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 47

Obligation for notification of unexpected or adverse effects

1 On becoming aware of information concerning the authorised biocidal product, or the active substance(s) it contains, that may affect the authorisation, the holder of an authorisation shall without delay notify the competent authority that granted the national authorisation and the Agency or, in the case of a Union authorisation, the Commission and the Agency. In particular, the following shall be notified:

a new data or information on the adverse effects of the active substance or biocidal product for humans, in particular vulnerable groups, animals or the environment;

b any data indicating the potential of the active substance for the development of resistance;

c new data or information indicating that the biocidal product is not sufficiently effective.

2 The competent authority that granted the national authorisation or, in the case of a Union authorisation, the Agency, shall examine whether the authorisation needs to be amended or cancelled in accordance with Article 48.

3 The competent authority that granted the national authorisation or, in the case of a Union authorisation, the Agency, shall without delay notify competent authorities of other Member States and, where appropriate, the Commission of any such data or information it receives.

Competent authorities of Member States that have issued a national authorisation for the same biocidal product under the mutual recognition procedure shall examine whether the authorisation needs to be amended or cancelled in accordance with Article 48.

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*.

Article 49

Cancellation of an authorisation at the request of the authorisation holder

At the reasoned request of an authorisation holder, the competent authority that granted the national authorisation or, in the case of Union authorisation, the Commission shall cancel the authorisation. Where such a request concerns a Union authorisation, it shall be submitted to the Agency.

Article 50

Amendment of an authorisation at the request of the authorisation holder

1 Amendments to the terms and conditions of an authorisation shall be made only by the competent authority that authorised the biocidal product concerned, or in the case of a Union authorisation, by the Commission.

2 An authorisation holder seeking to change any of the information submitted in relation to the initial application for authorisation of the product shall apply to the competent authorities of relevant Member States having authorised the biocidal product concerned, or in the case of a Union authorisation, the Agency. Those competent authorities shall decide, or, in the case of a Union authorisation, the Agency shall examine and the Commission decide whether the conditions of Article 19 or, where relevant, Article 25 are still met and whether the terms and conditions of the authorisation need to be amended.

The application shall be accompanied by the fees payable under Article 80(1) and (2).

3 An amendment to an existing authorisation shall fall under one of the following categories of changes:

a administrative change;

b minor change; or

c major change.

Article 51

Detailed rules

In order to ensure a harmonised approach to the cancellation and amendment of authorisations, the Commission shall lay down detailed rules for the application of Articles 47 to 50 by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

The rules referred to in the first paragraph of this Article shall be based, inter alia, on the following principles:

(a) a simplified notification procedure shall be applied for administrative changes;

(b) a reduced evaluation period shall be established for minor changes;

(c) in the case of major changes, the evaluation period shall be proportionate to the extent of the proposed change.

[[F1]*Article 52*

Period of grace

Notwithstanding Article 89, where the competent authority or, in the case of a biocidal product authorised at Union level, the Commission, cancels or amends an authorisation or decides not to renew it, it shall grant a period of grace for the making available on the market and use of existing stocks, except in cases where continued making available on the market or use of the biocidal product would constitute an unacceptable risk to human health, animal health or the environment.

The period of grace shall not exceed 180 days for the making available on the market and an additional maximum period of 180 days for the use of existing stocks of the biocidal products concerned.**]**

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.