LAW OF UKRAINE

On basic principles of and requirements to safety and quality of food products

(Vidomosti Verkhovnoi Rady Ukrainy (VVR), 1998, No. 19, Article 98)

{As amended according to Laws
No. 2681-III dated 13.09.2001, VVR, 2002, No. Article 1, Article 2
No. 191-IV dated 24.10.2002, VVR, 2002, No. Article 48, Article 359
No. 2116-IV dated 21.10.2004, VVR, 2005, No. Article 2, Article 33
No. 2189-IV dated 18.11.2004, VVR, 2005, No. Article 4, Article 91
No. 2863-IV dated 08.09.2005, VVR, 2005, No. 51, article 557}
{As amended by Law
No. 2809-IV dated 06.09.2005, VVR, 2005, No. 50, article 533}
{As amended according to Laws
No. 1104-V dated May 31, 2007, VVR, 2007, No. 35, article 485
No. 1665-VI dated 22.10.2009, VVR, 2010, No. Article 4, Article 23
No. 1778-VI dated 17.12.2009, VVR, 2010, No. Article 9, Article 83
No. 2436-VI dated 06.07.2010, VVR, 2010, No. 46, Article 540
No. 2973-VI dated 03.02.2011, VVR, 2011, No. Article 33, Article 326
No. 5316-VI dated 02.10.2012, VVR, 2013, No. Article 38, Article 502
No. 406-VII dated 04.07.2013, VVR, 2014, No. 20-21, Article 712}
{As amended by Law
No. 1602-VII dated 22.07.2014, VVR, 2014, No. 41-42, Article 2024}
{As amended according to Laws
No. 67-VIII dated 28.12.2014, VVR, 2015, No. Article 4, Article 19
No. 867-VIII dated 08.12.2015, VVR, 2016, No. Article 4, Article 40
No. 1983-VIII dated 23.03.2017, VVR, 2017, No. 25, Article 289
No. 2042-VIII dated May 18, 2017, VVR, 2017, No. 31, Article 343
No. 2264-VIII dated 21.12.2017}

This Law regulates the relations between executive authorities, foodstuff market operators and consumers of foodstuffs, and outlines the provisions for ensuring the safety and individual quality indicators of foodstuffs produced, circulated, imported (forwarded) to the customs territory of Ukraine and/or exported (forwarded) from it.

Section I
GENERAL PROVISIONS

Article 1. Terms and definitions

1. In this Law the terms are used in the following meaning:

1) agro-food market - an entity that creates appropriate conditions for sale (wholesale) of agricultural products, including foodstuffs, in specially equipped and designated areas in accordance with the law;

{Clause 2 of Part 1, Article 1 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

3) risk analysis - a process consisting of three interrelated components: risk assessment, risk management and risk notification;

{Clause 4 of Part 1, Article 1 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

5) flavorants - products other than those having exclusively sweet, sour or salty taste that are not used separately and added to foodstuffs in order to provide them flavor and/or taste, or to modify the flavor and/or taste and may contain foods and/or flavorants, and/or nutritional supplements. Flavors include aromatic substances, aromatics, heat-treated flavorants, smoky flavorants, flavor precursors, as well as other flavorants and mixtures thereof, which do not fall under these categories;

{Clause 6 of Part 1, Article 1 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

7) safe food product - a food product that does not produce a harmful effect on human health and is suitable for consumption;

{Clause 8 of Part 1, Article 1 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

9) withdrawal of food products - measures aimed at preventing distribution, demonstration or offering unsafe food products to consumers;

10) production - activities related to production of objects of sanitary measures, including all stages of the process, namely, initial production, preparation, mixing and associated procedures, processing, filling, packaging, recycling, and other changes in the condition of the object;

11) recall of food products - measures aimed at the return of unsafe food products sold or handed over to consumers, or which is accessible to consumers;

