



EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

This is about emotions... the ones that catch you when one of your favourite projects is attacked after months of hard work, when someone snaps at you unfairly or when you receive additional work you cannot refuse, even though you are already drowning. If you are at home, your reaction might be to start shouting, to demolish the reserve of chocolate or to go and hide in a corner and feel sorry for yourself for a while. This is not impossible at work (the mignonettes boxes are stored in the kitchen of the MCC) but is rarely welcomed! You are somehow expected to handle these emotions, land on your feet like a cat falling from a great height. This is even more the case when regulators are involved and are watching you. Actually, do you know that when you drop a cat it will swing its head to a horizontal, rearrange its rear, arch its back, and splay its legs, and all this before landing? I know that when I'm upset, my attempts of "rearranging" my fall make me look - in the best case - rather like a panicking bird, though I do not despair of - one day - being able to acquire the phlegm of the Cheshire cat (the floating head version, no feet, to simplify the moves).

Having been caught several times in March in situations where emotions reached a high level, I searched for some advice on the web. I found a site starting with the promising quote "Everything can be taken from a man but the last of human freedoms - the ability to choose one's attitude in a given set of circumstances". As there were some pro-active tips to apply "in case of disappointment/unhappiness" I immediately tried them out last week:

- Look at your mind set - Take a moment to realize that things won't always go your way. If they did, life would be a straight road instead of one with hills and valleys, ups and downs, right? And it's the hills and valleys that often make life so interesting. *OK, I'm certainly keen to have an interesting life but could one not leave my metals and metal projects wander in peace on the top of the hills? Climbing there was already worth the story*
- Adjust your goal - If you're disappointed that you didn't reach a goal, that doesn't mean the goal is no longer reachable. Keep the goal, but make a small change. *OK, sounds ~~reachable~~ reasonable...*
- Record your thoughts - Write down exactly what is making you unhappy. Once you identify the problem, start brainstorming ways to solve it or work around it. Remember, you always have the power to change your situation. *Ok this is actually where we start needing the tips about how to swing, arch, splay without getting a lumbago*
- Smile! Strange as it may sound, forcing a smile - or even a grimace - onto your face can often make you feel happy. Try it - you may be surprised! *Easy, I have a lot of grimaces in reserve...a bit tough though when you are recorded (Helsinki)*

Did these tips help me find the best attitude last week? To some extent, yes, as they made me realise that not only the tips but also the situation had to be taken with a pinch of salt... and a bit of settling time. And here we are like a Cheshire cat, stretching our legs and roaring on a sunny Sunday, with some changes brought to the project and a smile... Humour is emotional chaos remembered in tranquillity (J. Thurber)

Violaine Verougstraete, EHS director Eurometaux

ECHA REACH activities: hot topics

ECHA COMMITTEES

RAC

RAC28a: getting up to speed in Authorisation Applications and Cd restriction

RAC-28 devoted 4 days of discussions to Authorisation Applications and restrictions. On authorisation, RAC discussed in depth a number of phthalates uses and agreed on draft opinions for 4 uses. RAC also examined the first Authorisation Applications for arsenic trioxide. Industry STOs (Cefic, EM) can attend these discussions as observer but are not allowed to communicate directly with the authorisation applicants on the outcomes. There are however some generic lessons that can be drawn and may help in preparing an application. These will be taken forward to the Authorisation and Restriction platform. Also to note, a reference dose-response has been derived for trichloroethylene. The aim of setting reference DNELs and discussing the dose-response ahead of the application is to ensure consistency among applications and allow a more efficient evaluation by RAC but also to help applicants by providing them with a reference. Although these reference values are non-legally binding, one should acknowledge that a robust case will have to be presented by applicants if they choose to submit their dossier differently.

In the context of the restriction on an organic substance, among the proposed RMOs, the possibility to propose a harmonised exposure limit value (indicative or binding OEL) or a mandatory inhalation DNEL (in combination with a general requirement to protect against dermal exposure) to be used by registrants updating the CSRs were discussed. The restriction proposed by Sweden on Cd and Cd compounds in artist paints and pigments intended for the manufacture of artists' paints was estimated conform by RAC and the Public Consultation and was launched on March 19. Critical issues to solve in the coming months are the exact scope of the restriction, the reference to the Sludge Directive as possible RMO, the causality of the association used by Sweden to establish the risk (breast cancer) the overall Cd exposure and the proportionality (more information: Violaine Verougstraete, Christian Canoo, see also RAC highlights circulated on March 10).

