



EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

Work, being because of its excesses or because it is disappearing, is currently extensively questioned and debated by philosophes, sociologists and psychologists. Work is what confronts us to the world, to the intrinsic resistance of reality and transforms us. It is that part of ourselves that we engage, that part of intelligence we combine with existing constraints and prescriptions to 'make it work'. Working is mobilizing our creative intelligence to find solutions to a reality we do not control. It does not only engage our knowledge but our whole body, drawing on our resources in the deepest of our personality, the basis of our identity. Work mobilizes our whole subjectivity and takes us far beyond the work itself.

In working teams, in meetings, we all bring to the 'common table' our internal drives and tumults, contributing all together to the 'human factor' in the decisions taken, achievements and failures... examples of either grandeur or flaws.

It takes time to let one express his/her in-depth stirs, even more to pay attention and let those be. This time is vital though and a reason on its own to prioritise issues and agendas. Allowing the human factor to deploy itself and give each other the possibility to get acquainted to it, will keep it on the winning side rather than letting it burn us out.

Violaine Verougstraete, EHS director Eurometaux

ECHA REACH activities: hot topics

ECHA COMMITTEES

MSC-29 - 23-25 APRIL 2013

Testing proposals: the nano-concerns settled for Ag

Silver was one of the first metals that passed the Testing Proposal review up to the level of discussion at MSC, given two main outstanding issues related to the soil testing strategy and the question if nano-forms should also be tested under the REACH Testing Program forwarded by the Consortium. Both issues were settled, the latter concluding that the industry proposal at this stage does not cover the nano-form. The Netherlands will review this need later under the Substance Evaluation for Ag planned for 2014. This temporary solution is to the satisfaction of the industry (more information: Caroline Braibant or Hugo Waeterschoot).

CoRAP: MSC informed about the recent progress with the 2012 substance evaluations

MSC was briefed on the results and status of the first batch of Substance Evaluations (SEs) processed by ECHA after Member States developed 36 of them in 2012. 32 were screened for quality by ECHA and an equal number resulted in Draft Decisions (DD) for further data gathering, covering more than 170 new information requests (approximately covering 21% questions on Human Health effects, 35 % on Environment, 36% on exposure modelling for workers, consumers and the environment with smaller numbers on the CSRs and Substance Identification and physico-chemical properties). The DDs were sent on 4 April to all registrants leaving them with 30 calendar days to come forward with consolidated responses. The further approval mechanism was also explained to MSC.

The package contains one metal compound (Silica oxide) but many of the other comments are important for the wider metals sector. Cefic and Eurometaux therefore planned a workshop for 13 May to collect first experiences and industry is invited to share this with ECHA and the Member States at a special meeting organised end of May in Helsinki. NGOs saw this high number of recommendations as a clear sign of the low quality of most REACH files, a comment that was contested by ECHA. Once this experience collection is over, Eurometaux intends to organise a training session for metals on the present CoRAP list for 2014-2015 (more information: Hugo Waeterschoot).

SVHC identification: MSC took note of the outcome of the Public Consultation

At the MSC 29 meeting, organised just after the closure of the Public Consultation (PC) on the next SVHC list proposals (including Cd and Cd oxide), the MSC members shortly reviewed the main outcomes of the consultation process. Cd and Cd oxide received by far the most comments given the Cd sector and many related user sectors provided extensive comments during the PC. ECHA already grouped most of the comments indicating that the CMR properties were not challenged for Cd and Cd oxide but the potential Endocrine disruptor properties (as suggested by NGOs) and the Equivalent Concern properties related to Cd long term toxicity were challenged. The latter raised a principal question if STOT-RE 1 could become an indicator for equivalent concern and under which criteria? ECHA suggested organizing a discussion meeting on this point but Member States did not seem very interested (more information: Hugo Waeterschoot).

