoot and Martin Wieske).

INTERMEDIATES

Intermediates Taskforce: next meeting will take place on 28 June

ECHA is exploring how to best develop IUCLID/CHESAR/CSR in order to make them workable for complex substances too and is interested in understanding the approach metals are following, before the finalisation of a format. In this framework, ECHA asked to have a meeting to discuss formatting issues that the taskforce is working on to upgrade UVCB intermediate dossiers. The meeting will take place on 3 June: we will explain how UVCB pilot cases were developed to overcome formatting issues and limitations and provide industry with suggestions on how to improve the tools. Another meeting was agreed to explain and discuss UVCB classification aspects but was cancelled. We are in contact with ECHA to fix another date to discuss both UVCB classification and UVCB assessment, after the summer break, preferably early September. In the meantime, background documents and pilot cases will attain their final stage (more information: Federica Iaccino).

OTHERS

C&L Inventory

Eurometaux and Cefic submitted a preliminary proposal to ECHA to publish an extra field in the C&L Inventory from the IUCLID registration dossier that could explain that different hazard profiles are linked to the presence of impurities. Eurometaux will continue to work on the proposal and discuss possibilities with ECHA and other industry sectors.

At the end of June 2013, ECHA will update the C&L Inventory with the harmonised classification and labelling, according to the Dangerous Substance Directive (DSD) because the CLP/GHS section on the ESIS website, hosted by the Joint Research Centre, will be put out of use later this year. The old DSD classification should still be mentioned in the SDS for substances in a mixture until 1 June 2015 (more information: Inneke Claes).

REACH Communicators' network: Eurometaux' participation

Eurometaux now participates as well in the REACH Communicators' network established for ECHA and the Accredited Stakeholder Organisations. The aim of the network is to share information and work together in communication projects of mutual interest. Guy Thiran participated in the first call where topics like the objectives of the network, the sharing of information on ECHA communications activities (including the development of web pages for the general public), the promotion of upcoming events and exhibitions on the benefits of REACH were discussed. On the latter, Eurometaux submitted a short case study on "REACH stimulates the metals sector preparing for a broad international implementation of Chemicals management objectives" that may be considered for inclusion in the ECHA REACH Newsletter in autumn (more information: Guy Thiran).

EUROMETAUX Outreach

OECD evaluates a proposal to complement CoCAM guidance with metals environmental assessment specificities

Eurometaux and ICMC submitted a proposal to the OECD Hazard Assessment Task Force to consider complementing existing CoCAM guidance with metals-specific effects assessment aspects. OECD will discuss this proposal at its hazard assessment taskforce meeting end of June and hopefully agree to move forward, resulting in an update of the guidance for 2014. This initiative builds further on both the OECD 'metals' workshop held in September 2011, which identified several areas where metals environmental assessment required specific recognition, and on the invitation of CoCAM to the metal sector to submit REACH effects assessments to its review process. Such an OECD guidance update is welcomed by the metals and mining sector since allowing for leveraging European concept/method development at an international level and limiting the need to renegotiate metals assessment techniques and datasets at a regular basis in other OECD countries (more information: Hugo Waeterschoot and Violaine Verougstraete).

OECD updates its guidance on grouping and read-across and ...

the metals sector managed to prepare an update of the chapter dealing with grouping of metals and metal compounds. This updated chapter now includes the experience acquired by the metals consortia under REACH and builds further on the metals read-across workshop held in Helsinki in October. The proposed weight of evidence approach and concepts are illustrated with some examples. The proposed text will be discussed by the OECD hazard assessment taskforce meeting end of June and

will hopefully be included in the revised OECD guidance to be published by end of 2013 (more information: Violaine Verougstraete and Hugo Waeterschoot).

Calendar

- 3 June 2013: ECHA Press Conference – Helsinki (ECHA) (31st May 2013 registration deadline)
- 5-8 June 2013: RAC 25 – Helsinki (ECHA)
- 5-7 June 2013: SEAC 19- Helsinki (ECHA)
- 11-13 June: OECD Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology - Paris (OECD) and BIAC meeting
- 17 June 2013: 4th Authorisation Applications Training Workshop for potential applicants (with Eurometaux support) Inscription via ECHA website – Helsinki (ECHA)
- 20 June 2013: REACH Forum-MCC (EM)
- 21 June 2013: Reach Authorisation / Restriction Platform meeting-MCC (EM)
- 25 June 2013: The Biocides Stakeholders' day – Helsinki (ECHA)
- 25-26 June 2013 : OECD hazard Assessment Taskforce meeting- Paris (OECD)
- 27 June: IBC Informa Conference REACH: Legal Implications and Supply Chain Strategies 2013 –Brussels (IBC Informa)
- 27 June 2013: [European Commission Technical workshop on the Review of REACH](#). Eurometaux will give a presentation – Brussels (EC)
- June 2013 (no date): launch of public consultation on nanomaterials by Commission:
- 1-3 July 2013: Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals meeting – Geneva (UN)

Webinars <http://echa.europa.eu/support/training-material/webinars>

- 14 June 2013: [ECHA Webinar "IUCLID 5.5 basics"](#)
- 11 September 2013: : [ECHA webinar "How to bring your registration dossier in compliance with REACH - Tips and hints, part 4"](#)

REACH-IT closed for maintenance on 10 June

ECHA will carry out IT maintenance on Monday 10 June resulting in REACH-IT being unavailable during the entire day. Service will be restored Tuesday morning (more information: Inneke Claes).

Acronyms

CARACAL: Competent Authorities on REACH and the CLP Regulations	MSC: Member States Committee
CoCAM: Cooperative chemicals assessment meeting	MEP: Member European Parliament
CoRAP: Community Rolling Action Plan	NGO: Non-Governmental Organisation
DCG: Directors' Contact Group on REACH.	PBT: Persistent, Bio-accumulative and Toxic Chemicals
DE: Dossier Evaluation	PC: Public Consultation
DSD: Dangerous Substance Directive	PEG: Partner Expert Group
DU: Downstream User	RAAF: Read-across Assessment Framework
ENVI: Environment Committee	RCF: Refractory Ceramic Fibers
ES: Exposure Scenarios	SCED: Specific Consumer Exposure Determinants
eSDS: extended Safety Data Sheet	SE: Substance Evaluation
ESIS: European chemical Substances Information System	SME: Small and Medium-Sized Enterprise (under the REACH def.)
GaAs: Gallium Arsenide	SVHC: Substance of Very High Concern
GHS: Global Harmonised System	UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials
IUCLID: International Uniform Chemicals Information Database	vPvB: Very Persistent, very Bio-accumulative chemicals