EUROMETAUX
EUROPEAN ASSOCIATION OF METALS

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EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

Snapshot from a presentation seen this week: a hamster diligently activating a wheel, alluding to the ever increasing workload under REACH. I wonder how the hamster is actually feeling, trapped in its activity. Does he enter the wheel voluntarily driven by the simple perspective of the game or is there something irresistible to put things into motion? And once he has started running and senses the movement, how do the thrill of action and the possible weariness balance each other? Can he still have any impact on the speed of the wheel or does he just try to keep his grip? From what I remember as a kid, the hamster gets out of the wheel in due time, in order to shift to other activities or to get some rest. Some of us REACH managers always wait a bit longer, thereby risking a possible slip. Probably because we are not activating a single wheel but a succession of them and that the boost –and the beauty- of a harmonious, integrated movement somehow becomes addictive, outbalancing tiredness or questions. The belief that the wheels make sense keeps us sprinting.
REACH needs hamsters! We will need hamsters to cope with REACH in 2014, there is no doubt about that!
But we may build in some pauses in the ever turning wheel.
These last days of busy February (see below), I have had the privilege to witness two moments where the change in rhythm of the wheel allowed something different to emerge: one was the interactive group work on a RMO strategy and its associated challenges, the second one -over a coffee, thanks George!- involved one of our consultants sharing his reflections on combined exposure at the workplace. In both cases, the settings played a role.
Imagination needs time to deploy. Creativity requires putting some breaks on the wheels. Saint-Exupery wrote that "a rock pile ceases to be a rock pile the moment a single man contemplates it, bearing within him the image of a cathedral". Our sector has the potential, the assets and the right personalities to construct the cathedrals, let's work a bit in the moment!



Violaine Verougstraete, EHS director Eurometaux

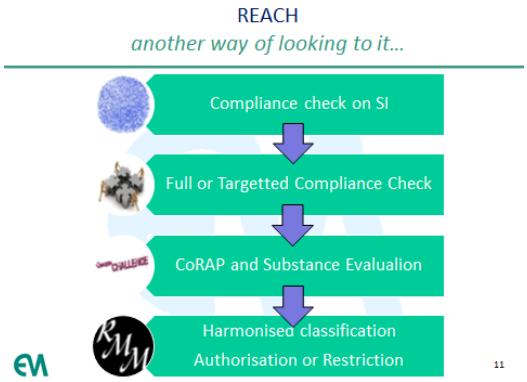
ECHA REACH activities: hot topics

ECHA COMMITTEES

MSC-34 (3-7 February): Substance Evaluation at full steam
Contrary to the previous MSC meetings that debated aspects of the authorisation scheme, the focus of the 34th meeting was mainly on Substance Evaluation (SE) and Testing Proposal Evaluations (TPE) for large "read-across" groups, in this case petroleum substances. Most important was that ECHA and MSC consistently applied the approach as developed for the large metals groups (e.g. Cobalt compounds). The annual MSC satisfactory survey demonstrated a widening gap between the "high satisfaction" expressed by Member States and the eroding trust by Stakeholders, mainly due to a lack of transparency and proportionality with the Authorisation system. A series of learning lessons were picked up from the SE and TPEs, several of them being of relevance to the metals sector. The highly technical recommendations will be included in the KnowMe database and summarized for the Evaluation Platform.
MSC also agreed with the update of the CoRAP list: it includes for the first time a metal compound and a substance for which the concern was not based on "risk grounds" but on exposure considerations only (Potassium TiO_2). This sets a precedent for the future. Industry further commented about the expressed concern for the CMR and high RCR entry on $AlCl_2$ which was thought to rely on too light evidence.
MSC took note of the new potential SVHC proposals that include again some Cd and B-based metal compounds (more information: Hugo Waeterschoot).

