

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 37

Derogations from mutual recognition

1 By way of derogation from Article 32(2), any of the Member States concerned may propose to refuse to grant an authorisation or to adjust the terms and conditions of the authorisation to be granted, provided that such a measure can be justified on grounds of:

- a the protection of the environment;
- b public policy or public security;
- c the protection of health and life of humans, particularly of vulnerable groups, or of animals or plants;
- d the protection of national treasures possessing artistic, historic or archaeological value; or
- e the target organisms not being present in harmful quantities.

Any of the Member States concerned may, in particular, propose in accordance with the first subparagraph to refuse to grant an authorisation or to adjust the terms and conditions of the authorisation to be granted for a biocidal product containing an active substance to which Article 5(2) or Article 10(1) applies.

2 The Member State concerned shall communicate to the applicant a detailed statement of the grounds for seeking a derogation pursuant to paragraph 1 and shall seek to reach an agreement with the applicant on the proposed derogation.

If the Member State concerned is unable to reach agreement with the applicant or receives no reply from the applicant within 60 days of that communication it shall inform the Commission. In that case, the Commission:

- a may ask the Agency for an opinion on scientific or technical questions raised by the applicant or the Member State concerned;
- b shall adopt a decision on the derogation in accordance with the examination procedure referred to in Article 82(3).

The Commission's decision shall be addressed to the Member State concerned and the Commission shall inform the applicant thereof.

The Member State concerned shall take necessary measures to comply with the Commission's decision within 30 days of its notification.

3 If the Commission has not adopted a decision pursuant to paragraph 2 within 90 days of being informed in accordance with the second subparagraph of paragraph 2, the Member State concerned may implement the derogation proposed pursuant to paragraph 1.

Status: Point in time view as at 31/01/2020.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

[^{F1}While the procedure under this Article is ongoing, the Member States' obligation to authorise a biocidal product within three years of the date of approval, referred to in the first subparagraph of Article 89(3), shall be temporarily suspended.]

4 By way of derogation from Article 32(2), a Member State may refuse to grant authorisations for product-types 15, 17 and 20 on grounds of animal welfare. Member States shall without delay inform other Member States and the Commission of any decision taken in this respect and its justification.

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:

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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.