Eurometaux
European Association of Metals

N°69 – September 2017

EUROMETAUX CHEMICALS MANAGEMENT NEWS



SPERCs Workshop - 20 October 2017

To register: please send an e-mail to: EHSAssistant@eurometaux.be

TABLE OF CONTENTS

ECHA REACH & CLP Activities: hot topics 3
ECHA Committees 3
Authorisation 4
UVCBs 4
Others 5
COMMISSION REACH & CLP Activities: hot topics/issues 5
DCG 5
Non Toxic Environment 5
EUROMETAUX REACH & CLP Activities: hot topics/issues 6
Resource mapping to respond to REACH / ECHA challenges 6
Nanos 8
Metal-specific REACH application tools and concepts 8
Metals and Inorganics Sectorial Approach 9
CALENDAR 9
ACRONYMS 10

© Eurometaux – All rights reserved

Dear REACH Forum and EHS members,

You have most probably noticed the change in name of your monthly favourite the REACH News. From now on, it will indeed be titled "Chemicals Management News" and not only be sent out to the REACH Forum members but also to the Eurometaux "EHS-ers". An easy way to increase the audience and achieve Pulitzer glory? Not really (not only ☺) : this change actually fits in very well with the surrounding regulatory world, where Circular Economy, the Non-Toxic Environment and all possible interface-related studies compel different parts of our knowledge, staff and daily activities to meet and function together.
We have always known -and claimed- that "silo working" has its limitations, however it is hard to deny that it is a rather convenient –even on a temporary basis –way to avoid the complexity and the uncertainty of some issues or actions. Isn't it easier to keep one's focus on two balls in the air (e.g. REACH registration and compliance) than having to juggle with multiple ones, moving in different dimensions and directions?
That's however what the autumn and winter trends look like in Regulation world: an explosion of layers and colours, with various shades emerging from all corners of the lifecycle, under the REFIT motto! Patchworks of data coming from different EHS pieces and concepts, each with their followers defying one another, different interpretations of risk flying around, all taking part in the ballet of the weight-of-evidence.
It may take some time for the authorities to follow the fashionista, by e.g. checking automatically whether taking a decision in the REACH cosmos would pre-empt sustainability or recovery in another part of the complex picture. They may even be tempted to only pull one strand of the wool skein (e.g. hazard) to motivate their expert judgment.
But industry has to know more and do better… By not hesitating to step in the multifaceted environment, by being keen to learn more and differently, by leaving details in the silo in order to perceive the holistic image and delineating the answers before the questions are posed and shortcuts are taken.
The sectorial approach, the risk-controlled environment as alternative to the Non-Toxic one are all efforts in that direction, to adapt to the autumn "tendance"; including this Chemicals Management News.
Please continue to let us know if it fulfils your expectations.

"Nothing in life is to be feared. It is only to be understood." (M. Curie)



Violaine Verougstraete, EHS director Eurometaux

© Eurometaux – All rights reserved

ECHA REACH & CLP Activities: hot topics

ECHA Committees

RAC-42: *a heavy meeting for the metals*

RAC agreed to the proposal from the Netherlands to classify cobalt metal for carcinogenicity as Carcinogen cat 1B H350 (all routes) with a specific concentration limit of 0.01 %), for mutagenicity (Mutagenicity Cat 2) and for toxicity to reproduction with regard to effects on sexual function and fertility (Repro cat. 1B). The final RAC opinion on titanium dioxide, concluding that it should be classified as a suspected human carcinogen Carcinogenicity cat 2; H350 (inhalation) was adopted in written procedure before RAC 42. Still on classification, the RAC experts voted against read-across and classification for acute toxicity inhalation for Ni sulfide and Ni sulfamate, CLH proposals submitted by industry. RAC considered the read across based on bioelution test data as too weak and not justifying the classification. Several comments had been made by Germany during the Public Consultation on the use of bioelution and the lack of standardised protocol. All these opinions will be available on ECHA's website in the coming weeks. The timing for the first discussion on granulated copper was confirmed (March 2018).
RAC also agreed on four draft opinions on specific uses of chromium (VI) substances and 1,2-dichloroethane (EDC) under the authorisation procedure. The draft opinions have now been sent to the applicants for comments before final adoption.
RAC also had a first discussion on 3 substances for which Commission requested RAC to provide support, by developing OELs in view of the 4th amendment of the Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (CMD). RAC's work is to evaluate the information already available in relevant international and national reviews as well as to assess the most recent scientific information, providing opinions in each case. The dossiers on nickel and compounds, benzene and acrylonitrile were prepared by ECHA over the summer. The discussion at RAC on nickel and compounds, attended by Adriana Oller as Eurometaux's accompanying expert, focused mostly around the mode of action considerations and the need to have quantitative dose-response data on these effects. The Nickel Institute/Nipera's engagement with ECHA earlier this year secured that industry's scientific input was considered. A four-week public consultation will begin on 9 October. The. Nickel Institute will be providing comments. Two further RAC discussions are scheduled (November 2017 and March 2018) to allow RAC to finalise the opinion that needs to be sent to the Commission end of March 2018 ((more information: Adriana Oller, Mike Taylor, Ruth Danzeisen and Violaine Verougstraete).

