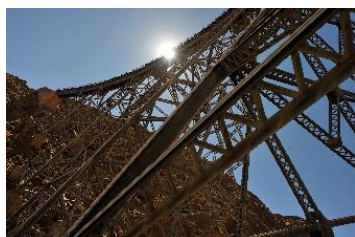


EUROMETAUX REACH PROGRAMME



More details: <https://brussels.setac.org>

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Dear REACH Forum member,

The French elections were -not unexpectedly- present in most conversations over the last weekend, prompting questions and statements issued in an increasingly overwrought atmosphere, ruining the efforts made to serve eye-catching meals or offer warm coffee. More than once it was uttered that, as the elector's freedom for the 'second tour' is now limited to choosing between pest and cholera, abstention is probably the way forward. My youngest one –formally not yet an adult- could not stop herself from reacting: 'Abstention? Not trying to block the Presidential road to Marine? How absurd is this?'

Her choice of the word 'absurd' made me think. Absurdism is one of those concepts I associate –since school- with Albert Camus and thus logically with France but I wondered how the term could relate to her perception of her political (adult) environment?

According to the sources I quickly consulted, "absurdity is born out of this confrontation between the human need and the unreasonable silence of the world" (Camus). Humans must live in a world that is -and will remain hostile or indifferent- towards them. In other words, the universe will never truly care for humanity the way we seem to want it to.

It is common -and reassuring- to assume that everything must have a purpose, a higher reason for existence. However, if one thing has a higher purpose, what is the reason for that purpose? Each new purpose must then be 'validated' by a higher one. Absurdism seems to consider that the efforts of humanity to find meaning or rational explanation in the universe ultimately fail because no such meaning exists, at least to human beings.

I remember my school teacher explaining that people create stories, or gods, transcending reality to fill this void and attempting to satisfy their need for a meaning. Could it be the same with political heroes or candidates for a Presidency?

It appears that some people who endorse abstention seem to expect that a high degree of abstention would give a signal that the population is lost in the void and that having France plunge in the abyss is unavoidable to regain some meaning, or a way towards it.

Critiques of absurdism have usually focused on the proposition that (life's) absence of meaning seems to remove any reason for living; replying that although the purpose may not be apparent, that does not confirm that it does not exist. But actually Camus had answered his proposition with methods of living with the absurd: through coping or through revolt, pointing out that this lack of purpose presents humankind with true freedom. And this is probably also the way here: the possibility of a high abstention is a signal to be coped with, to bring in some changes and meaning. But conditions and environment should provide the best ground to let them grow in true freedom, and that justifies to act rather than to abstain.

Violaine Verougstraete, EHS director Eurometaux

ECHA REACH Activities: hot topics

ECHA Committees

MSC-53: recognition for bioelution for grouping

MSC-53 considered the testing proposal on CoCl₂ as a representative for a group of Co-compounds. MSC agreed that the suggested grouping hypothesis based on bioelution evidence seems plausible and reached a unanimous decision on the testing proposal for a 2nd PNDT test. This recognition also received support from the EU animal welfare groups. This confirms the role and relevance of bioelution testing to define groups of substances for higher tier testing or waiving categories under REACH. The CoCl₂ case further confirmed the need to split substances with potential local effects in a different grouping from those with only systemic effects to prevent more sensitive local effects being chosen as the reference point for DNEL setting for all substances (more information: Ruth Danzeisen and Hugo Waeterschoot).

MSC-53: some new procedures put in place

MSC-53 adopted a new timing scheme for Dossier and Substance evaluation allowing more time for ECHA and Evaluating-MSs to review and respond to the comments of the Registrants on the PfoAs raised by MSCA's. Industry welcomed this given this period was so short that comments from IND didn't often receive the relevant recognition they needed. The new time schemes and integrated DE and SE procedure will soon be published on ECHA's website and be presented at the next meeting of the Eurometaux Evaluation platform in May. The ECHA secretariat provided a priority scoring to all SVHC substances included in the candidate list for the period mid 2016-2017, as a first step to start the prioritisation for the 9th list. Clear intermediate use volumes were not considered in the scoring and clarifications, when needed, were provided using the support of Art 36 letters. This latter procedure is new and industry is very much supported to comply with this request to ensure a proper scoring of the volume in scope of Authorisation (more information: Hugo Waeterschoot).

