



## EUROMETAUX REACH PROGRAMME

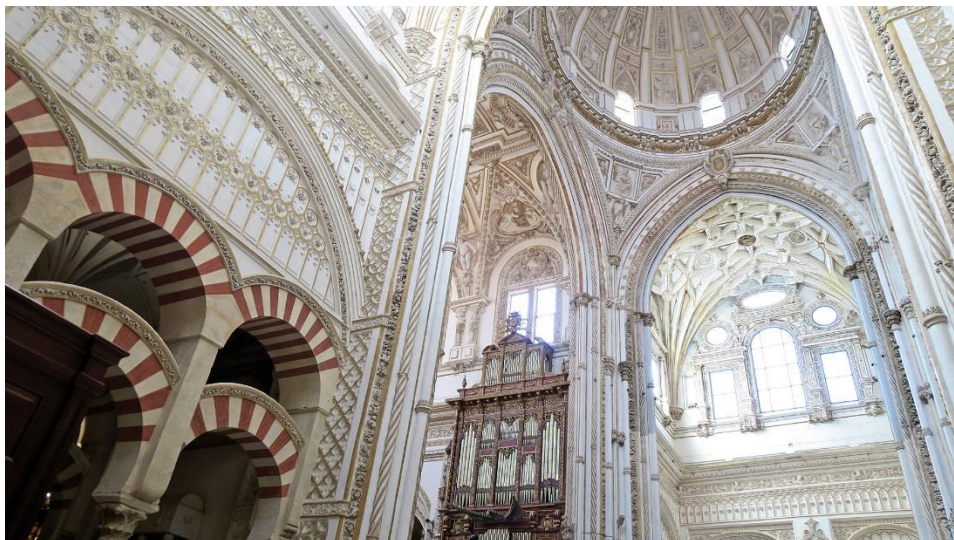
Dear REACH Forum member,

June has been a “floating” month. By the continuous rain that even succeeded in reducing the croaking frogs to calm, but mostly by emotions. A carousel of feelings, from large-scale to punctual reactions, engendered by the violence and sadness of the further bombings and the increasing uncertainties, uttered in shouts during football matches (a therapy for Belgium, even if on a temporary basis) or in silence when discovering the results of the UK referendum. A merry-go-round where sentiments are exacerbated and questions are coloured far beyond reason, driven also by the never easy pre-summer break rhythm. Can I let my daughter leave for Togo for one month without being sure she is connected; can I forgive John Cleese, my hero for so many years, for having altered “Mr Fawcett” from refined British humour to basics, can I still smile at that Member State claiming that guidance produced by industry is obviously biased, can I continue to whistle ‘always look at the bright side’ to my kids in the morning, can I look at changes as opportunities ...? Oh, the benefits of rationality! Dissecting the problems one by one, rationalising the steps, drawing pros and cons for proposed (multiple) solutions, discriminating outcomes and consequences: isn't this perfectly relaxing? No wonder some (regulators or scientists) prefer reason (A. Huxley: “Unlike the masses, intellectuals have a taste for rationality and an interest in facts”) over emotions.

After an overwhelming June, rationality sounded close to a holiday programme. Unless you do the mistake to take with you – following one of those New Years’ resolutions to become more cultivated in 2016- Nietzsche’s works as a summer reading. “In everything one thing is impossible: rationality.” This brought me back to square zero.

It is finally in Cordoba that I found a way to reconcile emotions with reason: the fabulous Mezquita, large enough to host reasoning and beliefs, passions and analysis, intuitions and reasons, celebrating the best of human’s nature in the end: the combination of all winds and elements. Or to use a formula from another philosopher - a Brit, as I could not do without-: “A man demonstrates his rationality, not by a commitment to fixed ideas, stereotyped procedures, or immutable concepts, but by the manner in which, and the occasions on which, he changes those ideas, procedures, and concepts”(S. Toulmin).

Enjoy the summer!



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Violaine Verougstraete, EHS director Eurometaux

# ECHA REACH activities: hot topics

## ECHA COMMITTEES

### **RAC-SEAC Chromates applications: *first large batch of chromates AfAs agreed at SEAC and RAC after challenging debates***

RAC-37 and SEAC-32 debated amongst other applications, the 5 outstanding uses for chromates submitted by the CTAC consortium, a large upstream application coordinated by importers and covering uses such as mixing and formulation, functional chrome plating and surface treatment for different sectors. RAC concluded to a “2 µg CrVI” reference value for the SEAC excess cancer risk impact assessment, stressing though that this value should not be considered as an endorsed ‘safe level’ given chromates were assessed as non-threshold substances. RAC also calculated the excess cancer risks that, for several uses, were much larger for the local Man via the Environment (MvE) scenario than for workplace scenarios. RAC further recommended a series of monitoring requirements and further exposure reduction measures. RAC made a recommendation to SEAC on the Review Period for uses where large uncertainties in the exposure situation were remaining. SEAC reviewed the different uses in detail, noting the wide scope often applied for and the differences in the extent and the level of proof on the information on alternatives between the uses. In general, SEAC concluded a 7 to 4 years Review Period, which was significantly lower than what the sector had requested (usually 12 or 7 years), based on the Assessment of Alternatives’ (AoA) uncertainties, the large impact of the MvE scenario and RAC’s recommendations for monitoring and exposure reduction conditions. SEAC added an additional condition proposing to the Commission to include a request for a more specific (narrow) scope of the uses applied for when the applicants submit their halfway review report. Eurometaux and Cefic reported the outcome and debated it with the sector. The main conclusions and learnings from this first large upstream application will be reviewed at the next Eurometaux Authorisation and Restriction platform meeting (28 September). ECHA also invited Cefic and Eurometaux to set up a review workshop early 2017 to draw learning lessons from this large metal Authorisation experience (more information: Violaine Verougstraete, Michel Vander Straeten and Hugo Waeterschoot).

