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 XV

INFORMATION AND COMMUNICATION

SECTION 1

Monitoring and reporting

Article 65

Compliance with requirements

1 Member States shall make the necessary arrangements for the monitoring of biocidal products and treated articles which have been placed on the market to establish whether they comply with the requirements of this Regulation. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products[(1)] shall apply accordingly.

2 Member States shall make the necessary arrangements for official controls to be carried out in order to enforce compliance with this Regulation.

In order to facilitate such enforcement, manufacturers of biocidal products placed on the Union market shall maintain, in relation to the manufacturing process, appropriate documentation in paper or electronic format relevant for the quality and safety of the biocidal product to be placed on the market and shall store production batch samples. The documentation shall include as a minimum:

a safety data sheets and specifications of active substances and other ingredients used for manufacturing the biocidal product;

b records of the various manufacturing operations performed;

c results of internal quality controls;

d identification of production batches.

Where necessary in order to ensure uniform application of this paragraph, the Commission may adopt implementing acts in accordance with the examination procedure referred to in Article 82(3).

Measures taken pursuant to this paragraph shall avoid causing disproportionate administrative burden to economic operators and Member States.

3 Every five years, from 1 September 2015, Member States shall submit to the Commission a report on the implementation of this Regulation in their respective territories. The report shall include in particular:

a information on the results of official controls carried out in accordance with paragraph 2;

b information on any poisonings and, where available, occupational diseases involving biocidal products, especially regarding vulnerable groups, and any specific measures taken to mitigate the risk of future cases;

c any available information on adverse environmental effects experienced through using biocidal products;

d information on the use of nanomaterials in biocidal products and the potential risks thereof.

Reports shall be submitted by 30 June of the relevant year and shall cover the period until 31 December of the year preceding their submission.

The reports shall be published on the relevant website of the Commission.

4 On the basis of the reports received in accordance with paragraph 3, and within 12 months from the date referred to in the second subparagraph of that paragraph, the Commission shall draw up a composite report on the implementation of this Regulation, in particular Article 58. The Commission shall submit the report to the European Parliament and to the Council.

Article 66

Confidentiality

1 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents[(2)] and the rules of the Management Board of the Agency, adopted in accordance with Article 118(3) of Regulation (EC) No 1907/2006, shall apply to documents held by the Agency for the purposes of this Regulation.

2 The Agency and the competent authorities shall refuse access to information where disclosure would undermine the protection of the commercial interests or the privacy or safety of the persons concerned.

Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests or the privacy or safety of the persons concerned:

a details of the full composition of a biocidal product;

b the precise tonnage of the active substance or biocidal product manufactured or made available on the market;

c links between a manufacturer of an active substance and the person responsible for the placing of a biocidal product on the market or between the person responsible for the placing of a biocidal product on the market and the distributors of the product;

d names and addresses of persons involved in testing on vertebrates.

However, where urgent action is essential to protect human health, animal health, safety or the environment or for other reasons of overriding public interest, the Agency or the competent authorities shall disclose the information referred to in this paragraph.

3 Notwithstanding paragraph 2, after the authorisation has been granted, access to the following information shall not in any case be refused:

a the name and address of the authorisation holder;

b the name and address of the biocidal product manufacturer;

c the name and address of the active substance manufacturer;

d the content of the active substance or substances in the biocidal product and the name of the biocidal product;

e physical and chemical data concerning the biocidal product;

f any methods for rendering the active substance or biocidal product harmless;

g a summary of the results of the tests required pursuant to Article 20 to establish the product's efficacy and effects on humans, animals and the environment and, where applicable, its ability to promote resistance;

h recommended methods and precautions to reduce dangers from handling, transport and use as well as from fire or other hazards;

i safety data sheets;

j methods of analysis referred to in Article 19(1)(c);

k methods of disposal of the product and of its packaging;

l procedures to be followed and measures to be taken in the case of spillage or leakage;

m first aid and medical advice to be given in the case of injury to persons.

4 Any person submitting information related to an active substance or a biocidal product to the Agency or a competent authority for the purposes of this Regulation can request that the information in Article 67(3) shall not be made available, including a justification as to why the disclosure of the information could be harmful for their commercial interests or those of any other party concerned.

Article 67

Electronic public access

1 From the date on which an active substance is approved, the following up-to-date information held by the Agency or the Commission on active substances shall be made publicly and easily available free of charge:

a where available, the ISO name and the name in the International Union of Pure and Applied Chemistry (IUPAC) nomenclature;

b if applicable, the name as given in the European Inventory of Existing Commercial Chemical Substances;

c the classification and labelling, including whether the active substance meets any of the criteria set out in Article 5(1);

d physicochemical endpoints and data on pathways and environmental fate and behaviour;

e the result of each toxicological and ecotoxicological study;

f acceptable exposure level or predicted no-effect concentration established in accordance with Annex VI;

g the guidance on safe use provided in accordance with Annexes II and III;

h analytical methods referred to under Sections 5.2 and 5.3 of Title 1, and Section 4.2 of Title 2 of Annex II.

2 From the date on which a biocidal product is authorised, the Agency shall make publicly and easily available free of charge the following up-to-date information:

a the terms and conditions of the authorisation;

b the summary of the biocidal product characteristics; and

c analytical methods referred to under Sections 5.2 and 5.3 of Title 1, and Section 5.2 of Title 2 of Annex III.

3 From the date on which an active substance is approved, the Agency shall, except where the data supplier submits a justification in accordance with Article 66(4) accepted as valid

by the competent authority or the Agency as to why such publication is potentially harmful for its commercial interests or any other party concerned, make publicly available, free of charge, the following up-to-date information on active substances:

a if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives of active substances which are known to be hazardous;

b the study summaries or robust study summaries of studies submitted to support the approval of the active substance;

c information, other than that listed in paragraph 1 of this Article, contained in the safety data sheet;

d the trade name(s) of the substance;

e the assessment report.

4 From the date on which a biocidal product is authorised, the Agency shall, except where the data supplier submits a justification in accordance with Article 66(4) accepted as valid by the competent authority or the Agency as to why such publication is potentially harmful for its commercial interests or any other party concerned, make publicly available, free of charge, the following up-to date information:

a study summaries, or robust study summaries, of studies submitted to support the biocidal product authorisation; and

b the assessment report.

Article 68

Record-keeping and reporting

1 Authorisation holders shall keep records of the biocidal products they place on the market for at least 10 years after placing on the market, or 10 years after the date on which the authorisation was cancelled or expired, whichever is the earlier. They shall make available the relevant information contained in these records to the competent authority on request.

2 To ensure the uniform application of paragraph 1 of this Article, the Commission shall adopt implementing acts to specify the form and content of the information in records. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2).

(**1**) OJ L 218, 13.8.2008, p. 30.

(**2**) OJ L 145, 31.5.2001, p. 43.

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.