CEFIC LRI B19 - Extrapolating the Applicability of Worker Exposure Measurement Data

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Introduction

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- Measured data preferred over modelled data
  - More uses for existing measured data exist, but are currently not used
- Read-across for toxicological data is accepted
- Read-across approaches currently do not exist for measured exposure data
- Measurement data for a substance under certain conditions might be used for other substances under similar conditions, or with the same substance under different circumstances where little data exists

Objectives

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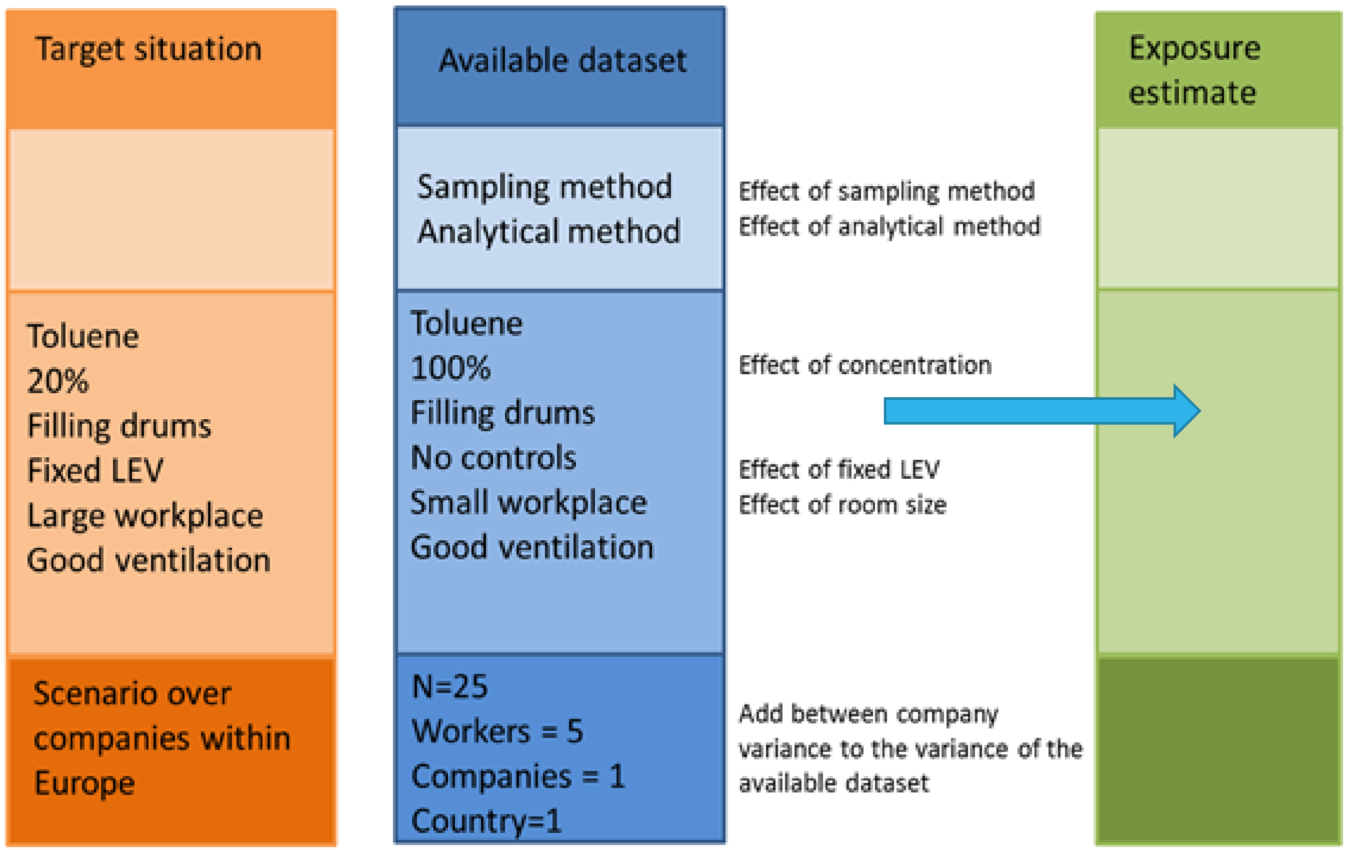
- To develop criteria to evaluate whether exposure measurements for a given substance and use scenario might be reasonably representative for another substance used in a similar scenario
- To develop a pragmatic and agreed process for incorporating existing exposure measurement data into worker exposure assessments that are typically undertaken in support of chemicals regulations
- Test the developed criteria and process on test cases
- Supported by stakeholders
- Project not intended to generate new knowledge on exposure determinants

