

The logo for Diversey, featuring the word "Diversey" in a white, sans-serif font on a dark blue background. To the right of the text is a white line-art icon of a stylized flower or plant with five petals and a stem with two leaves.

Diversey

BPF:

Biocidal product families

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ECHA Biocides Stakeholder Day October 2019



Diversey

Diversey is a provider of cleaning, sanitation and maintenance products, systems and services that efficiently integrate chemicals, machines and sustainability programs for e.g. facility management, health care, hospitality, retail and food service; in addition to food and beverage.

Headquartered in Fort Mill, South Carolina, USA, Diversey employs approximately 9,000 people globally, generating net sales of approximately \$2.6 billion in 2017.



Note for guidance link

CA-July19-Doc4.2-Final

<https://circabc.europa.eu/d/a/workspace/Space/sStore/71a22409-076c-4f2d-affe-dea810f128fd/CA-July19-Doc.4.2-Final%20-%20Guidance%20note%20on%20BPF%20concept.docx>



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3. PRACTICAL IMPLEMENTATION

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3.4. Post-authorisation notification of new products



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Pre submission meeting + Annex I

- **Step 1: Contact refMS/eCA**

- ASAP but not later than 18 months prior to the submission
- For Union: eCA agreement signature

- **Step 2: Discuss with your refMS/eCA**

- Meeting
- Present you family
 - Meta structure and products
 - Actives and substances of concern
 - Intended uses
 - PTs
 - User category/ies
- Present you testing strategy
- Risk assessment approach



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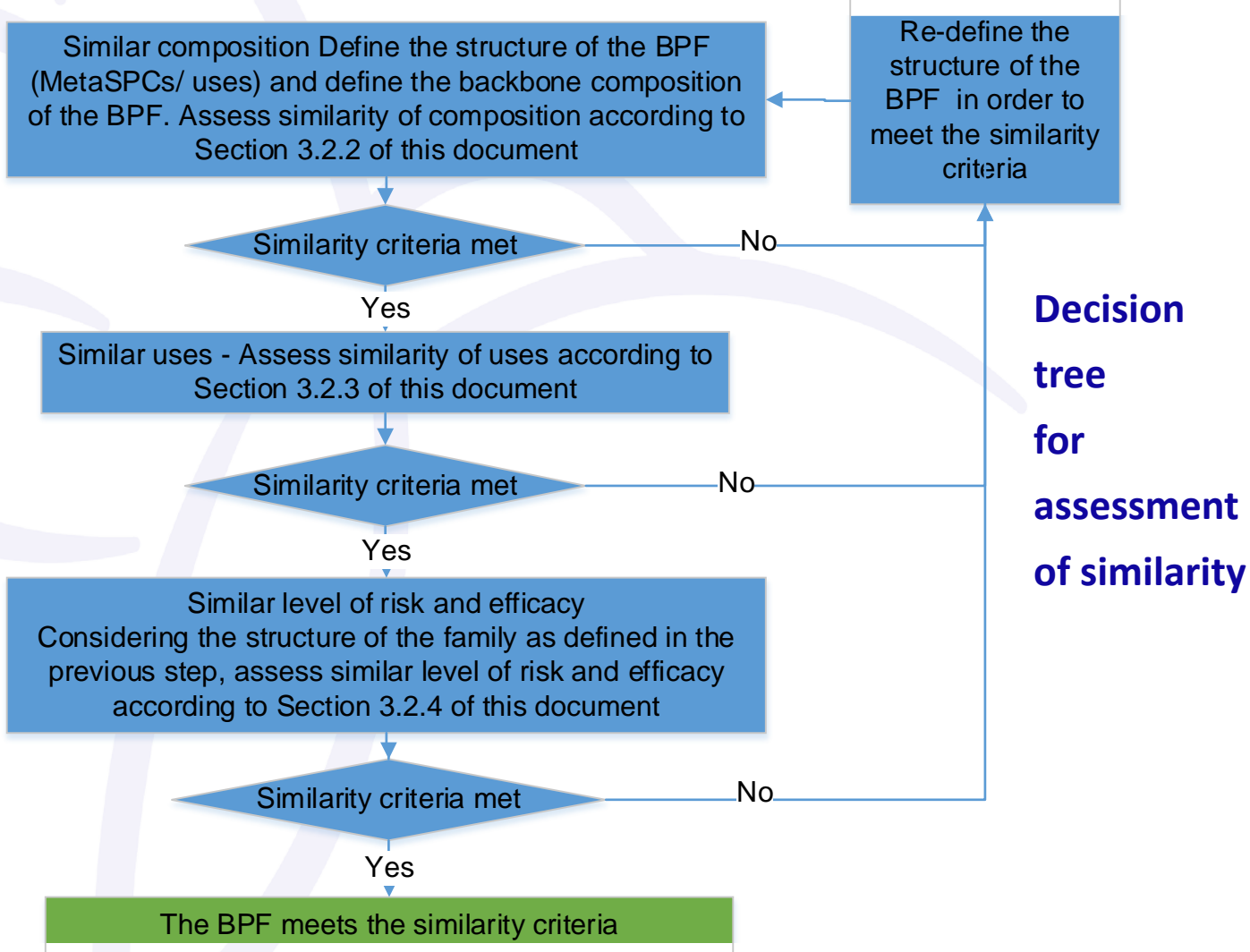
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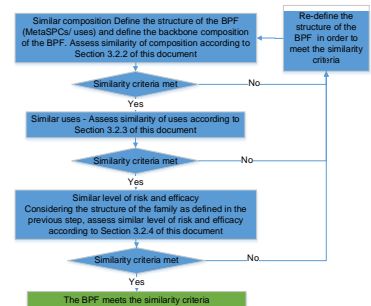
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Box 1: Similarity of composition within varied composition

