



EUROMETAUX CHEMICALS MANAGEMENT NEWS




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"Tom, this is Kate from the office. Boy, you're a hard person to reach when you're on vacation!"

REACH on the BEACH



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Dear REACH Forum member,

The summer break is here again! Sun and light are in the air, people wearing all colours of the rainbow, traffic in Brussels achieving an extra inch of recklessness (although for this one, the World Cup is a confounding factor) and serious REACH topics can be discussed over ice creams. Long live the summer!

The start of this break also sees two of my kids ending their studies, throwing their ceremony hats to the sky, making wild plans for long travels before joining the 'working community' in the autumn. Watching the flying hats of the medical students who took their oath yesterday in the centre of Brussels, I could not avoid thinking about how we -as society- are preparing our future workforce to the challenges they will have to face after this light-hearted moment. All these now "ex-students" -whatever their direction- who are on their way to become our new colleagues will need to shift from studying to learning, from an active interest to passion, from delimited periods of stress to a continuous workload, from "failure" measured by a holiday's KPI to the need to deliver to 'stay' in the race. Add to this that they will also need to grasp how to construct and maintain a balance with what they are also supposed to build at that age, i.e. the blocks of an independent, harmonious personal life.

Two years of politically-driven uncertainty about the possibility to ever practice in Belgium have taught these 1000 medical students what professional stress looks like. The EU harmonisation of studies, which reduced the 7-year Belgian cursus into a 6-year EU one has indeed resulted in a 'double cohort of medics on the market' this year. Although announced a while ago, it was never deemed enough of a priority for the Belgian politicians to anticipate it and to ensure that there would be adequate means to guarantee their education in hospitals and an access to a job after 7 years of successful studies. Demonstrating in ice cold December in front of the Brussels edifices -without receiving any attention from the authorities- was clearly a truth test for their passion but also left some doubts and fragility. The message was clear that there won't be enough space for everyone.

And still, remarkably, these students were listening carefully yesterday to the celebration speeches highlighting that intelligence can be continuously expanded with further work, that they now need to put in practice the studied matter - transforming it to learnings useful to society- that they will have to contribute to progress and access to care, respect experience and knowledge. Primum non nocere and understand more. Their response came as a boomerang: we take the world as it is today and will try to not further damage it. Primum non nocere and understand better.

A learning lesson that of course exceeds the limits of the medical school.



Violine Verougstraete, EHS director Eurometaux

ECHA REACH & CLP Activities: hot topics

ECHA Committees

RAC-45: agreed on the Environmental classification of granulated copper

The recent agreement by RAC on the environmental classification on granulated copper, an active biocidal substance, sets important precedents for the entire metal sector. For the first time it allows for a classification entry for a form with a specific particle size, calling into question the paradigm that metals can only have 2 entries (massive and powder). The environmental review for this data-rich substance was relatively well conducted by both the submitting country and the RAC rapporteur, providing recognition to the data rich nature of the substance and the metal specific classification guidance in CLP. In particular, the exclusive use of environmental toxicity data for standard species, as was suggested by France, ensures a level playing field, preventing that data-rich substances would be handled in a more precautionary way. Also to be noted, the case indicated where the dossiers for environmental classification of future copper cases can be further improved including the application of some specific data treatment methods for data-rich substances (full normalisation, SSDs, ..) (more information Stijn Baken and Hugo Waeterschoot).

RAC-45: zinc pyrithione ...a marine diatom putting a RAC seat at stake

RAC discussed several endpoints for zinc pyrithione (ZnPT), an active substance in biocidal products with a wide range of uses. The substance has no existing Annex VI. The interesting part on the environmental hazards was the discussion of the reliability of the study on the marine diatom, used by the dossier submitter to derive the acute and chronic M-factors. The draft versions of two new experimental studies (on the same marine diatom species) that were brought to the attention of RAC at a very late stage were considered, more specifically their impact on the M-factor. In this context, RAC agreed that the final study reports could be used to conclude on environmental hazards provided that they can be fitted into RAC's schedule and Eurometaux/accompanying expert were asked to confirm that the final study reports would be made available to ECHA before mid-July for a short targeted Public Consultation. RAC agreed with the Dossier Submitter's proposal to classify the substance into category 1 for STOT-RE, but that no classification was warranted for germ cell mutagenicity or fertility. The key debate however was for developmental toxicity, as industry and RAC's views differed on elements like the mechanism(s) of action and the presence of maternal toxicity. RAC concluded that there was insufficient data to conclude on a single mechanism of action of ZnPT and that the role of other possible molecular target(s) and mechanism(s) could not be ruled out. It was noted that although the effects were observed in the presence of maternal toxicity (at top doses) in several studies, the maternal toxicity was not demonstrated to be causative of the effects seen and there was no mechanistic data available to indicate specific maternally-mediated mechanisms that would imply that the developmental effects would not be relevant for humans. In conclusion, RAC agreed to classify the substance into category 1B for developmental toxicity. Due to the pending environmental studies, the dossier will be tabled for final adoption in September. The Rapporteurs will report the outcome of the Public Consultation on the environmental studies and adapt their conclusions if needed. RAC indicated that endpoints agreed at RAC 45 will not be reopened (more information: Carol Mackie and Violaine Verougstraete).

SEAC-39: finalises a restriction proposal for lead-based shot in wetlands and discusses an important first AfA Review Report on a recycling use

A discussion on lead uses was also on the table in SEAC with the review and adoption of an opinion on the Restriction on the use of lead-based shot for hunting in wetlands. SEAC reviewed the extensive comments received during the Public Consultation concluding they were either supportive to the proposed ban or not providing new evidence that would change the proportionality of the cost/benefit of the proposal. Some sources claimed that the proposal would implicate high costs and technical barriers, but evidence from countries that have been implementing the ban for years challenged this. SEAC further debated a most interesting first Review Report of an expired Application for Authorisation on the recycling case of DEHP in plastics. The update is considered of good quality. RAC already concluding that the use is adequately controlled while SEAC modelled the recycling future of DEHP in plastics concluding that a longer review period would reduce costs and impacts while increasing the benefits for society. Thereby they challenged the relevancy of the statements made by the NGO community on the need to reduce the Review Period to an absolute minimal to prevent SVHCs in the economic circle (more information: Hugo Waeterschoot).