SEAC-36 (September 11-14): *heavily focussed on restrictions, all with an interest of the metals sector*

SEAC discussed 3 restriction cases, 2 of them on metals (Pb). The remaining restriction case on diisocyanates (a widely used respiratory sensitiser in the polymer industry) is most interesting for the metals sector given investigating a new risk management approach whereby the supplier would be involved and co-responsible for a strict training scheme aiming to improve the handling conditions and exposure levels by users as far as possible. This new concept is promising but also probably very demanding and difficult to organise/assure, and therefore most relevant to follow in terms of potential relevance for the metals sector. The first of the 2 Pb restriction cases concerns the restriction of Pb stabilisers in plastics to limit imports given the voluntary phasing-out by the EU manufacturers. This case is most relevant for metals given it recognises the need for a specific treatment of recycling streams. Additionally, it overrules the generic problem of the cost benefits' assessment for Pb, namely that incremental IQ deficiencies have large impacts due to the non-threshold effect assumption and the multiplication of the small effect with the large number of children in the EU. The proposal applies a different benefits' assessment calculation technique based on emission reduction and its cost effectiveness. The second Pb restriction case proposes to restrict the use of Pb shot in wetlands. The case made less progress on the cost assessment than hoped for, given experts had probably no time over the holiday to scrutinise ECHA's well-developed argumentation. The benefits' assessment of the case is of very high interest given it is the first environmental impact assessment conducted for a restriction under REACH. This section of the restriction will be debated at the next meeting of SEAC end of November (more information: Hugo Waeterschoot).

MSC-55 (September 12-14): *progress with the 8th priority list, new SVHC proposals and timing of the CoRAP*

Besides on dossier evaluations of lower relevance for the metal sector, MSC focused most of its attention on the status of different lists that are part of the risk identification and risk management programmes of REACH. On CoRAP (the REACH multi-year rolling list of substances for Substance Evaluation), ECHA informed MSC and stakeholders that more than 25 new substances were selected by Member States announcing that the suggested list would become available by mid-October along the next MSC meeting. MSC will review the consistency and risk-based motivation of the new candidates aiming for adoption by the end of the year. It is presently unclear if the next version of CoRAP would contain additional metals, or shift the timing for existing metal evaluations (TiO_2, antimony, …). MSC also took note of the proposal and start of the Public Consultation to identify a series of chemicals such as SVHCs so they could be put on the candidate list. The proposals submitted by countries included 3 Cd compounds, some of them used in batteries and frits/pigments. This was expected while the proposal by the Netherlands to include Co_3O_4 with an impurity of > 0.1 % of NiO was not (see below). The Public

© Eurometaux – All rights reserved

Consultation ends on October 20, which should allow sectors and companies to react. Eurometaux intends to submit comments challenging the concept of impurities in substances as a driver for SVHC identification. The last list debated at MSC-55 was the progress made with the prioritisation for Annex XIV, for substances that were candidates for authorisation. The recently closed Public Consultation received only replies on NMP as a candidate, while the 6 others had none, which allowed the MSC to suggest moving forward with their recommendation as such. NMP was listed to increase the pressure on the Commission to progress with the "OEL-based" restriction which had been stalling for a long while. Commission indicated that progress was made recently, which was testified by the proposed restriction on NMP being forwarded to WTO for comments. Commission expects to submit a proposal for voting at one of the upcoming REACH Committee meetings, which would probably result in a deletion of the NMP from the ECHA opinion on the 8th list. However, this may create other issues given then the proposed priority list for Annex XIV would almost be empty … challenging the Commission to reflect on selecting previously prioritised substances (more information: Hugo Waeterschoot).

MB-47: *two very crucial proposals for the future of ECHA were tabled*
The Management Board of 20/21 September celebrated the end of the 2nd term of the present Executive Director, Geert Dancet who built up the agency in Helsinki from scratch to becoming one of the most successful in the EU. The Management Board subsequently reviewed the 3 remaining applications for the Executive Director's post, selecting Bjorn Hansen (presently head of unit for chemicals management at DG Environment) for this top function. The Management Board should also, in camera, have taken a decision on the new location for the agency but up to the publication of this Chemicals Management newsletter we have not heard anything about this decision (more information: Guy Thiran, Violaine Verougstraete or Hugo Waeterschoot).

