



N°114 – June 2021

EUROMETAUX CHEMICALS MANAGEMENT NEWS



Please join us online on:

- 31 August: Chemicals Management Steering Committee meeting
- Save the Date: Chemicals Management Autumn Week: 27/09 01/10

And our Summer special on the last page with our new acronym "CSfZ"

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Dear All,

Every year, on the last day of June, I am hit by the temptation to believe in the legendary "Summer break myth" in which mailboxes are transmuted into postcards from exotic places, coffee shots become iced or (m)cocktails, and "to read" lists have taken it over from the "to do" ones. It is the moment for good stories, allowing you to escape from the spring preoccupations and giving your brains some leeway.

Tales to read or to write? Is it not the moment to give it a go and put black on white, probably with a bit of fantasy, and hopefully some humour, the feelings and experiences you have experienced over the last months in our regulatory world? Was I the only one to imagine an alternative plot for Lord of the Rings taking place in the Commission corridors? Or inventing very strange zoom allergies for bioelution enemies? Well actually I just checked. The web is full of hints and tricks to write good stories. Herewith a couple of them*.

To note: every resemblance with real (regulatory) stories is purely a coincidence.

- Write in one sitting: write the first draft in as short a time as possible. Do not worry too much about plotting or outlining beforehand. You can do that once you know you have a story to tell in the first place. Your first draft is a discovery process.
- **Develop your protagonist.** Stories are about protagonists, and if you do not have a good protagonist, you will not have a good story. The essential ingredient for every protagonist is that they must make decisions. What is a protagonist? It is the character whose fate matters most to the story. To further develop your protagonist, use other character archetypes like the villain, the protagonist's opposite, or the fool, a sidekick character that reveals the protagonist's softer side (please assign: Commission, Member States, industry, NGOs)
- Create suspense and drama: to create suspense, set up a dramatic question. A dramatic question is something like "How many deaths from chemicals?" or, "Is the EU ready to give up industry competitiveness? By putting your protagonist's fate in doubt, you make the reader wonder: what happens next?
- Show but don't tell! When something interesting happens in your story that changes the fate of your character, don't reveal it but show the scene (decision?). The readers have a right to see the best parts of the story play out in front of them.
- Write good dialogues: it comes from two things: intimate knowledge of your characters and lots of rewriting. Each character must have a unique voice, and it is important to make sure your characters all sound different. Imagine a place where they could come together (e.g., HLRT)
- Edit like a pro: most professional writers write at least three drafts, with the first draft not to be shared with anyone (no leaks!). A first draft is a chance to explore the story and figure out what it is about. The second draft is meant for major structural changes and for clarifying the plot and characters of your novel or the key ideas of your non-fiction book. The third draft is for deep polishing.
- Know the rules, then break them: it seems that great writers know all the rules and break them. Not arbitrarily! They break them because their stories require a whole new set of rules. Respect the rules but remember that you don't serve the rules. You serve your stories.
- And find the right season to publish!! Know your target audience and find the way to make them await your story, manage expectations! (and share your stories with us!)

Happy summer!

Violaine Verougstraete

*: see for example https://thewritepractice.com/write-story/

COMMISSION

CARACAL-40: online meeting on 29-30 June

CARACAL's agenda covered a series of topics of direct relevance for the sector, related to classification, the REACH and CLP Revisions or the CSS. Eurometaux's input was prepared along a conference call on 24 June with the CARACAL Taskforce. Specific interventions were scheduled around the Restrictions Roadmap, bioelution, the 18th ATP (V2O5 and 2-EHA classification proposals). On other key topics, the sector will follow-up with written comments before end of August. A couple of presentations (e.g. on One Substance One Assessment (OSOA)) were uploaded after the preparatory call and will be further circulated (more information: Noam EL Mrabet).

EU AGENCIES

EUROPEAN CHEMICALS AGENCY (ECHA)

ECHA COMMITTEES

RAC functioning: an exchange with the RAC secretariat

There is increasing frustration and stress within industry on how RAC debates are run. Industry (Cefic, Cefic industry groups, Eurometaux) asked for the possibility to have an open exchange with the RAC chair and RAC secretariat to identify possibilities to improve the cooperation. A first exchange focused on classification took place on 22 June. Industry had identified some generic issues where reflection on the best modalities would be necessary (like weight of evidence, limited engagement of RAC members, interaction with stakeholders etc.), complemented by the presentation of some specific cases exemplifying these issues. ECHA shared its perspectives on the organisation of the RAC and the considerable time and resources constraints. A second meeting will be planned end of August to discuss possible ways forward. The outcomes will be presented to the Chemicals Management Steering Committee on 31 August (more information: Violaine Verougstraete).

