Eurometaux
European Association of Metals

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EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

Two months ago, the summer to come appeared to me as an ocean of quietude and time, where, between two finalized projects and a set of minutes, I could sort out the cupboards in the Eurometaux corridor, take a scandalously long lunch pause, and even add 'eat ice-cream with the staff at 4.00 pm' on an otherwise rather sober to-do-list; before leaving Brussels to get a sun tan.
Of course, nothing turned out as foreseen: the projects that I thought would be on their way to finalization appeared to need one additional review process, ECVAM did not come back to us saying that our bioelution protocol is so good that they are happy to support it without any further discussion and the "metal workshop" which took place last week in ECHA required in fine quite a lot of preparatory work.
However, I still had two weeks to drive to sunny Calvados, ready to experience once more this magic formula: the kids joining me in a small village inhabited with great smiling people, manual work outside to do some REACH brainwashing and reasonable amounts of cider (or worse if I decided to explore the local production).
But the atmosphere upon arrival turned out to be quite different as even deepest Normandy had been hit by terrorists, and the steel valves company employing most of the people in the village - recently taken over- had imposed a rather wild productivity plan, resulting in palpable bitterness, and even burnouts (an up to now unknown syndrome). The village seemed somewhat lost in its silence, 'healing its wounds'.
Progressively though, the Normans showed up 'at the Belgians' place' for increasingly longer 'aperos' and long, full tables of endless meals, evoking here and there that life remains to be celebrated, that taking things too personally is a waste of time as it is the group spirit that matters and even –stated formally after the Trou Normand- that although it is evident that we can all think differently, at least we should know why. Normans are not all naturally born speakers: words of wisdom are therefore immediately followed by a loud 'Santé' and rattled glasses to avoid any gravity settling down on the 'tablée'. In one of these moments, one of the revellers even started, for my benefit alone, the description of an Inconel alloy's properties, sure that it would control the emotionally charged atmosphere.
The two weeks were of course over before I realized it. So we cleaned and closed the house, gave the garden back to the apple trees and the birds and left behind the not totally finished painting of the window frames. But feeling grateful for the time we were permitted to spend there. And now of course, days are getting shorter, the sun tan has vanished, and I'm again behind my desk with the pending to do list on it as well as the on-hold projects but I'm still trying hard to preserve the learning of this summer: "you only live once-but if you work it right, once is enough (J.E. Lewis)".

Violaine Verougstraete, EHS director Eurometaux

ECHA REACH activities: hot topics

ECHA MEETINGS

"Metals framework" meeting on 30 August: *a very good kick-off event*
The metal sector was invited by ECHA on 30 August to discuss their future chemicals management strategy and the setup in this context of a "metals/inorganics" sectorial framework. Christel Musset (Director Registration) set the scene with a very interesting presentation reminding the participants of the 2020 Chemicals Management goals, ECHA's regulatory strategy and the post-2018 shift from registration to evaluation and risk management activities. ECHA also stressed the need to allocate resources most appropriately ("tackle what matters") and to keep industry in an 'acting' mode to work on risk management

and further improvement of the registration dossiers. Sectorial approaches could help to achieve these objectives and help with a categorisation of the registered chemical substances in the following categories:

No regulatory action Substances for which available data suggest that no regulatory action is needed at present
Information generation required Substances for which there is at present uncertainty regarding the hazardous properties and/or the potential for release to environment or exposure of humans; risk cannot be excluded although it cannot be established based on currently available data
Risk management required Substances for which there is risk and risk management has already been initiated or can be initiated on the basis of currently available data
Low priority substances Substances for which risk is unlikely but they need to be monitored

The metal sector was invited to join forces and to have a first exchange on the modalities of a cooperative sectorial metal strategy, to be implemented in the coming years. Key questions to be responded to include:

- Which (registered) substances are covered by Eurometaux? What about the other metals registered?
- How the dossiers were built and the substances grouped?
- What's the quality of the supply chain coordination and information? Volumes, uses, use conditions?
- What's the availability and quality of the hazard information?
- What are the barriers to updating dossiers?
- Is key info to prioritise/deprioritise present in the dossiers?

These questions will be further discussed with the REACH Forum but also with our colleagues of the REACH Alliance.
The second part of the workshop, which brought together a large and very senior ECHA representation and an extensive metals delegation, was devoted to the discussion of six main outstanding technical challenges estimated to hamper the sector in progressing effectively and efficiently with chemicals management, due to lack of consideration for metals specificities. For each of these challenges the metals sector suggested ways forward on how these "hurdles" could potentially be solved. ECHA reacted quite responsively to the suggestions and showed a clear willingness to solve several of these in partnership with Eurometaux and on a priority basis recognising available resources. The resulting actions will be further discussed with the Forum and the scientific groups. We would like to thank here all consortia and the Eurometaux REACH/EHS team who helped us, through preparation and attendance in making this workshop a success (more information: Hugo Waeterschoot and Violaine Verougstraete).

