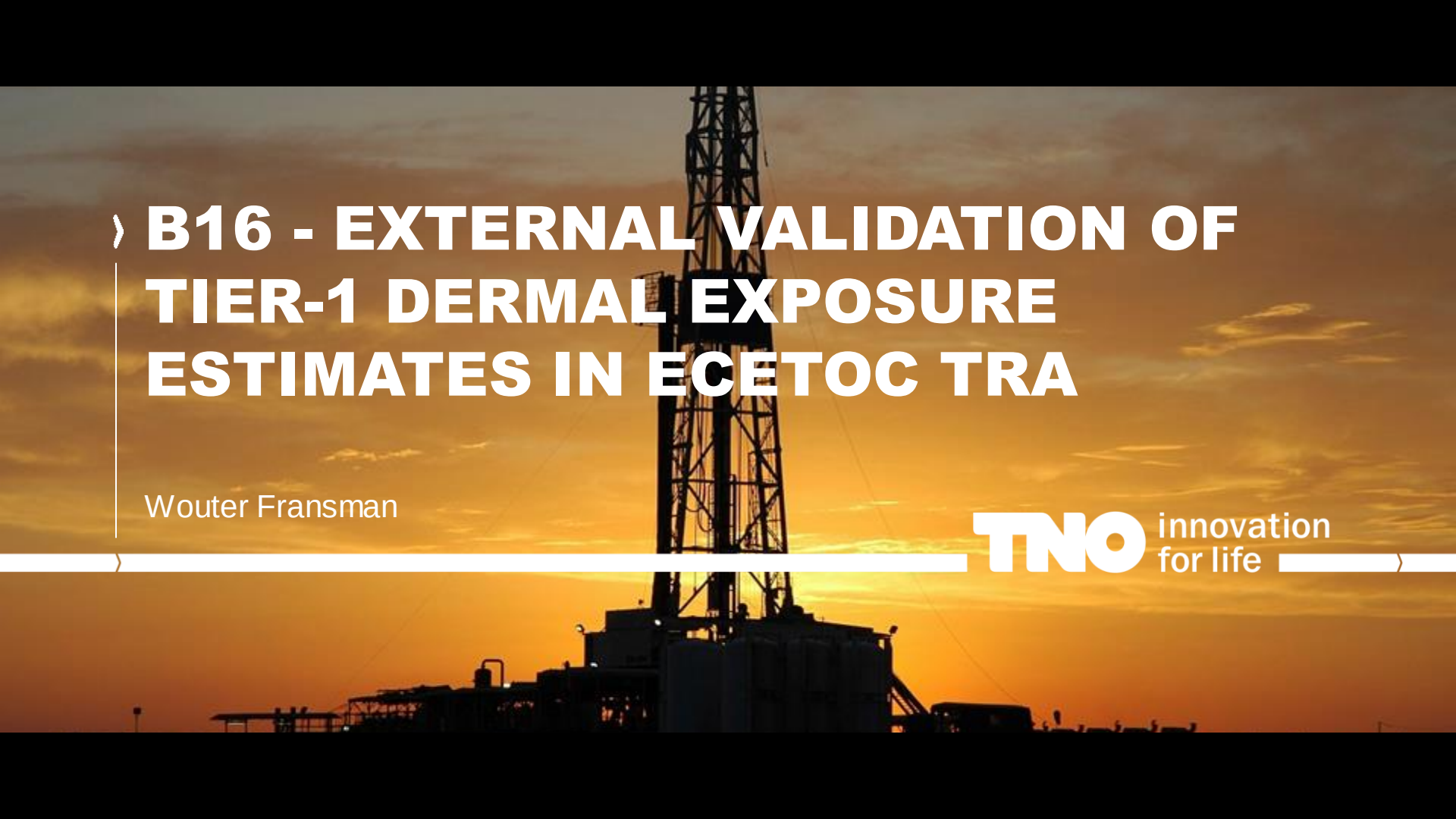


B16 - EXTERNAL VALIDATION OF TIER-1 DERMAL EXPOSURE ESTIMATES IN ECETOC TRA

Wouter Fransman

TNO innovation for life

STUDY BACKGROUND

- 1920-1950: exposure instruments were developed
- 1960s: personal sampling

- Not possible to measure exposure levels in all situations: exposure modelling

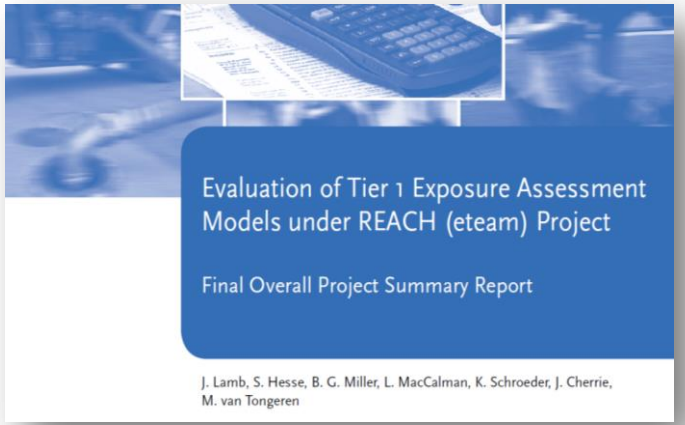
- 1990s: Estimation and Assessment of Substance Exposure (EASE)
- End 1990s: COSHH essentials
- From 2000 – nowadays a variety of exposure models has been developed.
- However, these models are mostly not, or only to a limited extent, validated

DERMAL RISK ASSESSMENT

- Dermal risk assessment considered complicated
  - Different health effects (systemic, local, allergic)
  - Different sampling methods
  - Different contamination routes and human behaviour
- Dermal exposure models less sophisticated and less generic compared with inhalation models
  - DREAM (semi-quantitative)
  - RISKOFDERM and BEAT (data driven)
  - ECETOC TRA (generic tier 1)
  - dART is in development
- Biomonitoring is performed for a subset of chemicals (all routes)

PERFORMANCE OF DERMAL EXPOSURE MODELS

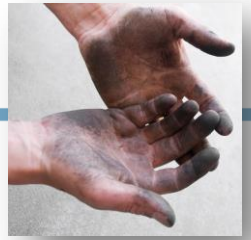