Authorisation

ECHA and *authorisation: a multitude of issues ongoing*
MSC handled a series of new AfAs, some still on Chromates, so reviewed those beyond the sunset date for these substances (22 September). For Eurometaux it is most interesting to note how these will be legally handled by ECHA and the Commission, even more so if the accordance check for one of them turns out to be negative. ECHA also recently published a publication on a meta-analysis of the first 100 AfAs focussing on the SEA impact assessment part. In overall the report claims "*a reduced risk from Annex XIV chemicals due to stricter controls and some substitution to safer alternatives*." Although, the latter is partly justified by the non-receival of applications for 7 substances on Annex XIV. The meta-analysis further estimated the aggregated benefits of authorisations to outweigh the remaining monetised risks for workers and the generic population by a factor 15 on average, while the applied conditions and monitoring requirements in 2/3 of the uses applied for would further improve the exposure conditions. Finally, ECHA stated that the agreed Review Period on average was 2.5 years shorter than requested, a comment that raised quite some critics from industry as it appears as a non-balanced view on content and quality of the submitted AfAs. The report will certainly be a catalyser for the debate at the upcoming ECHA workshop on Authorisation experience in November. Most recent ECHA activities in the frame of authorisation focus however on substitution, testified by the upcoming workshop on 8-9 October and the paper submitted by ECHA on this theme to CARACAL. Aim is to improve the quality and relevance of substitution assessments and in parallel promote innovation in this area where relevant. All main stakeholder organisations including Eurometaux received a request to participate in organising sectorial workshops around this theme, a request that was considered by Eurometaux's Authorisation and Restriction platform (more information: Hugo Waeterschoot).

UVCBs

UVCB formatting: *need to understand the big picture*
An informal discussion with ECHA (Hélène Magaud) took place on 7 September to achieve a common understanding of the metal UVCB registrations' structure, in order to see how the (new) functionalities of IUCLID (e.g. related to assessment entities) could help with the transparency of the dossier. The dossiers submitted in 2014 do indeed include only a part of the information on the UVCB's multiple constituents, coming from a 'parent' metal dossier. As in a registration dossier all study records are expected to be provided, the current format of the metal UVCB dossiers may trigger compliance checks. Also the chemical safety assessment is performed using a block approach, i.e. assessing each constituent individually but with only a preliminary proposal on how to combine the assessment across constituents. Whilst industry agrees with the principles to improve these dossiers and further enhance the understanding of the followed approach, practical solutions need to be found to prevent too much duplication of information, issues with data-sharing and unrealistic conclusions. Some ways forward have been suggested, which will now be tested by ARCHE and presented to the Intermediates Taskforce (more information: Federica Iaccino, Frederik Verdonck and Violaine Verougstraete).

© *Eurometaux – All rights reserved*

Others

Meeting of the ENES Coordination group: *preparing ENES 11 and 2018-2020*

On 8 September, the coordination group of the CSR/ES Roadmap, which involves ECHA, Industry sectors and Member States representatives met in the Metals Conference Centre to discuss the 2017-2020 programme for ENES, its governance and the planning for the next ENES event (23-24 November in Helsinki). How to achieve the overall objective of the ENES programme (ensure communication in the supply chains on uses and make conditions of safe use work in practice) was further discussed and agreed upon. The key tasks for 2017-2020 are to a) determine the different actors' information needs (content and form of information), b) connect practices under REACH with practices under other legislations (OSH, environment, consumer safety), c) develop and disseminate methods and tools (including guidance) to collect, process and communicate this information, d) adapt exposure assessment methods/tools to support the REACH Safety Assessment framework and e) inform and convince companies (and authorities) that it's worth the effort to implement/use the tools. A table of specific actions was reviewed, checking planning and relevance in view of the overall objective. It was also agreed that next ENES event (23-24 November) will provide on the first day hands-on exercises to better understand how the communication up and down the supply chain can work in practice, by means of exercises with harmonised and updated use maps prepared by downstream sectors. There will also be the opportunity for formulating companies to try out the way in which they can transform exposure scenarios received from their suppliers into meaningful information for their customers, supplied via the safety data sheet for the mixture. Companies will also be invited to give feedback on the information they may receive in the future with the safety data sheets. In a nutshell: the first day of ENES will be of particular relevance for practitioners generating safety data sheets or mixtures and those extracting information from safety data sheets relevant for the operations in their own company. On the second day, the ENES Coordination group will present the draft work programme until 2020, which also includes activities on SPERCs (developed by the industry and currently under the coordination of Eurometaux), inviting all participant to ask questions, to make proposals and/or to offer contributions. The programme aims to identify the remaining gaps in communication on safe use along the whole supply chain and find solutions. Registration for this event will be launched very soon. The 2017-2020 topic will be further discussed with the Eurometaux Exposure Scenarios Taskforce on 4 October (more information: Lorenzo Zullo and Violaine Verougstraete).