MSC-60: important conclusions on the different steps towards authorisation for Pb and Pb compounds

MSC agreed at its last meeting in June on several subsequent steps towards the prioritisation of substances for authorisation. First, they agreed on the proposal to provide SVHC status to lead metal and octoborate, making them both appear on the Candidate List. The new SVHC status was published end of June triggering the need for suppliers of articles to provide information to recipients to ensure the safe handling and use (Art. 33 of REACH). Suppliers of Pb metal as a substance or in a mixture, including in an alloy, should also indicate the SVHC status in their SDS when they next make an update. Secondly, MSC further agreed on the next step in the process. They proposed a draft list of substances for prioritisation for authorisation including 7 lead compounds, but no cadmium nor cadmium oxide, as was expected. The relevance of this draft 9th list is to provide the Commission with an opinion on what substances to include in future Annex XIV updates directly triggering AfA needs before the LAD. The Public Consultation on the priority list will, on request of industry, only start after the summer holiday for a period of 3 months, thereby also delaying its approval by MSC and ECHA until Q1 2019. ILA and Eurometaux have already reacted during the meeting indicating a lack of proportionality and relevancy to list these substances given their major or exclusive use in stabilizers is already "on the out phase" due to a voluntary action of the sector and an imminent EU-restriction. Registrants of the Pb compounds have also been asked by ILA to update their dossiers to indicate tonnages manufactured for export only, or to deactivate their registrations where no longer required (more information: Lisa Allen and Hugo Waeterschoot).

MB-50: interesting agenda before the break

The industry input in the discussions held by the ECHA Management Board at its 20-21 June meeting was prepared by a confcall with Cefic and Concawe on 13 June. Key items on the Management Board's agenda were the Strategic Management Board's workshop scheduled for the first afternoon debating topics like the REACH/ECHA Review elements and the UK withdrawal from the EU. Also, the annual report of the chair of the Board of Appeal and the update concerning new tasks for ECHA, namely the Waste Framework Directive, Poison Centres and the Delegation agreement for a European Union Chemicals Legislation Finder (EUCLEF) were items carefully followed up by industry. With regard to the latter, industry stated

that while more alignment between legislations from the perspective of information on chemicals can be supported, it seems inappropriate to start new tasks now and especially drawing resources from other activities without clear commitment of the Commission on funding. The Management Board was also informed on the outcomes of the 3rd REACH registration deadline, as well as of the immediate tasks faced by ECHA's staff related to the high number of registrations, such as processing the number of dossiers submitted just before the deadline, as well as the publication of information and processing of confidentiality claims. As there was also a short exchange with the Forum on the enforcement priorities proposed by the Forum, industry asked for more attention to be focused on the issue of "free riders" rather than on those that complied but could further improve (more information: Hugo Waeterschoot).

Authorisation

New fee legislation: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0895&from=EN>

Regulation (EC) N° 340/2008 on the fees and charges payable to the European Chemicals Agency in the context of Authorisation was amended and published on 22 June. Main changes address the fees for a joint application: [...]2. *The Agency shall levy a base fee for any application for an authorisation of a substance, as set out in Annex VI. The base fee shall cover the application for an authorisation for one substance and one use. The Agency shall levy an additional fee, as set out in Annex VI to this Regulation, for each additional use and for each additional substance that meets the definition of a group of substances as defined in point 1.5 of Annex XI to Regulation (EC) N° 1907/2006 and that is covered by the application. No additional fee shall be levied where more than one applicant is party to the application for an authorisation. Where the applicants that are party to a joint application for an authorisation are of different sizes, the highest fee applicable to any of those applicants shall be levied for that application. Where a joint application for an authorisation is submitted, the applicants shall make every effort to share the fee in a fair, transparent and non-discriminatory manner, in particular with regard to SMEs.*[...] The Authorisation and Restriction platform agreed at its last meeting (27 June) to analyse the updated fee regulation in detail (more information: France Capon and Hugo Waeterschoot).

Others

SPERCs Workshop: moving forward on the development of Quality Criteria

On 28 May, Eurometaux hosted the SPERCs workshop co-organised with the industry's SPERCs Taskforce, ECHA and Member States. The meeting was attended by a wide representation of the various industry sectors involved in the SPERCs' development activities, the ECHA Computational Assessment & Dissemination Unit and representatives from Germany, UK and Finland. The workshop aimed at aligning the understanding on the role of SPERCs in communicating information on (environmental) safe conditions of use along the supply chain and moving forward on the development of common criteria to be used by industry and authorities to evaluate the quality of the SPERCs' factsheets and the related background documents. The discussions were not easy, due also to the heterogeneity of challenges faced by the different industry sectors. Even if some issues still require further discussions - most probably bilaterally between ECHA and certain sectors - the overall outcome of the workshop was positive and a clear plan was agreed on for the coming months. The SPERCs Taskforce is planning to develop a revised version of the quality criteria and a supporting guidance document, which are expected to be finalised in cooperation with ECHA and Member States in 2018 (more information: Frederik Verdonck and Lorenzo Zullo).

