Active substances are substances or micro-organisms (including viruses and fungi) exercising a general or specific action on or against harmful organisms. They can be produced in the framework of industrial processes or generated *in situ* using precursors. Regulation (EU) No 528/2012 provides for an assessment of biocidal active substances leading to a European positive list of approved active substances. This assessment is therefore the first step in the authorisation process.

Approval regulations and non-approval decisions for biocidal active substances are submitted to a vote by all the countries of the European Union in the framework of the Standing Committee on Biocidal Products, chaired by the European Commission. The decision on the approval of a biocidal active substance is therefore European. The approval regulation for an active substance sets a date for approval of the substance, which corresponds to the deadline for the submission, under the BPR, of marketing authorisation applications for products containing this active substance (for the PT(s) covered by this approval regulation).

Active substances meeting the exclusion criteria listed in Article 5 of the BPR are not approved.

If an active substance is not approved, deadlines for the withdrawal from the market of existing products – i.e. containing the active substance – are established by Article 89.2.b) of the BPR:

- End of making available on the market: 12 months maximum from the date of the non-approval decision
- End of use: 18 months maximum from the date of the non-approval decision

1- How are the active substances assessed?

The conditions for the approval of an active substance are essentially the same as under Directive 98/8/EC. For the purpose of achieving a higher level of protection, new provisions have been made in Regulation (EU) No 528/2012, including the introduction of criteria for the

exclusion (Article 5) and substitution (Article 10) of active substances, according to their hazard properties (CMR, PBT, etc.). Certain substances that were outside the scope of Directive 98/8/EC are now covered. This is the case with substances generated *in situ* or nanoparticle substances.

To assess the risks with regard to human or animal health and the environment, the assessment is carried out from three angles:

- assessment of the hazard intrinsic to the active substance;
- assessment of the exposure of humans, animals and the environment;
- assessment of the substance's efficacy.

The approval of an active substance therefore depends on its use and, accordingly, on the exposure of users and the environment. The approval of active substances is therefore specific to a product type (PT). It is thus "active substance/PT" combinations that have been notified to the review programme for active substances (Annex II, Part 1 of Regulation (EU) No 1062/2014) and that are evaluated and ultimately the subject (or not) of an approval regulation.

2 - How are the active substances notified to the review programme assessed?

The substances that have been listed in Annex II (Part 1) of Regulation (EU) No 1062/2014 are subject to an assessment in the framework of the review programme at European level.

This programme, which should be completed in 2024 (according to Regulation (EU) No 736/2013):

- provides for an assessment of the physico-chemical, toxicological, ecotoxicological and environmental properties and the efficacy of all active substances notified;
- assigns the assessment of each active substance to a Member State of the European Union, known as the Rapporteur Member State, on the basis of dossiers submitted by the

industrial company.

For more details, a diagram of the procedure for the approval of active substances is available.

3 - What is the procedure for approval of a new AS/PT combination?

The procedure for the approval of a new AS/PT combination, i.e. one absent from the review programme, takes place in the same way as the assessment of an AS/PT combination notified to the review programme.

Pending the approval of a new AS/PT combination, products belonging to this PT and containing this active substance may not be placed on the market. There is nevertheless a procedure for placing on a national market a biocidal product whose AS/PT combination is undergoing assessment: the provisional marketing authorisation. The conditions for issuing a provisional authorisation are specified in Article 55(2) of the BPR.

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: 2 years

Validity of the approval: 10 years as a general rule

Fees payable to ANSES

- For one PT: 200,000 euros
- Per additional PT: + 100,000 euros

- For an active substance that is a micro-organism: 120,000 euros
- Per additional PT: + 60,000 euros

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 technical dossier. In section 13:

- Pro position de rapport d'éva

http://echa.europa.eu/fr/support/guidance-on-reach-and-clp-implementation/formats

- Letter of Access – si nécessaire
- Justifications concerning the exclusion criteria if necessary (Article 5 of the BPR)
- ECHA decision on "permission to refer" if necessary (Article 63 of the BPR)

FR or EN

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

FR

Supporting document (see ECHA website): "Approval of active substance"

FR or EN