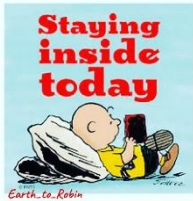




EUROMETAUX CHEMICALS MANAGEMENT NEWS



Some people are always grumbling because roses have thorns;
I am thankful that thorns have roses." --Alphonse Karr

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Dear All,

And now for the challenge! I usually love drafting the editorial part of the News, finding a new angle to explore, sharing with you an observation, pondering on words to find a correct balance, ending it with a quip. But difficult to do so in these times! For days now, I've been hesitating to open the template prepared by Ailsa, wondering how to structure my thoughts and start this.

I could go back to what I really want to tell you as absolute priority: you are all incredibly precious, your lives and well-being matter and I keep fingers and toes crossed (+ wash my hands, stay confined, etc), hoping we will all emerge from this crisis soon, as 'well as possible'.

These times muddle up all perspectives, make all priorities relative and reveal a lot about ourselves (often to a level we would like to have been spared of):

That humans need to have invested/invest enough in education and care for society and values to survive.

That humans are 'social contact animals' coping with some difficulty to being limited to virtual socialisation. Who has not dreamt recently about giving-receiving a hug, sharing part of our sandwich with a colleague, patting someone's shoulder? There are some actual boundaries to the Science-Fiction books we read as teenagers: we need basic, direct, real connexion.

That work can be a wonderful occupational therapy, allowing our minds to wander around and become free(r). True: this is not a revelation: if you are a "little" work-enthusiastic (!) like me, your partners and families have already told you that you were escaping from reality (and its related duties) by thinking about REACH and metals (as an example). But the demonstration has seldom been that obvious. We organise calls, agree on actions and plan more & more virtual meetings, become experts in Teams/GoToMeetings/Skype/Zoom -all opened on our desktop-, chat and oops the day is gone. One can even manage to get excited or upset during a call about a 'point of principle', as if we were in normal times thanks to microphones and cameras! Being for a moment your "normal" working self! Although, it is fair to say that after the ritual "stay safe" closing the call, one wonders where that "point of principle" fits in this overall scary picture. I acknowledge I'm depicting an 'easy' situation here: association work, like Eurometaux's work, can rather conveniently be transformed into confined teleworking. I realise the situation is not that simple for several of us and for relatives who are still forced to go out, be exposed and having to cope with that anxiety. Neither do I have to deal with three kids demanding continuous attention*. But one's mind needs, when possible, to hold on to an anchor to avoid getting flustered, carried away in a whirlwind of thoughts. And work is an accessible one for most of us.

That the flexibility and adaptability we seem to find are impressive, as well as the solutions humans implement, their acceptance of an altered rhythm. The 'regulatory' year had started with us frantically running from one issue to another, wondering how to transform the Green Deal into opportunities and address complex questions in a jiffy (and with not too many resources). There we are, super hamsters, tripping in wheels with changing or uncertain cadences. And we cope, as well as we can. And we say that we will learn from this. And we talk about an 'after' that won't be the same, will make more sense.

I hope this will indeed be the case: that our re-acquired adaptation competences won't push us to retrieve -as quickly as possible- the 'before' situation. But I'm optimistic!

That we do not hesitate anymore -because one does not know what tomorrow will be made of- to say: I love you guys. And that's it indeed: I love you guys -stay safe.

Violaine Verougstraete, Chemicals Management director Eurometaux

*but between us, I confess that I'm dreaming of having my 'medic' kids confined with me rather than being out there...

ECHA REACH & CLP Activities: hot topics

ECHA Committees

RAC-52: a shortened but intense week

The RAC shortened its two-week meeting to a single one, with several members participating remotely due to the COVID crisis. This did not prevent several relevant discussions to from taking place, as the quorum of RAC members in the room was met along the week. The RAC workplan presented by the secretariat confirmed the timings of the upcoming classification dossiers (on tellurium/tellurium dioxide, vanadium pentaoxide and barium diboron tetraoxide) but the question at stake now is how the meetings modalities will be adapted to the crisis and associated restrictions (e.g. with regard to participation of the stakeholders). Eurometaux and Cefic will initiate a discussion with ECHA to ensure stakeholders can attend the discussions (remotely or in writing). Two health health-based exposure limits at the workplace were discussed, for diisocyanates and lead/lead compounds respectively. Key issues on diisocyanates included the consideration of potency, the consideration of human data for the derivation of a reliable exposure-response relationship, the role and importance of dermal exposure and the setup of the Short-term Exposure Limits (STEL) vs. an 8 8-hour Time Weighted Average (TWA) value. Steve Binks and Cris

