



EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

"The two words **information** and **communication** are often used interchangeably, but they signify quite different things. Information is giving out; communication is getting through." (Sydney Harris).

Communication definitely makes the buzz in our information -overloaded societies. If we were to chat together on 'communication' at the Jardin de Nicolas, we would most probably realise that all of us have (different) expectations and beliefs on what allows you to 'get through' in terms of communication content, modalities and design. Actually, even the purpose of communication –more or less visible and conscious- will influence its effectiveness and its impact: one may have the ambition to increase the knowledge level of the audience, the other may want to explain and/ or justify on-going activities, the latter simply share the burden ☺.

Communication is a key pillar in REACH and we are making extensive use of 'communication and information tools': e.g. REACH news, highlights, reports, debrief webinars, REACH Forum slides, etc. Undoubtedly, you will find some of these tools more efficient than others in passing a message or simply more 'eye-catching'. Some may be too long or too late, or not meet the appropriate level of detail. One's threshold and optimal communication design are variable. As REACH team, we should however strive for a good, group- effective compromise...Rather than leaving John and me to endlessly discuss this "compromise" at the Jardin, we thought it would be a good opportunity to ask you to provide some quick feedback on the different communication tools. The accompanying email includes a 'takes you 2-minutes' survey and we would really appreciate if you could complete it and send it back to Ailsa (an alternative to the usual mignonettes will be served to those who have done so by the next Forum meeting). This will allow us to further improve the communication tools.

Although in the end... one will realise that whilst being important 'good communication' is not the panacea and will never substitute the efforts that are required from all, at both ends of the line of communication: the willingness to share, the willingness to listen

Violaine Verougstraete, EHS director Eurometaux



ECHA REACH activities: hot topics

ECHA COMMITTEES

MSC

MSC-32 a challenge for the metals sector: preparatory activity

The packed agenda for MSC-32 (4-8 November) includes crucial agenda items including among others, the next CoRAP update proposal, the first MSC debate on the outcomes of the Public Consultation on the 5th Priority list and the new prioritisation criteria for the identification of new Annex XIV candidates. A conference call with the consortia was organised on 29 October to review and debate Eurometaux's view on the two latter issues. The review of the new priority criteria concluded with significant progress as it now puts more weight on the PBT status and less on volume and wide dispersive use (WDU). However the proposal remains unsatisfactory with regard to the assessment and calculation of WDU: while it is

agreed that consumer and professional use would be of a higher concern than industrial use, it is suggested to lower the priority scoring for substances included in matrix-type materials, and thereby not available for exposure during manufacturing and use. Eurometaux was invited by the participating consortia to express these comments at the upcoming MSC meeting, in order to further improve the relevance of the priority setting for metals and inorganics (more information: Hugo Waeterschoot and France Capon).

RAC/SEAC

Pb metal CLH: submission of additional comments by industry and Eurometaux

As agreed with RAC during the September discussions on the Pb metal classification and its proposed Specific Concentration Limit (SCL), ILA/ILZRO submitted input based on pharmacokinetic models to further refine the calculation of the SCL. ILA/ILZRO proposed a different SCL for massive vs. powders based on a difference of bioavailability. Also as the link between the SCL, the physical form of the metal, the use of SCL for example in mixtures - like alloys- did not seem to be very clear to some RAC members, Eurometaux submitted a one-pager aiming at providing some background and clarifications. The one-pager also makes reference to what has been done in environmental classification for metals (more information: Craig Boreiko, Steve Binks, Hugo Waeterschoot and Violaine Verougstraete).

Restriction on Pb and its compounds: ILA/ILZRO submitted further comments and the Cu sector provided SEA evidence challenging the cost benefit of the Restriction

ILA/ILZRO also further submitted input on the SEAC opinion and more specifically on the monetised health benefit analysis for IQ loss; raising important aspects like the relevance e.g. of the population of children exposed, of using small fractions of individual IQ points in valuing Societal Costs; the derivation of daily intake factors, etc.

The copper sector further calculated that the proposed restriction on Pb and its compounds in articles intended for consumer use could have a very significant impact on the Cu brass sector, up to a value of 100 million a year. While the restriction focuses on applications of Pb and Pb compounds in articles that can be mouthed by children, it may mainly affect the brass recycling and manufacturing sector due to the presence of Pb impurities in the recycled copper streams. ECI calculated that the impact would be significant and presented a summary of this evidence to ECHA for review by SEAC. The sector also committed to prepare further detailed justification and a sensitivity analysis on how higher concentration limits based on bio-elution evidence could eventually define a more pragmatic solution without compromising children's safety. The case is of a precedent setting nature for the sector demonstrating that restrictions can affect different sectors than the ones focused on in the restriction and highlighted how bio-elution and SEA evidence can be used to define better cost-effective options (more information: Craig Boreiko, Steve Binks, Hugo Waeterschoot and Katrien Delbeke).