RAC-57: working groups for shorter plenary meetings, lithium discussions and asbestos OEL

The June RAC meeting started with the announcement that from October onwards, all Harmonised Classification and Labelling process (CLH) and Restriction topics on RAC's agenda will be discussed in devoted Working Groups before going to plenary. Working Groups aim at providing a substantial part of the necessary scrutiny of RAC opinions and at discussing technical details. They could remove up to 70% of the debating time from plenary and they operate under the same rules of procedure as RAC. The workplan, presented as usual at the start of the meeting, highlighted a number of interesting substances on the agenda like the ongoing restriction on lead in ammunition and fish tackle, the proposed classifications for lead (environment, to finalise in September), silver and three lithium compounds. ECHA also mentioned an ongoing study on welding fumes as groundwork before proposing a dose-response or Occupational Exposure Limit (OEL). New on the agenda was the presentation by an ECHA lawyer on the latest Court Cases involving RAC opinions. It would be interesting to draw the learning lessons from the increasing number of cases to identify what could/should be improved in the ongoing processes and aim herewith to avoid such burdensome (for all involved actors) and expensive recourses against the RAC opinions.

RAC finalised its opinion on the asbestos 'OEL'. It will be used by Commission in the review of the current OEL set in Directive 2009/148/EC on the protection of workers from the risks related to exposure to asbestos at work. The exposure response relationship included in the opinion describes how the level of excess cancer risk depends on the concentration of mixed asbestos fibres in the air. Important points for discussion included the remaining uncertainties (e.g., related to cancers observed in other organs than the lung or the mesothelioma), the analytic measurement of asbestos fibres and the justifications to include. With regard to restriction, besides lead in ammunition, the Committee discussed the restriction on hazardous substances that may be present in single-use baby diapers.

RAC also had a first discussion on the proposed classification of the three lithium compounds as toxic for reproduction (fertility and development). The debate focused on read-across and fertility. A follow-up discussion on developmental toxicity is scheduled for 6 July (RAC CLH Working Group meeting). On read-across: industry managed to raise its concerns about the inclusion of lithium hydroxide in the read-across,

as due to its corrosive properties it is impossible to expose people or animals to levels causing systemic effects. On fertility, the RAC supported a classification in category lB. Industry was able to raise some points, like the way the weight-of-evidence is applied, the incorrect reporting of industry study results, the quality/reliability criteria used and the weaknesses in the studies that were used for the classification. The Li CLH Taskforce was informed on these first outcomes on 16 June (more information: Violaine Verougstraete).

RAC-57: environmental classification of lead metal, a U turn into the wrong direction!

RAC continued to review the environmental classification of lead in metallic form during its June plenary session. Despite the extensive input from industry (ILA and Eurometaux) the discussions were difficult and frustrating given RAC took quite a precautionary approach. Different from the CLP metal's guidance and previously reviewed cases, the Rapporteurs concluded on an Ecotoxicity Reference Value (ERV) for Pb based on a single non-standard, low quality, outlying ecotoxicity data point. This is in contradiction to the guidance that recommends that in the case of data-rich substances a weight-of- evidence approach is used, considering the entire data set. The proposed ERV value is so low that it will result in significant risk management consequences not only for the lead sector but for all those using lead metal in low concentrations in alloys or mixtures or present as an impurity in scrap recycling. ECHA further presented how they would like to deal with the "massive" versus "powder" classification entry split, which is another crucial aspect of the ongoing review that could set a (un)fortunate precedent depending on its outcome. This discussion will be concluded in September based also on the legal relevance of releases from the use of articles made from lead (more information: Jasim Chowdhury, Steve Binks and Hugo Waeterschoot).

RAC-57 and SEAC-51: progress made with the restriction proposal to ban Pb in gun shot and bullets

Both RAC and SEAC debated the restriction proposal to ban the use of Pb in gun shot and bullets for outdoor shooting. The discussion focused on the review of the scope, impact and cost assessment. Both Committees suggested to consider extending the scope to indoor shooting and training but agreed that shooting for international competitions could remain exempted under strict registration conditions. RAC reviewed the impact on wildlife and human consumption of game meat concluding that the assessment was very conservative. Hence, they asked the dossier submitter to clarify this and/or propose a somewhat more realistic approach. RAC did not review the health impact on shooters as considered equal to previous restriction cases. SEAC focussed on the cost of switching to alternatives which seems reasonable for the uses in scope if considered over a longer-term period. At its next meeting SEAC will consider the proportionality of the restriction proposal but it already seems clear that any of the substitution options would be" reasonably proportional (more information: Hugo Waeterschoot).

