

## LAW OF UKRAINE

### On Introduction of Changes to the Law of Ukraine “On Quality and Security of Food Products and Food Raw Materials”

Verkhovna Rada of Ukraine hereby r e s o l v e s :

Introduce changes to the Law of Ukraine “On Quality and Security of Food Products and Food Raw Materials” (771/97-BP) (Vidomosti of Verkhovna Rada of Ukraine, 1998, № 19, pg.98) that shall read:

## “LAW OF UKRAINE

### On Safety and Quality of Food Products

This Law shall regulate relations between the bodies of executive power, producers, sellers (suppliers), and consumers of food products and envisage a legal order for ensuring the safety and quality of produced, circulated, imported and exported food products.

## **SECTION I: GENERAL PROVISIONS**

### Article 1. Terms and Definitions

The terms set out below in the present Law shall be used in the following meaning:

Agri-food market – specially equipped and specially allocated location that is used for providing services on establishing due conditions for the sale of agricultural products that are defined by this Law;

Accredited laboratory – a laboratory accredited in accordance with relevant legislation of Ukraine or international accreditation procedures;

Risk analysis – a process consisting of three interconnected components: risk assessment, risk management, and risk communication;

Arbitration analysis – laboratory analyses conducted in response to an appeal by a person against the results of previous laboratory analyses;

Flavourings – flavouring substances, flavouring preparations, process flavourings, smoke flavourings and mixtures thereof;

Flavouring preparation – a product, other than the flavouring substances, whether concentrated or not, with flavouring properties, which is obtained by appropriate physical processes (including distillation and solvent extraction) or by enzymatic or microbiological processes from material of plant or animal origin, either in the raw state or after processing for human consumption by traditional food-preparation processes (including drying, torrefaction and fermentation);

Flavouring substance – certain chemical substance which provides flavouring:

-By appropriate physical processes (including distillation and solvent extraction) or enzymatic or microbiological processes in materials of plant or animal origin either in the raw state or after processing for human consumption by traditional food-preparation processes (including drying, torrefaction and fermentation);

-By chemical synthesis or isolated by chemical processes and which is chemically identical to a substance naturally present in material of plant or animal origin as specified paragraph 9 of this Article;

-By chemical synthesis but which is not chemically identical to a substance naturally present in material of plant or animal origin as described in paragraph nine of this Article;

Safety (of food products) – state of a food product that is a result of production and circulation activities conducted in compliance with the requirements established by sanitary measures and/or technical regulations, and assures that the food product does not cause harm to human health (consumer health) when consumed according to its intended use;

Safe food product – a food product that does not create a harmful effect on human health directly or indirectly, provided that this food product is produced and circulated in compliance with the requirements of sanitary measures and is consumed (used) according to its intended use;

State inspector of veterinary medicine (hereinafter: veterinary inspector) – doctor of veterinary medicine, employed by the State Department of Veterinary Medicine (hereinafter: Department) and its territorial bodies, regional service of veterinary-sanitary control and supervision on the state border and in transport, other state institutions of veterinary medicine, that have authorities of the state veterinary inspector according to their position, or doctors of veterinary medicine, authorized by the Department, or, in the case of a foreign country, by its relevant veterinary state body, to perform inspections of animals and food products under Veterinary Service control with the purpose of protecting human and/or animal health, and, when required for international or domestic trade, perform certification of such in conformity with the requirements of the relevant international organizations and legislation of Ukraine;

Veterinary documents – international veterinary certificate, veterinary affidavit, veterinary card and information notes, issued by the state veterinary inspectors or authorized doctors of veterinary medicine, attesting to veterinary-sanitary status of food products under Veterinary Service control;

State veterinary-sanitary expertise – a set of necessary laboratory and special analysis, performed by the specialists of veterinary medicine of the state institutions of veterinary medicine to determine safety and quality of food products under Veterinary Service control, further processing or other use, analysis of production technology and technological equipment, which the producer and supplier must fulfill to ensure safety of a food product;

Veterinary-sanitary status – confirmation by the veterinary inspector of the adherence to veterinary-sanitary requirements at facilities (objects), under Veterinary Service control;

Veterinary-sanitary requirements – any measures, aimed to protect animal life and health, and also to protect human health from diseases that are common for humans and animals (zoonosis) including all relevant laws, decrees, resolutions, rule books, requirements and procedures, in particular anti-epizootic measures, criteria of end product security, processing and production methods, testing, inspection, certification and approval procedures, quarantine measures, provisions on relevant statistical methods, sampling procedures and methods of risk assessment, related to production and circulation of food products under Veterinary Service control;

Producer – natural person or legal entity (its branches, departments, other separate sub-units, representative offices), that is engaged in the economic activity of producing food products, food additives, flavourings, dietary supplements, processing aids, and production aids and materials with the intent to place them into circulation, as well as circulating the above;

Production – economic activity connected with the output of objects subject to sanitary measures, including all stages of the technological process as well as making, preparing, mixing and related procedures, treating, filling, packing, processing, restoring, and reconditioning of the object;

Conclusion of state sanitary-epidemiological expertise with regard to food product safety – a document of an established form, which, on the grounds of the results of risk analysis and verification (extended control) of the presented by a producer or supplier sample of the food product, food products' production and circulation aids and materials, production technologies and technological equipment, used in its production, specifies a list of sanitary measures and

technical regulations, which the producer and supplier must fulfill to ensure safety of the food product;

Expert Conclusion (veterinary) – a document, issued by the state laboratory of veterinary medicine, attesting to suitability or unsuitability for human consumption of food products under Veterinary Service control or their further processing or other use, and also pertaining to the analysis of production technology, which the producer and supplier must fulfill to ensure food product safety;

***Relevant international organizations*** – World Health Organization (WHO), the Codex Alimentarius Commission, the World Animal Health Organization (OIE), and other international organizations where recommendations, guidelines and standards associated with protection of human health and life from food-borne hazards are developed;

“Use-by-date” (final date of consumption) – the date on expiration of which under any stated storage conditions, the food product probably will not have the quality attributes normally expected by the consumers and therefore after this date, the food product should not be regarded as suitable for sale;

State sanitary-epidemiological expertise (for the safety of food products) – professional activity performed by the bodies, institutions and establishments of the State Sanitary-Epidemiological Service with the aim of prevention, decrease or elimination of possible harmful effect of the food product on human health that involves risk assessment, determination of appropriate sanitary measures and/or technical regulations for production and/or circulation of the food products, and verification (extended control) of correspondence to such measures and regulations of a sample of the food product, production and circulation aids and materials, presented by the producer or supplier; as well as new technologies and technological equipment;

State control – activity of state bodies of executive power conducted throughout the entire process of production and/or circulation of objects subject to sanitary measures aimed at ensuring compliance of persons engaged in production and/or circulation of such objects with relevant sanitary measures and technical regulations;

State monitoring of residues of veterinary preparations and contaminants in non-processed food products of animal origin and feed – carrying out programs, envisaged by the Sanitary Code of Terrestrial Animals of the OIE; “

State supervision – activity of state bodies of executive power conducted periodically with the aim to ensure compliance of persons engaged in production

and/or circulation of objects subject to sanitary measures and technical regulations with relevant sanitary measures and technical regulations;

Dietary supplement – vitamin, vitamin and mineral, or herbal supplements, separately and/or in combination, in the form of pills, tablets, or powders taken orally with food or to be added to food, within the limits of physiological norms, to supplement the intake (compared to normal food intake) of these substances; dietary supplements also contain or include various substances or mixtures of substances including protein, carbohydrate, amino acids, edible oils and extracts of plants and animal materials considered as necessary or beneficial to human nutrition and overall health;

Processing aid – any material, with the exception of the material of food equipment and utensils, not consumed as a food product by itself but used in the course of the production or processing of a food product, or the components thereof, to attain a particular technological objective, resulting in the presence of residues or in the formation of derivatives in the finished product;

Production and circulation aids and materials – materials or substances, including equipment and utensils, and packaging units (containers), that come into contact with food products and therefore may affect their safety;

Operating permit – a permit issued by the relevant chief state sanitary doctor and/or the relevant chief state veterinary inspector to the operator of a facility (object) on the grounds of verification of compliance of facilities (objects) with sanitary measures and technical regulations and allows the operator of the facility (object) to engage in economic activities as specified in this Law;

Label - any tag, notation, tally that contains pictorial or descriptive matter, written, printed, stenciled, embossed, or impressed on, and attached to a packaging unit (container) of a food product;

Unsuitable (“adulterated”) food product – a food product is deemed to be unsuitable for consumption (hereinafter: adulterated) if:

- It contains a poisonous or harmful substance which renders it unsafe for human health (except for substances which are not added substances, if such substances are present at levels not considered to be harmful to human health);

- It contains added poisonous or harmful substances (except for pesticides in agricultural raw materials, and also except for food additives, coloring agents or medicinal preparations for animals that are permitted and do not exceed established maximum residue limits or inclusion levels);

- It does not comply with mandatory minimum quality specifications;

- It is prepared, packed or otherwise produced or circulated in such manner and under such conditions which may cause its contamination and render it unsafe for human health;

- It is in whole or in part derived from a diseased animal or an animal that was slaughtered in a manner, other than in a supervised slaughterhouse;

- It is in a container or packaging unit which is composed in whole or in part of poisonous or harmful substance(s) that may render the food product unsafe for human health;

- It is intentionally exposed to irradiation, except for the use of irradiation technology for acceptable technical purposes and in conformance with established international requirements for the safe use and application of ionizing radiation technology;

- It contains a food additive that is not approved for use in Ukraine or a food additive that is not permitted for use in the specific food product or a food additive that is approved for use in the specific food product but has been added in amounts that exceed the inclusion level established by sanitary measures or technical regulations, or, if the latter do not exist, then the inclusion level established by the relevant international organizations;

- It contains pesticides or veterinary preparations or residues thereof, which are not permitted in the food product, or the residue of pesticides or veterinary preparations in a food product exceed the maximum residue limits established in sanitary measures or, if the latter do not exist, exceed the maximum residue limits established by the relevant international organizations;

- Any valuable constituent has in whole or in part been omitted or removed from the food product, if any substance has been substituted wholly or in part therefore, if damage or inferiority of the food product has been concealed in any manner, or to add bulk or weight, or to reduce its quality or properties, or unreasonably make it appear better or of greater value than it is;

- It does not otherwise comply with relevant sanitary measures or technical regulations;

Contamination – the introduction or occurrence (ingress or contamination) of contaminants in food products or the objects, which the food product comes into contact with;

Contaminant — any biological substance, including organisms, microorganisms and parts thereof, or a chemical substance, foreign matter or other substance, which threatens safety and suitability of a food product;

Interested trading partners – states and other subjects of international law that are participants of multilateral and bilateral agreements, of which Ukraine is also a participant, which regulate the application of sanitary measures, as well as members of relevant international organizations of which Ukraine is also a member;

Rule book – a compilation of sub-legal acts in the field of safety and quality of food products;

Identification – a procedure for confirming whether organoleptic, biological, physical and chemical parameters and properties that are specific to a given type of food product comply with those parameters and properties indicated in labeling of the food product, as well as confirming the commonly used name of the given type of a product and/or trademark and/or commercial (company) brand;

Smoke flavouring – smoke extract used in traditional food products smoking processes;

Meat – all edible parts of the animal;

Maximum residue limit (maximum permitted residue level) – maximum permitted content in food products or animal feed of a specific substance, including pesticides, veterinary preparations, feed additives, residues of processing aids, and other chemical or biological substances, intentionally used and/or required for the technology of growing, storing, transporting, or producing food products and the residues of which, including any derivatives of such substance, such as conversion products, metabolites, and reaction products of toxicological significance are unsafe for humans when their maximum permitted content in food products consumed by humans is exceeded;

Maximum level – maximum content (concentration) of a contaminant in a food product or animal feed that is permitted for such product;

International veterinary (sanitary) certificate – a certificate, the form and the content of which complies with the recommendations of the relevant international organizations, and which is issued by the state doctor of veterinary medicine in the exporting country according to the guidelines of the relevant international organizations, and which attests to the animal health status and/or requirements of human health protection that the exported food product must fulfill;

International standards, guidelines and recommendations – standards, guidelines, and recommendations that are developed and adopted by the Codex Alimentarius Commission, WHO, OIE and other international organizations involved in developing of recommendations, guidelines and standards related to protection of human life and health from food-borne hazards;

Minimum quality specifications – quality characteristics, prescribed in terms of organoleptic, chemical, biological and physical characteristics of a food product, that must be met by the relevant food product in order for it to be deemed suitable for human consumption during the shelf life of the food product;

Good Manufacturing Practices (GMP) – practices of production of the food products and food products' production and circulation aids and materials, which

are necessary to produce safe and quality products that comply with technical regulations, sanitary measures and other requirements prescribed by this Law;

Appropriate level of human health protection – level of protection deemed sufficient when developing sanitary measures to protect human health and life from an adverse effect which these sanitary measures are designed to address, i.e., the acceptable level of risk of an adverse effect occurring;

Harmful factor (in food products) – any chemical, physical or biological agent, substance, material or product, which affects, or under certain conditions or concentration levels, may negatively affect human health through its ingestion;

Unsafe food product – a food product that does not meet the requirements set forth by this Law;

Invalid international veterinary (sanitary) certificate – a certificate that is illegible, contains incomplete or fraudulent data, has an expired period of validity, has unauthorized alterations or erasures, has contradicting or incompatible information, has language that is incompatible with official certificate samples, is issued for food products that are prohibited from import, or otherwise does not comply with the requirements of the country of destination of the food product;

Non-processed food products of animal origin – meat, fish, mollusks, and crustaceans, including those that are fresh, chilled, or frozen, and also eggs, milk, honey and their products, that have been produced by changing the original state of such without adding food additives, flavourings, or any other food products;

Misbranded food product – a food product is deemed to be misbranded if:

- The label is false or misleading;
- The food product is offered for sale under the name of another food product;
- Information in the label is not presented in the state language;
- The food product is packaged, filled into its tare or prepared in a misleading manner;
- The label does not comply with mandatory labeling requirements of this Law;
- The label includes words, expressions or data that are difficult for reading and understanding by the ordinary consumer under normal conditions of using, displaying or selling of commodities;
- The food product has been subjected to any form of permitted radiation treatment for food safety and preservation purposes, and the name and the address of the producer which conducted radiation treatment is not included on the label, as prescribed by labeling requirements of this Law, except in the case of unpacked (bulk) commodities, which do not have immediate labeling, and information on

which must be accompanying circulation, specified in the accompanying documents, attesting to the fact that unpacked (bulk) food product has been subjected to radiation treatment;

