Biocidal Product Families (BPF):
Best Practice for Product Family Authorisations

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Topics

- Guidance on implementing the BPF concept
- Why a Working Party (WP) – outputs so far

Best Practice

- Initial thoughts when considering a BPF
- Understanding your intended BPF
- Pre-submission meetings

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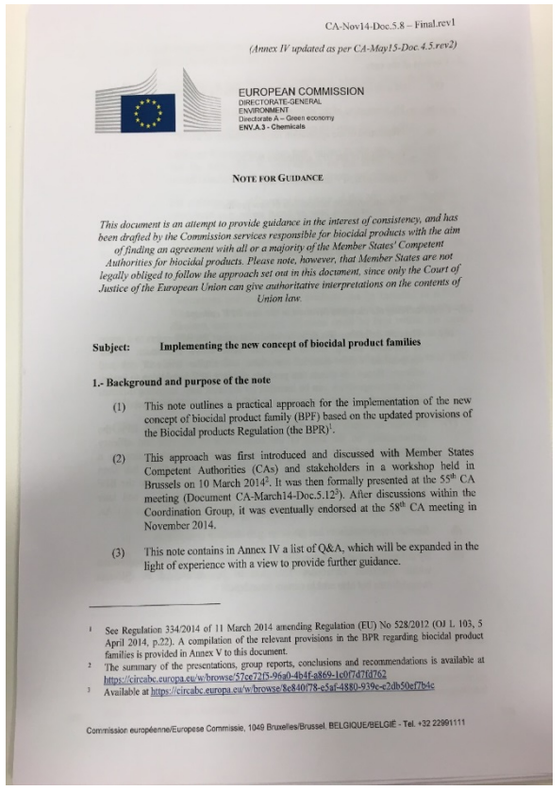
2014 Guidance note the BPF concept & Working Party

Guidance CA-Nov14-Doc.5.8 – Final.rev3:

- implementing the BPF concept
- meta-SPC concept
- Confirmed understanding of key elements (Art 3.1(s)):
  - ‘Similar composition’
  - ‘Similar uses’
  - ‘Similar levels of risk and efficacy’



CA-Nov14-Doc.5.8 – Final.rev1

(Annex IV updated as per CA-May15-Doc 4.5.rev2)

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 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.

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

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BPF Working Party

- Experience has identified some issues in **Note for Guidance**
- Particularly the broad definitions of ‘similarity criteria’
- Allows flexibility, but could be interpreted differently
  - Uncertainty how families should be designed & evaluated
- A common understanding is important for applicants, eCAs, cCA’s & the Agency → HARMONISATION

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Working Party

- Deadline extended to 31 Dec 2018 - further discussions in Working Party
- Ultimately reporting back to CG meetings for document agreements
- Documents should become publicly available following CG agreements
  - S-CIRCABC-ECHA-Biocide CG (Public)-Library Biocides Coordination Group (CG) - Public

So far:

- Grouping of co-formulants
- Splitting of Families: Handling ongoing applications where consideration of similarity change
  - evaluation, mutual recognition, or peer review
- How to improve and optimize pre-submission meetings
  - Clearly trying to consider at the start of the application/evaluation process checks on the ‘similarity criteria’ of products in a BPF

- Anticipate update/revision of general BPF concept guidance/Q&A section
  - To consolidate information

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Thoughts on Best Practice regarding BPFs

- Initial thoughts when considering a BPF
- Understanding your intended BPF
- Pre-submission meetings

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Initial thoughts when considering a BPF

- What flexibility do you really need? - rather than what can we have?
  - Nice to haves that are not really needed – add complexity and risk
  - Mindset to get whole product portfolio in, likely not good starting point
  - Is a BPF the best approach/ needed?

- Fees:
  - Yes - they are important, but should not be the overriding driver
  - Be prepared to advocate internally to be able to defend a quality dossier that meets the BPF criteria

- Do not underestimate the complexity and work of a BPF:
  - Significant extra work/expertise especially up front to design BPF + dossier defence
  - You understand the rationale – How will others?