RAC28b: Classification and SCL of borates compounds

RAC discussed the Annex XV submitted by Poland, who had proposed to modify the existing classification for reproductive toxicity for boric acid (from a category 1B to a category 2, based on epidemiological data, new evidence on mode of action and interaction with Zn). This proposal was supported by Industry. The Netherlands had submitted an Annex XV to classify DOT and DOA for Repro Category 1B, proposing also some SCLs. RAC estimated that the evidence was not strong enough to change the classification of boric acid and agreed to maintain the classification as 1B. DOT and DOA were classified as 1B. No classifications for environment or for other endpoints were agreed on. For DOT and DOA, considered as being of medium potency, RAC agreed on GCLs of 0.3%, in line with the recently published CLP guidance (0.3%). The case was a bit more complex for boric acid, as there is an existing SCL in the CLP Annex VI (5.5%) and the Polish Dossier Submitter had not proposed to revise the SCL. The current SCL was not modified, however RAC will stress in its Opinion that they feel that available data do not fit in with the SCL as derived according to the new methodology. This generates an inconsistency between the SCLs of the various borate compounds. Denmark announced that they would submit an Annex XV focusing on the 'harmonisation of the SCLs across the borates compounds (more information: Helen Kean, Violaine Verougstraete, see also highlights circulated on March 17).

SEAC

SEAC22: Restriction of Pb in consumer articles, SEAC agrees with the value of a "bioelution" based approach

Industry was shocked during the March meeting when realizing that the revised Restriction opinion as presented to SEAC did not include a reference to the possibility of using bioelution to modify the proposed restriction standard of 0.05 % of Pb content in consumer articles. Eurometaux motivated that such a clause was most needed to maintain the innovative capacity of the sector to promote and develop new alloy types with reduced leachability and to obtain a cost-effective solution for Cu-brass containing Pb impurities above the proposed concentration cut-off. The discussion turned out to be very difficult but in the end SEAC agreed to include a saliva bioelution testing approach allowing deviating from the standard Pb cut-off of 0.05 %. SEAC also agreed with a Cu-brass specific standard of 0.5 % further to the robust test programme conducted by the Cu sector. SEAC hereby sets an important precedent, recognizing the value and potential of bioelution tests, but also stimulating industry to act in order to achieve the harmonisation of the SOPs and bioelution guidance, preferably at international level (more information: Hugo Waeterschoot, Steve Binks and Violaine Verougstraete).

SEAC22: precedent created by the agreement on a batch of authorisation application cases and progress with many others

The March SEAC meeting was to a large extent devoted to a first 'content discussion' on the first phthalate authorisation cases and the conformity check of the As₂O₃ authorisation application. In particular, the authorisation request from a PVC recycling plant where phthalates are available as impurities in plastics triggered the interest of Eurometaux. This important case sets precedence on how to assess the relevance of authorised impurities in substances and will be finalized at the next SEAC meeting (June). So far the SEAC discussions seem to agree with the view of the metals sector that substances included in recycling streams are only authorised if they have a specified and aimed function in the recycled material. The 3 requests submitted to obtain an authorisation for As₂O₃ use (Zn refining and chip development sector) did all pass the conformity check level (more information: Hugo Waeterschoot).

INTERMEDIATES AND STRICTLY CONTROLLED CONDITIONS

Meeting on March 4 with ECHA's scientific adviser and experts from the SID, computational and Evaluation units

In follow up of the January meetings, ECHA has held internal discussions and communicated early March some practical suggestions for the iUVCB registrations to be submitted in April. Suggestions on SID, on how to best combine the information on the metal constituents to assess the properties of the UVCBs for classification & risk assessment, on the compilation of the dossiers (IUCLIDs & CSRs) and on the legitimate access to information on the constituents were communicated to Eurometaux. Immediate follow-up actions were to prepare an abstract summarising our approach for SETAC Basel (11-15 May 2014) and to compile a "SID plan" on possible changes in our dossiers vs. the 2010 registrations (more information: Federica Iaccino and Violaine Verougstraete).

