

MINISTRY OF HEALTH

PROPOSAL FOR THE ENACTMENT OF THE LAW ON FOOD SAFETY

CONTENTS OF THE LAW ON SAFETY OF FOODSTUFFS AND OTHER PRODUCTS AND MATERIAL IN CONTACT WITH FOODSTUFFS

I. GENERAL PROVISIONS

Article 1

This Law governs the conditions to ensure safety of food and products and materials coming into contact with foodstuffs, food production and trade, and the rights and obligations of natural and legal persons dealing in food production or trade, with the aim of providing protection of human health and consumer protection against fraud and ensuring free trade in domestic and foreign markets.

The provisions of this Law ~~related to regulating~~ admissible tar and nicotine levels, labeling, advertising and forewarning measures shall ~~relate to~~ apply also to tobacco products.

Article 2

The terms used in this Law shall have the following meaning:

1. "Food" / "Foodstuffs": any substance which in its processed, partially processed or unprocessed state is intended for human consumption as food and drink, and any ingredient used in food production, processing and preparation.

The term "food"/"foodstuffs" purports also drinking water from public waterworks, packed drinking water for the market, water intended for food production, as well as chewing gums.

2. "Raw food" is any food fit for consumption without any substantial modification of its original state.
3. "Processed food" is any food prepared for consumption in processing procedures significantly modifying the original state of the food raw material.

4. "Food raw material" is the product or cultivated plant or animal (including micro organisms) or product of mineral origin appropriate for food production, as well as plain and mineral drinking water.
5. "~~Food produced by means of innovated technologies~~ Novel foods" are the produced foodstuffs, raw food, or food raw materials still not available for common use, as follows:
 - produced by procedures previously not used, which cause substantial changes in food use and influence ~~the~~ nutritive values of ~~the~~ food, ~~the~~ human metabolism, or ~~the~~ level of undesirable substances in ~~the~~ food;
 - consisting of or containing genetically modified organisms;
 - produced from genetically modified organisms, not containing genetically modified organisms;
 - contains ingredients of new or deliberately modified primary molecular structures;
 - made of or is isolated from micro-organisms, fungi or algae;
 - made of or is isolated from plants cultivated in unconventional manner for which there exists no sufficient experience of safe use, and such that is made of raw materials of animal origin isolated from animals bred in unconventional manner for which there exists no experience of safe use;
6. "Food for particular nutritional uses" is food/foodstuffs differing by its contents or specific production procedures from food intended for general consumption, and meets the requirements of persons with special nutritional needs due to their health condition (metabolism, physiological needs, age, digestion problems);
7. "New product" is any food previously not produced by the domestic producer, ~~not~~ nor produced in such producer's production facilities and/or of composition and packaging unlike that of products previously produced, as well as any foodstuffs previously not imported from foreign producer and of composition or packaging unlike those previously imported.
8. "Safe food" are the foodstuffs meeting the ~~conditions~~ requirements prescribed with this Law.
9. "General food safety standard" is the set of requirements relating to food, food-labelling, additives, contaminants, pesticide and veterinary drug residues, hygienic practice, food produced with the use of ionizing radiation, food for particular nutritional uses, and to methods of sampling and sample analysis.
10. "Particular food safety standard" is the set of requirements in conformity with the general food safety standard but relating to particular types of food and incorporating the specific requirements for the particular types of food.

11. "Additive" is the substance added in food products, ~~has-used for~~ technological (including organoleptic) ~~use-purposes~~ in foodstuffs production, packaging, re-packaging, transport or storing, and appears or is expected to appear as a component of food products, integrally or as a by-product, or in some other way to affect the characteristics of the food products and, irrespective of its nutritional value, is ordinarily not used as food product or as an ingredient in food products.
12. "Food production" is the treatment, finishing, processing, preparation and packaging of food and products and matters coming into contact with the food intended for the market and ~~for~~ further processing. Preparation of food for public ~~eating—food providing?? places~~ catering is also considered food production.
13. "Food producer" is a legal or natural person conducting food production, including preparation of food for public ~~consumption~~ catering.
14. "Food production facility" is the facility or the space-area used for food production.
15. "Food packaging" is the activity of food packaging ~~food~~ in specified quantities, with the consumer not present, so that the content cannot be altered without opening or damaging the packaging.
16. "Food packaging material" is the material that comes in contact with the food and protects it against contamination and influences diminishing its nutritional value or quality. This material is ordinarily not used as food. The term packaging material shall include also tying and binding material.
17. "~~Auxiliary technological means~~ Processing aids" is any matter ordinarily not consumed as food but rather used for the purposes of food technological processing ~~-with the consequence of its residual or decayed~~ ^{*} elements unintentionally remaining in the food.
18. "Contaminant" ~~shall-is be~~ any ingredient inadvertently present in the food as a result of the process of food production and of the activities relating to plants growing and animal breeding, use of veterinary drugs and pesticides, and environmental and ecological contamination, and which create hazard to human health or unpropitious influence on the organoleptic qualities and the food content.
19. "System of risk assessment ~~of risk~~ at critical control points in food production and trade" is the system of production and trade control which enables identification, assessment, measures and supervision in cases of presence of detrimental substances in the food established at ~~expertly~~ proficiently determined control points, with the aim of ensuring food safety.

