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 IV

GENERAL PRINCIPLES CONCERNING THE AUTHORISATION OF BIOCIDAL PRODUCTS

Article 17

Making available on the market and use of biocidal products

1 Biocidal products shall not be made available on the market or used unless authorised in accordance with this Regulation.

2 Applications for authorisation shall be made by, or on behalf of, the prospective authorisation holder.

Applications for national authorisation in a Member State shall be submitted to the competent authority of that Member State ('the receiving competent authority').

Applications for Union authorisation shall be submitted to the Agency.

3 An authorisation may be granted for a single biocidal product or a biocidal product family.

4 An authorisation shall be granted for a maximum period of 10 years.

5 Biocidal products shall be used in compliance with the terms and conditions of the authorisation stipulated in accordance with Article 22(1) and the labelling and packaging requirements laid down in Article 69.

Proper use shall involve the rational application of a combination of physical, biological, chemical or other measures as appropriate, whereby the use of biocidal products is limited to the minimum necessary and appropriate precautionary steps are taken.

Member States shall take necessary measures to provide the public with appropriate information about the benefits and risks associated with biocidal products and ways of minimising their use.

6 The authorisation holder shall notify each competent authority that has granted a national authorisation for a biocidal product family of each product within the biocidal product family at least 30 days before placing it on the market, except where a particular product is explicitly identified in the authorisation or the variation in composition concerns only pigments, perfumes and dyes within the permitted variations. The notification shall indicate the exact composition, trade name and suffix to the authorisation number. In the case of a Union authorisation, the authorisation holder shall notify the Agency and the Commission.

7 The Commission shall, by means of an implementing act, specify procedures for the authorisation of the same biocidal products by the same or different enterprises under the same terms and conditions. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 82(3).

Article 18

Measures geared to the sustainable use of biocidal products

By 18 July 2015 the Commission shall, on the basis of experience gained with the application of this Regulation, submit to the European Parliament and the Council a report on how this Regulation is contributing to the sustainable use of biocidal products, including on the need to introduce additional measures, in particular for professional users, to reduce the risks posed to human health, animal health and the environment by biocidal products. That report shall, inter alia, examine:

(a) the promotion of best practices as a means of reducing the use of biocidal products to a minimum;

(b) the most effective approaches for monitoring the use of biocidal products;

(c) the development and application of integrated pest management principles with respect to the use of biocidal products;

(d) the risks posed by the use of biocidal products in specific areas such as schools, workplaces, kindergartens, public spaces, geriatric care centres or in the vicinity of surface water or groundwater and whether additional measures are needed to address those risks;

(e) the role that improved performance of the equipment used for applying biocidal products could play in sustainable use.

On basis of that report, the Commission shall, if appropriate, submit a proposal for adoption in accordance with the ordinary legislative procedure.

Article 19

Conditions for granting an authorisation

1 A biocidal product other than those eligible for the simplified authorisation procedure in accordance with Article 25 shall be authorised provided the following conditions are met:

[F1 a the active substances are included in Annex I or approved for the relevant product-type and any conditions specified for those active substances are met;**]**

b it is established, according to the common principles for the evaluation of dossiers for biocidal products laid down in Annex VI, that the biocidal product, when used as authorised and having regard to the factors referred to in paragraph 2 of this Article, fulfils the following criteria:

(i) the biocidal product is sufficiently effective;

(ii) the biocidal product has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;

(iii) the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;

(iv) the biocidal product has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:

— the fate and distribution of the biocidal product in the environment,

— contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,

— the impact of the biocidal product on non-target organisms,

— the impact of the biocidal product on biodiversity and the ecosystem;

c the chemical identity, quantity and technical equivalence of active substances in the biocidal product and, where appropriate, any toxicologically or ecotoxicologically significant and relevant impurities and non-active substances, and its residues of toxicological or environmental significance, which result from uses to be authorised, can be determined according to the relevant requirements in Annexes II and III;

d the physical and chemical properties of the biocidal product have been determined and deemed acceptable for the purposes of the appropriate use and transport of the product;

[F1 e where appropriate, maximum residue limits for food and feed have been established with respect to active substances contained in a biocidal product in accordance with Council Regulation (EEC) No 315/93(1), Regulation (EC) No 396/2005 of the European Parliament and of the Council(2), Regulation (EC) No 470/2009 of the European Parliament and of the Council(3) or Directive 2002/32/EC of the European Parliament and of the Council(4), or specific migration limits or limits for the residual content in food contact materials have been established with respect to such active substances in accordance with Regulation (EC) No 1935/2004 of the European Parliament and of the Council(5);**]**

f where nanomaterials are used in that product, the risk to human health, animal health and the environment has been assessed separately.

2 The evaluation of whether a biocidal product fulfils the criteria set out in point (b) of paragraph 1 shall take into account the following factors:

a realistic worst case conditions under which the biocidal product may be used;

b the way in which treated articles treated with the biocidal product or containing the biocidal product may be used;

c the consequences of use and disposal of the biocidal product;

d cumulative effects;

e synergistic effects.

