EUROMETAUX
EUROPEAN ASSOCIATION OF METALS

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EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

When earlier this year, I was first confronted to the common screening approach developed by ECHA and Member States to "systematically screen available information for substances in the REACH registration dossiers and other databases to identify substances for further processes like Dossier/ Substance Evaluation or regulatory risk management measures", and make links between the different REACH and CLP programmes, I could not refrain from thinking that a milestone had -intelligently- been reached. While our daily work is impacted by cost-effectiveness and cuts in resources, often resulting in refocusing certain activities and narrowing the scope of information we can pick up, ECHA has managed to set up a holistic approach, a 'thinking' "intended to ensure the swift progress of the screening activities, avoid duplication of work and minimize the risk of having the same substance being identified as suitable candidate for different (risk management) processes ...".
There is a rule in the game of chess that says that 'when you see a good move, look for a better one'. I suspect my father considered that teaching us to play chess was one of his educational tasks, as it forms memory, strategic thinking and forces patience (not my main character trait). One possibility when playing chess is to act offensively (or pro-actively) to impose your strategy; the other one would be to act defensively to give yourself time to understand what the other one has in mind while anticipating possible scenarios. It is that kind of strategy we are alluding to when, as REACH team, we propose that consortia re-do a kind of self-assessment to evaluate where possible risk management moves from authorities could hit. The idea is to put yourself in your challenger's shoes and have a look at your (company) substances' portfolio to assess if there is any weak point, a 'bishop' that may run to sacrifice? An internal exercise to do in view of a 'better move'.
To be honest, I never managed to learn to play chess adequately; I always ended up by throwing the chess pieces at my brother's face. But this time it may be worthwhile being more patient and increasing our knowledge of the game. Without – on the other hand- losing sight of the objective and falling in the pitfall Dostoyevsky once described: "like a chess-player, being more interested in the process of attaining his goal rather than the goal itself." But that's clearly where we need you all: also keeping your REACH team with two feet on the ground!

Violaine Verougstraete, EHS director Eurometaux

ECHA REACH activities: hot topics

ECHA COMMITTEES

RAC 32A: full week of authorisation and restriction discussions: *search for consistency on occupational exposure documentation and acceptable risk- further increasing efficiency*

Highlights of this first RAC week, devoted only to restriction and authorisation discussions, included the proposal to set up an expert group to discuss improved ways of dealing with health and environment impacts including the benefit analysis. This group will bring RAC and SEAC experts together and contribute to 'efficiency in restriction discussions'. On restrictions, an important agenda item was the continued discussion on the restriction of Bisphenol A (BPA) in thermal paper, to address the risks for human health of pregnant workers and consumers possibly exposed to BPA when handling this paper. EFSA made a presentation on the scientific opinion on BPA they recently finalized, addressing hazard, exposure and risks in specific (vulnerable) groups of the population. RAC will consider EFSA's findings in the Opinion, and to allow an in-depth discussion RAC's work will be extended to at least the next meeting in June (in line with Article 95 of REACH, Conflicts of opinion with other bodies). RAC also adopted an opinion in support of the proposal from France to restrict the use of inorganic ammonium salts in cellulose insulation materials. First discussions took place on restrictions on the manufacturing, use and

placing on the market of decaBDE and articles containing decaBDE>0.1% by weight (PBT, vPvB, neurotoxicity concerns) and Perfluorooctanoic acid (PBT, CMR). On authorisation, RAC examined 12 applications for authorisation on 17 uses of trichloroethylene and agreed on 11 draft opinions. Important to follow are the way the applicants use (and RAC assesses) monitoring data vs. modelled data, the calculations of 'overall excess risk', and the 'additional conditions' included by RAC in the Opinion (e.g. monitoring), for consistency reasons. RAC is further deriving reference DNELs and carcinogenicity dose response relationships, to increase their efficiency. Although being non-binding values, applicants are invited to use them in the hazard part of their applications and RAC will use these to evaluate the application. The reference values are published on ECHA's website. Along the same objective of increased efficiency, a 'fast-track' procedure for the handling of applications by RAC consultation was approved: for applications fulfilling a number of criteria, the system would thereby allow to save 'plenary time' for discussions. However, it increases the burden on the STOs who will have to carefully assess ahead of the plenary meeting what the remaining issues are for discussion and what was agreed during the RAC consultation that preceded the plenary discussion (more information: Violaine Verougstraete).