20. "Tobacco product" is the end product prepared of or with the use of raw tobacco for the purposes of smoking, chewing or ~~sniffings~~*snuffing*. The term covers also cigarette paper and other material in direct connection with the tobacco product, with the exception of cigarette filters, and smoking accessories.
21. "Tobacco products additive" is any material other than tobacco added into the tobacco product for the purposes of preparation, treatment, processing and packing with the intention of influencing the organoleptic, chemical, physical and microbiological characteristics of the product.
22. "Products and material that come into contact with the food in the course of food production, trade and consumption" include:
 - a. containers, utensils, machines and equipment used in food production and trade and in food packaging;
 - b. cleaning agents and disinfectants used or applied in food production and trade.
23. "Labelling" is the placement of identifying mark on the food or on its packaging, in the form of a picture, drawing, symbol or words, written, printed, imprinted, inserted, copied, drawn or otherwise applied on the food or its packaging or accompanying it, including labels, tags, stickers or other types of marks.
24. "Product specification" is the producer's written document on the production method, the content and the quantity of the components contained in the food commodity and on its labelling.
25. "Trade" is import, export, storing for sale and sale, and any other activity relating to food trading.
26. "Consumer" is a person purchasing and using food, for personal use or for use in his/her household.
27. "Sample" is the specimen or quantity of food given or received without payment.
28. "Advertising" is any presentation of food, products and materials that come into contact with food, and tobacco products, their trade mark or name, or the producer's trade mark, ~~by~~*by*, or by means of various methods, the objectives of the presentation notwithstanding. Advertising includes also:
 - a. sale of food, products and material that come into contact with food, as well as tobacco products, under any consumer-favoring conditions (coupons, reduced price for greater quantities purchased, free of charge samples with purchased foodstuffs and materials that come into contact with food and tobacco products).

- b. contacts with public aimed at promoting food and tobacco products, their trade marks or the producer's trade mark, as well as
 - c. provision of products-related information services to the consumers.
29. "Codes of good production and good hygienic practices" is the system of general principles to be observed in the production and trade of foodstuffs, products and materials that come into contact with food and relating to the stuff, facilities, equipment, materials, the condition of the materials entered, the documentation, hygiene maintenance, production technology and systems of control, with the aim of reducing to minimum the risk of contamination of food in the process of production or other human activities.
30. "Food use-by date" -is the time period within which the physical, chemical, microbiological and organoleptic qualities of the food produced, stored and transported under determined or specific conditions satisfy the conditions set forth under this Law, and the conditions of use stated in the product specification.
31. "Official food control" is the inspection/supervision/made by food inspectors with the aim of ascertaining the propriety of food, of additives, vitamins, mineral salts, oligo-elements and other additives intended for sale as such, and of products and materials coming into contact with food, with the aim of preventing risks to human health, ensuring fair commercial transactions and protecting consumers' interests, including provision of veritable information for the home market, as well as in export and import.
32. "Food trader" is the legal or natural person trading in foodstuffs and products and materials in contact with food.

II. Authorized Agency

Article 3

For the purposes of the conduct of professional and managing activities in the field of safety of food, products and materials coming into contact with food a Food DepartmentAgency (hereinafter: DepartmentAgency) shall be established as an agency at the Ministry of Health, authorized to conduct activities in this field.

Article 4

The DepartmentAgency shall be administered by a director.

The director, proposed by the Minister of Health, shall be appointed and discharged by the Government of the Republic of Macedonia.

III. Food Safety

Article 5

The food producer or trader shall be required to meet the food safety ~~conditions~~ requirements related to the chemical, physical, microbiological and organoleptic qualities of the food.

The producer shall be required to state the food safety characteristics in the product specification.

Food producers shall be required to ensure control of food safety in their own laboratory or in other accredited laboratory.

Article 6

Production and trade of unsafe food is ~~prohibited~~ prohibited.

Unsafe food under this Law, without prejudice to Article 2 item 8, under this Law shall be the food:

1. inadequate for human consumption, of expired use-by date or damaged packaging, which can have an adverse influence on the food quality.
2. produced or sold in violation of food hygiene requirements and inconsistent with the codes for good production and good hygienic practices;
3. misleading the consumers.
4. containing pathogenic microorganisms or pathogenic parasites or their secretions or other microorganisms or parasites or other germs detrimental to human health;
5. containing inadmissible pesticides and veterinary drugs residues or quantities of pesticides and veterinary drugs residues exceeding admitted levels;
6. containing toxic metals, non-metals, other chemical contaminants from the environment, as well as toxins and other matters in concentrations which could have adverse effect on human health;
7. mechanically contaminated with components which could have an adverse effect on human health or cause nausea;
8. containing additives the use of which in food production is inadmissible, or inadmissible quantities of additives, or additives applied in a technologically incorrect manner;
9. of composition or organoleptic characteristics changed due to physical, chemical, micro-biological or other processes;
10. containing radionuclides exceeding set limits or is radiated above the limits determined in the regulations;
11. lacking declaration or possessing declaration which does not indicate use-by-date;
12. the packaging lacks data stated in the declaration, in cases of food not in special packaging, or sold in its loose state;
13. food of animal origin not marked with safety stamp, as required by the regulations on veterinary health;
14. food presenting any kind of hazard to human health.

