



EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

A couple of years ago, a French singer wrote a ballad about time and more precisely about the incredible present he got by snatching a piece of time's jacket: a special moment, an additional instant per day, one additional minute after midnight. 24:01:60 seconds to be used to break away, to gather moon dust under our soles, our hair mingling with the stars. A minute on stilts, a handful of seconds reclaimed from the sea, a moment to spend snuggled in one another's arms.

I could not prevent myself thinking about it whilst participating in a big countdown on 31 December, people around me with their eyes fixed on watches and cell phones, shouting as one 6, 5, 4, 3, 2, 1..to the 00:00 second, which in turn suddenly seemed to put time "on hold" as everyone was applauding the new year to come, kissing and hugging without paying attention to the clock anymore.

Isn't that what the New Year brings us? Additional time, full of possibilities? A fresh start, an extra chance to do everything we want to do, a supplementary white page to be covered with writing and colours, another board to fill with positive goals and reasonable resolutions? A moment to embrace, to be thankful that we are here, breathing, alive and still able to take stock of the previous years! A blessing and a wish...A re-fill of energy to travel further and better, to fight against the elements and the contrary winds?

I wish you all of this and much more for the year to come.

Enjoy the new ride, share your laughs, 2017 will be wonderful!



Violaïne Verougstraete, EHS director Eurometaux

ECHA REACH activities: hot topics

ECHA COMMITTEES

MSC-51: tense debate on Equivalent Concern

MSC reviewed the Annex XV proposals for identification as a SVHC for a series of substances. This is a process that is usually only of administrative nature. MSC requires a unanimous opinion to have substances listed directly on the Candidate List and in the absence of consensus, it is the Commission who decides. The listing of two organic substances generated important debates at MSC-51: the first relates to the respiratory sensitisation properties (TMA), the other to an endocrine disrupting concern (Ter-Buthylphenol). In both cases some MSC members did not agree on the "equivalent concern level" and challenged the submitters to demonstrate that the effects under normal handling and use would not be reversible or of a lower impact. As a result, MSC could not reach agreement. Both cases are most relevant for the metals sector too given the Commission will now have to clarify on how to interpret the "equivalent concern level" for those two endpoints (more information: Hugo Waeterschoot).

MSC-51: business as usual on CoRAP and priority setting

MSC started to review the justifications for the new entries on the CoRAP, checking particularly whether those are “risk-based”, as required by REACH. The updated CoRAP does not contain new metals, in addition to those already included in the previous version. MSC further discussed the proposed postponement of the SE review year for more than 50 entries (out of a total of 115). In general, these postponements are caused by ongoing compliance checks to verify the quality of the standard information endpoints not covered by the SE initial concerns, a procedure that was recently introduced. It is planned to reach agreement on the updated CoRAP in February (at MSC-52), with a publication expected for mid-March. The ECHA secretariat confirmed that the outcome of substance evaluations for the year 2015 will be communicated to the Registrants by the end of April 2017 under the form of a draft decision, for a 30-day consultation period.

MSC was also informed about the revised planning for the 8th priority list suggesting candidates for Annex XIV. The first draft should be delayed and only debated in April, with the Public Consultation expected to run over the summer. This would still allow MSC to reach an agreement in October, as in previous years. ECHA provided MSC members and STO with an updated priority scoring spreadsheet, informing them that the scoring table included all information available from the Registration dossiers until October 2016. They mentioned that they corrected it for information on the volume/use. ECHA will now prepare a draft priority list on this basis. Cd and CdO could potentially be prioritised depending on how many higher scored substances are set aside by ECHA due to ongoing alternative risk management processes (restrictions) (more information: Hugo Waeterschoot).