ECHA*: *integration screening systems to achieve more consistency

ECHA and MSC debated a proposal to integrate the different substance screening systems that presently exist to identify substances for harmonized classification, dossier /substance evaluation and SVHCs. The aim is to align the different REACH tools in a more logical order of increasing evaluation or risk management level, starting with Substance Identity check (SID), Compliance Check in Dossier Evaluation and subsequently Substance Evaluation (SE) to determine potential listing as SVHC, the need for harmonized classification or additional data gathering needs. This streamlined approach was welcomed by industry given it would "reduce the number of surprise cases" for SE and SVHC. Alternatively it means that each SE will be preempted by a SID and a CC requiring additional attention of industry. The integrated screening approach is now under piloting and will most probably be applied from this spring on (more information: Hugo Waeterschoot).



INTERMEDIATES AND STRICTLY CONTROLLED CONDITIONS

A roadmap with short-, medium- and long-term actions on UVCB intermediates: As follow up of the meeting held with ECHA on 22 January, Eurometaux and ECHA further exchanged on the remaining issues to assess, and on their possible timing (before the deadline for the submission of the upgraded intermediates dossiers or after). Further to ECHA's suggestion, Eurometaux prepared a roadmap proposing short term, mid-term and long-term actions. This roadmap was presented to the Eurometaux Intermediates taskforce during a call on 24 February. ECHA took note of the roadmap and is trying to find some possible ways to facilitate some of the short-term actions (more information: Federica Iaccino and Violaine Verougstraete).

ECHA Substance Identification Team (SID) visits metal plants in Finland on the UVCB issue

A second outcome of the January discussion was the organization -with the ECHA Substance Identification & Data Sharing team- of plant visits in Finland. ECHA was most interested to better understand the complexity in composition and the variability of metal intermediate UVCBs and the difficulties to characterize these streams. The Head of Unit concluded that the visit to the Boliden's smelter and electro refining and Outotec's analytical department was "very useful in the ongoing discussions about the identification of substances in the metal". Industry in turn learned that several of the SID members had quite some experience in metals refinement and manufacturing due to previous positions in industry, which also helps the team in better understanding the metals complexity (more information: Katia Lacasse and Hugo Waeterschoot).

AUTHORISATION

NeRSAP 2 (Brussels, 26 February) an increasing network of growing interest

The Network of REACH Socio Economic and Assessment of Alternative Practitioners, i.e. a mix of member states, ECHA, consultants and Industry experts met for the second time. The network was created last year following an idea and the initiative of Eurometaux supported by Member States, Cefic and ECHA to stimulate exchanges on concepts, methods and experience with REACH/CLP SEA and AofA activity. This meeting debated extensively on 4 cases covering SEA models, a comparison of the SEA and AofA guidances between REACH and the Biocides Directive, how SEA and AofA could be handled in the first EU-fast track Restriction under REACH (article 129) and observations on the first submitted Authorisation Applications (incl. As_2O_3). Most interesting learning lessons for the metals sector were drawn and were then reported to the Authorisation and Restriction platform that met on 27 February. They will also be included in the KnowMe database. Metal sector attendees confirmed the need for consultants working for the sector on SEA and AOFA to participate in the NeRSAP network. Member States and ECHA's recognition for NeRSAP is high: the ECHA Management Board has now included the network in its multi-annual work plan as the forum for SEA and AofA learning (more information: Hugo Waeterschoot, France Capon, Aggie Kotze and Renaud Nicolay).

Authorisation*: *developing a third Risk Management approach

An increasing number of Member States express concerns that Authorisation would always be the preferred Risk Management route for substances on the Candidate List. This was recently more formally challenged by The Netherlands who launched a restriction on NMP (to cancel Annex XIV listing) and by concerns expressed by MSC members on substances on the 5th priority list, including the RCFs, a highly relevant material for the metals sector. A group of consortia explored with Eurometaux if an OEL-approach could provide an alternative approach to Authorisation and/or Restriction for inorganic CMR substances with exposure and uses limited to the workplace. Interests and experiences of several metals/inorganics with the EU-OEL system were exchanged at a meeting on 25 February. A potential strategy to achieve increased recognition by Member States for this third Risk Management approach was defined. It was agreed that a strategy and an advocacy paper would be developed in March in preparation of the REACH Forum meeting, so that an awareness raising and advocacy approach can be rolled out in Q2 (more information: Hugo Waeterschoot and Violaine Verougstraete).