COMMISSION REACH & CLP Activities: hot topics/issues

CARACAL

CARACAL-27: more work needed on TiO₂ and cobalt before taking final decision on the classification proposals

The CLP session of the 27th CARACAL meeting was organised in Brussels on 12 June. Besides the guidance on classification of metals in massive form (see more details below), the discussions on TiO₂ and Co classification were of particular importance for the metal sectors. CARACAL supported the proposal to take some time to reflect on the appropriateness of the methodology used to derive the Specific Concentration Limit for cobalt metal ("T₂₅ approach"). Questions on the applicability of the approach -initially based on a database of organic substances generating cancer via the oral route- were triggered among others by the implications of the low SCL for a number of activities, including recycling. It was therefore suggested to proceed temporarily with the 0.1% GCL and to set up an expert group to reflect on the methodology. The final decision on this proposal is expected to be taken at REACH Committee level in September as the REACH Committee only discussed the new ATP but did not vote. The discussion on TiO₂ was related to the possibility to assign a carcinogenic classification based on effects that appear to be more related to the physical form than to the intrinsic properties of the TiO₂. In addition to Commission's proposal for an Annex VI entry, UK and Slovenia presented a joint paper suggesting establishing a working group to take the discussions forward to identify the most appropriate regulatory measure. CARACAL expressed its views on

the two proposals and it seems that a majority has been asking for more time for additional discussions. Member States continued to express concerns at the 13 July REACH Committee. Here as well the decision will be taken in September. Important to realise is that the overall regulatory context around TiO₂ triggers national initiatives: for example, the French government is reported to be intending to ban the use of TiO₂ as a food additive (E171) by the end of the year, because there remain “serious doubts” on the health risks associated with its consumption. On the other hand, in Germany, the Scientific Service of the German Bundestag published a document highlighting that health risks are most likely to be expected from the inhalation intake in spray applications, that the risk of absorption via the skin - for example by using nanomaterial-containing sunscreen - for the healthy skin is considered low and reiterated the EFSA conclusion in their 2016 re-evaluation that there are no indications of health concerns for consumers from dietary intake (as E171). For information, the next CARACAL meeting will be held in November 2018 and minutes will be circulated soon (more information: Lorenzo Zullo).

CARACAL -27: REACH Review implementation and official announcement of MISA

The REACH part of the 27th CARACAL meeting was organised in Brussels on 27 June. One of the main topics on the agenda was the implementation and next steps of the REACH Review. Member States and stakeholders had the opportunity to express their views on proposals for actions presented by the European Commission covering: “update of the registration dossiers”, “substitution of SVHCs”, “simplification of the Authorisation process”, “improvement of the restriction procedure” and “application of the precautionary principle”. Eurometaux requested for more clarity on requirements for dossier updates stressing the need to also take into consideration the experience accumulated by industry. Eurometaux reiterated the need to follow a more holistic and risk-driven approach for restrictions. On Authorisation topics, Eurometaux confirmed its intention to organise a dedicated workshop on substitution (7 November) and promoted the possibility to use a “hybrid” approach for Applications for Authorisation (AfAs) as contributing to the “simplification” and efficiency of the process. Eurometaux will submit comments in follow-up. One topic on the agenda was dedicated to the Metals and Inorganics Sectorial Approach (MISA). The joint industry/authorities’ initiative was officially announced by ECHA. Positive comments on the expected improvement of the quality of the registration dossier were expressed by the participants, even if on some of the priorities addressed by MISA, some countries seem to still have a long learning process to cover on metals assessments, further highlighting the need for MISA. ECHA addressed the comments, stressing the importance for Member States to participate. The next CARACAL meeting will be held in November 2018 and the minutes of these June CARACAL meeting will be circulated soon (more information: Lorenzo Zullo).

CLP: Eurometaux’s draft note on exemption of labelling for massive forms forwarded to CARACAL

Eurometaux submitted to CARACAL a first draft note aiming at clarifying when the labelling for a massive metal, alloy or matrix type metal mixture can be waived. This follows a request from CARACAL last year, which considered that in the absence of guidance, the conditions in which there is an exemption on labeling for a substance classified as hazardous are unclear. The note is based on the principle that massive physical forms may prevent exposure from happening in conditions of reasonable expected use, therefore making a hazard label non-appropriate. The proposal covers both endpoints (human health and environment) and was forwarded early June to the Commission and CARACAL. The Commission reacted positively whilst at CARACAL, besides raising questions for further clarification, several countries showed interest to contribute to the refinement of the proposal. Eurometaux will collect the comments from Member States over the summer and prepare an amended draft for discussion at a webinar meeting with them after the summer break (more information Lorenzo Zullo and Hugo Waeterschoot).

Other

Commission Workshop 2nd REACH Review: communication event pointing towards issues to monitor

Commission held a Conference on 11 June to discuss the outcome and actions of the second REACH Review. Eurometaux was invited to contribute to the Panel on Enforcement and Coherence. The conference was very well attended and detailed notes were circulated to the REACH Forum on 13 June. Overall the audience agreed that REACH works well, with clear added value when it comes to data and knowledge and protection of health and environment. The Commission Staff Working Document issued in March is believed to be a fair reflection of the state-of-play and challenges ahead, however, several stakeholders asked for a more detailed and concrete workplan. The interventions made during the day allowed to identify a number of items to follow up, like the quality of the dossiers and the need to ensure compliance, the necessity to find incentives for updates, the simplification of the authorisation process and the need to have a level playing field by having efficient restrictions for Annex XIV substances that could enter the EU market via the articles’ route as well as the need for enhanced enforcement (more information: Pablo Rodriguez Dominguez, Marco Vallini and Violaine Verougstraete).

