DISCLAIMER: This document has been agreed on 12 March during the CG-34 meeting. The document CA-Nov14-Doc.5.8-Final will be updated accordingly after the discussion at CA level.

Working Party BPF concept – WP-BPF-8

Assessment of similarity in biocidal product families

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According to Article 3(1)(s) of the BPR, a biocidal product family (BPF) is defined as a group of products having similar uses, the same active substances, similar composition within specified variations and similar levels of risk and efficacy.

In order to assess whether a BPF meets the BPR definition of family with regards to similarity, the steps in Figure 1 should be followed. For each step the criteria detailed in each section of this document should be addressed.

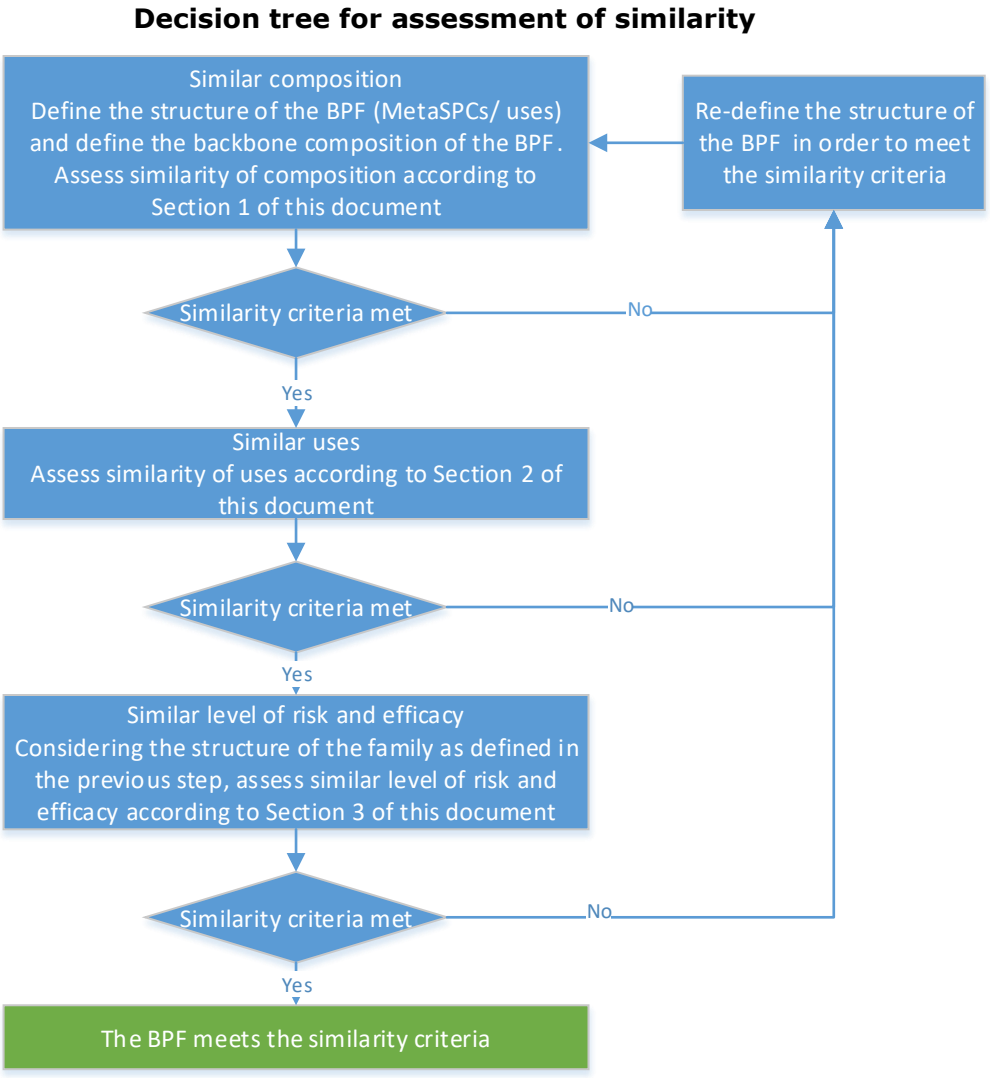


Figure 1. Overview of the approach for the assessment of similarity

Section 1 - Similarity of composition

1.1. Definition of similar composition

According to Article 3(1)(s) of the BPR a biocidal product family (BPF) refers to a group of products having similar uses, the same active substances, similar composition within specified variations and similar levels of risk and efficacy.

To allow for deciding which individual products can be regarded as similar in composition, a so called "backbone composition" should be established within a BPF. The proposed rule reads as follows

Each individual member of the BPF should contain the same basic set of ingredients[1], 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.

This backbone composition should contain a (combination of the) active substance(s) and a (combination of the) co-formulant (s), which is (are) essential to formulate all the products. The pre-requisite of "essential to formulate" refers to co-formulants such as complexing agents, binders, pH-regulators, or a specific solvent needed to formulate any individual product in the BPF. It does not refer to easy exchangeable co-formulants like perfumes, pigments, dyes, skin care agents, tensides or co-formulants added to address the needs for some envisaged individual uses, for example corrosion inhibitors or scale inhibitors.[2] Additionally, co-formulants added to ensure compatibility with a certain packaging material should not be considered as essential to formulate and, therefore should not be included in the backbone composition. A robust explanation on how the backbone composition has been derived from the individual product compositions should be provided by the applicant. The evaluating CA will judge such justification during the assessment of the applications in order to avoid any abuse of the concept by including "essential to formulate" co-formulants at a very low concentration (e.g. 0.1% or lower) in all products, so that any product falls within the "backbone composition" and therefore meets the criterion of similar composition.

An exception can be made for so called carrier-based products as defined in CA-Nov16-Doc.4.3-Final. Another exception could be made for concentrates which only consist of the active substance itself (e.g. intended to be diluted for in use concentration, see example 2, Annex A) or formulations of the active substance, that do not contain co-formulants which are essential to formulate the biocidal product (e.g. solid products as powders or tablets containing only certain co-formulants, see example 3, Annex A). In such cases it might be acceptable that the backbone composition only consists of the active substance itself.

The range of co-formulants that are essential to formulate belonging to the backbone composition have to be included in range starting above 0 percent minimal content. In addition, the minimal concentration shall be set in such a manner that the presence of each co-formulant remains determinant for each product included in the BPF.

It should also be made clear that this rule can only help to address the similarity of composition of individual products within a BPF-application. Situations may occur where individual products may pass the "similar composition" criterion but may fail to pass the "similar use" or "similar levels of risk and efficacy" criteria. Only products fulfilling all provisions of Article 3(1)(s) of the BPR will be accepted to stay in the BPF.

Several examples are presented in Annex A in order to illustrate how the proposed approach for "Similar composition" can be applied.

1.2. Grouping of co-formulants

According Article 3(1)(s) of the BPR a biocidal product family refers to a group of products having similar uses, the same active substances, similar composition within specified variations and similar levels of risk and efficacy. In order to define what is exactly authorised within a BPF it is crucial to make clear which variations in compositions are allowed for the

[1] The backbone composition can be defined by either individual co-formulants, or group(s) of co-formulants with the same function, grouped together by applying the grouping concept (see Section 1.2).

[2] It should be noted that there are co-formulants that could be considered either as essential or non-essential on a case by case basis. For example, a complexing agent would be considered as essential if it is needed to ensure the integrity of the product. However, if the complexing agent would be included in the product in order to address a need for complexation derived from the use of the product, the complexing agent would not be considered as essential to formulate.

authorisation.

Applications for BPF can contain biocidal products with diverse compositions. At 1st and even at 2nd level of information all possible co-formulants with their concentrations ranging from 0 % to the maximum concentration can be listed. In consequence, the SPC authorised as such would mean that from a legal perspective even a product only containing the active substance and solvent could be eligible for notification. Practically speaking such case would be highly unlikely to occur, but it cannot be ruled out that a product composition will be notified which was not in the range of the initial BPF assessment.

Grouping of products into meta-SPCs (2nd level of information) and specification of minimum concentration which is greater than zero and a maximum concentration of co-formulants at meta SPC level can avoid this situation.

