



EUROMETAUX REACH PROGRAMME

Dear REACH Forum member,

Last September, in those lines, I was contemplating what the key elements of a good (advocacy) story would be, observing my son's involvement in a Ken Follet book. Providing the reader with a good plot, properly structured and coherent, allowing him to be –sequentially- first intrigued, then knowledgeable and finally concerned seemed to be the secret. Now that the final decision on the Pb SCL is rapidly approaching, I wonder what the last pages of this long story will look like: a new twist in the plot, a call for a new book or only a couple of exhausted and frustrating last lines. After more than 2 years, clearly, the story tellers -on all sides- are tired. We have had it “all”: emotions in abundance, characters popping up or disappearing unexpectedly, lengthy chapters putting us off abruptly followed by a ‘crisis’ requiring night shifts, and a plot becoming more and more complex while the messages had to be simplified. And in addition, this book could not be put in a drawer for a single moment, which says a lot about the relevance of the story and the commitment of the Pb SCL taskforce.

Today, a Sun-day, I would like to be –for an instant- the author of the last pages, to be able to promise a ‘happy end’ to reward the arduous narration. But the pen is not ours. It seems evident that we will not all be happily walking into the sunset, while whistling “always look at the bright side of regulatory life”. In the best scenario, this end will look like a compromise, addressing part of the impacts we have identified, leaving others struggling with the full consequences. We can only hope that the “sacrifices to the compromise” will be as minimal as possible and try to find some way to make the conclusion bearable for all of us. And there we are: even if the authorities feel they bring the story to a close next Thursday, our writing is not over. “A classic is a book that has never finished saying what it has to say” (Italo Calvino).

Violaine Verougstraete, EHS director Eurometaux

ECHA REACH activities: hot topics

ECHA MEETINGS

MSC-40: CoRAP approval and further discussions on 6th priority list and first insight on 7th list

Eurometaux prepared for the debate in MSC-40 on the prioritisation scoring overview and selection proposals for the 7th priority list. ECHA however slowed down the process probably waiting for the outcome of the ECHA-Commission AFA streamlining reflection. ECHA has announced recently that they will allow industry to further update their registration files until the 1st of April and requested specific attention for detailed information demonstrating intermediate status as well as exemptions. Eurometaux immediately informed the concerned metal sectors of this opportunity. It is however expected that ECHA will present the new scoring list during MSC-40 (without proposing substances). The MSC-review on the 6th list is running in parallel with this. It is expected that the MSC debate on the extensive comments received during Public Consultation will reveal an indication on what substances may be selected. Metal Consortia and Eurometaux insisted on a change in view on Borates and Pb-compounds given listing them for authorisation would not provide benefits and would hamper industry. Finally it is expected that MSC will vote unanimously on the CoRAP 2015-2017 update including ZnOx amongst some Sn and Al compounds (more information: Hugo Waeterschoot).

MSC-40: changes to TPs and DE processes tabled: Eurometaux and ORO wrote a letter to raise concerns

Industry was lately informed about a series of smaller process changes in the MSC and ECHA reviews of Testing Proposals (TPs) and Dossier Evaluations (DE). ECHA would standardize the response time to update the Registration file in case of a Draft Decision (DD) on a TP to 60 days (after informing the lead registrant and with exception of complex cases), while this

option would be eliminated for Compliance Check updates. In parallel ECHA would publish “a pre-information list of substances ECHA would potentially conduct a CC on”. The change on the TP and the publication of the list are welcomed as those will increase transparency, predictability and the potential for anticipation and input by industry. However, Eurometaux and the Organisation of Only Representatives (ORO) challenge the deletion of the potential to update the registration file after a DD on a Compliance Check has been received. This process change, contrary to what is seen for TPs, would decrease industry’s potential to react. Eurometaux and ORO wrote a letter to the ECHA Director of Evaluation asking her to redraw this last change and complained on the retroactive introduction of these changes without any pre-consultation with industry. Both sectors also prepared an intervention at MSC on this issue (more information: Kate Belska, Noömi Lombaert and Hugo Waeterschoot).