### **MSC-48 – 7<sup>th</sup> Priority List: *for the first time debated in MSC, Article 58 (2) being the main challenge***

The second week of MSC-48 focused amongst others on the first debate of the draft 7<sup>th</sup> prioritisation list for Authorisation. Hugo Waeterschoot and Steve Binks attended the discussion on this item. The draft list contains in total 11 substances including 2 perborates and 4 lead compounds widely used in the lead battery sector, by far the largest use for lead compounds. Besides a short discussion on the (too short) Transitional Arrangements (Latest Application Dates or LADs), the debate focused on the lead compounds and in particular the relevance of the application of REACH Article 58 (2). The Rapporteur presented its first initial opinion, claiming that industrial workplace uses of the 4 lead compounds could be seen as meeting Article 58 (2), a conclusion concurred by ECHA. In addition, the Rapporteur concluded that the substitution pressure for batteries manufacturing was present for batteries covered under RoHS and ELV, which would support their exemption from Authorisation. Whilst recognizing this positive evidence for Article 58 (2), ECHA continues to reject the overall applicability of this exemption for the 4 lead compounds based on Man via the Environment concerns and in particular to prevent impacting the Commission’s power to use authorisations as a way to reduce exposure to the aquatic system under the Water Framework Directive. Eurometaux reacted by stating that this goes beyond the mandate of ECHA on the prioritisation process (more information: Steve Binks and Hugo Waeterschoot).

### **MSC-48: *first series of EOGRTS Testing Proposals reviewed***

Since the Extended One Generation Reprotoxicity Test (EOGRTS, OECD 443) was formally included in the REACH Annexes substituting the 2-generation reprotoxicity test (OECD 416), the Commission has sent more than 200 testing proposals for 2-generation studies back to industry. Industry got 90 days to submit a new proposal for the EOGRTS to provide evidence in order to design this higher tier test (the need for an F2, and sub cohorts for neuro-and immunotoxicity assessments). MSC debated a first extensive batch of updated Testing Proposals leading to experience building on what motivation is seen as sufficient and what is not. MSC also agreed on a decision tree whereby the 90 days test is used as a precursor to define the conditions for the EOGRTS. ECHA was mandated to review the interim recommendation of industry on the latter. The new experience and the decision scheme will be reviewed at the next meeting of the Evaluation platform on 17 November (more information: Hugo Waeterschoot).

## ECHA MEETINGS

### **Recycling and Authorisation: *the consultant, pilot case companies and Eurometaux presented the outcomes of the study***

A Eurometaux delegation, including Mike Holland, the independent consultant who conducted the Recycling and Authorisation study and representatives from the involved companies, met with a senior ECHA staff delegation on 6 June to exchange on the outcomes of the study. This was an opportunity to launch a debate on potential mitigation measures to prevent or limit the

impact of the Authorisation scheme on the recycling sector. The overall conclusions of the study were presented by Mike Holland, whilst Aurubis, Metallo Chimique and Umicore elaborated their individual pilot cases. Eurometaux complemented the briefing/discussion session by summarizing the issues that could hit the sector, highlighting their scale and proposed suggestions for “prevention or mitigation” measures. All depend on the legal interpretation of some REACH obligations, but are based on present experience with applications, with the main direct effect being related to the “*mixing for source and process optimisation*”, “*Annex XIV listed substances as constituents of UVCBs*” and the “*process chemical or intermediate status of carrier metals like Pb or Ni in e.g. precious metals refining processes*”. In addition, the study indicated where significant indirect effects could be expected, like on the availability of sourcing materials and the disposal of authorised impurities. ECHA welcomed and appreciated the study as well as the suggestions for mitigation measures, confirming they would further investigate the study reports and assess how and under which activities/programmes some of the suggested mitigation measures could be taken forward. As a follow-up of the meeting, ECHA visited the Umicore recycling plant in Hoboken on 28 June, checking the relevance and extent of the conclusions made in the case study. The visit confirmed the conclusions and especially their scale, therefore helping ECHA to understand better the importance of resolving the authorisation pressure for the recycling sector (more information: Violaine Verougstraete, France Capon, Michel Vander Straeten and Hugo Waeterschoot).

