EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate A – Green economy
ENV.A.3 - Chemicals

NOTE FOR GUIDANCE

This document is an attempt to provide guidance in the interest of consistency, and has been drafted by the Commission services responsible for biocidal products with the aim of finding an agreement with Member States' Competent Authorities for biocidal products. Please note, however, that Member States are not legally obliged to follow the approach set out in this document, since only the Court of Justice of the European Union can give authoritative interpretations on the contents of Union law.

Subject: Implementing the new concept of biocidal product families

1.- Background and purpose of the note

(1) This note outlines a practical approach for the implementation of the new concept of biocidal product family (BPF) based on the updated provisions of the Biocidal products Regulation (the BPR)[1].

(2) This approach was first introduced and discussed with Member States Competent Authorities (CAs) and stakeholders in a workshop held in Brussels on 10 March 2014[2]. It was then formally presented at the 55th CA meeting (Document CA-March14-Doc.5.12[3]). After discussions within the Coordination Group, it was eventually endorsed at the 58th CA meeting in November 2014.

(3) This note contains in Annex IV a list of Q&A, which will be expanded in the light of experience with a view to provide further guidance.

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1 See Regulation 334/2014 of 11 March 2014 amending Regulation (EU) No 528/2012 (OJ L 103, 5 April 2014, p.22). A compilation of the relevant provisions in the BPR regarding biocidal product families is provided in Annex V to this document.

2 The summary of the presentations, group reports, conclusions and recommendations is available at https://circabc.europa.eu/w/browse/57ce72f5-96a0-4b4f-a869-1c0f7d7fd762

3 Available at https://circabc.europa.eu/w/browse/8e840f78-e5af-4880-939e-e2db50ef7b4c

2.- Content of the note

(4) This note is structured in 5 sections addressing the following:

a) Understanding of the elements involved in the new BPF concept,

b) Preparation of the application for authorisation of a BPF,

c) Evaluation of the BPF application by CAs,

d) Content of a BPF authorisation and,

e) Post-authorisation notification of new products.

(5) The note also contains in Annex IV a list of Q&A, which reflects issues raised by CAs when dealing with BPF applications and how the Coordination Group (either thorough e-consultations or at CG meetings) will have agreed to address them.

2.1.- Understanding the elements involved in the new BPF concept

(6) The new definition of a BPF in Article 3(1)(s) of the BPR 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. Hence this means that products within a BPF, in addition to having different composition, can be intended for different uses, including different user categories, and also responding to different risk or efficacy levels.

(7) In order to clearly define what is exactly authorised within a BPF, the authorisation, on the basis of the conclusions of the risk and efficacy assessment leading to acceptable uses, shall provide information in a structured way. In this context, the concept of "*meta* SPC" has been introduced and now needs to be explained in order to facilitate the BPF design by the applicant, the subsequent assessment by CAs and later notifications of new products, so they can be handled within 30 days by CAs.

(8) Similar composition

(9) By definition, products belonging to a BPF must have a similar composition within specified variations. This has to be understood as different compositions but also within certain boundaries:

a) Actives substances contained in a BPF contributing to the efficacy of the products have to be present in each product of the BPF (i.e. content $\neq 0$[4]).

[4] An active substance present in any product in a concentration in which it can be proven to not add to the efficacy of the product, should not be regarded as an active and therefore does not have to be present in all products.

b) The formulation type has to be considered when deciding whether this criterion is met:

- Overall, a case by case assessment[5] will have to be applied regarding the impact on the overall assessment and *meta* SPC grouping.
- Different formulations types may belong to the same BPF provided that the differences in composition do not affect significantly the overall conclusions from the risk assessment and efficacy evaluation.
- For rodenticides, differences in terms of the bait carrier should be considered (e.g. cereal based vs. wax formulations). In addition, the assessment of efficacy is based on product (composition) specific data.
- For liquid formulations it should be necessary to specify whether the BPF covers water-based liquids, solvent-based liquids or emulsions only.
- Concentrate and ready to use products can be included in a BPF. Where the result of the risk assessment only allows for certain dilutions, concentrates and dilutions could be kept within the same *meta* SPC; otherwise, they should be allocated in different *meta* SPCs.

(10) The BPF composition range must be further specified for each *meta* SPC (*see example in Annex I*).

(11) Similar uses

(12) Similar uses for products belonging to a BPF have to be understood as different uses within the PT(s) to which the BPF belongs.

(13) Therefore, provided that the risk and efficacy assessment provides a positive outcome, products belonging to a BPF can include different:

a) User categories.

b) Target organisms (e.g. rats and mice or ticks and fleas).

c) Application methods (e.g. spraying and brushing).

d) Applications rates and frequency.

e) Fields of use (e.g. indoor or outdoor).

(14) As for a single biocidal product, a use is the result of the combination of the above elements within a given PT, in connection with its respective risk mitigation measures (RMM) and instructions for use.

(15) A BPF can include products containing more than one existing active substance or belonging to more than one PT[6]. PTs have not to be identical

[5] A justification for similarity of the composition within the BPF may be based, where appropriate, on existing guidance (e.g. EN 152 and EN 113 for PT8 or the EFSA's guidance on dermal absorption) and where relevant, on expert judgement.

for all *meta* SPCs. However, for existing products covered by a BPF, the deadlines to apply for authorisation and to grant the authorisation are triggered by the PTs of the individual products and not by those of the BPF.

