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Composition and quality requirements for food supplements and requirements for the provision of food information¹

Passed 12.11.2014 Annex 100

This Regulation is enacted on the basis of Sections 12(4) and 38(4) of the Food Act.

§ 1. General provisions

(1) For the purposes of this Regulation, food supplements are considered to be food the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect.

(2) For the purposes of this Regulation, nutrients are vitamins and minerals.

(3) Food supplements are placed on the market in prepacked form, alone or in combination, as set doses, such as capsules, pastilles, tablets, pills and other such forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.

(4) The requirements of this Regulation shall not apply to medicinal products within the meaning of the Medicinal Products Act.

§ 2. Composition and quality requirements for food supplements

(1) Only vitamins and minerals listed in Annex I to Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, pp. 51–57), in the forms listed in Annex II to that Directive, may be used in the composition of food supplements.

(2) If the nutrients referred to in subsection 1 are subject to requirements in respect of food additives under Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, pp. 1–295), the nutrients must meet those requirements.

§ 3. Requirements for the provision of food information concerning food supplements

(1) Where food information is provided concerning food supplements, the requirements of Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, amending Regulations (EC) No 1924/2011 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, pp. 18–63), and the requirements laid down in this Section shall be observed.

(2) The name under which products covered by this Regulation are marketed shall be ‘food supplement’.

(3) The labelling of food supplements shall bear the following information:

- 1) the names of the categories of nutrients or other substances that characterise the product or an indication of the nature of those nutrients or substances;
- 2) the recommended daily dose;
- 3) a warning not to exceed the stated recommended daily dose;
- 4) a warning to the effect that the food supplement should not be used as a substitute for a varied diet;
- 5) a warning to the effect that the product should be stored out of the reach of children.

(4) When providing food information about a food supplement, it is not permitted to imply that a balanced and varied diet cannot provide appropriate quantities of nutrients.

(5) The content of the nutrients or other substances with a nutritional or physiological effect shall be indicated on the labelling in numerical form, using the units set out in Annex I to Directive 2002/46/EC of the European Parliament and of the Council. The values declared shall be indicated in relation to the recommended daily dose and must be average values on the basis of the manufacturer's chemical analysis of the nutrient.

(6) Information on the content of nutrients shall also be expressed as a percentage of the daily reference intake for adults as set out in Part A.1 of Annex XIII to Regulation (EU) No 1169/2011 of the European Parliament and of the Council. This percentage may also be given in graphical form.

§ 4. Entry into force of this Regulation

This Regulation shall enter into force on 13 December 2014.

¹Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, pp. 51–57), amended by Directive 2006/37/EC (OJ L 94, 1.4.2006, pp. 32–33) and by Regulations (EC) No 1137/2008 (OJ L 311, 21.11.2008, pp. 1–54), (EC) No 1170/2009 (OJ L 314, 1.12.2009, pp. 36–42), (EU) No 1161/2011 (OJ L 296, 15.11.2011, pp. 29–30) and (EU) No 119/2014 (OJ L 39, 8.2.2014, pp. 44–45).

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