EUROMETAUX REACH & CLP Activities: hot topics/issues

Resource mapping to respond to REACH / ECHA challenges

EHS & REACH Steering Committee Meeting 21.06: *post-2018, and update on issues of strategic importance/information with possible impact on the sector/companies*

The Steering Committee was updated on the status of the discussions on the post-2018 EHS & REACH structure and the related financing, including the comments raised by the Eurometaux Executive and Management committees. The ensuing discussions allowed to refine the proposal to be made to the REACH Forum on 28 June. The Industrial Emissions Taskforce invited the EHS members to participate on the BREFs prioritisation survey to identify the interests in industrial emissions and facilitate the taskforce's work. Updates were provided on the EU Ambient Air Quality Directives' consultation and the REFIT of the water legislation. An intense discussion took place as well on the European Environment Agency's briefing on reduction of metal environmental pressure and the next actions to carry out in this context (e.g. comment on the use of the USETOX model). The discussions on the links between Circular Economy and chemicals management, impurities and status of waste activities highlighted again the need to have enough resources and multiple expertise in the sector to deal with the interface aspects. The Eurometaux secretariat from the Sustainability and EHS/REACH departments will further elaborate on the needs and possible ways forward over the summer. Finally, a number of REACH and CLP topics were evoked but rather from a resources and impacts on the sector point of view (more information: Violaine Verougstraete).

Authorisation & Restriction Platform meeting 27.06: *well attended meeting focussed on the authorisation steps of Pb and the challenge the Risk Management of Substances in Substances may pose*

The consequences of the agreement of MSC on the listing of lead-metal as an SVHC and the prioritisation of the 7 new Pb-compounds as well as the potential inclusion of 4 Pb-compounds used in batteries on Annex XIV were debated in a specific session during the A&R platform. The meeting recognised the precedent setting nature of the lead case and agreed on a common view on the overall pillars of the advocacy strategy as presented by ILA, but suggested some balance in respect to the order and scope. The meeting agreed to promote the non-proportionality of the inclusion in Annex XIV and if listed suggested pleading for a broad recognition of Article 58 (2) exemption as a Risk Management Measure (RMM) alternative, while in parallel the grouping of the 4 compounds with Pb-metal should be waited for. The second main debated item focussed on the challenge the Substances in Substances (SIS) RMM policy suggested in a CARACAL letter which could result in every non-intermediate use of a UVCB, mixture or substance, including an Annex XIV impurity or minor constituent, requiring future authorisation. A legal investigation was granted to REACHLaw for delivery by the end of the summer in preparation of a specific workshop on the theme on 18 September. Most Consortia confirmed the relevance of the SIS challenge for them, being it as manufacturer or as collateral damage as an impurity or minor constituent, providing a large support base for the projects. Finally, the A&R platform dedicated specific themes to its upcoming meetings (18 September on the Impurities issue and 17 December on the RMOa update and Materials Flow Assessment) (more information: France Capon and Hugo Waeterschoot).

REACH Forum meeting 28.06: *entering post-2018*

The REACH Forum meeting held on 28 June was particularly important since it marked the transition to the post-2018 REACH phase. New challenges ahead are mostly related to reaching the 2020 SAICM goals (REACH Review, mapping of the Chemical Universe) and/or the UN Sustainable Development goals of 2030 (risk management of substances of concern to minimise adverse effects). There is also a widening of the scope of chemicals management towards Circular Economy, requiring the gaps between waste, chemicals and articles to be addressed and resulting in increased attention for closing the loop but also for impurities and minor constituents in material flows. From now on, more than ever before, attention will need to be dedicated to completeness checks and appropriate risk management. To better adapt to this new phase, a proposal for modernising and simplifying Eurometaux's organisation was proposed and considered to be generally acceptable. Further contacts between the Eurometaux secretariat and the consortia will take place over the coming month. Progress was also made on the Metals and Inorganics Sectorial Approach (MISA) which is now ready to be kicked-off with the formalisation of the commitment and the organisation of the first workshop on "information requirements, weight-of-evidence and read-across" to be held in October. Among other topics, the REACH Review implementation was also discussed with focus on the actions currently under discussion between authorities (also see above). The six platforms that are linked to the REACH Forum provided an overview of the ongoing activities; this was a great opportunity to get a full picture of many chemical-related activities ongoing within Eurometaux. This meeting was an opportunity to learn from the experience developed on three classification dossiers (i.e. cobalt, copper granulate and lead) via targeted interviews conducted prior to the meeting. The next REACH Forum will be held on 19 September 2018 (more information: Lorenzo Zullo).

UVCB: summary of this year's highlights

On June 25th, a conference call was held with the taskforce to summarise this year's highlights. The year started with a lot of work devoted to the UVCB Dossiers updates: since January, consortia have started updates' submission and occasionally encountered technical failures linked to the IUCLID 6 specific UVCB formatting. To facilitate the exchange with the regulators and clarify the link between the IUCLID reporting and the UVCB assessment strategy, Eurometaux has contacted ECHA to discuss such failures and is now waiting for feedback. On the SID aspects, two positive feedbacks were shared with the taskforce: (1) the Inorganic Pigments Consortium reported the successful conclusion of their discussions on substance identification with ECHA, which led to the publication of a guidance document on the ECHA sector-specific webpage (<https://echa.europa.eu/support/substance-identification/sector-specific-support-for-substance-identification/complex-inorganic-pigments>) covering naming and SID reporting; (2) a couple of UVCBs inquiries were successfully submitted over the last months and good practices were shared with the taskforce to ensure that legal entities can provide complete reporting of SID information. Overall, dossier updates are continuing in 2018, while the UVCB assessment strategy and reporting will be crystallised in a complete Draft Guidance document (i.e. from identification, risk assessment and reporting), that will be submitted to ECHA and Member States by end of 2018 in the context of MISA. In parallel, due to the increasing interest of authorities in existing UVCB sectorial assessment methodologies, the inorganic UVCB Risk Assessment methodology will also be further discussed with the RIVM after the summer, to explain and exchange on the specific inorganic UVCB approach and thus allow Member States and ECHA to comment on the Draft Guidance (more information Federica Iaccino).

