

Application of the Read Across Concept to exposure assessment in the lubricant and metals industries

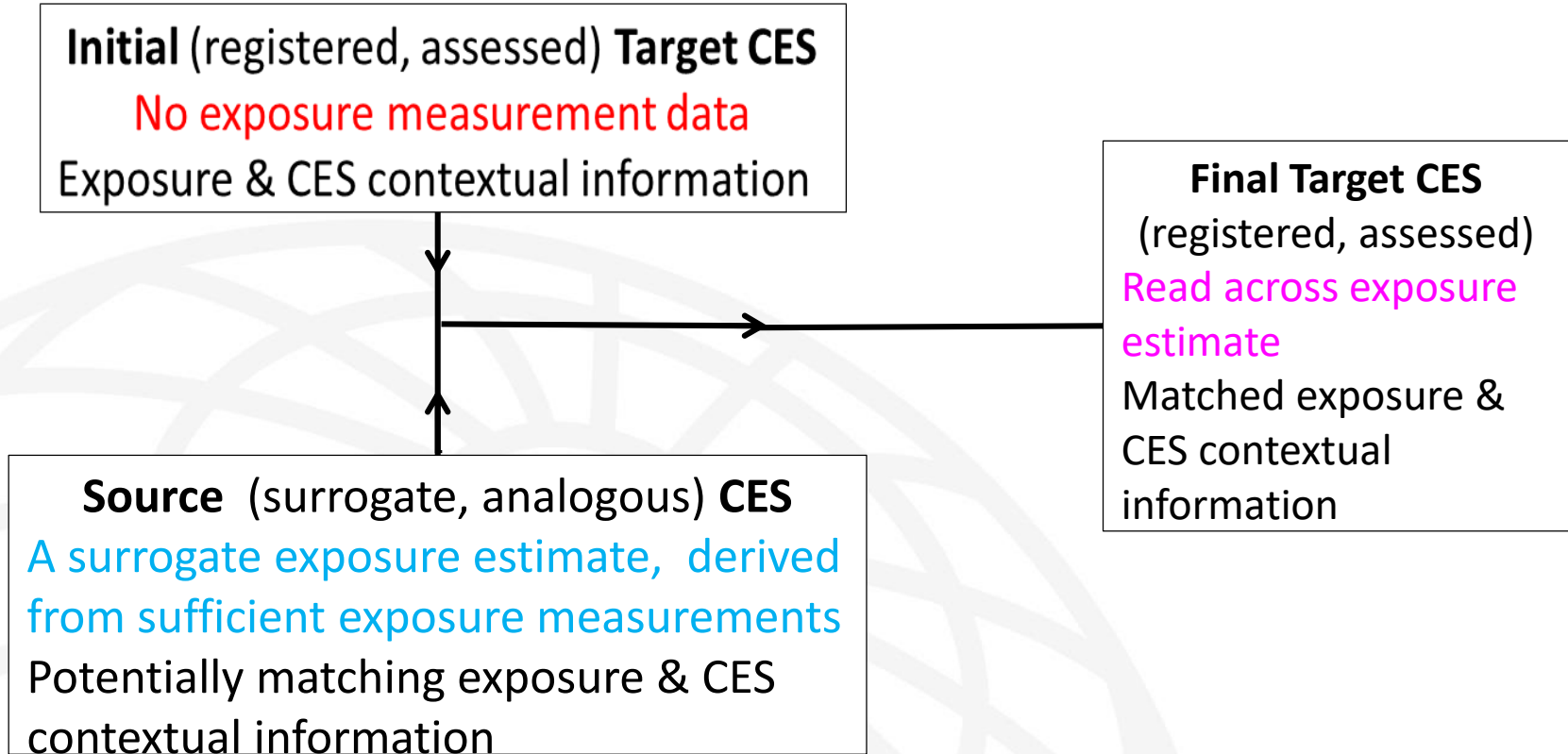
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Overview of Presentation



