These are defined in Article 3-1-a-ab) of Regulation (EU) No 528/2012. They concern changes that are not likely to modify the marketing authorisation decision as regards compliance with the conditions laid down in Articles 19 and 25 of the BPR (e.g. size of the packaging, changes to the shelf life or storage conditions, etc.).

The authorisation must be granted before implementation of the minor change.

See the minor change explanatory document
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Regulations

- In cases where France is RMS: Chapter II, Article 7 of Regulation (EU) No 354/2013
- In cases where France is CMS: Chapter II Articles 9 and 9a of Regulation (EU) No 354/2013

Timeframe

- In cases where France is RMS: 7 months with the possibility of a maximum of 4 further months if additional information is necessary.
- In cases where France is CMS: 3 months with the possibility of a maximum of 3 further months if additional information is necessary

Validity of the MA

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

Fees payable to ANSES

- All minor changes: 2000 euros
- In the case of mutual recognition of minor change: 800 euros

Composition of the dossier

Documents to be submitted on the R4BP

Language

Draft SPC (xml format)

EN

Draft RCP (xml format)

FR

Completed IUCLID dossier including expected changes. In section 13:

- LoA and/or data on active substances
- Product MSDS in French

- Label / draft label in French (and instructions for use in French, if appropriate)
- Supporting documents to demonstrate that the proposed changes would not adversely affect the
- Opinion issued by ECHA regarding the classification of the application – if necessary
- ECHA decision concerning technical equivalence – if necessary
- Written confirmation from the evaluating RMS stating their agreement to evaluate the application

FR or EN

Supporting document (see ECHA website) “Application for a minor change of a national/simplified aut

FR or EN

Detailed composition form in Excel or Word format

FR or EN