



EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

And here we are again, starting the summer with tired brains and bodies aching for quiet days, warmth and peaceful hours to share with the ones we chose...People run swiftly away from Brussels with holiday bags, leaving behind them the load of the last months, with the hope that it will have melted –or at least re-gained normal proportions- when they get back. It is the season of blossoming “out of offices” revealing here and there details of how one will get reacquainted with the feeling of having time for doing small but important things, rebuilding hereby his/her energy levels for the months to come.

In the office, the summer breath extracts us from the hamsters’ wheel and gives us the opportunity to collect and assemble the pieces of puzzles that have been spread all around over the last months. This healthy slowdown should allow us to go back to open trenches and do the key repair work we have been pushing off, due to lack of time or too much apprehension. The longer days and difference in rhythm somehow smooth the come-back of creativity and the required changes.

The Eurometaux REACH team is also going through changes in its staff and it seems like an opportune moment to reflect on the lessons we have learnt. Therefore, we will take the time to make sense out of this situation, in order to come back to you within a couple of weeks with a proposal of a stabilized and balanced structure for 2015, well-armed to affront the REACH challenges in front of us.

In the meantime, please let us wish you an excellent start of the break. Please do not hesitate to share your summer ideas or join us for the brainstorming meetings that will take place. Or have a sunny cocktail while checking our last page...

Violaine Verougstraete, EHS director Eurometaux

ECHA REACH activities: hot topics

ECHA COMMITTEES

RAC-29: Further capacity-building on authorisation applications, challenging cadmium restrictions and further actions to prepare the copper compounds CLH discussions

RAC, meeting from 2 to 6 June, extensively discussed authorisation applications for DEHP, DBP, Diarsenic trioxide and lead chromates. The discussions illustrated the delicate exercise in providing the right amount of information in the applications, the balance between trust and liability, simplicity and complexity, modelling and measurements in the descriptions. Eurometaux proposed to extract the horizontal learning lessons and precedent-settings from these first cases and to compile them in an equivalent of the annual ECHA Evaluation Report.

A first plenary discussion took place on the restriction of Cd and Cd pigments in artist paints and pigments intended for the manufacture of artists’ paints (Annex XV submitted by Sweden): ‘key issues’ including scope, exposure, starting point of the assessment were discussed. The Cd consortium had prepared this discussion in depth and was represented by Professor Erik Smolders (KUL), accompanying Eurometaux as stakeholder expert. The Public Consultation is still ongoing and the first in-depth discussion on a RAC opinion should take place in September.

On CLH aspects, ECHA proposed a new fast-track procedure for minor endpoints: selected hazard classes would be proposed for agreement in plenary through a list without further debate by RAC, thereby sparing some time that could then be devoted to more complex endpoints/discussions. This list of classes would be drafted after the Public Consultation and maintain the required transparency for stakeholders as agreement would still be in plenary. Downstream consequences would be looked at by ECHA based on the input provided during the Public Consultation. During the meeting Industry commented on the distinction to be made between harmonised endpoints and others and on the difficult assessment of

downstream consequences. Finally Eurometaux met the head of the Classification Unit and the Scientific Dossier Holder of the copper compounds classifications to discuss the organization of the next steps: the human health endpoints of the copper compounds CLH dossiers will be discussed in September RAC-30, while environment is scheduled for RAC-31. ECHA will organize an information session on the environmental aspects of the copper compounds dossiers in September alongside the meeting (more information: Violaine Veroustraete).

SEAC-23: Two restriction proposals on cadmium treated differently

The first restriction discussed was a Swedish proposal to adapt the existing restriction on cadmium and its compounds in paints. Industry reiterated its opposition in principle of this 'fast-lane' adaptation given the restriction was proposed to prevent a potential use that does not exist (Cd traces in marine antifouling paints) and there is consensus that no risk could be demonstrated. SEAC however endorsed that proposal, but displayed much more critical views when discussing the other Swedish initiative, i.e. a Restriction on cadmium in artist paints, where it expressed doubts about the relevance and proportionality of the proposed risk management approach. It is therefore not sure SEAC members will agree with the proposed restriction in September. Artists use Cd colours because of their brightness and resistance to fade. The artist community reacted fiercely during the ongoing Public Consultation indicating that more effective alternatives exist (labelling or collection of the cleaning waters/remaining tubes). It will be most interesting to see how SEAC will react on this (more information: Michel Vander Straeten and Hugo Waeterschoot).

