


EUROMETAUX CHEMICALS MANAGEMENT NEWS



REACH on the BEACH



TABLE OF CONTENTS

ECHA REACH & CLP Activities: hot topics	2
Others	2
COMMISSION REACH & CLP Activities: hot topics/issues	3
CARACAL	3
REACH Review	3
EUROMETAUX REACH, EHS & CLP Activities: hot topics/issues	4
Resource mapping to respond to REACH / CLP/EHS challenges	4
Metal-specific REACH application tools and concepts	5
Metals and Inorganics Sectorial Approach	6
FURTHER OUTREACH OF REACH.....	6
COMMUNICATION	7
CALENDAR	7
ACRONYMS	7
REACH on the BEACH 	9

Dear All,

For the summer I received a very amusing but also incredibly informative book about penguins and change management. The easy-to-read story is about a penguin colony that has been living, for many years, on an iceberg surrounded by a sea rich in food and walls of snow to shelter them from winter storms. The community is prosperous, well-structured and organised, and life on the iceberg seems 'without question'.

However, one of the animals in black and white tuxedo, 'unusually curious and observant' notices that the iceberg is melting and might break apart, which would without doubt be a disaster for the colony, above all if the iceberg were to split into pieces during the dark winter. Fred the observer knows he must do something, but what? The fable says that he is not in a position 'to make any pronouncements or dictate how others should act' and even worse, he 'has no track record as a credible iceberg forecaster', only a sum of data and observations in his briefcase. How he will manage to be heard and bring the colony to change patterns despite strong disbelief and resistance at the start (led by penguin NoNo), should not be revealed here. But the description of the challenges, the personalities in the group of penguins and the tactics used make it a memorable book, not least because some of these animals and their behaviours will sound and look quite familiar to you.

"Our iceberg is melting", by John Kotter and Holger Rathgeber, a strong recommendation in case you might (ever) have some 'obstacles' to deal with.

The book also finishes with a happy non-ending: the story continues in Antarctica, with the penguins dynamically balancing feelings and thinking, required adjustments and routines.

But the parable also continued this afternoon during a meeting in much warmer Brussels, when one of EM's valuable Freds wrote out an additional and unpublished chapter. He created in situ the 'yin yang penguins' colony, characterised by a very dignified gait and a special arrangement of the black and white colours illustrating -coincidentally- the necessary complementarity between Chemicals Management and Circular Economy on the (still) melting iceberg. Once the audience was visualising the penguins' situation with enough empathy -I surprised myself by wobbling on my chair, arms along my thighs and watching the sea (in Schuman!)- Fred used the gained understanding to identify the challenges and key messages for a possible change.

The future will tell how it will go with the yin yang colony, but I was definitely smiling while walking back to the office, grateful for the summer that once again allows to build or listen to stories that inspire actions.



Violaine Verougstraete, EHS director Eurometaux

ECHA REACH & CLP Activities: hot topics

Others

ENES 3.2 Meeting: MCC 3 July

One of the actions under the ENES Workplan 2018 addresses occupational exposure assessment. Experience since the first REACH registration deadline indeed shows that the current exposure assessment practice under REACH is facing a number of significant difficulties related e.g. to the variety of tools and methods that are available and the lack of common understanding/concept of which method/tool is most suitable for which type of substance or situation. Also, many of the input parameters for the tools refer to the comparable conditions of use, express those in different words and granularity, creating communication challenges. The aims of this action are thus to launch a process towards i) more common understanding among authorities, industry and tool owners on what the exposure assessment under REACH is meant to deliver, ii) have a common framework/platform under which the various tools and methods could work together in a consistent and efficient manner, and iii) improve the available methods and tools themselves. A first task is to perform a mapping of the tools, i.e. compare the scope of applicability of the tools and coverage of conditions of uses. A face-to-face meeting brought together ECHA and the workers' exposure tools owners (ART, ECETOC TRA, Stoffenmanager, MEASE) as well as RIVM and Eurometaux, and allowed an in-depth -and intense!- discussion on input parameters and conditions of use. A series of actions were agreed on as well to ensure this work would be well advanced by end 2018 (more information: Daniel Vetter Violaine Verougstraete).

