



EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

As you will read below, the consortia and the REACH team again managed to tackle a very active REACH month, and this despite the cold, the frost and the REACH issues falling like snowflakes on the (work) landscape. Freezing examples of those were the approval of the new CoRAP and the potential impact of the REACH Authorisation process on the recycling sector. Alternatively, issues like the need for an RMO before deciding SVHC listing ensured for warm and convivial debates, the successful set up of e.g. the SEA and AoA network and the meeting of the REACH forum provided some much needed spring energy, and here we are, as joyful as Easter bunnies looking forward to dealing with April!

We hope that in the meantime you could all take a couple of days of break, a deep breath and enjoy some chocolate eggs! The mignonettes of the metals conference centre will be there in any case if the latter should be missing!

Violaine Verougstraete, EHS director Eurometaux



ECHA REACH activities: hot topics

ECHA COMMITTEES

RAC 24, 5-8 MARCH 2013:

RAC-24 concluded on the reproductive toxicity of gallium arsenide, as being a 1B. A last public consultation will be launched soon. This decision from RAC marks the end of a long advocacy and scientific process, which generated a number of learning lessons both for the industry and the Eurometaux STO in terms of interaction with RAC, Commission and Downstream Users. RAC has also started to discuss the restriction of Pb and Pb compounds in consumer articles (the restriction concerns the placing on the market of articles that can be placed in children's mouths) and the dossier submitted by Sweden was estimated conform. Finally, RAC is further building up its capacity on authorisation files and the derivation of reference DNELs (More information: see highlights circulated on 13 March, Violaine Verougstraete).

SEAC 18, 6-8 MARCH 2013:

SEAC 18: remarkable conclusion on the “Nonylphenol” and “Lead in articles” restriction cases

SEAC surprisingly rejected the proposal for a restriction on Nonylphenol and derivatives at its latest meeting early March based on the argument that the “proportionality and the Effectiveness of the suggested restriction were not appropriately documented and demonstrated in the Annex XV prepared by Sweden”. Moreover, the restriction proposal is now formally annulled given Sweden did not succeed, for the 2nd time, to pass the Compliance Check by SEAC. Contrary to this case, SEAC approved the compliance check for Pb and Pb compounds in articles but requested a careful review of the scope given that it felt too broad (e.g. including crystal) and a call for realism. Industry concurred with this and stated the right to review the DNEL derived for Pb during the jewellery case 2 years ago given conducted in a “precautionary mode due to time concerns” (More information: Hugo Waeterschoot).

SEAC 18: more clarity on the interpretation of the Economic feasibility criterion

SEAC agreed on an update of the Economic Feasibility paper, a key decision tool for non-threshold Authorisation Applications. SEAC concluded that “*no financial threshold*” is required to distinguish between ‘feasible’ and ‘non-feasible’, thereby leaving more liberty to the submitters to prove the validity of their case. The ECHA-SEAC paper on Economic Feasibility was distributed to the Eurometaux REACH Authorisation-Restriction Platform (More information: Hugo Waeterschoot or Michel Vander Straeten).

ECHA OTHERS

The first CoRAP update: *several metal substances listed*

The first updated CoRAP was listed on the ECHA website on March 20 containing besides Ag, GaAs and Silicon, now also Tin and Aluminium-sulfate, Beryllium and Zn phosphate. The REACH Forum agreed to participate in a co-organized event with Cefic to learn from the 2012-2013 cases in order to prepare industry as effectively as possible for these listed (and future) Substance Evaluations. It was further agreed to organize a training workshop for the concerned consortia in the second half of 2013 to ensure full understanding of the process and the potential for interaction by industry (More information: Hugo Waeterschoot).

Commission, Council and Member States activities

REACH REVIEW

Further to the publishing of the report on the Review of REACH by the Commission at the beginning of February (http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review2012/index_en.htm) and the press release issued by Eurometaux, the topic was discussed in detail with the Eurometaux membership on 19 March 2013. Eurometaux reconfirmed its position that a big review is not supported, only minor modifications to guidance documents and annexes might be needed. For many of the issues raised by the Commission in its report, initiatives in which industry is involved are on-going or planned. Eurometaux will prepare a general reaction to the Commission’s report around the following main lines:

- REACH should not be considered in isolation, but should rather be linked to other fields which impact industry, e.g. sustainability
 - Information developed under REACH (data and expertise) should be used to create added value in other fields of legislation (EU and worldwide level)
 - Need for increased predictability and transparency of the REACH processes so as to achieve stability for industry
- (More information: Inneke Claes).