Article 7

Food produced and placed on the market shall conform to the requirements set forth in the Macedonian Codex on Food.

The Macedonian Codex on Food comprises all the regulations, rendered under this Law, relating to food produced and placed on the market in the Republic of Macedonia.

For the purposes of the Macedonian Codex on Food regular updating, the Minister of Health shall ~~institute~~ establish a Commission consisting of representatives of the Ministry of Health, Ministry of Agriculture, Forestry and Water Economy, Ministry of Economy, and renowned scholarly and expert figures and representatives of consumers' organizations.

The Commission is made up of 15 members. The Chairman of the Commission is appointed by the Minister of Health.

The Commission is an expert consultative body dealing with issues governed by the Macedonian Codex on Food and the methods of food analysis based on international scientific achievements.

The Commission may make recommendations related to its field of work, based on the international organizations recommendations adjusted as necessary to fit the requirements and the specifics of the country.

Article 8

The Minister of Health shall determine the general standards on food safety pursuant to this Law, as well as the special standards on the safety of particular types of food, in accordance with the general standards on food safety.

The Minister of Agriculture, Forestry and Water Economy shall ~~ratify~~ approve the general and special standards in the part of the requirements relating to pesticides and veterinary drugs residues in food.

VI. Safety of products and material coming into contact with food

Article 9

It is hereby prohibited that products and material coming into contact with food and planned to be used in a manner which might cause adverse effects to human health be produces or processed or placed in the market.

Article 10

The products and material used for food packing or coming into contact with food shall conform to the requirements prescribed by this Law so as not to cause change in the food which might have adverse effect on human health, or change the food appearance, taste or composition, or create possibilities for food contamination or penetration by extraneous substances or substances detrimental to human health.

Article 11

The Minister of Health shall prescribe:

- 1) list of substances approved for use in the production of products and materials coming into contact with food, the type of the particular matters approved for use, the criteria on substances purity and the specific conditions to be met in their use;
- 2) approved levels of ingredients which may get into or onto the food from such products and materials;
- 3) the manner of labeling of the products and materials intended to come into contact with food, as well as the requirements for the compulsory information to be declared on the packaging or in the accompanying documents.
- 4) designation of the quantities of particular matters in specified products and materials, limitations to the use of certain products and materials;
- 5) warnings, safety measures or instructions for actions to be taken in case of accident;
- 6) the manner of labelling and the extent of data to be declared on the products and materials, the type of products and materials to be placed on the market with an accompanying document, and the content and form of the accompanying document.

IV. Food production

Article 12

Production of food may commence when the preconditions relating to the space, facilities, equipment, machines, working instruments, sanitary-hygienic, veterinary and other conditions are satisfied in accordance with the codes for good production practices imperative to the production of safe food, prevention of environmental adverse influences on the production, and vice versa.

The detailed ~~conditions-requirements~~ to be satisfied in food production shall be prescribed by the Minister of Health, ~~subject to -in-~~ agreement ~~reached~~ with the Minister of Economy and the Minister of Environment and Spatial Planning.

The commencement of the production and any change in any of the preconditions for the commencement of the production shall be subject to approval by the ~~Food~~ DepartmentAgency.

The ~~DepartmentAgency~~ shall keep a register of approvals issued.

The manner in which the approval referred to in paragraph 3 of this Article shall be issued, and the form and content of the register referred to in paragraph 4 of this Article, shall be prescribed by the Minister of Health.

ALTERNATIVE: Instead of request for approval, the producer shall submit an ~~announcement~~ notification on the commencement of the business operation, and the producer's further business operation shall be subject to official control.

Article 13

The producer may use in food production only the raw materials, additives, ~~auxiliary technological means~~ processing aids, food packaging material and sanitary-hygienic substances satisfying the prescribed preconditions.

The Minister of Health shall prescribe the additives approved for use in food production and the maximum quantities of particular additives in a product, as well as the specific criteria and requirements on the purity of additives admissible in the food, the procedures for acquirement approval on the use of additives, the information on the packaging related to the additives contained in the food and the data in the accompanying documents, the sampling procedures and analysis methods, and the qualitative and quantitative content of the additives or of the food containing additives.

The preconditions to be met by food packaging materials and sanitary-hygienic substances shall be prescribed by the Minister of Environment and Spatial Planning.

Article 14

Food producers shall ensure that persons working in food production meet the requirements specified under this Law with regard to professional qualifications, health condition, basic knowledge in food hygiene in accordance with the codes on good hygienic practice, and in environment protection.

The minimum requirements with regard to professional qualifications and basic knowledge in food hygiene and environment protection shall be prescribed by the Minister of Health.

The Minister of Health shall install the program for the acquisition of the basic knowledge on food hygiene and environment protection and shall authorize the organizations to conduct program-based training and knowledge testing and to issue certificates on acquired basic knowledge on food hygiene and environment protection.

Checkups for the ascertainment of the state of health of the persons working in food production shall be conducted in conformity with the regulations on protection against infectious diseases.

The expenses for the training referred to in paragraph 3 and the establishment of the state of health referred to in paragraph 4 of this Article shall be borne by the food producer.

Article 15

Food producers may produce food for particular nutritional uses and novel foods ~~produced by means of innovated technologies~~ only upon prior approval issued by the ~~Department~~Agency.