Similarity of composition

-> Backbone composition

Within varied composition

-> Grouping of co-formulants



Box 1: Similarity of composition within varied composition +Annex 2

Backbone composition “Each individual member of the BPF should contain the same basic set of ingredients, which is essential to formulate all products within the biocidal product family. Individual products may still contain additional ingredients to comply with the needs for some envisaged individual uses.”

Refers to the actives and co-formulants needed to formulate any individual product in the family (e.g. solvent)

Not for easy exchangeable co-formulants (e.g. perfumes, dyes, pigment)

Exemptions: Carrier-based products, Concentrates which only consists of AS



Box 1: Similarity of composition within varied composition+Annex 3

Grouping of co-formulants

- Co-formulants need to be clearly defined in level 2 of the family
 - What is the worst case for risk or efficacy?
- Group some co-formulants together:
 - have the same function,
 - have the same impact on the classification
 - have the same impact on the level of risk and efficacy of the formulation.
- Allowed, but not mandatory
- By applicant sound technical arguments and where necessary data



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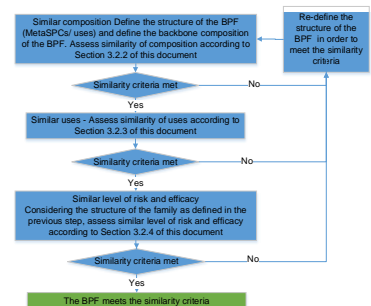
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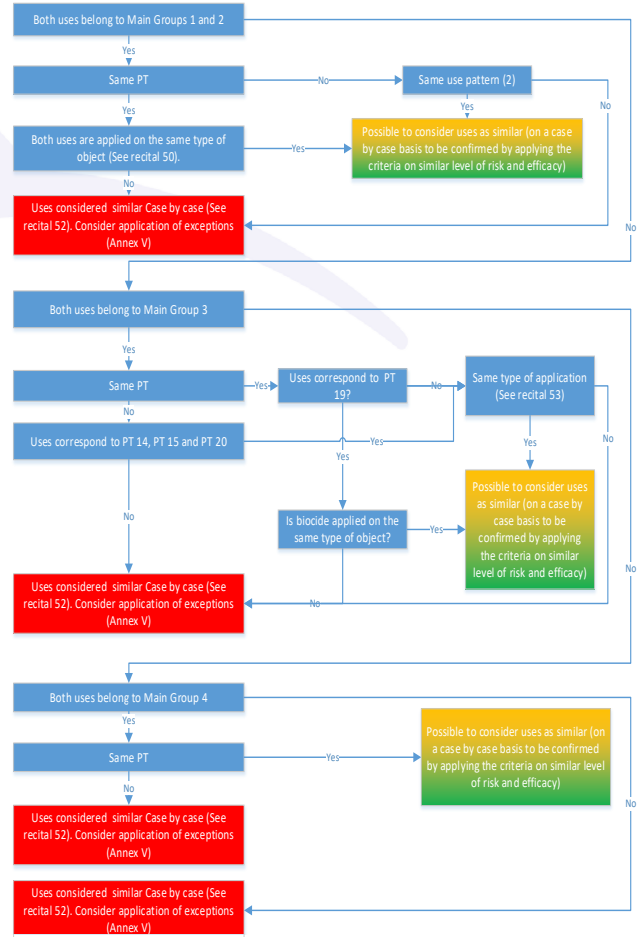




Box 2 Similarity of Uses

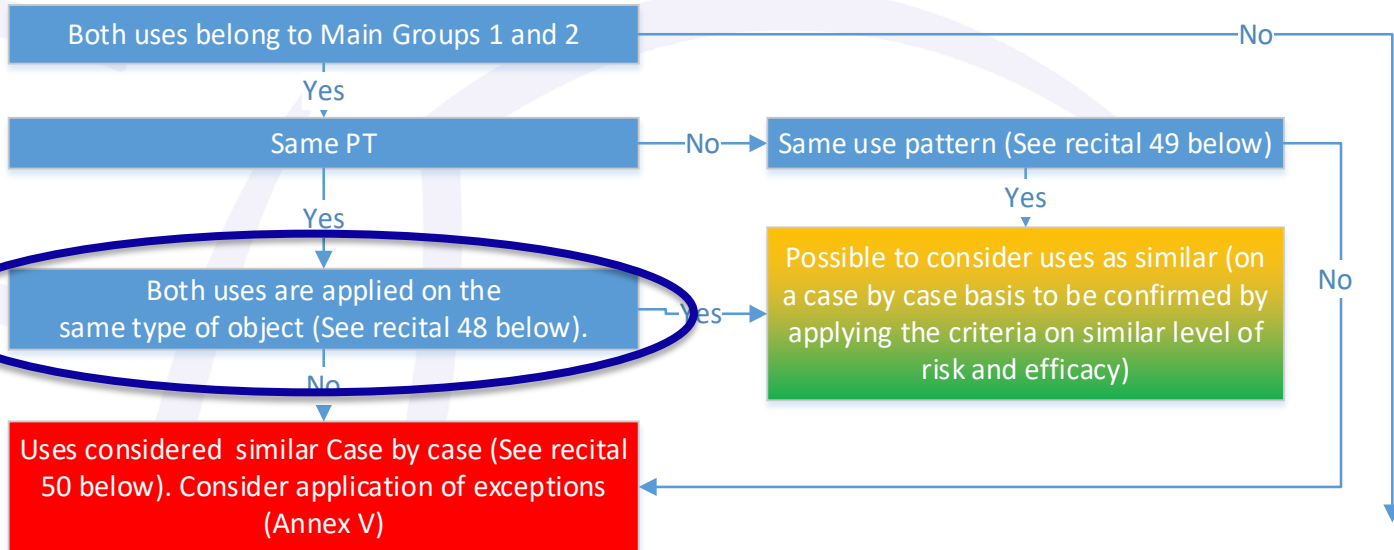
Criteria to assess whether a pair of uses within a BPF is similar are included in a decision tree

| | use 1 | use 2 | use 3 | use 4 | use 5 |
|-------|-------|-------|-------|-------|-------|
| use 1 | | ? | ? | ? | ? |
| use 2 | | | ? | ? | ? |
| use 3 | | | | ? | ? |
| use 4 | | | | | ? |
| use 5 | | | | | |





