



Downstream Users of Chemicals Co-ordination group

Scaling

DUCC/CEFIC ES Workshop

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Scaling –An Overview

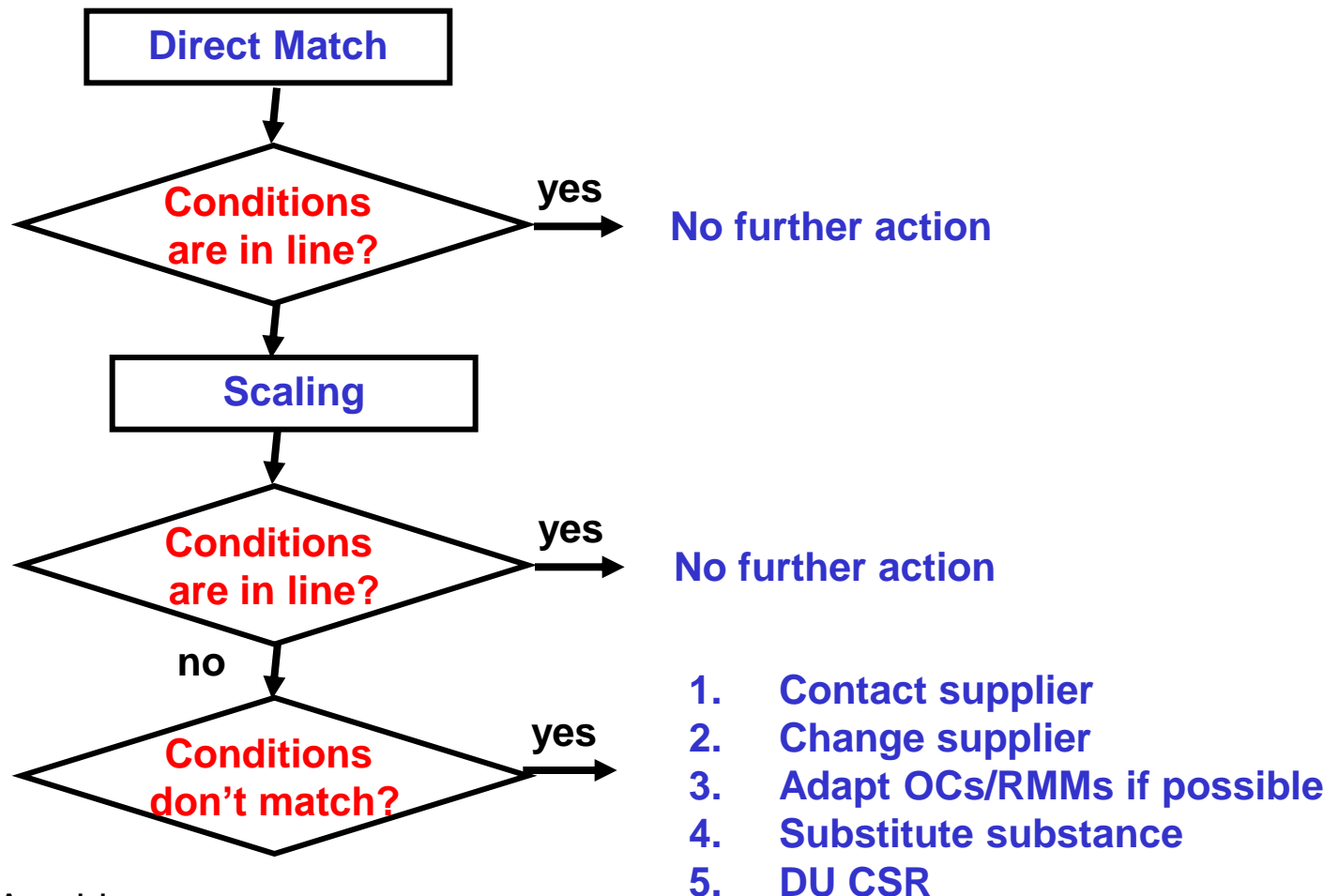
- ECHA: *„Scaling‘ is one method based on which a Downstream User (DU) can determine whether he works within the boundaries of an Exposure Scenario (ES) communicated to him.*
- *„Scaling‘ as such is not foreseen in the legal text.*
- REACH Art. 37.5: DUs have to identify and to conform to relevant information in the ES communicated to them.