The Minister of Agriculture, Forestry and Water Economy shall give ~~consent to the~~ consent to the issuance of the approval for the production of novel foods~~food produced by means of innovated technologies~~.

The types of food for particular nutritional uses and the approved levels of daily intake of vitamins and minerals shall be prescribed by the Minister of Health.

The manner of approval issuance and the required documents referred to in paragraph 1 of this Article shall be prescribed by the Minister of Health.

Article 16

The producer may produce food by means of ionizing radiation only upon prior approval by the ~~Department~~Agency.

The manner of approval issuance and the required documents referred to in paragraph 1 of this Article shall be prescribed by the Minister of Health.

Article 17

The expenses arising from the procedures ~~for issuing~~regarding approvals referred to in Articles 15 and 16 of this Law shall be borne by the food producer.

The amounts of the ~~expenditures~~expenses arising from the procedures of approval issuance referred to in Articles 15 and 16 of this Law shall be prescribed by the Minister of Health.

VI. Food Trade

Article 18

The food traded shall meet the conditions prescribed with this Law and the regulations ~~enacted based on~~under this Law.

Trading with food referred to in Article 6 of this Law is prohibited.

Article 19

Food producers may conduct food trade only in facilities, space and using equipment which have no adverse effects on food safety.

Food trade may be conducted also at markets and fairs under the conditions and in the manner prescribed by the Minister of Health, subject to common~~based on~~ agreement reached with the Minister of Economy and Minister of Environment and Spatial Planning.

Food trader placing food on the market shall, in addition to the general conditions prescribed by trade regulations, meet the special conditions prescribed by the Minister of Health.

Article 20

Food traders shall transport food by means of transport that fulfill the sanitary-hygienic conditions prescribed by the Minister of Health.

Article 21

Food storing shall be conducted in a manner ensuring food safety in all stages of food trade to the end consumer.

Food traders shall conduct regular inspections of the storage conditions and influence thereof on food safety.

Article 22

Food trade conducted in mobile ~~shops-facilities~~ (vans, street-vendors etc., trans. note) ~~is~~ shall be prohibited, ~~with the exclusion~~of fruit and vegetables.

Article 23

Processed food may be marketed through catering companies, mass caterers and through other commercial forms of catering.

Article 24

Food and raw material imported for domestic production and market and the food and raw material intended for export shall conform to this Law and to the regulations enacted on the basis of this Law.

Article 25

Food traders shall ensure that the persons conducting food trade possess basic knowledge in food hygiene and state of health as required by this Law.

Food traders shall ~~direct refer~~ the persons ~~referred to mentioned~~ in paragraph 1 of this Article to training ~~for the acquisition in which to acquire of~~ the knowledge referred to in paragraph 1 of this Article, conducted in conformity ~~to with~~ the Program referred to in Article 14 of this Law.

Checkups for the ascertainment of the state of health of the persons working in food trade shall be conducted in conformity with the regulations governing the sphere of protection against infectious diseases.

The expenses for the training referred to in paragraph 2 and for the conduct of the checkups referred to in paragraph 3 of this Article shall be borne by the food trader.

VII. System of risk assessment ~~of risk~~ at critical control points

Article 26

Food producers and traders shall apply in the respective processes of food production and trade the System of risk assessment ~~of risk~~ at critical control points.

The system referred to in paragraph 1 of this Article shall include:

- 1) analysis of possible risks of food contamination;
- 2) identification of the technological process stages where possibilities exist for the occurrence of potential risks and determining the stage which can be expected to be the critical point.
- 3) establishment and application of procedures for the monitoring and determined risk control at critical points;
- 4) periodical inspection of the activities referred to in items 1, 2 and 3 of this Article with regard to their efficiency or renewal in cases of changes in food production and trading processes, and keeping written records of the periodical inspections.

VIII. Supervision ~~of food and products and materials coming into contact with food~~ at in exports and import imports

Article 27

Imported food and products and material coming into contact with food shall be subjected to official control at the border, in the places designated for such purposes.

It is prohibited to import food, and products and material coming into contact with imported food, into the territory of the state, unless ~~it~~ such food has passed the official control of the import shipment.

As an exception to paragraph 2 of this Article, the inspector may permit entry of a shipment into the territory of the state and its transports to a storage meeting the conditions prescribed under this Law, after taking a sample for lab analysis to confirm such food safety.

Article 28

It is ~~hereby~~ prohibited to place on the market imported food, products and material coming into contact with food from import, unless such food has been approved by the inspector.

IX. Packaging

Article 29

The packaging should protect the food from contaminants and influences which could affect the nutritive value and safety of the food.

It is hereby prohibited that packaging products and material presenting danger to human health be used.

For the purposes of food packaging only reusable or recyclable products and material may be used, or such which can be safely dumped in conformity with the regulations governing protection of human environment and nature.

Article 30

The food shall be packed in a manner making impossible any change in the food unless the package is opened or damaged.

Food producers and traders shall pack the food in packaging ~~conforming~~ to the Macedonian Codex on Food.

The types and sizes of food packaging shall be prescribed by the ~~Minister~~ of Health.

~~X. Information Provision of information for the consumer for the consumer (food marking and markingslabelling)~~

Article 31

Food marking and labeling is done with the purpose of providing information for the consumers and food inspectors.

