Regulations

Chapter VI of Regulation (EU) No 528/2012

Timeframe

- Around 14 months with the possibility of a maximum 9-month suspension of the assessment if additional information is necessary.
- A synopsis of the information available via the link facilitates understanding of the overall procedure

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Validity of the MA

- 10 years as a general rule
- 4 or 5 years if the product contains an active substance meeting the criteria of Article 10(1) of the BPR and the comparative assessment provided for in Article 23(1) of the BPR enables the product to be authorised.

Fees payable to ANSES

- for one PT and one category of users: 40,000 euros
- Per additional PT, for one category of users: + 20,000 euros
- For one PT, per additional category of users: + 8000 euros

- product strictly identical to the reference product that enabled approval of the active substance: 12,000 euros

Composition of the dossier

Documents to be submitted on R4BP

Language

Draft SPC (xml format)

EN

Draft RCP (xml format)

FR

Completed technical IUCLID dossier. In section 13:

- PAR in ECHA format: http://echa.europa.eu/fr/support/guidance-on-reach-and-clp-implementation/formats

- 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

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

FR

Supporting document (see ECHA website): "Statement for national authorisation application"

FR or EN