

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 2

Renewal of Union authorisations

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

Status: Point in time view as at 31/01/2020.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. (See end of Document for details)

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.