



EUROMETAUX CHEMICALS MANAGEMENT NEWS



Chemicals Management Steering Committee: 05.09

Chemicals Management Autumn Week: 23-26.09

Featuring "Special Frank" Social Event

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Dear All,

Here we are! The days are starting to be subtly shorter, the various shades of green on the leaves are darkening, the early morning air smells of humidity and even the last heat peaks cannot make us forget the fact that we are in September, back to normal work rhythms. It is now time to pack your luggage for exotic places named meeting rooms and discover new agendas. Time to go on tour and come across different issues and fresh problems!

Are you worried by your September destinations? Feeling sad and anxious that the holidays are over? Experiencing the routine blues?

There are some ways to prolong the summer whirl a little bit!! Just include in your bags:

The anti-alarm clock:

this downloadable app postpones, upon 'unconscious and at random request' your wake-up call for 45 minutes



The improbable 'upgrade'...

from a hotel room with view of a wall to a suite with a terrace overlooking the Thames

A Hawaiian-flowerly dress or shirt

to wear during your first Helsinki trip

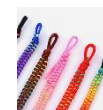


The latest 'what matters' agenda:

listing cocktail recipes instead of to-do lists

Material to create Brazilian bracelets

during the EM meetings' coffee breaks



(P)'OSH' sunglasses

displaying the meaning of all acronyms used during occupational hygiene debates

"X" Shampoo

changing your hair colour so drastically for one day that you can walk incognito in and around the Montgomery hotel

The Monty Python medieval coconut halves

to slightly alter the sound of the plane

A white t-shirt, a pen and an invitation to your colleagues

to write down ideas for your next holidays...

Enjoy the month!

Violaine Verougstraete, Chemicals Management director Eurometaux

ECHA REACH & CLP Activities: hot topics

ECHA Committees

RAC: preparations for September

RAC, RAC's secretariat and ECHA's Classification/Restriction experts have remained active during the main part of the summer. With regard to the CLH processes, in addition to the Public Consultation on the proposal to classify tellurium and tellurium dioxide as Reprotoxic 1B, H360FD that lasted until 16 August, a first draft opinion on the revision of the SCL for boric acid/6 borates has been prepared and a revised Annex XV has been submitted on vanadium pentoxide. As agreed at the June meeting, the RAC Rapporteurs have been further reflecting on the hazard and exposure parts of the cobalt salts' restriction,

generating an opinion that will be discussed in the second week of September (more information: Hugo Waeterschoot and Violaine Verougstraete).

EUROMETAUX CHEMICALS MANAGEMENT Activities

Resource mapping to respond to Chemicals Management challenges

Human Health Taskforce meeting: *a full agenda to celebrate August*

The Human Health experts met for a face-to-face meeting on 30th of August to take stock of the progress made on the "priority topics" agreed on earlier this year. Work is ongoing on the drafting of a multi-metallic questionnaire that could be used when setting up monitoring campaigns and that would highlight the minimum (information) requirements (e.g. on statistics, contextual information) to be met. A first draft will be circulated for comments in the coming months. Also, an update was provided by Steven Verpaele (NI) on a project aiming at assessing the performance of samplers currently used to measure worker's exposure to metal and metalloid particles in both laboratory and field settings. Expressions of interest to participate in this ambitious project that has already triggered interest from some authorities can be sent to Steven. The group also agreed that it would be relevant to collect dermal exposure datasets but also perform a literature search on dermal absorption of metals. Authorities are more and more interested by in workers' and consumers' exposure via the . Aim would be to assess whether the 'default' values proposed in the HERAG fact sheet on dermal exposure and absorption - based on the data available at the time of the publication-, can be confirmed or should be modified. The meeting was also a good opportunity to update the members on the activities of the T25/potency ECHA expert group, currently reviewing the existing CLP guidance to derive the potency (and define specific concentration limits) for carcinogenicity. The current CLP approach assumes a linear dose-response and uses as reference a database of oral carcinogens. It does not provide a specific procedure to adjust exposures to dusts/particulates that are very relevant for our sector. When the approach was applied to a series of NTP tested carcinogens, they all emerged as high potency, including talcum powder. This observation already would justify refining the current approach, but this requires data on the inhalation of carcinogens. The participants supported the setup of or the participation in a shadow group on Poorly Soluble and Low Toxicity particles and a proposal to work on an adverse outcome pathway, so as to better anticipate the potential impacts of the classification of TiO₂ or an OEL. On bioelution, some progress has been achieved over summer (detailed below). Finally, the drafting of a counterion file to include as part of the read-across justifications in the registration dossiers and the re-dynamisation of HeTAP were debated. Minutes will be circulated soon to the members of the taskforce as well as the documents to comment on (more information: Adriana Oller, Ruth Danzeisen, Daniel Vetter, Lorenzo Zullo and Violaine Verougstraete).