AUTHORISATION

Authorisation meeting planning: a draft schedule developed for early 2017 balancing priorities and resources
2016 was and still is the year that Authorisation Applications (AfAs) came on stream with more than 150 received by ECHA, mostly on chromates. Both the uses covered, as well as the horizontal learning lessons of those cases, are most relevant for the metals and inorganic sector at large and demonstrated shortcomings in methodological concepts (e.g. Man via the Environment, MvE) as well as the way in which industry demonstrate safe use for downstream applications. ECHA and Industry therefore scheduled a series of meetings and workshops for the first semester of 2017 aiming at improving the concepts and data development to achieve longer review periods and less stringent conditions when adopting AfA opinions in RAC and SEAC. The following meetings are temporally scheduled: to clarify the MvE issue: an Eurometaux science workshop (28 January), a capacity building session with RAC (March) and a NeRSAP meeting (16-17 May); a session with the Chromates user sector to draw learning lessons from the Chromates on 27 June and an AfA training session for upcoming applications (CTP-HT, Pb compounds, …) on 28 June. The dates will be confirmed in the coming weeks (more information: France Capon and Hugo Waeterschoot).

EUROMETAUX REACH activities: hot topics/issues

RESOURCE MAPPING TO RESPOND TO REACH / ECHA CHALLENGES

RMOa session with ECHA: ***excellent opportunity providing interesting and constructive feedback***

Over the last two years the Eurometaux A&R platform has developed a Risk Management Option assessment (RMOa) tool and complementary guidance. Both aim at stimulating industry to conduct voluntary assessments on the need for, and potential best options for risk management under REACH, CLP or other legislations, for "concerns" as now defined by the new REACH screening methodology in place since 2015. This allows industry to improve and update the registration files, collect additional relevant information in time and eventually anticipate regulatory risk assessment or risk management reviews. The guidance and practical experience as exemplified by several cases developed by the metals consortia (CoRC, NI, EPMF) as well as by a consultant for the organic sector were presented to an extensive ECHA staff representation (29 August 2016) in Helsinki. ECHA appreciated the tool very much and concurred with the main aim as expressed. It could certainly help the regulatory community in using a more holistic approach along with better and more relevant information when a substance is listed on the PACT list for RMOa assessment by the European Commission or a Member State. The broader scope of RMOas that can be assessed compared to REACH and the clear methodology were also recognised as valuable assets of the tool that could probably be used under the metals sectorial 'framework' strategy to assess the quality of the dossiers and potentially be of help in defining priorities (see above). In addition, all parties saw the value of presenting the guidance at the next RIME (Risk Management Experts) meeting this autumn, an opportunity ECHA will explore regarding how this could be best achieved (more Information: Carol Pettit, Kai Melzer, France Capon, Michel Vander Straeten or Hugo Waeterschoot).

Chemicals Management event: ***preparation of communication material and moderator identified***

The month of August has allowed to make further progress with the preparation for the half-day seminar to be held on 20 October "From words to action: defining the non-toxic environment": the last speakers have confirmed their participation in the two roundtables 'Where do we need to be by 2020?' and 'What steps should be taken now to work towards a common 2020 vision for Chemicals Management'? A moderator has been identified and will explore and exchange early September on possible ideas to keep the debate as dynamic and interactive as possible. Over the last weeks, we also benefited from the creativity and uncommon energy of Rebecca, a trainee who joined Eurometaux for the month of August. She had the challenging task to translate key pieces of work like the RMOa, the main outcomes of the Recycling and Authorisation study but also messages on the REACH review and the best use of REACH data in communication material that could be used on the day of the Chemicals Management event. The draft posters and handouts will soon be circulated to the REACH Forum and the Communication Committee for their comments and approval (more information: Guy Thiran, Chris Heron, Hugo Waeterschoot and Violaine Verougstraete).