Dissemination: *collection of comments on Infocards*

Infocards and Brief Profiles are dissemination tools introduced by ECHA to make the technical information published from the Agency's substance databases more accessible to the general public. This is in line with REACH and ECHA's legal obligations to make (non-confidential) information on chemicals publicly available. The Infocard functions as a 'first tier', providing a high-level summary for a broad public, consisting of information that is most relevant to an audience of consumers, downstream users and professionals active in the chemical industry. The Brief Profile is more detailed and works as 'second tier'. Due to the quantity of information and the number of chemicals, these dissemination tools are automatically generated based on the information available and are not manually verified. There may thus be errors, either related to the information provided in the different dossiers or linked to some lay-out choices. A couple of years ago, Eurometaux collected and aggregated the list of errors noticed by the REACH Forum members when checking the Infocards/Brief Profiles of their substances. A number of these errors were able to be fixed before the rush of the 2018 registration deadline. However, some errors remain and new ones may have popped up based on recent registrations. ECHA agreed with Eurometaux to launch a new round of comments but asked for them to be grouped again. If you see any mistake in the Infocard or Brief Profile, please list the substance and EC number, whether the error is in the Infocard or Brief Profile, which item (e.g. DNEL value) and your comment and be so kind to send this to Ailsa Lee (lee@eurometaux.be) (more information: Violaine Verougstraete).

COMMISSION REACH & CLP Activities: hot topics/issues

CARACAL

Follow-up comments: *cobalt metal's SCL requires the setup of an expert group*

In follow-up of the CARACAL-27 CLP discussions and more specifically the debate on cobalt metal and the way the SCL was derived, Eurometaux submitted comments to reiterate its support for ECHA's suggestion to have "an expert meeting to discuss and review in general the methodology for deriving SCLs for carcinogens depending on their respective potency". This suggestion had encountered some sympathy from Member States and other industry sectors. The comments also referred to the work that has been launched by industry, i.e. a review of the substances (organics, metal, metal compounds or inorganics) classified as carcinogenic in category 1 based on inhalation data in animals and the calculation of the "T25 potency" for these substances. This review should provide a first overview of the applicability of the method and will allow us to prepare the input into the expert group, if its setup is confirmed after the summer (more information: Lorenzo Zullo and Violaine Verougstraete).

TiO₂: *UK and Slovenia put on the table a possible solution to address the classification of TiO₂...and PSLTs*

Following the June CARACAL meeting and the recognition that more time was needed to reflect on the most suitable solution to classify TiO₂, and Poorly Soluble Low Toxicity (PSLT) particles in general, the United Kingdom and Slovenia have proposed an alternative to the classification of TiO₂ in Annex VI of the CLP. The proposal would be to create a new section in Annex II of the CLP regulation: "Annex II, Part 6: Special rules for the labelling of Poorly Soluble Low Toxicity substances and mixtures containing them". The section would initially list TiO₂ and will be populated in the future with additional substances characterised as PSLT. According to the proposal, placement on the market of substances listed in Annex II.6 as a powder or dust containing free respirable particles of diameter $\leq 10 \mu\text{m}$, or mixture (as a powder or dust) containing 1% w/w or more of free particles of those substances shall bear the statement: "EUHXXX – 'Warning! Contains respirable dust. Follow safety instructions'". Additionally, for those substances and mixtures that are not otherwise classified as hazardous, the label on the packaging shall also bear the statement: "EUH210 – 'Safety data sheet available on request'". Such a proposal would avoid the full classification of TiO₂ in Annex VI as carcinogen Category 2 by inhalation, which would create a precedent for other particles. On the other hand, PSLT not being totally defined yet, such an entry might bring some uncertainty and make it easier to add other PSLT to CLP. This proposal will probably have to go back to CARACAL for review and to the REACH Committee, but the timings need to be confirmed (more information: Violaine Verougstraete and Lorenzo Zullo).