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When to apply ,Scaling’*

Comparison: OCs/RMM – actual vs SDS



* Logic of draft ECHA guidance



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Scaling vs Downstream User Chemical Safety Assessment

- Scaling vs DU Chemical Safety Assessment (DU CSA)
 - Scaling - no notification to ECHA
 - DU CSA – notification to ECHA via REACH IT (REACH Art. 37.4), communication to Downstream Users.
 - Legally speaking, there is a significant difference.
- Technically speaking, there is little if any difference between ‚Scaling‘ and an exposure assessment.
- Conscious decisions need to be taken on whether he is performing scaling or a DU CSA.



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What will be addressed?

- Basics
 - An ,Interpretation of Scaling of ECETOC TRA‘ Assessments
 - An ECHA reply to the ,Interpretation‘
- Tools which are out for discussion
 - ES-Modifier
 - Eurometaux
 - Prototypes based on ECETOC TRA
 - Beyond scope: Tier 2-Scaling, company-specific solutions



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ECHA's current activities

- Development of DU guide including
- Criteria to decide whether scaling is applicable
- 5 examples illustrating where scaling is (not) applicable
 - Examples where scaling works and where it is not applicable in ECHA's view.
 - Worker, consumer, environment ES.



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ESmodifier[®]

- ESmodifier aim to assist DU and formulators
- Multifunctional stand alone tool
 - Scaling/modifying ES to fit own conditions
 - Consolidating ES on same substance from different suppliers
 - Preparation of ES for mixtures
 - Support to DU-CSR
- Organisation
 - Developed by DHI, economically supported by DK EPA and Danish Industry, will be freely available, Q4 2011
 - Support by TNO on mixture assessment, etc.

DU scaling tools in metal sector

- Supported by EUROMETAUX
- Purpose: to maximize coverage of ES applicability
- Free to DUs from metal sector, Excel-based

	Environment	Occupational
Tools in the background	EUSES	MEASE
Metal specifics	Fate parameters, natural and regional background concentrations, SPERCs	Use of measured data, metal specific PROCs, metal specificities in dermal & inhalation exposure
Download	http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool	http://www.ebrc.de/industrial-chemicals-reach/projects-and-references/mease.php
Developed by	ARCHE	EBRC



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A closer look into Scaling ECETOC TRA Tier 1 Assessments



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ECETOC TRA and Exposure Scenarios

- A large number of Exposure Scenarios have been generated using ECETOC TRA.
- Scaling rules for ECETOC TRA derived Exposure Scenarios are therefore particularly relevant.
- ECETOC is the science platform of the European chemical industry.
- ECETOC is an independent organisation and funded by its member companies.



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, Interpretation of Scaling of ECETOC TRA': Starting Points

- A TRA derived ES is described by several so-called Exposure Modifiers (e.g. for workers: exposure duration, concentration of substance, RMM, river dilution, etc.).
- An ES in an SDS specifies only one particular set of Exposure Modifier values for safe use (i.e. RCR <1).
- Additional sets are possible since e.g. a longer exposure duration may be compensated by a lower concentration of the substance.
- ECETOC TRA Assessment are inherently conservative. An RCR of 1 does not mean that a unacceptable risk is imminent but that refinement may be required.



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ECHA and ECETOC TRA Scaling – Current Discussion

ECHA-Comments on ECETOC TRA- Interpretation of Scaling	ECETOC
Only quantitative Exposure Scenarios can be scaled.	Agree
Scaling is tool-specific.	Agree
Scaling is restricted to determinants in the ES.	Agree



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ECHA and ECETOC TRA Scaling – Settling the Filling Up-Issue

ECETOC TRA-Interpretation of Scaling	ECHA
<p>Scaled RCR larger than RCR in ES is acceptable provided that</p> <ul style="list-style-type: none">• Scaled RCR <1 and• TRA scaling uses the same set of rules as in the CSR and scaling is restricted to the parameters identified by ECETOC TRA	<p>Under discussion</p>



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TRA-Scaling prototypes

- Excel based tools developed as ‚Proof-of principle‘
 - for workers
 - for the environment (the GEST-Tool)
- Make use of the so-called ‚Exposure Modifiers‘ according to the rules of the ECETOC TRA.
- TRA-based prototypes enable DUs to explore the boundaries of an ES without the risk of going beyond these:
 - TRA scaling uses the same set of rules as in the CSR.
 - TRA scaling uses the same set of input parameters.



