

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 IX

CANCELLATION, REVIEW AND AMENDMENT OF AUTHORISATIONS

Article 48

Cancellation or amendment of an authorisation

1 Without prejudice to Article 23, the competent authority of a Member State or, in the case of a Union authorisation, the Commission shall at any time cancel or amend an authorisation it has granted where it considers that:

- a the conditions referred to in Article 19 or, where relevant, in Article 25 are not satisfied;
- b the authorisation was granted on the basis of false or misleading information; or
- c the authorisation holder has failed to comply with its obligations under the authorisation or this Regulation.

2 Where the competent authority or, in the case of a Union authorisation, the Commission, intends to cancel or amend an authorisation, it shall inform the authorisation holder thereof and give it the opportunity to submit comments or additional information within a specified time limit. The evaluating competent authority or, in the case of a Union authorisation, the Commission, shall take due account of those comments when finalising its decision.

3 Where the competent authority or, in the case of a Union authorisation, the Commission, cancels or amends an authorisation in accordance with paragraph 1, it shall without delay notify the authorisation holder, the competent authorities of other Member States and, where relevant, the Commission.

Competent authorities that have issued authorisations under the mutual recognition procedure for biocidal products for which the authorisation has been cancelled or amended shall, within 120 days of the notification, cancel or amend the authorisations and shall notify the Commission accordingly.

In the case of disagreement between competent authorities of certain Member States concerning national authorisations subject to mutual recognition the procedures laid down in Articles 35 and 36 shall apply *mutatis mutandis*.

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Point in time view as at 31/01/2020.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.