Similarity of Uses – Focus Main group I & II





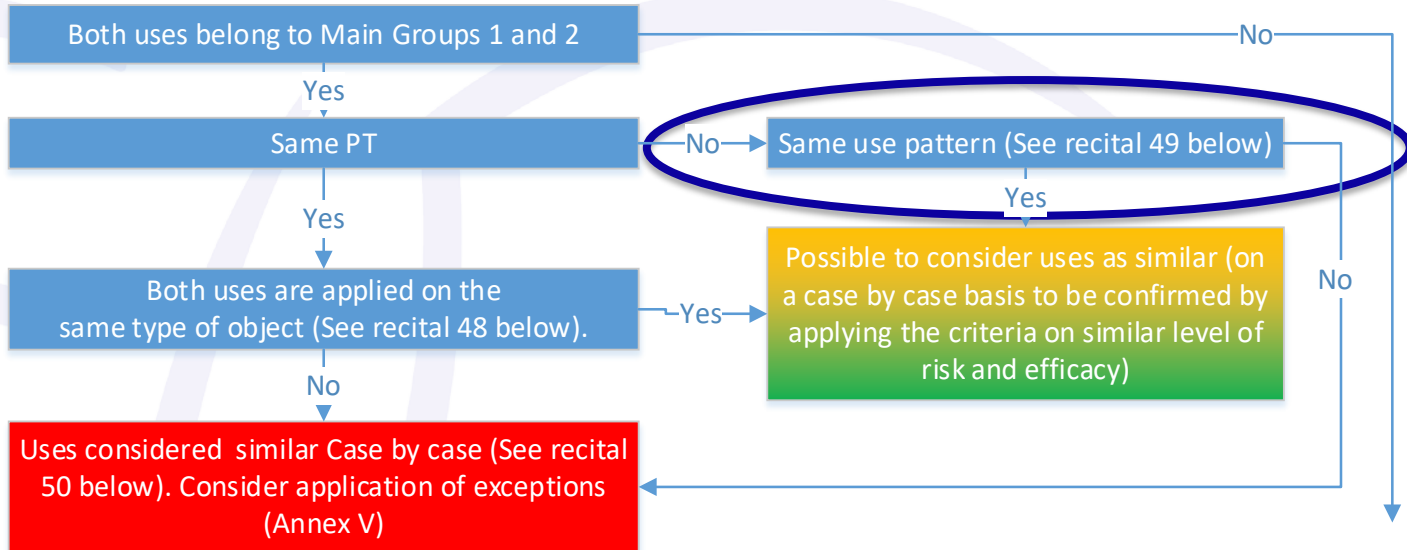
Similarity of Uses – Focus Main group I & II

Same type of "object" within the same PT (Recital 48):

- a) Application directly on human or animal skin.
- b) Hard surfaces such as for instance walls, floor, equipment, pipework, inner surfaces, soft surfaces such as for instance soft furnishing, textile disinfection, and other surfaces such as for instance hatching eggs, litter, surfaces associated with the housing and transportation of animals.
- c) Construction materials and hard surfaces.
- d) Laundry and textiles.
- e) Air and room disinfection (vaporised biocide).
- f) Products incorporated in treated articles.
- g) Water (or liquid) matrix (any kind of water)
- h) Surfaces in contact with water (or other liquid) and water (or liquid) matrix (other than waste water). Air condition systems, washing machines and crate washers .
- i) Chemical toilets
- j) Hospital waste
- k) Soil



