Text consolidated by Valsts valodas centrs (State Language Centre) with amending regulations of:

7 January 2021 [shall come into force on 14 January 2021].

If a whole or part of a paragraph has been amended, the date of the amending regulation appears in square brackets at the end of the paragraph. If a whole paragraph or sub-paragraph has been deleted, the date of the deletion appears in square brackets beside the deleted paragraph or sub-paragraph.

Republic of Latvia

Cabinet

Regulation No. 819

Adopted 18 December 2018

**Procedures for the Registration of Foods for Specific Groups and Procedures for the Payment of the State Fee**

*Issued pursuant to*

*Section 4, Paragraph 10.1, Clause 3 and Section 20, Paragraph two of the Law on the Supervision of the Handling of Food*

**I. General Provisions**

1. This Regulation prescribes:

1.1. the procedures for notifying of the distribution of foods for specific groups referred to in Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 and also the procedures by which such products are registered and registration thereof is cancelled;

1.2. the amount of the State fee for registration of foods for specific groups referred to in Paragraph 2 of this Regulation and the procedures for the payment of the State fee.

2. A food establishment shall notify the Food and Veterinary Service (hereinafter – the Service) of placing food products belonging to the following groups (hereinafter – food products) on the Latvian market:

2.1. infant formula and follow-on formula in accordance with Article 12 of Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding;

2.2. food for special medical purposes in accordance with Article 9 of Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes;

2.3. total diet replacement for weight control products in accordance with Article 7 of Commission Delegated Regulation (EU) 2017/1798 of 2 June 2017 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for total diet replacement for weight control.

**II. Procedures for Registration of Food Products and Cancelling of Registration**

3. A food establishment shall submit to the Service a notification for the registration of the food product (hereinafter – the notification) or shall send it by post or electronically if the notification has been drawn up in accordance with the laws and regulations regarding the drawing up of electronic documents. A sample of the notification form shall be available on the website of the Service, indicating the following information:

3.1. on the food product:

3.1.1. the name;

3.1.2. the name, the registration number in the Commercial Register, the address, telephone number, electronic mail address of the manufacturer;

3.1.3. the form of preparation;

3.1.4. the size of the unit of pre-packaging;

3.2. the group of food products – infant formula, follow-on formula, food for special medical purposes or total diet replacement for weight control products;

3.3. on the submitter of the notification:

3.3.1. the name of the food establishment, for a natural person – also the given name and surname;

3.3.2. for a legal person – the registration number in the Commercial Register and the legal address, for a natural person – the personal identity number and the address of the declared place of residence;

3.3.3. the actual address if it differs from the legal address or the address of the declared place of residence;

3.3.4. the contact person, telephone number, electronic mail address;

3.4. on the food establishment:

3.4.1. the name of the food establishment, for a natural person – also the given name and surname;

3.4.2. the registration number in the Commercial Register and the legal address of a legal person, for a natural person – the personal identity number and the address of the declared place of residence;

3.4.3. the actual address if it differs from the legal address or the address of the declared place of residence;

3.4.4. the contact person, telephone number, electronic mail address;

3.5. on the payment of the State fee – the payer of the State fee, the date of the payment and the amount paid;

3.6. on the method of receipt of the Service decision – to the indicated official electronic address, electronic mail address, postal address or in person;

3.7. a declaration that the information provided is true.

[*7 January 2021*]

3.1 In addition to the notification specified in Paragraph 3 of this Regulation, the food establishment shall submit to the Service:

3.11. a sample of the labelling text in the Latvian language.

3.1 2. a sample of the labelling text in the original language or the original packaging, or a photocopy.

[*7 January 2021*]

4. If the notification is submitted in paper form, the food establishment shall also submit electronically to the Service a sample of the labelling text in Latvian, using the available electronic data carriers. Such procedure shall also apply in the case referred to in Paragraphs 8 and 8.1 of this Regulation.

[*7 January 2021*]

5. In order to assess the conformity of the food product with the requirements laid down in the laws and regulations governing the field of handling of food, the Service may require the food establishment to provide any other information on the food product.

6. The Service shall take one of the following decisions within a month after receipt of the notification:

6.1. to register the food product and to include it in the Register of Foods for Specific Groups (hereinafter – the register) if the documents, which have been submitted by the food establishment to the Service, have been drawn up properly and contain complete information, and the food product conforms to the requirements laid down in the laws and regulations governing the field of handling food;

6.2. to refuse the registration if all the necessary documents have not been submitted or the food product does not conform to the requirements laid down in the laws and regulations governing the field of handling of food.

7. The Service shall create and maintain a register with added text of the labelling of the food product that is publicly accessible on the website of the Service.

