

DISCLAIMER: This document does not consist an exhaustive list of changes relevant for SBP applications.

How to classify and describe changes in application for same biocidal products

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Introduction

This is document provides examples of a description of the administrative changes and clarification on the administrative change number that needs to be included in the SBP applications. The list is available as an Annex to this document.

Annex: List of the administrative changes identified as relevant for SBP applications and corresponding change numbers

- i. Administrative changes referred to in **Section 1 of Title 1** of the Annex to Regulation (EU) No 354/2013 (changes requiring prior notification)

Detailed description of the change	Change number, according to the left column of the table in Section 1 of Title 1 of the Annex to Regulation (EU) No 354/2013
Change of the name of the biocidal product (family)	Change no. 1
Addition of trade names of the biocidal products	Change no. 2
A different authorisation holder for the same biocidal product application	Change no. 3
Addition of a manufacturer of the active substance or change in the manufacturer's identity or in manufacturing location	Change no. 5

- ii. Administrative changes referred to in **Section 2 of Title 1** of the Annex to Regulation (EU) No 354/2013

Detailed description of the change	Change number, according to the left column of the table in Section 2 of Title 1 of the Annex to Regulation (EU) No 354/2013
Change in the name, the administrative details or the formulating location of the biocidal product formulator, where the biocidal product composition and the formulating process remain unchanged.	Change no. 2
Deletion of a formulating location or a formulator of the biocidal product	Change no. 3
Addition of a formulator of the biocidal product	Change no. 4
Change in the name or the administrative details of a manufacturer of the active substance, where the manufacturing location and process remain unchanged and the manufacturer remains listed in accordance with Article 95(2) of Regulation (EU) No	Change no. 5

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Deletion of manufacturer or a manufacturing location of the active substance	Change no. 6
More precise instructions for use, where only wording but not content of instructions are changed	Change no. 7
Deletion of a use or target organism from the SPC of the SBP application (as a single biocidal product)	Change no. 8
Removal of a category of users	Change no. 9
Addition, replacement or modification of a measuring or administration device not relevant for the risk assessment and not regarded as a risk mitigation measure.	Change no. 10

Detailed description of the change	Associated change number, according to the left column of the table in Section 2 of Title 1 of the Annex to Regulation (EU) No 354/2013
Deletion of a meta-SPC in the SPC of the SBP application (as a BPF)	Change no. 8
Deletion of a product, use or target organism from a meta-SPC of the SBP application (as a BPF)	Change no. 8