MSC: expert group on UVCB substances

In response to the lower compliance of UVCB substances with standard testing requirements, MSC created a subgroup on UVCB substances. This new expert group is headed by the MSC-member of the Netherlands and aims for streamlining and facilitating relevant testing strategies to comply with REACH standard data gaps in a strategic and most suitable way for these substances. The group consists at this stage of exclusively MSC members and met for the first time during MSC-53. They will present at the MSC-54 their objectives, priorities and a work plan. Eurometaux already referenced at MSC-52 the work the sector did and does on inorganic-UVCBs requesting to fully recognise this and questioned if they could be part of the expert group if inorganic UVCBs would be discussed (more information: Hugo Waeterschoot).

Authorisation

AfA Seminar, Helsinki 18-19 April: *broad participation from the metals sector*

ECHA, Eurometaux and Cefic coordinated for the 6th time an Authorisation Application briefing and training seminar, this time held in Helsinki on 18-19 April. The seminar which was widely attended by the metals sector due to upcoming applications for CTP and potential applicants for Pb-compounds, focussed on the new practical AfA guide ECHA prepared earlier this year together with Eurometaux and Cefic, using presentations by consultants on existing cases to demonstrate some critical aspects like what management model to choose. The second day focussed on a long series of questions received in advance from potential applicants attending the meeting and allowed for substance specific debates including on CTP and Pb-compounds. It was obvious that the CTP-HT application provides extra challenges given combining an HH endpoint with threshold while the ENV PBT endpoint lacks a threshold. During the workshop Commission reported slow progress with the Implementation Acts on low volumes and spare parts while announcing a revision of the fees for authorisation, which would be to increase the fee for different uses whilst eliminating it for joint applicants for the same use which would be more in line with ECHA's workload and promote more joint applications at DU level (more information: Hugo Waeterschoot).

ECHA meetings

Bioelution Expert Group, Helsinki 26-27 April: *second face-to-face meeting*

The experts from the Member States, Commission and ECHA came together to further discuss bioelution and its use in the context of Article 12(b) of the CLP. At the first face-to-face meeting, the scope of the discussions was narrowed to focus on alloys, systemic effects via the oral route. Even so this second meeting was also attended by the representatives of the plastics and organic sectors. The Expert Group is expected to deliver a background document to CARACAL in June, to support the legal application and guidance of CLP Article 12(b). Three draft papers had been prepared ahead of the meetings, discussing applicability of bioelution, technical aspects of bioelution assays and its use in a regulatory context. From these papers, ECHA had extracted 'issues for debate', instructing the meeting participants to express agreement/disagreement. However, although progress has been made on a number of issues, the aspects of how the Eurometaux bioaccessibility-based approach fits with the current text of Article 12(b), its conservatism and uncertainties, still remain to be addressed. Germany in particular expressed some concerns and indicated that they have an alternative proposal, which would be using a 'maximum amount of metals ions' that could be released for a specific metal and that would be defined when classifying the metal (with a possible safety factor if there are uncertainties). Germany has been asked to work out their proposal more in detail. A webinar will be set up second part of May to explain more in detail the proposed bioaccessibility-based classification schemes, so as to ensure their understanding but also highlight that the proposed industry approach uses the same classification reasoning as currently in CLP for mixtures, substituting the concentration by the bioaccessible concentration. It has also been proposed to discuss further the uncertainties on the assay (pH, loading, physical form to test) in the context of the validation of the protocol with ECVAM. A document integrating the inputs from the three areas and the April discussions will be circulated to the Eurometaux Bioelution Taskforce for comments after 15 May (more information: Adriana Oller and Violaine Verougstraete).

