

# **A FOODSTUFFS**

## **A1 The Food Act**

Food Act (July 1999) © Estonian Translation and Legislative Support Centre

Passed on 25 February 1999

(RT\* I 1999, 30, 415),

entered into force 1 January 2000,

amended by the following Act:

16.06.99 entered into force 01.01.00 - RT I 1999, 58, 608.

Chapter 1

General Provisions

§ 1. Scope of application of Act

(1) This Act provides the bases for the handling of food and raw material for food for marketing purposes, the self-checking of a food business operator, and state supervision in order to ensure food safety and the conformity of food to other requirements.

(2) This Act does not apply to narcotic substances, tobacco and tobacco products, and medicinal products governed by the Medicinal Products Act (RT I 1996, 3, 56; 49, 954; 1997, 93, 1564; 1998, 36/37, 554).

(3) This Act applies to the handling of alcohol in so far as the handling of alcohol is not regulated by other Acts.

§ 2. Food and food supplements

(1) Food is a foodstuff or a mixture of foodstuffs which is intended for human consumption in either unprocessed or processed form.

(2) In addition to the provisions of subsection (1) of this section, chewing gum and food supplements, food additives and other substances which are used to prepare food and which are not generally consumed separately are deemed to be food. The requirements applicable to food also apply to water used to prepare food and to water for human consumption.

(3) A food supplement is a nutrient or mixture of nutrients which is not classified as a medicinal product or semi-medicinal product and which is used in addition to food to satisfy of the nutritional requirements of the human body. Vitamins, mineral nutrients and mixtures thereof, extracts of plant and animal origin and other similar substances are food supplements.

§ 3. Raw material for food and initial processing thereof

(1) Raw material for food is any product produced in the agricultural sector or a subsector thereof and also any natural product acquired by hunting or fishing or in some other manner which may be used to prepare food.

(2) The initial processing of raw material for food is an activity which results in raw material fit for the preparation of food.

(3) A person who operates only in the area of activity specified in subsection

(1) or (2) of this section is deemed to be a producer or processor of raw material for food respectively.

§ 4. Raw material for food used for human consumption

Provisions regulating food and the handling thereof apply to raw material for food used for human consumption unless otherwise provided for in this Act or legislation established on the basis thereof.

§ 5. Food and raw material for food for marketing purposes

(1) Food and raw material for food is deemed to be for marketing purposes if it is handled for the purpose of sale and sold as a commercial activity of a food business operator.

(2) This Act also applies to food and raw material for food, the handling of which is a commercial or non-commercial activity of a food business operator and which is transferred in some other manner for a charge or without charge, unless otherwise provided for in this Act or legislation established on the basis thereof.

§ 6. Handling of food and raw material for food for marketing purposes and food business operator

(1) The handling of food and raw material for food for marketing purposes (hereinafter handling) is the production, supply and initial processing of raw material for food, the preparation, sale and transfer in some

other manner of food for a charge or without charge, and import, export and other operations by which food or raw material for food becomes accessible to other food business operators or consumers.

(2) A food business operator is a person who is engaged in one or more of the forms of handling specified in subsection (1) of this section.

## Chapter 2

### Approval of Food Business

#### § 7. Approval

(1) Approval is a procedure during which the compliance of an enterprise or part thereof where food or raw material for food is handled (hereinafter food business) with the requirements provided for in this Act and other legislation is assessed and confirmed.

(2) The compliance of a food business with the requirements shall be assessed and confirmed in whole or, if the parts of the food business are located separately or several forms of handling are performed, in parts.

#### § 8. Approval requirement

(1) A food business shall be approved before handling is commenced. A food business which only produces raw material of plant origin, supplies natural products or rears farm animals and which sells or transfers in some other manner the specified raw materials, products or animals for further handling need not be approved.

(2) Approval shall be arranged by form of handling and for the conditions of handling of a specific raw material for food or food group in the food business undergoing approval.

(3) A food business operator shall give written notification of any changes to the construction, production process or organisation of work of the food business and of any other restructuring which changes the conditions which existed upon approval to the supervisory agency which organised approval. Handling is prohibited during restructuring and may be continued after the restructuring is complete only with the permission of a supervisory official.

(4) Projects involving new structures, repairs and fundamental technological restructuring shall be approved by a supervisory agency which organises approval.

#### § 9. Organisation of approval

(1) On the basis of a written application from a food business operator, the Veterinary and Food Board or the Health Protection Inspectorate shall organise approval and make an appropriate decision pursuant to the competence provided for in subsections 47 (1) or (2) of this Act. (16.06.99 entered into force 01.01.00 - RT I 1999, 58, 608)

(2) At the request of a food business operator, a supervisory official of the relevant supervisory agency shall provide explanations for compliance with the requirements prescribed in this Act and legislation established on the basis thereof which are necessary upon approval and concern the approved food businesses.

(3) The Government of the Republic shall establish the procedure for the proceedings of approval of food businesses engaged in different forms of handling.

#### § 10. Approval of food business and refusal to approve

(1) The head of a supervisory agency or a supervisory official authorised by him or her shall confirm by a decision of approval that a food business complies with the requirements provided for in this Act and other legislation.

(2) If, on the basis of assessment results, a food business does not comply with the requirements, the food business shall not be approved and the refusal to approve shall be justified in the corresponding decision.

(3) The head of a supervisory agency or a supervisory official authorised by him or her shall make a decision within twenty working days after receipt of an application. In order to clarify additional circumstances, the term for making the decision may be extended to forty working days. A supervisory official shall notify the applicant in writing of the extension of a term.

(4) A decision of approval or a decision to refuse approval shall be sent to the applicant in writing.

#### § 11. Repeal of decision of approval

(1) A decision of approval shall be repealed if the food business operator is unable to comply with the requirements concerning food or raw material for food due to the permanent conditions prevailing in the food business or upon the existence of a hazard to human health.

(2) A supervisory official exercising supervision over a food business operator shall make a proposal to repeal a decision of approval to the head of the supervisory agency, who has the right to repeal the decision. A written decision to repeal the decision of approval shall be issued to the food business operator.

