



EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

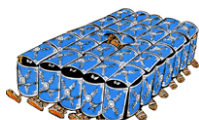
As a Belgian, I have always been “naturally” exposed to comics. At home, they kept us quiet for hours. One of my favorites was an ‘Asterix the Gaul’ book. Briefly, it tells how Asterix and Obelix voluntarily join Caesar’s army to find Tragicomix, who has been forcibly enrolled and is fighting in North Africa. Both enlist a group of ‘apprentice’ legionnaires trained in Rome before being sent to the North African front. The differences in motivations and cultures in the group are however so striking that they affect the overall preparation of the group and slow down the journey to North Africa – thereby creating the main part of the pitch. Besides showing all possible misunderstandings and impacts generated by the (individual) differences, it also describes with a lot of humour how the (Roman) organization starts to vacillate, when unable to deliver a kind of “harmonized assemblage”.

I could not help but think about some of the Asterix’ scenes last week when reflecting back on the REACH activities in January. One of the main achievements has undoubtedly been the discussions with ECHA on the UVCBs’ assessment methodology and reporting aspects.



In addition to the very good participation on ECHA’s side, discussions have been of high technical & scientific value and demonstrated both credibility and willingness to find solutions on both sides. As industry, we however got a clear warning: it will only be by explaining more, in a clearer manner and by being consistent within the sector that we will avoid Evaluation activities. There now lays our challenge...ensuring consistency, making progress as a group while respecting the different agendas of the consortia, differences in working styles, the different perceptions of urgency!

As Eurometaux, we can only make one plea –but it is a very concerned one- to avoid rushing now to make dossiers without taking the time to agree on generic, consistent –metal sector- justifications/explanations on topics that may fire back. Several of the ongoing compliance checks -on ‘simple’ substances- are targeting exactly this lack of documentation and consistent argumentation. They now require significant efforts to be addressed. Let’s not make the same mistake twice! Let’s discuss and exchange! If you have not been actively involved up to now in the discussions on the UVCB assessment methodology –as consortia or consultant- please ask, check, contact. It will only be as a group that we will make it, in April and in the coming years.



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Violaine Verougstraete, EHS director Eurometaux

**<http://lencyclopedia.free.fr/citq.php>

ECHA REACH activities: hot topics

ECHA COMMITTEES

RAC

Harmonised Classification on Cu compounds: ongoing Public Consultation

The CLH files related to the Harmonized Classification proposal by France for the Cu compounds are among the largest of the ECHA-CLP-RAC history. Industry consequently felt quite stretched when ECHA started the Public Consultation over the Christmas Holidays. The case is not only critical for Cu, but also for the metals sector as such, as it uses techniques and approaches for data rich substances and specific metal concepts like the Unit World Model. Eurometaux therefore supported ECI by critically reviewing the exhaustive input the sector has prepared for the Public consultation, both on the

environmental and the health hazard identification. The proposal to organize a session on the UWM along SETAC Basel (see below) is also part of this support strategy (more information: Katrien Delbeke, Carol Mackie, Hugo Waeterschoot or Violaine Verougstraete).

SEAC

Restriction of Cd in paints: ECHA replied to the letter of the metals sector

In December the metals sector contested the conformity of the ECHA Restriction proposal on Cadmium in pigments by writing a letter to the SEAC committee. The compounds reviewed in the Restriction are not classified as hazardous and no hazard or EU-wide risk was derived, a prerequisite for the conformity of an EU-wide Restriction. Eurometaux stated that such a case would set a precedent that could not be supported by industry also considering the information on the (safe) uses. Eurometaux received recently a formal reply from ECHA "clarifying" that indeed an exceptional procedure had been followed given the lack of an "empowerment for Commission to amend the Annexes from the Cd in pigments Directive without going to a full Restriction process". ECHA therefore submitted such a restriction. The letter further claims that the "*unacceptable risk from this substance is evident because of its existing entry (in Annex XVII)*". ECHA uses this also as a justification to submit a very simplified Annex XV restriction dossier without any hazard or risk justification. Eurometaux remains convinced that the case does not fulfil the minimal requirements for a Restriction case and would support the Cd sector if they would like to further challenge this (more information: Hugo Waeterschoot).

