Republic of Latvia

Cabinet
Regulation No. 685
Adopted 1 December 2015

Requirements for Food Supplements

Issued pursuant to
Section 4, Paragraph two and Paragraph 10.[1], Clause 2, Section 13, Paragraph three, Clause 3 of the Law on the Supervision of the Handling of Food and Section 7, Paragraph two of the Advertising Law

I. General Provisions

1. This Regulation prescribes:
1.1. the mandatory safety requirements for food supplements;
1.2. the procedures for registering food supplements, suspending or restricting their circulation and cancelling registration;
1.3. the requirements for additional labelling of food supplements;
1.4. the requirements for the advertising content and presentation.

2. This Regulation shall not apply to medicinal products.

3. It shall be permitted to place food supplements on the market in Latvia, if they:
3.1. have been notified to the Food and Veterinary Service (hereinafter – the Service) and included in the register of food supplements;
3.2. have been presented as food products and are delivered to the end consumer in pre-packaged form only.

4. A food establishment (hereinafter – the establishment) shall ensure that there is information on the products distributed thereby at the trading site of the relevant food supplements.

5. The Service shall not restrict or prohibit the trade in food supplements due to their composition, manufacturing specification, presentation or labelling, if they conform to the requirements of this Regulation and the laws and regulations governing the circulation of food.

II. Mandatory Safety Requirements

6. Food supplements are foodstuffs whose purpose is to supplement the normal diet in the form of concentrated sources of nutrients (vitamins and minerals) or other substances with a nutritional or physiological effect, alone or in combination. Food supplements are marketed in specific doses in capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.

7. Maximum amounts of vitamins and minerals present in food supplements per daily dose of consumption as recommended by the manufacturer shall be set, taking the following into account:

7.1. upper safe levels established by scientific risk assessment based on generally accepted scientific data;

7.2. varying degrees of sensitivity of different consumer groups;

7.3. intake of vitamins and minerals from other dietary sources;

7.4. recommended doses of vitamins and minerals for a consumer.

8. Only such vitamins and minerals may be used in the manufacture of food supplements and in such forms as defined in:

8.1. Commission Regulation (EC) No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements;

8.2. Commission Regulation (EU) No 1161/2011 of 14 November 2011 amending Directive 2002/46/EC of the European Parliament and of the Council, Regulation (EC) No 1925/2006 of the European Parliament and of the Council and Commission Regulation (EC) No 953/2009 as regards the lists of mineral substances that can be added to foods;

8.3. Commission Regulation (EU) No 119/2014 of 7 February 2014 amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards chromium enriched yeast used for the manufacture of food supplements and chromium(III) lactate tri-hydrate added to foods;

8.4. Commission Regulation (EU) No 2015/414 of 12 March 2015 amending Directive 2002/46/EC of the European Parliament and of the Council as regards (6 S)-5-methyltetrahydrofolic acid, glucosamine salt used in the manufacture of food supplements.

III. Procedures for Registering, Suspending or Restricting the Circulation and Cancelling Registration

9. In order to register a food supplement, the establishment shall submit the following to the Service:

9.1. a notification for the registration of the food supplement (Annex 1) (hereinafter – the notification);

9.2. a sample labelling of the food supplement in the original language (for example, a box, label or clearly visible photocopy of the original packaging with legible text, or a scanned mock-up);

9.3. a sample text of the labelling and other information in Latvian which will be attached to the food supplement.

10. If the notification is submitted in printed form, the establishment shall submit in addition the sample and information referred to in Sub-paragraph 9.3 of this Regulation to the Service using the electronic data carriers available.

11. The Service may request an opinion from the State Agency of Medicines:

11.1. if the information indicated in the notification shows that the food supplement is a medicinal product;

11.2. if the Service establishes that the food supplement notified or included in the register is being distributed as a medicinal product in another European Union Member State;

11.3. taking into account the information received from the competent authorities of other European Union Member States.

12. The Service may, if necessary, request any other information on the food supplement from the establishment in order to assess its conformity with the requirements of the laws and regulations governing the circulation of food.

13. If changes are made to a registered food supplement, the establishment shall submit a notification to the Service regarding changes in a registered food supplement (Annex 2).

14. Prior to submitting the notification referred to in Paragraphs 9 and 13 of this Regulation, the establishment shall pay the State fee in accordance with a regulatory enactment regarding the State fee for the registration of a food supplement.

15. The Service shall, within one month after receipt of the documents referred to in Paragraphs 9 and 13 of this Regulation, take a decision to:

15.1. register the food supplement in the register of food supplements of the Service or to refuse registration, if the product does not conform to the requirements of the laws and regulations governing the field of food circulation;

15.2. make changes in the register of food supplements or to refuse to make changes, if the product does not conform to the requirements of the laws and regulations governing the field of food circulation.

