

Exposure Scenario Building under REACH

Learning from the Arona Network Process

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- What is the Arona Network ?
- Exemplification of Exposure Scenario Building and Chemicals Safety Assessment
- Learning Points

The Arona Network

- Series of 5 workshops for industry in the framework of the REACH Implementation Project (RIP) 3.2-2
 - Organized by the ECB in co-operation with the CEFIC led RIP 3.2-2 consortium
 - 2/06, 6/06, 11/06, 3/07, 8/07
- Platform to discuss approaches and experience related to exposure scenario building in practice
- About 120 persons in the Arona Network

What is an exposure scenario?

- A set of information describing the conditions under which a dangerous substance can be manufactured and used safely (= adequate control)
 - Documentation in the CSR
 - Input information for exposure estimates, enabling to carry out a chemicals safety assessment
 - Instructive guidance for preparation makers, e.g. paints, lubricants, adhesives, cleaners
- A set of information describing the conditions under which all the (dangerous) substances in a preparation can be safely used
 - Instructive guidance for users of preparations in industry and the professional sector

ES core information (1)

	Short title:	
1	Description of activities, processes	
2	duration and frequency of use, for which the RMMs ensure adequate control of risk	
3	Product specification (concentration or % of substance in preparation or article)	
4	Physical form of product; volume/surface ratio for articles	
5	Amount of substance per time or activity,	
6	Other operational conditions of use (if relevant) <ul style="list-style-type: none">• temperature• emission or release factors determined by technology;• Capacity of receiving environment (water flow; room size x ventilation rate)• other	

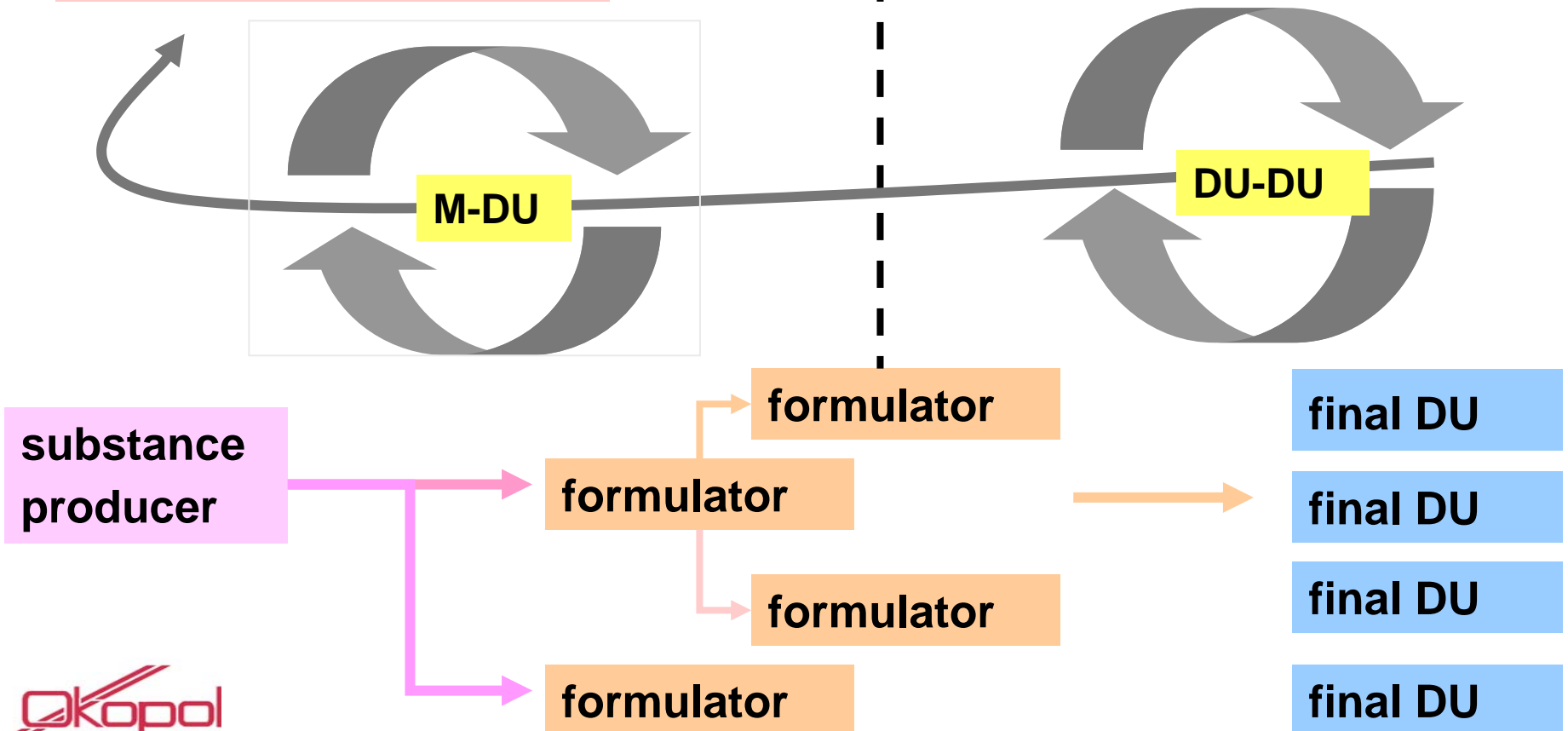
ES core information (2)