The lead metal environmental classification: *preparing for a critical last debate in CARACAL*

CARACAL will, in its upcoming session mid-September consider if Member States have last comments on the proposed 15th ATP proposal before progressing towards the new approval procedure. This version includes the contested draft environmental classification for Pb metal. Some national federations contacted CARACAL members informing them on the erroneous scientific/technical base of the proposal given lacking a distinctive classification for massive versus powder metal as exists for several other metals previously assessed for harmonised classification. ILA and Eurometaux presented the Commission with the first results of the ongoing retesting of the snail study on *Lymnea stagnalis*. According to some toxicity data, this species turned out to be the most sensitive one and drives the environmental classification while in nature this organism is not sensitive. The test was therefore redone this time according to the OECD test guideline (published in 2016). While only interim results are now available it demonstrates that the organism is far less sensitive than defined by RAC, making the present RAC classification on lead metal invalid. In a common letter, ILA and Eurometaux have therefore asked the Commission to postpone the decision, waiting for the final test to be published and subsequently to reconsider the environmental classification of lead metal according to the metal CLP guidance and the updated results from the test (more information: Jasim Chowdhury, Steve Binks and Hugo Waeterschoot).

Metal-specific REACH application tools and concepts

Bioelution: *progress made over the summer*

The work that was planned over the summer to reply to the questions of ESAC (ECVAM experts' panel) on the gastric bioelution protocol has progressed well. The aim is to submit a package early September, including replies to the points raised by the experts, a revised SOP, a summary of additional tests that have been run and an updated literature review on the composition of the gastric fluid composition. If ESAC considers this submission satisfactory, the protocol will move on to the next step, i.e. potentially becoming a guidance note at OECD level (like the TDp OECD N°29). This requires the submission of the gastric protocol in a specific template before 15 November. After that, support from OECD countries like Australia, US, Canada and others will be needed to ensure the OECD Testing Guidelines group takes on the project. Once the OECD activities

have been launched, ECHA will reconvene the Bioelution Expert group to further discuss how to use the bioelution test results in CLP classification schemes. How to use bioelution for read-across and grouping will be covered by an industry note-reviewed by ECHA- that will constitute a MISA deliverable. As acceptance of the approach is still at stake, it is crucial to apply it and document how it is done and publish the results as much as possible (more information: Adriana Oller, Kate Heim and Violaine Verougstraete).

Metals Sectorial Approach

MISA UVCB Workshop preparation meeting: 29.08.19

The 3rd MISA workshop will be held on 5 November and will be dedicated to the inorganic UVCB assessment methodology. To ensure a good preparation of the workshop, a day's meeting was organised on 29 August; first to allow industry to discuss how to present a specific inorganic UVCB assessment to ensure clarity in reporting to ECHA and Member States on the constituents' approach and secondly to approach any open issue. During the meeting, the slags, Doré furnace UVCB case was used to provide the practical example on how to apply the methodology explained in the "Industry guide for inorganic UVCB assessment" (shared in July). The group agreed on how to improve the key messages in the presentation of the specific assessment and on the need to discuss and solve the IUCLID reporting, to ensure a pragmatic approach. Furthermore, the possibility to translate the existing multi-metallic database into an online tool including several functionalities such as an alert system for any update submitted in the database or the possibility to associate Assessment Entities templates for easier data sharing was also debated and approved. The online version of the database will be ready in Q1 2020 and a beta version available in November 2019. The last point of discussion was the set-up of a dedicated platform of experts (i.e. consultants) to allow consistency in the refinement of the dossiers and timely updates after the 3rd MISA workshop: the group exchanged on how to harmonise the assessments in IUCLID, on how to facilitate company/consortia workload, on how to avoid duplications and overlaps of work in different consortia and eventually simplify communication with ECHA during the updates. The practical set-up of the platform will be further discussed for final approval in September (more information: Federica Iaccino, Lorenzo Zullo and Violaine Verougstraete).

MISA Webinar: 30.08.19

A webinar was held on 30 August to reflect on and present the progress made with the programme up to now. ECHA presented the analysis of the workplans they have received up to now and some generic observations with regard to timing and content. They reiterated how important it is to demonstrate some progress with the approach as there is some scepticism from Member States about sectorial approaches in general, that are believed to delay the improvement of the registration information. They explained how they intend to proceed further to monitor progress, i.e. using IT tools to follow the update history of dossiers and get overviews of the data availability, looking into the workplans both from an aggregate and metal group point of view (and engaging with consortia), and by further applying ECHA's regulatory strategy that includes screening and opening of dossiers. Eurometaux presented a high-level overview of the replies provided by the consortia/associations to the progress survey launched in July. The outcomes complemented each other nicely and, in some cases explained ECHA's observations. Learning lessons included for example that resources remain a point for attention and that some methods and reporting issues caused delays. But also, there are some aspects like the TCC, testing decisions etc. that play a role. Eurometaux and ECHA will sit together on 3 September to agree on what can be done to further support the programme and define KPIs that can be reported to CARACAL and RIME to increase the trust in the programme. The minutes of the webinar will be circulated soon. Comments on the updated rolling plan can still be sent to Eurometaux until 5 September. After that, it will be published on the ECHA website and the REACH Metals Gateway (more information: Federica Iaccino, Lorenzo Zullo, Hugo Waeterschoot and Violaine Verougstraete).

