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 I

SCOPE AND DEFINITIONS

Article 1

Purpose and subject matter

1 The purpose of this Regulation is to improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and the use of biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment. The provisions of this Regulation are underpinned by the precautionary principle, the aim of which is to safeguard the health of humans, the health of animals and the environment. Particular attention shall be paid to the protection of vulnerable groups.

2 This Regulation lays down rules for:

a the establishment at Union level of a list of active substances which may be used in biocidal products;

b the authorisation of biocidal products;

c the mutual recognition of authorisations within the Union;

d the making available on the market and the use of biocidal products within one or more Member States or the Union;

e the placing on the market of treated articles.

Article 2

Scope

1 This Regulation shall apply to biocidal products and treated articles. A list of the types of biocidal products covered by this Regulation and their descriptions is set out in Annex V.

2 Subject to any explicit provision to the contrary in this Regulation or other Union legislation, this Regulation shall not apply to biocidal products or treated articles that are within the scope of the following instruments:

a Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community[(1)];

b Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC;

c Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[(2)], Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[(3)] and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision

of medicinal products for human and veterinary use and establishing a European Medicines Agency[4];

d Regulation (EC) No 1831/2003;

e Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs[5] and Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin[6];

f Regulation (EC) No 1333/2008;

g Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods[7];

h Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed[8];

i Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market[9];

j Regulation (EC) No 1223/2009;

k Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys[10].

Notwithstanding the first subparagraph, when a biocidal product falls within the scope of one of the abovementioned instruments and is intended to be used for purposes not covered by those instruments, this Regulation shall also apply to that biocidal product insofar as those purposes are not addressed by those instruments.

3 Subject to any explicit provision to the contrary in this Regulation or other Union legislation, this Regulation shall be without prejudice to the following instruments:

a Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[11];

b Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work[12];

c Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work[13];

d Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption[14];

e Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations[15];

f Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work[16];

g Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy[17];

h Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work[18];

i Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants[19];

j Regulation (EC) No 1907/2006;

k Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising[(20)];

l Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals[(21)];

m Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures[(22)];

n Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides[(23)];

o Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer[(24)];

p Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes[(25)];

q Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions[(26)].

4 Article 69 shall not apply to the carriage of biocidal products by rail, road, inland waterway, sea or air.

5 This Regulation shall not apply to:

a food or feed used as repellents or attractants;

[[F1]b biocidal products when used as processing aids within the meaning of Regulation (EC) No 1831/2003 and Regulation (EC) No 1333/2008.**]**

6 Biocidal products which obtained final approval under the International Convention for the Control and Management of Ships' Ballast Water and Sediments shall be considered as authorised under Chapter VIII of this Regulation. Articles 47 and 68 shall apply accordingly.

7 Nothing in this Regulation shall prevent Member States from restricting or banning the use of biocidal products in the public supply of drinking water.

8 Member States may allow for exemptions from this Regulation in specific cases for certain biocidal products, on their own or in a treated article, where necessary in the interests of defence.

9 The disposal of active substances and biocidal products shall be carried out in accordance with the Union and national waste legislation in force.

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 3

Definitions

1 For the purposes of this Regulation, the following definitions shall apply:

a 'biocidal product' means

— any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,

— any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

A treated article that has a primary biocidal function shall be considered a biocidal product.

b ‘micro-organism’ means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including lower fungi, viruses, bacteria, yeasts, moulds, algae, protozoa and microscopic parasitic helminths;

c ‘active substance’ means a substance or a micro-organism that has an action on or against harmful organisms;

d ‘existing active substance’ means a substance which was on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development;

e ‘new active substance’ means a substance which was not on the market on 14 May 2000 as an active substance of a biocidal product for purposes other than scientific or product and process-orientated research and development;

f ‘substance of concern’ means any substance, other than the active substance, which has an inherent capacity to cause an adverse effect, immediately or in the more distant future, on humans, in particular vulnerable groups, animals or the environment and is present or is produced in a biocidal product in sufficient concentration to present risks of such an effect.

Such a substance would, unless there are other grounds for concern, normally be:

— a substance classified as dangerous or that meets the criteria to be classified as dangerous according to Directive 67/548/EEC, and that is present in the biocidal product at a concentration leading the product to be regarded as dangerous within the meaning of Articles 5, 6 and 7 of Directive 1999/45/EC, or

— a substance classified as hazardous or that meets the criteria for classification as hazardous according to Regulation (EC) No 1272/2008, and that is present in the biocidal product at a concentration leading the product to be regarded as hazardous within the meaning of that Regulation,

— a substance which meets the criteria for being a persistent organic pollutant (POP) under Regulation (EC) No 850/2004, or which meets the criteria for being persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) in accordance with Annex XIII to Regulation (EC) No 1907/2006;

g ‘harmful organism’ means an organism, including pathogenic agents, which has an unwanted presence or a detrimental effect on humans, their activities or the products they use or produce, on animals or the environment;

h ‘residue’ means a substance present in or on products of plant or animal origin, water resources, drinking water, food, feed or elsewhere in the environment and resulting from

the use of a biocidal product, including such a substance's metabolites, breakdown or reaction products;

i 'making available on the market' means any supply of a biocidal product or of a treated article for distribution or use in the course of a commercial activity, whether in return for payment or free of charge;

j 'placing on the market' means the first making available on the market of a biocidal product or of a treated article;

k 'use' means all operations carried out with a biocidal product, including storage, handling, mixing and application, except any such operation carried out with a view to exporting the biocidal product or the treated article outside the Union;

l 'treated article' means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products;

m 'national authorisation' means an administrative act by which the competent authority of a Member State authorises the making available on the market and the use of a biocidal product or a biocidal product family in its territory or in a part thereof;

n 'Union authorisation' means an administrative act by which the Commission authorises the making available on the market and the use of a biocidal product or a biocidal product family in the territory of the Union or in a part thereof;

o 'authorisation' means national authorisation, Union authorisation or authorisation in accordance with Article 26;

p 'authorisation holder' means the person established within the Union who is responsible for the placing on the market of a biocidal product in a particular Member State or in the Union and specified in the authorisation;

q 'product-type' means one of the product-types specified in Annex V;

r 'single biocidal product' means a biocidal product with no intended variations as to the percentage of the active or non-active substances it contains;

