Workshop ECHA
Metals-exposure related issues
July 2, 2010
Draft report

Participants: The workshop was attended by close to 20 ECHA participants, Kristina Saarinen (SYKE) and 12 industry representatives/consultants.

Welcome words by Peter Lepper (ECHA).

Introduction:

The chair (Hugo Waeterschoot, Eurometaux) welcomed the participants and explained the objectives of the workshop, namely an exchange of thoughts on several projects using new scientific/technical multi-metallic data sets, risk assessment and processes recently developed by industry scientists and REACH managers to promote and facilitate high quality registrations that might be of help for the evaluation phase of REACH. It is obvious that both ECHA and industry, want to promote the success of REACH. There are still, however, some outstanding scientific/technical issues specifically for the metals sector to resolve, new tools to be developed, etc. This workshop would therefore provide an opportunity to take stock of what is available and what is currently under development in this respect.

Presentation 1. Generic overview of the projects: why and how they fit together, planning and status (Violaine Verougstraete, Eurometaux)

In addition to metal-specific challenges (background, bioavailability, speciation…), metals are facing a number of generic challenges under REACH and CLP, like the need to

- **have good and representative data that can be used to assess exposure, hazard & risk**
- **allow adequacy between identified risk and its management**
- **have the appropriate methodologies & tools for assessing risk, hazard and implement the appropriate management**

The projects presented have been defined to address these challenges. Most projects build on experience in the ESR. The outcomes naturally need to be communicated and explained in order to make the best possible use of them. It was also stressed that those projects and tools can be applied as such to several metals, some other metals may have certain specificities which could mean that further development/ refinement of the generic metals approaches might be required, or in some cases a completely different approach could be needed altogether.
Some general timelines on the current status and further steps, of the various projects were also presented.

Presentation 2. Diffuse sources (Annick Van Hyfte, ARCADIS)

Key messages on diffuse sources can be summarised as follows:

- Emissions of diffuse sources can be important for metals and could potentially outweigh emissions from industry. It is therefore essential to develop a general overview of relevant contributing sources in order to put them into perspective.
- The relative importance of product releases versus point source emissions varies largely between metals and environmental compartments, and should be carefully considered
- Continental assessments are best estimated by carefully defining regional emissions, and subsequently the “drivers” behind them (e.g. release per km driven), so they can be used to define the continental release estimate

There are still some outstanding issues at present, however, which preclude good diffuse source analyses under REACH. These include:

- The EUSES model surface is still based on the EU 15 situation; consequently, emission and mass flow for the EU27 is applied to the EU15 surface (while the surface and populations have increased in the meantime)
- A reasonable representative EU region should represent 4-5% of the surface of the EU to fit in with the Regional model rather than the former 10%. This was illustrated by comparing the use of 10% versus specific datasets. In addition, the use of 5% of the surface was tested, and still appeared to be conservative

General recommendations resulting from the presentation included:

- A detailed investigation of the diffuse sources' contribution to regional emissions helps to put point source and product-related emissions into perspective, and sets forth a good basis for eventually required RMM's
- Continental emissions should be developed with good knowledge of regional emission drivers and how these may differ between countries
- The Netherlands fit in well with a defined region in EUSES, and thus remain an excellent reference country. This is important for the metals sector, being the best documented country for regional diffuse emissions into the EU
- The REACH EUSES model has not yet been adapted to the extended EU surface (from EU 15 to EU 27), and is therefore unnecessarily conservative
- It is recommended to adapt the parameters of the EUSES continental level assessment to the EU27 situation
- A reasonable representative EU region should rather represent 4 or 5% of the surface of the EU (comparable with 10% of EU15) to fit in with the Regional model definition
- Specific knowledge on translators/drivers/causes in respect of diffuse emissions is preferable to upscaling from Regional to Continental or vice versa, instead of the default 10% (5%) rule

Questions:

Q1 The transparency of the mentioned emission inventories and emission drivers should be documented in a transparent way. Indeed industry realises the importance of documenting the identified sources, and uncertainty analyses have been carried out to confirm relevance. The key message to industry is that the assessment should be documented in a transparent way, both on sources and drivers.