RAC-39B: glyphosate and vitamin D3 CLH proposals

The second week of RAC-39 focused on some interesting CLH discussions. RAC held a preparatory discussion on the CLH of glyphosate. Glyphosate is a well-known weed killer, which already has some harmonised classifications for eye damage and toxicity to aquatic life (*Aquatic Chronic 2*). Germany has proposed to add a classification for *STOT RE 2*. *This is also the opportunity to review the data on CMR endpoints*. The issue is that some other organisations such as IARC have recently classified the substance as probably being carcinogenic for humans (Group 2A) (limited evidence in humans; sufficient evidence in experimental animals). So as to provide RAC with a good overview on the different scientific views, ECHA invited six organisations to give presentations (BAuA as the Dossier Submitter, EFSA, IARC, the joint FAO/WHO meeting on pesticide residues (JMPR), industry’s glyphosate task force and a representative of civil society (Health And Environmental Alliance, HEAL). All of the presentations are now available on ECHA’s website <https://echa.europa.eu/-/the-committee-for-risk-assessment-starts-discussing-the-harmonised-classification-for-glyphosate>. The actual RAC discussions will start in March 2017. RAC’s final opinion can be expected during 2017. Vitamin D3 is currently being evaluated as new biocidal active substance under Directive 98/8/EC for use as rodenticide. The existing harmonised classification (Acute Tox. 3, Acute Tox. 2, STOT RE 1) was reviewed. Interesting aspects that were reviewed included mutagenicity (RAC concluded to no classification as the condition ‘other *in vivo* somatic cell genotoxicity tests which are supported by positive results from *in vitro* mutagenicity assays’ were not fulfilled with the weakly positive Comet assay alone) and reproductive toxicity (no classification was agreed on with an interesting intervention on the differences between species in the homeostasis of calcium, modifying thereby the sensitivity to vitamin D3) (more information: Violaine Verougstraete).

INTERMEDIATES AND STRICTLY CONTROLLED CONDITIONS

Intermediates: ECHA agrees with a follow-up on the “Intermediates programme”

The Intermediates programme of the Authorisation and Restriction platform aimed at clarifying -as extensively as possible- which uses of (potential) SVHC/Annex XIV substances could be considered as ‘intermediates’ uses or not. In 2016, the programme resulted in a “voluntary sectorial industry guidance” reviewed by ECHA, which reduced the uncertainty on what would achieve intermediate status or not, also increasing the consistency between users’ assessments. Eurometaux and ECHA debated the continuation of the programme for 2017, all parties being very favourable to it. The suggestion submitted for approval to ECHA’s management and the Eurometaux A&R includes two sub-projects: 1° the selection by ECHA of “best case examples” from the guidance notes provided in 2016, in close cooperation with the concerned sectors and 2° a new series of substance/sector cases to be developed and reviewed, extending the scope from intermediates to also address the articles boundaries’ issue. Consortia and user groups that are interested in participating in this follow-up programme are invited to express their interest in the coming weeks (more information: Hugo Waeterschoot and Violaine Verougstraete).

ECHA MEETINGS

ECHA Management Board: targets for 2018-2020 work plan defined

Mid-December, ECHA’s Management Board meeting held its last meeting of the year. The meeting focused primarily on strategic planning aspects. The adoption of the updated Programme document for 2017-2019 went smoothly.