Similarity of Uses – Focus Main group I & II





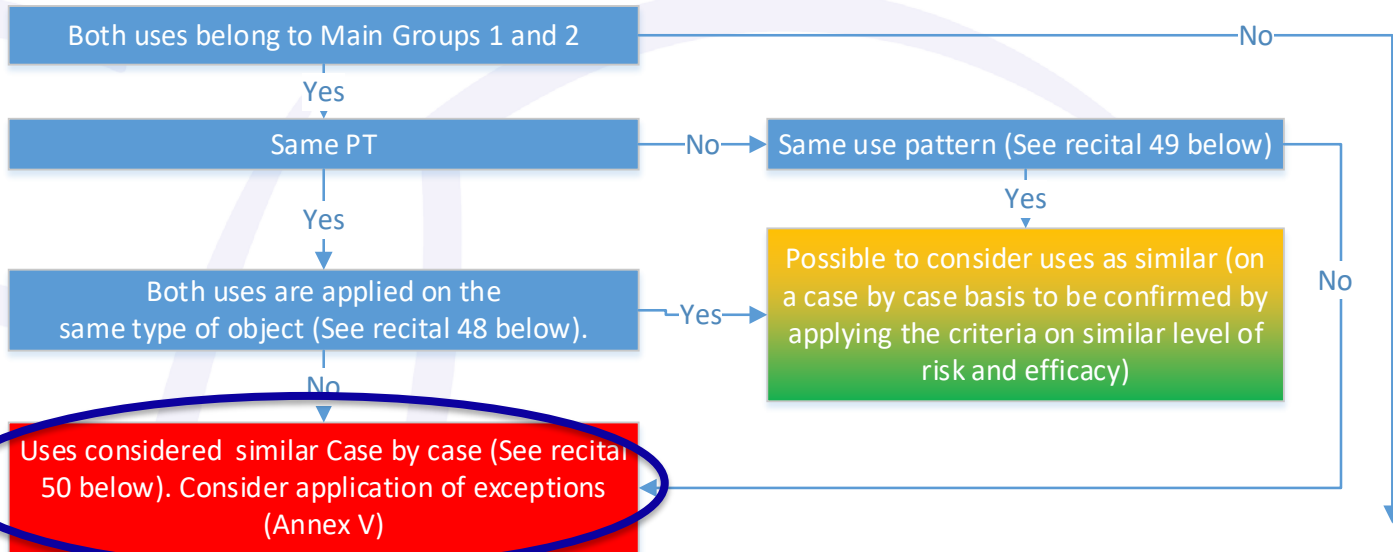
Similarity of Uses – Focus Main group I&II

Same use pattern for different PTs (Recital 49):

- a) Application directly on human or animal skin.
- b) Application in pipework / inner surfaces (CIP)/ surface in contact with water (or other liquid)
- c) Application on hard or soft surfaces/ instruments/ equipment (other than hatching eggs, surfaces associated with the housing and transportation of animals and application via room disinfection)
- d) Application on laundry and textiles
- e) Air disinfection and application for room disinfection (vaporised biocide)
- f) Products incorporated in treated articles
- g) Application on a water matrix (other than waste water, manure)
- h) Application on waste water and manure



Similarity of Uses – Focus Main group I & II





Similarity of Uses – Focus Main group I&II

Exceptions that are be considered as similar on a case by case basis (Recital 50):

- a) PT1 (Human hygiene) and the following uses:
 - PT2 and PT4: Disinfection of hard surfaces instrument and equipment.
 - PT2: Products to be incorporated in textiles, tissues and materials with the purpose of producing treated articles with disinfecting properties.
 - c) PT2 disinfectants for pipework/inner surfaces (CIP)/ Surface in contact with water and PT3 products used for disinfection of the materials and surfaces in contact with water associated with the housing or transportation of animals (e.g. in aquaculture).
- Etc
- h) Other use patterns that might be agreed by the CG.



