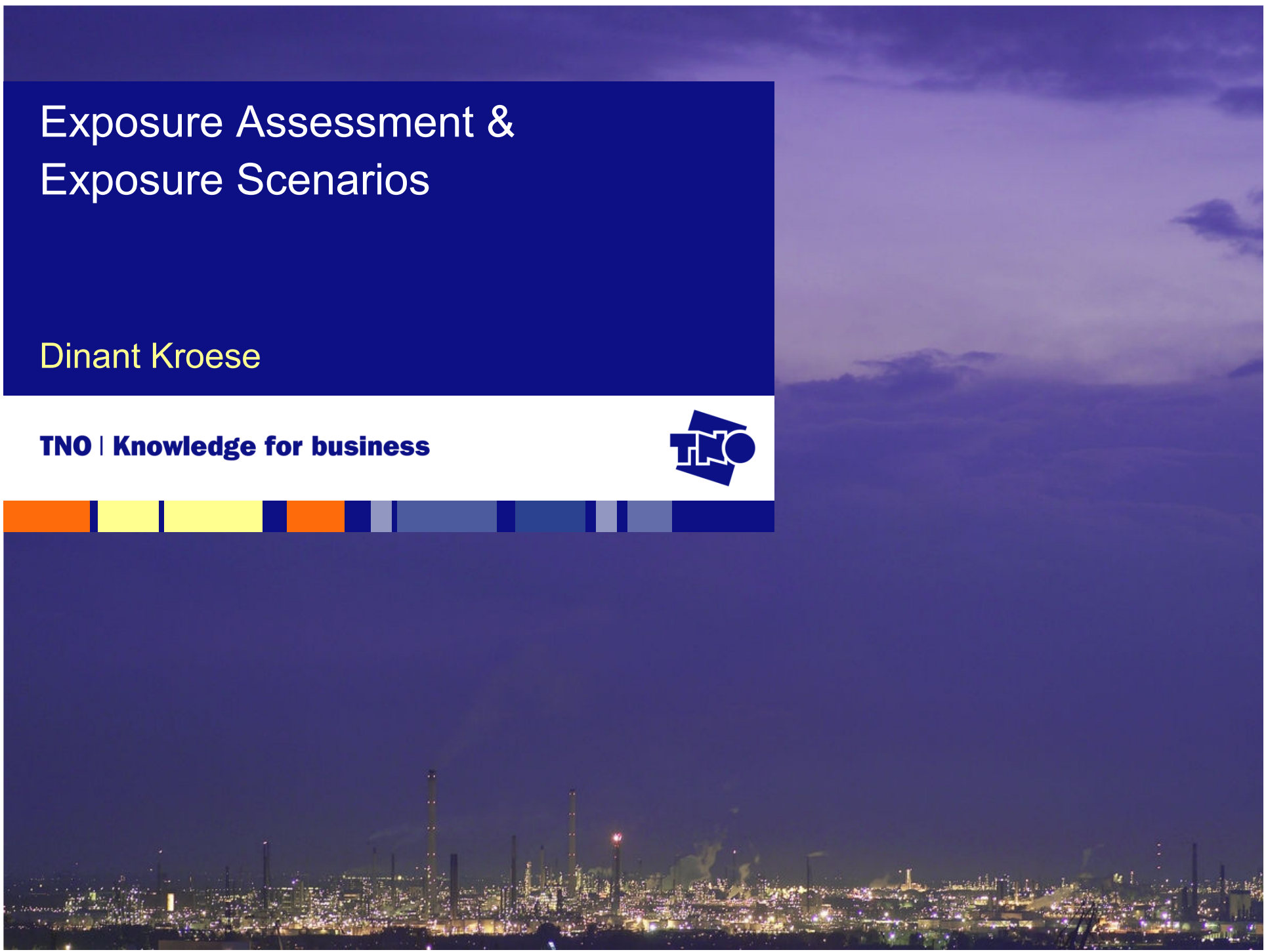
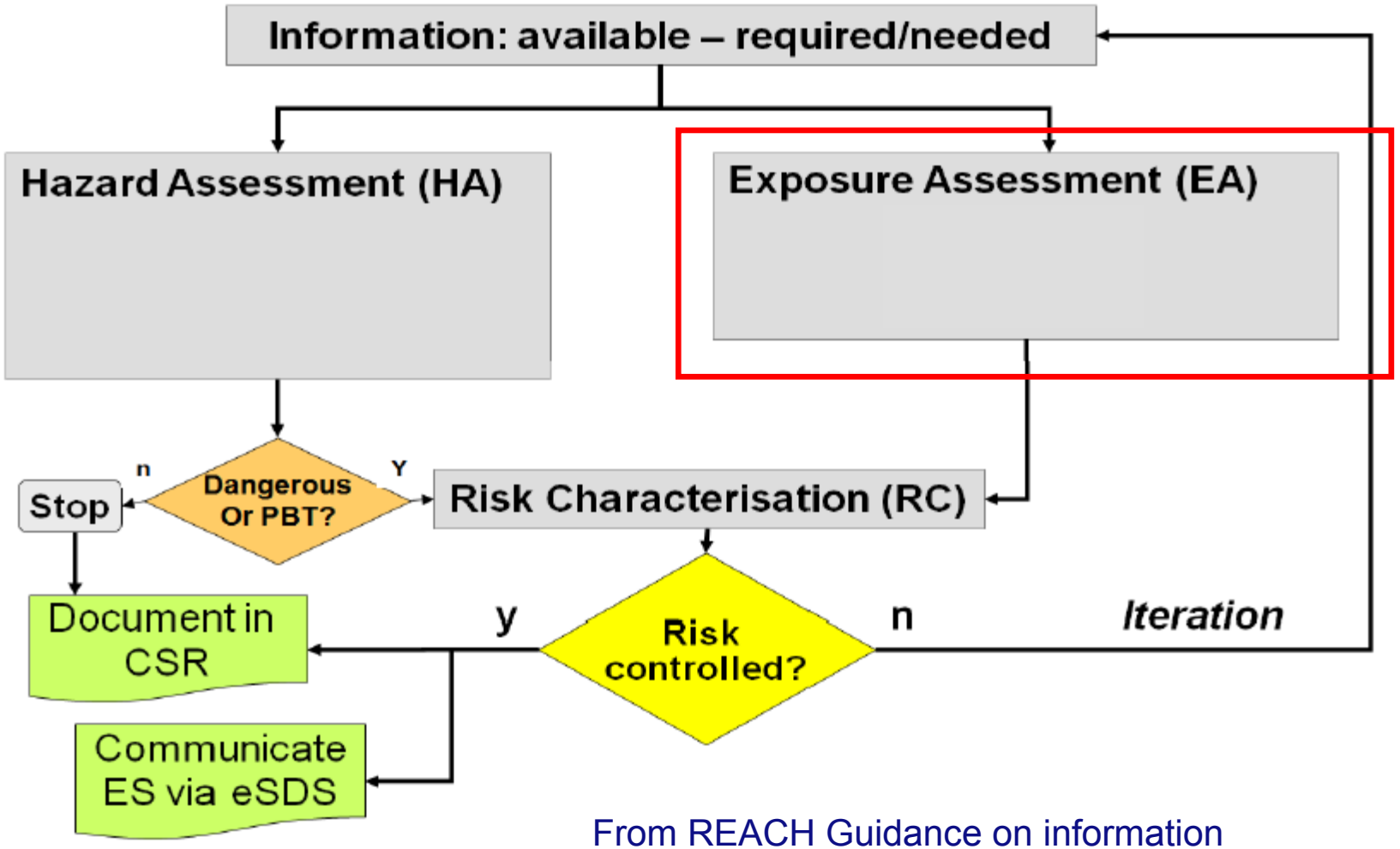
Exposure Assessment & Exposure Scenarios

