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

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	paya	ble to	o ANS	SES
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-	ΑII	minor	changes:	2000	euros
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 In the case of mutual recognition of minor change: 800 et 	di illilloi change, ooo euro		יייטו	1 CCCGIIII	muluai	<i>-</i> UI	case	1111110	_
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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

Minor change

Written by DPR Biocides - Anses - Last Updated Thursday, 08 September 2016 16:05

- 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 websit	te) "Application for a	minor change of a	national/simplified aut
FR or EN				
Detailed co	omposition form in Excel or W	ord format		
FR or EN				