(3) A food business operator may re-apply for approval if the circumstances on which the repeal of the decision of approval were based cease to exist.

### Chapter 3

#### Requirements for Food

##### § 12. General requirements

(1) Food which is sold or transferred in some other manner shall not endanger human health and shall conform to other requirements provided for in this Act and other legislation (hereinafter conform to the requirements).

(2) Food shall not contain parasites, pests or foreign substances which harm the properties of the food or endanger human health.

(3) It is prohibited to handle food or raw material for food which is spoilt or contaminated or which does not conform to microbiological requirements, or food spoilt as a result of the use of an unsuitable production process or due to odour, flavour, colour or other circumstances which are not characteristic of the food. The Government of the Republic shall establish the microbiological requirements for food groups.

(4) In addition to the provisions of this Chapter, food shall conform to the composition and quality requirements characteristic of the food. The Government of the Republic shall establish the composition and quality requirements by food group.

(5) Meat to be sold fresh or transferred in some other manner must be declared fit for human consumption as a result of a veterinary check. Fitness for human consumption shall be certified by an animal health certificate. Meat which is not declared to be fit for human consumption is deemed to be unfit for human consumption and the handling thereof is prohibited. The fitness for human consumption of other fresh food of animal origin to be sold or transferred in some other manner shall be certified pursuant to the provisions of the food hygiene rules.

##### § 13. Novel foods

(1) Novel foods are food which has not previously been used as food to a significant degree and:

1) which contain or consist of genetically modified organisms;

2) which are produced from, but do not contain, genetically modified organisms;

3) which have a new or intentionally modified primary molecular structure;

4) which consist of or are isolated from micro-organisms, fungi or algae, or are prepared from raw material for food which has not previously been used to a significant degree;

5) to which a production process not generally used has been applied which gives rise to significant changes in the composition or structure of the food which affect its nutritional value, the level of undesirable substances or metabolism.

(2) Novel foods shall conform to the requirements and shall not mislead the consumer or differ from the food which they are intended to replace to such an extent that the novel foods would be disadvantageous for the consumer as regards nutritional value and metabolism.

(3) Before the handling of a novel food is commenced, the conformity of the novel food to the requirements shall be examined and assessed and a permit for the handling thereof shall be obtained from the Veterinary and Food Board.

(16.06.99 entered into force 01.01.00 - RT I 1999, 58, 608)

(4) The Government of the Republic shall establish the methods for assessment of the conformity of novel foods to the requirements and the procedure for the application for and issue of handling permits.

##### § 14. Food for particular nutritional uses

(1) Food for particular nutritional uses is food which is intended for persons with different nutritional needs from normal and which is therefore prepared using a special production process or which has a different composition from food for normal consumption. Baby food and food for young children are also deemed to be food for particular nutritional uses.

(2) Food for particular nutritional uses shall conform to the requirements, be clearly distinguishable from food for normal consumption and be used for the declared purposes.

(3) Before the handling of food for particular nutritional uses is commenced, the conformity of the food for particular nutritional uses to the requirements, the existence of special characteristics and the presumed effect shall be examined and assessed, and a permit for the handling thereof shall be obtained from the Veterinary and Food Board.

(4) The Government of the Republic shall establish the procedure for the application for and issue of permits for the handling of food for particular nutritional uses.

(5) Having regard to the purpose of the use of food for particular nutritional uses and the special characteristics of food groups, the Government of the Republic shall establish composition and quality requirements for food for particular nutritional uses, requirements for the substances used to prepare food for particular nutritional uses and requirements for the handling of food for particular nutritional uses.

#### § 15. Frozen food and frozen raw material for food

(1) Frozen food or frozen raw material for food is food or raw material for food which has been subjected to a freezing process and then stored at the temperature prescribed for the food or raw material for food. In order to ensure the conformity of such food to the requirements, the period of freezing shall be as short as possible.

(2) The requirements provided for in the Food Hygiene Requirements and in other legislation and the special requirements for handling frozen food established by the Government of the Republic shall be observed during the handling of frozen food and frozen raw material for food.

#### § 16. Food additives

(1) A food additive is a substance of natural or synthetic origin which is added to food during handling in order to affect the properties thereof. Food additives are not generally consumed separately or used as the main ingredients of food.

(2) It is permitted to use food additives in a manner, in a food group and to the extent of the permitted levels established pursuant to this Act and only if it is impossible to achieve the purposes for which the food additive is used in any other manner.

(3) The Government of the Republic shall establish the list and permitted levels of food additives permitted in food by food group, and the conditions and methods of the use of food additives.

(4) The Government of the Republic shall establish the requirements for food additives permitted in food.

#### § 17. Artificial flavourings

(1) It is permitted to use artificial flavourings which conform to the requirements (hereinafter flavourings) during the handling of food.

(2) The Government of the Republic shall establish the list and permitted levels of flavourings permitted in food by food group, the requirements for flavourings and the conditions and methods of the use and preparation of such substances.

#### § 18. Processing aids

(1) A processing aid is a substance used in the handling of food which is removed from the food although it may be technically impossible to avoid presence of residues or derivatives of the substance in the food.

(2) The Government of the Republic shall establish the requirements for processing aids, the conditions and methods of use thereof and the permitted levels of residue content in food.

#### § 19. Contaminants

(1) A contaminant is a substance which is present in food or raw material for food as a result of substances used in the production or initial processing of the raw material for food, or which is present during handling or as a result of environmental contamination, and which may endanger human health or harm the properties of the food.

(2) It is prohibited to handle food and raw material for food which contains prohibited contaminants or contaminants in amounts which are larger than permitted.

(3) The Government of the Republic shall establish the list and permitted levels of permitted contaminants by food group. The Minister of Agriculture shall establish the procedure for the regulation of supervision of contaminants in order to ensure the safety of food of animal origin.

#### § 20. Adulteration of food

(1) It is prohibited to adulterate food and handle adulterated food.

