



Managing PMT/vPvM substances in consumer products through the concepts of essential-use and functional substitution

A case study for cosmetic products

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The essential-use concept: a new approach to manage hazardous chemicals?

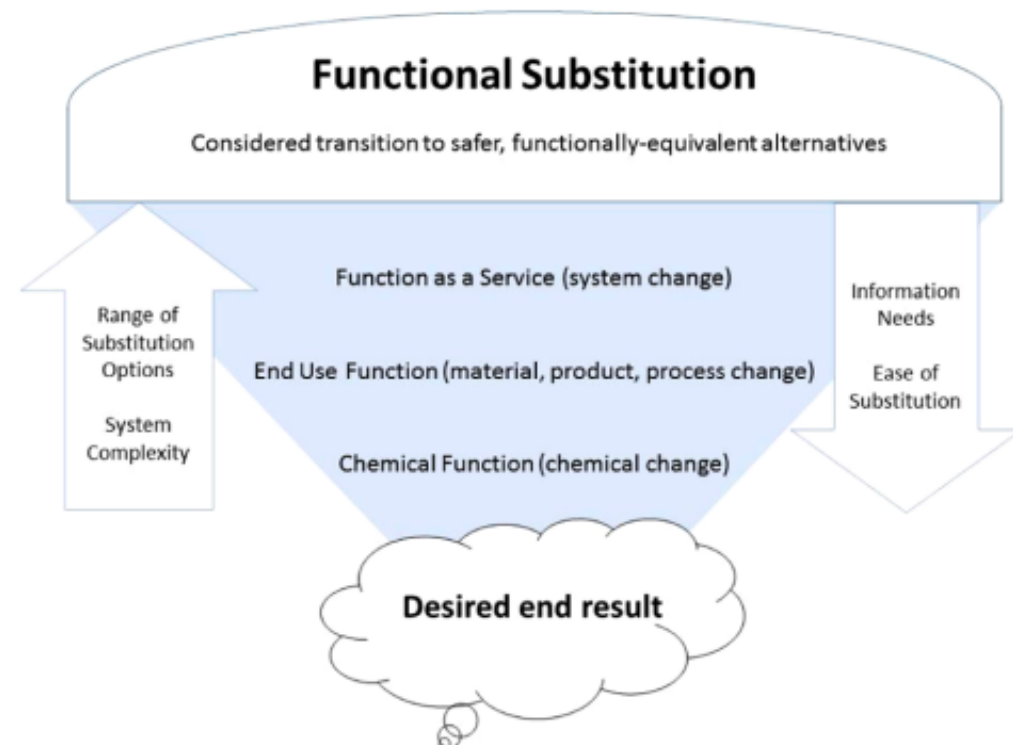
«controlled substance should qualify as “essential” only if:

- (1) it is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and*
- (2) there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health»*