RAC 32B: CLH debates: ***search for consistency on occupational exposure documentation and acceptable risk***
A couple of authorisation applications and CLH dossiers were discussed during the second week of the RAC March meetings. Six opinions for CLH were approved. An interesting debate was on Linalool, a fragrance which is widely used in consumer products, including detergents, household products and cosmetics. This substance has currently no harmonised classification in Annex VI to the CLP. Sweden has proposed a classification as skin sensitizer. A lower potency category (Skin Sens. 1B; H317) was however assigned (more information: Violaine Verougstraete).

SEAC 26: ***Clarification of Review Periods for Authorisation applications***
As for RAC, SEAC reviewed a series of Authorisation Applications at its latest session. The Committee concluded a wide range of Review Periods (RP) and conditions, often for reasonably comparable uses. The Review Periods ranged from 4 to 12 years and were allocated based on the quality of the "minimal exposure proof" as well as on the "robustness of the SEA assessment". The meeting demonstrated further that AfAs for uses like "reformulation" or "repackaging" do not require an AoA and only a very limited SEA. An analysis of the RP allocation will be presented to the next Eurometaux Authorisation and Restriction platform (more information: Hugo Waeterschoot).

SEAC 26: ***Cd compounds in artists paints-the restriction definitively rejected.***
The Public Consultation on the potential restriction of Cd compounds in artist paints did not provide new evidence that could contest/change the draft opinion of both ECHA Committees. SEAC therefore concluded at its session to (definitively) reject the case proposed by Sweden to restrict the use of Cd compounds in artist paints based on a lack of demonstration of a risk requiring EU-wide risk management and the non-proportionality of the proposed measure. The case proves further that adequate scientific, technical and socio-economic information from industry and other parties can effectively challenge a restriction proposal of a Member State, by effectively using the Public Consultation (more information: Christian Cannoo and Hugo Waeterschoot).

ECHA MEETINGS

ECHA Management Board (ECHA MB): ***Changes in the funding structure of ECHA could lead to increased fees for industry***
Eurometaux, Cefic and IMA reviewed the extensive documentation for the ECHA MB meeting scheduled for March 19-20 and prepared joint input. Industry in general is represented in the Management Board by Cefic's Executive Director. Most important aspects debated included the ECHA budget and resources situation for 2015 and the first draft for a 2016 work plan. The resources are as expected constrained, exacerbated by the decision of Commission (DG GROW) to significantly reduce its funding contribution for the regular REACH activities, which may result in an increase of the fees later this year. Eurometaux and Cefic prepared an intervention to challenge this, stating that programmes run for the general community and on request of Member States (like Substance Evaluations, Restrictions and Member States CLH proposals) should remain fully funded by public means and not by industry while Registration related aspects (Dossier compliance, Biocides classification files and Authorisations) should in principle be paid from the industry fees (more information: Hugo Waeterschoot).

Assessment entity workshop co-organised by ECHA, Cefic and Eurometaux at the MCC: ***increasing understanding***
The Assessment Entity (AE) is a concept developed for the purpose of data sorting in IUCLID, aiming at increasing transparency of the information provided to regulators (via IUCLID and CSRs) or to the generic public (via the dissemination website) in cases of complex assessments. This concept has no impact on the information requirements and safety assessment methodology, only on the reporting of the information. The workshop on March 10 aimed at sharing the experience acquired in testing the concept with real cases but also to identify with the participants the additional possible benefits it could have for their dossiers. Easier generation of CSR; decrease of manual editing for complex cases was one of

the identified benefits. It was clarified that using the assessment entity approach is an option and that there are no intentions to make it mandatory. The availability of the assessment entity object in IUCLID 6 will not trigger a need for update, and it will be up to each registrant, depending on his case, to decide whether he wants to update his dossier to make it more transparent or not. It was nevertheless mentioned that if the data are already reported in the dossier (for example having used templates to report several endpoint summaries, like in our iUVCB dossiers) then adding assessment entities should not require too much effort as it is mainly about linking the data. A couple of features should be investigated in details, e.g. enabling bulk functionality when importing information from existing dossiers into the AE concepts. The specifications for IUCLID are to be finalised by end April 2015 and testing may still take place in May-June. Volunteers to test the specifications in collaboration with ECHA are welcomed and requested to flag it to ECHA (iuclid6@echa.europa.eu) (more information: Koen Oorts, Arne Burzlaff, Federica Iaccino and Violaine Verougstraete).