ECHA OTHERS

Eurometaux invited to reflect on Stakeholders' roles

Eurometaux has been invited by the ECHA Communication Unit to make a presentation on Eurometaux as accredited stakeholder, what its roles and organization on REACH are, and how it interacts with ECHA? The objective of ECHA was to increase awareness about stakeholder engagement activities but also to give the ECHA staff a better understanding of how stakeholders are working to implement European chemicals legislation. Hugo Waeterschoot made a very well attended presentation on 6 February, explaining the roles of Eurometaux as representing, communicating, anticipating, learning, and facilitating structure. The meeting was introduced by the Executive Director and attended by more than 50 staff including several heads of units. The presentation allowed to raise attention for the specificities of metals and requested a more pragmatic approach for data-rich well-regulated chemicals, like metals. The question and answer session confirmed that most ECHA staff were not aware about the extensive collaborative activity level between Consortia and Eurometaux and the systemic attention for identifying and communicating horizontal learning (more information: Hugo Waeterschoot and Violaine Verougstraete).

REACH-IT and IUCLID User Group meeting

On 26-27 February, representatives from Cefic, CONCAWE and Eurometaux met with ECHA's Computational Unit to discuss future plans for REACH-IT and IUCLID. ECHA explained the plans for the release of REACH-IT 2.7 around mid-April 2014 such as the new Terms and Conditions ensuring that only competent users can read the messages in the mailbox, and these mailbox messages will be considered as read after 7 days, modifications following the 4th ATP to the CLP, incorporation of the simple authorisation applications in the process flow. ECHA also invited industry to brainstorm on possible major modifications for REACH-IT 3.0 to prepare for the 2018 registration deadline and at the same preparing the system for post 2018 tasks where the focus will shift from submitting registration dossiers to maintaining registration dossiers. These modifications will include amongst others a new messaging/task/action system, better user management, management of the pre-SIEF and Joint Submission including the updates of the joint part of the dossiers. Further, the upcoming release of IUCLID 5.6 planned for mid-April and the future plans for IUCLID 6 were discussed (more information: Inneke Claes).

EUROMETAUX REACH activities: hot topics/issues

AUTHORISATION

Authorisation & Restriction (A&R) platform: review of the 2013 performance and definition of objectives for 2014

The Authorisation and Restriction Platform could, despite the tight and full agenda of last year, provide a very positive report on 2013 deliveries versus objectives. The creation of a SEAC and SEA/AofA network (NeRSAP), the efforts to influence Member States' policy and strategy on RMO and on the SVHC roadmap, amending the priority scoring for Annex XIV to a less discriminative system for metals and inorganics and the combined advocacy on the RCF prioritisation case are a couple of examples that achieved more than what was originally aimed for. Only the reporting system of companies interest for "Authorisable" chemicals underscored and the A&R platform agreed to reiterate the request in 2014 so that companies have the opportunity to express needs for support on Authorisation and Restriction cases. The A&R platform also defined 6 new key objectives for 2014 balancing strategic importance, workload and timing for 2014. The most important new objectives include the RMO strategy (see below), the development of the OEL approach as an alternative for Authorisation and Restriction and the build- up/exchange on materials flow methodology and SEA experience within the sector. The A&R platform chairs will report both 2013 performances and new objectives to the REACH Forum meeting in April (more information: Hugo Waeterschoot, France Capon and Aggie Kotze).

