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The Swedish Food Agency's Regulations on food supplements;

adopted on 12 May 2023.

By virtue of Sections 5-7 of the Food Ordinance (2006:813), the Swedish Food Agency lays down[1] the following.

Scope

Section 1 These regulations shall apply to foodstuffs placed on the market as food supplements.

Terms and definitions

Section 2 'Food supplements' means foodstuffs which

1. are intended to supplement the normal diet;
2. are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination; and
3. are supplied in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles and other similar

1 See Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, as amended by Commission Regulation (EU) 2021/418. See also Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

preparations of liquids or powders designed to be taken in measured small amounts.

‘Nutrients’ means vitamins and minerals.

Packaging and labelling

Section 3 Food supplements may be delivered to the ultimate consumer only in pre-packaged form.

Section 4 The name of the food for products covered by these regulations shall be ‘food supplement’.

Section 5 General provisions on food information can be found in:

1. Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 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, and
2. The Swedish Food Agency’s Regulations (LIVSFS 2014:4) on food information.

Section 6 Without prejudice to application of the provisions laid down in Section 5, packaging containing food supplements shall be labelled with the following:

1. the names of the categories of nutrients or other substances that characterise the product, or the nature of those nutrients or other substances;
2. the recommended daily dose of the product;
3. that the recommended daily dose must not be exceeded;
4. that food supplements should not be used as a substitute for a varied diet; and
5. that food supplements should be stored out of the reach of young children.

Section 7 The labelling and presentation of food supplements may not include any claim or implication that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

Section 8 The amounts of nutrients and other substances with a nutritional or physiological effect present in the product shall be declared on the labelling in numerical form. The amounts indicated shall relate to the content in the recommended daily dose of the product.

The amounts indicated shall be an average based on the manufacturer's analysis of the product and shall be expressed in the units for vitamins and minerals set out in Annex I to Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.

Section 9 The amounts of vitamins and minerals shall be expressed as a percentage of the reference values set out in Annex XIII to Regulation (EU) No 1169/2011 of the European Parliament and of the Council.

The percentage referred to in the first paragraph may also be expressed in graphical form.

Vitamins and minerals

Section 10 Only vitamins and minerals listed in Annex I to Directive 2002/46/EC of the European Parliament and of the Council may be used in the manufacture of food supplements.

Section 11 Only those compounds of vitamins or minerals listed in Annex II to Directive 2002/46/EC of the European Parliament and of the Council may be used in the manufacture of food supplements.

Such vitamin or mineral compounds shall, where appropriate, meet the purity criteria which

1. the Commission has adopted in accordance with Directive 2002/46/EC of the European Parliament and of the Council; or

2. are established by Union law and are applicable to the manufacture of foodstuffs for purposes other than food supplements.

In the absence of established purity criteria, the generally accepted purity criteria recommended by international bodies shall apply.

1. These regulations shall enter into force on 1 July 2023.

2. These regulations repeal the Swedish Food Agency's Regulations (LIVSFS 2003:9) on food supplements.

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