(2) The following are deemed to be adulteration:

1) alteration of the composition of food without alteration of the labelling;

2) alteration of labelling without alteration of the actual composition;

3) addition of other substances in any manner to food or processing food with such substances in order to conceal the lower value of the food or non-conformity of the food to the requirements;

4) handling during which the business name or trade mark of another undertaking is used without the permission of the undertaking.

#### Chapter 4

#### General Requirements for Handling

#### § 21. Ensurance of conformity of food to requirements during handling

(1) Handling shall be carried out pursuant to the requirements provided for in this Act and other legislation and during handling it shall be ensured that the food which is obtained conforms to the requirements.

(2) During handling it is prohibited to use substances or materials the composition or effect on humans of which is not known, which do not conform to the requirements provided for in legislation, or the use of which is prohibited by legislation.

(3) It is prohibited to store substances and materials which may cause the contamination of food or raw material for food or harm the properties thereof at handling sites.

(4) If, as a result of examinations, the harmfulness of a treatment or substance to human health becomes evident, it is prohibited to use the treatment or substance during handling. The Government of the Republic shall establish the list of treatments and substances which are prohibited during handling.

#### § 22. Obligations of food business operators during handling

(1) Food business operators are responsible for the conformity of handled food, handled raw material for food and the handling to the requirements, and are required to use every opportunity in order to ensure such conformity.

(2) A food business operator shall observe the storage requirements which are set out on the packaging or in the accompanying document of food and which are determined by the producer or packager of the food on the basis of shelf life tests. The Government of the Republic shall establish the procedure for conducting shelf life tests.

(3) A food business operator shall not accept, use during handling or distribute food and raw material for food which does not conform to the requirements.

(4) It is prohibited to use food or raw material of animal origin if the animal has been treated with medicinal products, semi-medicinal products or substances having a hormonal action and the withdrawal period after use thereof has not ended.

#### § 23. Recording requirement of food business operators

(1) Food business operators shall use only raw material for food which is of identifiable origin and maintain written records of obtained raw material for food and of the amount of food handled and distributed which is produced from the obtained raw material for food.

(2) In order to harmonise and specify record-keeping, the Minister of Agriculture shall establish the conditions and procedure for compliance with the recording requirement.

#### § 24. Technical description of food

(1) During industrial food processing, food business operators shall observe the technical description requirements chosen or prepared by themselves.

(2) For the purposes of this Act, the technical description of food is any document which describes the properties and preparation of the food and contains the following information concerning the food:

1) the name;

2) the properties of the finished product and of the ingredients thereof;

3) the production process used, above all the aspects which are significant for food safety;

4) the methods of assessment of conformity to the requirements;

5) the packaging and labelling requirements;

6) the transportation and storage conditions.

#### § 25. Conditions of food businesses

(1) The technical conditions and organisation of work of food businesses shall enable observance of the requirements provided for in this Act and other legislation.

(2) If circumstances become evident which bring about or may bring about changes to these conditions to an extent which means that food safety is not ensured, the food business operator shall promptly notify the supervisory agency concerned thereof.

#### § 26. Food hygiene

(1) For the purposes of this Act, food hygiene is the methods which a food business operator implements in all forms of handling and in all stages of handling in order to ensure the conformity of food to the requirements.

(2) A food business shall comply with, and the territory, buildings, facilities and premises thereof and their planning, and the machinery, handling equipment and organisation of work shall conform to the requirements provided for in the Food Hygiene Requirements and other food hygiene rules. The requirements for the hygiene of means of transport, transportation of food and raw material for food and

supply of water and sewerage, for the hygiene of handling and of employees of food businesses, and for the self-checking of food business operators shall also be established by the Food Hygiene Requirements.

(3) The Government of the Republic shall establish the Food Hygiene Requirements.

(4) In addition to the Food Hygiene Requirements, the Minister of Agriculture may establish rules necessary to ensure food hygiene which concern raw material for food and by different form of handling.

#### § 27. Employees of food businesses

(1) Food business operators are required to explain the handling requirements arising from legislation to the employees and verify compliance therewith.

(2) Employees who handle food or raw material for food must have professional knowledge and shall know and observe the food hygiene requirements.

(3) Employees who do not directly handle food or raw material for food shall know and adhere to the food hygiene requirements to the extent necessary to ensure food safety.

(4) Food business operators shall organise supervision related to the food hygiene of employees.

#### § 28. Permitting employee to work

(1) An employee who handles food and an employee who in the course of his or her duties comes into direct contact with food or raw material for food or the handling equipment thereof shall undergo medical examination prior to the commencement of an employment relationship and regularly during the employment relationship in order to detect any infectious or parasitic diseases and to prevent the spread thereof and he or she shall hold a health certificate pursuant to the Public Health Act (RT I 1995, 57, 978; 1996, 3, 56; 49, 953; 1997, 37/38, 569) and legislation established on the basis thereof.

(2) Food business operators shall require employees who handle food and employees who in the course of their duties come into direct contact with food, raw material for food or the handling equipment thereof to perform the obligations specified in subsection (1) of this section.

(3) An employee of a food business shall inform the food business operator or representative thereof of any health disorder or illness which the employee has, of any contact which the employee has with a person suffering from an infectious disease and of any other hazards which may cause the contamination of food.

(4) An employee who does not hold a valid health certificate, who may spread infectious agents or parasites or who has another health disorder or illness which is harmful in terms of food safety shall not be permitted to work in a position where he or she may contaminate food.

#### § 29. Food hygiene training in food businesses

(1) A food business operator shall prepare a plan concerning food hygiene training for the employees of the food business which sets out the purposes, scope, timetable and procedure of the training.

(2) On the basis of a training plan, a food business operator shall periodically organise food hygiene training which corresponds to the duties of the employees and assess the knowledge of the employees concerning food hygiene.

(3) The execution of a training plan shall be monitored by a supervisory official who has the right to make proposals for amendments to the training plan and provide explanations concerning the preparation thereof.

#### § 30. Cleaning, disinfection and pest control

(1) In order to clean and disinfect a food business and its territory, premises, machinery and handling equipment and in order to conduct pest control, a food business operator shall use only such equipment, substances and methods which do not cause the contamination of food, harm the properties thereof or endanger human health.