Workshop on RMO strategy*: *a challenging strategy and knowledge building exercise

The SVHC roadmap of the Commission increased the relevance and recognition of RMO as tool for SVHC identification or other Risk Management options. Therefore, the metals sector launched an initiative to raise the knowledge of the consortia on how to anticipate and build strategies to develop shadow RMOs, in view of the increasing number of substances (including metals) that will require RMO and the systemic approach provided by the roadmap. A first interactive training workshop took place on 27 February back to back with the A&R platform, generating a stepwise expertise building approach to RMO. Participants were challenged to review potential metal sector SVHC cases and define areas of concern for RMO assessment and fitness checks for different Risk Management options including potential reporting formats. Eurometaux will, based on this experience, develop schematic guidance including a couple of examples. It is the objective of the A&R platform to test some of the concept principles informally with regulators and couple this with feedback to be sent back to industry to improve the acceptability of the proposed guidance (more information: Hugo Waeterschoot and Michel Vander Straeten).

Preparation of the Cd restrictions discussions coming up at RAC/SEAC

Cd consortium experts kindly briefed Eurometaux on the main issues at stake with the ongoing and forthcoming Cd restrictions discussions at RAC and SEAC. The first restriction is in fact an amendment to the existing Restriction on Cd as impurity in anti-fouling paints. It proposes an extension to the presence of Cadmium in paints as an impurity, and to the presence of Cadmium in painted articles placed on the EU market. Main issue at stake is that any extension, or amendment, of an existing restriction must be based on a risk assessment and on clearly identified risks to be addressed on a Community-wide basis, conditions which are not met in this case. Eurometaux wrote a letter to ECHA in December to highlight the possible precedent-setting. ECHA acknowledged the raised concerns but argues that the main objective of the proposal is to improve implementation and enforceability of the restriction, and as such is justified. The second restriction concerns Cd in artist paints and in pigments intended for the manufacture of artists' paints (with derogation for maintenance of art and historic buildings and their interior). Sweden has performed quantitative risk assessments using two different endpoints, i.e. more bone fractures in males and females of approximately 50 years of age and postmenopausal breast cancer. Assuming that the effects of cadmium on fracture and breast cancer cases from a full restriction on the use of cadmium based artists' paints will grow linearly from zero at the time of implementation the following effect levels will be reduced after 150 years: for female fractures -47 cases; breast cancers -16 cases/year. Besides the proportionality issue, concerns are the referred studies and dose-responses based on the Annex XV proposal, the identification of the involved Cd compounds (more information: Christian Cannoo, Hugo Waeterschoot and Violaine Verougstraete).

CLASSIFICATION

Pb SCL follow-up

The survey launched by ILA and Eurometaux on the possible socio-economic impacts of the Pb metal classification and its associated specific concentration limit of 0.03% generated a lot of interesting data, which were compiled in a background document and presentation in view of a meeting with DG ENT and DG ENV on 17 February. The Commission acknowledged the issue and the fact that they would need to have internal discussions to identify possible ways forward. Industry was recommended to mobilise the members of the CARACAL sub-group (Member States) to whom a draft 7th ATP was circulated so as to ensure that they would raise at least some questions on the impacts of the Pb classification and the SCL. Thanks to a huge mobilization of the membership, a position paper, a compilation of existing standards/Pb regulations, a summary of bioavailability knowledge and experience on bio-elution, were all managed to be prepared and circulated before the very short deadline (28 February). We would like to explicitly thank here all commodities/associations, federations and companies for their incredible support. We now expect Commission to come back to us with some feedback (more information: Steve Binks, Hugo Waeterschoot and Violaine Verougstraete).

Preparation of the RAC discussions on boric acid and 2 borates compounds:

The borates consortium organised a briefing for Eurometaux/Cefic to highlight the main aspects at stake in the forthcoming discussions at RAC on the Polish proposal to re-classify boric acid for reproductive toxicity (for example, the appropriate consideration of epidemiological and mechanism of action data). Such briefings are extremely useful and helpful ahead of the Helsinki meetings to facilitate the preparation/reporting of the Eurometaux representatives, so many to the Consortium (more information: Roger Doome, Helen Kean, Violaine Verougstraete).