- Exposure models validated to a limited extent
- Evaluation of Tier 1 Models under REACH
  - Sponsored by BAUA
  - Evaluation of inhalation and dermal models



- Results: 4.2.5.4 Dermal exposure

"The quantity of dermal exposure data available was judged to be insufficient to allow for a reasonably comprehensive evaluation of the dermal exposure estimates from the tools. In addition, dermal measurements were obtained using different methods, leading to different results for which no consistent conversion factors exist (Gorman Ng et al., 2014). Hence, no results for dermal exposure are presented in this report".

- Last year TNO and Triskelion validated the dermal module of ECETOC TRA (sponsored by CEFIC LRI - B16)

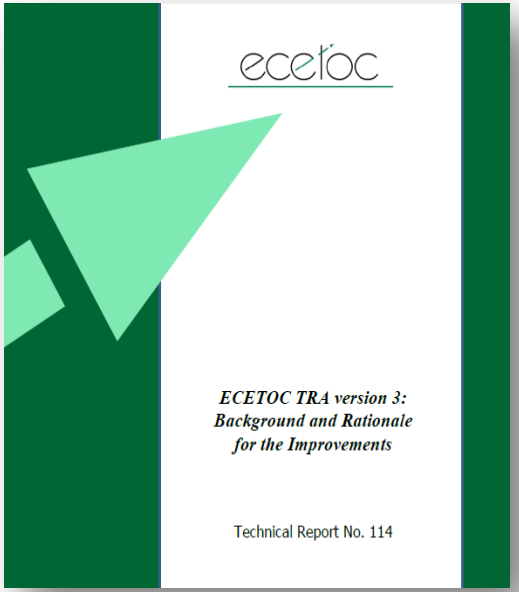


ECETOC TRA

- Tier 1 exposure model for estimating inhalation and dermal exposure
  - Screening, conservative
  - EASE and additional exposure measurement data
  - (limited to) potential dermal hand exposure
- The model is estimating exposure (mg/kg/day)
  - Process categories (PROCs)
  - Industrial or professional use
  - LEV use
  - Solid / liquid
  - Dustiness / vapour pressure
  - Concentration
  - Duration of exposure
  - Glove use