COMMISSION REACH & CLP Activities: hot topics/issues

DCG

Sherpa: *are EU Commission and ECHA taking the right approach to help SMEs with the 2018 REACH registration deadline?*

ECHA and the European Commission expressed their concern about possible supply chain disruptions due to REACH cost barriers for SMEs, for LoA and joint registrations, especially for the 2018 registration deadline. In July ECHA sent the Sherpas Directors Contact Group a document containing a proposal for a pragmatic solution under the form of a recommendation "to consider to provide free access to data and joint registrations to SMEs on a voluntary basis". In a joint statement Cefic, CONCAWE and Eurometaux strongly reacted indicating that the proposal was not in line with various REACH principles and might have additional negative side effects, including a further reduction of SMEs commitment to post2018 consortia activities. ECHA and Commission recognised that the proposal was probably "too extreme" however they would have hoped for industry to be supportive in finding a proper solution for SMEs. On 12 September a brainstorming session with Cefic, Eurometaux and ECHA was organised in Helsinki: on that basis ECHA sent Cefic and Eurometaux a revised proposal that was however not very different from the initial one, but better exemplified. Several participants of the 27/9 REACH Forum meeting requested that Eurometaux takes a strong position against ECHA's proposal and to also put the legal arguments on the table. It was emphasised for example that industry should not be responsible for finding a solution to a problem that was already pointed out when REACH was under development and that authorities underestimated at that time. Eurometaux is currently discussing internally to identify the next steps to be taken (more information: Lorenzo Zullo, France Capon, Caroline Braibant and Violaine Verougstraete).

Non-Toxic Environment

Study on Non-Toxic Environment released: *some work ahead*

The European Commission will develop by 2018 "a Union strategy for a non-toxic environment that is conducive to innovation and the development of sustainable substitutes including non-chemical solutions". In this context, a 1115 pages study was presented by a consortium of consultants, providing a comprehensive overview of the state of play and identifying gaps and deficits in the current EU chemicals policy and legislative framework in relation to - for example - substitution and grouping

© *Eurometaux – All rights reserved*

of chemicals, chemicals in articles and non-toxic material cycles and programmes on the development of new, non/less toxic substances. The report makes some recommendations with the ultimate goal being the creation and maintaining a non-toxic environment that is free from exposures, to minimise and eliminate all exposures to hazardous substances. Taken at face value, this objective is worrying as it focuses heavily on hazard. There are however, in the formulated recommendations, a number of 'hooks' where we could anchor Eurometaux's vision of a fully risk-controlled Europe, where hazardous substances are used only when it is certain they will not cause harm to human health or the environment. We promoted this vision last year at our 'Non-Toxic Environment Event' but it is now urgent to put it more into practice to ensure we can offer authorities an alternative to only hazard-based legislation. A first brainstorming will take place with members on the 5th of October on how to work on this (more information: Chris Heron, Hugo Waeterschoot and Violaine Verougstraete).

EUROMETAUX REACH & CLP Activities: hot topics/issues

Resource mapping to respond to REACH / ECHA challenges

REACH Forum Meeting: ***no rest for the REACH Forum***

The REACH Forum met on 27 September. The status of actions agreed at the last meeting was presented and confirmed to be on track. The REACH Forum made progress on the "metals and inorganic sectorial approach"; the majority of consortia confirmed their intention to participate in the first phase, requiring the compilation of baseline reports by the end of November. The need for more clarity on future involvement of Members States in the overall programme was considered an important element to be addressed. An overview of the expected 2018 activities as well as a budget proposal for 2018 were presented, without important concerns being raised on the proposal. However, it was agreed that the budget structure would need to be re-discussed in the context of the restructuring of the post 2018 REACH and EHS activities. Further reflection on an optimal structure will be launched in the coming months, accompanied by the running of 'scenarios' considering the differences in membership, fees and interests of REACH and EHS members. In the meantime, Eurometaux proposed to slightly revise the current Eurometaux EHS structure by expanding the EHS Steering Committee to become an EHS & REACH Steering Committee, where REACH advocacy decisions would be discussed with the REACH and EHS chairs of the platforms and taskforces. A draft paper describing the emerging issue of "impurities subject to authorisation" was presented; it was agreed to identify this topic as a new priority. Among several classification issues, Eurometaux secretariat reported that RAC agreed to classify cobalt metal as Carcinogenicity cat 1B (all routes) with the SCL of 0.01% as proposed by The Netherlands. The main issues at stake with the environmental classification of copper and lead were presented as well. The REACH / OSH interface was still on the agenda with focus on the development of BOELs for Nickel, for which, unlike the usual procedure, a recommendation will be delivered by RAC instead of SCOEL. The REACH Forum exchanged also on the initiative of the International Council on Mining and Metals (ICMM) to establish a group to handle International Chemicals Management aspects and it was concluded that alignment with Eurometaux activities will be needed to ensure optimisation of resources and avoid duplication of the work. The outcomes of the Data-Sharing Taskforce meeting and in particular the proposal by ECHA to facilitate the access to the data for the SMEs triggered some energetic discussions at the end of the meeting. The next meeting will be held on the 20 December and minutes will be circulated soon (more information: Lorenzo Zullo).