Read-across framework



Work content

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- **WP 1: Define the adequate dataset**
- **WP 2: Develop a framework to consistently and transparently extrapolate existing exposure measurement data**
- **WP 3: Stakeholder engagement**
- **WP 4: Validation of the framework using case studies**
- **WP 5: Reporting and writing a draft-publication**
- Active dialogue with the LRI monitoring group welcomed and encouraged

Stepwise framework

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- Step 1: evaluation of the **data quality** of the source data
- Step 2: evaluate similarity between source situation and target situation, based on **mapping** the two situations for relevant read-across parameters
- Step 3: **statistical correction** on differences between source situations and the target situation and calculation of uncertainty
- Step 4: **Reporting**

Step 1: Technical adequacy & Adequacy of context

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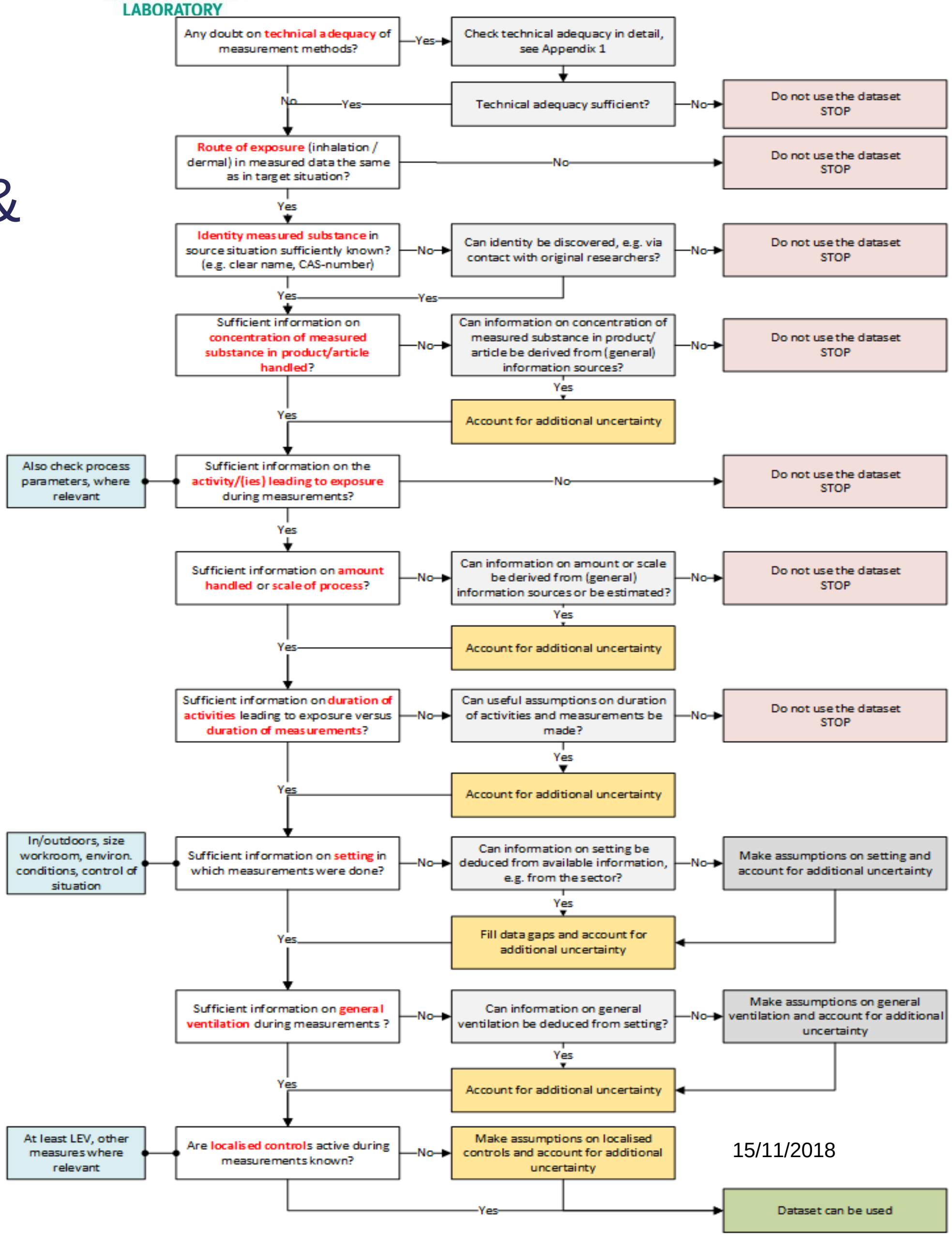
- Route of exposure
- Measured substance
- Concentration in product
- Activities
- Scale
- Workplace setting
- General ventilation
- Localized controls