Food producers and traders shall mark the packaging of the food to be ~~put in trade~~placed on the market with labels written in Macedonian and easy to ~~understand~~ comprehend.²

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Article 32

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Food producers and traders shall ~~label~~provide the food intended to be ~~put in trade~~placed on the market with the following data:

1. name of the product put to sale;
2. geographic origin of the product;
3. name of the food producer or trader ~~stated~~presented in a manner enabling its easy recognition;
4. foodstuffs net weight or volume, and for tobacco products number of pieces or their weight;
5. the raw materials and additives used in the preparation of the food, with the exception of tobacco and tobacco products, per quantity, in declining order;
6. the date of minimum durability (best before...) or in the case of foodstuffs which, from the microbiological point of view are highly perishable, the 'use by' date;
7. specific conditions for storing imperative in preserving the safety of the foodstuffs, recommendations for terms of use when such have considerable influence on the 'best-use by' term of foodstuffs use;
8. energetic composition ~~when of~~are intended for ~~special nutritive use~~particular nutritional uses;
9. number of ~~the~~approval for foodstuffs ~~manufactured~~produced by means of ~~inniovated~~innovated technologies and foodstuffs for ~~special nutritive use~~particular nutritional uses.

The food producer or trader shall, in addition to the data referred to in paragraph 1 of this Article, indicate on the food the data required pursuant to special standards for particular types of foodstuffs.

The manner of food labeling shall be prescribed by the Minister of Health.

Article 33

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Food labeling or advertising with data suggesting medicinal properties associated to prevention or cure of diseases, emphasizing as specific food qualities similar to those of other foodstuffs of the same quality, and the use of pictures, drawings, signs, slogans or ~~text words~~ which might mislead the purchaser as to the identity of the product, its origin, composition, quality, purpose and effects is ~~hereby~~ prohibited.

Advertisements may contain information pursuant to Article 32 of this Law.

~~It is hereby prohibited that the following be used in F~~ food advertising must not use:

1. Statements suggesting ~~elimination~~cure, easing or prevention of diseases;
2. Notes in the form of ~~doctor's~~physician's advices or ~~doctor's~~physician's findings;
3. Descriptions of diseases;
4. Statements by third parties, especially acknowledgements, commendations or recommendations referring to ~~elimination~~the cure or easing of diseases;

5. ~~pictures~~ Pictures of presenting persons in professional ~~doctor's~~ physician's clothes or practicing ~~physician's~~ doctor's profession or ~~sales-selling~~ medicines;
6. Texts or written data suggesting that certain diseases can be treated by the foodstuffs.

The prohibition referred to in paragraph 3 of this Article does not refer to foodstuffs intended for particular nutritional uses.

Article 34

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~~It is hereby prohibited that labelling~~ Labels of food for infants no older than six months and small children no older than 12 months ~~must not~~ contain ~~text~~ words, photographs, drawings or other graphic presentations discouraging in any way breast-feeding, except as illustration of the methods for the preparation of the foodstuffs, as well as terms such as: - humanized-, ~~meternalized~~ maternalized- or similar.

~~It is hereby prohibited to advertise~~ Advertising of artificial milk and other foodstuffs intended for infants of no more than 6 months, ~~as well as nursing~~ -bottles, ~~nursing bottle~~ ~~teatlike~~ teats, caps and ~~nipples~~ pacifiers as well as other foodstuffs with ~~an adverse~~ ~~effect~~ a negative influence on breast-feeding, ~~is prohibited.~~

~~It is hereby prohibited that P~~ Producers and traders ~~must not~~ give information to the public with regard to foodstuffs and objects referred to in paragraphs 1 and 2 of this Article.

The manner and content of the notification on the food referred to in paragraph 1 of this Article shall be prescribed by the Minister of Health.

Article 35

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Advertising of tobacco products and their trademarks is ~~hereby~~ prohibited.

Article 36

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~~Producers of t~~ Tobacco products ~~producers~~ shall place on the original packaging warnings on the harm ~~fulness of those such~~ products ~~can cause for to~~ human health, ~~and as well as~~ ~~indicate~~ the admitted levels of tar and nicotine.

Article 37

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Advertising of alcohol beverages and their trademarks/ alternative: beverages containing more than 18 vol.%/ outside the place of their sale, ~~shall be is hereby~~ prohibited.

XI. Official food control

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Article 38

Official food control is conducted in all phases-stages of food manufacture-production and trade-sale.

Official food control shall be conducted by the DepartmentAgency, through its food inspectors.

Article 39

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Inspection of food manufacture-production and tradesale shall be conducted in all phases stages of food manufacture and saleproduction and trade, and shall include in particular:

1. raw materials, additives, auxiliary technological substances and all other substances used in the-food production;
2. semi-products or ready-prepared food, their place of production and the market they are intended for notwithstanding;
3. products and materials which might come into contact with the food;
4. procedures and means used in cleaningcleansing, disinfection, disinfestation, and other pest control proceduresoperations;
5. state-conditions and use of locations, facilities, rooms, offices, space surrounding the equipment, transport means, machines and equipment in all phases-stages of foodstuffs manufacture or sale-of production or sale foodstuffs;
6. food production technological processes for food production;
7. packaging, labelling, public-information to public and advertising, as well as presentations of food and products and-and material coming into contact with the food;
8. the system of risk assessment at critical control points in the-food production or sale-trade done byused by the-the producer or trader;
9. methods and ways of food preservation;
10. hygiene and state of hehealth condition of the persons in direct or indirect contact with materials or foodstuffs or materials.