Authorisation and Restriction platform: ***an intense information exchange and the launch of many actions***

Eurometaux's last Authorisation and Restriction platform (A&R) took place on 26 September in Brussels. Participants were challenged by a loaded agenda, a reflection of the long list of ongoing activities. The secretariat informed the members on the restriction cases debated in RAC and SEAC and the status of the different risk management lists (see above). The increased attention of ECHA and Commission on the theme of substitution was also reported. The meeting further focussed in particular on two more generic horizontal aspects of high relevance for risk management of metals at the workplace, in particular Authorisation. The first concerned exploring *the legal basis for the interpretation in the ECHA and MSC opinion of REACH Article 58 (2).* This article defines that alternative EU-wide substance specific RMMs can exempt a use from authorisation. However, both ECHA/MSC's opinions rejected the relevance of this article for the 4 Pb compounds recently prioritised based upon additional criteria like the need for a substitution driver in the alternative legislation, proposing an "ion theory" instead of limiting the scope of the authorisation to the substance listed on annex XIV, … and many more issues. To check the validity of and basis for these additional requirements, ILA, NI, EPMF and Eurometaux ordered a legal review by Mayer-Brown. The first results of this study were presented to the A&R platform. It was agreed to further work on a couple of issues before circulating it wider as an internal paper at this stage. The second item that drew specific attention from the A&R platform was the project of ECHA to launch RMOas on impurities in substances. This inspired The Netherlands to suggest SVHC status for Co_3O_4 with > 0.1 % of NiO as a SVHC candidate aiming for the gradual substitution by Co_3O_4 without such CMR impurity. The Co, Ni sector and A&R platform commonly agreed that this does not make sense given, among others, that such low concentrations

© Eurometaux – All rights reserved

do not cause any risk at the workplace and furthermore discourage recycling (containing more oxides). But the A&R platform did recognise the importance to pay more attention to the risk management of impurities in recycling and complex substances, resulting in a thought-starter paper prepared by the secretariat on the issue of impurities. This matter was therefore prioritised together with the issue on substitution and Article 58 (2) as main headlines for the platform's next year's work plan (more information: France Capon and Hugo Waeterschoot).

Co CLH Meeting: ***taking stock of RAC and preparing the next steps***

The Cobalt CLH Taskforce, which brings together all industry parties interested/impacted by the classification of cobalt metal as carcinogen cat 1B (all routes) and the SCL of 0.01% as mutagen category 2 and reprotoxic cat 1B for fertility, had a meeting on 28 September to ensure a common understanding of the RAC opinion and agree on the next steps to achieve a better result. The latter are formulated along the following axes: prepare a clear and robust 'story telling' on the socio-economic impacts to be used in advocacy with authorities and further work on bioelution (acceptance and data) to try to mitigate the consequences of the SCL on materials where the content of cobalt metals does not predict the actual release of cobalt ion. It was re-clarified that the SEA data to be generated shall focus on additional costs (beyond self-classification), thus relate primarily to the 'carcinogenicity by all routes' and the SCL. A first planning of the advocacy actions (with timelines, activities) was presented and will be refined in the coming weeks. It has also been agreed to work on the self- classification of mixtures to ensure consistency across sectors: this will require some further guidance/trainings to be made available along 2018. Draft minutes of the meeting will be circulated soon with a proposal for next calls. Finally, the meeting identified the generic learning lessons to be drawn from the cobalt case for the other metals, for example the notion of potency of metals and the use of human data in the context of the methodology applied to derive the SCL or the 'all routes' issue that can hardly be overruled without already available carcinogenicity studies by the oral/dermal routes. Those aspects will be further discussed at the forthcoming Risk Assessment and Classification taskforce meeting (11-12 October) (more information: Ruth Danzeisen, Brigitte Amoruso, Paul Marsh, Hugo Waeterschoot and Violaine Verougstraete).

