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 II

APPROVAL OF ACTIVE SUBSTANCES

Article 4

Conditions for approval

1 An active substance shall be approved for an initial period not exceeding 10 years if at least one biocidal product containing that active substance may be expected to meet the criteria laid down in point (b) of Article 19(1) taking into account the factors set out in Article 19(2) and (5). An active substance that falls under Article 5 may only be approved for an initial period not exceeding five years.

2 The approval of an active substance shall be restricted to those product-types for which relevant data have been submitted in accordance with Article 6.

3 The approval shall specify the following conditions, as appropriate:

- a the minimum degree of purity of the active substance;
- b the nature and maximum content of certain impurities;
- c the product-type;
- d manner and area of use including, where relevant, use in treated articles;
- e designation of categories of users;
- f where relevant, characterisation of the chemical identity with regard to stereoisomers;
- g other particular conditions based on the evaluation of the information related to that active substance;
- h the date of approval and the expiry date of the approval of the active substance.

4 The approval of an active substance shall not cover nanomaterials except where explicitly mentioned.

Article 5

Exclusion criteria

1 Subject to paragraph 2, the following active substances shall not be approved:

- a active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, carcinogen category 1A or 1B;
- b active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, mutagen category 1A or 1B;
- c active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, toxic for reproduction category 1A or 1B;

d active substances which, on the basis of the criteria specified pursuant to the first subparagraph of paragraph 3 or, pending the adoption of those criteria, on the basis of the second and third subparagraphs of paragraph 3, are considered as having endocrine-disrupting properties that may cause adverse effects in humans or which are identified in accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties;

e active substances which meet the criteria for being PBT or vPvB according to Annex XIII to Regulation (EC) No 1907/2006.

2 Without prejudice to Article 4(1), active substances referred to in paragraph 1 of this Article may be approved if it is shown that at least one of the following conditions is met:

a the risk to humans, animals or the environment from exposure to the active substance in a biocidal product, under realistic worst case conditions of use, is negligible, in particular where the product is used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment;

b it is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; or

c not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance.

When deciding whether an active substance may be approved in accordance with the first subparagraph, the availability of suitable and sufficient alternative substances or technologies shall be a key consideration.

The use of a biocidal product containing active substances approved in accordance with this paragraph shall be subject to appropriate risk-mitigation measures to ensure that exposure of humans, animals and the environment to those active substances is minimised. The use of the biocidal product with the active substances concerned shall be restricted to Member States in which at least one of the conditions set out in this paragraph is met.

3 No later than 13 December 2013, the Commission shall adopt delegated acts in accordance with Article 83 specifying scientific criteria for the determination of endocrine-disrupting properties.

Pending the adoption of those criteria, active substances that are classified in accordance with Regulation (EC) No 1272/2008 as, or meet the criteria to be classified as, carcinogen category 2 and toxic for reproduction category 2, shall be considered as having endocrine-disrupting properties.

Substances such as those that are classified in accordance with Regulation (EC) No 1272/2008 as, or that meet the criteria to be classified as, toxic for reproduction category 2 and that have toxic effects on the endocrine organs, may be considered as having endocrine-disrupting properties.

Article 6

Data requirements for an application

1 An application for approval of an active substance shall contain at least the following elements:

a a dossier for the active substance satisfying the requirements set out in Annex II;

b a dossier satisfying the requirements set out in Annex III for at least one representative biocidal product that contains the active substance; and

c if the active substance meets at least one of the exclusion criteria listed in Article 5(1), evidence that Article 5(2) is applicable.

2 Notwithstanding paragraph 1, the applicant need not provide data as part of the dossiers required under points (a) and (b) of paragraph 1 where any of the following applies:

a the data are not necessary owing to the exposure associated with the proposed uses;

b it is not scientifically necessary to supply the data; or

c it is not technically possible to generate the data.

However, sufficient data shall be provided in order to make it possible to determine whether an active substance meets the criteria referred to in Article 5(1) or Article 10(1), if required by the evaluating competent authority under Article 8(2).

3 An applicant may propose to adapt the data as part of the dossiers required under points (a) and (b) of paragraph 1 in accordance with Annex IV. The justification for the proposed adaptations to the data requirements shall be clearly stated in the application with a reference to the specific rules in Annex IV.

4 The Commission shall be empowered to adopt delegated acts in accordance with Article 83 specifying criteria for determining what constitutes adequate justification to adapt the data requirements under paragraph 1 of this Article on the grounds referred to in point (a) of paragraph 2 of this Article.

Article 7

Submission and validation of applications

1 The applicant shall submit an application for approval of an active substance, or for making subsequent amendments to the conditions of approval of an active substance, 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 Agency shall inform the applicant of the fees payable under Article 80(1) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating competent authority accordingly.