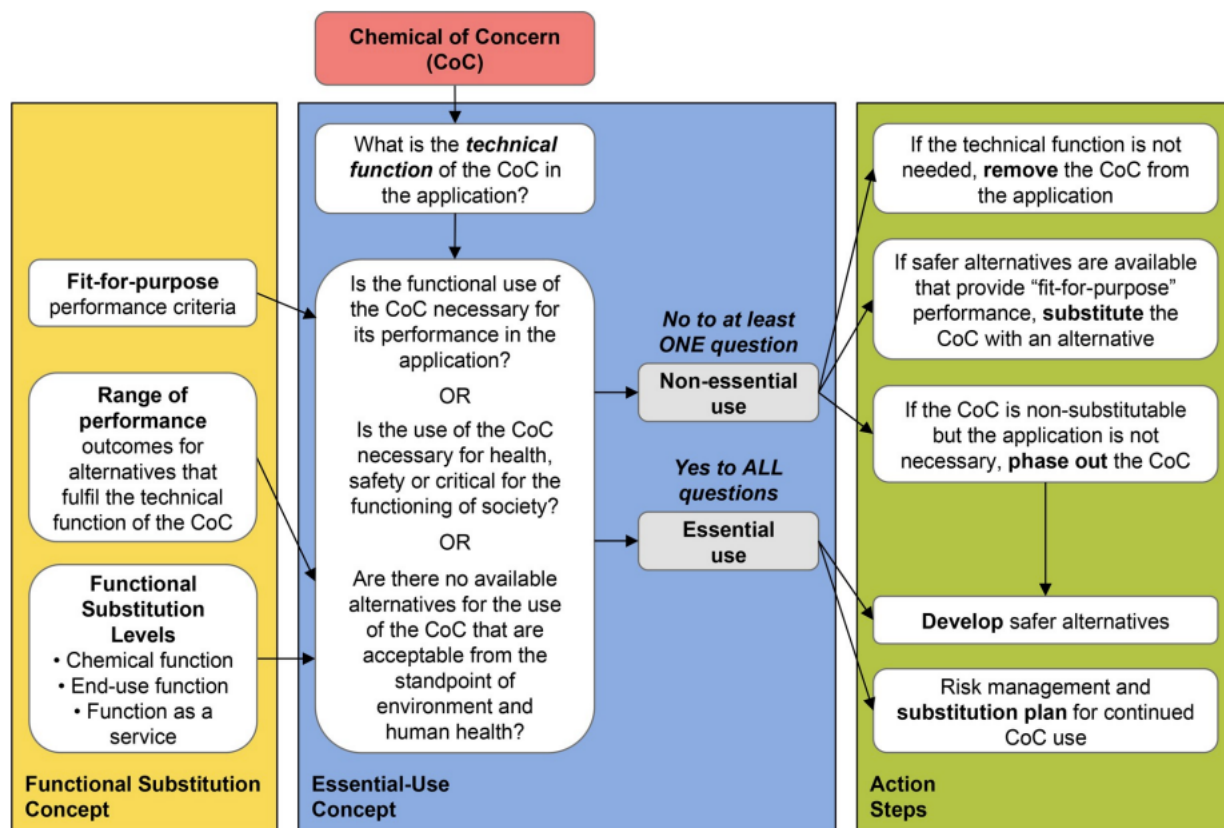
Montreal Protocol, 1987

Functional substitution: a new approach to chemical alternative assessment?

- Alternatives assessment focused on the function provided by the chemical of concern
- Simultaneous consideration of chemical function, end-use function and function as a service



The combination of the essential-use and functional substitution concepts



Source: Roy et al. (2022)

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Viewpoint

Combined Application of the Essential-Use and Functional Substitution Concepts: Accelerating Safer Alternatives

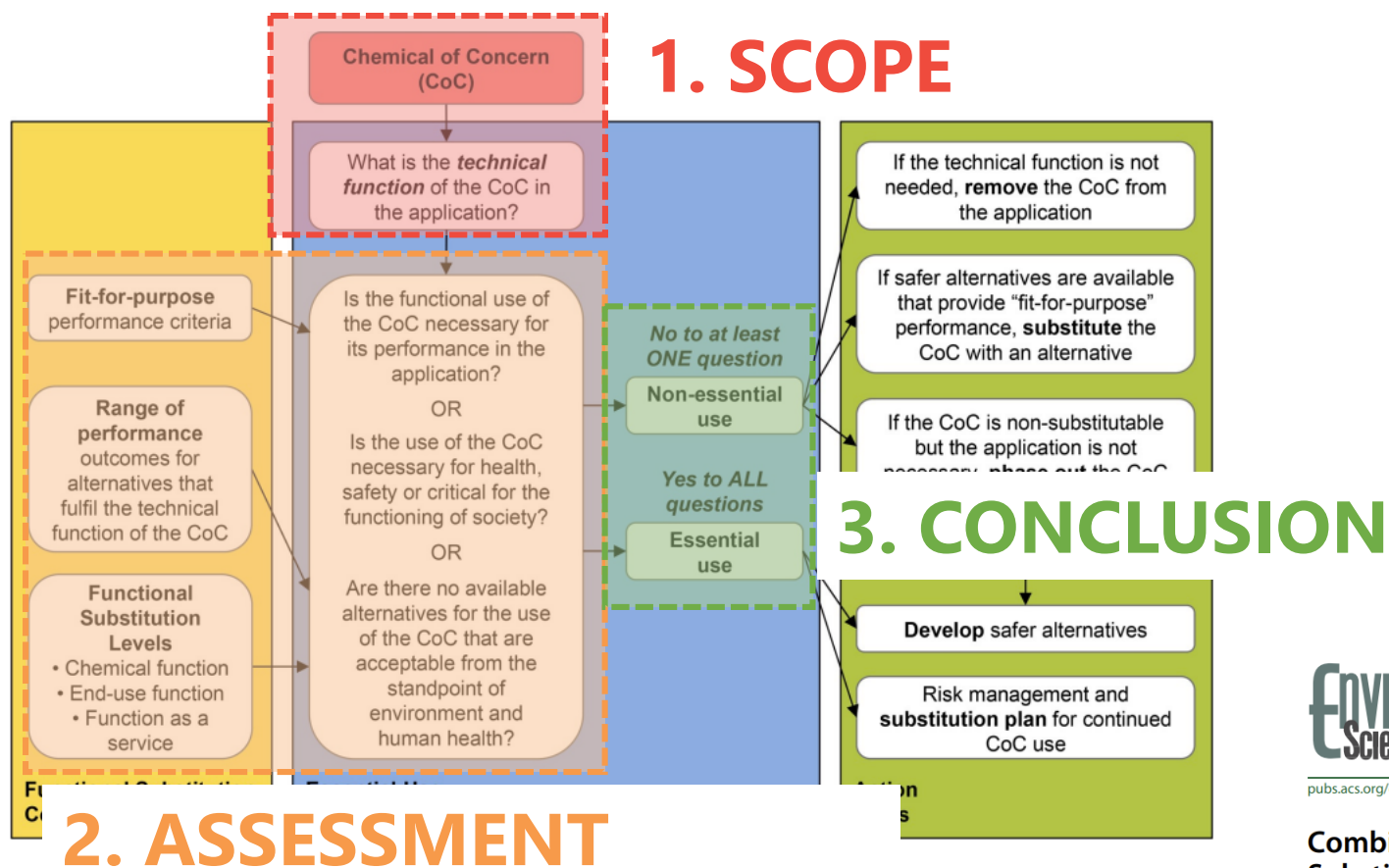
Monika A. Roy, Ian Cousins, Elizabeth Harriman, Martin Scheringer, Joel A. Tickner,* and Zhanyun Wang