(2) The Government of the Republic shall establish the requirements for the substances permitted to be used for cleaning, disinfection and pest control and the conditions and methods of use of such substances.

#### § 31. Materials and articles intended to come into contact with food

(1) Materials and articles intended to come into contact with food shall not cause the contamination of food, harm the properties thereof or endanger human health and shall conform to the requirements for materials and articles permitted to come into contact with food.

(2) The Government of the Republic shall establish the requirements for materials and articles permitted to come into contact with food, the special requirements for the groups thereof and the methods for testing the safety of such materials and articles.

#### § 32. Water used

(1) Water used in food businesses shall conform to the quality requirements for drinking water established pursuant to the Water Act (RT I 1994, 40, 655; 1996, 13, 241; 1998, 2, 47; 61, 987; 1999, 10, 155). Ice and steam used shall be obtained from drinking water which conforms to the requirements. As an exception, sea water which does not endanger human health may be used for the

initial processing of fish on fishing vessels at sea.

(2) Water which does not conform to the quality requirements for drinking water and which is used as cooling water for machinery, for obtaining steam which does not come into contact with food or for other similar purposes shall be directed into a correspondingly marked system which is separate from the drinking water system and which cannot be joined to the drinking water system or opened on the handling premises.

#### § 33. Transportation of food and raw material for food

(1) Food and raw material for food shall be transported using means of transport which have the necessary conditions for the preservation of the properties of the food and raw material for food and where it will not be contaminated or deteriorate.

(2) Food and raw material for food shall not be transported together with substances which may contaminate the food or raw material for food or harm its properties.

(3) Food and raw material for food in liquid, granulated or powder form which is not prepackaged may be transported only using means of transport, containers or vessels which are prescribed therefor and correspondingly marked.

#### Chapter 5

#### Self-Checking of Food Business Operator

##### § 34. Self-checking requirement

(1) Food business operators are required to verify the conformity of food, raw material for food and the handling thereof to the requirements (hereinafter self-checking) and to implement measures in order to ensure such verification. The measures implemented shall be prepared in writing and form a self-checking system.

(2) Food business operators shall determine the stages of handling which are significant in terms of food safety (critical points), monitor them and register the results of the monitoring in accordance with the Food Hygiene Requirements and the requirements of other food hygiene rules.

(3) The self-checking system shall be approved by a supervisory agency which exercises supervision over handling. Supervisory agencies have the right to make proposals for the alteration and development of a self-checking system if it becomes evident that the existing system cannot ensure food safety, and to provide explanations, if necessary, for the creation and alteration of a self-checking system.

(4) Food business operators shall promptly inform the supervisory agency concerned of any deficiencies detected in the course of self-checking, due to which it cannot be ensured that the food does not present a danger to human health, and shall implement the necessary measures to eliminate the deficiencies.

##### § 35. Declaration of conformity

(1) A declaration of conformity which proves the conformity of food to the requirements is a written document issued by the producer of the food which confirms that the food conforms to the requirements provided for in legislation or to other requirements. A declaration of conformity shall be issued at the request of a food business operator who further handles the food.

(2) A declaration of conformity shall confirm that the food conforms to the requirements specified in the declaration provided that the requirements set out by the issuer are observed during further handling.

(3) A declaration of conformity shall be issued for a specified period either for the continual preparation of the same food or with regard to a lot. An amount of food which is prepared under the same conditions and with the same name and properties is deemed to be a lot. Each lot of food shall have a specific code.

(4) If a declaration of conformity is issued for the continual preparation of food, the lots included therein shall be related to the declaration of conformity. A declaration of conformity issued with regard to a lot shall include a reference to the specific lot.

##### § 36. Content of declaration of conformity

A declaration of conformity shall contain the following information:

- 1) the name, seat and address of the issuer and the mark of identification of the declaration of conformity;
- 2) the name of the food and other information necessary for determination of the food;
- 3) a reference to the requirements to which conformity is proved;
- 4) the date of issue and the name, signature and position of the person who issued the declaration of conformity.

##### § 37. Certification

(1) Certification is a procedure which is organised by an independent third party (hereinafter certification body) on the basis of a written application from a food business operator in order to prove the conformity

of the quality system of the food business operator or the conformity of a specific handled food to the requirements, in respect of which the application for proof of conformity is made.

(2) Certification is optional and a food business operator who applies for certification shall bear the expenses of certification.

(3) If certification provides a positive result, the certification body shall issue a certificate of conformity which confirms the conformity of the food or the quality system to the requirements.

## Chapter 6

### Presentation of Information

#### § 38. Requirements for information

(1) Food which is sold or transferred in some other manner shall be labelled in Estonian and in such a manner which ensures the food business operator who further handles the food and the consumer have the necessary information concerning the food and which allows a supervisory agency to carry out supervisory operations. The information provided concerning food and the labelling thereof shall not mislead the consumer.

(2) If a finished product is used to prepare food instead of the raw material for food which would ordinarily be expected, such information shall be indicated on the labelling.

(3) A producer is required to inform the consumer of the origin of the raw material used. The Government of the Republic shall establish the procedure for informing.

(4) If food contains genetically modified organisms or is composed thereof, information provided with regard to the food shall conform to the requirements of the Release of Genetically Modified Organisms into the Environment Act (RT I 1999, 10, 151).

(5) The Government of the Republic shall establish the requirements for the labelling of food and the procedure for labelling and dissemination of information in any other manner. The Government of the Republic shall also establish the special requirements and procedure for the labelling and dissemination of information in any other manner by food group.

#### § 39. Restrictions on presentation of information

Upon the labelling of food and dissemination of information concerning food in any other manner, it is prohibited to:

1) attribute properties or effects to the food which the food does not possess;

2) attribute special characteristics to the food when all food in the food group possesses similar characteristics;

3) refer to properties of the food which prevent, treat or cure disease.

#### § 40. Restriction on alteration of labelling

(1) The alteration of labelling without the alteration of the actual properties of food is deemed to be adulteration of the food, except for the specification of labelling or the correction of misleading labelling.

