



EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

She started shouting over the phone...My first reaction was one of a child: I sank onto my chair, pushed it backwards to increase the distance between myself and the phone, looked at the floor and felt my stomach turn upside down. A second later, I summoned myself: "Sit up straight! This call is bringing together adults invited to exchange scientific thoughts. There is no reason to be impressed, you did not do anything wrong".

The yelling continued, evoking principles, values, and threats. All adults were crushed in a deep silence.

I felt anger taking it over. The aggressive tone was indicating so much distrust and suspicion, but also a lack of listening, that it was difficult not to feel offended or perhaps even guilty for something we did badly or did not do. However I had to find a way back to "calm waters", my (industry) position in this call did not allow me to let my feelings take over. I started to depict in my mind the office the lady was probably sitting in, sketching the colours of the walls; guessing the number of square meters she had to stretch her legs, the number of cups of cold coffee standing on the desk. I stood up, hopped on one foot to the window to look out at the Brussels sky. The temptation to stop the shouting by hanging up the phone was still overwhelming, this was not working out. I then imagined the lady waking up too early, choosing her clothes and shoes, preparing her breakfast (cereal probably), wondered whether she took plain or skimmed milk. But I realized quickly that my unconscious self was actively pouring pepper on her cereal, so I left it there. Though I did wonder if the "inertia" that seemed to have hit the other participants on the call could also be linked to the fact that I was not the only creating recipes for spicy breakfasts.

For how long was she going to keep on ranting?

I realised that by wandering around, my mind was able to work again, I had left the panic mode, and was searching actively for some of the reasons explaining the dynamics of what was happening: statements rather than exchanges, beliefs instead of science, and defensive attitudes. "Reading between the lines and analysing drivers" is something you (should) learn in this regulatory world, but maintaining some empathy for the unsaid in the middle of a conflict can be as painful as a dancer being 'en pointe'. In particular, because after empathy, some ways forward need to be found to address these drivers.

Question is then how do you alleviate mistrust except by commitment, lack of understanding other than by capacity-building, lack of willingness other than by power games, individual concerns except by cooperation? And this before the meeting is over. Sure that the response to the question is case-by-case, bringing in ad hoc creativity, and that answers will be tailored to the situation and the topic. But a complexifying factor is (the lack of) time: patience is not anymore a virtue we can promote without consequences. We must fit into 'time slots' and 'momentums' because those openings may not come back. I was taught as a kid that 'he that can have patience can have what he will' (B. Franklin). But unfortunately I now seem to experience more of this one: "How can a society that exists on instant mashed potatoes, packaged cake mixes, frozen dinners, and instant cameras teach patience to its young?" (P. Sweeney). The time factor is affecting our dynamics, solutions and cooperative mood, for good or invalid reasons. In the end, there is no substitute for hard work, 23 or 24 hours a day. And there is no substitute for patience and acceptance.

Violaine Verougstraete, EHS director Eurometaux

Getting stressed-out



Before Work

After Work

ECHA REACH activities: hot topics

ECHA COMMITTEES

MSC-52: Dossier (DE) and Substance Evaluation (SE) list announcements

MSC-52 agreed and adopted the CoRAP 2017-2018 by consensus and announced that the CoRAP will be formally published on 21 March. To be aware of are the changes in timings for several Substance Evaluations, driven by ongoing Compliance Checks. The timing of the 3 Sb compounds was reconfirmed while TiO₂ was postponed to 2018. The latter raised some debates as now the CLH proposal will be run in advance of the SE, which could have helped clarify the carcinogenicity concern. The delay on the SE for TiO₂ is explained by the ongoing court case and the outstanding debate on Substance Identity. A surprise addition to CoRAP was potassium permanganate by France for urgent review in 2017 for suspected reproductive toxicity properties and high exposure. On DE, MSC members are involved in the annual screening exercise for the concerns identified by ACROSS. This year, the focus remains on the higher tier endpoints (Repeated dose, Reproductive Toxicity and long term environmental effects). The draft result of the screening was published as well as the list of substances for potential compliance check including tin metal as a candidate. ECHA invites the companies that are concerned to update the Registration dossier by the end of April. Previous experience indicated that the quality of the waivers or read-across justifications are usually the main focus of the review (more information: Hugo Waeterschoot).

