

Republic of Latvia
Cabinet
Regulation No. 819
Adopted 18 December 2018

**Procedures for Registration of Foods for Specific Groups and Procedures
for 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 the notification of registration of the food product to the Service (Annex 1) or shall send it by post or electronically if the notification has been drawn

up in accordance with the laws and regulations regarding drawing up of electronic documents. The following shall be appended to the notification:

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

3.2. a sample text of the labelling of the food product in the official language.

4. If the notification (Annex 1) is submitted in paper format, a food establishment shall additionally submit the relevant information and the sample referred to in Sub-paragraph 3.2 of this Regulation to the Service also in electronic format, using the electronic data carriers.

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. In the event of any changes to the labelling of a registered food product, the food establishment shall immediately submit to the Service the notification (Annex 2) with the added new text of the labelling and a sample labelling of the product in the original language (for example, a label or clearly visible photocopy of the original with legible text, or a scanned mock-up). The Service shall make changes to the register within a month after receipt of the notification (Annex 2).

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.

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. If after receipt of all the necessary documents the Service establishes non-conformity of food products with the laws and regulations governing the field of handling of food or the food product is not registered, the State fee shall not be reimbursed.

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

Notification of Registration of Foods for Specific Groups

1. Food product subject to registration

- manufactured in the third country
- manufactured in any of the European Economic Area States
-

2. Information on the food product

- 2.1. Name of the product _____
- 2.2. Name of the manufacturer _____
- 2.3. Address of the manufacturer _____
- 2.4. Type of preparation _____
- 2.5. Size of the pre-packaging unit _____
- 2.6. Product group
- 2.6.1. infant formulas
- 2.6.2. follow-on formulas
- 2.6.3. food for special medical purposes
- 2.6.4. total diet replacement for weight control products

2.7. A brief description of the special composition or manufacturing process of the food product whereby the product is clearly distinct from food for normal consumption and therefore is intended for specific nutritional purposes

3. Information on the submitter of the notification

- 3.1. Food establishment (name) or natural person (given name, surname) _____
- 3.2. Registration number of the legal person in the Enterprise Register or personal identity number of the natural person _____
- 3.3. Legal address (for a natural person – address of the declared place of residence) _____

3.4. Actual address (to be left blank if it is the same as the legal address or address of the declared place of residence)

3.5. Contact person

3.6. Telephone number

3.7. Electronic mail address

4. Information on the food establishment (to be filled in case different from the submitter of the notification)

4.1. Food establishment (name) or natural person (given name, surname)

4.2. Registration number of the legal person in the Enterprise Register or personal identity number of the natural person

4.3. Legal address (for a natural person – address of the declared place of residence)

4.4. Actual address (to be left blank if it is the same as the legal address or address of the declared place of residence)

4.5. Contact person

4.6. Telephone number

4.7. Electronic mail address

5. Documents appended

5.1. Original or photocopy of the labelling or packaging¹ _____ copy(-ies)

5.2. Sample text of the labelling in the official language on _____ page(-s)

5.3. Original of the authorisation or certified copy of authorisation and translation in the official language (if authorisation is in a foreign language) on _____ page(-s)

5.4. Other documents _____ page(-s)

Note. ¹ If the original is to be prepared in Latvian after the registration of the food product, in addition information must be submitted that the original will be submitted to the Food and Veterinary Service after its preparation.

6. Information on the payment of the State fee²

Payer of the State fee

(name of the food establishment or given name, surname of a natural person)

Payment date

Amount paid _____

Note. ² Section shall be filled in if payment of the State fee is made via the payment service provider.

7. Type of receipt of the decision taken by the Food and Veterinary Service

Mark with

In person, visiting the Food and Veterinary Service³

By post to the legal address³

By sending an electronic document to the electronic mail address (the decision is signed with a secure electronic signature and contains a time stamp)³

Note. ³ If an official electronic address account has been activated for the person, the decision will be sent to the official electronic address.

8. Certification

I hereby confirm that the information provided is true, the information indicated in the notification and documents appended thereto is accurate.

_____	_____	_____
(position)	(given name, surname)	(signature ⁴)

(telephone number)		

(date ⁴)		

Note. ⁴ The details of the document “signature” and “date” shall not be completed if the document has been drawn up in accordance with the laws and regulations regarding drawing up of electronic documents.

Acting for the Minister for Agriculture – Minister for Transport

Uldis Augulis

Notification of Changes to Registered Foods for Specific Groups

1. Food product

Name of the food product _____
Registration number of the food product _____

2. Changes made

No.	Changes	Mark as required	Describe in greater detail
2.1.	Name of the product		
2.2.	Name of the manufacturer		
2.3.	Address of the manufacturer		
2.4.	Contact person, contact information		
2.5.	Type of preparation		
2.6.	Size of the pre-packaging unit		
2.7.	Purpose of use		
2.8.	Other changes to labelling		

3. Submitter of the notification

3.1. Food establishment (name) or natural person (given name, surname) _____
3.2. Address (legal and actual if different from the legal address, for a natural person – address of the declared place of residence) _____
3.3. Contact person _____
3.4. Telephone number and electronic mail address for correspondence with the Food and Veterinary Service _____

4. Documents appended

4.1. Original or photocopy of the labelling or packaging¹ _____ copy(-ies)
4.2. Sample text of the labelling in the official language on _____ page(-s)
4.3. Original of the authorisation or certified copy of authorisation and translation in the official language (if authorisation is in a foreign language) on _____

Note. ¹ If the original is to be prepared in Latvian after the registration of the food product, in addition information must be submitted that the original will be submitted to the Food and Veterinary Service after its preparation.

5. Type of receipt of the decision taken by the Food and Veterinary Service

Mark with

In person, visiting the Food and Veterinary Service²

By post to the legal address²

By sending an electronic document to the electronic mail address (the decision is signed with a secure electronic signature and contains a time stamp)²

Note. ² If an official electronic address account has been activated for the person, the decision will be sent to the official electronic address.

6. Certification

I hereby confirm that the information provided is true, the information indicated in the notification and documents appended thereto is accurate.

(position)	(given name, surname)	(signature ³)
(telephone number)		
(date ³)		

Note. ³ The details of the document “signature” and “date” shall not be completed if the document has been drawn up in accordance with the laws and regulations regarding drawing up of electronic documents.

Acting for the Minister for Agriculture – Minister for Transport

Uldis Augulis