**NOTE:**

1. **This supporting document should only be used to submit applications for the renewal of several national authorisations linked together by mutual recognition** (i. e. in line with Regulation (EU) No 492/2014 ([link to legislation](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0492&qid=1400844968258&from=EN), [link to regulatory pages](http://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products/national-authorisation-renewal/mutual-recognition-evaluation-process))) **and for which there is an agreement between their authorisation holder(s) that the renewal applications are assessed together by the same reference Member State (rMS).**

If you want to apply for the renewal of the national authorisation of a single biocidal product or a biocidal product family in accordance with Article 31 of the BPR (i.e. one Member State), a different supporting document should be used, which is to be submitted to the relevant Member State only. ([link to legislation](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02012R0528-20220415&from=EN), [link to regulatory pages](http://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products/national-authorisation-renewal/national-authorisation-evaluation-process))

1. **The asset numbers of all the national authorisations which should be considered together by the rMS should be listed in this supporting document.** This is necessary to enable all involved MSs (rMS and concerned MSs (cMSs)) to know that the renewal application they receive is linked to other applications and which MS should act as rMS.
2. **If you are not able to group in only one submission all the renewal applications, all the submissions related to the group of national authorisations to be renewed together should contain the same supporting document (i.e., filled in with the same list of assets).** The different submissions may be done by one or by several authorisation holders.

# Supporting document for the grouped renewal of several national authorisations subject to mutual recognition under Article 2 of Regulation (EU) No 492/2014

*Please note that if the supporting document is not included or filled in the application may not be processed.*

1. **List of all the assets linked by mutual recognition and for which there is an agreement between their authorisation holder(s) that the renewal applications are assessed together by the same reference Member State:**

| **Reference Member State** | **Reference Asset number** | **Product name(s)** |
| --- | --- | --- |
| *Indicate here the reference member state for your application. If different from the MS which evaluated the initial application, please fill in the relevant information below* |  |  |

The reference Member State is different from the one which evaluated the initial application for national authorisation; the initial application was evaluated by [*please provide the name of that MS*] and its outcome was the creation of the following asset: [*provide the asset number*]

| **Asset number[[1]](#footnote-2)** | **Product name** | **Obtained by same product authorisation**  **(Y)** |
| --- | --- | --- |
| *Provide the asset numbers assigned by R4BP 3 of all the national authorisations linked by mutual recognition to be renewed together and for which there is an agreement between their authorisation holder(s) that the renewal applications are assessed together by the same reference Member State.* | *Indicate the product name as stated in R4BP 3.* | *Indicate “Y” where the asset has been granted through the same product authorisation from a mutually recognised asset, otherwise leave empty.* |
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1. **Statement:**

The undersigned applicant hereby confirms that the authorisations in question fall within the scope of Regulation (EU) No 492/2014, as provided for by its Article 1(2) and (3).

**Applicant company name:**

**Date of the application:**

1. **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[[2]](#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**[[3]](#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[[4]](#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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1. **List of all approved or pending changes for the product (family), following the first authorisation or the last renewal of the reference product (family)[[5]](#footnote-6)1**

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| **Change no.** | **BPD/BPR** | **R4BP3 case** | **ADC/MIC/MAC[[6]](#footnote-7)2** | **Short description of the nature of the change** |
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|  |  | **Countries where a decision on the change was either taken or is still pending** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | AT | BE | BG | CZ | CY | DE | DK | EE | EL | ES | FI | FR | HR | HU | IE | IT | LT | LV | LU | MT | NL | PL | PT | RO | SE | SI | SK | CH | IS | LI | NO |
| **Change no.[[7]](#footnote-8)1** | 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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Indicate either an A (approved), N (non-approved), P (pending) or an X (not applicable)

1. [↑](#footnote-ref-2)
2. Add rows if necessary [↑](#footnote-ref-3)
3. 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)
4. Add rows if necessary [↑](#footnote-ref-5)
5. 1 Add rows if necessary [↑](#footnote-ref-6)
6. 2 Administrative change/Minor change/Major change [↑](#footnote-ref-7)
7. 1 Add rows if necessary [↑](#footnote-ref-8)