

REACH – brief explanation

- Registration manufacturers, importers
 - Technical dossier
 - Chemical Safety Report
- Evaluation authorities
 - Compliance, dossier and substance
- Authorisation
 - Very hazardous substances
 - Also possibly "Restrictions"
- CHemicals
- Pre-registration
 - Stimulate cooperation



Chemical Safety Report

- Human health hazard assessment
 - Identification of Derived No Effect Level
- Environmental hazard assessment
 - Identification of Predicted No Effect Concentration
- Persistent, Bioaccumulation & Toxic (PBT) Carcinogenicity,
 Mutagenicity & Reprotox → authorisation
- + if classified (Classification & labeling criteria)
- Exposure assessment
- Risk Characterisation
- Exposure Scenarios (safe use description)
- Extended SDS

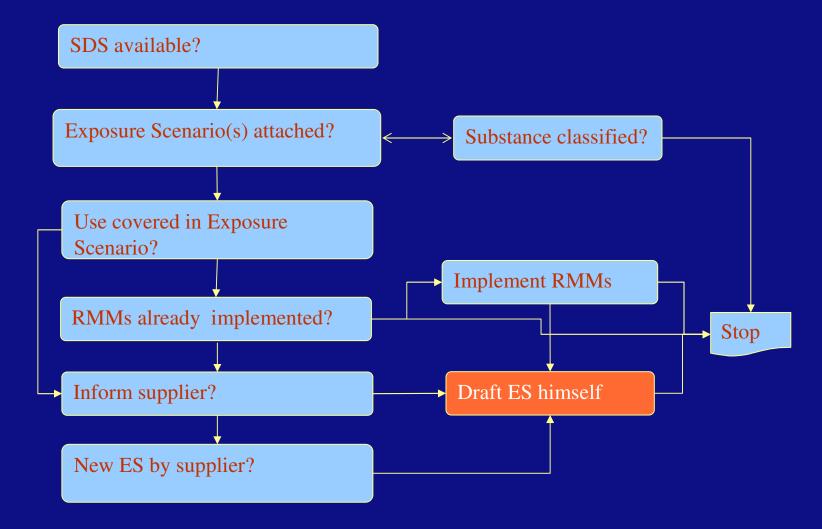


Exposure Scenarios under REACH

- Descriptions of "Safe handling" of a substance
 - Focus on risk management
- Part of Chemical Safety Report
 - Responsibility of registrant (in general)
 - For full product chain
- Linked to exposure assessment
- Communication to users via SDS
- Broad / generic ←→ narrow / specific
- Format and contents in development



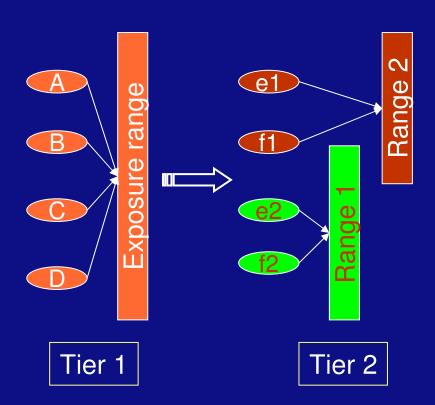
Exposure Scenario by Downstream user?





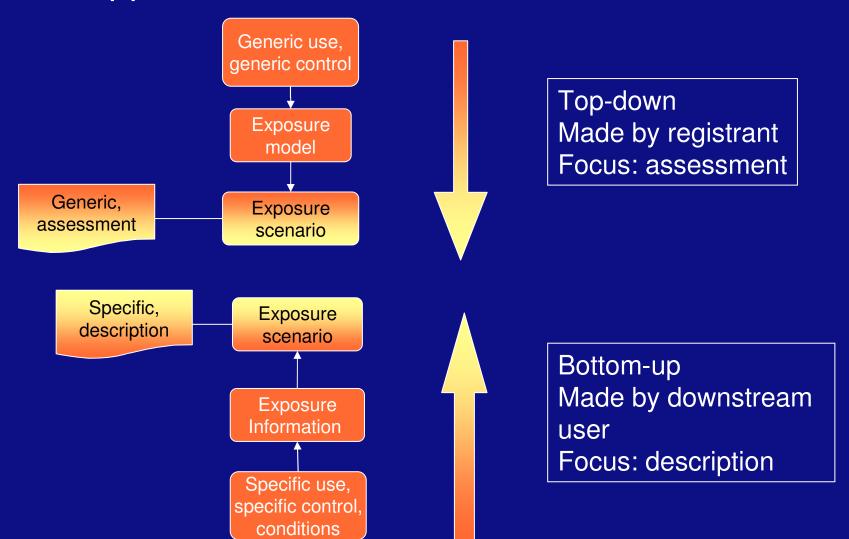
Determinants in Exposure scenario

- Highly critical determinants
 - Necessary for rough assessment
 - Phys. Chem. Substance/product
 - IFV
 - Minimal amount
- Important determinants
 - Percentage in product
 - Amount used/use rate
 - Type and size of packaging
 - Other RMMs
 - Viscosity of product
- Complicated assessmenst
 - More specific inputs
 - Measurement of exposure



