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, 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).

[For information only: the suggested amendments are marked with bold type.]

I

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

Section 7 shall be amended as follows:

Presentation and content of the labelling

The legal name for products covered by this regulation is “food supplement”.

The name “food supplement” is reserved for products that fulfil the provisions in this regulation.

Food supplements shall be labelled with the following particulars:

1. the name of the categories of nutrients or other substances with a nutritional or physiological effect that characterise the product, or an indication of the nature of

these

2. a recommended daily dose

3. a warning not to exceed the recommended daily dose

4. a statement that food supplements should not be used as a substitute for a varied diet

5. a statement that the products should be stored out of the reach of children

Food supplements with folic acid for women who are planning a pregnancy, or who might become pregnant, shall be labelled as follows: “Folate reduces the risk of neural tube defects. Folic acid is a form of folate. Women who are planning a pregnancy, or who might become pregnant, are advised to take a daily supplement of 400 micrograms of folic acid from at least one month prior to, and during the first three months of pregnancy, in addition to folate from a varied diet.” The labelling shall be placed in the principal field of vision.

Section 8 shall be amended as follows:

Declaration of amounts

Food supplements shall be labelled with the amount of the nutrients or other substances with a nutritional of physiological effect, expressed in numerical form per recommended daily dose. The units to be used for vitamins and minerals shall be those specified in annex 1 in this regulation.

The amount of nutrients or other substances with a nutritional of physiological effect shall be average values based on the manufacturer’s analysis of the product.

In addition to the labelling pursuant to paragraph 1, the amounts of those vitamins and minerals which are listed in **annex XIII, part A in regulation (EU) No. 1169/2011 on food information to consumers, which is implemented in regulation 28 November 2014 No. 1497 on food information to consumers, article 1,** shall also expressed as a percentage of the reference values as mentioned in the annex in the regulation on food information to consumers. The percentage of the reference values shall be expressed per daily dose. The percentage of the reference values may also be given in graphical form.

Section 11 shall be amended as follows:

Dispensation

The Norwegian Food Safety Authority may in particular cases grant dispensation from the provisions in this regulation, provided it will not conflict with Norway's international obligations, including the EEA agreement.

Section 13 shall be repealed.

Section 14 shall be amended as follows:

Entry into force and transitional provisions

This Regulation, with the exception of section 10, enters into force on 28 May 2004. Simultaneously, the Regulation of 25 September 1986 No. 1918 on production and sales etc. of vitamin and mineral supplements is repealed. Section 10 will enter into force on a date as decided upon by the Ministry.

Food supplements with a minimum content of 1 µg vitamin D per daily portion of consumption are permitted to be produced and labelled until 24 September 2015. These products may be marketed until stocks are exhausted.

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, can continue to produce and label food supplements in accordance with the decision on dispensation before xx.xx.2016. 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 are permitted to be produced and labelled before xx.xx.2016. These products may be marketed until stocks are exhausted.

Food supplements with a minimum content of 25 µg folic acid per daily portion of consumption, or a minimum content of 200 mg potassium per daily portion of consumption, are permitted to be produced and labelled before xx.xx.2016. These products may be marketed until stocks are exhausted.

Annex 1 shall be amended as follows:

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 **per** recommended daily dose*	*Maximum amount **per** recommended daily dose*
Vitamins		
Vitamin A (µg RE)	**120**	1500
Vitamin D (µg)	2,5	20
Vitamin E (mg α-TE)	**1,8**	30
Vitamin K (µg)	**11**	200
Thiamin (mg)	**0,17**	2,4
Riboflavin (mg)	**0,21**	2,8
Niacin (mg NE)	**2,4**	32
Folic acid (µg)	**30**	200
Folic acid (µg) [1]	**400** [1]	**400** [1]
Vitamin B_6 (mg)	**0,21**	4,2
Pantothenic acid (mg)	**0,9**	15
Vitamin B_{12} (µg)	**0,38**	9
Biotin (µg)	**7,5**	225
Vitamin C (mg)	**12**	200
Minerals		
Calcium (mg)	**120**	1500
Phosphorus (mg)	**105**	1500
Magnesium (mg)	**56**	**250**

Iron (mg)	**2,1**	27
Copper (mg)	**0,15**	4
Iodine (µg)	**23**	225
Zinc (mg)	**1,5**	25
Manganese (mg)	**0,3**	5
Selenium (µg)	**8,3**	100
Chromium (µg)	**6**	125
Molybdenum (µg)	**7,5**	250
Sodium (mg)		500
Potassium (mg)	**300**	1000
Fluoride (mg)	0,1	0,5
Chloride (mg)		750
Boron (mg)		1
Silicon (mg)		400

[1] Only valid for food supplements for women who are planning a pregnancy, or who might become pregnant.

Item 10 under *A. Vitamins* in annex 2 shall be amended as follows:

10 **FOLATE**

a) pteroylmonoglutamic acid

b) **calcium-L-methylfolate**

c) (6S)-5-methyltetrahydrofolic acid, glucosamine salt

II

The Regulation enters into force on the day of publication.