Novel food – a food product, including ingredients of such food product, that has not yet entered consumer market of Ukraine, because the food product:

- Has a new or intentionally modified primary molecular structure;
- Contains or consists of genetically modified organisms;
- Is produced from, but not contains genetically modified organisms;
- Consists of or is isolated from micro-organisms, fungi or algae;
- Contains or is isolated from plants and ingredients of food products isolated from animals, except for food products, including ingredients of such food products, obtained by traditional breeding practices and having a history of safe food consumption;
- Is produced using a production process not used previously, where that process may give rise to significant changes in the composition or structure of the food products or ingredients of such food products, and may affect their nutritional value, metabolism, or level of harmful factors;

Objects subject to sanitary measures – food products, including food for special dietary uses, functional food, as well as food additives, flavourings, dietary supplements, processing aids, and production and circulation aids and materials;

Circulation – moving (transporting) or storing, and any actions related to the transfer of proprietary or possession right, including, selling, exchanging or granting;

Equipment and utensils – equipment, machines, kitchen appliances, kitchen devices, cutlery and tools, instruments and other means, the surfaces of which have direct contact with a food product during its production and circulation;

Mandatory safety parameters – parameters that are scientifically justified, and adopted through a procedure established by legislation (sanitary normatives), including maximum residue limits (hereinafter - MRL), maximum levels (hereinafter - ML), acceptable daily intake (hereinafter - ADI), and inclusion levels, which when violated in food products may cause a harmful effect on human health;

Packaging unit (container) – any packaging, including wrappers, regardless of material and form, which encloses completely or partially a food product, enabling its delivery as a single item. (A container may enclose several units);

Operator of facilities – producer that performs the types of activities envisaged by this Law using the facilities (objects) which it owns or for which it has the right to use;

Risk assessment – scientifically based process consisting of the following: (i) hazard identification, (ii) hazard characterization, (iii) assessment of the impact, and (iv) risk characterization;

Lot – any definitive amount of a food product with the same name and properties that is prepared under the same conditions at the same facility (object);

Pesticide – toxic substances, their compounds or mixtures of chemical or biological origin intended to destroy, regulate, and terminate the development of rodents, weeds, trees, shrubs, polluting fish, and hazardous organisms, the activities of which are causing damage to plants, animals, and people, and (causing damage to) material value and causing harm to humans consuming food products when residue levels of pesticides found in such products exceed MRLs . In addition to pesticides, the following shall be included: substances intended for use as a plant growth regulator, defoliant, desiccant, fruit-thinning agent, or sprouting inhibitor and substances applied to crops either before or after harvest to protect the commodity from deterioration within the period of storage and transportation, except for fertilizers, nutritional substances for plants and animals, and veterinary preparations;

Risk communication – interactive exchange of information on risk among risk assessors, risk managers, interested trading partners, and other interested parties;

Nutritional value – the total of the natural basic components of a food product including carbohydrates, proteins, fats, vitamins, minerals and salts;

Mark of suitability – a mark that is used in accordance with the provisions of this Law for the purpose of confirming the suitability of non-processed food product of animal origin for human consumption.

Facilities (objects) – any territory, buildings or complex of buildings, premises, structures, equipment and other means, including transportation means, used in production or circulation of objects subject to sanitary measures;

Acceptable certificate – an international sanitary or veterinary certificate that is not invalid or falsified;

Suitability of a food product or suitable food product – state of a food product or a food product that is acceptable for human consumption, i.e. is safe and complies with minimum quality specifications, in accordance with its intended use;

Border state inspector of veterinary medicine (hereinafter: border veterinary inspector) – veterinary inspector of appropriate qualification, authorized by the Department to check import, transit, and export consignments of food products under Veterinary Service control and to permit their entry or exit depending on their suitability for human consumption, and to issue international veterinary certificates;

Border inspection posts – facilities (objects) located at the border points on the state border of Ukraine, including points on the roads, railway stations, airports, sea and river ports, where relevant state control (inspection) is carried out for imported and exported consignments of commodities that cross the state border of Ukraine;

Border sanitary inspector – an official of the State Sanitary-Epidemiological Service of appropriate qualification, authorized by the Chief State Sanitary Doctor of Ukraine to check import, export and transit consignments of the objects subject to sanitary measures, except for food products under Veterinary Service control, and permit their entry or exit depending on their suitability for human consumption;

Reference (arbitration) laboratory – laboratory, authorized by the Chief State Sanitary Doctor of Ukraine and/or Chief State Veterinary Inspector of Ukraine, respectively, that is involved as a "third party" to resolution of disputable issues following the results of laboratory analysis;

Risk – the likelihood of the occurrence and the likely magnitude of the consequences of an adverse impact of sanitary measures during a specified time period;

Inclusion level – the maximum permissible amount (content) of a substance that may be used in or be added to the food product;

Extraction solvent – any substance for dissolving a food product or any component thereof, including any contaminant present in or on that food product, which is used in an extraction procedure during the processing of food products or of components of food products and which must be removed because it may result in the unintentional, but technically unavoidable, presence of residues or derivatives of substances in the food products;

Extended control – the process of verifying the safety and minimum quality specifications of an object subject to sanitary measures on the basis of laboratory analysis of such, which is conducted by the Veterinary or Sanitary Service according to their competencies;

Plant products (food products of plant origin) – mushrooms, berries, vegetables, fruits, and other food products of plant origin that are intended for human consumption;

Sanitary measure for food safety (hereinafter: sanitary measure) – application of any laws, resolutions, other normative-legal acts, requirements procedures for protection of human life and health from risks arising from food additives, contaminants, toxins, or disease-causing organisms in food products under Sanitary Service control and food products under Veterinary Service control, for which compliance is mandatory. Sanitary measures include, in particular, mandatory safety parameters of the end product; processes and production methods; expertise, inspection, certification and approval procedures; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; packaging and labeling requirements directly related to the safety of food products;

Sanitary inspector – official of the State Sanitary-Epidemiological Service, who has special medical education, and is authorized to perform state sanitary-epidemiological supervision;

Certificate of suitability for human consumption – a document of strict accountability, that is issued for a single occasion by the relevant chief state sanitary doctor or chief state veterinary inspector, according to their competence, based on the results of state control or extended control, and attests to suitability for human consumption of the food product, according to its intended use;

Agricultural products – agricultural food products of animal and plant origin, that are intended for human consumption either in their raw or processed state as food ingredients;

Standard – a document approved by the central body of executive power on technical regulation and consumer policy issues, that establishes, for common and systematic use, the rules, guidelines, or characteristics for products, related processes or services, with which compliance is mandatory. It shall not include requirements for food safety, prescribed by sanitary measures, and may include or deal exclusively with symbols, packaging, marking, or labeling requirements as they apply to a product or process, or with terminology requirements as applied to a process, product or service;

Shelf life – a period of time determined by the producer of a food product, within which the food product, if the relevant storage and transportation requirements are fulfilled, shall preserve its compliance with mandatory safety parameters and minimum quality specifications;

Technical regulation – normative-legal act, adopted by the central body of executive power on technical regulation and consumer policy issues, which lays down product characteristics or their related processes and methods of production, including the applicable administrative provisions, with which compliance is mandatory. It shall not include the requirements on food safety, prescribed by sanitary measures, and may include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or method of production;

Process flavouring – a product which is obtained according to Good Manufacturing Practices by heating (to a temperature not exceeding 180 °C for a period not exceeding 15 minutes) a mixture of ingredients, not necessarily themselves having flavouring properties, of which at least one contains nitrogen (amino) and another is a reducing sugar;

Authorized laboratory – an accredited laboratory that is granted the right by the relevant state body to test (measure parameters, analyze) according to specific methods and procedures, food products, food additives, dietary supplements, processing aids, and production and circulation aids and materials for the purpose of implementing extended control (verification);

Risk management – the process of weighing policy alternatives based on the results of a risk assessment and, if required, selecting and implementing appropriate management (control) options, including regulatory measures;

Falsified (international sanitary or veterinary certificate) – a certificate that is not approved for use, or is issued with violation of the form, established by an official certification body of the exporting country, or is issued by unauthorized persons, organizations, or other entities, or contains misleading or unreliable information;

Functional food – a food product that contains medicinal means (product) as components and/or is proposed for prevention or mitigation of human disease conditions;

Food additive – any substance which, although usually not considered to be a food product or any part of it, are nevertheless, added to a food product for technological purposes during production process and which, as a result, becomes an integral part of a food product (the term does not include contaminants,

pesticides or substances added to food products to improve their nutritional properties);

Food product (food) – any substance or product (raw one, including agricultural product, non-processed, semi-processed or processed one), intended for human consumption. Food product shall include drink, chewing gum and any other substance, including water, intentionally incorporated into the food product during its manufacture, preparation or treatment;

Food for special dietary uses (consumption) – those food products which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition of a human and/or specific disease or disorder and which are sold as such, including food products for infants, sportsmen, and elderly people. The composition of these food products must be significantly different from the composition of ordinary food products of comparable nature, if such ordinary food products exist, but they may not be substitutes for medicinal means (products);

HACCP (Hazard Analysis and Critical Control (regulation) Points) – a system for identification, evaluation, analysis and control of hazards, which are significant for food safety;

Quality of food products – the degree of excellence of properties and distinctive characteristics of a food product that is capable of fulfilling the needs (requirements) and desires of those consuming or using such food products;

international sanitary certificate — certificate, the form and the content of which complies with the recommendations of relevant international organizations and is issued by the authorized body of the country of origin, and attests to the suitability for human consumption of the food products, except for products under Veterinary Service control

Meat processing, fishing, fish processing, milk processing enterprises – facilities of any type of ownership, engaged in processing meat, raw milk of commodity type, live, chilled or frozen fish, other seafood, aimed at obtaining finished food products

Enterprises of wholesale storage of non-processed food products of animal origin (refrigerator complexes, refrigerators, specialized wholesales) – facilities of any type of ownership, engaged in storing raw materials and finished food products under prescribed conditions, aimed at their further wholesale;

Official (authorized) doctor of veterinary medicine – specialist of veterinary medicine, authorized by the Department and/or its territorial bodies to execute his/her official powers, related to protection of animal health and life, and

protection of human health from diseases that are common for humans and animals (zoonosis), inspection of consignments (goods) under his/her control, and issuance of necessary accompanying veterinary documents.

## Article 2. Legislation on Safety and Quality of Food Products

Legislation of Ukraine on the safety and quality of food products shall consist of the present Law and other acts of legislation issued pursuant to this Law

The special legislation of Ukraine regarding separate categories of food products shall comply with the provisions of this Law

This law shall not apply to tobacco and tobacco products and to special requirements for food products related to the fact of presence in the latter of genetically modified organisms or their components, regulated by special legislation, as well as to food products produced for personal consumption.

## SECTION II. PARTICIPATION OF THE STATE IN ENSURING THE SAFETY AND QUALITY OF FOOD PRODUCTS

### Article 3. State Provision for the Safety and Quality of Food Products

The State shall ensure the safety and quality of food products to fulfill the objective of protecting the life and health of population from harmful factors that may be present in food products, by means of:

Establishing mandatory safety parameters for food products;

Establishing minimum quality specifications for food products through technical regulations;

Establishing sanitary measures and veterinary-sanitary requirements for facilities (objects) and persons, engaged in the process of production, sale (supply), storage (displaying) of food products;

Ensuring that novel foods are safe for human consumption prior to their circulation in Ukraine;

Establishing standards for food products with the aim of their identification;

Ensuring that that food for special dietary uses, functional foods, and dietary supplements fulfill claimed special characteristics and are safe for human consumption and especially for those with special dietary needs;

Informing and increasing awareness of producers, sellers (suppliers), and consumers about food safety and good manufacturing practices;

Establishing requirements for knowledge and skills of responsible personnel of producers, sellers (suppliers);

Establishing requirements for the health status of responsible personnel of producers and sellers (suppliers);

Participating in the work of the relevant international organizations that establish sanitary measures and food product standards at the regional and global level;

Conducting state control in facilities (objects) where food products, that present a significant risk to human health and life, are produced and processed;

Conducting state supervision to verify fulfillment by producers and sellers (suppliers) of objects subject to sanitary measures of the requirements of this Law;

Identifying violations of this Law and taking necessary actions to bring to account those who do not comply with the provisions of this Law.

#### Article 4. State Bodies Ensuring Elaboration, Adoption and Implementation of Sanitary Measures with Regard to Safety and Quality of Food Products

1. The system of state bodies which, within their competence, provide for elaboration, adoption and implementation of sanitary measures, as well as state control and supervision over their observance shall include:

The Cabinet of Ministers of Ukraine;

The central body of executive power on health protection issues;

The State Sanitary-Epidemiological Service of Ukraine (hereinafter: Sanitary Service);

The State Service of Veterinary Medicine of Ukraine (hereinafter: Veterinary Service);

The central body of executive power on agrarian policy issues;

The central body of executive power on technical regulation and consumer policy issues;

2. The central body of executive power in the sphere of health protection shall be a body that adopts appropriate level of protection of human health, mandatory safety parameters and minimum quality specifications for food products, rule book and good manufacturing practices for food products, and coordinates the activities of the bodies of executive power on issues of safety and quality of food products.

#### Article 5. Food Products and Facilities (Objects), at which the Food Products are Under Sanitary Service and Veterinary Service Control

1. The Sanitary Service shall implement state supervision (state sanitary-epidemiological supervision) for all the objects subject to sanitary measures. Sanitary Service shall implement state control in cases, prescribed by sanitary legislation, for the following food products at the facilities (objects) engaged in their production and/or circulation (hereinafter: food products under Sanitary Service control):

1) All food products for special dietary uses;

2) All functional foods;

3) All food products other than those identified in paragraph 2 of this Article.

2. The Veterinary Service shall implement state control and state supervision for the following food products (hereinafter: food products under Veterinary Service control):

- 1) Non-processed food products of animal origin at the facilities (objects) engaged in their production;
- 2) All plant products, agricultural products and non-processed food products of animal origin sold at agri-food markets.

3. Veterinary Service shall implement state control over production and finished products at meat processing, fishing, fish processing, milk processing enterprises, which use non-processed food products of animal origin as raw materials, and at the enterprises of wholesale storage of non-processed food products of animal origin.