ECHA MEETINGS

ECHA Workshop on CSR/ES/RMMs: 22-23 October

At the demand of Member States, ECHA organised a workshop to make better use of the information embedded in the CSRs and Exposure Scenarios for Risk Management, building further on the CSR-ES Roadmap published in July. ECHA solicited support from Member States for further standardisation and additional IUCLID fields that would allow them to identify priority substances for Risk Management on an automated basis. Member States on the other hand requested a much broader focus. Industry was invited to present how they collected the information for Registrations and what challenges they encountered in keeping it updated. The workshop established and reviewed tables on relevant information for prioritisation to be included in the IUCLID 6.1 review. Different than for most organic chemicals, metal registrations include monitoring data sets including regional assessment. Any new data requirement -being it obligatory or voluntary- should allow for measured data overruling modelled assumptions to avoid metals being treated in a discriminatory way. It was further noted that materials flow analysis (like included in the ESR files) and diffuse sources analysis could help in defining or excluding inorganic substances candidates for further Risk Management (more information : Hugo Waeterschoot, see also summary report circulated on 25 October).

ECHA OTHERS

REACH Enforcement Forum open session

Once a year, the REACH Enforcement Forum opens one of its meetings to stakeholders with a one day session where the national enforcement authorities give an overview of the harmonised REACH and CLP enforcement projects carried out under the umbrella of the group and where the stakeholders are given the possibility to present issues of relevance to the Forum. Eurometaux presented the following two topics: Added value of creation by using REACH data and methodologies in

other EU or national policy fields and Views from the non-ferrous metals industry on recycled substances and Authorisation . Stakeholders were further invited to provide suggestions for future harmonised enforcement projects and to contribute to an on-going project to identify analytical methods to check compliance with existing restrictions in Annex XVII of REACH (more information: Inneke Claes).

A second NeRSAP meeting in the planning: Belgium will take the lead

The success of the first Network meeting of SEA and AofA practitioners (April 2013) inspired ECHA, SEA experts and Eurometaux/Cefic to organize a second session. Eurometaux organised and facilitated the recent preparatory discussions, which resulted in the recommendation to go for a limited number of more in-depth reviews. Belgium volunteered to organize this second session of NeRSAP in February 2014 (date to be confirmed). A search for new SEA or AofA concepts will now start in order to raise “innovative cases” at the meeting. The metals and organic sectors are invited to give input and the metals consortia are herewith invited to explore best cases to present (more information: Hugo Waeterschoot).

The 5th ENES workshop will take place in Brussels on 21-22 November

About 120 representatives from Member State Competent Authorities, ECHA, industry parties and other stakeholders will be participating and exchange information on the CSR/ES roadmap, harmonising approaches for e.g. building short titles of ES, Specific Consumer Exposure Determinants (SCEDs), methodologies for mixtures ES and other related topics. This ENES workshop is funded by industry associations representing manufacturers, downstream users and end-users, including Eurometaux. Highlights will be circulated to the Exposure Scenarios Taskforce (more information: Violaine Verougstraete).

Nanomaterials

Many activities on nanomaterials took place over the last month. At the 3rd and last meeting of the “Group on assessing already registered nanomaterials” on 30 September, the debate focused on exposure scenarios and risk characterisation of three registered nanomaterials. The 2nd and 3rd October Setac conference “Fate and ecotoxicity of nanoparticles in the environment” included a presentation on “Experiences and challenges in risk assessment of metal nanoparticles” by ARCHE. The presentations are available from this web page

http://sesss07.setac.eu/programme/speaker_presentations/?contentid=718&pr_id=624&last=692

The ECHA Nanomaterials Working Group meeting on 1 and 2 October included topics such as characterisation/substance identity, read-across -with examples from silver, zinc oxide and calcium carbonate, coating and toxicokinetics- on the agenda. The European Commission and the Joint Research Center launched the idea of generic forms which could simplify substance identification (more information: Caroline Braibant, Christine Spirlet and Inneke Claes).

Commission REACH activities

Directors’ Contact Group

The Directors’ Contact Group was put in place to solve practical issues with REACH registrations which were identified ahead of the 2010 registration deadline. The group consists of representatives from ECHA, the European Commission and Industry. Eurometaux is represented by John Schonenberger from ECI. The group continued its activities for the 2013 registration deadline. As all parties involved found that the group provided a good platform to discuss practical issues, it was decided to continue its operation also for the 2018 registration deadline. The mandate of the group will be slightly modified with a stronger focus on SMEs and a possibility to cover issues arising with other duties under REACH and the CLP Regulation as classification and Authorisation (more information: Inneke Claes).