AUTHORISATION

5th, 6th and 7th lists: ***the situation somewhat demystified but far from clear***

The Authorisation and Restriction platform asked Eurometaux to clarify as much as possible the situation on the 5th, 6th and 7th priority lists for Annex XIV updates. Several sources were consulted confirming the Commissions' intentions to combine the 5th and 6th lists review in autumn, when the policy discussion between OSH and REACH have been clarified and the first Implementing Act on the Simplification of Authorisation has been agreed. Commission further clarified that they are considering a biannual update of the Annex XIV list instead of an annual one, independently of ECHA rhythm of prioritizing substances (so far an annual activity). ECHA and MSC are expected to conclude/vote in June on the 6th list while they have already started preparatory activities for the 7th list, on which a first proposal can be expected by or after the summer (Public Consultation in autumn). Several sources also seem to highlight that substances that would not be picked up for the 6th list would automatically be included in the 7th, which would be an unfortunate situation for the metals sector (more information: Hugo Waeterschoot).

Substitution: ***ECHA started an exercise to promote substitution cases – Eurometaux declined to support this activity***

ECHA noted that most applicants for Authorisation claimed (and demonstrated) absence of technical and economical~~ly~~ feasible substitutes (alternatives). Challenging the view of industry that alternatives are rarely available for substances presently on Annex XIV, ECHA launched an initiative to raise awareness on the existence of potential substitutes by opening a website and preparing webinars to present "good cases". ECHA solicited the support of industry including the metal sector for this initiative. Eurometaux, supported by its Authorisation and Restriction platform, declined participation given the demonstration on the availability of technical and economical feasible substitutes should be made in the Authorisation Applications and not in public due to their case specificity and often confidential character. Moreover, Eurometaux questioned if such activity is ECHA's core business given the present constrained resource conditions (more information: Hugo Waeterschoot).

COMMISSION REACH activities: hot topics/issues

CARACAL-17 meeting on March 26 & 27: ***classification and REACH work continue***

Eurometaux and IMA-Europe participated on behalf of the REACH Alliance to the 17th meeting of CARACAL.

During the CLP session: the CLP exemptions for feed additives were discussed, and more particularly, whether and when CLP labelling would apply to feed additives. Though most vocal Member States were of the opinion that CLP labelling should apply to feed additives to also protect workers, no firm recommendation can be anticipated before April 27.

Eurometaux took the opportunity to alert CARACAL members on the inappropriateness of the approach RAC has followed to derive the environmental CLH for copper compounds. Member States were requested to consider the fact that copper compounds were assessed as data-poor substances, with too much conservatism, and to ensure that the copper compounds case does not set a precedent for future data-rich substances subject to CLH. This request was supported by two Member States. Eurometaux furthermore shared its initial comments on the limitations of the C&L Platform project while one Member State expressed concerns on the role played by 'impurities' in achieving a common classification entry under CLP or defining substance identity under REACH; this will be monitored very carefully. Finally, it was noted that it is not intended to change the definition of 'placing on the market' but to clarify its interpretation as part of the transition towards the full implementation of CLP after June 2015 and that CARACAL is willing to move forward in clarifying Article 8(5) of the CLP regulation regarding the quality requirements for laboratories performing physical hazards tests for CLP purposes.

During the REACH session: participants were updated on the recent developments around nanomaterials (cf. dedicated item further below), and the proposed Implementing Act on Data-Sharing was discussed. Many participants showed hesitation associated to the enforcement, retroactivity, and definition of cost considering ongoing update work under DE and SE among others. It was however also regarded as a tool to facilitate the enforcement of the OSOR principle by ECHA. It was proposed to discuss the proposal in the DCG again. The possible increase of information requirements in Annex VII (by revising or deleting Annex III for example) was supported by various Member States and NGO though due consideration for animal welfare and the burden for SME was requested. Industry in particular highlighted the fact that changing the information requirements so close to the 2018 deadline would not be practical (supported by DG ENV), and that cost estimations done on the basis of (Q)SAR are not adequate for inorganic substances. DG SANTE is progressing with the setting of criteria to define Endocrine Disruptors (ED), but it has taken longer than anticipated due to the existing scientific controversy. Combined effects are also of concern. The ongoing comprehensive impact assessment is a pre-requisite to any legislative proposal on ED.