5th priority list: first activities started

ECHA presented the generic criteria that were used for the selection of potential substances for the 5th priority list. They focused on substances added to the candidate list in 2012 but excluded Pb compounds and others with ongoing RMO activity by Member States. This probably makes the list much shorter and clarifies which substances may appear (see Eurometaux REACH Forum slides of 19 March). ECHA does not intend to select many substances for the 5th list, given they expect to receive in 2016 series of Authorisation Applications that would -due to the delayed Authorisation Date (AD) for the chromates- coincide with the submissions under the 5th list. Eurometaux will inform the members as soon as the new list is formally known, given it may include for the first time substances with horizontal (multi-metallic) interest like the Refractory Ceramic Fibers (more information: Hugo Waeterschoot).

Planning calendar ECHA Committees for 2014: ECHA Committees fully deployed

With the last 2 REACH programs starting in 2013 (Substance Evaluation and Authorisation Applications), the workload of the REACH Committees is further ramping up. ECHA just released its 2014 planning calendar for all its formal Committee meetings which may be helpful for Consortia involved in different REACH activities (Restrictions, Authorisations, Harmonised classification, ..). Eurometaux will also use this calendar to develop the 2014 action plan for the September REACH Forum meeting. The calendar can be downloaded from the REACH metals gateway, members section (more information: Violaine Verougstraete or Hugo Waeterschoot).

ECHA MEETINGS

Preparing for the Sediments workshop of 7-8 May 2013: solid preparatory work

The Nickel Sediments research program as a follow-up of the former Risk Assessment under the ESR regulation promoted the idea from ECHA to organise the first ECHA science workshop along the concept of improving effects and risk assessment methodology of chemicals in sediments (see also Reach News of last month). Eurometaux and Nipera are, with ECHA staff, scientists and regulators, part of the Organising Committee that selected a distinguished program. The workshop is prepared around 3 background papers covering effects-, exposure assessment and risk characterisation, as well as case examples (including Nickel). Close to 100 worldwide scientists will discuss the papers and examples to provide guiding principles and practical solutions to improve sediments risk assessments (REACH, WFD, ...) (more information: Chris Schlekot or Hugo Waeterschoot).

ECHA OTHERS

C&L Inventory: updates following submission of registration dossiers

If a company which submitted a C&L notification for a substance now submits a registration dossier for the same substance with a new C&L, the entry in the C&L Inventory will be automatically updated in line with the registration dossier. For group notifications, the situation is more difficult. The electronic identifier of the companies (UUID) in a group of notifiers is not extracted and kept separately or linked to the REACH-IT account of that company member of the group. Hence, if a company part of a group notification, now submits a registration dossier, the C&L will show up as a new entry in the inventory. ECHA therefore recommends companies that submitted a group notification, to withdraw their "group membership" if they submit a registration dossier for the same substance to ensure that the inventory contains the correct information (more information: Inneke Claes).

"Double" joint registration entries on the dissemination website

For some substances, "double joint registrations" show up in the dissemination portal (e.g. for CaCO₃, aluminium, iron, polychloro copper phthalocyanine, trisodium hexafluoroaluminate). However, the search results link to the same published dossier which contains all of the information submitted by the different registrants. The dissemination system extracts all of the substance identifiers provided by registrants from their registration dossiers to allow -for example- any variant CAS numbers, IUPAC names, or public names for a substance and makes them available and searchable on the ECHA website. As some registrants did not enter the CAS number in their dossiers, these dossiers show up as an additional entry on

the dissemination website. ECHA is aware of the issue and considers it high priority to come up with a solution for this (more information: Inneke Claes).

“Opt-out” for joint submissions of registration dossiers: ECHA clarifies

ECHA clarified that if companies cannot agree on the costs for data-sharing within a joint submission, this is not considered by ECHA as a valid reason for a company to “opt-out” of the joint submission and submitting a separate registration dossier. These cases have drawn the attention of ECHA and will be investigated (more information: Inneke Claes).

