Biocidal Product Family Work in Progress

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cefic sector group

Overall aim

- Facilitate access to the market by authorising a group of biocidal products as a Biocidal Product Family (BPF)

- Allow variations in composition without adversely affecting risk and efficacy of the Biocidal Products (BPs) belonging to a BPF

- Facilitate the placing on the market of new BPs within the ranges of the family, but not explicitly identified in the original authorisation
  - No notification needed for variation in composition of the pigments, perfumes and dyes (PPDs)
  - Notification process (30 days before placing on the market)

Legal frame

Article 3 (s)

'biocidal product family' means a group of biocidal products having:

(i) similar uses;

(ii) the same active substances (AS);

(iii) similar composition with specified variations; and

(iv) similar levels* of risk and efficacy;

***Article 19 (6):**

- maximum risks to human health, animal health and the environment
- minimum level of efficacy

over the whole potential range of products within the biocidal product family

Legal frame

- All authorisation types are possible:
  - National Authorisation
  - Mutual Recognition
  - Union Authorisation
- Application of the Changes Regulation
- Application of the Same Biocidal Product Regulation (needs further clarification)

Implementation

WORK IN PROGRESS

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Work in Progress

- A.I.S.E. & Cefic Workshop on March 10th, 2014
- Commission proposal (CA-March14-Doc.5.12[1])
  - information in a structured way: 3-level approach
  - *meta* SPC concept
- Discussions at Coordination Group meetings

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[1] https://circabc.europa.eu/w/browse/8e840f78-e5af-4880-939e-e2db50ef7b4c