#### Article 6. Authorities of the Sanitary Service

The Sanitary Service shall:

1) Participate in the National Codex Alimentarius Commission of Ukraine on issues within its competence, including developing and reviewing sanitary measures;

2) Establish sanitary (hygiene) requirements for facilities (objects) engaged in production and circulation of food products, food additives, flavourings, dietary supplements, production and circulation aids and materials, and processing aids;

3) Adopt mandatory safety parameters for food products and other objects subject to sanitary measures;

4) Enforce and conduct state supervision of the implementation of sanitary measures in part of compliance with the requirements of sanitary legislation for objects subject to sanitary measures, which regulate protection of human life and health, and conduct state monitoring of its results;

5) Consult and educate producers and sellers (suppliers) about HACCP or similar systems of assuring safety of production of the food products under Sanitary Service control;

6) Implement state supervision over the implementation of HACCP and similar systems of assuring quality and safety, used by producers of food products under Sanitary Service control, food additives, flavourings, dietary supplements, and processing aids, and by sellers (suppliers) of food products, food additives, flavourings, dietary supplements, and processing aids;

7) Conduct state control and/or state supervision at facilities (objects) engaged in production of food products under Sanitary Service control, food additives, flavourings, dietary supplements, and processing aids;

8) Conduct state control and/or state supervision at all facilities (objects) engaged in circulation of food products, food additives, flavourings, dietary supplements, and processing aids;

- 9) Issue certificates of suitability for human consumption upon request of interested parties on the basis of the results of extended control of food products;
- 10) Implement programs for random control and standard control of food products during their circulation;
- 11) Carry out extended control based on the professional judgment of the sanitary inspector or within the framework of random control program for food products, that is implemented in course of state supervision, to verify:
  - a) The nutritional value of the food product as declared by the producer;
  - b) Compliance with mandatory safety parameters and minimum quality specifications for the food product;
  - c) Safety of objects subject to sanitary measures;
  - d) Validity of conditions for use of food products, including compliance with the producer stated instructions on storage, transportation, displaying for sale, and preparing food products, observance of which shall guarantee safety of food products;
- 12) In conjunction with other relevant state bodies, participate in the development of standards for food products and production and circulation aids and materials;
- 13) In conjunction with other relevant state bodies, participate in the development of technical regulations establishing minimum quality specifications for food products;
- 14) In conjunction with other relevant state bodies, participate in the development of technical regulations, for food additives, flavourings, processing aids, production and circulation aids and materials, and for facilities (objects);
- 15) Order and perform laboratory analysis to assess the safety and quality of food products under Sanitary Service control;
- 16) Organize and perform state sanitary-epidemiological expertise;
- 17) Establish the frequency, on the basis of risk analysis, of state supervision of facilities (objects) engaged in production and circulation of food products under Sanitary Service control;
- 18) Conduct standard and extended sanitary border control for consignments of food products under Sanitary Service control that are imported or exported;
- 19) Identify and approve the list of food products that inherently present a high and low risk to human health;
- 20) In conjunction with other relevant state bodies authorize accredited laboratories to conduct analysis (tests) for verifying parameters of safety and quality of food products under Sanitary Service control;
- 21) Provide consent to:
  - a) Technical conditions of food product production;
  - b) Technical regulations and standards applicable to objects subject to sanitary measures;

c) Designs of facilities (objects) engaged in production and circulation of food products;

d) Measurement techniques and methods for testing food products under Sanitary Service control for compliance with relevant sanitary measures;

23) Adopt the lists of:

a) Measurement techniques and methods for testing food products under Sanitary Service control for compliance with relevant sanitary measures

b) Laboratories designated for identifying, testing, and assessing the efficacy of food for special dietary uses, functional food, and dietary supplements;

24) Issue operating permits to operators of facilities (objects) engaged in production of food products under Sanitary Service control, and maintain registers of such operating permits;

25) Issue operating permits to operators of facilities (objects) engaged in circulation of food products, and maintain registers of such operating permits;

26) Specify the form and content of information on the acquisition and use of food products, food additives, flavourings, and processing aids that must be maintained by persons engaged in their production to enable traceability of such products;

27) Register and keep the State Register of Food for Special Dietary Uses and Functional Foods; Dietary Supplements; the Register of Food Additives, Flavourings, and Processing Aids; the Register of Conclusions of Sanitary-Epidemiological Expertise;

28) Undertake sanitary-epidemiological investigation aimed at revealing the causes and conditions that result in the circulation of food products that are unsafe or unsuitable for consumption, the occurrence and spread of infectious diseases through food products, and food poisoning of groups of people or individuals and takes measures for termination of their further spread;

29) Undertake measures, within its competence, to eliminate violations of this Law and bring to account persons guilty of such violations in accordance with legally established procedures.

## Article 7. Authorities of the Veterinary Service

The Veterinary Service shall:

1) Participate in the work of the National Codex Alimentarius Commission of Ukraine for issues within its competence, including developing and reviewing sanitary measures;

2) Conduct state veterinary-sanitary control and supervision at facilities (objects) engaged in growing (producing) animals, non-processed food products of animal origin and circulation of agricultural products, and

- issue relevant veterinary documents attesting to the veterinary-sanitary status thereof;
- 3) Conduct ante-mortem inspection of animals and post-mortem inspection of their products at slaughterhouses, and also conduct post-mortem inspection of game animals, at facilities (objects) intended for such purpose;
  - 4) Enforce and conduct supervision of the implementation of sanitary measures in part of compliance with the requirements of the Law of Ukraine “On Veterinary Medicine” (2498-12) and other normative-legal acts, which regulate protection of animal life and health, and also protection of people from diseases that are common for people and animals (zoonosis) applicable to objects subject to sanitary measures that under Veterinary Service control;
  - 5) Advise and educate producers of food products under Veterinary Service control about HACCP or similar systems of assuring safety and quality;
  - 6) Implement state supervision over the implementation of HACCP and similar systems of assuring safety and quality, used by producers of food products under Veterinary Service control;
  - 7) Conduct state control and/or state supervision at facilities (objects) engaged in production and circulation of food products under Veterinary Service control;
  - 8) Issue certificates of suitability for human consumption upon request of interested parties on the basis of state control or the results of extended control for food products under Veterinary Service control;
  - 9) Carry out extended control based on the professional judgment of the veterinary inspector or within the framework of random control program for food products under Veterinary Service control in order to verify:
    - a) Nutritional value of the food product declared by the producer;
    - b) Compliance with minimum quality specifications of the food product;
    - c) Compliance with mandatory safety parameters of the food products under Veterinary Service control;
    - d) Validity of conditions for use of food products, including producer stated instructions with regard to impact of storage, transportation, displaying for sale, and preparing food products on the safety of food products under Veterinary Service control;
  - 10) Conduct standard and extended sanitary border control of import, transit, and export consignments of food products under Veterinary Service control;
  - 11) Issue operating permits to the operators of facilities (objects) engaged in production of food products under Veterinary Service control, and agri-food markets, and maintain registers of such;

- 12) Issue international veterinary certificates for food products under Veterinary Service control;
- 13) Authorize accredited laboratories to conduct analysis (tests) for verifying parameters of safety and quality of food products under Veterinary Service control;
- 14) Approve measurement techniques and methods for testing food products under Veterinary Service and the lists of such;
- 15) Approve the list of reference laboratories for conducting arbitration analysis of food products under Veterinary Service control;
- 16) Implement random control programs and standard control programs for food products under Veterinary Service control during their circulation and in course of implementation of national programs of state monitoring of maximum residue limits of veterinary preparations and other contaminants in food products under Veterinary Service control;
- 17) Establish the frequency, on the basis of risk analysis, of state supervision of facilities (objects) engaged in production of food products under Veterinary Service control;
- 18) Order and perform laboratory analysis to assess the safety and quality of food products under Veterinary Service control;
- 19) In conjunction with other relevant state bodies, develop standards for food products under Veterinary Service control;
- 20) Participate in the development of technical regulations establishing minimum quality specifications for food products under Veterinary Service control;
- 21) Conduct epizootic investigation or, if necessary, participate in sanitary-epidemiological investigations aimed at determining the reasons and conditions which lead to circulation of unsafe or unsuitable for consumption food products under Veterinary Service control;
- 22) Undertake measures, within its competence, to eliminate violations of this Law and bring to account persons guilty of such violations in accordance with the procedure established by law.
- 23) Establish and adopt veterinary-sanitary requirements for facilities (object) engaged in production and circulation of food products under Veterinary Service control;
- 24) Participate or adopt mandatory safety parameters for food products under Veterinary Service control;
- 25) Organize and perform state veterinary-sanitary expertise;
- 26) Provide consent to technical conditions for production, technical regulations, standards, designs of facilities (objects) of food products under Veterinary Service control.

## Article 8. National Codex Alimentarius Commission of Ukraine

1. National Codex Alimentarius Commission of Ukraine shall recommend and the Chief State Sanitary Doctor of Ukraine shall adopt the following:

- 1) Maximum residue limits of pesticides and veterinary preparations for food products;
- 2) Inclusion levels or maximum content levels of contaminants, food additives and processing aids in food products;
- 3) Methods and procedures for implementing state supervision, state control, extended control, and control of risks presented by food products under Sanitary Service control;
- 4) Recommended acceptable daily intake of dietary supplements;
- 5) Requirements for implementation of HACCP or similar systems of assuring safety and quality during production and circulation of food products under Sanitary Service control;
- 6) An annual program for random extended control for all food products under Sanitary Service control that are circulated in Ukraine.

2. The National Codex Alimentarius Commission of Ukraine shall recommend, and the Chief State Sanitary Doctor of Ukraine and Chief State Veterinary Inspector of Ukraine shall jointly adopt:

- 1) Requirements for implementation of HACCP or similar systems of assuring safety during production of food products under control.

3. The National Codex Alimentarius Commission of Ukraine shall recommend, and the Chief State Veterinary Inspector of Ukraine shall adopt:

- 1) Methods of controlling zoonosis; pathologoanatomic methods of the post-mortem stage;
- 2) Maximum residue limits of veterinary preparations for each component administered to animal feed and finished animal feed;
- 3) Inclusion levels for feed additives in or on animal feed;

4. The National Codex Alimentarius Commission of Ukraine shall:

- 1) Coordinate activities on harmonization of national legislation with international legislation in the sphere of safety and quality of food products;
- 2) Prepare drafts of new sanitary measures and amendments to existing sanitary measures;

- 3) Unify scientific-methodical approaches for development of sanitary measures and technical regulations, risk assessment and determination of mandatory safety parameters for food products, as well as development of methods and procedures for ensuring safety of food products during the process of their production and circulation;
  - 4) Facilitate introduction of new technologies for production of food products, international standards and national technical regulations regarding food production technology, international sanitary measures, and new methods of analysis of food products recommended by the relevant international organizations;
  - 5) Perform functions of information-enquiry service ensuring provision of information on issues of the activities of the Codex Alimentarius Commission and introduction of its recommendations and decisions in Ukraine;
  - 6) Take part in meetings of the Codex Alimentarius Commission and its committees;
  - 7) Organize scientific and expert research on issues within its competence.
5. The National Codex Alimentarius Commission of Ukraine shall act on the basis of the regulations, adopted by the Cabinet of Ministers of Ukraine.

#### Article 9. Laboratories Evaluating the Safety and Quality of Food Products

1. Laboratory measuring, testing and/or analysis of food products to assess their safety and quality may be conducted by the following accredited laboratories:
  - 1) Laboratories of the facilities (objects) producing and/or circulating food products;
  - 2) Laboratories of the Sanitary and Veterinary Services;
  - 3) Laboratories of the central body of executive power on technical regulation and consumer policy issues;
  - 4) Other laboratories.
2. The laboratories referred to in paragraph one of this Article shall be accredited for metering according to international requirements and shall be subject to accreditation for conducting laboratory analysis of food products according to international standards, guidelines and recommendations by the national accreditation body of Ukraine or by a comparable foreign accreditation body.
3. Laboratory measuring, testing and/or analysis of food products for the purposes of state control and state supervision, including when importing or exporting, shall be conducted by accredited laboratories authorized by the Chief State Sanitary Doctor of Ukraine for food products under Sanitary Service control,

and by the Chief State Veterinary Inspector of Ukraine for food products under the Veterinary Service control.

4. The procedure and criteria for authorizing laboratories, including arbitration laboratories, for conducting diagnostics analysis for the purposes of state control or state supervision shall be elaborated by the National Codex Alimentarius Commission of Ukraine and adopted by the Chief State Sanitary Doctor or Chief State Veterinary Inspector of Ukraine within their competence.
5. Measurement techniques and methodologies for analysis of food products for verifying mandatory safety parameters and minimum quality specifications thereof shall be in accordance with international standards, guidelines and recommendations and be adopted by the Chief State Sanitary Doctor of Ukraine for food products under the Sanitary Service control and the Chief State Veterinary Inspector of Ukraine for food products under Veterinary Service control.

#### Article 10. Powers of Sanitary Inspectors

1. When performing state control and/or state supervision, a sanitary inspector shall be empowered to:
  - 1) Have unhindered access without prior notice to facilities (objects) engaged in production or circulation of objects subject to sanitary measures at any time within normal working hours;
  - 2) Inspect, in compliance with the requirements of the legislation, any buildings, vehicles, interim and other facilities (objects), test laboratories located at a facility (object);
  - 3) Inspect the sanitary status of facilities (objects) engaged in production and/or circulation of objects subject to sanitary measures;
  - 4) Inspect the compliance with hygiene requirements and established timeframes for medical examination of the personnel, which comes in direct or indirect contact with food products, and in case of violation of the above requirements and timeframes, issue a directive suspending their work until the violation is eliminated;
  - 5) During state supervision assess the systems that are based on HACCP principles;
  - 6) Inspect and take samples of food products at any stage of production and their labeling, non-food substances and objects, production and circulation aids and materials, and materials and equipment used for testing, controlling technological processes, and for cleaning and technical maintenance of the premises;

- 7) Check and obtain copies of documents to verify compliance with the requirements of this Law, as well as materials on the systems of internal control of safety and quality, including HACCP systems;
  - 8) Evaluate the results of laboratory analysis of samples of the objects specified in item 6 of paragraph one of this Article;
  - 9) Issue a directive to temporarily prohibit circulation of food products that are suspected to be unsafe, unsuitable for consumption, or misbranded until the results from laboratory analysis of such food products are available;
  - 10) Issue a directive to eliminate violations of the conditions for maintaining an operating permit;
  - 11) Collect evidence that is necessary to justify a suspicion of violation of sanitary measures and conditions for maintaining an operating permit, which includes taking of samples of materials and substances that confirm the suspicion or record the violation in a documentary form;
  - 12) Conduct sanitary-epidemiological investigations of violations of this Law.
2. Chief state sanitary doctors or their deputies shall exercise the following powers:
- 1) Issue a resolution to correct the labeling or otherwise correct the misbranding of a food product or other object subject to sanitary measures;
  - 2) Issue a resolution to treat, process (recondition) or utilize (change the intended use) of a food product;
  - 3) Issue a resolution to destruct of an object subject to sanitary measures by its owner under supervision of the sanitary inspector;
  - 4) Apply to the court with an application to make a decision on confiscation and destruction of an object subject to sanitary measures in the cases envisaged by this Law;
  - 5) Issue a resolution regarding suspension of production;
  - 6) Issue, suspend and revoke operating permits for facilities (objects) engaged in production and/or circulation of food products under Sanitary Service control.