Williams (ILA) participated as industry experts in the lead discussion. This debate focused on a number of key issues and allowed to collect the reactions from the RAC members on some of the proposals made, but no conclusions were drawn as the Rapporteur was absent. One of these issues is the desirability of having an air value in addition to a biological limit value (BLV), as requested for by the Commission requests. The co-rapporteur started his presentation by listing the arguments for focusing on a BLV and having only a complementary air value (i.e. the BLV is critical for adverse health effects that we see in all epidemiological studies, the background exposure has dropped considerably over the last years meaning that results from older studies on the correlation between air levels to Pb-B are not representative for the current situation anymore, personal and occupational hygiene affects lead uptake and thus internal exposure and exposure towards different lead compounds may result in different internal lead levels) but then continued by presenting possible models/approaches to support a Pb-air value that is very low ($3.9 \mu\text{g}/\text{m}^3$). What was also discussed is the inclusion of a statement to address potential reproductive toxicity in women in of childbearing age, as the proposed point of departure is based on subtle neuro-behavioural effects in workers, occurring at higher levels than those estimated to cause developmental toxicity. The statement in the Chemicals Agents Directive could state that the exposure of fertile women to lead of fertile women should be minimised or avoided in the workplace because the BLV for lead is not protective of the offspring of women of childbearing age and that the lead blood level for women of childbearing age should not be higher than the reference values of the respective general populations not occupationally exposed to lead. The RAC chair, in agreement with the co-Rapporteur, decided to continue the discussions on lead at the June meeting, stressing that the discussions on neurotoxicity and point of departure need to be held in detail, in presence of the rapporteur. In follow-up of the discussion, industry experts provided a package of information to the RAC secretariat, supporting the (appreciated) interventions they had made during the meeting. Most of the rest of the week was taken up by the debate on the microplastics restriction and in particular the discussions on the derogations. The discussion here as well will be continued at the June meeting. RAC also discussed also some Applications for Authorisation (AfAs) on the last days of the week (more information: Steve Binks, Cris Williams and Violaine Verougstraete).

SEAC-46: Co-salts restriction case finalised and 2nd Public consultation opened

During its March meeting, SEAC reviewed the outcome of the RAC assessment on the Restriction of 5 Cobalt salts reconfirming that the original proposal of the Dossier Submitter (ECHA) was not the best or even a proportional risk management option. On the RAC opinion, SEAC confirmed that a Time Weighted Average TWA 8-hour value based on a respirable Cobalt fraction was a step forward in the right direction but challenged the value ($1 \mu\text{g}/\text{m}^3$) as the health benefits were minimal compared to the cost of the measure and questioned if an EU-wide Binding OEL (B-OEL) for Co and inorganic Co compounds would not be a better measure to take. SEAC was not able to confirm the latter and neither could they confirm if a TWA value of $10 \mu\text{g}/\text{m}^3$ was a better solution given the evidence to conclude in this manner was not available in the dossier. The outcome of this opinion is an enormous improvement from the point of departure and opening door for the Commission to consider an EU-OEL as a valid alternative to consider. In follow-up of the RAC and SEAC opinions ECHA launched (somewhat surprisingly) the 2nd public consultation on the 25th of March which will now run for 60 days. SEAC invited the sector to submit further information on the B-OEL aspect as well as on the scope of some of the exemptions (use as fertiliser, on which RAC and SEAC have opposite opinions). This restriction case sets a clear precedent on how future workplace exposure control measures on metals could be set. This is one more reason to pursue a B-OEL as a more appropriate risk management option. The Risk Management TF meeting of 30 March discussed how other sectors and users could be of help in this respect (see further). (more information: Hugo Waeterschoot).

MB-57: Corona impacted the agenda which included the financing of ECHA's activities whilst leaving some uncertainty on how other important agenda items were progressing

The ECHA management Board (MB) had scheduled an important meeting to solve its conflict with the Commission on how to resolve its significant budget shortage for the years to come. The meeting was replaced by a webinar that focussed mainly on the Corona virus outbreak and its consequences for ECHA, as well as on the reply to the Commission on the budget situation. The MB also approved the annual report 2019 which provides a good overview of its activities and progress made with its multiyear objectives. However, industry challenged the "overly optimistic style" and the lack of attention for outstanding issues of concern, like the guidance on nanos that is still lacking) or the still outstanding response on the intermediates court case requiring guidance change, ...). It is further unclear what will happen with the other agenda items of high relevancy and importance for the sector like the update of the Substitution Strategy (see further) on which industry wanted to make clear recommendations to the MB (more information: Hugo Waeterschoot).

ECHA Others

Authorisation

Granted Authorisation applications challenged: Commission has started sending letters to applicants asking for substitution plans

The General Court case T837/16, dated March 2019, of Sweden against the Commission on Pb-chromates motivated the Commission to reconsider already agreed applications for authorisations. Amongst other issues, the court case indicated that 'where (...) there remain uncertainties as regards the condition relating to the lack of availability of alternatives, it must be concluded that the applicant for authorisation has not discharged the burden of proof and, therefore, that he cannot be granted authorisation' (par 79). This case challenged the broad scope of several granted authorisations given they included sub-uses (utilisations) that would or would not be substitutable. However, the court case also provides a solution in stating that "suitable alternatives may be available in general", but that those alternatives could not be technically or economically feasible for a specific applicant; meaning that in those cases the authorisation must not be refused'. This triggered the Commission to dispatch a series of letters to applicants representing different types of substances and uses, many of them including decorative platers using chromates. The letters asked to submit a substitution plan if suitable alternatives were available and unless companies could prove non-feasibility. These letters created lots of confusion on what Commission's intention was and also some panic given uses like decorative chrome plating could lose their permit by the end of the summer. Eurometaux was solicited to facilitate an exchange between authorisation applicants that received the letters, ECHA and the Commission, to get clarity on the case as well as receiving some guidance on how to resolve this difficult situation. The scheduled meeting was however postponed due to the Corona virus outbreak (more information: Hugo Waeterschoot).