MSC

MSC workshop on "5 years Compliance Check experience" and the development of a strategic plan on CCs for 2014-2018

Eurometaux participated in a high level ECHA workshop reviewing 5 years Compliance Check (CC) experience and defining a strategic outline for ECHA's Compliance Check programme for the period 2014-2018. The workshop, attended by MSC and Management Board members, as well as by several ECHA directors, debated in depth how the Compliance Check programme could be made more effective, to stimulate a high level of Chemicals management in the EU. While the tone at the start of the workshop was rather hostile towards industry, it quickly turned and became supportive towards a common view that would benefit the companies that make all reasonable efforts to comply with the REACH registration requirements. On the other hand, there will be an increasing focus on the non-compliance status of the companies that effectively try to escape REACH obligations in a non-legally acceptable way. Eurometaux could -through a common position with Cefic- obtain more recognition for data-rich dossiers and made the plea that this data availability would not result in almost automated risk management consequences as it is currently the case. Member States and ECHA had sympathy for this reasoning and agreed to rather focus the future CCs on the substances not yet governed by existing risk management legislation (e.g. Endocrine disruptors of PBTs). The meeting also debated on how MSC could better reward comprehensive and complete registration cases, like many metals cases, in order to promote an attitude towards continuous improvement of registration files (more information: Hugo Waeterschoot).

CoRAP: Eurometaux arguments to reduce the levels of concerns accepted

Eurometaux got the opportunity to react on the draft CoRAP update for the 2014-2016 rolling plan period and stressed that the concerns brought up by the Member States, like for example the health properties of AlCl₂, should be based on fundamental and robust evidence rather than on potential concerns. MSC and ECHA agreed and published on March 28 the updated CoRAP list, with a deletion of the health endpoint concern for AlCl₂ (by France) and the cancellation of the entry for GaAs, the latter based on the conclusion by Latvia that the CMR and exposure concerns are solved. The GaAs case is most interesting given this 'deletion' is based on the voluntary commitment of industry to conduct and submit the outcomes of an exposure monitoring programme carried out during the manufacturing and use of GaAs (more information: Hugo Waeterschoot).

EUROMETAUX REACH activities: hot topics/issues

AUTHORISATION

Eurometaux organized a workshop on Authorisation Applications on March 26-27

Eurometaux -supported by Cefic- organised further to the suggestion of ECHA, a workshop to explore the options & best ways for industry to submit Authorisation Applications for large sectors, with the objective of enhancing and promoting the success level. The Chromium case was chosen as an indicative example for this purpose and resulted in an intensive and

highly successful workshop. More than 60 participants from industry, Member States, Commission and ECHA attended the workshop at the MCC. The most relevant outcome for the metal sector is a better overview on which application submission strategy is the most relevant and a Q&A on critical questions in respect to Authorisation Applications that is directly useful for any further metal authorisation case (more information: Aggie Kotze, France Capon and Hugo Waeterschoot).

Authorisation and Restriction platform: an updated RMO development guidance and a workshop in September

As mentioned in the February REACH News, the Authorisation and Restriction platform held last month a brainstorming session on how a shadow Risk Management Option analysis could be developed in anticipation of such potential activity by Member States. The outcome and recommendations of the workshop were taken forward by Eurometaux in an updated slide deck and meeting report aimed at drafting RMO guidance and developing specific examples. Eurometaux investigated and succeeded in receiving the support from ECHA and Commission for a workshop to be held on this theme in September. Eurometaux will now plan the event, so that Consortia can develop Shadow RMOs in due time for further possible prioritisation activities by ECHA (more information: Michel Vander Straeten and Hugo Waeterschoot).

INTERMEDIATES

iUVCB submissions: generic introductions to include in the dossiers

To introduce the specific iUVCB approach in the iUVCB CSRs, a series of generic introductions were prepared by Eurometaux/EBRC and ARCHE based on the discussions held with ECHA and in the Intermediates taskforce. These 'introductions' provide both a generic high-level paragraph to be included at the beginning of the CSR sections (classification, hazard assessment, exposure assessment and risk characterisation) and a text highlighting relevant information to be included, together with some table templates. In addition to those introductions, some generic statements were developed to report the current status of the assessment and the expected updates (in particular on topics as man via the environment or combined toxicity). Consortia starting to work on iUVCBs assessment are encouraged to contact Eurometaux, to receive detailed information on the methodology and the developed reporting templates (both on CSR and IUCLID) (more information: Federica Iaccino and Violaine Verougstraete).