12TH CARACAL MEETING OF 13-14 MARCH 2013

At the CARACAL meeting on 13 and 14 March 2013, the following ‘hot’ topics of interest for the metals industry were discussed: the REACH and Nanomaterials review, recycled substances and authorisation (see separate article in this newsletter), CMRs in consumer articles, the ATPs to the CLP, updating of Annex VI and poison centres.

On the Commission roadmap for SVHC, Eurometaux and Cefic made a statement on behalf of industry, to point out the importance of the initiative and to ask for more transparency and quality criteria for the RMO analysis (see separate article in this newsletter). Eurometaux reaffirmed its support for the OECD CoCAM program and indicated the willingness from some metals consortia to submit data from REACH registration dossiers for assessment.

IMA-Europe and Eurometaux submitted comments on the Commission’s proposal for the justification to demonstrate the need for an action at EU level for proposals for harmonised classification. The Commission accepted to include the possibility to refine group entries due to the availability of new data. A report with the highlights of the meeting will be circulated (More information: Inneke Claes).

AMENDED FEES REGULATION

The amendment to the Fees Regulation entered into force on 22 March 2013 (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:079:0007:0018:EN:PDF>).

In addition to setting out the new fees for the submission of registration dossiers (the fees for SMEs were lowered, whereas the fees for large companies were increased), the amendment also specifies some fees for the update of dossiers (e.g. for

dissemination of data, for study summaries or robust study summaries) and explains under which conditions the fees are not refundable (e.g. not providing information by the set deadline). It also recommends an annual review of the fees. The fee calculator plugin for IUCLID has also been updated and can be downloaded from the IUCLID website. A briefing note on the amended regulation is available from the REACH Metals gateway (More information: Inneke Claes).

SHERPA TELEPHONE CONFERENCE OF 12 MARCH 2013

For the moment, there are no meetings of the DCG foreseen until after the 2013 registration deadline. In the meantime, issues are followed-up by the Sherpa's by telephone conference. The following points were discussed on 12 March 2013: ECHA's quality assistance tool, authorisation and recycling and a draft document on achievements of the DCG. The next telephone conference will be held at the end of April (More information: Inneke Claes).

IRISH PRESIDENCY AND REACH, 20 MARCH: *an open debate on the role of RMO*

The Irish presidency organized a high level meeting in Dublin (20 March 2013) to review topical (hot) REACH issues with lots of focus on the Risk Management Option analysis pre-empting a listing on the ROI as potential SVHC substance for the candidate list. Several countries informed the conference that they launched national activities to select chemicals for the SVHC list beyond the classical CMRs. Germany presented its HERO (High Expected Regulatory Outcome) concept whereby also STOT 1, acute toxicity and ecotoxicity category 1 would be included to determine if REACH or other tools would be most effective. Contrary to this German approach based on arithmetics, Denmark indicated that they were working on a list of "undesirable materials" also based on a wider scope of concerns. The EU Commission confirmed they expect PBTs and Substances of Equivalent concern (Endocrine Disruptors and Respiratory Sensitizers) of growing importance for next SVHC listings (More information: France Capon and Hugo Waeterschoot).

ENVIRONMENTAL COUNCIL AND RMO: *general support for an early RMO*

Member states and Commission now clearly agree on the relevance of an RMO on a potential SVHC as early as possible in the national selection process, in line with the joint position and request of industry. Industry further asked for adding the need for more transparency by requesting the publication of the RMOs. Eurometaux complemented this common position with a request for "*ensuring the quality of RMOs*" by an interactive data input process with industry. With the notable exception of France, the UK and probably Belgium, Member States are not so keen to either share RMOs or interact with industry to improve the quality. The Eurometaux RMO advocacy platform therefore tried to put emphasis on Spain, Italy and Poland to define a position in favour of an open interactive process including a quality assurance (More information: France Capon and Hugo Waeterschoot).