AUTHORISATION

Preparation of ECHA-Commission workshop on Applications for Authorisations: *a significant metal industry contribution*

ECHA and Commission, supported by industry, will organise a workshop on 10 -11 February on “experience and future needs on Applications for Authorisations” (AfAs). As the preparation and processing of AfAs has now become somewhat routine in certain industry sectors and in RAC and SEAC, it will allow looking back on what worked or not. This first session will be complemented by “a forward looking” session on how AfAs can be improved and which needs require solutions. France Capon (from EPMF) was selected as one of the 2 key industry presenters of this session that will be co-chaired by Jack De Bruijn (ECHA) and Hugo Waeterschoot. Aggie Kotze will co-present a poster session on RMM experience. The metals sector has also prepared a Survey-monkey questionnaire for the industry participants to summarize experience and suggestions for improving the relevancy of AfAs. The recent authorisation experience review and the identification of points for improvement by Eurometaux’ Authorisation and Restriction Platform were most helpful to prepare the metals sectors input for this workshop. The workshop will end with an “after meeting session” where industry participants can collectively define learning lessons and needs for advocacy (more information: Aggie Kotze, France Capon and Hugo Waeterschoot).

Streamlining the Authorisation process: *mixed feelings*

It is expected that both ECHA and the Commission will, at the 10-11 February workshop, shed more light on their planning for streamlining the Authorisation Application process. Aspects like lighter conditions for “small volume uses” and “spare parts” are known to be on the table but industry has also raised needs on “bio-essential” applications and recycling to avoid too significant impacts on the sectors. Alternatively Eurometaux remains very sceptic and careful in promoting the “streamlining suggestions” given most of the substances it aims at should not have been on Annex XIV, as exposure is limited to the workplace. The main focus should be on the relevance of the assessment of substances that would enter Annex XIV. There are more relevant RMM solutions than authorisation for substances with bio-essential uses and with exposure limited to the workplace only, and Eurometaux fears the programme will lower the barrier for such substances. This does not mean that the spare parts issue should not be resolved under the programme: a solution is needed for chromates and probably others in the future (more information: France Capon, Aggie Kotze and Hugo Waeterschoot).

ECHA OTHERS

Assessment entity: *a workshop co-organised by ECHA, Cefic and EM at the metals conference centre on 10 March*

Over the last months, ECHA and industry have been reflecting on how to facilitate the reporting of information for complex assessment cases (e.g. where the registered substance chemically transforms during the use or in the environment or where the registered substance is of complex composition and the various (group of) constituents behave differently). The working title for this work is “assessment entity” and the concept was worked out by ECHA on the basis of real cases. The 10 March workshop aims at communicating the outcomes of this work, in an interactive, capacity-building way. It will start with a presentation of the concept and how it could be articulated in IUCLID, illustrated with cases, followed by a Q&A session (more information: Violaine Verougstraete).

ECHA/EFSA Topical Scientific Workshop on Soil Risk Assessment

ECHA has launched the preparation of their next Topical Scientific workshop, which will focus on Soil Risk Assessment, and take place on 7-8 October. A scientific committee has been set up to define the scope and concept of the workshop. We are very proud to announce that Ilse Schoeters has been invited to join the scientific committee (more information: Ilse Schoeters and Violaine Verougstraete).

Commission REACH activities: hot topics/issues

REACH impact on innovation and competitiveness: *an opportunity to demonstrate impact due to RMM to support REFIT and the REACH review process*

A consultancy team consisting of CSES, RPA and Ökopol has been appointed by the European Commission to conduct a study to evaluate the changes in the operational conditions and the structure of the chemicals industry and downstream industries, after the introduction of the REACH Regulation, focusing on the period 2010 - 2013. While comparable business impact studies have already been carried out in the past, this one requires more attention from industry and in particular from the metals sector. Indeed, the impact assessment will zoom in on the consequences of Risk Management Measures such as authorisation, restriction and probably others. Moreover, the Commission indicated that the outcome of this study would be instrumental for the Authorisation streamlining process. The outcomes of this study will also be used for the REACH Review to be started in 2017. At the methodology validation workshop held mid-January, industry expressed its surprise about the tight timeline to carry out the different work packs (a report should become available by May) while outcomes are expected to be used in the medium or longer term. The restricted deadlines would however allow Commission to use the outcomes for the REFIT project, which requested having a look at the efficiency of the impact of Authorisation on industry. Eurometaux and Eurofer therefore provided extensive comments to the consultancy groups, requesting that the scope, aims and questions posed would allow assessing the impact of RMMs. Eurometaux will inform the members as soon as receiving the background package, with an encouragement to participate actively (more information: Hugo Waeterschoot).