REACH Review

Submission of follow-up comments to CARACAL: *an occasion to reiterate our 5 key priority messages*

The review of REACH is ongoing. In March 2018, a European Commission communication listed 16 areas where specific actions could be implemented to improve the overall functioning of REACH. The initial focus, currently under discussion at CARACAL level, is on the: "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 is preparing a set of comments as follow-up to the documents shared by Commission/ECHA at the last CARACAL meeting. This will be the opportunity to review and reiterate in more detail, where relevant, the five key messages we submitted during the consultation: i) Evaluate actual exposure to make risk management effective, ii) Recognise the RMOA tool for more effective risk management", iii) "Reflect about the Authorisation process and simplify it (hybrid model for AfAs, authorisation per substance use", iv) "Boost the use of REACH Registration datasets in the EU and abroad", v) "Prevent duplication of Risk Management requirements". The draft comments will be circulated soon to the REACH Forum and EHS & REACH Steering Committee for review (more information: Lorenzo Zullo).

EUROMETAUX REACH, CLP & EHS Activities: hot topics

Resource mapping to respond to REACH / CLP/ EHS challenges

SPERCs Quality Criteria: *the work is proceeding following June's workshop with ECHA and Member States*

The June workshop organized by the industry SPERCs Taskforce -in cooperation with ECHA and Member States- helped to align the understanding of the role of SPERCs in communicating information on (environmental) safe conditions of uses along the supply chain. The discussions also provided some steering for the next steps, i.e. the development of criteria to be used by industry and authorities to evaluate the quality of the SPERCs' factsheets and the related background documents. The SPERCs Taskforce is now actively working on the follow-up actions. A revised version of the quality criteria, simplified and more focused on the assessment of the drivers for environmental release has been circulated by Eurometaux. The SPERCs' Taskforce is invited to send comments in August and during the first half of September a call will be held that aims to finalise the revised version of the quality criteria, including the supporting guidance, before it is shared with ECHA and Member States (more information: Frederik Verdonck and Lorenzo Zullo).

WFD REFIT: 4th Joint Association Meeting

On 30th July, we hosted at the Metals Conference Centre the 4th industry meeting for the preparation of joint positions on the evaluation of the Water Framework Directive (WFD) and related consultation expected mid-September. Cefic, Concawe (FuelsEurope), Ecpa, Eurofer, Euromines and Eurometaux participated in the meeting and it proved to be a fruitful occasion to analyse the priority topics for impact and decide on the most important ones (non-deterioration principle; prioritisation; River Basin Specific Pollutants, ecological versus chemical status) for our joint advocacy. The proposal of a common storytelling conveying a positive message on the industry's achievements in the life span of the WFD (since year 2000) was also discussed (to be brought forward) (more information: Annalisa Bortoluzzi).

HAZBREF project: *latest news*

The EU funded project HAZBREF (2017–2020) aims to enhance the way hazardous chemicals are addressed in the IED BREFs by contributing to the systematic utilisation of data from various EU regulatory frameworks (including REACH; www.syke.fi/projects/hazbref). A main project activity (Work Package 3 - Policy improvements) is to analyse in depth the interfaces and gaps between the different European legislative frameworks, in particular the Industrial Emission Directive (IED) and its BREFs and BAT conclusions, the REACH regulation, the Water Framework Directive (WFD) and the EU waste legislation (focusing on circular economy aspects). The report "Analysis of the interfaces between different regulatory frameworks" by HAZBREF project partners should be released in August for comments by stakeholders and presented/discussed in a workshop in Berlin on the 25th September (more information: Annalisa Bortoluzzi).

