Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin

Practical experience gained on the new BPF concept.

Vague BPF definition in BPR…

Article 3 paragraph 1 BPR:

(s) ‘biocidal product family’ means a group of biocidal products having:

(i) similar uses;

(ii) the same active substances…;

(iii) similar composition with specified variations; and

(iv) similar levels of risk and efficacy

Development of the BPF concept

- First BPF concept (CA-Nov14-Doc.5.8 – Final.rev3) was silent on similarity but introduced the meta-SPC concept
- This led to the approach to present add. BPs in an add. meta-SPC if they required a separate assessment
- This let to unmanageable applications with 10 meta-SPCs, 100 ingredients and up to 10.000 BPs
- CG gave a mandate to a working party (IND, MSACA, COM and ECHA)
- → The new BPF concept (CA-July19-Doc.4.2-Final - Guidance note on BPF concept_rev1)

Vague BPF definition and new BPF concept

The new BPF concept defines similarity in order to

- **ensure a manageable size (one core assessment)**
- **avoid redundant applications**

Article 3 paragraph 1 BPR:

(s) 'biocidal product family' means a group of biocidal products having:

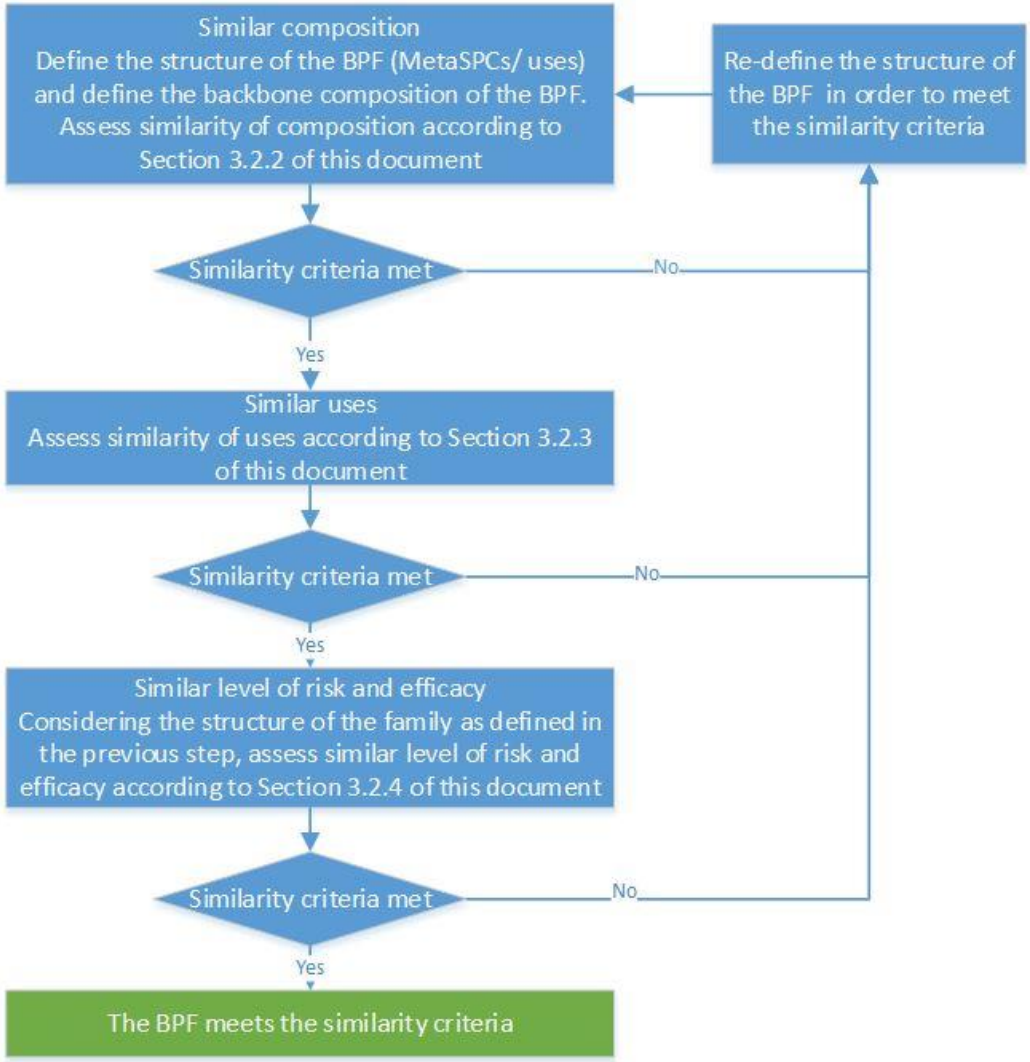
(i) similar uses (matrix);

