

Mutual recognition

Written by DPR Biocides - Anses - Last Updated Wednesday, 09 August 2017 13:32

In order to harmonise the European market and simplify the authorisation procedures for making products available on the market, the assessment of a biocidal product can be shared between the Member States concerned. In this case, the decision and, where appropriate, the authorisation conditions are harmonised. These are called "mutual recognition procedures" (described in Chapter VII of the BPR).

An application for mutual recognition may be made in several Member States at the time of submitting the first MA application on the European market. In this case, the mutual recognition is known as "simultaneous", and the corresponding procedure is described in Article 34 of Regulation (EU) No 528/2012. It should be noted that the French version of the Summary of Product Characteristics (*Résumé des Caractéristiques du Produit* - RCP) must be provided to ANSES within 10 days of the reference Member State sending the SPC in English.

- See explanatory diagram of the [simultaneous mutual recognition procedure](#) 

Mutual recognition can also be requested after a marketing authorisation has been granted by a Member State. In this case, the mutual recognition is known as "sequential", and the procedure is described in Article 33 of the BPR.

- See explanatory diagram of the [sequential mutual recognition procedure](#) 

Regulations

- Simultaneous (or parallel) mutual recognition: Chapter VII, Article 34 of Regulation (EU) No 528/2012
- Sequential mutual recognition: Chapter VII, Article 33 of Regulation (EU) No 528/2012

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Timeframe

- Simultaneous (or parallel) mutual recognition: around 18 months with the possibility of six additional months in the event of disagreement between the Member States concerned.
- Sequential mutual recognition: Around 6 months with the possibility of six additional months in the event of disagreement between the Member States concerned.

Validity of the MA: Expiry date identical to that of the reference MA.

Fees payable to ANSES

- for one PT and one category of users: 15,000 euros
- for one PT, per additional category of users: 8000 euros
- for one category of user, per additional PT: 7500 euros

Composition of the dossier for a sequential mutual recognition

Documents to be submitted on the R4BP

Language

Draft SPC (in .xml format)

FR

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Translation of the national MA

FR

LoA for active substances

FR or EN

LoA for product data if the MA holder is different between the RMS and the CMS

FR or EN

Draft label for the product/instructions for use, if appropriate

FR

Proposed product SDS

FR

List of all trade names included in each meta-SPC of the family product *for family application*

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FR

Composition of the dossier for a parallel mutual recognition

Documents to be submitted on R4BP

Language

Draft SPC (in .xml format

EN

LoA for active substances

FR or EN

LoA for product data if the MA holder is different between the RMS and the CMS

Mutual recognition

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FR or EN

SDS for the ingredients present in the product

FR or EN

List of all trade names included in each meta-SPC of the family product *for family application*

FR

The French summary of product characteristics (*Résumé des Caractéristiques du Produit - RCP*) must be submitted within 10 days of the reference MA being obtained.