Pb metal advocacy: *brainstorming*

A small group came together on 31 July to reflect on the strategy for REACH Annex XIV advocacy and communications. Although this brainstorming was initially driven by the recent Candidate Listing of lead metal, lead compounds were also part of the debate as principles and issues are common and decisions on compounds will be precedent-setting for lead metal (e.g. on REACH Article 58(2), impurities management, grouping, balance Circular Economy/Chemicals Management). The group discussed where and when could industry best deliver its advocacy considering the regulatory timelines and how to best ensure coordination/coherence of the messages. In respect to data development on SEA and scoping, some key milestone dates were defined that would allow consortia to plan in time for the upcoming public consultations. This discussion was key to prepare a face-to-face meeting to be held on 15 October at the Metals Conference Centre, to which all sectors impacted by

the Candidate Listing of lead metal will be invited to and presented with an action plan for Q4 2018-2019. The invitation and draft agenda will follow soon. Preparatory material (i.e. strategy papers) will be circulated ahead of the meeting (more information: Lisa Allen, Steve Binks, Hugo Waeterschoot and Violaine Verougstraete).

Lead metal environmental classification: *challenging draft RAC Rapporteurs opinion for debate mid-September at RAC*

The RAC Rapporteur has now prepared a draft opinion on the proposal from Denmark to classify lead metal as acute and chronic 1 for the environment with an M factor 10 (meaning a cut-off of 0,025% for mixtures), independent of the physical form. The Rapporteur considered the input received from some Member States but regrettably few of Industry's observations. There remain several important issues that create damaging precedent for the future environmental harmonised classification of metals. Important is the fact that the rapporteur supports Denmark's proposal not to differentiate between a classification for the massive form and the powder. In addition, the rapporteur also provided support to Denmark's position that it is not possible to undertake a comparison between toxicity and T/Dp results at different pH levels and the use of non-standard test species. Conclusively, the proposal isn't in line with the metals classification strategy of the CLP for several aspects therefore raising serious concern for the metal sector at large and lead in particular. ILA and Eurometaux are currently preparing a strategy to ensure effective input at the upcoming RAC meeting (more information: Jasim Chowdhury, Steve Binks and Hugo Waeterschoot).

Cobalt CLH call: *summer briefing*

A call was held on 23 July with the taskforce, to discuss the way forward for the review of the CLP methodology used to derive potency and associated SCLs, to have a first discussion on possible arguments to support a split concentration limit according to the physical form of cobalt and to describe the next steps in the advocacy programme. The review of the CLP "T25 approach" is carried out to provide input to the "expert group on the potency methodology" once it has been set up. A first overview was prepared by CI/Nipera/EM already and is now being reviewed by consultants for its credibility and robustness. Ideally the metals/inorganic cases included in the paper should be complemented with examples of organic inhalation carcinogens. It was agreed that a small subgroup of the taskforce will further reflect on the elements that could support a difference in concentration limits between the massive and powder forms, with a first call on 2 August. With regard to advocacy, the next steps are to continue outreach towards the Member States to ensure that the REACH Committee supports the setup of the expert group on potency and the GCL of 0.1% ad interim. It was also expected that a discussion on the cobalt classification would take place at the EPG meeting early July and a set of slides/briefing note prepared by CI/EM was forwarded to the German representatives, but the topic was only briefly evoked and referred to CARACAL. Further advocacy material will be prepared and posted for the Commission Inter-service and WTO consultation and the next call will take place on 7 September (more information: Brigitte Amoruso, Ruth Danzeisen, Paul Marsh, Jenny Poulter, Hugo Waeterschoot and Violaine Verougstraete).