Nanomaterials

At the CARACAL Subgroup on nanomaterials meeting on 24 October, the European Commission could unfortunately not yet present a proposal for the revision of the Annexes of REACH to incorporate nanomaterials. The results from the public consultation of mid-September were presented as well as some elements of an impact analysis study. Based on the results of the public consultation, the European Commission presented a document with some initial ideas on the revision of the Annexes. A detailed German proposal for the revision of the Annexes was also discussed. The European Commission expects to have a proposal ready before the Summer of 2014 (more information: Caroline Braibant, Christine Spirlet and Inneke Claes).

EUROMETAUX REACH activities: hot topics/issues

INTERMEDIATES

REACH Intermediates Taskforce meeting outcomes

One of the main topics for discussion was the informal inquiry ECHA sent to Eurometaux on the timing of the Intermediates updates as they have not received any updated Article 10 dossiers up to now. Eurometaux provided a status report on the challenges and work dealt with since December 2012, including on communications with ECHA (meetings, inquiry note). A final meeting to discuss the overall CSA flow for inorganic UVCB assessment with ECHA is foreseen early 2014. After that, companies will have 3 months sharp to submit their updated registration dossiers. Also discussed were the outcomes of the meeting with ECHA on the MeClas tool and applied complex inorganics classification principles (3 October, Helsinki). The meeting was successful in terms of ECHA's acceptance of the tool and its scientific basis. Some actions were identified to further improve transparency of the tool, so that regulators would feel more comfortable in accepting its use and being able to check on possible misuses. The taskforce further discussed the preparation of pilot cases which highlighted some remaining issues that need to be aligned. A IUCLID template for metals and complex materials has been prepared in order to minimise efforts, and harmonise the way common metal information (i.e. metal waivers) are stored in IUCLID (more information: Federica Iaccino).

Multi-Metallic Database

Several discussions are on-going on "combined toxicity" in EU scientific committees, EU authorities and at OECD level. The current approaches are often based on knowledge on substances' modes of action. Currently, such knowledge represents a data gap in the metals sector, which will need to be faced. It is proposed –in a first step- to identify and list target organs for the different metals, in order to predict where combined toxicity could eventually be expected. The multi-metallic database contributors have been asked to further provide such information and the exercise is on-going. In the coming weeks, all updated information (currently listed in the human health sheet), will be summarised in a specific target organ column in the DNELs summary sheet (more information: Federica Iaccino).

AUTHORISATION

Strategic advice on the choice of Risk Management Option

One year after the withdrawal of the Cobalt compounds from the proposed 4th priority list for Annex XIV listing, ECHA presented the findings of its preliminary study on the relevance of an alternative Risk Management measure (i.e. Restriction) for these compounds. Eurometaux and CDI organized a strategic review session on consequences and best options of Authorisation vs. Restriction, and how to pursue the most relevant one. While it is not clear at this stage how the Commission wants to further progress, it is anticipated that its focus will be on the plating sector. If this should be the case, it would leverage the Risk Management measure to a horizontal issue relevant to several metals. This would require a multi-metallic debate, an action tabled for the Authorisation and Restriction platform scheduled for the 21st of November (more information: Hugo Waeterschoot, Violaine Verougstraete or Carol Pettit).

5th prioritisation list for Annex XIV listing: further debate on the RCF proposals

The RCF sector and Eurometaux met the Commission on the proposal to include Refractory Ceramic Fibres (RCFs) on the 5th prioritisation list. The sector confirmed that the continuous substitution pressure on RCFs has limited their use to the applications where the RCF fibers are absolutely needed and not replaceable. Both the sector and Eurometaux stressed that appropriate RMMs were already in place, rendering the listing on the authorisation list not effective and a burden to industry. The sector further announced that new scientific findings indicated that a classification as carcinogen category 1 would not be warranted, which stimulated Commission to encourage industry to prepare a declassification proposal together with a volunteering EU Member State. While the Commission has no influence –at this stage- on the debate in MSC, they clearly understood that a potential listing would not create the expected benefits for society (more information: Hugo Waeterschoot).

SUBSTANCE EVALUATION

Substance evaluation: how could industry interact with the substance evaluating country?

