



EUROMETAUX REACH PROGRAMME

Dear REACH Forum members,

The (very) small village of Swiss Normandy where I'm spending most of my holidays counts several workers of a company located nearby that produces 'fuel valves' in metal. These locals alternate their work shifts with activities they traditionally do in the village, like helping with the cattle, managing the woods and...contributing to the production of cider or calvados. All acquired competences are used, across ages and generations. 'Hanging in there' for a while, and provided your stomach can cope with their generosity and the alcohol, they will share with you their views on all topics you might be interested in. Suspecting my genuine interest in metals, one of them explained to me the process of arc welding whilst repairing a grating; another started to reflect on the interactions of the industry with India whilst supervising the football club's barbecue; and questions on substitution of 'materials' were served with coffee. The latter, in particular, drew my attention as the considerations they brought up also regularly pop up in our REACH debates. Substitution is presented more and more as the 'solution' to respect 'ecology' but the information that accompanies it is rather limited. My coffee-hosts immediately stated that they are not against changes or reflecting about adaptations in processes but they were wondering how much we know about the strengths and weaknesses of the proposed alternatives, in a global perspective? The replacement of the - at least one decade-old - fridge of the house immediately provided us with a 'case study': the seller kindly warned me that I should not count on a 10-year functioning as the substitution of the "Freon" by other 'heavier gases for ecological reasons'- causes more frequent failures as the motor is not totally adapted yet. He kindly deplored it but also announced me 'tout de go' that this is now the trend: marketing devices with shorter life spans, as people will prefer to replace rather than repair. While I was hoping mezzo voce that recycling would then be able to address the trend (with an 'acute thought' for our SCL debate), he added: 'Madame, be careful with the transport: these new fridges cannot be transported horizontally. They have to remain vertical...you know ...these new gases'...And there we go I thought, I have to substitute my car with a van to buy a new fridge. A coup of calva, santé!

Violaine Verougstraete, EHS director Eurometaux

ECHA REACH activities: hot topics

ECHA MEETINGS

CSR/ES roadmap: next ENES (Exchange Network on Exposure Scenarios) meeting will take place in Brussels on 18-19 November

The CSR/ES roadmap coordination group has held calls to start the organisation of ENES 7. Have already been identified as topics for the programme: ES for mixtures; extended use maps; ECom developments (including standard phrases); promotion of the structured ES Short Titles and the presentation of the interim results from the BAUA project that is trying to make the link between existing risk management advice and REACH exposure scenarios. Expected outcomes of the latter are the application of "control banding approach" to specification of risk management measures in the REACH CSA and the connection of established risk management for particular sectors, product/substance types to the registrant's exposure assessment under REACH. The links with the use descriptors and exposure tools make this project relevant to our sector as well. ECHA has also proposed to add a session on Guidance updates i.e. CSA-related Guidance affected, scope of changes and timeline(s) to gather input from stakeholders on the items that should be reviewed / added / made obsolete as a preparatory step in advance of the formal Guidance review and revision procedure with Partner Expert Groups (PEGs) etc. More information on ENES and the CSR/ES

roadmap can be found here: <http://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios> / <http://echa.europa.eu/csr-es-roadmap> (more information: Violaine Verougstraete).

Commission REACH activities: hot topics/issues

CARACAL

CARACAL-15: Substance Evaluation, REACH and recycling, cadmium in plastics and a bit of bioelution...

