



EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

"Emerging" from the REACH Forum meeting two weeks ago, I realised that my overall feeling after a day of exchanges and discussions was an immense gratitude towards you all. Presenting the 'essentials' of REACH programmes – which usually announce forthcoming increases in workload and stress-; highlighting new- not- yet-tackled-but-urgent issues and potential weaknesses of the sector, reporting learning lessons (with the "lesson" part often being tougher than the "learning") does not sound like the most attractive outline for a mid-September meeting. Knowing that in addition we had to present a financing proposal requesting additional efforts and commitment from all consortia rendered my sleeping pattern the night preceding the meeting rather interesting. However, "do not change slides or strategy at 4.00 a.m., wait for daylight to come" is a rule I fixed myself over the last years (after a couple of bad experiences). With reason, because the daylight actually became even brighter once the meeting began. Your presence, your attention, your input, your general support but also the expression of your concerns, altogether made it: feeling to be a group, the Forum being for us all the harbour and "ark of metals" to cross the choppy REACH seas.

As you will read below, September has been rich in winds and waves. Therefore in conclusion to this monthly REACH news editorial, I firmly believe that the most appropriate words are without any doubt 'thank you for being there!'

Violaine Verougstraete, EHS director Eurometaux

ECHA REACH activities: hot topics

ECHA COMMITTEES

MSC 31, HELSINKI 25-27 SEPTEMBER:

Workshop on new prioritisation scheme for Annex XIV: a constructive dialogue

MSC experts held a workshop on 24 September, in preparation of a new set of criteria to define priority substances for Annex XIV listing. ECHA circulated in advance a thought starter including several options. This thought starter was analysed during a webinar of the Eurometaux Authorisation and Restriction platform, so as to define our main concerns and suggestions. The workshop itself was open and constructive, and industry could effectively participate. The main suggestions to MSC on the criteria included: more emphasis (weighting) on PBTs and vPvBs and potentially also Endocrine disruptors, more equal weighing between "intrinsic properties scoring" and "exposure estimating criteria", and a review of the "Wide Dispersive Use" (WDU) criterion. Contrary to ECHA who promoted a scoring based on PROCs, the workshop proposed a factor based on the use type (Consumer, Industrial or Professional use) multiplied by relative volume. Hereby, they suggested -for the first time- a potential for refinement if mass flow data were to be available in the Registration dossier. This proposed outcome is certainly more aligned with Eurometaux's views than the present scoring system and ECHA's ideas of a more automated system. It was presented to MSC for consideration (more information: Hugo Waeterschoot).

Highlights of an "in-between" MSC!

The September MSC meeting is usually a transitional meeting with lots of reporting but -except on Dossier Evaluation- no in-depth discussion and decision making.

- With regard to Dossier Evaluation (DE): most Testing Proposals and Compliance Checks reviewed this time focused on the issue of mutagenicity testing (sequence and relevance of the different test types, waiving potential, etc...). The outcome of this complicated and quite important debate for the metal sector may require an update of the HERAG fact sheet. Its impact and consequences will be reviewed at the next Eurometaux Evaluation panel meeting.

- On Substance Evaluation (SE), MSC confirmed that the next CoRAP list (2014-2016) will become available for review and discussion at the next MSC meeting (November). A doubling of the number of substances for 2015 and a high number for 2016 are expected, presumably including several metal compounds. Member States also made good progress with the review and interaction with registrants of the 2012 substance evaluations. The 7 first draft decisions on SEs are expected for plenary review in November.
- On Authorisation: MSC took note of the launch of the Public Consultations on the new Candidate List substances and on the 5th priority list, which includes Refractory Ceramic Fibres (RCFs). High numbers of comments were noted on RCFs, which will be debated in November (also see below).
- MSC supported the outcome of the workshop on the prioritisation criteria (see above) and even emphasized more focus on PBT substances and a substantial review of the WDU criterion. Based on this MSC recommendation, ECHA promised to come forward with a criteria proposal end of October for a debate at the November meeting. MSC 32 in November will be extremely charged, resulting in a clear warning/request from the ECHA secretariat to Member States and industry to strive for a high level of efficiency and focus (more information: Hugo Waeterschoot).

