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 X

PARALLEL TRADE

Article 53

Parallel trade

[[F1]1 By way of derogation from Article 17, a competent authority of a Member State ('Member State of introduction') shall, at the request of the applicant, grant a parallel trade permit for a biocidal product that is authorised in another Member State ('Member State of origin') to be made available on the market and used in the Member State of introduction, if it determines in accordance with paragraph 3 that the biocidal product is identical to a biocidal product already authorised in the Member State of introduction ('the reference product').**]**

The applicant who intends to place the biocidal product on the market in the Member State of introduction shall submit the application for a parallel trade permit to the competent authority of the Member State of introduction.

The application shall be accompanied by the information referred to in paragraph 4 and all other information necessary to demonstrate that the biocidal product is identical to the reference product as defined in paragraph 3.

2 Where the competent authority of the Member State of introduction determines that a biocidal product is identical to the reference product, it shall grant a parallel trade permit within 60 days of receipt of the fees payable under Article 80(2). The competent authority of the Member State of introduction may request from the competent authority of the Member State of origin additional information necessary to determine whether the product is identical to the reference product. The competent authority of the Member State of origin shall provide the requested information within 30 days of receiving the request.

3 A biocidal product shall be considered as identical to the reference product only if all the following conditions are met:

- a they have been manufactured by the same company, by an associated undertaking or under license in accordance with the same manufacturing process;
- b they are identical in specification and content in respect of the active substances and the type of formulation;
- c they are the same in respect of the non-active substances present; and
- d they are either the same or equivalent in packaging size, material or form, in terms of the potential adverse impact on the safety of the product with regard to human health, animal health or the environment.

4 An application for a parallel trade permit shall include the following information and items:

- a name and authorisation number of the biocidal product in the Member State of origin;
- b name and address of the competent authority of the Member State of origin;

c name and address of the authorisation holder in the Member State of origin;

d original label and instructions for use with which the biocidal product is distributed in the Member State of origin if it is considered as necessary for the examination by the competent authority of the Member State of introduction;

e name and address of the applicant;

f name to be given to the biocidal product to be distributed in the Member State of introduction;

g a draft label for the biocidal product intended to be made available on the market in the Member State of introduction in the official language or languages of the Member State of introduction, unless that Member State provides otherwise;

h a sample of the biocidal product which is intended to be introduced if it is considered as necessary by the competent authority of the Member State of introduction;

i name and authorisation number of the reference product in the Member State of introduction.

The competent authority of the Member State of introduction may require a translation of the relevant parts of the original instructions for the use referred to in point (d).

5 The parallel trade permit shall prescribe the same conditions for making available on the market and use as the authorisation of the reference product.

6 The parallel trade permit shall be valid for the duration of authorisation of the reference product in the Member State of introduction.

If the authorisation holder of the reference product applies for cancellation of authorisation in accordance with Article 49 and the requirements of Article 19 are still fulfilled, the validity of the parallel trade permit shall expire on the date on which the authorisation of the reference product would normally have expired.

7 Without prejudice to specific provisions in this Article, Articles 47 to 50 and Chapter XV shall apply *mutatis mutandis* to biocidal products made available on the market under a parallel trade permit.

8 The competent authority of the Member State of introduction may withdraw a parallel trade permit if the authorisation of the introduced biocidal product is withdrawn in the Member State of origin because of safety or efficacy reasons.

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 31/12/2020.

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.