To facilitate the definition of meta SPCs and to avoid excessive splitting, applicants should be allowed, when appropriate, to group co-formulants having the same function, e.g. emollients, thickeners, wetting agents and complexing agents as shown in the example below (Table 1). By declaring a range for the group of co-formulants (with the minimum concentration >0%) and the minimum = 0% and maximum concentration of each member of the group, the grouping approach avoids that a product composition will be notified which is not covered by the assessment of the BPF as authorised. It should be allowed, but not mandatory, to group some co-formulants together, provided that they:

- have the same function,
- have the same impact on the classification (i.e. resulting in the same hazard and safety statements) for the whole formulation
- have the same impact on the level of risk and efficacy of the formulation.

It should be noted that as a prerequisite for grouping a clear definition of the function of a co-formulant is needed and that grouping may not always be possible. In all cases any chosen grouping must be supported by the applicant in the dossier using sound technical arguments and where necessary data.

If grouping is applied then it is also necessary to specify if co-formulants grouped together are meant to be used in combination or if they should be used exclusively, either the one or the other.

Table 1 gives an example how grouping of co formulants following the rules as given above could look like. The example shows how Level 2 ranges are defined based on the minimum and maximum concentrations from the individual products within the meta-SPC. It is also shown how co-formulants grouped together are meant to be used, either in combination or if they should be used exclusively, either the one or the other.

Table 1 – example meta SPC

	Level 2 - Meta SPC		**Level 3 - Individual Products within the meta SPC**						
Function	**min(%)**	**max(%)**	1	2	3	4	5	6	7
Active Substance	0.15	0.50	0.25	0.50	0.15	0.30	0.15	0.45	0.30
Complexing Agents A and B can only be used alter-natively. The content of the complexing agent in the formu-lation should be in the range of 1.00 to 3.00	**1.00**	**3.00**							
Complexing agent A Complexing agent B	0.00 0.00	3.00 1.90	 1.90	1.00	1.50	1.00	3.00	2.50	2.50

Thickeners A and B can be used either alter-natively or in combination. The total content of thickeners in the formulation should be in the range of 0.50 to 1.00	**0.50**	**1.00**							
Thickener A	0.00	1.00			0.1		1.00		
Thickener B	0.00	0.75	0.50	0.50	0.45	0.50		0.75	0.75
Emollients A and B can be used either alter-natively or in combination. The total content of emollients in the formulation should be in the range of 4.12 to 9.20	**4.12**	**9.20**							
Emollient A	0.00	8.70	8.00	8.00	8.70	8.00	8.00	3.00	
Emollient B	0.00	0.50	0.50						
Emollient C	0.00	4.12			0.5			4.00	4.12
Wetting Agents A and B can be used either alter-natively or in combination. The total content of wetting agents in the formulation should be in the range of 0.15 to 2.6	**0.15**	**2.6**							
Wetting Agent A	0.00	0.20		0.15	0.20				
Wetting Agent B	0.00	2.58	0.15			0.15		2.50	2.58
Wetting Agent C	0.00	1.50		0.10		0.10	1.50	0.10	
Solvent	83.7	94.13	ad 100	ad 100	ad 100	ad 100	ad 100	ad 100	ad 100

Section 2 - Similarity of uses

The general criteria for deciding on whether a pair of uses is considered as similar is detailed on the decision tree included below. Within a given family, all possible pairs of uses should be considered as similar.

An automated tool in the form of a matrix has been developed to assist on the application of the criteria referred to in the decision tree in Figure 2 (See Annex C).

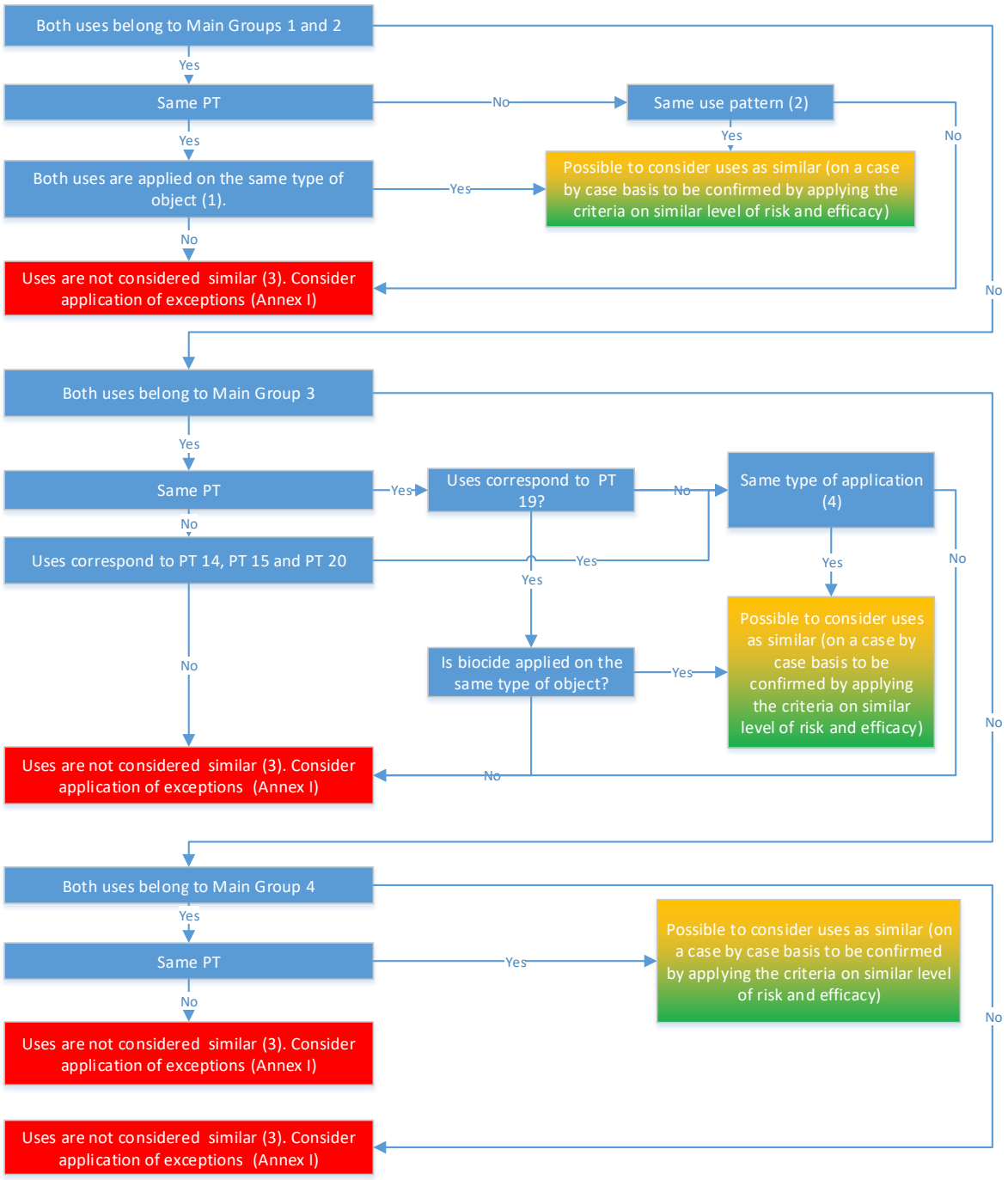


Figure 2. Criteria to assess similarity of uses.

(1) Same type of "object" **<u>within the same PT</u>** for main groups 1 and 2 has been considered as when the object subject to the application of the biocidal product in both uses falls in one of the following categories:

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

(2) Same use pattern **<u>for different PTs</u>**:
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

(3) Based on expert judgement and agreed by the experts from the WP on the BPF concept, the following uses falling outside of the criteria outlined in the decision tree could also be considered as similar on a case by case basis:
a. PT1 (Human hygiene) and the following uses:
i. PT2 and PT4: Disinfection of hard surfaces instrument and equipment.
ii. PT2: Products to be incorporated in textiles, tissues and materials with the purpose of producing treated articles with disinfecting properties.
b. PT5 (Drinking water) and the following uses:
i. PT4 Products used to be incorporated into materials which may enter into contact with food.
ii. PT4 Disinfectants for hard surfaces/ instrument/ equipment disinfection.
c. PT2 disinfectants for pipework/inner surfaces (CIP)/ Surface in contact with water and PT3 use for 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).
d. PT3 products for instrument/equipment disinfection and PT3 products to be directly applied on animal skin.
e. PT22 and PT1 and PT3 products used on human or animal skin
f. Insecticides used for PT8 and PT18
g. PT 3 Surfaces associated with the housing and transportation of animals, PT3 soft surfaces, PT3 Hard surfaces/ instrument/ Equipment disinfection and PT4 disinfectants for pipework/inner surfaces (CIP).
h. Other use patterns that might be agreed by the CG.
i. PT2 disinfectants for pipework/inner surfaces (CIP)/ Surface in contact with water and PT2 disinfectants on a water matrix (e.g. industrial water) with the aim to disinfect both water and the industrial pipeline.