Article 40

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The inspection referred to in Article 39 of this Law shall include one or more of the following inspection procedures:

- 1) general check-examination of data on-relating to the producer and trader;
- 2) taking samples for lab analyses and testing;
- 3) stuff hygiene control;
- 4) documentation control;
- 5) check and control of the systems of verification used by the producers and traders and the results thereof;
- 6) check and control of the values registered by means of producer's or trader's gaugersing instruments, and a check and control with the inspector's gaugersgauging instruments.

For the purposes of the inspection, the food producer ~~or and~~ trader shall ~~enable allow~~ the inspectors contacts with ~~responsible persons in charge~~ persons and employees.

Article 42

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The inspector shall prove his official capacity with inspector's identification card.

The form and content, as well as the manner of the inspector's I.D. issuance and withdrawal shall be prescribed by the Minister of Health.

Article 43

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Appointed to the position of inspector may be any person meeting the following conditions, in addition to those prescribed with the regulations governing appointment of government civil service officers ~~appointments~~: university degree in medicine, ~~veterine~~ veterinary medicine, biology, food processing technology and working experience of at least 3 years in corresponding profession.

Article 44

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For the purposes of the inspection, the inspector shall have the right and duty to:

- 1) request insight into information and original documents relating to the production and ~~sale~~ trade, and for the purposes of his / her own inspection file also a copy of the documents;
- 2) conduct inspection on the site at the food producer's or trader's;
- 3) take free of charge samples for lab analyses and tests;
- 4) order measures for the elimination of the ~~ascertained diffieciencies~~ deficiencies ascertained;
- 5) ~~to~~ ban the use of production or trading facilities and equipment ~~for production or sale~~ or part of ~~them~~ such in cases of violation of standards and requirements under this Law and regulations based on this Law;
- 6) ~~to~~ ban the production or sale of foodstuffs ~~re~~presenting risk to human health;
- 7) ~~to~~ order destruction or ~~to destruet~~ destroy unsafe food;
- 8) ~~start~~ initiate misdemeanor or criminal proceedings in cases of perpetrated misdemeanor or criminal acts under pursuant to this or other law;
- 9) undertake other measures for the protection of the health of the people against unsafe food.

As an exception to paragraph 1 item 7 of this Article, and upon request submitted by food producer or trader, the inspector may ~~give consent~~ approve to the use of foodstuffs for other purposes, ~~following and in accord~~ based on with the opinion of a professional institution.*

Article 45

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The inspector shall keep as business secret all facts and data he ~~has learnt~~ in the course of the inspection and which are confidential or represent a secret ~~with regard~~ associated to ~~to the~~ food producers or traders interests.

~~In case of violation~~ Should the inspector violate of the the provision referred to in paragraph 1 of this Article, ~~the/she~~ inspector shall be charged with violation of official authorization pursuant to this Law.

Article 46

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The inspector shall order the measures within his authorization in a form of a written decision ~~order the measures under his jurisdiction, in conformity with~~ pursuant to the regulations on the general administrative procedure, except when otherwise prescribed under this Law.

Food producers and traders shall ~~carry out~~ effectuate the measures contained in the inspector's decision.

The appeal against the decision shall not postpone its execution.

The appeal against the inspector's decision shall be resolved in the second ~~degree~~ instance by the Minister of Health.

Article 47

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When ascertaining existence of immediate danger to the life and health of ~~the~~ people, the inspectors shall issue verbal order for urgent and immediate elimination of the deficiencies ascertained, and such order shall be stated in a memo.

In the instances referred to in paragraph 1 of this Article, the inspectors shall issue a written decision within 48 hours from the issuance of the verbal order.

Article 48

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Food producers and traders shall enable unhindered conduct of inspection and ~~give~~ supply true and accurate data, information, samples and other materials as requested by the inspector, free of charge.

Article 49

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The manner of conduct of the inspection and the manner of sampling shall be prescribed in greater detail by the Minister of Health.

Article 50

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The examination and analyses of food and objects and material coming into contact with food shall be conducted by accredited laboratories.

The accreditation of the laboratories referred to in paragraph 1 of this Article shall be made pursuant to the regulations governing accreditation.

Article 51

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The expenses for the lab examinations and analyses shall be borne by the foodstuffs producer or trader.

Article 52

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The producer or trader may request second opinion on the safety of the food sampled in the course of the inspection, to be issued by another accredited laboratory.