12) appropriate international organizations - the World Health Organization (WHO), the Codex Alimentarius Commission, the International Office of Epizootics (OIE) and other international organizations that develop recommendations, guidelines, standards, and other health protection documents for protecting people from risks associated with using foodstuffs, as well as other individual food quality indicators;

13) pure sea water - natural, artificial or purified seawater that does not contain contaminating microorganisms or toxic marine plankton in quantities that can directly or indirectly affect the suitability of foodstuffs for consumption;

14) potable water - food product suitable for human consumption;

15) clean water - pure sea or fresh water, which corresponds to the safety indicators of pure sea water;

16) hygienic requirements - measures and conditions necessary for management of hazardous factors and ensuring the suitability of foodstuffs for human consumption, taking into account their intended use;

{Clause 17 of Part 1, Article 1 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

{Clause 18 of Part 1, Article 1 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

{Clause 19 of Part 1, Article 1 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

20) dietary supplement - food product, consumed in small defined quantities in addition to normal diet, which is a concentrated source of nutrients, including protein, fat, carbohydrates, vitamins, minerals (the list is not exhaustive), and made in the form of tablets, capsules, pills, powders, liquids or other forms;

21) auxiliary processing material - any material other than materials from which tools and equipment are produced which are not consumed by themselves and used in the manufacture or processing of a food product or its components to achieve a particular production purpose, resulted in the presence of residues or formation of derivatives in the final food product;

22) operating permit - an authorization document issued by a territorial authority of the competent authority of the market operator on the results of inspection of its establishments and certifying the right of the market operator to exercise the activities related to production and/or storage of foodstuffs of animal origin determined by this Law;

{Clause 22 of Part 1, Article 1 as amended by Law No. 2264-VIII dated 21.12.2017}

23) label - a tag, a label, or a sticker containing drawings or inscriptions, written, printed, printed with a stencil, pressed or indented and affixed to a food package unit;

24) contamination - presence or appearance of unsafe factor in a food product;

25) contaminating matter means any biological material, including organisms, microorganisms and their parts, or chemical, foreign impurity or other substance that has been not deliberately appeared in a food product and poses a threat to safety of the food product;

26) interested trading partner is a state and other subject of international law that is a party to multilateral and/or bilateral agreements, to which Ukraine is also a party, which regulates application

of sanitary measures, as well as a member of relevant international organizations, which include Ukraine;

27) catering establishment - a restaurant, bar, cafe, dining room, snack bar, pizzeria, cookery, a kiosk or other institution that provides food for an unlimited number of individuals. Attribution to public catering establishments does not depend on territorial features (place) of the economic activity in catering and a degree of accessibility of food to any persons;

28) ingredient - any substance, including nutritional supplements, flavorants and enzymes, ingredient parts used manufacture or preparation of a food product, remaining in the finished product, even in a modified form. Residues of veterinary medicines and pesticides are not considered ingredients;

29) information on food product – is an information on properties of a food product communicated to consumers in marking, adding accompanying material to it, means of electronic data transmission, or in any other way, including advertising;

30) final consumer - a consumer who uses a food product exclusively for his/her own consumption;

31) competent authority means a central executive authority that implements the state policy in the field of safety and individual food quality indicators;

32) component – an aggregate of ingredient(s) and substance(s);

33) corrective action - an action determined and implemented in order to eliminate the cause of a discrepancy identified;

{Clause 33 of Part 1, Article 1 as amended by Law No. 2042-VIII dated May 18, 2017}

34) correction - an action that is determined and implemented in order to eliminate the discrepancy detected, including the handling of unsafe food products, aimed at preventing their consumption by a person;

{Clause 34 of Part 1, Article 1 as amended by Law No. 2042-VIII dated May 18, 2017}