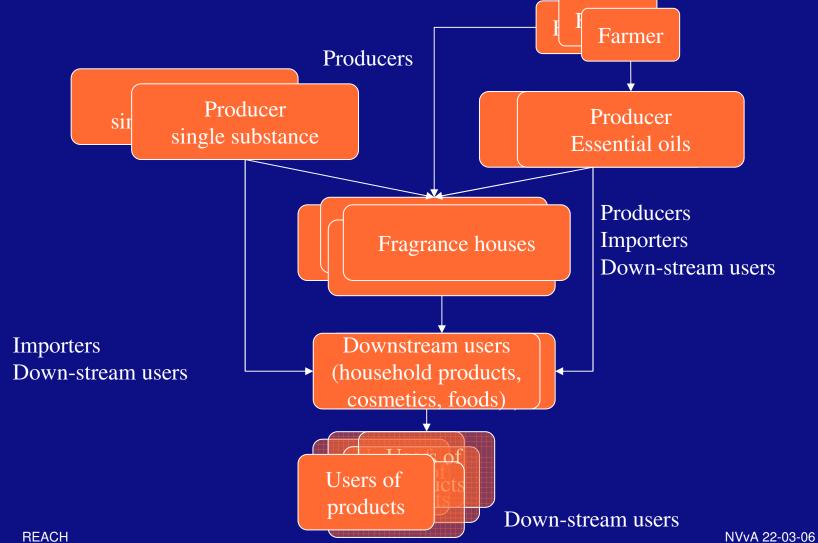


Two approaches





SPORT - complex product chain

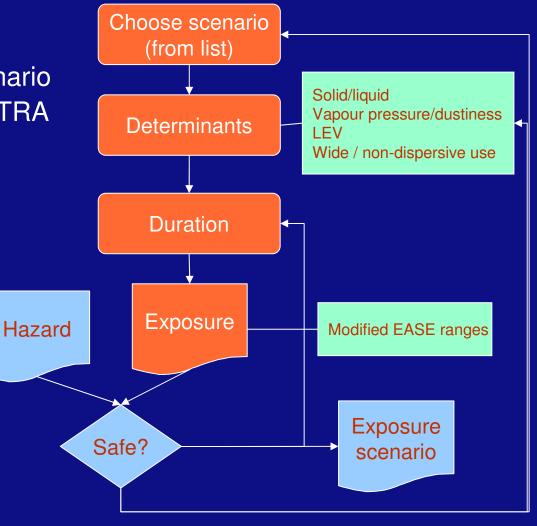




REACH Implementation Project 3.2-1

- Description of process
- "Tentative" Exposure Scenario
- Assessment → ECETOC TRA
- "Final" ES
- Annex to the SDS







Example outcome "Tier 1" ECETOC TRA

Table 2. The first iteration of Tier 1 assessment of the production of paint; inhalation exposure

Table 2. The first iteration of field assessment of the production of paint, finalation exposure								
Task	Duration	LEV	Substance	GEV ¹⁾	Estimated	MOE	Assessment	Further
		present?			exposure ¹⁾		factor	assessment
								required
$Mixing^{a)}$	> 4 hours	Yes	Diethanolamine	1	1	1	2	Yes
			Turpentine	1	25	0.04	2	Yes
			Ethylene glycol	Not relevant	25			
			monoethyl ether					
			Yellow 53	1	5	0.2	2	Yes
$Mixing^{b)}$	1-4 hours	No	Diethanolamine	1	3	0.33	2	Yes
			Turpentine	1	30	0.03	2	Yes
			Ethylene glycol	Not relevant	30			
			monoethyl ether					
			Yellow 53	1	15	0.07	2	Yes
(Dis)charging	1-4 hours	No	Diethanolamine	1	6	0.17	2	Yes
			Turpentine	1	30	0.03	2	Yes
			Ethylene glycol	Not relevant	30			
			monoethyl ether					
			Yellow 53	1	30	0.03	2	Yes
Filling	1-4 hours	No	Diethanolamine	1	6	0.17	2	Yes
			Turpentine	1	60	0.017	2	Yes
			Ethylene glycol	Not relevant	60			
			monoethyl ether					

RIP 3.2 – Textile dye

Scenario	Industrial use of textile dyes
Activities	 Industrial textile dyeing (exhaust process and padding process) Raw material and onsite waste handling
Conc. in product	Up to 100 %
Duration/ frequency	Full shift, full year
RMM required	Always
	 LEV for weighing and mixing
	Segregate weighing area
	Closed or covered mixer or hopper
	High contamination
	Chemical resistant gloves
	Half mask filter with FFP1



'VASt' project



- Information on processes, tasks, controls
 - Branches
 - Prior information at TNO
- Top-down: assessment cf. RIP 3.2 approach
 - Per process step
 - Discuss with industry
- Bottom-up:
 - Specific information including exposure data
 - Structured workplace visits
 - Per full process
 - Discuss with industry



Primer-surfacer in car body repair - top-down

Based on substance with highest risk

Scenario	Car body repair painting primer-surfacer			
Activities	Filling spray gunSpraying			
Type of substances	Liquids and solids (powders)			
Duration and frequency	Daily; filling ≤ 1 hour per day; spraying ≤ 4 hour per day			
Risk management measures	Filling: In mixing room; LEV (reduction $\geq 90\%$) Spraying: In preparation room: LEV (reduction $\geq 98\%$) Both: Gloves APF ≥ 6 + respiratory protection APF ≥ 4			



Exposure data?