#### **Data-Sharing: ECHA Guidance still does not address key implementation concerns!**

The revision of the ECHA Guidance on data-sharing was seen as a last opportunity to make data-sharing expectations consistent with the REACH Regulation, and in particular to ensure that the requirements such as those of ‘unanimous consent’ and ‘making every effort’ could be implemented in a practical manner. However, at its 15 June meeting, the Partner Expert Group (PEG) discussed a revised version of the Guidance that addressed many other details, but not those considered as crucially important for Industry. As agreed by the REACH Forum’s Data-Sharing Taskforce, comments will be prepared on the version of the Guidance circulated by ECHA after the PEG meeting in early July, and a letter will be prepared to alert DG Secretariat-General on aspects which are clearly going beyond the legal text and/or missing in the updated Guidance, and would go against the principle of Better Regulation. Such aspects include: the change in rules between 2010, 2013 and 2018 which effectively creates unfair situations vis-à-vis early registrants; no definition of “potential registrants” who could challenge the data-sharing conditions applicable in each case even if it does not register in the end; no practical recommendations on how to achieve “unanimous consent” or “making every effort” in practice, giving all rights to one unique undefined potential registrant; the need to justify/allocate administrative costs to specific substances and tonnage band requirements; and ECHA’s reluctance to give any recommendation on the ideal minimum date by which potential registrants should approach existing co-registrants to discuss data-sharing conditions. The next meeting of the Data-Sharing TF will take place towards the end of August, in order to finalise the advocacy approach towards the Commission. Concawe and Cefic have been invited to join this advocacy effort (more information: Caroline Braibant).

#### **Management Board: the BoA annual report and a reflection on trends for future ECHA activity are highlights**

The ECHA Management Board (n° 42) met in Helsinki on 22 and 23 June. Cefic and Eurometaux reviewed in extenso the meeting documents identifying issues for interventions and defining the key documents for industry (Eurometaux’s input is available on request). The Annual report of the Chairman of the Board of Appeal was one of the more important briefing documents describing in summary the outcome and consequences of the Appeal cases finalized in 2015 (like on OSOR and on Intermediates (Vecco-case)). It further demonstrated that the outcome of the BoA appeals and deliberations, changes the interpretations of ECHA and the Committees thereby effectively impacting the dossier and substance evaluation decisions. The paper will be distributed to the REACH Forum as soon as formally released by ECHA. A second most interesting document provided background and input for the MB brainstorming workshop on the next strategic plan covering the period after the next registration deadline. The briefing note provided 4 trends to consider for the future role and tasks of ECHA (in general): from continuing ongoing activities at incremental improvement rate, over integrating REACH with other risk management legislation like RoHS, ELV and others, up to real “out-of-the-box thinking” on ECHA becoming an enabling/supporting agency to strengthen industry’s capacity to produce and use chemicals. The outcome of this MB debate (not yet received from Cefic at the publishing of the REACH news) together with the trends briefing paper will be excellent preparatory material for the Eurometaux Chemicals Management seminar in October (more information: Guy Thiran, Violaine Verougstraete and Hugo Waeterschoot).

## **NANOMATERIALS**

#### **Despite Commission’s delay in amending REACH Annexes, ECHA updates its Guidance: Industry to prepare**

Four ECHA Guidance documents have been drafted or updated in order to clarify how to assess nanomaterials under REACH: an appendix to the Guidance on Registration to define ‘nanoforms’, an appendix to the Guidance on Information Requirements and CSA on grouping and read-across of nanomaterials, and new guidance documents describing how to address human health and environmental hazard information requirements. Eurometaux comments have been prepared by the respective PEG representative and the Nano Taskforce and submitted to ECHA. As regards nanoforms, the key concern relates to the

undistinguished reference to surface chemistry, surface treatment, and coating, which mean different things in Industry's jargon. As regards the application of read-across and grouping on nanomaterials, and hence the human health and environmental assessment of nanomaterials, the guidance documents incorrectly assumed that effects of the nanomaterials would always be different from those of the coarser forms of the same substance, and thereby generally miss covering how data on such coarser forms may be suitable for nanomaterials, or vice-versa. Many information requirements are made nanomaterial-specific when they are actually not specific to nanomaterials. ECHA will now revise the various documents in light of these comments and recirculate updated versions to the PEGs. After that, the guidance documents will be sent to CARACAL (maybe CARACAL 22, taking place on 19-20 October) for final approval before publication. According to ECHA's latest schedule, publications should take place in May 2017. As indicated at the 26 March meeting, ECHA expects industry to spontaneously update their dossiers to transparently report nanomaterial information. If voluntary updates are not submitted, ECHA will possibly formally request these updates via e.g. Article 36 letters (more information: Caroline Braibant).

#### **No EU Nanomaterials Registry but an EU Nanomaterials Observatory... *Coming by end 2016?***

The Impact Assessment Report for an EU Nanomaterials Observatory has been accepted by the Regulatory Scrutiny Board (RSB), but it has not yet been published, and the Commission has hence not yet formally approved the project, nor can it be formally delegated to ECHA. Still, ECHA is working on early planning phases of the project, in order to have a first version of the Observatory online by the end of the month (minimum 5 months after the task delegation has been formalised). The aim of the Observatory is to increase the transparency on nanomaterials without creating new obligations, especially for companies. ECHA will manage the Observatory, taking over from information gathered by JRC. ECHA will collect information that is available (or provided on a voluntary basis), filter it, and post it on the Observatory. Information will be targeted at various audiences, from MSCAs 'down to' workers and consumers. A kick-off 2-year budget has been granted and will be renewed as per the achievements (more information: Caroline Braibant).