Dinant Kroese

TNO | Knowledge for business



Chemical Safety assessment scheme



From REACH Guidance on information requirements and CSA – Part D

CONTENTS

What is an Exposure Scenario?

Conditions and risk management measures representing control of risk for manufacture and use of a **substance**

- Documentation in the CSR
- Input information for exposure estimates
- Instructive guidance for preparation makers, e.g. paints, lubricants, adhesives, cleaners

Conditions and risk management measures representing control of risk for manufacture and use of a **preparation**

- Instructive guidance for users of preparations in industry and the professional sector

What is a Generic Exposure Scenario?

(Partial) description of conditions and risk management measures representing control of risk for manufacture and use of **a number of substances or preparations (in a number of situations)**

- An ES valid for several substances or preparations
- Basis for individual ES for separate substances or preparations

Tiered approach for Exposure Scenarios

Tier 1:

tool / simple, broadly applicable and conservative

Tier 2:

tool /

- more differentiation in situations compared to Tier 1 tools
- more Risk Management Measures included
- more input data needed
- more specific, possibly less conservative assessment

or measured data (with contextual information)

Tiered approach for Exposure Scenarios

Tier 1:

tools: worker: ECETOC TRA

consumer: CONSEXPO (simple)

Tier 2:

tools: worker: Stoffenmanager (inhalation)

RISKOFDERM (dermal)

consumer: CONSEXPO (full version)

or **measured data** (with contextual information)

Measured data

- Idealy: focused measurements (often impracticable)

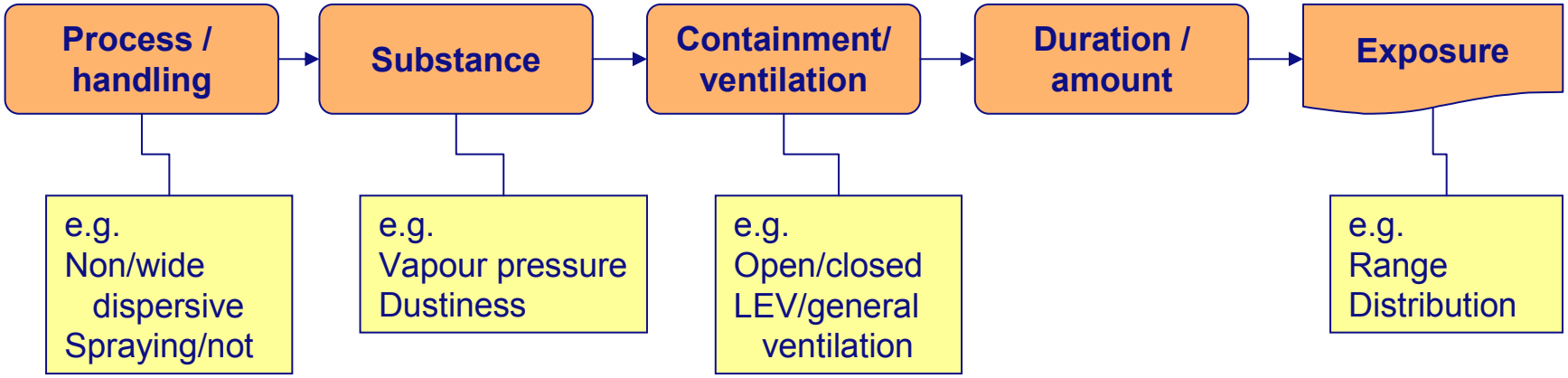
- Other options:
  - Literature search – few with context
  - Own databases – few scenarios

- Choice
  - Inhalation data STEAMBASE
  - Dermal data RISKOFDERM
    - (with limited suppl. literature)

Table 5.6 Scenario 1.14, Mixing/dilution (small scale) in terms of

Sample identifier	Quantity of formulation processed/used (litres)	Physical state of formulation	Sample duration (mins)	% analyte in formulation	Hand exposure (mg)	Whole body exposure (excl hands) (mg)	Hand exposure deposition rate (mg/min)	Wh bo expo (e: han (mg/
04-088	3g	Solid	8	32	1.491	15.891	0.186	1
04-089	3g	Solid	6	32	1.185	0.000	0.198	0
04-090	3g	Solid	12	32	2.370	0.484	0.198	0
04-091	3g	Solid	4	32	1.023	0.000	0.256	0
04-092	3g	Solid	4	32	0.883	0.000	0.221	0
04-093	3g	Solid	4	32	0.000	0.047	0.000	0
04-094	3g	Solid	4	32	7.724	1.031	1.931	0
04-095	3g	Solid	4	32	3.078	1.841	0.770	0