- The Read Across Concept – why use it?
- Summary of the Stepwise Approach
- The start – developing (study) quality and (surrogate measurement) read across criteria
- Application of the read across criteria
- Examples of use in the lubricant and metals industries

Read Across Concept

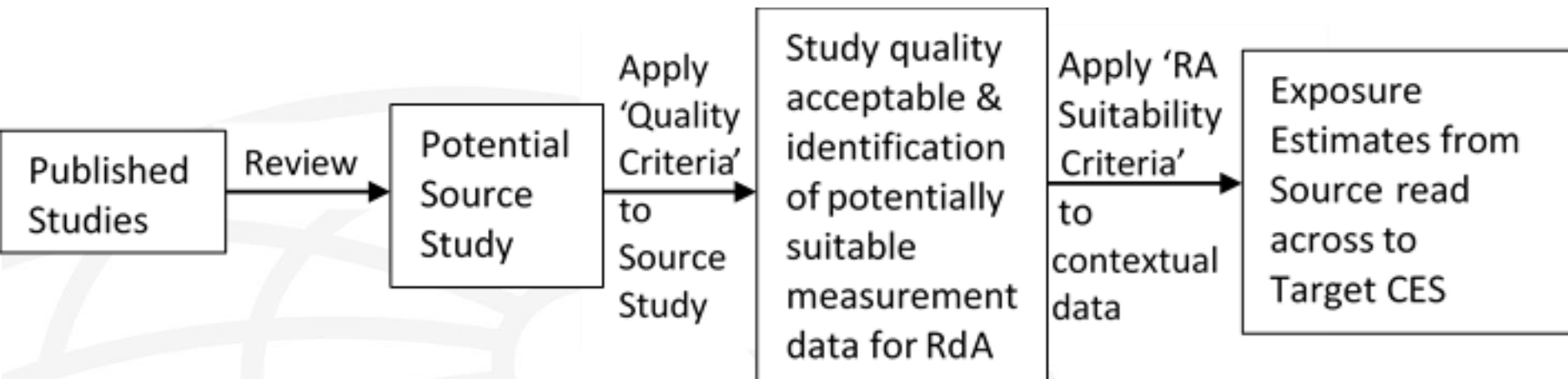


Read Across Concept



Read Across may be used to assign an inhalation or dermal exposure estimate to a (measurement-poor) recipient or 'target' contributing exposure scenario (CES), based on appropriate measurement data from a suitable (measurement rich & 'matching') donor or 'source' CES.

Stepwise Approach for Read Across



Quality Criteria for verifying a source study

- Surrogate data published in peer reviewed papers or other documents
- Standard sampling & analyses methods & validation of other methods used to obtain surrogate data & determine exposure estimate
- Presence of some measure of consistency linking source study to target ES
- Limited or no exposure modelling opportunities

Read Across Suitability Criteria

- Surrogate material has:
 - Same physical state and routes of exposure
 - Similar physicochemical properties, 'severity' in terms of health effect endpoints and similar composition
- Surrogate process employs similar:
 - Operations and activities
 - RMM e.g. containment, LEV
 - PPE
- Industrial sectors are similar

Application of Criteria

- Read across from surrogate to target
 - cautiously (for 'similar')
 - appropriately e.g. relevant physicochemical properties
- Assign a 'relevance rating' to each criteria to determine read across suitability:-
Excellent > **Strong** > **Good** > **Reasonable** > Poor
- Sufficient 'good' or above criteria indicates suitable match & read across can proceed
- Excess 'reasonable' scores indicates poor match and should be revised.