(4) In this context, same type of application is understood as when products corresponding to both uses are being used either as bait or used for direct kill. However, in the case of PT18 products, on a case by case basis it could be possible to consider as similar uses for direct kill and as a bait. This is for example the case of products in the form of sugar granules that can be diluted in water.

Section 3 – Similar level of risk and efficacy

1) Definition of a BPF

When defining a BPF the following agreed approach must be taken into account:

a) Definition of similar composition

b) Grouping of co-formulants in biocidal product families

c) Criteria/Matrix to assess similarity of uses

2) Definition of the core

In order to ensure a manageable size the BPF must be generally defined by one core assessment. The core should include a significant[3] proportion of the BPF.

Furthermore, applications which are in a large part redundant should be avoided because they cause unnecessary additional cost both to applicants and eCAs. Therefore MS can accept that a core includes more than one meta-SPC[4] if the products **cannot** be presented in one meta-SPC. This can in particular be appropriate in order to:

a) Include BPs into one BPF that can be covered by one core assessment but due to different H&P phrases or formulations types[5] need to be separated into different meta-SPCs (see Example 1.1 in Annex D.1);

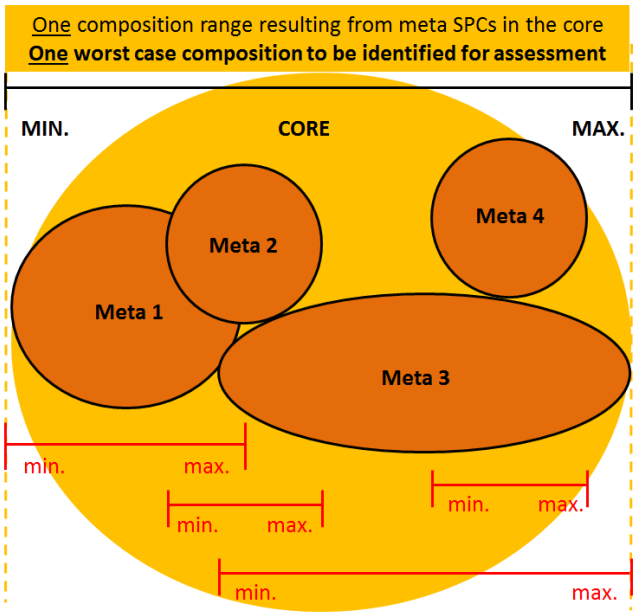
b) Include concentrates and corresponding RTU products into one BPF (see Example 1.2 in Annex D.1).[6]

[3] It is up to the evaluating CA/refMS to decide whether the core includes a significant proportion of the BPF. In any case applications which would be largely redundant should be avoided.

[4] However, the meta-SPCs should not be used to structure the risk assessment, but only to improve the readability of the SPC, fulfil the requirements of Article 17 (6) (one unique set of information per meta-SPC), provide clarity about the overall BPF-structure. In fact the meta-SPCs are the result of the assessment and not the starting point.

[5] E.g. powder, granules, tablets of same composition are all diluted to the same in use concentration.

[6] The use of the concentrate includes only an additional mixing and loading step before application. Therefore, in cases where the concentrate and RTU products are in the same BPF, it would be acceptable to consider an additional core composition consisting of the concentrate for the mixing and loading stage (see Annex 1 example 1 for an illustration of this case).



Scheme 1: Example of core consisting of 4 meta-SPCs.

3) Composition to be taken into account for the core assessment

The assessment is based on one worst case composition. This worst case composition might be different from area to area.[7] In order to fulfil the provisions of Article 19 paragraph 6 (a) BPR the applicant must identify the worst and best case composition of the core to be assessed.

The worst case composition to be taken into account should include a significant proportion of the level 1 family range.[3]

Please, consider Annex D.1 for some examples.

a) Worst case composition to be taken into account for risk core assessment

The worst case composition to be taken into account is generally defined by e.g.:

i) Highest (in use)[8] concentration of active substance

ii) Highest (in use) concentration of co-formulants negatively effecting the risk

Please, consider Annex D.2 for some examples.

The worst-case core formulation does not need to represent all highest component concentrations, nor contain all components of the formulation (these can be presented as an extension (see chapter 7 and example in Annex D.6) to the core), if a core assessment of these would result in an overestimation of risk or significantly restrict the authorisation overall. In such cases a lower core formulation than the family Level 1 maximum can be set. However, this core formulation should still include a significant proportion of the total Level 1 BPF.

b) Worst case composition to be taken into account for efficacy core assessment

The worst case composition (e.g. representative test product(s) and expert judgement/bridging studies where applicable) to be taken into account is generally defined by e.g.

i) Lowest (in use) concentration of active substance

[7] E.g. human health (HH), environment (ENV), efficacy (EFF).

[8] Regarding concentrates two concentrations have to be taken into account. Concerning mixing and loading (dilution step) the concentrate. Concerning the in use formulation (dilution) the RTU concentration.

ii) Lowest (in use) concentration of co-formulants positively effecting efficacy

iii) Highest (in use) concentration of co-formulants negatively effecting efficacy

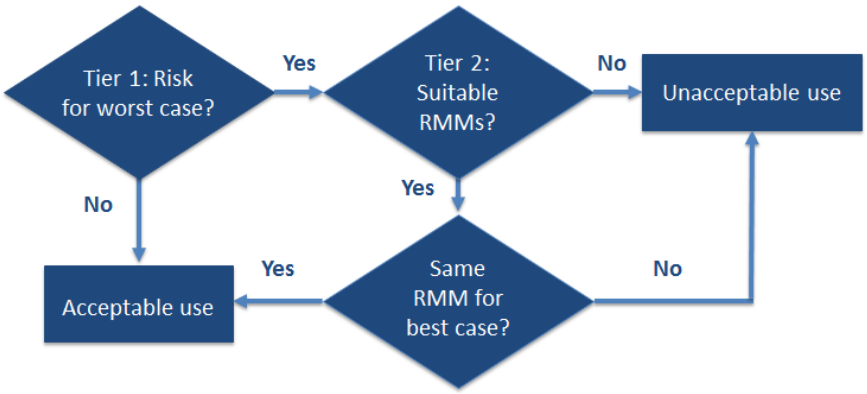
iv) Phys. chem. property (e.g. pH value) which is most unfavourable for efficacy

Justification should be given why the chosen test product(s) covers the whole core. This can include expert judgement or bridging studies where applicable.

In cases where the minimum concentration of active substance, or associated co-formulant compositions, do not support the majority of the targets/label claims within the core it is possible to set the worst-case composition for efficacy at another location within the Level 1 family range (with products inside core formulation evaluated as a subset (see chapter 6), and products outside the core formulation evaluated as an extension (chapter 7). This can be an important tool in supporting para. 77 of Annex VI of the BPR.

4) Risk assessment of the uses

While there is only "one" worst case composition to be taken into account, generally[9] every use applied for in the SPC needs to be assessed. When assessing the uses the different parameters defining the use are taken into account.[10] Since Article 17 paragraph 6 BPR (addition of further BP to an authorised BPF) requires a notification only, a use within the core must have one consistent set of RMMs etc. (see Annex D.3 for an example). Therefore, a use needs be assessed as described in the following scheme:



Scheme 2: Workflow for risk assessment of a use.

a) In Tier 1 the worst case composition and the worst case for each parameter[10] are taken into account.

b) If there is no risk for the worst case composition the whole use is acceptable.

c) If there is a risk a refinement is necessary (Tier 2).

d) If there are suitable RMMs it has to be kept in mind that there can be only one set of RMMs for a given use.

e) Therefore, it has to be checked if the RMMs are the same for the best case composition.