SEAC-51: a milestone discussion on Substitution Plan reviews for upstream applications

SEAC reviewed the applicants' comments when finalising its opinion on the Substitution plans for 4 upstream applications, 3 of them related to the use of chromates for decorative plating. They reconfirmed all 4 cases being "non-credible" mainly because they felt that the representativeness of the data for all companies involved in these supply chains could not be sufficiently demonstrated. On the other hand, SEAC concluded positively (i.e., credible) on the substitution plans of some joint, but not upstream, applications. This clear difference in opinions left an impression on the observing Stakeholders that SEAC was reluctant to conclude on upstream applications. By returning these dossiers to the Commission marked as being non-credible, they set a dangerous precedent and challenge for the plating sector (more information: Michel Vander Straeten and Hugo Waeterschoot).

MSC-74: more and more evaluations agreed under written procedure and existing procedures updated

MSC is approving more and more testing proposals, dossier evaluations and substance evaluations under written procedure including those for which thorough MSC debates were expected like for the substance evaluation on titanium dioxide. This lack of plenary sessions raises the question on how critically the different Member States assess the draft decisions from ECHA and the evaluating Member State, as well as the comments submitted by the registrants. Industry raised this concern with the ECHA secretariat who promised to continue and further improve the reporting on the written approvals by organising special after-meeting sessions for stakeholders. This means that stakeholders could still raise questions for clarifications on the reached conclusions providing the registrants stress their case with Eurometaux or any of the other regular stakeholders in advance of the MSC meeting to be able to define appropriate questions on the written approval round. Also, MSC reviewed and adopted at its meeting an update of all its procedures related to testing proposals, dossier and substance evaluations as well as for prioritisation and

CoRAP listing. A most interesting exercise that clarified many procedural aspects! Eurometaux will distribute the updated procedures to the relevant taskforces (Evaluation and Risk Management Taskforce) as soon as they become publicly available. Finally, MSC clarified the timing for the upcoming 11th priority list for authorisation. The start of the discussion is postponed until autumn (more information: Hugo Waeterschoot).

ECHA OTHER ACTIVITIES

MB-62: focus on accounts approval, CSS involvement and REACH revisions

The June Management Board meeting traditionally approves the accounts of the previous year. This provided an insight on the decrease of ECHA's incomes related to the registration fees and how the Commission compensated those. Commission and ECHA confirmed that they are jointly working on a new fee system to fill the annual gap left by the declining number of new registrations. ECHA presented to the board a reporting format and a status update on its CSS linked activities in support of the Commission. To highlight: the development of a prioritisation system for restrictions for certain hazard classes by September 2021, the set-up of a repository of limit values by December 2021, the definition of a set of chemicals management progress indicators by 2024 and a transfer of tasks on the Battery regulation, RoHS-and ELV Directives to ECHA by 2022. The second day of the meeting was devoted to a strategic review workshop to prepare ECHA for the REACH revisions. Industry was represented by Marco Mensink (Cefic). No minutes have been received yet (more information: Hugo Waeterschoot).

EUROMETAUX CHEMICALS MANAGEMENT

EUROMETAUX FUNCTIONING

Human Health Taskforce meeting: efficient overview -with a big thanks to the chairs, speakers and volunteers!

The Taskforce had a full agenda for its summer call, that started by discussing a mind map on combined effects for workers and the EFSA guidance on grouping chemicals into assessment groups for human risk assessment of combined exposure to multiple chemicals, on which a consultation was running until 30 June. A status update was provided on bioelution, highlighting a number of actions to be carried out over the summer break, to prepare the next OECD Expert Group and CARACAL Subgroup on Bioelution meetings to be held in the autumn. The group was informed on the ongoing work in a GHS Informal Working Group on the mutagenicity criteria as well as on a proposal made by Denmark in the Member States Committee to revise the testing strategy for chromosome aberrations concern. Steven Verpaele (NI) explained to the taskforce the web-based workplace exposure measurements database that continuously collects workplace exposure data for metals and metalloids and the latest achievements of the international sampler comparison study. Aims of the latter are to get updated standards aligned with the outcomes of this study and provide the most cost-efficient and beneficial sampling and analytical protocols for the metals industry. ECHA's Expert Group set up to discuss the approach to derive potency and concentration limits has finalised part of its work on an inhalation database (see also below). Lara Van de Merckt (Eurometaux) and Ruth Danzeisen (CI) described the outcomes and further actions before CARACAL's update in November. Finally, Lorenzo Zullo (Eurometaux) presented a quick update on the work done in the CARACAL Subgroup on Endocrine disruptors (human health aspects).

Main agreed actions were circulated on 24 June, while detailed minutes were circulated on 30 June. A next call will take place in October. In the meantime, further exchanges will take place with the members who kindly volunteered to help on combined toxicity and/or bioelution (more information: Adriana Oller, Ruth Danzeisen, Daniel Vetter and Violaine Verougstraete).

CHEMICALS STRATEGY FOR SUSTAINABILITY

CSS Project Group meeting: 3rd meeting already!