Access to MSC for discussions on Authorisation prioritisation for accredited stakeholders: proposal to limit access

ECHA circulated a proposal to limit the representation of stakeholders to MSC deliberations on the priority selection for the candidate list. Only the formal Stakeholder Representatives (including Eurometaux, Cefic and Concawe) could attend in the future, which would exclude specific representatives for the substances under consideration (e.g. RCFs, phthalates, ...). The proposal was driven by a series of (internal industry) conflicts on who should represent a given substance. Eurometaux recognized the difficulties but nevertheless protested formally given this would reduce the potential for technical input/response during MSC discussions, a comment that was countered by ECHA and MSC since that kind of input rather go to the Public Consultation. While the proposal was tabled for MSC decision it was withdrawn at the last moment by ECHA based on the comment that *"the document caused misunderstandings and was therefore temporally withdrawn"*. It is unclear at this stage what those misunderstandings were but it seems quite unlikely that MSC will go back to its original intention (more information: Hugo Waeterschoot).

RAC 26, HELSINKI 9-13 SEPTEMBER:

Pb CLH

Pb was indisputably the substance that drew the most attention both for CLH and Restriction during the RAC week. RAC agreed to classify Pb metal as repro 1A (for fertility and developmental effects, plus a classification for lactation), without distinction of the physical form (massive versus powder). The discussion on the Specific Concentration Limit (proposal: 0.03%) has started but will only be finalised in December. Industry received the possibility to submit additional data in the coming weeks to further refine the calculations used by the Rapporteurs to derive the SCL and alleviate some uncertainties. However, the probability to achieve a higher SCL –that would have no/less impact on e.g. alloys, slags, recycling sectors where Pb occurs as impurity or is used for malleability reasons- seems very limited. To follow up: some RAC members stressed the need to take bioavailability into consideration for potency considerations (e.g. massive versus powder). Industry will try to further elaborate on this as well in order to prepare the December discussions (more information: Craig Boreiko, Steve Binks, Aggie Kotze, Violaine Verougstraete).

CLH process: information submitted after the Public Consultation

Industry, Eurometaux and RAC have now been faced several times with information/comments our industry experts wish to submit for consideration by RAC when the possible window for submission of input (Public Consultation) is over. This has mainly happened in the case of new issues appearing during the CLH debate (e.g. secondary versus primary effects, additional classification on lactation, uncertainties in methodology), for which industry estimated fairly and correctly contributed with their data/ interpretation. Such a possibility was however not built in the revised CLH process. Eurometaux discussed this several times with the RAC Secretariat. Maybe as a result, the ECHA Head of Classification Unit made a presentation at RAC 26 summarising under which conditions information submitted after the end of the PC would be considered (more information: Violaine Verougstraete).

Pb restriction: a second draft opinion on the Pb restriction was presented. Key issues for discussion in RAC were scope, derogations/exemptions, mouthing time (typical-worst case) and migration limits. The industry submission of release data from alloys (in saliva mimicking fluid) was qualified as high quality data and contributed significantly to the discussion on a possible migration limit rather than a concentration cut-off for alloys that would go for release testing. Unfortunately the hazard assessment part of the current restriction dossier that builds on the previous Pb in jewellery dossier (and associated uncertainties) could not be re-opened while the impact of this restriction case is larger. The discussion at RAC shall be finalised at the next meeting (more information: Craig Boreiko, Steve Binks, Aggie Kotze, Violaine Verougstraete).

Launch of the first Authorisation Application (AA), not necessary a precedent setting case

SEAC reviewed the first Authorisation Application submitted to SEAC and RAC thereby launching the Compliance Check procedure and in general the Authorisation review process. After a quite detailed introduction of the file, focused on the specific use of the substance in aeronautical applications, SEAC approved the compliance check but requested the registrant to clarify some technical aspects. While most interesting, the relevance of this first case is very limited and restricted to a check on how the process functions effectively, given the requested application is very narrow in scope, relates to a single company only and a very clear/simple case too, favouring the application. The debate in December on a recent series of AAs for phthalates would therefore - from a content/process perspective - be much more interesting for the metals sector (more information: Hugo Waeterschoot).

