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 VII

MUTUAL RECOGNITION PROCEDURES

Article 34

Mutual recognition in parallel

1 Applicants wishing to seek the mutual recognition in parallel of a biocidal product which has not yet been authorised in accordance with Article 17 in any Member State shall submit to the competent authority of the Member State of its choice (‘the reference Member State’) an application containing:

a the information referred to in Article 20;

b a list of all other Member States where a national authorisation is sought (‘the Member States concerned’).

The reference Member State shall be responsible for the evaluation of the application.

2 The applicant shall, at the same time as submitting the application to the reference Member State in accordance with paragraph 1, submit to the competent authorities of each of the Member States concerned an application for mutual recognition of the authorisation for which it has applied to the reference Member State. This application shall contain:

a the names of the reference Member State and of the Member States concerned;

b the summary of biocidal product characteristics referred to in Article 20(1)(a)(ii) in such official languages of the Member States concerned as they may require.

3 The competent authorities of the reference Member State and of the Member States concerned shall inform the applicant of the fees payable in accordance with Article 80 and shall reject the application if the applicant fails to pay the fees within 30 days. They shall inform the applicant and the other competent authorities accordingly. Upon receipt of the fees payable under Article 80, the competent authorities of the reference Member State and of the Member States concerned shall accept the application and inform the applicant indicating the date of acceptance.

4 The reference Member State shall validate the application in accordance with Article 29(2) and (3) and inform the applicant and the Member States concerned accordingly.

[[F1]Within 365 days of validating an application, the reference Member State shall evaluate the application and draft an assessment report in accordance with Article 30 and shall send its assessment report and the summary of biocidal product characteristics to the Member States concerned and to the applicant.**]**

5 Within 90 days of receipt of the documents referred to in paragraph 4, and subject to Articles 35, 36 and 37, the Member States concerned shall agree on the summary of biocidal product characteristics, and shall record their agreement in the Register for Biocidal Products. The reference Member State shall enter the agreed summary of biocidal product characteristics

and the final assessment report in the Register for Biocidal Products, together with any agreed terms or conditions imposed on the making available on the market or use of the biocidal product.

6 Within 30 days of reaching agreement, the reference Member State and each of the Member States concerned shall authorise the biocidal product in conformity with the agreed summary of biocidal product characteristics.

7 Without prejudice to Articles 35, 36, and 37, if no agreement is reached within the 90-day period referred to in paragraph 5, each Member State that agrees to the summary of biocidal product characteristics referred to in paragraph 5 may authorise the product accordingly.

Textual Amendments

F1 Substituted 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).

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.