Base estimate

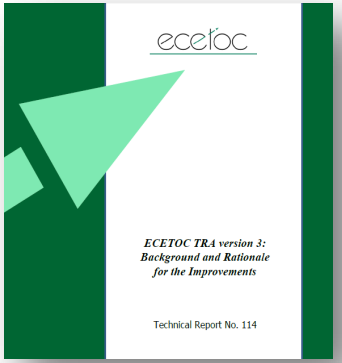
Reduction factors



VALIDATION OF ECETOC TRA

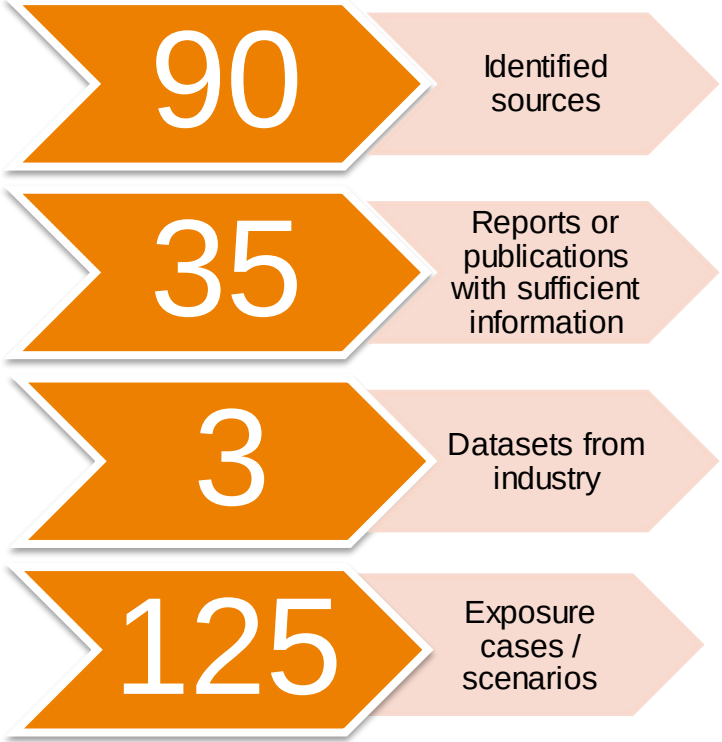
- Validation of the dermal module by comparison of measured exposure and estimated exposure

- Identification of data sources:
  - From reviewed papers and reports
  - Request for data to industry (42 members of ECETOC)



- Information sources screened on:
  - Sufficient documentation of contextual information (reconstruct the measured situation)
  - Sufficient documentation of sampling methods and exposure levels (to judge about the quality of the study)

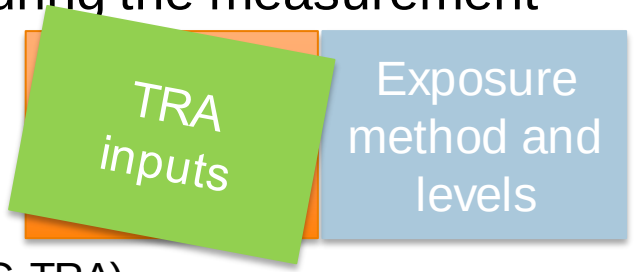
AVAILABLE EXPOSURE MEASUREMENTS



For each scenario, contextual information on exposure determinants, sampling methods and exposure levels were stored in a datasheet

METHODS (MODEL ESTIMATES)

- The provided information about the conditions during the measurement study should be translated to model inputs
- Preferably not based on a single experts opinion
- Expert elicitation process was organised
  - Experts were selected (criteria: experience with ECETOC TRA)
  - The 125 scenarios were divided into four groups (approx. 30 scenarios)
  - Each expert was sent an excel sheet with information
  - Assessment was blind for measured values
  - Based on the information a consensus input for each TRA determinant was provided



RESULTS

- 16 contacted experts (75%) participated in the consensus exercise.

