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 2

Information about biocidal products

Article 69

Classification, packaging and labelling of biocidal products

1 Authorisation holders shall ensure that biocidal products are classified, packaged and labelled in accordance with the approved summary of biocidal product characteristics, in particular the hazard statements and the precautionary statements, as referred to in point (i) of Article 22(2), and with Directive 1999/45/EC and, where applicable, Regulation (EC) No 1272/2008.

In addition, products which may be mistaken for food, including drink, or feed shall be packaged to minimise the likelihood of such a mistake being made. If they are available to the general public, they shall contain components to discourage their consumption and, in particular, shall not be attractive to children.

2 In addition to compliance with paragraph 1, authorisation holders shall ensure that labels are not misleading in respect of the risks from the product to human health, animal health or the environment or its efficacy and, in any case, do not mention the indications 'low-risk biocidal product', 'non-toxic', 'harmless', 'natural', 'environmentally friendly', 'animal friendly' or similar indications. In addition, the label must show clearly and indelibly the following information:

a the identity of every active substance and its concentration in metric units;

b the nanomaterials contained in the product, if any, and any specific related risks, and, following each reference to nanomaterials, the word 'nano' in brackets;

c the authorisation number allocated to the biocidal product by the competent authority or the Commission;

d the name and address of the authorisation holder;

e the type of formulation;

f the uses for which the biocidal product is authorised;

g directions for use, frequency of application and dose rate, expressed in metric units, in a manner which is meaningful and comprehensible to the user, for each use provided for under the terms of the authorisation;

h particulars of likely direct or indirect adverse side effects and any directions for first aid;

i if accompanied by a leaflet, the sentence 'Read attached instructions before use' and, where applicable, warnings for vulnerable groups;

j directions for the safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on the reuse of packaging;

k the formulation batch number or designation and the expiry date relevant to normal conditions of storage;

l where applicable, the period of time needed for the biocidal effect, the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during use and transport;

m where applicable, the categories of users to which the biocidal product is restricted;

n where applicable, information on any specific danger to the environment particularly concerning protection of non-target organisms and avoidance of contamination of water;

o for biocidal products containing micro-organisms, labelling requirements in accordance with Directive 2000/54/EC.

By way of derogation from the first subparagraph, where this is necessary because of the size or the function of the biocidal product, the information referred to in points (e), (g), (h), (j), (k), (l) and (n) may be indicated on the packaging or on an accompanying leaflet integral to the packaging.

3 Member States may require:

a the provision of models or drafts of the packaging, labelling and leaflets;

b that biocidal products made available on the market in their territories be labelled in their official language or languages.

Article 70

Safety data sheets

Safety data sheets for active substances and biocidal products shall be prepared and made available in accordance with Article 31 of Regulation (EC) No 1907/2006, where applicable.

Article 71

Register for Biocidal Products

1 The Agency shall establish and maintain an information system which shall be referred to as the Register for Biocidal Products.

2 The Register for Biocidal Products shall be used for the exchange of information between competent authorities, the Agency and the Commission and between applicants and competent authorities, the Agency and the Commission.

3 Applicants shall use the Register for Biocidal Products to submit applications and data for all procedures covered by this Regulation.

4 Upon submission of applications and data by applicants, the Agency shall check that these have been submitted in the correct format and notify the relevant competent authority accordingly without delay.

Where the Agency decides that the application has not been submitted in the correct format, it shall reject the application and inform the applicant accordingly.

5 Once the relevant competent authority has validated or accepted an application, it shall be made available via the Register for Biocidal Products to all other competent authorities and to the Agency.

6 The competent authorities and the Commission shall use the Register for Biocidal Products to record and communicate the decisions they have taken in relation to the authorisations of biocidal products and shall update the information in the Register for Biocidal Products at the time such decisions are taken. The competent authorities shall, in particular, update the information in the Register for Biocidal Products relating to biocidal products which have been authorised within their territory or for which a national authorisation has been refused, amended, renewed or cancelled, or for which a parallel trade permit has been granted, refused or cancelled. The Commission shall, in particular, update the information relating to biocidal products which have been authorised in the Union or for which a Union authorisation has been refused, amended, renewed or cancelled.

The information to be introduced into the Register for Biocidal Products shall include, as appropriate:

a the terms and conditions of the authorisation;

b the summary of the biocidal product characteristics referred to in Article 22(2);

c the assessment report of the biocidal product.

The information referred to in this paragraph shall also be made available to the applicant through the Register for Biocidal Products.

7 In the event that the Register for Biocidal Products is not fully operational by 1 September 2013 or ceases to be operational after that date, all obligations in relation to submissions and communication placed upon Member States, competent authorities, the Commission and applicants by this Regulation shall continue to apply. With a view to ensuring the uniform application of this paragraph, particularly with regard to the format in which information may be submitted and exchanged, the Commission shall adopt the necessary measures in accordance with the examination procedure referred to in Article 82(3). Those measures shall be limited in time to the period strictly necessary for the Register for Biocidal Products to become fully operational.

8 The Commission may adopt implementing acts laying down detailed rules on the types of information to be entered in the Register for Biocidal Products. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2).

9 The Commission shall be empowered to adopt delegated acts in accordance with Article 83 laying down supplementary rules for the use of the Register.

Article 72

Advertising

1 Any advertisement for biocidal products shall, in addition to complying with Regulation (EC) No 1272/2008, include the sentences ‘Use biocides safely. Always read the

label and product information before use.'. The sentences shall be clearly distinguishable and legible in relation to the whole advertisement.

2 Advertisers may replace the word 'biocides' in the prescribed sentences with a clear reference to the product-type being advertised.

3 Advertisements for biocidal products shall not refer to the product in a manner which is misleading in respect of the risks from the product to human health, animal health or the environment or its efficacy. In any case, the advertising of a biocidal product shall not mention 'low-risk biocidal product', 'non-toxic', 'harmless', 'natural', 'environmentally friendly', 'animal friendly' or any similar indication.

Article 73

Poison control

Article 45 of Regulation (EC) No 1272/2008 shall apply for the purposes of this Regulation.