SPC - Summary of Product Characteristics

Administrative information

Name, Manufacturing address, Authorisation Number, Expiry date

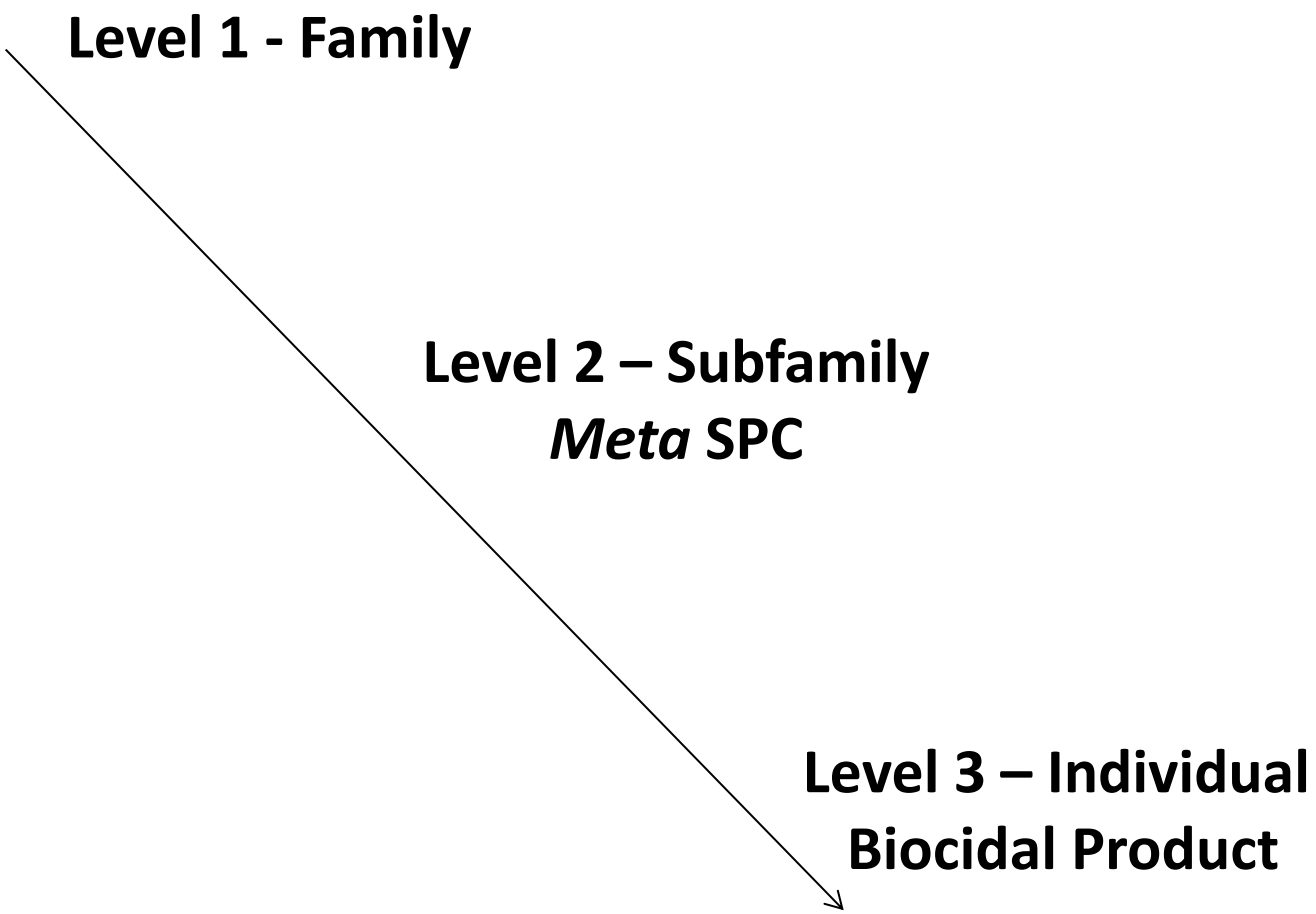
Composition information

Active Substance + non-Active ingredients, classification, hazard and precautionary statements

Information linked to the use

Product type, Target organism(s), Field(s) of use, Application method(s)/rate(s), Category(ies) of users, Pack information, Instructions to use, Risk Mitigation Measures

3-level approach



3-level approach

Level 1 - Family

Authorisation Number (AN)

Level 2 - Subfamily

***Meta* SPC**

AN + *meta* SPC suffix

Level 3 - Individual Biocidal Product

AN + *meta* SPC suffix + BP suffix

3-level approach

Family - Level 1

- **Different classification**
- Composition range of the family **(AS ≠ 0)**
- Variation in the formulation type

***meta* SPC - Level 2**

- **Same classification**
- Composition range of the sub-family **(AS ≠ 0)**
- PT variation possible
- Same set of H&P statements
- Same set of RMMs

Individual BP - Level 3

- H&P statements relevant to the individual product
- RMMs relevant to the individual product

AS = active substance // PT = Product type // BP = Biocidal Product
H&P = hazard and precautionary // RMM = Risk Mitigation Measures

Grouping products into Family

- Strictly within ranges (variations in terms of composition, product formulation, claim, use)
- A new product within the defined ranges may be notified

<u>Remember</u>

- Grouping will not always be possible
- Some products will not fit into the defined ranges

Dossier Assessment

- At the family level and where not possible at the meta SPC level?

- Maximum risk
- Minimum efficacy

- Flexible and case-by-case considerations will have to be allowed when discussing variations in the composition and the impact on the overall risk assessment and *meta* SPC grouping

Practical considerations

- Pre-submission meeting with the evaluating Member State
- Seek opportunities whereby it is avoided that the entire family application is jeopardised in case of a concern with an individual biocidal product or a *meta* SPC within that family
- For multi-PT (product type) combinations, deadline for applications for authorisation - same rules as established for single products[1]

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[1] https://circabc.europa.eu/sd/a/a51ecad8-187e-4be6-887c-8026f33bb8c5/CA-Sept13-Doc.6.2.b%20-%20Multi-PT_products.doc

Further work

- Development of guidance (Q&A?)
- Submission/authorisation tools:
  - SPC template for Families (level 1, 2, 3)
  - How to apply suffixes in practice
  - IT system (R4BP3)
- Risk assessment and evaluation of dossiers
- Dossier building (read – across between products)

Concluding thoughts…

- Encourages innovation by the development of products of "same or lower risk" and "minimum level of efficacy"
- Reduction of workload for both Member State and applicants for the same (more?) number of biocidal products

- Grouping the most relevant number of BPs - challenge

- Cost reduction?
- Biocide Product Family & "Same product" authorisation?

Thank you for your attention!

Table of Silence – Tg Jiu - Romania