



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 all or a majority of the 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 2014². It was then formally presented at the 55th CA meeting (Document CA-March14-Doc.5.12³). 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.

2.- Content of the note

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>

- (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 through 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 $\neq 0^4$).
 - b) The formulation type has to be considered when deciding whether this criterion is met:

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.

- Overall, a case by case assessment⁵ 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 PT⁶. 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.

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*.

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

product⁷ (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 statements⁸, 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 level⁹ (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 – Final¹⁰ (see also sections on the *preparation of the application and content of the BPF authorisation*).

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 application¹¹ 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 dissemination¹² 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 belongs¹³, 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 authorisation¹⁴ or,

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 belongs¹⁵.

- (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			
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
PT PT 3, PT 4			
Authorisation Nr: 1			

Identical in all *meta* SPCs

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

Identical in all *meta* SPCs

Can vary by *meta* SPC

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)

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			

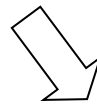
Autorisation holder Manufacturer(s) BP Manufacturer(s) AS			
Type of formulation Liquid, water based, ready-to-use			
Composition			
Name	Function	CAS No.	Content of meta SPC
AS 1	Active substance	12345	10 - 15
AS 2	Active substance	12346	5
Non-AS 1	Solvent	12347	45 - 60
Non-AS 2	Surfactant	12348	0 - 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: 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: 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 applicants¹⁶

- 1) A document including only the first level information:
 - a) Proposed family name.
 - b) Product type(s).
 - c) Administrative details: authorisation holder, product manufacturer(s), active substance(s) manufacturer(s).
 - d) Formulation type(s).
 - e) Product family composition range (e.g. tabular format as in section 2.1 of the current SPC template for a BPF).

- 2) For each *meta* SPC (i.e. second level information), an annexed document including:
 - a) The composition range for the products included in the *meta* SPC (e.g. using a similar table as above),
 - b) The following information in a format similar to sections 3 to 6 of document CA-Sept14-Doc.5.4-Final¹⁷, that is:
 - Hazard and precautionary statements, which shall be the same all the products included in the *meta* SPC,
 - The intended uses for the products included in the *meta* SPC, presented with the instructions for use, RMMs and other directions for use that are use-specific,
 - The general directions for use that are valid for all the intended uses,
 - Any other relevant information,
 - c) A table with the trade name(s) and the exact composition of each product included in the *meta* SPC (i.e. third level information).

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.

¹⁷ Agreed SPC template for single biocidal products.

Annex III

Content of the BPF authorisation – "BPF SPC"¹⁸

I.- First level information:

- 1) Family name.
- 2) Product type(s).
- 3) Administrative details: authorisation holder, product manufacturer(s), active substance(s) manufacturer(s).
- 4) Family authorisation number, date of authorisation and expiry date.
- 5) R4BP asset reference number
- 6) Formulation type(s).
- 7) Product family composition range (e.g. tabular format as in section 2.1 of the current SPC template for a BPF)¹⁹.

II.- Second information level (*meta* SPCs):

- 1) The family authorisation number, including the suffix identifying the *meta* SPC.
- 2) PT(s) of the *meta* SPC.
- 3) Formulation type(s) and where relevant, concentrate vs. ready to use.
- 4) Specific composition range for the (products included in the) *meta* SPC (e.g. using a similar table as under item 6 above).
- 5) Hazard and precautionary statements, which shall be the same for all the products included in the *meta* SPC.
- 6) The authorised uses of the products covered by the *meta* SPC (i.e. different combinations of user category/target organism/field of use/application methods/pack size & material/application rate and frequency), presented together²⁰ with their associated instructions for use

¹⁸ 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.

¹⁹ See footnote 12.

²⁰ Until the SPC editor or SPC generator are fully adapted to the principles agreed under document CA-Sept14-Doc.5.4-Final, where any directions for use under items 7 to 9 are use-specific, they should be clearly allocated to the relevant authorised uses.

and relevant RMMs, which shall cover all the products included in the *meta* SPC.

- 7) The particulars of likely direct or indirect effects, first aid instructions, emergency measures to protect the environment.
- 8) The instructions for safe disposal of the product and its packaging.
- 9) The conditions of storage and shelf-life of the product under normal conditions of storage.
- 10) Other information.

III.- Third information level (by *meta* SPC):

- 1) List with all the products included in the *meta* SPC at the time of authorisation, indicating per product the:
 - Trade name(s).
 - Specific composition of the product within the variations of the *meta* SPC.
 - Authorisation number (i.e. including the BPF authorisation number, the suffix identifying the *meta* SPC and the suffix identifying the specific product).

Annex IV

Q&A on the implementation of the new BPF concept

(Example - to be further completed)

Q1: How to extend the composition range of a BPF – major vs. minor change?

A1: 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.

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).