(2) It is prohibited to repackage food if the use by date or date of minimum durability is indicated on the sales packaging of the food. The dates on the sales packaging shall not be altered and the food shall not be marketed after the use by date has passed.

## Chapter 7

### Import, Export and Supervision

#### § 41. Customs posts located on border

(1) Food and raw material for food shall be imported and exported through customs posts located on the border which are prescribed therefor (hereinafter border crossing points).

(2) Border crossing points shall have the technical capability to perform the supervisory operations provided for in this Act and other legislation.

(3) The Government of the Republic shall establish the list of border crossing points prescribed for the import and export of food and raw material for food.

(4) Transit shall be carried out through the border crossing points prescribed for the import and export of food and raw material for food. Supervision over food and raw material for food in transit shall be exercised on the general bases provided for in this Act and other legislation in order to prevent infectious diseases or if such supervision is prescribed by an international agreement with the country of destination.

#### § 42. Import

(1) The import of food and raw material for food which does not conform to the requirements provided for in this Act or other legislation is prohibited.

(2) An importer shall notify the border crossing point of a planned import not later than twenty-four hours in advance.



(3) Food and raw material of animal origin may be imported from an exporting enterprise which is approved and registered by a supervisory agency authorised by the country of origin and which is approved by the Veterinary and Food Board.(16.06.99 entered into force 01.01.00 - RT I 1999, 58, 608)

(4) In order to attest the conformity of food and raw material for food to the requirements, the importer shall submit the document issued by the supervisory agency authorised by the country of origin.

#### § 43. Activity licence of importer

(1) An importer shall hold an activity licence for the import of food and raw material for food, which is issued for up to two years pursuant to the procedure established by the Minister of Agriculture.

(2) The issue of an activity licence shall be refused if the importer:

- 1) does not submit the necessary documents for the issue of an activity licence or
- 2) submits inaccurate information to the issuer of activity licences.

(3) Activity licences shall be extended on the same bases as activity licences are issued.

(4) The issuer of an activity licence may revoke an activity licence if the importer:

- 1) repeatedly imports food or raw material for food which does not conform to the established requirements;
- 2) repeatedly submits inaccurate information to the supervisory agency concerned;
- 3) submits inaccurate information to the issuer of activity licences and an activity licence is issued to the importer irrespective of the inaccurate information;
- 4) submits a written application therefor.

#### § 44. Supervisory operations at border crossing points

(1) Supervisory officials of the Plant Production Inspectorate and the Veterinary and Food Board shall exercise supervision over food and raw material for food (including phytosanitary and veterinary control) at border crossing points.(16.06.99 entered into force 01.01.00 - RT I 1999, 58, 608)

(2) A supervisory official shall check the existence of the required documents, the correspondence of the food and raw material for food to the description presented in the documents, and the conformity of the documents, food and raw material for food to the requirements provided for in legislation.

(3) If import is permitted, a supervisory official shall issue a certificate under the conditions and pursuant to the procedure established on the basis of subsection (6) of this section.

(4) If an importer of food or raw material for food has declared the destination of a lot, the documents shall be verified on the border but other supervisory operations specified in subsection (2) of this section may be performed at the destination of the lot. It is prohibited to handle the lot or a part thereof before the supervisory operations are performed.

(5) Expenses caused to an importer in the course of supervision proceedings due to the decision of a supervisory official shall not be compensated, except for damage caused by unlawful action.

(6) The Minister of Agriculture shall establish the conditions and procedure for the supervision of food and raw material for food and phytosanitary and veterinary control thereof upon import and admittance into a customs warehouse, and also the list of goods subject to such control.

(7) In order to import particular raw material for food or food of a particular food group, an application for an import permit shall be made to the supervisory agency concerned. The Government of the Republic shall establish the list of the specified raw materials for food and food groups and the procedure for the application for and issue of import permits.

#### § 45. Food and raw material for food which does not conform to requirements

(1) If food or raw material for food does not conform to the requirements, and depending on the harmfulness of the food or raw material for food, a supervisory official shall designate the food or raw material for food for reprocessing, destruction or return to its country of origin, taking into consideration the wishes of the importer if possible.

(2) If food or raw material for food is designated for reprocessing, the supervisory official shall make a corresponding notation in the certificate specified in subsection 44 (3) of this Act.

(3) The return of food and raw material for food which does not conform to the requirements to the country of origin and the seizure of food and raw material for food designated for destruction shall be organised by the customs authorities pursuant to the Customs Act (RT I 1998, 3, 54; 36/37, 552; 51, 756; 1999, 10, 156).

#### § 46. Export

(1) Exported food and raw material for food shall conform to the requirements in force in Estonia and also to the requirements of the country of destination, if such requirements are known and an international

agreement prescribes ensurance of conformity thereto. Supervision over exported food and raw material for food shall be exercised by the supervisory agency concerned.

(2) At the request of a supervisory agency of the country of destination, the supervisory agency concerned shall issue a document certifying the conformity of the food or raw material for food to the requirements.

(3) At the request of the country of destination, a certificate of conformity concerning the food and issued by a certification body specified in § 37 of this Act is required.

#### **Chapter 8**

#### **General Organisation of Supervision**

##### **§ 47. Supervisory agencies**

(1) The Veterinary and Food Board shall organise the approval of food businesses, make appropriate decisions and exercise supervision over food business operators in all forms of handling, except in the cases specified in subsections (2) and (3) of this section.(16.06.99 entered into force 01.01.00 - RT I 1999, 58, 608)

(2) The Health Protection Inspectorate shall organise the approval of retail establishments and mass caterers, make appropriate decisions and exercise supervision over food business operators in the specified forms of handling.

(3) The Consumer Protection Board shall exercise supervision over the conformity of the composition of food, conditions of preservation of food and presentation of information to the established requirements in the retail and wholesale stages.

##### **§ 48. Supervisory officials and supervision**

(1) Supervisory officials shall, according to their competence, exercise supervision over the conformity of the handling of food and raw material for food to the requirements, and the compliance of a food business operator with the self-checking requirements in all forms of handling and in all stages of handling. Supervisory operations shall usually be performed without warning the food business operator beforehand.