10th priority list for Authorisation: public consultation launched on 5 March - except a borate compound, no metals this time

ECHA launched a public consultation on its proposal for a 10th recommendation for the Commission on substances that could be priority candidates for authorisation. The long-expected proposal was somewhat a relief, noting that neither lead metal nor cadmium metal and compounds were on the suggested list. Despite its low priority scoring, disodium octoborate was the only metal compound selected based on the criterion of grouping for intersubstitutability with existing borate compounds (incl. boric acid) selected in previous years. Lead metal scored high enough to be selected but was not due to workload considerations. Its selection was therefore postponed. Cadmium and cadmium compounds scored too low to be selected this year. Companies and Consortia can react to this consultation before 5 June 2020 if they use this borate substance and/or any of the other substances proposed, by using the following link: <https://echa.europa.eu/recommendation-for-inclusion-in-the-authorisation-list>. The Lead sector will make the most of this "welcomed" delay to progress with the B-OEL concept to help prevent Lead from ending up on Annex XIV (more information: Hugo Waeterschoot).

Substitution strategy

ECHA: updating its strategy on substitution to safer alternatives

ECHA scheduled to update its Substitution Strategy to cover the period 2020-2021. The present strategy was published in 2018 focussing mainly on awareness raising and promoting substitution to safer alternatives. This included a request to sectoral organisations like Eurometaux to set up such activity. We replied to this demand by organising the workshop in Antwerp in November 2018 where we developed the sustainable substitution concept promoting a much more holistic view that includes risk considerations, technical and economic feasibility but also attention for recycling (circularity) and climate impact, by using clear examples. ECHA presented its updated draft strategy to the ECHA-MB meeting in March (see above) hereby launching the approval procedure without any public consultation or openness on the draft strategy. From what we heard about the update, ECHA does not aim to extend the scope of substitution beyond what is presently foreseen (under the restriction and authorisation schemes and the Biocides regulation). So far so good. Less positive seems that no attempt is being made to broaden the considerations for substitution with more risks and sustainability aspects like the Circular Economy (CE). Eurometaux will therefore, in concertation with Cefic, prepare a written reaction to the ECHA Management Board calling for such an extension of considerations and a possibility to provide technical comments to the paper. The Risk Management Taskforce concluded that "the substitution strategy guides ECHA, SEAC and the Commission and should therefore raise our attention to improve the concept along the suggestions made at the Antwerp workshop" (more information: France Capon, Klaus Kamps and Hugo Waeterschoot).

COMMISSION Activities: hot topics/issues

CARACAL

CARACAL: latest administrative information

- CARACAL-34 is CANCELLED due to the COVID-19 outbreak. Many agenda items will be dealt with by written procedure by 8 May. A few other agenda items are moved to CARACAL-35. The Chemicals Management department will circulate a full summary of actions and relevant documents available in the coming weeks
- CARACAL is officially renewing its industry membership ("observers") and Eurometaux is applying to secure a seat (more information: Noam El Mrabet).

CARACAL subgroups on Endocrine Disruptors and REACH data requirements: *Eurometaux's input following the 7/2 kick-off meeting*

Following the kick-off meeting of the CARACAL subgroups on "Endocrine disruptors" and on "Information Requirements" organised on the 7th of February, Eurometaux submitted its comments that underlined the main concerns for the metals industry. On REACH information requirements attention was raised on the need to better clarify the species on which reprotoxicity/PNDT studies are conducted, underlining also the inappropriateness of the use of rabbits for testing certain substances. Additionally, Weight of Evidences should be maximised to minimise the amount of *in vivo* studies.

On the evaluation of endocrine disrupting properties, it was recommended to adopt a trigger-based approach in case of positive/negative test results. The use of standardised tests and guidelines is also considered important; however, this should not prevent the use of existing data that have already been generated. Moreover, when dealing with "hormone levels", for metals it is crucial to take into account information on normal hormone levels and their variability for different species.

The second meeting of the CARACAL subgroup on Information Requirement is planned to be held on the 2nd of July and it is intended to discuss amendments to Section 8.4. (mutagenicity/genotoxicity) across all Annexes; additional topics might be added. There is currently no information about the 2nd meeting of the subgroup on Endocrine Disruptors (more information: Violaine Veroustraete, Marnix Vangheluwe, Lorenzo Zullo)

OTHERS

WG Chemicals Webinar – 17 March 2020

Being held during the first week of Belgian measures put in place to reduce the spread of the Covid-19 virus, the Commission decided to hold the meeting remotely. This ended up by not being a big success due to major technological issues, and therefore the agenda was reduced to a discussion on the Watch List Monitoring Requirements and a short update on the EEA Emissions inventory project. On the latter the group was informed that the meeting end of April is postponed to September, but a webinar will take place anyway. The planned discussion on the Priority Substances Update has been cancelled and announced by the EC to be dealt with in writing. Till date we have not received any further written information on the process (more information: Nathalie Kinga Kowalski).

Launch of IED Inception Impact Assessment

On the 24th March Commission launched the Inception Impact Assessment (IIA) for the Industrial Emissions Directive. Stakeholders can comment on the IIA till 21st April 2020. First points on a draft answer were discussed at the last Industrial Emissions Taskforce conference call (see below). The IIA will be followed by a 12 week consultation in the late summer (Q3 2020) to feed in the Impact Assessment. The EC wants to conclude the IIA by end of the year (more information: Nathalie Kinga Kowalski).