The CSS PG had its third meeting on 15 June. On the agenda was a review of the quite long list of actions from the first two meetings in April, most of which had been completed, with a few still in progress. The group then moved onto recent developments on CSS topics since the end of April, and next steps. On the

High-Level Roundtable (HLRT) there was an exchange of views on how the operation of the group could be best designed in order to facilitate meaningful discussions between members on topics, how to create capacity to handle a suitable number of topics in a reasonable time frame, and what topics should be near the top of the priority list. That was all in preparation for further discussions amongst the Sherpas of the HLRT members (please see next section). On Safe and Sustainable-by-Design (SSbD) the mapping study on criteria recently completed by DG RTD was briefly reviewed, in the light of the stakeholder survey that was in progress at the time – with comments due from Eurometaux by 30 June (see below). There followed another useful discussion on the Essential Use Concept (EUC) where the group explored the scope and definition of "consumer use" and the Analysis of Alternatives (AoA) applied in the context of the EUC. On the latter, even though industry has experience with the process, the view was that the application of AoA for essential uses is quite different to how it is carried out under REACH Authorisation and / or Restriction – and that further clarity and guidance is urgently needed. The meeting proceeded with updates on the REACH and CLP Inception Impact Assessments, the One-Substance-One-Assessment approach, and concluded with suitable immediate next steps. The next meeting is set for 5 July (more information: Simon Cook).

CSS High-Level Roundtable (HLRT): Industry Sherpas meeting

Following the first meeting of the HLRT on 5 May, discussions have taken place on how the group will operate moving forward, and what topics will be discussed in future meetings, and when. On 16 June the Commission released three documents relating to future meetings: i) the agenda for the 2nd HLRT to be held (online) in November - the date is not set; ii) Rules of Procedure for the HLRT; and iii) a list of proposed discussion topics – prepared by Commission from input received to date from HLRT members. The list of meeting topics was discussed in the Cefic HLRT cross sector groups on 17 & 18 June. Eurometaux's main concern was that the topics relating to coherence between CSS and other key EU / global objectives, and better use of existing regulatory tools, are either absent, or late in the timeline.

On 22 June, the Commission ran a meeting for the 32 HLRT Sherpas during which the agenda, Rules of Procedure, and list of proposed topics was discussed. The topic for the next meeting will be enforcement – although there was some pushback given that HLRT has limited power to act to improve enforcement. It does appear that the way the HLRT is intended to operate may make it difficult for the members to have meaningful discussions on the topic list. Reaching consensus is not a stated objective, and the reports produced and adopted by the group are likely to be a collection of position statements. The number of topics is at least as large as the number of planned meetings, and the timeline is long – which means that some topics will not be touched on until 2023-24 – so prioritisation is going to be important.

Eurometaux has the option to provide written comments on the above by 9 July (more information: Simon Cook).

CSS Cross Industry meetings: Essential Uses - Safe & Sustainable by Design

Participation in these two groups is useful, with respect to gaining insight into the topics themselves, and looking at alignment between different industry groups on positions, strategies, and tactics. On the Essential Use Concept (EUC) on 21 June, the feeling was that there is a still a distinct lack of clarity on many aspects – for example, the status of the Commission's work streams, how EUC might be applied within REACH, and how it is defined. Despite this, some groups are proactively developing proposals for a way forward. Other groups feel that it is still too early to do this given the high level of uncertainty around the topic. Intermediate views also exist, and no firm views in some cases.

On Safe and Sustainable-by-Design (SSbD) there was a useful alignment discussion on 25 June relating to industry input into the stakeholder survey on SSbD criteria for chemicals and materials. There was quite broad alignment, with the strong view that any objective to enable non-toxic circularity while at the same time avoiding substances of concern (SoCs) in waste and recycled materials (as proposed by the Commission) is internally contradictory – particularly for metals. Stakeholders agreed to highlight this contradiction in their responses, and also to talk about the SSbD concept in general terms, to try to broaden the discussion on criteria as far as possible, taking into account all aspects of sustainability throughout the full lifecycle of chemicals and materials. Stakeholders also agreed not to highlight specific sectors / applications which should be a considered a priority for SSbD criteria for chemicals and materials. Eurometaux's input submitted into the survey took this into account, and also member input kindly provided though the Sustainability Committee and CSS Project Group (more information: Simon Cook and Kamila Slupek).

REACH REGISTRATIONS

Addressing unclear and inconsistent wording in REACH information requirements: Commission proposal under consultation

Last week the European Commission initiated some activities to remove inconsistencies and improve the wording related to REACH information requirements (i.e., REACH Annexes VII to X). They have now drafted a proposal and launched a Public Consultation, open until 19 July. The Registration Taskforce has already started to analyse it and found that further improvement is still required. In some cases, in particular on the mutagenicity endpoints, the new wording seems to provide more confusion and even more testing requirements. Eurometaux is currently evaluating with Cefic the possibility to submit a joint response to the consultation (more information: Sandra Carey, Kerstin Heitmann, Federica Iaccino and Lorenzo Zullo).

