Regulations: Chapter XII, Article 55(2) of Regulation (EU) No 528/2012

Comments

- If the substance is not ultimately approved, the marketing authorisation decision taken by the competent authority is annulled.
- The biocidal product contains (a) new active substance(s) undergoing assessment.
- The competent assessment authority has presented a recommendation with a view to approving the new active substance.

Validity of the MA: 3 years

Fees payable to ANSES

- For one application: 40,000 euros
- Transformation of a provisional MA into a MA: 5000 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:

- 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

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)

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

Supporting document (see ECHA website): "Application for provisional authorisation"