7	Risk management measures; efficacy of measures to be quantified; <ul style="list-style-type: none">• Occupational measures• Environmental measures• Consumer related measures	
8	Waste related measures (including substances in articles at the end of service life)	
9	Prediction of exposure and reference to the source of prediction;	
10	Variables and algorithm for scaling the ES to specific conditions at DU level (including underlying assumptions)	

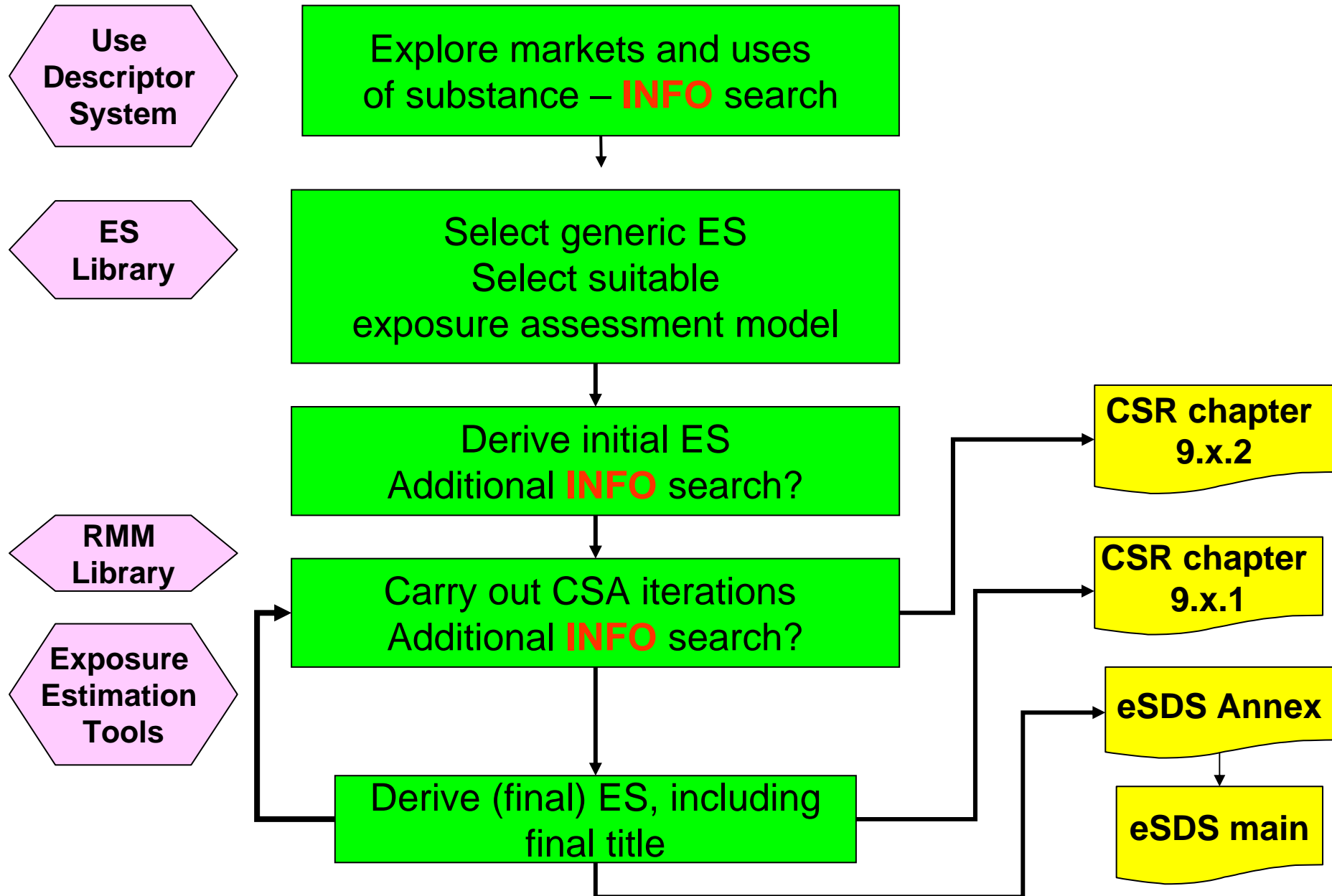
Overall process of ES building

- Identification of uses
- Conditions of use
- ES building
- CSA/CSR (M/I)

- Identification of uses
- Information on existing conditions of use
- Tentative ES building



ES Building – workflow, outcome, tools



Exemplified product and process types (1)

Case by product/process type	
rim block air freshener	Aise
spray air freshener	Aise
household cleaner	Aise
laundry detergent powder	Aise
hard surface cleaner	Aise
2c repair adhesive	Feika
2c structural joining automotive	Feika
2c flooring	Feika
plastic compounds for film blowing	EUPC
plastic compounds for cable coating	EUPC
Inks and cleaners on screen printing	CEPE

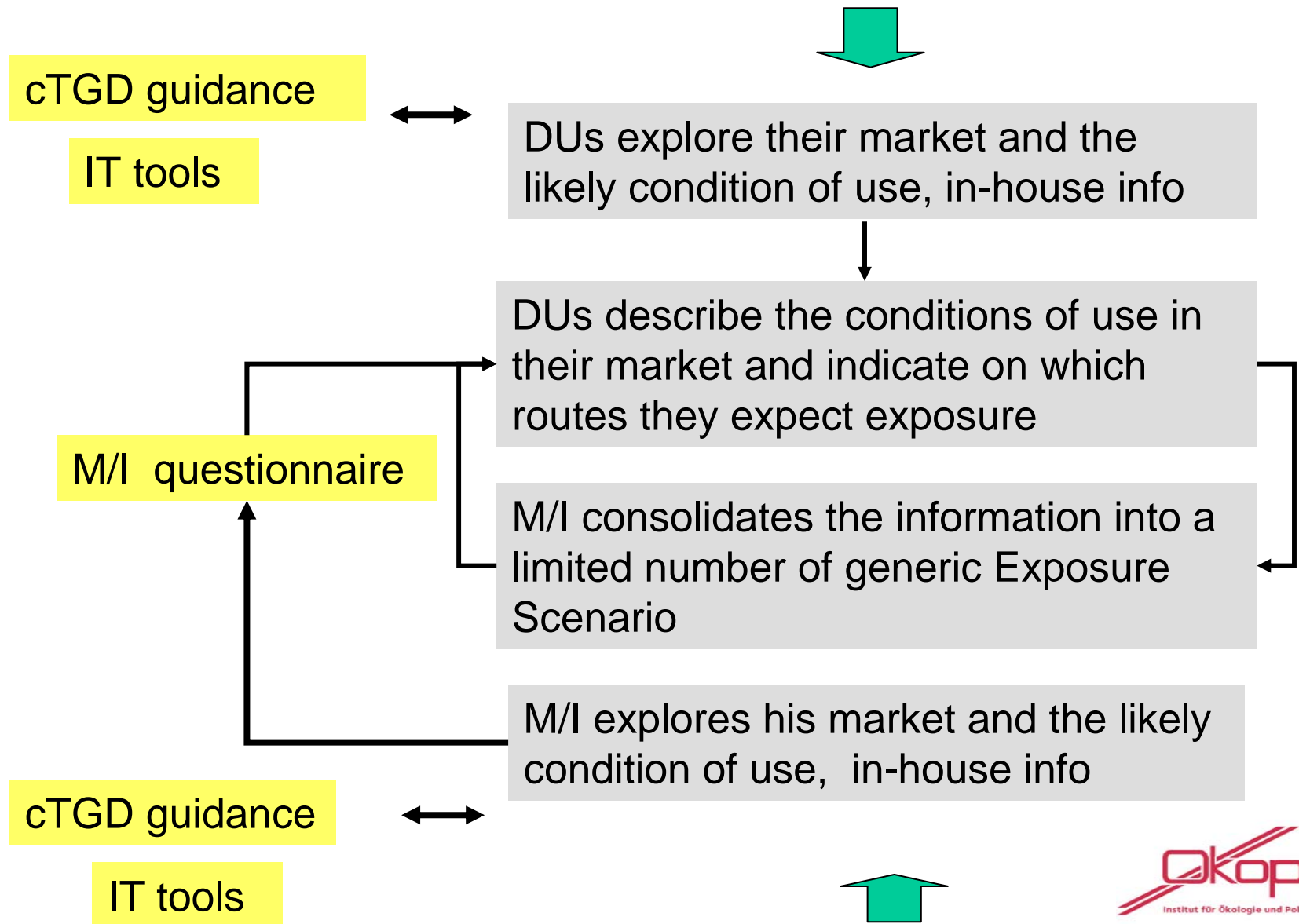
Product types, process types (2)

Case by product/process type	
textile dye and finishing agents (into article)	TEGEWA
processing auxiliaries for textile finishing	TEGEWA
protective coating spray (auto/manually)	CEPE
protective coating roller/brush	CEPE
deco-paint (outdoor/indoor), spray or brush	CEPE
processing chemicals, pulp and paper	CEPI
professional use of NPK fertilizer	EFMA
industrial metal processing and finishing	EUROMETAUX
service life of metals in water boiler	EUROMETAUX
metal article waste (wet mech. processing)	EUROMETAUX
processing chemicals for semiconductors	SEMATECH

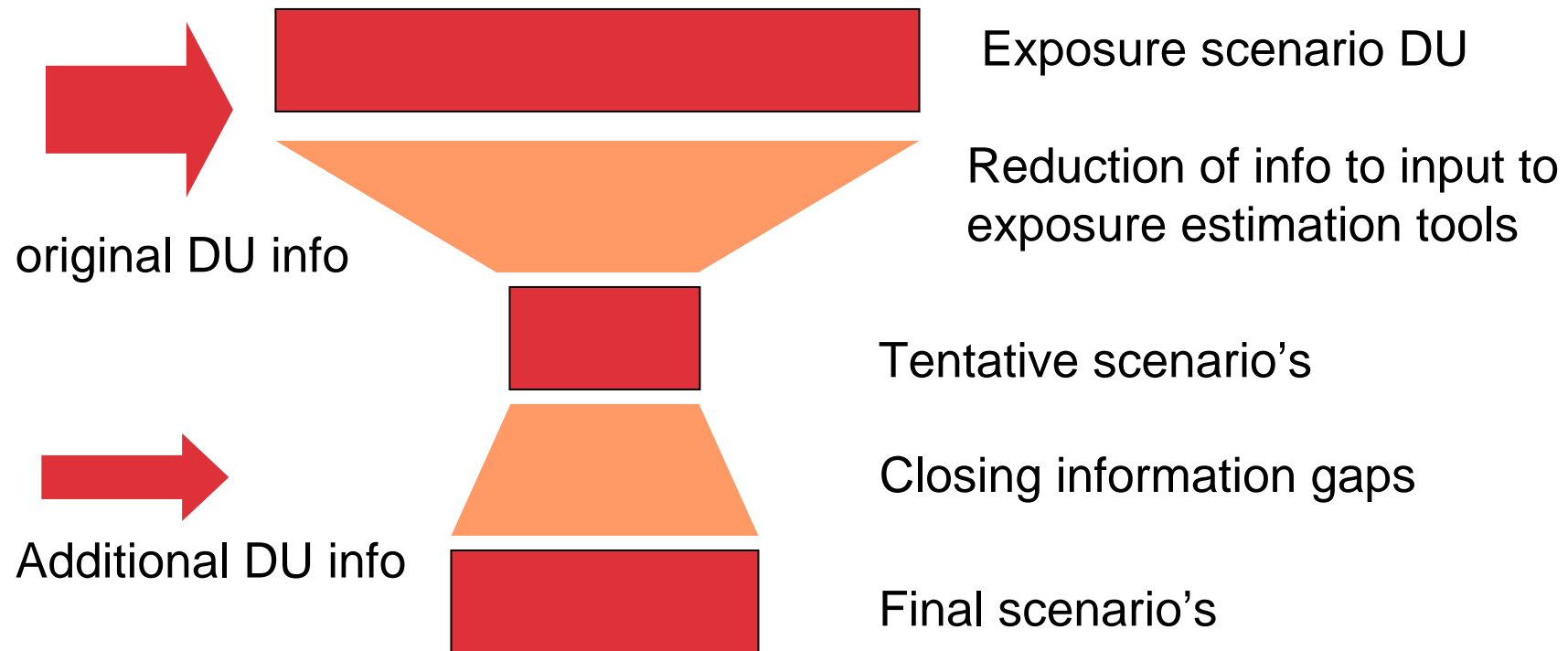
Exemplified substance markets

Case by substance type	
solvent, coupling agent, intermediate	Dow
stabilizer	Ciba Specialities
aerosol propellant	BP
intermediate, Solvent	Lyondell
solvent	Shell
pressure transfer agent	Shell
intermediate, solvent	Dow Corning
solvent	Exxon + Brenntag
surfactant	Cognis
solvent	3M
monomer	3M

ES Building Process – A Team Work



Striking the balance between *generic* and *specific*



* Copied from DOW/Jotun case

Win-win related to „generic-specific“ balance

	M/I	DU
ES to be as generic as possible	Avoidance of bureaucracy	Flexibility
ES to be as specific as needed	Re-assurance related to product safety	Usefulness

Learning points (1)

- Building exposure scenarios requires communication over three or more levels in the chain, the number of companies using the substance rapidly grows from level to level
 - New communication processes in the chain should take place **now**, rather than after registration
 - DU association need to act in a new role
 - New web based information exchange tools needed.
- The current tools available for exposure assessment from a top-down perspective (based on modelling) are not yet fully suitable to demonstrate safe use in an easy and effective manner:
 - The tools tend to be too conservative (tier 1), thus do not support to quickly distinguish between safe uses and additional risk management needs.
 - The tools do not support iteration by introducing additional risk management measures.

Learning points (2)

- As it seems, there is a huge amount of measured exposure data existing in the market. However it is not yet clear how to make these data on a regular basis available for the CSA process.