EUROMETAUX REACH activities: hot topics/issues

AUTHORISATION AND RMO

RMO session on 8 April 2013: how can the metal sector contribute actively?

While embracing the RMO tool as a pre-selector for SVHC listing, Member States raised concern related to the workload this may cause given more than 400 RMOs will have to be developed by them in the years to come. Eurometaux believes industry can help Member States in achieving this objective while ensuring a high quality level. The Eurometaux Authorisation-Restriction platform will therefore hold a workshop on 8 April pm, sharing experience on RMO and discussion between Consortia, seeing what contributions (and format) can be prepared for (More information: France Capon and Hugo Waeterschoot).

NeRSAP: first platform meeting of SEA and AoA practitioners on 9 April 2013 in Brussels

Eurometaux will host the first network meeting of REACH SEA and AoA practitioners (NeRSAP) at the metals conference center in Brussels on 9 April. The network aims for bringing SEA and AoA practitioners together to exchange on SEA and AoA practices, experiences and concepts/methodologies. The platform offers a neutral forum whereby such exchanges would allow for interaction and learning improvement by practitioners. The metals sector will present several practical cases at this event through its SEA and AoA consultants (More information: Violaine Verougstraete and Hugo Waeterschoot).

REACH Authorisation: a challenge for the Recycling sector?

Recent CARACAL papers on the recycling of plastics from the Commission and the Netherlands confirmed the concern of the metals industry that the recycling sector can be seriously hit by Authorisation requirements. Indeed the recycling sector may under certain conditions and scenarios require Authorisation Applications (AA) for SVHC substances included as impurities or deliberately added to the materials. Slags, alloys and recycling materials containing metal oxides like fumes, may be particularly vulnerable to this obligation. Eurometaux responded at CARACAL stressing the need for "a pragmatic solution" that recognizes the value of recycling and both the EHS Committee and the REACH Forum agreed at their meetings to launch an investigation to define when and under which conditions this may become an issue for the sector. A briefing call, inquiry and internal workshop will be planned for the weeks to come to prepare a relevant answer for ECHA and Commission just after the summer (More information: Michel Vander Straeten and Hugo Waeterschoot).

REACH FORUM

The most recent meeting of the REACH Forum on 19 March was well-attended. Important topics on the agenda were intermediates (including how to agree on data sharing) and authorisation/restriction.

At the end of the meeting, the preparation of a solid Eurometaux work plan for 2-3 years for REACH related issues was discussed. This should help to allocate the scarce resources of the Secretariat and the consortia in the best way. The consortia agreed to provide the Secretariat with an assessment of the priorities for their sectors which will serve as input for a strategic plan to be discussed at the upcoming meetings of the REACH Forum (More information: Inneke Claes).

INTERMEDIATES TASKFORCE

The taskforce is working on the finalisation of pilot cases and internal guidance sections on UVCB classification and risk assessment. It also agreed on the IUCLID format and how to report data for the inorganic UVCBs assessment. The details of the chosen option are now used to prepare data sharing agreements. These agreements will be further circulated to the taskforce and will include a "note" stressing the appropriate use of the data and a possible addendum to include data sharing of exposure data. Eurometaux has asked ECHA to have possible dates for a meeting where the approaches and the proposed reporting format could be presented. The taskforce will be invited again to prepare this meeting with ECHA as soon as the timing aspects have been clarified (More information: Federica Iaccino).

OTHERS

The EM REACH Team is really pleased to announce that Michel Vander Straeten will from now on join the REACH team and reinforce capacities on SEA, authorisation versus recycling etc. Welcome on board Michel! (More information: Violaine Verougstraete).