CLASSIFICATION

Pb SCL follow-up

The Pb SCL taskforce has continued its advocacy efforts during the month of March by contacting Member States Competent Authorities and Commission and asking them to consider the postponement of the inclusion of the classification of metallic Pb and related SCL in the 7th ATP, to allow the possible revision of the guidance on the derivation of SCLs for inorganics and substances with human evidence and the carry out of a bioelution test programme to demonstrate the reduced accessibility for different physical forms of Pb, as well as from special mixtures and complex inorganic materials containing metallic forms of Pb. Guy Thiran and Hugo Waeterschoot from Eurometaux met DG ENT Director Gwenole Couzigou. DG ENT listened carefully to the concerns expressed and concluded that a majority of Member States will have to be convinced to support the review of the SCL procedure and the suggested postponement, but if so they would be prepared to act accordingly. In follow-up DG ENT provided Eurometaux with an opportunity to present the issue and impact assessment at Caracal (on April 3), at the ESPG meeting (on April 4) and at the Raw Materials Supply Group. Eurometaux appreciated these advocacy communication opportunities and prepared target specific presentations for each of the three events together with the ILA and the taskforce (more information: Steve Binks, Violaine Verougstraete and Hugo Waeterschoot).

Cobalt and CLH: a conflict between the MSC testing recommendation and the Dutch view for a harmonized classification?

Eurometaux supports the concerns raised by the Cobalt consortium on the intention of The Netherlands (see Registry of current Harmonised Classification and Labelling intentions) to submit early 2015 two Annex XV proposals in view of the harmonisation of the CMR classification of Cobalt compounds. This intention is in conflict with the agreed MSC testing proposal for these health endpoints. Eurometaux therefore contacted the Netherlands, Commission and ECHA in order to explore how this conflict could be addressed and how full recognition for the approved Cobalt test work could be achieved before any further pre-emptive decisions on the classification of specific Co compounds are taken. This discussion is still ongoing (more information: Brigitte Amoruso and Hugo Waeterschoot).

METAL-SPECIFIC REACH APPLICATION TOOLS AND CONCEPTS

MEASE and ETEAM

On March 24-25, the preliminary outcomes of the ETEAM project were presented during a conference organized by BAUA bringing together regulators from the Member States and ECHA, industry and model developers. This project aimed at validating the Tier 1 assessment tools for occupational exposure referred to in the ECHA guidance (ECETOC TRA, MEASE, Stoffenmanager, EMKG). Contractors are IOM and Fraunhofer with the model developers and ECHA being part of the

associated Advisory Board. A number of recommendations were issued to all tools after some scenarios were identified as potentially generating under-conservative estimates. Important to stress is that IOM used a rather limited number of measured data points to be compared to the predictions of MEASE, a tool based on a huge database of measured data. Another generic comment was that it should be clarified whether the tools assume good occupational practice. The outcomes will be further discussed by the Advisory Board. Eurometaux and EBRC are currently examining how to address ETEAM's current and future recommendations. Specific warnings on the applicability domain of MEASE, i.e. that the tool should be used only for metals and inorganic metal compounds assessment and that it generally assumes good occupational hygiene practice will be posted on the MEASE website and in the tool itself. In the medium term, a version 2.0 of MEASE should be developed, including more monitoring data for more metals and a publication on scientific principles and underlying database (more information: Daniel Vetter and Violaine Verougstraete).

OTHERS

Follow-up Exposure Scenarios meeting on February 4: Section 3.7 not mandatory before early 2016

ECHA confirmed that it will not be mandatory to complete (parts of) IUCLID section 3.7 before the first quarter of 2016. Improvements to the technical completeness check, which would also cover section 3.7, are planned for the release of the next major version of REACH-IT (version 3) and IUCLID (called "version 6.1" for the moment), currently foreseen for early 2016 (Q1) (more information: Inneke Claes).

Health news

In view of the chocolate addiction developed by some members of the REACH Team (see Editorial), it has been agreed that from now on the mignonettes at the MCC will be replaced by dried fruit bars (more information: Anne Heymans).