### OTHERS

#### **CSR/ES roadmap activities: *a survey and a warning to improve communication with downstream users***

The CSR/ES Roadmap coordination group has recently launched a survey to assess the relevance of the CSR/ES Roadmap activities for industry and Member States at large; as well as the effectiveness of the work in generating useful outputs and efficiency in terms of effort compared to outcome. The Eurometaux Exposure Scenario Taskforce completed this survey at its last meeting. The results of this survey will be analysed by two independent consultants, having either a Member State or industry background and will be reported to the ENES community. A clear initial message is that the tools that have been created by these activities should now be implemented to be of added value. Industry is expected to take up the 'products' (e.g. use maps, volume/uses, IUCLID 6, Chesar etc...) to improve communication in the supply chain. ECHA is now very actively promoting the use maps and will host the existing ones, to serve as 'relay' to facilitate their communication. Geert Dancet, ECHA's Executive Director, has called on both downstream users and registrants' associations to mobilise all the relevant sectors as much as possible to produce the "sector use maps" in order to support the development of meaningful exposure scenarios for the 2018 registration or when updating previously submitted registrations. Although the format of the promoted use maps (uses-based rather than substance-based) does not perfectly fit the metals ES and the existence of alternative ways to communicate with downstream users in the sector, the Eurometaux ES Taskforce members indicated their willingness to contribute to use maps developments or the application of use maps to collect information when needed and to further work on improving communication within the supply chain (more information: Federica Iaccino and Violaine Verougstraete).

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## COMMISSION REACH activities: hot topics/issues

### CARACAL

#### **CARACAL 21: *many key discussions before the summer break, written comments under preparation***

The second CARACAL meeting of 2016 took place on 29-30 June. As usual, the content of the background documents and proposed REACH Alliance statements were discussed with the REACH Forum and the REACH Alliance. As regards CLP topics, the Commission provided an update on bioelution (see below) and on the status of the next ATPs to CLP: the 9<sup>th</sup> will be published in July; the 10<sup>th</sup> will be discussed by the REACH Committee in July while the 11<sup>th</sup> should be discussed by the REACH Committee in 2017. The 12<sup>th</sup> will aim at aligning CLP, REACH Annex II and the related Guidance, with the 6<sup>th</sup> revision of GHS and announced changes in Title 14.7 of SDS discussed in UN GHS Subcommittee. The Commission also clarified that the additivity approach can be applied on a case-by-case basis to other endpoints than acute toxicity, irritation or the environmental classification. CLH dossier submitters may hence propose additivity for e.g. CMRs and other endpoints included

in the CLH proposal. CLH Dossier submitters were also invited to include additional endpoints to CMR and sensitisation ones, in order to ensure proper RMMs are applied on substances. Member States generally support the idea of setting up a CLH Roadmap to address all classifications issues within a dedicated framework, as discussed in a recent CLH workshop. As regards REACH topics, the Commission presented its revised proposal for a restriction of CMRs in textiles taking into account the comments received via the public consultation. Eurometaux welcomed the narrower scope for this test case, and asked no other restriction cases to be addressed before the Article 68(2) restriction approach delivers learning lessons on the textiles case. With the removal of all textile accessories from the scope of articles covered, fewer metals should be included in the resulting scope, which should be defined in autumn 2016. As regards Authorisation, ECHA presented an update on the ongoing preparation by the AfA Taskforce, of a practical guide to support future applicants in the preparation of their Applications. In particular, guidance on the use description and the minimum information requirements to maximise the completeness of the Applications are likely to improve their quality. The guide should be presented to CARACAL 22. Ongoing work by RiME on sensitisers and so-called 'impurity cases' was also presented; Eurometaux will provide written comments on the approach to address impurities of concern in substances. ECHA invited Member States and Stakeholders to react on some recommendations of its Article 117 or REACH Review Report. ECHA clarified that before an Implementing Regulation making dossier updates mandatory is considered, other approaches to incentivise such updates should be considered. As regards extending the review periods of Authorisation Applications, not all Member States supported the suggestion to grant periods longer than 12 years, even in justified cases. A call was made to make better use of public consultations on Priority Lists in order to collect more information on (efforts made to identify) possible alternatives (more information: Caroline Braibant).

### **Second C&L Inventory project results: *not better than first project results, ECHA thinking of other ways to clean Inventory***

Two molybdenum and seven tungsten substances were in scope of the second pilot project, which was finalised on 21 June, with the release of REACH-IT 3. Since only little use of the C&L Platform was made and the Platform is not compatible with REACH-IT 3, ECHA decided to discontinue this tool. At the CARACAL 21 meeting, Eurometaux asked a placeholder note to be added on REACH-IT inviting notifiers to use the REACH registrants' contact details to comply with Article 41 of CLP, in place of the discontinued C&L Platform. ECHA's most immediate priority is now to clean the C&L Inventory (and with this, the classification information in the Brief Profiles), and a first approach to define an 'agreed entry' in the context of Article 41 was discussed in CARACAL 21. Eurometaux stressed the importance to recognise the hierarchical dominance of classifications submitted in REACH dossiers vis-à-vis any other classification notified to the Inventory. ECHA is developing criteria to set up an automated tool to clean the Inventory. Some of these criteria appear to be shortcuts that may not deliver actual convergence of the Inventory. Eurometaux will submit written comments on the suggested criteria and monitor more radical solutions that intend to be considered by the Commission (e.g. revision of the CLP Regulation) (more information: Caroline Braibant).