MSC-52: a first glimpse of the 8th priority list for Authorisation and the new LAD setting method

ECHA presented a first proposal for a draft 8th priority list for Authorisation at the MSC-52 meeting. Despite some metal compounds scoring high, they were not selected because ECHA suggested to limit the list –this time– to only 7 substances. This is aimed to encourage Commission to pick up some of the previous prioritised substances for Annex XIV listing (from the 4th, 5th and 6th lists). Other substances of high priority like lead compounds were probably not selected given their main use in PVC stabilisers is phasing out, based on industry's voluntary commitment, complemented by an upcoming Restriction on their use in articles. Finally, two highly scored substances were not selected presumably because of their announced reclassification (from 1B to 2). Both “non-selections” could set quite some precedents if adopted. NGOs complained on the low number of selected substances, insisting that the list be increased with all substances scoring “high”, which could bring many more metals into the picture (Pb compounds and Cd and CdO). MSC will debate the selected suggestion by ECHA at MSC-53, which is scheduled for mid-April. Contrary to previous years, the Public Consultation on the 8th proposed list will run earlier and already be launched in March. For the first time ECHA applied the new Latest Application Date method when proposing LADs for the 7 suggested substances for the 8th list. This approach, which considers the complexity of the development of AfAs for industry (including the complexity of the supply chain, the number of expected applications and uses) has been requested by Eurometaux for a long time (more information: Hugo Waeterschoot).

MSC-52: recognition of Eurometaux's concerns for more transparency on written procedure conclusions on DEs and SEs

The outcome of the annual MSC performance review was presented to MSC. The appreciation for MSC activities remains high and its efficient organisation and management of dossiers were praised. A major comment brought up by Eurometaux addressed the decreased transparency that is due to the increased use of written procedures (preventing discussions in MSC) on Testing Proposals, Dossier and Substance evaluations. This comment was acknowledged: the chair agreed to provide a debrief on such cases for the Regular Stakeholder Observers, at each MSC meeting, to help them define the horizontal learning lessons. The non-transparent and confusing conclusion setting and voting on the 7th priority list, raised by Eurometaux on the Pb compounds, was also formally recognised and ECHA will check how this can be prevented for the 8th list (more information: Hugo Waeterschoot).

AUTHORISATION

AfA training for potential future applicants on 18-19 April: a combined effort from ECHA, Eurometaux and Cefic

ECHA, Eurometaux and Cefic organise every 2 years a training session for future Authorisation Applicants. This year's session is scheduled for 18 and 19 April in Helsinki. As these trainings intentionally focus on practical experience, it will start with a presentation and explanation of the recently published “ECHA Practical Guide on how to apply for Authorisation” (https://echa.europa.eu/documents/10162/13637/apply_for_authorisation_en.pdf/bd1c2842-4c90-7a1a-3e48-f5eaf3954676) complemented by case studies presented by consultants on different aspects like organisation, SEA and AOA development, etc. The second day will focus on the questions raised by participants whilst completing their registration as well as providing discussions in “café style” on specific themes like the upcoming CTP-HT AfA challenge. The interactive nature of

the workshop will allow participants to discuss AfA aspects directly with ECHA staff including the chairs of the Committees that will review the Applications once they have been submitted (more information: Hugo Waeterschoot or Erwin Annys).

COMMISSION REACH activities: hot topics/issues

CARACAL

Next meeting scheduled for 22-23 March: a heavy agenda and a preparatory call for 16 March

The European Commission has circulated a draft agenda, which includes several relevant items. A preparatory call with the REACH Alliance is scheduled on 16 March. The first day will be devoted to REACH related issues, with for example the presentation of the results of the study on 1-10 tonnes registration, a discussion on skin sensitisers in the SVHC roadmap, an update on the status of CMR1a/1b restriction on textiles (fast-track procedure); discussions on the 7th EAP, on Circular Economy and in particular the Chemicals/Products/Waste Interface as well as REACH REFIT. Among the topics identified for Day 2, the sector should certainly screen and prepare potential comments on the following topics: Fitness check of chemicals legislation (excluding REACH), bioelution, selenium in massive form and bridging principles (more information: Lorenzo Zullo and Hugo Waeterschoot).