Q2 How can consistency of the exposure estimation approaches and of the assessments across industry be ensured? Some coordination work is already ongoing between Consortia, and industry realises the importance of drafting further guidance for metals in this respect. Working by tiers seems to be recommended: if data and specific tonnages are available, these will be used; otherwise, defaults could be used. Experiences with the different metals will be grouped in order to propose relevant default assumptions. It was noted that the OECD is also carrying out such coordination activity by preparing a compendium of approaches and default values. Within the metals sector, Eurometaux is coordinating the metals' analyses of diffuse sources.

Q3 Will registration by different legal entities lead to different diffuse registrations? For most metals, one CSA/CSR -with one set of ES- will be submitted per metal (compound). Metals in alloys are also covered by these dossiers. Local exposure information will be reported by company, but in a common CSR. This "unique dossier" will facilitate the transparency of the emissions reported. In addition, some metals are ready with their diffuse analysis, while others may include this in a future update, and others have no need to do so (low diffuse sources contribution). It is recognised that the diffuse sources analysis as proposed by the metals sector goes further than the strict legal requirements, but

it is welcomed by both ECHA and industry, since it helps to put point source results into perspective; the overall estimation is closer to the ecological reality; and it enables the most effective Risk Management Measures to be defined, if necessary.

The original purpose of the regional model was not to model specific countries. By "chance", at that time the outcomes of the exercise fitted in well with the NL, where there was already a EUSES version available. It seems somewhat trivial, however, to compare 10% rule emissions to real data. The idea was that the rule would be of application for a standard region for substances without data so as to have a reasonable worst-case estimation. The question arose as to how good the NL model was today, and whether datasets existed for other countries. The most important aspect is to identify "the emission driver", and use this to upscale to continental level. One important question regarding the regional defined driver is whether that use is comparable across the EU (e.g. when using African fertilisers vs. Russian fertilisers).

ECHA noted that there might indeed be a need to look into some of the parameters of EUSES, since these had not been corrected for in the CHESAR tool. Those present were curious to check if going from 10% to 5 % had a significant impact on risk. Emissions are reduced by 50%, which can be significant, especially for metals where, at local level, the RCR was already above 1, simply because of diffuse sources. It is essential for it to have an impact on how to handle and understand the data and the contributions of the different sources. In preparing the registration dossier, monitoring data and emission inventories are really used in order to understand contributions rather than to have a quantitative contribution

Conclusion: a good registration dossier could define the best RMM option on the basis of monitoring data and diffuse sources analyses.

Presentation 3a and 3b: GEMAS (Clemens Reimann, NGU and Koen Oorts, ARCHE)

The chair introduced the GEMAS project, noting that defining 'background concentrations' at an EU scale and at a high level of quality was a real challenge. GEMAS collected such evidence and even went a step further by assessing parameters for bioavailability at EU scale, too.

Clemens Reimann presented the history of the GEMAS project and the main outcomes. The key strengths of the GEMAS projects are definitely the large sampling size, the fact that all samples have been analysed in a single lab, the fact that more than 30 metals are included and the high quality control levels. Maps were presented, demonstrating this mapping at continental scale. It was also demonstrated that, when the number of samples increases, the resolution also increases but the general pattern remains. It is important to keep a balance between having a high resolution and maintaining a vision at continental level.

Furthermore, the project made it possible to have a very good understanding and robust dataset of the background metal concentrations and geo-referenced bioavailability indicators.

Questions
Q1: Terminology is an issue: e.g. how can "natural" and "anthropogenic" background be distinguished? Would it not be preferable to speak of ambient vs. natural backgrounds? Smelters' impact can only be seen at a very local scale. A certain amount of metal definitely comes from anthropogenic sources, but this is not notable at regional or continental level, even with this very advanced monitoring programme.

Koen's presentation illustrated what can be done with the GEMAS data under REACH, e.g. PEC, PNEC and RCR mapping in a geo-referenced way, statistically treating the evidence, etc. It is obvious that not all registrations may be as fully developed as the cases presented, but there is certainly potential for doing so in future. The presentation focused on risk characterisation for use at the regional scale

under REACH. However, the GEMAS data could be of interest for soil strategies and the framework directive.

The participants agreed that GEMAS is an impressive piece of work that advances regional assessments to a great extent.

It was further questioned if water surfaces were taken into account and whether, besides the maps shown, there were also maps including metal concentrations in waters, etc. that were considered..