Application of Criteria



- Lubricant industry
- Metals industry



Lubricant (1)–source verification using 'Quality Criteria



Source information & quality criteria for source study	Target for read across	
	Lubricant loading	Cleaning & maintenance
Source for read across	Lubricant unloading monitoring survey	Cleaning & maintenance HFO
90 th % ^{ile} exposure estimate surrogate	Dermal & Inhalation	Dermal
Peer reviewed surrogate data	Same report	Paper (Christopher et al, 2011)
Standard/validated monitoring methods	European Standard EN 689 Air & dermal (glove) sampling & analyses methods validated	European Standard EN 689 Dermal (glove & wipe) sampling & analyses methods validated
Consistency requirement	Same monitoring campaign Same researchers carrying out both lubricant surveys	Same research organisation carrying out both lubricant and HFO surveys
Modelling opportunity	NA - Loading & Unloading closely related (reverse of each other)	No relevant 'Dermal Exposure Operation' option in RISKOFDERM model

Lubricant (2)–application of ‘materials’ criteria



Source information & criteria for read across	Target for read across	
	Lubricant loading	Cleaning & maintenance
Source for read across	Unloading monitoring survey	Cleaning & maintenance HFO
90 th % ^{ile} exposure estimate surrogate for RdA	Dermal & Inhalation	Dermal
Materials have same state and similar properties	Excellent match All measured	Strong match Vapour press. & boiling pnt.
Materials have same routes of exposure	Excellent match Dermal & inhalation	Excellent match Dermal
Materials have similar ‘severity’	Excellent match – Both reprotoxins	Strong match – Reprotoxin 1B (Lubricant) Group 2B carcinogen (HFO)
Materials are employed in similar industrial sectors.	Excellent match – Lubricant production sectors	Good match – Marine, power plant & vehicle engine lubricants (Lubricant) Marine and power plant fuel (HFO)
Materials have similar composition	Excellent match Same	Reasonable match

Lubricant (3)–application of ‘process’ criteria



Source info & criteria for read across	Target for read across	
	Lubricant loading	Cleaning & maintenance
Source for read across	Lubricant unloading monitoring survey	Cleaning & maintenance HFO
90 th %ile exposure estimate surrogate for read across	Dermal & Inhalation	Dermal
Process employs similar operations & activities	Very strong match Unload from bottom, load from top tanker	Strong match Same manual tasks – spading pipes, stripping pumps, cleaning filters
Operators wear similar PPE	Excellent match	Strong match
Process employs similar RMM	Excellent match - LEV for loading	Strong match
Overall suitability for read across	EXCELLENT	GOOD

Metals (1)–application of ‘materials’ criteria



Source info & criteria for read across	Target for read across	
	Metal salt A packaging	Metal compound packaging
Source for read across	Metal salt B product ⁿ monitoring survey	Metal production monitoring survey
90 th % ^{ile} exposure estimate surrogate for read across	Dermal	Dermal
Materials have same state and similar prop	Strong match – powder, soluble, density	Strong match – powder, insoluble, density
Materials have same routes of exposure	Excellent match - Dermal	Excellent match - Dermal
Materials have similar ‘severity’	Excellent match – Group 1 carcinogens	Strong match Carcinogens - 2B & 1
Materials are employed in similar industrial sectors	Excellent match – Same, both production	Strong match – Production & DSU
Materials have similar composition	Good match – % metal ion just higher in source	Good match - % metal higher in source, oxid ⁿ states variation

Metals (2)–application of ‘process’ criteria

Source info & criteria for read across	Target for read across	
	Metal salt A packaging	Metal compound packaging
Source for read across	Metal salt B product ⁿ monitoring survey	Metal production monitoring survey
90 th %ile exposure estimate surrogate for read across	Dermal	Dermal
Process employs similar operations & activities	Excellent match - Automated, little manual intervention	Excellent match - Semi-automated, manual interventions
Operators wear similar PPE	Strong match	Strong match
Process employs similar RMM	Strong match - LEV	Strong match
Overall suitability for read across	STRONG	GOOD

Discussion

- This is a simple, pragmatic and relatively quick approach for justifying (or not) the read across of surrogate exposure data
- Expert judgement has a part to play when determining the source study quality and the suitability for read across
- More rigorous studies into reading across of exposure data are currently underway e.g. CEFIC-LRI funded project led by TNO

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