Data-Sharing Meeting/DCG (25.09.2017): ***very efficient meeting***

On 25 September, the Data-Sharing taskforce came together for a very efficient meeting, taking stock of the progress made on the set of papers developed since the last meeting (OSOR principle vs. variability of impurity profiles; consortium membership vs. LoA purchasers; 12-year copyright rules; criteria and bottlenecks associated with spontaneous/maintenance dossier updates profiles; and fiscal implications of reimbursements) but also to discuss a number of ongoing/future issues having direct impact on the maintenance of the dossiers and data-sharing agreements. ECHA's proposal in the context of the Directors Contact Group, to facilitate 2018 registrations of SMEs by making data and access to the joint submission available in certain cases for free to SMEs was discussed in detail. Up to now Cefic, Eurometaux and Concawe were aligned to refuse this proposal and expressed their arguments for doing so in a letter to the DCG. The revised proposal by ECHA may however trigger some divisions. It was therefore proposed to the Data-Sharing taskforce to check the revised version of ECHA's proposal and propose some factual comments, prepare an overview of what the impacts are of this proposal on our sector by collecting/providing some information on e.g. how may SMEs have already bought LoA, check for alliances to avoid being isolated in the discussion with ECHA and to prepare a reaction to the press release that ECHA will issue at short notice. It is suggested that this reaction focuses on the principles and on the sources of the issue and not specifically on the SMEs-related proposal. This topic was further discussed at the REACH Forum (see above). The Data-Sharing Taskforce discussed other issues at its meeting like the full opt-out in practice, free-riding in the context of Dossier updates, data-sharing post-2018 and global data-sharing, and identified for each item, a series of actions to be performed. The minutes were circulated on 28 September and the next meeting will be fixed on an ad-hoc basis or back-to-back with the Forum meeting. A big thanks to the incredibly effective chairs (more information: Caroline Braibant, France Capon and Violaine Verougstraete).

Meeting on TiO2: ***communicating impacts***

Eurometaux participated very briefly -unfortunately- in a meeting informing the users of TiO2 on the outcomes of the RAC discussion (see RAC item) and agreeing with the users on the next steps to be taken. This kind of meeting, where views on what a classification means in practice or where it will possibly set precedents is extremely useful to better grasp advocacy priorities and objectives. It also allows to sketch the overall context of the discussions and the links with other 'hot topics' like the nanos issue, the CLP REFIT and the handling of 'dusts' under CLP (more information: Violaine Verougstraete).

Pb Environmental CLH issue: ***challenging the basics of the metals environmental classification scheme***

The proposal submitted by Denmark for an environmental classification of Pb metal was recently posted on ECHA's website thereby opening the Public Consultation until 30 October. The proposed classification is at least remarkable given it does not provide for a distinction between the classification of the massive and the powder form, uses different data treatment rules as agreed during previous data rich metal cases and rejects the validity and relevancy of the GHS and CLP metals environmental classification scheme and Transformation Dissolution test. In essence, this proposal neglects the gains in improved assessment methodologies for the environmental classification assessments of the last 15 years since the UN-GHS

© *Eurometaux – All rights reserved*

and OECD adopted respectively the metals classification scheme and criteria and the Transformation Dissolution protocol. The consequences of the proposal may be severe, especially for the users, when they will have to consider a massive metal classified in the strictest environmental classification categories with an M factor of 10 making all mixtures/alloys containing > 0,025 % of Pb metal classifiable for the environment. Quite logically, Eurometaux received a mandate from the REACH Forum to exceptionally participate in the Public Consultation of this substance given the significant metal conceptual aspects and methods at stake. The Danish proposal also sparked the creation of a Eurometaux Metal Environmental Classification taskforce, to raise awareness and promote a correct classification of metals including Pb (more information: Steve Binks and Hugo Waeterschoot).

Upcoming SPERCs Workshop: *20 October at Metals Conference Centre*
The cross-industry initiative on the Environmental Release Categories (SPERCs) is proceeding under the chairmanship of Eurometaux. The full-day SPERCs workshop to be held on the 20 October at the Metals Conference Centre is approaching. The workshop will take stock of the situation of development, improvement and homogenisation of the SPERCs across the industry and define the next steps. Several industry sectors will present their case studies: non-ferrous metals (Eurometaux), lubricants additives (ATIEL), paint/printing inks (CEPE), crop protection (ECPA), adhesives, sealants and construction chemical products (EFCC/FEICA), solvents (ESIG/ESVOC), fertilisers (Fertilizers Europe). The level of details/conservatisms and the quality of the background documents are some of the aspects to be discussed. Overlaps among sectors will also need to be addressed to avoid the publication of multiple conflicting SPERCs for the same substances and uses. As already agreed in 2016 a review process is considered necessary to make industry's SPERCs more "trustable". Participants will have the opportunity to comment on a preliminary set of quality criteria that has been already circulated and to discuss the way in which the review (internal and/or external) will be conducted. The workshop will also be an opportunity to provide an update on the OECD project "Matrix project between Emission Scenario Documents and SPERCs" (more information: Frederik Verdonck and Lorenzo Zullo).