A difficult but reasonably fruitful debate on the Pb Restriction case

A significant proportion of the debate at SEAC was focused on Pb. Both the scope and a first review of the cost benefits assessments were the main points of attention. With regard to the scope the proposal is now restrained to articles that can be reasonably exposed and mouthed by children. SEAC pushed RAC to be clearer on what articles would fall under the scope and which would not, given this is the starting point for the cost benefit analysis. The Pb sector and Eurometaux raised concerns and provided extensive input on the analytical costs which were highly underestimated and the way how the benefits were assessed (sum of incremental benefits). A correct assessment would indeed challenge the validity of the cost/benefit conclusion! At this stage, it is unclear to what extent industries' comments will be considered, but at least the Pb sector achieved the possibility to submit additional explanations in writing. SEAC also appreciated the extensive technical input from the Cu-alloy sector. As a result of this input, and after a long and extensive debate, SEAC changed its position and accepted a higher Pb % for this type of alloys. Even more importantly, SEAC acknowledged the relevancy of saliva bio-elution testing. The latter and the other debates on the Pb case are setting crucial precedents and will require further work from Eurometaux and consortia, such as ensuring that bio-elution methods become more "standardized" and/or achieve international recognition (more information: Hugo Waeterschoot and Craig Boreiko).

SEAC settled dispute on Authorisation Review Time proposal

ECHA resubmitted a proposal to provide some clarity to RAC, SEAC and industry about suggested Review Times (RT) for previously granted Authorisation Applications. While it is up to Commission to decide, they had asked ECHA explicitly for an opinion from both committees. The proposal was debated at a joint RAC/SEAC session attended by Commission and the text was subsequently approved by SEAC. In general, RAC members contested to some extent their role in setting a Review Time but agreed with the principle to provide a signal if the applicants' AA is of good quality (green light), needs some improvement (orange) or lacks significant decisive points (red). SEAC considered standard timings of 4, 7 and 12 years, based on the applicants' requests and motivation and the RAC quality signal. The shortest RT would be proposed if the original application would be somewhat deficient or concerns a "bridging timing" (remaining time needed for a planned phase out). The longest RT could even be extended but would require extensive motivation based on factual evidence justifying the lack of economical or technical substitutes. The medium timing would normally be the standard for compliant AAs. While some experts and NGOs further criticized what they see as too lengthy RTs, ECHA's proposal received support from industry given it is a) balanced and b) provides some certainty to the applicant to consider the relevance of submitting an AA. The first experience with the RT will be reviewed next year by the Eurometaux Authorisation and Restriction platform (more information: Hugo Waeterschoot and Violaine Verougstraete).

AUTHORISATION

PUBLIC CONSULTATIONS (PC) ON AUTHORISATION STEPS: Metal sector first co-ordinated horizontal response on RCFs

The Public Consultation on the new suggestions for the candidate list runs until 17 October and includes Pb diacetates and Cd sulphide for CMR and Equivalent Concern (STOT). It is beyond doubt that ECHA will adopt the new proposals in Dec given the equivalent to present Cd/Pb substances on the candidate list. Cd sulphide warrants some attention given widely occurring as a natural impurity in primary materials. The Public Consultation on the proposal for the 5th priority list for Annex XIV closed on 23 September, raising a long series of responses on RCFs mainly from industry, given that they are widely used for thermal insulation, also throughout the metals sector. Eurometaux therefore facilitated and co-ordinated the response of the non-ferrous metals sector to the PC through the drafting of a consolidated set of contributions. The main comments focused on the difficulties with the definitions that make it very unclear what is covered and what is not, the split into two entries which doubles the cost, the intersubstitutability with substances of similar hazard profile and the absence of exposure due to controlled conditions during use, installation and removal of the insulation. Eurometaux members therefore do not support the listing given it will be inefficient and not contribute to a safer workplace environment. The November Eurometaux Authorisation and Restriction Platform will debate on the next steps and evaluate the relevancy and efficiency of a combined action for such 'horizontally-relevant' substances (more information: Hugo Waeterschoot and Michel Vander Straeten).