## **BIOELUTION**

### **Commission preparing legal interpretation of 'not biologically available' in Article 12(b) of CLP: *flexibility needed***

At CARACAL 21 the Commission presented an oral update on the conclusions reached by its legal services on the interpretation of Articles 12(b), 6(3), and the related recitals of the CLP Regulation. Commission's legal services concluded that experience with the setting of SCL and GCL, or even environmental classifications, indicates that there is a need for flexibility in interpreting the terms 'not biologically available' (which cannot, in practice, mean 'zero bioavailability'). Furthermore, it was stressed that Articles 6(3) and 12(b) do apply to human health hazard classes, including CMRs, which means that bioelution can be used to inform the human health classification of a given mixture. Member States will most probably submit comments in writing on the document under preparation by the Commission, as well as join a proposed expert group to discuss on the approach towards implementing bioaccessibility results in the classification of alloys and other metal-containing materials. ECVAM should in turn develop and validate the testing protocol, based on the file to be submitted by Eurometaux in July (more information: Federica Iaccino and Violaine Verougstraete).

## **NANOMATERIALS**

### **3<sup>rd</sup> Regulatory Review on nanomaterials: *far too early, preliminary conclusions not surprising...***

Three consultants have been appointed to prepare DG ENV's contribution to the 3<sup>rd</sup> regulatory review on nanomaterials. They presented their preliminary findings at a workshop on 21 June. Eurometaux had provided its input on the review via a specific survey. At the workshop, Member States, NGOs and industry complained that the Commission is investing resources in this exercise when other actions on nanomaterials that have been due for a long time now have not yet been finalised. As presented by the consultants, the 3<sup>rd</sup> review did not yield different results or conclusions than the 2<sup>nd</sup> review: there is overall insufficient data on nanomaterials and still many test methods lacking for nanomaterials (for environmental assessment in particular). The priority should be to clarify the definition and information requirements/classification rules in REACH and CLP. Comments on

the consultants' report are due by mid-July, who will then finalise their study in September. Meanwhile, other DGs are in charge of assessing other aspects than the environmental legislation (more information: Caroline Braibant).

## **OTHERS**

### **Strategy for a non-toxic Environment of the 7<sup>th</sup> EAP : *grouping, substitution and 26 metals/inorganics are neurotoxic***

On 8-9 June, Commission held a workshop on a Strategy for a Non-toxic Environment of the 7<sup>th</sup> Environmental Action Programme. This workshop aimed at identifying key players and stakeholders in the context of the non-toxic environment strategy Commission intends to present by 2018. This strategy should address important gaps in the protection of health and environment – conducive to innovation; approaching chemicals aspects of the 7<sup>th</sup> EAP 2050 vision, setting objectives for e.g. 2030 and presenting first steps to approach the objectives. A study was launched in December 2015 to provide the “basis” for the strategy. A group of consultants, led by Milieu, is in charge of describing the current state of play, identifying gaps and deficits in current policy, identifying and describing “improvement opportunities”, including short, mid and long term ones, hard/soft ones around the following topics: substitution and grouping, chemicals in products and non-toxic material cycles, protection of children and vulnerable groups, extremely persistent chemicals, policy means, Innovation and Competitiveness, a green Chemicals Programme and early warning systems for approaching chemical threats. Participants to the workshop were asked to participate in breakout sessions and submit completed questionnaires after the workshop to provide ‘food for thought’ to the consultants. Inputs will be consolidated in a report provided to Commission. Hot topics to note: grouping for substitution, protection of vulnerable groups (with emphasis on neurotoxicity, lack of trust from NGOs in REACH data (more information: Violaine Verougstraete).

### **Commission-ECHA workshop on SEA: *NGOs and EP challenge SEA relevance and SEAC process***

On 29 June, the Commission and ECHA co-organised a workshop to clarify the role and relevance of Socio Economic Assessments (SEA) in Restrictions and Authorisations as well as how they are developed by ECHA-SEAC and used by the Commission for decision-making. More than 130 participants attended representing Member States, NGOs, the European Parliament (EP), industry associations and representatives from the Commission and ECHA. The workshop was set up to reply to the questions of the EP on the value of SEAs and the increasing pressure from green-NGOs to reduce or even skip the use of SEAs in chemicals management decision making. The NGOs requested more emphasis to be placed on the Analysis of Alternatives (AoA) and challenged the concept of monetising human and environmental impacts in the SEA. They questioned as well the acceptability of decisions made on the proportionality between costs and benefits. The EP also took position on the role of SEA in the decision-making on chemicals management mainly driven by the anecdotal DEHP case (phthalate impurity in recycled plastics). Representatives of the EP explained they do not reject the value of a SEA but feel it should only be used after the AoA has clearly demonstrated that progressive substitution was not feasible. Their main concerns relate to the decision process whereby they strongly disagreed with SEAC making proportionality judgements based on SEA, AoA and CSR information in the opinion making process. According to the EP, it should be the Commission and not ECHA who should decide whether the benefits outweigh the costs. ECHA, industry (Cefic and Eurometaux) and Commission explained the value, role and importance of SEAs as factual evidence-based allowing to scope, scale and monetise the impact, thereby supporting the acceptance of an informed decision by the Commission. Furthermore, it was recognised that the quality of SEAs needs improvements especially on the societal impacts (called “the broader picture” by NGOs and EP) and the ‘value added’ or welfare of society. This is not necessarily a negative recommendation for AfAs given it would allow to value and refine the Man via the Environment assessments and include other impacts/costs/benefits for society such as for energy or materials use (including recycling). Other recommendations included e.g. conducting a SEA early on to inform decision-making rather than justify foregone conclusions, base the non-use scenario on the least cost practicable option and enhanced communications between risk assessors, managers and SEA analysts. The outcome of the workshop will be reported to CARACAL, the ECHA Committees and the European Parliament (more information: France Capon, Lisa Allen, Carol Pettit or Hugo Waeterschoot).