XII. Penalty provisions

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Article 53

A fine of MKD 80,000 to 240,000 shall be imposed on ~~the a~~ legal person for the following misdemeanors:

- 1) ~~fails failure~~ to meet food safety conditions referred to in Article 5 paragraph 1 of this Law;
- 2) ~~fails failure~~ to provide laboratory control of food safety (Article 5 paragraph 3);
- 3) ~~unsafe foodstuffs produces production~~ or ~~puts in placement on~~ the market ~~unsafe foodstuffs~~ (Article 6);
- 4) ~~produces production~~ or ~~puts in placement on~~ the market ~~of~~ foodstuffs ~~inconsistent to not meeting~~ the requirements under the Macedonian Codex on Food;
- 5) ~~produces production~~ or ~~puts in placement on the the~~ market ~~of such~~ foodstuffs and products and materials coming into contact with food ~~which as can be detrimental present hazard for to~~ human health (Article 9);
- 6) ~~commences commencement of~~ operation prior to ~~meeting the fulfillment of~~ the conditions prescribed with Article 12 of this Law;
- 7) ~~in the~~ production of food ~~uses using~~ raw materials, additives, ~~auxiliary technological means processing aids~~, food packaging material and hygiene ~~means substances~~ not meeting the prescribed conditions (Article 13)
- 8) ~~produces production of~~ foodstuffs for particular nutritional uses, ~~foodstuffs produced by means of innovated technologies novel foods~~ and foodstuffs treated with ionizing radiation without prior approval for such production (Articles 15 and 16);
- 9) ~~food trade s in foodstuffs in breach violation~~ of Article 19 of this Law;
- 10) ~~food trades trading food~~ in mobile ~~facilities facilities~~ (Article 22);

- 11) ~~places placement~~ on the market ~~of~~ food processed ~~contrary in violation of~~ to Article 23 of this Law;
- 12) imports ~~of~~ foodstuffs not meeting the provisions under this Law (Article 24);
- 13) ~~in failure to apply the system of risk assessment at critical control points in the process of food~~ the production and ~~sale trade of foodstuffs does not apply the system of assessment of risk at critical control points~~ (Article 26);
- 14) imports ~~of~~ or ~~sells trade in~~ foodstuffs or products and materials coming into contact with ~~imported~~ food ~~from import~~ without prior inspection or ~~inspector's~~ ~~inspector's~~ approval (Articles 27 and 28);
- 15) uses ~~of~~ packaging products and materials ~~which represent~~ ~~presenting~~ risk ~~for to~~ human health (Article 29, paragraph 2);
- 16) ~~labels labelling~~ and/or ~~advertises advertising~~ and/or ~~gives provision of~~ information on food for use by infants and small children, in violation of Article 34 of this Law;
- 17) ~~fails failure~~ to enable unhindered inspection and to give true and accurate data, information, samples and other materials as requested by the inspector (Article 48).

Misdemeanors referred to ~~in~~ paragraph 1 of this Article shall entail, in addition to fines, a safety measure imposed on the legal person responsible for ~~it such misdemeanors~~ – a ~~three months to one year~~ ban on the conduct of the business activity ~~of a duration of three months to one year~~.

Misdemeanors referred to ~~in~~ paragraph 1 of this Article shall entail a fine of MKD 15,000 to 45,000 for the legal person's employee in charge as well as a safety measure – a ~~three months to one year~~ ban on holding ~~senior managerial~~ position ~~in duration of three months to one year~~.

Article 54

A fine of MKD 40,000 to 120,000 shall be imposed on the legal person for the following misdemeanors:

- 1) ~~fails failure~~ to state the safety characteristics of the food in the product specification (Article 5 paragraph 2).
- 2) ~~allows admission of~~ persons not ~~meeting satisfying~~ the ~~conditions requirements~~ set forth ~~in under~~ Article 14 of this Law to work in the process of food production.
- 3) ~~Conducts conduct of~~ food transport in transport vehicles ~~not not~~ satisfying ~~prescribed the~~ conditions ~~prescribed~~ (Article 20).
- 4) ~~Fails failure~~ to conduct regular control of storage conditions and effects thereof for food safety;
- 5) ~~admission of allows~~ persons not meeting the conditions set forth in Article 25 of this Law to work in the process of food trading and marketing.
- 6) ~~Produces production~~ or uses ~~of~~ packaging materials which cannot be reused or recycled or cannot be ecologically disposed ~~of~~ (Article 29, paragraph 3);

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- 7) ~~Does not failure to~~ pack the food in the manner prescribed under Article 30 of this Law;
- 8) ~~Marks labeling and marking of~~ food package intended for marketing in a manner inconsistent with Article 31 paragraph 2;
- 9) ~~Fails failure~~ to mark the food in accordance to Article 32 of this Law;
- 10) ~~Labels labelling~~ and ~~advertisings of~~ foodstuffs ~~in manner contrary counter to~~ Article 33 paragraphs 1 and 3 of this Law;
- 11) ~~Advertises advertising of~~ tobacco products and/or their brand names (Article 35);
- 12) ~~Fails failure~~ to place a warning ~~on the harmfulness of the tobacco product to human health~~ on ~~the the product's~~ original package ~~on the harmfulness of the tobacco product to human health~~ and/or ~~does failure to not~~ indicate the admissible levels of tar and nicotine (~~article Article~~ 36);
- 13) ~~Advertises advertising of~~ alcohol drinks and their brand names ~~in manner contrary contrary to~~ Article 37 of this Law;
- 14) ~~Does not failure to~~ enable the ~~ionspectorinspector~~ contact with persons in charge and employees during the inspection (Article 41, paragraph 2)

Misdemeanors referred to in paragraph 1 of this Article shall entail, in addition to fines, a safety measure imposed on the legal person responsible for it – a ~~three months to one year~~ ban on the conduct of the business activity ~~of a duration of three months to one year~~.