The Management Board maintains a high pressure on ECHA and increased to 220 the number of Compliance Checks to be achieved per year (+ 25%). ECHA's 'Pilot project on collaborative approach to address groups of substances under evaluation', presented by Geert Dancet, ECHA's Executive Director was also debated. The Management Board expressed support for elements like the proposed collaboration between ECHA, industry, Member States to improve compliance and quality of existing registrations and addressing groups of substances. The implementation of the proposed Pilot Project will be further discussed by the MB Working Group on Planning and Reporting. The discussion on the 2018-2020 Programming document focused mainly on its agreement process, and referred to the need to consider the outcome of the Environmental Council meeting of 19 December. The Programming document 2018-2020 builds on 4 pillars (further data compliance, use by Authorities of REACH data, addressing scientific challenges and embracing current (REACH-CLP) and new legislative tasks). With regard to the new tasks, the document quotes the following points of interest: support to the European Poison centres, maintaining the EU nanomaterials observatory, developing the EU chemicals finder, extension of the ED assessments to Biocidal active ingredients and support of the Circular Economy package. The adoption of the final version of the documents should take place Q3 2017. Other aspects that were debated quite extensively were ECHA's proposal for an Integrated Regulatory approach that would include sectorial approaches (e.g. on metals) as well as the potential to consider some substances of lower priority. Some Member States and NGOs expressed concerns with regard to this last suggestion. Finally, the Board agreed to a timing for the development of a vision on "Chemicals Management by 2025", with a first concrete draft to be expected by the end of 2017. Eurometaux reviewed most materials, which were provided at very short notice, and provided comments to Cefic to allow them to also bring up the metal's sector views (more information: Violaine Verougstraete and Hugo Waeterschoot).

ECHA monthly call: free riding during updates and next Compliance Check campaign

ECHA's monthly call with industry took place on 16 December. These calls focusing on Registration-related aspects, are kindly set up by Cefic and allow to raise points of cross-industry interest requiring some (further) attention by ECHA. Of direct relevance to the Forum was the announcement that the next 'Compliance Check' soft letters campaign will take place end of January, with focus on "exposure". ECHA reported that there was a good response from industry on the two last campaigns and that they are considering re-organizing a webinar. Eurometaux raised the difficulty faced with updates, more specifically with 'free-riding of co-registrants' during significant updates of files triggered by e.g. testing or other regulatory requirements and necessitating important resources. There is no mechanism at this stage to 'ensure' that co-registrants continue to contribute their right share of the dossier updates. ECHA confirmed that they are willing to reflect on solutions. Eurometaux requested to have a meeting with ECHA's Head of the Computational unit and an ECHA lawyer, so as to launch a search for concrete ways out, based e.g. on a couple of practical cases (more information: Caroline Braibant, France Capon and Violaine Verougstraete).

OTHERS

ENV-RAAF: guidance works for metals but language and some concepts need recognition of metal specific properties and aspects

End of November ECHA released its draft Environmental Read-Across Assessment Framework (ENV-RAAF) for a quick check by stakeholders. Several metal consortia took up the challenge and compared the draft guidance with existing environmental effects data sets. Eurometaux collected the comments and suggestions, and based on these prepared some proposals for amending the guidance. The pilot and review exercise of the metals sector concluded that the ENV-RAAF approach can work for metals. However, the language and some concepts are still too much focused on the typical properties of organics and need either to be complemented by some text specific to metals (e.g. transformation) or by clearly indicating that metals are excluded from some of the concepts' scope (e.g. structural similarity). ECHA very much appreciated the input of the metal sector and organised at short notice a discussion in ECHA to review the metals' comments, so as to assess which ones they could address before the publication of the guidance in February (more information: Hugo Waeterschoot).

Experience with Authorisation Applications: a workshop with the Dutch metal sector confirming the relevance to reapply in order to reduce the economic impact

The Dutch metal, engineering and technology sector FME-Metaalunie and the Dutch surface treatment sector (ION) ordered a study to assess the economic consequences of the Authorisation of CrVI for the Dutch Economy. The research institute Panteia interviewed many sector representatives and users, concluding that the economic impact (mainly loss of turnover and job losses) would depend a lot on the granted Review Period (RP) that is obtained, from nearly 50 % reduction of the workforce for a short RP of 4 years to close to no impact for an RP of 12 years. The study explained that this effect was mainly due to the uncertainty a short RP puts on users and especially their customers thereby promoting sourcing the EEA abroad. Approximately 50 persons attended a workshop organised on 5 December to discuss these outcomes, and raised concerns that the short RP advised by ECHA (SEAC) for functional and decorative chrome plating could have a detrimental effect. They questioned if advocacy at Commission level would be a relevant avenue to explore in order to prolong the RP. While ECHA explained the AfA