MSC

MSC prepares for the adoption of CoRAP 2014-2016: no surprises to be expected!

It is expected that MSC will adopt the CoRAP 2014-2016 at its meeting in February, thereby formalizing the selected substances as well as their reasons of concerns. GaAs, Ag, AlCl₃, AlSO₄, TiO₂ ... are among others on the list for review in 2014, 2015 and 2016 (including justification documents). In line with the new procedure, all except Ag and GaAs will undergo a full Compliance Check, leaving out the issues selected for Substance Evaluation. Eurometaux will assure a review of the learning experience on the full compliance checks and the completed Substance Evaluations at its upcoming Evaluation platform meeting, to provide experienced-based support to the involved Consortia (more information: Hugo Waeterschoot).

INTERMEDIATES AND STRICTLY CONTROLLED CONDITIONS

On 22 January a metals delegation involving Eurometaux, Katia Lacasse, ARCHE and EBRC met ECHA experts from the SID, Classification, Evaluation and Computational units to present the approach developed for the inorganic UVCBs' Chemical Safety Assessment, illustrating it with a pilot case. The meeting set up by ECHA's Scientific Adviser allowed a good –and intense- interaction on a number of scientific/assessment concepts. While the approach appeared to be overall acceptable to ECHA, several areas for improvement were identified to improve the robustness of dossiers. In view of the tight timelines to submit the 'upgraded' intermediates dossiers (end of April), ECHA recommended industry to provide them with a roadmap of actions that will be carried out at short term (before the submission deadline), at medium- and long term (reflected in dossiers updates). Transparency and consistency across the dossiers will be essential to avoid evaluation activities. On formatting and reporting aspects, ECHA evaluation and computational units committed to help in identifying best workable solutions. ECHA stressed that they expect submissions by the companies who committed to upgrade their intermediates dossiers last year (37 under EM umbrella/60 expected) and will 'use' the April deadline to identify the registrants not following up (more information: Federica Iaccino, Hugo Waeterschoot and Violaine Verougstraete).

AUTHORISATION

5th priority list for Annex XIV: ECHA prepares submission for Commission including the RCFs

MSC agreed in December to nominate all 5 substances reviewed for the 5th prioritisation list. There was however no consensus, neither on Authorisation being the most effective risk management tool nor on the way the agreement was achieved at MSC level. This resulted in a series of minority positions and Member States comments, reflecting these concerns, in the minutes of the meeting. ECHA collected these early January and is currently preparing an ECHA opinion on the 5th prioritisation list. While it cannot be expected that ECHA will change their opinion, it will need to be a balancing act and it will be most interesting to see how they will handle the raising concern of the non-effectiveness of Authorisation as an appropriate risk management measure for the selected chemical (more information: Hugo Waeterschoot).

NeRSAP 2: scheduled for 26 February

The second meeting of the Network of Experts on Socio Economic assessment and Assessment of Alternatives will meet on 26 February in Brussels. The network allows governmental, ECHA, SEAC and Industry experts to “review best cases of scientific and technical/methodological development on SEA and AofA” without the constraints of a formal ECHA meeting. Eurometaux is organizing the meeting from a content perspective and established the agenda for the Organising Committee whilst the Belgian government acts as sponsor this time. Consultants working for Consortia can submit a participation request if interested (more information: Michel Vander Straeten and Hugo Waeterschoot).

ECHA OTHERS

Discussion with ECHA on metal specificities in ECHA tools:

On 23 January EBRC, ARCHE and Eurometaux met several representatives from the ECHA computational unit to achieve a better *understanding* on a number of ‘reporting-related’ issues in IUCLID, Chesar and the CSR plug-in -linked e.g. to metal specificities- in view of identifying/preparing the specifications for the next versions of IUCLID and Chesar. As this exchange took place just after the meeting on the inorganic UVCB CSA approach (22 January), several aspects related to formatting and reporting of information on multiple constituents were also discussed in-depth. A number of actions for further input and/or clarification have been identified and will be followed up by EBRC/ARCHE and communicated to the Exposure Scenarios as taskforce, as partly related also to the streamlining and updates of ES (e.g. PROCs, use of measured data, compliance by downstream user) (more information: Federica Iaccino and Violaine Verougstraete).