Further outreach of REACH

OECD

OHT call and comments

The OECD Taskforce on Exposure Assessment is currently working on an OECD harmonized template (OHT) to report basic summary information on use patterns of a substance, the conditions of use and the related exposure estimates. ECHA, who is in the driving seat, has circulated a first proposal for discussion to the taskforce. The expected benefits of structuring information on use and exposure, are a better understanding of the uses by authorities, more transparency in exposure estimation and facilitation of reporting key information by industry that may justify a low rank of a substance, allowing the systematic differentiation among uses where the nature of the use drives certain legal requirements or exemptions and enabling the dissemination of non-confidential information on use and conditions of use. OECD templates are aimed at developers of database systems, as they prescribe the formats by which information can be entered and maintained in database management systems such as IUCLID. Important for us is that specifications of sections 3.5 and 3.7 of IUCLID 5.4 and of the future IUCLID 6.1 are linked with the content of the OHT. Interestingly ECHA's draft included a reference to the chemical entity concept we discussed previously for UVCBs (with focus on the information related to the release/exposure which is to be used in the risk characterisation) (more information: Violaine Verougstraete).

Calendar

- 2-3 April: CARACAL (Brussels)
- 4 April: ESPG (Brussels)
- 7-11 April: MSC-35 (Helsinki)
- 28-29 April: ECHA Seminar on the basics of AfA (for beginners) – ECHA (Helsinki)
- 29-30 April: ECHA Workshop on lessons learned from AfA – ECHA (Helsinki)
- 6 May: Authorisation & Restriction Platform – MCC (Brussels)
- 8 May: REACH Forum – MCC (Brussels)
- 12-16 May: SETAC (Basel) http://www.setac.org/events/event_details.asp?id=310405
- 19-20 May: CLP mixtures FECC-DUCC-Cefic-EM workshop (MCC)

- 22 May: WS on Bioelution/Bioaccessibility: A Promising Alternative To Animal Testing For Human Health Effects Assessment - (Radisson Blu Hotel, Brussels)
- 2-6 June: RAC-29 (Helsinki)
- 10-13 June: MSC-36 (Helsinki)
- 11-13 June: CARACAL (Brussels)
- 17 June: Authorisation & Restriction Platform – MCC (Brussels)
- 18 June: Evaluation Platform – 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)
- 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

AICl ₂ : Dichloroaluminium	GaAs : Gallium Arsenide
As ₂ O ₃ : Arsenic trioxide	GCL : Generic Concentration Limit
ATP : Adaptation to Technical Progress	IUCLID: International Uniform Chemicals Information Database
BAuA : Federal Institute for Occupational Safety and Health	ILA : International Lead Association
CARACAL: Competent Authorities for REACH & CLP	IOM : Institute of Occupational Medicine
CC: Compliance Check	MCC : Metals Conference Centre
Cd : Cadmium	MEASE: Metals EASE
CEFIC : The European Chemical Industry Council	MSC: Member States Committee
CLH : Harmonised Classification and Labelling process	OECD: Organisation of Economic Cooperation and Development
CLP: Classification, Labelling & Packaging Regulation	OEL: Occupational Exposure Limits
CMR : Substances classified as Carcinogens, Mutagens or toxic to Reproduction	OHT : OECD Harmonised Template
Co : Cobalt	Pb : Lead
CoRAP : Community Action Rolling Plan	PBT : Persistent, Bioaccumulative and Toxic Chemicals
CSR: Chemical Safety Report	PVC : Polyvinyl Chloride
Cu : Copper	RAC: ECHA Risk Assessment Committee
DG ENT : DG Enterprise	RMO : Risk Management Option
DNEL: Derived No Effect Level	SCL: Specific Concentration Limit
DOA : Disodiumoctaborate anhydrate	SEAC: ECHA Socio-Economic Committee
DOT : Disodiumoctaborate tetrahydrate	SETAC : Society of Environmental Toxicology and Chemistry
DUCC : Downstream Users of Chemicals Co-ordination	SID: Substance Identification
ECETOC : European Centre for Ecotoxicology and Toxicology of Chemicals	SOP : Standardised Operating Protocol
ECHA : European Chemicals Agency	STO : Stakeholder Observer
EMKG : Einfaches Maßnahmenkonzept für Gefahrstoffe	iUVCB: inorganic Unknown or Variable Composition, Complex Reaction Products and Biological Materials
ESPG : group of experts on Enterprise and SME Policies	GCL : Generic Concentration Limit
ETEAM : Evaluation of the Tier 1 Exposure Assessment Models	Zn : Zinc
FECC : European Association of Chemical Distributors	