16. If the Service receives new information or performs repeat check of the existing information on the basis of which it may be concluded that the registered food supplement may cause or causes threats to human health, the Service shall take a decision to restrict or temporarily suspend the trade in the food supplement or to remove it from circulation. In accordance with the laws and regulations regarding the operation of the rapid alert system in circulation of food and circulation of animal feed, the Service shall without delay inform the Member States and the European Commission about the decision taken.

17. If the food supplement included in the register causes threats to human health, the Service shall take a decision to cancel the registration of the food supplement and shall delete it from the register of food supplements.

18. If the food supplement included in the register does not cause threats to human health, however, does not conform to the requirements of the laws and regulations governing the field of food circulation, the Service may take a decision to suspend the trade in the food supplement until the elimination of non-conformities. If the non-conformities detected are not eliminated, the Service may take a decision to cancel the registration of the food supplement.

19. The Service shall create and maintain a register of food supplements. The register shall be published on the website of the Service. The following information shall be included in the register:

19.1. the name and address of the manufacturer;

19.2. the name and address of the food establishment operator (for example, importer, distributor) responsible for the food supplement and involved in the circulation of food;

19.3. the list of ingredients of the food supplement and the quantity of nutrients or other substances with nutritional or physiological effect per daily dose (also names of the used plants in Latvian and Latin);

19.4. the recommended daily dose of the food supplement;

19.5. the form of preparation of the food supplement, the size of the pre-packaging and packaging unit;

19.6. text of the labelling and other information, if such is to be attached to the food supplement, for example, sample instructions for use.

20. If the food supplement included in the register of food supplements is not placed on the market anymore, the establishment shall inform the Service thereon, and the Service shall delete the food supplement from the register of food supplements.

IV. Requirements for Additional Labelling and Advertising

21. Food supplements shall be labelled in accordance with the procedures laid down in the regulatory enactment regarding the requirements for packaging of pre-packaged food and 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 (hereinafter – Regulation No 1169/2011). The following additional information shall be included in the labelling:

21.1. the trade name "food supplement";

21.2. the names of the categories of nutrients or substances that characterise the food supplement or an indication of the nature of those nutrients or substances;

21.3. the dose of the product recommended for daily consumption;

21.4. a warning not to exceed the stated recommended daily dose;

21.5. a statement to the effect that the food supplement should not be used as a substitute for a nutritious and balanced diet;

21.6. a warning that the food supplement should be stored out of the reach of children;

21.7. in numerical form – the amount of the nutrients or substances with a nutritional or physiological effect in mass or volume units per daily dose. Vitamins and minerals shall be indicated in the specified units of measurements in accordance with the requirements of the laws and regulations referred to in Paragraph 8 of this Regulation;

21.8. the amount of vitamins and minerals in percentage from the reference value of nutrients indicated in Part A of Annex XIII to Regulation No 1169/2011. The amount of vitamins and minerals in percentage may also be given in graphical form.

22. The minimum amount of vitamins and minerals per daily dose recommended by the manufacturer shall not be significantly less than the amount of vitamins and minerals indicated in Part A, Paragraph 2 of Annex XIII to Regulation No 1169/2011.

23. The amount of nutrients indicated in the labelling or of other such substances having a nutritional or physiological effect:

23.1. shall conform to the amount of a food supplement recommended as a daily dose;

23.2. shall be the average amount on the basis of the testing results of the food supplement performed by the manufacturer.

24. The labelling, presentation and advertising of the food supplement must not include:

24.1. indication that the food supplement prevents, treats or cures diseases, or mentioning of such possibility;

24.2. any explicit or implicit indications that a balanced and varied diet cannot provide appropriate quantities of nutrients.

25. It shall be permitted to advertise only food supplements included in the register of food supplements.

26. Advertising of the food supplement shall include indications “Food supplement” and “Food supplement does not replace a nutritious and balanced diet”.

27. The indication “Food supplement does not replace a nutritious and balanced diet” shall cover not less than five per cent of the volume of the advertising. The size of letters shall be such that the indication would cover as large part of the space provided for the text as technically possible.

V. Closing Provision

28. Abbreviation RDD (recommended daily dose) may be used for food supplements which have been placed on the market and labelled until 13 December 2016 in order to express the reference value to the amount of vitamins and minerals in percentage from the recommended daily dose indicated in Part A of Annex XIII to Regulation No 1169/2011.

Informative Reference to European Union Directives

This Regulation contains legal norms arising from:

1) 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;

2) Commission Directive 2006/37/EC of 30 March 2006 amending Annex II to Directive 2002/46/EC of the European Parliament and of the Council as regards the inclusion of certain substances.

