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 32

Authorisation through mutual recognition

1 Applications for mutual recognition of a national authorisation shall be made in accordance with the procedures set out in Article 33 (mutual recognition in sequence) or Article 34 (mutual recognition in parallel).

2 Without prejudice to Article 37, all Member States receiving applications for mutual recognition of a national authorisation for a biocidal product shall, in accordance with and subject to the procedures set out in this Chapter, authorise the biocidal product under the same terms and conditions.

Article 33

Mutual recognition in sequence

1 Applicants wishing to seek the mutual recognition in sequence, in one or more Member States ('the Member States concerned'), of the national authorisation of a biocidal product already granted in another Member State in accordance with Article 17 ('the reference Member State') shall submit an application to each of the competent authorities of the Member States concerned containing, in each case, a translation of the national authorisation granted by the reference Member State into such official languages of the Member State concerned as it may require.

The competent authorities of the Member States concerned shall inform the applicant of the fees payable under 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 Member States concerned shall accept the application and inform the applicant indicating the date of acceptance.

2 Within 30 days of acceptance referred to in paragraph 1, the Member States concerned shall validate the application and inform the applicant accordingly, indicating the date of the validation.

Within 90 days of validating the application, and subject to Articles 35, 36 and 37, the Member States concerned shall agree on the summary of biocidal product characteristics referred to in Article 22(2) and shall record their agreement in the Register for Biocidal Products.

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

4 Without prejudice to Articles 35, 36, and 37, if no agreement is reached within the 90-day period referred to in the second subparagraph of paragraph 2, each Member State that agrees to the summary of biocidal product characteristics referred to in paragraph 2, may authorise the product accordingly.

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.

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(3) 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.

Article 35

Referral of objections to the coordination group

1 A coordination group shall be set up to examine any question, other than matters referred to in Article 37, relating to whether a biocidal product for which an application for mutual recognition has been made in accordance with Article 33 or 34 meets the conditions for granting an authorisation laid down in Article 19.

All Member States and the Commission shall be entitled to participate in the work of the coordination group. The Agency shall provide the secretariat of the coordination group.

The coordination group shall establish its rules of procedure.

2 If any of the Member States concerned considers that a biocidal product assessed by the reference Member State does not meet the conditions laid down in Article 19, it shall send a detailed explanation of the points of disagreement and the reasons for its position to the reference Member State, the other Member States concerned, the applicant, and, where applicable, to the authorisation holder. The points of disagreement shall be referred without delay to the coordination group.

3 Within the coordination group, all Member States referred to in paragraph 2 of this Article shall use their best endeavours to reach agreement on the action to be taken. They shall allow the applicant the opportunity to make its point of view known. Where they reach agreement within 60 days of the referral of the points of disagreement referred to in paragraph 2 of this Article, the reference Member State shall record the agreement in the Register for Biocidal Products. The procedure shall then be considered to be closed and the reference Member State and each of the Member States concerned shall authorise the biocidal product in accordance with Article 33(4) or Article 34(6) as appropriate.

Article 36

Referral of unresolved objections to the Commission

1 If the Member States referred to in Article 35(2) fail to reach agreement within the 60-day period laid down in Article 35(3), the reference Member State shall immediately inform the Commission, and provide it with a detailed statement of the matters on which Member States have been unable to reach agreement and the reasons for their disagreement. A copy of that statement shall be forwarded to the Member States concerned, the applicant and, where applicable, the authorisation holder.

2 The Commission may ask the Agency for an opinion on scientific or technical questions raised by Member States. Where the Commission does not ask the Agency for an opinion it shall provide the applicant and, where applicable, the authorisation holder with the opportunity to provide written comments within 30 days.

3 The Commission shall adopt, by means of implementing acts, a decision on the matter referred to it. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

4 The decision referred to in paragraph 3 shall be addressed to all Member States and reported for information to the applicant and, where applicable, the authorisation holder. The Member States concerned and the reference Member State shall, within 30 days of notification of the decision, either grant, refuse to grant or cancel the authorisation, or vary its terms and conditions as necessary to comply with the decision.

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.

While the procedure under this Article is ongoing, the Member States' obligation to authorise a biocidal product within two 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.

Article 38

Opinion of the Agency

1 If so requested by the Commission pursuant to Article 36(2) or Article 37(2), the Agency shall issue an opinion within 120 days from the date on which the matter in question was referred to it.

2 Before issuing its opinion, the Agency shall provide the applicant and, where applicable, the authorisation holder with an opportunity to provide written comments within a specified time limit not exceeding 30 days.

The Agency may suspend the time limit referred to in paragraph 1 to allow the applicant or the authorisation holder to prepare the comments.

Article 39

Application for mutual recognition by official or scientific bodies

1 Where no application for a national authorisation has been submitted in a Member State for a biocidal product that is already authorised in another Member State, official or scientific bodies involved in pest control activities or the protection of public health may apply, under the mutual recognition procedure provided for in Article 33 and with the consent of the authorisation holder in that other Member State, for a national authorisation for the same biocidal product, with the same use and the same conditions for use as in that Member State.

The applicant shall demonstrate that the use of such a biocidal product is of general interest for that Member State.

The application shall be accompanied by the fees payable under Article 80.

2 Where the competent authority of the Member State concerned considers that the biocidal product fulfils the conditions referred to in Article 19 and the conditions under this Article are met, the competent authority shall authorise the making available on the market and use of the biocidal product. In that case, the body that made the application shall have the same rights and obligations as other authorisation holders.

Article 40

Supplementary rules and technical guidance notes

The Commission shall be empowered to adopt delegated acts in accordance with Article 83 laying down supplementary rules for the renewal of authorisations subject to mutual recognition.

The Commission shall also draw up technical guidance notes to facilitate the implementation of this Chapter and, in particular, Articles 37 and 39.

Status:
Point in time view as at 22/05/2012.

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.