#### Article 11. Powers of Veterinary Inspectors

1. When performing state control and/or state supervision for food products under Veterinary Service control in facilities (objects) engaged in the production and circulation of such food products, a veterinary inspector shall have the rights specified in Items 2, 3, 5, 11 of paragraph 1 of Article 10, and chief state veterinary inspectors shall have the rights specified in paragraph 2 of Article 10 hereof.

2. Veterinary inspectors and chief state veterinary inspectors shall also be empowered to:

- 1) Have unhindered access without prior notice to facilities (objects) engaged in production and circulation of food products under Veterinary Service control at any time within normal working hours;
- 2) Apply the mark of suitability for human consumption to an animal carcass or part thereof, to a packaging unit or container of non-processed food products of animal origin.

#### Article 12. Principles and Procedures for conducting State Control and State Supervision

1. When implementing state control and state supervision of food products and other objects subject to sanitary measures, the methods used for such shall be commensurate with the goals sought. State control shall be conducted continuously and randomly (random control) and may be extended and standard.
2. State supervision of objects subject to sanitary measures shall be conducted without prior notice, regularly, according to prescribed programs for inspection, specifying the frequency of inspections and the procedure for state supervision over the compliance of the objects subject to sanitary measures with the requirements, established by this Law and other normative-legal acts.
3. The frequency of state supervision implemented for any particular facility (object) subject to the provisions of this Law or any object subject to sanitary measures, including that implemented within the framework of random control programs for food products , shall reflect:
  - 1) Identified risks associated with the object subject to sanitary measures or the facility (object) as well as with the technology of production and/or processing;
  - 2) The results of previous state supervision;
  - 3) The reliability of control procedures undertaken by the operator of the facilities (objects) to ensure compliance with relevant sanitary measures and technical regulations;
  - 4) Existing suspicion of non-compliance of the operator of the facility (object) with the requirements of this Law and other normative-legal acts.
4. If in the course of state supervision, based on the professional judgment of a sanitary inspector, there is a suspicion that a food product or other object subject to sanitary measures under Sanitary Service control, is unsafe, unsuitable for consumption or misbranded, or, based on the professional judgment of a veterinary inspector, there is a suspicion that a food product

under Veterinary Service control is unsafe or unsuitable for consumption, the sanitary inspector or veterinary inspector (hereinafter: relevant inspector) shall take samples of the object without compensation to the owner and issue a directive to temporarily prohibit circulation of such food product or other object subject to sanitary measures, and inform the relevant chief state sanitary doctor or relevant chief state veterinary inspector, or their deputies, on the latter.

5. Samples of objects subject to sanitary measures that are taken in response to a suspicion or established fact that that such objects are unsafe or unsuitable for consumption shall be promptly forwarded to an authorized laboratory for analysis. Authorized laboratory shall promptly report the results of its analysis to the relevant chief state sanitary doctor or relevant chief state veterinary inspector, or their deputies with the purposes to adopt a decision regarding further disposition of the above object subject to sanitary measures.
6. Upon receipt of the results of the laboratory analysis, relevant chief state sanitary doctor or chief state inspector of veterinary medicine or their deputies shall adopt a decision on actions to be taken pursuant to paragraphs 7 and 8 of this Article.
7. Should, based on laboratory analysis of the food product or other object subject to sanitary measures, a violation of the provisions of this Law be revealed, the relevant chief state sanitary doctor or relevant chief state inspector of veterinary medicine, or their deputies, shall take the following actions:
  - 1) In the case of misbranding - issue a resolution to correct the labeling or otherwise correct the misbranding;
  - 2) In the case of unsuitability for consumption:
    - a) If the food product remains safe for human consumption, or other object subject to sanitary measures can be made suitable for use in the production of food products or other uses – issue a resolution to treat, process or utilize (change its intended use) the latter;
    - b) If the food product is unsafe for human consumption, but safe for other uses – issue a resolution to withdraw it from circulation and prohibit its intended use.
8. If laboratory analysis confirms that an object subject to sanitary measures is not safe for human consumption or other uses, the relevant chief state sanitary doctor, relevant chief state inspector of veterinary medicine, or their deputies shall issue a resolution to withdraw such object from use or circulation and obligate the owner of this object to destroy the object under the supervision of a relevant inspector.
9. A decision to further dispose of the object subject to sanitary measures, samples of which were taken due to a suspicion or established fact of being unsafe or unsuitable for consumption, must be informed to the producer and/or seller

(supplier) within one working day upon receipt of the laboratory report specified in paragraph 5 of this Article.

10. Decisions of the relevant chief state sanitary doctor or relevant chief state veterinary inspector on disposing of food products or other objects subject to sanitary measures may be appealed to the higher level official or in court.
11. Damages caused to the operator of the facility (object) due to unlawful prohibition on circulation of an object subject to sanitary measures, suspension or stoppage of the production process, or application to such person of other administrative-economic sanctions, provided for in this Article, shall be reimbursed according to the procedure, stated by the Economic Code (436-15) and other laws of Ukraine.

### Article 13. Obligations of Sanitary and Veterinary Inspectors

1. When performing state control and/or state supervision, a sanitary inspector or a veterinary inspector shall be obliged to:
  - 1) Comply with the requirements of this Law and other normative-legal acts issued pursuant to this Law;
  - 2) Ensure confidentiality of any information which contains commercial secrets, except for cases stipulated by Ukrainian legislation;
  - 3) Present documents that prove identity as a sanitary or veterinary inspector;
  - 4) Verify implementation of relevant sanitary measures established for facilities (objects) which are inspected;
  - 5) Issue and provide documents with regard to carrying out inspections and taking of samples, prescribed by relevant normative-legal acts, issued pursuant to this Law.
2. The relevant inspector who violates the requirements of this Law or other normative-legal acts, issued pursuant to this Law, shall be held liable as prescribed by the legislation.

### Article 14. Developing, Reviewing, Revising, Adopting and Applying Sanitary measures

1. Sanitary measures shall be developed, reviewed, and revised by the National Codex Alimentarius Commission of Ukraine, relevant bodies of state power, according to this Law, and adopted by the Chief State Sanitary Doctor of Ukraine, central body of executive power in the sphere of health protection and/or the Chief State Veterinary Inspector of Ukraine, within their competence, and in compliance with the following requirements:

- 1) All sanitary measures shall be based on scientific principles and available scientific justifications, except for cases specified in item 4 of paragraph 1 of this Article;
  - 2) If international standards, guidelines and recommendations exist, they shall be used as the basis for the development of sanitary measures, except for cases when such international standards, guidelines, and recommendations are insufficient for ensuring appropriate level of human health protection;
  - 3) In case international standards, guidelines and recommendations do not exist or are insufficient for ensuring appropriate level of human health protection, sanitary measures shall be drafted based on a risk assessment, taking into account the risk assessment methods according to the norms established by the relevant international organizations;
  - 4) When scientific justifications needed for risk assessment are insufficient or in urgent circumstances that may cause or threaten to cause human health problems, sanitary measures shall be developed on the basis of available relevant information, obtained from the relevant international organizations, or sanitary measures employed by interested trading partners.
2. All sanitary measures, including measures adopted in urgent circumstances, shall be reviewed and updated in order to ensure conditions, under which such measures would apply only within the limits of what is necessary to protect human health:
    - 1) As new scientific information becomes available;
    - 2) When substantive comments from interested trading partners are received.
  3. Sanitary measures shall not be more trade-restrictive than necessary to achieve appropriate level of human health protection taking into consideration technical and economic feasibility.
  4. An overview of proposed sanitary measures and procedure for obtaining the information about such measures, as well as comments about their application shall be published in mass media.
  5. All proposed sanitary measures, that do not conform to international standards or for which no international standards exist, and it is expected that they may have a significant effect on export opportunities of interested trading partners, shall be notified through the centre for processing enquiries and providing notifications (hereinafter: enquiry and notification centre) no less than 60 days before preparing a final draft sanitary measure in accordance with the provisions of relevant international agreements.
  6. Comments received as a result of the notification and publication of proposed new or changed sanitary measures shall be taken into consideration in a non-discriminatory manner before such measures are adopted. When requested in writing by a person or interested trading partner, the enquiry and notification

centre shall provide the text of the proposed sanitary measure, and, whenever possible, identify the provisions, which in substance deviate from international standards, guidelines and recommendations.

7. In urgent circumstances however, sanitary measures may be adopted before notification, provided that such notification is done promptly and without delay.
8. All new and revised sanitary measures after their adoption shall be published promptly in the relevant official gazette and shall come into force no earlier than 6 months from the date of relevant publication.
9. In the case of urgent circumstances, and also in case of application of measures that reduce import restrictions, a sanitary measure may come into force as of the date of adoption, provided it is subsequently published in the relevant official publication.
10. When preparing, reviewing, revising, adopting and applying sanitary measures, relevant measures that are applied in another country shall be considered equivalent to those applied and adopted in Ukraine, if the other country shows in an objective manner that its measures achieve such level or higher level of human health protection as is required by Ukraine.
11. All sanitary measures shall be applied only to the extent necessary to protect human health and without unjustified discrimination between food products produced domestically and imported food products, or between different suppliers of imported food products.
12. The Cabinet of Ministers of Ukraine, based on the recommendations of the National Codex Alimentarius Commission of Ukraine, shall ensure adoption of normative-legal acts to implement the provisions of this Article.

#### Article 15. Appropriate level of Human Health Protection

1. The Chief State Sanitary Doctor, upon the recommendation of the National Codex Alimentarius Commission of Ukraine, shall determine the appropriate level of human health protection from food borne hazards.
2. The appropriate level of human health protection shall be determined based on the following:
  - 1) The general health status of the population and risks inherent for the sphere of human vital activities;
  - 2) Standards, guidelines and recommendations of the relevant international organizations;
  - 3) Minimizing negative impact on international and domestic trade when applying sanitary measures.

## Article 16. Provision of Information on Relevant Sanitary Measures and Technical Regulations

1. Upon the request of any person of Ukraine or any person of other country, the enquiry and notification centre shall provide the latter with any information concerning sanitary measures and relevant technical regulations for objects subject to sanitary measures.

Such information includes the following:

- 1) Scientific justification for sanitary measures that are applied on both imported and domestic food products;
- 2) Procedures and means of risk assessment of food-borne hazards for human health, as well as the data of the reports related to such risk assessment;
- 3) Procedures and means of controlling food products in Ukraine;
- 4) Current instructions, requirements, and procedures of food product inspection and control;
- 5) Information about membership and participation of Ukraine in the relevant international organizations or international agreements regarding sanitary measures and the texts of such agreements;
- 6) Any other relevant information.

2. The Cabinet of Ministers shall prescribe the regulations on the enquiry and notification centre, procedure for providing information and payment of costs for carrying out the above work and rendering of services.

## Article 17. Control, Inspection and Approval Procedures

- “1. The Sanitary Service and the Veterinary Service shall envisage, with respect to all procedures of state control and state supervision (hereinafter: procedures) the following requirements:
- 1) Such procedures conform to international standards, guidelines and recommendations of the relevant international organizations;
  - 2) Such procedures are executed expeditiously and without unjustifiable delay;
  - 3) Taking of samples is limited to what is necessary and justified;
  - 4) The applicant requesting procedures of control, inspection and approval must be immediately informed of any deficiencies in the application;
  - 5) The results of the procedure shall be promptly transmitted to the applicant in written form and complete manner;
  - 6) The expected time for completing such procedures shall be communicated to the applicants upon their request;

- 7) Such procedures shall be applied equally to objects subject to sanitary measures of foreign as well as domestic origin;
  - 8) All adopted procedures, including procedures to ensure that a food product that has been changed (treated, processed or otherwise changed) continues to meet requirements of sanitary measures, as well as the information required to conduct procedures must be limited to what is necessary for the fulfillment of sanitary measures;
  - 9) Aimed at protecting commercial interests of an applicant, the rules for preserving confidentiality of information, provided by the applicant, shall be observed;
  - 10) The fees charged for control, inspection and approval procedures shall be equal for objects subject to sanitary measures of domestic origin and of foreign origin;
  - 11) The taking of samples and carrying out procedures associated with use of facilities (objects) shall minimize inconvenience and be equitable for imported, exported, and domestic objects subject to sanitary measures;
  - 12) Consideration of complaints regarding control procedures, if the complaint is justified;
- 1.
  2. Sanitary Service and Veterinary Service shall conduct control, inspection and approval procedures to ensure fulfillment of the requirements of sanitary measures.

#### Article 18. State Sanitary-Epidemiological Expertise and Veterinary-Sanitary Expertise

1. State sanitary-epidemiological expertise shall be required for:
  - 1) Novel food;
  - 2) Food products for special dietary uses, functional foods, dietary supplements, food additives, flavourings and processing aids with the aim to approve their registration and use in Ukraine;
  - 3) Production and circulation aids and materials that are placed into circulation;
  - 4) Designs of facilities (objects) for production and circulation of food products;
  - 5) Facilities (objects) for production and circulation of food products for issuing an operating permit or its renewal after suspension of such permit;

- 6) Systems of assuring safety and quality at facilities (objects) for production and circulation of food products;
  - 7) Technologies not previously in use in Ukraine;
  - 8) Food products that are brought to Ukraine for the first time, and for which the supplier does not have a valid conclusion of sanitary-epidemiological expertise or a producer declaration issued to this supplier.
2. The procedure, methods, and scope of required analysis for state sanitary-epidemiological expertise shall take into account the level of risk to human health of the objects subject to such expertise, including whether or not the object, quality and safety assurance system, and technologies subject to state sanitary-epidemiological expertise has been approved by the relevant international organizations for use in, on, or with food products.
  3. State sanitary-epidemiological expertise of the objects identified in paragraph 1 of this Article, with the exception of novel food, shall be conducted within 30 working days upon receipt of a complete application for such expertise. State sanitary-epidemiological expertise for novel food shall be conducted within 90 working days upon receipt of a complete application for expertise of a novel food.
  4. In the event that state sanitary-epidemiological expertise is not completed within the time-period specified in paragraph 3 of this Article, the requester of the expertise shall be provided with a written justification of the reasons of prolongation of the time-period for conducting the expertise.
  5. The Chief State Sanitary Doctor of Ukraine shall establish the requirements for an application, procedures for carrying out state sanitary-epidemiological expertise and for keeping the Register of Conclusions of State Sanitary-epidemiological Expertise, provision of information from such, and its publication.
  6. The Cabinet of Ministers of Ukraine shall prescribe the procedure for payment and the cost of performing work on sanitary-epidemiological and veterinary-sanitary expertise.
  7. The following shall be subject to veterinary-sanitary expertise:
    - 1) food products of animal origin under Veterinary Service control;
    - 2) designs of facilities (objects) for production and circulation of food products under Veterinary Service control;
    - 3) facilities (objects) for production and circulation of food products under Veterinary Service control with the aim to issue an operating permit or renew the latter after suspension;
    - 4) facilities (objects) producing food products under Veterinary Service control for their import to Ukraine, and export facilities (objects) with the purpose of relevant registration;

5) Systems of assuring quality and safety at facilities (objects) for production and circulation of food products under Veterinary Service control.