Classification Mapping Tool: *to be released in September!*

The classification of substances under CLP and in the REACH dossiers can be subject to revision, following proposals for harmonised classification, as outcome of substance evaluations and following the publication of new data. The impacts for the industry of classifications of substances and mixtures are not limited to the requirements referred to in the CLP Regulation (i.e. SDS and labelling). Classifications also have direct and indirect repercussions throughout a broad range of legislations, along the lifecycle of a substance or mixture. During the past months a Eurometaux Taskforce, in cooperation with the consultant Regulatory Compliance Ltd, has worked to develop a "Classification Mapping" tool to facilitate the identification of the links between hazardous classifications, legislative provisions and potential impacts on industry. Such a tool would help companies and associations to evaluate the implications of current, as well as potential future (re)classifications. The work is almost completed; a final review of the tool is currently ongoing. The official release is expected in September. This has been a very good learning exercise and an internal discussion is foreseen in September to share experiences gained during the project and to explore possible way forwards (more information: Lorenzo Zullo).

Metal-specific REACH application tools and concepts

Bioelution: *ECVAM questions*

Work is ongoing on the questions posed by ECVAM in the context of the validation of the gastric test protocol. Among others, ECVAM identified some aspects in the protocol where there was still a too high degree of freedom and that may cause variability between the results and the test labs. This very relative flexibility had been built in our submission that was delivered in February, to consider the differences in approaches and habits of the labs who have generated results for our sector over the last years but it is clear that the SOP that will be issued at the end of this validation step will be even more precise. Ensuring that the labs take over the final SOP will be key to have results accepted by authorities. This will be further discussed at the bioelution workshop on 10 August (more information: Adriana Oller and Violaine Verougstraete).

CLP-GHS: Rapid Removal-communication within the metals sector and start of the outreach

Industry, with the help of ETAP, developed an alternative tool based on the Transformation Dissolution protocol to assess the Rapid Removal potential of metals to achieve a level-playing field for environmental classification with organics chemicals. The review of the proposals made by industry and the development of specific guidance is now included formally under the MISA programme for 2019. This will subsequently require validation and follow-up at OECD/UN level before it could be formally implemented in the legal texts/guidance of CLP and GHS. Industry therefore created an awareness group at ICMM level to raise international industry awareness and support for advocacy activity at that level. With this aim in mind, an awareness briefing paper was drafted by ICMM/ICA and reviewed by Eurometaux. In addition, we have started with the first of a series of support building contacts with authorities (ENV. Canada) given the OECD requires multiregional support to change existing guidance. Further contacts with EU authorities will also be launched but only after the lead metal environmental classification has been finished.

Metals and Inorganics Sectorial Approach

MISA SAT-HH: self-assessment tool, workplan template and follow-up letter to inorganic sectors

The first MISA thematic workshop will take place on 2 October in Brussels and focus on information requirements for human health, adaptations, waiving, read-across and weight-of-evidence. During the workshop, MISA consortia (including their consultants) and ECHA will exchange on the interpretation / applicability of adaptation arguments (including waiving, read-across and weight-of-evidence), learn from comparing adaptation motivations and agree on the generic elements to include in the dossiers. To facilitate the preparation of the workshop, a "self-assessment template tool" has been prepared and circulated to the REACH Forum members. This tool is composed of a list of questions/tick-boxes that focus on reproductive toxicity, repeated dose toxicity and mutagenicity. Completing it should help the consortia to have a good overview of their dossiers for these endpoints, the adaptations used and how read-across has been used. It has also been asked to consortia to share a completed version with Eurometaux before 25 August, so that Eurometaux can extract the key learning lessons and questions posed (anonymised) to prepare the workshop with ECHA on 30-31 August. ECHA will prepare the workshop by providing 'best practices' or less good cases with regard to acceptance so that a good understanding can be reached on 2 October. Also, still in preparation for the MISA participants, is a "consortium workplan template", which can be used by participating consortia to exchange bilaterally with ECHA e.g. after a workshop to indicate how and when they will update their dossiers. The template will be circulated soon for comments and finalisation. Please also allow us to remind you that participants to MISA should communicate the list of substances they want to include under the programme by 25 August. A 'signature round' will be organised in September (modalities will be communicated soon). Finally, ECHA and Eurometaux have sent a letter to the REACH Alliance and other associations involved with metals/inorganics to invite them to participate in MISA. Their response is also expected by the end of August (more information: Guy Thiran, Hugo Waeterschoot and Violaine Verougstraete).