Tier 1 model: ECETOC TRA

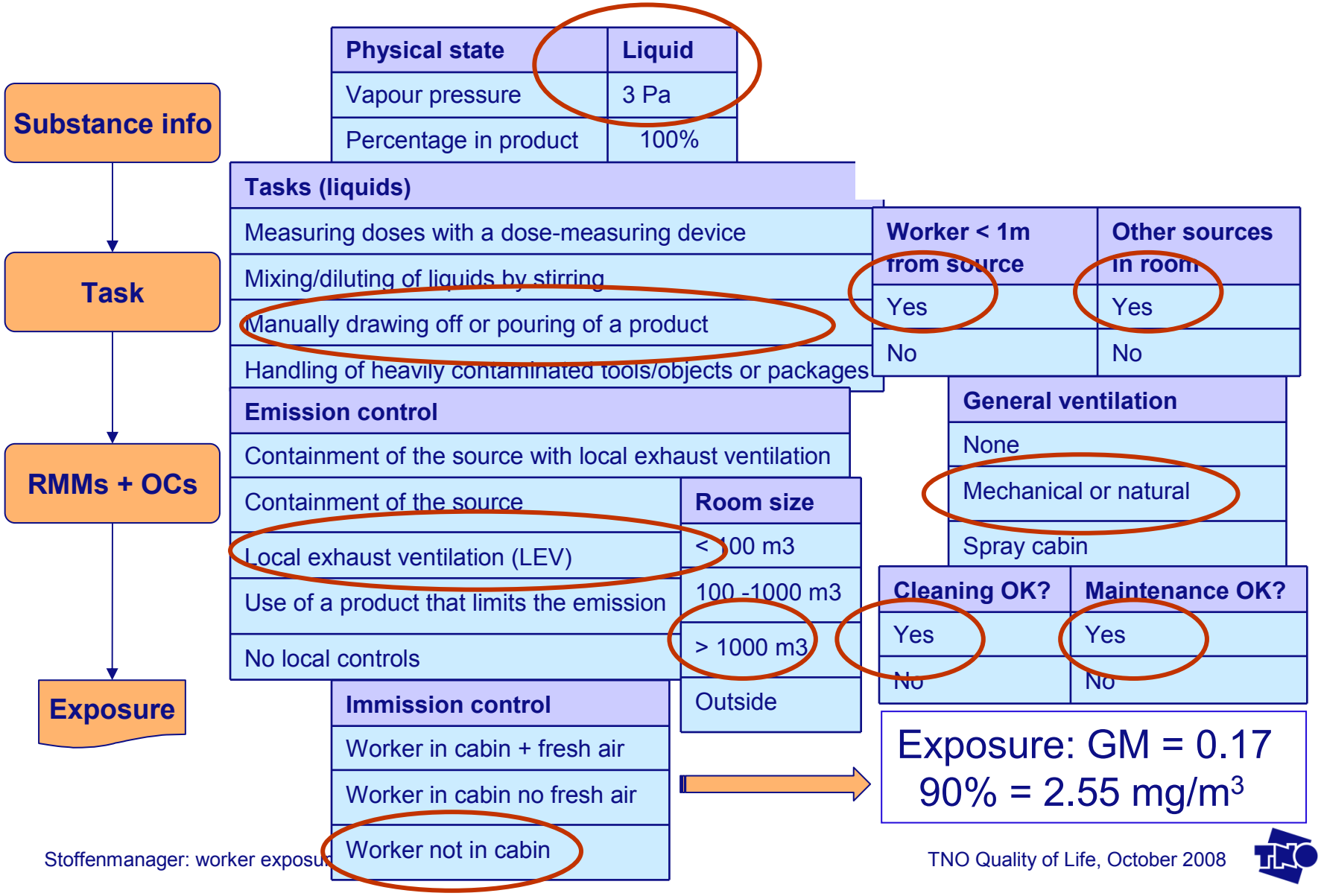


- Limited number of parameters
- Rough categorisation, few options
- Some unclear terminology or unclear differences between options
- Meant for full shift exposure