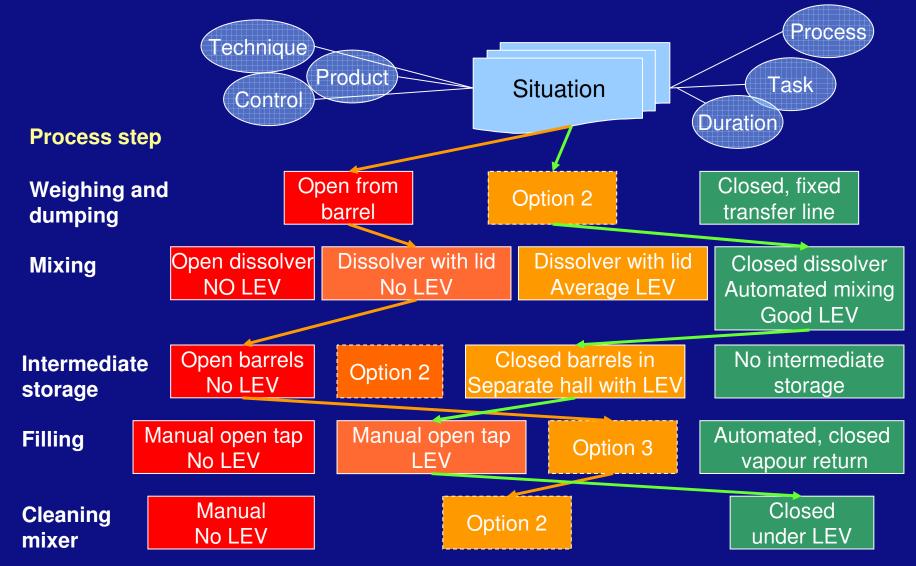
- Paint industry
 - Volatile Organic Compounds (total)
 - Limited detail (tasks + exposure controls)
 - More useful data available confidentiality
 - Limited other data sets from research sufficient details
 - Powder dumping
 - Liquid transfer
- Car body repair shops
 - No data at companies
 - Some useful data from research
- Large data gaps!







Bottom-up: Exposure Scenario Builder

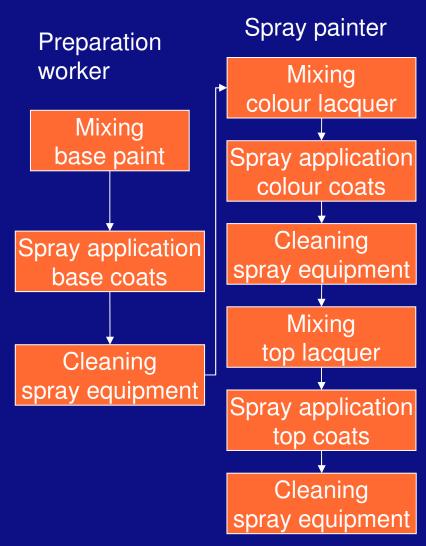




Bottom-up - Car body repair painting

- General process flow
- Limited variation in major process steps
- Fixed combinations task, work area and controls
- One single scenario for whole industry





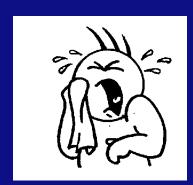
Exposure scenario car body repair painting

Exposure contro	I measures available and in use		
General	Mechanical area ventilation		
Mixing	 LEV at edges of work tables No LEV above weighing balance Close paint cans after use 		
Spraying	Base coat LEV ceiling to wall compartmenting by plastic curtains Colour and top coats Spray booths with laminar flow system: ceiling to bottom Both HVLP spray guns		
Cleaning spray equipment	LEV at spray gun cleaning machine and at edges of work tables		



Exposure scenarios for REACH Why should the user care?

- "Top-down" scenarios
 - Generic and conservative
 - Not fit to users
- Possibly many scenarios for the same process
 - Several suppliers , many substances



- Active users
 - Cooperation in branche(s) → market power
- "Bottom-up" scenarios
 - Structure available information
 - Use, Processes, Conditions, RMM, Exposure levels
 - Understandable for downstream users
 - Flexibility in Exposure Scenarios



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REACH

Final recommendations

- Provide information upstream
- Use generic tools, models
- And specific information
- Gather exposure data
- Cooperate in product chain
- Use occupational hygiene expertise

Thank you!

Advanced tool needed



