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.

Documents to be submitted on R4BP

Language

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

FR or EN

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