

Draft Regulation amending the Regulation on Food Supplements

Statutory Authority: Laid down by the Ministry of Health and Care Services on [date] pursuant to Act of 19 December 2003 No. 124 relating to food production and food safety, etc. (Food Act) section 9 and 10, cf. Decision no. 1790 of 19 December 2003 concerning delegation of authority and Act of 17 December 2004 No. 101 on the European notification duty for technical regulations (EEA Consultation Act).

I

The following amendments are made in the Regulation of 20 May 2004 No. 755 on Food Supplements:

Section 7a shall be as follows:

§ 7a. *Special requirements for folic acid and vitamin C*

Food supplements that contains more than the recommended daily portion of consumption for adolescents from 11 years and up to 18 years old in one measured small unit quantity, shall be labelled: «Can be injurious to health for children and adolescents less than 18 years».

Food supplements that contains more than the recommended daily portion of consumption for children from 3 years and up to 11 years old in one measured small unit quantity, shall be labelled: «Can be injurious to health for children and adolescents less than 11 years».

Food supplements that contains more than the recommended daily portion of consumption for children from 1 and up to 3 years old in one measured small unit quantity, shall be labelled: «Can be injurious to health for children and adolescents less than 3 years».

Section 7b shall be as follows:

§ 7b. *Special requirements for vitamin D*

Food supplements that contains more than the recommended daily portion of consumption for adolescents from 11 years and up to 18 years old in one measured small unit quantity, shall be labelled: «Can be injurious to health for children and adolescents less than 18 years».

Food supplements that contains more than the recommended daily portion of consumption for children from 3 years and up to 11 years old in one measured small unit quantity, shall be labelled: «Can be injurious to health for children and adolescents less than 11 years».

Section 7c shall be as follows:

§ 7c. *Special requirements for calcium*

Food supplements that contains more than the recommended daily portion of consumption for adults and adolescents from 11 years and up to 18 years old in one measured small unit quantity, shall be labelled: «Can be injurious to health for adults and adolescents from 11 years and up to 18 years old».

Section 14, subsection 4, 5 and 6, shall be amended as follows:

Food business operators that before the entry into force of this regulation, have been granted dispensation to place on the market food supplements with 400 µg folic acid per daily portion of consumption, may continue to produce and label food supplements in accordance with the decision on dispensation until xx.xx.2017 *[the date 6 months after the regulation enters into force will be inserted]*. These food supplements may be marketed until stocks are exhausted.

Food supplements with a maximum content of 600 mg magnesium per daily portion of consumption may continue to be produced and labelled until xx.xx.2017 *[the date 6 months after the regulation enters into force will be inserted]*. These products may be marketed until stocks are exhausted.

Food supplements with a maximum content of 1500 mg calcium per daily portion of consumption may continue to be produced and labelled until xx.xx.2017 *[the date 6 months after the regulation enters into force will be inserted]*. These products may be marketed until stocks are exhausted.

Annex 1 shall be amended as follows:

Annex 1. Vitamins and minerals which may be used in the manufacture of food supplements

Note: The annex states the minimum and maximum amount of vitamins and minerals per daily dose as recommended. In this context, "recommended" indicates the daily dose the manufacturer of the food supplement recommends, and that shall appear in the labelling of the food supplement, according to section 7.

| | Minimum amount <i>per</i> recommended daily dose | Maximum amount <i>per</i> recommended daily dose for | | | |
|-----------------------------|--|---|--|---|--|
| | | young children from 1 year and up to 3 years old | children from 3 years and up to 11 years old | adolescents from 11 years and up to 18 years old | adults from 18 years old |
| | | Special labelling requirements: see section 7 | Special labelling requirements: see section 7 | Special labelling requirements: see section 7 | Special labelling requirements: see section 7 |
| <i>Vitamins</i> | | | | | |
| Vitamin A (µg RE) | 120 | | | | |
| Vitamin D (µg) | 2,5 | 16 | 15 | 40 | 80 |
| Vitamin E (mg α-TE) | 1,8 | | | | |
| Vitamin K (µg) | 11 | | | | |
| Thiamin (mg) | 0,17 | | | | |
| Riboflavin (mg) | 0,21 | | | | |
| Niacin (mg NE) | 2,4 | | | | |
| Folic acid (µg) | 30 | 160 | 260 | 560 | 960 |
| Vitamin B ₆ (mg) | 0,21 | | | | |
| Pantothenic acid (mg) | 0,9 | | | | |

| | | | | | |
|------------------------------|------|-------------|-------------|------------|-------------|
| Vitamin B ₁₂ (µg) | 0,38 | | | | |
| Biotin (µg) | 7,5 | | | | |
| Vitamin C (mg) | 12 | 230 | 477 | 955 | 1000 |
| <i>Minerals</i> | | | | | |
| Calcium (mg) | 120 | 1026 | 1052 | 776 | 705 |
| Phosphorus (mg) | 105 | | | | |
| Magnesium (mg) | 56 | 85 | 120 | 280 | 350 |
| Iron (mg) | 2,1 | | | | |
| Copper (mg) | 0,15 | | | | |
| Iodine (µg) | 23 | | | | |
| Zinc (mg) | 1,5 | | | | |
| Manganese (mg) | 0,3 | | | | |
| Selenium (µg) | 8,3 | | | | |
| Chromium (µg) | 6 | | | | |
| Molybdenum (µg) | 7,5 | | | | |
| Sodium (mg) | | | | | |
| Potassium (mg) | 300 | | | | |
| Fluoride (mg) | 0,1 | | | | |
| Chloride (mg) | | | | | |
| Boron (mg) | | | | | |
| Silicon (mg) | | | | | |

The heading of annex 2 shall be amended as follows:

Annex 2: Vitamin and mineral substances which may be used in the manufacture of food supplements

II

The Regulation enters into force on the day of publication.