Step 2: Mapping source & target situation

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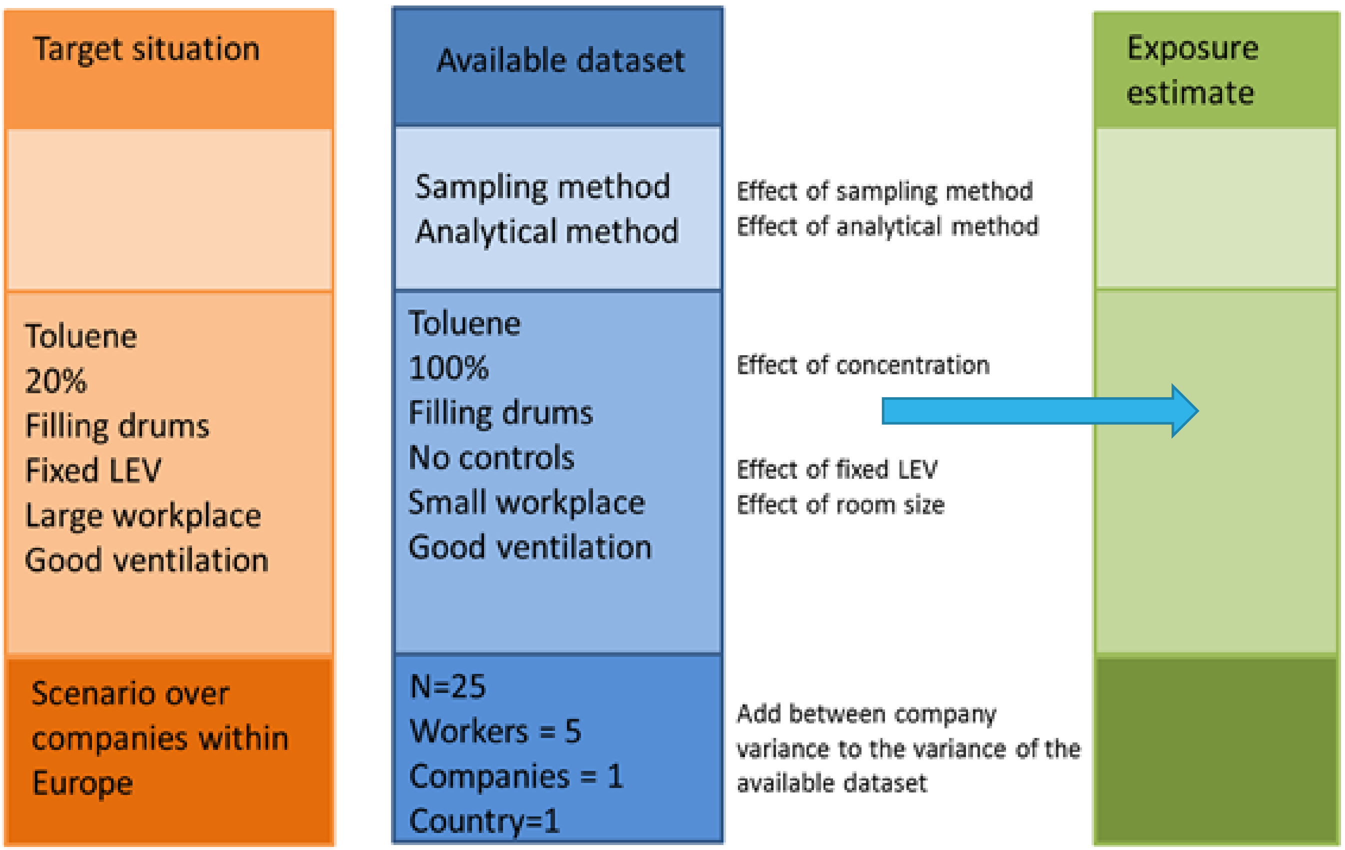
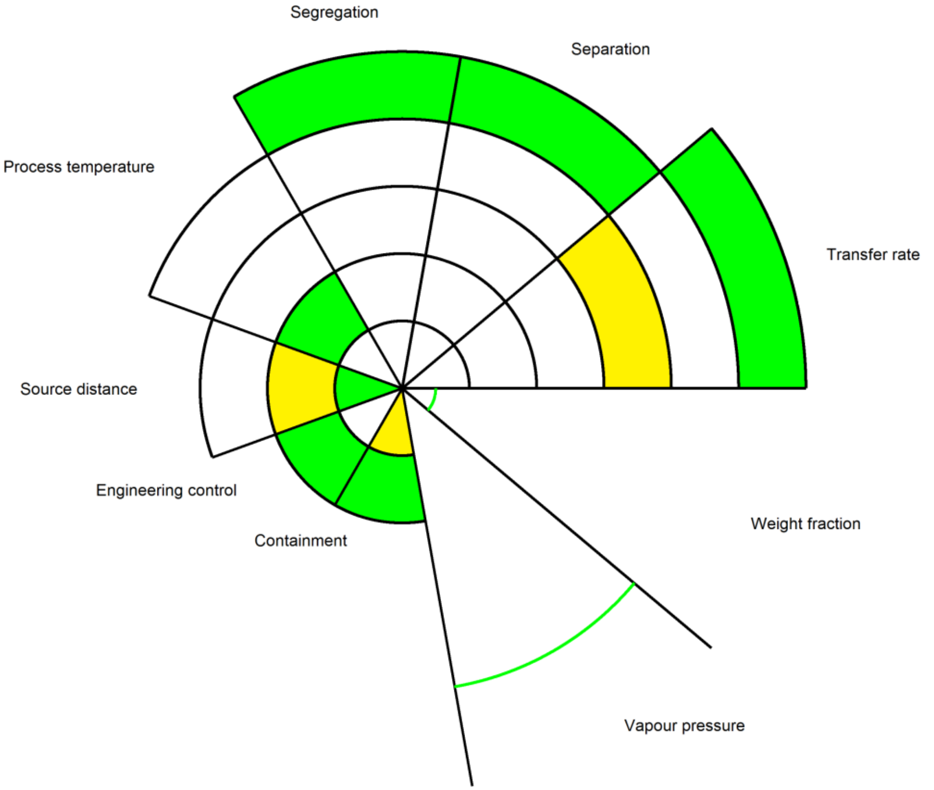


Step 2: Mapping source & target

Simple representation of exposure

Determinant	Levels	Adjustment factor	Ratio
Transfer rate	Over 1000 l min^{-1}	1	0.1
	10 – 100 l min^{-1}	0.1	
Source distance	Far field (between 1 and 4m)	3	3
	Far field (over 4m)	1	
Containment	No containment	1	0.3
	Partial containment	0.3	