METAL-SPECIFIC REACH APPLICATION TOOLS AND CONCEPTS

Sediments: outcome of the Nickel Sediments evaluation setting precedence for sediment Risk Assessment for metals under REACH

ECHA published the final outcome of its review on the sediments testing obligation for Nickel and sediments toxicity and risk assessment, decided years ago under the ESR programme. The Nickel sector, Denmark and Eurometaux were successful in encouraging ECHA to take responsibility for a sediments science workshop (7-8 May 2013, see previous REACH News). Eurometaux will in follow-up present the GEHS meeting to agree on a metals sector workshop in September with ECHA to review the outcome of the science conference and define the need for the metals guidance update. In addition the case learned the metals sector how further information/testing requirements under REACH dossier or Substance evaluations will be concluded (More information: Chris Schlekot, France Capon and Hugo Waeterschoot).

Further outreach of REACH

OECD

On 26 March, Eurometaux met Joop de Knecht, Dan Merckel and Hirofumi Aizawa, from the Environment Health and Safety Division of OECD to discuss a number of topics, including input in the CoCAM programme (currently threatened because of a lack of submissions by countries and industry). OECD agreed to further try to clarify the possible interaction (in terms of timing and activities) between the CoCAM discussion that could be used as data quality check and the REACH processes.

CoCAM allows disseminating and protecting effects datasets by having those discussed at OECD, summarized and falling under Mutual Agreement of Data. Other issues that were discussed were the guidance the metals sector could provide on specific aspects in environmental effects assessment (further to the 2011 workshop), input on the guidance on grouping and on diffuse sources/PRTR. These very constructive discussions ended by identifying a number of actions that will help us to raise metal specificities and that will be followed up by commodities, consortia and the GEHS group (More information: Violaine Verougstraete and Hugo Waeterschoot).

Calendar

- 8 April 2013: Eurometaux RMO training workshop - MCC
- 9 April 2013: First Industry-ECHA-Member States SEA-AofA network meeting - MCC
- 24-25 April 2013: MSC - Helsinki
- 7-8 May 2013: Sediments workshop, Helsinki
- 23-24 May 2013: ECHA workshop on Substance Evaluation and CoRAP experience- Helsinki
- 5-8 June 2013 : RAC 25 - Helsinki
- 5-7 June 2013: SEAC 19- Helsinki
- 17-18 June 2013: 4th Authorisation Applications workshop- Helsinki
- 20 June 2013: REACH Forum-MCC
- 21 June 2013: Reach Authorisation / Restriction Platform meeting-MCC
- 25 June 2013: Biocides stakeholder day
- 25-26 June: OECD hazard Assessment Taskforce meeting- Paris
- 17 September 2013: REACH Forum-MCC
- 12 November: Reach Authorisation / Restriction Platform-MCC
- 17 December 2013: REACH Forum-MCC

Webinars

- 8 April: How and when DU need to report to ECHA
- 14 May: How to bring your registration dossiers in compliance with REACH – tips and hints part 4
<http://echa.europa.eu/support/training-material/webinars>

Acronyms

AA: Authorisation Applications	OECD: Organisation for Economic Cooperation and Assessment Development
AoA: Assessment of Alternatives	PBT: Persistent Bioaccumulative and Toxic
ATP : Adaptation to Technical Progress	PRTR: Pollutant Register of Toxic Releases
CARACAL: Competent Authorities on REACH and the CLP Regulation	RAC: Risk Assessment Committee
CLP: Classification, Labelling and Packaging Regulation	RMO : Risk Management Option analysis
CMR: Carcinogens, Mutagens Reproductive Agents	ROI: Register of Intentions (for SVHC or Registration or harmonised CL&L)
CoCAM: Cooperative chemicals assessment meeting	SEA: Socio-Economic Assessment
CoRAP: Community Rolling Action Plan	SEAC : Socio-Economic Analysis Committee
DCG: Directors' Contact Group	SME: Small and Medium-Sized Enterprise (under the REACH def.)
DNEL: Derived No Effect Level	STO: Stakeholder Observer
ESR: Existing Substances Regulation	STOT: Specific Target Organ Toxicity (classification endpoint)
GEHS: Group on Environment & Health Sciences of Metals	SVHC: Substance of Very High Concern
HERO: High Expected Regulatory Outcome	UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials
IUCLID: International Uniform Chemicals Information Database	



Bye for this month.....