SEAC-23: SEA discusses Authorisation for As₂O₃ in zinc electrowinning

SEAC thoroughly discussed the first Authorisation applications for a metal compound, i.e. As₂O₃ used in the removal of metal impurities from the leaching solution in zinc electrowinning processes. The applications went through the SEA route (non-threshold substance), which means that SEAC will have to decide on whether the benefits of continued use outweigh the costs for society. SEAC took note of additional questions on exposure raised by RAC and of what were perceived as conservative man via environment calculations. They looked at the overall proportionality of the cost and benefit data. There was a discussion of the cost increases linked to alternatives which had been checked by the rapporteurs for their chemical consistency (more information: Michel Vander Straeten and Hugo Waeterschoot).

SEAC-23: SEAC clarifies its views on how it will evaluate applications for authorisation

SEAC debated on how to deal with applications for uses that are too widely or unclearly scoped. Such applications will be examined but risk a negative opinion, a shorter review period and additional conditions. The Committee is still divided on what to do when RAC rejects the adequate control claim for an application for authorisation. It agreed that the dossier has to be evaluated further, under the SEA route, although it may not contain the necessary socio-economic data. But, it remains unclear how much time and efforts the SEAC rapporteurs should invest in trying to develop a view on the cost and benefits related to that application. It was also agreed that each application would be evaluated independently, on its own merits and irrespective of the presence of other substances on the applicants' premises. There will thus be no combination of exposures, which can be important in the context of surface treatment for example. SEAC made clear that an existing national ban should not influence the decision on granting or refusing an authorisation (more information: Hugo Waeterschoot and Michel Vander Straeten)

MSC-36: Fierce debate on the relevance of a 6th prioritisation list for authorisation

MSC debated early June the proposal from ECHA for a 6th priority list. ECHA selected all substances with a high scoring after applying the new prioritisation method that was agreed end 2013, resulting in a list of 21 substances including Borates, Coal Tar Pitch, and a series of Pb compounds. MSC members were divided on the value and relevance of presently pursuing with a new list, noting the initiative of the Commission to review the efficiency and relevance of the authorisation process. Actually, a majority proposed halting the system temporarily. Eurometaux requested a postponement of the 6th list motivated by the concerns raised by MSC and by the legal obligation only applying every second year. Eurometaux also questioned how the new prioritisation selection criteria could be successfully applied given the Candidate List consisted mainly of CMRs, while PBTs and Endocrine Disruptors are aimed for under the new method. The selection should therefore be postponed until the Candidate List is complemented with such substances. ECHA reacted by stating that MSC cannot reject the development of a 6th list this year given this task was within ECHA's Working Plan, agreed by the Management Board (more information: Hugo Waeterschoot).

MSC-36: Start of the public consultation on the 6th list in September, also SEA data required this time!

Eurometaux requested at the meeting to start the Public Consultation after the summer given the difficulty to collect adequate information and to reach downstream users during the holiday period. After long deliberations, MSC suggested launching the consultation in September, starting with all 21 high-scored substances, but following the comments received it clearly aims to reduce the number of prioritized substances. The ECHA Public Consultation collecting information from industry and stakeholders - that could alter or confirm the priority scoring - will consequently run from early September until November. It was also confirmed by the Commission that in parallel they will launch a Public Consultation to collect socio-economic impact information on the substances proposed for the 6th list. They proposed an indicative questionnaire for

doing so. The Eurometaux Authorisation and Restriction platform has therefore initiated a communication exercise to its membership to raise awareness for this important parallel SEA public consultation, to stimulate companies, consortia and downstream users to start this activity over the summer (more information: Hugo Waeterschoot, France Capon and Aggie Kotze).

MSC-36: Substance Evaluation (SE), a review of last years' experience and exchange on the final steps of SE reporting

MSC reflected on the progress made with the SE process over the last 3 years. This largest REACH programme is indeed nearing its full first cycle (from CoRAP selection to conclusion setting). Overall, MSC concluded that there was the need for more harmony concerning the level and quality of the SEs and discussed measures on how this could be promoted. This issue as well as the need to communicate the horizontal learning lessons from Substance Evaluations (e.g. how to handle nanoforms under REACH, or how to assess regional monitoring data, ...) were raised by Eurometaux as the main concerns of industry in a statement consolidated with Cefic. MSC also debated how they would not like to go forward with the Publication of the Substance Evaluation Report (SER) (in addition to the SE decision) and prepared an opinion on this for the upcoming CARACAL. Cefic and Eurometaux agreed to intervene on this at the CARACAL session given the SER is a critical support document for industry to understand the basis and ground of the SE decision. MSC also discussed the final steps of the SE process, i.e. when industry has submitted its testing obligations or information gathering to ECHA, as resulting from a SE decision. They debated the conditions of the review of this information and the modalities to conclude on it (either a closure by preparing "a conclusion document" or non-compliance by preparing a Statement of Non-Compliance (SONC) for the Member States (more information: Hugo Waeterschoot).