On the topic of streamlining and simplification of Applications for Authorisation (AfA), Industry noted that average cost figures per AfA announced at the recent workshop were not representative of all cases and that it is too early to announce such figures. Simplification can make the AfA process much more effective, especially for specific cases, among which recycling could be considered. A Member State indicated that RiME will now also endeavour to monitor Authorisation activities; some Member States are concerned that Authorisations are granted too systematically to applicants, and that it hence does not foster substitution. The update on RiME insisted on the RMOa approach becoming a standard approach, and the fact that the Registration Dossier is in all cases the starting source of information.

CARACAL also discussed the proposed updated TCC tool for IUCLID 6, which may trigger additional mandatory fields, as well as some heavy manual migration steps, especially for dossiers including non-standard information such as inorganics (more information: Caroline Braibant and Roger Doome).

EUROMETAUX REACH activities: hot topics/issues

REACH FORUM

REACH Forum meeting March 17: ***Review of issues at ECHA, Commission and industry level resulting in a 'heavy agenda'***

The recent REACH Forum meeting was among one of the densest in terms of participation, agenda, and discussions. Participants were briefed on the change in requirements for reproductive toxicity testing (EOGRTS and PNDT) and the need to properly justify any waivers for this endpoint in their dossier. As regards classification, they were alerted on the upcoming 9th ATP of CLP (which includes copper compounds and should include lead metal) and the need to monitor CLH activities under REACH as well as other legislation including Biocides and Plant Protection Products, to prevent inappropriate precedent-setting. Experience shows that classification requires anticipative and preventive preparation, and better communication and advocacy. Participants were furthermore recommended to participate in the 'CLP for mixtures' training organised by Eurometaux on April 14, and to demonstrate their compliance with Article 41 of CLP by using the C&L Platform for their relevant substance(s). The template message proposed by Eurometaux can be used for this purpose. As regards risk management, participants were reminded to monitor the release of the 5th, 6th, and 7th Priority Lists for Authorisation and in particular the way in which volume/use data and intermediate uses have been considered to adjust the priority scores of the listed substances, as applicable. Here again, experience shows that preventing inefficient risk management measures requires anticipative action and preparation, for which the Authorisation and Restriction platform is developing a dedicated Strategy and implementation plan. The status of the REACH Forum so far is healthy, and the REACH Forum agreed upon an approval process for new unbudgeted projects. In order for the REACH Forum and Eurometaux's work to continue successfully, participants were reminded to read the briefing notes in advance of the meetings, and the Co-Chairs discussed with the REACH team on how to achieve an appropriate balance in meeting the expectations of the participants (information vs. strategic decisions, discussion vs. presentation etc. (more information: Caroline Braibant).

AUTHORISATION

Metal oxides: ECHA and ***the metal sector up for a clarification exercise on intermediate status in use applications***

ECHA noted differences in opinions between industry and Member States on the status of metal oxides (and other metal compounds) in the manufacturing of materials like glass, crystal, enamels, ceramics, frits but also with regard to the use of Coal Tar Pitch in anodes. They have contacted the metals sector to ask whether this could be clarified in a joint initiative. Differences in opinions often result in precautionary worst case assumptions, thereby increasing the priority ranking of such materials for authorisation schemes. The need to prepare an Authorisation Application is also often unclear for industry. Eurometaux organized on March 18 a well-attended briefing conference call with concerned Consortia and Downstream User

groups, which concluded to the added value of contributing to a technical / scientific exchange, in order to demonstrate intermediate status or to confirm where this wouldn't apply. It was proposed to organise a series of mini-workshops of Consortia and Downstream User sectors (back-to-back) aiming at providing and discussing technical evidence with ECHA while maintaining consistency between the different DU applications. This would result in "sector fact sheets" and a selected example that would then be made available to ECHA to improve their intermediate guidance or Practical Guide. The workshops will be planned for the end of June and be coordinated by the A&R platform (more information: France Capon, Aggie Kotze and Hugo Waeterschoot).