(ii) the same active substances…;

(iii) similar composition (backbone) with specified variations (grouping); and

(iv) similar levels of risk and efficacy (one consistent set of RMMs per use and "one" worst case composition)

Today no advice on how to best develop a BPF



Dr. Thilo Walther, Federal Office for Chemicals (BfC)
Group 5.4 (Authorisation of Biocidal Products)

So far practical experience gained on:

- Similarity of composition (backbone)
- Specified variations (grouping)
- Similarity of uses (matrix)
- Splitting of on-going applications
- Impression that BPs are presented in more meta-SPCs than needed
- Impression that sometimes composition of different meta-SPCs is expected to be considered separately
- Worst case composition (WCC) for HH/ENV

Similarity of composition (backbone)

- In our experience backbone concept proved as useful
- As a rule of thumb 90+ % of applications pass the test
- However, arbitrary BPFs are split (e.g. a BPF with powders and suspensions)

Similarity of composition (backbone)

- Nevertheless, sometimes before splitting a second look must be taken in order to avoid redundant applications

	Meta 1 (Min = Max)	Meta 2 (Min = Max)	Meta 3 (Min = Max)	Meta 4 (Min = Max)
AS	*5*	*10*	*10*	*1*
Filler	*95*	*90*	*18*	*9*
Water	**0**	**0**	**72**	**90**
Form. type	**Dustable powder**	**Wettable powder**	**Suspension concentrate**	**Suspension (concentrate) for direct application**

- The dustable powder lacks the water and is used as dust
- While upon mixing and loading water is added to the wettable powder
- Accepting meta 2-4 in one application gives more similar BPF

Specified variations (grouping)

- Limited experience until today
- In our experience mainly to large variations in composition make an application unmanageable
- Mixed expirence because IND choses different levels of complexity