EUROMETAUX REACH activities: hot topics/issues

CLASSIFICATION

Pb metal classification and SCL: *the last final stretch*

On 5 February, the REACH Committee will conclude its discussions on the 7th ATP, which includes the proposed classification and associated SCL for Pb metal. An updated advocacy package was prepared to respond to the note recently issued by the Commission, which proposes a way forward mainly based on CLP article 12(b)). While the note demonstrates that the Commission is taking seriously the impacts Member States and industry have identified; the proposed solution still raises questions with regard to its applicability and consistency. The members of the Pb SCL taskforce are currently contacting the supportive Member States to ask for either the removal from the metallic lead and the associated SCL from the 7th ATP for the time being or alternatively for the removal of the 7th ATP entry for Pb in massive form (>1mm), or a higher SCL for massive Pb that would reflect its lower bioavailability, or a footnote to be added to the Annex VI entry to allow use of relative bioavailability (bioelution-based) for classification of substances/mixtures containing Pb. The outcomes of the REACH Committee will be communicated as soon as made available (more information: Steve Binks, Hugo Waeterschoot and Violaine Verougstraete).

Bioelution: *discussion with BAUA, call with ECVAM, interest from Chile*

A joint, streamlined industry view on how to generate and interpret bioelution results is not only a key requirement for the Pb SCL discussion but also for the forthcoming CLP/GHS mixtures deadlines. A Guidance Note, reviewed by authorities, at international or EU level, would be the most efficient tool to ensure this consistency. Eurometaux and commodities have contacted several OECD Countries and ECVAM/JRC over the last two years to request them to bring the concept to the OECD Testing Guidelines programme. Recent developments include a useful technical discussion with the German BfR (kindly set up by the WVM), a call with ECVAM and contacts with Chile and Australia. The exchanges have pointed to the need to develop a note with a more limited but well defined scope and use, as a first step. The exact scope will be clearer once a decision has been taken on the Pb metal SCL issue as in all scenarios, the acceptance of bioelution and some guidance on bioavailability will have to be developed (more information: Adriana Oller and Violaine Verougstraete).

Planning follow-up steps for the Cu compounds environmental classification proposed by RAC: *a challenge to convince the Commission on the overly precautionary assessment conducted by RA*

Eurometaux provided support to the Cu sector in the planning of possible actions towards ECHA and Commission in follow-up of the recent RAC review on Cu compounds. Eurometaux's focus is mainly on the overly precautionary assessment conducted for a data rich substance, which sets a dangerous precedent. Actions included a careful review and response to the RAC draft minutes that were somewhat deficient in critical aspects of the debate. In parallel Eurometaux is trying to convince the OECD to include the development of criteria on the "removal of the water column", allowing to improve metals fate assessment schemes used for both risk and hazard assessment. Finally, Eurometaux is actively reflecting on how to ensure that future

RAC debates on metal environmental reviews would be followed and understood by more RAC members and be of a higher quality (more information: Hugo Waeterschoot and Katrien Delbeke).

AUTHORISATION

Participation in Cefic's Authorisation Seminar: *Eurometaux presented the A&R platform's view on the need for more emphasis on RMO to prevent Authorisation when not effective*

On 13 January, Cefic organised a seminar on Authorisation experience and invited Eurometaux as well as the two co-chairs of the A&R platform to contribute to the debate on Authorisation experience. Eurometaux's presentation focussed on the need for more emphasis from both authorities and industry for the RMO assessment upfront the RMM selection, convinced that this is the only relevant way to ensure RMMs are actually needed and effective once implemented. The Eurometaux activity on the RMO template was presented as well as the request to industry to be more pro-active in gathering RMO relevant information for all potential SVHC substances. Cefic members were aligned on this policy recommendation and it was proposed to consider organising a combined training on the RMO Template for industry later this year. The breakouts organised by Cefic on the different steps of the authorisation prioritisation and application provided quite interesting input for Eurometaux's A&R platform (more information: Hugo Waeterschoot, Aggie Kotze and France Capon)

Authorisation vs. OELs: *cross-industry initiative to solicit support from Commissioners*