Objectives of the project

- Explore the potential of essential-use and functional substitution concepts to phase-out PMT/vPvM substances
- Case study for cosmetic products



Overview of the method



Source: Roy et al. (2022)

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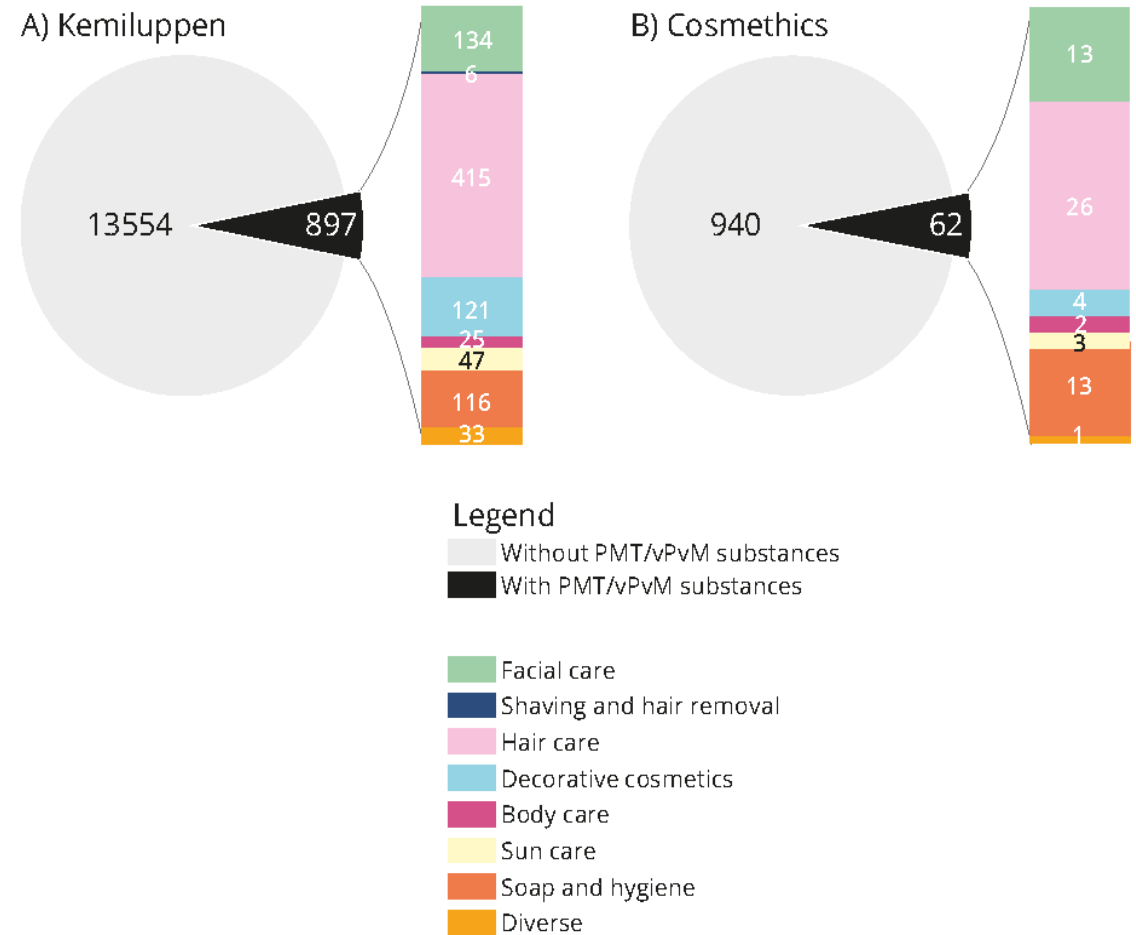
Viewpoint