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## **EUROMETAUX REACH activities: hot topics/issues**

### **REACH Forum: *extraordinary meeting held on 23 June hosted a strategic brainstorming session***

Members of the REACH Forum discussed three strategic items at their recent meeting: issues to be proposed for ECHA's inorganics/metals framework, key messages and speakers' profiles for the October 2016 Chemicals Management Seminar, and Eurometaux 5 top-recommendations to improve the operation of REACH in the context of the REACH Review. Six issues were proposed by the Eurometaux staff as priorities to handle within the inorganics/metals framework based on the inputs of the consortia and their own experience with ECHA discussions, namely read-across, iUVCBs, Human Health and environmental classification, Recycling and Authorisation, and “allocation of exposure” (background, diffuse sources etc.). Those issues were

further ranked, discussed and selected on the basis of the following criteria: metal-specific issue requiring a metal/inorganic-specific solution, of interest to at least 3 metals, relevant for risk management, can be realistically solved within a short timeframe (e.g. 2-3 years), and can be addressed by ECHA (i.e. not depending on e.g. Commission or Member States). The selected issues now need to be prepared for presentation to ECHA on 29-30 August. As regards the Chemicals Management Seminar (20 October 2016), a Save the Date invitation will soon be circulated, and ideas of constructive speakers were asked for. The *ad hoc* group organising the event will finalise the title, and identify key messages to be transmitted by the speakers, including those developed in the context of the REACH Review (cf. item below) (more information: Caroline Braibant, Hugo Waeterschoot and Violaine Verougstraete).

#### **REACH Review: 5-top recommendations approved by REACH Forum imply a number of commitments from Industry...**

At their 23 June meeting, the members of the REACH Forum discussed the draft proposal on the Eurometaux contribution to the REACH Review. Five recommendations were made based on the discussion held with the Reach Review Task Force on 9 June: 1. to optimise the REACH Registration process so that the quality of dossiers increases and REACH datasets do become EU and international references; 2. to optimise the REACH Evaluation processes in order to arrive at more acceptance of waivers and adaptations, and more relevant/proportionate information requests; 3. to further embed RMOA in an existing regulatory system and develop a more methodological approach towards the performance of RMOA; 4. to promote use-specific RMOs to avoid duplication of requirements; and 5. to eliminate duplication or incoherence with other policy objectives legislation. For authorities to be able to implement these recommendations, registrants should endeavour to proceed to regular updates of dossiers and the collection and reporting of volume/use and exposure/use information, as well as the proactive preparation of RMOA relevant information, so it is available as soon as the substance is e.g. listed on PACT. An update of the draft REACH Review paper will be prepared in order to integrate comments received and clarify what Eurometaux's position is on a possible revision of the REACH text. The paper will also set the scene to prepare a response for the upcoming public consultation and key messages for the 20 October event mentioned above (more information: Caroline Braibant).

#### **7<sup>th</sup> Priority List for Authorisation: defining an advocacy strategy in July and implementing it end of August**

The Eurometaux A&R Platform held a debrief conference call to assess the outcome of the MSC debate on the prioritisation discussion for the listing of Pb on the 7<sup>th</sup> list. The call recognised the principle nature of the debate on the exemptions based on Article 58 (2) (alternative EU-wide substance-specific Risk Management measures) and agreed to support the Pb sector. It was agreed to develop a strategy and key messages for an advocacy campaign towards key MSCAs by the end of July and to organise and deliver on this starting from end of August. Key in the debate is the recognition of a BOEL as an appropriate RMM for the workplace, rejecting including the Man via the Environment endpoint when not relevant for the substance use, and limiting the need to prove RMM coverage for the lifetime of the substance, but not beyond (Any further person interested in this advocacy activity can give a sign to Lisa Allen (ILA) or Hugo Waeterschoot).

#### **Exposure Scenario Taskforce meeting: several topics debated**

On 16 June, the Exposure Scenario Taskforce met for a lively debate of several topics, from Eurometaux's participation in the ECHA/ENES/CSR ES roadmap to the debate of specific topics such as "occasional exposure" and the different role and weight of the Exposure Scenarios in the registration or in the authorisation context. Experience and news were shared on the new tools IUCLID 6, Chesar 3, MEASE 2 and SPERCs. It was unanimously agreed that Eurometaux should remain in the ECHA/ENES/CSR ES roadmap group as the information shared during those meetings is of relevance for the sector. One of the main topics that arised within the group this year was the importance to trace and communicate the ratio between volume & use of substances in the EU market. Eurometaux proposed to work on a mass flow analysis and to further exchange with ECHA on how to report this information in IUCLID 6. With respect to IUCLID 6, a further training will be organised by EBRC and ARCHE after the summer (timing and modalities will be further communicated). The minutes of the meeting will be circulated soon to the ES Taskforce (more information: Violaine Verougstraete and Federica Iaccino).