The Nickel Institute took the lead in an initiative to convince high level EU executives (Commissioners level) for a broader view on the selection of the most appropriate RMM. Indeed, despite authorities' theoretical recognition that the best regulatory option to manage identified risks can be identified in other regulations than REACH, at this stage RMOs within REACH (in particular authorisation) seem to be clearly preferred by REACH authorities. For substances handled exclusively in the workplace, alternative OEL based approaches could be more effective and relevant but need support and recognition by the different DGs (ENV-GROW-EMPLOY), hence raising awareness with the Commissioners. In support of this appreciated initiative Eurometaux organised a conference call to help ensure the input of the Consortia members to align to this activity. Members reacted and contributed actively. The initiative is expected to result in a co-signed meeting requests to the different Commissioners involved (more information: Kai-Sebastian Melzer, France Capon, Aggie Kotze and Hugo Waeterschoot).

Authorisation and Restriction Platform projects: *extensive input received on all 3 projects and meeting with ECHA scheduled*

Members were asked to provide input on each of the 3 projects of the A&R platform, namely *the thought starter on an alternative RMM strategy, the waste/recycling and authorisation note and the RMO template and pilot case development*. Lots of valuable inputs were received allowing Eurometaux to update each of those notes in the weeks to come. Eurometaux very much appreciates the support of the Cobalt consortium to develop a pilot case on the RMO template as well as the sector reviews of potential recycling streams that could be hampered by authorisations in the future. The latter indicated that certain sectors can be vulnerable as the recycling material contains potential SVHC metals acquiring a function when reused. Alternatively, other sectors seem to be struggling to conduct this impact review. The overall input provides a valuable contribution in preparation for the scheduled informal exchange with ECHA's directorate on Risk Management planned for 11 February afternoon (more information: Michel Vander Straeten, Hugo Waeterschoot, Aggie Kotze and France Capon).

OTHERS

Re-launch KnowMe database

The KnowMe database has been set up to ensure transfer of knowledge and regular update on decisions rationales and discussions ongoing at ECHA Committees. All lessons learnt are stored and shared according to levels with increasing details in an excel file, so that consortia can select the level of information that best suits their needs. Each and every entry in the database is categorized by relevance for consortia: relevance is flagged using colour codes in order to clarify the scope of the information given (i.e. red: alert; orange: warning; yellow: for restricted number of users; green: for limited restricted number of users). Based on these colour codes, the user can quickly identify key or critical communication and decide whether to address only the main topics or dive into technical issues. The database will finally be published on the REACH Metals Gateway by Easter 2015, together with its Manual of Use (more information: Federica Iaccino).

EXPOSURE SCENARIOS

Participation in Cefic call on volume tracking: *same objectives but some sector specificities*

Eurometaux has been invited by Cefic to comment on a proposal to be submitted to ECHA, and which is suggesting alternative indicators to the volume/use information to be included in IUCLID 6. While both sectors aim at improving the overall prioritisation system (for Evaluation and/or Risk Management) by providing relevant information, there are some differences in the proposed approaches metals and organics are promoting, linked for example to data availability, structure of the supply chain or metal specific aspects (physical form and impact on release). The topic will be further discussed in the context of the CSR/ES roadmap coordination group activities, as the development of methods for registrants to estimate substance volumes supplied in the different uses of a substance (in order to support the environmental part of the chemical safety assessment under REACH) is one of the actions of the Roadmap (action 2.6) (more information: Violaine Verougstraete).

Interaction with the ESCOM group on the metals standard phrases catalogue: *metals phrases available*

EBRC has developed a list of standard phrases that are felt to be missing in the current ESCOM catalogue to cover the metals Exposure Scenarios. Those phrases also cover the MEASE exposure determinants. The list has been circulated for review within the Exposure Scenarios Taskforce and a discussion has been initiated with the Cefic ESCOM project to assess if and how the "metal standard phrases" could be integrated in the ESCOM (more information: Daniel Vetter and Violaine Verougstraete).