[[F1]s 'biocidal product family' means a group of biocidal products having:

(i) similar uses;

(ii) the same active substances;

(iii) similar composition with specified variations; and

(iv) similar levels of risk and efficacy;**]**

t 'letter of access' means an original document, signed by the data owner or its representative, which states that the data may be used for the benefit of a third party by competent authorities, the Agency, or the Commission for the purposes of this Regulation;

u 'food' and 'feed' mean food as defined in Article 2 of Regulation (EC) No 178/2002 and feed as defined in Article 3(4) of that Regulation;

[[F2](v)**]** [F2]. . . . . .

w 'technical equivalence' means similarity, as regards the chemical composition and hazard profile, of a substance produced either from a source different to the reference source, or from the reference source but following a change to the manufacturing process and/or manufacturing location, compared to the substance of the reference source in respect of which the initial risk assessment was carried out, as established in Article 54;

x 'Agency' means the European Chemicals Agency established by Regulation (EC) No 1907/2006;

y ‘advertisement’ means a means of promoting the sale or use of biocidal products by printed, electronic or other media;

z ‘nanomaterial’ means a natural or manufactured active substance or non-active substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm.

Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials.

For the purposes of the definition of nanomaterial, ‘particle’, ‘agglomerate’ and ‘aggregate’ are defined as follows:

— ‘particle’ means a minute piece of matter with defined physical boundaries,

— ‘agglomerate’ means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components,

— ‘aggregate’ means a particle comprising strongly bound or fused particles;

aa ‘administrative change’ means an amendment of an existing authorisation of a purely administrative nature involving no change to the properties or efficacy of the biocidal product or biocidal product family;

ab ‘minor change’ means an amendment of an existing authorisation that is not of a purely administrative nature and requires only a limited re-assessment of the properties or efficacy of the biocidal product or biocidal product family;

ac ‘major change’ means an amendment of an existing authorisation which is neither an administrative change nor a minor change;

ad ‘vulnerable groups’ means persons needing specific consideration when assessing the acute and chronic health effects of biocidal products. These include pregnant and nursing women, the unborn, infants and children, the elderly and, when subject to high exposure to biocidal products over the long term, workers and residents;

ae ‘small and medium-sized enterprises’ or ‘SMEs’ means small and medium-sized enterprises as defined in Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises[(27)].

2 For the purposes of this Regulation, the definitions laid down in Article 3 of Regulation (EC) No 1907/2006 shall apply for the following terms:

a ‘substance’;

b ‘mixture’;

c ‘article’;

d ‘product and process-orientated research and development’;

e ‘scientific research and development’.

3 The Commission may, at the request of a Member State, decide, by means of implementing acts, whether a substance is a nanomaterial, having regard in particular to Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial[(28)], and whether a specific product or group of products is a biocidal product or a treated article or neither. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

4 The Commission shall be empowered to adopt delegated acts in accordance with Article 83 in order to adapt the definition of nanomaterial set out in point (z) of paragraph 1 of this Article in view of technical and scientific progress and taking into account the Recommendation 2011/696/EU.

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).

F2 Deleted 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).

(**1**) OJ L 92, 7.4.1990, p. 42.
(**2**) OJ L 311, 28.11.2001, p. 1.
(**3**) OJ L 311, 28.11.2001, p. 67.
(**4**) OJ L 136, 30.4.2004, p. 1.
(**5**) OJ L 139, 30.4.2004, p. 1.
(**6**) OJ L 139, 30.4.2004, p. 55.
(**7**) OJ L 354, 31.12.2008, p. 34.
(**8**) OJ L 229, 1.9.2009, p. 1.
(**9**) OJ L 309, 24.11.2009, p. 1.
(**10**) OJ L 170, 30.6.2009, p. 1.
(**11**) OJ 196, 16.8.1967, p. 1.
(**12**) OJ L 183, 29.6.1989, p. 1.
(**13**) OJ L 131, 5.5.1998, p. 11.
(**14**) OJ L 330, 5.12.1998, p. 32.
(**15**) OJ L 200, 30.7.1999, p. 1.
(**16**) OJ L 262, 17.10.2000, p. 21.
(**17**) OJ L 327, 22.12.2000, p. 1.
(**18**) OJ L 158, 30.4.2004, p. 50.
(**19**) OJ L 158, 30.4.2004, p. 7.
(**20**) OJ L 376, 27.12.2006, p. 21.
(**21**) OJ L 204, 31.7.2008, p. 1.
(**22**) OJ L 353, 31.12.2008, p. 1.
(**23**) OJ L 309, 24.11.2009, p. 71.
(**24**) OJ L 286, 31.10.2009, p. 1.
(**25**) OJ L 276, 20.10.2010, p. 33.
(**26**) OJ L 334, 17.12.2010, p. 17.
(**27**) OJ L 124, 20.5.2003, p. 36.
(**28**) OJ L 275, 20.10.2011, p. 38.

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.