Green Deal Activities

New Circular Economy Action Plan: *adopted*

On 11 March, the European Commission adopted its new Circular Economy Action Plan. Dubbed as "one of the main building blocks of the European Green Deal", this action plan made an attempt, in one of the leaked versions, to present the definition of substances of concern (see CM News N°97), but it was dropped in the final version. As a reminder, the leaked draft stated that the scope would include Substances of Very High Concern (SVHCs), CLP Annex VI substances with chronic effects and other substances posing technical problems for recycling. Meanwhile, the official tracking table for the Action Plan still mentions that "methodologies to track substances of concern" and "harmonised information systems for the presence of substances of concern" are expected for 2021 – whatever these substances will be in the end (more information: Kamila Slupek and Noam El Mrabet).

Effects of combined exposure: a new requirement that may challenge the sector for the years to come

The need to handle the effect of the combination of substance and mixtures exposures at the workplace for consumers or the environment was already reflected upon during the early days of the REACH Guidance development. This endpoint is included in the legal text but was, at the time, (correctly) postponed ensuring focus on the registration of the effects and exposures of single chemicals. A recent Council recommendation as well as a reminder in the Green Deal priorities indicated the “urgent need to cover for the effects of the combined exposure of chemicals”. Kemi and RIVM took leadership by organising 2 workshops to progress on this concept. The first workshop was attended by close to 50 Member State representatives and scientists as well as by Cefic and Eurometaux and took place in Leiden on 6 March. Its conclusion was to progress with the original concept from 15 years ago by including a mixtures assessment factor (MAF) on the Risk Characterisation Ratio (RCR) or on the Predicted No-Effect Concentration/Derived No-Effect Level (PNEC/DNELs). Industry’s delegations asked for pragmatic solutions whereby tiered approaches, sector specific considerations (like correction for natural background) and a sufficiently long entry into force should be warranted. The Member States supported by the Commission agreed to present a paper to CARACAL on the concept and how to evolve. This issue will clearly affect all REACH dossiers and is especially a challenge for the metals sector because of e.g. background levels and natural occurrence. It was therefore raised as an important item at the Science Forum meeting this month, confirming the need for close follow-up (more information: Hugo Waeterschoot).

EP ENVI: meeting 17/02/2020

Among other topics, the MEPs discussed the fate of the Ambient Air Quality Directive and Water Framework Directive (WFD). The discussions were introduced by the Commission, here by Veronica Manfredi, with briefs on the REFIT exercises. Furthermore, the Commission underlined these activities as being important for the zero-pollution ambition of the Green Deal. The discussion on the Air Quality Policy was rather short: a few MEPs questioned the fact of waiting for the WHO Air Quality Guidelines Update (in 2021) and would like to see actions asap. French MEP Pascal Canfin underlined the need to remember to have the right measures for the levels and not only focus on the “right levels”. While on the WFD, the MEPs emphasised the importance to stick to the outcome of the REFIT exercise, which considers the WFD fit for purpose. Some MEPs mentioned that they do not understand why it is still under the Commission’s prerogative to estimate if the WFD needs to be opened or not. The EC highlighted, that they might only consider reviewing the Environmental Quality Standards (EQS) Directive (more information: Nathalie Kinga Kowalski).

European Council ENVI: meeting 05/02/2020

After the European Parliament meeting, the Council also discussed the Air and Water legislations’ future. Each topic was introduced separately by Commissioner Sinkevicius, after which several Member States gave their opinions. The Council considered the established air quality standards as being effective and remaining essential to protect human health but supported an alignment with the WHO Air Guidelines. Doing that, CZ called for attention on the technical limitations of mitigation measures to achieve the air quality standards. The Council adopted the proposed conclusions to further work on combatting air pollution as this is deemed as being crucial to fulfil a Zero-Pollution ambition. On the WFD the MSs were rather divided, though keeping their comments high level: ES, FR, DE, IT, GR, FI, LU, DK supported the REFIT conclusions to focus on implementation improvement. They highlighted the importance of coherence with other policies, addressing new emerging pollutants and to better support measurements financially. On the other side SE, RO, LV, HU, NL, EE, MT were reserved about maintaining the WFD as it is. In their view implementation improvement cannot overcome the uncertainty of the 2027 deadline due to a lack of connection, especially to climate change policies or administrative burden. Overall, all Member States highlighted to maintain the ambition and objectives of the WFD (more information: Nathalie Kinga Kowalski).

EUROMETAUX CHEMICALS MANAGEMENT Activities

Resource mapping to respond to Chemicals Management challenges

Human Health Taskforce: a call to prepare MISA 4

The Human Health Taskforce and more specifically the exposure assessment enthusiasts had a call on 2 March to prepare the MISA 4 workshop on exposure and review the draft Self-Assessment tool for worker’s assessment prepared by Eurometaux and EBRC. Although the workshop has now been cancelled, some very useful comments and feedback were received from the participants and will be integrated in the revised versions of the workshop agenda and preparatory material (more information: Daniel Vetter, Adriana Oller, Ruth Danzeisen and Violaine Verougstraete).