- There is an increasing understanding on the tri-fold function of the exposure scenario in the REACH system. It is still a challenge to serve all three function in one system, based on standard language.
 - M/I's own documentation and CSR for the authorities,
 - Set of information to be fed into exposure assessment tools (enable to compare with DNEL and PNEC)
 - Instructive guidance for customers how to safely use the substance.
 - Formulators
 - Professional and industrial end users

Learning points (3)

- There is a growing understanding how formulators should work with the extended safety data sheets received from their suppliers. Based on a number of practical examples, a generic workflow has been developed in RIP 3.5, starting with simple solutions and only suggesting complex solutions where really needed.
- Difficulty for industry to feed the existing experience related to exposure assessment and risk management into the EU guidance development
 - Infrastructure and capacity at the level of CEFIC and national associations not fully established.
 - Capacity at company level bound in own preparatory work
 - Lack of awareness that guidance development at EU level is key to harvest efficiency gains through REACH at a later stage.

Learning points (4)

A networking process has really started, showing the first productive outcomes:

- German organisations working in the field of occupational health and safety have started to translate their risk management advice into English to make it accessible for the REACH process through the risk management library.
- Co-operation among downstream sectors have started to build generic exposure scenarios for similar processes in different sectors of industry
- During the RIP 3.2.2 process various downstream user organisation (formulators level) have started/increased their efforts to develop generic exposure scenarios for the conditions of use related to the products of their sector.
- The Arona Network is a platform for substance manufacturers, formulators and users of chemicals to arrive at a common understanding on what has to be done.

Thank You !