

# **ECHA experience of Tier 1 human exposure models**

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## ECHA experiences

- REACH and exposure assessment
- The challenge of exposure assessment
- Experience with models
- Reflections and the future



# Overview

## Recap on exposure assessment concept under REACH

- Risk Management Measures /Operational Conditions in the exposure scenario + exposure estimate
- Demonstration of safe use (= adequate control of risk)
- Exposure Scenarios for Registrants, for the authorities and for downstream users

## Worker exposure assessment under REACH?

- Establishing safe use **in a REACH context**

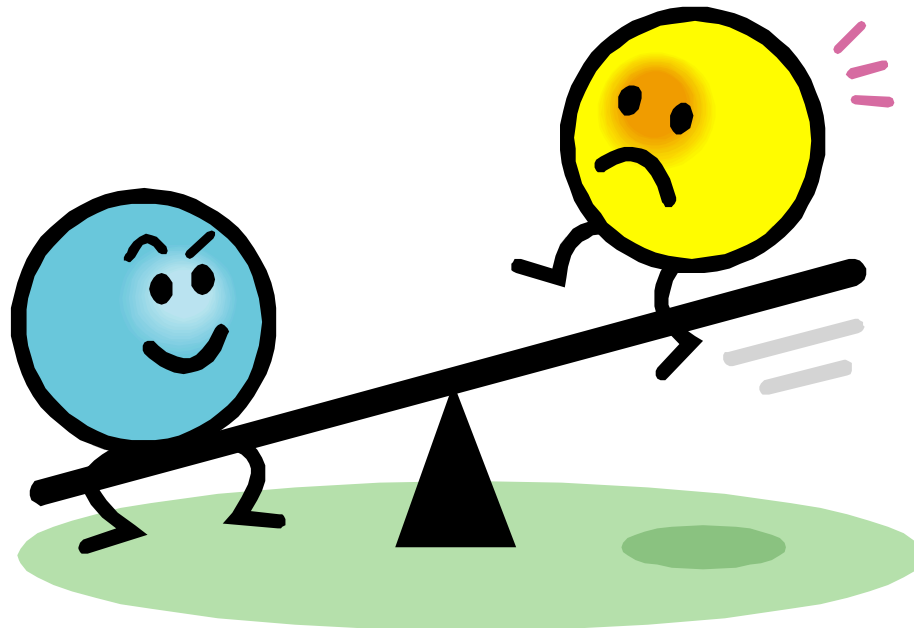
which means

- Credible characterisation of risk **in a REACH context**
- Identifying credible appropriate risk management measures for communication down the supply chain
- Measures that do not stifle innovation

## What is desired from exposure assessment?

- Transparent
- Flexible
- Interpretable and consistent
- Relevant, realistic (but in context of final exposure scenario)
- Compatible with registration needs and other processes – restriction, authorisation – well described for screening
- Validation of exposure estimates and modifying factors
- Uses appropriate terminology
- Support production of ES for many uses in many dossiers
- Agreement on inputs and outputs
- (Relatively) Simple to do and easy to interrogate

## Balanced outcome



Ideal

Non-ideal

# The challenge of exposure assessment



# The challenge of top down exposure assessment

- **Sufficiency of information** on uses and conditions of use available to Registrants
- **Generic assessment** complementing existing workplace-specific assessments – an interpretation issue
- **Scale** – huge number of assessments in very short time – have to use tools available
- **Many assessors** – not always completely expert in the field
- **Tools** not fully adapted to REACH
- **Purism v pragmatism**





## So many variables

- Gas, vapour, liquid, solid, aerosol, volatility
- Pure or in mixtures, solutions or suspensions
- Miscible/immiscible
- Contained, dust suppressed, dispersed
- Hot or cold – air or surface
- Frequency, duration
- Scale of use, size of room, ventilation arrangements



Huge variability in workplace operational conditions and RMMs

Just some of the many things that impact on exposure, may appear in models and have to be dealt with by Registrants