[9] For each use it should be checked whether it is already covered by a use previously assessed. The applicant is strongly encouraged to structure and present the uses applied for in an appropriate way in order to minimise the overall workload.

[10] E.g. in use concentration(s), application rate, frequency of application, user category, field of use, application method.

f) If the RMMs are the same for the best and worst case composition the use is acceptable.

g) If the RMMs are not the same for the best and worst case composition, level of risk of the use is considered as not similar and therefore the use as unacceptable (subject to the application of subsets – see chapter 6 and example in Annex 4).[11]

5) Efficacy assessment of the uses

While there is only "one" worst case composition to be taken into account generally[9] every use needs to be assessed. When assessing the uses the different parameters defining the use are taken into account.[12]

6) Subsets to the core

There may be cases where the efficacy[13] or a safe use[14] cannot be supported over the whole composition range of the core. In such cases it can be appropriate to set the worst-case composition for efficacy or risk at another location within the core range and manage the other target organisms/risks as subsets to the core.[15]

There are three possible types of subsets (see scheme 3 below) which require different numbers of refinements[16] of the core assessment:

a) Subsets in order to address different levels of risk (see subset 1 in yellow below) require a refinement[17] of the human/animal health and/or environmental risk assessment using a different worst case composition from within the already established core.[18]

b) Subsets in order to address different levels of efficacy[19] (see subset 2 in blue below) require a refinement[20] of the efficacy assessment using a different worst case composition from within the already established core.[18]

c) Subsets in order to address different levels of risk and efficacy (see subset 3 in green below) require a human/animal health and/or environmental risk assessment

[11] In this case the applicant has two options: Either the use applied (one box in the SPC) is split into uses (e.g. with different application rates) or the use is presented in a subset.

[12] E.g. target organisms, contact times, clean/dirty conditions, in use concentration(s), application rate.

[13] E.g. for different target organisms, development stages or label claims (e.g. nest kill, shorter contact time).

[14] E.g. for different user categories (e.g. non-professional user) or fields of use (e.g. outdoor use).

[15] In principle each subset can include as many meta-SPCs as the core but generally not more.

[16] Subsets triggering a complete re assessment of all parameters from the core are not acceptable. Only re assessments with a limited number of parameters changed are acceptable.

[17] A refinement allows to refine the risk assessment by taking into account more realistic values (here e.g. an active substance concentration of only 5-10 % for products for non-professional users instead of 5-20 % for the core which includes the products for the professional user.

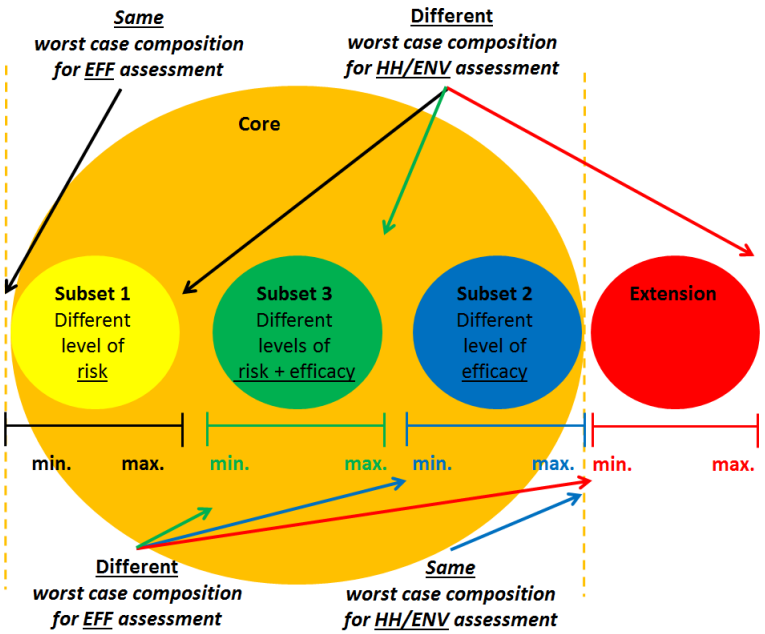
[18] To be identified for the subset in accordance with chapter 3.

[19] This could be an important tool in supporting para. 77 of Article VI of the BPR. This should be discussed in detail in the relevant Expert Working Groups.

[20] A refinement allows to refine the efficacy assessment by taking into account more realistic values (here e.g. an active substance concentration of 15-20% for products against an additional target organism instead of 5-20 % for the core which includes the products against three other target organisms.

as well as efficacy assessment using a different worst case composition from within the already established core.[18]

Please, consider Annex 4 for an example regarding subset 1 (different level of risk) and Annex D.5 for an example regarding subset 2 (different level of efficacy).



Scheme 3: Visualisation of possible groups of additional products and corresponding core composition

7) Extensions to the core

There may be cases where the inclusion of an additional group of products to the core would significantly restrict the overall authorisation.[21] It can be appropriate to manage such differences in composition as an extension to the core (see extension in red in scheme 3 above).

Given the definition of an extension (an additional group of products outside the core) they could require a complete assessment:

a) a human/animal health and environmental risk assessment as well as efficacy assessment

and

b) an assessment of physical, chemical and technical properties as well as physical hazards and respective characteristics

each with a worst case composition different from the one for the core.[18]

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.

Please, consider Annex D.6 for an example regarding an extension.

[21] E.g. where the worst-case core formulation of the core does not represent all highest component concentrations, nor contain all components of the formulation.

8) Assessment of the uses of the subsets and extensions

Generally all the uses from the subsets and extensions are assessed in accordance with chapter 4.[9] However, depending on the type/scope of the subsets, the scope of the extensions and the differences between uses in the core and the subsets/extensions they may consider only the refinement of some aspects of the core assessment.

9) Limitation of possible number of subsets and extensions

In order to avoid applications which are in a large part redundant MS can accept the inclusion of subsets and extensions into a BPF application. The extra workload for the eCA depends on the type/scope of the subsets (see chapter 6 a) to c) above) and the range/scope of the extensions.

Therefore, in order to still ensure a manageable size of the BPF, it is appropriate to limit the overall number of subsets and extensions that are acceptable.

MS should generally accept only extensions and subsets requiring overall not more than three refinements per family (via subsets and/or extensions).[22] However, 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 (i.e. no maximum upper limit set for para. 77 to facilitate its application by directing refinement flexibility to the other areas of the family).

[22] Refinements of: 1. Human/animal health risk assessment; 2. Environmental risk assessment; 3. Efficacy assessment

Annex A – Examples to illustrate how the proposed approach for "Similar composition" can be applied

Example #1

BPF containing PT3 Iodine products for teat disinfection:

The backbone composition is defined as

- active substance
- a complexing/solubilising agent (grouping has been applied to allow for different chemicals to be used)
- water as solvent (the solvent has been particularly specified to make clear that the BPF will only contain aqueous products)

For some specific uses additional components (i.e. non essential to formulate) can be added to the product composition, like emollients and wetting agents for teat spraying products. For teat dipping, where higher viscosity is needed a thickener will be added. These components would not be included in the backbone composition.

Example #2

A BPF consisting of three creosote products, one of them consisting of 100 % Creosote, while the second and third members also include a solvent.

Strictly speaking the undissolved product would not comply with the provision of at least one co-formulant essential to formulate. On the other hand the applicant could argue that the exception for concentrates should apply. In this case the products containing only the active substances, which itself is already a liquid, would be regarded as concentrate intended to be diluted with a solvent, whereas the product containing the solvents represents a ready-to-use product (or a less concentrated concentrate). In this case it is suggested, that the eCA could accept creosote as the backbone composition.

Example #3

A BPF containing Calcium Hypochlorite consisting of 3 meta-SPCs, all cover solid (powder & tablet) products. The first meta-SPC contains 100% active substance as a powder product. The second meta-SPCs contains the active substance, an anti-scale agent and a dye. The third meta-SPC contains the active substance, an anti-scale agent, a dye and a formulation aid for tablet formulation (classification is different to meta SPC 2).

All three products are solid formulations, two of them containing different co-formulants, which could be considered as not essential to formulate with the exemption for the aid for tablet formulation. The later should be discussed how essential this co-formulant should be seen.

