Scientific seminar

Improving the Man via the Environmental Scenario for inorganics with emphasis on metals

Brussels, 26 January 2017, from 10h to 16h30
Metals Conference Centre
100, Rue du Duc -1150 Brussels, Belgium

Co-chaired by Eurometaux, RIVM and ECHA

Background:

The man via the environment (MvE) scenario of the EUSES model estimates the potential exposure to a chemical of the general population mainly exposed to it via food, air and drinking water, both at local and at regional scale. When EUSES was developed in the nineties, it was intended to be a first tier model that would be able to screen for potential risks under the Existing Substances Risk Assessment programme. The model was taken forward under REACH, with the warning that "*the assessment should be seen as a helpful tool for decision making but not as a prediction of the human exposure actually occurring at some place or time*."

Since then, the model has been widely used for "safe use demonstration" in registration REACH dossiers but also in Restriction proposals and Applications for Authorisation (AfA's), whereby, default release factors and tier I EUSES assumptions are often used for purposes that lie beyond screening. Where default release estimates and EUSES model parameters are not appropriately adjusted to reflect the actual exposure scenario, this may lead to uncertain and conservative exposure estimations, especially for metals. This 'conservatism' culminated in the man via the environment assessments of the chromates AFAs .. In some cases, health impacts on the general population in these applications (e.g. cancer burden), were calculated by the applicants to be comparable to or even larger than the impacts estimated for workers. The main reasons for this were the screening nature of the model, the absence of relevant datasets to overrule the defaults in the model, and typical parameters for metals not being considered appropriately.

This case as well as others demonstrated the need for identifying which parameters, modeling assumptions and parameters could be improved to increase the relevancy and scientific correctness of the MvE scenario for REACH registration, restriction and AfA purposes.

The metals sector as well as some regional authorities (e.g. Flanders) have extensive experience with higher tier MvE modelling and tiered data gathering. This experience may form a good starting point to improve the MvE modeling for metals and by analogy also for most inorganics.

Aims and Scope of the workshop

Contribute to the technical and scientific improvement of the quality and relevancy of MvE scenarios for metals for Registration, Restriction and AfA purposes, by defining the appropriate modelling parameters and tiered data levels

How?

The following key issues/questions may help to define an improved MvE assessment scheme for metals:

- How important is the conservatism introduced by the exposure estimates for the MvE scenario compared to other steps such as the estimation of the excess cancer risk?
- Which are the key modelling parameters requiring metal-specific approaches (e.g. air deposition models, soil ageing modeling, plant uptake modeling, bio-concentration in fish and cattle, dose estimation of the local population, …).
- How can we better identify/describe the importance of the regional and local background assessments
- Given metal exposures can be multiple including natural, would an "added risk approach" be relevant?
- Can we identify alternative exposure models (e.g. MERLIN EXPO), possibly to be tailored further for metal-specific needs?
- Do sensitivity assessments play a role in determining the need for model and data improvement.
- Which kind of data sets are relevant to improve the MvE assessment for metals? Can those be organised in tiers?
- Can we draw lessons from existing MvE experiences, from the chromates model estimates in the AfA to sophisticated field based cases?

Who should attend?

- Scientists involved in exposure measurements and modelling for "general population scenarios"
- Scientists and regulators involved in the review and assessment of MvE datasets/outcomes for Risk management purposes.
- REACH consortia scientific managers
- Consultants with experience in MvE assessments
- Regulatory authorities' representatives who use the outcome of MvE assessments for opinion or decision making

Practicalities:

- This scientific meeting will be co-chaired by RIVM, Eurometaux and ECHA
- The seminar will run under the Chatham house rule
- A meeting report will be made available aiming to summarize the scientific technical recommendations from the seminar. This could include suggestions for modeling improvements, tiered approaches assessment approaches and data needs as well as "good case examples"
- The seminar takes place at the MCC 100 Rue du Duc/Hertogstraat, Brussels close by Montgomery metro station on 26 January from 10h00 to 16h30
- Participation is free of costs. Please send your interest to participate to ehsassistant@eurometaux.be

Draft programme:

The program builds upon existing experiences to define potential areas and concrete suggestions for improvements.

Session 1: ***introduction: setting the scene***

- MvE assessment is used for different REACH purposes, Registration, Restrictions and AfAs.
  In the case of AfAs, the MvE's contribution seems often an important part of the health impact of metals when demonstrating safe use demonstration or performing socio-economic impact assessment? What are the "generic needs" (building blocks) for improvement? (Eurometaux, Hugo Waeterschoot)
- How were EUSES MvE's scenario built, what are the boundaries of the present model and what refinement needs were already identified? (RIVM, Joost Bakker)

Session 2: ***on existing experiences: from pure modeling with EUSES to refined and monitoring based assessments***

- The REACH guidance on MvE in short and a re-cap on the chromates, arsenic MvE modelling in existing AfA cases (Peter Simpson, ECHA)
- MvE scenarios in REACH registration files for metals (Frank Van Assche, IZA/Eurometaux)
- The Genk case: a site specific risk assessment on the impact of nickel and chromate compounds on the population surrounding a stainless steel smelter/recycler (tbc)

Session 3: ***Modelling aspects and key data sets that may improve the assessment in a tiered way***

- What key assumptions drive the technical assessment and can be improved through local/regional data gathering and the sensitivity assessment of key contributing parameters? (Eurometaux)
- Modelling ambient air concentration of metals at the local scale: tiered approaches and data requirements, (VITO)
- Plant uptake evidence experience and its impact on the overall intake (tbc)
- The role and relevance of diet study information in improving the human MvE exposure modelling (KUL, Erik Smolders)
- Alternative modelling options for integrated MvE exposure at the regional and local scale: development of a tiered approach for metals in the MERLIN-expo tool? (ARCHE, Frederik Verdonck + VITO, Katleen De Brouwere)

Discussion and way forward:

- Participants will be engaged in a discussion on:
  - What are the main data gaps to improve scientifically, for metals and inorganics?
  - What are the most relevant tiered data levels to improve the MvE assessment of metals?
  - What tiered modelling features could be improved and is MERLIN-expo a good tool for assessing MvE for metals?

Conclusions by the co-chairs