(2) Upon the presentation of identification, a supervisory official has the right to verify without hindrance the compliance of a food business with the established requirements and the conformity of its territory, premises, means of transport, machinery, food and raw material for food, handling, materials intended to come into contact with food, labelling of packaging and other matters to the established requirements. A supervisory official also has the right to perform other necessary supervisory operations and examinations, verify the compliance of employees with the hygiene requirements and assess their knowledge related to hygiene.

(3) A supervisory official has the right to demand explanations and documents from a food business operator and, with the knowledge of the food business operator or the representative thereof, use equipment in order to make a record of the situation. A supervisory official has the right to take notes and to receive extracts from the food business operator and up to two copies, without charge, of each appropriate document submitted to the food business operator.

(4) A food business operator is required to assist a supervisory official in the performance of duties prescribed for him or her by this Act and other legislation.

(5) A supervisory official is required to maintain business and production secrets which become known to him or her. Information relating to the harmfulness of food may be disclosed.

(6) The Government of the Republic shall establish the procedure for supervision of the slaughter of animals in slaughterhouses, the initial processing of raw material for food and the handling of food.

(7) The Government of the Republic shall approve the food safety monitoring programmes. Monitoring shall be financed from funds allocated from the state budget to the Ministry of Agriculture for monitoring.

##### **§ 49. Taking and analysis of control samples in course of supervision**

(1) A supervisory official has the right, pursuant to the established procedure and at the expense of a food business operator, to take the quantity of control samples necessary in order to carry out laboratory analyses. Analyses shall be carried out using methods in accordance with Estonian or international standards or other equivalent methods. A food business operator has the right to carry out an independent analysis of a sample in another laboratory at the expense of the food business operator.

(3) The results of an analysis shall be issued as a test report which, in addition to the results of the analysis, shall also contain other information related to the analysis.

(4) The Government of the Republic shall establish the procedure for the taking and analysis of control samples. The Government of the Republic or, on the authorisation of the Government of the Republic, the Minister of Agriculture shall establish the methods for the taking and analysis of samples by food group or

characteristic indicator in order to verify the conformity of food and raw material for food to the requirements and conformity to the requirements established with regard to handling.

#### **§ 50. Precept of supervisory official**

(1) Upon detection of an offence, a supervisory official shall issue a precept in which he or she shall:

- 1) call attention to the offence;
- 2) require termination of the offence and
- 3) require the performance of operations necessary for the termination of the offence and the prevention of future offences.

(2) If a supervisory official detects circumstances which endanger human health, or if an immediate hazard to human health or the environment exists, he or she shall issue a precept concerning the partial or total suspension of handling and demand the removal of food and raw material for food from handling. A food business operator is required to facilitate the removal of food and raw material for food from handling.

(3) At the request of a food business operator, a supervisory official shall grant permission to continue handling if the circumstances which gave rise to the suspension have ceased to exist.

#### **§ 51. Contestation of precept or decision of supervisory official**

(1) If a food business operator does not agree with a precept or decision of a supervisory official, the food business operator may file a complaint to the director general of the supervisory agency concerned within ten working days after the date on which the food business operator becomes aware of the precept or decision. Filing a complaint does not release a food business operator from compliance with a precept or decision.

(2) The director general of a supervisory agency or his or her deputy shall review a complaint within ten working days after receipt of the complaint. In order to clarify additional circumstances, the director general of the supervisory agency may extend the term for making the decision to thirty working days.

(3) Upon the review of a complaint, the director general of the supervisory agency concerned or his or her deputy shall make a decision to uphold, amend or repeal the precept or decision and shall inform the food business operator of the decision in writing.

(4) Regardless of a decision made pursuant to subsection (3) of this section, a food business operator has the right of recourse to an administrative court. Recourse to an administrative court does not release a food business operator from compliance with a precept or decision.

### **Chapter 9**

#### **Laboratories**

#### **§ 52. Authorisation of laboratories to analyse control samples taken in course of supervision**

(1) Control samples shall be analysed in laboratories authorised to carry out the corresponding analyses.

(2) Only laboratories accredited for analyses may be authorised to carry out such analyses. A laboratory whose competence to carry out analyses is officially approved by an accreditation institution is deemed to be accredited.

(3) The right to operate as an approved laboratory shall be granted by a directive of the Minister of Agriculture, which shall set out the scope of authority. Authorisation shall be granted on the basis of a written application from a laboratory. The Government of the Republic shall establish the procedure for application for authorisation and the authorisation criteria.

(4) If there is no approved laboratory to carry out an analysis, the analysis may be carried out in a laboratory which does not have appropriate authorisation. In such case, the person who orders the analysis shall be responsible for the use of the results.

(5) If an approved laboratory does not perform its duties as required, the Minister of Agriculture has the right to grant a term of up to three months for the elimination of deficiencies. If the deficiencies are not eliminated, authorisation shall be revoked in part or in full. During the time prescribed for the elimination of deficiencies, authorisation is deemed to be suspended.

#### **§ 53. Authorisation of reference laboratory**

(1) The Minister of Agriculture shall organise supervision of the activities of approved laboratories through a laboratory authorised therefor (hereinafter reference laboratory). Authorisation to operate as a reference laboratory shall be granted to one laboratory in each area of activity and the procedure for application for authorisation and the authorisation criteria shall be provided for in legislation established pursuant to subsection 52 (3) of this Act.

(2) A reference laboratory shall base its operations on government orders submitted by the Minister of Agriculture. Fulfilment of the orders shall be financed from funds allocated from the state budget to the Ministry of Agriculture for fulfilment of such orders.