Data-sharing

ECHA Survey on updates: *need to raise awareness that there are challenges*

REACH requires registrants to ensure the maintenance of their REACH dossiers and their update with any relevant new information, without undue delay. ECHA observed that while many registrants pro-actively manage their dossiers to ensure that they are up to date and as accurate and complete as possible, this is not always the case. ECHA would like to better understand the main obstacles and drivers for registrants in providing updates to their REACH registrations dossiers. This should enable ECHA to help support registrants in this process and ensure that the quality of dossiers submitted is of a good

standard. Amec Foster Wheeler and Peter Fisk Associates have been contracted by ECHA to further explore this topic. A survey has been launched and can be found here: <https://www.surveymonkey.co.uk/r/ECHASTudy>. This survey is the opportunity for the sector to raise issues we are already encountering with increasing demotivation and free-riding as well with data-sharing issues. The Eurometaux Data-Sharing Taskforce has prepared a briefing note that outlines the main issues we are facing and that can be used as a starting point. Please do not hesitate to contact the secretariat if you would like to have more information. It is essential that we highlight, through this survey, that thought-through mechanisms and solutions are essential to continue to fulfil REACH's objectives whilst keeping the burden bearable (more information: Caroline Braibant, France Capon and Violaine Verougstraete).

Others

PACT list: *updated with mixtures and update announced for Co-salts*

The PACT list was recently updated with 2 "substances" that are mixtures in industry's view, namely an indium-tin mixture (ITO) and a "hard metal alloy". Both were listed by The Netherlands aiming at performing a RMOa based on CMR concerns. While industry does not contest the potential hazard properties, Eurometaux would like to challenge the extension of the PACT list -including all its potential consequences- to mixtures and will formally contact ECHA in this respect. In addition, the metals sector was informed that the PACT will be updated very soon to announce the initiative for the development of a Restriction on the 5 Co salts. Those salts have been previously prioritised by ECHA for authorisation, confirming thereby the final conclusion of the Commission on the required Risk Management Measures for these salts (more information: Hugo Waeterschoot).

COMMISSION REACH Activities: hot topics/issues

Commission consultation on interface Waste/Chemicals/Products: *comments and cases before 7 July*

The European Commission is running a stakeholder consultation regarding the interface between chemicals, products and waste legislation, in support of its commitment under the Circular Economy Action Plan to analyse this interface and deliver a recommendation on policy options by the end of 2017. The proposed options shall aim at helping to overcome unnecessary barriers hindering the transition of recycled materials into fit-for-purpose products that can be reintroduced into the productive economy, while addressing substances of concern and facilitating the traceability and risk management of chemicals in the recycling process. Input from stakeholders is requested on four issues estimated to create obstacles for a smooth transition of recycled materials from waste to new products: 1) insufficient information about substances of concern in products and waste, 2) presence of substances of concern in recycled materials (and in articles made thereof, including imported articles, 3) uncertainties about how materials can cease to be waste, and 4) difficulties in the application of EU waste classification methodologies and impacts on the recyclability of materials. The deadline for submitting views, concrete cases and figures on the consultation paper is 7 July 2017. Eurometaux is currently preparing a targeted questionnaire to help with collecting replies and cases, as this consultation is a very good opportunity to highlight our difficulties with the impacts of classifications and authorisation, specificities of the metal sector when it comes to inputs and outputs (more information: Kamila Slupek, Chris Heron, Annalisa Bortoluzzi and Violaine Verougstraete).

The non-toxic environment: *the EU Parliament stimulates dialogue on the right balance between innovation and precaution*

The British MEP, Julie Girling, organised on 26 April the event "The non-toxic environment: striking the right balance between innovation and precaution" with very relevant speakers from OECD, the European Commission (DG GROWTH), ECHA, CEFIC and the NGO EEB. OECD highlighted how their broad concept of innovation associated to strong governance and policy could support reduction of hazardous chemicals in products. DG GROWTH explained the regulatory achievements of the past 15 years including REACH/CLP, and stressed the need to enhance scientific knowledge on chemicals and to use the precautionary principle very consciously. ECHA pointed out that 20.000 chemicals are expected to be registered in 2018 and the knowledge gap will be a crucial issue to be addressed especially with regards to chronic toxicity. Additionally, the possibility to reduce by one or two orders of magnitude the DNELs was proposed as a political approach to address the combination of effects. EEB indicated that much more should be done and presented the precautionary principle and the similarity approach as necessary tools. During the following debate the international dimension of the problem was raised. Ms Girling concluded the discussion by saying that increased discussion on global regulatory environment is certainly needed and that the non-toxic environment can be reached only through ambitious regulatory targets and strong government leadership (more information: Lorenzo Zullo).