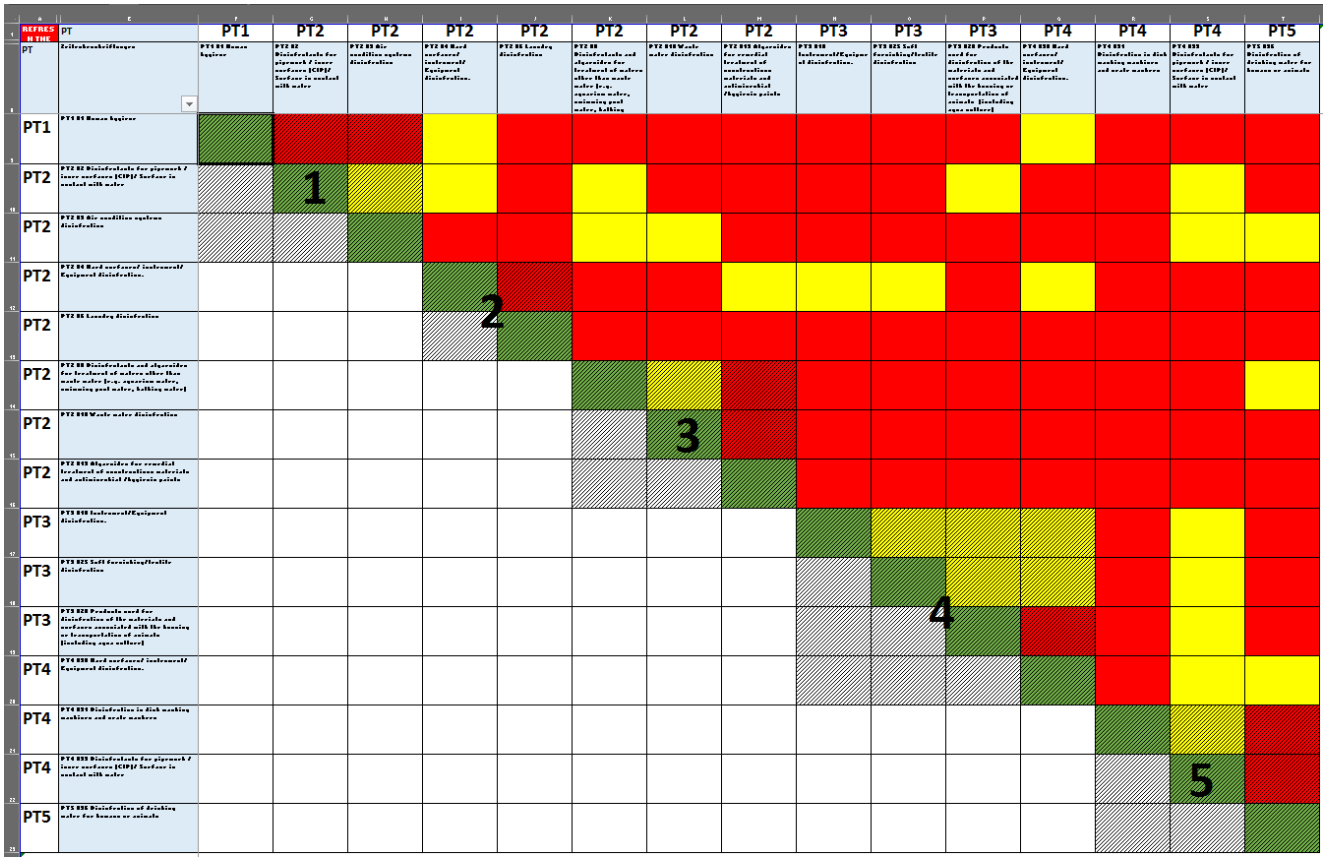
- 75 % AS, 0-0.0005% Dye(s), 0-0.0005% Perfume(s), up to 100% water

  versus

- 85 ingredients: 11 not grouped + 9 groups (number of ingredients per group 4-47)

Similarity of uses (matrix)

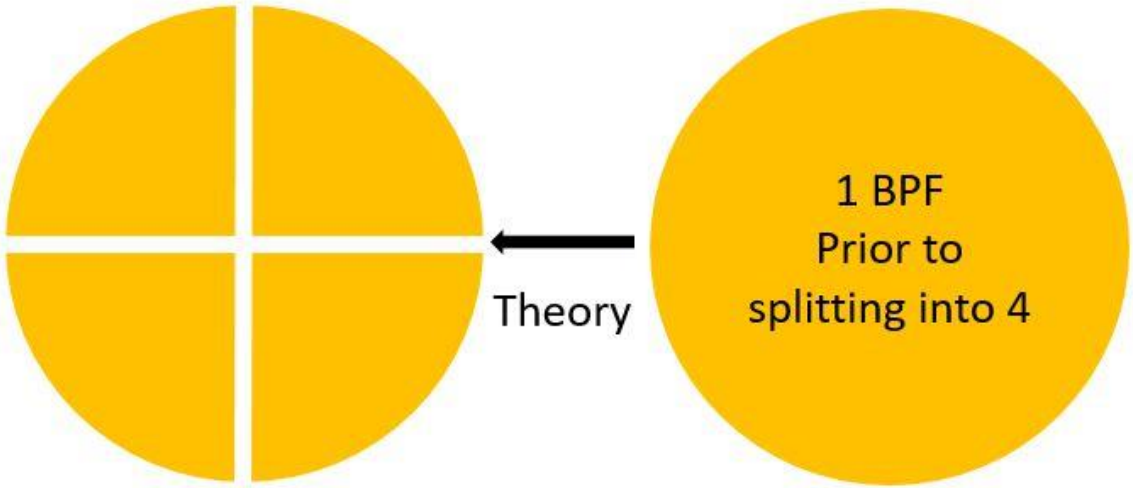
- Limited experience until today. Manageability v. redundancy
- 15 use patterns → 15 (green), 10 (yellow) or 5 (yellow + 2 red) BPFs