There is a great difference in land use across the EU; it is thus difficult to extrapolate. However, datasets from other projects exist (e.g. FOREGS, groundwater, JRC, etc.) and could be combined with GEMAS to extend to other land uses.

To conclude, GEMAS generated extensive new high quality evidence which can be used to establish regional background and geo-referenced risk characterisations including bioavailability corrections at EU level and in a statistical way. GEMAS will also be very useful for other regulatory areas.

Presentation 4a and 4b: Bioavailability Screening Tools for Metals Aquatic Risk Assessment (Emily Rogevich, NiPERA and Koen Oorts, ARCHE)

The presentation of E. Rogevich aimed to provide an overview of where we are with regard to **aquatic bioavailability correction models** after the ESR risk assessments programme. Accounting for bioavailability is an important step in understanding effective risk at a specific operational site or region, and bioavailability models have been used to varying degrees in the RA running under the Existing Substances Regulation on Cu, Cd, Ni, and Zn. REACH guidance promotes the use of bioavailability correction for local and regional risk characterization when appropriate models are available.

Excel-based BLM models have been developed in order to practically implement bioavailability corrected PNECs for a series of metals. These Excel screening models do not replace the full BLMs, but are easier to handle and can be incorporated into data management tools. Their predictions are more conservative and based on information provided by routinely screened input parameters, and run normalisations for many input combinations: e.g. the water-screening model has been developed from more than 10,000 hypothetical combinations of water properties. The integrated Excel sheet model is of a precautionary nature in comparison with the full BLM model.

K. Oorts presented the **soil PNEC calculator tool**, stressing the importance of considering bioavailability for soil. The total metal concentration in soil is a poor predictor for toxicity and risk. Furthermore, there is no generally accepted method for directly measuring the bioavailable fraction in soil. In general two important aspects that influence bioavailability in soil should be considered, namely, the effects of soil properties and the effects of ageing and leaching
Regression models between metal toxicity and soil properties (pH, organic matter content, texture, CEC) and leaching/ageing factors were derived for a range of soils and several species (plants, invertebrates and micro-organisms) and for various metals (Cu, Ni, Zn, Co, Mo).

The Excel soil PNEC calculator takes all those bioavailability-influencing parameters into account, and was developed in collaboration with UK Environment. The model takes full consideration of all data and procedures of the EU RAR for Cd, Cu, Pb, Ni and Zn. It calculates PNEC values for generic scenarios, for a standard soil type or site-specific conditions, depending on the information available. The PNEC soil calculator can be downloaded from http://www.arche-consulting.be/Metal-CSA-toolbox/soil-pnec-calculator. It is important to note that both total and added approaches are included. When the PEC is known, the risk characterization ratio (RCR) and the potentially affected fraction (PAF) are calculated automatically.

A demonstration of the Excel tool revealed how GEMAS data provided site-specific PNEC data throughout Europe and by comparison with corresponding PEC also made it possible to define geo-referenced soil RCR's for agricultural and grazing land for the entire EU and beyond.

Both bioavailability correction models are certainly of broader relevance than REACH and can, for example, be used for the WFD or soil strategy policy. The tools are freely downloadable, and feedback is most welcome.

Questions
Q1: How is grain size taken into account and how it is determined whether it is correlated with toxicity? Grain size is, in fact, measured in the soil samples used, and is either directly (through %clay) or indirectly (through CEC) correlated with metal toxicity

Q2: what is meant by "local natural background concentration", and could this influence the RCR?. Natural background varies widely over Europe (sometimes to 2 orders of magnitude). In addition, it can contribute significantly to the risk. For example, for water, a risk for a Dutch river (the Geule river, high in natural Zn) was observed (RCR>1). Some Greek soils also showed an RCR>1 for Ni. In the case of the river, the explanation for the RCR was the ambient background due to old mining activities. In Greece, the reason was the natural occurrence of the metal. The local/regional ambient concentration identified by GEMAS helps to explain things. If you look at the GEMAS EU map of the RCR for Pb, a 'hot spot' is noted for Southern Spain. The question is, can this be explained by a local ambient concentration? An investigation confirmed that the source was historical mining activities. Exploring local/regional concentrations defined by GEMAS therefore help to assess relevance and apply appropriate management solutions, where relevant.