3 A biocidal product shall only be authorised for uses for which relevant information has been submitted in accordance with Article 20.

4 A biocidal product shall not be authorised for making available on the market for use by the general public where:

a it meets the criteria according to Directive 1999/45/EC for classification as:

— toxic or very toxic,

— a category 1 or 2 carcinogen,

— a category 1 or 2 mutagen, or

— toxic for reproduction category 1 or 2;

[F1 b it meets the criteria according to Regulation (EC) No 1272/2008 for classification as:

— acute oral toxicity category 1, 2 or 3,

— acute dermal toxicity category 1, 2 or 3,
— acute inhalation toxicity (gases and dust/mist) category 1, 2 or 3,
— acute inhalation toxicity (vapours) category 1 or 2,
— specific target organ toxicity by single or repeated exposure category 1,
— a category 1A or 1B carcinogen,
— a category 1A or 1B mutagen, or
— toxic for reproduction category 1A or 1B;

c it consists of, contains or generates, a substance that meets the criteria for being PBT or vPvB in accordance with Annex XIII to Regulation (EC) No 1907/2006;**]**

d it has endocrine-disrupting properties; or

e it has developmental neurotoxic or immunotoxic effects.

5 Notwithstanding paragraphs 1 and 4, a biocidal product may be authorised when the conditions laid down in paragraph 1(b)(iii) and (iv) are not fully met, or may be authorised for making available on the market for use by the general public when the criteria referred to in paragraph 4(c) are met, where not authorising the biocidal product would result in disproportionate negative impacts for society when compared to the risks to human health, animal health or the environment arising from the use of the biocidal product under the conditions laid down in the authorisation.

The use of a biocidal product authorised pursuant to this paragraph shall be subject to appropriate risk mitigation measures to ensure that exposure of humans and the environment to that biocidal product is minimised. The use of a biocidal product authorised pursuant to this paragraph shall be restricted to Member States in which the condition of the first subparagraph is met.

[F1 6 The assessment of the biocidal product family conducted according to the common principles set out in Annex VI shall consider the maximum risks to human health, animal health and the environment and the minimum level of efficacy over the whole potential range of products within the biocidal product family.

A biocidal product family shall be authorised only if:

a the application explicitly identifies the maximum risks to human health, animal health and the environment, and the minimum level of efficacy, on which the assessment is based, as well as the permitted variations in composition and uses referred to in point (s) of Article 3(1) together with their respective classification, hazard and precautionary statements and any appropriate risk mitigation measures; and

b it can be established based on the assessment referred to in the first subparagraph of this paragraph that all the biocidal products within the family comply with the conditions set out in paragraph 1.

7 Where appropriate, the prospective authorisation holder or its representative shall apply for the establishment of maximum residue limits with respect to active substances contained in a biocidal product in accordance with Regulation (EEC) No 315/93, Regulation (EC) No 396/2005, Regulation (EC) No 470/2009 or Directive 2002/32/EC, or for the establishment of specific migration limits or limits for the residual content in food contact materials with respect to such substances in accordance with Regulation (EC) No 1935/2004.**]**

8 Where, for active substances covered by Article 10(1)(a) of Regulation (EC) No 470/2009, no maximum residue limit has been established in accordance with Article 9 of that Regulation at the time of the approval of the active substance, or where a limit established in accordance with Article 9 of that Regulation needs to be amended, the maximum residue limit

shall be established or amended in accordance with the procedure referred to in Article 10(1)(b) of that Regulation.

9 Where a biocidal product is intended for direct application to the external parts of the human body (epidermis, hair system, nails, lips and external genital organs), or to the teeth and the mucous membranes of the oral cavity, it shall not contain any non-active substance that may not be included in a cosmetic product pursuant to Regulation (EC) No 1223/2009.

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).

Article 20

Requirements for applications for authorisation

1 The applicant for an authorisation shall submit the following documents together with the application:

a for biocidal products other than biocidal products meeting the conditions laid down in Article 25:

(i) a dossier or letter of access for the biocidal product satisfying the requirements set out in Annex III;

(ii) a summary of the biocidal product characteristics including the information referred to in points (a), (b) and (e) to (q) of Article 22(2), as applicable;

(iii) a dossier or a letter of access for the biocidal product satisfying the requirements set out in Annex II for each active substance in the biocidal product;

b for biocidal products that the applicant considers meet the conditions laid down in Article 25:

(i) a summary of the biocidal product characteristics as referred to in point (a)(ii) of this paragraph;

(ii) efficacy data; and

(iii) any other relevant information in support of the conclusion that the biocidal product meets the conditions laid down in Article 25.

2 The receiving competent authority may require that applications for national authorisation be submitted in one or more of the official languages of the Member State where that competent authority is situated.

3 For applications for Union authorisations submitted under Article 43, the applicant shall submit the summary of the biocidal product characteristics referred to in point (ii) of paragraph (1)(a) of this Article in one of the official languages of the Union accepted by the evaluating competent authority at the time of application and in all official languages of the Union before the authorisation of the biocidal product.