METAL-SPECIFIC TOOLS

Bioelution and alloys classification schemes: ***making progress***

ECHA's Classification Unit has invited MSCAs and CARACAL observers to nominate participants for an expert group on bioelution. This group will discuss and provide advice on the use of bioelution in the context of Article 12(b) of the CLP and work in parallel with the methodological development of the bioelution protocol conducted by the JRC ECVAM. Eurometaux has nominated Adriana Oller (Nipera) as representative of the metal sector to participate in a meeting in Helsinki in the autumn and follow-up webex sessions later this year. In parallel a shadow group has been set up to prepare and coordinate our input. The alloys classification schemes circulated over the summer will constitute a first source of input from the sector. ECHA has welcomed Eurometaux's suggestion to be provided with these schemes and accompanying explanatory note by mid-September -before the expert group meeting- so as to prepare the discussions. The preparation of the new round robin testing is proceeding further, so as to be ready to start as soon as there is feedback from ECVAM (more information: Adriana Oller, Federica Iaccino and Violaine Verougstraete).

UVCB

SID inorganic UVCBs: ***positive feedback and suggestions***

Since the last meeting we had with the ECHA SID Unit in December 2015, we have developed and tested an approach to improve SID of inorganic UVCBs in order to meet regulatory acceptance. To ease and harmonise this exercise, we prepared an excel template starting from the indications of the REACH Guidance that identifies *process*, *source* and *composition* as the parameters to be reported to provide unambiguous identification of any UVCBs. The core exercise was to translate the

industrial knowledge on substance identity into a well reported substance identification, despite substance complexity and variability, to ensure that evaluators will also be able to assess substance identity and substance sameness (as for inquiries). ECI, EPMF, Nickel Institute & Nipera worked on the template with the aim of distinguishing between *decisive parameters* for substance identification (for fixed depictants, or with low variability), parameters that are only indicative (i.e. with medium variability) and parameters with low substance identification potential (i.e. with large variability). To do so, we asked them to fill in the template and to assign a level of variability to each parameter, identifying high, medium, low variability and fixed parameters (e.g. < 5% variability). The examples that were developed looked very promising in reaching a good compromise between industrial SID refinements and regulatory requirements. We have submitted these examples to the SID Unit in ECHA to ensure our approach meets their expectations. We hope to arrange a web conference or conference call in the coming weeks and we will keep you posted with the outcomes (more information: Frederik Verdonck, Katia Lacasse, Katrien Arijs and Federica Iaccino).

Further outreach of REACH

OECD

OECD Taskforce on Hazard Assessment: ***good news from the OECD secretariat on the naming of Guidance documents***
In the July REACH News, we mentioned that a revised version of the 'Guidance on the incorporation of the bioavailability concepts for assessing the chemical ecological risk and/or environmental threshold values of metals and inorganic metal compounds' had been submitted to the OECD secretariat, who subsequently circulated it to the Taskforce on Hazard Assessment for a last round of comments. In the accompanying email the OECD secretariat had indicated that they would draft a short document clarifying the rationale behind the naming of documents discussed in the context of the OECD Taskforces to address a comment made by Germany on the 'industry source' of the guidance note. The internal operational document circulated by the OECD secretariat in August states that Guidance and other documents are produced with the aim of promoting harmonisation. The naming 'Guidance' addresses documents on how to perform a test or study - specific tests, endpoints, scenarios or documents for methodological approaches and frameworks for testing and assessment. Based on this description, the OECD secretariat concludes that the bioavailability document should be named "Guidance Document on the Incorporation of Bioavailability Concepts for Assessing the Ecological Risk and/or Environmental Quality Standard Setting of Inorganic Metals and Metal Compounds". Comments can be submitted until 9 September (more information: Marnix Vangheluwe, Benjamin Davies, Hugo Waeterschoot and Violaine Verougstraete).

OECD Taskforce on Exposure Assessment: ***occupational and consumer exposure, block 2 metals guidance on fate modelling***
Eurometaux attended the OECD TFEA meeting hosted by BAuA (Dortmund) end of August. The meetings of this technical taskforce are the opportunity to be updated on the topics of interest for the OECD countries (e.g. 3D printing in Denmark, dermal exposure in Germany, children's health in The Netherlands) but also to exchange on a number of approaches and tools under development, ranging from Emission Scenarios Documents to models assessing consumer exposure in Japan. The EU JRC presented the Information Platform for Chemical Monitoring (IPChem), which implements searching facilities for discovering, accessing and retrieving chemical monitoring data across various media whilst the Canadian and the OECD secretariat presented an update on the combined exposure project. As one of the items of interest is releases from products, Eurometaux had suggested that KTH make a presentation on releases from metal surfaces, completed with a couple of slides on bioelution. Eurometaux and ICMM have also presented a proposal to develop a second block of metals guidance on exposure assessment and fate of metals & inorganic metal compounds. The countries can make comments on the relevance and usefulness of the proposal until the end of October. Important will be to ensure that some key countries, like the US, Canada and Japan express some interest in this project that covers the Unit World Model, Man via the Environment and diffuse sources. A two-pager will be prepared by ICMM, stressing the added value of this piece of guidance, to be shared for example with the NAMC (more information: Ben Davies, Hugo Waeterschoot, Marnix Vangheluwe and Violaine Verougstraete).

