Regulations: Chapter V, Articles 25 to 27 of Regulation (EU) No 528/2012

Timeframe

Around 4 months with the possibility of a maximum 3-month suspension of the assessment if additional information is necessary.

Comments

- The product must specifically meet the conditions set out in Article 25 of the BPR.
- Making the product available on the market of other Member States is done by notification according to Article 27 of the BPR. There is no procedure for mutual recognition.

Validity of the MA: 10 years.

Fees payable to ANSES

- for one PT and one category of users: 12,000 euros
- Per additional PT, for one category of users: + 2400 euros
- For one PT, per additional category of users: + 6000 euros

- Notification of a product that was subject to a simplified MA procedure – no payment

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 IUCLID dossier. In section 13:

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

FR or EN

Table of intended uses in Word format

FR or EN

Detailed composition form in Excel or Word format

FR or EN