Article 21

Waiving of data requirements

1 By way of derogation from Article 20, the applicant need not provide data required under that Article 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.

2 The applicant may propose to adapt the data requirements of Article 20 in accordance with Annex IV. The justification for the proposed adaptations to the data requirements shall be clearly stated in the application with reference to the specific rules in Annex IV.

3 In order to ensure the harmonised application of paragraph 1(a) of this Article, the Commission shall be empowered to adopt delegated acts in accordance with Article 83 specifying criteria for defining when the exposure associated with the proposed uses would justify adapting the data requirements of Article 20.

Article 22

Content of authorisation

1 An authorisation shall stipulate the terms and conditions relating to the making available on the market and use of the single biocidal product or the biocidal product family and include a summary of the biocidal product characteristics.

2 Without prejudice to Articles 66 and 67, the summary of the biocidal product characteristics for a single biocidal product or, in the case of a biocidal product family, the biocidal products within that biocidal product family, shall include the following information:

a trade name of the biocidal product;

b name and address of the authorisation holder;

c date of the authorisation and its date of expiry;

d authorisation number of the biocidal product, together with, in the case of a biocidal product family, the suffixes to apply to individual biocidal products within the biocidal product family;

e qualitative and quantitative composition in terms of the active substances and non-active substances, knowledge of which is essential for proper use of biocidal products; and in the case of a biocidal product family, the quantitative composition shall indicate a minimum and maximum percentage for each active and non-active substance, where the minimum percentage indicated for certain substances may be 0 %;

f manufacturers of the biocidal product (names and addresses including location of manufacturing sites);

g manufacturers of the active substances (names and addresses including location of manufacturing sites);

h type of formulation of the biocidal product;

i hazard and precautionary statements;

j product-type and, where relevant, an exact description of the authorised use;

k target harmful organisms;

l application doses and instructions for use;

m categories of users;

n particulars of likely direct or indirect adverse effects and first aid instructions and emergency measures to protect the environment;

o instructions for safe disposal of the product and its packaging;

p conditions of storage and shelf-life of the biocidal product under normal conditions of storage;

q where relevant, other information about the biocidal product.

Article 23

Comparative assessment of biocidal products

1 The receiving competent authority or, in the case of an evaluation of an application for a Union authorisation, the evaluating competent authority, shall perform a comparative assessment as part of the evaluation of an application for authorisation or for renewal of authorisation of a biocidal product containing an active substance that is a candidate for substitution in accordance with Article 10(1).

2 The results of the comparative assessment shall be forwarded, without delay, to the competent authorities of other Member States and the Agency and, in the case of evaluation of an application for a Union authorisation, also to the Commission.

[[F1]3 The receiving competent authority or, in the case of a decision on an application for a Union authorisation, the Commission, shall prohibit or restrict the making available on the market or the use of a biocidal product containing an active substance that is a candidate for substitution where a comparative assessment, performed in accordance with the technical guidance notes referred to in Article 24, demonstrates that both of the following criteria are met:**]**

a for the uses specified in the application, another authorised biocidal product or a non-chemical control or prevention method already exists which presents a significantly lower overall risk for human health, animal health and the environment, is sufficiently effective and presents no other significant economic or practical disadvantages;

b the chemical diversity of the active substances is adequate to minimise the occurrence of resistance in the target harmful organism.

4 By way of derogation from paragraph 1, a biocidal product containing an active substance that is a candidate for substitution may be authorised for a period of up to four years without comparative assessment in exceptional cases where it is necessary to acquire experience first through using that product in practice.

5 Where the comparative assessment involves a question which, by reason of its scale or consequences, would be better addressed at Union level, in particular where it is relevant to two or more competent authorities, the receiving competent authority may refer the question to the Commission for a decision. The Commission shall adopt that decision by means of implementing acts in accordance with the examination procedure referred to in Article 82(3).

The Commission shall be empowered to adopt delegated acts in accordance with Article 83 specifying the criteria for determining when comparative assessments involve questions better addressed at Union level and the procedures for such comparative assessments.

6 Notwithstanding Article 17(4), and without prejudice to paragraph 4 of this Article, an authorisation for a biocidal product containing an active substance that is a candidate for

substitution shall be granted for a period not exceeding five years and renewed for a period not exceeding five years.

7 Where it is decided not to authorise or to restrict the use of a biocidal product pursuant to paragraph 3, that cancellation or amendment of the authorisation shall take effect four years after that decision. However, where the approval of the active substance which is a candidate for substitution expires on an earlier date, the cancellation of the authorisation shall take effect on that earlier date.

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).

Article 24

Technical guidance notes

The Commission shall draw up technical guidance notes to facilitate the implementation of this Chapter and, in particular, Article 22(2) and Article 23(3).

(1) **[**[F1]Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 37, 13.2.1993, p. 1).**]**

(2) **[**[F1]Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).**]**

(3) **[**[F1]Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).**]**

(4) **[**[F1]Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10).**]**

(5) **[**[F1]Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).**]**

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).

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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.