#### **Bioelution: the round robin cookbook is at its final stage**

After months of intensive discussions and exchanges with consortia and commodities experts, the round robin *cookbook* is reaching its final stage. The cookbook sets operational procedures to ensure that pending issues in the gastric bioelution protocol for alloys and complex materials are addressed. It was also prepared to guarantee that laboratories participating to the round robin testing possess equal analytical capacity and would work following the provided testing conditions, so as to reduce as much as possible inter-laboratories variability. The next step is now to finalise the practicalities of the round robin testing, selecting participating laboratories and organising collection of testing materials. Meantime, further contacts with ECVAM should ensure we move along consistently (more information: Adriana Oller, Federica Iaccino and Violaine Verougstraete).

## COMMUNICATION ACTIVITIES

### **ICA HESD meeting: *mixture toxicity***

Eurometaux was kindly invited by the International Copper Association to make a presentation along the following – challenging–title: A vexing problem: How do we study, regulate and manage the world of health and environmental effect of chemical mixtures involving metals? This invitation was a fantastic opportunity to bring together bits and pieces of regulatory developments and approaches that are currently developed to address this science and policy question in one consolidated presentation, with particular focus on the inorganic UVCB placeholder we included in the REACH dossiers and that needs to be tackled in the coming year (more information: Scott Baker and Violaine Verougstraete).

### **Shanghai 21-22 June: *China inspectors briefed on metals REACH and CLP experience and trends***

Eurometaux and ECHA presented –following an invitation from the Chinese government– their experience and learning lessons with the REACH and CLP schemes including looking towards new trends. The Chinese authorities were in particular interested in the metals experience, and testified their appreciation by a long series of questions on the feasibility and workability of REACH guidance. China emphasized that they focus much more on REACH and CLP guidance than any other system, given the existing practical guidance and the large import/export market with the EU. China plans to implement close to 140 REACH and CLP guidances into Chinese standards and announced they will develop and implement later this year the metals classification guidance (and examples) as included in the CLP (section drafted by Eurometaux based on MERAG) (more information: Hugo Waeterschoot).

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## Further outreach of REACH

### OECD

#### **OECD Taskforce on Hazard Assessment meeting: *ICMM & Eurometaux attend***

ICMM and Eurometaux attended the OECD Taskforce on Hazard Assessment meeting (20-21 June) as BIAC representatives and received among others an update from various jurisdictions on recent regulatory activities (Canada, US and EU), an update on Integrated Approaches to Testing and Assessment (IATA) and Adverse Outcomes Pathways (AOP work) as well as a presentation on an interesting US project on uncertainty in read-across. The idea is to develop a new read-across approach (GenRa) that makes read-across predictions consistent and provides a means of evaluating uncertainties. They will use databases from e.g. US and REACH to look at the data and investigate where and how to have the greatest scientific confidence in making read-across predictions. The metals sector presented the latest version of the metals bioavailability guidance, submitted for review to the Taskforce mid May. A controversy raised about the naming of the guidance was triggered by Germany: could it be considered as an OECD guidance document if it was drafted by industry? Germany also contested the need to have such complicated and complex bioavailability models, as there is still too much embedded uncertainty. Industry reacted strongly; emphasising that the document is the result of a collective effort involving several countries and that such initiatives should rather be encouraged than mistrusted. The meeting concluded that the document will be further revised to take into account written comments from Canada and others at the meeting, including clarification that this guidance is for risk assessment and not for classification and labelling (a concern of ECHA) and will be recirculated for endorsement. The OECD Secretariat will propose a correct naming of document (more information: Marnix Vangheluwe, Ben Davies, Hugo Waeterschoot and Violaine Verougstraete).

#### **Switzerland updates its chemicals management law: *allowing registration and authorisations being based on EU dissemination data***

Switzerland (CH) presented at the Shanghai workshop its plans to update its national chemicals law. In essence, CH will introduce REACH and CLP including the Risk Management part on restrictions and authorisations (!) but with remarkable differences. Registration of existing and new chemicals will not be needed when the substance has a dataset on the REACH-ECHA “dissemination website” meaning that registration in CH is only needed when a new substance is put on the market that is not registered in the EU. On risk management: CH will take over the EU Annex VI while complementing it with some additional Swiss reviews. Restrictions will be implemented as in the EU if they make socio-economic sense for the country, whilst CH will also recognise Annex XIV Authorisation updates after a SEA and relevance screening. Most notable is that Swiss companies will not have to submit an AfA for a use when an EU company got an authorisation granted for that use. The (free) use of EU data without LoA was included on the request of the Swiss chemical sector based on cost concerns for LoAs and the establishment of an AfA file. Both ECHA and Eurometaux reacted strongly indicating that the use of data from consortia requires a rightful access permit. Eurometaux will investigate with its members on how to react on this concern (more information: Hugo Waeterschoot).