Overall the eCA could accept the active substance as a backbone, at least for meta SPC 1 and 2, meta SPC 3 has to be discussed further and decided on a case by case basis. If a tablet could still be formed without the co-formulant (even though with somewhat different physical/structural properties), the co-formulant could be considered as not essential and not included in the backbone composition. In case of doubt, the eCA should also consider whether the criteria for similarity of uses and similar level of risk and efficacy are met.

Example #4

A BPF with CMIT/MIT as active substance, including glycol based, water based and powder based formulations.

It should be evaluated whether the solvents meet the criteria defined in the document on grouping of co-formulants.[23] Depending on the outcome, the family should be either split into two families (solvent based and powder based) or into three families, glycol based, water based and powder based.

Example #5(a)

A BPF with Isopropyl alcohol, including products with 50-70% of the active substance and different co-formulants where water is added to the composition up to 100%. The products can be used as RTU hand rubs with skin care agents, hand rub with a thickener (viscous liquid), sprays without co-formulants or pressurized containers delivering the product as aerosol.

Regarding similar composition the backbone composition can be defined as Isopropyl alcohol and water. This will allow a range of different aqueous products considered as similar because the co-formulants, except water are not essential to formulate the biocidal product. The conceivable range and the different ways of application should be addressed by the check for similar level of risk and efficacy.

Example #5(b)

A BPF with Isopropyl alcohol, including products with 50-70% of the active substance and different additives where the composition is added with water up to 100% and including wipes impregnated with the same formulations. In this case the exception for carrier-based products could apply and wipes would be accepted as part of the BPF (providing that similar uses and similar level of risk and efficacy are satisfied).

Example #6

A BPF with a solid active substance mainly formulated as dispersion or slurry, which can be easily incorporated into molten plastics. The BPF should also contain the solid active substance as such.

The product with the active substance would not comply with the similar composition criterion. It could be suggested to define two BPF, one with the active substance as backbone composition and one with the active substance and the co-formulants necessary to form a stable dispersion or slurry. Solid formulations and dispersion/slurry formulations would trigger two different sets of phys-chem data, most likely also different approaches for human health exposure. Therefore this set of products should be dealt with in two separate BPF.

Example #7

A BPF which consists of an aqueous solution of sodium hypochlorite and different co-formulants.

Defining the backbone composition consisting of sodium hypochlorite and water would comply with the proposed criterion. This will allow a range of different aqueous dilutions to be considered as similar. The conceivable range should be addressed by checking the criteria for similar uses and similar level of risk and efficacy.

Example #8

A BPF which consists of an aqueous solution of lactic acid and in some low concentration lactic acid products, sulfuric acid is added as a pH regulator in order to reach an appropriate

[23] Refer to document CG-30-2018-07. The criteria defined for grouping of co-formulants states that grouping of co-formulants is possible provided that they (a) have the same function, (b) have the same impact on the classification (i.e. resulting in the same hazard and safety statements) for the whole formulation and (c) have the same impact on the level of risk and efficacy of the formulation.

pH for efficacy purposes (but not necessary for the stability of the product).

The backbone composition would be defined as water and lactic acid, as sulfuric acid is not essential to formulate stable products. If sulfuric acid would be needed in order to obtain a stable formulation, then it should be included in the backbone composition. In that case, products without sulfuric acid would need to be in a different family.

Annex B – Exception for similarity of uses

The exception aims at allowing a certain level of flexibility when assessing similarity of uses and reduce the number of applications to be prepared and evaluated by applicants and MSs.

It is important to note that, in all cases, when defining the structure of the family, the limitations introduced by the conditions of "similar composition" (Section 1) and "similar level of risk and efficacy" (Section 3) will need to be considered. In other words, accepting that the exception would apply does not negate the need to fulfil the condition of "similar composition" and "similar level of risk and efficacy".

Criteria for applicability of the exception

The exception allows considering as similar in each family a maximum of two pairs of uses that are *a priory* considered as "non-similar". In this context, where applicable, a use has to be understood as a use pattern (i.e. as those listed in Annex 2).

In order to illustrate the application of this exception, we can consider the following theoretical example to assess similarity of uses of a possible family with five different uses.

Let's imagine that, according to the criteria on similarity of uses, we could construct a matrix with the outcome below that indicates in red those pairs of uses that are not similar, and in green those pairs that are similar.

	use 1	use 2	use 3	use 4	use 5
use 1					
use 2					
use 3					
use 4					
use 5					

In this example, there are more than two red cells (non-similar pairs of uses), and therefore not all five uses could be included in the same family.

One of the possible options would be having two families with the structure given below:

- Family 1:It includes "use 1", "use 2" and "use 3" where exception (1) has been applied two times to consider as similar the pairs of uses "use 1/use 3" and "use 2/use 3".

	use 1	use 2	use 3
use 1			
use 2			
use 3			

Exception →

	use 1	use 2	use 3
use 1			
use 2			
use 3			

- Family 2: Family includes "use 4" and "use 5" where exception (1) has been applied one time to consider as similar the pair of uses "use 4/use 5"

	use 4	use 5
use 4		
use 5		

Exceptions →

	use 4	use 5
use 4		
use 5		

Other arrangements would also be acceptable as long as a maximum of two red cells would be present in each family.

Annex C – Uses matrix

A tool in the form of a matrix has been developed according to the criteria described in section 2 in order to assist in the decision of considering similarity of uses. Please note that the matrix is an indication/reflection of the outcome of the *decision tree*. The basis for decision on similarity of uses is the general criteria included in the decision tree and associated text[24].

The matrix is based on a traffic light code:

- Red: uses cannot be considered as similar.
- Yellow: uses may be considered as similar on a case by case basis.
- Green: uses can be considered as similar.

The matrix has been constructed including a number of possible use patterns to which the different specific uses (as described in the tables of section 4 in the SPC) can be assigned. The list of use patterns included in the matrix is given below:[25]

PTs	Ref	Use object, pattern category	Use pattern
PT1	#1	**(2)a, (3)ai, (3)aii, (3)e**	Human hygiene
PT2	#2	**(1)b, (1)h, (2)b, (3)c**	Disinfectants for pipework / inner surfaces (CIP)/ Surface in contact with water
PT2	#3	**(1)g, (1)h, (2)b, (2)g**	Air condition systems disinfection
PT2	#4	**(1)b, (1)c, (2)c, (3)ai**	Hard surfaces/ instrument/ Equipment disinfection.
PT2	#5	**(1)b, (1)d, (2)c, (3)aii**	Soft furnishing/textile disinfection
PT2	#6	**(1)d, (2)d**	Laundry disinfection
PT2	#7	**(1)e, (2)e**	Air disinfection
PT2	#8	**(1)g, (1)h, (2)g**	Disinfectants and algaecides for treatment of waters other than waste water (e.g. aquarium water, swimming pool water, bathing water)
PT2	#9	**1(i)**	Disinfection of chemical toilets
PT2	#10	**(1)g, (2)h**	Waste water disinfection

[24] The matrix reflects the application of the agreed criteria to the currently identified patterns of use : Therefore applicants and MSs are expected to follow the outcome of the current matrix . Where a use pattern is not found in the matrix, then the criteria should be applied on a case by case basis.

[25] Not all use patterns are specified, therefore a use pattern "other" has been included where necessary to address other uses within a given PT.