Step 3: Read-across, variability & uncertainty

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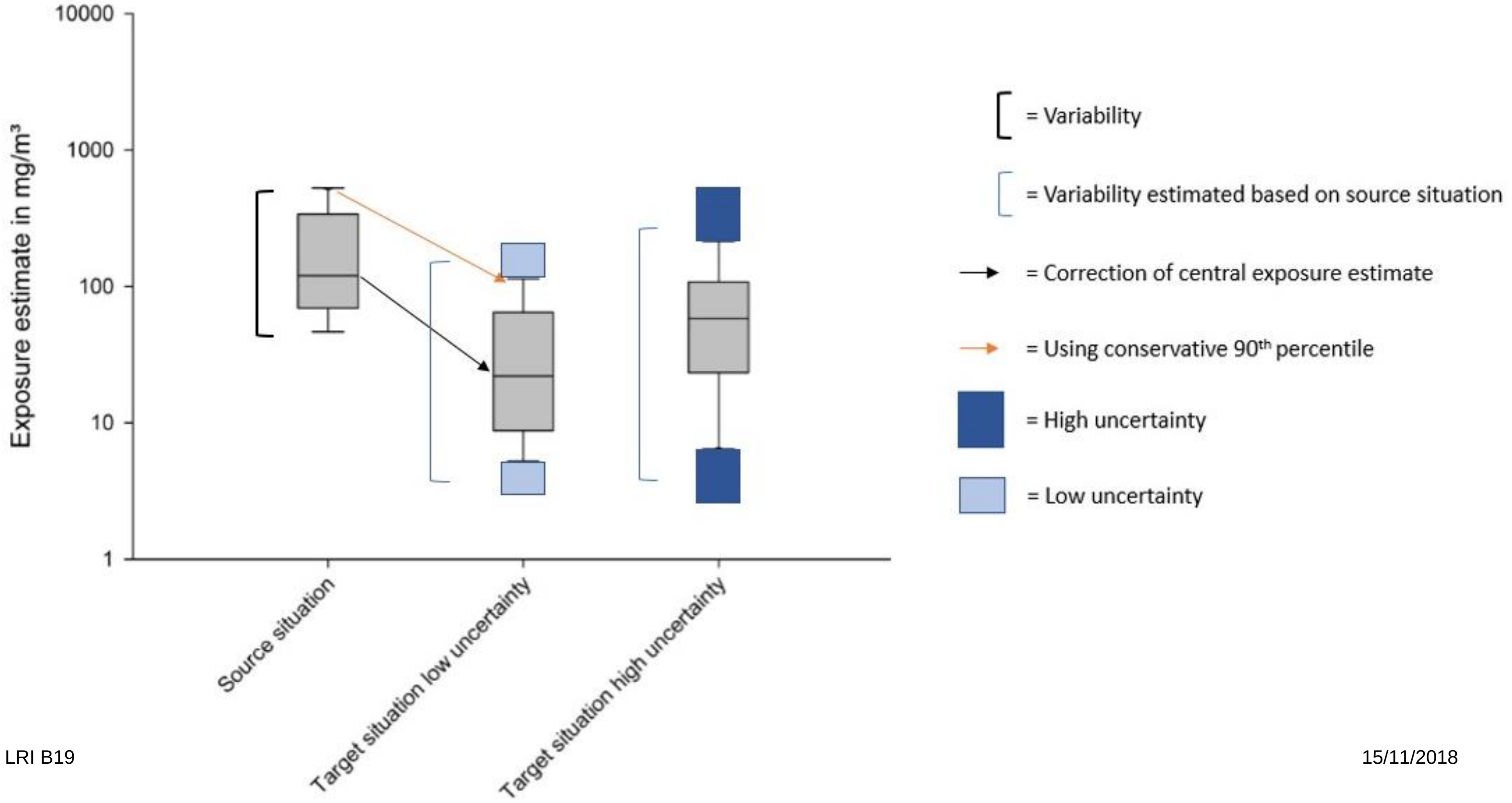

Step 3: Read-across, variability & uncertainty

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- Substance emission potential:
  - Dustiness/volatility
  - Weight fraction
- Activity emission potential:
  - Activity description (PROCs)
  - Amount of substance used
  - Duration of exposure
- Engineering controls:
  - Mechanical ventilation
  - Local control measures
- Workplace configuration:
  - Premise setting (industrial/professional)
  - Environmental conditions
  - …….