Cross-industry initiative: *OEL to address risk at the workplace in line with aim for 'Better Regulation'!*

The cross-industry initiative (or CII) aims at introducing greater efficiency and proportionality in the field of chemicals management by promoting the implementation of workplace legislation instead of REACH Authorisation when there is a need to tackle risks which are specific to the workplace. It defends the principle that workplace legislation is designed to tackle risks at the workplace without distinction of the use made of the substance (i.e. intermediate or not), and is more likely to be better implemented by companies compared to Authorisation, which exempts intermediate uses and is not yet fully known by most downstream users and SMEs. The initiative has been published by ENDS Europe and ChemicalWatch; and the EEB and ETUC have already reacted against the approach proposed by Industry. A small delegation representing the larger CII group (> 40 associations including Eurometaux) has met with the Cabinet of Commissioner Thyssen (Employment, Social Affairs, Skills and Labour Mobility) and the Cabinet of the Commission's Secretary-General on March 17 and 18, respectively. The initiative was also presented to DG ENV (Director-General Falkenberg) as part of a more general exchange on Circular Economy and a third formal meeting with Vice-President Katainen (Jobs, Growth, Investment and Competitiveness) will take place on April 9. Meetings held so far have indicated the likelihood of support for the initiative (especially from a 'better regulation' standpoint) but also a need to tackle possible weaknesses along the way. One of the weaknesses identified already relates to the OEL derivation, and its uneven use and enforcement across the EU. The review of the workplace legislation gives an opportunity to identify areas for improvement but to strengthen its proposal industry needs to be able to demonstrate how well workplace legislation is in place and concretely protects workers. As a next step, the group foresees to contact Member State representatives in Brussels and nationally, and to translate the initiative into a more intuitive flowchart or decision-tree to be used with more interlocutors (more information: Kai-Sebastian Melzer and Caroline Braibant).

CLASSIFICATION

Bioelution workshop on March 20: *a 'double act' to clarify (mis) understandings and identify remaining work*

A 'working meeting', partly attended by representatives from the European Commission, was held on March 20 with the objective to come to a common understanding with respect to the application of bioelution for the classification of alloys. Those discussions are relevant both for the 'Pb metals SCL issue' and the approaching deadline for the classification of mixtures under CLP and GHS. Bioelution provides for an alternative classification methodology for 'special mixtures' considering the specific properties of alloys (and bioavailability rather than the content of the metals in the alloy). The meeting was also held in preparation of a workshop with Member States that will be facilitated by the European Commission on April 27. The draft report and the presentations of the workshop have been circulated to the participants and can be further requested. We would like to thank the speakers and all participants for their very useful input and suggestions (more information: Hugo Waeterschoot and Violaine Verougstraete).

Pb SCL: an expert meeting on April 27 facilitated by the Commission: *a list of questions and preparatory material*

The REACH Committee meeting of February halted the Pb metal classification proposal in Annex VI based on the potential impact of the SCL of 0.03% on Pb- containing materials. Commission was asked to organise an expert session with Member States to clarify the alloys case and use of bioelution. This meeting will take place on April 27. Commission has defined a list of questions they would like to circulate to the participants to encourage them to prepare for the discussion and make as much progress as possible at the meeting. This draft list was sent to Eurometaux for quick comments. Questions are structured in two blocks: a first block of generic questions on e.g. the bioelution concept, release/surface as intrinsic property and the legal CLP framework, which will be critical to pass to be able to discuss the specific questions on the bioelution test methodology. Commission also asked Eurometaux to provide some preparatory material. An industry note based on extracts of the HERAG alloys fact sheet and the bioelution roadmap, aimed at providing some background and support information to tackle the block of generic questions was submitted to Commission on March 30. The next steps will be to ensure that industry can provide satisfactory responses to the generic questions at the meeting so as to convince the Member States to accept the concept and move to the specific questions. After that, responses to the specific questions will have to be prepared (e.g. a revised standard operating protocol (more information: Hugo Waeterschoot and Violaine Verougstraete).

Participation to the Plastics matrix encapsulation workshop on March 24: *a list of questions and preparatory material*
Eurometaux was invited by PlasticsEurope to present the metal sector's experience on bioelution and classification of 'matrix' materials at the Matrix Encapsulation Workshop organised in Brussels. Discussions were very interesting as this group is currently exploring e.g. the possibility to predict releases/migration via exposure modelling approaches, the importance of physical form and the difficult boundaries between hazard and risk when it comes to classification. They are also investigating the possibilities that articles 10 and 12 of the CLP may offer. It has been agreed to keep each other informed on further work and developments (more information: Violaine Verougstraete).