The 15th meeting of the Competent Authorities for REACH and CLP met on 8 and 9th of July in Brussels. The seat of the REACH Alliance was shared by IMA and Eurometaux. A preparatory industry meeting/call was organized to define the input for the session and the proposed interventions were pre-discussed with Cefic, checking if they could be supported in common. This preparatory approach was certainly most useful to increase the awareness and attention of CARACAL. Main issues of relevance to the REACH Forum included the possible extension of the CSA/CSR obligations to 1-10 tons CMRs (that may trigger changes in letters of access), the announcement of a workshop on SID in October and the revision of the TCC. Commission prepared a very short paper on the waste issue related to some of the End-Of-Life conditions exclusively focusing on the REACH objectives. Member States and Eurometaux/Cefic were all aligned in stating that *"a much more holistic view is required to provide support for both REACH and Resources Policy Objectives, thereby inviting Commission to organize a forum/workshop on how these two aims could be integrated to ensure that recycling would not be hampered by Authorisation. Commission promised to consider this for the end of the year. The second main issue for industry related to ECHA's report to CARACAL was on the outcome of the ECHA-MS-Management Board Substance Evaluation workshop. While MS and industry have noted a clear improvement since last year in the interaction between industry and the evaluating MSCA and are aligned on most of the recommendations to further improve the SE-programme, the discussion demonstrated a clear difference in opinion on making the Substance Evaluation Report (SER) available to industry. ECHA has also presented the outcome of the Cadmium restriction proposal in plastics that could not demonstrate any risk so far. Member States were divided on what further Risk Management would be relevant and legally possible. This case is very important for ECHA as well as for industry in order to check how REACH can or cannot proceed with a restriction case or any other Risk Management Measure, when a risk scenario is lacking. During the CLP session of CARACAL, Eurometaux made a plea to have a country agree to take the lead to bring the bioelution concept to the OECD. Although several country representatives acknowledged the importance of this test, no one volunteered to take the lead on this programme, leaving industry with the need to find a lead country outside the EU or to further convince the Commission/JRC to submit a proposal to OECD. The agenda item that concerned providing a short status of the 7th ATP was removed as the Commission services were still discussing some issues, including the Pb SCL case. At the time of CARACAL, the inter-service Commission consultation was not launched yet, but it was started a couple of days later (more information: see draft minutes circulated on 14 July, or Violaine Verougstraete and Hugo Waeterschoot).*

Discussion with DG ENT on the OSOR principle and the double registration case of ATO: a letter to the registrants and a case to make in November

On 4 July, Karine Van de Velde and Eurometaux met DG ENT to have their views and suggestions for possible solutions in the framework of enforcement. A presentation was prepared to give background information on the antimony consortium and its responsibilities, the existing assessment activities of ATO and the huge difficulties raised by the registration of ATO outside the Joint Submission by an Italian Trader who received a registration number despite the OSOR principle. The impacts of this case exceed ATO as it directly challenges the value of the REACH spirit and its legal principles and sets dangerous misleading precedents for future registrants. The existence of consultants offering 'cheap opt out dossiers' was also mentioned as threatening the overall quality of the submissions. DG ENT agreed that it is a clear case of no respect of the OSOR principle and there is indeed a need for concerted action involving the registrants' member states but stressed that such actions are difficult to set up. They recommended to try once more to find an agreement, make a deal with AMIK and proposed to send a letter recalling the basic REACH principles (OSOR/one JS) in a generic way to all ATO registrants. They also recommended that Eurometaux bring the issue (not only the ATO case but also others, in a generic way), to the open session of the REACH Enforcement Forum in November (more information: Karine Van de Velde, Violaine Verougstraete, Hugo Waeterschoot and Nadia Vinck).

EUROMETAUX REACH activities: hot topics/issues

AUTHORISATION

6th priority list Public Consultations (PCs): *Eurometaux organized awareness raising call*

Early July Eurometaux prepared a briefing package and organized a conference call to raise awareness for Consortia and companies on the importance of the upcoming Public Consultations regarding the draft 6th list. ECHA, MSC and COM propose to launch a parallel consultation (one classical ECHA PC on the prioritisation of the substances and a second - new - one for Commission on the potential socio-economic business impacts) which will last 3 months starting as of 1 September. The draft 6th list has the potential to seriously affect the metals sector given ECHA suggested to start listing all potential high ranking SVHC candidate listed substances (21 substances were selected and half of them affect the metals/inorganics sector directly (e.g. Borates, Hydrazine, Coal Tar Pitch, Pb compounds, ...). Following the comments submitted by the various stakeholders into the PC, MSC may reduce the 6th list proposal. This will result in the various substances competing for high quality input into the PCs. Therefore, raising awareness and clarifying objectives on how one can respond to the PC was the main aim of the conference call. Furthermore, Eurometaux requested that Consortia and companies carefully review whether the potentially listed substances (such as hydrazine and others) may be used as reagents or in process mixtures to avoid any collateral damage under the authorisation scheme. This initiative was complemented by a number of specific briefing sessions to prepare Consortia for the PC (more information: Hugo Waeterschoot, Aggie Kotze and France Capon).