Upon receipt of the fees payable under Article 80(1), the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly, indicating the date of the acceptance of the application and its unique identification code.

3 Within 30 days of the Agency accepting an application, the evaluating competent authority shall validate the application if the data required in accordance with points (a) and (b) and, where relevant, point (c) of Article 6(1), and any justifications for the adaptation of data requirements, have been submitted.

In the context of the validation referred to in the first subparagraph, the evaluating competent authority shall not make an assessment of the quality or the adequacy of the data or justifications submitted.

The evaluating competent authority shall, as soon as possible after the Agency has accepted an application, 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.

4 Where the evaluating competent authority considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the validation of the application 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 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirement laid down in paragraph 3.

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 and the Agency accordingly. In such cases, part of the fees paid in accordance with Article 80(1) and (2) shall be reimbursed.

5 On validating an application in accordance with paragraph 3 or 4, the evaluating competent authority shall without delay inform the applicant, the Agency and other competent authorities accordingly, indicating the date of the validation.

6 An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraph 2 of this Article.

Article 8

Evaluation of applications

1 The evaluating competent authority shall, within 365 days of the validation of an application, evaluate it in accordance with Articles 4 and 5, including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 6(3), and send an assessment report and the conclusions of its evaluation to the Agency.

Prior to submitting its conclusions to the Agency, the evaluating competent authority shall give the applicant the opportunity to provide written comments on the assessment report and on the conclusions of the evaluation within 30 days. The evaluating competent authority shall take due account of those comments when finalising its evaluation.

2 Where it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a specified time limit, and shall inform the Agency accordingly. As specified in the second subparagraph of Article 6(2), the evaluating competent authority may, as appropriate, require the applicant to provide sufficient data to permit a determination of whether an active substance meets the criteria referred to in Article 5(1) or Article 10(1). The 365-day period referred to in paragraph 1 of this Article shall be suspended from the date of issue of the request until the date the information is received. The suspension shall not exceed 180 days in total unless it is justified by the nature of the data requested or by exceptional circumstances.

3 Where the evaluating competent authority considers that there are concerns for human health, animal health or the environment as a result of the cumulative effects from the use of biocidal products containing the same or different active substances, it shall document its concerns in accordance with the requirements of the relevant parts of Section II.3 of Annex XV to Regulation (EC) No 1907/2006 and include this as part of its conclusions.

4 Within 270 days of receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the approval of the active substance having regard to the conclusions of the evaluating competent authority.

Article 9

Approval of an active substance

1 The Commission shall, on receipt of the opinion of the Agency referred to in Article 8(4), either:

a adopt an implementing Regulation providing that an active substance is approved, and under which conditions, including the dates of approval and of expiry of the approval; or

b in cases where the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2), are not satisfied or where the requisite information and data have not been submitted within the prescribed period, adopt an implementing decision that an active substance is not approved.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

2 Approved active substances shall be included in a Union list of approved active substances. The Commission shall keep the list up to date and make it electronically available to the public.

Article 10

Active substances which are candidates for substitution

1 An active substance shall be considered a candidate for substitution if any of the following conditions are met:

a it meets at least one of the exclusion criteria listed in Article 5(1) but may be approved in accordance with Article 5(2);

b it meets the criteria to be classified, in accordance with Regulation (EC) No 1272/2008, as a respiratory sensitiser;

c its acceptable daily intake, acute reference dose or acceptable operator exposure level, as appropriate, is significantly lower than those of the majority of approved active substances for the same product-type and use scenario;

d it meets two of the criteria for being PBT in accordance with Annex XIII to Regulation (EC) No 1907/2006;

e there are reasons for concern linked to the nature of the critical effects which, in combination with the use patterns, amount to use that could still cause concern, such as high potential of risk to groundwater, even with very restrictive risk management measures;

f it contains a significant proportion of non-active isomers or impurities.

2 When preparing its opinion on the approval or renewal of the approval of an active substance, the Agency shall examine whether the active substance fulfils any of the criteria listed in paragraph 1 and address the matter in its opinion.

3 Prior to submitting its opinion on the approval or renewal of the approval of an active substance to the Commission, the Agency shall make publicly available, without prejudice to Articles 66 and 67, information on potential candidates for substitution during a period of no

more than 60 days, during which time interested third parties may submit relevant information, including information on available substitutes. The Agency shall take due account of the information received when finalising its opinion.

4 By way of derogation from Article 4(1) and Article 12(3), the approval of an active substance that is considered as a candidate for substitution and each renewal shall be for a period not exceeding seven years.

5 Active substances that are considered as candidates for substitution in accordance with paragraph 1 shall be identified as such in the relevant Regulation adopted in accordance with Article 9.

Article 11

Technical guidance notes

The Commission shall draw up technical guidance notes to facilitate the implementation of this Chapter, in particular Article 5(2) and Article 10(1).

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.