ECHA OTHERS

ECHA MANAGEMENT BOARD, HELSINKI 26-27 SEPTEMBER: 2014 ECHA work plan and 2014-2018 multi-year strategic plan adopted

The ECHA Management Board (MB) met in Helsinki and agreed amongst others on the ECHA 2014 work plan and the 2014-2018 multi-year strategic plan. Both are crucial documents for Eurometaux and Consortia to plan their future REACH activities. The 2014 work plan was already considered when Eurometaux drafted the outline for the REACH Forum programme and priorities. The EM REACH team plans to present the most important and relevant multi-year REACH objectives at one of the next Forum meetings. Eurometaux also requested Cefic (who represents industry in the MB) to raise the attention of the ECHA Executive Director for “more added value creation for the EU industry” on ECHA’s international programme. ECHA signs bilateral agreements with other countries while leaving industry completely out of this debate contrary to the countries ECHA is signing with! (more information: Hugo Waeterschoot and Guy Thiran).

Substance brief profiles: ECHA workshop on 3 December

ECHA is restructuring its dissemination portal to make it more accessible for “the public at large”.

The following 3 tier structure to present information on substances is envisaged:

- Level one: “info card” – simple information (substance name, EC-CAS numbers, C&L, uses)
- Level two: substance brief profile (in addition: physico-chemical properties, some information on human health and environmental endpoints, uses at substance level using use descriptor system (not company level))
- Level three: information which is currently disseminated

These plans will be discussed with accredited stakeholders at a workshop which will take place on 3 December at the ECHA’s offices in Helsinki (more information: Inneke Claes).

Targeted Compliance Checks and comments on draft decisions: *Some practical information*

For the regular compliance checks of a full dossier and for the assessment of testing plans, ECHA offers registrants the possibility of a scientific discussion. They provide contact details of the ECHA expert who can be contacted during the 30 day commenting period following a draft decision.

For targeted compliance checks, where ECHA checks a particular topic through submitted registration dossiers for different substances and by different registrants, this possibility of a one-to-one discussion with ECHA is not foreseen. ECHA prefers to organise webinars to explain to all registrants involved at the same time what the issue is and give recommendations on how to fill-in/correct the registration dossier. Companies have to use web forms to submit replies to draft decisions and this system does not allow industry to keep track of the actual submitted information other than by making a series of screen shots. ECHA acknowledges the problem, but due to confidentiality of the submitted information, the content of the submission cannot be sent by email. ECHA is assessing if - in the next upgrades of REACH-IT - it would be possible to make this information available in the REACH-IT account of the registrant (more information: Inneke Claes).

Commission REACH activities: hot topics/issues

Nanomaterials: Public consultations on the revision of the Annexes of REACH and on the definition of nanomaterials

The European Commission consulted stakeholders on 2 topics related to nanomaterials:

- 5 possible policy options to adapt the REACH Annexes and guidance documents to incorporate the necessary requirements for nanomaterials
- Definition of nanomaterials

The input into these consultations submitted by EPMF, IZA and Eurometaux can be obtained from the Secretariat (EHSAssistant@eurometaux.be). The results of the consultations as well as the Commission’s plans for the revision of the REACH Annexes will be presented at the 24 October meeting of the CARACAL subgroup on nanomaterials (more information: Inneke Claes).

A discussion with representatives from DG ENV/DG ENT on the impact of the Pb Specific Concentration Limit

Further to the discussions on the Pb metal classification and its associated SCL at RAC 26, Eurometaux asked for a meeting with representatives of DG ENV and DG ENT to a) brief them on the main outcomes and key issues of the September RAC discussions, b) update them on the assessment of the impacts of a 0.03% SCL for a number of sectors and c) explore possible way forwards. The meeting, which took place on 30 September, was constructive and allowed for fair exchanges. Commission identified a number of areas where further clarification/documenting would be valuable and made some suggestions for possible further efforts. A follow-up call was organised with ILA as most of those areas for clarification/input require specific Pb expertise and additional resources. A short report proposing further actions will be circulated very soon to the SCL- interested/affected metals and sectors (more information: Hugo Waeterschoot and Violaine Verougstraete).