Authorisation

Cadmium REACH consortium meeting: preparing in due time

The Cadmium REACH Consortium and Eurometaux organised a workshop to take stock of the status of the 9th priority list and anticipate possible further activities related to the potential nomination of cadmium compounds. The participants discussed the uses documented in the registration files for these compounds and got an update on the ongoing discussion at authorities' level on Substance in Substances, as the latter may target "non-aimed uses" of cadmium present as impurity in materials. In a second session, updates were provided on regulatory topics like the AfA procedure and the relation with other Risk Management Measures like Restriction or OELs. Finally, the group reflected on organisational aspects, so as to be better prepared with regard to resources and ways forward (more information: Christian Canoo and Hugo Waeterschoot).

Classification

Cobalt CLH call: before and after CARACAL and the REACH Committee

Two calls were organised before and after the CARACAL and REACH Committee meetings (12-13 June) to update the Cobalt CLH Taskforce on the technical aspects associated to a possible mitigation of the classification and SCL as proposed by RAC (i.e. review of the current CLP methodology) and the advocacy actions needed to support those. The calls also allowed to finalise the overview of the SEA impacts and to start a discussion on possible arguments on a split concentration limit for massive and powder forms. Although the discussions at CARACAL and in the REACH Committee were rather positive, resulting in the proposal to set up an Expert Group to work on the potency methodology and to include for now the GCL instead of the SCL in the ATP, further advocacy is needed to ensure the REACH Committee in September supports it with a vote. Advocacy material for meetings with Member States, the Enterprise Policy Group, and the WTO consultation is available or will soon become available on the Dropbox maintained by the CI/CoRC. A report on downstream legislation/derogations will be shared soon as well. The next call is scheduled for 23 July 15:00 (more information: Brigitte Amoruso, Ruth Danzeisen, Jenny Poulter, Hugo Waeterschoot and Violaine Verougstraete).

Nanos

Nanos: a Topsy-Turvy World

After the voting on the REACH Annexes Amendments of the Nanomaterials documents Eurometaux still identified some major problematic parts with which the new regulations for registration will face enforcement difficulties. At the CARACAL meeting it was confirmed that e.g. the tonnage to be considered is the overall tonnage of the substance and not of the nano-part. This means that any amount of Nanos appearing with the production of a substance causes the need to comply with the Nanomaterials Annexes. Additionally, it was announced that the planned consultation for a future review of the definition recommendation is planned over the summer but will last 14 weeks. However, any changes due to a review won't impact the current REACH Annexes – the opportunity of a horizontal definition of Nanos for all (specific) regulations has been missed by the Commission. During the last REACH Forum meeting on 28 June it became clear that any support which can be given should be shared now, since Eurometaux is preparing to attain a shared statement paper with other industry associations.

The definite statement and following actions are discussed within the dedicated Nanos Taskforce (more information: Nathalie Kinga Kowalski).

Metal-specific REACH application tools and concepts

Bioelution: *first response from ECVAM and workshop on the use of a bioelution correction for complex materials*

In follow-up of the submission made by the sector in February on the gastric bioelution protocol, ECVAM sent a list of questions they would like to have clarifications on before proceeding further with the validation. The questions can broadly be divided in three categories: editorial ones, questions related to the specifications of the protocol and more complex ones that will require discussion with the different metals as they relate to the use of e.g. epoxy samples and the selection of reference materials. A small group of 'volunteers' will take the lead in preparing responses to these questions and circulate the draft for a quick review to the Bioelution Taskforce. Also an industry workshop will be held on 10 August at the MCC to further agree on how to use the bioelution results for complex materials like slags and align on the communication to be done in the SDS for alloys (more information: Adriana Oller, Kate Heim and Violaine Verougstraete).

HeTAP workshop on 12 June: *Metals & Minerals Carcinogenicity: Identifying Mode of Action Based Thresholds*

The aim of the workshop was to map the current science on the genotoxicity of metals, in particular the evidence needed to identify the mode-of-action based threshold (or the non-threshold) of a carcinogen. The audience included academics, authorities and industry experts. The workshop started with a scene-setting presentation, also briefly recalling the regulatory background for these discussions (e.g. the work done by the Joint RAC/SCOEL Taskforce on the threshold issue) and a keynote speech on "Developing an Integrated Approach to Testing and Assessment (IATA) for non-genotoxic carcinogenic chemical substances at the OECD". Four case studies for Ni, Cd, Co and Sb were presented subsequently and debated. In the afternoon, a think tank session was held to respond to specific questions and address recommendations for next steps. A report including the generic learning lessons will be prepared over the summer (more information: HeTAP group).

REACH Metals Gateway: *up and running*

We are happy to announce that our new REACH Metals Gateway website is now online: <https://www.reach-metals.eu/>. An e-mail was sent to the REACH Forum on Friday 29 June with instructions on how to access the members' area. The calendar page (accessible to REACH Forum members) has been created with all REACH related meetings & documents as from January 2018. For the past meetings all the meeting documents have been uploaded and for future meetings you will find the agendas and other documents (which will be regularly updated as soon as they become available). Following numerous requests so as to better prevent overlapping meetings in the future, we plan to add the dates of other consortia meetings in the calendar when we receive them. And last but not least ☺, there will also be a direct link to access the Chemicals Management News <https://www.reach-metals.eu/reach/chemicals-management-news-2>. Please do not forget that after logging in, all documents available should be treated as confidential (more information: Sofiana Dokou).

