# Supporting document for the application of a major 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 R4BP 3.

\*\*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 (family)**

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. **Major 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. **Minor change(s) (optional)[[1]](#footnote-1)**

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)[[2]](#footnote-2)**

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)(1): one proposed major 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.

**New information on the active substance submitted as part of the application**

Indicate whether new information on the active substance is submitted as part of the application:

[ ]  yes

[ ]  no

N.B.: new information on the active substance is information that was not assessed during the approval of the active substance.

List in the table below all the new information on active substance submitted in the application.

| **Active substance[[3]](#footnote-3)** | **Location in the IUCLID dossier** | **File name in the IUCLID dossier** | **Title and author of the document** | **Area the new information concerns** | **Aim of the new information** |
| --- | --- | --- | --- | --- | --- |
| *Indicate here the name and respective CAS number of the active substance the new information is pertinent to.* | *Indicate here under which section of the active substance data set section of the IUCLID dossier is the document available.* | *Indicate here the file name of the document.* | *Indicate here the title and the author of the document concerning new information on the active substance.* | *Indicate here all the areas the new information on the active substance concerns. Indicate “APCP” if the new information concerns Analytical methods and Physico-Chemical Properties, “EFF” if it concerns efficacy, “ENV” if it concerns environment, “HH” if it concerns human health and “Animal health” if it concerns animal health.* | *Describe here more which endpoint value the new information on the active substance affects and in what way (e.g., refinement of an existing endpoint value, data for an endpoint not considered during the active substance approval etc.).* |
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**Indicate in the table below if the new information on the active substance submitted in your application has been submitted for another application and include the details of those applications:**

| **Application type** | **New information submitted in another application****(Y)** | **Name of applicant** | **Asset/case number** | **Date of submission** |
| --- | --- | --- | --- | --- |
| Technical equivalence assessment application that has been closed with the decision that technical assessment was established**[[4]](#footnote-4)** | *Indicate “Y” where the new information on the active substance submitted in your application was submitted in this application type and fill out the row accordingly, otherwise leave the entire row empty.*  | *Indicate the asset owner as stated in R4BP 3.* | *Provide the asset number assigned by R4BP 3. For ongoing applications provide the case number assigned by R4BP 3.* | *Indicate the date of submission as stated in R4BP 3.* |
| Inclusion in the Article 95 (active substance supplier) list application closed with the decision of inclusion on the Article 95 list2 | *Indicate “Y” where the new information on the active substance submitted in your application was submitted in this application type and fill out the row accordingly, otherwise leave the entire row empty.*  |  |  |  |
| Biocidal product/biocidal product family authorisation, renewal or change application2 | *Indicate “Y” where the new information on the active substance submitted in your application was submitted in this application type and fill out the row accordingly, otherwise leave the entire row empty. In case your product/product family contains more than one active substance indicate here which active substance the new information is pertinent to.* |  |  |  |

In case you indicated above that the new information on the active substance was submitted in a biocidal product or biocidal product family authorisation, change or renewal application, fill out the additional table below:

| **Asset/case number[[5]](#footnote-5)** | **Procedure type** | **Product name** | **Reference Member State/ evaluating Competent Authority** |
| --- | --- | --- | --- |
| *Provide the asset numbers assigned by R4BP 3 of all the relevant applications. For ongoing applications provide the case number assigned by R4BP 3 of all the relevant application types.* | *Indicate “NA” if the application concerns a national authorisation procedure. Indicate “SA” if the application concerns a simplified authorisation procedure. Indicate “UA” if the application concerns a Union authorisation procedure.* | *Indicate the product name as stated in R4BP 3.* | *Indicate here the reference Member State for the relevant national authorisation (NA) application, or evaluating Competent Authority for the relevant simplified (SA) or Union authorisation (UA) application.* |
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**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 major change application is combined with minor changes. [↑](#footnote-ref-1)
2. Used only if the major change application is combined with administrative changes. [↑](#footnote-ref-2)
3. Add rows if necessary [↑](#footnote-ref-3)
4. Add rows if you the new information on the active substance submitted in your application has been submitted for more than one application of this type. [↑](#footnote-ref-4)
5. Add rows if necessary [↑](#footnote-ref-5)