

Comparative environmental risk assessment of biocides - a chance to get better products

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Comparative
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Can this chance be used with reasonable effort?

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- Comparative assessment of biocidal products mandated by the biocidal product regulation (BPR)

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- Comparative assessment of biocidal products mandated by the biocidal product regulation (BPR)
- For products containing a Candidate for Substitution as active substance

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- Performed by the Competent Authority

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- Comparative assessment of biocidal products mandated by the biocidal product regulation (BPR)
- For products containing a Candidate for Substitution as active substance
- Performed by the Competent Authority
- Technical Guidance Note provides a tiered assessment scheme

Flow chart constructed according to the TGN

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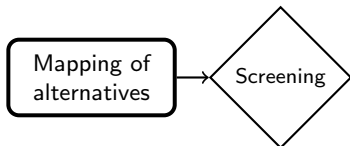
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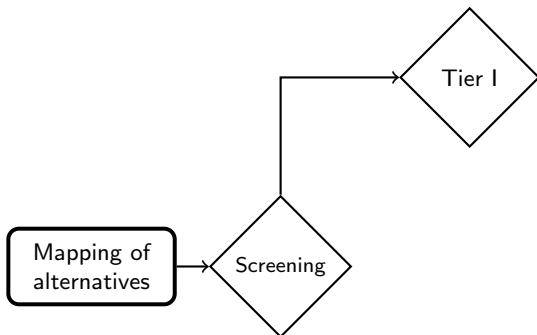
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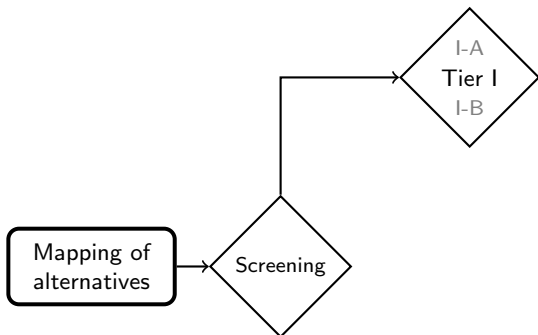
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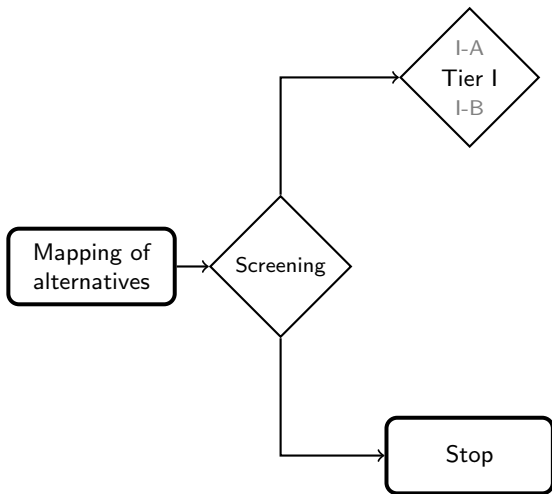