Dr. Thilo Walther, Federal Office for Chemicals (BfC)
Group 5.4 (Authorisation of Biocidal Products)

Splitting of on-going applications

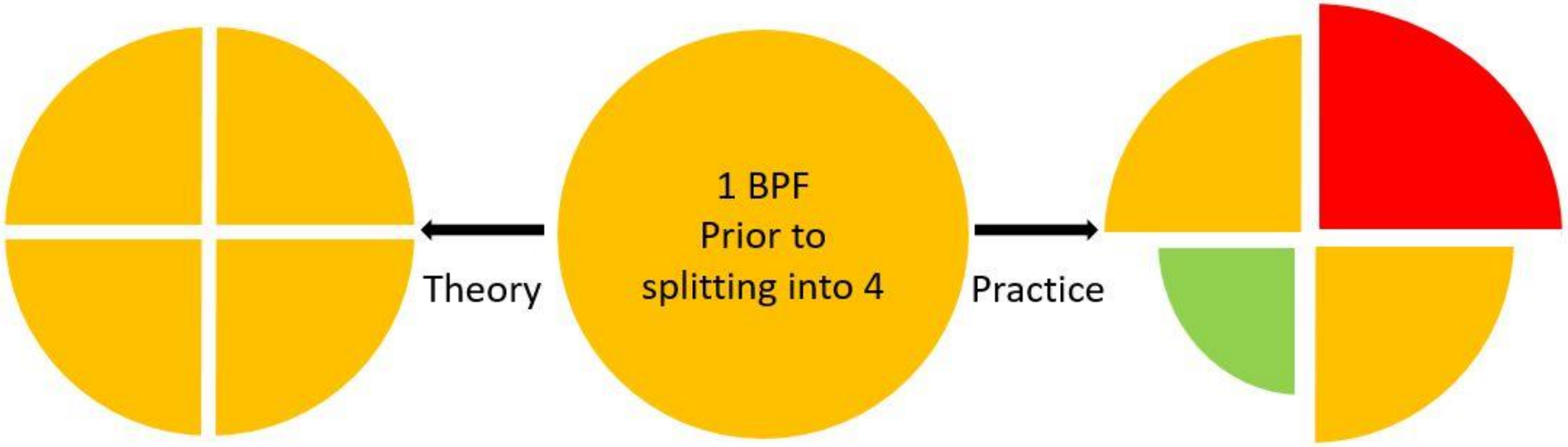
- Limited experience until today



- In practice not as easy as foreseen

Splitting of on-going applications

- In practice there are more modifications in addition to the splitting



- Therefore, updated IUCLID dossiers are necessary (3 for new applications as well as 1 updated for original application)
- Preferably 4 new applications are needed in order to have a clear picture in R4BP (dossiers, draft SPCs and references for MR and BB)

Impression that BPs are presented in more meta-SPCs than needed

- BPF concept: “…meta-SPCs … a way to present a group of similar BPs that can be covered by one (core) assessment but **cannot be presented in one meta-SPC…**” (due to different H&P phrases or formulations types (e.g. conc. and corresponding RTUs))

Applicants need to understand that:

- Number of meta SPCs increases only complexity
- No matter in how many meta SPCs the BPs and uses are presented the assessment is the same