Equation 1 Read-across read-across factor= Substance read-across factor * Activity read-across factor * Engineering control read-across factor * Workplace configurations read-across factor

Equation 2 Substance read-across factor = DV * WF

DV = the dustiness or volatility read-across factor; WF = weight fraction read-across factor

Equation 3 activity Read-across factor = A_t * A * D

A_t the activity type; A is the amount of substance used; D the duration of exposure

Equation 4 Engineering control read-across factor= MV * RMM

MV is the mechanical ventilation; RMM the risk management and local control methods

Equation 5 Workplace configuration read-across factor= P * EC

P is the premise setting; EC is the environmental conditions

Step 3: Read-across, variability & uncertainty

Example: Substance emission potential

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- Calculating difference between direct dustiness values (when known)
- Using the direct values is the preferred choice

Dustiness target situation	Dustiness source situation	Dustiness read-across factor
4000	3000	1.33
3000	4000	0.75
750	2500	0.3
10000	250	40

- Calculating difference between indirect dustiness values (when direct dustiness values are unknown

Dustiness target situation	Dustiness source situation	Dustiness read-across factor
Firm granules, flakes or pellets (0.01)	granules, flakes or pallets (0.03)	0.33
Fine dust (0.3)	Granules, flakes or pallets (0.03)	10
Indicative dustiness firm granules, flakes or palets (100 mg/kg)	Indicative dustiness granules, flakes or pallets (300 mg/kg)	0.33
Indicative dustiness fine dust (3000 mg/kg)	Indicative dustiness granules, flakes or pallets (300 mg/kg)	10

Rules

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- Data quality of the source data
- Physical state and exposure route should be the same
- Activity should fall in the same category (some read-across within PROCs is considered acceptable)
- The ‘use-rate’ of the task should differ no more than two categories as used in ART
- Read-across is not to be performed over generally different types of localized control measures

Case studies

to illustrate the framework and show the proof of principle

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Case study	Source substance	Target substance(s)	Substance class	Source scenario	Target scenario(s)	Characteristics	Extrapolations
Case study 1	Propylene oxide	Same substance or other gases	Gas (pure substance)	Synthesis/manufacturing process: Use in closed, continuous process with occasional controlled exposure – PROC2	Same as source scenario; More closed activity (PROC1)	Industrial production Far-field Indoors Containment	Dispersion Containment Substance Indoors/Outdoors
Case study 2	Inhalable dust	Respirable dust	Abrasive (respirable) dust	Grinding, cutting and polishing of stone	Same as source scenario	Professional use Near-field Indoors	Indoors/outdoors Engineering controls Dispersion
Case study 3	Toluene in lubricating oil	Same substance	Aerosol (complex mixture)	Machining metal parts/ high speed processes	Same as source scenario	Near-field Indoors Single company	Dispersion Engineering controls
Case study 4	Inhalable dust	Same substance	Inhalable dust	Wrapping of bread in industrial bakeries	Same as source scenario	Near-field Indoors	Contamination Dispersion Dustiness
Case study 5	Benzene from gasoline	Same substance	Vapour (complex mixture)	Top-loading of gasoline Filling of drums with gasoline	Same as sources scenarios	Far-field Outdoors Multiple source datasets	Use-rate Distance to source Benzene concentration Controls

Case studies
to illustrate the framework and show the proof of principle

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- Evaluation of the data quality of the source dataset(s)
- Mapping of source dataset to the determinants of an exposure modelling tool;
- To identify what determinants might potentially be varied in read-across, what are their bounds and what is the appropriate range of extrapolation
- Calculation of summary statistics from source data
- Calculation of raw and calibrated read-across scores;
- Calculation of best estimate exposures (for a given summary statistic) in target exposure scenarios alongside an appropriate measure of uncertainty,
- Verification of the read-across approach, using summary statistics calculated from data on the target scenarios