Metals and Inorganics Sectorial Approach

Framework for Cooperation: *a formal MISA framework agreement with the European Chemicals Agency*

On 28 June, Eurometaux and ECHA signed a Joint Statement on the Metals and Inorganics Sectorial Approach (MISA). This milestone event formalises the cooperation to work together with ECHA to help improve assessments on metals and inorganics as well as furthering the standards of chemicals management. MISA has the aim to i) improve the completeness and quality of the REACH dossiers/information; ii) help solving outstanding technical challenges for the metals/inorganics sector; iii) allow capacity-building, collective debates and guidance methods for metals/inorganics in an organised and planned way (through thematic workshops). It has been elaborated in the context of ECHA's Integrated Regulatory Strategy and is in line with the 2020 Strategic Approach to International Chemicals Management (SAICM). The signing of this agreement will provide a framework for metals and inorganics consortia to engage in the MISA programme by signing the Framework for Cooperation and the related action plan, thus committing to engage the necessary resources to support and review MISA's activities for the period 2018-2020 (more information: Ailsa Lee, Hugo Waeterschoot and Violaine Verougstraete).

MISA SAT-HH: *the first Self-Assessment Template developed and circulated for comments*

Several workshops will be organised under the MISA programme to progress on the outstanding technical themes while in parallel facilitating the further improvement of the registration files where relevant. Selective themes were agreed upon between industry and ECHA providing priority on the information gap filling, adaptations of data requirements and read-across for the Mutagenicity, Repeated dose and Repro-/developmental endpoints as well as long-term environmental toxicity. The REACH Forum agreed previously to promote self-assessment to ensure the Consortia are well prepared to discuss this theme with ECHA on the first workshops scheduled for 2 October (Human Health) and 7 February (Environment). A small

group of volunteers drafted a first Self-Assessment Template for these Human Health endpoints (SAT-HH), which was provided to the REACH Forum attendees during the 28 June meeting. Comments can be forwarded in return and Consortia are very much stimulated to use the self-assessment questionnaire in an active way to define their potential outstanding challenges on these endpoints and define the questions to pose to ECHA. Consortia are invited to provide Eurometaux with a summary of their experiences with the SAT-HH by 25 August, so as to allow Eurometaux to prepare the first workshop with ECHA in a specific meeting to be held on 30-31 August (more information: Koen Oorts, Violaine Verougstraete, Jelle Mertens or Hugo Waeterschoot).

Pb REACH consortium general assembly meeting: *MISA in a risk-controlled environment*

Eurometaux was kindly invited to the General Assembly of the Lead REACH Consortium on 20 June to present the Metals and Inorganics Sectorial Approach, and in particular the opportunities MISA may offer in the current regulatory context. This cooperation with ECHA will provide forums for exchanges with authorities and allow for increasing awareness/understanding of metal-specificities and existing metals knowledge. These activities will help the sector to further promote its vision of a risk-controlled environment rather than one primarily driven by hazard and the need to have 'non-toxic materials cycles' (more information: Violaine Verougstraete).

FURTHER OUTREACH OF REACH

ISES: *first Workshop of the European branch of the International Society of Exposure Science held on 19/20 June in Dortmund*

ICdA, EBRC and Eurometaux participated in this first workshop that aimed at kicking off the community building activity for a long-term exposure science strategy in Europe, starting a solution-oriented dialogue among stakeholders across sectors and identifying key questions, issues and needs for EU exposure science. A number of actions were agreed upon during these two days: like the establishment of working groups focusing on projects addressing the priority needs for exposure science, establishing an ISES-Europe website that will serve as an initial platform for the exposure science community, building a community of practice and establishing an ISES-Europe advisory board and reaching out to and aligning with the needs of existing societies, organisations, authorities and industry where exposure science is relevant. The workshop outcomes will be published in an Exposure Science Strategy report/paper. The workshop was also the opportunity to present posters on MEASE 2.0 and on Cd (bio)monitoring, recalling the importance of the latter to consider the different routes of exposure and ensure an appropriate follow-up of the workers (more information: Noömi Lombaert, Mik Gilles, Daniel Vetter and Violaine Verougstraete).

COMMUNICATION

OECD

Working Party on Hazard Assessment: *Paris 26-27 June*

The Working Party had as usual an agenda covering a range of topics, from IT tools and platforms (e.g. ecChemportal or OHT) to the development of approaches like on the risk assessment of combined exposures to multiple chemicals or Integrated Approaches to Testing and Assessment (IATA). The participants also got an update on a document addressing Guiding Principles for Establishing Weight of Evidence for Chemical Assessment that will be circulated for review in Q3 2017. A collaboration on aspects of Occupational Exposure in terms of Establishing Workplace Exposure Limits is currently envisaged and Canada will draft a proposal for consideration by the taskforce. Participating countries were also keen to further exchange on the topic of prioritisation (best practices, frameworks etc.). Finally, several meetings were announced like the one that will discuss in September possible case studies to include in a guidance document on the characterisation, validation and reporting of physiologically based models for regulatory applications. Detailed notes are available on request (more information: Violaine Verougstraete).

Others

Helsinki Chemicals Forum:

On 25 June, Geert Dancet (former Executive Director of ECHA) came to Eurometaux to meet representatives from IMA, Eurofer and Eurometaux and discuss how to make the Helsinki Chemicals Forum (HCF) more attractive for inorganics. He

recalled that the Helsinki Chemicals Forum is an annual governmental non-commercial event, whose success confirms Helsinki as a centre of excellence on Chemicals Management. Geert Dancet has now taken over the function of Secretary General. The objectives and roles of the HCF include among others promoting International Chemicals Management, providing conclusions on selective themes for regulatory fora and having a network function. Up to now most of the industry participants are from the organics sectors and the HCF would like to increase the inorganics's interest. The sectors asked for more recognition for inorganic themes in the programme (e.g. Chemicals Management and Circular Economy) and the response was a proposal from the HCF to have an inorganics' representative in some of the organization bodies of this event. The next HCF is scheduled back-to-back with SETAC in May 2019, in Helsinki (more information: Guy Thiran, Hugo Waeterschoot and Violaine Verougstraete).

