

# Requirements for exposure modelling in context of REACH

Workshop on “Theoretical Background and Application of Occupational Exposure Models”

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ECHA



Exposure models are used (in registration) to:

- **Generate risk management advice**, for all uses of the substance during its life cycle (including DU uses)
- The information on conditions of use (CoU) downstream available to the registrant is not as detailed as the information he can obtain for his own site(s)
- The advice generated is of a generic nature and requires confirmation from the DU, that still has obligations to perform a workplace risk assessment under OHS.
- Exposure models are a pragmatic solution for the registrant to determine his safe-use advice. The level of precision in the exposure estimate has only a limited impact on the right choice of measures.

- Refers to models/tools existing when REACH started.
- Updated if new relevant information is available. Relevant means: Impact on risk management and sufficient basis to achieve consensus among stakeholders.
- The last update (2016) took into account preliminary findings from studies on tool reliability (E-Team).
- It is consulted and agreed with:
  - Member states competent authorities
  - Industry representatives
  - EU Commission
  - Others (NGO, academia if relevant)

# Role of models in other processes

- In other process (i.e. authorisation) the outcome of the exposure assessment determines which uses of a substance can continue.
  - Normally the applicant has detailed information on CoU for the uses in he is applying for, and the CSR includes site-specific information
  - The estimates from models normally need to be confirmed with adequate measured data.
- For waiving toxicity studies, the CSR needs to demonstrate negligible exposure (with high reliability)

# Role of exposure modelling under OHS (i)

- The employer has the obligation of assess the risk to hazardous chemicals
- Often involves exposure estimation to compare with a reference value (e.g. OEL)
- Guidelines (e.g. EN 689) allow estimation of exposure by means other than measurements:
  - E.g. earlier measurements (or direct reading results)
  - Measurements of comparable processes or substances
  - Other calculations based on info (e.g quantities and ventilation)
  - Exposure modelling
- Determine whether exposure is above the OEL ( => RMM) or **well** below

# Role of exposure modelling under OHS (ii)

- Acceptance of modelled data may depend on
  - difference in approach between and within MS
  - hazard profiles of substances (e.g. CMRs may require measured data)
- Labour inspector survey 2018:
  - 18 of 20 MS: require quantitative assessment if national binding OEL exists
  - 9 of 20 MS: require quantitative assessment for CMR with no OEL/ reference value
  - 13/20 MS accept modelled data for quantitative assessment

# Generic requirements in regulatory context

- Transparency, in particular in terms of:
  - Applicability domain
  - Impact on exposure of the different input parameters
- Ideally allow to start with low level of sophistication.  
For REACH registration:
  - More exposure banding than precise exposure estimates
  - Differentiation in exposure should be proportionate with the differentiation in risk management.
  - For more hazardous substances more precise exposure estimates may be needed (Tier 2/ measurements )

## Issues to be solved

- Variety of tools available but missing framework on applicability of models
- Different status for the available tools in terms of ownership, maintenance and validation
- Different level of acceptance depending on the regulation (REACH vs OHS), the REACH process (registration/authorisation) and MS
- Gaps in applicability domain (nanomaterials, gases, fibres etc)
- No framework connecting obligations under OHS and REACH despite the similarity of the requirements



## Vision

- Achieve a framework that:
  - Supports the assessor in choosing the most adequate method (tool(s) or measured data) for the type of substance and use-situation to be assessed
  - Supports the communication of safe use advice
  - Supports lower tier for simpler cases
  - Has been agreed by both REACH and OSH communities (within authorities and industry) → to improve the acceptance /usability of exposure data between OSH and REACH
- Put in place a platform for developing the common framework