# Supporting document for the application of a minor change to a national authorisation under Regulation (EU) No 354/2013

*Please note that your application cannot be processed if the supporting document is not included with your change application or properly filled in.*

**Authorisation(s) affected by the proposed change(s)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Product (family) name\*** | **Asset number\*** | **Reference Member State\*\*** | **Concerned Member States\*\*\*** |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. |

\*product/product family name and asset number should be indicated as given in R4BP3.

\*\*indicate the reference (one) Member State which will process the change request. If the changes are not sought in the Member State which evaluated the initial application, the applicant shall provide written confirmation that the new Member State CA agrees to be the reference Member State.

\*\*\*if applicable, indicate Member States, which will act as concerned Member States during processing of the change request.

**Description of all the proposed changes to the product**

Where a change leads to or is the consequence of other changes of the terms of the same authorisation, please include a description of the relation between the changes.

* + 1. **Minor change(s)**

Please provide a detailed description of the proposed change(s) clearly indicating whether the change is an addition or modification. In addition, please justify that the proposed change(s) do not adversely affect the conclusions previously reached concerning the compliance with the conditions set out in Article 19 of Regulation (EU) No 528/2012 (“BPR”). You should reflect on all following items:

* Do the physico-chemical properties, physical hazards and chemical identity fulfil the conditions of Art. 19(1)(c) and (d) of the BPR following the change?
* Is efficacy of the product(s) still sufficiently demonstrated following the change?
* Does the human health risk assessment remain unaffected by the change?
* Does the environmental risk assessment remain unaffected by the change?

For a biocidal product family, please indicate the meta-SPC(s)/product(s) concerned by the change.

Add rows, if necessary.

| **#** | **Detailed description of the change** | **Detailed justifications** | **Member State(s) in which the change has already been agreed** |
| --- | --- | --- | --- |
|  | Click or tap here to enter text. | **Physico-chemical properties, physical hazards and chemical identity:**Click or tap here to enter text.**Efficacy:**Click or tap here to enter text.**Human health:**Click or tap here to enter text.**Environment:**Click or tap here to enter text. | Click or tap here to enter text. |

* + 1. **Administrative change(s)** **(optional)[[1]](#footnote-1)**

Please select the nature of the change from the dropdown menu and provide a detailed description of the change. It should be clearly indicated whether the change concerns an addition, modification, or deletion. In case of modification, please provide both the old and new text.

For a biocidal product family, please indicate the meta SPC(s)/product(s) concerned by the change.

Please note that a transfer of the authorisation to a new holder (Change number 3 of Section 1 of Title 1 of the Annex to the Regulation (EU) No 354/2013) is only feasible through the submission of an NA-TRS application.

Add rows, if necessary.

|  |  |  |  |
| --- | --- | --- | --- |
| **#** | **Nature of the change** | **Detailed description of the change** | **Member State(s) in which the change has already been agreed** |
|  | Choose an item. | The proposed change concerns Choose an item.Click or tap here to enter text. | Click or tap here to enter text. |
|  | Choose an item. | The proposed change concerns Choose an item.Click or tap here to enter text. | Click or tap here to enter text. |
|  | Choose an item. | The proposed change concerns Choose an item.Click or tap here to enter text. | Click or tap here to enter text. |

**Grouping of changes**

If you indicated more than one proposed change, please justify the grouping of the changes in accordance with Article 4(2)(c) of Regulation (EU) No 354/2013:

[ ]  Article 4(2)(c)(2): one proposed minor change; all other proposed changes are a direct consequence of that change.

[ ]  Article 4(2)(c)(3): all proposed changes are a direct consequence of a new classification of the active substance(s) or non-active substance(s) contained in the product or of the product itself.

[ ]  Article 4(2)(c)(4): all proposed changes are a direct consequence of a specific condition of the authorisation.

**Annex I. List of all approved or pending changes for the biocidal product (family), following the first authorisation or the last renewal of the product (family)**

Please list all changes that you applied for since the first authorisation or the last renewal of the biocidal product/product family, whichever is the latest. For each change, please indicate the case number, the type: administrative (ADC), minor (MIC) or major change (MAC), the status: approved / pending and provide a brief description of the change. Add rows, if necessary.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **#** | **R4BP 3 case No** | **Type of change** | **Status** | **Brief description of the change** |
|  | Click or tap here to enter text. | Choose an item. | Choose an item. | Click or tap here to enter text. |
|  | Click or tap here to enter text. | Choose an item. | Choose an item. | Click or tap here to enter text. |

1. Used only if the minor change application is combined with administrative changes. [↑](#footnote-ref-1)