ECHA to revoke registration numbers in more cases

ECHA currently revokes registration numbers when registrants fail to pay the correct fees (e.g. following SME verification, see article on the REACH-IT mailbox). ECHA is now investigating if other cases can be identified where registration numbers should be revoked. One such case could be if the registrant submitted an erroneous substance identity. Other quality defects such as not carrying out a certain test, or failure to give ample justification for not carrying out a test, are not considered sufficiently bad to revoke a registration number (more information: Inneke Claes).

ECHA to check substance ID of 2013 registration dossiers and automated screening for Areas of Concern (AoC)

ECHA will conduct an IT-based screening on the substance identity of all registrations it receives for the 2013 deadline, with the aim of helping industry to proactively improve the quality of their dossiers. Topics that will be checked include the following: function of stabiliser as given by the registrant in his substance identity which is not in line with the function as defined under REACH; concentration ranges and values inconsistent or missing; missing spectra without justification; and inconsistency in chemistry – identifiers for chemical structure. Based on the screening results, registrants will (or have) receive(d) an informal letter from ECHA providing advice on how to address the most typical substance identification shortcomings. A first batch of such letters was sent on 30 April 2013. ECHA will not directly follow up on these letters, they are purely an opportunity for registrants to check and spontaneously update their dossiers. At the end of 2013, the Agency will launch more systematic actions to improve substance identity information. An IT-based screening of specific substance identity information in all REACH registrations and automated checks of the Chemical Safety Reports (use and exposure information) are in the pipeline. Further topics that will be checked (AoC – Areas of Concern) include repeated dose toxicity, development toxicity and environmental persistence. At that stage, failure to address any detected shortcomings may lead to legally binding follow-up actions from ECHA. ECHA already stated in the past that the automated IT-based screening tool will also be used to identify chemicals for evaluation under the community rolling action plan for substance evaluation, for harmonised classification and labelling, and to identify SVHCs (more information: Inneke Claes).

Draft revised guidance on SDS sent to PEG

ECHA has sent a draft revised guidance on the compilation of safety data sheets to the Partner Expert Group (PEG) for comments. The main modification is a new annex which provides detailed guidance on how to integrate exposure scenario in a SDS and how to extend a SDS by attaching the exposure scenario. Guidance is provided on the correlation between the exposure scenarios and SDS sections. This information is currently part of the “Guidance on Information Requirements and CSA”. The most important part in the guidance document on SDS for the metals is the Appendix 3 on special mixtures which contains the specific elements for metals/alloys. This appendix has not been modified (except for the update of a reference) and is not open for comments. Eurometaux as member of the PEG will provide input for this consultation (more information: Inneke Claes).

Commission REACH activities: hot topics/issues

The SVHC Road map: political agreement followed by the launch of the implementation phase

The EU Competitive and Environmental Councils of February and March provided political support for the REACH Road Map to ensure that the 2020 target of all relevant SVHC substances being put on the candidate list would be met. Eurometaux, its members and supporting organisations and companies provided significant advocacy efforts alongside the industry position papers and objectives (recognition of RMO early in the process, quality assurance and possibility for industry to provide data) which were clearly fruitful. The political approval allowed Commission and ECHA to organise a first implementation workshop (18-19 April) together with the Member States but without possibility for Industry or NGOs to attend. ECHA and the MSs welcomed the Eurometaux-Cefic position paper prepared for this occasion and further discussed some of the ideas included in it. Most Member States seem to be prepared to inform Industry early on of RMO activity, therefore allowing data input and would even consider publishing the main outcomes. A pre-listing of intended RMOs is one of the options they are debating. No progress has however been made yet with the quality assurance (the position paper and more background can be obtained from France Capon or Hugo Waeterschoot).

CASG nanos 15 April, 2013: Does REACH cover nanomaterials?