### SECTION III. RIGHTS AND OBLIGATIONS OF PRODUCERS AND SELLERS (SUPPLIERS)

#### Article 19. Rights of Producers and Sellers (Suppliers)

Persons who in accordance with this Law are engaged in production and circulation of food products shall have the following rights:

- 1) To receive, according to established procedure, necessary, available and true information from relevant bodies of executive power on the results of state control and state supervision over production and circulation of their food products;
- 2) To obtain from suppliers of agricultural products, food products, food additives, flavourings, and food product processing (production) aids, a producer declaration as specified in Article 21 of this Law;
- 3) To request confidentiality of any information and non-disclosure of confidential information, except for cases stipulated by current legislation;
- 4) To appeal the results of laboratory analysis when such results differ from those obtained by the producer using the same or identical methods of analysis and conduct arbitration analysis in an authorized and accredited arbitration laboratory;
- 5) To appeal any decisions of relevant inspectors that are related to their economic activity in accordance with legislation of Ukraine;
- 6) To apply to court for protection of their rights;
- 7) To claim reimbursement for damages resulting from supply to them of unsuitable for consumption, misbranded or unsafe objects subject to sanitary measures, under condition of their use and storage in accordance with instructions provided by their supplier;
- 8) To have indemnity from reimbursement of damages related to the food product being unsuitable for consumption or unsafe as a result of violation of relevant sanitary measures by other persons, including consumers.

#### Article 20. Obligations of Producers and Sellers (Suppliers)

1. It shall be prohibited for persons engaged in the activities of production or circulation of food products to produce and/or circulate food products that are unsafe, unsuitable for consumption or misbranded.
2. Placing into circulation of objects subject to sanitary measures by a producer and/or seller (supplier) shall be understood to be a declaration of the safety of

such object and its compliance with the requirements of this Law, and compliance with other mandatory requirements established by relevant technical regulations.

3. 30 days prior to first placing into circulation in Ukraine of objects subject to sanitary measures, except food products under Veterinary Service control, a producer or seller (supplier) which places these objects into circulation for the first time shall be obliged to provide a notification thereof and a producer declaration to the Chief State Sanitary Doctor of Ukraine.
4. 30 days prior to first placing into circulation in Ukraine of the food products under Veterinary Service control, a producer or seller (supplier), which places these food products into circulation for the first time, shall be obliged to provide a notification thereof and a producer declaration to the Chief State Veterinary Inspector of Ukraine.
5. The Chief State Sanitary Doctor of Ukraine and Chief State Inspector of Veterinary Medicine of Ukraine shall adopt the form and the procedure for providing the notification prescribed in paragraphs 3 and 4 of this Article.
6. Persons engaged in production or circulation of food products shall be obliged to:
  - 1) Comply with the requirements of this Law;
  - 2) Implement sanitary measures and Good Manufacturing Practices, HACCP systems and/or other systems of assuring safety and quality during production and circulation of food products;
  - 3) Ensure use in food products of permitted ingredients that shall be used within permitted limits, be safe and of an appropriate quality;
  - 4) Ensure availability of sufficient and reliable information on the nutritional value, composition, appropriate storage conditions, precautions, and preparation of food products;
  - 5) Provide a producer declaration in accordance with the provisions of Article 21 of this Law;
  - 6) Ensure appropriate storage and/or display conditions for food products;
  - 7) Prevent sale of unsafe, unsuitable for consumption and misbranded food products;
  - 8) Should it be revealed that the food products, which they produced or circulated, are unsafe, unsuitable for consumption or misbranded, voluntarily withdraw such food products;
  - 9) Correct deficiencies of food products, which they produced or circulated, that fail to comply with the requirements of this Law;
  - 10) Provide unhindered access for the relevant inspector conducting state control or state supervision to facilities (objects) engaged in production or circulation of food products during normal business hours and permit the

taking of samples of objects subject to sanitary measures, as well as other materials and substances at the above facilities (objects), and provide, upon request of the relevant inspector, documents necessary for this purpose;

- 11) To compensate consumers, in accordance with the law, for damages caused by consumption of unsuitable for consumption or misbranded food products and consumption of food products that were proved to be unsafe when stored or prepared and/or consumed according to instructions provided by the producer and/or seller;
- 12) Keep records of the acquisition, with reference to the relevant producer declaration, and use of food products, food additives, flavourings, and processing aids, that are used for production or circulation of food products, during three years to ensure traceability of such food products. For serially produced food products, food additives, flavourings, and processing aids, such records shall be kept according to lot numbers.

#### Article 21. Producer Declaration

A producer of agricultural products intended for human consumption, of food products, food additives, flavourings, or processing aids shall be obliged to issue producer declaration for these objects when placing them into circulation.

Producer declaration shall attest to compliance of food products, food additives, flavourings, or processing aids with the requirements specified in the declaration under condition that the requirements set out by the producer are observed during further handling.

Producer declaration shall be issued for a specified time-period either for serial production of the same food product, food additive, flavouring, or processing aid or for a lot.

Should a producer declaration be issued for serial production of a product, the lots referred to therein shall be specified in such producer declaration. Producer declaration issued for a lot shall include a reference to a specific lot.

Producer declaration shall contain the following information:

- 1) The name and address of the producer;
- 2) The name of the food product, food additive, flavouring, processing aid and other information necessary for identification of the product;
- 3) A reference to the sanitary measures, technical regulations, or standards to which conformity is attested and the conditions under which such conformity will be maintained (i.e. conditions of transportation, storage and other conditions of circulation);
- 4) The date of issuance, the name, signature and position of the person who issued the producer declaration;

- 5) For food products produced in Ukraine - the control (registration) number assigned to the producer upon obtaining of an operating permit in accordance with the provisions of Article 22 of this Law.

The producer issuing a producer declaration shall have documentary evidence of the validity of his/her declaration. In particular, the protocols (reports) of measurements and analysis conducted by an accredited laboratory, documents regarding the implementation at the production facility (object) of HACCP or similar systems of assuring safety and quality of produced goods, operating permits and documents on the results of state control and state supervision of the Sanitary and/or Veterinary Service, accordingly, shall be recognized as such documentary evidence.

#### SECTION IV. STATE REGULATION OF THE SAFETY AND QUALITY OF FOOD PRODUCTS

##### Article 22. Operating Permit for Facilities (Objects) Engaged in Producing, Processing or Selling Food Products

1. Operators of facilities (objects) engaged in the activities of production, and/or circulation of food products under Sanitary Service control in Ukraine shall obtain an operating permit from the relevant chief state sanitary doctor for each such facility (object) used for conducting the above activities. The facility (object) subject to obtaining an operating permit shall be assigned a unique control (registration) number. The facility (object) and its operator shall be entered into the register of facilities (objects) maintained according to the procedure established by the central body of executive power in the sphere of health protection.
2. Operators of facilities (objects) engaged in the activities of production of food products under Veterinary Service control, and operators of agri-food markets shall obtain an operating permit from the relevant chief state veterinary inspector for each facility (object). The facility (object) subject to obtaining an operating permit shall be assigned a unique control (registration) number. The facility (object) and its operator shall be entered into the register of facilities (objects) maintained according to the procedure, established by the central body of executive power on agrarian policy issues.
3. The registries referred to in paragraphs 1 and 2 of this Article shall be publicly available in electronic and/or other form.
4. The Cabinet of Ministers of Ukraine, based on a joint submission of the central bodies of executive power in the sphere of health protection and on agrarian policy issues, shall prescribe the form and conditions for the operating permit, procedure for obtaining, suspending, revoking and renewing the operating permit, as well as payment for obtaining the latter.

Article 23. Suspension, Revocation and Renewal of the Operating Permit for  
Facilities (Objects)

1. The operating permit shall not be suspended:
  - 1) If during state control or state supervision, the relevant inspector reveals a violation of conditions for maintaining an operating permit that may be immediately corrected in the presence of the latter;
  - 2) If during state control or state supervision, the relevant inspector reveals a violation of conditions of maintaining the operating permit, which may not be immediately corrected, but does not constitute an immediate danger to health or life of the population.
2. In the case specified in item 2) of paragraph 1 of this Article, the relevant inspector shall issue a directive (order) to correct the violation and/or temporarily prohibit circulation of the relevant objects subject to sanitary measures, and immediately report the latter to the relevant chief state sanitary doctor or relevant chief state veterinary inspector, or their deputies, and control over the implementation of the requirements of the above directive.
3. If during state control or state supervision, the relevant inspector reveals a violation of conditions for maintaining an operating permit, which presents an immediate danger to health or life of the population, relevant inspector shall issue a directive to suspend the operation of the facility (object) and/or temporarily prohibit the circulation of the objects subject to sanitary measures, related to such violation, and immediately report to the relevant chief state sanitary doctor or relevant chief state veterinary inspector, or their deputies, which shall issue a resolution on suspending the operating permit, based on the above directive.
4. If the operator of the facilities (objects) subject to state control or state supervision does not fulfill the requirements of the directives, specified in paragraphs 2 and 3 of this Article, within established period, the relevant chief state sanitary doctor or relevant chief state veterinary inspector, or their deputies, shall issue a resolution to revoke the operating permit for the facility (object) and shall remove such facility (object) from the relevant register according to established procedure.
5. The suspension and/or revocation of an operating permit for a facility (object) shall be announced publicly aimed at protecting consumer health.
6. The operator of a facility (object), for which its operating permit has been revoked, shall not be permitted to apply for another operating permit earlier than six months from the date of revocation of the operating permit.
7. The operator of the facility (object), for which its operating permit has been suspended or revoked, may lodge an appeal regarding the suspension or revocation of such operating permit with the higher level chief state sanitary

doctor or chief state veterinary inspector within ten days from the receipt of the decision, or may lodge an appeal with the court.

An appeal of adopted decision shall not suspend application of the decision.

#### Article 24. Approved Exporting Facilities (Objects)

1. A person that holds an operating permit for a facility (object) engaged in production of food products and that has an intent to export food products under Sanitary Service control to those countries of destination, which have specific requirements for facilities (objects), production processes, storage conditions, or other similar requirements related to food products may apply to the Sanitary Service requesting official verification of their compliance with such requirements, and in the case of food products under Veterinary Service control - to the Veterinary Service (hereinafter: relevant service).
2. The relevant service shall approve the facilities (objects), based on the results of an official verification of fulfilling all the requirements prescribed by a country of destination, to which such facilities (objects) intend to export food products (hereinafter: approved export facilities (objects)), and shall make relevant statement in the operating permit.
3. Any product being exported to a country of destination that originated in an approved export facility (object) shall be marked according to the requirements of the country of destination. If necessary, such marking may include the control (registration) number, as referred to in Article 22 of this Law.
4. The relevant service shall maintain a register of approved export facilities (objects) specifying the country of destination and each type of food product for which fulfillment of the prescribed requirements was verified. The register shall be publicly available in electronic and/or printed form.
5. The procedure for carrying out the official verification of fulfilling the requirements prescribed by a country of destination, to which the operators of approved facilities (objects) intend to export food products, the procedure for approval of export facilities (objects), registration and removal from register shall be established thereafter by the central body of executive power in the sphere of health protection and by the central body of executive power on agrarian policy issues.
6. The Cabinet of Ministers of Ukraine shall prescribe the amount of payment for carrying out official verification of fulfilling the requirements, envisaged by the country of destination.

#### Article 25. Removal of Approved Exporting Facilities (Objects) from the Register of Approved Export Facilities (objects)

1. If during state control and/or state supervision, the relevant inspector determines that approved export facilities (object) fail to comply with the requirements of a country of destination, the relevant inspector shall state the fact of violation of these requirements in the document on inspection fulfillment and immediately inform the relevant chief state sanitary doctor or relevant chief state inspector of veterinary medicine, or their deputies.
2. Relevant chief state sanitary doctor or relevant chief state inspector of veterinary medicine, or their deputies, shall make a decision on excluding such facilities (objects) or certain types of food products, produced at such facilities (objects), from the register of approved export facilities (objects) according to established procedure.
3. The operator of approved export facility (object) may lodge an appeal for a decision on temporary or permanent removal of such facility (object) or a certain type of a food product produced in such facility (object) from the Register of approved export facilities (objects) with the higher level chief state sanitary doctor or chief state veterinary inspector during 10 days upon receipt of the decision, or may lodge an appeal with the court.

An appeal of adopted decision shall not suspend application of the decision.

4. In case the decision on temporary or permanent removal of approved export facilities (objects) or a specific type of food products produced at such facilities (objects) from the register of approved export facilities (objects) has been adopted, the relevant service shall promptly notify the competent authority in the country of destination.
5. The competent authority of any country of destination, for which the relevant service has conducted official verification of fulfillment of prescribed requirements, shall have unhindered access to approved export facilities (objects) with the purpose to inspect such facilities (objects) to verify fulfillment of prescribed requirements. The competent authority of the country of destination shall be obliged to notify the relevant service at least 48 hours in advance of the above inspection.
6. If as a result of inspecting approved export facilities (objects) to verify fulfillment of prescribed requirements, the competent authority of a country of destination concludes that such facilities (objects) fail to fulfill established requirements, the relevant service shall suspend or remove from register its approval of the facility for exporting food products to the relevant country of destination in accordance with the decision of the above competent authority of the country of destination. The decision of the competent authority of the country of destination on suspension or revocation from the register of the approval of the facility for exporting food products to the relevant country of destination shall not be eligible for an appeal.

## Article 26. Requirements for Facilities (Objects) Producing Food Products to be Imported into Ukraine

1. The Sanitary Service and the Veterinary Service (hereinafter: relevant service) may, in accordance with their competencies, establish requirements for facilities (objects), production processes, storage conditions, or other requirements for food products under Sanitary Service control and food products under Veterinary Service control, that are being imported into Ukraine. Such requirements shall not exceed the analogous requirements imposed on domestic producers engaged in the production and/or circulation of such food products.
2. The relevant service may verify compliance of facilities (objects), production processes, storage conditions and other requirements in countries, from which food products are being imported (hereinafter: facilities (objects) approved for importing into Ukraine). The relevant service shall have unhindered access to the facilities (objects) approved for importing into Ukraine to inspect these facilities (objects) for fulfilling the requirements referred to in paragraph 1 of this Article. The relevant service of Ukraine shall inform the relevant competent service of the country-importer about the above inspection at least 48 hours prior to inspection.
3. Import of food products or other objects subject to sanitary measures from facilities (objects) for importing into Ukraine shall not be allowed if during inspection relevant service finds out that the latter fail to fulfill established requirements.
4. The central body of executive power in the sphere of health protection shall maintain the register of facilities (objects) for importing food products into Ukraine for food products under Sanitary Service control.
5. The central body of executive power on agrarian policy issues shall maintain the register of facilities (objects) for importing food products into Ukraine for food products under Veterinary Service control.
6. The procedure of inspecting fulfillment of the requirements referred to in paragraph 1 of this Article, the procedure for registration and removal from the register of the facilities (objects) approved for importing into Ukraine shall be established thereafter by the central body of executive power in the sphere of health protection and by the central body of executive power on agrarian policy issues.

## SECTION V. PRODUCTION OF FOOD PRODUCTS

### Article 27. Requirements for Production of Food Products

1. Food products produced in Ukraine must be safe, suitable for consumption, appropriately marked, and comply with relevant sanitary measures and technical regulations.
2. Aimed at ensuring that food products produced in Ukraine are safe, it shall be prohibited to use:
  - 1) Food additives that are not registered for use in Ukraine;
  - 2) Flavourings and processing aids that are not registered for use in Ukraine;
  - 3) Dietary supplements that are not registered for use in Ukraine;
  - 4) Production and circulation aids and materials that are not allowed for direct contact with food products;
  - 5) Production and circulation aids and materials that by their nature or composition may impart contaminants in food products;
  - 6) Food products as ingredients for production, including agricultural products, if the latter contain harmful factors at levels exceeding mandatory safety parameters.
3. Producers engaged in production of food products under Sanitary Service control shall be obliged to get consent from central executive power body in the sphere of health protection for their production technology.
4. Producers engaged in production of food products under Veterinary Service control shall be obliged to get consent from central executive power body in the sphere of agrarian policy for their production technology.

#### Article 28. State Registration of Food for Special Dietary Uses, Functional Foods and Dietary Supplements

1. It shall be prohibited to place into circulation food for special dietary uses, functional foods and dietary supplements that have not been subjected to state sanitary-epidemiological expertise and state registration.
2. The Cabinet of Ministers of Ukraine shall establish:
  - 1) The procedure for including food products in the category of food for special dietary uses, functional foods and dietary supplements;
  - 2) The procedure for state registration of food for special dietary uses, functional foods and dietary supplements;
  - 3) The procedure for maintaining the state register of food for special dietary uses, functional foods and dietary supplements;
  - 4) The procedure for providing information available in the state register of approved food for special dietary uses, functional foods and dietary supplements.

- 5) The cost of works related to state registration of food for special dietary uses, functional foods and dietary supplements according to the provisions of Article 57 of this Law.

#### Article 29. Requirements for Production of Food for Special Dietary Uses, Functional Foods and Dietary Supplements

1. It shall be prohibited to produce food for special dietary uses, functional foods and dietary supplements that have not been subjected to state sanitary-epidemiological expertise and state registration.
2. Food products that are used for production of food for special dietary uses, functional foods and dietary supplements shall comply with mandatory safety parameters and minimum quality specifications that are acceptable for the consumer with special dietary needs as specified in sanitary measures and technical regulations.
3. Dietary supplements may be added to specific food products, taking into account the inclusion level, specified in relevant sanitary measures, and may be produced for direct consumption as a food product itself.

#### Article 30. Registration of Food Additives for Food Products

1. Food additives shall be allowed for use in production of food products, and be allowed in food products in circulation upon their registration with the central body of executive power in the sphere of health protection.
2. Food additives shall be entered into the relevant register upon request of a producer and/or a seller (supplier) or on recommendation of the National Codex Alimentarius Commission of Ukraine, based on the sanitary-epidemiological normatives with regard to the inclusion level for such food additives in certain types of food products, and the conclusion of the state sanitary-epidemiological expertise, approved by the Chief State Sanitary Doctor of Ukraine.
3. In the process of registration of a food additive it shall be necessary to:
  - 1) Specify the food products, to which such food additive may be added, and the conditions under which it may be added;
  - 2) Limit the food additive to the lowest level of use that is necessary to achieve the desired effect;
  - 3) Take into account any acceptable daily intake or other equivalent assessment of the amounts of intake of the food additive, and its probable daily intake from all sources, including possible daily intake of the food additive by special groups of consumers.
4. A food additive shall be allowed for use in Ukraine provided that:

- 1) There is a justified technological need for a food additive, and this purpose may not be achieved by other technologically practicable means;
  - 2) The food additive presents no hazard for the consumer health at the level of use proposed, which may be proved on the basis of available scientific evidence;
  - 3) The food additive does not mislead the consumer.
5. Any producer may request registration of a food additive by submitting to the central body of executive power in the sphere of health protection an application for registration of a food additive, accompanied by relevant documentation showing that the food additive complies with the provisions of paragraphs 2, 3 and 4 of this Article. If the food additive has been allowed for use by the relevant international organizations, information in support of the latter shall be attached to the application for registration. A decision on registration or refusal in registration of a food additive for production of food products in Ukraine or circulation of food products, containing such food additive, shall be issued within 120 working days of receipt of a complete application.
6. Any food additive, for which registration has been requested, and which was allowed for by the relevant international organizations, shall be subject to express registration. Express registration shall include an overview of the report of the relevant international organizations justifying the possibility to use a food additive. Such overview shall take into account the circumstances and conditions specific to the population of Ukraine, as well as the technical and economic feasibility of detecting the presence and/or level of use of the food additives in food products relative to inclusion levels adopted by the relevant international organizations. Under the express registration procedure, the decision on registration or refusal in registration of a food additive for production of food products in Ukraine or circulation of food products, containing such food additive, shall be issued within 30 working days of receipt of a complete application.
7. The procedure for registration of food additives shall be established by the central body of executive power in the sphere of health protection.
8. The cost of works related to registration of food additives shall be prescribed by the Cabinet of Ministers of Ukraine.

#### Article 31. Requirements for Use of Flavourings

1. The provisions of this Article shall not apply to:
  - 1) Edible substances and products intended for direct consumption as such, with or without reconstitution,
  - 2) Substances which have exclusively a sweet, sour, or salt taste,

- 3) Materials of plant and animal origin, having inherent flavouring properties, where they are not used as flavouring sources.
2. Flavourings shall not contain any harmful factors in the amounts exceeding maximum levels and shall not result in the presence of undesirable substances in food products in the amounts exceeding those specified by mandatory safety parameters.
3. Flavourings that may be used for food products that are produced and circulated in Ukraine shall be subject to registration with the central body of executive power in the sphere of health protection upon the request of a producer and/or seller (supplier), or upon the recommendation of the National Codex Alimentarius Commission of Ukraine, based on hygienic normatives with regard to inclusion levels for such flavourings in certain types of food products and based on the conclusion of state sanitary-epidemiological expertise, approved by Chief State Sanitary Doctor of Ukraine.
4. Any producer may request registration of flavourings by submitting to the central body of executive power in the sphere of health protection a request for registration of a flavouring, accompanied by relevant documentation showing that the flavouring complies with the provisions of paragraphs 2 of this Article. If the flavouring has been allowed for use by the competent international organizations, information in support of the latter shall also be attached to the application for registration. A decision on registration or refusal in registration of a flavouring for production of food products in Ukraine or circulation of food products, containing such flavouring, shall be issued within 120 working days of receipt of a complete application.
5. Any flavouring, for which registration has been requested and which has been allowed for its use in food products by the relevant international organizations, shall be subject to express registration. Express registration shall include an overview of the report of the relevant international organizations justifying the possibility to use the flavouring. The overview shall take into account the circumstances and conditions specific to the population of Ukraine, as well as the technical and economic feasibility of detecting the presence and/or level of use of the flavouring in food products relative to inclusion levels approved by the relevant international organizations. According to express registration procedure, the decision on registration or refusal in registration of a flavouring for production of food products in Ukraine or circulation of food products, containing such flavouring, shall be issued within 30 working days of receipt of a complete application.
6. The central body of executive power in the sphere of health protection shall prescribe the procedure for registration of flavourings.
7. The cost of works related to registration of flavourings shall be prescribed by the Cabinet of Ministers of Ukraine according to Article 57 of this Law.

## Article 32. Requirements for Use of Processing Aids

Processing aids that are used in production of food products, which are circulated in Ukraine, shall not result in the presence of harmful factors in food products in the amounts exceeding maximum residue limits.

The terms of use, maximum residue limits in food products and minimum quality specifications for processing aids that are used in the production of food products, shall be determined by the Chief State Sanitary Doctor of Ukraine, taking into account the recommendations of the National Codex Alimentarius Commission of Ukraine.

## Article 33. Animal Slaughter

1. It shall be prohibited to slaughter animals that are not accompanied by a veterinary document, attesting to the health of animals, presented for slaughter, and the veterinary-sanitary status of the facility (object) of origin of such animals.
2. It shall be prohibited to slaughter equidae and other ungulates, as well as poultry and rabbits in the amount exceeding 10 head per day, anywhere except in slaughterhouses that have an operating permit and are registered with the Veterinary Service.
3. Slaughterhouses with an average daily throughput of no more than 10 cattle, 30 pigs, 50 sheep or goats, 500 head of poultry, or 250 rabbits shall be exempted from the requirement to implement a HACCP system.
4. State veterinary control shall be compulsory for all animals before slaughtering, except for forced slaughter animals and hunted game animals, if their products are intended for human consumption.
5. All animals shall be subjected to compulsory state veterinary-sanitary control after slaughtering (post-mortem control), including forced slaughter animals and hunted game animals, regardless of whether their products are intended for human consumption or for feeding animals .
6. Veterinary inspectors shall conduct ante- and post-mortem inspection for both healthy and sick equidae and other ungulates, and for poultry and rabbits.
7. The presence of a veterinary inspector shall be compulsory prior to slaughter, during slaughter, and after slaughter in the slaughterhouses, specified in paragraph 3 of this Article. All slaughterhouses that, due to the volume of their daily throughput, do not have the continuous presence of a veterinary inspector shall arrange for state veterinary control during slaughter according to the procedure prescribed by the Veterinary Service.
8. The veterinary inspector shall stamp all carcasses and parts thereof that are found to be suitable for human consumption with the mark of suitability. When

permitted by relevant sanitary measures, the mark of suitability shall be applied in the form of a seal on the product packaging, and the veterinary inspector shall issue a relevant veterinary document, which stipulates suitability of the product for human consumption and bears the mark of suitability.

9. The veterinary inspector shall take samples of all carcasses or parts thereof that are suspected to be not suitable for human consumption (hereinafter: unsuitable product), in accordance with the relevant rule book, and maintain such samples in a condition appropriate for laboratory analysis for no less than 72 hours. Within this period of time, the veterinary inspector shall notify the owner of the carcass of his/her suspicion and prescribe appropriate storage conditions for the unsuitable product.
10. The owner of an unsuitable product may request a laboratory analysis of the unsuitable product samples within 72 hours from the moment of taking of samples. Such analysis shall be conducted by an accredited laboratory, authorized for conducting analysis to determine suitability for human consumption.
11. The owner of non-processed food products of animal origin that have been found unsuitable for human and animal consumption based on the laboratory analysis, and with regard to which a decision on their destruction has been made, may destroy such products himself/herself under control of a veterinary inspector.
12. Hunting societies and legal entities engaged in hunting activities shall provide temporary storage for game animals and game carcasses as well as facilities (objects) for state post-mortem control of game after they have been caught or shot. Upon request of hunting societies and legal entities, the relevant inspector shall conduct an inspection. If the game is suitable for human consumption, the veterinary inspector shall apply the mark of suitability to the carcass. If it is not possible to apply the mark of suitability to the carcass, the veterinary inspector shall issue a certificate of suitability for human consumption bearing the mark of suitability.
13. The mark of suitability shall include the control (registration) number of the slaughterhouse or, when animals are not required to be slaughtered at a slaughterhouse, a unique number identifying the laboratory or other facility (object) where a veterinary inspector applies the mark of suitability.
14. The Chief State Veterinary Inspector of Ukraine shall prescribe the form and content of the mark of suitability, as well as the ways and procedures for applying the mark of suitability to carcasses, parts thereof, packaging for carcasses and parts thereof, and the certificate of suitability for human consumption.

Article 34. “State Veterinary-Sanitary Control at Meat Processing, Fishing, Fish Processing and Milk Processing Enterprises, and also at the Enterprises of Wholesale Storage of Non-processed Food Products of Animal Origin (refrigerator complexes, refrigerators, specialized wholesales)”

1. State veterinary-sanitary control and supervision (within its competence) at meat processing, fishing, fish processing and milk processing enterprises, and also at the enterprises for storage of products of animal origin, shall be conducted with the aim to ensure epizootic well-being when receiving and processing raw materials of animal origin, and also with the aim to control compliance with necessary veterinary-sanitary, sanitary (hygienic) requirements for ensuring safety of finished products of animal origin.

2. State veterinary-sanitary control shall be conducted by official doctors of veterinary medicine (within their competence). Depending on the amounts of production of the economic entity, official doctor may have a deputy.

3. Official doctors of veterinary medicine shall be subordinated to chief state veterinary inspectors of rayons, cities, cities if Kyiv and Sebastopol, oblasts, Autonomous Republic of Crimea, shall be on the staff of rayon (city) state hospital of veterinary medicine, and in the city of Kyiv – of the state veterinary medicine amalgamation and financed from general and special funds the State Budget of Ukraine. Activities of the state doctors shall be controlled by the State Department of Veterinary Medicine and its territorial bodies. It shall be prohibited for other services to interfere in the activities of official doctors.

4. In their activities official doctors of veterinary medicine shall be independent, shall exercise their duties in a professional manner, and be guided by relevant Regulations, adopted through a legally established procedure, this Law and other normative-legal acts.

5. Official doctor of veterinary medicine shall provide consent to assigning and dismissing from the office of the personnel of the veterinary medicine service of an economic entity, shall control the activities of the latter, organize professional education and upgrading of skills, prescribe rights and obligations.