FURTHER OUTREACH OF REACH

Upcoming conferences: Eurometaux, EPMF, NI and ARCHE provide active input and training at the Bratislava REACH conference (September 3-4)

The metals sector will be participating actively to the REACH Conference in Bratislava given it is a quite unique non-commercial event supported by REACH MSCA authorities from Visegrad countries. Besides raising the agenda and concerns of the metals sector and metal specific aspects we aim for contacts with local authorities (given often supportive for industry views on REACH Risk Management aspects) and industry sectors. The metals contribution covers the requirements after the REACH registration deadline, the supply chain communication aspects, MISA and the link with the circular economy. The day after the conference Eurometaux and Arche will provide a training session for DU sectors on how to comply with the next step of their supply chain obligations now the latest registration deadline is past. This includes hand-on attention for tools like the scaling tool, SPERCS, MEASE and MeClas. Anybody interested in the conference can find the programme on <https://reachconference.eu/en/conference/> and Consortia are encouraged to raise the attention in particular of their members in these countries (more information: France Capon and Hugo Waeterschoot).

COMMUNICATION

Others

Save the date for the EHS Autumn Week at the Metals Conference Centre!

The meetings are expected to be organized as follows:

- Monday 24 September: Industrial Emissions Taskforce (starting with lunch at noon)
- Tuesday 25 September: Water Taskforce (including a workshop on the WFD REFIT)
- Wednesday 26 September: Risk Assessment and Classification Taskforce (including a MeClas training)
- Thursday 27 September: Risk Assessment and Classification Taskforce

Without forgetting an unforgettable social event ☺ on the Wednesday evening (more information: Sofiana Dokou).

CALENDAR

- 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)
- 24-27 September: EHS Autumn Week – 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	MSCA: Member States Competent Authorities
ART: Advanced REACH Tool	OECD: Organisation of Economic Cooperation and Development
BREF: Best available technology Reference document	PSLT: Poorly-Soluble Low Toxicity
CARACAL: Competent Authorities for REACH and CLP	RAC: Risk Assessment Committee
CLP: Classification, Labelling and Packaging Regulation	REFIT: Regulatory Fitness & Performance Programme (EU)
DNEL: Derived No Effect Level	RIVM: National Institute of Public Health and the Environment (The Netherlands)
DU: Downstream User	RMOA: Risk Management Option Analysis
EC (number): European Commission (number)	SAT-HH: Self-Assessment Template Tool – Human Health
ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals	SCL: Specific Concentration Limit

ECVAM: European Centre for the Validation of Alternative Testing Methods	SDS: Safety Data Sheet
ENES: Exchange Network on Exposure Scenarios	SEA: Socio-Economic Analysis
EPG: Expert Partner Group	SOP: Standard Operating Procedure
ETAP: Environment Toxicity Advisory Panel	SPERC: Specific Environmental Release Category
GCL: Generic Concentration Limit	SVHC: Substance of very High Concern
GHS: Global Harmonised System of classification and labelling of chemicals	T/Dp: Transformation/Dissolution protocol
HAZBREF: Hazardous industrial chemicals in the IED BREFs	TRA: Targeted Risk Assessment (tool)
IED: Industrial Emission Directive	UN: United Nations
MEASE: Occupational Exposure Assessment Tool for REACH	WFD: Water Framework Directive
MeClas: Metals Classification Tool	WFO: World Health Organisation
MISA: Metals & Inorganics Sectorial Approach	WTO: World Trade Organization

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