EUROMETAUX REACH Activities: hot topics/issues

Resources mapping

Cross-Industry Initiative (CII): *strategic meeting held on 12 April*

At the spring meeting of the CII, the Chairpersons of the respective working groups of the CII (general coordination, industry outreach, Member States outreach, MEP engagement, Trade Union engagement, Flowchart) provided status updates and the participants discussed the next actions to be taken. The Commission would be approached to share CII input on criteria for choosing OSH over REACH Authorisation in RMOAs. Outreach activities towards industry stakeholders will proceed to promote a better understanding of the initiative across key industry stakeholders and to involve more industry sectors. Following the recent contacts with authorities in Poland, Lithuania, Spain and Greece, the activities at Member State level will continue with focus on the alignment of REACH and OSH. At Parliament level, the CII would seek to leverage the current CMD legislative debates to raise awareness for the CII and interlinkages between OSH and REACH. The CII will also continue its engagement with social partners to gauge their interest in a framework for a social dialogue on the establishment of OEL values. As proposed by Eurometaux, a new working group has been set up to discuss the involvement of RAC in OEL-setting. All Eurometaux members (regardless of membership in the CII) are welcome to join that Working Group (more information: Kai-Sebastian Melzer and Lorenzo Zullo).

Classification

Cu-granules: *public consultation launched*

A Public Consultation to collect additional relevant information on Cu granules was listed on 4 of April on ECHA's website. The substance is an active ingredient in biocides and will therefore be reviewed for all potential and relevant hazard endpoints. This triggers a 45 day PC culminating in a formal classification proposal by RAC, by the latest in 18 months from now. The case may set a series of precedents on the environmental endpoint for the metals sector and is therefore of general importance. Indeed, the submitting country (France) applied Transformation Dissolution data in an appropriate way, and agreed to focus on standard species only (due to the data richness of the file). ECI, the biocides sector and Eurometaux support this but have comments on the need for guidance regarding "rapid removal" for inorganics, the grouping of ecotoxicity data for data-rich substances, and on the Weight of Evidence assessment of the Fish data. Additionally, the case opens an interesting view on SIDs and the recognition of different physical forms of Copper given the Biocides regulation classifies each individual active ingredient form (more information: Stijn Baken, Carol Mackie and Hugo Waeterschoot).

Classification mapping: *assessing the impact of substance reclassification along the entire supply chain.*

In the framework of REACH and CLP the hazardous classification of substances can be subject to revision. The impacts for the industry of substance reclassification are not limited to the requirements established by the CLP regulation (i.e. labelling) but may have direct and indirect repercussions through a broad range of legislations all over the entire supply chain. A dedicated taskforce was created in January within Eurometaux (Classification Mapping TF) to support the identification of the impacts. So far the taskforce has identified more than 60 different legislations covering, among others, substance handling, transport, workers protection, consumer products, waste, industrial emissions and environment. The work is now focused on the analysis of the links between hazardous classifications, legislative provisions and industry impacts. The final outcome, which is expected to be a flexible tool to allow the application of this assessment under different classification scenarios, is expected to be completed by the end of 2017. Additionally, the taskforce designed a new functionality in MeClas to automatically identify how the reclassification of an individual substance could trigger the classification of mixtures such as UVCBs and alloys. This new functionality is expected to be implemented in Q3 2017 (more information: Frederik Verdonck and Lorenzo Zullo).