CALENDAR

New

- **10 August: Bioelution Workshop: how to use the bioelution results for complex materials? – MCC (Brussels)**
- **10-14 September: RAC-46 – ECHA (Helsinki)**
- **10-14 September: SEAC-40 – ECHA (Helsinki)**
- **12-13 September: Scientific Workshop on Grouping of Nanomaterials - NanoReg2/ Gracious – OECD (Paris)**
- **18 September: Authorisation & Restriction Platform (Impurities issues) – MCC (Brussels)**
- **19 September: REACH Forum – MCC (Brussels)**
- **27-28 September: Management Board-51 – ECHA (Helsinki)**
- **8-12 October: MSC-61 – ECHA (Helsinki)**
- **16 October: Nanos Taskforce – MCC (Brussels)**
- **17 October: Evaluation Platform – MCC (Brussels)**
- **28 October-31 October: RAC-47 – ECHA (Helsinki)**
- **6-7 November: NMEG12 – ECHA (Helsinki)**
- **7-8 November: NeRSAP/Substitution Workshop – UA (Antwerp)**
- **8-9 November: WS Implementation REACH Info Requirements for Nanomaterials – ECHA (Helsinki)**
- **19-23 November: RAC-48 (A)– ECHA (Helsinki)**
- **26-30 November: RAC-48 (B)– ECHA (Helsinki)**
- **26-30 November: SEAC-41 – ECHA (Helsinki)**
- **10-14 December: MSC-62 – ECHA (Helsinki)**
- **13-14 December: ECHA Management Board-52 – ECHA (Helsinki)**
- **17 December: Authorisation & Restriction Platform (RMOa update/MFA) – MCC (Brussels)**
- **18 December: REACH Forum - MCC (Brussels)**

ACRONYMS

AfA: Application for Authorisation	OEL: Occupational Exposure Limit
ATP: Adaptation to Technical Progress	OHT: OECD Harmonised Template
BREF: Best available technology Reference document	PSLT: Poorly-Soluble Low Toxicity
CARACAL: Competent Authorities for REACH and CLP	RAC: Risk Assessment Committee
CLH: Harmonised Classification and Labelling process	REFIT: Regulatory Fitness & Performance Programme (EU)
CLP: Classification, Labelling and Packaging Regulation	RIVM: National Institute of Public Health and the Environment (The Netherlands)
DEHP: Di(2-ethylhexyl) phthalate	RMM: Risk Management Measures
ECVAM: European Centre for the Validation of Alternative Testing Methods	RMOa: Risk Management Option analysis
EUCLEF: European Chemicals Legislation Finder (Study)	SAICM: Strategic Approach to International Chemicals Management
GCL: Generic Concentration Limit	SAT-HH: Self-Assessment Template - Human Health endpoints
HCF: Helsinki Chemicals Forum	SCL: Specific Concentration Limit
IATA: Integrated Approaches to Testing and Assessment	SDS: Safety Data Sheet
ISES: International Society of Exposure Science	SCOEL: Scientific Committee on Occupational Exposure Limits

IUCLID: International Uniform Chemicals Information Database	SDS: Safety Data Sheet
LAD: Latest Application Date	SEA: Socio-Economic Assessment/Analysis
MB: Management Board	SEAC: Socio-Economic Analysis Committee (ECHA)
MEASE: Occupational Exposure Assessment Tool for REACH	SETAC: Society of Environmental Toxicology and Chemistry
MFA: Mass Flow Analysis	SID: Substance Identity
MISA: Metals & Inorganics Sectorial Approach	SIS: Substances In Substances
MSC: Member States Committee (ECHA)	SPERC: Specific Environmental Release Category
MISA: Metals and Inorganics Sectorial Approach	SSD: Species-Sensitive Distribution
MSC: Member State Committee	SVHC: Substance of very High Concern
NGO: Non-Governmental Organisation	USETOX: The UNEP-SETAC toxicity model
OECD: Organisation of Economic Cooperation and Development	UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials

ERRATUM from the May version - with our apologies

ECHA Workshop on COLLA: *the antimony case and useful learnings for MISA*

ECHA organised on 7-8 May a workshop to assess and evaluate the learnings from the Collaborative Approach (COLLA). In essence, this project aimed at assessing grouping strategies and modalities of interaction between Member States and industry, with the ultimate aim to improve the relevance and speed of evaluation exercises. One of the pilot cases that was assessed focused on antimony compounds. The overall learnings were positive, at least with regard to the interaction between Member States and industry and the gains in efficiency and relevance by applying discussed grouping strategies. On the other hand, Member States issued critiques about ECHA's role and the heavy administrative oversight. **The 2 substances added to CoRAP are part of iza's scope of work. Hence the outcome of the COLLA for antimony was that in addition to the 3 already listed antimony 3+ substances, 2 more antimony 3+ compounds were added to CoRAP too, to enable a formalised parallel/group evaluation of all antimony 3+ REACH registered mono-constituent/non UVCB/non-intermediate antimony substances. Antimony 5+ substances may be next in line for CoRAP after the initial antimony 3+ group has been evaluated (more information: Caroline Braibant and Hugo Waeterschoot).**