PTs	Ref	Use object, pattern category	Use pattern
PT2	#11	**(1)j**	Hospital waste disinfection
PT2	#12	**(1)k**	Soil disinfection
PT2	#13	**(1)c, (1)f, (2)f**	Algaecides for remedial treatment of constructions materials and antimicrobial /hygienic paints
PT2	#14	**(1)f, (2)f**	Products used to be incorporated in textiles, tissues and materials with the purpose of producing treated articles with disinfecting properties
PT2	#15	**(1)f, (2)f**	Products used to be incorporated in paints with the purpose of producing treated articles with disinfecting properties
PT2	#17	**(1)e, (2)e**	Room disinfection (vaporised biocide)
PT2	#16	**(1), (2)**	Other PT2
PT3	#18	**(1)b, (1)c, (2)c, (3)d, (3)g**	Instrument/Equipment disinfection
PT3	#19	**(1)a, (2)a, (3)d, (3)e**	Disinfecting soaps
PT3	#20	**(1)a, (2)a, (3)d, (3)e**	Oral hygiene products
PT3	#21	**(1)a, (2)a, (3)d, (3)e**	Corporal hygiene products
PT3	#22	**(1)b**	Disinfection of hatching eggs
PT3	#23	**(1)a, (2)a, (3)d, (3)e**	Animal feet disinfection
PT3	#24	**(1)a, (2)a, (3)d, (3)e**	Teat disinfection
PT3	#25	**(1)b, (1)d, (2)c, (3)g**	Soft furnishing/textile disinfection
PT3	#26	**(1)b, (2)h**	Disinfection of manure and litter
PT3	#27	**(1)e, (2)e**	Room disinfection
PT3	#28	**(1)b, (3)c, (3)g**	Products used for disinfection of the materials and surfaces associated with the housing or transportation of animals (including aqua culture)
PT3	#29	**(1), (2)**	Other PT3

PTs	Ref	Use object, pattern category	Use pattern
PT4	#30	**(1)b, (1)c, (2)c, (3)ai, (3)bii**	Hard surfaces/ instrument/ Equipment disinfection.
PT4	#31	**(1)h**	Disinfection in dish washing machines and crate washers
PT4	#32	**(1)e, (2)e**	Room disinfection (vaporised biocide)
PT4	#33	**(1)b, (1)h, (2)b, (3)g**	Disinfectants for pipework / inner surfaces (CIP)/ Surface in contact with water
PT4	#35	**(1)f, (2)f, (3)bi**	Products used to be incorporated into materials which may enter into contact with food
PT4	#34	**(1), (2)**	Other PT4
PT5	#36	**(2)g, (3)bi, (3)bii**	Disinfection of drinking water for humans or animals
PT6	#37	**(2)f**	Preservatives for products during storage
PT7	#38	**(2)f**	Film preservatives
PT8	#39	**(2)f, (3)f**	Wood preservatives
PT9	#40	**(2)f**	Fibre, leather, rubber and polymerised materials preservatives
PT10	#41	**(2)f**	Construction material preservatives
PT11	#42	**(2)b, (2)g**	Preservatives for liquid-cooling and processing systems
PT12	#43	**(2)b, (2)g**	Slimicides
PT13	#44	**(2)g**	Working or cutting fluid preservatives
PT14	#45		Rodenticides - Use as bait
PT14	#46		Rodenticides - direct kill
PT14	#47		Other PT14
PT15	#48		Avicides - Use as bait
PT15	#49		Avicides - direct kill
PT15	#50		Other PT15
PT16	#51		Molluscicides, vermicides and products to control other invertebrates - Use as bait

PTs	Ref	Use object, pattern category	Use pattern
PT16	#52		Molluscicides, vermicides and products to control other invertebrates direct kill
PT16	#53		Other PT16
PT17	#54		Piscicides - Use as bait
PT17	#55		Piscicides - direct kill
PT17	#56		Other PT17
PT18	#57		Insecticides, acaricides and products to control other arthropods - Use as bait
PT18	#58	**(3)f**	Insecticides, acaricides and products to control other arthropods - direct kill
PT18	#59		Other PT18
PT19	#60		Repellents and attractants used directly on human or animal skin or on clothing
PT19	#61		Repellents and attractants not used directly on human or animal skin or on clothing
PT20	#62		Control of other vertebrates - Use as bait
PT20	#63		Control of other vertebrates - Other uses (direct kill)
PT21	#64		Antifouling products
PT22	#65	**(3)e**	Embalming and taxidermist fluids

Annex D – Similar level of efficacy and risk examples

Annex D.1 (Examples of a core including more than one meta-SPC)

<u>Example 1.1</u> BPs that can be covered by one core assessment but due to different H&P phrases cannot be presented in one meta-SPC:

The BPF applied for includes only RTU products (10-20 % active substance dissolved in 70-85 % solvent). The products are available with different combinations of pigments, perfumes and dyes (PPD). These PPD (2.5-5 %) include a substance of concern (SoC, e.g. a preservative) which triggers a hazard-phrase (e.g. EUH 208 Contains SoC1…). These products are presented in meta SPC 1 (see table 1 below).

Additionally, products are placed on the market which have the same active substance, solvent and PPD content. However, these PPD include a different SoC (e.g. another preservative) which triggers a different hazard-phrase (e.g. EUH 208 Contains SoC2…). These products are presented in meta SPC 2 (see table 1 below).

The core composition (see table 1 below (columns in orange)) is based on the largest variations (smallest min. value and largest max. value of all the meta SPCs) of each ingredient. In this case the core composition also represents the overall Level 1 family composition range.

Table 1

Ingredients	**Core composition**		**Meta 1**		**Meta 2**	
			Reason for creation of add. meta:		CLP different to meta 1 (incl. SoC2 instead of SoC1)	
	Min	**Max**	**Min**	**Max**	**Min**	**Max**
Active substance	10	20	10	20	10	20
Solvent	70	85	70	85	70	85
PPD incl. SoC1	0	5	2.5	5	0	0
PPD incl. SoC2	0	5	0	0	2.5	5

The products with different PPD combinations cannot be presented in one meta-SPC because of different H-phrases which must be entered in chapter 3 of the SPC. However, as long as all the products can be covered by the same core assessment (e.g. because the sensitising preservatives are similar) a separate application which would be in a large part redundant should be avoided. An example for the identification of the worst case combination for such a core can be found in Annex 2 (Example 2.1)).

<u>Example 1.2</u> Concentrate and corresponding RTU products in one BPF:

The BPF applied for includes concentrates (60-80 % active substance dissolved in 20-40 % Solvent 1). Before use the user dilutes the concentrates with solvent 2 (1:9 ratio). Accordingly, the in-use concentration is 6-8 % active substance. These concentrates are presented in meta SPC 1 (see table 2 below).

Additionally, the corresponding RTU products are placed on the market. The only difference is that there is no mixing and loading step for the user. These RTU products are presented in meta SPC 2 (see table 2 below).

The concentrates and RTU products cannot be presented in one meta-SPC because of different active substance contents which must be entered in chapter 2.1 of the SPC. For meta SPC 1 this is 60-80%. For meta SPC 2 this is 6-8 %.

While the core composition is normally based on the largest variations (smallest min. value and largest max. value of all the meta SPCs) of each ingredient the inclusion of concentrate and RTU into one BPF makes it necessary to consider a „second" core composition for the core assessment (see table 2 below (columns in orange)). This is the only scenario where MS consider more than one core composition as acceptable.

Table 2

Ingredients	***Level 1***		**Core composition**				**Meta 1**		**Meta 2**	
			Concentrate		**RTU**		**Reason for creation of add. meta:**		RTU corresponding to meta 1	
	Min	**Max**	**Min**	**Max**	**Min**	**Max**	**Min**	**Max**	**Min**	**Max**
Active substance	*6*	*80*	60	80	6	8	60	80	6	8
Solvent 1	*2*	*40*	20	40	2	4	20	40	2	4
Solvent 2	*0*	*90*	0	0	90	90	0	0	90	90

Annex D.2 (Examples regarding identification of the worst-case compositions for the risk assessment)

<u>Example 2.1</u> BPs that can be covered by one core assessment but due to different H&P phrases cannot be presented in one meta-SPC:

a) The information on ingredients and core composition is taken from example 1.1 above.

b) For each ingredient a value for worst and best case must be chosen. This value might be different from area to area (here human health and environment).

c) For each ingredient/value chosen a detailed justification must be provided in the PAR.[26] An example outcome of such a justification could be:

- Active substance: Toxicological relevant for both human health and environmental risk assessment. Min = best case. max = worst case.
- Solvent: In this example toxicologically not relevant.
- "PPD incl. Soc1" and "PPD incl. Soc2": Not the PPDs (different ones in meta 1 and meta 2) but only SoC1 and SoC2 are relevant for human health risk assessment. The properties of SoC1 and SoC2 are similar. Although the core composition includes 0-5 % "PPD incl. SoC1" and 0-5 % "PPD incl. SoC2" neither meta 1 nor meta 2 can include products without SoC 1 or 2 (see Table 3 below). Accordingly, it is justified to choose 2.5 % as best case and 5 % as worst case.

d) In this case the core composition also represents the overall Level 1 family composition range.