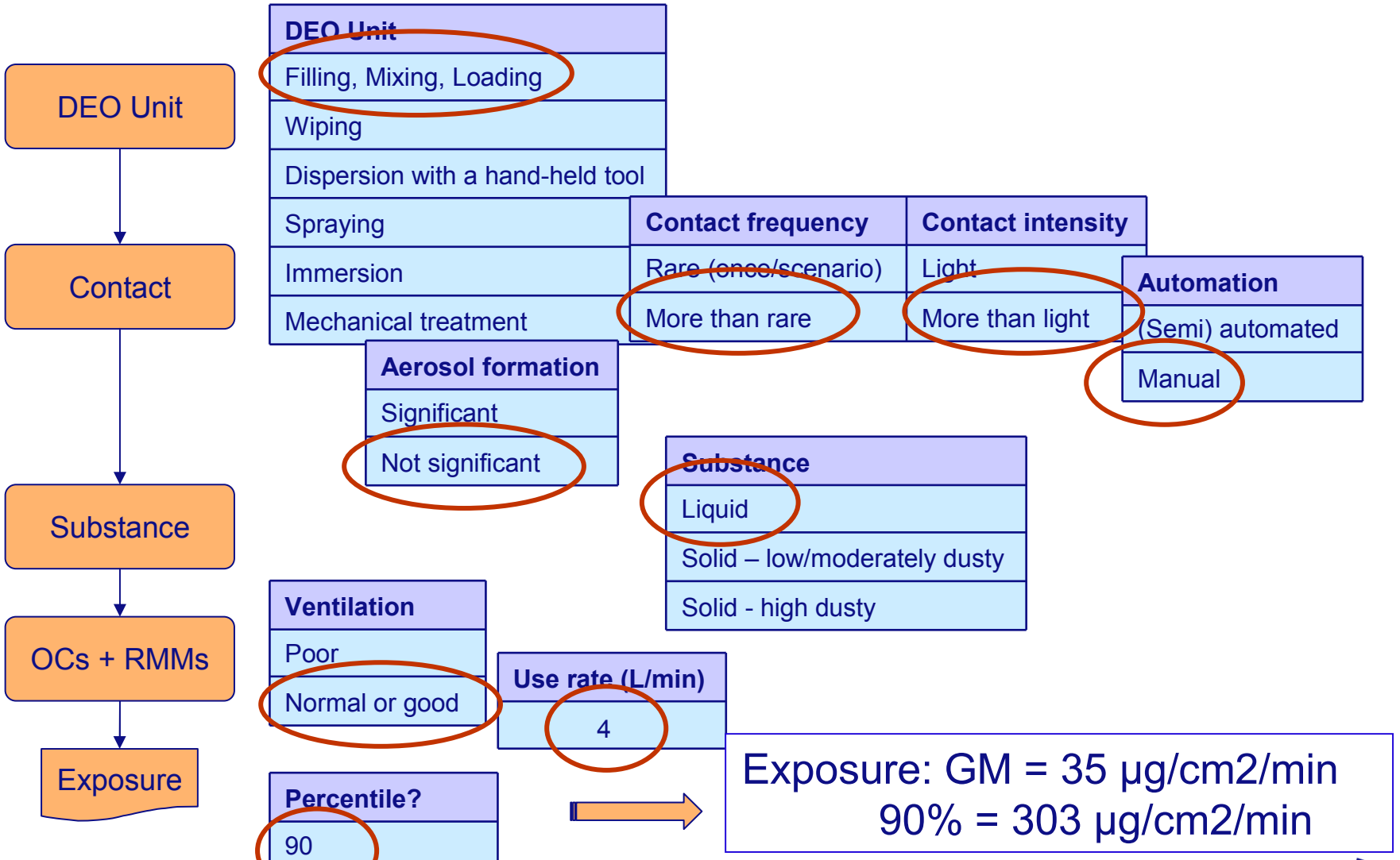
Higher tier models

- Existing models (mentioned in Guidance)
  - Stoffenmanager (inhalation only)
  - RISKOFDERM (dermal only)
  - CONSEXPO (all routes)
- Model in development
  - Advanced REACH Tool (first inhalation, later also dermal)
- Possibly highly specific models
  - Spray application
  - Ad hoc models

