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 V

SIMPLIFIED AUTHORISATION PROCEDURE

Article 25

Eligibility for the simplified authorisation procedure

For eligible biocidal products, an application for authorisation may be made under a simplified authorisation procedure. A biocidal product shall be eligible if all the following conditions are met:

(a) all the active substances contained in the biocidal product appear in Annex I and satisfy any restriction specified in that Annex;

(b) the biocidal product does not contain any substance of concern;

(c) the biocidal product does not contain any nanomaterials;

(d) the biocidal product is sufficiently effective; and

(e) the handling of the biocidal product and its intended use do not require personal protective equipment.

Article 26

Applicable procedure

1 Applicants seeking the authorisation of a biocidal product meeting the conditions of Article 25 shall submit an application to the Agency, informing it of the name of the competent authority of the Member State that it proposes should evaluate the application and providing written confirmation that that competent authority agrees to do so. That competent authority shall be the evaluating competent authority.

2 The evaluating competent authority shall inform the applicant of the fees payable under Article 80(2) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

Upon receipt of the fees payable under Article 80(2), the evaluating competent authority shall accept the application and inform the applicant accordingly, indicating the date of the acceptance.

3 Within 90 days of accepting an application, the evaluating competent authority shall authorise the biocidal product if satisfied that the product meets the conditions laid down in Article 25.

4 Where the evaluating competent authority considers that the application is incomplete, it shall inform the applicant as to what additional information is required and shall set a

reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days.

The evaluating competent authority shall, within 90 days of receipt of the additional information, authorise the biocidal product if satisfied, on the basis of the additional information submitted, that the product meets the conditions laid down in Article 25.

The evaluating competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant accordingly. In such cases, where fees have been paid, part of the fees paid in accordance with Article 80(2) shall be reimbursed.

Article 27

Making available on the market of biocidal products authorised in accordance with the simplified authorisation procedure

1 A biocidal product authorised in accordance with Article 26 may be made available on the market in all Member States without the need for mutual recognition. However, the authorisation holder shall notify each Member State no later than 30 days before placing the biocidal product on the market within the territory of that Member State and shall use the official language or languages of that Member State in the product's labelling, unless that Member State provides otherwise.

2 Where a Member State other than that of the evaluating competent authority considers that a biocidal product authorised in accordance with Article 26 has not been notified or labelled in accordance with paragraph 1 of this Article or does not meet the requirements of Article 25, it may refer that matter to the coordination group established in accordance with Article 35(1). Article 35(3) and Article 36 shall apply *mutatis mutandis*.

Where a Member State has valid reasons to consider that a biocidal product authorised in accordance with Article 26 does not meet the criteria laid down in Article 25 and a decision pursuant to Articles 35 and 36 has not yet been taken, that Member State may provisionally restrict or prohibit making available on the market or use of that product on its territory.

Article 28

Amendment of Annex I

1 The Commission shall be empowered to adopt delegated acts in accordance with Article 83 amending Annex I, after receiving the opinion of the Agency, in order to include active substances provided that there is evidence that they do not give rise to concern according to paragraph 2 of this Article.

2 Active substances give rise to concern where:

a they meet the criteria for classification according to Regulation (EC) No 1272/2008 as:

— explosive/highly flammable,

— organic peroxide,

— acutely toxic of category 1, 2 or 3,

— corrosive of category 1A, 1B or 1C,

— respiratory sensitiser,

— skin sensitiser,
— germ cell mutagen of category 1 or 2;
— carcinogen of category 1 or 2,
— human reproductive toxicant of category 1 or 2 or with effects on or via lactation,
— specific target organ toxicant by single or repeated exposure, or
— toxic to aquatic life of acute category 1;

b they fulfil any of the substitution criteria set out in Article 10(1); or

c they have neurotoxic or immunotoxic properties.

Active substances also give rise to concern, even if none of the specific criteria in points (a) to (c) are met, where a level of concern equivalent to that arising from points (a) to (c) can be reasonably demonstrated based on reliable information.

3 The Commission shall also be empowered to adopt delegated acts in accordance with Article 83 amending Annex I, after receiving the opinion of the Agency, in order to restrict or to remove the entry for an active substance if there is evidence that biocidal products containing that substance do not, in certain circumstances, satisfy the conditions set out in paragraph 1 of this Article or in Article 25. Where imperative grounds of urgency so require, the procedure provided for in Article 84 shall apply to delegated acts adopted pursuant to this paragraph.

4 The Commission shall apply paragraph 1 or 3 at its own initiative or at the request of an economic operator or a Member State providing the necessary evidence as referred to in those paragraphs.

Whenever the Commission amends Annex I it shall adopt a separate delegated act in respect of each substance.

5 The Commission may adopt implementing acts further specifying the procedures to be followed with respect to an amendment of Annex I. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).