

Establishment of Procedure for Application for and Issue of Permits for Handling of Food for Particular Nutritional Uses¹

Government of the Republic Regulation No. 26 of 31 January 2000

(RT² I 2000, 8, 50),

entered into force 6 February 2000.

The Regulation is established pursuant to subsection 14 (4) of the Food Act (RT I 1999, 30, 415; 58, 608).

Chapter 1

General Provisions

§ 1.

To establish the procedure for and conditions of application for and issue of permits for the handling of food for particular nutritional uses and refusal of issue, and partial and total suspension of permits.

§ 2.

Food for particular nutritional uses is food which is intended for persons with nutritional needs differing from normal nutritional needs and who, due to the disturbance of digestive processes or metabolism, or a special physiological condition, need food which differs from food for normal consumption in its composition and which is labelled according to special requirements.

§ 3.

A permit for the handling of food for particular nutritional uses (hereinafter handling permit) is a document issued by the Health Protection Inspectorate which grants manufacturers, packers and importers the right to handle food for particular nutritional uses.

§ 4.

Handling permits shall be issued regarding the following food for particular nutritional uses:

- 1) infant formulae and follow-on formulae;
- 2) baby foods and food for young children, including cereal products and cereal foods;
- 3) energy-reduced foods;

- 4) dietary foods for special medical purposes, including food with reduced sodium content and gluten-free foods;
- 5) food for sportsmen, including food intended to meet the expenditure of intensive muscular effort;
- 6) food for persons suffering from carbohydrate-metabolism disorders (diabetics);
- 7) other food for particular nutritional uses.

§ 5.

The Health Protection Inspectorate has the right to issue handling permits regarding food for particular nutritional uses which is manufactured, placed on the market or transferred in some other manner in Estonia if:

- 1) it complies with the provisions of § 14 of the Food Act (RT I 1999, 30, 415; 58, 608);
- 2) its compliance with the requirements has been examined and assessed;
- 3) it is properly labelled.

Chapter 2

Application for Handling Permits

§ 6.

Manufacturers, packers and importers of food for particular nutritional uses (hereinafter applicant) shall apply for handling permits.

§ 7.

In order to obtain a handling permit for the first time, an applicant shall submit an application to the Health Protection Inspectorate containing the following information:

- 1) the name, food group and purpose of use of the food for particular nutritional uses;
- 2) the name, address, fax number or e-mail address and commercial registry code of the applicant, in the case of a sole proprietor, his or her personal identification code, or in the absence thereof, his or her date of birth;
- 3) the name and address of the manufacturer.

§ 8.

An applicant shall append the following documents to an application for handling food for particular nutritional uses:

- 1) the technical description of the food pursuant to § 24 of the Food Act in the case of food for particular nutritional uses manufactured in Estonia;
- 2) the samples of labelling of the sales packaging and other written information, including instructions for use in Estonian and in the language of the manufacturing country;
- 3) a copy of the decision which approves the sector of handling of the food business, or a copy of the activity licence of the importer;
- 4) the results of examinations carried out in compliance with international requirements or other reliable evidence concerning suitability of the food to be used as food for particular nutritional uses.

§ 9.

A separate application shall be submitted regarding each food for particular nutritional uses and it is deemed to be submitted on the date when the Health Protection Inspectorate receives all the required documents.

Chapter 3

Assessment of Food for Particular Nutritional Uses

§ 10.

Before issue of a handling permit, the Health Protection Inspectorate shall assess the safety of the food for particular nutritional uses, the existence of special characteristics, presumed effect and compliance of such food with the legislation in force.

§ 11.

If the safety, presumed effect, compliance of the special characteristics and purpose of use of food for particular nutritional uses is not sufficiently proven, the Health Protection Inspectorate may demand from an applicant additional information and the results of laboratory tests which prove the existence of the special characteristics of such food and the correspondence of the information presented on the labelling with the intended purpose.

§ 12.

The Health Protection Inspectorate has the right to demand the taking of control samples and analysis of food for particular nutritional uses pursuant to the established procedure.

§ 13.

The Health Protection Inspectorate has the right to involve experts in the review of applications for food for particular nutritional uses and assessment of the presumed effect, purpose of use and compliance with the requirements.

Chapter 4

Issue and Extension of Handling Permits and Refusal to Issue Permits

§ 14.