## Chapter 10

### Liability

#### § 54. Administrative liability of legal person

If a legal person:

- 1) violates the requirements for the safety of food or raw material for food provided for in this Act and legislation established on the basis thereof in a manner which endangers human health or the environment, a fine of up to 100 000 kroons or up to ten times the value of the lot which is the object of the violation shall be imposed;
- 2) presents false information concerning the composition or properties of food or raw material for food, the content of food additives, contaminants or micro-organisms in food or in raw material for food, or other circumstances provided for in this Act and legislation established on the basis thereof, or falsifies accompanying documents, sales documents or other certification documents, a fine of up to 50 000 kroons or up to ten times the value of the lot which is the object of the violation shall be imposed;
- 3) violates the handling requirements or the requirements for food or raw material for food provided for in this Act and legislation established on the basis thereof, except in the case specified in clause 1) of this section, a fine of up to 50 000 kroons or up to five times the value of the lot which is the object of the violation shall be imposed;
- 4) operates without approval or an activity licence provided for in this Act and legislation established on the basis thereof, a fine of up to 50 000 kroons or up to five times the value of the lot which is the object of the violation shall be imposed;
- 5) fails to comply with the self-checking requirement provided for in this Act and legislation established on the basis thereof, a fine of up to 50 000 kroons shall be imposed;
- 6) violates the requirements established for the employees of a food business provided for in this Act and legislation established on the basis thereof, a fine of up to 25 000 kroons shall be imposed;
- 7) violates the requirements provided for in this Act and legislation established on the basis thereof for the presentation of information concerning food or raw material for food, a fine of up to 25 000 kroons or up to three times the value of the lot which is the object of the violation shall be imposed;
- 8) fails to submit the required documents provided for in this Act and legislation established on the basis thereof to the supervisory official or hinders supervisory operations in another manner, a fine of up to 10 000 kroons shall be imposed.

#### § 55. Proceedings of administrative offence matters of legal persons

The Directors General and Deputy Directors General of the Veterinary and Food Board and the Health Protection Inspectorate, the heads and deputy heads of local offices of the Veterinary and Food Board and the Health Protection Inspectorate, the Director General and Deputy Director General of the Consumer Protection Board, officials authorised by the Director General of the Consumer Protection Board, and administrative court judges have the right to hear administrative offence matters specified in § 54 of this Act and to impose punishment.

(16.06.99 entered into force 01.01.00 - RT I 1999, 58, 608)

(2) The Directors General and Deputy Directors General of the Veterinary and Food Board or the Health Protection Inspectorate, the heads and deputy heads of local offices of the Veterinary and Food Board and the Health Protection Inspectorate, the Director General and Deputy Director General of the Consumer Protection Board and officials authorised by the Director General of the Consumer Protection Board have the right to impose a fine of up to 10 000 kroons in administrative offence matters specified in § 54 of this Act. Only administrative court judges may impose larger fines. (16.06.99 entered into force 01.01.00 - RT I 1999, 58, 608)

(3) Administrative court judges shall hear administrative offence matters related to seizure.

(4) The following have the right to prepare reports concerning administrative offence matters specified in § 54 of this Act:

1) the Director General and Deputy Director General of the Veterinary and Food Board and officials exercising supervision;

(16.06.99 entered into force 01.01.00 - RT I 1999, 58, 608)

2) the Director General and Deputy Director General of the Health Protection Inspectorate and officials exercising supervision;

3) the Director General and Deputy Director General of the Consumer Protection Board and officials exercising supervision.

(5) A report shall set out the following:

- 1) the date and place of preparation thereof;
- 2) the name and address of the agency in whose name the report is prepared;
- 3) the official title, given name and surname of the person who prepares the report;
- 4) the name and address of the offending legal person;
- 5) the given name, surname and position of the representative of the administrative offender;
- 6) the place, time and description of the offence;
- 7) statements by witnesses, expert opinions, analyses and other materials which prove the commission of the offence;
- 8) a reference to the provision of law or other legislation which prescribes liability for the offence;
- 9) an explanation from the representative of the administrative offender and a notation that the representative of the administrative offender has been advised of the right to obtain legal assistance;
- 10) other information as required.

(6) The official who prepares the report and the representative of the offender shall sign the report. If the representative of the offender refuses to sign the report, a corresponding entry shall be made in the report. Written notations made by the representative of the offender concerning the report and refusal to sign the report shall be annexed to the report.

(7) If an administrative offender is an official of a legal person, the administrative penalty shall be imposed on the legal person pursuant to the procedure provided for in this Act or imposed on the official pursuant to the procedure provided for in the Code of Administrative Offences (RT 1992, 29, 396; RT I 1997, 66-68, 1109; 73, 1201; 81, 1361 and 1362; 86, 1459 and 1461; 87, 1466 and 1467; 93, 1561, 1563, 1564 and 1565; 1998, 2, 42; 17, 265; 23, 321; 30, 410; 34, 484; 36/37, 552 and 553; 38, 562; 51, 756 and 759; 52/53, 771; 60, 951 and 952; 64/65, 1004; 86/87, 1409; 98/99, 1574; 103, 1695; 108/109, 1783; 1999, 4, 53; 10, 149 and 156; 16, 267, 271, 272 and 276; 1999, 23, 350).

(8) Administrative offence matters of legal persons shall be heard pursuant to the procedure provided for in the Code of Administrative Offences, unless otherwise prescribed by this Act.

#### § 56. Seizure of food and raw material for food which is object of administrative offence

(1) In the event of an administrative offence specified in clause 54 1) of this Act, the food or raw material for food which was the object of an offence may be seized in order to designate the food or raw material for food for destruction.

Food and raw material for food subject to seizure shall be confiscated by a supervisory official who has the right to prepare administrative offence reports according to subsection 55 (4) of this Act.

(3) Confiscated food or raw material for food shall be stored in a place determined by the supervisory official who confiscated the food or raw material for food until the administrative offence matter is heard. Confiscated food and raw material for food may also be deposited by the administrative offender. The storage facility shall be sealed.