Update of the Registration dossiers: ECHA commented the Cefic-Eurometaux joint guidance on REACH Article 22

Eurometaux is continuing the work with Cefic to develop a joint guidance document on REACH Registration dossier updates related to REACH Article 22 and the 2020 Implementing Regulation 2020/1435, which clarifies the meaning of updating "without undue delay".

The document was shared with ECHA, who already submitted some comments. No comments were raised on the section containing the co-registrants check list that was developed by Eurometaux; this is certainly a sign of the good work conducted by the Registration Taskforce!

A meeting with ECHA to finalise the open points will be held in July. The date has not been identified yet (more information: Sandra Carey, Kerstin Heitmann, Federica Iaccino and Lorenzo Zullo).

RISK MANAGEMENT

Risk Management Taskforce meeting: status of priority lists and open brainstorming on risk management

The Risk Management Taskforce met on 22 June and was well attended. In a first session, Eurometaux clarified the status of the 10th priority list (published on 14 June) and the timing for the 11th priority list for substances to be included on the Authorisation List (Annex XIV). The launch of this list is postponed until fall and may include Pb metal. The next step in the selection procedure consists in the Commission preparing a draft update of Annex XIV. This draft list was published post-RMTF meeting and includes besides Tetraethyl lead no metal or metal compounds. More interesting is the Commission's reasoning and why they proposed a postponement of the listing of borates and a series of lead compounds used in the manufacturing of batteries and Pb stabilisers. The Commission first wants more clarity on the impact of the recent restriction aiming at the phase-out of Pb stabilisers in PVC and the update of the B-OEL on Pb before considering further risk management action.

Finally, Eurometaux presented the recently published draft Group Restrictions Roadmap and agreed to set up a specific session early August to define an opinion on it. In the second session of the RM TF, the Cobalt Institute shared many learnings from the industry-RMOa they conducted on Co metal. These learnings were most relevant to update the Eurometaux RMO guidance as well as for other consortia who plan to undertake such an exercise.

The third and last session consisted in a panel discussion reflecting on potential ideas for Risk Management under the REACH review. A panel with Geert Dancet, Lisa Allen, Sigrídur Ingimarsdóttir and Hugo Waeterschoot exchanged first ideas on how Risk Management could be improved and made more relevant, pragmatic, and effective. These recommendations will be helpful in the development of Eurometaux's suggestions to improve Risk Management within the REACH Review (more information: Hugo Waeterschoot and Michel Vander Straeten).

Authorisation: Information session with CETS on the outcome of the Substitution Plans on Decorative plating

Eurometaux organised a debrief on the outcome of the recent June SEAC session that assessed the submitted substitution plans for upstream and joint applications for Cr6+ in decorative plating. Eurometaux indicated and elaborated on the conclusions of SEAC to reconfirm the "non-credible" status for upstream applications and "credible" status of the others. Applicants felt that upstream applications were not fairly reviewed and were the victim of a divergence of views between the Commission and ECHA on the relevancy of upstream applications. Eurometaux agreed with this concern and suggested to carefully evaluate the arguments of the updated SEAC opinions once adopted to define how to best react to the Commission. The latter is now

faced with a very difficult position, given REACH allows upstream applications for authorisations but a court case on Sodium dichromate made this in practice almost impossible. It was agreed that CETS would further progress on the sector's position with ECHA whilst Eurometaux would support such activity by focusing on the need to review the relevancy of authorisation in case of workplace (only) concerns (more information: Dave Elliot, Michel Vander Straeten and Hugo Waeterschoot).

INDUSTRIAL EMISSIONS

Industrial Emissions: follow-up

Several activities have taken place in the context of the review of the Industrial Emissions and European Pollutants Release and Transfer Register (E-PRTR) Directives. Up to now, Commission has not reacted to the position papers submitted by the members of the Industrial Emissions Alliance including Eurometaux. Two stakeholder workshops will be held on 7th and 8th July 2021 to present the first Impact Assessment on the revision of IED and E-PRTR respectively. Keynote for the IED workshop will be given by Florika Fink-Hooijer Director General, DG ENV. The IED workshop will provide a brief summary of results of the Open Public Consultation and Targeted Stakeholder Survey (TSS) and provide a summary of the Impact Assessment to date, including the range of options currently being assessed. The final Impact Assessment should be presented in September and approved by the Commission Regulatory Scrutiny Board in November.

In follow-up of the TSS, Eurometaux has been contacted to participate in a focus group discussing "Operator's industrial transformation plan & related permit review" and participated in meetings on 21 and 23 June. Thanks a lot to the members of the Taskforce who provided input! (and to Lorenzo!)