Prime Minister — Laimdota Straujuma

Minister for Agriculture — Jānis Dūklavs

Annex 1
Cabinet Regulation No. 685
1 December 2015

Notification for the Registration of a Food Supplement

1. Food supplement

Name of the food supplement		
Manufacturer	name, registration number of the establishment	
	state	
	address	
	contact telephone number and electronic mail address	
Type of preparation[1]		
Size of the pre-packaging unit[2]		
Size of the packaging unit[3]		
Recommended daily dose[4]		

2. Ingredient(s)

No.	Ingredient[5]	Amount and unit of measurement[6]

3. Establishment

(the entrepreneur, importer or distributor responsible for information on food products and involved in circulation of food)[7]

Establishment (name, registration number)	
State	
Address (legal and actual)	
Contact telephone number and electronic mail address	
Notes	

4. Establishment

Establishment (name, registration number)	
State	
Address (legal and actual)	

Contact telephone number and electronic mail address	
Notes	

5. Documents attached to the notification

1.	Sample text of the labelling in Latvian on ... pages.
2.	Information attached to the labelling (sample instructions for use or other information, if such is to be attached to the packaging) on ... pages.
3.	Sample labelling in the original language (for example, box, label or clearly visible photocopy of the original packaging with legible text, or scanned mock-up)[9] in ... copies.
4.	Other documents on ... pages.

6. Information on the payment of the State fee[10]

Payer of the State fee (name, registration number of the establishment)	
Payment date	

7. Type of receipt of the decision of the Service

1.	Send the decision to the electronic mail address indicated	
2.	Send the decision to the postal address indicated: legal actual	 ☐ ☐
3.	Receive the decision in person	☐

Notes.
[1]For example, tablets, capsules, powder.
[2] For example, tablets 0.5 g each.
[3] For example, 30 tablets in a 420 ml bottle. If the food supplement is to be offered with different types of flavour, please, specify it in this section.
[4] For example, two tablets per day.
[5] If the composition of the food supplement includes vitamins or minerals, the types of their chemical compounds shall be indicated. For plants their botanical name in Latvian and Latin, the part of the plant used (for example, blossoms, root) and the type of their preparation (for example, tablets, capsules, powder, essence, extract) shall be indicated. The ratio of plant in relation to essence shall be indicated in addition for a plant essence.
[6] For nutrients or substances with a nutritional or physiological effect the amount shall be indicated in a daily dose in numerical form in mass or volume units of measurement.
[7] Section shall be filled in, if the name of the establishment referred to in Paragraph 1 of this Annex is different.
[8] Section shall be filled in, if the submitter of the notification is none of the establishments referred to in Paragraph 1 or 3 of this Annex.

[9] If the original is to be prepared in Latvian after the registration of the food supplement, in addition a certification must be submitted that the original will be submitted to the Service after its preparation.
[10] Section shall be filled in, if payment is made in a credit institution.

Minister for Agriculture Jānis Dūklavs

Annex 2
Cabinet Regulation No. 685
1 December 2015

Notification of Changes in a Registered Food Supplement

1. Food supplement

Name of the food supplement	
Registration number of the food supplement	

2. Changes made[1]

No.	Changes	Mark as required	Describe in greater detail
1.	Name of the food supplement		
2.	Name of the manufacturer		
3.	Address of the manufacturer		
4.	Name of the establishment		
5.	Address of the establishment		
6.	Type of preparation		
7.	Size of the pre-packaging unit		
8.	Size of the packaging unit		
9.	Recommended daily dose		
10.	Ingredients		
11.	Amount of ingredients		
12.	In the labelling or other information attached		

3. Establishment

Establishment (name, registration number)	
Country	
Address (legal and actual)	
Contact person	
Contact telephone number and electronic mail address	

4. Documents attached to the notification

1.	Sample text of the labelling in Latvian on ... pages.
2.	Information attached to the labelling (instructions for use or other information, if such is to be attached to the packaging) on ... pages.
3.	Sample labelling in the original language (for example, box, label or clearly visible photocopy of the original packaging with legible text, or scanned mock-up)[2] in ... copies.
4.	Other documents on ... pages.

5. Information on the payment of the State fee[3]

Payer of the State fee (name, registration number of the establishment)	
Payment date	

6. Type of receipt of the decision of the Service

1.	Send the decision to the electronic mail address indicated	
2.	Send the decision to the postal address indicated: legal actual	 ☐ ☐
3.	Receive the decision in person	☐

Notes.
[1] A food supplement with a labelling previously included in the register may be placed on the market until the end of expiry date, if such food supplement and its labelling conforms to the requirements of laws and regulations.
[2] If the original will be prepared in Latvian, after the registration of the food supplement, it must be additionally indicated that the original will be submitted to the Service after its preparation.
[3] Section shall be filled in, if payment is made in a credit institution.

Minister for Agriculture Jānis Dūklavs

