State of play on biocidal product family

ECHA biocides webinar

15 October 2020

Overview

- Scope
- Implementation of the BPF concept
- Tips for pre-submission meetings
- Support
- Authorisations for BPF UA
- Take home messages

Scope

- A development following the concept of frame formulations under the Biocidal Products Directive 98/8/EC.
- Article 3(1)(s) of the BPR: a 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 risks and efficacy
- All the above criteria shall be fulfilled to define a family

Implementation: 2014 Guidance

- CA-Nov14-Doc.5.8-Final rev3: Note for Guidance: ‘Implementing the new concept of biocidal product families’
  - Broad definition of ‘similar composition’; ‘similar uses’ and ‘similar levels of risk and efficacy’
  - Three levels of information at the SPC
    - Overall product composition of the family
    - Meta-SPCs
    - Individual biocidal products
  - All products within a biocidal product family are covered by the same authorisation under the Biocidal Products Regulation.
  - Post-authorisation notification of new products

Implementation: creation of a Working Party

- Set up to provide the Commission with recommendations to revise the Note for Guidance of 2014
- Mandate received by the ECHA Coordination Group in July 2017
- Membership: Competent authorities, accredited stakeholders associations, ECHA

Implementation: Guidance of 2019

- Problems with the former guidance addressed in the new guidance
  - Concept of similarity not well defined
  - Various interpretation by applicants
  - Uncertainty about the family design and on how to evaluate applications in a harmonized way
- Applicable since 1 October 2019
- Available in CIRCABC (CA-DocJuly19-Doc.4.2-Final-rev1)

Implementation: 2019 Guidance

- Clarify the ‘similarity’ concept for a more consistent interpretation
  - Similar composition (backbone composition) with specified variations (grouping of CoF)
  - Similar uses (matrix tool)
  - Similar levels of risk and efficacy (a significant portion of the BPF covered by core assessment)
- Describe best practice in pre-submission meetings
- Adress the splitting of families for ongoing applications and its consequences (IT, timelines, fees)
- Post autorisation notification of new products

Tips for pre-submission meeting(s)

- Seek the support of a competent authority as soon as possible
- Obtain the signed agreement at least 1 year before the expected date for submission
- Organise meeting(s) during the year before the submission
- Relevant items for discussion at the pre-submission meeting(s): see Annex I to the 2019 Guidance

Support

- CA-DocJuly19-Doc.4.2-Final-rev1 applies since 1 October 2019
- Support : National helpdesk list
- Private consultancy
- ECHA biocide day 2019
- ECHA website on supporting document: overview of BPF

Applications for BPF Union Authorisation

- Union authorisation at Union level
- First Union authorisation granted in 2018
- Since then 16 UA granted containing 105 products
- Number of MSCAs involved in UA : 13

Take home messages

- Be fully responsible for the content and quality of your dossier
- Arrange a pre-submission meeting with the authority
- Keep the size of your product family manageable
- Present in an appropriate way the uses applied for
- Provide robust explanation for the deviation to the general principles of the guidance
- Consult Annex VIII of the Note for Guidance for Q&A pairs on BPF related issues
- Consult the ECHA BPF webpage

Thank you

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