Combined Application of the Essential-Use and Functional Substitution Concepts: Accelerating Safer Alternatives

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Identification of the chemical of concern

- 10 000 substances listed in Cosing database
- 50 substances potential PMT/vPvM
- ~6% of cosmetics products contained PMT/vPvM substances



Definition of the technical function

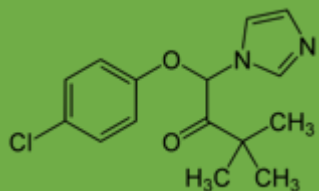
CLIMBAZOLE

CAS Number: 38083-17-9

Technical function:

Preservative and anti-seborrheic agent

Type of products: Shampoos
(as anti-dandruff agent)

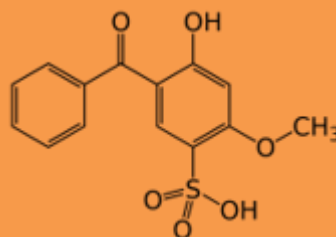


BENZOPHENONE-4

CAS Number: 4065-45-6

Technical function: UV filter
and UV absorber

Type of products: All types of
cosmetic products

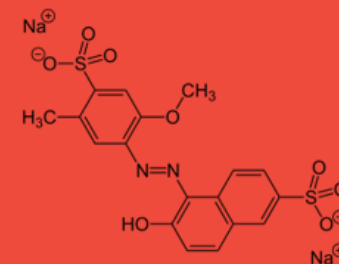


ALLURA RED

CAS Number: 25956-17-6

Technical function: Pigment

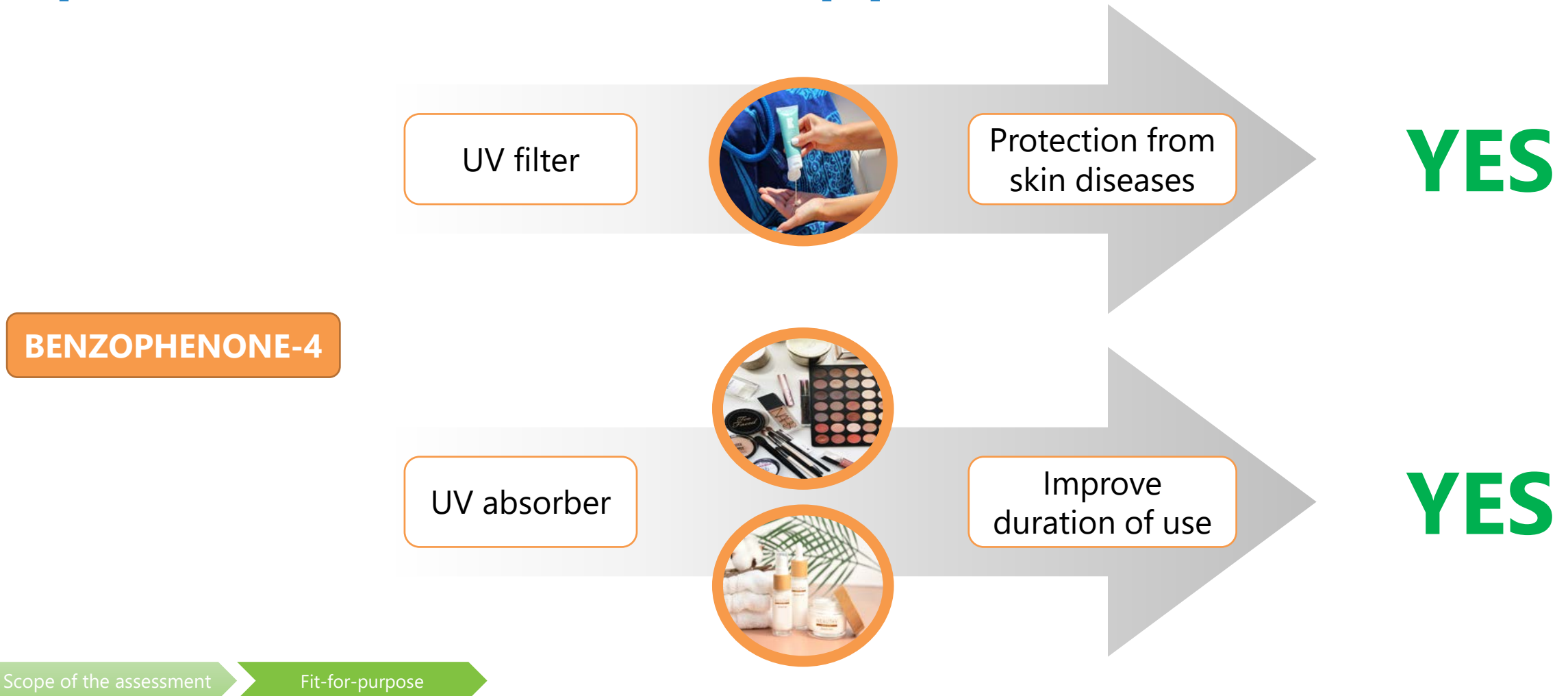
Type of products: All types of
cosmetic products