EUROMETAUX REACH activities: hot topics/issues

RESOURCE MAPPING TO RESPOND TO REACH / ECHA CHALLENGES

Post-2018 REACH activities brainstorming: very good suggestions on what to keep or improve

On the 23 February, consortia companies and the REACH team came together to discuss post 2018 needs and define collectively how to adjust the existing structures at consortia and Eurometaux level to ensure appropriate support on REACH and CLP, in a cost-effective way. The meeting started with the analysis of the responses to a SurveyMonkey questionnaire circulated before the meeting, showing for example significant expertise on Registration amongst the responders but less on Evaluation and Risk Management, which will be the main focus of the activities post 2018 at ECHA level. There is some understanding of the future but with uncertainty (e.g. on resources, expertise, responsibility, liability) that is increasing with time. The present participants asked to pay specific attention to 'structural and organisational aspects' (e.g. EHS vs. REACH aspects, commodities vs. consortia when designing 'adjusted REACH structures' and highlighted the importance to invest further in communication strategies on the post 2018 needs and resources required to maintain the quality of the REACH activities. Participants were then asked to identify one element to keep, one to improve after 2018, at Eurometaux and consortia level. Based on their input, a first sketch of a structure was elaborated. The discussions will be further reflected in a draft note that will be circulated to the Forum with a proposal of a structure, to be refined in an iterative way (more information: Guy Tiran, Hugo Waeterschoot and Violaine Verougstraete).

A&R platform reflected on how to best organize for successful Applications for Authorisation (AfAs)

More than 25 participants attended and participated actively in a brainstorming session to reflect on how the metal sector could best build its experience and organise itself to deal with future Authorisation Applications, for manufactured products or substances used in critical or potentially substitutable uses. This interactive session started with a review of the outcomes of a questionnaire completed beforehand by metal companies, consortia and Downstream Users, followed by the testimony of a manufacturer/user of Annex XIV substances (Umicore) and a Downstream User (SAFT), explaining how they see Authorisation and its challenges. The discussion confirmed the need for specific expertise in different domains (not necessarily readily available at the sector level) to ensure that the application is of high quality from the start. It highlighted also the importance of an excellent communication between downstream users and suppliers to ensure the efficiency of the process. The session recommended to reflect about the creation of "a pool of expertise" composed of consultants, companies, experts from Consortia, and Eurometaux that could be kept up to date with the metal specificities of AfA preparation, submission and review. Consortia, companies or downstream users that need to prepare for AfAs could then draw resources from this team to prepare AfAs in an efficient and high quality way. The conclusions of the session have been presented to the REACH Forum for approval, followed by a thought starter to be developed by Easter (more information: France Capon, Klaus Kamps and Hugo Waeterschoot).

REACH Review/REFIT: formulation of key messages

In follow-up to the response submitted to Commission's consultation end of January, Eurometaux's REACH Forum is now starting to extract and define the key industry messages that could be further used in the REFIT discussions with EU institutions, Member States and with other industry sectors to seek alignments and synergies. Those key messages will soon be posted on the Eurometaux policy website (<https://www.eurometaux.eu/eu-policy/environment-and-health/reach-review/>). Eurometaux will focus its communication on industry's continuous support to REACH and its "fully risk-controlled Europe" vision, the promotion of the quality of the REACH datasets and the need to use them including in the framework of other EU and non-EU legislative frameworks. The need to focus on what matters, taking into due consideration exposures and metal specificities, the promotion of an appropriate and formalised RMOA and use-specific authorisations are key elements we will further promote as well as the request to have an improved enforcement to assure a level-playing field between companies within and outside the EU (more information: Lorenzo Zullo, Hugo Waeterschoot and Violaine Verougstraete).

REACH/OSH discussions:

At the beginning on 2017, the European Commission (DG EMPL) launched a [communication on the modernisation of its OSH legislation and policy](#) ("Safer and Healthier Work for All"). With regards to the scientific basis of any occupational safety and health action, the communication mentions that the European commission will seek advice from the Scientific Committee on Occupational Exposure Limits (SCOEL) or from the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA). In February, CII outreach activities have 'targeted' authorities including the Greek Permanent Representation, the Polish Ministry of Economy and the Lithuanian MSCA. The CII also gave a presentation to BusinessEurope during which the Health and Safety Working Group showed support for the CII position regarding the need to set OELs in the framework providing the most specialised expertise (more information: Lorenzo Zullo).

METAL-SPECIFIC REACH APPLICATION TOOLS AND CONCEPTS

CSR/ES Roadmap: Eurometaux involved in cross-industry SPERCs activities

In 2017, Eurometaux took over the chairmanship of the cross-industry SPERCs Taskforce (Lorenzo Zullo and Frederik Verdonck). This taskforce was created several years ago to discuss common approaches and formats to develop SPERCs. The different sectors involved in the taskforce are currently focusing on reworking the SPERC factsheets into the new agreed format, preparing the related background documents and reducing the overlap between SPERCs across sectors. This activity is expected to be completed by April 2017. A dedicated workshop will be organised in Q3 2017. A review process (internal or external, to be defined) based on quality control criteria is expected to be discussed/established in 2018. The metal SPERCs is followed up by the Exposure Scenarios taskforce (more information: Frederik Verdonck and Lorenzo Zullo).