Session to prepare the position of Risk Management Strategies: *undoubtedly a challenge*

Eurometaux invited individuals from the metals sector with experience in authorisation to help define a Eurometaux strategy. Besides the challenge on how we can develop a strategy for our Risk Management policy activities the expert consultation aimed at providing strategic input on how: 1) To build and ensure effective expertise on the issue at all relevant levels (industry, ECHA, Member States); 2) How and when to influence Risk Management Measures, in a proactive and efficient way to ensure Risk Management Measures (RMM) are and remain (cost)-effective; 3) Ensuring that all involved stakeholders are preparing and anticipating the RMM programmes in an effective way. A series of recommendations were developed during this brainstorming session which will be incorporated by Eurometaux into a draft strategic paper in August in preparation for the next Authorisation platform and subsequent REACH Forum meeting (more information: Aggie Kotze, Violaine Verougstraete and Hugo Waeterschoot).

Risk Management Option-template and reviews: *several consortia active in considering/preparing RMO assessments*

Several Consortia are engaged in industry RMO assessments for (potential) SVHC substances in order to use the opportunity provided in the Commission-ECHA SVHC roadmap to "*facilitate selecting the best Risk Management Option*", or for use under the 6th priority List Public Consultations. Most of them use the suggested RMO template that allows for a strategic reflection on how the best RMO can be determined. This RMO-format and strategic approach deliberately deviates from the one used by Member States because it promotes a broader and more strategic assessment. The format as well as indicative examples will be presented in a workshop with ECHA and Commission in the autumn as soon as enough representative material has been collected and the Eurometaux REACH Authorisation and Restriction platform has been able to draw the generic learning lessons from the exercise (more information: Michel Vander Straeten and Hugo Waeterschoot).

Interpretation of the Authorisation Guidance on Substances in Substances: *Eurometaux joined the Cefic position*

Cefic asked Eurometaux for its support on the draft opinion on how to handle "Annex XIV substances in substances" and its potential interpretation under the Authorisation scheme. Eurometaux could align with Cefic's draft position. This issue is comparable to that of impurities in recycled (non-waste) materials, meaning that the function of the "impurity/Annex XIV substance" in the use phase would determine its status under Authorisation. The use phase would be authorisable under REACH if the concerned impurity has a clear functional use in a concentration above the classification trigger and the use falls within the scope of the Authorisation scheme (more information: Hugo Waeterschoot).

Latest Application Date (LAD): *Eurometaux assessed experience calling for more recognition for the supply chain complexity.*

Eurometaux was challenged by ECHA on its comments on the prioritisation procedure for Annex XIV listing, "*to consider other factors than "ECHA workload considerations for setting the LAD"*". Aiming for an improvement of LAD

setting given large numbers of metals risk potential Authorisation threat, Eurometaux conducted a short review study on existing cases and experience. The review could identify that the number of steps in the supply chain, the number of uses to be covered and especially the way how and at what level the applications were prepared (in “a generic authorisation consortium”, or rather “use specific application consortia”) provided a much better way to define a LAD. Eurometaux concluded that - while more complex - recognition for these considerations would increase the relevance of the LAD setting for the metals/inorganic sector hence probably somewhat reducing its economic impact (more information: Hugo Waeterschoot).

EVALUATION

Testing proposals (TP) and Dossier Evaluations (DE): *interesting learnings from challenging cases*

Under its support programme, Eurometaux provided Consortia and member companies with technical advice and opinions based on cross-substance experience. Two interesting learning cases came out of this support programme: 1) Legal Entities receiving a final decision on a TP can decide to deviate from it by developing alternative information gathering or testing IF this results in better evidence to resolve the legal concern. However, the LR remains liable in such a case in the event that ECHA-MSD should afterwards disagree with the quality of the outcome, 2) reagents used in metals manufacturing steps that are not included in the final end product aimed for (e.g in a by-product stream) cannot be considered as an intermediate. The cases will be further elaborated in the Evaluation platform in autumn given their potential relevance for the inorganic sector (more information: Hugo Waeterschoot).

