DISCLAIMER: This document has been agreed on 3 July 2018 during the CG-30 meeting. The document CA-Nov14-Doc.5.8-Final will be updated accordingly after the conclusion of the Working Party on the Biocidal Product Family concept.

Working Party BPF concept

Splitting of families for ongoing applications

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1. Introduction

During the evaluation, mutual recognition or peer review of an application for product authorisation, it is possible that a decision is taken that the original structure of a biocidal product family needs to be split due to the conclusion that the products in the family do not fulfil the definition of a biocidal product family in the BPR (i.e. not having either similar uses, composition or level of efficacy or risk).

This document summarises the agreed way forward related to the following points when a family is split:

- IT issues,
- Timelines,
- Fees,
- Other considerations.

2. How to address different issues when a BPF has to be split

In general, equal treatment of applicants should be ensured and there should not be an advantage for applications resulting from splitting a BPF compared to applications where the BPF had been correctly structured from the beginning.

IT issues

The following way forward was agreed:

- No modification of the sequence of tasks will be made in R4BP 3 to address the issue. The initial application will continue, but just with the products having similar uses, composition and levels of risk and efficacy. One or more new (product or product family) application(s) for authorisation should be submitted to address the part(s) of the original BPF that are no longer covered by the initial application.
- In order to follow a harmonised approach and to ensure that all Member States (MSs) treat applicants in an equal manner, the following was agreed: where the evaluating Competent Authority (eCA) would like to shorten the timelines of the new application resulting from splitting the original BPF, it will be the responsibility of the eCA to

manage the duration of each of the steps for the new application(s). For example:

- the validation task can be completed on the same day that the task is initiated,
- the evaluation of the phys-chem properties and where relevant, other parts of the assessment of the initial application, can be handed over for the assessment of the new application(s).

Timelines and legal deadlines in the BPR

It should be clarified that the submission of the initial application for the original BPF warrants that all the existing products initially covered by that BPF can benefit from the provisions of Article 89 of the BPR regarding the transitional period.

The following way forward was agreed:

- Splitting of the family will not result in the split product(s) that belonged to the original BPF as not being covered by the provisions under Article 89 of the BPR:
  - These products will continue to be allowed to be made available on the market and used in accordance with the national systems of MSs,
  - The three-year deadline in Article 89(3) of the BPR would count as from the active substance approval date; or the submission of the original application where the 3 year period is over for the relevant AS or PT.
- Applicants and eCAs will make use of their best endeavours to ensure that the split applications are handled in due time.

Fees

As mentioned above, in general, equal treatment of applicants should be ensured and there should not be an advantage for applications resulting from splitting of a BPF compared to applications where the BPF had been correctly structured from the beginning. However, fees should be proportionate to cover the amount of work performed by the relevant CA. The following way forward was agreed:

- Fees from MSs are decided at National level.
- ECHA fees: In case of UA procedures, the fee Regulation does not foresee any reduction when a new application is submitted. A new application for a product or product family will be treated as a new application in terms of fees.

Other considerations

The applicant may choose the most suitable product authorisation procedure for the application of the new product(s) or product family authorisation.

However, in the case of an applicant changing from a Union authorisation (UA) procedure to a mutual recognition (MR) procedure (or the other way around), it is strongly recommended that the eCA/refMS for the original UA/NA application is selected as the eCA/refMS for the new procedure. This way, the new procedure(s) can benefit from the initial assessment of the original application, and, where possible, from any fee waving by the eCA/refMS.

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