Biocidal product families – what's new?

Biocides Day

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Overview

- Setting the scene
- Updated Note for Guidance
- Take-home messages

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Biocidal product family concept

- Article 3(1)(s) of the BPR
- ‘Biocidal product family’ means a group of biocidal products having:

  (i) similar uses

  (ii) the same active substances

  (iii) similar composition with specified variations

  (iv) similar levels of risk and efficacy

Practical implementation

Note for Guidance 'Implementing the new concept of biocidal product families'

- Definition of 'similar composition', 'similar uses' and 'similar levels of risk and efficacy'
- Three levels of information
    1. Overall product family
    2. Meta-SPCs
    3. Individual biocidal products
- Authorisation decision including only a 'BPF SPC'
- Post-authorisation notification of new products

Certain aspects required clarification

Very broad definitions of ‘similar composition’, ‘similar uses’, ‘similar levels of risk and efficacy’

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Flexibility but also interpretation in different ways

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Uncertainty on how families should be designed and evaluated in a harmonised way

Working Party established

- Set up to:
  - Clarify the issue of ‘similarity’
  - Provide Commission with recommendations to revise the Note for Guidance
- Mandate received by the Coordination Group in July 2017
- Members from Member States, accredited stakeholder organisations (A.I.S.E., CEFIC, SMEunited), Commission and ECHA

Main agreements

- Clarify the ‘similarity’ concept
  - Similar composition
  - Similar uses
  - Similar levels of risk and efficacy
- Advise how to group co-formulants
- Describe the best practice for pre-submission meetings
- Address splitting of families for ongoing applications

Updated Note for Guidance available

- Agreed at the CA meeting in July 2019
- For new applications, valid as of 1 October 2019
- Repeals the previous Note for Guidance
- Available on our website: Product family page

- 😐 Reduced flexibility
- 😐 Sometimes case-by-case assessment necessary
- 😐 Consequences of splitting ongoing applications

- ☺ Increased predictability
- ☺ Criteria for more consistent interpretation of BPF
- ☺ Pragmatic way forward when Art.3(1)(s) is not met

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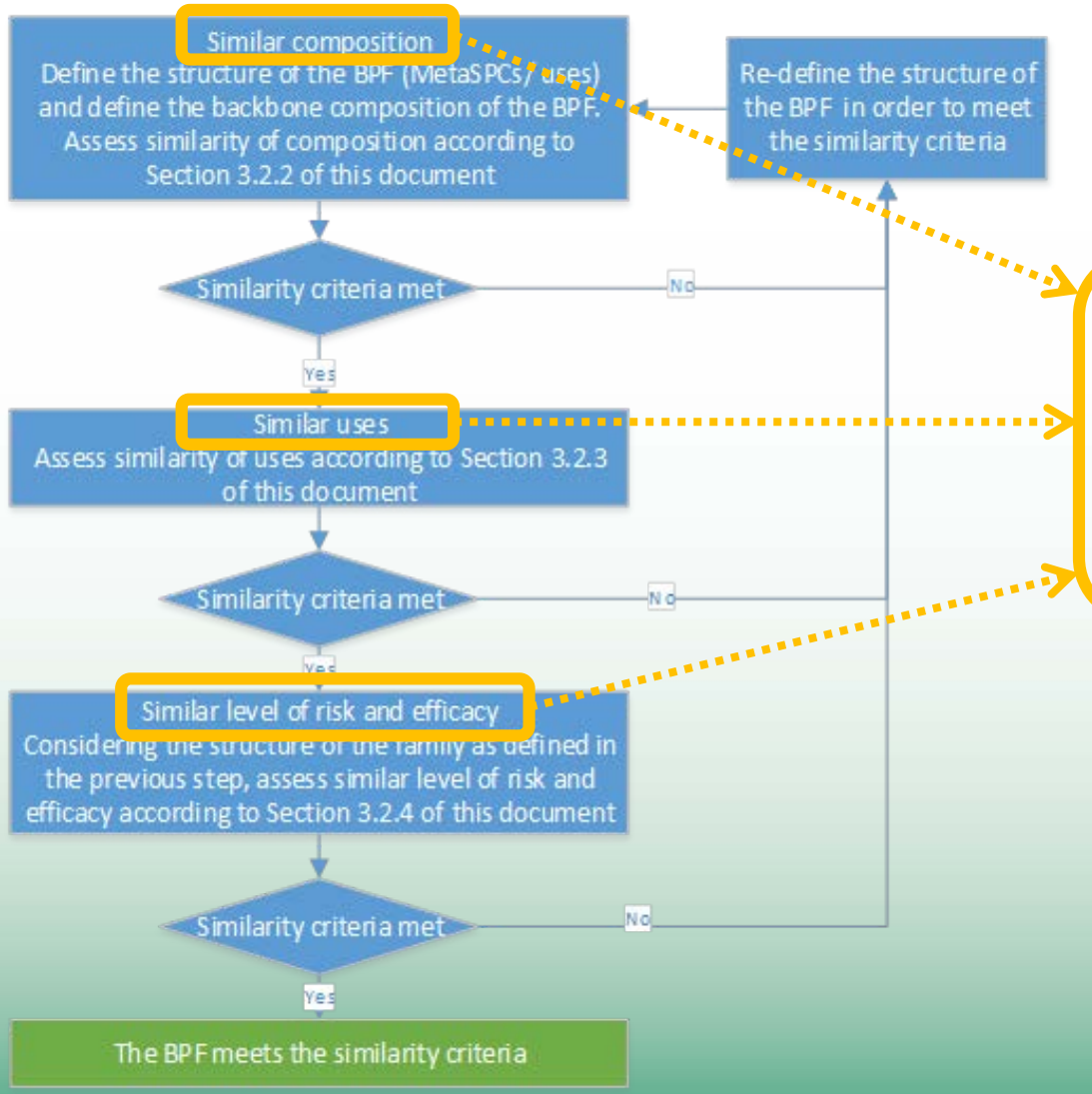
Follow the decision tree