Basic principle behind BPF concept/assessment

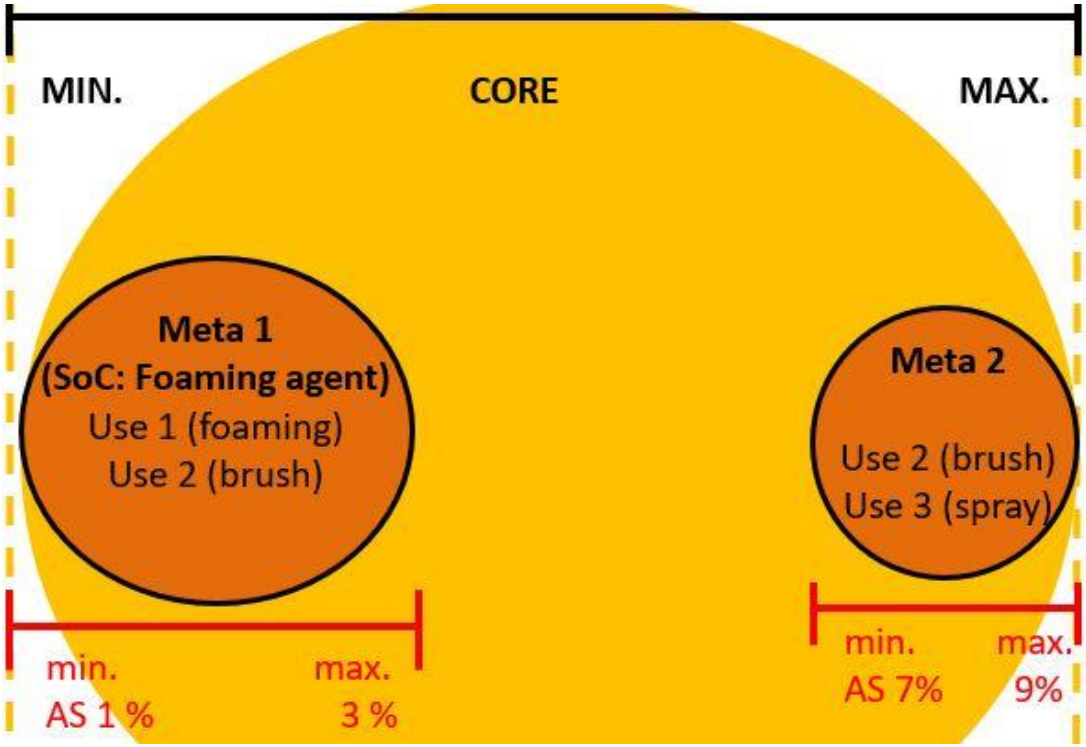
- As a first step, the MSCA checks if the BPF similarity criteria are fulfilled:
  - ✓ Same AS?
  - ✓ Is there a backbone?
  - ✓ How looks the matrix?

- Then comes MSCAS reverse conclusion. As the BPs are similar:
  - ✓ They can be covered by one core assessment
  - ✓ based on “one” WCC.

Dr. Thilo Walther, Bundesstelle für Chemikalien
Fachgruppe 5.4 (Zulassung von Biozidprodukten)