Misdemeanors referred to in paragraph 1 of this Article shall entail a fine of MKD 10,000 to 30,000 imposed on the legal person's employee in charge as well as a safety measure – a ~~three months to one year~~ ban on holding ~~senior managerial position in duration of three months to one year~~.

XIII. TRANSITIONAL AND CONCLUSIVE PROVISIONS

Article 55

Pending the establishment of inspector's ~~function office~~ within the ~~Directorate Agency~~, the inspections shall be conducted by the existing state inspectorates and offices:

- 1) State Sanitary and Health Inspectorate, ~~in conformity with pursuant to~~ the provisions under the Law on Sanitary and Health Inspection;
- 2) State Market Inspectorate, ~~in conformity with pursuant to~~ the Law on Trade and the Law on Quality Control of Agricultural and Food Products in ~~International Foreign~~ Trade;
- 3) Veterinary Office, ~~under pursuant to~~ the Law ~~ion~~ Veterinary Health;

Article 56

Based on the inspection conducted ~~in conformity with pursuant to~~ Article 55 of this Law, the ~~Department Agency~~ shall have the right to:

- 1) order that ascertained deficiency or irregularity in the operation which might cause ~~detrimental adverse~~ effects to people's safety and health be eliminated;

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- 2) prohibit conduct of business activity, completely or partially, use of equipment, as well as conduct of activities of individuals, when the conditions set forth ~~under in~~ this Law are not met;
- 3) prohibit use of facilities and equipment for food production and trade or part thereof in cases of failure to maintain the standards and requests under this Law and the regulations enacted on the basis of this Law;
- 4) prohibit the production and trade of food ~~representing~~ risk to human health;
- 5) order destruction or ~~destruct~~ destroy unsafe food;
- 6) order other measures for the protection of the health of the people.

Article 57

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Food- producers and traders shall harmonize their activities with the provisions ~~under of~~ this Law within one year ~~from following~~ the entry of this Law into force.

The producers referred to in paragraph 1 of this Article shall, within one month ~~from following~~ the date of the expiration of the time limit referred to in paragraph 1 of this Article, submit a request to the ~~Department~~ Agency for the issuance of the approval referred to in Article 8 paragraph 3 of this Law.

Should the producer fail to submit such request within the period set forth in paragraph 2 of this Article, it shall be deemed that such approval was not granted.

Article 58

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Producers of food for particular nutritional uses, ~~food produced by means of innovated technologies~~ novel foods, and food treated with ionizing radiation shall, within 9 months ~~from following~~ the entry of this Law into force, submit ~~a request~~ to the ~~Direction~~ Agency ~~a request~~ for ~~an~~ approval ~~for of~~ the production of ~~the such~~ given type of foodstuffs.

Article 59

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Procedures for the import ~~procedures for of~~ foodstuffs and material and objects coming into contact with food, ~~functional in effect~~ on the day of this Law entry into force, shall continue to apply in accordance with the provisions of the regulations in ~~force effect~~ on the day of the import request filing, except when this Law ~~is is not more favourable to them~~ beneficial.

Article 60

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Pending the accreditation ~~pursuant in accordance with to~~ the regulations ~~relating to governing~~ accreditation of laboratories, examination and analyses ~~if of~~ food and products and materials coming into contact with food shall be conducted by the ~~existing~~ currently accredited laboratories.

Article 61

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The Department Agency shall commence its activities on the day of the director's appointment.

The Government of the Republic of Macedonia shall, within three (3) months following the day of the entry into force of this Law, appoint the director to the Directorate Agency director.

The Agency dDirector of the Directorate shall enact bring forth thea Rule-rule book on the organizational setting and jobs systematization of positions within three months following the date of his/her appointment at the latest.

The existing inspectors shall be taken over assumed by the Department Agency within three months following the enactment bringing of the rule_-book referred to in paragraph 3 of this Article.

Article 62

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The Minister of Health* shall enact bring forth the general statutory documents regulations under this Law in no later than within one year following the entry of this Law into force.

Pending the enactment of the general statutory documents regulations referred to in paragraph 1 of this Article the existing regulations shall apply, unless contrary provided they are not contrary to the provisions of this Law.

Article 63

On the day of entry into force of this Law the provisions under the Law on Ssanitary Ssafety* of Foodstuffs and Objects for General Use (Official Gazette of SFRY , No. 53/91 and Official Gazette of RM No. 15/95) relating to foodstuffs, vessels, tools, equipment and instruments for the production and trade in foodstuffs and objects coming into contact with foodstuffs, and packaging for foodstuffs, tobacco, tobacco products and smoking accessories and the Law on sanitary control of foodstuffs and objects for general use (Official Gazette of SRM, No. 29/73, 37/86 and Official Gazette of RM No. 15/95).

On the day of the assumption of the conduct of inspection by the Department Agency, and in conformity with the provisions of this Law, the provisions relating to foodstuffs inspection under: Law on Veterinary Health, Law on Sanitary and Health Inspection (Official Gazette of RM No. 19/95) Law on Trade, Law on the Control of the Quality of Agricultural Products and Foodstuffs in International Trade (Official Gazette of RM No. 5/96), the Law on Market Inspection (Official Gazette of RM No. 35/97 and 23/99) shall cease to apply.

Translated by: *Ljubica Arsovska*
September 2001

Article 64

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This Law shall enter into force on the eighth day following its publication in the “Official Gazette of the Republic of Macedonia”.