EXPOSURE SCENARIOS

Exposure Scenarios Taskforce meeting: *standard phrases, tools and testing of formats*

The taskforce met on 4 July to discuss a number of recent developments of the CSR/ES roadmap like the extended use maps, short titles for ES, standard phrases and information on tonnages/use and to agree on actions to carry out in the coming months. Also the recent developments at OECD level of the OHT (OECD harmonized template on uses and exposure information, see below) were evoked. A number of templates will be tested out by a subgroup of the taskforce early August. A first ‘catalogue’ of metal standard phrases -based on the original work of Umicore and completed by EBRC and ARCHE, will be circulated in August to the whole taskforce for comments and corrections so as to be able to increase in the medium term the consistency and harmonization between the metals ES. A template for a UVCB eSDS will also be developed soon. Finally, an update on the Chesar development plans, the validation of the MEASE tool by the ETEAM project and the work on the SPERCs was provided by EBRC and ARCHE (more information: draft minutes circulated on 14 July, Frank Van Assche and Violaine Verougstraete).

OTHERS

REACH Forum: *REACH structure for 2015: pools of experts to be constituted*

A note summarising the main outcomes of the webinar held with the consortia on 30 June to discuss the possible REACH Forum structure for 2015 as well as the comments received in follow-up was circulated on 18 July. All received comments confirmed the choice of option 1, *no increase in budget but with consortia contributing to expertise at multi-metallic level*. A ‘matrix of areas’ highlighting where expertise from consortia would be needed was circulated as well, asking consortia to volunteer before 15 August some resources in ‘pools’ (Advocacy, Evaluation, SEA, IT, REACH Seminar). The primary objective of the constituted pools will be to work for the community of the REACH Forum, in a multi-metallic way. Expected benefits are the diversification and increase of the available expertise (capacity building) of the sector, finding ways to address the possible weaknesses and some alleviation of the REACH team’s workload. An overview of all Eurometaux actions on REACH for 2014 has also been circulated, to identify possible redundancies or ‘non-priorities’ for the Forum. Finally the budget overview for the first part of 2014 as well as an overview of the status/issues of the different projects was included in the package, circulated on 18 July (more information: Violaine Verougstraete).

METAL-SPECIFIC REACH APPLICATION TOOLS AND CONCEPTS

Alloys fact sheets: *drafts to become available soon*

In 2008-2009, a project was started to draft a MERAG/HERAG alloys fact sheet, explaining how to address the specificities of alloys in risk assessment, classification and Exposure Scenarios under REACH. The drafts were brought

to a 2 days-science consolidation workshop in 2009 where a 'bioelution-based correction' on the alloy classification was presented to stakeholders (ECHA, Commission and industry) for the first time. At that stage, we realized that as long as the bioelution concept had not been further elaborated, we would not be able to finalize the human health classification chapter of the fact sheet. The Nickel Institute and Eurometaux decided to re-launch the work on the fact sheet a couple of months ago, now progress has been made on bioelution (roadmap, workshop). The scope of the fact sheet has been re-focused towards the need to meet the CLP/GHS deadlines for mixtures. The section on Exposure Scenarios for alloys will become a stand-alone document. Drafts are currently being checked by the original authors and will be circulated for comments shortly after the summer to allow organizing explanatory sessions and gathering experience in due time (more information: Adriana Oller and Violaine Verougstraete).

Further outreach of REACH

OECD

OECD Harmonised Template on Uses and Exposure information (OHT): *a high speed global project*