FURTHER OUTREACH

ETAP

The Environmental Toxicology Panel (ETAP) meeting: *replying to scientific challenges posed by the metal commodities*

The ETAP panel met end of August in Aix-en-Provence at the office of Rio Tinto's legacy management department under the auspices of the supporting metal commodities. This panel of distinguished independent scientists debated and provided scientific advice on Issues of Concern raised by the sector. In addition, they presented to the metals sector what are, in their view, recent important publications that could trigger scientific challenges for the metals sector. Responses and presentations from the panel members included amongst many others the following key messages: 1) a clear indication that other climate zones than the EU moderate climate zone (e.g. Scandinavian boreal regions) are not more sensitive to metals when using organisms relevant for that zone in the testing schemes, 2) whereas the metal binding mechanisms are somewhat different, marine sediments do not seem more sensitive than freshwater sediments and marine toxicity data can be used to model marine sediment toxicity if this evidence is lacking, 3) toxicogenomics is a fastly developing area driven by experience from the pharmaceutical sector - moreover, it is widening its application field for chemicals assessment from a screening tool to areas such as Environmental DNA mapping and Microbiomes, complex techniques that allow refined impact assessments - question remains on how to interpret these measurements in respect to their real impact that requires either classification or risk management, 4) "metals as endocrine disruptors" as many metals play a key role in e.g. neurotransmitter and neurohormone functioning. It was recommended that the metals sector carefully assesses the relevancy and applicability of the 5 tier OECD assessment scheme to metals, given metals will be assessed along these criteria in the future. Eurometaux attended the session as an observer and will report its main learning lessons at the upcoming science forum meeting during the Chemicals Management week (more information: Jelle Mertens, Stijn Baken and Hugo Waeterschoot).

CALENDAR

- 5 September: Chemicals Management Steering Committee – **Avenue de Tervueren 168** (Brussels)
- 09-13 September: RAC-50 (A) – ECHA (Helsinki)
- 09-13 September: SEAC-44 – ECHA (Helsinki)
- 16-20 September: RAC-50 (B) – ECHA (Helsinki)
- 17 September: Risk Management Taskforce – **Avenue de Tervueren 168** (Brussels)
- 18 September: CARACAL 31 – Commission (Brussels)
- 23-26 September: Chemicals Management Autumn Week – **BluePoint** (Brussels)
- 24-25 September: WFD CIS Strategic Coordination Group (TBC; Brussels)
- 26-27: NeRSAP 8 – FRAM (Gothenburg, Sweden)
- 26-27 December: MB-55 – ECHA (Helsinki)
- 21-25 October: MSC-66 – ECHA (Helsinki)
- 5 November: MISA UVCB Workshop TBC (Brussels)
- 12-13 November: WFD CIS Strategic Coordination Group TBC (Brussels)
- 14 November: Evaluation Platform –MCC (Brussels)
- 25-29 November: RAC-51 (A) – ECHA (Helsinki)
- 25-29 November: SEAC-45 – ECHA (Helsinki)
- 2-6 December: RAC-51 (B) – ECHA (Helsinki)
- 9-13 December: MSC-67 – ECHA (Helsinki)
- 17 December: Chemicals Management Steering Committee – MCC (Brussels)
- 16-17 December: MB-56 – ECHA (Helsinki)
- **18** December: Risk Management Taskforce – MCC (Brussels)

ACRONYMS

CARACAL: Competent Authorities for REACH and CLP
CLH: Harmonised Classification and Labelling process
DNA: Deoxyribonucleic acid
ECVAM: European Centre for the Validation of Alternative Testing Methods
ESAC: ECVAM experts' panel
ETAP: Environmental Toxicology Advisory Panel
HeTAP: Human Health Toxicity Technical Advisory Panel
IUCLID: International Uniform Chemicals Information Database
OECD: Organisation of Economic Cooperation and Development
OEL: Occupational Exposure Limit
RAC: Risk Assessment Committee
RIME: Risk Management and Evaluation Platform
SOP: Standard Operating Procedure
TDp: Transformation Dissolution protocol
UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials