German Federal Institute for Risk Assessment

Assessment of plant protection products and co-formulants – Germany’s experience

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Pesticides Safety

Do we have enough data to conclude that plant protection products are safe?

Do we use all data that are available?

Which data are missing?

BfR

What is currently done?

active substances

safener / synergists

+

solvents

emulsifiers

preservatives

wetting agents

.....

composition,
phys-chem, acute toxicity,
acute eco-toxicity,
dermal absorption

comprehensive data set
reference values
quantitative risk assessment

safety data sheets,
+ legal classifications,
ECHA notifications

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What is currently done?

co-formulants

product

active substance

active substance

active substance

classification & labelling

reference values

exposure

risk assessment

risk mitigation measures

qualitative

quantitative

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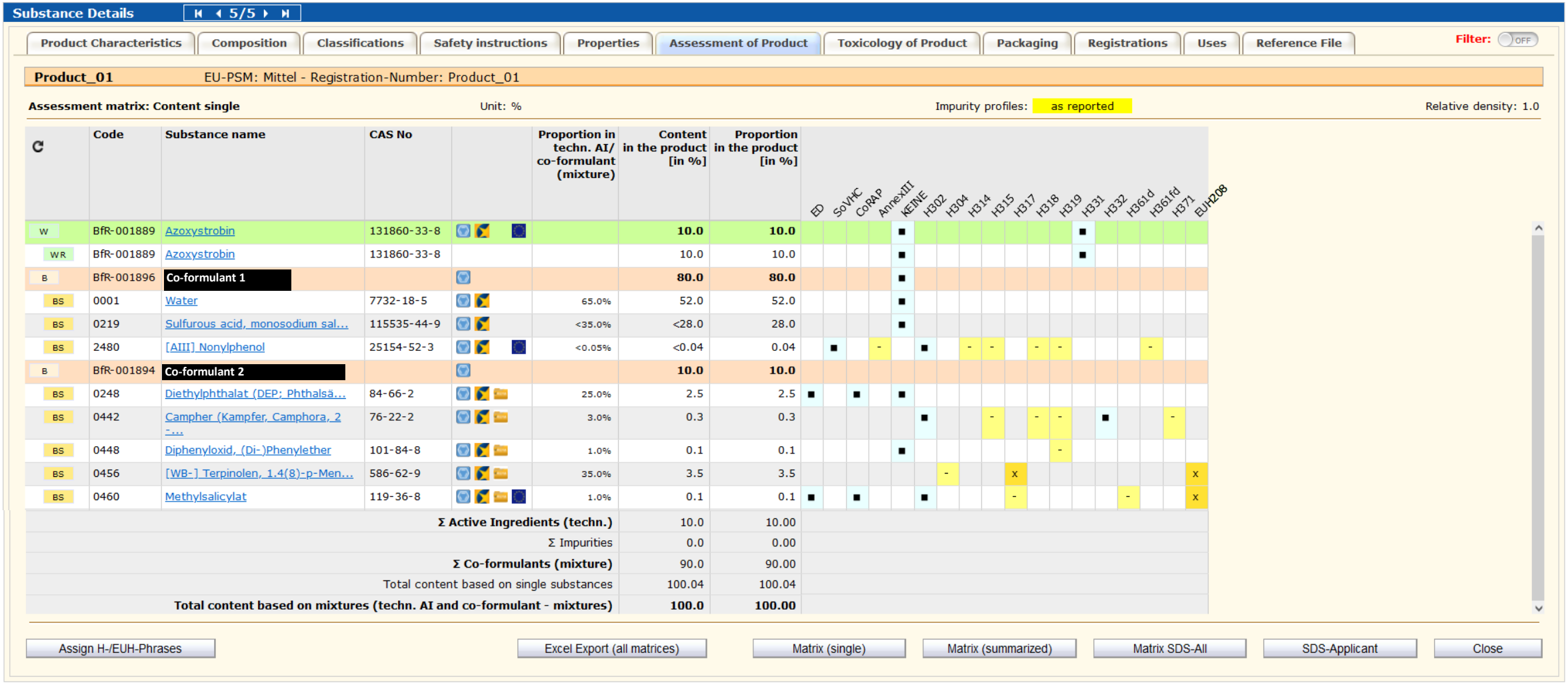
What is currently done?



Substance Details 5/5

Product Characteristics | Composition | Classifications | Safety instructions | Properties | Assessment of Product | Toxicology of Product | Packaging | Registrations | Uses | Reference File

Filter: OFF

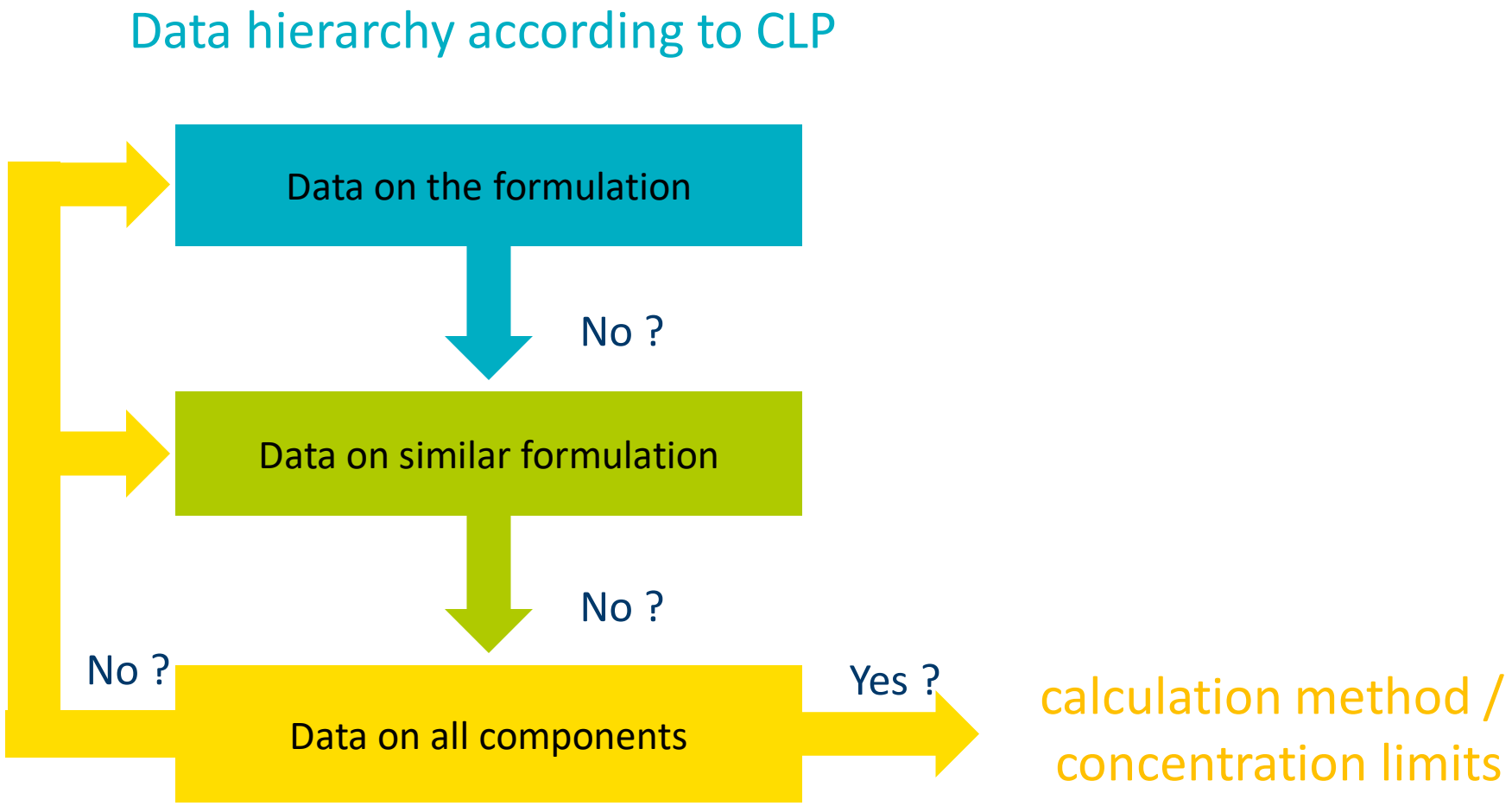
Product_01 EU-PSM: Mittel - Registration-Number: Product_01

Assessment matrix: Content single Unit: % Impurity profiles: as reported Relative density: 1.0

	Code	Substance name	CAS No	Proportion in techn. AI/ co-formulant (mixture)	Content in the product [in %]	Proportion in the product [in %]	ED	SoVHC	CoRAP	AnnexIII	KEINE	H302	H304	H314	H315	H317	H318	H319	H331	H332	H361d	H361fd	H371	EUH208
W	BfR-001889	Azoxystrobin	131860-33-8		**10.0**	**10.0**					■							■						
WR	BfR-001889	Azoxystrobin	131860-33-8		10.0	10.0					■							■						
B	BfR-001896	**Co-formulant 1**			**80.0**	**80.0**					■													
BS	0001	Water	7732-18-5	65.0%	52.0	52.0					■													
BS	0219	Sulfurous acid, monosodium sal...	115535-44-9	<35.0%	<28.0	28.0					■													
BS	2480	[AIII] Nonylphenol	25154-52-3	<0.05%	<0.04	0.04		■		-		■		-	-		-	-				-		
B	BfR-001894	**Co-formulant 2**			**10.0**	**10.0**																		
BS	0248	Diethylphthalat (DEP; Phthalsä...	84-66-2	25.0%	2.5	2.5	■		■		■													
BS	0442	Campher (Kampfer, Camphora, 2-...	76-22-2	3.0%	0.3	0.3						■			-		-	-		■			-	
BS	0448	Diphenyloxid, (Di-)Phenylether	101-84-8	1.0%	0.1	0.1					■							-						
BS	0456	[WB-] Terpinolen, 1.4(8)-p-Men...	586-62-9	35.0%	3.5	3.5						-			x									x
BS	0460	Methylsalicylat	119-36-8	1.0%	0.1	0.1	■		■			■			-						-			x
				Σ Active Ingredients (techn.)	10.0	10.00																		
				Σ Impurities	0.0	0.00																		
				Σ Co-formulants (mixture)	90.0	90.00																		
				Total content based on single substances	100.04	100.04																		
				Total content based on mixtures (techn. AI and co-formulant - mixtures)	**100.0**	**100.00**																		

Assign H-/EUH-Phrases | Excel Export (all matrices) | Matrix (single) | Matrix (summarized) | Matrix SDS-All | SDS-Applicant | Close

What is currently done?



Do we underestimate the toxicity of mixtures?

acute oral		CLP calculation method				
	category	1	2	3	4	none
in vivo	1	**0**	0	0	0	0
	2	0	**2**	0	0	0
	3	0	0	**1**	**1**	**2**
	4	0	0	2	**36**	15
	none	0	1	0	27	**291**

acute dermal		CLP calculation method				
	category	1	2	3	4	none
in vivo	1	**0**	0	0	0	0
	2	0	**1**	0	0	0
	3	0	0	**0**	0	**1**
	4	0	0	0	**1**	0
	none	0	0	3	3	**362**

acute inhalation		CLP calculation method				
	category	1	2	3	4	none
in vivo	1	**0**	0	0	0	0
	2	0	**0**	0	0	0
	3	0	0	**0**	**2**	0
	4	0	3	1	**24**	9
	none	0	2	1	22	**180**

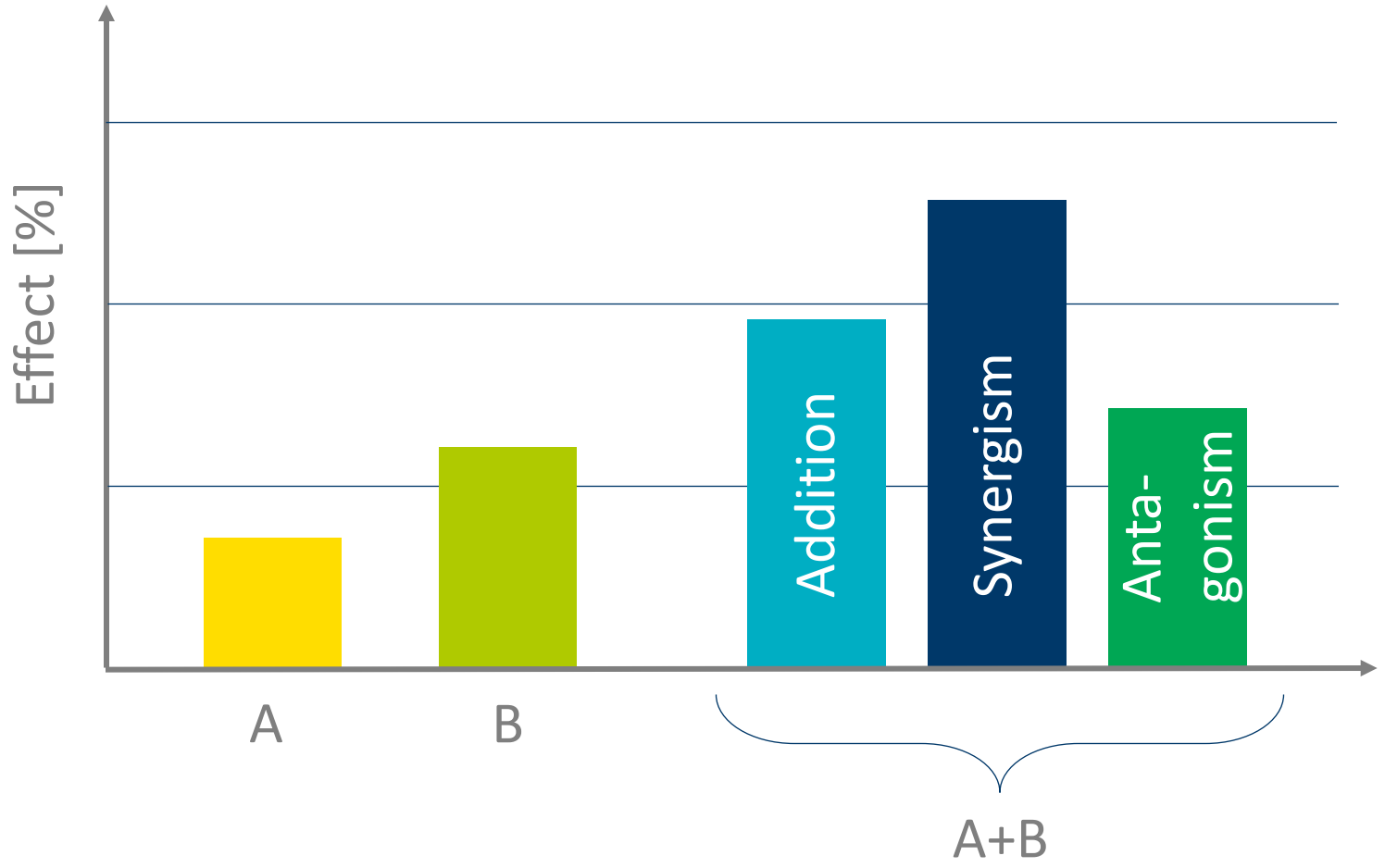
Do we underestimate the toxicity of mixtures?

skin irritation		CLP rules for mixtures		
	category	1	2	none
in vivo	1	**0**	0	0
	2	2	**19**	**15**
	none	8	65	**275**

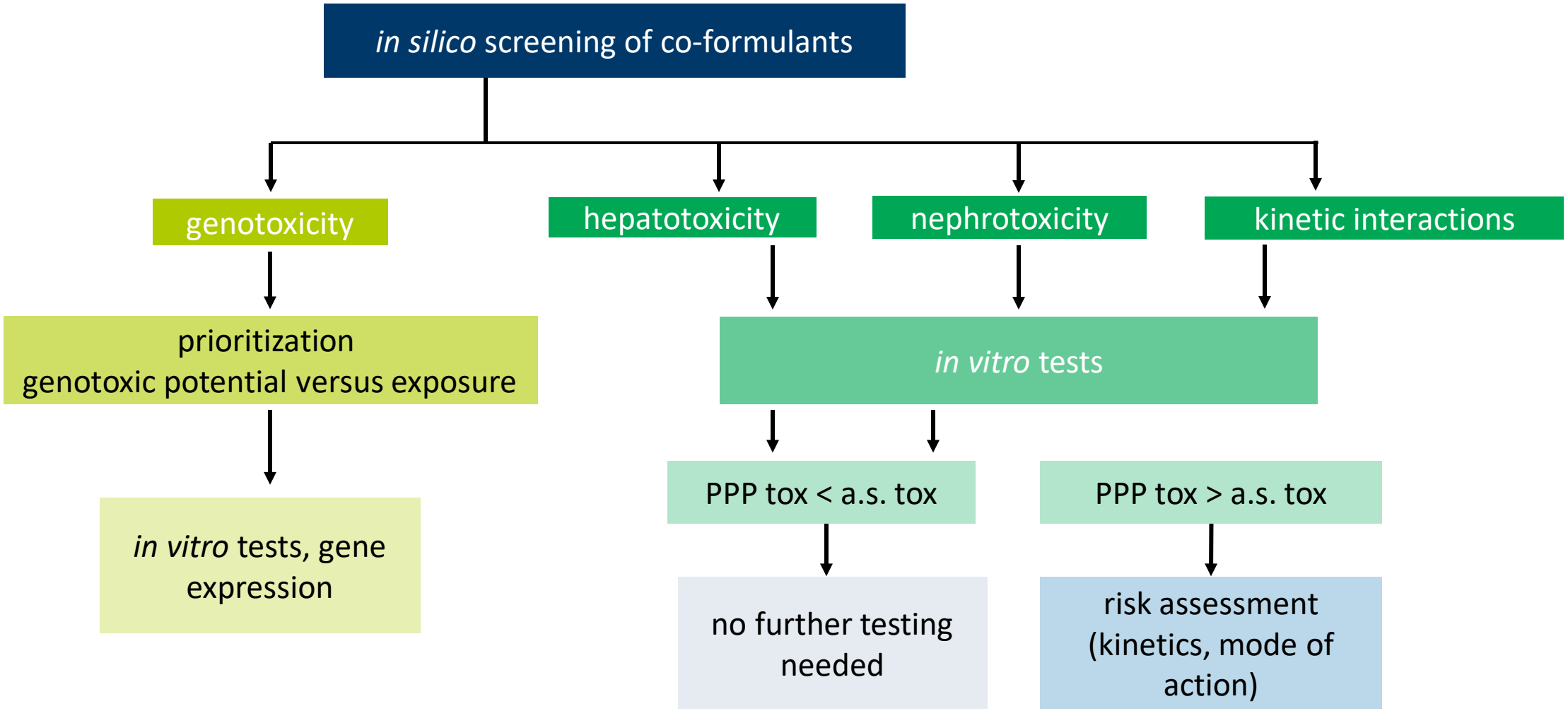
eye irritation		CLP rules for mixtures		
	category	1	2	none
in vivo	1	**31**	**5**	**2**
	2	36	**28**	**9**
	none	70	55	**143**

skin sensitisation		CLP rules for mixtures	
	category	1	none
in vivo	1	**67**	**33**
	none	90	**175**

Do we underestimate the toxicity of mixtures?



What to do in the future?



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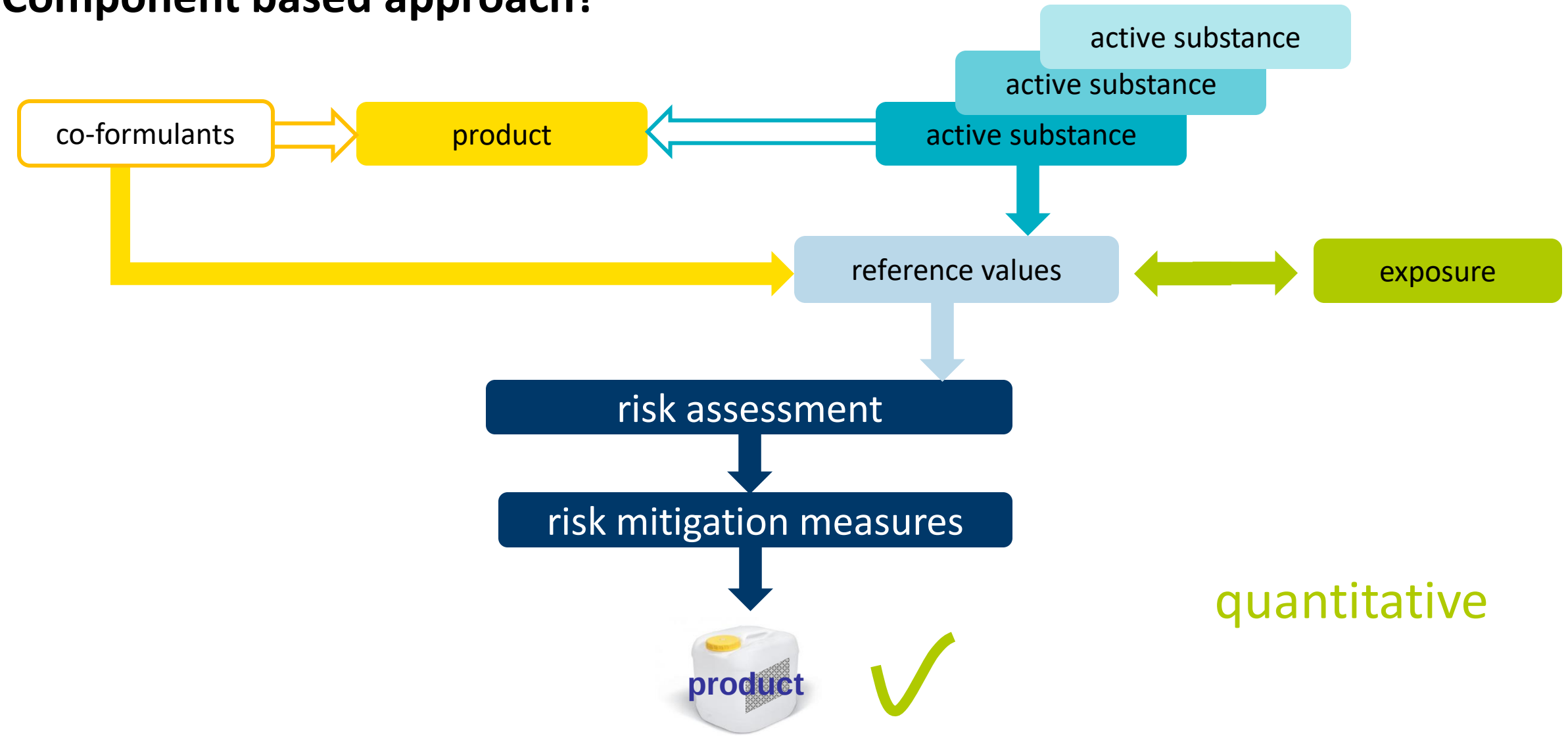
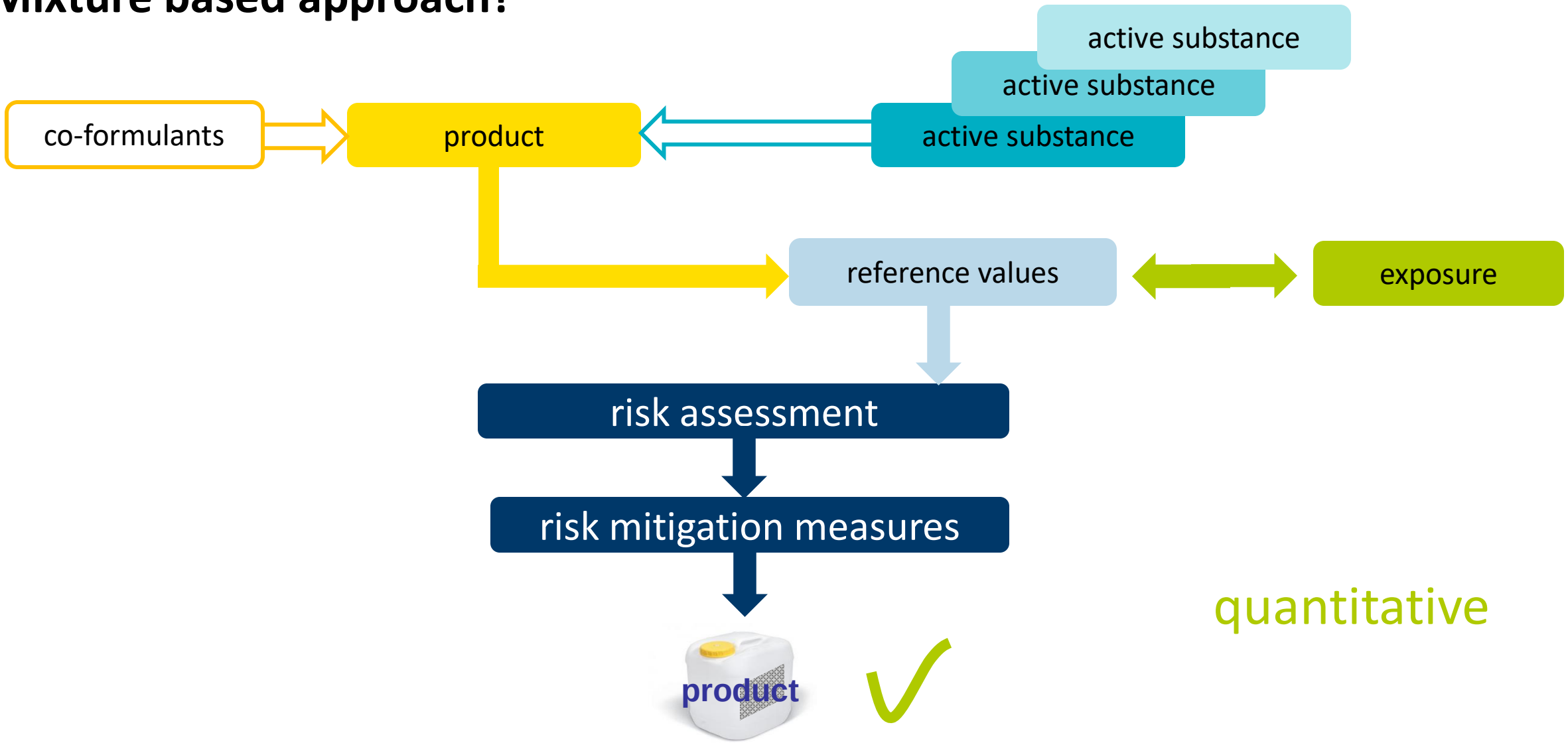
Component based approach?



Mixture based approach?



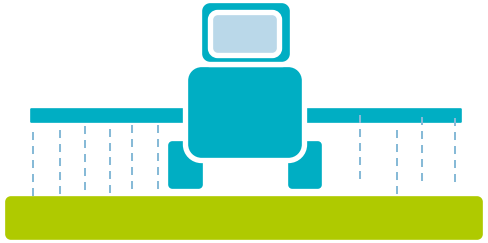
What to do in the future?

consumer exposure

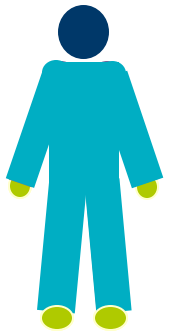
magnitude of co-formulant residues ?

indirect exposure

environmental exposure

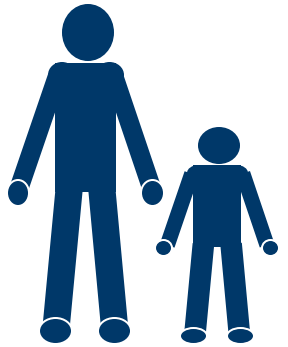


operator exposure



direct exposure

bystander/resident exposure



co-formulants correlate with active substance residues

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Summary

What we already do

- amend list of unacceptable co-formulants
- require additional studies according to data requirements in special cases
- use data under REACH
- require detailed composition down to single substances
- conduct combined quantitative risk assessment for active substances
- conduct qualitative risk assessment for co-formulants

What could be done in the future

- define and identify critical co-formulants or mixtures
- develop animal-free testing strategies for critical mixtures
- monitor critical co-formulants
- conduct quantitative risk assessment for critical co-formulants
- conduct quantitative risk assessment for critical mixtures

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