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Understanding your family – Create a summary

Prepare a detailed overview summary structure of <u>potential</u> BPF

- Create a detailed summary to avoid getting lost in the details
- Summarise both 1st level (overall BPF) and 2nd level (meta-SPCs)
  - **Formulation type:** incl. RTU or concentrate
  - **Composition and specific defined functions of co-formulant:** ranges of AS & each co-formulant, grouping by function (if wished). identify SOC
  - **Classification:** in depth review of C&L at meta-SPC level: recent SDSs + public sources

- **Detailed description of uses**
  - PTs & User categories
  - Application: methods, concentrations in use, number & rates
  - Target organisms/development stage
  - Including **<u>any</u>** relevant aspects of use

- **Instructions for use & (RMMs <u>especially use specific</u> – *requires initial assessments***
- **Your initial Meta-SPC rationale and structure should start to become clear**

Compare against BPF criteria → Re-structure? additional BPFs? Separate PAs?

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2nd information level (meta-SPCs)

Meta-SPC 1

Formulation type: Liquid formulation - water based
RTU or concentrate: RTU

Name	Function	CAS No.	Content %
AS 1	Active	12350	0.80
AS 2	Active	12351	0.25
Non-AS 1	Solvent	Water	79.95- 93.95
Non-AS 2	Binder	-	3-5
Non-AS 3	Surfactant	12353	2.0
Non-AS 4	Pigment	12354	0-3
Non-AS 5	Pigment	12355	0-3
Non-AS 6	Pigment	-	0-3
Non-AS 7	Pigment	-	0-3

SOC: Non-AS 3

Concentration in use: 100%

C&L: H412, EUH208 & P102, P273, P260, P501

PT(s): PT8 – Use class 2 & 3
User category: Industrial

Application methods:
1. Automated spraying
2. automated dipping
3. Flow-coating

Applications: 1-2 apps. – target 150 ml product/m^2

Target organisms: decay fungi & disfiguring fungi

Use specific instructions of use[a]: -

Use specific RMM[a]: Automatic dipping Only for use dipping processes where all treatment/drying processes are automated
Check to make sure there are not use specific differences
e.g. due to risk assessment outcomes within the meta-SPC

Storage conditions, disposal and shelf-life[a] are the same across all BPs in meta-SPC 1 *Pay particular attention to shelf-life*

Meta-SPC 2

Formulation type: Liquid formulation - water based
RTU or concentrate: Concentrate

Name	Function	CAS No.	Content %
AS 1	Active	12350	8
AS 2	Active	12351	2.5
Non-AS 1	Solvent	Water	19.5-39.5
Non-AS 2	Binder	-	30-50
Non-AS 3	Surfactant	12353	20

SOC: Non-AS 3
Concentration in use: 10%
C&L: H411, H317 & P261, P273, P280, P302+352, P333+313, P501

PT(s) PT8 – Use class 2 & 3
User category: Industrial

Application methods:
4. Automated spraying
5. Automated dipping
6. Flow-coating

Applications: 1-2 apps. – target 150 ml product/m^2

Target organisms: decay fungi & disfiguring fungi

Use specific instructions of use[a]: -

Use specific RMM[a]: Automatic dipping Only for use dipping processes where all treatment/drying processes are automated
Check to make sure there are not use specific differences
e.g. due to risk assessment outcomes within the meta-SPC

Storage conditions, disposal and shelf-life are the same across all BPs in meta-SPC 2. *Pay particular attention to shelf-life*

Meta-SPC 3

Formulation type: Liquid formulation - water based
RTU or concentrate: RTU

Name	Function	CAS	Content %
AS 1	Active	12350	0.80
AS 2	Active	12351	0.25
Non-AS	Solvent	Water	81.95- 95.95
Non-AS	Binder	-	1-3
Non-AS	Surfactant	12353	2.0
Non-AS	Pigment	12354	0-3
Non-AS	Pigment	12355	0-3
Non-AS	Pigment	-	0-3
Non-AS	Pigment	-	0-3

SOC: Non-AS 3
Concentration in use: 100%
C&L: H412, EUH208 & P102, P273, P260, P501

PT(s) PT8 – Use class 2 & 3
User category: Professional

Application methods:
7. Brushing/roller (indoor/outdoor)
8. hand-held spraying (outdoor)
9. Manual dipping

Applications: 1-2 apps. – target 150 ml product/m^2

Target organisms: decay fungi & disfiguring fungi

Use specific instructions of use[a]: -

Use specific RMM[a]: Manual dipping: must be carried out in contained area on impermeable surface. **In situ uses:** do not contaminate plant life, aquaria, fish bowls, ponds *Check to make sure there are not use specific differences*
e.g. due to risk assessment outcomes within the meta-SPC

Storage conditions, disposal and shelf-life are the same across all BPs in meta-SPC 3. *Pay particular attention to shelf-life*

Really understanding your Family – Other considerations

Start:

1: 1st Initial BPF summary

2: Check against: more obvious BPF criteria

Some criteria are more obvious & can be tested with less effort
e.g. BP's same C&L in a Meta-SPC /Storage stability

Early stage: determine worst-case uses
Map out & where possible calculate all risk assessment scenarios – ***avoid surprises!***

- Check risk assessment assumptions for key inputs & consider key cut-offs

Risk envelopes? – Map within +

Re-think/re-structure/re-check

Cost/complexity considerations?