ECHA MEETINGS

ECHA management board: Eurometaux attended the June meeting in the name of Industry

Guy Thiran attended the ECHA Management Board meeting. Besides the classical management topics the most interesting agenda items for industry covered the changes agreed on the ECHA Multi-Annual Working Plan 2014-2018 (MAWP) and a debrief on ECHA's Board of Appeal. On the MAWP the Management Board concluded that the annexes will be reviewed annually whereas the strategy and the body of the text will be fixed for five years unless there is an imminent need for changes. This also helps industry to better anticipate and plan REACH activities for the years to come. Several Management Board members emphasized that the progress with ECHA recommendations for the Authorisation List should continue as planned, calling for the separation of the ECHA process from policy developments at Commission level. After more than 40 appeals, the Board of Appeal became a mature body of ECHA, delivering high quality decisions in a timely fashion. It was concluded by the Management Board as well as by industry that the appeal system is functioning well and that the appeal proceedings can help to clarify grey areas of the legislation and uncover shortcomings in the REACH processes (more information: Guy Thiran and Hugo Waeterschoot).

Commission REACH activities: hot topics/issues

SVHC

Endocrine disruptors: Release of a route map and the start of an expert group on Endocrine Disruptors to speed up identification as SVHC

Endocrine Disrupting properties are specifically listed as endpoint of high concern for SVHC identification. Given there is no existing classification system for endocrine disruption, ECHA created an expert group to identify substances presenting such properties for REACH as well as for the Plant Protection Products and the Biocidal Products Regulation. The Commission has released a roadmap on Endocrine Disrupting Chemicals (EDCs) to define criteria to identify endocrine disrupting chemicals in the context of EU legislation. The roadmap defines options for regulatory decision making under REACH (baseline scenario) or specific sectorial legislation underlining the need for risk-benefit analysis and proportionality assessment before recommended risk management measures like SVHC listing. Consortia could at this stage already screen to see if their substance would fit the WHO/IPCS hazard definition for EDCs so that they can act/respond to the Public Consultation on the roadmap that will take place later this year (more information: France Capon and Hugo Waeterschoot).

EUROMETAUX REACH activities: hot topics/issues

AUTHORISATION

Authorisation and Restriction platform meeting

The Eurometaux Authorisation and Restriction platform held an extraordinary meeting on the 17th of June to reflect on the outcome of the MSC-36 meeting in respect to the status of the 6th prioritisation list. It was concluded to proceed advocating the abandon of the 6th list until more PBT/ED substances have entered the Candidate List and until industry has had more time to anticipate information needs for a correct priority setting, given the recent change of the selection criteria. Eurometaux was also tasked to check with Commission if the parallel socio-economic impacts Public Consultation would take place later this year and if the questions could be made available well in advance given the importance of this process in the final selection of chemicals for authorisation (more information: Hugo Waeterschoot, France Capon and Aggie Kotze).

REACH and recycling: Commission visits Metallo-Chimique

On 24 June 2014, 8 representatives from the Commission (DG Environment and DG Enterprise) joined an industry delegation for a visit of Metallo-Chimique and to discuss the issues recycling has with REACH, especially authorisation.

Industry explained i.a. the technically and economically important links between various recycling loops, involving many metals (likely to fall under authorisation or not) and the potentially huge disruptive effects of Authorisation affecting complexly inter-twinned value chains. The notion of 'recycling leakage' out of Europe was discussed. In our next steps, we will address the Commission's invitation to provide data or develop illustrative cases to help them better understand Industry's concerns about the impacts of authorisation on metals and their recycling. Such an input will already have to be ready for the public consultation on the 6th priority list (Pb in particular), which will be launched in September. (more information: Michel Vander Straeten and Patrick Van den Bossche).

Consortia: Support for planning on authorisation preparedness

Several Consortia invited Eurometaux to speak at their REACH General Assembly meetings to raise the awareness of their members for the potential upcoming listing on the authorisation list of chemicals of relevance for them. While companies are usually well aware about the impact of the authorisation scheme for the substance they manufacture, further attention should be paid to the "potential collateral damage" associated with the listing of substances like borates used in flux materials for slagging, or hydrazine used in high temperature anticorrosive applications. Such applications are widespread. Eurometaux provided further guidance on what kind of advocacy and preparatory activities could be most effective to either delay or avoid the listing or, in the case this would be unavoidable, to plan for addressing it in the best way (more information: Hugo Waeterschoot).

