These are defined in Article 3-1-a-aa) of Regulation (EU) No 528/2012. Some must be notified prior to their implementation (e.g. product name, transfer of the authorisation to another holder, etc.) and others may be notified no later than one year after their implementation (e.g. certain amendments to the conditions of use, classification and labelling, etc.).

Regulations: Chapter II, Article 6 of Regulation (EU) No 354/2013

Timeframe

- 30 days after payment of the required fees
- An explanatory diagram of the procedure 

is available.

Validity of the MA

- Expiry date identical to that of the reference MA.
- No new MA number is issued.

Fees payable to ANSES

For all types of administrative changes: 800 euros per application

Composition of the dossier

Documents to be submitted on R4BP

Language

Draft RCP (xml format)

FR

Supporting document (see ECHA website) “Notification for an administrative change of a national/sim

FR or EN

Opinion issued by ECHA regarding the classification of the application – if necessary

EN

Cross-certificate of acceptance of the product transfer – in case of transfer of the authorisation

FR

Extract from the Commercial Register or any other official document showing the change in holder na

FR

LoA updated for AS and/or reference product – in case of transfer of the authorisation , or change in t

FR or EN

New LoA for active substance – in case of addition or modification of AS manufacturer

FR or EN