35) maximum residue limit (the maximum allowable level of residues) - maximum content of certain substances in foods, including pesticides, veterinary medicines, feed additives, residues of auxiliary material for recycling, or other chemical or biological substances deliberately used and/or required by technology of rearing/growing, storing, transporting, producing foodstuffs and their residues, including derivatives of such substances, such as products of conversion, metabolism, reactions, those that have toxicological significance and are unsafe to human body in the event of exceeding the maximum allowable level in foods consumed by humans;

36) maximum permissible level - a maximum permissible content (concentration) of contaminants in a food product that is permissible for such a product;

37) small establishments - establishments, supplying food to final consumers, which have no more than ten people of working personnel, occupy an area not exceeding 400 square meters, or establishments, which do not provide food to final consumers and have no more than 5-people staff;

38) marking - words, descriptions, marks for goods and services, trademark name, images or symbols relating to foodstuffs and placed on any packaging, labels (stickers), consumer containers, back labels, collar labels, tags, corks, leaflets, documents, messages, other packaging elements that accompany or belong to such foodstuffs;

39) methodical guidelines - guidelines for implementation of general hygiene requirements, as well as other requirements specified by the safety legislation and individual quality indicators of foodstuffs, developed by an associations of market operators and approved by the relevant state authority;

{Clause 40 of Part 1, Article 1 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

41) international standards, instructions and recommendations - standards, instructions, recommendations and other documents developed and approved by the relevant international organizations;

42) adequate level of protection of human health – a level of protection considered sufficient during taking sanitary measures for protection of human health and life from harmful effect, for which such sanitary measures are developed, in particular, an acceptable level of risk from occurrence of harmful effect;

43) unsafe factor in a food product means any chemical, physical, biological factor of a food product or its condition, which may cause harmful effect to human health;

44) unsafe food product - a food product that is unsafe to health and/or unsuitable for consumption.

When establishing a level of food product unsafety, the following should be taken into account:

normal conditions of use of the food product by consumers, each stage of its production, processing and circulation;

information provided to the consumer, in particular about marking, including information on the end-sale date, and other publicly available information for avoidance of adverse health effects associated with the food product or a category of foodstuffs.

When determining the unsafety of the food product for health, a due account should be paid to:

possible short-term or long-term impact of the food product on human health and on future generations;

possible toxicity accumulation effect:

special sensitivity of an organism of separate category of consumers, if the food product is intended for this category of consumers;

{Clause 45 of Part 1, Article 1 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

46) unprocessed food product - a non-processed food product, except for separation in parts, cutting, bone separation, chopping, breaking, removing the skin, cleaning, trimming, removing the shell or other cover, cooling, freezing and defrosting;

47) improperly marked food product - a food product is considered to be improperly marked if the marking does not meet the requirements of Article 39 hereof;

48) unfit food product – a food product that contains foreign matter and/or items damaged in a different way and/or damaged by mechanical, and/or chemical and/or microbial factors.

Unfit product has no harmful effect on human health in case of intended use under normal conditions;

49) novel food product or ingredient - a food product or ingredient that is substantially different from those of the usual foodstuffs or ingredients available on the market, that should be evaluated from the point of view of its effect on the health of consumers;

50) objects of sanitary measures - food, auxiliary materials for processing, objects and materials in contact with food;

{Clause 50 of Part 1, Article 1 as amended by Law No. 2042-VIII dated May 18, 2017}

51) circulation - selling and/or storing foodstuffs for sales purposes, including offering for sale and/or other form of transfer, sale, distribution or any other form of transfer irrespective of its payable of free distribution. Actions related to referral for recycling (change of intended use), withdrawal and/or recall, and/or disposal of food products are not considered the circulation;

52) tools and equipment - equipment, machines, kitchen tools and appliances, cutlery, tools and other means, the surfaces of which may come in direct contact with the food product during its production and circulation;

53) package unit means any package, including a wrapper, irrespective of the material and form, which partially or completely covers the food product, for its supply as a separate unit (the container may contain several packages). A unit of a product isolated from the rest by a technological packaging material (preventing sticking, freezing, mixing parts of products between themselves), as well as packaging, which is an element of serving at catering establishments is not considered a package unit;