CLASSIFICATION

Pb SCL: further advocacy at all levels and a bioelution talk at CARACAL

Early June, DG ENT indicated that they had not managed to convince DG ENV to go for a different 'way forward' in the 7th ATP than taking over the RAC Opinion. In follow-up a call was held with the dedicated taskforce and several advocacy actions were launched. Both the inter-service consultation at Commission level and Member States have been targeted by EM sending letters to high-level members of staff in DG Trade, DG ENV, DG ENT and contacts with MSCAs to reiterate our key messages. A number of companies have also contacted the recently elected MEPs. We would like to thank here the members of the taskforce for their contagious energy in addressing this issue. The draft 7th ATP should be briefly discussed at the next CARACAL meeting on 8-9 July before going to the REACH Committee in September. Eurometaux has been invited to give a short presentation on 'bioelution' at the meeting, in the hope to identify a lead country to bring the concept to OECD, a key aspect in the regulatory acceptance of bioelution results (more information: Violaine Verougstraete, Steve Binks and Hugo Waeterschoot).

Meeting French authorities on Pb SCL in Paris: a challenge

A3M managed to organize on June 20 a meeting with representatives from the French Ministry in charge of CLP (Direction Générale du Travail), Sylvie Dugeon (MSCA contact) as well as a representative from the Direction Générale de la Compétitivité, de l'Industrie et des Services. Eurometaux participated as well. The discussion illustrated again how difficult it can be to take a step back from a specific mandate to consider an issue in a more holistic way and to fully comprehend the possible consequences of a decision (like a classification at the workplace) on other aspects like market perception, blacklisting, trade distortions and recycling incentives. As impact assessment and communicating data and outcomes to regulators will be tools we will need to handle more and more, it is essential we continue to build capacity on these aspects (more information: Martine Heulot, Sébastien Sureau and Violaine Verougstraete).

METAL-SPECIFIC REACH APPLICATION TOOLS AND CONCEPTS

Bioelution workshop: *report and presentations circulated*

A report summarising the main outcomes and recommendations of the May 22 bioelution workshop, kindly revised by the chair Dr. Helmut Greim and the speakers, was circulated on June 10 to the participants of the workshop with the presentations. The report was also sent to several contact points in ECHA and the Commission. One of the main conclusions of the workshop is the need to further work on the standardization of the protocol and to streamline the interpretation of the results. To support the latter, the bioelution roadmap will soon be revised in line with the comments received at the workshop. Further support of a lead country will be sought for to bring the concept to the OECD Testing Guidelines platform (more information: Violaine Verougstraete).

COMMUNICATION ACTIVITIES

Informa legal conference: *feedback on ECHA-MS REACH Enforcement (REF) programmes*

On the 24th of June at a workshop co-hosted by lawyer offices and Informa, Eurometaux attended and gave a talk on its experience with Evaluation. The workshop was interesting, providing an excellent report of the vice chair of the ECHA-REACH Forum on the outcome of the REF 3 programme and the planning for REF 4. The REF 3 report on the REACH compliance of importers was recently posted on the ECHA website. More than 3600 registrations and > 500 importers were checked. REF 3 concluded among others to a higher than average awareness level and low non-compliance rate for the metals sector (4%) while the average for manufacturers was 16 % and the overall average > 25%! Importers scored amongst the worst and several non-compliance follow-up actions were taken. National inspectors will now start soon REF 4 focusing on Authorisation compliance in the supply chain. Substances will be reviewed as soon as their Sunset days of Annex XIV expire. As₂O₃ was quoted as one of the substances included in the program noting a low number of downstream users requested for an application. The Forum speaker further announced new Forum activities to increase harmony on the follow-up on SONC letters (Statements of None Compliance) (more information: Hugo Waeterschoot and Caroline Braibant).

