
Biocidprodukt-
familier

Biocidproduktfamilien

Meta SPC

Individuelle produkter i familien

Meta SPC

- A *meta* SPC is the second level of information which is used to focus the BPF information and facilitate the notification procedure

- 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

Meta SPC

- Similar compositions within a specified variation, which fall within the specified variations of the whole BPF

Meta SPC

- Similar uses resulting from the risk and efficacy assessment, which are associated to a common set of RMMs

- The same hazard and precautionary statements

- A common set of first aid instructions, disposal, storage and shelf life

Q&A

- **Q4:** Should concentrate and ready-to-use products be in the same or different meta-SPCs?

- **A:** In principle it is expected that concentrates will have different hazard and precautionary statements so they would have to be put in separate meta-SPCs (unless the concentrate and the RTU products have the same H&P statements).

Q&A

- **Q6:** Can a single application for a PT 14 BPF contain grain, wax block, paste and gel baits formulations, having each formulation its own level 2 meta-SPC?

- **A:** Yes, this may be possible as long as all the necessary data to support any proposed read across between formulations both in terms of palatability or field trials is submitted within the application.

Q&A

- **Q10:** Can the description of a use in a meta-SPC be formulated as "and/or" (e.g. target organisms, application methods)?

- **A:** No, in accordance with the agreed approach under document CA-Sept14-Doc.5.4-Final (SPC template), any use must be described clearly indicating which target organisms or applications methods are relevant for such a use.

The 4 elements in the assessment

- ***Similar composition***
- ***Similar uses***
- ***Similar levels of risk***
- ***Similar levels of efficacy***

Similar composition

- 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 ≠ 0).

- The formulation type has to be considered when evaluating "similar composition"
  - 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.
  - Liquid formulations (water-based, solvent-based, emulsion)
  - Concentrate and ready to use products

Similar uses

- Different similar uses within the PT(s) to which the BPF belongs can include
  - User categories
  - Target organisms
  - Application methods (e.g. spraying and brushing)
  - Applications rates and frequency
  - Fields of use (e.g. indoor or outdoor)

- 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

Similar levels of risk

- Different levels of acceptable risk resulting from the assessment of the maximum risks
  - to human health, animal health and the environment

Similar levels of risk

- BPF (1st level)
  - Shall consider the maximum risks to human health, animal health and the environment
  - Different RMMs within the same BPF
  - Different classification and labelling (C&L)

- Each *meta* SPC (2nd level)
  - Own set of RMMs
  - Hazard and precautionary statements must be the same
  - If overall “worst case” for the entire BPF is not possible, then focused assessment at *meta* SPC level

Similar levels of risk

- Where an eCA concludes that an unacceptable risk is identified for some uses within the whole BPF, the eCA can

  – Create a new *meta* SPC
  – Authorise some of the uses proposed within a given *meta* SPC only
  – Not authorise a proposed *meta* SPC

Similar levels of efficacy

- Different levels of proven efficacy resulting from the assessment of the minimum level of efficacy

Q&A

- **Q20:** How to understand "similar levels of efficacy" within one meta-SPC?

- **A:** The minimum level of efficacy for each use should be ensured at meta-SPC level for the different target organisms and application methods. The minimum efficacy for any use has to be above the minimal requirements within the available guidance.

Candidate for substitution

- 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.

Content of the BPF authorisation

- For dissemination and enforcement purposes Each and every product of a BPF should have its own SPC (“product-specific SPCs”)

- 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

- The authorisation decision for the BPF will only include a “BPF SPC”, which will include the three-level information for the authorised BPF (CA-May15-Doc.4.6.a-Final)

Post-authorisation notification

- Where a new product within a family is to be placed on the market, the authorisation holder shall notify 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 particular product is explicitly identified in the BPF authorisation
  - The variation in composition concerns only pigments, perfumes and dyes within the permitted variations in the BPF authorisation

Post-authorisation notification

- The notification shall only indicate the exact composition and trade name of the product, as well as the suffix to the authorisation number

- It is essential that the notification clearly identifies the *meta* SPC to which the product belongs

Post-authorisation notification

- 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

  – Update the “BPF SPC” by adding to the third level information the new product details
  – Make the “product-specific SPC”, as provided by the applicant and reviewed by the CA, available in the R4BP3 for dissemination purposes

Q&A

- **Q22:** Should a product-specific SPC include all the authorised uses in the meta-SPC, or only those uses that might be relevant for the individual product?

- **A:** Any product specific-SPC shall contain all the authorised uses within the meta-SPC to which the individual product belongs. This does not prevent though the AH from including just some of those authorised uses on the label of the individual product (see next Q&A).

Q&A

- **Q26:** Which authorisation number and trade name should be on the label of a product placed on the market without being notified because of a change concerning PPDs concentration only?

- **A:** Where an individual product of a BPF is subject to a change in PPDs not requiring notification, the product resulting from such a change shall be placed on the market with the same authorisation number. The same applies for the trade name, unless two or more different trade names have been allocated to the initial product and the applicant decides to place the product resulting from the change on the market with a different name.

Specifikke spørgsmål

- Q: Risikovurdering ift. dermal absorption når produktet indeholder varierende mængder a.s. og dermed kan påvirke absorptionen

- A: Der skal udføres en risikovurdering af begge koncentrationer hvis det ikke umiddelbart kan vurderes hvad der vil være worst case

Specifikke spørgsmål

- Q: Pigment pastaer. Kan have varierende indhold af hjælpestoffer og kan dermed bidrage til den samlede mængde i produktet af f.eks. vand.

- A: Tages med på CG møde