The allocation within a *meta* SPC of different PTs should be based on the similarity of the intended uses with a view to limit the complexity of the risk and efficacy assessment (e.g. PT2 and PT4 uses) (*see example in Annex I*).

(16) Similar levels of risk

(17) Similar levels of risk for products belonging to a BPF have to be understood as different levels of acceptable risk resulting from the assessment of the maximum risks (to human health, animal health and the environment) identified in the application, in connection with the assessment of the minimum level of efficacy and the permitted variations in composition together with their respective classification, hazard and precautionary statements and any appropriate RMMs.

(18) Products belonging to a BPF can have different RMMs within the same BPF, but each *meta* SPC should have its own set of RMMs in order to facilitate the post-authorisation notification of new products belonging to that *meta* SPC. However, these RMMs have not to be identical for all the authorised uses within a *meta* SPC (e.g. those related to the user category) (*see also paragraph 26 and section on post-authorisation notification*).

(19) Products belonging to a BPF can have different classification and labelling (C&L) within the same BPF, but the hazard and precautionary statements must be the same for all products covered by one *meta* SPC.

(20) Similar levels of efficacy

(21) Similar levels of efficacy for products belonging to a BPF have to be understood as different levels of proven efficacy resulting from the assessment of the minimum level of efficacy, identified in the application, in connection with the assessment of the maximum risks (to human health, animal health and the environment) and the permitted variations in composition.

(22) Meta-SPC

(23) In the context of the new BPF concept a *meta* SPC has to be understood as the description, with a similar structure as in the SPC of a single biocidal

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[6] With regard to the deadline for application for product authorisation under the BPR, applicants should follow for a BPF the same rules as established for single products in document CA-Sept13-Doc.6.2.b Rev.1 on *Authorisation under the Biocidal Products Regulation of products containing more than one existing active substance or belonging to more than one product-type*.

product[7] (*see example in Annex I*), of a group of products within the BPF having:

a) Similar compositions within a specified variation, which fall within the specified variations of the whole BPF,

b) Similar uses resulting from the risk and efficacy assessment, which are associated to a common set of RMMs. However, products within a *meta* SPC can have different RMMs and instructions for use linked to each authorised use (e.g. to a different user category or application method),

c) The same hazard and precautionary statements[8], and

d) A common set of first aid instructions, disposal, storage and shelf life.

(24) Where the assessment of the maximum risk and minimum level of efficacy for the entire BPF is not possible, that assessment may be done at *meta* SPC level[9] *(see also section on BPF evaluation*).

(25) A BPF can consist of one or more *meta* SPCs. The number of *meta* SPCs has to be carefully considered by the applicant, to ensure that the assessment by CAs and the post-authorisation notification of new products does not become overly complex and difficult to manage (*see also sections on the preparation of the application and on BPF evaluation*).

(26) Where a *meta* SPC contains several similar uses (i.e. different combinations of user category, target organism, field of use, application method, etc.), these uses will have to be clearly associated with the relevant instructions for use and RMMs in accordance with the principles agreed in document CA-May14-Doc.5.6 – Final[10] (*see also sections on the preparation of the application and content of the BPF authorisation*).

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[7] See the SPC template agreed under document CA-Sept14-Doc.5.4–Final, available at https://circabc.europa.eu/w/browse/8aa3692b-9a69-43c7-b30b-d9db9a276830.

[8] In accordance with Article 22(3) of the CLP Regulation, the labelling of the products will only include the P statements which are relevant for the intended uses of the products.

[9] The level at which the assessment should be done is mainly dictated by the complexity of the BPF, so an assessment at the first or second level may occur when necessary.

[10] *Discussion paper on the content of label of single biocidal products with regard to the authorised uses in the SPC*, available at https://circabc.europa.eu/w/browse/f818ccf3-207f-408f-a3cf-c62422fdf346

2.2.- Preparation of the application for authorisation of a BPF

(27) Pursuant to Annex III to the BPR, applicants ought to initiate a pre-submission meeting with their eCA. In case of a BPF, such meetings should be organised as early as possible in order to discuss the approach foreseen by the applicant and possible issues, such as the ones listed below, with a view to facilitate the later assessment of the application:

a) The whole BPF design, and in particular the number of *meta* SPCs proposed by the applicant within the proposed composition ranges,

b) The maximum risk/minimum efficacy parameters chosen by the applicant for the whole BPF or, where appropriate, at *meta* SPC level,

c) In case of Union authorisation (UA) applications, the next steps of the pre-submission process.

These pre-submission meetings are however not expected to result in a detailed pre-evaluation of the whole BPF and will be without prejudice of issues that may be raised during the assessment.

(28) For the purpose of the assessment by CAs of the identified maximum risk within the whole BPF or a *meta* SPC, applicants have to justify in detail the basis for its identification and to present assessments of the risks for various uses within the risk envelope of the BPF or the *meta* SPC. These risk assessments, presented as supporting information in the dossier, could be evaluated by CAs not only to confirm the maximum risks identified but also to authorise some uses within the BPF or *meta* SPC when the chosen (maximum risk) use leads to an unacceptable risk (e.g. risks for human health between spray and brushing applications).