Compliance checks on metal and metal compounds: high ECHA-Consortia activities despite the Christmas break

End 2013, ECHA forwarded several Draft Decisions on compliance checks of registrations to metals Consortia either in preparation of a Substance Evaluation (e.g. GaAs) or to highlight potential specific concerns (SIDs, high RCRs, AF ...). Eurometaux provided active support in exchanging experiences with the Consortia and participating in ECHA briefing calls/meetings when asked for by Industry. The concerns expressed were often of a “horizontal nature” for the metals. Those will therefore be further taken forward by the Eurometaux Evaluation platform covering e.g. when would doping be considered a downstream use or when as a NONS, the level of substance specific justification to justify deviating from the default Human Health Assessment Factors.

The contacts with ECHA demonstrated that a collaborative attitude could achieve up to one additional month to update the registration files to cover the raised concern(s) (more information: Hugo Waeterschoot, Karin Van de Velde, Birgit Müller).

REACH Enforcement: Forum invited proposals for harmonised projects

As of 2014, the REACH Enforcement Forum will carry out harmonised enforcement projects in 4 phases (scope - preparation- operational phase – reporting), at a rate of one project per year. As part of a drive to work closer with Accredited Stakeholder Organisations, the latter were invited to submit proposals for new projects. Eurometaux proposed 3 projects:

- Check REACH compliance of imports (substances/mixtures)
- Check correct application of OC and RMM by DU as recommended in the ES/SDS or of information received according to Art 32 (d) from suppliers
- Check of proof of legitimate access to data used in registration dossiers and implementation of actions in case of non-compliance (both for lead-registrant and co-registrants)

More information on the REACH Enforcement forum and the finalised enforcement projects can be found on the ECHA website (<http://echa.europa.eu/about-us/who-we-are/enforcement-forum>). In a related development, the Commission co-financed an interesting “Study on the protection of research data and recommendations for access and usage” (<http://webdoc.sub.gwdg.de/univerlag/2013/legalstudy.pdf>) (more information: Inneke Claes).

Meeting of the CSR/ES coordination group: defining an action plan

The coordination group, bringing together ECHA, a number of Member States and industry sectors to discuss the implementation of the CSR/ES roadmap met on January 20. The roadmap aims at improving the quality information on the safe use of chemicals in the REACH chemical safety report and the extended safety data sheet. The different action areas of the roadmap (see also ECHA website: <http://echa.europa.eu/csr-es-roadmap>) were reviewed with a ‘critical eye’ by all actors in view of priorities, timing and resources. One of the actions of direct relevance to the metals sector is the definition of the volume tracking method (action 2.6). The outcomes of the meeting and resulting actions will be further discussed at forthcoming Exposure Scenarios Taskforce meeting (more information: Violaine Verougstraete).

Commission REACH activities: hot topics/issues

The future of the Authorisation scheme: the Commission starts reflection on the future of Authorisation prioritisation

The latest failure to reach a common view at MSC on the 5th priority list inspired Commission to launch a strategic reflection in February on how to prioritise and focus substances for authorisation. Eurometaux and the Co-chairs of the Authorisation and Restriction platform held a brainstorming session to anticipate this discussion and plan to submit a paper on this in February for discussion with Commission and ECHA (after members' review) and try to convince DG ENV that not "every substance on the Candidate List should eventually go for authorisation". This debate is most critical for a series of metal compounds where an EU-wide OEL or a Restriction can be far more effective. The recognition of "substance specific exemption" -legally speaking not escaping authorisation- (critical for Pb compounds) would also be part of this discussion (more information: Hugo Waeterschoot, France Capon or Aggie Kotze).

REACH Directors' Contact Group: new mandate leading up to 2018 registration deadline

The Directors' Contact Group (DCG) provides a platform for the informal exchange of views and information between the European Chemicals Agency (ECHA), the Commission and Industry Associations. Eurometaux is represented by John Schonenberger (ECI & REACH Forum co-chair). At the DCG meeting on 15 January 2014, the following topics were discussed:

- The new mandate of the third term of the DCG leading up to the 2018 registration deadline was adopted. At the request of industry and supported by DG ENT, the practical and cross-sector issues which might arise with authorisation applications were added as one of the topics to monitor
- In general, there will be some particular attention for SMEs throughout the work of the third mandate
- A document with the accomplishments of DCG2 was approved
- A mandate was given to sherpas (in charge of preparing the DCG meetings) to work on SIEF management as well as data and cost-sharing issues

Further Information can be found on ECHA's website (<http://echa.europa.eu/en/about-us/partners-and-networks/directors-contact-group>) (more information: Inneke Claes).

REACH and RoHS: Commission Common Understanding Paper

The Commission has produced a paper on a "Common understanding on how to manage future regulatory action on the same chemical substances under REACH and RoHS" for the Competent Authority workshop on "Managing risks related to chemicals: REACH and sector specific legislation", held on 8 November 2013 Brussels

(http://ec.europa.eu/enterprise/sectors/chemicals/reach/events/index_en.htm#h2-2). The paper was also discussed at the last CARACAL meeting on 26-28 November 2013. This paper has to be seen in close connection to the currently ongoing revision of Annex II of RoHS (Restriction of hazardous Substances in EEE) with the restrictions and methodology the Commission wishes to develop to assess potential future restrictions under RoHS.

Cefic, Orgalime and Eurometaux have jointly been advocating that the potential overlaps and contradictions between REACH and RoHS should be avoided. Therefore, the Commission paper was very much welcomed, although from a practical point of view, there is still no guarantee that duplication and contradiction will indeed be avoided in the future. Therefore, Cefic, Orgalime and Eurometaux issued a joint paper with comments on the Commission's "Common Understanding" with as main messages that a) the REACH risk assessment procedures need to be taken up for RoHS implementation in order to provide for one holistic commonly accepted scientific and technical substance evaluation method that should be valid under both legal acts, b) the REACH Regulation should be the primary vehicle to gather information on substances, c) the RoHS methodology should specify what information needs to be gathered for a proper implementation of the RoHS Directive and d) the RMO analysis under REACH needs to fully take into account existing legal measures and objectively choose the best legal instrument in case additional risk management is necessary (more information: Inneke Claes).

EUROMETAUX REACH activities: hot topics/issues

RESOURCE MAPPING TO RESPOND TO REACH / ECHA CHALLENGES

Strategic support for Consortia REACH activities' planning: learning from experience and planning for the best options

Several consortia and companies are challenged with ongoing prioritisation, RMO or Authorisation/Restriction, or Compliance Check activities. Eurometaux therefore started a service of REACH strategic planning support calls (RSPS-calls) for member consortia/companies to help them with identifying possible options and strategies, based on the experience gained with other substances and the networks at ECHA and Commission level. While such concerns usually pop up at short notice, Eurometaux would like to invite Consortia interested in such RSPS-calls to identify their needs and timing as early as possible to allow the best intelligence to be collected in advance. Aspects covered last month included the choice and relevance of

RMMs under Authorisation or Restriction, how to obtain access to completed RMOs on metal compounds, availability and planning for alternative RMM tools and exploring collective interest, compliance check support activities, etc. (more information: Hugo Waeterschoot and Violaine Verougstraete).

Planning of the different platform/technical meeting activities: maximizing the efficiency of the meeting calendar

The Eurometaux staff and platform co-chairs will develop an integrated REACH Eurometaux meetings calendar to increase the efficiency of the members travel and calendar planning. Meetings will be as far as possible scheduled back-to-back depending on the theme and expertise required and in line with the REACH-ECHA-Caracal timing and agenda needs. This integrated planning will be sent very soon to the members of the REACH Forum and the relevant taskforces (more information: Cathy Martin, Ailsa Lee or Violaine Verougstraete).

AUTHORISATION

Strategic objectives for the Eurometaux Authorisation and Restriction platform: anticipating the 2014 agenda

Eurometaux and the co-chairs of the Authorisation and Restriction platform mapped Industry's needs for 2014 related to the Authorisation and Restriction processes, now that the ECHA and Commission SVHC and RMO Roadmaps as well as the new prioritisation approach for complementing Annex XIV are known. The aim of the exercise was to anticipate and plan important tools to be developed, define when/where generic advocacy activity and workshops would be required in 2014 to ensure the metals industry is well prepared to limit SVHC-and prioritisation listing. This is now turned into a coherent work programme for 2014 which will be presented to the platform. The proposed programme includes 2 smaller workshops (RMO and materials flow, downstream users and authorisation/restriction) and activities covered by 5 platform sessions spread over 2014 (more information: France Capon, Aggie Kotze, Hugo Waeterschoot).

EU-wide OELs a better risk management tool for many inorganics: Consortia requested an exchange of thoughts

Potential exposure to CMR metal compounds hazard is restricted to the industrial occupational setting given professional and consumer use for such substances is only allowed with a "derogation restriction". This makes an EU-wide OEL approach a much more efficient and appropriate way to handle outstanding potential exposure for workplace than authorisation. The discussion on this alternative to authorisation is presently a "hot" topic in Brussels given its relevance for Cd and Pb-compounds -on the Candidate list- and for RCFs and Co compounds - prioritised for Annex XIV listing. SCOEL and other bodies had or have these metal compounds on their agenda for OEL review but the process is cumbersome and slow and many do not have a finalized EU-wide OEL, which is a prerequisite for Commission to cancel the need for an Authorisation. Metal Consortia involved in the authorisation selection process have already communication programmes in place to contact relevant EU bodies but asked Eurometaux to check how/if some coordination could be organised to stimulate the relevant EU bodies to proceed in a coherent matter. Eurometaux will hold a conference call on 5 February launch this activity (more information: Violaine Verougstraete and Hugo Waeterschoot).

CLASSIFICATION

Assessing the impact of the Pb Specific Concentration Limit

In December, RAC agreed on the classification of Pb metal as repro cat 1A and on the associated SCL of 0.03%. In practice it means that materials containing more than 0.03% of Pb metal will be classified according to the Pb classification, i.e. toxic for reproduction and have to be labelled. These classifications and SCL apply to all forms of Pb. The RAC Opinion is now on its way to the Commission who will include it in the draft 7th ATP for voting by the REACH Committee in June. As industry has claimed that the SCL will have a number of consequences on materials where Pb could be present as impurity or for a functional reason (scrap, slags, alloys), Commission has asked Eurometaux to provide them in February with actual socio-economic data and facts on those impacts. A template questionnaire was circulated to the membership and downstream users/sectors in December 2013 and on 30 January a call was organised with the sectors/companies that provided or will provide input (deadline 3 February COB) to discuss the first outcomes of the questionnaires. Based on the overall input, a case will be built up and presented to DG ENV and DG ENT representatives around mid-February. If no way forward can be found with the Commission, advocacy activities will be launched to explain the impacts to the Member States Competent Authorities participating in the REACH Committee (more information: Violaine Verougstraete and Hugo Waeterschoot).

SETAC Europe (May Basel): Eurometaux contributes and co-organises sessions

ECHA and Eurometaux will co-host a SETAC session on sediments' hazard and risk assessment, in follow-up to ECHA's successful topical workshop on sediments held in May 2013. The meeting's topics for presentations and poster submissions have been screened and arranged to form a consistent programme, with a high and interesting focus on metals' scientific developments. Hugo Waeterschoot has been invited by ECHA and Henrik Tyle (DK) to provide a presentation on the strengths and weaknesses of implementation bioavailability correction tools for metals for chemicals management under REACH, in the context of the special REACH session organised in one of the larger meeting venues at SETAC Basel. Eurometaux consulted the consortia for their support and will prepare the presentation together with ARCHE. Another contribution from the metals sector relates to organizing the workshop on the Unit World Model's capacities to improve metals hazard and risk assessment. The objective of the Consortia and Eurometaux is to gain more understanding and support for the UWM by the scientific community before the debate on its use and relevance starts at EU, OECD or UN level (more information: Hugo Waeterschoot).

