

4.5 Final conclusions for safe use methodology for mixtures and way forward to ENES6

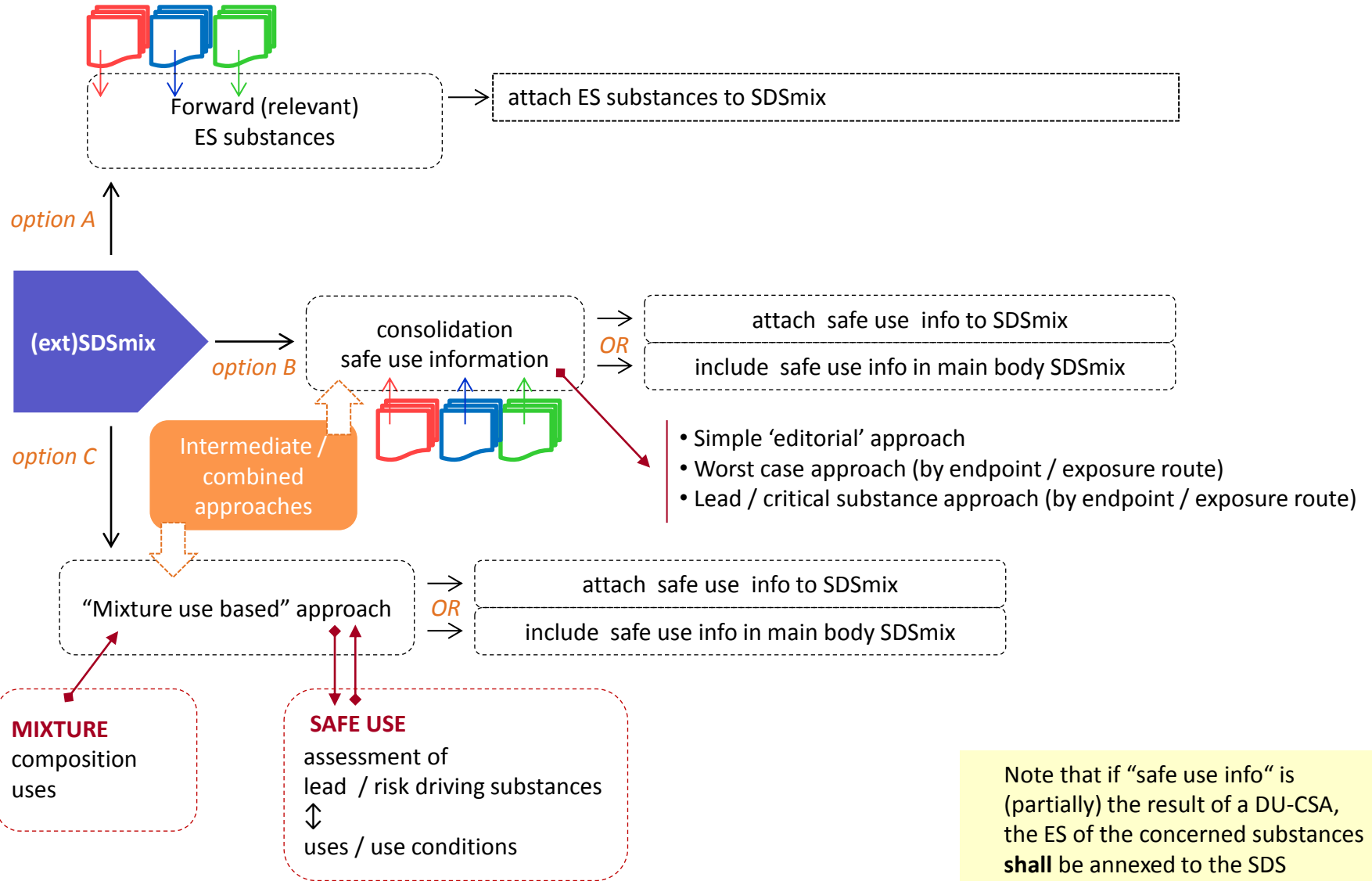
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Main approaches



- 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



Result mapping exercise



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

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

From ENES4 to ENES5

- At ENES4 three concepts were known and presented
- At ENES5 the mapping shows 15 concepts
- Looks like real science: we need more information and test them out
- People work in silence and are all trying to find their tailor made solution
- We all have the same problem in industry



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ENES5

- 15 approaches mapped in two categories with some working in both directions
 - Top – down
 - Bottom – up
- Maybe this can be renamed in another way
 - General approach of handling mixtures (communication in both directions)
 - Sector specific approach of handling mixtures (communication to suppliers)

ENES5

- General approaches making use of DNEL/PNEC
- Not everything is covered in all approaches
- What if no DNEL/PNEC?
- Differences between pure substances and substances in mixtures
 - Concentration
 - Volatility
 - Form

ENES5

- Consideration of additivity
- Probably more similarities than differences in the approaches
- Sector specific approaches interesting as long they are not getting out of the domain of the application
- Potential disconnection between mixture analysis and information on substance level
- Potential synergistics effect not covered by any method

Authorities' view

- No acceptance for black box approaches
 - Documentation of the process is needed to get acceptance
 - Justification is needed when deviating from the general line
- What if no DNEL/PNECs are available?
 - PBT, ED
 - Exposure based adaptation without DNEL/PNEC
 - DMEL or how is it handled by SCOEL?
- Endpoints not covered by CLP
- Give the methods the same result? Test and compare!
- Be precise

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Industry's view

- Scaling in the guidance for DU is considered as very restrictive
 - Not above the RCR corresponding to the RMM of the individual substances
 - Even if far below 1
- Boundaries of scaling need to be defined on solid technical basis and transparent scaling approaches established
- Industry proposals for improvements on scaling are available
- Need to avoid mass notifications and minimise the number of substance ESs annexed to mixture SDSs for end users



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From ENES5 to ENES6

- « explosion » of approaches needs control: from 3 to 15 and back to 2?
- Let's bring the contributors together, share experiences, clarify and bring together the best out of the different approaches and come back hopefully with one general approach, and allow some sector specific approaches
- A political discussion is needed on electronic delivery of SDS and ES



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Thanks for your attention