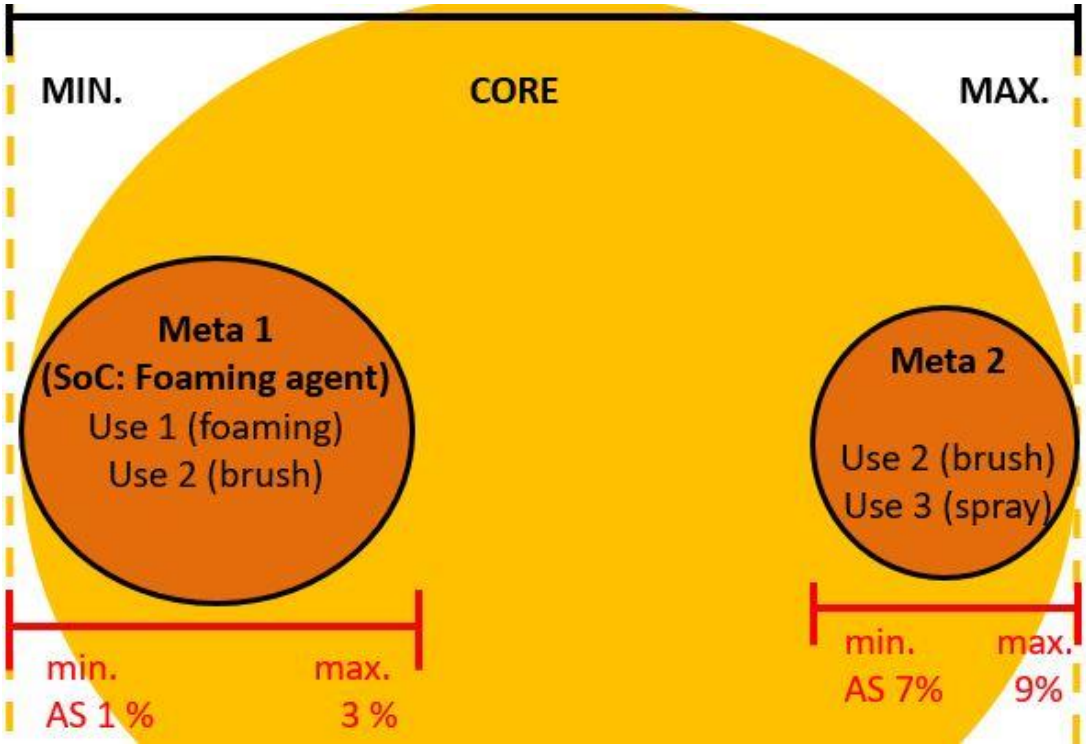
Impression that sometimes composition of different meta-SPCs is expected to be considered separately

- IND occasional approach: One assessment per meta SPC because BPs used for spraying are different
- IND wrong assumption: The SoC must not be taken into account for spraying.



Impression that sometimes composition of different meta-SPCs is expected to be considered separately

- IND approach and assumption are wrong
- One risk assessment of each use (1, 2 + 3) based on one WCC
- Question to be asked: Are use 1, 2 and 3 safe with 9% AS and SoC?
- Parameters (application rate, user, area) for each use taken from SPC



Worst case composition (WCC) for HH/ENV

- Limited experience until today
- Not every ingredient has to be taken into account but also not only AS and SoCs:
- **Active substance(s)**
- **SoCs**
- A substance increasing the dermal absorption (e.g. DMSO);
- A substance effecting the entry into the environment (e.g. binders);
- A substance (synergist) increasing the effect of the active substance;
- …
- *Please note, the WCC for EFF is normally different from the one for HH/ENV. A concept was agreed in the EFF WG.*

Practical experience gained on splitting

- **1 BPF: 1 use pattern, 7 metas + 91 ingredients + 10.000 BPs →**
- 1 BPF: 3 metas + 16 ingredients + 5 BPs
- 1 BPF: 5 metas + 85 ingredients (11 not grouped + 9 groups) + 84 BPs

- **1 BPF: 12 use pattern, 4 meta SPCs with 8 ingredients and 5 BP →**
- 1 sBP (PT2-5), 1 BPF PT3 (2 metas) and 1 BPF PT2-4 (2 metas)

- **1 BPF: 11 use pattern, 10 metas + 20 ingredients + 16 BPs →**
- sBP, BPF1 (Conc) + BPF2 (RTU)

Conclusion – Regarding BPF concept

- **New BPF concept proofed useful so far**
- Limited experience until today
- Criteria lead to more manageable applications
- Exceptions allow to avoid redundant applications
- Will in the long run lead to timely and predictable decisions

- **However, BPF concept will need (as foreseen) further development**
- WCC
- Grouping
- Splitting

Conclusion – Regarding manageability

- **To many uses**

and/or

- **to many variations in composition** (to many ingredients (no matter whether grouped or not))

still lead to unmanageable applications (unmanageable for IND+CA)

Many thanks for your attention.
Do you have any questions?

Dr. Thilo Walther, Federal Office for Chemicals (BfC)
Group 5.4 (Authorisation of Biocidal Products)

Contact

Dr. Thilo Walther, Dipl.-Chem.
Federal Institute for Occupational Safety and Health (BAuA)
Federal Office for Chemicals (BfC)
Friedrich-Henkel-Weg 1-25
44149 Dortmund
Germany
E-Mail: ChemG@baua.bund.de