Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (Text with EEA relevance)

CHAPTER III

RENEWAL AND REVIEW OF APPROVAL OF AN ACTIVE SUBSTANCE

Article 12

Conditions for renewal

1 The Commission shall renew the approval of an active substance if the active substance still meets the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2).

2 In the light of scientific and technical progress, the Commission shall review and, where appropriate, amend the conditions specified for the active substance referred to in Article 4(3).

3 The renewal of an approval of an active substance shall be for 15 years for all product-types to which the approval applies, unless a shorter period is specified in the implementing regulation adopted in accordance with point (a) of Article 14(4) renewing such an approval.

Article 13

Submission and acceptance of applications

1 Applicants wishing to seek renewal of the approval of an active substance for one or more product-types shall submit an application to the Agency at least 550 days before the expiry of the approval. Where there are different expiry dates for different product-types, the application shall be submitted at least 550 days before the earliest expiry date.

2 When applying for the renewal of the approval of the active substance, the applicant shall submit:

a without prejudice to Article 21(1), all relevant data required under Article 20 that it has generated since the initial approval or, as appropriate, previous renewal; and

b its assessment of whether the conclusions of the initial or previous assessment of the active substance remain valid and any supporting information.

3 The applicant shall also submit the name of the competent authority of the Member State that it proposes should evaluate the application for renewal and provide written confirmation that that competent authority agrees to do so. That competent authority shall be the evaluating competent authority.

The Agency shall inform the applicant of the fees payable under Article 80(1) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating competent authority accordingly.

Upon receipt of the fees payable under Article 80(1), the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly, indicating the date of the acceptance.

4 An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraph 3 of this Article.

Article 14

Evaluation of applications for renewal

1 On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for approval or, as appropriate, the previous renewal, the evaluating competent authority shall, within 90 days of the Agency accepting an application in accordance with Article 13(3), decide whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary taking account of all product-types for which renewal is requested.

2 Where the evaluating competent authority decides that a full evaluation of the application is necessary, the evaluation shall be carried out in accordance with paragraphs 1, 2 and 3 of Article 8.

Where the evaluating competent authority decides that a full evaluation of the application is not necessary, it shall, within 180 days of the Agency accepting the application in accordance with Article 13(3), prepare and submit to the Agency a recommendation on the renewal of the approval of the active substance. It shall provide the applicant with a copy of its recommendation.

The evaluating competent authority shall, as soon as possible after the Agency has accepted an application, notify the applicant of the fees payable under Article 80(2). The evaluating competent authority shall reject the application if the applicant fails to pay the fees within 30 days of the notification and shall inform the applicant accordingly.

3 Within 270 days of receipt of a recommendation from the evaluating competent authority, if it has carried out a full evaluation of the application, or 90 days otherwise, the Agency shall prepare and submit to the Commission an opinion on renewal of the approval of the active substance.

4 The Commission shall, on receipt of the opinion of the Agency, adopt:

a an implementing regulation providing that the approval of an active substance is renewed for one or more product-types, and under which conditions; or

b an implementing decision that the approval of an active substance is not renewed.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

Article 9(2) shall apply.

5 Where, for reasons beyond the control of the applicant, the approval of the active substance is likely to expire before a decision has been taken on its renewal, the Commission shall, by means of implementing acts, adopt a decision postponing the expiry date of approval for a period sufficient to enable it to examine the application. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2).

6 Where the Commission decides not to renew or decides to amend the approval of an active substance for one or more product-types, the Member States or, in the case of a Union authorisation, the Commission shall cancel or, where appropriate, amend the authorisations of biocidal products of the product-type(s) concerned containing that active substance. Articles 48 and 52 shall apply accordingly.

Article 15

Review of approval of an active substance

1 The Commission may review the approval of an active substance for one or more product-types at any time where there are significant indications that the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2) are no longer met. The Commission may also review the approval of an active substance for one or more product-types at the request of a Member State if there are indications that the use of the active substance in biocidal products or treated articles raises significant concerns about the safety of such biocidal products or treated articles. The Commission shall make publicly available the information that it is carrying out a review and shall provide an opportunity for applicant to submit comments. The Commission shall take due account of those comments in its review.

Where those indications are confirmed, the Commission shall adopt an implementing Regulation amending the conditions of approval of an active substance or cancelling its approval. That implementing Regulation shall be adopted in accordance with the examination procedure referred to in Article 82(3). Article 9(2) shall apply. The Commission shall inform the initial applicants for the approval accordingly.

On duly justified imperative grounds of urgency the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 82(4).

2 The Commission may consult the Agency on any questions of a scientific or technical nature related to the review of approval of an active substance. The Agency shall, within 270 days of the request, prepare an opinion and submit it to the Commission.

3 Where the Commission decides to cancel or amend the approval of an active substance for one or more product-types, the Member States or, in the case of a Union authorisation, the Commission shall cancel or, where appropriate, amend the authorisations of biocidal products of the product-type(s) concerned containing that active substance. Articles 48 and 52 shall apply accordingly.

Article 16

Implementing measures

The Commission may adopt, by means of implementing acts, detailed measures for the implementation of Articles 12 to 15, further specifying the procedures for the renewal and review of the approval of an active substance. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
There are outstanding changes not yet made to Regulation (EU) No 528/2012 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.