Eurometaux attended this CARACAL subgroup on nanomaterials (CASG-nanos) meeting and made a presentation on behalf of industry, prepared with IMA, Cefic and NIA on the topic 'Can REACH adequately cover nanomaterials?'. Main conclusions from industry were that no major revision of REACH and no separate piece of legislation are currently needed. Focus should be on a better implementation, the follow-up of registration dossiers and enforcement, so that the information necessary for an adequate hazard and risk assessment becomes available. If refinement is needed, this could be done through adaptation of existing tools, guidance, REACH Annexes. Other topics discussed on the agenda included e.g. status report on activities carried out by stakeholders and regulatory bodies (Member States, ECHA, OECD), impact assessment, nano information via a Web portal, etc. (more information: Inneke Claes).

EUROMETAUX REACH activities: hot topics/issues

AUTHORISATION

RMO workshop: the need for industry preparatory work to be recognized

The implementation of the SVHC Road Map will promote more RMOs being conducted in preparation of ROI listing. Industry may have to play a role in this process, recognizing that important information for a balanced RMO cannot be found in the Registration files. Eurometaux organised therefore on 8 April an internal industry workshop (also attended by Cefic) to exchange the so-far limited Industry experience on RMOs and concluded to the value of voluntary data gathering to preempt data requests. The possible format that would be relevant to collect such information in a voluntary mode was also discussed (more information: France Capon or Hugo Waeterschoot).

NeRSAP meeting: a promising start

Eurometaux organised and hosted the first meeting of the Network of REACH Socio-economic and Assessment of Alternative Practitioners (NeRSAP) in Brussels on 9 April, a combined initiative from industry, Member States and ECHA. The NeRSAP network aims at developing and promoting good science and practices in SEA and AoA assessments for REACH through exchange on examples, concepts and methods. The meeting was well attended by SEA and AoA professionals including representation from countries in the SEAC. The practical contributions from the metals sector in particular were valued and seen as the way forward for the Network. The value for industry is in promoting the knowledge and quality of these critical tools for which experience is still in the build-up phase (more information: France Capon or Hugo Waeterschoot).

INTERMEDIATES

ECHA has now agreed with the principle to have a workshop to discuss the classification and risk assessment approaches developed by the Taskforce and that will be used to "upgrade" the UVCB intermediate dossiers. A suitable date should be defined soon. The UVCB internal guidance will constitute the basis for preparing the meeting with ECHA, and an updated version addressing inquiries and classification has been circulated for comments to the taskforce. Most of the pilot cases are in their finalisation stage too. A separate document describing the UVCB risk assessment approach is still under preparation. Data reporting modalities in IUCLID for UVCB intermediates were also further clarified and an exchange with ECHA on those formatting aspects shall take place in June. The progress made on the data sharing and exchange aspects allowed us to prepare a data sharing agreement, currently under finalisation. It will soon be sent to the REACH Forum. The goal is to celebrate the success of this multi-metal exercise by the next REACH Forum (20 June) (more information: Federica Iaccino).

COMMUNICATION ACTIVITIES

Eurometaux made a presentation at the last Informa Conference 'CLP & GHS 2013' on the topic: "Real-Life Industry Experience to Date: Including ATPs, Changes in Annex VI & Coping with Different Regional Transition Periods". Eurometaux evoked the different challenges met by industry to be compliant with CLP and GHS in 2010 and up to now. The implementation of the CLP requires a build-up of knowledge and understanding in a continuous mode as the text and the criteria are complex moving targets, with changes in methodologies and Annexes via the ATPs. Understanding the downstream consequences and links of classifications with other pieces of legislation need time and expertise that are not self-evident. The multiple classifications in the C&L inventory -as well as the limited success of the platform- raised the concern whether industry as a whole will wait for data mining initiatives from authorities in the C&L inventory to (be able) to agree on classifications. Also, how to bring in new data (e.g. to refine old group entries) and/or new approaches (removal from the water column,

complex materials) in the CLH and CLP mechanisms in place was evoked, as well as the regional differences in GHS implementation. The presentation ended by proposing some solutions like training industry (ATP and guidance changes, communication duties, CLH process), tracking changes in other jurisdictions via a set-up of GHS databases and the MeCLAS tool (more information: Violaine Verougstraete and Hugo Waeterschoot).