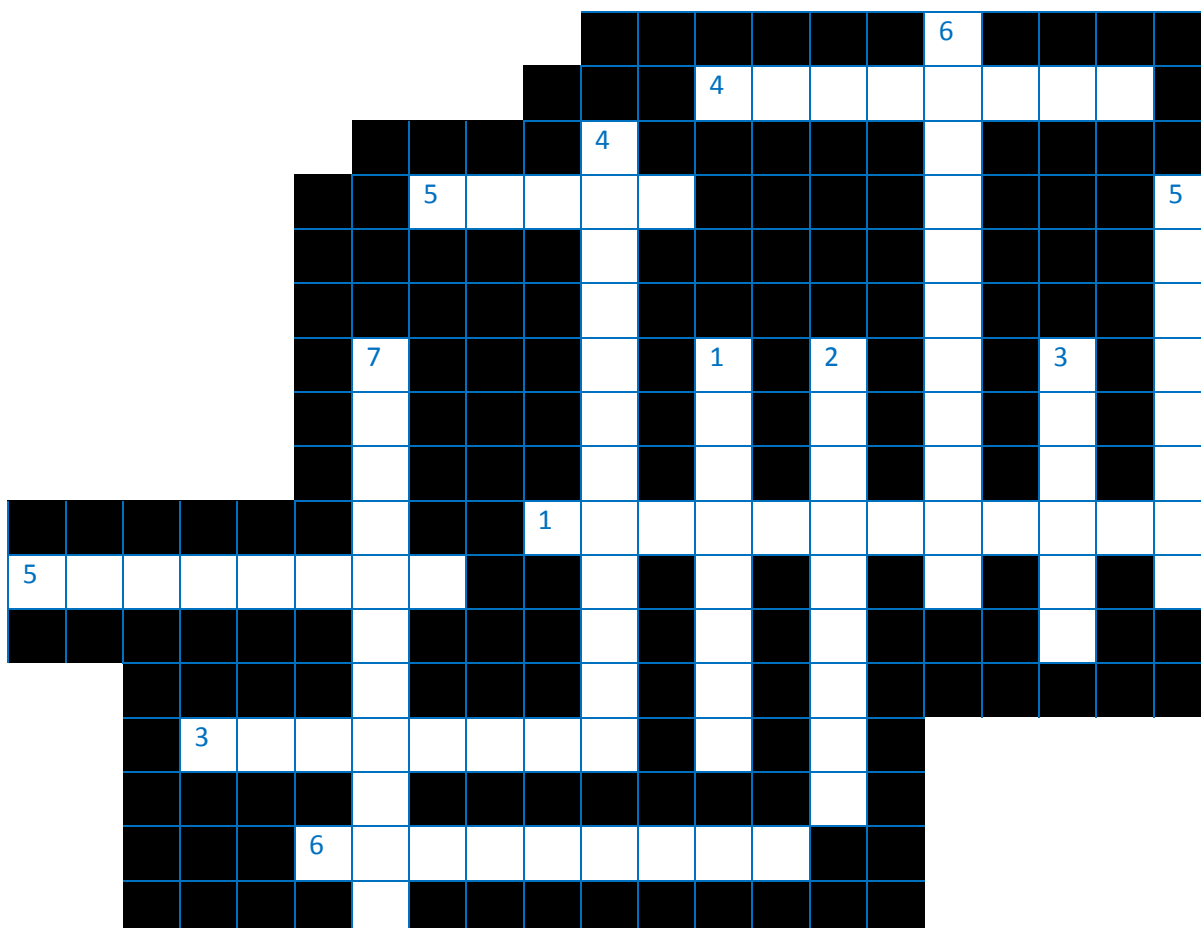
MISA CROSSWORD

Across

1. Submission of documentation which shows that the substance you deal with is handled safely throughout the supply chain
2. A solid material which is typically hard, shiny, malleable, fusible, and ductile
3. A distinct compound or substance, especially one which has been artificially prepared or purified
4. Speak to (someone) for the first time about a proposal or request
5. The state of having no protection from something harmful
6. Relating to or denoting compounds which are not organic

Down

1. The quality of being toxic or poisonous
2. Of or like a sector
3. A formal assessment of something with the intention of instituting change if necessary
4. Material having particles or constituents of nanoscale dimensions
5. A thing that is composed of two or more separate elements
6. A plan which is designed to continue over a period of time and is subject to regular review and updating (2 words)
7. The surroundings or conditions in which a person, animal, or plant lives or operates



TEST YOUR KNOWLEDGE

1. What is a Bordeaux-mixture?
 - a. a mixture of different types of Bordeaux wine
 - b. a mixture of calcium sulfate and copper hydroxide (to combat certain fungi in vine-growing)
 - c. the various populations immigrating to Bordeaux
2. What other metals come into the composition of lead-shot?
 - a. Antimony & Arsenic
 - b. Arsenic & Germanium
 - c. Antimony & Tellurium
3. Which God endowed Midas, King of the Phrygians, with the power of turning everything he touched into Gold?
 - a. Vulcain
 - b. Dionysos (God of the grape harvest, winemaking and wine, of ritual madness, fertility, theatre and religious ecstasy in ancient Greek religion and myth)
 - c. Helios
4. When did Nickel begin to arouse real interest in Europe?
 - a. 1700s
 - b. 1600s
 - c. 1800s (a Ni-Cu-Zn alloy was introduced in Europe in 1700, but real interest started in 1833 in the UK and more so from 1881 when Switzerland followed by the US used a Ni-Cu alloy for its coins)
5. What is Gangue?
 - a. All the worthless elements that are present in an ore
 - b. A process in which recoverable elements are floated in a dense liquor
 - c. An agglomeration of dusts achieved by mixing them with water

TEST YOUR KNOWLEDGE: 1: b (to combat certain fungi in vine-growing) – 2: a – 3: b (God of the grape harvest, winemaking and wine, of ritual madness, fertility, theatre and religious ecstasy in ancient Greek religion and myth) – 4: c (a Ni-Cu-Zn alloy was introduced in Europe in 1700, but real interest started in 1833 in the UK and more so from 1881 when Switzerland followed by the US used a Ni-Cu alloy for its coins)

MISA CROSSWORD
Across: 1. Registration / 2. Metal / 3. Chemical / 4. Approach / 5. Exposure / 6. Inorganic
Down: 1. Toxicity / 2. Sectorial / 3. Review / 4. Nanomaterial / 5. Compound / 6. Rolling plan / 7. Environment