Presentation 5. MECLAS tool (Marnix Vangheluwe, ARCHE)

Moving from REACH to CLP and the notification deadline, the afternoon session addressed two methodological approaches/tools of relevance for the classification of metals and complex materials. In the metals/minerals industry, there are hundreds of complex materials (including ores and concentrates, intermediates and others) for which there are no full registration files but for which classification needs to be determined.

The classification of these materials is complex, since (1) the composition of these materials is often variable, (2) classification is often driven by impurities, (3) it requires reference toxicity values for other substances, and (4) additional aspects like speciation and mineral structure influence toxicity. MECLAS, a metals classification expert tool developed by the metals industry, provides a tiered approach for the classification of complex materials, starting from the worst-case classification based on the concentration of soluble components (Tier 0), moving to the following tiers according to additional knowledge available on speciation, TDp or bio-elution, or direct toxicity response of the mixture. The MECLAS tool integrates a quality check of the ecotox reference data included and

ensures the latter's confidentiality. It currently supports DSD and CLP-consistent classification, but this base model can be extended to integrate other aspects, such as regional GHS, downstream legislation, etc.
The MECLAS tool is web-based: www.meclas.eu; a first version will be available in mid-July. An online demonstration was given.

Presentation 6. The Ticket Unit World Model (Hugo Waeterschoot, Eurometaux)

The Ticket UWM developed by industry following the SETAC PBT Pelston Workshop (2002) provides a tool for regulatory support for REACH and CLP. Its history and its potential applications were presented. Focus was put on the use of the UWM for ***classification*** purposes, since the UWM can predict successfully the elimination from the water column of a whole series of metals, which is an important part of the chronic aquatic toxicity assessment. There is a clear need for the model, given the fact that the chronic cut off limits are different depending whether the substances are non-rapidly degradable substances or rapidly degradable. The rapid degradation can be demonstrated by elimination from the water column (70 % in 28 d's), and net binding to the sediment fraction can be proven. Elimination studies and data proving the binding to AVS in sediments are key in this respect, and are all integrated in the UWM.
It was briefly explained how the model works. A user-friendly version has recently been made available and is freely downloadable from www.unitworldmodel.net. The use of standard conditions required for classification purposes is facilitated by defining the model parameters in accordance with the standard parameters for lakes in EUSES.
Examples of the application of the UWM –with regard to the removal from the water column- were provided.

Questions:
For classification, emphasis was placed on the need for consistency with the organics sector, as well as the need to well target applications in the current status of the UWM.
The UWM can be successfully used for hazard evaluation, as explained above. The model demonstrates removal from the water column. However, there was also a clear warning not to use it - at this stage- for risk assessment purposes or chronic applications such as PBT assessments.
Validation of the model was demonstrated; the publication of the results of the validation study and a detailed description of the model and its application were identified as being relevant in order to promote acceptance.
Further questions, e.g. relative to accounting for seasonality, or suspended particles, were put forward, indicating that the model should currently only be used for hazard ID - and definitely not for chronic risk assessment purposes. It has, however, been demonstrated that the existing model is more than sufficient for classification.

Conclusions

The workshop made it possible to exchange and discuss in a very constructive way a number of science issues on which the metals sector has been working over the past couple of years, in parallel with the implementation of REACH.
The metals risk assessments in the Existing Substances Regulation (ESR) context generated a great deal of data and raised generic questions requiring multi-metallic approaches or concepts (e.g. natural background throughout the EU, the contribution of diffuse sources, bioavailability correction, etc.). Over past two years, Industry had focused on developing science-based solutions for these fundamental questions, mainly using the experience of the metals review under the ESR and OECD SIDS system.

A wealth of information has now been developed - e.g. the diffuse sources and GEMAS projects - and is now made available through websites. The developed tools/methodologies (BLM screening tools)

allow for bioavailability correction at local, regional and continental level for the aquatic and soil compartments. The sediments compartment remains an area for further work.

Today's explanations also proved that including data on other relevant sources could sometimes increase the RCRs at regional scale. It brings the assessment closer to the ecological reality, however.

The metals sector has made the commitment to consistently work on these scientific aspects, striking a balance between assessment and management, pragmatism and methodological development, both on a short- and long-term basis.

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