54) individual food product quality indicators - indicators and/or properties of food products used to perform one or more tasks:

separation of traditional food product from other foodstuffs;

establishment of requirements for baby food, for foodstuffs for special medical purposes, and for foodstuffs, which are a complete substitute for conventional foodstuffs for weight control;

informing consumers about the properties of a food product, including by marking;

55) food market operator (the market operator) means an entity which carries out business with or without the aim of acquiring profit and managing establishments for initial production, production, sales and/or circulation of food products and/or other objects of sanitary measures (other than

materials that come in contact with food) and which is responsible for meeting the requirements of this Law, the safety legislation, and individual quality indicators of foodstuffs. The market operators cover individuals carrying out activities for or without profit and engaged in production and/or circulation of foodstuffs or other objects of sanitary measures. The agro-food market is also considered a market operator;

56) risk assessment - a scientifically substantiated process inclusive of identification of unsafe factors, characterization of the unsafe factor, an assessment of its impact, and characterization of the risk;

57) packaging - placing one or more primary foodstuffs in other package (container);

58) safety parameters - parameters, including maximum residue limits, maximum levels, permissible daily doses, levels of inclusions, non-compliance with which in food products may lead to a harmful effect on human health, scientifically substantiated and approved by the central executive body responsible for implementation of the state policy in the field of healthcare;

(59) batch means any quantity of food product of the same name and properties specified by market operator that has been produced for the time period specified by that operator under the same conditions of manufacture at the same establishments;

60) consignment batch – a consignment accepted for carriage from one sender to one or more receivers under one or more waybills/consignment notes;

{Clause 61 of Part 1, Article 1 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

62) initial product – a primary product that include plant products, livestock products, fisheries and hunting products;

63) initial production - production and cultivation of products, including harvesting, milking, animal breeding prior to slaughter, hunting animals, fishing and collecting wild plants;

64) initial packaging - packaging of foodstuffs in any wrapper or packaging (container) that is in direct contact with the food product;

65) risk notification – an exchange of information and findings throughout the process of risk analysis with regard to hazardous factors and risks, risk factors and perceptions of risk between risk assessment specialists, risk management, consumers, market operators and other stakeholders;

66) nutritional value - all major natural components of food products, including carbohydrates, proteins, fats, vitamins, minerals and salts;

{Clause 67 of Part 1, Article 1 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

{Clause 68 of Part 1, Article 1 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

69) establishments - buildings or complex of buildings, premises, buildings, equipment and other means, including vehicles, as well as a land plot used for production and/or circulation of objects of sanitary measures;

70) materials in contact with food, - items and materials that come in contact with food and thus may affect their safety and other product characteristics;

{Clause 71 of Part 1, Article 1 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

72) prerequisite program - basic conditions and activities that are mandatory for maintaining hygienic conditions at all stages of the foodstuffs manufacturing chain;

73) plant products - mushrooms, berries, vegetables, fruits and other food products intended for human consumption;

74) traceability - the ability to identify a market operator, time, place, subject and other terms of delivery (sale or transfer) sufficient to establish the origin of foodstuffs, animals intended for manufacture of foodstuffs, materials in contact with food or substances intended for inclusion, or expected to be included in food products, at all stages of production, processing and circulation;

75) selling - transfer, exchange, delivery under contracts, and alienation by other way of food products from one person to another irrespective of whether the transfer is paid or free, and/or in another form;

{Clause 76 of Part 1, Article 1 is deleted according to the Law No. 2042-VIII dated 18/05/2017}

77) risk - the possibility of occurrence of a harmful effect on human health and a degree of that effect, which comes from unsafe factor(s) in a food product;

78) level of inclusions - the maximum permissible amount (content) of a substance or ingredient that may be a part or added to a food product;

79) movable and/or temporary establishments - temporary facilities, movable vehicles intended for trade;