Only products fulfilling all similarity criteria in Art. 3(1)(s) of BPR will be accepted to stay in the same family

Define the structure of the family

- Meta-SPC
  - One or more meta-SPC
  - Carefully consider the number of meta-SPC
- Uses
  - Describe the uses in detail
  - Associate the relevant instructions for use and RMMs

Establish the 'backbone composition'

Definition:

*Each individual member of the BPF should contain the same basic set of ingredients, which is **essential to formulate all products** within the biocidal product family. Individual products may still contain additional ingredients to comply with the needs for some envisaged individual uses.*

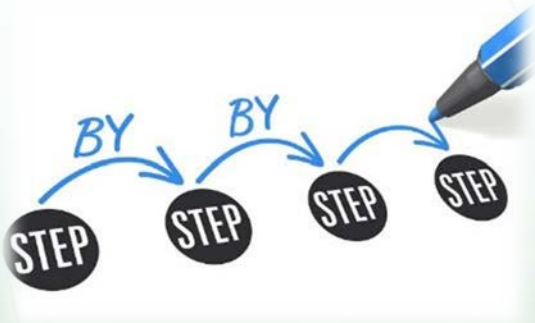
- one or more active substance(s)
- one or more co-formulant(s) essential to formulate all products
  - ☺ for example: binders and solvents
  - 😐 for example: perfumes, pigments and dyes

You could group the co-formulants

- At meta-SPC level
- Minimum concentration > 0% up to maximum concentration
- Grouping allowed providing co-formulants have:
  - Same function
  - Same impact on the classification for the whole formulation
  - Same impact on the level of risk and efficacy of the formulation

Proceed based on the decision tree

- Within a family all possible pairs of uses should be considered as similar
- Automated tool under development
- Some flexibility allowed:
  - in each family, maximum two pairs of uses that are beforehand considered as ‘non-similar’ are allowed



Define the ‘core’ assessment

- Including a significant proportion of the product family
- Assessment based on one worst-case composition (might be different from area to area)
- Every use to be assessed
- Subsets and extensions to the core
- No more than 3 refinements

Tips (1/2)

- Look for a competent authority (refMS or eCA) as soon as possible
- Obtain their signed agreement at least 1 year before the expected date for submission
- Organise a meeting during the year before submission

Tips (2/2)

Some relevant items for discussion at the meeting:

- Similar conditions of use (for Union authorisation)
- Overview of the family
- Justification for similarity
- Testing strategies
- Definition of worst-case assessments
- Where relevant, exclusion criteria and/or comparative assessment
- Fees

Keep in mind

- Equal treatment should be ensured
- Initial application with products meeting the criteria + new applications needed for products no longer covered
- Existing products benefit from transitional measures of Art. 89 of BPR
- New application for Union authorisation = new fee
- Choose the most suitable product authorisation procedure for the new authorisation

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Take-home messages (1/2)

- Be fully responsible for the content and quality of your dossier
- Arrange a pre-submission meeting with refMS or eCA
- Keep the size of your product family manageable
- Justify the reason for creating more than one meta-SPC
- Limit the number of subsets and extensions

Take-home messages (2/2)

- Present in an appropriate way the uses applied for
- Provide a robust explanation for the derivation of the backbone composition
- Demonstrate the rationale behind grouping of co-formulants
- For new applications, follow the guidance already now

Thank you

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