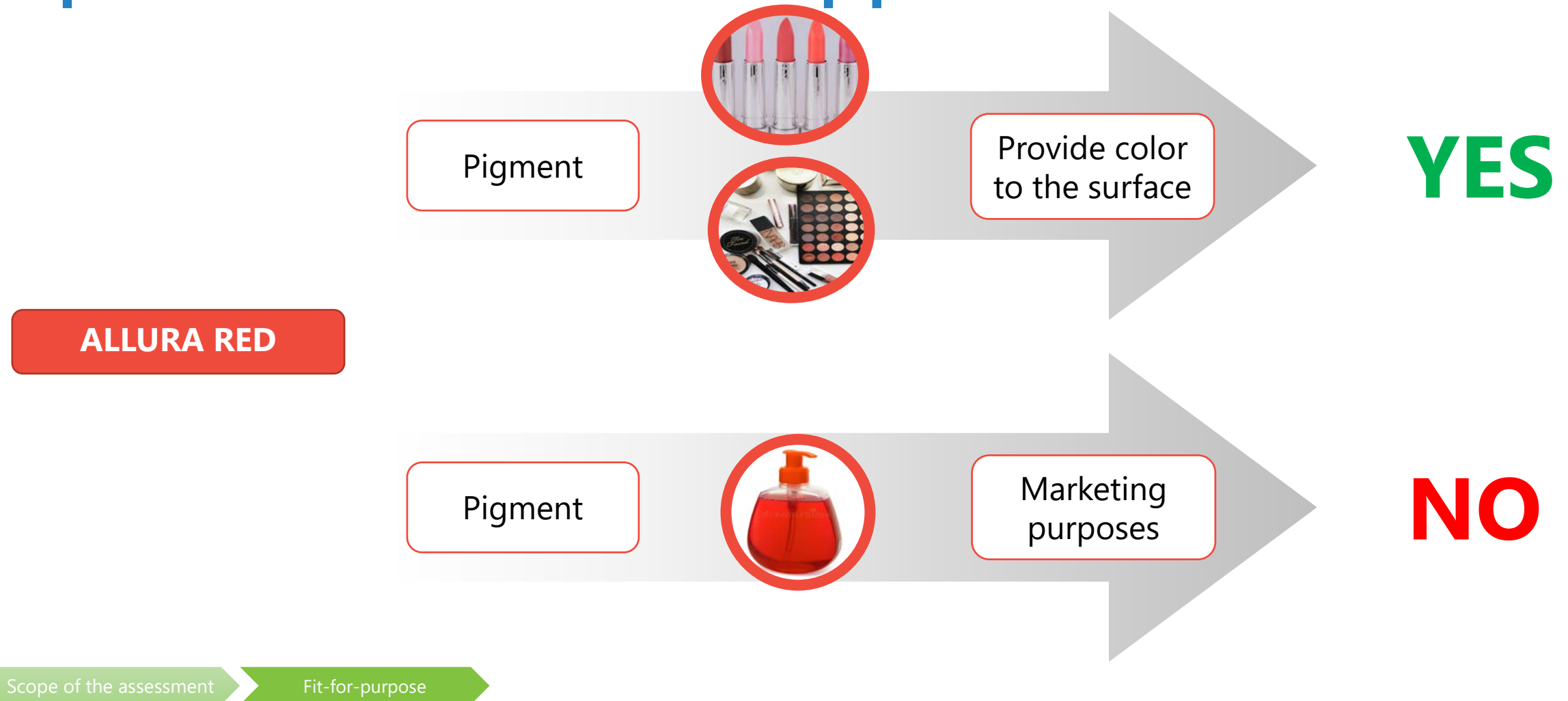
Is the function necessary for the performance in the application?