(29) Until an agreed template for the SPC of a BPF is available on the basis of the new BPF concept, for the purpose of the submission within an application[11] of the three-level information established in the Commission proposal, applicants should submit the elements detailed in Annex II to this document as a supporting document attached to the R4BP3 application.

[11] For the purpose of the pre-submission meetings with CAs referred to in paragraph 27, other formats can be used provided that they present a clear overview of the whole BPF (e.g. table listing the concentration ranges, user categories, application methods, claim/target organisms and hazard & precautionary statements for each *meta* SPC).

2.3- Evaluation of the BPF application

(30) In accordance with Article 19(6) of the BPR, the assessment of the BPF shall consider the maximum risks (to human health, animal health and the environment) and the minimum level of efficacy over the whole potential range of products within the biocidal product family, which shall be explicitly identified within the application (*see paragraph 28 above*).

(31) Where that assessment (of the maximum risks and minimum efficacy) on the basis of an overall "worst case" for the entire BPF is not possible, that assessment may be focused at *meta* SPC level, taking into consideration the composition of the products and the different uses described in each *meta* SPC.

(32) Where such a single "worst case" scenario at *meta* SPC level cannot be identified, an assessment of the different maximum risks and minimum efficacy levels that might be relevant for the uses covered by a *meta* SPC (e.g. spraying vs. wiping; different target organisms, etc...) has to be performed.

(33) Where an eCA concludes that the maximum risks/minimum efficacy use identified in the application for the whole BPF or a *meta* SPC leads to an unacceptable outcome, but other uses proposed within that BPF or *meta* SPC for which a maximum risk/minimum efficacy assessment has been provided by the applicant lead to an acceptable outcome, the eCA can, on a case by case basis:

a) Create a new *meta* SPCs so the conditions in paragraph 23 are met.

b) Authorise some of the uses proposed within a given *meta* SPC only.

c) Not authorise a proposed *meta* SPC, but still authorise the rest of *meta* SPCs covered by the BPF.

(34) Where the BPF contains an active substance which is a candidate for substitution, the intended uses within each *meta* SPC will be subject to comparative assessment. As a result, all or some of those uses could be eventually prohibited or restricted where suitable alternatives meeting the criteria set in Article 23(3) of the BPR are available.

2.4.- Content of the BPF authorisation

(35) Although Article 22(1) and (2) of the BPR can be open to interpretation as to whether a SPC should be available for each and every product of a BPF, for dissemination purposes and to facilitate enforcement, it would seem more appropriate that each and every product of a BPF should have its own SPC.

(36) This approach is further justified with a view to facilitate application for authorisation of a same biocidal product on the basis of a product belonging to a BPF.

(37) For the purpose of the new BPF concept, it is therefore agreed that:

a) The authorisation decision will only include a "BPF SPC", which will include the three-level information for the authorised BPF (*see Annex III to this document*) and will be subject to dissemination[12] by ECHA.

b) However, for dissemination and enforcement purposes, "product-specific SPCs" will need to be generated.

This should be done by combining the BPF administrative details, the authorised uses (and RMMs), hazard and precautionary statements and other elements (e.g. first aid instructions, etc.) of the *meta* SPC to which the product belongs[13], together with the trade name(s) and specific composition of the product within the ranges of that *meta* SPC.

Until improved IT tools are available to automate this generation, CAs are invited to generate these SPCs manually and may require support from applicants to do so.

These product-specific SPCs will be made available in the R4BP3 and disseminated by ECHA, so they can be found by inspectors or the general public when searching by the product authorisation number or trade name(s) of the products as they are made available on the market.

(38) ECHA will provide further instructions with regard to the handling of the BPF authorisations and associated SPCs in the R4BP3.

2.5.- Post-authorisation notification of new products

(39) In accordance with Article 17(6) of the BPR, the authorisation holder (AH) shall notify (through the R4BP3) each CA that has granted a national authorisation for a BPF of each product within that family at least 30 days before placing it on the market, except where:

a) A particular product is explicitly identified in the BPF authorisation[14] or,

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[12] The provisions in Article 22(e) of the BPR will apply (i.e. only non-active substances knowledge of which is essential for the proper use of the product have to be listed). The function of these non-active substances has to be deleted in the final SPC. Where a CA wishes including the full composition of the BPF within the authorisation decision, that CA can either refer to the composition in the IUCLID file or attach to the decision in the R4BP3 a confidential document containing that composition, which shall not be used for dissemination purposes.

[13] The SPC editor is intended to eventually support users to create the product-specific SPCs by automatically combining the information from the *meta* SPC. Hence, only the product-specific information would have to be filled in (i.e. trade name(s), specific composition and authorisation number).

[14] It is therefore not necessary for all products within the BPF to be placed on the market at the time of authorisation.

b) The variation in composition concerns only pigments, perfumes and dyes within the permitted variations in the BPF authorisation.

(40) In line with Article 17(6), it is proposed that the notification shall only indicate the exact composition and trade name of the product, as well as the suffix to the authorisation number (i.e. already including the BPF identifier and the *meta* SPC suffix).