Bioelution Expert Group: *discussions questioning the toxicology of metals and communication on mixtures*

The 25 January face-to-face meeting of this group, which brings together Member States, Commission, ECHA and industry representatives, agreed to draft sections of texts on 3 areas of acceptance, i.e. the applicability of bioelution, the technical aspects of the bioelution assays and the use of bioelution in the regulatory context. The text contributions, which shall highlight where there is consensus and issues where there is no agreement, will be discussed at a next meeting in April and merged in a report to be provided to Commission in May. The drafting of these areas sections of text is quite difficult and intense, and not only due to the tight timelines. Some Member States are still in disagreement with Commission's legal analysis of CLP article 12(b) and are using this group to re-open the discussion on policy principles instead of debating science, others are questioning metal science up to the most basic assumptions (role of the metal ion) and the specificities of alloys. It is also obvious that some members of the group are convinced that industry would like to use the bioaccessible concentrations, instead of the default mixtures system, to avoid classification and escape its responsibility to provide information on its alloys to the supply chain. It is proposed to discuss the impacts/consequences of these discussions on 'communication', SDS and testing at the next Risk Assessment and Classification Taskforce meeting (4-5 April) because some 'commitment' may need to be taken (more information: Adriana Oller).

ETAP: project on extending the Transformation Dissolution protocol to cover for degradation assessment

A science exchange organised by Eurometaux at SETAC Basel in 2014 raised the idea to directly measure rapid degradation in an objective way by a modification of the Transformation Dissolution protocol. The proposed modifications included a degradation and a resuspension step to assess measuring rapid degradation for CLP/GHS classification purposes for metals/inorganics. The ETAP members, under the lead of Emily Garman (Nipera) took up this challenge and started a testing programme with CanMET (Natural resources Canada) aimed at defining how the existing OECD TDp protocol can be extended and how selected metals would behave. The first phase of the programme (defining testing conditions and compiling preliminary data for short-term removal tests) show promising results for the extended protocol. Conference calls with the

sponsors were organised in February to define the next steps, including extending the testing phase to cover the full 28 days, organising a session at the upcoming SETAC meeting in Brussels to present and discuss the outcome of the phase 1 science work, and launching a discussion with ECHA at a special seminar in the summer along the ETAP/ICMM-CMWG meetings (more information: Emily Garman and Hugo Waeterschoot).

Further outreach of REACH

OECD

OECD: building and exchanging experience and methods on SEA for chemicals management

Eurometaux participates in the OECD project aiming at building and exchanging experience on how countries use SEA technology for Chemicals Management decisions. ECHA is co-sponsor of this programme and has shared relevant Restrictions as example cases on how SEA could help in demonstrating or rejecting the proportionality of suggested restriction measures. The US and Canada also proposed examples including Co and Ni. A series of conference calls in February was set up to select the relevant examples to be used for OECD guidance development. Agreement was reached on the list of substances, which does not include Co and Ni, in line with Eurometaux and ECHA's comments. A comparative analysis of the cases and how SEA has influenced the decision-making will be presented and debated at an OECD workshop on 30/31 August in Ottawa, Canada (more information: Hugo Waeterschoot).

Working Party on Exposure Assessment: *Matrix ESD-SPERCs*

OECD circulated a document on "Matrix Project between Emission Scenario Documents (ESDs) and SPERCs" prepared under the supervision of the Working Party on Exposure Assessment (former Task Force on Exposure Assessment). This document will be published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology of the OECD. It is intended to provide insights on differences and similarities between the OECD ESDs and the EU SPERCs and ideas on whether/how the ESDs and the SPERCs could be used and improved. The cross-industry SPERCs Taskforce was given the possibility to comment on it. This was considered a unique possibility to widen the scope of SPERCs to an international perspective and to become the reference to be used in REACH-similar legislative frameworks outside the EU. A dedicated presentation on SPERCs at OECD level could also be envisaged, probably in 2018 when there will be more progress on quality criteria and on the review process (more information: Frederik Verdonck and Lorenzo Zullo).