Box 2 Similarity of Uses

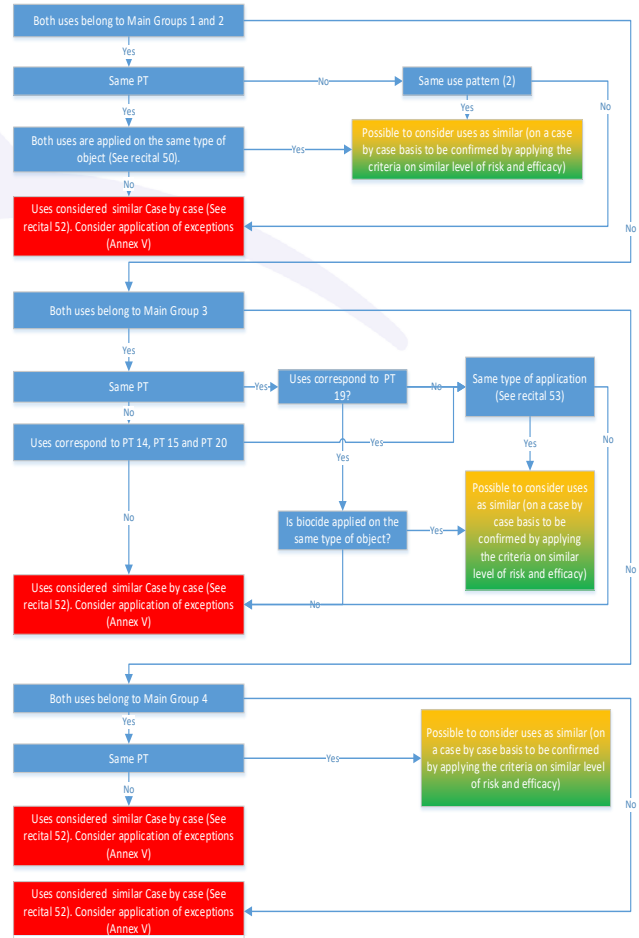
Criteria to assess whether a pair of uses within a BPF is similar are included in a decision tree



An automated tool in the form of a matrix has been developed to assist on the application of the criteria (Annex 4)



Some flexibility is possible in order to avoid unnecessary submissions: in each family a maximum of **two** pairs of uses that are *a priori* considered as "non-similar" is allowed. (Annex 5)





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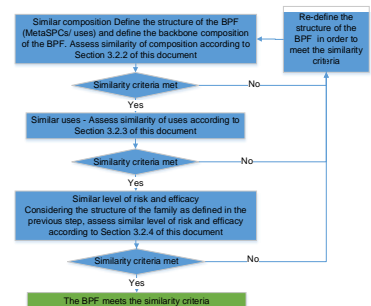
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Box 3 Similar levels of risk and efficacy + Annex 6 and 7

Section 1 Composition to be taken into account for the core assessment

Section 2 Worst case composition to be taken into account for risk core assessment

Section 3 Worst case composition to be taken into account for efficacy core assessment

Section 4 Risk assessment of the uses

Section 5 Efficacy assessment of the uses

Section 6 Subsets to the core

Section 7 Extensions to the core

Section 8 Assessment of the uses of the subsets and extensions

Section 9 Limitation of possible number of subsets and extensions

Section 10 Meta-SPC



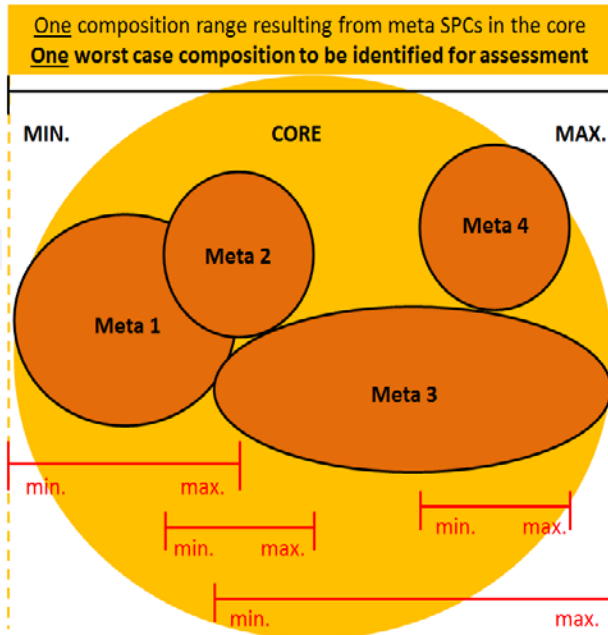
3.2.4. Similar levels of risk and efficacy + Annex 6 and 7

One core assessment on significant portion of family.