The first years' experience with the REACH Substance Evaluation program was assessed at an ECHA workshop before the summer. One of the main recommendations issued by the workshop participants was to develop a best practice guidance for

Member States and Industry on how to interact before and during the Substance Evaluation review as well as during the follow-up period. Eurometaux prepared some suggestions to encourage interactive and formal exchange with the evaluating country and submitted those to the Taskforce in charge to develop a proposal for Caracal. This Taskforce is headed by Ireland. Cefic proposed a charter between Industry and ECHA to promote best practice interaction, with the aim to ensure a constructive input and review of substance evaluations. At its first meeting of the Substance Evaluation platform (28 November) Eurometaux will further explore the charter as well as the learning lessons from the Substance Evaluation process (more information: Hugo Waeterschoot).

METAL-SPECIFIC REACH APPLICATION TOOLS AND CONCEPTS

Presentation of the MeClas tool to ECHA

On 3 October, an industry delegation went to ECHA to present the MeClas tool (www.meclas.eu) and the approaches used for classification of inorganic complex materials, including alloys and UVCBs. The meeting was well attended by ECHA experts from the Classification, the Evaluation and the SID Units. The most important outcome is that the tool, its calculations and assumptions are not questioned. We got a number of questions and recommendations on the inputs and outputs of the tool, mainly to increase its transparency and regulatory use, which were further discussed with the MeClas Steering team and the Intermediates Taskforce. This is an important step in terms of acceptance of the tool and concepts/database behind it and we would like to thank herewith all contributors (more information: Violaine Verougstraete).

Metals workshop on sediments environmental Risk Assessment

In follow-up of ECHA's first topical science workshop on the theme of sediments hazard assessment (May 2013), Eurometaux organized a debriefing & next steps session on sediments 'assessment for the REACH Consortia/EHS scientists. The session, held on 18 October, was chaired by Prof. Dr. Ronny Blust (UA-Universiteit Antwerpen) and attended by ECHA. ECHA explained the main findings of the May workshop and announced that they would launch a revision of the REACH environmental risk assessment guidance in 2014. Chris Schlekatek presented a best case assessment on sediments hazard and risk assessment. Marnix Vangheluwe had prepared a series of practical recommendations on what sections of the guidance would need an update and what main concerns should be covered. It was recommended to the Consortia to anticipate the sediments guidance update and to use the MERAG Fact Sheet update process for this purpose given the MERAG credibility and the scientific independence of this project (more information: Chris Schlekatek and Hugo Waeterschoot).

COMMUNICATION ACTIVITIES

REACH Intermediates- Presentation at the 7th Annual REACH and CLP implementation Marcus Evans Conference- Amsterdam

Federica Iaccino and Violaine Verougstraete gave a presentation on Intermediates and Information requirements: How to comply with data-sharing and new Approaches for Chemical Safety Assessment at the latest Marcus Evans Conference on REACH and CLP. This was the opportunity to summarise and present the Taskforce work done on Intermediates since 2010, starting from the decision trees and RiCOG issued after the publication of the updated ECHA guidance, up to the still on-going efforts on data-sharing and IUCLID templates. The presentation was well received and is available on request (more information: Federica Iaccino).

Presentation on Reach Forum activities 2013-2014, 2014-2016

An overview of the REACH Forum activities, on the information flow and work plan/challenges for the next years has been provided to the Copper Compounds General Assembly (2 October). The purpose was also to highlight the links and need for consistency and joint action on issues of relevance (e.g. CLH discussions for Cu, concept of degradability, impact of the Pb SCL) (more information: Violaine Verougstraete).

The Iron REACH General Assembly met on 30 October giving a status update on the different REACH aspects. Eurometaux provided a presentation on the REACH Forum activities, put in the context of long term objectives and core principles, and identifying areas of potential concern for the sector. Sandra Carey (IMO) followed up with an overview of EU and International programmes where REACH data can be used -or would be useful- as well as of the challenges of the internationalisation of chemicals management programmes at global level (more information: Hugo Waeterschoot and Sandra Carey).

Presentation at the Eurometaux General Assembly: substitution, a driver in Chemicals Management

A presentation highlighting the impacts of the REACH authorisation and restriction programmes on chemicals management drivers like market access, innovation vs. existing chemicals was provided to the Eurometaux General Assembly meeting on 30 October. Substitution of SVHC chemicals—and the parallel development of alternatives - will significantly impact and re-shuffle chemicals management in the coming years, and not only in the EU. In the EU, authorisation and substitution activities under REACH have been driven by the political spirit of a toxic free environment and the belief that substituting chemicals of concern will stimulate innovation, thereby giving Europe a competitive advantage in the longer run. The Commission/EU Member States have however started to recognize that an action carried out by the EU in isolation could hamper the EU industry. They have therefore started to actively promote and enhance international recognition of the substitution measures and progress made in Europe, inviting other jurisdictions to follow. Several jurisdictions have already expressed clear interest. For example, Asian countries are closely following up the REACH outcomes given they want to maintain market access to the EU, by far their largest market in the world for finished goods. They also want to develop timely alternatives if needed. The General Assembly agreed with the recommendation to further reflect strategically on how to better anticipate globalisation and trends in chemicals management, ensure fair treatment of metals and make best use of opportunities (more information: Hugo Waeterschoot, Guy Thiran and Violaine Verougstraete).