Registration Taskforce: is keeping up with REACH registration dossiers’ challenges

The last meeting of the Registration TF took place on 19 March. Despite it being organised online due to the COVID-19 situation, the taskforce progressed well with the various items on the agenda. The upcoming Implementing Regulation on

duties to update the registration dossiers is expected to be discussed/voted in the REACH Committee within this year; as soon as the final version is available, Eurometaux will consider developing a brief document summarising the main requirements, that would also take into account the co-registrants' roles and duties. Particular attention was dedicated to the new REACH information requirements on nanomaterials. Following a round table exchange of experiences, the taskforce was invited to keep Eurometaux informed about remaining issues, such as technical challenges to group and characterise metals in nanoforms, and the suitability of existing guidance documents. It is expected that several dossier updates might fail to pass the Technical Completeness Check (TCC), and in particular its revised version that is planned to be introduced by ECHA by the end of April 2020, which will also include manual checks of information on uses and exposure scenarios contained in the Chemical Safety Reports. Therefore, Eurometaux, besides preparing a two-pager to help dealing with the TCC, will also continue gathering and sharing experiences from consortia to help addressing upcoming issues in a timely manner. REACH-IT and the well-known problem of free riders was also discussed. Considering that no solutions have been found yet, Eurometaux is planning to prepare a new concise document to reiterate the issue with the aim of reopening the discussion with ECHA. Finally, as part of the cross-industry activities related to specific Environmental Release Categories (SpERCs), the taskforce agreed to engage an external consultant to assess the quality of the SPERCs developed by Eurometaux, in preparation to the review to be conducted by national authorities in 2020. The minutes of the meeting will soon be shared (more information: Caroline Braibant, Sandra Carey, Federica Iaccino and Lorenzo Zullo).

Risk Management webinar: *recent ECHA publications guided the discussion*

The Risk Management Taskforce meeting of Q1 2020 was turned into a webinar due to the COVID-19 virus outbreak. The agenda was heavily loaded by recent ECHA and Commission initiatives including: the outcome of the SEAC opinion on the Co-salts restriction case, the ECHA and OECD substitution activities, the publication and launch of public consultation on the 10th priority list for authorisation and the recent letters from the Commission on the need for substitution plans for applications already granted. All these issues are reviewed in more detail in this newsletter. In this respect, the RM TF concluded to support the Cobalt Institute's activity on promoting a B-OEL for Co as a more appropriate alternative Risk Management Measure for metals, requesting that Eurometaux secretariat carefully review and invest in improving the substitution strategy activities of ECHA and the OECD. The Taskforce also supports that Eurometaux act as a facilitator for clarifying the Commission Substitution Planning request, although also inviting Cefic to join this initiative. Finally, the RM TF agreed with the 2020-2021 priorities of the TF presented by the chairs, including 4 strategic pillars (working on tools, strategies and processes and some recent relevant court cases), the overall key messages to pass and the 3 main priority items to progress with: the sustainable substitution concept to tackle a too much hazard based approach, changing the present focus that is on authorisation and restriction towards a broader sustainable risk management concept and the new requirements on substitution planning as a consequence of the court case. (more information: France Capon, Klaus Kamps, Violaine Verougstraete and Hugo Waeterschoot).

Chemicals Management Spring Week

Science and Regulatory Forum: *incredible attendance*

The meetings of the Science and Regulatory Forum were set up as virtual meetings, acting a bit as 'test cases' for Eurometaux to assess how to best combine the information-providing role of the Forum meetings with virtual interventions of guest speakers in a palatable format, which would allow interactions but also provide enough comfort to the participants. The agendas were streamlined and some 'IT' related instructions were circulated beforehand but it is primarily the heart-warming presence of the members (up to 72 participants on Day 3), the 'discipline' with the GoToMeeting tool and the thorough preparation of the meetings by the Chemicals Management department secretariat that made it 'happen'. Commission and OECD intervened in the meetings shedding some light on the Green Deal and the Chemicals Strategy for Sustainability, Jean-Pierre de Bruxelles (FuelsEurope) explained how integration of policies means opportunities and challenges and the metals industry speakers provided excellent presentations, encouraging us to further reflect, also on what will come after the COVID crisis. A special thanks to all of you, including of course the whole team, for this success. But we are definitely looking forward to moving back to an "in vivo" format for the autumn meetings. Minutes will be circulated asap (more information: Violaine Verougstraete).

Metal-specific tools

Bioelution: *EURL ECVAM on gastric bioelution protocol is positive -further work on sample repository for OECD's test guideline*

EURL ECVAM has now finalised its extensive and thorough validation of the gastric bioelution Standard Operating Procedure (SOP) and published its opinion, which is favourable. EURL ECVAM had also submitted a project proposal for the development of a test guideline in November. Several comments were submitted by OECD countries in the course of January, triggering EURL ECVAM to prepare a detailed response to the comments document. The next step is now to convince the OECD Testing

Guidelines Working group to include the drafting of the test guideline in their 2020 work programme. This will be decided on at the 20-21 April virtual meeting of the Working Group. As part of the OECD process, a sample repository of proficiency and reference materials is to be established. Industry has to identify: 1) which metals and alloys should be included in the repository as proficiency (to ensure laboratory consistency and proper technique) and reference (for comparison in the classification of alloys) materials; 2) a facility that could serve as the repository of the samples and can manage the database of test results; and 3) potential test laboratories for the initial testing of the sample repository materials. A document describing the criteria to identify the needed sample (metals, forms, size, amount, etc.) was distributed to metal representatives and discussed during a conference call. If the gastric bioelution protocol is approved for the work programme this year, the repository will need to be set up right away and the initial testing will need to start soon afterwards; the repository is a key component of the protocol. NiPERA and Eurometaux are assisting each representative with identification and sourcing of the samples. The EU Commission is also relaunching the activities of the Bioelution expert group. This group will have as mandate to "provide advice to the Commission and serve as a platform for the exchange of views, in particular on the question: how and under which conditions the *in vitro* bioaccessibility of a hazardous metal in a metal compound or an alloy can be used for the (refinement of the) classification of alloys under CLP. Industry can nominate a limited number of observers. A first meeting of this group is planned for September (more information: Kate Heim, Adriana Oller & Violaine Verougstraete).