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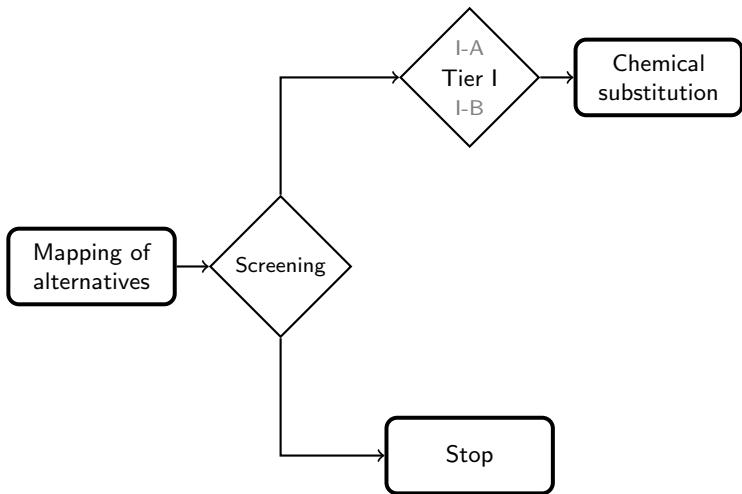
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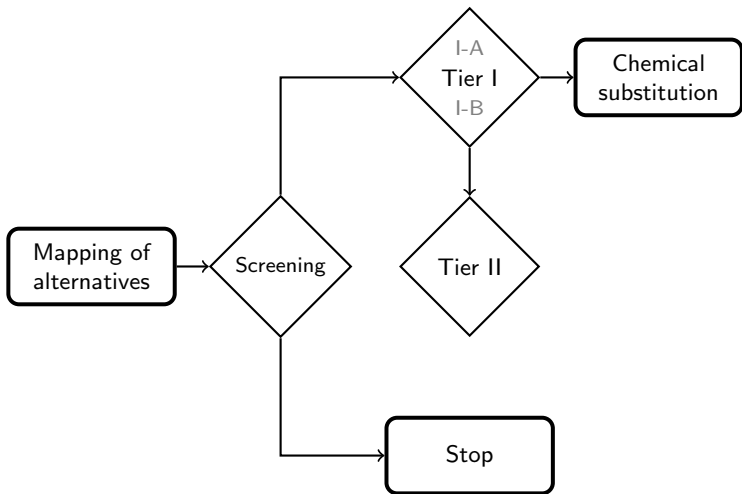
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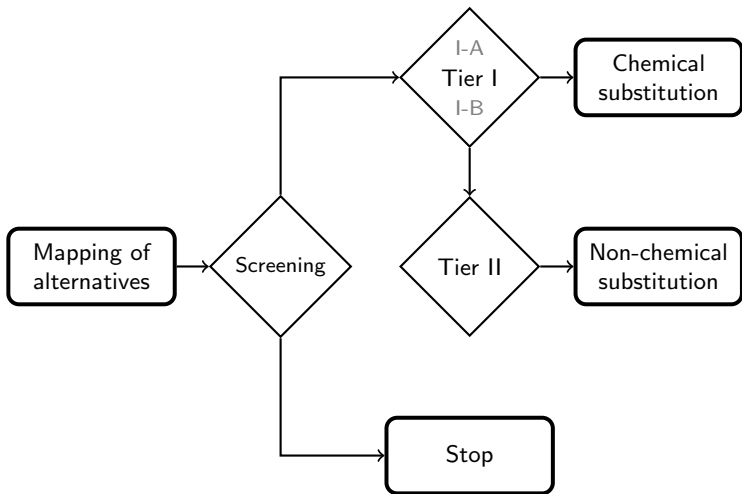
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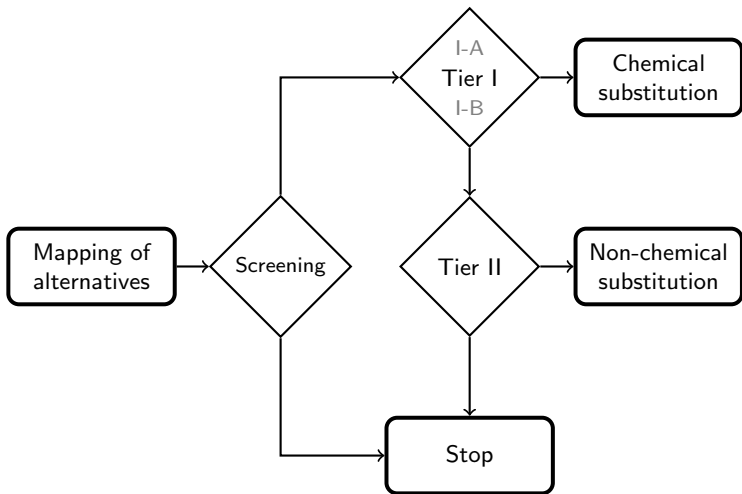
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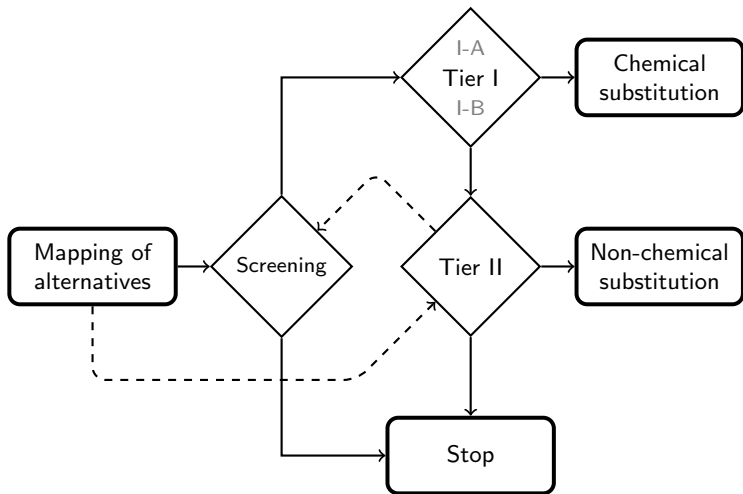
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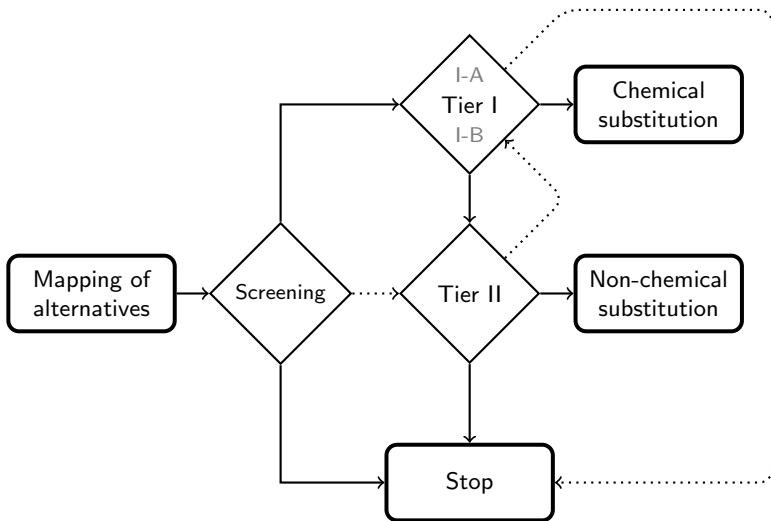
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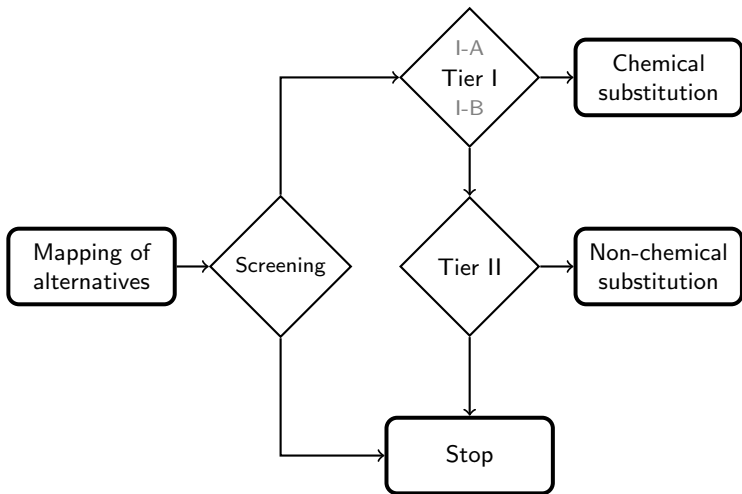
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- First comparative assessments have been performed by member states

Current situation

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- First comparative assessments have been performed by member states
- Almost all assessments stop at the screening step due to a lack of chemical diversity

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- First comparative assessments have been performed by member states
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- Close to zero experience with Tier I

Current situation

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- First comparative assessments have been performed by member states
- Almost all assessments stop at the screening step due to a lack of chemical diversity
- Close to zero experience with Tier I
- How to evaluate practical and economic disadvantages?

Current situation

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- First comparative assessments have been performed by member states
- Almost all assessments stop at the screening step due to a lack of chemical diversity
- Close to zero experience with Tier I
- How to evaluate practical and economic disadvantages?
- How to compare non-chemical alternatives (Tier II)?

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- Analyse existing guidance

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- Analyse existing guidance
- Test current guidance with case studies

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- Describe shortcomings

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- Analyse existing guidance
- Test current guidance with case studies
- Describe shortcomings
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Sponsor Umweltbundesamt → Focus on environmental risks

Products registered in Germany

Wood preservative products

PT 8

Propiconazole,
tebuconazole, IPBC, ...

Ant control products

PT 18

Spinosad, fipronil,
indoxacarb, deltamethrin,
imidacloprid

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Intended use according to the TGN:

Use description element	Example
Product Type (Description of the authorised use)	PT 19 Repellent
Target organism(s)	Mosquito (adult)
Field of use	Indoor use
Category(ies) of users	General public
Application method(s)	Spraying

Use description elements

Ant control products (PT 18)

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In practice, different wording is used in every document!

→ Use description elements need to be harmonised

Groups of comparable products

Ant control products (PT 18)

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Target	Field of use	User	<i>n</i>
<i>Lasius niger</i>	Outdoor	Non-professionals	9
<i>Lasius niger</i>	Indoor	Non-professionals	8
<i>Lasius niger</i>	Indoor	Professionals	5
<i>Lasius niger</i>	Outdoor	Professionals	5

→ We compare risks of product uses, not risks of products!

Label claims

Ant control products (PT 18)

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Generally consist of

- Target organisms, but also
- Type of effects (knockdown, reduce, kill, complete control/colony kill/nest kill)

→ The effect type should be part of the use description

Use description elements

Wood preservative products (PT 8)

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			Relevant product	Product 2	... Product n
Application aim		preventive	y	y	
		curative	n	n	
target organism	wood rotting fungi	wood rotting basidiomycetes	y	y	
		wood rotting ascomycetes, deuteromycetes (soft rot fungi)	n	y	
		sap stain fungi	n	y	
	wood disfiguring fungi	blue staining fungi	n	y	
		mould fungi (= Schimmelpilz)	n	y	
		wood destroying insects	n	n	
Use class		1	n	n	
		2	n	y	
		3	y	y	
		4	n	n	
Category of users / Application method	non-professional (nP)	brushing	y	y	
		spraying	n	n	
	professional (P)	brushing	y	y	
		spraying	n	n	
		dipping	n	n	
		injection	n	n	
	industrial users (IU)	penetrative process	n	n	
		automated brushing	n	n	
		flow coating= deluging= surface coating	n	y	
		spraying	n	y	
		dipping	n	y	
		flow-tunnel	n	n	
		Vacuumat	n	n	
Vakuum-und Druckinjektion	n	n			
penetrative process	n	n			

TGN proposal

Three different modes of action should remain for resistance management

Competent authorities can waive this for certain uses
→ Guidance, e.g. on ant control products, would be helpful

Chemical diversity screening

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TGN proposal

Three different modes of action should remain for resistance management

Competent authorities can waive this for certain uses

→ Guidance, e.g. on ant control products, would be helpful

Case study for PT 18: Available products contain two different triazoles (same mode of action) and IPBC

→ TGN criterion not fulfilled, but non-authorisation would often not lead to a change in chemical diversity

Based on information from Summary of Product Characteristics (SPC)

- H/P-statements
- Risk mitigation measures (RMMs)

Tier I-A

Example for ant control products

TGN: Is the relevant product a negative outlier?

id	Sentence	1	2	11	4	3
H410	Very toxic to aquatic life with long-lasting effects	+				
(R50/53) H412	Harmful to aquatic life with long-lasting effects		+	+	+	+
S-36	Apply only in areas that are not liable to submersion or becoming wet i.e. protected from rain, floods and cleaning water	+	+	+	+	+
S-105	Do not use where release to drains (sewer) and/or surface water cannot be prevented	+				
S-202	Place inaccessible to children, companion animals and non-target animals	+		+		
U-5	Keep birds from feeding on target animals	+	+			
U-11	Do not use more than two bait boxes per site					+
U-20	Only use in cracks or crevices	+		+		
U-21	Remove spillage	+				

Tier I-A

Example for ant control products

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S-202	Place inaccessible to children, companion animals and non-target animals	+		+		
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Findings Tier I-A

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- RMMs need to be harmonised (ongoing)
- Information in SPCs is often insufficient
- Decision rules in TGN do not resolve ambiguous situations

Compare risks based on the Product Assessment Report (PAR)

Compare risks based on the Product Assessment Report (PAR)

- Risk quotients

Compare risks based on the Product Assessment Report (PAR)

- Risk quotients (compare like with like)

Compare risks based on the Product Assessment Report (PAR)

- Risk quotients (compare like with like)
- Other relevant characteristics (very open): Soil DT₅₀?
Fish EC₅₀? Aquatic PNEC? What if there is more than
one active substance?

Tier I-B: Potential approach 1

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- Try to identify the most critical risk quotient for the use

Tier I-B: Potential approach 1

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- Try to identify the most critical risk quotient for the use
- Recalculate risk quotients (PEC/PNEC) for all comparable products using equivalent assumptions

Tier I-B: Potential approach 1

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- Try to identify the most critical risk quotient for the use
- Recalculate risk quotients (PEC/PNEC) for all comparable products using equivalent assumptions
- Sum up risk quotients for active substances, metabolites and substances of concern

Tier I-B: Potential approach 1

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- Try to identify the most critical risk quotient for the use
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- Define threshold for significantly lower risk quotients

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Problems:

- Sometimes more than one relevant scenario

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Problems:

- Sometimes more than one relevant scenario
- Recalculations very time consuming

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Score significant differences in risk:

- Different PBT classification (P, B, T, vP, vB)

Tier I-B: Potential approach 2

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- Scores would be needed for PBT criteria and RMMs

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Score significant differences in risk:

- Different PBT classification (P, B, T, vP, vB)
- Different risk mitigation measures

Problems:

- Scores would be needed for PBT criteria and RMMs
- A threshold for the total score would be necessary

- Guidance currently not clear enough

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- Guidance currently not clear enough
- Burden of proof is with non-authorisation

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Thank you for your attention!

Tier I: The outlier concept of the TGN

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TGN: Is the **relevant product** an outlier in terms of risk?

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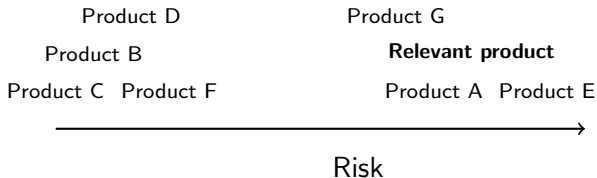
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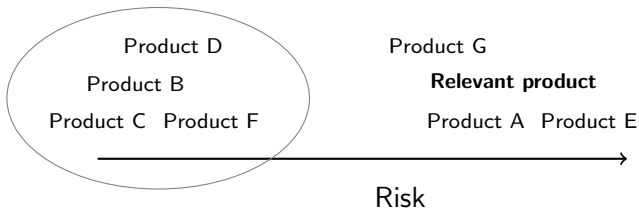
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TGN: Is the **relevant product** an outlier in terms of risk?

Chemical diversity sufficient?



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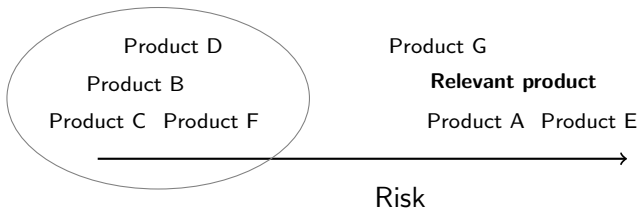
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TGN: Is the **relevant product** an outlier in terms of risk?

Chemical diversity sufficient?



→ Non-authorisation may be reasonable regardless if outlier