Calendar

- **2 March:** REACH Forum – MCC (Brussels)
- **6-10 March:** RAC-40 + SEAC-34 – ECHA (Helsinki)
- **13-17 March:** RAC-40 + SEAC-34 – ECHA (Helsinki)
- **30-31 March:** ECHA Management Board – ECHA (Helsinki)
- **4-5 April:** ECHA Stakeholders' Day – ECHA (Helsinki)
- **4-5 April:** Risk Assessment and Classification Taskforce meeting – MCC (Brussels)
- **18-19 April:** Annual AfA training seminar for potential future applicants – ECHA (Helsinki)
- **24-28 April:** MSC-53 – ECHA (Helsinki)
- **15 May:** A&R Workshop with ECHA on Intermediates/articles – MCC (Brussels)
- **16 May:** Evaluation Platform meeting – MCC (Brussels)
- **17 May:** A&R Platform meeting – MCC (Brussels)
- **18 May:** NeRSAP – ECHA (Helsinki)
- **29 May – 2 June:** RAC-41 – ECHA (Helsinki)
- **5-9 June:** RAC-41 + SEAC-35 – ECHA (Helsinki)
- **12-16 June:** SEAC-35 + MSC-54 – ECHA (Helsinki)
- **20 June:** REACH Forum – MCC (Brussels)
- **20-21 June:** ECHA Management Board – ECHA (Helsinki)
- **30-31 August:** OECD Workshop (Ottawa)

- **4-8 September:** RAC-42 – ECHA (Helsinki)
- **11-15 September:** SEAC-36 + MSC-55 – ECHA (Helsinki)
- **18-22 September:** RAC-42 + SEAC-36 – ECHA (Helsinki)
- **26 September:** A&R Platform meeting – MCC (Brussels)
- **27 September:** REACH Forum – MCC (Brussels)
- **28-29 September:** ECHA Management Board – ECHA (Helsinki)
- **23-27 October:** MSC-56 – ECHA (Helsinki)
- **22 November:** Evaluation Platform meeting – MCC (Brussels)
- **23 November:** A&R Platform meeting
- **27 November – 1 December:** RAC-43 + SEAC-37 – ECHA (Helsinki)
- **4-8 December:** RAC-43 + SEAC-37 – ECHA (Helsinki)
- **11-15 December:** MSC-57 – ECHA (Helsinki)
- **14-15 December:** ECHA Management Board – ECHA (Helsinki)
- **20 December:** REACH Forum – MCC (Brussels)

NB: Please note that RAC/MS/SEAC dates are all tentative and can be subject to change

Acronyms

ACROSS: ECHA Integrated Substance Screening Tool	MvE: Man via the Environment
AfA: Application for Authorisation	NTE: Non Toxic Environment
CanMET: Natural Resources Canada	OECD: Organisation of Economic Cooperation and Development
CII: Cross Industry Initiative	OEL: Occupational Exposure Limit
CLH: Harmonised Classification and Labelling process	OSH: Occupational Safety Health
CLP: Classification, Labelling and Packaging Regulation	PNEC: Predicted No-Effect Concentration
CMR: Carcinogens, Mutagens or toxic to Reproduction	RAC: Risk Assessment Committee
CMWG: Chemicals Management Working Group	REFIT: Regulatory Fitness & Performance Programme (EU)
CoRAP: Community Action Rolling Plan	RMM: Risk Management Measures
CSR: Chemical Safety Report	RMOa: Risk Management Option analysis
CTP-HT: Coal Tar Pitch High Temperature	SAICM: Strategic Approach to International Chemicals Management
DE: Dossier Evaluation	SCL: Specific Concentration Limit
DU: Downstream User	SDS: Safety Data Sheet
EAP: Environmental Action Programme	SCOEL: Scientific Committee on Occupational Exposure Limits (EU)
EIF: Entry Into Force	SE: Substance Evaluation
ECVAM: European Centre for the Validation of Alternative Testing Methods	SEA: Socio-Economic Assessment/Analysis
ENES: Exchange Network on Exposure Scenarios	SEAC: Socio-Economic Analysis Committee (ECHA)
ES: Exposure Scenarios	SETAC: Society of Environmental Toxicology and Chemistry
ESD: Emission Scenario Documents	SID: Substance Identity
ETAP: Environmental Toxicology Advisory Panel	SIEF: Substance information exchange forums
GCL: Generic Concentration Limit	
GDP: Gross Domestic Product	SPERC: Specific Environmental Release Category
GHS: Globally Harmonized System	STO: Stakeholder Observer
LAD: Latest Application Date	SVHC: Substance of very High Concern
MEASE: Occupational Exposure Assessment Tool for REACH	TDp: Transformation Dissolution protocol
MERAG: Metals Environmental Risk Assessment Guide	TSCA: Toxic Substances Control Act (US)
MSC: Member States Committee (ECHA)	UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials