

Notification of an experiment (see Article 56 point 2 of the BPR) likely to result in the release into the environment of a non-authorised biocidal product or (new) non-approved active substance is sent to ANSES, which maintains a register of these experiments.

In the event that the conditions of the experiment would have a negative impact (adverse effects) on humans, animals or the environment, ANSES sends substantiated findings calling for the experiment to be prohibited to the Ministry of the Environment within 45 days of the date of notification.

Such an experiment is then subject to a prior "R&D MA" that determines its implementation conditions, after consultation with ANSES (see Article 56 point 3 of the BPR).

It is possible to apply directly for an MA without the need for notification.

Comments

Notifications for R&D relate solely to products that contain:

- approved active substances
- or new active substances that have not yet been approved

R&D notifications do not need to be made for products subject to the provisions of the transitional period (i.e. whose active substances are in the review programme) because these products can be placed on the market according to the national provisions.

Regulations: Article 56 of Regulation (EU) No 528/2012

Timeframe

- 45 days in the case of a notification
- 14 months in the case of an R&D authorisation

Validity of the MA: 2 years maximum

Fees payable to ANSES

- Notification of an R&D activity: 800 euros
- R&D authorisation: 3,000 euros

Composition of the dossier

It is important to provide a review of the available data. The dossier can therefore be supplemented with any other information deemed useful.

Documents to be submitted on the R4BP

Language

Completed IUCLID technical dossier (with information indicated in article 56.2 of BPR)

R&D and Tests

Written by DPR Biocides - Anses - Last Updated Thursday, 07 July 2016 15:48

FR or EN