For this purpose, it is essential that the notification clearly identifies the *meta* SPC to which the product belongs[15].

(41) AHs may support CAs by providing with the notification a draft "product-specific SPC", which should be checked by CAs before making it available in the R4BP3 for dissemination purposes.

(42) Where a CA does not object to the notification within the 30-day period referred to in Article 17(6) of the BPR, that CA will have to:

a) Update the "BPF SPC" by adding to the third level information the new product details (e.g. trade name(s), specific composition within the *meta* SPC ranges and authorisation number) and,

b) Make the "product-specific SPC", as provided by the applicant and reviewed by the CA, available in the R4BP3 for dissemination purposes.

[15] This means that the AH will have to accept the set of RMMs covering all the authorised uses for that *meta* SPC. This does not mean though that all the authorised uses have to be presented on the product label (i.e. partial label-SPC correspondence) as agreed in document CA-May14-Doc.5.6 – Final.

Annex I

Illustration of the relationships between the different information levels within a BPF

1st level: Overall Information

Name of the family

Autorisation holder
Manufacturer(s) BP
Manufacturer(s) AS

→ **Identical in all *meta* SPCs**

The "broad" category needs to be identical in all *meta* SPCs

Type of formulation

Liquid formulation, water based

Composition

Name	Function	CAS No.	Content whole BFP
AS 1	Active substance	12345	5 - 20
AS 2	Active substance	12346	5 - 15
Non-AS 1	Solvent	12347	45 - 60
Non-AS 2	Surfactant	12348	0 - 15
Pigment 1	Pigment	12349	0 - 10
Perfume 2	Perfume	12340	0 - 10

→ **ALL a.s. have to be:**

- **approved for the relevant PTs**
- **present in each BP of the BPF with the function "active substance" (content ≠ 0)**

Identical in all *meta* SPCs

Can vary by *meta* SPC

PT

PT 3, PT 4

Authorisation Nr: 1

BPF

BPF

2nd level: *meta* SPCs

Autorisation holder
Manufacturer(s) BP
Manufacturer(s) AS

Type of formulation

Liquid, water based, ready-to-use

Composition

Name	Function	CAS No.	Content of meta SPC
AS 1	Active substance	12345	5 - 10
AS 2	Active substance	12346	15
Non-AS 1	Solvent	12347	45 - 60
Non-AS 2	Surfactant	12348	0
Pigment 1	Pigment	12349	0 - 10
Perfume 2	Perfume	12340	0 - 10

Hazard and precautionary statements

Same hazard and precautionary statements for all BP covered by subfamily

Authorised uses, instructions for use & RMMs (presented by use)

PT 3

Non-professional user

Wiping with treated tissue, spraying, brushing

Store in a cool place

Authorisation Nr: 1-1

Autorisation holder
Manufacturer(s) BP
Manufacturer(s) AS

Type of formulation

Liquid, water based, ready-to-use

Composition

Name	Function	CAS No.	Content of meta SPC
AS 1	Active substance	12345	10 - 15
AS 2	Active substance	12346	5
Non-AS 1	Solvent	12347	45 - 60
Non-AS 2	Surfactant	12348	0 - 15
Pigment 1	Pigment	12349	0 - 10
Perfume 2	Perfume	12340	0 - 10

Hazard and precautionary statements

Same hazard and precautionary statements for all BP covered by subfamily

Authorised uses, instructions for use & RMMs (presented by use)

PT 3, PT 4

Professional user

Spraying, brushing, dipping

Wear PPE

Store in a cool place

Authorisation Nr: 1-2

Autorisation holder
Manufacturer(s) BP
Manufacturer(s) AS

Type of formulation

Liquid, water based, concentrate

Composition

Name	Function	CAS No.	Content of meta SPC
AS 1	Active substance	12345	15 - 20
AS 2	Active substance	12346	15
Non-AS 1	Solvent	12347	45 - 60
Non-AS 2	Surfactant	12348	15
Pigment 1	Pigment	12349	0 - 10
Perfume 2	Perfume	12340	0 - 10

Hazard and precautionary statements

Same hazard and precautionary statements for all BP covered by subfamily

Authorised uses, instructions for use & RMMs (presented by use)

PT 4

Professional user

Spraying, brushing, dipping

Wear PPE

Store in a cool place

Authorisation Nr: 1-3

3rd level: list of biocidal products

E.g. *meta* SPC 1-2

3rd level: list of biocidal products

Trade name(s)

Exact composition

Name	Function	CAS No.	Content
AS 1	Active substance	12345	10
AS 2	Active substance	12346	5
Non-AS 1	Solvent	12347	45
Non-AS 2	Surfactant	12348	5
Pigment 1	Pigment	12349	0
Perfume 2	Perfume	12340	5

Authorisation Nr: 1-2-1

Trade name(s)

Exact composition

Name	Function	CAS No.	Content
AS 1	Active substance	12345	13
AS 2	Active substance	12346	5
Non-AS 1	Solvent	12347	50
Non-AS 2	Surfactant	12348	10
Pigment 1	Pigment	12349	5
Perfume 2	Perfume	12340	10

Authorisation Nr: 1-2-2

Trade name(s)