EUROMETAUX REACH activities: hot topics/issues

EXPOSURE SCENARIOS TASKFORCE: streamlining exposure scenarios and updating tools

The Exposure Scenarios taskforce met on 23 September to discuss possible actions in the overall framework of the CSR/ES Roadmap promoted by ECHA, most industry sectors and a number of Member States. The Roadmap has as main objectives to improve the clarity and accuracy of the information provided along the supply chain, and to help industry update existing information already submitted to ECHA (CSR) or supplied to downstream users (ES). The project P7 - streamlining ES (part of the funding proposal submitted to the consortia) and aiming at improving consistency, standardisation and coherence of metals ES and their understanding by our downstream users; facilitating updates of ES and inclusion in IUCLID (sections 3.5 and 3.7) - was supported by the Taskforce. How CHESAR could possibly be used in this context –provided some metal-specific adaptations would be brought in the next version- was discussed as well as a possible update of the MEASE tool (project P8). The draft minutes will be circulated soon with a clarifying note on the ECHA guidance B8 (scope for exposure assessment) (more information: Violaine Verougstraete).

INTERMEDIATES: a reply from ECHA to our inquiry note and formatting aspects

ECHA has replied to the note we sent highlighting metal specificities in UVCB inquiries. They asked for some examples to better understand the metal cases. We are working to provide them with exhaustive examples and expect to have additional exchanges in the coming weeks. We are also further discussing with ECHA the possibility to use an inorganic UVCB (anonymised or hypothetical) as test case to enhance the reporting of such complex dossiers in IUCLID 6.1 and/or improve CHESAR so as to make it a possible supporting tool (more information: Federica Iaccino).

RECYCLED SUBSTANCES AND REACH AUTHORISATION: 3 September brainstorming session

Some 25 company, association and consortia representatives participated in the brainstorming session. They discussed a working paper that had been sent in advance in which possible regulatory overlaps or inconsistencies between the waste regime and the substance (REACH) regime were examined. The debates focussed on the criteria one might apply in practice to distinguish between the two regimes, especially for the 'materials' that might be in a grey area. Concepts such as 'impurity' and 'function' have been identified as playing a key role and will be further developed in a new paper under development and will be tested with some voluntary companies. Inneke Claes will present the first identified concerns to the ECHA Forum for Exchange of Information on Enforcement on 29 October 2013 (more information: Inneke Claes).

REACH FORUM MEETING 17 SEPTEMBER 2013

There was an excellent turnout for the meeting with sometimes very lively discussions. The main topic on the agenda was the planning of the 2014-2015 activities of the REACH Forum and the budget. The following topics were also covered during the meeting: intermediates/UVCBs, the use of REACH data for other purposes (including CoCAM), last information on ECHA evaluation activities, authorisation and classification. The meeting was concluded with an information exchange between consortia. The presentations and background material are posted on the REACH metals gateway and short draft minutes focusing on actions will follow shortly. The next meeting will take place on 17 December 2013 (more information: Inneke Claes).

COMMUNICATION ACTIVITIES

INFORMA CONFERENCE (4-5 SEPTEMBER): Substance evaluation a first public experience exchange

Eurometaux attended, and provided together with ECHA, a presentation on one years' experience with substance evaluation at the Informa Conference, zooming in on the need for an interactive relationship with the Reviewing Country and the need for an early identification and anticipation of the identified concerns in the CoRAP. The paper will be the basis for an internal Eurometaux review of the first Substance Evaluation experiences for debate/ training at the Eurometaux evaluation platform meeting in November (28 November). IMA (Roger Doome) presented an interesting presentation on the nanos experience under REACH). Differently than in the past the conference was attended by a number of lawyers making it probably less attractive for companies but more so for Eurometaux as it allowed to get some background information on e.g. the ongoing legal cases and opinions of the ECHA Board of Appeal. A review is planned for the next Authorisation and Restriction platform meeting (see calendar) (more information: Hugo Waeterschoot).