A 3rd draft of the OHT proposal, prepared by ECHA, was circulated on 11 July for comments and will be discussed by the OECD Exposure Assessment Taskforce in Tokyo on 4-5 September. As a brief reminder: the aim of the OHT is to facilitate more worldwide exchange of information on exposure through a common language and data structure applied by developers of data base systems. What is currently developed in the template will be the basis for IUCLID 6.1 used in REACH, explaining ECHA's very active role in this project. Further to comments submitted among others by Eurometaux, fields have now been included that allow to report measured data, data on bioavailability and on releases from articles. A number of aspects in this OHT template, related specifically to REACH (e.g. SCC...) and possible overlaps/duplications of work for the registrants are discussed in parallel with the EU Member States and industry. A meeting will take place in Eurometaux on 27 August to discuss the chemical entity concept, which is a new IUCLID functionality to improve the clustering/reporting of substance information within a substance data set for "complex assessment cases", i.e. when several sets of data, reflecting different properties may play a role for conducting the exposure and risk assessment of the registered substance under REACH. This concept, that should be seen as a kind of 'router' in the IUCLID may be helpful in complex IUCLIDs we have to complete like for our inorganic UVCBs (more information: Violaine Verougstraete).

OECD organometals testing strategy guidance: *Eurometaux and CDI teamed up in commenting*

Canada developed for the OECD a draft guidance on the testing strategy for organometals and organo metal salts. ECHA had already made reference for the need of such guidance in respect to inorganics to clarify when standard testing or non-standard alternative approaches should be recommended. The Cobalt Development Institute (CDI) and Eurometaux reviewed the draft guidance proposal and suggested significant areas of improvement in general recognizing the need to clearly distinguish between organo-metal salts that easily dissociate in water and others because of their completely different environment fate and toxicity. The recognition for the bioavailability of the dissociated metal component and the use of the TICKET-Unit World Model for the fate assessment of the metal component were also recommended to the OECD. The outcome of this review will be circulated to the Eurometaux GEHS group as well as to the Consortia (more information: Paul Marsh and Hugo Waeterschoot).

Calendar

- **27 August:** Chemical Entity Discussion – MCC (Brussels)
- **8-12 September:** RAC-30 (Helsinki)
- **15-19 September:** MSC-37 (Helsinki)
- **24 September:** Authorisation & Restriction Platform – MCC (Brussels)
- **25 September:** REACH Forum – MCC (Brussels)
- **1 October:** Director's Contact Group (Brussels)
- **2-3 October:** RAAF (Read-Across Assessment Framework)- ECHA (Helsinki)
- **6-7 October:** SID workshop-ECHA (Helsinki)
- **21-22 October :** REACH Seminar (Brussels)
- **27-31 October:** MSC-38 (Helsinki)
- **24-28 November:** RAC-31 (Helsinki)
- **1-5 December:** RAC-32 (Helsinki)
- **8-12 December:** MSC-39 (Helsinki)
- **16 December:** Authorisation & Restriction Platform – MCC (Brussels)
- **17 December:** REACH Forum – MCC (Brussels)

Acronyms

ATO: Antimony Tin Oxide	MS: Member State
CARACAL: Competent Authorities for REACH & CLP	MSC: Member States Committee
CLP: Classification, Labelling & Packaging Regulation	MSCA: Member State Competent Authority
CMR: Substances classified as Carcinogens, Mutagens or toxic to Reproduction	OECD: Organisation of Economic Cooperation and Development
CSA: Chemical Safety Assessment	OHT : OECD Harmonised Template
CSR: Chemical Safety Report	OSOR: One Substance, One Registration
DE: Dossier Evaluation	PEG: Partner Expert Group
ECHA : European Chemicals Agency	PC: Public Consultation
ENES:Exchange Network on Exposure Scenarios	RAC: ECHA Risk Assessment Committee
ES: Exposure Scenarios	RMM: Risk Management Measures
eSDS: extended Safety Data Sheet	SCL: Specific Concentration Limit
ETEAM: Evaluation of Tier 1 Exposure Assessment Models	SE: Substance Evaluation
GHS: Global Harmonised System / Standard	SEA: Socio-economic Analysis
HERAG: Health Risk Assessment Guidance for metals	SER: Substance Evaluation Report
IUCLID: International Uniform Chemicals Information Database	SID: Substance Identity
JRC: Joint Research Centre	SPERC: Specific Environmental Release Category
LAD: Latest Application Date	SVHC: Substances of Very High Concern
LR: Lead Registrant	TCC: Technical Completeness Check
MEASE: Occupational Exposure Assessment Tool for REACH	TP: Testing Proposals
MERAG : Metals Environmental Risk Assessment Guide	UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials

And...REACH on the BEACH



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