Co CLH Taskforce meeting: *debates on SEA, bioelution and advocacy on 28 April*

The Co CLH Taskforce came together end of April, to brainstorm, in a mix of plenary and breakout sessions, on how to further tackle the impacts of the Dutch proposal to classify cobalt metal as carcinogen 1B, (with a specific concentration limit of 0.01%), as mutagen 2 and as repro 1B. This was the first face-to-face meeting since the end of the Public Consultation and the CDI/CoRC secretariat explained that more than 300 comments had been submitted into the ECHA website. Several MSCAs expressed agreement with the Dutch proposal. On the other hand, all industry stakeholders agreed with CDI/CoRC's technical position. The Netherlands will prepare a 'response to comments' for the technical points. The taskforce then split into two groups discussing science and socio-economic aspects, respectively. The SEA session aimed at briefly summarising the various cases identified by each sector, at indicating whether the cobalt is added intentionally, or present as an impurity,

stating the key socio-economic points and identifying case examples. The 'science breakout' recalled the main scientific arguments that will be brought up at RAC in September to avoid classification for all routes, avoid a cross-over of the cobalt compounds discussion with cobalt metal, contest the mutagenicity classification and the agreement on a repro classification while testing is still ongoing. On the SCL, it was agreed to try to strive towards the GCL of 0.1% (challenging the non-threshold approach referring to e.g. essentiality, lack of positive epidemiological data...) and to further work on the acceptance of the bioelution concept. In the afternoon, both groups met again to discuss a series of advocacy actions at various levels (MSCAs, Commission, EP, ...). A plan with clear timelines and key messages for each milestone/audience will be worked out by the CDI/CoRC and Eurometaux secretariats. Eurometaux Executive Committee has been briefed- at its meeting of 20 April- on the importance and relevance of this classification proposal for the sector and supported the setup of generic advocacy on alloys but also asked to launch a reflection on how such cases could be prevented (more information: Ruth Danzeisen, Carol Pettit, Brigitte Amoruso, Hugo Waeterschoot and Violaine Verougstraete).

Metals Specific REACH tools and concepts

Bioelution: *green light from ECVAM*

The last day of March, Eurometaux received the signal from ECVAM that it could proceed to a full test submission for the bioelution protocol. ECVAM had consulted its network of regulators (PARERE - Preliminary Assessment of Regulatory Relevance) and on the basis of their feedback completed their assessment of industry's pre-submission (July 2016). They have identified a list of questions to be addressed in addition to the template to be completed. Preparing this full submission will require significant resources and multi-disciplinary expertise as the questions cover a range of issues, from quite precise technical details up to validation information (literature review). An "action plan" will be worked out and communicated to the Bioelution Taskforce, in parallel with the drafting of key supporting messages for the June CARACAL meeting (more information: Adriana Oller and Violaine Verougstraete).

Metals Sectorial Approach **NEW**

Metal Sectorial Approach: *first meeting of the Steering Committee*

In March, the Eurometaux REACH Forum recommended to set up a Steering Committee to develop the modalities of the Metals Sectorial approach and to interact with ECHA, to guarantee that on the one hand the views and interests of the metal sector are well defended whilst a very open and transparent communication towards memberships and authorities is ensured. The Steering Committee, headed by Dirk Vandenberghe (President of Eurometaux) and Guy Thiran (Director General of Eurometaux) met for the first time on 3 April, to explore the best possible ways forward. The President indicated in his introduction the need for the alignment of industry and ensure credible progress on chemicals management, in particular in the context of the WSSD 2020 targets. While recognising the challenges, the Steering Committee reconfirmed the value of a sectorial approach to move towards ECHA's targets for 2020 (i.e. mapping of the chemicals universe, putting aside uses and substances of low priority and identifying those that still require further work). The Committee insisted on the need to progress in parallel on two axes, i.e. a) improving the REACH dossiers to ensure completeness and quality and b) solve key outstanding technical aspects that could improve the assessment of metals. The modalities of participation in the approach need to be defined further. Defining a "charter" outlining the commitments from all involved actors could be considered. The first action will be to develop a 'tick-box'-like template to be circulated to have a first overview of the baseline situation and help to prioritise the work on the technical issues. The Committee also requested to receive a formal written letter from ECHA to confirm their contribution and the value this approach could bring to the sector. Eurometaux communicated to ECHA the main outcomes of the Steering Committee meeting, with emphasis on the expressed requests (*post meeting information: Eurometaux received recently a letter from ECHA confirming the relevance of the issues raised by industry and announcing a formal letter as requested*) (more information: Violaine Verougstraete and Hugo Waeterschoot).