Exact composition

Name	Function	CAS No.	Content
AS 1	Active substance	12345	15
AS 2	Active substance	12346	5
Non-AS 1	Solvent	12347	60
Non-AS 2	Surfactant	12348	15
Pigment 1	Pigment	12349	10
Perfume 2	Perfume	12340	5

Authorisation Nr: 1-2-3

BPF

Product-specific SPCs *(for dissemination only)*

Trade name(s)

Autorisation holder

Manufacturer(s) BP

Manufacturer(s) AS

Type of formulation
Liquid, water based, ready-to-use

Composition

Name	CAS No.	Content
AS 1	12345	10
AS 2	12346	5
Non-AS 1	12347	45
Perfume 2	12340	5

Hazard and precautionary statements
H xxx
P xxx

Authorised uses, instructions for use & RMMs (presented by use)
PT 3, PT 4

Professional user

Dipping, spraying, brushing

Wear PPE

Store in a cool place

Authorisation Nr: 1-2-1

Trade name(s)

Autorisation holder

Manufacturer(s) BP

Manufacturer(s) AS

Type of formulation
Liquid, water based, ready-to-use

Composition

Name	CAS No.	Content
AS 1	12345	13
AS 2	12346	5
Non-AS 1	12347	50
Perfume 2	12340	10

Hazard and precautionary statements
H xxx
P xxx

Authorised uses, instructions for use & RMMs (presented by use)
PT 3, PT 4

Professional user

Dipping, spraying, brushing

Wear PPE

Store in a cool place

Authorisation Nr: 1-2-2

Trade name(s)

Autorisation holder

Manufacturer(s) BP

Manufacturer(s) AS

Type of formulation
Liquid, water based, ready-to-use

Composition

Name	CAS No.	Content
AS 1	12345	15
AS 2	12346	5
Non-AS 1	12347	60
Pigment 1	12349	10

Hazard and precautionary statements
H xxx
P xxx

Authorised uses, instructions for use & RMMs (presented by use)
PT 3, PT 4

Professional user

Dipping, spraying, brushing

Wear PPE

Store in a cool place

Authorisation Nr: 1-2-3

Annex II

Content of the three-level information to be submitted by applicants[16]

Applicants will have to submit a draft SPC of the BPF in accordance with document CA-May15-Doc.4.6.a-Final[17]. The full composition of the individual products will have to be given by other means, such as the IUCLID file and/or the excel file embedded in the PAR template[18] used by the applicants to prepare the draft risk assessment.

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[16] ECHA will provide further guidance regarding the preparation of a draft "BPF SPC" by using the SPC editor or the SPC generator from an IUCLID file. See specific instructions available at http://echa.europa.eu/documents/10162/14938692/addendum_specific_instructionsproduct_family_applications_en.pdf

[17] Available at https://circabc.europa.eu/w/browse/9193f037-0443-4232-8a13-1949bb1bbcc8

[18] PAR templates for national and Union authorisation procedures are available at http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/formats

Annex III

Content of the BPF authorisation – "BPF SPC"

The SPC of the BPF will contain the three-level information referred to in document CA-May15-Doc.4.6.a-Final.

Annex IV

Q&A on the implementation of the new BPF concept

Section 2.1.- Understanding the elements involved in the new BPF concept

Similarity between formulations:

(1) **Q:** For a PT 3 BPF (teat dipping), can a liquid and a gel formulation be put into the same family?

A: It depends on a case by case assessment looking at the toxicological properties, dermal absorption and exposure patterns of the involved products. The degree of thickness in the gel should be also considered, as this might also have implications in terms of efficacy.

(2) **Q**: For a PT 3 BPF, can the liquid and the gel formulation be put into the same meta-SPC?

A: With a view to facilitate post-authorisation notifications of new products (i.e. by notifying the trade name(s) and specific composition of the product only) and to produce product-specific SPCs, a meta-SPC should only contain products with one formulation type. Otherwise, it would be uncertain which formulation type is relevant for which individual product. Therefore, the liquid and the gel formulation should be allocated in two different meta-SPCs.

(3) **Q:** For a PT 3 BPF, could impregnated wipes be included in the same meta-SPC as the liquid formulation?

A: It could be possible provided that the risk assessment and efficacy assessment also cover the impregnated wipes. If not, they should be allocated in two different meta-SPCs.

(4) **Q:** Should concentrate and ready-to-use products be in the same or different meta-SPCs?

A: In principle it is expected that concentrates will have different hazard and precautionary statements so they would have to be put in separate meta-SPCs (unless the concentrate and the RTU products have the same H&P statements).

(5) **Q:** How should footnote 5 in document CA-Nov14-Doc.5.8–Final be interpreted (i.e. that a justification for similarity of the composition within the BPF may be based, where appropriate, on existing guidance (e.g. EN 152 and EN 113 for PT8 or the EFSA's guidance on dermal absorption) and where relevant, on expert judgement)?

A: The footnote considers examples, not a formal requirement, and certainly allows for expert judgement when concluding on similar composition. The EFSA guidance document can be used to support that a composition is similar, but

fulfilling the criteria of the EFSA guidance is not a pre-requisite for a composition to be considered as similar.