NANOMATERIALS

Re-activation of the Eurometaux Nanomaterials Task Force: *wake up call to all commodities and national federations*
Nanomaterials are increasingly becoming a truly multi-metallic issue which justifies the need to're-activate' the Nanomaterials Task Force of Eurometaux. A brainstorming conference call was held on March 23 in which the participating commodities were updated on the various initiatives and discussions at ECHA, Commission and OECD levels which are monitored by C. Spirlet, C. Braibant and K. Oorts, respectively, on behalf of/for Eurometaux. A number of reports are expected in April/May 2015 that may clarify the possible change in the regulatory/political landscape for nanomaterials in the EU. In particular, we expect the Commission to be able to come with concrete proposals on whether and how the definition of nanomaterial and the annexes of REACH should be adjusted. We also hope the Commission will clarify its position regarding a possible EU inventory of nanomaterials. Member States have launched a number of registries in 2014 that are not all identical and produce results which are difficult to compare and bridge. The US EPA has recently also proposed reporting and record keeping requirements on nanoscale materials in the marketplace (http://www.epa.gov/oppt/nano/); EU registrants of nanomaterials may hence need to report this information to the US too. At ECHA level, work continues to clarify read-across principles, and to identify and tackle remaining challenges of environmental risk management of nanomaterials. OECD has also announced a workshop on read-across to be organised in the second half of 2015. A number of substances are subject to Substance Evaluation due to their 'nano' component (e.g. Ag since 2014 and ZnO as from 2016); Eurometaux will monitor these 'pioneer' cases to inform all members on the minimum requirements that should be met to satisfy REACH requirements for nanomaterials (more information: Christine Spirlet, Koen Oorts, and Caroline Braibant).

METAL-SPECIFIC REACH APPLICATION TOOLS AND CONCEPTS

Guidance on risk assessment of inorganic UVCBs (iUVCBs): a significant achievement!

The Guidance on iUVCB assessment has been finalised and will be circulated to the Intermediate Task Force and the REACH Forum members. It will also be posted on the REACH Metals Gateway. The main objective of this guidance document is to support the preparation of iUVCB intermediates dossiers compliant with the December 2010 ECHA Guidance on Intermediates and the ECHA Practical Guide on intermediates. The guidance reflects the work carried out by the Eurometaux REACH Task Force on Intermediates (ex-SCC Taskforce), the experiences gained as well as the outcomes/conclusions of the meetings held with ECHA in 2012-2014. This guidance is structured to allow a complete assessment of iUVCB, from substance identification and hazard classification to final chemical safety assessment. Thanks a lot to all contributors (more information: Federica Iaccino and Violaine Verougstraete).

Discussion on UVCB profiles with Director of Registration: *possible solutions to be confirmed*
In December Eurometaux sent a letter asking ECHA to leave out of the first generation of Substances Brief Profiles the inorganic UVCB dossiers submitted in April. The Substances Brief Profiles aim at providing information on substances in a tiered way (with increasing level of detail) among others to the general public. These Profiles are based on the information included in IUCLID, REACH IT and the C&L inventory. Unfortunately only the information included in the standard fields of IUCLID can be extracted whilst metal and inorganic UVCB registrants often used free text and/or templates to report metal specific aspects or units. For UVCBs, the situation is even more confusing as to be able to report our assessment based on constituents, we had to work with IUCLID templates, resulting in inappropriate communication (e.g. a range of DNELs is given (from µg to mg/m³), without explaining the followed approach or specifying from which constituent the value comes from). This gives a wrong signal with regard to the quality of our dossiers and the commitment in the UVCB work. The assessment entity currently developed by ECHA will help to clarify this situation by 'wrapping' the constituents datasets in IUCLID 6.1, but only in 2016. Eurometaux met Ms Musset early March to discuss possible solutions: leave out values like PNECs/DNELs, refer to constituents' profiles or wait for IUCLID 6.1 to generate Profiles for our UVCBs. ECHA should communicate the selected option in the coming weeks (more information: Hugo Waeterschoot and Violaine Verougstraete).

MeClas survey launched: ***a survey to ensure the tool's database remains up to date and in line with the consortia recommendations***

The MeClas Steering Committee, who supervises the strategic directions, the updates and the overall quality of the MeClas tool, has recommended launching a systematic exercise to inquire about ongoing/future plans to update classifications/M factors/SCLs/ERVs/TRVs so as to e.g. be able to include warnings in MeClas when such changes are anticipated. A survey has been circulated to the REACH Forum and MeClas users https://qtrial2015az1.az1.qualtrics.com/SE/?SID=SV_9vrz8Kr86nFPSjX The survey questionnaire also enquires whether consortia would agree to have the database put online for registered MeClas users/sponsors and to publish the values in the MeClas scientific publication. This is to respond to a request from authorities, keen to assess the quality and acceptance of the tool. The use of TRVs/ERVs for other purposes than hazard classification would still require the consent of the responsible consortia. Finally, as the extension of MeClas from the EU CLP to other GHS systems has been estimated as being a priority for this year, the survey aims at collecting information on self-classifications and/or information from other countries/systems like the US, Canada, Japan etc. (more information: Frederik Verdonck, Patrick Van Sprang, Hugo Waeterschoot and Violaine Verougstraete).