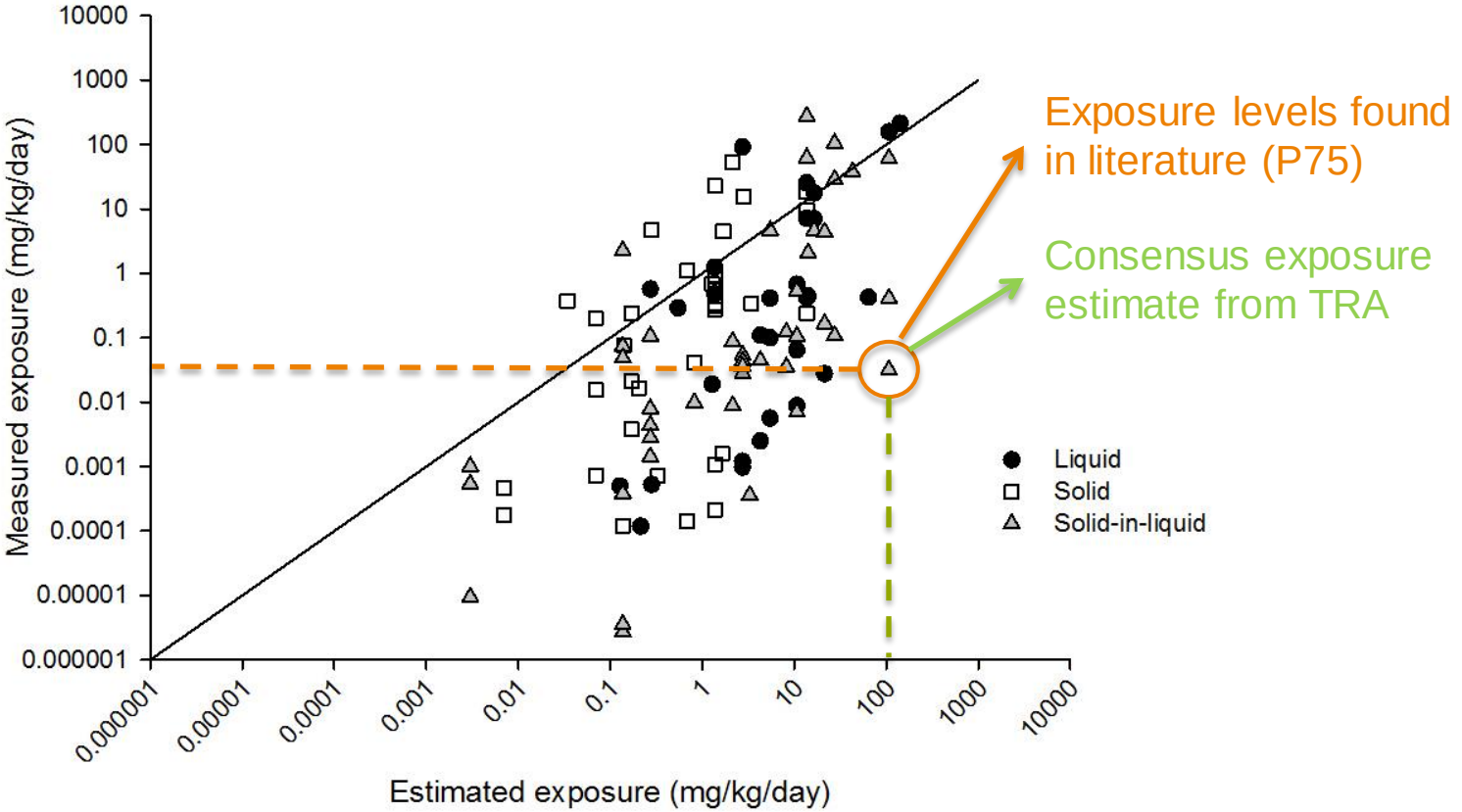
- Each exposure case was assessed by 4 experts.
  - An input scored by 3 or 4 of the experts was decided to be the consensus input