Stoffenmanager example



RISKOFDERM example



3. Experience

- Tier 1 models are very rough
  - Easy and useful for first check
  - Difficult to show control of risk for more hazardous substances
- Existing measured data difficult to interpret
  - Unexplained unexpected high values
  - Variation between apparently similar exposure groups
- Inputs for models (both Tier 1 and further) often difficult to choose
  - E.g. ‘scenario’ in ECETOC TRA
  - E.g. ‘use rate’ in RISKOFDERM

3. Experience (2)

General approach

- Try to find a suitable GES
  - Adapt this to your chemical, with possibly further small modifications
- Otherwise take Tier 1 estimations
  - Do reality check whether existing data do not facilitate a change
- In case no control of risk… try further Tier models or measured data

Summary

- Many approaches based on knowledge of present OC + RMM
- ECETOC TRA based estimates easy to make

- What if Tier 1 assessments do not show control of risk?
- How to account for within sector variation?

- More complex situations that do not fit Tier 1 assessments

→ Build up GES from specific to generic

→ Use measured data or further Tier models

- Generic Exposure Scenarios possible for substance groups
  - Ranges of physico-chemical characteristics
  - Ranges of DNELs

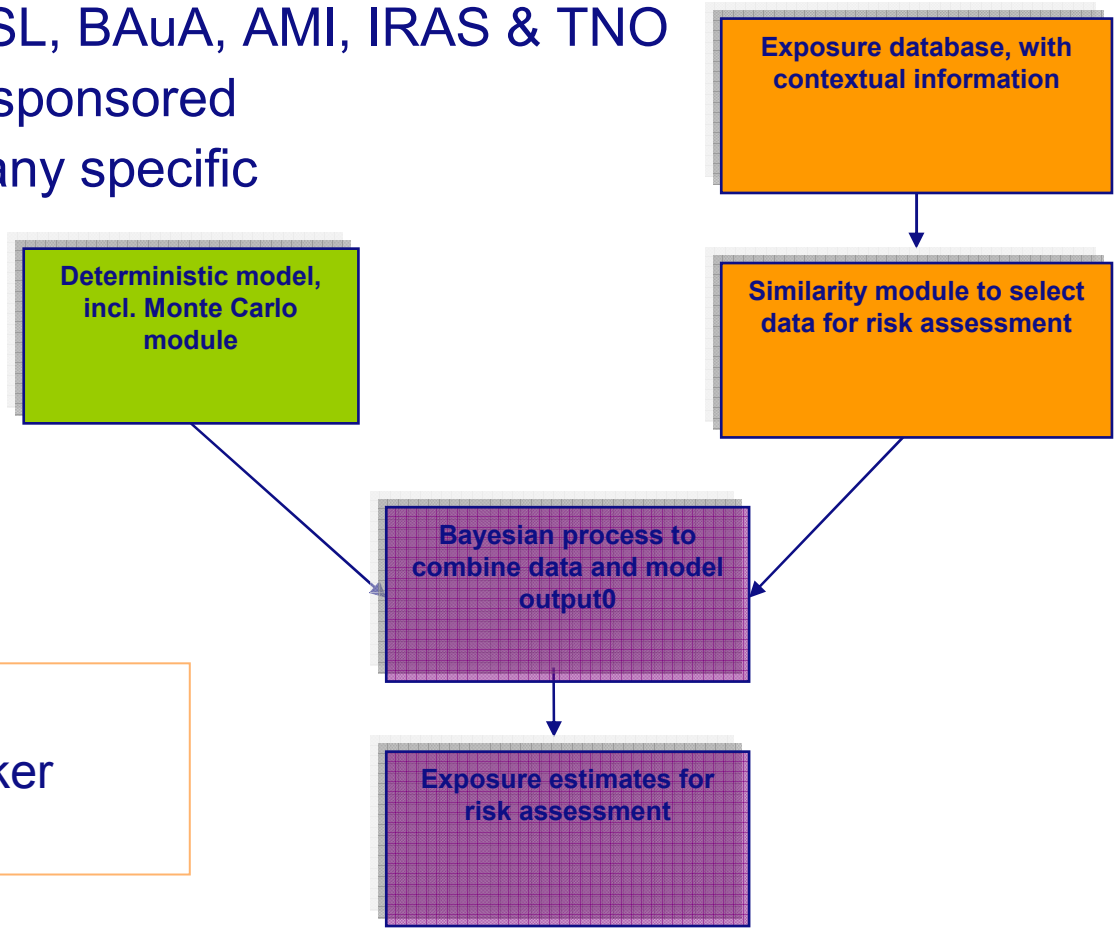
4. Developments in Exposure Assessments

- New versions of ECETOC TRA expected in April
  - Worker part
    - Take account of all Process Categories
    - Differentiation between industrial and professional
  - Consumer part
    - Simplified Tier 1 version of CONSEXPO
    - Broad product categories with some subcategories
  - Acceptance of changes for REACH Guidance through Guidance update