Worst case assessment for

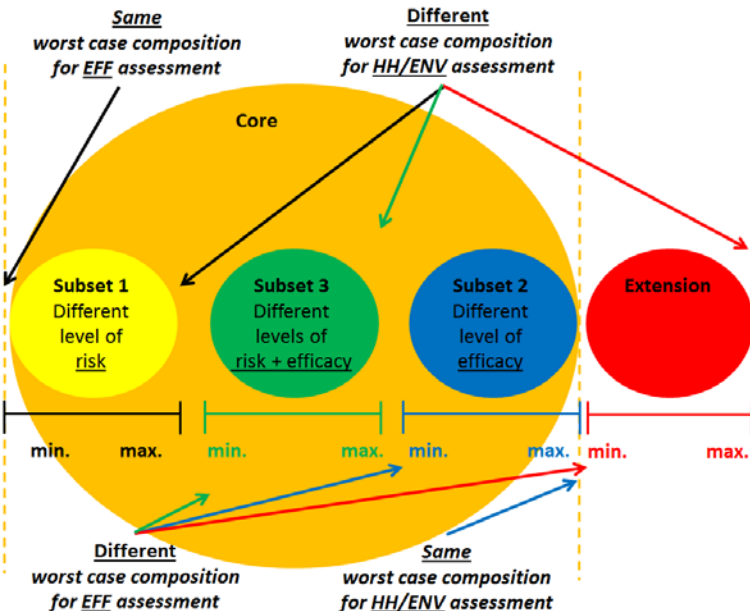
- Risk assessments
- Efficacy

for every use.





3.2.4. Similar levels of risk and efficacy + Annex 6 and 7



Extension possible if inclusion would significantly restrict overall authorization.

E.g. for different fields of use (e.g. outdoor use)

Subset possible if where the efficacy or a safe use cannot be supported over the whole composition range of the core.

E.g. for different user categories (e.g. non-professional user).



3.2.4. Similar levels of risk and efficacy + Annex 6 and 7

75. However, in order to ensure a manageable size of the BPF such extensions triggering a complete re-assessment of all BPF parameters independent from the core assessment are not acceptable. Only extensions which are limited to a number of refinements of the original core assessment are acceptable.
78. ...MS can accept the inclusion of subsets and extensions in a BPF.
80. MS should generally accept only extensions and subsets requiring overall not more than three refinements per family (via subsets and/or extensions). ... subsets considered as necessary in order to support para. 77 of Annex VI of the BPR are supported and would not be included as part of these three refinements ...



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Splitting of families ongoing applications

Splitting of a Family during evaluation, mutual recognition or peer review is possible: e.g. not having either similar uses, composition or level of efficacy or risk.

Keep in mind: This guidance could be applied for applications submitted before 01/10/2019 if the applicants agree.

Initial application continues

New application has to be made for the “splitted” parts:

- All products still covert by transition provision (BPR article 89)
- Review concluded in the same “original” time path
- Fees for this new application? eCA/refMS fee and ECHA fee



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To think about ...

- **Family concept has more restrictions versus a single registrations**
- **Family needs more explaining**
 - Where to explain family in PAR template
 - Where to explain Core/Extension/Subsets
 - SPC editor versus grouping of ingredients
- **For already submitted dossier, guidance is not applicable but rMS/eCA might not agree with applicants view on either similar uses, similar composition or similar level of efficacy or risk**





International Association for Soaps,
Detergents and Maintenance Products



Thank you!

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