Metals Sectorial Approach

MISA: workshop on exposure cancelled and other news

The MISA 4 workshop on Exposure, initially scheduled for 23-24 April, has of course been cancelled. A new date is now actively being sought for with ECHA. This does however not prevent Eurometaux from further working and exchanging with ECHA on the format of the workshop and the self-assessment tool. Also, one of the important discussions that was on the agenda for the workshop related to the new Technical Completeness Checks and checks of the metal CSR. The idea was to ensure ECHA and the sector had a good understanding of both the expectations and the issues & work-arounds. This has been further discussed by the Registration Taskforce (see above) and it was agreed to collect cases where we would face some difficulties. With regard to the updates that were committed in the workplans for the previous MISA activities, the impact of the crisis is acknowledged. Consortia are invited to inform ECHA via the MISA functional mailbox about the difficulties they are encountering to meet the announced deadlines.

Finally, the results of the surveys the consortia kindly completed in December and January on the mapping of the Chemicals Universe were communicated to ECHA, who will use the coming weeks to assess what can be done/corrected before the next 'snapshot' of the database (more information: Hugo Waeterschoot, Federica Iaccino and Violaine Verougstraete).

UVCB: some progress on the reporting issue

Eurometaux and ECHA had a discussion early March on the 'formatting of the inorganic UVCB dossiers', or more precisely how to best compile the data on the inorganic UVCB constituents in the UVCB IUCLID/CSR dossier in a way that the dossier is complete and understandable but also efficient and can be updated. Since the MISA UVCB November workshop, Eurometaux, ARCHE, EBRC and ECHA have been exchanging on different reporting options. A proposal was sent to ECHA, with a follow-up call and the development of a set of slides using the Slags Doré furnace example. These slides have been evaluated by ECHA and the meeting on 11 March aimed at defining a common way forward. ECHA indicated that the overall "Lead Constituent" approach industry would like to apply (limiting the reporting of the complete datafiles to lead constituents and reporting endpoint summaries for relevant constituents) may be acceptable but further work is needed to define and report as transparently as possible what is a lead or relevant constituent, to what level of details to go with regard to the information, the role of the multi-metallic database, what to do if no PNEC/DNEL is available etc. Also, the impact of "exposure" on the hazard driven selection of the lead constituent and the combined risk need to be further elaborated. Eurometaux proposed to further work out one dossier to show what the IUCLID and CSR would look like. The outcomes would be assessed by ECHA for their comprehensiveness and translated in an agreed format for these complex dossiers (more information: Federica Iaccino and Violaine Verougstraete).

Water

Water Taskforce Conference Call: 18 March 2020

In the view of the different activities ongoing, the Water Taskforce met virtually to discuss the next actions on the Priority Substances Update and EEA Emissions Inventory project involvement. On the Priority Substances (PS) it was decided, in case no new information is sent by the EC, to aim for sending a letter in the coming weeks to the Sub-Unit Director calling for an adequate and transparent procedure. In preparation of the upcoming EEA Emissions Inventory webinar the Taskforce agreed to leave the work to the core group of ECI, IZA and NiPERA, as done so far. Because of specific interest, ILA will join the core group as well. Further, the Taskforce exchanged on the current situation of the WFD implementation: some members are

having problems to receive their environmental permits by strict interpretation of the non-deterioration principle and the phasing-out of the Priority Hazardous Substances. It was decided to continue to map via Eurometaux secretariat the implementation experiences in the different EU Member States, to develop knowledge on possible solutions (more information: Nathalie Kinga Kowalski).

Industrial Emissions

Industrial Emissions Conference Call: 1 April 2020

The secretariat invited the Industrial Emissions (IE) Taskforce for a conference call to update on some of the most urgent issues tackled by the TF: the Industrial Emissions Directive (IED) revision process, current knowledge on the Best available technology Reference document (BREF) programme and planned advocacy activities. As above reported, the IIA has been launched, which was mainly discussed during the call. The TF agreed that Eurometaux shall address practicalities of the procedure, such as the missing staff working document of the evaluation, but also use this consultation to draw attention to most relevant topics which should be addressed in the impact assessment, like the IED scope & purpose in view of including decarbonisation and Circular Economy policies, linked trade-offs with decarbonisation efforts, securing the integrated approach, the missing definition of a BAT-AEL derivation process, etc. A first draft will be shared with the IE Taskforce before Easter. Facing the spread of Covid-19 over Europe some members flagged that some Member States will not meet the implementation deadline for the Non-Ferrous Metals (NFM) BREF (30th June). Eurometaux has already addressed this problem to the Commission. With the current postponements of diverse Seville process meetings, it is also unclear whether the time planning of the Large Volume Inorganic Chemicals (LVIC) and Surface Treatment of Metals BREFs will be maintained (more information: Nathalie Kinga Kowalski).

