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 VIII

UNION AUTHORISATIONS OF BIOCIDAL PRODUCTS

SECTION 1

Granting of Union authorisations

Article 41

Union authorisation

A Union authorisation issued by the Commission in accordance with this Section shall be valid throughout the Union unless otherwise specified. It shall confer the same rights and obligations in each Member State as a national authorisation. For those categories of biocidal products referred to in Article 42(1), the applicant may apply for Union authorisation as an alternative to applying for a national authorisation and mutual recognition.

Article 42

Biocidal products for which Union authorisation may be granted

1 Applicants may apply for Union authorisation for biocidal products which have similar conditions of use across the Union with the exception of biocidal products that contain active substances that fall under Article 5 and those of product-types 14, 15, 17, 20 and 21. The Union authorisation may be granted:

a from 1 September 2013, to biocidal products containing one or more new active substances and biocidal products of product-types 1, 3, 4, 5, 18 and 19;

b from 1 January 2017, to biocidal products of product-types 2, 6 and 13; and

c from 1 January 2020, to biocidal products of all remaining product-types.

2 The Commission shall by 1 September 2013 draw up guidance documents on the definition of ‘similar conditions of use across the Union’.

3 The Commission shall submit a report to the European Parliament and the Council on the application of this Article by 31 December 2017. That report shall contain an assessment of the exclusion of product-types 14, 15, 17, 20 and 21 from the Union authorisation.

The report shall, if appropriate, be accompanied by relevant proposals for adoption in accordance with the ordinary legislative procedure.

Article 43

Submission and validation of applications

1 Applicants wishing to apply for Union authorisation in accordance with Article 42(1) shall submit an application to the Agency, including a confirmation that the biocidal product would have similar conditions of use across the Union, informing the Agency of the name of the competent authority of the Member State that they propose should evaluate the application and providing written confirmation that that competent authority agrees to do so. That competent authority shall be the evaluating competent authority.

2 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 acceptance.

3 Within 30 days of the Agency accepting an application, the evaluating competent authority shall validate the application if the relevant information referred to in Article 20 has been submitted.

In the context of the validation referred to in the first subparagraph, the evaluating competent authority shall not make an assessment of the quality or the adequacy of the data or justifications submitted.

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

4 Where the evaluating competent authority considers that the application is incomplete, it shall inform the applicant what additional information is required for the evaluation of the application and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days.

The evaluating competent authority shall, within 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirement laid down in paragraph 3.

The evaluating competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant accordingly. In such cases, part of the fees paid in accordance with Article 80(1) and (2) shall be reimbursed.

5 On validating the application in accordance with paragraph 3 or 4, the evaluating competent authority shall, without delay, inform the applicant, the Agency and other competent authorities accordingly, indicating the date of the validation.

6 An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraph 2 of this Article.

Article 44

Evaluation of applications

1 The evaluating competent authority shall, within 365 days of the validation of an application, evaluate it in accordance with Article 19, including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 21(2), and send an assessment report and the conclusions of its evaluation to the Agency.

Prior to submitting its conclusions to the Agency, the evaluating competent authority shall provide the applicant with the opportunity to provide written comments on the conclusions of the evaluation within 30 days. The evaluating competent authority shall take due account of those comments when finalising its evaluation.

2 Where it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a specified time limit, and shall inform the Agency accordingly. The 365-day period referred to in paragraph 1 shall be suspended from the date of issue of the request until the date the information is received. However, the suspension shall not exceed 180 days in total other than in exceptional cases and where justified by the nature of the information requested.

3 Within 180 days of receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the authorisation of the biocidal product.

If the Agency recommends the authorisation of the biocidal product, the opinion shall contain at least the following elements:

a a statement on whether the conditions laid down in Article 19(1) are fulfilled, and a draft summary of biocidal product characteristics, as referred to in Article 22(2);

b where relevant, details of any terms or conditions which should be imposed on the making available on the market or use of the biocidal product;

c the final assessment report on the biocidal product.

4 Within 30 days of submitting its opinion to the Commission, the Agency shall transmit to the Commission, in all the official languages of the Union, the draft summary of the biocidal product characteristics, as referred to in Article 22(2), where applicable.

5 On receipt of the opinion of the Agency, the Commission shall adopt either an implementing regulation granting the Union authorisation to the biocidal product or an implementing decision stating that the Union authorisation of the biocidal product has not been granted. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

The Commission shall, at the request of a Member State, decide to adjust certain conditions of a Union authorisation specifically for the territory of that Member State or decide that a Union authorisation shall not apply in the territory of that Member State, provided that such a request can be justified on one or more of the grounds referred to in Article 37(1).

SECTION 2

Renewal of Union authorisations

Article 45

Submission and acceptance of applications

1 An application by or on behalf of an authorisation holder wishing to seek the renewal of a Union authorisation shall be submitted to the Agency at least 550 days before the expiry date of the authorisation.

[[F1]. . . . .**]**

2 When applying for renewal, 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 authorisation or, as appropriate, previous renewal; and

b its assessment of whether the conclusions of the initial or previous assessment of the biocidal product 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 to it 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 to it under Article 80(1), the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly, indicating the date of acceptance.

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

Textual Amendments

F1 Deleted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

Article 46

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 Union authorisation or, as appropriate, the previous renewal, the evaluating competent authority shall, within 30 days of the Agency accepting the application in accordance with Article 45(3), decide whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary.

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 and 2 of Article 44.

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, prepare and submit to the Agency a recommendation on the renewal of the authorisation. 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 the application, inform the applicant of the fees payable under Article 80(2) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

3 Within 180 days of receipt of a recommendation from the evaluating competent authority, the Agency shall prepare and submit to the Commission an opinion on the renewal of the Union authorisation.

4 On receipt of the opinion of the Agency, the Commission shall adopt either an implementing Regulation to renew the Union authorisation or an implementing decision to refuse to renew the Union authorisation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

The Commission shall renew a Union authorisation, provided that the conditions set out in Article 19 are still satisfied.

5 Where, for reasons beyond the control of the holder of the Union authorisation, no decision is taken on the renewal of the authorisation before its expiry, the Commission shall grant the renewal of the Union authorisation for the period necessary to complete the evaluation by means of implementing acts. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2).

Status:
Point in time view as at 31/01/2020.

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.