

Renewal of approval of active substances

Written by DPR Biocides - Anses - Last Updated Monday, 11 July 2016 13:53

Regulations: Chapter III, Articles 14 and 15 of Regulation (EU) No 528/2012

Comments

- According to Article 12 of the BPR, it is necessary to check whether the substance still meets the conditions referred to in Article 4 or 5.
- Renewal of approval for an active substance must be requested at least 550 days before expiry of the approval date (or of the closest expiry date for multi-PT active substances).

Timeframe

Between 12 and 25 months depending on whether or not the competent assessment authority decides that renewal of the approval requires an exhaustive assessment of the application.

Validity of the approval: 15 years as a general rule

Fees payable to ANSES

- For one PT: 100,000 euros
- Per additional PT: + 50,000 euros

- For an active substance that is a micro-organism: 60,000 euros
- Per additional PT: + 30,000 euros

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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 R4BP

Language

Completed IUCLID dossier. In section 13:

- Draft assessment report (draft AR) whether the conclusions of the previous assessment are still valid
<https://assessment.a.eu/fr/support/guidance-on-reach-and-clp-implementation/formats>

- Letter of access – if necessary
- Justification concerning exclusion criteria – if necessary
- Permission to refer' decision granted by ECHA – if necessary
- Any other document not previously submitted to the R4BP

FR or EN

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

FR

Supporting document (see ECHA website): « Approval for active substance »

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