Case studies
Results and conclusions

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- The case studies demonstrated the wide applicability of the framework
- Case studies 4 and 5: read-across worked well
- Case studies 1, 2 and 3: highlighted issues that warrant further research:
  - Read across from one PROC to another needs to be made with caution
  - The effect of room ventilation is in need of further study
  - Further study of the correction applied to single company datasets is suggested

Read-across framework

Summary

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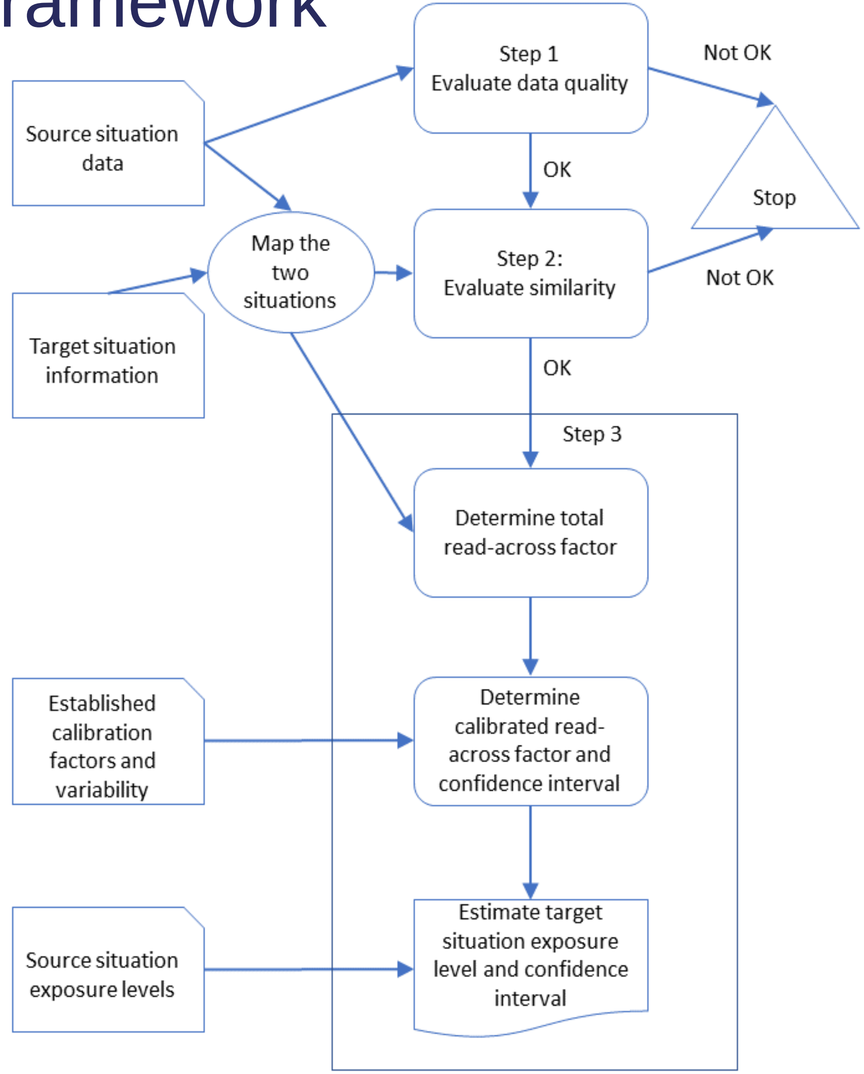

Recommendations for future work

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- Further testing of data with limited quality
- Further testing adequacy of the developed rules
- Sensitivity analysis on the read-across framework
- Improve the calibration (parameter specific)
- Development of IT tool, and testing by external exposure experts
- Further support by stakeholders

Take home messages

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- Framework to facilitate read-across of inhalation exposure data
  - evaluating data quality
  - evaluate for sufficient similarity between source situations and target situations
  - calculation of read-across factors to correct the source exposure levels towards the target situation.
- Read-across framework calibrated using a large set of data
- Demonstrated to be workable using five case studies
- Further developments are needed to create an IT tool that can be used by exposure assessors.

Thank you for your attention!

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