



Overview methods currently being developed to determine and communicate safe use information for mixtures

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Downstream Users of Chemicals Co-ordination group

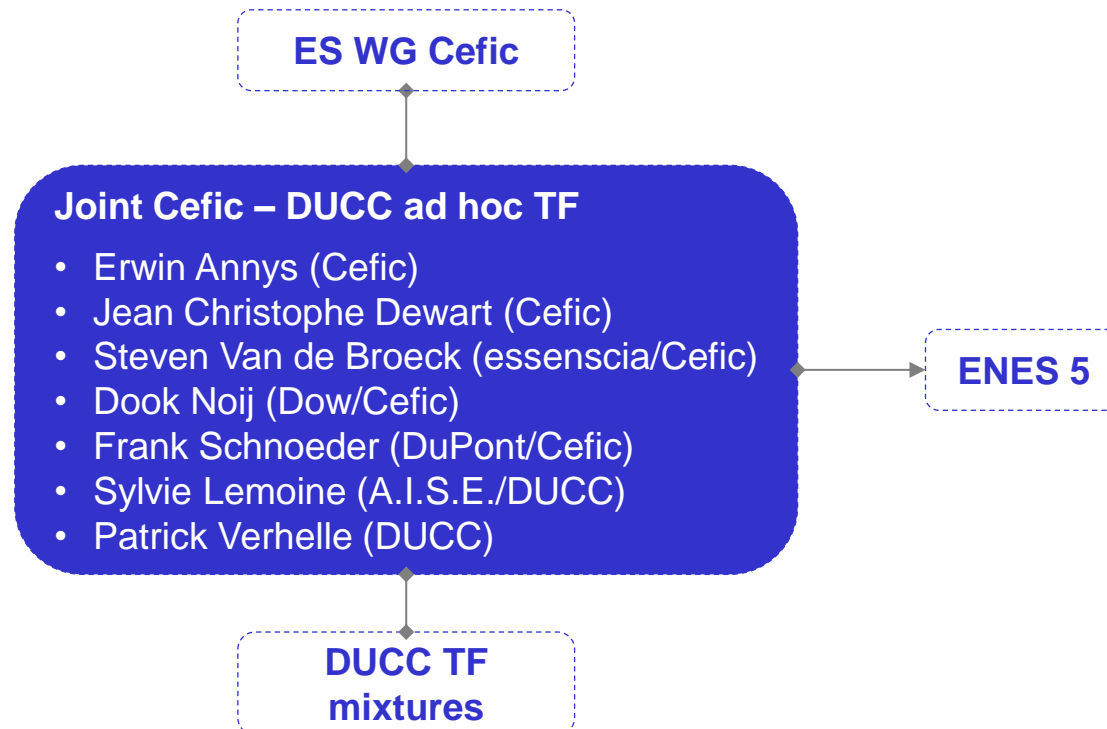
Introduction

- **How to handle ES information for substances in mixtures has been already the subject at several ENES meetings**
- **mid July ECHA released the CSR roadmap targeting the improvement of the CSR and SDS and which is built around 5 general areas of work**
- **one general area of work is understanding and processing of exposure scenario information at formulators' level. Crucial to this is the (further) development of methodologies for converting the substance-related safety advice in the exposure scenarios into communication on safe use of (substances in) mixtures**
- **According to the road map implementation plan, following activity is foreseen:**

Set up an industry task group to prepare for ENES 5 which is dedicated to addressing current issues on REACH implementation and mixtures. The preparatory work will include: mapping out and systematically comparing the existing industry approaches and commonly applied methods to link exposure scenarios for substances generated under REACH with the advice on safe use for mixtures. Identify and disseminate good practice elements that can be broadly applied.

Joint Cefic-DUCC ad hoc TF

- A joint Cefic-DUCC TF is set up to prepare for ENES 5
- Area of work ad hoc TF
 - collection of information on various approaches being developed for handling safe use information for mixtures (mapping exercise)
 - comparison of existing industry approaches

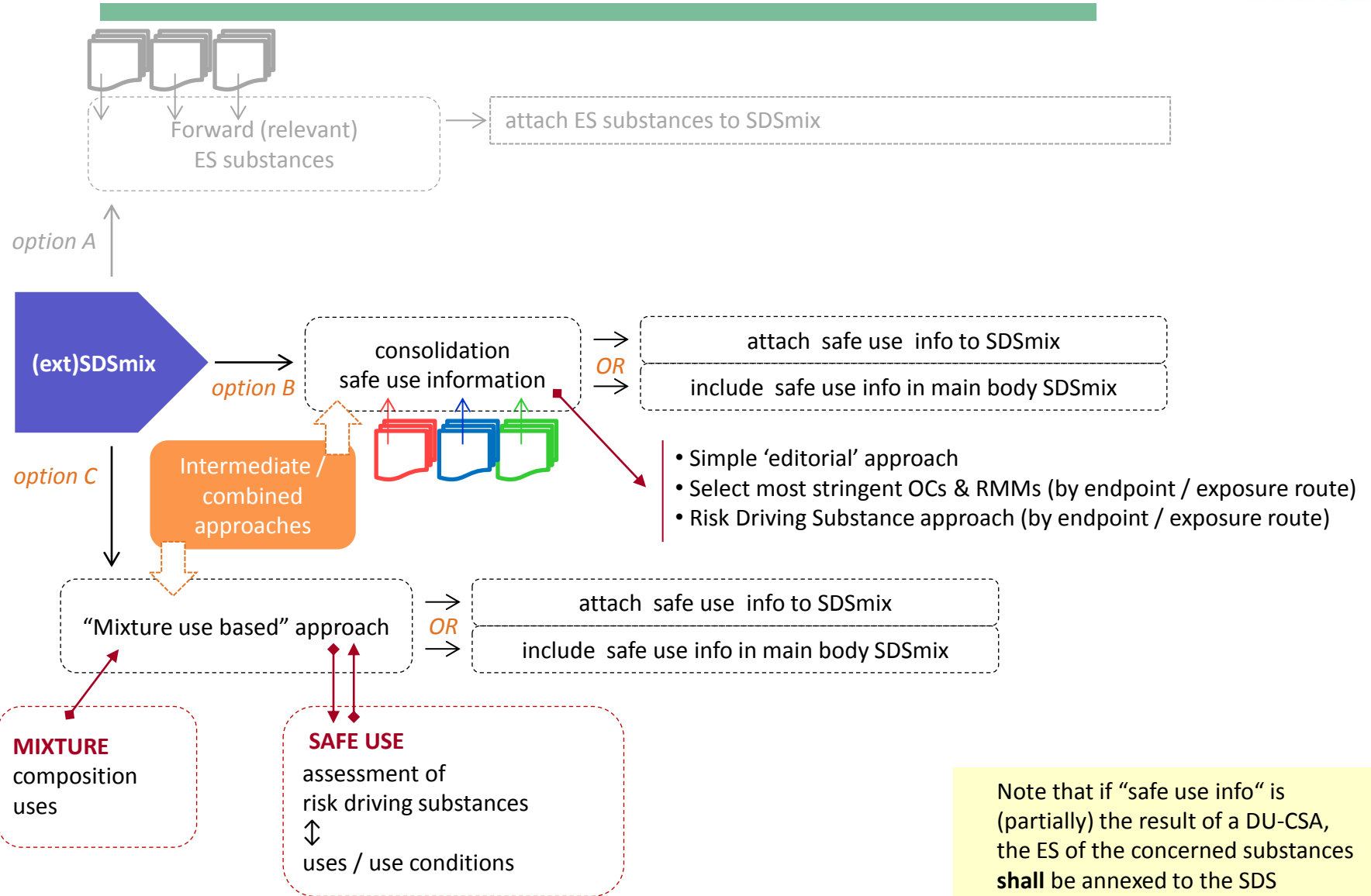


Main approaches

- **Until now 3 main approaches are identified:**
 - A. forwarding (relevant) ES substances
 - B. consolidation of safe use information (top down)**
 - C. 'mixture use based' approach (bottom up)**



Overview main options



Set up mapping exercise

- For options B and C a matrix of key elements was determined
- Questionnaire template has been developed focussing on key elements options 2 and 3
- Questionnaire template sent to companies / sector organisations that have previously indicated (e.g. during ENES) that they are developing a methodology

Note that the objective of the mapping exercise was to obtain an overview of methods, but that the result is not an exhaustive compilation of methods, nor a 'positive list' of applicable methods



Result mapping exercise

Ref.	Developer	Bottom up?	Top down?
BU.1	FEICA	↑	
BU.2	ATIEL/ATC	↑	
BU.3	CEPE	↑	
BU.4	NVZ/A.I.S.E.	↑	
BU.5	INFRA	↑	
BU.6	Jongerius/Caesar Consult	↑ ↔ ↓	↓
BU.7	Resins Technical Platform	↑ ↔ ↓	↓
BU.8	Plastics Europe / EUPC	↑	
TD.1	FECC		↓
TD.2	Ecomatters & TNO Triskelion		↓
TD.3	essenscia	↑ ↔ ↓	↓
TD.4	Zschimmer & Schwarz		↓
TD.5	VCI/Cefic		↓
TD.6	BASF		↓
TD.7	Axalta PC		↓

- 15 approaches mapped
- Sector associations play important roll in developing methodologies
- Equal share bottom up vs. top down approaches

Scope?



Ref.	Targeting specific sector?	Uses	Target (HH and/or ENV)	phys. state mix?
BU.1	adhesives, glues, ...	I/P	HH/ENV	L/S
BU.2	lubricants	I/P	HH/ENV	L
BU.3	paints, printing inks, artists' colours	I/P	HH/ENV	L/S
BU.4	detergents	P	HH/ENV	L/S
BU.5	fragrance compounds + endproducts	I/P	HH/ENV	L
BU.6		I/P	HH/ENV	L/S
BU.7	resins	I/P	HH/ENV	L
BU.8	plastics	I/P	HH/ENV	L/S
TD.1		I	HH/ENV	L/S
TD.2		I/P	HH/ENV	L/S
TD.3		I/P	HH/ENV	L/S
TD.4		I/P	HH/ENV	L/S
TD.5		I/P	HH/ENV	L/S
TD.6		I/P	HH/ENV	L/S
TD.7		I/P	HH/ENV	L/S

Uses: Industrial use - Professional use
Target: Human Health - ENVironment
Phys. State: Liquid - Solid

- Bottom up approaches targeting (a vast majority of)* sector specific products and related uses**
 - * Meaning 80-90% of mixtures used in a sector are covered
 - = products falling within certain boundaries wrt hazard properties, phys-chem properties and/or no-effectlevels
- All methodologies aiming to address all targets**
- For some top down approaches specific limitations may apply**
 - TD.2 exclusion of CMRs if no DN(M)EL available
 - TD.5 in case of dust and aerosol formation.
 - TD.7 exclusion of some PROCs



Current status?

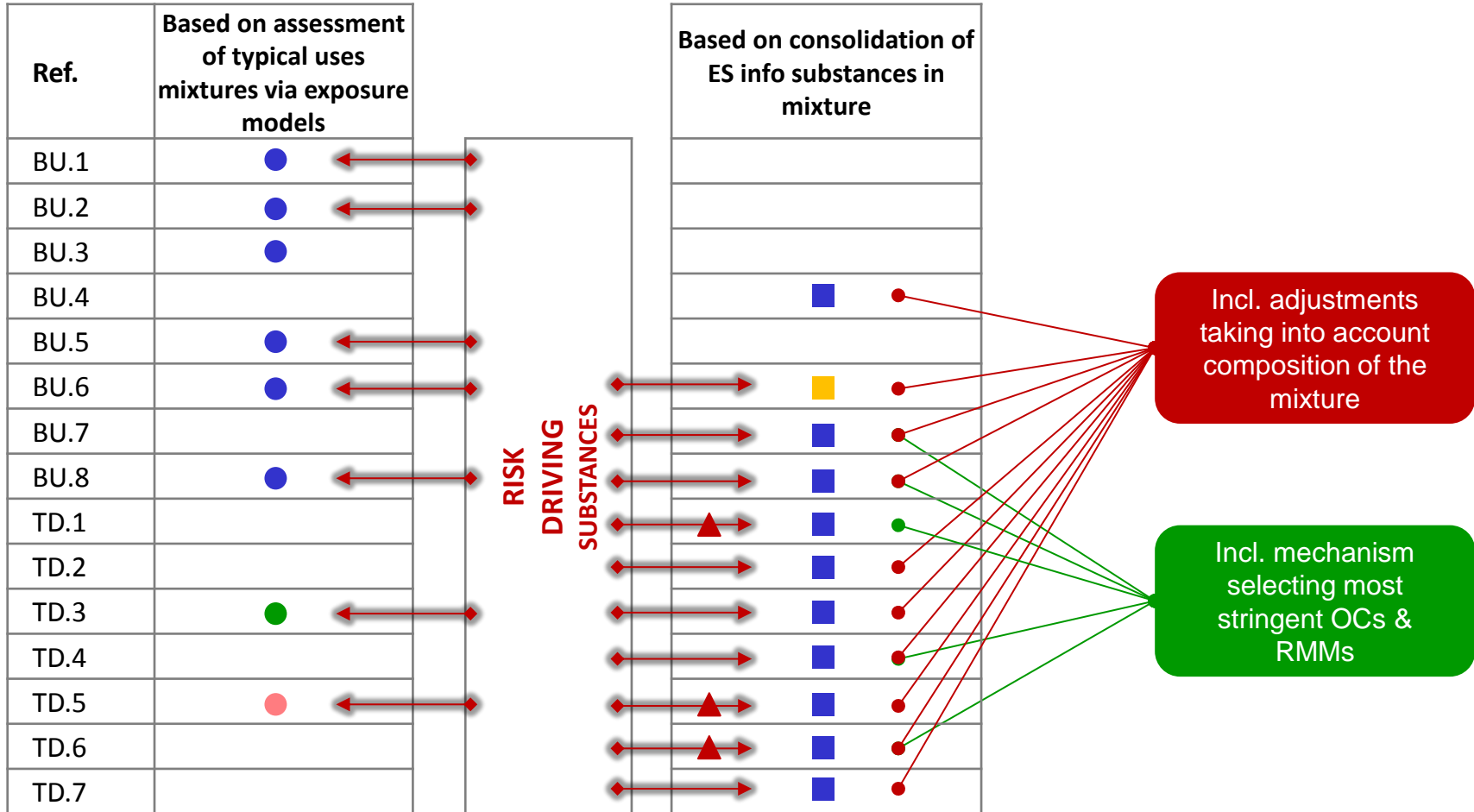
Ref.	Human health	environment
BU.1	(3)	(3)
BU.2	(1)	(1)
BU.3	(3)	(4)
BU.4	(2)	(2)
BU.5	(3)	(3)
BU.6	(2)	(2)
BU.7	(3)	(4)
BU.8	(2)	(2)
TD.1	(4)	(4)
TD.2	(4)	(4)
TD.3	(2)	(4)
TD.4	(1)	(1)
TD.5	(1)	(2)
TD.6	(2)	(2)
TD.7	(1)	(1)

- Ca. 50% of the methods are as such fully elaborated but practical applicability/feasibility is only in a few cases extensively tested
- Further elaboration and testing of methods needed (especially for the environmental part) before they are ready to use

- (1) Fully elaborated + extensively tested on mixtures
(2) Fully elaborated, but (more) testing on mixtures required
(3) Partially elaborated
(4) Concept



Defining safe use info for mixtures



● option

● only if no ES RDS available

■ If used as top down

▲ RDS + substances with specific hazard properties

Defining safe use info mixtures

- **Bottom up approaches**
 - (re-)assessment of (risk driving) substances taking into account the uses of the mixture
 - this assessment is done during the development of the method and is not required by those applying the method
 - **Top down approaches**
 - consolidation of ES-info from (risk driving) substances
 - ES-info substances adjusted taking into account the concentration of substances in the mixture and OC/RMM for mixture use
 - **Risk driving substances (RDS) are key to determine safe use info**
 - RDS are identified based on a combination of:
 - Classification substances / mixture
 - DNEL/PNEC
 - Exposure potential
 - Mixture composition
- (see next slide)



Identification Risk Driving Substances

Ref.	Elements taken into account to identify Risk Driving Substances			
	Hazard classification substances / mixture	DNEL/PNEC	Exposure potential	Mixture composition
BU.1	●	●	●	●
BU.2		●	●	●
BU.3	not applicable			
BU.4	not applicable			
BU.5	●	●	●	●
BU.6	●	●	●	●
BU.7	●		●	●
BU.8	●			●
TD.1	●			●
TD.2	●	●	●	●
TD.3		●	●	●
TD.4		●	●	●
TD.5	●			●
TD.6	●	●		●
TD.7	●		●	●



Communicating safe use info

Ref.	Consolidation into main body	Consolidation into annex	Annexing substance(s) ES	Two Annexes*
BU.1	●	●		
BU.2	●	●		
BU.3	●	●		
BU.4		●		
BU.5		●		
BU.6		●		
BU.7		●		●
BU.8		●		●
TD.1		●	●	
TD.2	●	●		
TD.3	●	●		
TD.4		●		
TD.5	●	●	●	
TD.6	●	●		
TD.7		●		

- Communicating safe use info via an annex is the preferred way
- Depending on some characteristics of the mixture e.g. when it's not classified, consolidation into the main body is also an option

*Annexing both consolidated mixture safe use information and substance(s) ES



Practicalities for formulators

Ref.	Required level of expertise to apply the method				Level of automation		
	H	M	L	N	F	P	N
BU.1			●		● ↔ ●		
BU.2		● ↔ ●				●	
BU.3			● ↔ ●	●		●	
BU.4		●				●	
BU.5		●			●		
BU.6			●		● ↔ ●		
BU.7	●						●
BU.8			●			●	
TD.1		●				●	
TD.2		●			●		
TD.3		●				●	
TD.4		● ↔ ●			●		
TD.5		●			● ↔ ●		
TD.6		● ↔ ●			● ↔ ●		
TD.7	●				●		

High
Medium
Low
None

* If used as top down: medium -> high

Full
Partially
None

	Guidance?	Tool / guidance freely available?
BU.1		
BU.2	●	●
BU.3	●	●
BU.4	●	●
BU.5		
BU.6	●	
BU.7	●	●
BU.8	●	
TD.1		
TD.2	●	
TD.3		
TD.4	●	●
TD.5	●	●
TD.6	●	●
TD.7	●	

● yes
● Under development

Practicalities for formulators

- Applying the methods assumes knowledge of REACH processes, classification and/or (for environment) ability to research hazard properties, but depending on the characteristics of the mixtures concerned, this knowledge can be very basic
- Different approaches seem to have potential for automation to some extent. Carefully evaluation of the right balance between flexibility versus standardisation is needed.

General conclusions

- **No ‘one size fits all’ method, all methods have their remits and both ‘top-down’ and ‘bottom-up’ can be envisaged**
- **A lot of effort has been already be invested by industry in the development of methods and approaches to compile safe use information for mixtures**
- **Further testing is needed to gain more experience using the methods**
- **Identification of Risk Driving Substances is a key element to determine safe use info for mixtures**
- **Safe use info is aligned with characteristics and uses of mixtures and safe use conditions often need to be adjusted to them**