INTERMEDIATES

Approaching deadline for submitting 'upgraded' UVCB dossiers

Via conference call to the REACH Intermediate Task Force on 24 February. During the call, it was explained that to ensure consistency across UVCBs dossiers, Eurometaux is drafting "generic introductory texts" with the consultants to be included in the CSR, together with clear overview of key information that need to be reported. Such documentation and relevant information will be circulated within the taskforce as soon as finalized (more information: Federica Iaccino and Violaine Verougstraete).

OTHERS

Exposure Scenarios Taskforce: a meeting and several actions for the coming months

The Exposure Scenarios Taskforce met on 4 February to discuss the status of the CSR/ES Roadmap driven by ECHA, Member States and industry sectors and in particular the possible resulting actions for the metals consortia. Volume tracking, standard phrases and improving communication with downstream users become high-level priorities. A number of activities are ongoing both at OECD and ECHA level to streamline as much as possible the contents of ES/CSRs and allow a better extraction of the information needed in the REACH programmes, requiring some follow-up by the metals sector. Other aspects discussed at the meeting included consumer exposure, IUCLID sections 3.5-3.7 and ES for mixtures (more information: Frank Van Assche, Federica Iaccino and Violaine Verougstraete).

REACH Cross sector Group

Eurometaux attended the REACH Cross Sector Group. This group comprises representatives of manufacturers, formulators and downstream users and the aim is to discuss and exchange information on REACH related topics with an emphasis on cooperation along the supply chain. At the meeting on 18 February hosted by ASD, the following topics were discussed: evidence of registration related withdrawal of products, the SVHC Roadmap, Authorisation developments and the UNEP initiative on Chemicals in Products. The next meeting will take place early July (more information: Inneke Claes).

METAL-SPECIFIC REACH APPLICATION TOOLS AND CONCEPTS

Bio-elution: workshop in May, contacts with Danish and Belgian authorities and a poster at SOT

A workshop will take place on 22 May in the Radisson Blu Hotel (Brussels) to discuss with regulators how the concepts of bioavailability/bioaccessibility can be applied to metal substances in the context of REACH/CLP/GHS. More specifically it is proposed to discuss the possible applications of bioaccessibility data for metals and the boundaries of the proposed approach. The aim is to present the key conceptual and technical aspects, illustrate their application with some real cases and to respond to questions and comments. Also contacts have been taken with the Danish and Belgian Coordinators active in the OECD Test Guideline programme, to ask for their support to bring bio-elution to this OECD platform later this year. Finally a poster on the outcomes of the round robin test will be presented in March at the Society of Toxicology meeting in Phoenix, Arizona (more information: Violaine Verougstraete).

COMMUNICATION ACTIVITIES

Eurometaux made a presentation at the last Informa Conference on Chemical Control and Hazard Communication Regulations, held in Berlin on 11-13 February. Eurometaux presented its experience with CLP, the C&L inventory and the possibilities/difficulties for re-classifying substances with entries in Annex VI. The presentation was also an opportunity to raise the more downstream consequences of CLP (GaAs, Pb SCL) and plead for a more integrated approach (more information: Violaine Verougstraete).

Eurometaux's REACH team was kindly invited by the cobalt and the copper consortia to present highlights on the 2014 REACH challenges and tasks. Emphasis was put on the Evaluation activities (Substance and Dossier Evaluation) and the need to remain up to speed with the horizontal learning lessons and precedents. The Evaluation report published last week by ECHA (http://echa.europa.eu/documents/10162/13628/evaluation_report_2013_en.pdf) (see also summary circulated to the REACH Forum on 26 February) reinforces the message that consistency is not a 'vain word' and that industry should remain pro-active. Other aspects brought up during these presentations were ongoing developments of relevance for authorisation like the reference DNEL, the links between ECHA-OECD and the overall REACH Forum support. These possibilities to interact with the consortia members and respond to their questions are welcomed by the REACH team and help us to further identify needs/work areas (more information: Hugo Waeterschoot and Violaine Verougstraete).