assessment programme and the information used to define the RP and conditions, Eurometaux explained briefly the reasons behind the short RPs recommendations by SEAC and RAC for some applications on decorative plating: lacking quality and representativeness. Other downstream users' oriented applications that provided better and more evidence on exposure, uses, impact and potential alternatives, obtained longer RP recommendations. The following debate animated by FME concluded it being probably more relevant and efficient to prepare for reapplications at the downstream user (surface treatment) level than launching an extensive policy debate (more information: Robert van Beek: Robert.van.beek@fme.nl and Hugo Waeterschoot). <https://www.fme.nl/sites/default/files/documenten/Panteia%20Final%20Report%20Economic%20Impact%20%20Chrome%20VI.pdf>; <https://www.fme.nl/nl/nieuws/fme-metaalunie-en-ion-bespreken-chroom-vi-problematiek-echa>).

EUROMETAUX REACH activities: hot topics/issues

RESOURCE MAPPING TO RESPOND TO REACH / ECHA CHALLENGES

REACH Forum meeting on 21 December: *stimulating meeting before the Christmas bubbles*

The REACH Forum had an interesting agenda planned for its last meeting of the year, including a debate on the metal sectorial approach (status and next steps) and the Pilot Project focused on Evaluation as proposed by Geert Dancet. Whilst the sectorial approach focuses on risk management and on 'where to focus regulatory action?', the Pilot Project also presented by ECHA's Executive Director at Eurometaux on 15 December, primarily targets main shortcomings on key human health and environmental hazards in existing Registration Dossiers, in particular waivers and data - to see whether the registrants are ready to address these shortcomings proactively - before Compliance Checks are launched. The timings for both initiatives are different, as the sectorial approach mainly concerns the post 2018 registration period while the Pilot Project should run mainly in 2017. The sectorial approach targets the metal sectors as a whole, the Pilot Project will rely on the willingness of specific consortia to become a test case. The Forum debated the main challenges associated with such initiatives: need to have positive incentives to justify the input of additional resources, need to have fair rules of the game, need to be able to solve technical issues, consideration of exposure/uses as key elements and need to address difficulties with updates/maintenance, the outcome must be recorded officially to be used in the further regulatory process in and outside the EU. With regard to the latter, a first proposal of a "quality performance progress programme" that could be used as 'agreed outcome' was presented. These topics will be further debated at the next meeting. The REACH Forum also discussed briefly the evaluation of the different REACH Taskforces and Platforms' performances in 2015-2016 and objectives for 2017 and the possibility to organise a workshop in Q1 2017 to discuss the post 2018 activities. A status report was provided on the budget for the 2017 REACH activities and projects. Other updates related on how to handle upcoming requests for applications, the Article 58(2) issue, REACH and OSH, possible consequences of Brexit, the REACH/CLP REFIT. The meeting was concluded as usual by an information exchange between Consortia and the helpful conclusions of the Co-Chairs. A draft Executive Summary will be circulated soon (more information: Lorenzo Zullo, Hugo Waeterschoot and Violaine Verougstraete).

Bioelution *preparing the face-to-face meeting of 25 January*

Further discussions took place in December with ECHA and Commission to prepare the face-to-face meeting with the Bioelution Expert Group end of January. With the hope to facilitate the dynamics, Industry has proposed that ECHA send in advance of the meeting some tables highlighting the aspects for which a general agreement is anticipated based on the current knowledge/ experience, issues where agreement is possible but require further data/evidence (trying to specify further which kind of data may feed in the discussion), and issues for which consensus may be lacking for the moment, and definitely requiring a discussion on 25 January. On their side, Commission and ECHA also had a clarifying discussion in ECVAM on what is expected on the validation aspects on how to further facilitate those. The preparatory material for the meeting will be shared with Eurometaux's Bioelution Taskforce as soon as it becomes available (more information: Adriana Oller, Federica Iaccino and Violaine Verougstraete).