(6) **Q:** Can a single application for a PT 14 BPF contain grain, wax block, paste and gel baits formulations, having each formulation its own level 2 meta-SPC?

A: Yes, this may be possible as long as all the necessary data to support any proposed read across between formulations both in terms of palatability or field trials is submitted within the application.

(7) **Q:** Can a single application for a PT 3 BPF contain five products, three of which are based on iodine and the two others on PVP-iodine?

A: Yes, this is possible since the implementing Regulation approving iodine for PT 3 also includes polyvinylpyrrolidone iodine (PVP-iodine).

Similar uses:

(8) **Q:** Can an application for a PT3 BPF group teat dipping products and disinfectants of instruments or hard surfaces?

A: Overall, the note for guidance considers similar uses as different uses within the PT(s) to which the BPF belongs. However, on a case by case basis the eCA may consider that the intended uses within an application are not similar, as they would require almost complete and non-complementary risk and efficacy assessments. Therefore, teat dipping products and disinfectants of instruments or hard surfaces might be better authorised through two different PT3 BPFs. If the eCA would agree to include such uses in the same BPF, then these should probably be included in different meta-SPCs.

Meta-SPC concept:

(9) **Q:** How to address a change in the C&L of a product resulting in different H&P statements compared to the rest of members in the same meta-SPC?

A: A new meta-SPC should be created for those products having different H&P statements. In accordance with Article 2(2) of the changes Regulation[19], the authorisation holder (AH) would have to request ECHA an opinion regarding the classification of such a change (minor vs. major). It has to be noted that the wording "hazard statements" also covers "supplementary hazard statements" such as the EUH statements.

(10) **Q:** Can the description of a use in a meta-SPC be formulated as "and/or" (e.g. target organisms, application methods)?

[19] Implementing Regulation (EU) No 354/2013 (OJ L 109, 19.4.2013, p. 4.).

A: No, in accordance with the agreed approach under document CA-Sept14-Doc.5.4-Final (SPC template), any use must be described clearly indicating which target organisms or applications methods are relevant for such a use.

(11) **Q:** Should all the products in the same meta-SPC have the same first aid instructions, disposal, storage and shelf life?

A: Yes, in accordance with document CA-Nov14-Doc.5.8–Final, it is required (as for the RMMs) that a common set of those elements is proposed at meta-SPC level, so that any products notified post-authorisation of the BPF and belonging to that meta-SPC are subject to such a set. However, where some of those elements are use-specific (e.g. use specific RMMs, first aid instructions or emergency measures to protect the environment), these elements can be presented in the SPC in the respective section[20]. But whereas use-specific information can be presented in a meta-SPC, it is not possible to present product-specific information at meta-SPC level (e.g. a different shelf life).

(12) **Q:** Should the meta-SPC level specify the manufacturers which are relevant for the different individual products included in that meta-SPC?

A: All the manufacturers of the individual products belonging to the BPF have to be listed in the first information level, so there is no need to repeat this information at meta-SPC level.

Once the BPF has been authorised and a product-specific SPCs is generated for dissemination purposes, only the relevant manufacturer(s) for that specific product should be listed provided that this information is available to the CA (either in the PAR or in the post-authorisation notification provided by the AH).

(13) **Q:** How to deal with the concentration range of the ingredients in case of a meta-SPC that only contains one product at the authorisation stage?

A: For this kind of cases, the applicant should propose a “hypothetical” range of product composition in that meta-SPC in which the only currently available product fits and that allows similar products with different specific composition to be notified in the future.

Where an applicant does not intend to notify additional products in the future into that meta-SPC, the exact composition or a “range” with identical minimum and maximum limits (e.g. 3% - 3%) should be given in the meta-SPC.

(14) **Q:** Can a BPF authorisation have one or more meta-SPCs without any individual product at the third information level?

A: No. The meta-SPC concept represents a way of grouping a number of related individual products within a family at the authorisation stage, which also enables a simple post-authorisation notification process in accordance with Article 17(6) of the BPR. Therefore, at the authorisation stage any meta-SPC should at least

[20] See document CA-May15-Doc.4.6.a-Final (SPC template for a BPF).

contain one individual product. Where a new individual product to be notified does not fit into an existing meta-SPC, the AH should apply for a change to the BPF authorisation to create a new meta-SPC.

(15) **Q:** Can an individual product of a BPF (e.g. insecticide placed on the market as a ready-to-use non-refillable dual bait station) containing the same AS also contain two mixtures falling under two different meta-SPCs due to a different classification?

A: No. An individual product of a BPF, in the form in which it is supplied to the user, can only belong to a single meta-SPC and have a unique authorisation number including the suffix of that meta-SPC. Therefore, the classification of any mixtures in the product should be compatible with the hazard and precautionary statements in the meta-SPC to which the product belongs. Where this is not possible, the product should be redesigned and no longer supplied to the final user as a dual insect bait station but as two separate products belonging to two different meta-SPCs.

Where none of the two options above are suitable for the applicant, the product in the form of a dual insect bait station could also be authorised as a single biocidal product.

Section 2.2.- Preparation of the application for authorisation of a BPF

(16) **Q:** Footnote 11 in document CA-Nov14-Doc.5.8–Final refers to other formats that may be used in the context of the pre-submission meetings to provide a clear overview of the whole BPF; Is this a formal requirement? Could this overview document also be submitted within the application for authorisation?