- Advanced REACH Tool for Tier 1 (inhalation) expected end 2009
  - Model based on source-to-target concept
  - Bayesian combination with measured data

Development of ART

- ART = Advanced REACH Tool
- Consortium: IOM, HSL, BAuA, AMI, IRAS & TNO
- CEFIC/Eurometaux sponsored
- May be made company specific

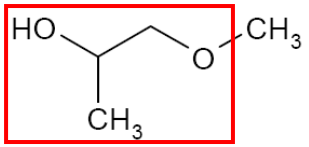
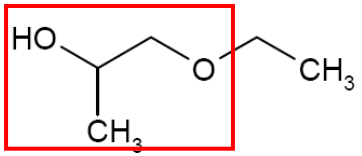
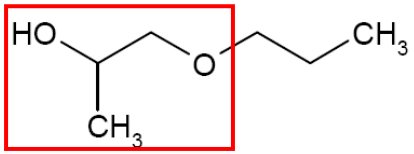
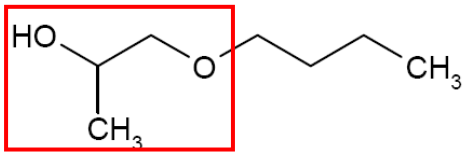


Goal:
A tier 2 tool for refined worker exposure assessment

Development of hazard assessment

target

source

Substance	DNEL
 Methoxypropan-2-ol (PGME)	11.0 mg/m^3 45.1 mg/m^3
 2-propanol, 1-ethoxy- (PGEE)	22.2 mg/m^3
 1-Propoxy-2-propanol	22.1 mg/m^3
 propylene glycol n-butyl ether (PnB)	14.8 mg/m^3

Based on AF of 2 for read across

Based on own testing data

Instead of deterministic a probabilistic derivation of a DNEL to allow a full probabilistic RC

4. Developments in Exposure Assessments (2)

Free web based CSA tool for registrants

- Extracts relevant information from IUCLID5 (DNELs, R-phrases, physchem data..);
- Asks for exposure determinants input from User

Simple Version: 01/12/09

Extended Version: 01/04/10

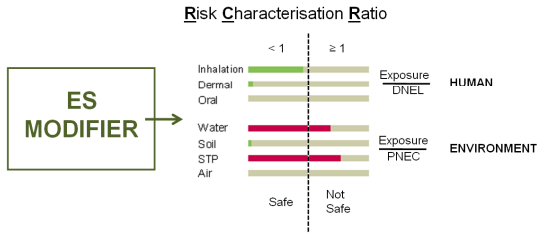
to:

- Give a **1e tier** exposure assessment (with ECETOC TRA model, for worker & cons)
- Calculates RCR for all relevant scenarios and combinations of applicable routes
- If 'control of risks': - provides '+' descriptions for SDS+
  - documents conclusion in CSR
- If 'no control of risks': - indicates that User should perform **2nd tier** assessment
  - asks for result 2nd tier to conclude yes/no 'control of risks'

ES Modifier & chain communication

- ES Modifier: An IT-tool for formulators
- With the ES modifier a user may:
  - Develop an ES for mixtures
  - Scaling: check OCs and RMMs in the ES received
- Models included:
  - ECETOC TRA, EUSES, ERC's, StoffenManager, RiskOfDerm, COSHH-BAUA
- CEFIC and DUCC on board
  - Include in mapping

Key OUTPUT: Calculation of **RCR**



DANISH MINISTRY OF THE ENVIRONMENT
Environmental Protection Agency

DHI WATER & ENVIRONMENT

Thank you for your attention!