Proc	62% consensus
Professional / industrial use	86%
Solid / liquid	90%
Dustiness / Vapour pressure	64%
Concentration	90%
LEV use	92%
Glove use	97%
Duration	88%
Consensus for all inputs	25%

RESULTS

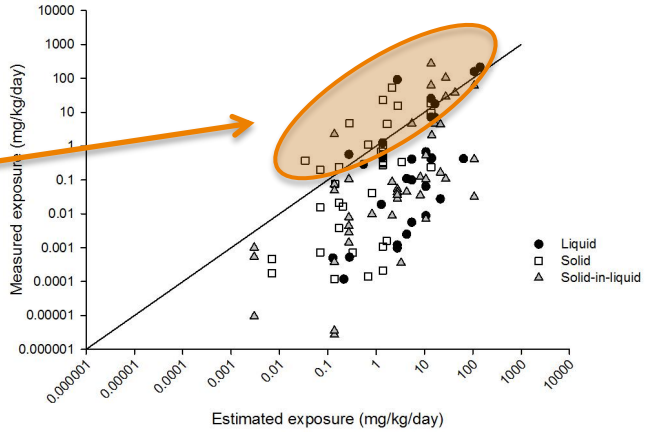
- Non-consensus: teleconference with the LRI Monitoring group
  - Each determinant was discussed till a consensus input was derived
- After consensus procedure: 15 cases excluded because of lack of consensus (due to inconsistent information)
- 110 exposure cases (n = 1,761 measurements) were available for direct comparison of exposure estimate and 75th percentile of measured values

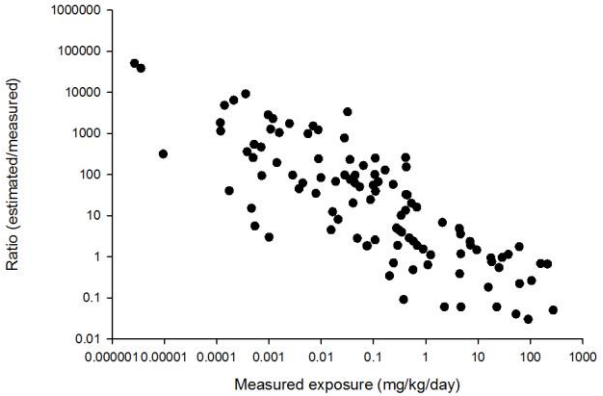
RESULTS


Measured exposure (mg/kg/day)
10000
1000
100
10
1
0.1
0.01
0.001
0.0001
0.00001
0.000001
Estimated exposure (mg/kg/day)
0.000001
0.00001
0.0001
0.001
0.01
0.1
1
10
100
1000
10000
Liquid
Solid
Solid-in-liquid
Exposure levels found in literature (P75)
Consensus exposure estimate from TRA

RESULTS

- Underestimation in 20% of the cases
  (Estimate versus P75)
- Model explained 37% of the variance
  (of the (aggregated) P75)
- ECETOC TRA seems to be applicable for solid in liquids
- Clear trend in overestimation of low exposures and underestimation of high exposures





RESULTS

- Determinant analysis (mixed regression models):
  - Sampling method, glove use, PROC, concentration
  - 62% explained variance (compared to the 37% explained by the model)
- Effect of gloves: factor 34 (data: 97%, 80% professional, 90% industrial)
- Interception sampling methods (cotton gloves, patches) 6 times higher compared with removal methods (tape stripping, hand wash).
- Large overestimation for (very) diluted products
  (lowest category <1% versus pesticides with <0.01%)
- No effect of professional vs industrial, LEV, vapour pressure or dustiness

LIMITATIONS

- Relatively large numbers of exposure measurements available for:
  - Product transfer (PROCs 8a, 8b and 9)
  - Spray applications (PROCs 7 and 11)
  - Rolling and brushing (PROC 10)
  - Low volatile substances
- Limited data for:
  - Large part of the PROCs estimating low exposures
  - Including manufacturing of chemicals in closed systems (PROCs 1,2,3,4)
  - Volatile substances