OECD will also organise a Best Available Technique (BAT) Expert Group Webinar on 6 July and has circulated the draft activity 5 report (on value chain approaches to determining BAT for industrial emissions.

To note as well, the announcement by Commission that there will be a possibility to comment on the « reporting of 'production volume' for the E-PRTR database in follow-up of the E-PRTR modalities defined by the 2019 Commission Implementing Decision. The decision will provide common definitions for production volume units and metrics for each of the industrial activities covered by the E-PRTR (more information: Lorenzo Ceccherini and Violaine Verougstraete).

WATER

Water Taskforce meeting: very tempting panache of topics

The Water Taskforce meeting of the 10th of June had a very busy agenda and was full of interesting discussions.

First, Professor Sean Comber gave a presentation of the two reports he finalised within the ETAP project and the EEA diffuse emission project. One is on the quantification of the sources of metals to sewage treatment works the second on the wider apportionment of diffuse sources of metals to the aquatic environment. Following Sean Comber's presentation, Frank Van Assche reported back on the workshop held by EEA/Deltares on the 8th of June about the diffuse emission to water where Sean presented the outcomes of the two reports mentioned above. The aim of this project is to help Member States to report better on their diffuse sources. EEA/Deltares are now drafting factsheets for each of the 13 emission pathways. We will be involved in the review of some of the factsheets when completed and they are to be presented in September 2021.

JRC/EC are still working on the candidates' dossiers, for the moment only silver (Ag) (of our substances) has been sent out to the SCHEER. We still have not heard back from the SCHEER (but it should not be long now). For the existing Priority Substances, not much is known for the moment, the focus is only on candidates. JRC and Commission will have internal discussions about which existing Priority Substances they will have time to review after June 2021. Katrien Arijs (EPMF), who is following the silver case gave an overview of this EQS dossiers' frustrating saga. This was followed by a presentation from Graham Merrington (WCA) on their last - very interesting - published paper: "Using Water Framework Directive Watch List datasets to estimate European-wide chemical exposures and potential aquatic risks: representativity and uncertainty?".

The taskforce then dived into the sediments topic. Stijn Baken (ECI) started by reporting back on the Copper marine sediment EQS workshops organised on behalf of DK and SE. Three main aspects were discussed there, namely bioavailability, background concentrations and ecotoxicity (and assessment factors). This

presentation was then followed by an overview given by Chris Cooper (IZA) of the draft CIS guidance document on sediment management in the context of the Water Framework Directive (WFD).

A short overview of the Zero Pollution Action Plan was presented with a focus on water, and how to tackle the Water legislations within the ZPAP.

The last presentation of this Water Taskforce meeting was about Sustainable Finance and was presented by Laura Fazio Bellacchio (EM), especially on the substantial contribution of C24 to water.

Next meeting: Please save the date for the next Water Taskforce meeting that will be held on 18 November (more information: Lara Van de Merckt).

TOOLS

Verougstraete).

T25/potency: follow-up work on the oral database

Calls were organised in June to update the NI, CI and Co CLH Taskforce members on the outcomes of the work done by the ECHA Expert Group on the T25/potency issue. This Expert group was set up following discussions on the relevance of the T25 method to set concentration limits in CLP, in particular for inhalation. Industry contributed to this Expert Group and hoped to achieve three elements. First, reflect non -linear dose responses when doing dose-response calculations by applying the Benchmark dose (BMD) methodology and comparing it with the T25 method included in the CLP Guidance. Secondly, consider the route of exposure and differentiate oral and inhalation routes of exposure by generating separate databases. In case the number of substances would be enough in both, substances would be ranked as high, medium or low potency in each database. These two requests have been discussed and worked on by the Expert group. To date, the inhalation database is close to being finished, with BMDs (10 and 25) modelled and compared with the T10/25s. Something to note is that the BMD and T25 correlate quite well for the substances analysed. However, the consensus in the EG was to keep the BMD as a preferred methodology as, unlike the T25 method, it considers all doses tested as well as the dose-response curve. As the inhalation database contains only 50 substances, it is now proposed as a next step to compare the BMDs/T25s for the oral database (which contains many more substances) and verify statistically if this correlation is significant. The work on the oral database has started and will be finished by the end of August. Setting the thresholds and ranking the substances will then be done for both databases and the report of this work will be presented at the November CARACAL. Note that a publication of this work is also foreseen by some of the volunteers from the EG. In addition, we would like to conduct complementary studies internally, especially regarding the comparison of potency of inorganics by route of exposure and the influence of the portal of entry effect (more information: Ruth Danzeisen, Adriana Oller, Lara Van de Merckt and Violaine

METALS & INORGANICS SECTORIAL APPROACH (MISA)

