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Applications for a same biocidal product of an individual product of a biocidal product family

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The purpose of the document CA- March15-Doc4.7 - Final is to clarify whether an individual product as member of a biocidal product family can be chosen as reference product for a Same Biocidal Product application in accordance with Regulation (EU) 414/2013 (SBP Regulation).

For a SBP approval of a single biocidal product, it is important that the reference product can be clearly identified, and that the same product is identical to the reference product.

Taken the above into consideration for a Biocidal Product Family, the Commission considers that:

- any individual product of a biocidal product family can be accurately identified
- any difference between the same product and related product can be assessed by comparing the respective draft SPCs

Consequently, and read in connection with Article 17(3) of the BPR, the SBP Regulation can be interpreted as follows:

“Where a same product authorisation is sought for a BPF, the related reference product has to be understood as the "related reference BPF".

Where a same product authorisation is sought for a single biocidal product, the related reference product can be either a single biocidal product or an individual biocidal product belonging to a BPF authorisation.

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Differences between the same biocidal product/BPF and the related reference product/BPF may concern, among other information which can be the subject of an administrative change, the following:

- For a BPF, a reduced number of meta SPCs and/or reduced intended uses for certain meta SPCs compared to those in the related reference BPF.
- For a biocidal product, a number of reduced intended uses compared to those in the SPC of reference related product."

Examples for the specific differences listed above are shown in the annexes of the CA-document (CA- March15-Doc4.7 - Final).

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The authorization of a same biocidal product/BPF is a separate authorization and can be changed or cancelled independently from the related reference product/BPF.

It is important to note that SBP Regulation sets separate procedures for the same authorisations to be granted by national Competent Authorities or by the Commission. This means that an application for a same biocidal product/BPF shall follow the same procedure as the related reference product/BPF, e.g., where a BPF has been authorised for Union Authorization (UA), an application for a same BPF or a same biocidal product of one of the individual products of a BPF can only be submitted to ECHA as an application for Union authorisation.

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For the application for same biocidal product of an individual product of a BPF, specific information need to be submitted as a supporting document, such as:

- Reference case/authorization number of the reference BPF
- Product specific SPC generated for dissemination purposes
- Detailed description of the individual product (where SBP is linked to an application for BPF authorization)
- Differences between same product and reference product (i.e., trade names, different manufacturer/as supplier, reduced uses / claims, etc.)
- Identity confirmation (same and reference product are identical in terms of composition)
- Letter of Access to reference product data
- Letter of access to the active substance(s)
- Draft SPC for the same biocidal product

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Submission of the application can be properly done via R4BP.

For further information /support on same biocidal product application, please also consult the ECHA Website.

Sources

CA- March15-Doc4.7 - Final

(EU) 414/2013

ECHA – Same Biocidal Product Authorization

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