Further outreach of REACH

OECD

Mo in Washington: ring the bell!

IMOA successfully secured OECD Mutual Acceptance of Data (MAD) status for their effects dataset for a number of molybdenum compounds at the CoCAM meeting that took place mid-October in Washington. This very positive outcome was preceded by a significant effort of the IMOA team to draft the required documents and to respond to the comments raised by the OECD countries, but also greatly contributed to the credibility of the metals sector at OECD level. We hope IMOA will not take offence that we are 'recycling' the very nice picture they sent around to announce the results of the discussions but we would also like, as Eurometaux, to ring the bell for IMOA! (more information: Sandra Carey).



Future of CoCAM/CoCAP: a metals project

Eurometaux participated in the call of the Steering Group set up by OECD to discuss the future of the CoCAM programme (after April 2014), and supported the proposed objectives; i.e. develop and apply integrated approaches of testing and assessment, exchange experience among member countries in assessing chemicals, identify issues for collaborative work to avoid duplication of effort and develop guidance for assessing the hazards of chemicals. More specifically for metals, the current proposal from the OECD Secretariat includes a project on *methodology development related to the behaviour of metals/inorganics*. A better understanding of metal behaviour and developed metals approaches (on effects quality assessment, Biotic Ligand models, the soil aging models, the added risk approach, the Unit World Model...) will facilitate a better interpretation of toxicity data and the understanding of more complex dossiers of data rich metals and support regulatory bodies in their management decisions to manage these metals. OECD will revise their proposal based on the comments of the Steering Committee (which includes ECHA and main CoCAM players) and submit it for discussion at the OECD Joint Meeting in February (more information: Violaine Verougstraete).

Calendar

- 4-8 November: MSC-32: ECHA (Helsinki)
- 21 November: Authorisation & Platform Meeting – MCC (Brussels)
- 21-22 November: 5th meeting of ENES (Brussels)
- 28 November: Evaluation platform meeting – MCC (Brussels)
- 2-5 December: RAC-27 ECHA (Helsinki)
- 9-11 December: SEAC-21 ECHA (Helsinki)
- 9-13 December: MSC-33 ECHA (Helsinki)
- 17 December: REACH Forum – MCC (Brussels)

2014

- 1 April: REACH Forum – MCC (Brussels)
- 25 September: REACH Forum – MCC (Brussels)
- 17 December: REACH Forum – MCC (Brussels)

Acronyms

AofA: Assessment of Alternatives	MAD: Mutual Acceptance of Data
CARACAL: Competent Authorities on REACH and the CLP Regulations	MeCLAS: Metals Classification (Tool)
CLH: Harmonised Classification & Labelling process	MeRAG: Metals Environment Risk Assessment Guide
CLP: Classification Labelling & Packaging Regulation	MSC: Member States Committee
CoCAM: Cooperative chemicals assessment meeting	NeRSAP: Network of REACH Socio-Economic and Assessment of Alternative Practitioners
CoCAP: Cooperative Chemicals Assessment Programme	OECD: Organisation of Economic Cooperation and Development
CSA: Chemical Safety Assessment	PBT: Persistent Bio-accumulative Toxic Substances
CSR: Chemical Safety Report	RAC: ECHA Risk Assessment Committee
DNEL: Derived No Effect Level	RCF : Refractory Ceramic Fibres
ECI: European Copper Institute	RiCOG: Rigorous Containment Guide for Strictly Controlled Conditions
ENES: Exchange Network on Exposure Scenarios	RMM: Risk Management Measures
ES: Exposure Scenarios	SCED: Specific Consumer Exposure Determinants
ESR: Existing Substances Regulation	SCL: Specific Concentration Limit
ILA: International Lead Association	SID: Substance Identification
ILZRO: International Lead Zinc Research Organization	SEAC: ECHA Socio-Economic Committee
IMoA: International Molybdenum Association	SME: Small and Medium-Sized Enterprise
IQ: Intelligence Quotient	SVHC: Substance of Very High Concern
IUCLID: International Uniform Chemicals Information Database	UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials
	WDU: Wide Dispersive Use