Further outreach of REACH

OECD

OECD Taskforce on Hazard Assessment: *support for developing metal guidance at OECD!*

Eurometaux participated in the OECD Taskforce on Hazard Assessment meeting on June 10-11, among others to ask for the support from the taskforce to develop OECD guidance on the environmental risk assessment of metals, based on the MERAG fact sheets. The MERAG fact sheets are currently updated to include the most recent experience, acquired in the EU (REACH, CLP) or elsewhere. An ICMM-EM proposal had been circulated in advance of the meeting, proposing to focus first on the following key concepts for metals: data handling, read-across and bioavailability correction. It was proposed by the OECD secretariat to hold a workshop on the topics of bioaccumulation and biomagnification assessment for metals and inorganic metal compounds early 2015. The proposal and presentation were supported by the Taskforce, also thanks to the contacts companies, commodities, ICMM and Eurometaux had with authorities ahead of the meeting, e.g. in Australia, Canada, China, Denmark (thanks all!). Also ECHA and the EU Commission supported the initiative. The first step is to finalise the update of the MERAG fact sheets and their review by industry and subsequently by the UK Defra, a key MERAG partner. A number of other topics of interest were discussed during the meeting like a GHS global list, combined toxicity, a Canadian guidance on organometals, the future of CoCAM; further detailed in the highlights circulated by Eurometaux on 16 June (more information: Violaine Verougstraete, Ben Davies and Hugo Waeterschoot).

OECD Harmonised Template on Uses and Exposure information: *a high speed global project*

The OECD Taskforce on Exposure Assessment is proceeding further with the drafting of the harmonised template to report use and exposure information, under the very efficient lead of ECHA. This initiative is supported actively by a number of non-EU OECD countries like the US, Japan, Canada, Australia. Several calls were held in June, both on the purely OECD aspects and on the possible 'consequences' on REACH and IUCLID 6.1 (with the EU countries and EU industry). Eurometaux sent in some comments to support the possibility to report measured data, bioavailability and 'release from articles' data when available. We also supported the introduction of the chemical entity concept, a kind of router to structure information provided in IUCLID in case of complex dossiers like UVCBs, Multi Constituent Substances (MCS), classified impurities, etc. The OHT should be tested for its feasibility: if you are interested to test the format, please let us know! (more information: Violaine Verougstraete).

OTHERS

Taiwan

From information provided by Dieter Drohmann, Chemservice Gmbh: The chemical inventory of Taiwan allows to nominate additional substances through a “grandfathering” procedure to get listed on the ECN inventory. A chemical substance, that was imported, manufactured, handled, used and sold in Taiwan from 1st of January 1993 – 31st of December 2011, is subject to the second supplementary ECN procedure. So follow this last chance to easily nominate your substance to the Taiwanese inventory, as the New Substances procedure (NCN) will start as of 2015. The time window for nomination from 1st June - 31st July 2014 is quite short, reason why we are recirculating this information (more details: Hugo Waeterschoot) .

Calendar

- **9 July:** REACH cross-sector meeting (Brussels)
- **8-9 July:** CARACAL (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)
- **1 October:** Director’s Contact Group (Brussels)
- **21-22 October :** REACH Seminar (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

CARACAL: Competent Authorities for REACH & CLP	MERAG : Metals Environmental Risk Assessment Guide
CLH : Harmonised Classification and Labelling process	MCS: Multi Constituent Substances
CLP: Classification, Labelling & Packaging Regulation	MSC: Member States Committee
CMR: Substances classified as Carcinogens, Mutagens or toxic to Reproduction	NCN: New Substances Procedure - New Chemical Substance Notification (Taiwan)
CoCAM: Cooperative chemicals assessment meeting	OECD: Organisation of Economic Cooperation and Development
CoRAP : Community Action Rolling Plan	OHT : OECD Harmonised Template
DBP: Dibutyl phthalate	PBT : Persistent, Bioaccumulative and Toxic Chemicals
DEHP: Di(2-ethylhexyl)phthalate	RAC: ECHA Risk Assessment Committee
DEFRA: Department for Environment, Food & Rural Affairs	REF: REACH EnFORCEment
ECHA : European Chemicals Agency	SCL: Specific Concentration Limit
ECN: Existing Chemical Substance Nomination (Taiwan)	SE: Substance Evaluation
ED: Endocrine Disruptor	SEA: Socio-economic Analysis
EDC: Endocrine Disrupting Chemical	SEAC: ECHA Socio-Economic Committee
GHS: Global Harmonised System / Standard	SER: Substance Evaluation Report
ICMM: International Council on Mining and Metals	SONC: Statement of Non-Compliance
IPCS: International Programme on Chemical Safety	SVHC: Substances of Very High Concern
IUCLID: International Uniform Chemicals Information Database	UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials
MAWP: Multi-Annual Working Plan (ECHA)	WHO: World Health Organization

REACH on the BEACH

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APPLICATION
BORATES
CONSULTANT
ECHA
EXPOSURE
HYDRAZINE
MEASE
MECLAS
RESTRICTION
REVIEW
RMO
SUNSET
TIER

A A I Z L I Q S P Z L D Z I I
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