Nanos

Nanomaterials: ECHA/industry actions following the entry into force of the new REACH data requirements

Starting from 1st of January 2020, registration dossiers must comply with new information requirements on nanomaterials according to the updated REACH Annexes. ECHA expressed concerns regarding the amount of updates received since January. ECHA was expecting updates for approximately 300 substances but they received one order of magnitude less. ECHA will update the European Commission and Member States (MSs) via a document to be submitted to CARACAL. In order to better understand the technical issues that industry is facing and to provide further guidance, on the 30th of March ECHA co-organised, in cooperation with CEFIC, Eurometaux and NIA (Nanotechnology Industries Association), a two-hour webinar. The webinar, attended by approximately 100 participants, was also intended to set a dialogue between registrants and authorities, to learn from each other and to identify issues and find solutions. The main focus was on building and justifying "sets of similar nanoforms". Several technical questions remain open and will be addressed in future exchanges. Pending issues are also related to additional ECHA guidance documents that might only be published in 2021, as well as the not yet finalised OECD guidelines. Eurometaux would like to take the occasion to recommend paying particular attention to the presence of particles in nanoforms in metals (i.e. looking at the "tails" in the distribution curve) since they might trigger the need to introduce nano-specific information in the registration dossier, even if the nano-forms are not intentionally manufactured. Based on the experiences of some consortia, generating such information requires significant effort in terms of time and resources, also taking into consideration potential technical issues in running the tests (more information: Violaine Verougstraete, Lorenzo Zullo)

Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS)

Review of the RoHS Directive: preliminary results of the evaluation study presented 30/3 workshop

On 30 March, the European Commission (DG Environment), in cooperation with the appointed external consultant Ecorys, organised an online workshop to present the preliminary findings of the study supporting the Evaluation of the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS). The study looked at the effectiveness and efficiency of the Directive, as well as its relevance, added value and coherence with other legislative frameworks related, among others, to chemical, waste and circular economy. Eurometaux believes that the review of RoHS should lead to the creation of more synergies with REACH. Specifically, Eurometaux is promoting the "One Substance, One Assessment" principle, meaning that datasets and related assessments conducted on substances within REACH should be used as a starting point to introduce substances in the scope of RoHS. The Risk Management Options Analysis conducted under REACH is considered an important tool to properly identify the most suitable legislative framework to regulate the use of specific substances. Currently, the identification of substances to be restricted or exempted under RoHS is done in a completely

independent process, which is considered to lack transparency and scientific robustness. As a follow up to the workshop, Eurometaux is planning to submit written comments. After the finalisation of the RoHS evaluation report, the European Commission will conduct an impact assessment to compare different legislative review options. An inception impact assessment is expected to be published around the summer (more information, Caroline Braibant, Violaine Verougstraete, Lorenzo Zullo).

OUTREACH

OECD

OECD: *planning to develop guidance for Member States on Substitution to safer alternatives*

Not only ECHA, but also OECD is these days active on the substitution agenda. The OECD asked a consultant to draft a first guidance outline on how to select chemicals for substitution and a generic frame on how to proceed. The draft will be presented at an OECD workshop dedicated to this theme and scheduled for the end of April. Kai Melzer from the Nickel Institute and co-chair of the BIAC Chemicals group took leadership in coordinating industry's response on the draft paper. This paper suggests a first selection based on a hazard comparison basis before considering other aspects like exposure, or technical feasibility. The BIAC response under preparation promotes that hazard comparison, risk considerations, technical and economic feasibility including sustainability considerations (like circularity) should be considered collectively in a weight of evidence approach to define if and by what the chemical can be substituted. This much more holistic approach would prevent regrettable substitutions, for example by using substances with a lower hazard but higher exposure pattern, or substances that would hamper recycling, or have a significant negative impact on the climate policy. BIAC replied to an OECD questionnaire and will present its vision demonstrated by examples at the workshop (more information: Kai-Sebastian Melzer and Hugo Waeterschoot).

OTHER

Data availability: *REACH Compliance part 3*

The third part of the series of publications triggered by the German authorities "REACH Compliance project: Data availability of REACH registrations" has now been published. It addresses the findings of the project for registration dossiers of the medium tonnage band (100-1000 tons/year). The objective of the project was to assess the availability and quality of the information on toxicological and ecotoxicological endpoints in lead and individual dossiers. Eight endpoints (developmental, reproductive and repeated dose toxicity, mutagenicity, biotic and abiotic degradation, bioaccumulation and ecotoxicity) and the environmental exposure assessment were included in the investigation. While the availability of standard information (guideline studies) was addressed within the screening, data waiving/adaptations were analysed during the formal and refined check. According to the criteria applied within the project, 14 % to 57 % (on average 45 %) of the evaluated data for a specific endpoint were considered "compliant", 9 % to 46 % (on average 24 %) "non-compliant", and 11 % to 76 % (on average 31 %) "complex" (without conclusion within the scope of the project). The results of the project revealed that at least 24 % of the assessed endpoint entries failed to be in compliance with the REACH requirements. Thus, the availability and quality of toxicological and ecotoxicological information provided in registration dossiers may be subjected to improvements. The publication can be found here: https://www.umweltbundesamt.de/sites/default/files/medien/1410/publikationen/2020-03-02_texte_39-2020-reach-compliance-part-3.pdf The first two parts, "Screening of chemicals > 1000 tpa" (Springer et al., 2015) and "Evaluation of data waiving and adaptations for chemicals ≥ 1000 tpa" (Oertel et al., 2018b), have already been published and indicate a need for improvement in REACH registrations of the high tonnage band (≥ 1000 tpa).