CONCLUSIONS

- ECETOC dTRA underestimated in 20% of the cases
- Overestimate low exposures and underestimate high exposures
- The model explained 37% of the variance
- The model could also be applied to solid-in-liquid products
- Glove protection factor in the data higher than in the model (97% vs 80-90%)
- Interception methods factor 6 higher compared with removal methods
- Dermal exposure measurement data is lacking in a large set of conditions

GENERAL FINDINGS

- Dermal exposure the little brother of inhalation exposure

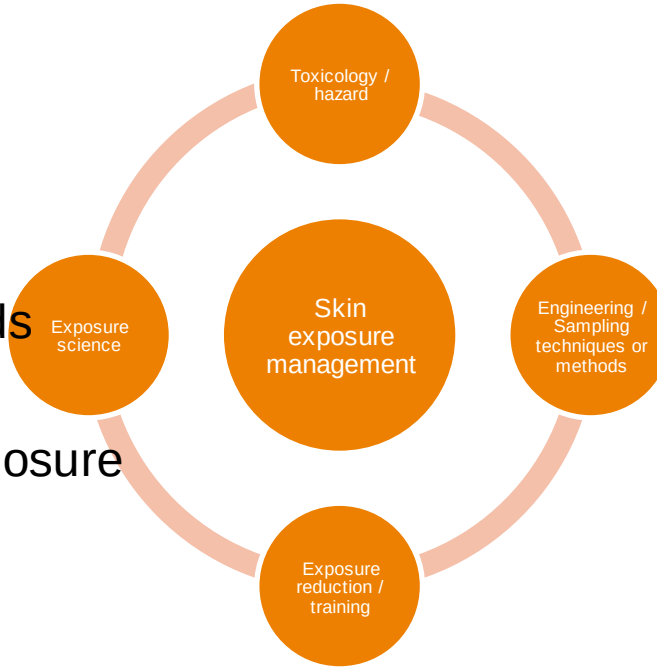
- Why……??
  - Dermal sampling methods are not standardised yet
  - Dermal exposure limits are not established in all cases
  - Dermal exposure models are less sophisticated

  - Volatile substances are replaced by low-volatile components
  - (Inhalation diseases are replaced by dermal diseases)

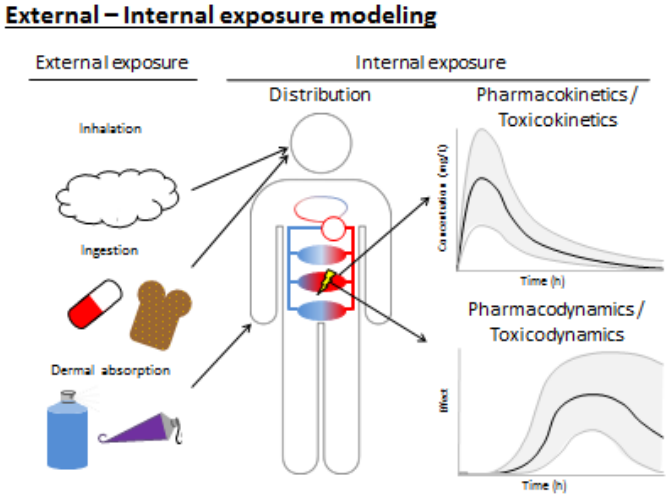
We have a mission!!!

WORK TOGETHER!

- Knowledge developed, but not yet sufficient evidence for quantitative risk assessment
- Skin exposure management
  - Derive relevant exposure limits (based on effects)
  - Develop and standardise accurate sampling methods
  - Improve the exposure science related to dermal exposure
  - Intervene on the right places and train our workers



FUTURE WORK



- Towards Tier 2 sophisticated models:
  - potential dermal exposure (dART)
  - aggregated exposure (BROWSE)
  - internal exposure (benzene, chlorpyrofos)
- More experimental and standardised field data needed
  - Most of the available data is from the early 2000s (ROD, BEAT)
  - Harmonization and acceptance of measurement methods (SYSDEA)
- DNELs for dermal exposure: push by legislation


THANK YOU FOR YOUR ATTENTION
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