On 25 June, the minutes of the last MISA webinar on exposure (addressing consumer exposure, Humans exposed via the Environment as well as some first learnings of the Technical Completeness Check) were posted on the MISA blog. Main learnings were posted on the REACH Metals Gateway public page as well as on the ECHA MISA webpage. This posting completed the list of 'learnings' on the fourth MISA activity 'exposure'. As a consequence, ECHA asked the consortia/associations to submit their workplans by 30 June, explaining how they would improve the exposure sections of their registration dossiers where relevant. In the context of the two last exposure workshops, participants identified the potential to carry out some multi-metallic projects that would help the sector to reply to regulatory challenges (including the CSS and the ZPAP), making best use of the existing resources (and existing work). These projects were discussed along a webinar on 11 June with the MISA consortia and the Environment Taskforce. Consortia/associations made a first priority ranking from a list of six projects and for two projects directly relevant to MISA, some paragraphs were drafted for inclusion in the workplans. ECHA was also informed on this list of projects and possible ways forward. More detailed project descriptions will be drafted and circulated in July, so that consortia/associations can indicate/confirm their interest (more information: Federica Iaccino, Hugo Waeterschoot and Violaine Verougstraete).

OUTREACH

OECD

OECD/BIAC: joint meeting

The first meeting of the OECD Chemicals and Biotechnology Committee (which replaced the Joint Meeting) was held on 8 to 10 June.

At the meeting the Defined Approach for Skin Sensitisation was agreed, the first formal approval for any Defined Approach (DA) so far. Getting the DA ready for adoption took years and work on further DAs will remain taxing and slow.

The meeting also reflected on the OECD's work to come up with new methodologies to assess substances for their immunotoxicity. Because of the alleged impact of immunotoxicants on the severity of COVID-19 in patients, this topic is high on the agenda of regulators. Under the lead of Japan, an *in vitro* test method is being developed and it is planned to integrate that test method into an IATA approach.

The idea for a Global Forum on Environment dedicated to mercury was discussed and a number of Member States found the scope to narrow. The UK notably suggested to make the Forum not only about mercury, but also about lead and cadmium.

Furthermore, the proposal to discuss the Essential Use Concept as Risk Management Option in the OECD Working Party on Risk Management was largely welcomed (more information: Kai-Sebastian Melzer).

OECD Working Party on Hazard Assessment: need to follow up on grouping guidance

The WPHA met online on 24 and 25 June and discussed a series of aspects related to hazard and risk assessment, from Adverse Outcomes Pathways (AOPs) to Testing Guidelines, but also tools like IUCLID and the QSAR toolbox. Several countries presented an update on the status of their risk assessment activities, allowing thereby to draw some learnings on how prioritisation and new approaches methodologies (NAMs) are applied. An update was also provided on the APCRA project, i.e., the international governmental collaboration bringing together governmental entities engaged in development of new hazard, exposure, and risk assessment methods and approaches. PFAs were very present on the agenda as well as discussions on the PMT (Persistent, Mobile, Toxic) item.

Last year the group had evoked the possibility of updating the OECD Guidance Document on Grouping Chemicals and a discussion took place this year to identify the level of effort needed to update or draft new sections. This Guidance document includes a section on metal and metal compounds (including some metal examples) that was drafted and agreed after multiple iterations in 2015. It identifies bioaccessibility as a line of evidence in the grouping approaches. This section has now been heavily commented on by the German BfR, questioning the consideration of bioavailability for grouping and read-across. The driver for these comments is clearly the ongoing discussion (at the OECD Expert Group and in the CARACAL Subgroup) on the use of bioelution for the classification of alloys. Contact has been taken with the OECD secretariat to ensure other views can be included as well as some of their comments are not at all aligned with the MISA agreements, the Read-Across Assessment Framework (RAAF) and our REACH dossiers. Detailed notes are available on request (more information: Violaine Verougstraete).

OECD Working Party on Exposure Assessment: interesting topics!

The 5th meeting of the OECD Working Party on Exposure Assessment (WPEA) was held as a remote conference on 28-29 June 2021. It was attended by 56 delegates from 22 countries/regions and international organisations. Interesting to note for the metals sector is the progress made by Japan on the Emission Scenario Document on smelting and disposal of metals used in electrical and electronic products. A project proposal 'Using Adverse Outcome Pathways (AOP) to address combined exposures to chemicals with relevant effect-biomarkers' aiming at providing guiding principles based on selected case studies was endorsed. Status updates were provided on an Occupational Biomonitoring with the presentation of the outline of a draft report. Canada and Germany presented two interesting studies on dermal exposure (craft & toys, exposure of workers during timber impregnation with creosote and processing of impregnated wood), which although not directly related to metals provides useful information on parameters and algorithms. The WPEA also discussed some of the impacts of the response to the Covid-19 pandemic impacts (e.g., environmental and health effects of the increased use of personal protective equipment, both in terms of direct exposure to chemicals and in terms of plastic waste containing chemicals). In this context The Netherlands presented a health assessment of ethanol-containing hand sanitiser. The UK presented work on environmental exposure scenario for chemicals in tyre wear particles, in which zinc was mentioned.