Data-sharing: *letter to Commission and meeting on 19 January*

The updated (version 3.0) Guidance on data-sharing has been published by ECHA, revising and developing further a number of key aspects brought in by the Implementing Regulation on joint submission of data and data-sharing. On 14 December, Cefic-Concawe and Eurometaux also sent a joint letter to DG ENV and DG GROW, expressing their concerns on two aspects that are insufficiently addressed by the updated Guidance and may cause major difficulties in future implementation: a) there is no definition of "potential registrants" able to challenge existing data-sharing agreements, entitling thereby anyone in the SIEF to submit a challenge, even if finally it does not register, b) there are no practical recommendations on how to achieve "unanimous consent" or "making every effort". This means that any "potential registrant" can challenge decisions, made by all other registrants, without having to provide any type of rational justification. This letter was an action point agreed by the Forum in September. In addition, the REACH Forum had agreed to organise a meeting of a "Data-Sharing Taskforce" to allow

an exchange of experiences, including on 'itemisation' of the costs. As several consortia have mentioned an issue with costs/data-sharing along updates, this item will be put on the agenda as well. The meeting will take place on 19 January at the MCC, from 10:30 onwards (more information: Caroline Braibant, France Capon and Violaine Verougstraete).

Inorganic UVCB work: *site visit by ECHA*

In addition to the ongoing discussions on the inorganic UVCB SID refinement and on the ad hoc SIP developed and submitted to ECHA in August, ECHA's SID Unit team shared some further questions on the specific Legal Entity variability and on how it fits within the defined generic SIPs. To better address these questions, it was proposed to have a meeting combined with a site visit. The aim would be to discuss the inorganic UVCB SID in practice, from an industrial site's perspective, describing the industrial processes related to a specific example, highlighting the variability of source materials in the broader context of 'market reality'. Additional information will be shared with the Intermediates Taskforce in January, once ECHA's intentions with regard to the site visit are clarified (more information: Federica Iaccino, Katrien Arijs and Frederik Verdonck).

METAL-SPECIFIC REACH APPLICATION TOOLS AND CONCEPTS

Industry-RMOa: *the metal industry presented its guidance to DG ENV/DG GROWTH*

Further to the discussion ECHA had with the metal sector on the 'RMOa tool & Guidance' on 29 August, ECHA proposed to RIME to have a workshop on how to further improve the quality and relevance of RMOas. The proposal was turned down at that time by some Member States and DG ENV, wondering whether more investment in RMOas would actually significantly improve risk management or rather further delay the RMM selection process. This triggered the metals sector to ask DG ENV for a possibility to present the Industry-RMOa tool, which principally aims at improving the quality of the process and the possible contributions to it. An extensive delegation of DG ENV and DG GROW representatives attended the presentation session on 20 December, chaired by Sylvain Bintein (DG ENV). Eurometaux presented the Industry RMOa guidance, emphasising its main aims: being a self-reflecting tool on "potential concerns" that would require risk management, with its scope having evolved over time from the SVHC Roadmap to the ACROSS system, encouraging consortia to assess what exposure sources of a metal element would matter from a risk management perspective and to plan for, collect and include risk management-relevant information in the Registration file. The 'allocation of exposure sources' linked to risk management highlighted the importance of materials flow and diffuse sources analyses. Three brief case studies illustrated the different steps and added value of the approach. At the end of the meeting, the Commission confirmed the relevance and importance of the Industry-RMOa initiative, understanding also that the primary intention is not to aim at interfering in the RIME discussion. Eurometaux once again raised the possibility to have an RMOa workshop organized at/around a RIME meeting. Commission confirmed they would attend such an event if it is organised (more information: France Capon, Hiram Moerman, Michel Vander Straeten, Lorenzo Zullo, Violaine Verougstraete and Hugo Waeterschoot).

