Regulations: Chapter VIII of Regulation (EU) No 528/2012

Timeframe

Around 21 months with the possibility of a maximum 10-month suspension of the assessment if additional information is necessary.

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 (with the exception of subparagraph a), 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

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 the R4BP in French or English

Draft SPC

Completed IUCLID technical dossier.	In section 13 of IUCLID:

-	LoA and/or data on active substance(s)	
-	Proposed product SDS	**in French**
-	Draft label for the product/instructions for use	**in French,**
-	SDS for each product ingredient	
-	ECHA decision on the “permission to refer” – if necessary	
-	ECHA decision on technical equivalence – if necessary	

Provide confirmation that the conditions of use would be similar throughout the Union

Table of uses (varies according to the PT of the product – see the Documentation/Models section)

Table of detailed composition (see the Documentation/Models section)

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

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