## Calendar

- **6-8 July:** ECHA-OECD symposium on cost –benefit impact assessments for chemicals management – ECHA (Helsinki)
- **29-30 August:** inorganics framework workshop tbc –ECHA (Helsinki)
- **31 August-1 September:** OECD Taskforce on Exposure Assessment meeting –BAUA (Dortmund)
- **5-9 September:** RAC 38A – ECHA (Helsinki)
- **12-16 September:** RAC 38B – ECHA (Helsinki)
- **12-16 September:** SEAC – ECHA (Helsinki)
- **12-15 September:** ICHMET 18<sup>th</sup> International Conference on Heavy Metals in the Environment (Ghent)
- **13-15 September:** MSC 49 – ECHA (Helsinki)
- **28-29 September:** Management Board – ECHA (Helsinki)
- **28 September:** Authorisation & Restriction Platform – MCC (Brussels)
- **29 September:** REACH Forum - MCC (Brussels)
- **19-20 October:** CARACAL 22 (Brussels)
- **20 October (pm):** Chemicals Management Event (Brussels)
- **8-9 November:** 2016 European REACH Congress (Düsseldorf) - For further information please visit the [website](#)

## Acronyms

AfA : Application for Authorisation	LoA: Letter of Access
A&R : Authorisation and Restriction	MB: Management Board
AoA : Assessment of Alternatives	MEASE: Occupational Exposure Assessment Tool for REACH
AOP: Adverse Outcomes Pathways	MSC: Member States Committee
ATP : Adaptation to Technical Progress	MvE: Man via the Environment
BOEL: Binding Occupational Exposure Limit	OECD: Organisation of Economic Cooperation and Development
BoA: Board of Appeal	OEL: Occupational Exposure Limits
C&L: Classification & Labelling	OSOR: One Substance, One Registration
CARACAL: Competent Authorities on REACH and CLP Regulations	PACT: Public Activities Coordination Tool
CHESAR: Chemical Safety Assessment and Reporting Tool	PEG: Partner Expert Groups
CLH: Harmonised Classification Proposal	RAC : Risk Assessment Committee (ECHA)
CLP: Classification, Labelling and Packaging Regulation	RCR: Risk Characterisation Ratio
CMR: Substances classified as Carcinogens, Mutagens or toxic for Reproduction	REACH IT : REACH Information Technology system
CSA/CSR: Chemical Safety Assessment/Report	RiME: Risk Management Experts
EAP: Environmental Action Programme	RMM: Risk Management Measures
ECVAM: European Union Reference Laboratory for alternatives to animal testing	RMOa: Risk Management Option analysis
ELV : End-of-life Vehicles Directive (2000/53/EC)	RSB : Regulatory Scrutiny Board
EOGRTS: Extended One Generation Reproductive Toxicity Test	RoHS : Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (Directive 2002/96/EC)
ES : Exposure Scenario	SCL: Specific Concentration Limit
GCL: Generic Concentration Limit	SEA : Socio-Economic Analysis
GHS: Global Harmonised System of classification and labelling of chemicals	SDS: Safety Data Sheet
IATA: Integrated Approaches to Testing and Assessment	SEAC : Socio-Economic Analysis Committee (ECHA)
IUCLID: International Uniform Chemical Information Database	SPERCS: Specific Environmental Release Category
iUVCB : Inorganic Unknown or Variable Composition, Complex Reaction Products and Biological Materials	UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials
JRC: Joint Research Centre	
LAD: Latest Application Date	

# REACH on the BEACH



Wishing you all a great summer, wherever you are, whatever you do ...

Mind the gap.....fill in with the correct metal

1. Foods that are a great source of ..... include lean red meats like beef, lamb and liver and seafood such as oysters and lobster. Whole grains, seeds, beans, nuts, and almonds are all good sources if grown in zinc rich soil.
2. The word ..... is one of the few words in the English language that is nearly impossible to rhyme. Words such as orange, purple, breadth, wolf, depth, angst, gulf, ninth and twelfth are also difficult or impossible to rhyme. While there are some words that do actually rhyme with these examples they are usually very rare or hardly used in the modern English language
3. In Germany during medieval times, a red mineral was found that looked like copper ore (rock). When miners couldn't extract any copper from it, they blamed a mischievous sprite of German mythology, ..... They decided to call this ore Kupfernichel, with the German word for copper being Kupfer.
4. The symbol for ....., Pb, comes from the Latin name for the metal, plumbum. The English words "plumbing" and "plumber" are derived from this Latin name.
5. Over 81,000 kgs (179,000 lbs) of ..... was used to build The Statue of Liberty.
6. Alchemy was a kind of pre-science that existed from about 500 B.C. to about the end of the 16th century. Alchemists wanted to find a way of changing lead, iron, and other metals into gold. They also wanted to find a way of having eternal life. Alchemy contained too much magic and mysticism to be a real science, but alchemists developed a number of techniques and produced many new materials that were later found to be useful in modern chemistry. .... was one of these materials.
7. .... gets its name from the Greek word *selene*, which means moon. Selene also was the Greek goddess of the moon.
8. .... improves the strength of steel at high temperatures
9. In 1797, Nicholas Louis Vauquelin recognized the element in emeralds. In 1828 Friederich Wöhler and Antoine Bussy isolated the metal ..... from beryl and emeralds independently of each other.
10. In the 1850s, ..... was more valuable than gold – it was priced at \$1,200 per kg and gold at \$664 per kg.

1. Zinc – 2. Silver – 3. Nickel – 4. Lead – 5. Copper – 6. Antimony – 7. Selenium – 8. Molybdenum – 9. Beryllium – 10. Aluminium.