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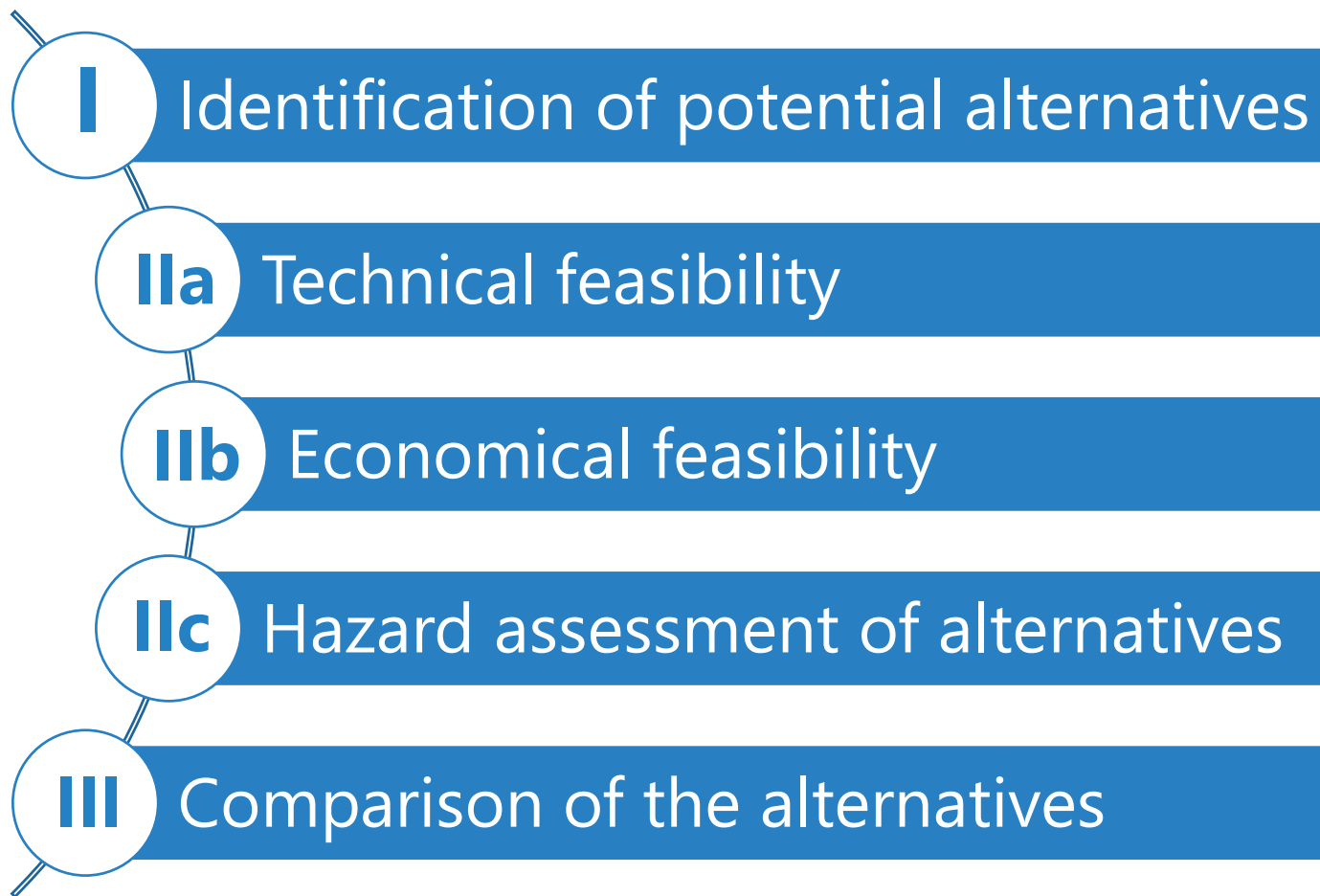
Is the function necessary for the performance in the application?



Assessment of the alternatives



Source: ECHA (2011)



Scope of the assessment

Fit-for-purpose

Assessment of
alternatives

Identification of the alternatives

Identifying potential alternatives

- CosIng database
- SpecialChem (cosmetic ingredient database from the industry)
- Lists of authorised food additives (for the pigment)

Shortlisting potential alternatives

- The Subport database (collection of 33 lists of restricted chemicals)
- Annex III to the cosmetic product regulation (restricted substances)
- ECHA database: C&L notification, PACT and Annex III inventory to REACH

Scope of the assessment

Fit-for-purpose

Assessment of
alternatives

Identification of
alternatives

Technical and economical feasibility

- **Technical feasibility**

- Case-by-case basis, so difficult to properly assess outside of the industry
- "*~25% of cosmetics products reformulated every year*"
 - All potential alternatives with same chemical function considered technically feasible