Further outreach of REACH

ICMM's Chemicals Management Working Group meeting in Toronto to review and define co-ordinated international programmes

ICMM's semestrial CMWG meeting took place in January in Toronto and was attended by several Commodities as well as by ICMM. Of particular relevance to the REACH programme were the discussions on the planning for the OECD CoCAP environmental guidance development and the update of MERAG. MERAG will be used as a vehicle to ensure input into the OECD Hazard Assessment Taskforce activities as well as for the ECHA Environmental guidance update planned for the second half of this year. The meeting reviewed the different relevant MERAG fact sheets, identified the key issues to be updated or complemented and identified potential examples. Each commodity/consortium was requested to take responsibility for a fact sheet. The report of this session will be circulated to the GEHS Risk Assessment Working Group (more information: Benjamin Davies and Hugo Waeterschoot).

CORRIGENDUM: Following the article that appeared in REACH News N°24, we wish to apologize for a mistake that appeared and has been corrected in red (thanks a lot John!) in the text below:

Restriction of Pb in consumer articles that can be mouthed by children

RAC also finalised the discussion on the restriction of Pb compounds in articles for consumer use after some back and forth discussions on the scope and the wording used in the Opinion, for example on mouthing time. The work done on alloys and submitted by the copper industry has been acknowledged by RAC and allows derogation from **the 0.05%** limit content if the concentration of lead in the brass alloy does not exceed 0.5% by weight of lead (expressed as metal).

Calendar

- 4 February: Exposure Scenarios Meeting – MCC (Brussels)
- 26 February: NeRSAP 2 (Brussels)
- 26-27 February: ECHA REACH IT User Group meeting (Helsinki)
- 19 March: Stakeholder Workshop on the nanomaterials Definition:, Brussels (restricted access)
- 20-21 March: CARACAL Subgroup on nanomaterials (Brussels)
- 25-26 March: ETEAM Conference: validation work of Tier 1 tools including MEASE (Dortmund)
- 27 & 28 March: WS on Applications for Authorisation submissions to facilitate an optimal submission and handling process – MCC (Brussels)
- 1 April: REACH Forum – MCC (Brussels)
- 2-3 April CARACAL (Brussels)
- 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)
- 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)
- 11-13 June : CARACAL
- 25 September: REACH Forum – MCC (Brussels)
- 17 December: REACH Forum – MCC (Brussels)

Acronyms

AofA: Assessment of Alternatives	OC: Operational Conditions
CARACAL: Competent Authorities for REACH & CLP	OECD: Organisation of Economic Cooperation and Development
ChESAR: Chemical Safety Assessment & Reporting Tool	OEL: Occupational Exposure Limits
CMR : Substances classified as Carcinogens, Mutagens or toxic to Reproduction	PROC: Process Code
CMWG: Chemicals Management Working Group	RAC: ECHA Risk Assessment Committee
COB: Close of Business	RCF: Refractory Ceramic Fibers
CoCAP: OECD Cooperative Chemicals Assessment Programme	RMM: Risk Management Measures
CoRAP : Community Action Rolling Plan	RMO : Risk Management Option
CSA: Chemical Scientific Approach	RoHS: Restriction of certain Hazardous Substances
CSR: Chemical Safety Report	RSPS-calls: REACH Strategic Planning Support -calls
DCG: Directors' Contact Group	SCL: Specific Concentration Limit
DU: Downstream User	SCOEL: Scientific Committee on Occupational Exposure Limits
ECHA : European Chemicals Agency	SEAC: ECHA Socio-Economic Committee
EEE: Electrical and Electronic Equipment	SETAC: Society of Environmental Toxicology & Chemistry
ES: Exposure Scenarios	SID: Substance Identification
IUCLID: International Uniform Chemicals Information Database	SIEF: Substance Information Exchange Forum
MERAG: Metals Environment Risk Assessment Guide	SME: Small & Medium Sized Enterprise
MSC: Member States Committee	SVHC: Substance of Very High Concern
NONs: new substances under the former New Substances registration scheme	UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials
	UWM: Unit World Model