6. Veterinary-sanitary control of compliance by an economic entity with veterinary, sanitary requirements, rules and measures during processing, storage, transportation and sale of products of animal origin shall be conducted by specialists of veterinary medicine of an economic entity under control of the official doctor of veterinary medicine. The structure and the number of staff of specialists of veterinary medicine of an economic entity shall be prescribed by the state veterinary inspector.

7. Obligations of the official doctor of veterinary medicine shall include control of:

7.1. Compliance of raw materials of animal origin with accompanying veterinary documents and marks of suitability;

7.2. Compliance with sanitary (hygienic) requirements of the technology for processing raw materials of animal origin;

7.3. Compliance of technological regimes of processing raw materials of animal origin that has certain restrictions for use;

7.4. Compliance of temperature regimes in course of production of food products of animal origin;

7.5. Veterinary-sanitary evaluation of raw materials of animal origin (including, parasitologic);

7.6. Taking of samples of raw materials and finished food products to implement the National Monitoring Plan, and in case of production needs – with the aim to determine their safety, in course of implementing sectoral control and export;

7.7. Utilization of food waste of animal origin;

7.8. Observance by the owners of the enterprises of HACCP system. Providing appropriate recommendations that are necessary for implementation of the latter;

8. Owners of facilities (objects) shall have the right to sell only those products of animal origin that are produced under state veterinary-sanitary control and supervision (within the limits of competence) and are permitted for sale and storage with drawing up, if necessary, relevant veterinary documents attesting to their safety.

9. Official doctors of veterinary medicine shall periodically, with the aim of taking necessary measures, inform relevant chief state veterinary inspectors about violations of sanitary measures, which may lead to worsening of security of products of animal origin, threat of complication of the epidemic and epizootic situation.

10. Functions of exercising by official doctors of veterinary medicine of state veterinary-sanitary control at meat-processing, fishing, fish processing, milk processing enterprises and enterprises of wholesale storage on non-processed food products of animal origin shall be defined by standard instructions for relevant enterprises with regard to carrying out veterinary-sanitary control, adopted through a joint order of the Chief State Veterinary Inspector of Ukraine and Chief State Sanitary Doctor of Ukraine.

Sanitary Service and Veterinary Service shall conduct state supervision at the above facilities within the limits of their competence.

Planned measures of state supervision by the Sanitary Service and Veterinary Service at the above facilities shall be performed pursuant to an agreed upon schedule, adopted through a joint order of the chief state veterinary inspector and chief state sanitary doctor of relevant territories.

11. Activities of the specialists of veterinary medicine and sanitary-epidemiological service shall be performed in a mutually agreed manner, avoiding duplication of functions and with maximum facilitation of the activities of an enterprise.

## Article 35. “Agri-food Markets

1. It shall be prohibited to circulate non-processed milk and homemade soft cheese, as well as carcasses or parts of carcasses of equidae and other ungulates of household slaughter, in agri-food markets.
2. Whole carcasses of poultry, rabbits, and small game animals, fish, honey, eggs, and plant products may be sold at agri-food markets provided they are verified for suitability for human consumption prior to their sale. The owner of such carcasses shall be obliged to take them for an analysis to the state laboratory of veterinary-sanitary expertise at the agri-food market. Such laboratory shall perform analysis of the above-mentioned food products for their suitability for human consumption in accordance with the relevant rule books.
3. Chief State Veterinary Inspector of Ukraine and Chief State Sanitary Doctor of Ukraine shall determine the list of food products of animal and plant origin that may be sold in agri-food markets.
4. A certificate of suitability for human consumption bearing the mark of suitability shall be issued by a veterinary inspector for each carcass or when appropriate, a lot of carcasses of poultry, rabbits, and small game animals that are confirmed to be suitable for human consumption.
5. Carcasses not suitable for human consumption, which, based on the results of laboratory analysis, may be used for animal consumption, shall be scored across the entire carcass by a veterinary inspector to indicate that the product is not suitable for human consumption.
6. Owners of plant products intended for sale in the agri-food market shall be obliged to take them for an analysis to the state laboratory of veterinary-sanitary expertise at the agri-food market. Suitability of plant products for human consumption shall be attested to by the relevant laboratory certificate.
7. The food products specified in paragraphs 2 and 5 of this Article, that are not suitable for human consumption, do not present an immediate danger (low risk) to human health, shall be subject to prohibition for sale or utilization by the owner. Food product that is not suitable for human consumption, presents an immediate danger (high risk) for human health, shall be subject to urgent withdrawal by the owner and utilization or destruction under control of veterinary inspector according to current legislation.
8. In the case that the owner of the unsuitable food product refuses to destroy such food product voluntarily, the state veterinary inspector shall submit a claim with the relevant court to issue a decision for such destruction.
9. Trade places at agri-food markets shall be provided by their operators to persons selling whole carcasses or parts thereof of equidae and other ungulates slaughtered at slaughterhouses, whole carcasses of poultry, rabbit, and small game animals, fish, honey, eggs, and plant products only upon presentation by the latter of a certificate of suitability for human consumption for the above products, issued by the state laboratory of veterinary-sanitary expertise at the

agri-food market. Administration (owner) of the agri-food market shall be obliged to provide adequate office premises for laboratory use.

Laboratories shall not bear responsibility for the sale of products that did not pass veterinary-sanitary expertise. Administration (owner) of the agri-food market shall bear responsibility for providing a permit to sell such products. Agri-food market shall be prohibited from functioning in case of absence of the laboratory of veterinary-sanitary expertise.

## SECTION VI. CIRCULATION OF FOOD PRODUCTS

Article .36. Requirements for Circulation of Objects Subject to Sanitary Measures.

1. It shall be prohibited to:
  - 1) Circulate food products at facilities (objects) that do not comply with the requirements of sanitary measures;
  - 2) Sell home-prepared food products;
  - 3) Circulate non-processed food products of animal origin, including animal carcasses, which themselves and/or their packaging bear no mark of suitability (marking in form of mark of suitability) in case of absence of relevant veterinary documents.
2. It shall be prohibited to circulate objects subject to sanitary measures that:
  - 1) are unsafe;
  - 2) are unsuitable for consumption;
  - 3) are misbranded;
  - 4) are not registered or not approved in accordance with the provisions of this Law, or contain food additives, flavourings that are not registered in accordance with this Law;
  - 5) do not comply with technical regulations;
  - 6) are smuggled into the territory of Ukraine;
  - 7) have a "Use-by- date" that has passed.
3. Food products, specified in items 2) and 3) of paragraph 1 of this Article, shall be withdrawn according to the procedure established by this Law.
4. Food products that were withdrawn from circulation due to violations, specified in items 3) and 4) of paragraph 2 of this Article, may be returned to circulation provided that the marking is corrected and the registration is carried out in accordance with the procedure established by this Law.

5. Food products that were withdrawn and that cannot be returned into circulation shall be used for other than human consumption purposes, or shall be destroyed in accordance with the procedure established by the legislation.
6. Destruction of food products, returning them to circulation for human consumption or for other than human consumption purposes shall be performed by the producer (owner) at his/her own expense. The procedure for destruction of food products or the conditions that must be met for returning them to circulation for human consumption, or for other than human consumption purposes shall be established by the relevant chief sanitary doctor or chief veterinary inspector.

#### Article 37. Circulation of Novel Food

1. Novel food containing, consisting of, or produced from genetically modified organisms (GMOs) shall be regulated by the provisions of special legislation. The provisions of this Article shall not apply to food additives, flavourings and extraction solvents.
2. Novel food shall not:
  - 1) Present a danger for the consumer;
  - 2) Mislead the consumer;
  - 3) Differ from the food products that they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer.
3. The producer, importer, or seller that is placing novel food into circulation in Ukraine (hereinafter: applicant) shall submit an application for conducting state sanitary-epidemiological expertise to the central body of executive power in the sphere of health protection. The application shall contain information demonstrating that the novel food complies with the provisions of paragraph 2 of this Article, as well as an appropriate proposal for its presentation and labeling, in accordance with the requirements of this Article.
4. State sanitary-epidemiological expertise shall be conducted within the time-period specified in Article 18 of this Law.
5. The conclusions of state sanitary-epidemiological expertise shall be provided to the applicant and shall contain a decision on whether or not the novel food is permitted for circulation, the conditions of the permit, and, when appropriate:
  - 1) The conditions of use of the food product;
  - 2) The intended use of the food product and its specification;
  - 3) All the specific labeling requirements, stipulated in Article 37 of this Law.
6. The applicant may appeal the conclusion of state sanitary-epidemiological expertise that does not permit circulation of a novel food with the Chief State

Sanitary Doctor of Ukraine within 30 days of receipt of this conclusion, or may appeal it to the court.

#### Article 38. Requirements to Labeling Food Products

1. It shall be prohibited to circulate food products that are not labeled in accordance with this Law and the relevant technical regulations. All food products circulated in Ukraine shall be labeled in the state language of Ukraine and contain the following information in a form understandable for the consumer:
  - 1) The name of the food product;
  - 2) The name and complete address and telephone number of the producer, the address of the facilities (objects) of production and, for imported food products - the name, complete address, and telephone number of the importer;
  - 3) The net quantity of the food product in prescribed units of measurement (weight, volume, or count);
  - 4) The composition of the food product in order of preponderance of ingredients, including food additives and flavourings, used in the production thereof;
  - 5) Calories and nutritional value in terms of the amount of protein, carbohydrate, and fat in prescribed units of measurement per 100 grams of the food product;
  - 6) Use-by date or date of production and shelf life;
  - 7) Production lot number;
  - 8) Conditions of storage and use if the food product requires certain storage and use conditions to ensure its safety and quality;
  - 9) Warnings for consumption of food products by certain categories of the population (children, pregnant women, the elderly, sportsmen, those with allergies) that may experience adverse health effects when consuming such products.
2. For certain categories of food products, the relevant technical regulations may establish specific mandatory labeling requirements other than those provided for in this Article.
3. Labeling of bulk food products shall be in the state language of Ukraine in accordance with the procedure established in technical regulations for certain food products.
4. It shall be prohibited to include on the label information on dietary and functional properties of a food product without a permit from the central body of executive power in the sphere of health protection.

5. The text for labeling food for special dietary uses, functional foods and dietary supplements shall be subject to compulsory approval by the central body of executive power in the in the sphere of health protection. The procedure for approval of the text for labeling food for special dietary uses, functional foods and dietary supplements shall be established by the central body of executive power in the in the sphere of health protection.
6. Labels of food products that include symbols must contain only those symbols that are approved by the relevant international and regional organizations on standardization issues.
7. Claims in labels of food products that are of interest to consumers and intended to prevent deceptive practices, or distinguish one food product from another, such as “all natural”, “organic”, “original”, “free of GMOs” (genetically modified organisms) etc. and other information in addition to that, specified in this Article, shall be subject to verification according to a procedure, prescribed by relevant normative-legal acts issued for implementation of this Law.
8. The description of specific symbols, their use, and marking of food products with bar codes shall be in accordance with the procedure established by the Cabinet of Ministers of Ukraine

#### Article 39. Requirements for Advertising of Food for Special Dietary Uses, Functional Food and Dietary Supplements

1. Advertising of food for special dietary uses, functional food and dietary supplements without prior consent for the text from the central body of executive power in the sphere of health protection shall be prohibited.
2. The following shall be prohibited for use in advertising food for special dietary uses, functional food and dietary supplements:
  - 1) Phrases about possible curative effects or pain relief;
  - 2) Letters of thankfulness, acknowledgement, and advice, if they relate to treatment or easing of disease conditions, as wells as reference to such information;
  - 3) Phrases that cause or contribute to a feeling of negative psychological condition.

#### SECTION VII. INTERNATIONAL TRADE

#### Article 40. Food Products Prohibited for Import

Import of food products that are unsafe, unsuitable for consumption or misbranded, or that do not comply with relevant technical regulations or sanitary measures shall be prohibited.

#### Article 41. Carrying Food Products for Personal Use into Ukraine

Ukraine's citizens, foreigners, and persons without citizenship that are entering Ukraine must declare the type and volume of all food products of animal origin and fresh (raw) products of plant origin that they are carrying for their personal consumption to the relevant border inspector. Any such products that present a high risk for human health, a high risk of animal disease introduction or transmission, or a high risk of introducing hazardous organisms into Ukraine, as determined pursuant to this and other relevant laws, shall be prohibited from entry.

#### Article 42. Requirements for Import Consignments of Objects subject to Sanitary Measures

When so required by current sanitary measures, import consignments of objects subject to sanitary measures shall be accompanied by:

- 1) For food products - an original international veterinary (sanitary) certificate (hereinafter: international certificate), which attests to suitability for human consumption;
- 2) For other objects subject to sanitary measures - documentation and/or marking identifying the facilities (objects) where the object subject to sanitary measures was produced (hereinafter: facility (object) of origin).

#### Article 43. Border Inspection Posts

1. Import and export of food products and other objects subject to sanitary measures shall be allowed only through the border inspection posts that are designated for such (hereinafter: designated border inspection posts).
2. All consignments referred to in paragraph 1 of this Article that arrive at other than a designated inspection post shall be redirected to the nearest designated border inspection post and shall be moved through the territory of Ukraine in transit regime.

#### Article 44. Border Control for Import Consignments of Food Products

1. Any import consignment of food products shall be subject to border control by sanitary or veterinary border inspector (hereinafter: relevant border inspector)

in order to ensure compliance with relevant sanitary measures and technical regulations that are in effect at the moment.

2. All import consignments of food products shall be subject to standard veterinary or sanitary border control, which is carried out at designated border inspection post, and envisages verification of documentation and visual inspection.
3. Extended veterinary or sanitary control of import consignments of food products shall be carried out at the customs house of the consignment destination and shall be mandatory when:
  - 1) The consignment is designated for such control under the random veterinary or sanitary control program prescribed in Article 46 of this Law;
  - 2) The food product in at least one consignment of the last five consignments of the specific food product from the specific facility (object) of origin was found to be unsafe, unsuitable for consumption, misbranded, or otherwise lacking compliance with technical regulations or sanitary measures;
  - 3) An obvious violation of relevant sanitary measures has been detected during veterinary or standard sanitary border control.
  - 4) A food product is brought into customs territory of Ukraine by a producer or supplier for the first time and is not accompanied by a producer declaration issued to this supplier.
4. Import consignments of food products that inherently present a high risk to human health shall be subjected to extended sanitary border control according to a plan based on the results of previous extended sanitary control of such food products that are imported from the same facilities (objects) of origin and/or by the same importer or exporter from the country of origin and/or from the same country of origin.
5. Extended veterinary or sanitary border control shall not be conducted for import consignments of a food product when the provisions of paragraphs 2 and 3 of this Article do not apply and when:
  - 1) The consignment is subject to a bilateral agreement regarding recognition of the equivalence of general sanitary measures, or sanitary measures specific to types or groups of food products, between the exporting country and Ukraine that is applicable to the food product in the consignment;
  - 2) All food products in the consignment originate from facilities (objects) designated for import into Ukraine and registered according to established procedure;
  - 3) All food products in the consignment present a low level of risk to human health due to the inherent properties of the food product.