METAL-SPECIFIC REACH APPLICATION TOOLS AND CONCEPTS

Joint industry meeting on alloys classification and bioelution: *Exchanges on alloys classification and bioelution*

Eurometaux participated in a meeting set up by Euroalliages, aiming at exchanging on the available approaches to classify alloys and at discussing action steps of common interest regarding the international regulatory acceptance of bioelution tests. The meeting was a good opportunity to clarify the status of the HERAG and MERAG alloys fact sheets. Both fact sheets are currently under finalization and should be published in March. It is proposed to have an alloys' classification training on April 14 at the Metals Conference Centre. The group further agreed on aligning actions with regard to bioelution, first targeting the acceptance of the concept before the reproducibility of a specific protocol (more information: Nadia Vinck and Violaine Verougstraete).

COMMUNICATION ACTIVITIES

Participation in NI RMOA workshop: *interesting information on REACH, ES and OELs*

On 29 January the Nickel Institute has organised a workshop for their members and nickel compounds downstream users to discuss the RMOAs and the general topic that arises from them, i.e. OELs as alternative to REACH authorisation. Eurometaux was invited to give a presentation on REACH Authorisation vs. OELs – a topic of cross-industry relevance. This was also the opportunity to present the proposed RMM strategy. The workshop included excellent and informative presentations on e.g. the draft conclusions of the French RMOA, the OEL setting process, and the ongoing/planned work on Exposure Scenarios (more information: Kai-Sebastian Melzer, Irene Cañas Sierra and Violaine Verougstraete).

Further outreach of REACH

OECD

Discussion with OECD on next steps for the environmental risk assessment guidance on metals and fate modelling

Eurometaux and ICM met Joop de Knecht (OECD) on 22 January to discuss possible 2015 activities including the progression of MERAG update and translation into OECD guidance, and inform him on possibilities for involvement of OECD in the APEC activity. A number of actions were agreed on comprising e.g. the sending of the finalized MERAG fact sheets in February to OECD along with a table of contents for the proposed OECD guidance. The draft guidance for block 1 (data handling and bioavailability correction) should be circulated to the OECD Taskforce on Hazard Assessment in May and be discussed from June onwards. It is proposed to hold a workshop in Q3 2015 to discuss the main comments. This workshop may be held back-to-back with a meeting on fate for ionics aiming at discussing the principles, where do we have guidance and models (like the UWM) and what weight of evidence approaches are needed? (more information: Hugo Waeterschoot, Ben Davies and Violaine Verougstraete).

Webinar REACH CLP NAMC

Early January Hugo Waeterschoot participated in a well-attended webinar for the North American Metal Council and made a presentation highlighting the main challenges and concerns of the metal sector in respect to the implementation of REACH and CLP/GHS. He also referred to some critical OECD programmes and initiatives of the metals sector at international level (e.g. MERAG update). NAMC members showed interest in MECLAS and NAMC will explore if the OECD metals environmental guidance initiative could be supported by the North-American countries. The presentation was not circulated to the Consortia given this was a private initiative organised beyond the Eurometaux REACH Forum but can be obtained on simple request (more information: Hugo Waeterschoot).

Participation in ICMM CMWG: Eurometaux's input focused on UWM and MERAG update

Eurometaux attended part of the ICMM semestrial CMWG meeting where companies and associations discuss activity on international chemicals management. Eurometaux's contributions focused on presenting a way forward on how to take the UWM metals fate model and "metals removal of the water column" concept forward to the OECD. Eurometaux also co-chaired the session on the MERAG fact sheet review process. The comments received from the peer reviewers (country inputs, individual researchers and ETAP members) were extensive but constructive and useful. These comments helped to better define the scope and demonstrated the need to further explain some of the metal specific risk assessment concepts. ARCHE will now focus first on updating the fact sheets for the first OECD TFHA review block, those on data quality and relevancy as well as on bioavailability corrections for the 3 relevant compartments (more information: Marnix Vangheluwe and Hugo Waeterschoot).