8. If changes are made to the labelling of a registered food product, the food establishment shall without delay submit a notification of the change to the Service. A sample of the relevant form is available on the website of the Service. The following information shall be indicated in the notification of the change:

8.1. regarding the food product:

8.1.1. the name and registration number of the food product;

8.1.2. the changes made affecting the name of the product, the name of the manufacturer, the address of the manufacturer, the contact person, the telephone number, the electronic mail address, the form of preparation, the size of the unit of pre-packaging, the purpose of use or the labelling;

8.2. regarding the submitter of the notification:

8.2.1. the name of the establishment, for a natural person – also the given name and surname;

8.2.2. the registration number in the Commercial Register and the legal address of a legal person, for a natural person – the personal identity number and the address of the declared place of residence;

8.2.3. the actual address if it differs from the legal address or the address of the declared place of residence;

8.2.4. the contact person, telephone number, electronic mail address;

8.3. regarding the food establishment:

8.3.1. the name of the food establishment, for a natural person – also the given name and surname;

8.3.2. the registration number in the Commercial Register and the legal address of a legal person, for a natural person – the personal identity number and the address of the declared place of residence;

8.3.3. the actual address if it differs from the legal address or the address of the declared place of residence;

8.3.4. the contact person, telephone number, electronic mail address;

8.4. an indication regarding the need to maintain the labelling previously included in the register, indicating the exact period until which the labelling previously entered in the register is to be kept in the register;

8.5. regarding the method of receipt of a Service decision – to the indicated official electronic address, electronic mail address, postal address or in person;

8.6. a declaration that the information provided is true.

[*7 January 2021*]

8.1 In addition to the notification referred to in Paragraph 8 of this Regulation, the food establishment shall submit to the Service:

8.11. a sample of the labelling text in the Latvian language;

8.1 2. a sample of the labelling text in the original language or the original packaging, or a photocopy.

[*7 January 2021*]

8.2 The Service shall take the decision to make changes to the register or to refuse to make changes within a period of one month after receipt of the notification of changes if the food does not conform to the requirements of the laws and regulations governing the field of food distribution.

[*7 January 2021*]

9. If the Service receives new information or after repeated examination of the current information concludes that the registered food product causes or may cause threats to human health, the Service shall take the decision to cancel the registration of the food product and shall delete it from the register.

10. If a registered food product is no longer placed on the market, the food establishment shall inform the Service thereof and the Service shall delete the food product from the register within a month.

10.1 The food establishment may also submit the information specified in Paragraphs 3, 3.1, 8, and 8.1 of this Regulation electronically by completing an online form on the website of the Service www.pvd.gov.lv (e-service) and for identification purposes using the shared solution for the identification of a person of the State information system integrator under supervision of the State Regional Development Agency.

[*7 January 2021*]

**III. Amount of the State Fee and Procedures for the Payment Thereof for Foods for Specific Groups**

11. The State fee shall be paid in the following amount:

11.1. for registration of food products that have been manufactured in the third country, except for the food products referred to in Sub-paragraph 2.1 of this Regulation – EUR 228;

11.2. for registration of food products that have been manufactured in any of the European Economic Area States, except for the food products referred to in Sub-paragraph 2.1 of this Regulation – EUR 100;

11.3. for registration of food products referred to in Sub-paragraph 2.1 of this Regulation – EUR 43.

12. The State fee shall be paid prior to submitting the notification referred to in Paragraph 3 of this Regulation regarding the registration of food products.

[*7 January 2021*]

13. The State fee shall be paid in one of the following ways:

13.1. at the Service, using a payment card;

13.2. via such payment service provider who has the right to provide payment services within the meaning of the Law on Payment Services and Electronic Money.

14. If the payment is made via the payment service provider, the person shall indicate the name of the relevant food product in the field where the purpose of payment is indicated.

15. The State fee shall be transferred into the revenue account of the State basic budget in the Treasury.

**IV. Closing Provisions**

16. The following Regulations are repealed:

16.1. Cabinet Regulation No. 962 of 12 October 2010, Regulations Regarding the State Fee for Registration of Infant Formulas (*Latvijas Vēstnesis*, 2010, No. 164; 2013, No. 154);

16.2. Cabinet Regulation No. 530 of 15 September 2015, Regulations Regarding Specific Requirements for Dietary Food and Additional Labelling Thereof and Procedures for Registration, Handling of Dietary Food and Payment of the State Fee for Dietary Food (*Latvijas Vēstnesis*, 2015, No. 192).

17. Infant formulas and dietary foods for special medical purposes registered in the Service before coming into force of this Regulation shall retain the status of registered food products.

18. The requirements laid down in this Regulation shall be applied as follows:

18.1. from 22 February 2021 – to follow-on formulas manufactured from protein hydrolysates;

18.2. from 27 October 2022 – to total diet replacement for weight control products.

19. The Regulation shall come into force on 1 January 2019.

Prime Minister Māris Kučinskis

Acting for the Minister for Agriculture – Minister for Transport Uldis Augulis

**Annex 1**

Cabinet Regulation No. 819

18 December 2018

**Notification of Registration of Foods for Specific Groups**

[7 January 2021]

**Annex 2**

Cabinet Regulation No. 819

18 December 2018

**Notification of Changes to Registered Foods for Specific Groups**

[7 January 2021]