- **Economical feasibility**

- Very difficult to assess outside of the industry

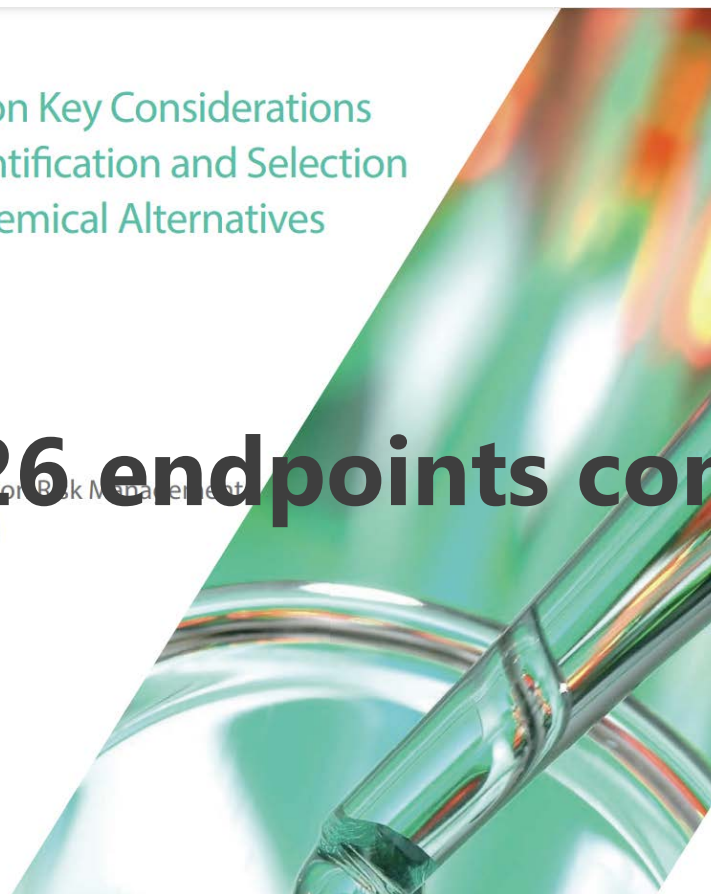
Hazard assessment

Guidance on Key Considerations
for the Identification and Selection
of Safer Chemical Alternatives