A: No, this document is not considered as a formal requirement. However it is helpful, both for the applicant and CAs, to provide an overview of the BPF before preparing the draft SPC of the BPF and to discuss the envelope approaches. The overview document may also be submitted within the application as a supporting document. However, the information submitted in the draft SPC should be regarded as the relevant one for the application. Such an overview document of the BPF could potentially also be included as an appendix to the PAR (but not as a part of the authorisation decision or SPC of the BPF).

(17) **Q:** Can a concentration range for pigments, perfumes and dies (PPDs) be allowed at level 3 when indicating the exact composition of the individual products of the BPF?

A: No, the exact concentration for PPDs (not allowing ranges) shall be specified at level 3 for each individual product of the BPF.

(18) **Q:** In terms of Letters of Access (LoA) to the active substance(s) dossier; shall the applicant for a BPF authorisation submit a LoA for each individual product of the BPF?

A: No, in accordance with Article 20(1)(c) of the BPR, a LoA to each active substance will be sufficient to cover all the products within the BPF application.

Section 2.3.- Evaluation of the BPF application

(19) **Q:** Should the outcomes of paragraph 33 of document CA-Nov14-Doc.5.8–Final be regarded as alternative options (e.g. not to authorise the whole meta-SPC even if there are some safe and efficacious uses)?

A: No, the outcome under paragraph 33(c) is only applicable where no safe and efficacious use is identified within a given meta-SPC. When deciding whether to create a new meta-SPC or to authorise a meta-SPC with just one or a few uses, the eCA should also check with the applicant what option is most suitable in terms of the regulatory management of the BPF authorisation.

(20) **Q:** How to understand "similar levels of efficacy" within one meta-SPC?

A: The minimum level of efficacy for each use should be ensured at meta-SPC level for the different target organisms and application methods. The minimum efficacy for any use has to be above the minimal requirements within the available guidance.

(21) **Q:** If efficacy against a number of target organisms is demonstrated for a meta-SPC, is it possible to market a product within that meta-SPC with claims against an additional target organism?

A: No. All target organisms in the product claims must be included in the relevant meta-SPC.

Section 2.4.- Content of the BPF authorisation

Product-specific SPC for dissemination purposes:

(22) **Q:** Should a product-specific SPC include all the authorised uses in the meta-SPC, or only those uses that might be relevant for the individual product?

A: Any product specific-SPC shall contain all the authorised uses within the meta-SPC to which the individual product belongs. This does not prevent though the AH from including just some of those authorised uses on the label of the individual product (see next Q&A).

Moving from the authorised uses in a meta-SPC to labels:

(23) **Q:** Have all the authorised uses in the meta-SPC to which an individual product belongs be included on the label?

A: No, a selection of uses can be done at the label stage. However, in accordance with document CA-May14-Doc.5.6–Final, for a particular use there should be full correspondence with the relevant meta-SPC. For example, if one use combines different application methods (brushing and roller) at meta-SPC level, the label shall reflect brushing and roller.

Changes to the BPF authorisation:

(24) **Q:** How to extend the composition range of a BPF – major vs. minor change?

A: The application type of such extension of the family needs to be decided on a case-by-case basis, depending on the extent of the scientific/technical assessment to be performed.
Until detailed guidelines on classification on changes are made available by ECHA, the AH may request the Agency to provide an opinion on the classification in accordance with the criteria laid down in the Annex to the changes Regulation of a change not listed in one of the tables of that Annex.
The opinion shall be delivered within 45 days following receipt of the request and payment of the fee referred to in Article 80(1)(a) of Regulation (EU) No 528/2012.
The Agency shall publish the opinion after deletion of all information of commercial confidential nature.

Section 2.5.- Post-authorisation notification of new products

(25) **Q:** What concentration changes are allowed for PPDs without requiring a notification?

A: PPD changes within the authorised composition ranges of the relevant meta-SPC are allowed, provided that they only concern PPDs; that is, the changes do not affect the concentration of other co-formulants, including water.

(26) **Q:** Which authorisation number and trade name should be on the label of a product placed on the market without being notified because of a change concerning PPDs concentration only?

A: Where an individual product of a BPF is subject to a change in PPDs not requiring notification, the product resulting from such a change shall be placed on the market with the same authorisation number. The same applies for the trade name, unless two or more different trade names have been allocated to the initial product and the applicant decides to place the product resulting from the change on the market with a different name.

(27) **Q:** In the context of a post-authorisation notification, the AH can support CAs by providing a draft “product-specific" SPC; what composition should be included in such a draft?

A: This draft SPC shall only contain the specific product composition in terms of active substance(s) and non-active substances knowledge of which is essential for the proper use of the product. The submission of this draft SPC is without

prejudice of the formal notification in which the AH shall indicate the exact product composition, trade name(s) and the suffix to the authorisation number (i.e. already including the BPF identifier and the meta-SPC suffix).

(28) **Q:** Where an AH wishes to place a new product on the market containing a new component (e.g. a P, P or D) or one of the existing components at a concentration which is out of the permitted variations, a change to the BPF authorisation has to be agreed first by the relevant CA or the Commission. Once the BPF authorisation has been amended, has the above-mentioned new product to be notified in accordance with Article 17(6) of the BPR before being placed on the market?