They will investigate emissions and fate of tyre wear particles, their leaching potential; and the potential risk to the UK environment. Detailed notes are available on request (more information: Violaine Verougstraete).

OTHERS

Communications on the Zero Pollution Ambition: nice opportunities!

Eurometaux was kindly invited to make a presentation on the Zero Pollution Ambition, its impacts and necessary (re-)actions in the Eurobat Forum on 18 June and the General Assembly of the Pb consortium on 29 June. A big thanks for these opportunities to provide overviews on an increasingly complex regulatory landscape, that requires the sector to run in parallel a series of technical and advocacy actions and to continuously reflect on how to ensure coherence and understanding. These communications also allow to better grasp the concerns and get input from the sectors, crucial to give sense to the ongoing programmes (more information: Violaine Verougstraete).

CALENDAR

Please find here below a non-exhaustive list of the meetings that are planned so far for after the summer 2021.

Please save the dates for the meetings of interest for you.

For meetings at Eurometaux

For the moment due to the current situation, it will be possible to join our meetings by Webex (links to join will be sent ahead of the meetings).

Any further update, decisions and/or cancellations will of course be communicated in due time.

For meetings at ECHA

ECHA meetings, including those of formal ECHA bodies, will be held remotely until further notice. ECHA will keep the situation under review and will provide any further information as appropriate. This information is published on ECHA's website

Further information on the COVID-19 situation information can be found on the ECDC website

- 5 July: Chemicals Strategy for Sustainability PG Meeting
- 31 August: Chemicals Management Steering Committee Meeting
- 06-10 September: ECHA RAC-58 & SEAC-52 Meetings
- 13-17 September: ECHA RAC-58 & SEAC-52 Meetings
- 21 September: Risk Management Taskforce Meeting
- 23-24 September: ECHA MB-63 Meeting
- 22-23 September: ECHA Committee Meeting TBC
- 27 September-1 October: Chemicals Management Autumn week
- 05-06 October: WPC meeting TBC
- 11-15 October: ECHA MSC-75 Meeting
- 26 October: Evaluation TF Meeting
- 10 November: CARACAL TF Meeting
- 18 November: Water TF Meeting
- 17-18 November: CARACAL 41 TBC
- 22-26 November: ECHA RAC-59 & SEAC-53 Meetings
- 29 November-3 December: ECHA RAC-59 & SEAC-53 Meetings
- 08 December: Chemicals Management Steering Committee Meeting
- 07-08 December: ECHA Committee Meeting (TBC)
- 13-17 December: ECHA MSC-76 Meeting

- 15-16 December: ECHA MB-64 Meeting
- 21 December: Risk Management Taskforce Meeting

GENERAL INFORMATION & ACRONYMS

Follow the logo and check out our new Metals Gateway website.



This website is a (new) one stop information source for regulators & risk assessors dealing with metals/metal compounds and is tailored to the specific needs of the metals industry sector.

A continuously updated list of acronyms is available under the Reach Metals Gateway (RMG)

CHEMICALS STRATEGY for **ZENITUDE**



Can you find the correct vacation quotation.......

| A. The vacation we often need | 1. and all day to do it in. |
|---|--|
| B. A vacation is having nothing to do | 2. Make The Days Count! |
| C. Don't pick a job with great vacation | 3is that you find out how many good, kind people |
| time. | there are. |
| D. Vacation | 4. Pick one that doesn't need escaping. |
| E. One of the great things about travel | 5calories don't count! |
| F. Don't Count The Days. | 6is freedom from our own mind. |

European General Knowledge Quiz

- 1) Which European Country has no monarchy?
 - a) Belgium
 - b) Liechtenstein
 - c) Finland
 - d) Norway
- 2) Which European Country won the most Eurovision song titles?
 - a) Ireland
 - b) United Kingdom
 - c) Luxembourg
 - d) Sweden
- 3) Which European Flag has the most colours?
 - a) Croatia
 - b) North Macedonia
 - c) Portugal
 - d) Vatican City
- 4) Which of these languages is the most commonly spoken first language in Europe?
 - a) English
 - b) French
 - c) German
 - d) Italian
- 5) Which of these countries is in the European Economic Area, but not the European Union?
 - a) Slovenia
 - b) Iceland
 - c) Lithuania
 - d) Malta
- 6) Which European country has the longest total coastline?
 - a) United Kingdom
 - b) Norway
 - c) Greece
 - d) Italy

Quotes: A-6 / B-1 / C-4 / D-5 / E-3 / F-2 Quiz: 1) Finland 2) Ireland 3) Croatia 4) German 5) Iceland 6) Norway