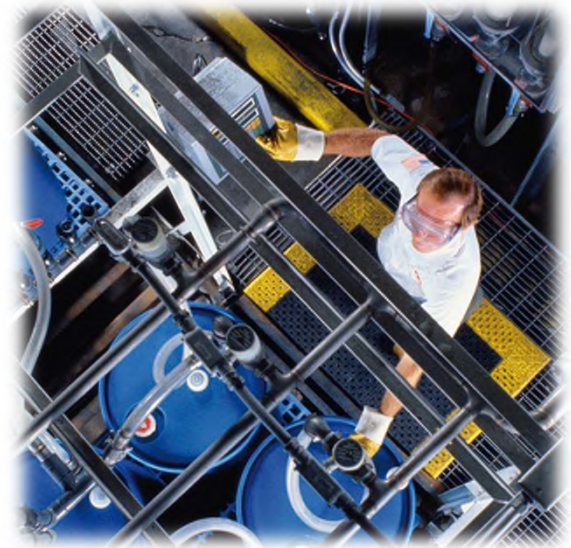
# Worker exposure



- **Chemical manufacturing**
  - Should typically be high integrity plant with good modern controls and relatively well-defined tasks, few people
- **Formulating,**
  - Mixing, adding: more processes and more opportunities for contact, more people
- **Industrial end users**
  - Using products, and possibly lots of them
  - Perhaps less well-specified controls – need to rely on SDS
  - Greater variety in chemical safety assessment – jobs, tasks, process
- **Professionals**
  - Limited access to expert resource, limited access to advice and equipment, ill-defined workplace

## So what is exposure?

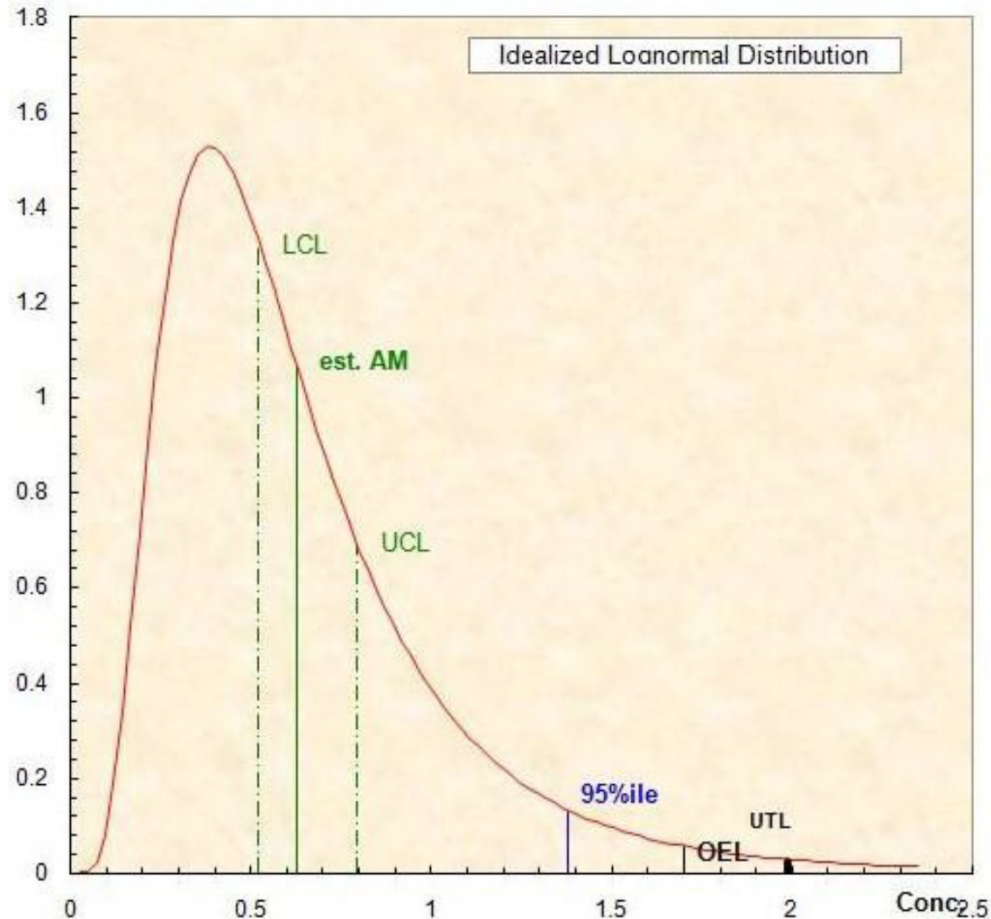
- Never the same twice
- A distribution – can be narrow or very wide
- Variability
  - Industries
  - Processes
  - Tasks
  - People
  - Control approaches



Open question :  
90<sup>th</sup> percentile  
of what?