(1) The Health Protection Inspectorate shall decide the issue or extension of a handling permit or refusal therefrom not later than on the twentieth working day after submission of the application and shall inform the applicant of the adopted decision.

(2) Upon refusal to issue or extend a handling permit, the Health Protection Inspectorate shall issue a reasoned decision in writing to the applicant concerning the refusal.

§ 15.

Upon first application, a handling permit shall be issued for a term of one year. The same permit may be extended for three years without demanding additional documents if the application contains a confirmation concerning the validity of the information submitted before.

§ 16.

(1) A handling permit shall be issued and delivered to the applicant on a letter-head with security features in a single copy.

(2) A handling permit shall be issued after the submission of a document certifying the payment of state fees.

§ 17.

A handling permit shall contain the following information:

- 1) the name, address, registration number, telephone number, fax number and e-mail address of the issuer;
- 2) the name of the document "*Eritoidu käitlemise luba*" ["Permit for Handling Food for Particular Nutritional Uses"] and the registration number thereof;
- 3) the place and date of issue and period of validity of the permit;
- 4) the name, food group and purpose of use or special characteristics of the food for particular nutritional uses;

- 5) the name, address, fax number or e-mail address of the applicant for the handling permit, the commercial registry code, or the personal identification code of the sole proprietor, or in the absence thereof, the date of birth;
- 6) the name and address of the manufacturer of the food for particular nutritional uses;
- 7) the signature and seal of the Director General of the Health Protection Inspectorate;
- 8) the signature, name and official title of the person who prepared the permit.

Chapter 5

Suspension of Handling Permits

§ 18.

The Health Protection Inspectorate may partially or totally suspend a handling permit on the basis of a precept of a supervisory official if circumstances which endanger human health or the environment are detected and, upon handling of food for particular nutritional uses, the handler violates the requirements for advertising, presentation of information or labelling.

§ 19.

Upon suspension of a handling permit, importation of food for particular nutritional uses to Estonia and the marketing thereof, including retail trade in Estonia, are prohibited until the grounds for suspension are eliminated.

§ 20.

A handling permit may be partially or totally suspended or extension of a permit may be refused in the following cases:

- 1) use of the food for particular nutritional uses has caused health disorders to consumers;
- 2) the food for particular nutritional uses is not in compliance with the requirements or does not correspond to the stated purpose;
- 3) significant changes which damage and mislead consumers have been made to the composition and labelling of the food for particular nutritional uses;
- 4) the applicant has submitted inaccurate information;
- 5) on the basis of latest scientific achievements, the former purposes of the food for particular nutritional use are re-assessed and information is obtained which proves the inaccuracy of the submitted information and the harmful effects of the food to users.

§ 21.

If the grounds for suspension of a handling permit are eliminated, the applicant may submit a new application in compliance with this Procedure to the Health Protection Inspectorate.

§ 22.

The Health Protection Inspectorate shall send a written notice concerning the partial or total suspension of a handling permit to the manufacturer and importer.

§ 23.

The Health Protection Inspectorate shall give notification only of the prohibition on food for particular nutritional uses which is not in compliance with the requirements and of suspension of handling permits in a daily national newspaper or through other media. Notification of cancellation of the prohibition shall be given in the same manner and through the same media as the decision concerning the prohibition.

§ 24.

The Health Protection Inspectorate shall register applications, handling permits and refusals to issue permits and shall preserve each application, copy of a handling permit and documentation which is the basis of the permit for five years.

Chapter 6

Implementing Provisions

§ 25.

(1) As of 1 June 2000, food for particular nutritional uses may be imported and new foods for particular nutritional uses may be placed on the market only on the basis of handling permits.

(2) Until 1 January 2001, current handlers are permitted to continue the manufacture and packing of food for particular nutritional uses without handling permits. Until this date, food for particular nutritional uses which is manufactured and packed without a handling permit may be sold or transferred in some other manner into public use until stocks run out, but not after the date of minimum durability.

¹ The requirements of the Directives 89/398/EEC (OJ L 186, 30.06.1989, p. 27), 91/321/EEC (OJ L 175, 4.07.1991, p. 35), 92/52/EEC (OJ L 179, 1.07.1992, p. 129), 96/5/EEC (OJ L 049, 28.02.1996, p. 17) and 96/8/EEC (OJ L 055, 6.03.1996, p. 22) of the European Economic Communities have been taken into account in the drafting of this Regulation.

² RT = *Riigi Teataja* = *State Gazette*