Table 3

Ingredients	**Justification**	**Core composition**		**Meta 1**		**Meta 2**		**Human/animal health risk assessment**		**Environmental risk assessment**	
				Reason for creation of add. meta:		CLP different to meta 1 (incl. SoC2 instead of SoC1)					
		Min	**Max**	**Min**	**Max**	**Min**	**Max**	**Best case**	**Worst case**	**Best case**	**Worst case**
Active substance	Always relevant	10	20	10	20	10	20	10	20	10	20
Solvent	Not relevant	70	85	70	85	70	85	Not relevant			
PPD incl. SoC1	SoC1 and SoC2 = SoC for HH Cannot be in one meta but same effect on HH	0	5	2.5	5	0	0	2.5	5	Not relevant	
PPD incl. SoC2		0	5	0	0	2.5	5				

[26] The necessary level of detail and the generally acceptable line of argument should be discussed in detail in the relevant Expert Working Groups.

Example 2.2 Concentrate and corresponding RTU products in one BPF:

a) The information on ingredients and core composition is taken from example 1.2 above.
b) For each ingredient a value for worst and best case must be chosen. This value might be different from area to area (here human health and environment).
c) While the core assessment is normally based on one worst case composition only the dilution of the concentrate (mixing and loading step before application) makes it necessary to consider a „second" worst case composition for the core assessment. This is the only scenario where MS consider more than one worst case composition as acceptable (see table 4 below).
d) For each ingredient/value chosen a detailed justification[26] must be provided in the PAR. An example outcome of such a justification could be,
    - Active substance: Toxicological relevant for both human health and environmental risk assessment. Min = best case. max = worst case.
    - Solvent: In this example toxicological relevant for environmental risk assessment. Min = best case. max = worst case.
    - Solvent 2: In this example toxicologically not relevant.

Table 4

Ingredients	Justification	Core Composition				Human/animal health risk assessment				Environmental risk assessment			
		Mixing & loading		In use		Mixing & loading		In use		Mixing & loading		In use	
		Min	Max	Min	Max	Best case	Worst case	Best case	Worst case	Best case	Worst case	Best case	Worst case
Active substance	Always relevant	60	80	6	8	60	80	6	8	60	80	6	8
Solvent 1	SoC for ENV	20	40	2	4	Not relevant				20	40	2	4
Solvent 2	Not relevant	0	0	90	90	Not relevant				Not relevant			

Annex D.3 (Example regarding one consistent set of RMMs for a use)

After having identified a worst case composition every use is assessed. When assessing the uses the different parameters defining the use are taken into account. Every use must have one consistent set of RMMs. However, these can be use specific and differ from use to use.

Example 3.1 – Two uses with different application methods. – Each use having one set of consistent RMMs. Therefore, both uses can be part of one BPF.

Use # 1 – Brush application

Product Type	8
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	a, b, c
Field(s) of use	A
Application method(s)	Brushing
Application rate(s) and frequency	100 mL / m^2
Category(ies) of users	Prof
Pack sizes and packaging material	1, 2, 3

RMMs: No PPE necessary.

Use # 2 – Spray application

Product Type	8
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	a, b, c
Field(s) of use	A
Application method(s)	Spraying
Application rate(s) and frequency	100 mL / m^2
Category(ies) of users	Prof
Pack sizes and packaging material	1, 2, 3

RMMs: PPE necessary.

Example 3.2 – Two uses with different in use concentrations. – Each use having one set of consistent RMMs. Therefore, both uses can be part of one BPF.

Use # 1 – Spray application low application rate

Product Type	3
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	a, b, c
Field(s) of use	A
Application method(s)	i
Application rate(s) and frequency	1 % BP concentrate in water 10 mL dilution / m2
Category(ies) of users	Prof
Pack sizes and packaging material	1, 2, 3

RMMs: No PPE necessary.

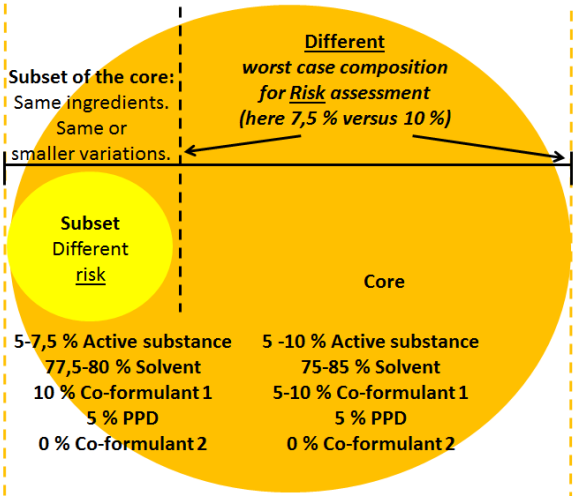
Use # 2 – Spray application high application rate

Product Type	3
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	a, b, c
Field(s) of use	A
Application method(s)	i
Application rate(s) and frequency	25 % BP concentrate in water 10 mL dilution / m2
Category(ies) of users	Prof
Pack sizes and packaging material	1, 2, 3

RMMs: PPE necessary.

Annex D.4 (Example regarding subset with different level of risk)

The BPF applied for includes one active substance (5-10 %) which is dissolved in a solvent (75-85%). In order to keep the active substance in solution co-formulant 1 (5-10%) is needed. The products of the BPF are available with different combinations of pigments, perfumes and dyes (PPD overall always 5%).



Scheme 4: Visualisation of core and subset.

There is only one use for professional users (use 1, regarding the uses and an overview of the composition ranges see Table 4 below).

After having identified the relevant worst case composition for the core, every use in the core (here use 1 only) is assessed: PPE is required and the set of RMMs is consistent (same RMMs from best to worst case (5-10 % active substance)). Furthermore, efficacy against all target organisms was proven with 5% active substance (the worst case concentration regarding efficacy).

However, there is another use (use 2) some potential products of the BPF are currently used for:

Non-professional users use these products against the same target organisms as professional users.

If included in the core the risk assessment this use would have to be based on the worst-case composition (10 % active substance). When using this 10% value, the result of the risk assessment would be as follows: 1. With 10 % active substance PPE would be required for the non-professional user (which is not foreseen by the BPR) and 2. The PPE is not necessary with 5 % active substance and so this use does not meet the criterion for similar level of risk since the RMMs do not match across the whole composition range of the core (i.e. 5 to 10%) for the non-professional user (see section 4 of this document). Therefore, the non-professional use cannot be included within the core.

However, on review of the risk assessment for the non-professional use an active substance concentration of 5 to 7,5 % results in no PPE being required, thereby supporting the principles of the BPR and also the requirement for RMMs applicable to both the worst and best-case formulations to be the same (section 4 of this document).

Therefore, the use can be presented as a subset to the core because the potential products for the non-professional user include the same ingredients with the same or less variation as that of the core composition (see Scheme 4 above or yellow columns in Table 4 below). In this case the core composition also represents the overall Level 1 family composition range.

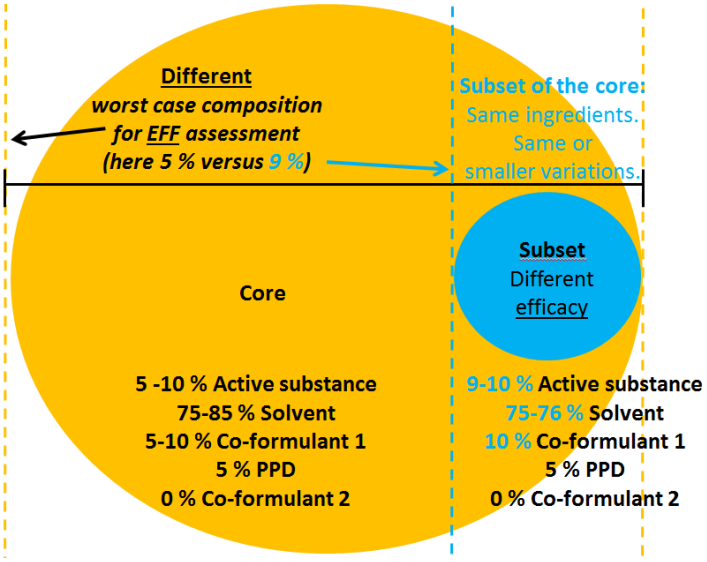
Table 4

Ingredients	**Classification**	**Core composition**		**Subset (Different risk)**	
		Min (%)	**Max (%)**	**Min (%)**	**Max (%)**
Active Substance	XYZ	5	10	5	7,5
Solvent	SoC ENV	75	85	77,5	80
Co-formulant 1	SoC HH	5	10	10	10
PPD	-	5	5	5	5
Uses		1: Professional user PPE: Gloves and mask		-	
		-		2: Non-professional user No PPE	

This subset would make only one refinement to the core composition necessary (whether the products can be supported for the non-professional user without PPE across the composition range of 5 to 7,5 % active substance), assuming that all the other areas (environment, phys. chem/hazard and efficacy) are covered already by the assessment of the core.

