

## **Renewal of a biocidal product**

Written by DPR Biocides - Anses - Last Updated Thursday, 07 July 2016 15:52

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**Regulations:** Chapter VI, Article 31 of Regulation (EU) No 528/2012

### **Timeframe**

Between 7 and 16 months depending on whether or not the competent assessment authority decides that the product assessment must be exhaustive.

**Validity of the MA:** 10 years

### **Fees payable to ANSES**

- With full assessment: 40,000 euros
- With limited assessment: 10,000 euros
- By mutual recognition: 15,000 euros

### **Composition of the dossier**

Initially, written agreement should be sought from the competent authority chosen for the assessment work. This document should be submitted to ECHA.

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| <b>Documents to be submitted on R4BP</b> |
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| <b>Language</b> |
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Draft SPC (xml format)

EN

Draft RCP (xml format)

FR

Completed technical IUCLID dossier. In section 13:

- Assessment of whether the conclusions of the previous assessment are still valid
- LoA and/or data on active substances
- Product MSDS in French
- MSDS of each ingredient
- Label / draft label in French (and instructions for use in French, if appropriate)
- 'Permission to refer' decision granted by ECHA – if necessary
- ECHA decision concerning technical equivalence – if necessary

FR or EN

Table of intended uses in Word format

FR or EN

Detailed composition form in Excel or Word format

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Written confirmation from the evaluating RMS stating their agreement to evaluate the application

List of all trade names included in each meta-SPC of the product family – only for family

FR

Supporting document (see ECHA website): “Renewal of single national authorisation”

FR or EN