COMMUNICATION

Chemicals Management: *new trainee Heidi*

Dear Colleagues, my name is Heidi NORTHSHIELD (American but Belgian-born, trilingual) and I'm the new intern for Eurometaux! I have a bachelor's degree in nursing and I'm currently finishing my master's degree in Biomedical Science (Toxicology specialisation). I was introduced to regulatory toxicology through one of Violaine Verougstraete's university courses and developed a keen interest for it. Therefore, I chose to do my internship at Eurometaux where I could directly learn all about regulatory toxicology in practice. During my 12-week internship, I'll be analysing best practice cases which successfully follow directives and meet emission limit requirements. These cases will be shared with the Commission to highlight our emission reduction successes and published on our website to promote our business. For this project we ask you

to contact Eurometaux with examples of your activities' emission pollution measures which reflect the best available technologies, investments done in environmental performance and our sector's share in pollution reduction. Do not hesitate to share your success cases with me before the end of April!

Kind regards, Heidi. chemtraine2@eurometaux.be

CALENDAR

Due to the outbreak of Covid-19, some of the meetings are postponed or being held virtually. We will keep you updated as well as possible.

For info the current mandatory period to cancel or postpone conferences is limited to 31 May in Finland

- 20-24 April: MSC-69 – ECHA (Helsinki)
- 22-23 April: WFD – CIS: WG Groundwater – (Zagreb, Croatia) – **Cancelled**
- 22April: EEA diffuse emissions project stakeholder workshop (Delft) - **Webinar (face-to-face meeting on 9-10 September)**
- 23-24 April: MISA 4 Workshop – ECHA (Helsinki) – **Postponed to a later date**
- 27April: Stakeholder Workshop Case Studies HAZBREF project (Stockholm) - Webinar
- 12 May: Risk Management TF meeting – TBD (Brussels)
- 13-14 May: WFD – CIS: SCG & Art. 21 – (To be confirmed)
- 13-15 May: CEM Conference (Krakow) – Postponed to 7-9 October
- 19 May: Evaluation Taskforce – TBD (Brussels)
- Back-to-back Meeting Water & IE TF – TBC (Brussels)
- 1-5 June: SEAC-47 – ECHA (Helsinki)
- 2-3 June: ECHA: Safer Chemicals Conference: **ECHA are considering the options and will provide more information soon**
- 2-5 June: RAC-53 – ECHA (Helsinki)
- 5-6 June: Final Stakeholder Meeting HAZBREF project (Dessau) – Webinar
- 8-12 June: SEAC-47 – ECHA (Helsinki)
- 8-12 June: RAC-53 – ECHA (Helsinki)
- 8-12 June: MSC-70 – ECHA (Helsinki)
- 12 June: IED Stakeholders Workshop – (To be defined)
- 15-16 June: WFD – CIS: Water & Marine Directors meeting – (Zagreb, Croatia)
- 17 June: Chemicals Management Steering Committee – MCC (Brussels)
- 17-18 June: MB-58 – ECHA (Helsinki)
- 7-9 July: Metals Academy Course – The Priorij (Corsendonck)

ACRONYMS

AfA: Application for Authorisation	MISA: Metals and Inorganics Sectorial Approach
BIAC: Business and Industry Advisory Committee to the OECD	MS: Member State
BLV: Biological Limit Value	NFM: Non-Ferrous Metals
B-OEL: Binding Occupational Exposure Limit	OECD: Organisation of Economic Cooperation and Development
BREF: Best available technology Reference document	OEL: Occupational Exposure Limit
CARACAL: Competent Authorities for REACH and CLP	PC: Public Consultation
CE: Circular Economy	PNDT: Pre-Natal Development Test
CLP: Classification, Labelling and Packaging Regulation	PNEC: Predicted No-Effect Concentration
CSR: Chemical Safety Report	RAC: Risk Assessment Committee
DNEL: Derived No-Effect Level	RCR:
ED: Endocrine Disruptors	REFIT: Regulatory Fitness & Performance Programme (EU)
EEA: European Environment Agency	RM: Risk Management
ECVAM: European Centre for the Validation of Alternative Testing Methods	RoHS: Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment

EURL ECVAM: European Union Reference Laboratory for Alternatives to Animal Testing	STEL: Short term Exposure Limits
GD: Green Deal	SEAC: Socio-Economic Analysis Committee (ECHA)
IE: Industrial Emissions	SPERC: Specific Environmental Release Category
IED: Industrial Emissions Directive	STM: Surface Treatment of Metals and Plastics BREF
IIA: Inception Impact Assessment	SVHC: Substance of very High Concern
IUCLID: International Uniform Chemicals Information Database	TCC: Technical Completeness Check
LVIC: Large Volume Inorganic Chemicals	TWA: Time Weighted Average
MAF: Mixtures Assessment Factor	UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials
MB: Management Board (ECHA)	WHO: World Health Organisation