Nanos

ETAP Issue of Concern
Last month Eurometaux received a reply from the Environment Toxicity Advisory Panel (ETAP) on the questions regarding "Nanoparticle exposure and transformation, with specific reference to environmental classification". Among other detailed descriptions and elaborations, lack of in-situ ENP measurements for model calibration and validation and clear characterisation of ENP sources are identified as major issues for not being able to develop ENP models for regulatory assessments. Further quantifying methods are still under development. So far, only single particle inductively coupled plasma mass spectrometry (SP-ICP-MS) is seen as a reliable technique, although it is still hardly possible to distinguish ENPs from natural colloids. Thus, it is difficult to apply the typical risk assessment paradigms. It depends how the toxicity is seen to weather different properties and forms (individual/ aggregated, coating, dissolved forms, others) and how acute or chronic toxicity is tested. Anyhow, so far, data shows that the solubility and effect in aquatic organisms is less than for soluble salts, making evidence on the latter a good and precautionary reference for this endpoint. Finally, a recent study concludes that there is a need to modify test guidelines and guidance documents that apply the traditional risk assessment paradigm to nanomaterials (more information: Christine Spirlet, Nathalie Kinga Kowalski).

12th International Conference on the Environmental Effects of Nanoparticles and Nanomaterials (ICEENN 2017)
The yearly ICEENN meeting brings scientists, experts and stakeholders together to discuss recent developments in the technology, uses and regulation of nanomaterials. During the conference, it was clear that research focuses on Silver and Copper nanoforms, although Zinc is still a concern. The nano(form)s used in research are often enough analytical lab grade or self-made materials (not representative) instead of commercial products. As there is no formal standardisation of testing and that tested nanomaterials vary (coating, size and conditions), toxic effects in environment and the human body are difficult to interpret and often inconsistent. So far, research agrees that different environmental conditions and exposure scenarios need to be considered during risk assessment of new nanomaterials. Scientists working on regulation claim "new" approaches are needed to tackle nanos in legal aspects, which so far is not approached by the decision makers (more information: Christine Spirlet, Nathalie Kinga Kowalski).

Metal-specific REACH application tools and concepts

ECVAM Bioelution meeting*: constructive meeting but announcing further work*
The validation of the gastric fluid bioelution protocol was discussed with several representatives from ECVAM during a whole day meeting on 26 September. A package of information had been sent to ECVAM ahead of the meeting. In addition to discussing the status of completion of the responses to the questions posed by PARERE (ECVAM's network of Member States performing a preliminary Assessment of Regulatory Relevance of methodologies), the test submission template, and the

© Eurometaux – All rights reserved

ongoing work on ~12 appendices, the results from a recent bioelution test requested by ECVAM were described. This test examined the release of Ni ions from a simple mixture of Fe, Cr, and Ni powders versus the release from SS316 powder containing the same bulk concentration as the mixture. This test clearly illustrated the matrix effect of the alloy. The meeting was very constructive and the discussions quite helpful in clarifying the remaining work. To secure the validation of the method, ECVAM recommended that we be very clear on its applications. Bioelution tests' have been extensively used in the REACH context for read-across and grouping, to fulfil information requirements, and also in test proposals. This application is now being challenged by some Member States (e.g. RAC-42 decisions on Ni compound classifications). The second application is for the refining of bulk concentration of classified metals in alloys for self-classification. In this case, the bioaccessible concentration of the metal in the alloy is calculated based on bioelution results and compared to the GCL or SCL. This application was last discussed at CARACAL: concerns still remained but work on the protocol was encouraged. This latter application has gained higher relevance on the context of the recently recommended SCL for cobalt metal. In the coming weeks, work will continue to revise and complete the submission package targeted for delivery before the end of the year. Additional tests will be considered as needed (more information: Adriana Oller and Violaine Verougstraete).