Important: check your REACH-IT mailbox

It is very important, that once they have submitted their registration dossier, the registrants regularly check their REACH-IT mailbox. ECHA will send all communications regarding the registration dossiers only to the REACH-IT mailbox. This includes reminders to pay the registration fee, feedback on SME verification and payment of additional fees, testing proposal feedback, quality observation letters, Article 36 letters, communication on substance evaluation, ... The deadlines to reply are extremely short (typically a couple of weeks) and if the deadline for feedback to ECHA is expired, there is no going back! If the registrant e.g. does **not** pay the additional fee for a large company in time, the registration number he initially received can be revoked by ECHA (more information: Inneke Claes).

Calendar

- 7-8 May 2013: Topical Scientific Workshop on Risk Assessment for the Sediment Compartment – Helsinki (ECHA)
- 16-17 May 2013: Fourth Meeting of the ECHA-Stakeholder Exchange Network on Exposure Scenarios (ENES 4) – Helsinki (ECHA)
- 23-24 May 2013: Workshop on Substance Evaluation and CoRAP experience- Helsinki (ECHA)
- 5-8 June 2013: RAC 25 – Helsinki (ECHA)
- 5-7 June 2013: SEAC 19- Helsinki (ECHA)
- 11-13 June: OECD Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology - Paris (OECD)
- 17 June 2013: 4th Authorisation Applications Training Workshop for potential applicants (with Eurometaux support) Inscription via ECHA website – Helsinki (ECHA)
- 20 June 2013: REACH Forum-MCC (EM)
- 21 June 2013: Reach Authorisation / Restriction Platform meeting-MCC (EM)
- 25 June 2013: The Biocides Stakeholders’ day – Helsinki (ECHA)
- 25-26 June 2013 : OECD hazard Assessment Taskforce meeting- Paris (OECD)
- 1-3 July 2013: Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals meeting – Geneva (UN)

Webinars <http://echa.europa.eu/support/training-material/webinars>

- 14 May 2013: How to bring your registration dossiers in compliance with REACH – Tips and Hints (Part 3)
- 11 September 2013: How to bring your registration dossier in compliance with REACH – Tips and Hints (part 4)

Acronyms

AD: Authorisation Date	MeCLAS: Metals Classification (Tool)
AoA: Assessment of Alternatives	MSC: Member States Committee
ATP : Adaptation to Technical Progress	NeRSAP: Network of REACH Socio-Economic and Assessment of Alternative Practitioners
CARACAL: Competent Authorities on REACH and the CLP Regulations	PC: Public Consultation
CAS (number): (unique numerical identifiers assigned by the Chemical Abstracts Service	PEG: Partner Expert Group
C&L: Classification & Labelling	RMO : Risk Management Option analysis
CLH: Harmonised Classification	ROI: Register of Intentions (for SVHC or Registration or harmonised CL&L)
CLP: Classification, Labelling and Packaging Regulation	SDS: Safety Data Sheet
CMR: Carcinogens, Mutagens Reproductive Agents	SE: Substance Evaluation
CoRAP: Community Rolling Action Plan	SEA: Socio-Economic Assessment
CSR: Chemical Safety Report	SEAC : Socio-Economic Analysis Committee
DD: Draft Decisions	STOT: Specific Target Organ Toxicity (classification endpoint)
ESR: Existing Substances Regulation	SVHC: Substance of Very High Concern
GHS: Global Harmonised System	UUID: Electronic Identifier of Companies
IUCLID: International Uniform Chemicals Information Database	UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials
IUPAC: International Union of Pure and Applied Chemistry	WFD: Water Framework Directive