IZA: *appreciated initiative to improve the ecological relevance of metals Risk Assessment (RA)*

On 1 December, IZA and ARCHE jointly organised a brainstorming session with a selection of invited academic experts on how to further integrate ecological aspects into environmental risk assessment of metals. Indeed, present RA-approaches are purely ecotoxicology-based, which may have consequences that do not seem logical, e.g. when more evidence on new species becomes available, PNEC values usually decrease, which contrasts with the broader evidence base. The reason for this observation is that ecological considerations are not or insufficiently integrated in the assessments. While ETAP scientists and scientists that worked on metals environmental risk assessments concluded that existing approaches could still be somewhat improved (e.g. probabilistic assessments), they confirmed that new avenues need exploration to create breakthroughs in the environmental and ecological relevance of hazard and risk assessments of metals. One such paradigm that needs change is the assumption that "all species occur in all ecoregions and under all chemical – physical conditions". This often leads to the tests made on organisms, outside of their ecological boundaries or habitats, resulting in sensitive but unrealistic results. The meeting formulated a number of approaches that may lead to better integration of ecological principles in RA. The issue will be further discussed with the Eurometaux RA working group in order to broaden support and explore ways to involve the Commission and ECHA in the debate (more information: Frank Van Assche, Patrick Van Sprang and Hugo Waeterschoot).

Calendar

- **10 January:** Exposure Scenario Task Force – MCC (Brussels)
- **19 January:** Data Sharing Task Force – MCC (Brussels)
- **26 January:** Man via the Environment/Scientific Seminar – MCC (Brussels)
- **21 February:** CSR/ES Roadmap Coordination Group – MCC (Brussels)

- **6-10 February:** MSC-52 – ECHA (Helsinki)
- **28 February:** 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)
- **24-28 April:** MSC-53 – 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)
- **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)
- **27 September:** REACH Forum – MCC (Brussels)
- **28-29 September:** ECHA Management Board – ECHA (Helsinki)
- **23-27 October:** MSC-56 – ECHA (Helsinki)
- **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	OSH: Occupational Safety Health
AfA: Application for Authorisation	PNEC: Predicted No-Effect Concentration
BAUA: Federal Institute for Occupational Safety and Health	RA: Risk Assessment
CC: Compliance Check	RAC: Risk Assessment Committee (ECHA)
CII: Cross Industry Initiative	RAAF: Read-Across Assessment Framework
CLH: Harmonised Classification and Labelling process	REFIT: Regulatory Fitness & Performance Programme (EU)
CLP: Classification, Labelling and Packaging Regulation	RMM: Risk Management Measures
CMR: Substances classified as Carcinogens, Mutagens or toxic to Reproduction	RMO: Risk Management Options
CoRAP: Community Action Rolling Plan	RMOa: Risk Management Option analysis
DU: Downstream User	RP: Review Period
EEA: European Economic Area	SE: Substance Evaluation
EFSA : European Food Safety Authority	SEAC: Socio-Economic Analysis Committee (ECHA)
ECVAM: European Centre for the Validation of Alternative Testing Methods	SID: Substance Identity
EFSA: European Food Safety Authority	SIEF: Substance information exchange forums
ENV RAAF: Environmental Read-Across Assessment Framework	SIP: Substance Identification Profile
ES: Exposure Scenarios	STO: Stakeholder Observer
FAO: Food and Agriculture Organization (UN)	STOT-RE: Specific Target Organ Toxicity (classification endpoint) - Repeated
FME: Dutch employers' organisation in the technology industry	SVHC: Substance of very High Concern
HEAL: Health & Environmental Alliance	TMA: Trimellitic anhydride
IARC: International Agency for Research on Cancer	(i)UVCB: (inorganic)Unknown or Variable Composition, Complex Reaction Products and Biological Materials
MB: Management Board (ECHA)	WHO: World Health Organization
MSC: Member States Committee (ECHA)	