FURTHER OUTREACH OF REACH

OECD

SPERCs: *getting more international visibility*

Different industry sectors in Europe, including Eurometaux, have developed over the last years some specific Environmental Categories to improve, harmonise and make more consistent the way in which different companies assess environmental exposure. The work, which has also received input from Member States, has been coordinated during the past years by a European cross industry task (SPERCs TF, now chaired by Eurometaux). An industry workshop is foreseen to be organised in 2017. A quality check will be conducted in 2018-2019. The overall work will be completed with an external review process expected to be conducted in 2019-2020. Recently, the SPERCs have also received attention at international level. OECD made a comparison between SPERCs and OECD's Environmental Scenario Documents, providing suggestions and recommendations on possible further collaboration. This is considered an important step towards the international recognition of the work done by the European industry, facilitating the possibility to use the SPERCs beyond REACH and in legislative frameworks outside of Europe (more information: Frederik Verdonck and Lorenzo Zullo).

International

Turkey: *Turkish-REACH soon be agreed*

Turkey has already implemented the GHS legislation known as "SEA" and considers approving an elaborated Chemicals Management legislation called KKIK, most probably before the summer. Both regulatory requirements are remarkably similar to the EU-CLP and REACH including: a full recognition of the EU-CLP up to the 3rd ATP except for Borates and White Spirit, a chemicals management system based on registration (all tonnages together by 2022), evaluation, restrictions (equal to annex XVII) and even authorisations (including the recognition of Annex XIV). Main differences include the lack of a Chemicals Agency and the single registration deadline. No doubt this is important for the metals sector in the EU as it acknowledges trade between Turkey and the EU block (more information: Hugo Waeterschoot).

CALENDAR

- **16 May:** A&R Platform meeting – MCC (Brussels)
- **17 May:** Evaluation Platform meeting – MCC (Brussels)
- **18 May:** NeRSAP – ECHA (Helsinki)
- **29 May – 2 June:** RAC-41 – ECHA (Helsinki)
- **May-June:** CASG Nano meeting – Brussels (Date to be confirmed)
- **8-9 June:** RAC-41 – ECHA (Helsinki)
- **5-9 June:** 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)
- **28-29 June:** CARACAL 24 – Brussels (Provisional)
- **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)

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

ACRONYMS

AfA: Application for Authorisation	OECD: Organisation of Economic Cooperation and Development
ATP: Adaptation to Technical Progress	OEL: Occupational Exposure Limit
CARACAL: Competent Authorities for REACH and CLP	OSH: Occupational Safety Health
CII: Cross Industry Initiative	PACT: Public Activities Coordination Tool
CLP: Classification, Labelling and Packaging Regulation	PARERE: Preliminary Assessment of Regulatory Relevance
CMD: Carcinogens and Mutagens Directive	PBT: Persistent, Bio-accumulative and Toxic Chemicals
CMR: Carcinogens, Mutagens or toxic to Reproduction	PC: Public Consultation
CTP-HT: Coal Tar Pitch High Temperature	PfoA: Perfluorooctanoic Acid
DNEL: Derived No Effect Level	PNDT: Pre Natal Development Test
DU: Downstream User	RMOa: Risk Management Option analysis
ECVAM: European Centre for the Validation of Alternative Testing Methods	SCL: Specific Concentration Limit
GCL: Generic Concentration Limit	SEA: Socio-Economic Assessment/Analysis
HH: Human Health	SID: Substance Identity
MeClas: Metals Classification Tool	SPERC: Specific Environmental Release Category
MSC: Member States Committee (ECHA)	(i)UVCB: (inorganic) Unknown or Variable Composition, Complex Reaction Products and Biological Materials
MSCA: Member States Competent Authorities	WSSD: World Summit on Sustainable Development