ICMM

ICMM CMWG: ***Industry met in Raleigh back-to-back with the ETAP session***
The semestrial session of the Chemicals Management Working group of ICMM took place this time in Raleigh on 25-26 August, back-to-back with the annual ETAP meeting. Reviews were provided on recent regulatory initiatives on chemicals management in the US (new TSCA legislation), in Canada (the DSL, lacking much progress at the moment) and the EU (REACH). A major part of attention was dedicated to the OECD programme on the metals environmental guidance. The meeting thanked the authors

of the bioavailability guidance (Arche, Eurometaux and contributing consortia) which recently achieved approval from the OECD and can now be used as a reference document. Industry submitted a proposal to the OECD TFEA, for a second block of guidance to be development this time on exposure and fate assessment of metals in the environment. IMO aspects as well as a short report on the recent APEC Chemicals Forum sessions complemented the discussions (more information: Ben Davies and Hugo Waeterschoot).

OTHERS

ETAP: ***fruitful meeting with interesting new avenues to explore on critical issues like data poor metals and Rapid Removal***
The 21st meeting of the ETAP panel, a group of external high level scientists with good knowledge on metals' science aspects advising the metals commodities, took place in Raleigh RDU (NC-US) on 22-24 August. Eurometaux was permitted to attend the meeting as observer and also represented the interests of the Precious Metals sector. The panellists provided suggestions on issues raised by the metals sector amongst others on how to further proceed on demonstrating Rapid Removal for metals for classification purposes, the variability of organic matter (critical in bioavailability assessments) and novel ways to measure or estimate it and furthermore to decrease uncertainty for data poor metals with limited test data. The latter (called QiCAR) would allow to reduce assessment factors based on a kind of QSAR modelling for inorganics. Each panellist also provided during the meeting an "emerging issues presentation", whereby the member indicated what new issues are appearing that would require at least some attention from the sector. A debrief on the outcome of the ETAP panel is scheduled for the upcoming Eurometaux science meetings evaluating what issues industry would further consider and develop to enhance the environmental risk assessments for chemicals management or EQS setting (more information: Hugo Waeterschoot).

Calendar

- **5-7 September:** Eurotox (Sevilla)
- **5-9 September**: RAC 38A – ECHA (Helsinki)
- **12-16 September**: RAC 38B – ECHA (Helsinki)
- **12-16 September**: SEAC 32 – ECHA (Helsinki)
- **12-15 September**: ICHMET 18th International Conference on Heavy Metals in the Environment (Ghent)
- **13-15 September**: MSC 49 – ECHA (Helsinki)
- **28-29 September**: Management Board – ECHA (Helsinki)
- **27 September**: REACH on metallurgical final slags - A & R Platform – MCC (Brussels)
- **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*
- **16 November: Authorisation & Restriction Platform** – MCC (Brussels)
- **17 November**: Evaluation Platform – MCC (Brussels)
- **23-24 November:** IUCLID 6 Chesar 3 training – MCC (Brussels)

Acronyms

AfA : Application for Authorisation	**NAMC: North American Metals Council**
A&R : Authorisation and Restriction	**NeRSAP: Network of REACH Socio-Economic and Assessment of Alternative Practitioners**
BAuA: The Federal Institute for Occupational Safety and Health	**OECD: Organisation of Economic Cooperation and Development**
CLP: Classification, Labelling and Packaging Regulation	**PACT: Public Activities Coordination Tool**
CMWG: Chemicals Management Working Group	**QSAR: Quantitative Structure-Activity Relationship (models to predict toxicity)**
CTP-HT: Coal, Tar, Pitch-High Temperature	**RAC : Risk Assessment Committee (ECHA)**
DSL: Domestic Substances List	**RIME: Risk Management Experts**
ECVAM: European Union Reference Laboratory for alternatives to animal testing	**RMOa: Risk Management Option analysis**

ETAP: Environmental Technologies Action Plan	**SEAC : Socio-Economic Analysis Committee (ECHA)**
JRC: Joint Research Centre	**SID: Substance Identity**
KTH: Royal Institute of Technology, Sweden	**TFEA: Task Force on Exposure Assessment**
MSCA: Member States Competent Authorities	**TSCA: Toxic Substances Control Act (US)**
MvE: Man via the Environment	**(i)UVCB: (inorganic)Unknown or Variable Composition, Complex Reaction Products and Biological Materials**