OTHERS

Increased attendance of ECHA meetings by the metals sector: ***how to cope?***

A striking consequence of the prioritisation of metal and metal compounds in a number of REACH programmes is the increasing number of meetings/discussions metal sector representatives need to attend in Helsinki. As most of those meetings are scheduled between October and April (due to the long holiday season in the Nordic countries), Eurometaux has invested in a 'meetings kit' including phototherapy eyewear and antislip protectors to cover shoes in icy periods. It is available on request (more information: Ailsa Lee and Violaine Verougstraete).

COMMUNICATION ACTIVITIES

REACH Conference by Czech MSCA: an opportunity to network with MSCAs from new EU countries

Eurometaux spoke on the invitation of K. Blaha (vice chair ECHA Management Board) at the REACH conference of new EU countries (mainly former Eastern bloc countries) meeting in Pruhovice (Czech Republic) sharing experience on the prioritization for authorisation and AfAs. This annual meeting is one of the only opportunities for industry to network with new country MSCAs, countries that increasingly participate, especially in MSC and SEAC, and often take an independent opinion, more supportive for industry. The meeting was also attended by the Commission, the OECD and enforcement authorities resulting in some lively debate on the low value of the Authorisation process. It seems that most former Eastern bloc countries are supportive about the idea of industry being more careful with the selection of substances for Annex XIV, providing priority to those that can't be regulated under OSH (e.g. PBTs). Many of them are also concerned about the potential impact Authorisation could have on the recycling and resources policy. DG ENV plead somewhat the opposite indicating that REACH has been quicker and more effective than OSH in protecting workers, which in turn was answered by the statement that "workers protection based on checking exposures at the workplace by OSH being much more relevant for workers then "paper DNEL exercises"". The presentations of this interesting workshop will be distributed to the REACH Forum when available (more information Hugo Waeterschoot).

Eurometaux press release on the authorisation simplification process: ***need for a significant overhaul of the authorisation process***

Eurometaux, welcomed in a recent press release the Public Consultation of the Commission's REACH authorisation procedure for applications on uses of Annex XIV substances 'in low volumes' and uses in 'legacy spare parts', that runs until end of April. While these first two specific uses will not be of great help for the metals sector, Eurometaux hopes they act as a first step of a process in realigning the efficiency of the authorisation application system. The press release invites "*the Commission to continue developing implementing acts on the simplification of authorisation applications for uses in bio-essential applications, uses in long term type approval product applications, but also for process chemicals and recycling materials if they would be caught by the scope of Annex XIV*". But more importantly Eurometaux is asking for a much more significant review of the REACH Risk Management Measures (RMM) identification process, in order to align the potential need for risk reduction or substitution with the reality at the workplace or the environment. "*Most of the inorganics on the candidate list for CMR reasons have been under scrutiny for decades, so uses are anyway limited to those that were not considered technically or economically substitutable*", clarified Eurometaux. The efficiency of a system like authorisation is therefore "*close to nil if not negative*", while better and more relevant and efficient alternatives exist such as harmonized Occupational Exposure Limits for the workplace and others (for information: see enclosure, Hugo Waeterschoot).

Further outreach of REACH

OECD

Discussion with OECD secretariat on MERAG to OECD environmental risk assessment guidance on March 27: ***preparation of a discussion with the OECD Taskforce on Hazard Assessment (TFHA)***

The aim of the meeting is to discuss the next steps of the drafting of the OECD guidance on 'environmental risk assessment of inorganics, based on the updated MERAG fact sheets. A possible outline of the "bioavailability part of the guidance" had been prepared by ARCHE ahead of the meeting. It will discuss bioavailability for the three environmental compartments and include specific aspects in metal effects assessment like acclimatisation and adaptation, test medium and test design, test substance. The purpose of such OECD guidance is to be more practical than descriptive, explaining the steps to be followed and associated data needs, the drivers and parameters, the conditions and boundaries. Draft guidance should be submitted mid-May for discussion and hopefully further support at the next TFHA meeting on June 15-16 (more information: Marnix Vangheluwe, Ben Davies, Hugo Waeterschoot and Violaine Verougstraete).