Metals and Inorganics Sectorial Approach

Making progress: *a set of documents for the REACH Forum*, informal meeting with ECHA and discussion with the REACH *Forum on the 27th*

The secretariat further worked on the documents prepared and commented by the Steering Committee so as to have a package to circulate before the REACH Forum meeting including a general action plan, a draft charter, business-like messages to justify resources and a baseline report template. The latter in particular required some further fine-tuning to ensure it could serve as an internal exercise for the consortia to define their 'starting-point' in this programme, as well as common sectorial issues. The template was also turned into a more user-friendly format (SurveyMonkey) in an attempt to reduce the workload for the consortia who are asked to complete it by the end of November. Additional comments on the template were received at the REACH Forum meeting and will be included. Based on the completed baseline reports, the Steering Committee will extract early December a high-level overview to help identify common priorities/interests for dossier improvement actions (axis 1) and for progressing with the parallel technical support programme (axis 2). This high-level overview will be presented to the REACH Forum at the December meeting for validation and be used as basis for a workshop to be organised with ECHA early 2018. One of the main aims of this workshop will be to build trust in the approach, with industry's analysis to be complemented with ECHA's results of their own screening of the metal dossiers, so as to be able to establish a common action plan and clarify outstanding process/reporting aspects. An informal discussion with ECHA along the margins of the RAC/SEAC meetings allowed to ensure alignment on the ongoing work but also to raise the issue of the participation of the Member States in the approach. ECHA has indeed a duty of transparency vs. the Member States on such initiatives. Participation of Member States in the approach has been discussed with the Steering Committee in August: while some members fear that it may encourage Member States to do 'evaluation avant la lettre', others believe that having Member States on board offers several opportunities, ranging from capacity-building on metals to possible reduction in duplicating initiatives to checking the REACH data. A one-pager should be prepared by the secretariat and ECHA that can be communicated to the MSCAs (more information: Lorenzo Zullo, Hugo Waeterschoot and Violaine Verougstraete).

CALENDAR

- **4 October**: Exposure Scenarios Taskforce – MCC (Brussels)
- **5 October**: NTE brainstorming –MCC (Brussels)
- **9-10 October:** ECHA workshop on Substitution (Helsinki)
- **12-13 October:** ECHA Substance Evaluation workshop (Helsinki)
- **18 October :** ECHA's Accredited Stakeholder Workshop (Brussels)
- **23-27 October**: MSC-56 – ECHA (Helsinki)
- **Week of 6-11 November**: Exact date to be confirmed:2017 Forum's Open session for ECHA's Accredited Stakeholders Organisations
- **21 November:** Nanos Taskforce meeting (Brussels)
- **22 November**: Evaluation Platform meeting (Brussels)
- **23 November**: A&R Platform meeting (Brussels)
- **23-24 November**: ENES (Helsinki)

© *Eurometaux – All rights reserved*

- **27 November – 1 December:** RAC-43 + SEAC-37 – ECHA (Helsinki)
- **4-8 December**: RAC-43– ECHA (Helsinki)
- **11-16 December:** MSC-57 – ECHA (Helsinki)
- **14-15 December**: ECHA Management Board – ECHA (Helsinki)
- **20 December:** REACH Forum (Brussels)

NB: Please note that some RAC/MSC/SEAC dates are tentative and can be subject to change and that there have been recent changes in some of the dates, with the second weeks of SEAC meetings being cancelled in September & December

ACRONYMS

AfA: Application for Authorisation	NMP: N-Methyl-2-pyrrolidone
BOEL: Binding occupational exposure limit	OECD: Organisation of Economic Cooperation and Development
CARACAL: Competent Authorities for REACH and CLP	OEL: Occupational Exposure Limit
CLH: Harmonised Classification and Labelling process	OSH: Occupational Safety Health
CLP: Classification, Labelling and Packaging Regulation	OSOR: One Substance, One Registration
CMD: Carcinogens, Mutagens Directive	PARERE: ECVAM's network of Member States
CMR: Carcinogens, Mutagens or toxic to Reproduction	RAC: Risk Assessment Committee
CoRAP: Community Action Rolling Plan	REFIT: Regulatory Fitness & Performance Programme (EU)
CSR: Chemical Safety Report	RMM: Risk Management Measures
DCG: Directors Contact Group	RMOa: Risk Management Option analysis
ECVAM: European Centre for the Validation of Alternative Testing Methods	SCL: Specific Concentration Limit
ENES: Exchange Network on Exposure Scenarios	SCOEL: Scientific Committee on Occupational Exposure Limits (EU)
ENP: Engineered Nanoparticle	SEA: Socio-Economic Assessment/Analysis
ES: Exposure Scenarios	SEAC: Socio-Economic Analysis Committee (ECHA)
ETAP: Environmental Toxicology Advisory Panel	SME: Small and medium-sized enterprise
GCL: Generic Concentration Limit	SP-ICP-MS: Inductively Coupled Plasma Mass Spectrometry
GHS: Globally Harmonized System	SPERC: Specific Environmental Release Category
ICMM: International Council on Mining and Metals	SVHC: Substance of very High Concern
IUCLID: International Uniform ChemicaL Information Database	UVCB: Unknown or Variable Composition, Complex Reaction Products and Biological Materials
LoA: Letter of Access	WTO: World Trade Organisation
NTE: Non-Toxic Environment	

© Eurometaux – All rights reserved