A: Where the new product is explicitly identified in the application for a change of the BPF and the change is agreed on by the CA, the new product should be listed in the amended SPC of the BPF authorisation and no further notification is needed[21].

Where the new product has not been identified in the application, the new product has to be notified in accordance with Article 17(6) of the BPR once the change has been agreed on.

[21] The applicant would have to provide though a draft "product-specific SPC", which should be checked by CAs before making it available in the R4BP3 for dissemination purposes.

Annex V. BPR provisions on biocidal product families

Recital 36

To facilitate access to the market it should be possible to authorise a group of biocidal products as a biocidal product family. Biocidal products within a biocidal product family should have similar uses and the same active substances. Variations in the composition or the replacement of non-active substances should be specified, but may not adversely affect the level of risk or significantly reduce the efficacy of the products.

Recital (-1a) of Regulation 334/2014

Article 3(1) (s) and Article 19(6) of Regulation (EU) No 528/2012 should be amended to allow similar biocidal products to be part of a family if they can be satisfactorily assessed based on identifiable maximum risks and minimum efficacy.

Article 3(1)

(m) national authorisation' means an administrative act by which the competent authority of a Member State authorises the making available on the market and the use of a biocidal product or a biocidal product family in its territory or in a part thereof;
(n) 'Union authorisation' means an administrative act by which the Commission authorises the making available on the market and the use of a biocidal product or a biocidal product family in the territory of the Union or in a part thereof;
(aa) 'administrative change' means an amendment of an existing authorisation of a purely administrative nature involving no change to the properties or efficacy of the biocidal product or biocidal product family;
(ab) 'minor change' means an amendment of an existing authorisation that is not of a purely administrative nature and requires only a limited re-assessment of the properties or efficacy of the biocidal product or biocidal product family;

Article 3(1), point (s), as amended by Regulation 334/2014

"(s) "biocidal product family" means a group of biocidal products having
(1) similar uses,
(2) the same active substances,
(3) similar composition with specified variations and
(4) similar levels of risk and efficacy; "

Article 17

3. An authorisation may be granted for a single biocidal product or a biocidal product family.

6. The authorisation holder shall notify each competent authority that has granted a national authorisation for a biocidal product family of each product within the biocidal product family at least 30 days before placing it on the market, except where a particular product is explicitly identified in the authorisation or the variation in composition concerns only pigments, perfumes and dyes within the permitted variations. The notification shall indicate the exact composition, trade name and suffix to the authorisation number. In the case of a Union authorisation, the authorisation holder shall notify the Agency and the Commission.

Article 19(6), as amended by Regulation 334/2014

"6. The assessment of the biocidal product family conducted according to the common principles set out in Annex VI shall consider the maximum risks to human health, animal health and the environment and the minimum level of efficacy over the whole potential range of products within the biocidal product family.

A biocidal product family shall be authorised only if

(a) the application explicitly identifies the maximum risks to human health, animal health and the environment and the minimum level of efficacy on which the assessment is based, as well as the permitted variations in composition and uses referred to in Article 3(1) (s) together with their respective classification, hazard and precautionary statements and any appropriate risk mitigation measures, and

(b) it can be established based on the assessment referred to in the first subparagraph that all the biocidal products within the family comply with the conditions set out in paragraph 1. "

Article 22 - Content of authorisation

1. An authorisation shall stipulate the terms and conditions relating to the making available on the market and use of the single biocidal product or the biocidal product family and include a summary of the biocidal product characteristics.
2. Without prejudice to Articles 66 and 67, the summary of the biocidal product characteristics for a single biocidal product or, in the case of a biocidal product family, the biocidal products within that biocidal product family, shall include the following information:
(a) trade name of the biocidal product;
(b) name and address of the authorisation holder;
(c) date of the authorisation and its date of expiry;
(d) authorisation number of the biocidal product, together with, in the case of a biocidal product family, the suffixes to apply to individual biocidal products within the biocidal product family;

(e) qualitative and quantitative composition in terms of the active substances and non-active substances, knowledge of which is essential for proper use of biocidal products; and in the case of a biocidal product family, the quantitative composition shall indicate a minimum and maximum percentage for each active and non-active substance, where the minimum percentage indicated for certain substances may be 0 %;
(f) manufacturers of the biocidal product (names and addresses including location of manufacturing sites);
(g) manufacturers of the active substances (names and addresses including location of manufacturing sites);
(h) type of formulation of the biocidal product;
(i) hazard and precautionary statements;
(j) product-type and, where relevant, an exact description of the authorised use;
(k) target harmful organisms;
(l) application doses and instructions for use;
(m) categories of users;
(n particulars of likely direct or indirect adverse effects and first aid instructions and emergency measures to protect the environment;
o) instructions for safe disposal of the product and its packaging;
(p) conditions of storage and shelf-life of the biocidal product under normal conditions of storage;
(q) where relevant, other information about the biocidal product.

Annex VI

20. The information provided on the biocidal product family shall permit the evaluating body to reach a decision on whether all the products within the biocidal product family comply with the criteria under Article 19(1)(b).