3: Check other BPF criteria including Risk/efficacy assessments (If not done earlier) - *use information/ knowledge you already have*

between meta-SPCs

- *Excel file/table + numbering uses helps*
- *Identify additional specific assessments*
  e.g. Specific/ increase in SOC or additional label claim/target organism

What's not covered/safe?
Per meta-SPC: Are there different use specific? RMMS/instructions? ***= issue***

Re-think/re-structure/re-test

4. Data gap analysis – testing strategy / justifications

5. Re-test BPF structure based on results/justifications

`Well prepared' quality dossier – all aspects considered Clear communication to aid evaluation

What Data is needed?
Core + Additional data requirements from guidance?
Additional data need driven by RAs?
e.g. dermal penetration or semi-field leaching (PT8)
Are justifications/bridging solid, well reasoned/defendable?
Data/information on SOC(s)?

Testing: Defined representative worst-case product(s)?
Efficacy: likely lowest AS content/lowest application rate/worst case use/conditions.
Environment/Exposure: likely highest AS content/application rate/worst case conditions
Influence of co-formulants?
Be mindful of 'cut-offs' in guidance
→ ensure all aspects supported in BPF covered

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Benefits of understanding/summarising & testing intended BPF

Help to:

- agree on clear intentions internally in an organization
- compare/testing to some BPF criteria
- business discussions on what is and what is not possible/ or practical
- reduce risk of surprises: E.g. worst-case is not actually the worst-case, C&L different in a meta-SPC or use specific RMMs different in same meta
- identifying relevant data generation/justification needs + risks to BPF structure
- identify earlier dossier preparation/complexities and costs
- clearly /concisely present BPF rationale/justifications to eCA

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Agree on RMS (eCA) & Pre-submission meetings

CG-30-2018-06 AP 15.2 Best Practices pre-submission meeting Final

Obligatory – but really key for families - **2 step process**

Please pay attention to other aspects in paper not mentioned here

Step 1: Agree on the eCA (Contact with CAs & obtaining eCA agreement)

- Contact CA's as soon as possible
  - no later than 18 months before the submission date/deadline + meet CA soon after
  - Try to get signed eCA agreement >1 year before submission
- Provide information at least 1 week before the meeting, include at least

Step 2: Pre- submission meeting

When?: after eCA has signed agreement & during year before submission

In general only 1 physical meeting suggest to cover at least:

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Step 2: Pre-submission meetings with rMS (eCA)

Likely Agenda items

- 1st level and meta-SPC summary information for the BPF
- Justification on why uses, composition/levels efficacy & risk are ‘similar’ within whole BPF
- How many meta-SPCs & structure
  - Why the structure?
- Specific information requirements?
- Testing strategies:
  - definition of representative products at BCF/meta-SPC level
  - E.g. Efficacy impact of co-formulants, worst-case scenario (e.g. soiling)
  - Seek agreement of eCA if lack of guidance exists
- What are worst-case risk assessments for Env. and Human health
- If relevant: Article 5(2) and/or comparative assessment
- Fees and admin

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Pre-submission meetings with rMS (eCA)

Opportunity for you to:

→ explain your BPF structure, its rationale, the uses and likely worst-cases

→ have initial feedback on proposed approaches, intended assessments, testing proposals.

- So be clear on what you , the applicant, want out of this meeting

- Prepare very well, albeit some information may not yet be available to you

- Face to face meeting, with CA specialists present is preferential
  - I hope CAs can accommodate <u>all</u> such requests - its important for both parties

The dossier content & quality remain totally the responsibility of the applicant

eCAs are clear they cannot provide the type/level of support that consultancy companies can

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Key take homes

- **Understand the existing guidance on BPFs and the outcomes of the BPF WP**
- Understand & check your intended families
- Summaries of key info. helps – in many development/communication aspects
- Unless v. simple families → Really significant effort/resources needed up front in order to design your family in line with criteria (often incl. data/risk assessments)

Thank you for your attention

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