What do we  
select for  
regulatory  
purposes?

What is the  
relevant  
distribution?



## What does REACH ask for?

- Describe all uses and the related activities of workers . Each use to be covered by an exposure scenario.
- Derive exposure estimates for each exposure scenario
- All routes – and combinations
- Duration and frequency according to operational conditions

# What helps the REACH Process?

Risk Management Measures such that:

- The registrant demonstrates that safe use is possible in practice
- The downstream user gets clear information on the level of control required
- The end user gets clear description of conditions for safe use
- Appropriate information is communicated in a flexible form

## What does REACH NOT ask for?

- Exposure estimate for all uses
  - non supported uses
- Exposure levels **beyond the reasonably foreseeable**
- Extreme duration and frequency beyond exposure scenario limits
- Non-compliant activities of workers – incorrect use of PPE and engineering controls





## ECHA experiences with models

- ECETOC TRA used almost always - “preferred model”
- Other models used rarely – **only for refinement**
- Boundaries of model not always appreciated
- Modeling used irrespective of the volume of substance used  
– for kgs and tonnes



## ECHA experiences with models

### TRA common specific issues identified in dossiers

- Assessing aerosols - difficult
- Fugacity band selection in TRA – especially dust-generating solids
- Vapour pressure at elevated temperature
- Dermal exposure and LEV modifier (v3 addresses this issue)
- Dermal predictions have been insensitive to duration and concentration – other models use different approaches
- Assessing ionic inorganic substances in aqueous solutions
- Assessing gases

# ECHA experiences with models

## TRA - common issues related to RMMs

- Focus on limited number of measures (LEV & PPE)
- Precise in required effectiveness of measure - difficult for DU to demonstrate this is achieved – **what does 95% lev effectiveness really mean? (an enhanced control strategy?)**
- Prescriptive, if interpreted too strictly, giving downstream users little room for flexibility



# ECHA experiences with models

## General issues with all models related to RMMs

- RMMs may not be fully suited to scenario (e.g. LEV impractical, dermal exposure other than “hands” may be important and not addressed)
- Alternative control options not apparent
- Substance related RMMs may not be suited to mixtures of chemicals



May lead to implementation of inappropriate RMMs on site

## Dermal exposure – many confounding factors

- Exposure to hands, forearms, body, face, neck and through protective clothing
  - Potential dermal exposure – the challenge
  - Actual dermal exposure – what gets onto the skin
  - Systemic dose – what gets into the body (compare with systemic DNEL)
- Exposure from handling, touching contaminated surfaces, dispersive tasks
- Protective clothing can act as barrier... and source
  - inside of gloves often contaminated
  - clothing worn for a number of days
  - contact during removal and clearing up
  - bellows effect – leads to deposition of aerosol inside protective clothing barrier



# Exposure via the dermal route

Challenge

Duration

Absorption

Distribution

## A challenge in REACH



Source; HSE – Reproduced with permission

# The future and what are the priorities?

- Demonstrate adequate control in the dossier
- Translate information from the chemical safety quantitative assessment into something that is meaningful and useful in the workplace. The exposure scenario for communication needs to be realistic, interpretable and achievable.
- Avoid operational conditions and risk management measures that lead to unacceptable residual risk to workers

## The future?

- What issues require attention/more research?
  - New data (?) and better interpretation of what we have already
  - Understanding the right distributions
  - Assessment of exposures and use descriptor develop in harmony;
  - Model outputs easy to incorporate in CSR format
  - Development of meaningful way of specifying RMMs

Looking to ETEAM to highlight obvious issues to be addressed  
– what are the implications for models and modelling and  
specification of risk management measures

## The future?

- Longer term development in models that are in harmony with REACH processes and needs
- Concretely describe work processes and tasks in the description of uses
- Defining/describing risk management measure effectiveness – integration within models?
- Evolution not revolution
- Making it happen and achieving consensus





# Questions



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