Further outreach on REACH

OECD

OECD visiting Eurometaux offices: an open debate on the future of CoCAM, metals risk assessment and grouping guidance

Joop De Knecht, coordinating several programmes in the Environment, Health and Safety Division for the OECD, visited the Eurometaux offices on 20 September to brainstorm among others on how to best plan the development of OECD Environmental risk assessment guidance for metals, as supported in June by the OECD Taskforce on Hazard Assessment (HATF). Eurometaux used this opportunity to express its opinion on the future of the CoCAM programme. Eurometaux underlined the importance of the MAD agreement and the added value for industry CoCAM & metal-specific guidance can play in this respect. The discussion identified a 'concept' that would combine both aspects for metals and inorganics. The future of CoCAM (starting second half of 2014) will now be discussed by an OECD Steering Committee but Eurometaux will provide comments in line with this 'concept'. The Consortia interested in the CoCAM review have been informed about the discussion and were asked to confirm whether they would be interested in a review under the present system or under the future system (more information: Violaine Verougstraete and Hugo Waeterschoot).

OECD CoCAM review on metals: Mo is progressing, while Cu and Co have confirmed their intentions regarding the CoCAM review

The OECD CoCAM review process was launched over the summer for a number of Molybdenum compounds. The International Molybdenum Association (IMOIA) submitted the dossier and the level of interest expressed by the reviewing OECD countries has been extensive (just under 200 comments were received from 6 countries). The time constraint of less than a month in which to respond to all comments is a significant challenge for IMOIA, and this was discussed with the OECD Secretariat. The next step in the process is face-to-face discussions in Washington at the mid-October CoCAM 5 meeting. Earlier this week, the Cobalt and Copper sector organizations formally expressed interest to participate in the CoCAM review under the present system (more information: Sandra Carey, Katrien Delbeke, Carol Pettit).

Eurometaux continues to promote at ECHA level the review of datasets provided by CoCAM as a quality assurance which should assist/facilitate with Member States' reviews for Dossier and Substance Evaluation (more information: Hugo Waeterschoot or Violaine Verougstraete).

Calendar

- 22-23 October: Workshop on CSR-ES roadmap, making the most on information in the CSRs (Helsinki)
- 24 October: Task Force on REACH Intermediates – MCC (Brussels)
- 24 October meeting of the CARACAL subgroup on nanomaterials – COM (Brussels)
- 29 October: REACH Enforcement Forum-16 - stakeholder open session – ECHA (Helsinki)
- 12 November: Authorisation & Platform Meeting – MCC (Brussels)
- 21-22 November 2013: 5th meeting of ENES (Brussels)
- 28 November: Evaluation platform meeting
- RAC -7, 2-5 December (Helsinki)
- SEAC-21: 9-11 December (Helsinki)
- MSC-32: 4-8 November (Helsinki) ; MSC-33 : 9-13 December (Helsinki)
- 17 December 2013: REACH Forum – MCC (Brussels)

Acronyms

AA: Authorisation Application	MB: Management Board
CHESAR: Chemical Safety Assessment & Reporting Tool	MSC: Member States Committee
CLH: Harmonised Classification & Labelling process	OECD: Organisation of Economic Cooperation and Development
CMR: Substances classified as Carcinogens, Mutagens or Toxic to Reproduction	PBT: Persistent, Bio-accumulative and Toxic Chemicals
CoCAM: Cooperative chemicals assessment meeting	PC: Public Consultation
CoRAP: Community Rolling Action Plan	PROC: Process Code
CSR: Chemical Safety Report	RAC: ECHA Risk Assessment Committee
DD: Draft Decisions	RCF : Refractory Ceramic Fibres
DE: Dossier Evaluation	SE: Substance Evaluation
ENES: Exchange Network on Exposure Scenarios	SEAC: ECHA Socio-Economic Committee
ES: Exposure Scenarios	STOT: Specific Target Organ Toxicity (classification endpoint)
HERAG: Health Risk Assessment Guidance for Metals	UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials
IUCLID: International Uniform Chemicals Information Database	vPvB: Very Persistent, very Bio-accumulative chemicals
MAD: Mutual Acceptance of Data (OECD)	WDU: Wide Dispersive Use