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Scaling Example - ECETOC TRA derived Exposure Scenarios

- Example substance: ethyl acetate
- Example use: Formulation of adhesives

- Three steps in scaling
 - Sorting the incoming ES information
 - Comparison with information on own use
 - Adjusting the exposure modifiers (if possible)



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Sorting the incoming ES information

Substance:	Ethylacetat
Registration number:	01-2119475103-46-
Version of SDB / Supplier:	2010-12-01
Data copied from eSDS on:	15.02.2011 (Training)
Data copied from eSDS by:	participants

1 Short Title of ES					
1.1. SU Settings	industrial	industrial	industrial	industrial	industrial
1.2. Used Modells for Exposure Scenario					

Worker safety - Use descriptors

	Exposure Modifier					
	LEV considered for Dermal	1	2	3	4	5
2 Relevant Process Category (PROC)						
3.1. Duration and frequency of exposure [min or h]	No	>4 hours (default)	>4 hours (default)	>4 hours (default)	>4 hours (default)	>4 hours (default)
3.2. Phase of matter	Liquid	>4 hours (default)	>4 hours (default)	Liquid	Liquid	Liquid
3.3. Conc. in Preparation [%]	> 25%	1 - 4 hours	1 - 4 hours	> 25%	> 25%	> 25%
4 Outdoor or LEV?	Outdoors	15 mins - 1 hour	15 mins - 1 hour	Indoors with LEV	Indoors with LEV	Indoors with LEV
		< 15 mins	< 15 mins	Indoors with LEV	Indoors with LEV	Indoors with LEV

Worker Safety - Risk Management

5.1. Respiratory protection	Respiratory protection is not used	Respiratory protection is not used	Respiratory protection is not used	Respiratory protection is not used	Respiratory protection is not used
5.2. Dermal protection	no	no	no	Chemically resistant gloves with employee training	Chemically resistant gloves with employee training
6.1. Inhalation Risk Characterization Ratio (RCR-inhal)	$RCR_{inhal} = \frac{predicted Exposure_{inhal}}{DNEL_{inhal}}$			0,25	0,25
6.2. Dermal Risk Characterization Ratio (RCR-dermal)				0,01	0,01

Comparison with information on own use

	Use information			Exposure Modifying factors		LEV considered for dermal?	RPE	Dermal protection	RCR after Scaling		
	PROC	Solid	SU	Duration	Conc. in Preparation	No			Outdoor or LEV?	RCR _{DU,In} Inhalativ	RCR _{DU,D} Dermal
Addition of other raw materials via the manhole	4	no	3	1 - 4 hours	Not in a mixture	Indoors without LEV	Respiratory protection is not used	Chemically resistant gloves with employee training	1,51	0,01	1,52
Sampling	3	no	3	< 15 mins	Not in a mixture	Indoors without LEV	Respiratory protection is not used	no	0,25	0	0,25
Pump from predilution vessel into reactor	8a	no	3	15 mins - 1 hour	Not in a mixture	Indoors without LEV	Respiratory protection is not used	Chemically resistant gloves with employee training	0,5	0	0,5
Addition of Isocyanates via manhole	4	no	3	1 - 4 hours	Not in a mixture	Indoors without LEV	Respiratory protection is not used	Chemically resistant gloves with employee training	1,51	0,01	1,52

Note: green fields indicate

Inhalation protection for „Addition of other raw materials“ and „... of Isocyanates via manhole“ (PROC 4) no sufficient as RCR >1

=> Improve RMM or change operational conditions

e.g. install local exhaust ventilation or reduce duration of use

=> Check safe use with adjusted conditions

Adjusting the exposure modifiers

	Use information			Exposure Modifying factors		LEV considered for dermal?	RPE	Dermal protection	RCR after Scaling		
	PROC	Solid	SU	Duration	Conc. in Preparation	No			Outdoor or LEV?	RCR _{DU,In} Inhalativ	RCR _{DU,D} Dermal
Addition of other raw materials via the manhole	4	no	3	1 - 4 hours	Not in a mixture	Indoors with LEV	Respiratory protection is not used	Chemically resistant gloves with employee training	0,15	0,01	0,16
Sampling	3	no	3	< 15 mins	Not in a mixture	Indoors without LEV	Respiratory protection is not used	no	0,25	0	0,25
Pump from predilution vessel into reactor	8a	no	3	15 mins - 1 hour	Not in a mixture	Indoors without LEV	Respiratory protection is not used	Chemically resistant gloves with employee training	0,5	0	0,5
Addition of Isocyanates via manhole with LEV	4	no	3	1 - 4 hours	Not in a mixture	Indoors with LEV	Respiratory protection is not used	Chemically resistant gloves with employee training	0,15	0,01	0,16

Note: green fields indicate



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Next Steps

- Enforcers need to be informed about scaling.
- ‚Scaling‘ vs DU CSA in tools other than TRA:
Definitions of the area of applicability (by tool owners and in communication of ES to DUs).
- Higher tier assessments: Set of scaling rules and discrimination ‚Scaling‘ vs DU CSA may be developed.