6. The Chief State Sanitary Doctor shall, upon consent from the Chief State Veterinary Inspector of Ukraine and upon the recommendation of the National Codex Alimentarius Commission of Ukraine, adopt the list of food products that inherently present a high and low risk to human health and the criteria for establishing the program, referred to in paragraph 3 of this Article”.

#### Article 45. Border Control for Import Consignments of Objects subject to Sanitary Measures

1. Sanitary border control for consignments of food additives, flavourings, dietary supplements, processing aids, and production and circulation aids and materials shall include verification of documentation, and as appropriate, verification of the labeling of these objects and extended control.
2. Extended control of objects subject to sanitary measures other than food products shall be conducted in accordance with an established frequency, taking into account:
  - 1) Possible risks that may be associated with the object;
  - 2) The history of compliance of the object and facility (object) of origin and/or importer or exporter from the country of origin and/or country of origin with relevant sanitary measures.
2. The Chief State Sanitary Doctor of Ukraine and Chief State Veterinary Inspector of Ukraine shall establish the procedure for conducting extended control for import consignments of objects subject to sanitary measures other than food products.

#### Article 46. Random Sanitary Border Control of Import Consignments of Food Products

1. Mandatory extended veterinary or sanitary control under a random sanitary control program shall be applied during a calendar year for a specifically determined percentage of consignments of food products other than those food products which inherently present a high risk to human health as identified according to the provision of paragraph three of Article 44 of this Law.
2. The specifically determined percentage of consignments referred to in paragraph one of this Article shall be determined on the basis of monitoring the data and extended control.
3. The Chief State Sanitary Doctor of Ukraine and Chief State Veterinary Inspector of Ukraine shall, upon the recommendation of the National Codex Alimentarius Commission of Ukraine, prior to the beginning of each calendar year, approve the specifically determined percentage of consignments referred to in paragraph one of this Article.

## Article 47. Standard Veterinary and Sanitary Border Control for Import Consignments of Food Products

1. Standard veterinary or sanitary border control shall be implemented by the relevant border inspector and consist of the following:
  - 1) If the food products are, according to current legislation of Ukraine, subject to phytosanitary or veterinary-sanitary border control, - verification that the consignment has been subjected to such control, carried out by the state bodies, for further customs clearance according to current legislation of Ukraine;
  - 2) Verification that the consignment is accompanied by acceptable relevant international certificates, if such international certificates are required by current sanitary measures;
  - 3) Random verification that the food products in the consignment correspond to the relevant international certificates, if such international certificates are required by current sanitary measures;
  - 4) Random verification of the compliance of the labels on the food products with technical regulations and sanitary measures, and the appropriateness of marking of the food products;
  - 5) Detection of visible violation of sanitary measures by visually examining the packages of the food products for defects and, when necessary, opening the packages to look for any contamination;
  - 6) Verification that a mark of suitability has been applied to the carcasses, parts of carcasses, or packaging for carcasses or parts of carcasses in the country of origin, identifying the facility (object) of origin.
2. When the consignment is required to be accompanied by a relevant international certificate and is found to not have an acceptable international certificate or the international certificate does not correspond to the food product in the consignment, the provisions of Article 47 of this Law shall apply.
3. If the food product in the consignment does not have a label in accordance with technical regulations or sanitary measures, or is suspected of being otherwise misbranded, the consignment shall be subject to the provisions of Article 48 of this Law.
4. If an obvious violation of sanitary measures is detected during visual examination of the packages of the food products for defects, or contamination is found in the packages, or, based on the professional judgment of the relevant inspector, there is reasonable suspicion of violation of relevant sanitary measures, or if the carcasses or the packaging units with parts thereof have no mark of suitability, the consignment shall be subjected to extended veterinary or sanitary border control.

#### Article 48 . Consignments with Unacceptable International Certificates

1. When a consignment of food products is required to be accompanied by a relevant international certificate and the relevant border inspector finds that the relevant international certificate accompanying a consignment of food products is unacceptable, or the food products in a consignment are not those described in the accompanying relevant international certificate, the relevant border inspector shall notify the relevant chief state sanitary doctor or chief state veterinary inspector, or their deputies, and the consignment shall be held in an appropriate place at the designated border inspection post;
2. The relevant chief state sanitary doctor or relevant chief state veterinary inspector, or their deputies, shall immediately inform the importer or his/her authorized representative and contact the relevant official body, which issued the certificate, of the exporting country, aimed at conducting consultations on further actions with regard to the above consignment.
3. If it has been determined during consultations with the official competent body of the exporting country that the relevant international certificate is not fraudulent or otherwise falsified, upon the request of the importer or his/her authorized representative, the food products in such consignment may be subjected to extended veterinary or sanitary control to determine the suitability of the food products and the possibility of their further import.
4. If it has been determined during consultations with the official competent body of the exporting country that the relevant international certificate is fraudulent or otherwise falsified, such consignment shall be rejected and shall be destructed in an appropriate manner of at the expense of the importer or the owner.

#### Article 49. Consignments with Misbranded Food Products that are Imported.

1. Import consignments of food products that are labeled with violations of the requirements of this Law may, upon the consent from the relevant border inspector, be transported to the customs house designated by the customs authority to have the labeling corrected in order to bring the labeling into compliance with this Law. Upon completion of the corrective actions, the consignment of food products shall be subjected to extended veterinary or sanitary control in accordance with the provisions of Article 49 of this Law.
2. If the relevant border inspector determines that it is not possible or expedient to correct the labeling of the food product in the consignment, the consignment shall be subjected to the provisions of Article 51 of this Law.

#### Article 50. Extended Sanitary Control of Food Products that are Imported

1. In the cases referred to in Articles 47-49 of this Law, the importer or his/her authorized representative shall be informed in writing of the decision to implement extended control of the import consignment of food products. The date and time of receipt of such notice by the importer or his authorized representative shall be recorded.
2. Import consignments of food products that present an immediate threat to human or animal health due to potential for transmitting zoonosis or other animal diseases and therefore are to be subjected to extended veterinary or sanitary control shall be held at the designated border inspection post in an appropriate place (object) where the risk to human or animal health is minimized.
3. Except as provided in paragraph two of this Article, import consignments of food products that are subject to extended veterinary or sanitary control shall be transported under the supervision of customs authority to the customs house of the consignment destination.
4. Samples of the food products from the consignment shall be taken in accordance with the sampling plan and/or procedures specified in the relevant sanitary measures. Amount of samples should be sufficient for conducting an arbitration analysis at the relevant arbitration laboratory in case of appeal of the results of extended control.
5. The samples from the consignment shall be subject to laboratory analysis deemed appropriate by the relevant inspector based on the potential risk to human health presented by the objects in the consignment, including in particular:
  - 1) If the consignment contains food products that inherently present a high risk to human health, - an analysis related to the potential source(s) of risk for human health, as identified in the relevant sanitary measures for food products with high risk for human health;
  - 2) If a violation of relevant sanitary measures is visually detected during standard veterinary or sanitary border control, or the relevant border inspector suspects the food product is unsafe or unsuitable for consumption, - an analysis related to visually detected violations or with regard to which there is a suspicion;
  - 3) If the consignment is subject to extended sanitary control under the random veterinary or sanitary control program, or the food product has been re-labeled, - an analysis related to the most common human health risks specific to the food product in the consignment according to the relevant sanitary measures;
  - 4) If the consignment is subject to extended sanitary control because the food product was previously found to be unsafe, unsuitable for consumption, misbranded, or otherwise lacking compliance with technical regulations or

sanitary measures, - an analysis related to the indicators that constituted the grounds for the prior prohibition from import of such food product, according to the relevant sanitary measures, an analysis for the most common human health risks specific to the food product in the consignment, according to the relevant sanitary measures;

- 5) If the food product is being imported for the first time from a certain facility (object) of origin, - an analysis for the most common human health risks specific to the food product in the consignment according to relevant sanitary measures.
6. If the protocol (report) of laboratory analysis referred to in paragraph five of this Article stipulates that the food products are safe, suitable for human consumption, comply with technical regulations and sanitary measures, the relevant inspector shall inform the customs authorities according to the established procedure to enable completion of customs clearance of the consignment.
7. If the protocol (report) of laboratory analysis or an expert conclusion referred to in paragraph five of this Article stipulates that the food products are unsafe, unsuitable for consumption, or they do not comply with technical regulations and sanitary measures, such food products in a consignment shall be denied entry into Ukraine as food products, and the provisions of Article 51 of this Law shall apply thereto.
8. The importer or his/her authorized representative shall be provided with a reasonable explanation of the reasons for prolongation of the time-period of laboratory analysis, if the laboratory analysis within an extended sanitary control has not been completed within the time-period established for the relevant analysis, or if the complexity of laboratory analysis requires longer time-period.

#### Article 51. Disposition of the Consignments Denied Entry

1. Food products in a consignment that are found to be unsafe, unsuitable for consumption, misbranded, or otherwise lacking compliance with technical regulations or sanitary measures shall be denied entry for human consumption (hereinafter: rejected food products).
2. All rejected food products that present a high risk for human and animal health and are not eligible for processing (treatment) shall be destroyed according to the procedure prescribed by the Cabinet of Ministers of Ukraine.
3. Rejected food products that are not subject to paragraph two of this Article shall be returned unless the importer or his/her authorized representative, upon consultation with the relevant border inspector, agrees to treat the rejected food products or downgrade thereof to the category other than for human consumption.

4. Rejected food products that have been excluded from the category of food products for human consumption shall be marked on each packaging with a well visible warning “Not for human consumption” or, in the absence of packaging, shall be marked or packaged in such a manner as to enable marking of the packaging with the warning “Not for human consumption”.
5. The treatment of rejected food products referred to in paragraph three of this Article and marking of rejected food products as referred to in paragraph four of this Article shall be completed by the importer under supervision of a sanitary inspector or veterinary inspector according to their competencies.

Article 52. Import Restrictions for Food Products of Animal Origin due to Office International Epizootic (OIE) List Diseases

1. The Chief State Veterinary Inspector of Ukraine may, when so recommended by the relevant international organizations or, as determined by a risk analysis, to be necessary to achieve the appropriate level of human and animal health protection, restrict or prohibit imports of food products of animal origin from certain countries or zones within certain countries due to a confirmed outbreak of the OIE List diseases that can render food products of animal origin unsafe. Such restrictions or prohibitions shall be repealed upon confirmation of the end of the outbreak of the disease and confirmation of the safety of food products of animal origin.
2. In the event of a restriction or prohibition on import of food products of animal origin as provided in paragraph one of this Article, a permit to bring in prohibited or restricted food products of animal origin from the country, countries, or zones within certain countries shall be deemed invalid and cancelled for all consignments of such products, including those consignments that have already left the country of origin if the departure date from said country was within the incubation period for the OIE List diseases, which is calculated from the date of confirmation of the outbreak of such disease.

Article 53. Conditions, Applicable to Consignments of Food Products that are Exported

When it is required by the importing country, export consignments of food products must be accompanied by:

- 1) Original international veterinary (sanitary) certificates, issued by the relevant authorized body, attesting to suitability of the food products for human consumption;
- 2) Documentation or marking, which indicates the facility (object) from which the food products originate.

#### Article 54. Issuance of International Veterinary (Sanitary) Certificates for Consignments of Food Products that are Exported

1. International veterinary (sanitary) certificates for consignments of food products, intended for export, shall be issued exclusively for the products produced at the approved export facilities (objects) registered in accordance with the established procedure.
2. Export consignments of food products that must be accompanied by an original international veterinary (sanitary) certificate attesting to suitability of the food products for human consumption and compliance with the food safety requirements of the importing country shall be certified immediately prior to exporting.
3. The international certificate referred to in paragraph two of this Article shall be printed, have a serial number and conform to the model certificate of the relevant international organizations or to the format and content requirements set forth by the importing country.
4. The procedure for issuing international veterinary (sanitary) certificates for consignments of food products, intended for export, shall be prescribed by the Chief State Sanitary Doctor of Ukraine or Chief State Veterinary Inspector of Ukraine.

#### SECTION VIII. INTERNATIONAL COOPERATION

#### Article 55. International Cooperation of Ukraine in the Sphere of Food Safety and Quality

International cooperation of Ukraine in the sphere of food safety and quality shall be conducted by means of:

- 1) Participation in the work of the relevant international organizations;
- 2) Conclusion of international agreements, including bilateral agreements on mutual recognition of sanitary measures;
- 3) Harmonization of sanitary measures and technical regulations with international standards, guidelines, and recommendations for food products, and with conformity assessment procedures.

#### Article 56. International Agreements of Ukraine

Should current international agreement of Ukraine, recognized as binding by the Verkhovna Rada of Ukraine, establish rules other than those provided in the this Law, rules of such international agreement shall prevail.

## SECTION IX. FINANCIAL SUPPORT

### Article 57. Financing of Services Rendered

All fees charged in connection with any administrative procedures, laboratory analyses, expertise, control and other procedures required in accordance with this Law shall be equal to their actual cost.

### Article 58. Financing of State Supervision

State supervision for objects subject to sanitary measures shall be conducted free of charge and financed from the general and special funds of the State Budget of Ukraine.

## SECTION X. RESPONSIBILITY

### Article 59. Responsibility for Violating Requirements of the Present Law

Violation of requirements of the present Law shall impose civil-legal, administrative and criminal liability stipulated by the law .

## SECTION XI. FINAL PROVISIONS

1. This Law shall come into force from the day of its publication, except for paragraph two of Article 33 and paragraph one of Article 35, which shall come into force from 1January 2010.
2. Until laws of Ukraine and other normative-legal acts of Ukraine are brought into compliance with the norms of this Law, they shall apply to the extent that they do not contradict this Law.
3. Within six months he Cabinet of Ministers of Ukraine shall:
  - 1) Submit for consideration of the Verkhovna Rada of Ukraine proposals on amending the laws of Ukraine resulting from this Law;
  - 2) Bring its normative-legal acts in compliance with this Law;
  - 3) Within competence of the Cabinet of Ministers of Ukraine ensure adoption of normative-legal acts envisaged by this Law;

- 4) Ensure revision and annulment by the ministries and other central bodies of executive power of Ukraine of their normative-legal acts, which are inconsistent with the present Law.

President of Ukraine  
Kyiv, 6.09.2005  
N 2809-IV