Annex D.5 (Example regarding subset with different level of efficacy)

The BPF applied for includes one active substance (5-10 %) which is dissolved in a solvent (75-85%). In order to keep the active substance in solution co-formulant 1 (5-10%) is needed. The products of the BPF are available with different combinations of pigments, perfumes and dyes (PPD overall always 5%).



Scheme 5: Visualisation of core and subset.

There is only one use against target organism 1 (regarding the uses and an overview of the composition ranges see Table 5 below).

After having identified the relevant worst case composition for the core, every use in the core (here use 1 only) is assessed: No unacceptable risks are found. There is one consistent set of RMMs across the composition range (see section 4 of this document), and efficacy against target organism 1 was proven with 5% active substance (the worst case concentration regarding efficacy.

Nevertheless, there is a second use some potential products of the BPF are currently used for:

The parameters (application method, rate etc.) of this use are the same as for use 1 apart from the target organism. Target organism 2 is more demanding. An effective treatment is only possible with products containing 9-10 % of active substance. The efficacy cannot be supported over the whole composition range of the core, therefore use 2 (i.e. target organism 2) cannot be included into the core because for the core the efficacy was proven with 5 % active substance only.

However, this second use can be presented as a subset to the core because the potential products against target organism 2 include the same ingredients with the same or less variation as that of the core composition (see Scheme 5 above or blue columns in Table 5 below). In this case the core composition also represents the overall Level 1 family composition range.

Table 5

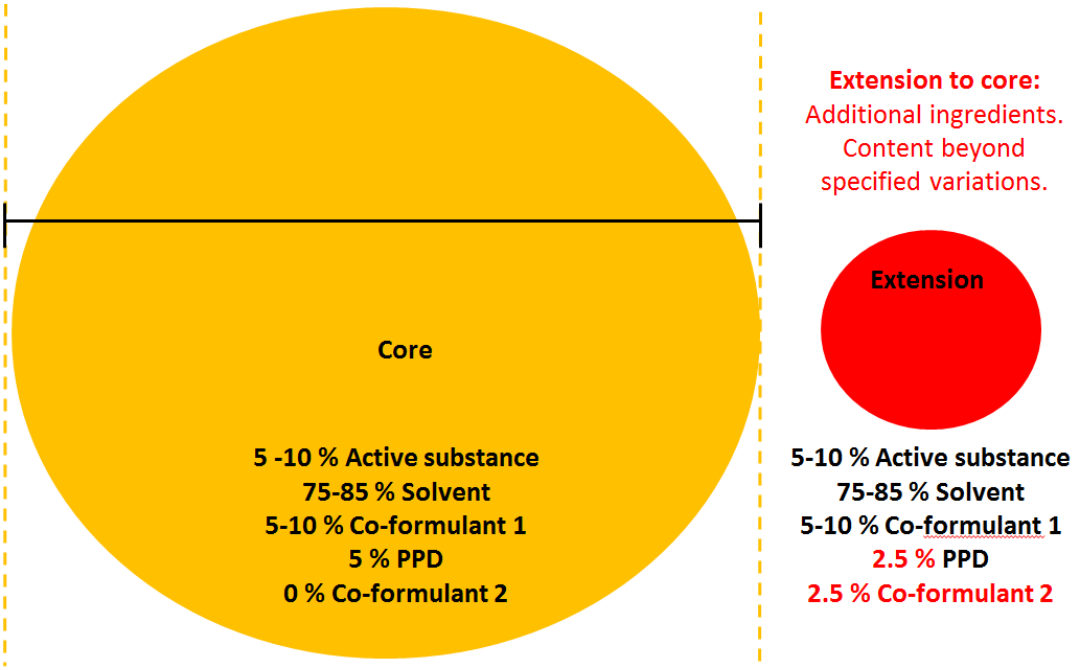
Ingredients	Classification	Core composition		Subset (Different efficacy)	
		Min (%)	Max (%)	Min (%)	Max (%)
Active Substance	XYZ	5	10	9	10
Solvent	SoC ENV	75	85	75	76
Co-formulant 1	SoC HH	5	10	10	10
PPD	-	5	5	5	5
Uses		1: Against Target org. 1		-	
		-		2: Against more demanding target org. 2	

This subset makes only one refinement to the core composition necessary (i.e. evaluation of a dataset to show that the products with 9 % active substance are effective against target organism 2 or not), as all the other areas (human health, environment and phys. chem/hazard) are covered already by the assessment of the core.

However, if the subset is considered as necessary in order to support para. 77 of Annex VI of the BPR then it would not be included as part of the refinements described in section 9 of this document for which an upper limit of three is normally applied (i.e. the three refinements described in section 9 can be used on other subsets or extensions within the family).

Annex D.6 (Example regarding extension)

While the second use (target organism 2) from Annex 5 of this document can be presented as a subset, there is another use for some products similar to that of the BPF dossier prepared so far. Some of the parameters of this additional use are the same (e.g. product type, target organism, application rate and type as well as packaging) as for use 1 evaluated within the core, but the field of use is different. The conditions for this additional field of use are more demanding (e.g. outdoor instead of indoor use) and in order to be effective under these harsher conditions, co-formulant 2 needs to be added which is a substance of concern for human health. At the same time the perfumes are removed (now overall only 2.5 % PPD instead of 5% in core and subset). The products belonging to the additional use 3 (e.g. outdoor instead of indoor use) cannot be presented as a subset to the core because they include co-formulant 2 which is not part of the core formulation, and while they still include "PPD" this is only present at 2.5% which is outside of the specified variations of the core.



Scheme 5: Visualisation of core and extension.

However, the products belonging to additional use 3 (e.g. outdoor instead of indoor use) can be added to the BPF as an extension as the formulation range required is outside of the core composition (see section 7 of this document).

This extension would require three refinements (assessment of certain parameters for human health, environment and efficacy). Full re-assessment of all parameters of the core is not required for this additional use 3 and it therefore meets the criteria for similar risk and efficacy (as specified in section 7 of this document). In this case the overall Level 1 family will be made up of a combination of both the core and extension compositions.

Table 6

Ingredients	Classification	*Level 1*		Core Composition		Extension	
		Min (%)	***Max (%)***	**Min (%)**	**Max (%)**	**Min (%)**	**Max (%)**
Active Substance	XYZ	*5*	*10*	5	10	5	10
Solvent	SoC ENV	*75*	*85*	75	85	75	85
Co-formulant 1	SoC HH	*5*	*10*	5	10	5	10
PPD	-	*2.5*	*5*	5	5	2.5	2.5
Co-formulant 2	SoC HH	*0*	*2.5*	0	0	2.5	2.5
Uses		-		1: Against Target org. 1		-	
				-		2: Against target org. 1 but under more demanding conditions	

This extension requires three refinements to the original core assessment (using the outdoor use scenario, resulting in evaluation of a dataset/reasoned case for the targets outdoors plus an extension to the human health and environmental risk assessment). For this example it is assumed that other areas (phys chem/hazard) are covered already by the original assessment of the core. As such, a full re-assessment of all parameters of the core is not required for this additional outdoor use and it therefore meets the criteria for similar risk and efficacy (as specified in section 7 of this document). Three refinements to the core composition are the maximum allowed in order to define similar levels of risk and efficacy (see section 9 of this document).

However, when this extension refinement example is applied in combination with the efficacy subset addition from Annex 5 of this document, the number of refinements to the original core composition now totals 4 (1 for the subset plus 3 for the extension), which is outside the maximum that can be applied in accordance with section 9 of this document. In such a case it needs to be decided which refinements to the core assessment should be managed as part of a separate family application.