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 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).

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.