(4) Proceedings for the enforcement of decisions on seizure shall be effected pursuant to the procedure prescribed in the Code of Administrative Offences. Chapter 11 Implementing Provisions

#### § 57. Amendments to Code of Administrative Offences

In subsection 208 (2) of the Code of Administrative Offences (RT 1992, 29, 396; RT I 1997, 66-68, 1109; 73, 1201; 81, 1361 and 1362; 86, 1459 and 1461; 87, 1466 and 1467; 93, 1561, 1563, 1564 and 1565; 1998, 2, 42; 17, 265; 23, 321; 30, 410; 34, 484; 36/37, 552 and 553; 38, 562; 51, 756 and 759; 52/53, 771; 60, 951 and 952; 64/65, 1004; 86/87, 1409; 98/99, 1574; 103, 1695; 108/109, 1783; 1999, 4, 53; 10, 149 and 156; 16, 267, 271, 272 and 276; 1999, 23, 350), the words "the heads of local offices, their deputies and veterinarians of the national veterinary authority" are substituted by the words "the heads of local offices, their deputies and veterinary supervisory officials".

#### § 58. Amendments to State Fees Act

The State Fees Act (RT I 1997, 80, 1344; 86, 1461; 87, 1466 and 1467; 93, 1563; 1998, 2, 47; 4, 63; 23, 321; 36/37, 552 and 553; 52/53, 771; 57, 859; 59, 941; 60, 951; 61, 979 and 985; 64/65, 1004, 1005 and 1008; 86/87, 1408; 97, 1519; 103, 1701; 108/109, 1783; 111, 1829; 1999, 16, 275; 23, 355; 24, 359 and 360;

25, 364) is amended as follows:

- 1) sections 87, 88 and 89 are repealed;
- 2) section 871 is amended and worded as follows:

"§ 871. Issue and extension of activity licence of importer

(1) A state fee of 25 000 kroons shall be paid for the issue of an activity licence for the import of food and raw material for food. A state fee of 2000 kroons shall be paid for the extension of an activity licence for the import of food and raw material for food.”; sections 872 and 873 are added to the Act worded as follows:

**§ 872. Issue of handling permit**

(1) A state fee of 3300 kroons shall be paid for a permit for the handling of novel foods.

(2) A state fee of 1500 kroons shall be paid for a permit for the handling of food for particular nutritional uses.

**§ 873. Grant of authorisation**

(1) A state fee of 1500 kroons shall be paid for initial authorisation of a laboratory to analyse control samples taken in the course of supervision.

(2) A state fee of 3000 kroons shall be paid for initial authorisation to operate as a reference laboratory.”

**§ 59. Amendments to Public Health Act**

The Public Health Act (RT I 1995, 57, 978; 1996, 3, 56; 49, 953; 1997, 37/38, 569) is amended as follows:

1) in clause 7 (2) 2) the words “foodstuffs, food,” are omitted;

2) clause 12 (1) 1) is amended and worded as follows:

“1) production of materials intended to come into contact with food, raw material for food, mineral water and drinking water;”.

**§ 60. Amendments to Consumer Protection Act**

The Consumer Protection Act (RT I 1994, 2, 13; 1995, 20, 297; 1996, 49, 953; 1997, 93, 1561; 1999, 10, 156; 24, 359) is amended as follows:

1) in clause 11 (2) 5) the words “the Ministry of Agriculture” are substituted

by the words “the Veterinary and Food Board”; (16.06.99 entered into force 01.01.00 - RT I 1999, 58, 608)

2) in subsection 11 (3) the words “foodstuffs and other” and the words “health protection rules upon the preparation, storage, transportation and sale of foodstuffs” are omitted.

**§ 61. Amendments to Advertising Act**

Section 201 is added to the Advertising Act (RT I 1997, 52, 835) worded as follows:

“§ 201. Advertising of food

(1) Upon the advertising of food, it is prohibited to:

1) attribute properties or effects to the food which the food does not possess;

2) attribute special characteristics to the food when all food in the food group possesses similar characteristics;

3) refer to properties of the food which prevent, treat or cure disease.

(2) The advertising of breast milk substitutes, including infant formulae and follow-on formulae, is prohibited.”

**§ 62. Amendments to Organic Agriculture Act**

The Organic Agriculture Act (RT I 1997, 51, 823) is amended as follows:

1) in subsection 2 (1) the words “arises from subsection 2 (2) of the Food Act (RT I 1995, 21, 324; 1996, 49, 953) and” are omitted;

2) in clause 3 2) the words “clause 3 1) of the Food Act” are substituted by the words “the Food Act”;

3) in subsection 13 (3) the words “and, in the case of imported foodstuffs, also the import permit or a notarised copy thereof” are omitted;

4) subsection 20 (2) is repealed;

5) in subsection 23 (1) the words “subsection 17 (1) of the Food Act” are substituted by the words “the Food Act and legislation established on the basis thereof”.

**§ 63. Approval of operating food businesses and validity of state activity licences**

(1) A food business which is operating and subject to approval on the date of entry into force of this Act shall be approved by not later than 1 January 2003.

(2) State activity licences for the import of foodstuffs into Estonia which were issued before the entry into force of this Act shall be valid for two years as of the entry into force of this Act. Before the expiry of an activity licence, an importer has the right to apply for the issue of a corresponding activity licence pursuant to subsection 43 (3) of this Act. The provisions of this Act concerning activity licences apply to state activity licences.

**§ 64. Repeal of Food Act**

The Food Act (RT I 1995, 21, 324; 1996, 49, 953) is repealed.

**§ 65. Reorganisation of work of supervisory agencies**

**(1) The Government of the Republic shall complete the reorganisation of the work of supervisory agencies arising from this Act by 1 January 2001.**

**(2) Until reorganisation, supervisory agencies shall perform their current duties, unless otherwise provided by other Acts.**

**§ 66. Entry into force of Act**  
**(1) This Act enters into force on 1 January 2000, except the provisions delegating authority which enter into force at the time provided for in subsection (2) of this section, and § 34 and subsection 52 (2) which enter into force on 1 January 2002, and subsection 52 (1) which enters into force on 1 July 2000.**

**(2) The provisions which delegate authority for the issue of regulations of the Government of the Republic or ministers and which are contained in this Act enter into force on the tenth day after the publication of this Act in the Riigi Teataja. A regulation issued on the basis of the provisions delegating authority shall not be enforced before the entry into force of this Act.**