Calendar 2015

- **2-5 February:** MSC-40: way forward with 6th authorisation list, adoption of CoRAP update,... – ECHA (Helsinki)
 - **10-11 February:** ECHA-Commission-Industry Workshop on Streamlining and Simplifying Authorisations (Helsinki)
 - **11 February pm:** informal meeting with ECHA on Eurometaux's RMM projects
 - **18 February:** Authorisation & Restriction Platform – MCC (Brussels)
 - **2-6 March:** RAC 32a – ECHA (Helsinki)
 - **9-13 March:** SEAC 26 – ECHA (Helsinki)
 - **10 March:** assessment entity workshop-MCC (Brussels)
 - **10-13 March:** RAC 32b – ECHA (Helsinki)
 - **17 March:** REACH Forum – MCC (Brussels)
 - **20-24 April:** MSC-41 – ECHA (Helsinki)
 - **26 May:** Evaluation Platform – MCC (Brussels)
 - **27 May:** Authorisation & Restriction Platform – MCC (Brussels)
 - **1-5 June:** RAC 33 – ECHA (Helsinki)
 - **8-12 June:** MSC-42 – ECHA (Helsinki)
 - **8-12 June:** SEAC 27 – ECHA (Helsinki)
 - **3 September:** Authorisation & Restriction Platform – MCC (Brussels)
 - **7-11 September:** RAC 34 – ECHA (Helsinki)
 - **7-11 September:** SEAC 28 – ECHA (Helsinki)
 - **14-18 September:** MSC-43 – ECHA (Helsinki)
 - **23 September:** REACH Forum – MCC (Brussels)
 - **7-8 October:** ECHA/EFSA Topical Scientific Workshop on Soil Risk Assessment – ECHA (Helsinki)
 - **26-30 October:** MSC-44 – ECHA (Helsinki)
 - **23-27 November:** RAC 35a – ECHA (Helsinki)
 - **30 November – 4 December:** RAC 35b – ECHA (Helsinki)
 - **30 November – 4 December:** SEAC 29 – ECHA (Helsinki)
 - **7-11 December:** MSC-45 – ECHA (Helsinki)
 - **15 December:** Evaluation Platform – MCC (Brussels)
 - **16 December:** Authorisation & Restriction Platform – MCC (Brussels)
 - **17 December:** REACH Forum – MCC (Brussels)
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Acronyms

ATP: Adaptation to Technical Progress	HERAG: Health Risk Assessment Guidance for metals
A&R: Authorisation and Restriction	IUCLID: International Uniform Chemicals Information Database
AfA: Application for Authorisation	ICMM: International Council on Mining and Metals
APEC: Asia-Pacific Economic Cooperation	JRC: Joint Research Centre
ARCHE: Assessing Risk of Chemicals http://www.arche-consulting.be/	KnowMe: Knowledge on Metals database
BAUA: Federal Institute for Occupational Safety and Health (Germany)	MEASE: Occupational Exposure Assessment Tool for REACH
BfR: Bundesinstitut für Risikobewertung	MERAG: Metals Environmental Risk Assessment Guide
CC: Compliance Check	MSC: ECHA Member States Committee
CEFIC: European Chemical Industry Council	NAMC: North American Metals Council
CLP: Classification Labelling and Packaging Regulation (EU)	OECD: Organisation of Economic Cooperation and Development
CMWG: Chemicals Management Working Group	OEL: Occupational Exposure Limits
CSES: The Centre for Strategy and Evaluation Services	ORO: Organisation of Only Registrants
CSR: Chemical Safety Report	Pb SCL: Lead Specific Concentration Limit
CoRAP: Community Action Rolling Plan	REACH: Registration, Evaluation, Authorisation and Restrictions of Chemicals
DD: Draft Decisions	RA: Risk Assessment
DE: Dossier Evaluation	RAC: ECHA Risk Assessment Committee
DG ENV : Directorate-General Environment (within the EU Commission)	REFIT: Commission's Regulatory Fitness and Performance programme
DG GROW: DG ENT	RMM: Risk Management Measures
DG EMPLOY: Directorate-General Employment, Social Affairs and Inclusion	RMOA: Risk Management Options Analysis
DG SANCO: Directorate-General for Health and Consumers (within the EU Commission)	RMO: Risk Management Options
EBRC: consultancy http://www.ebrc.de/index.php	RPA: Risk and Policy Analysts Ltd.
ECHA: European Chemicals Agency (REACH)	SEAC: ECHA Socio-Economic Committee
ECVAM: European Centre for the Validation of Alternative Testing Methods	SVHC: Substance of Very High Concern
EPMF: European Precious Metals Federation	TP: Testing Proposal
ES: Exposure Scenarios	TFHA: Task Force on Hazard Assessment (OECD)
ETAP: Environment Toxicity Advisory Panel (Industry sponsored science panel)	UWM: Unit World Model
GHS: Globally Harmonized System of Classification and Labelling of Chemicals	WVM: Wirtschaftsvereinigung Metalle