→ **Total of 26 endpoints considered**



Series on Risk Management
No. 60



Scope of the assessment

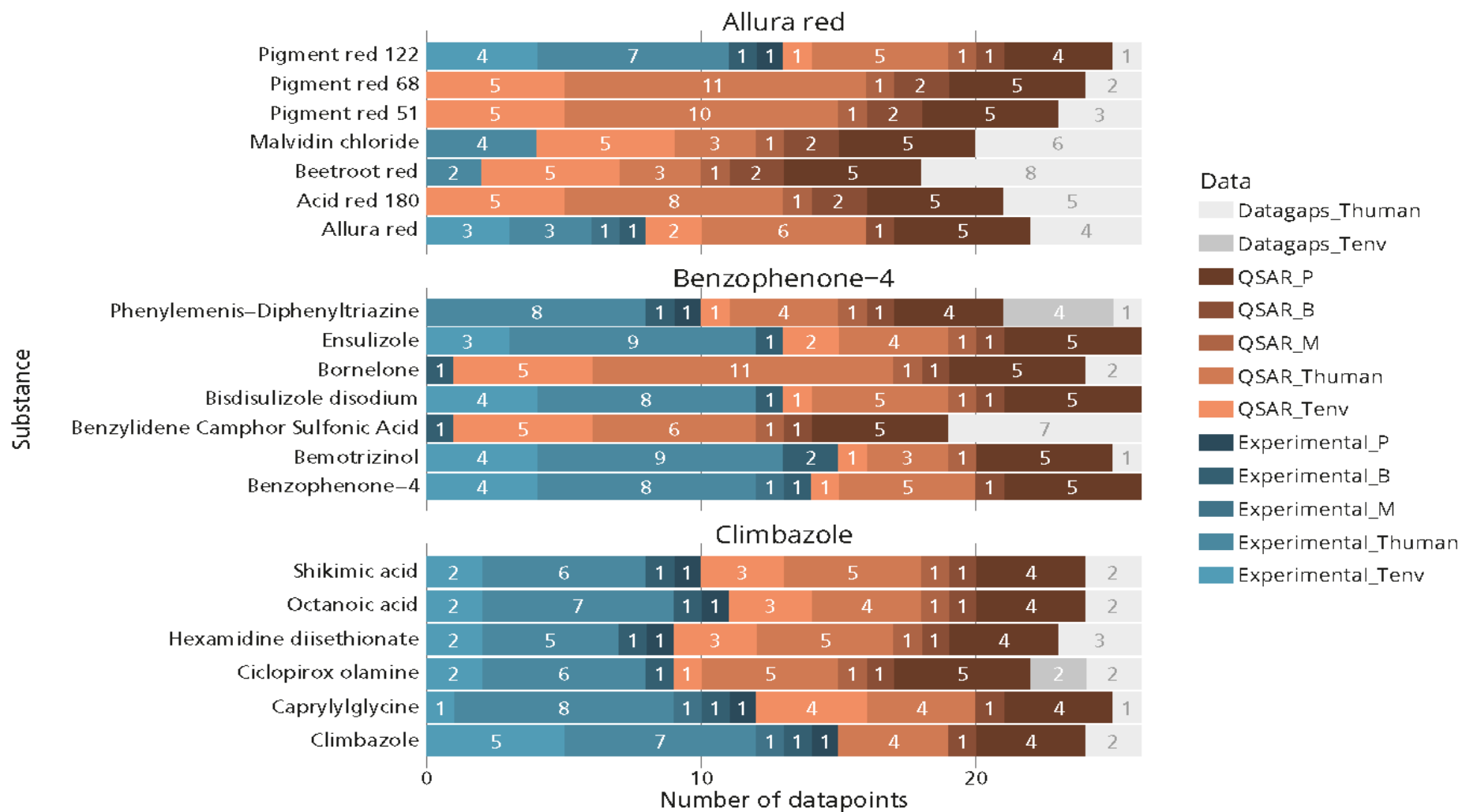
Fit-for-purpose

Assessment of
alternatives

Hazard assessment

Source: OECD, 2021

Hazard assessment



Scope of the assessment

Fit-for-purpose

Assessment of
alternatives

Hazard assessment

Comparison of the alternatives

- Comparison of alternatives with MCDA methods based on hazard profile
 - Heat map
 - MAUT
 - ELECTRE III
- Safer alternatives available for all case study

Use case	Chemical name	Ranking		
		Heatmap	MAUT	ELECTREIII
Pigment	Allura red	3	4	3
	Malvidin chloride	6	2	2
	Beetroot red	1	1	1
	Pigment red 51	3	5	5
	Pigment red 68	2	6	3
	Acid red 180	7	7	7
	Pigment red 122	5	3	5
UV - filter	Benzophenone-4	2	4	3
	Ensulizole	1	1	1
	Benzyldiene camphor sulfonic acid	5	5	7
	Bisdisulizole disodium	2	3	5
	Bemotrizinol	4	2	2
	Bornelone	7	6	5
	Phenylemenis-diphenyltriazine	6	7	3
Anti-seborrheic	Climbazole	6	6	5
	Octanoic acid	3	2	1
	Caprylylglycine	2	3	2
	Shikimic acid	1	1	4
	Ciclopirox olamine	4	4	2
	Hexamidine diisethionate	5	5	6

Necessity for health, safety and functioning of society

Substance name	Chemical function	Is the use of the chemical justified?	No safer alternative available?	Necessary for health and safety?
Benzophenone 4	UV absorber or UV filter	YES	NO	Assessment not needed
Allura Red	Pigment	NO, if for marketing purposes YES otherwise	NO	Assessment not needed
Climbazole	Anti-dandruff agent	YES	NO	Assessment not needed

Conclusion on essentiality

Substance name	Chemical function	Is the use of the chemical justified?	No safer alternative available?	Necessary for health and safety?	Conclusion
Benzophenone 4	UV absorber or UV filter	YES	NO	Assessment not needed	NON-ESSENTIAL
Allura Red	Pigment	YES NO, if use for marketing purposes	NO	Assessment not needed	NON-ESSENTIAL
Climbazole	Anti-dandruff agent	YES	NO	Assessment not needed	NON-ESSENTIAL

Scope of the assessment

Fit-for-purpose

Assessment of alternatives

Necessity for health and safety

Conclusion

Main message of the study

- Essentiality of a use mostly depends on availability of safer alternatives
- Chemical alternative assessments are crucial to avoid regrettable substitution
- Functional substitution approach allows to identify uses for which a detailed chemical alternatives assessment is not necessary

Outlook

- Further work on the evaluation of the reliability of the hazard data is needed
- Further work on assessment of technical and economical feasibility is needed
- Here, focus only on use phase of the substance, further work should take into account the whole life cycle of the products (e.g. Is change of packaging indeed safer?)

Acknowledgement

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Questions?



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