Further outreach of REACH

OECD

BIAC and OECD Joint Meeting on 10-12 February: the metals guidance development programme will need more OECD countries support

The OECD Joint Chemicals group is the highest governing body with respect to Chemicals Management and coordinates the programme and its different activities. The future of the CoCAM process was one of the main debated issues. The proposed future activities were screened in terms of priority. While GHS activities got clearly overarching support by OECD countries, the metals programme did not really receive a high level of interest so far. ICMM and Eurometaux will therefore have to lobby some of the new OECD countries to support the relevance of such a programme for them before the Hazard Assessment Taskforce develops a prioritisation proposal. The pilot programme on the Substance Identification for UVCBs, currently focusing on oleochemicals, raised concerns from countries. Additional hydrocarbon groups were selected for the next steps, resulting in a delay of a potential extension to UVCB metal compounds after 2014. OECD also welcomed the streamlining of the nanomaterials programme merging different project teams and programmes and provided strong support for the further capacity building of developing countries so as to ensure they could better use existing OECD chemicals management tools and data sets (extension of knowledge beyond the MAD countries) (more information: Benjamin Davies and Hugo Waeterschoot).

Calendar

- 19 March: Stakeholder Workshop on the nanomaterials Definition:, Brussels (restricted access)
- 20-21 March: CARACAL Subgroup on nanomaterials (Brussels)
- 25-26 March: ETEAM Conference: validation work of Tier 1 tools including MEASE (Dortmund)
- 27 & 28 March: WS on Applications for Authorisation submissions to facilitate an optimal submission and handling process – MCC
- 1 April: REACH Forum – MCC (Brussels)
- 2-3 April CARACAL (Brussels)
- 28-29 April : ECHA Seminar on the basics of AfA (for beginners) – ECHA (Helsinki)
- 29-30 April : ECHA Workshop on lessons learned from AfA – ECHA (Helsinki)
- 12-16 May : SETAC (Basel) http://www.setac.org/events/event_details.asp?id=310405
- 19-20 May : CLP mixtures FECC-DUCC-Cefic-EM workshop (MCC)
- 22 May: WS on Bio-Elution/Bioaccessibility: A Promising Alternative To Animal Testing For Human Health Effects Assessment - (Radisson Blu Hotel, Brussels)
- 25 September: REACH Forum – MCC (Brussels)
- 17 December: REACH Forum – MCC (Brussels)

Acronyms

AofA: Assessment of Alternatives	NMP: 1-Methyl-2-pyrrolidone
ASD: Aerospace and Defence: Industries Association of Europe	OECD: Organisation of Economic Cooperation and Development
BIAC: Business and Industry Advisory Committee to the OECD	OEL: Occupational Exposure Limits
CARACAL: Competent Authorities for REACH & CLP	RAC: ECHA Risk Assessment Committee
CC: Compliance Check	RCF: Refractory Ceramic Fibers
C&L: Classification & Labelling	RCR: Risk Characterisation Ratio
CLP: Classification, Labelling & Packaging Regulation	RMO : Risk Management Option
CMR : Substances classified as Carcinogens, Mutagens or toxic to Reproduction	SCL: Specific Concentration Limit
CoCAM: Cooperative chemicals assessment meeting	SE: Substance Evaluation
CoRAP : Community Action Rolling Plan	SEA: Socio-Economic Assessment
CSR: Chemical Safety Report	SEAC: ECHA Socio-Economic Committee
DNEL: Derived No Effect Level	SID: Substance Identification
ECHA : European Chemicals Agency	SIEF: Substance Information Exchange Forum
ED: Endocrine Disruptor	SVHC: Substance of Very High Concern
ES: Exposure Scenario	TPE: Testing Proposal Evaluations
IUCLID: International Uniform Chemicals Information Database	UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials
MSC: Member States Committee	UNEP: United Nations Environment Programme