Calendar

- **14 April (pm)**: CLP for Mixtures Training – MCC (Brussels)
- **16-17 April:** Workshop on the use of REACH/CLP information at industrial sites - ECHA (Helsinki)
- **20-24 April**: MSC 41 – ECHA (Helsinki)
- **21 May**: Authorisation & Restriction Platform – MCC (Brussels)
- **20-21 May:** Exchange Network on Exposure Scenarios (ENES) – ECHA (Helsinki)
- **26 May**: Evaluation Platform – MCC (Brussels)
- **27 May**: 10th Stakeholders' Day – ECHA (Helsinki)
- **1-5 June**: RAC 33 – ECHA (Helsinki)
- **8-12 June**: MSC 42 – ECHA (Helsinki)
- **8-12 June**: SEAC 27 – ECHA (Helsinki)
- **15-16 June**: 8th Meeting of the Task Force on Hazard Assessment – OECD (Paris)
- **17- 18 June:** 7th Meeting of the Task Force on Exposure Assessment – OECD (Paris)
- **3 September**: Authorisation & Restriction Platform – MCC (Brussels)
- **7-11 September**: RAC 34 – ECHA (Helsinki)
- **7-11 September**: SEAC 28 – ECHA (Helsinki)
- **14-18 September**: MSC 43 – ECHA (Helsinki)
- **23 September**: REACH Forum – MCC (Brussels)
- **7-8 October:** ECHA/EFSA Topical Scientific Workshop on Soil Risk Assessment – ECHA (Helsinki)
- **26-30 October**: MSC 44 – ECHA (Helsinki)
- **23-27 November**: RAC 35a – ECHA (Helsinki)
- **30 November – 4 December**: RAC 35b – ECHA (Helsinki)
- **30 November – 4 December**: SEAC 29 – ECHA (Helsinki)
- **7-11 December**: MSC 45 – ECHA (Helsinki)
- **15 December**: Evaluation Platform – MCC (Brussels)
- **16 December**: Authorisation & Restriction Platform – MCC (Brussels)
- **17 December**: REACH Forum – MCC (Brussels)

Acronyms

AE: Assessment Entity	MERAG: Metals Environmental Risk Assessment Guide
AfA: Application for Authorisation	MSC: ECHA Member States Committee
AoA: Assessment of Alternatives	OECD: Organisation of Economic Cooperation and Development
CARACAL: Competent Authorities for REACH & CLP	OEL: Occupational Exposure Limits
CII: Cross Industry Initiative	OSH: Occupational Safety Health
	OSOR: One Substance, One Registration
CEFIC: European Chemical Industry Council	PBT: Persistent, Bio-accumulative and Toxic Substances
C&L: Classification & Labelling	PNDT: Pre-Natal Development Test
CLH: Harmonised Classification	PNEC: Predicted No-Effect Concentration
CLP: Classification, Labelling & Packaging Regulation	RAC: ECHA Risk Assessment Committee
CMR: Substances classified as carcinogens, mutagens or toxic to reproduction	REACH IT: ECHA's central IT system
CSR: Chemical Safety Report	RIME: ECHA Risk Management Expert meeting
DCG: Director's Contact Group	RMM: Risk Management Measures
DNEL: Derived No-Effect Level	RMOa: RMOA: Risk Management Options Analysis
DE: Dossier Evaluation	RP: Review Periods
DU: Downstream User	SCL: Specific Concentration Limit
EEB: European Environmental Bureau	RP: Review Periods
EFSA: European Food Safety Authority	SCL: Specific Concentration Limit
ED: Endocrine Disruptor	SE: Substance Evaluation
EOGRTS: Extended One-Generation Reproductive Toxicity Study	SEA: Socio-Economic Assessment
ERV: Ecotoxicity Reference Values	SME: Small or Medium size Enterprise
ETUC: European Trade Union Confederation	STO: Stakeholder Observer
GHS: Global Harmonised System / Standard	TCC: Technical Compliance Check
HERAG: Health Risk Assessment Guidance for metals	TFHA: Taskforce on Hazard Assessment
IUCLID: International Uniform Chemical Information Database	TRV: Toxicity Reference Value
iUVCB: inorganic Unknown or Variable Composition	US EPA: US Environmental Protection Authority
MeClas: Metals Classification Tool	vPvB: Very persistent very bioaccumulative