80) sanitary or phytosanitary measure - any measure conducted for the purpose of:

protection of life or health of animals or plants from the risks arising from penetration, rooting or spread of harmful organisms, diseases, organisms that are carriers of diseases, as well as pathogens;

protection of life or health of people and/or animals from the risks arising from additives, contaminants, toxins or pathogens contained in food or feed;

protection of life or human health from the risks arising from diseases transmitted by animals, plants or products produced from them, or as a result of penetration, rooting or spread of harmful organisms;

avoidance or limitation of other damage caused by penetration, rooting, or spread of harmful organisms.

Sanitary or phytosanitary measures, inter alia, include all regulations regarding food safety, animal health and plant quarantine; production processes; testing, inspection and approval procedures; quarantine regimes, including relevant requirements for transportation of animals or plants, or materials required for their survival during transportation; provisions on relevant statistical methods, sampling procedures and methods of risk analysis; packaging and labeling requirements that are directly related to the safety of foodstuffs;

81) Hazard Analysis and Critical Control Point System (HACCP) is a system that identifies, evaluates and controls hazards that are critical to the safety of foodstuffs;

82) production phases and circulation of foodstuffs - any stages, including production, storage, transportation, sale or delivery of foodstuffs to final consumers;

83) standard is a document developed by consensus and approved by an authorized organization that establishes rules, instructions or specifications that relate to activities or their results, including products, processes or services that are not mandatory. Standards may contain requirements for terminology, labels, packaging, marking or labeling applicable to a specific product, process or service. Standard does not include food safety requirements established by sanitary measures;

84) technical regulations - a normative legal act approved by a decision of the Verkhovna Rada of Ukraine, the Cabinet of Ministers of Ukraine, joint or individual decisions of European legislative bodies - the European Commission, the European Council, the European Parliament, which define the characteristics of products or related processes or methods of production, as well as requirements for services, including the relevant provisions, observance of which is mandatory. Technical regulations may also include requirements for terminology, labels, packaging, and marking that apply to a particular product, process or production process. Technical regulations do not include sanitary measures. In the absence of a technical regulation regarding a certain object of regulation approved by a decision of the Verkhovna Rada of Ukraine or the Cabinet of Ministers of Ukraine, if applicable, the technical regulations of the European Union should apply;

85) specifications - a document approved by a market operator, which specifies the technical requirements for foodstuffs and/or the processes of their production;

86) traditional food product - a food product with special characteristics that clearly distinguish it from other products of the same type as a result of using traditional ingredients and/or due to traditional composition and/or use of traditional production/processing technology. A traditional food product is one that is used in practice and/or meets the specifications that have existed for the past 30 years before determining whether a food product falls under the traditional category. Changes in packaging and labeling, which do not change the specific characteristics of the traditional product, do not influence on its definition as traditional;

{Clause 87 of Part 1, Article 1 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

88) risk management - a process of choosing alternative solutions based on the results of risk assessment and, if necessary, selecting and implementing appropriate management tools (controls), including corrective measures;

{Clause 89 of Part 1, Article 1 is deleted according to the Law No. 2042-VIII dated May 18, 2017}
{Clause 90 of Part 1, Article 1 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

91) food supplement - a substance that is not normally considered a food product or ingredient but is added to a food product for technological purposes during the production process and as a result becomes an integral part of the product (the term does not include pollutants, pesticides or substances added to foodstuffs to improve their nutritional properties);

92) food product - a substance or product (unprocessed, partially processed or processed) intended for human consumption. Food products include beverages (including potable water), chewing gum and any other substances specifically included in the food product during manufacture, preparation or treatment.

The term "food product" does not cover:

feed;

animals not intended for human consumption;

{Paragraph four of Clause 92 of Part 1, Article 1 as amended by Law No. 2042-VIII dated May 18, 2017}

plants (before harvesting);

medicines;

cosmetic products;

tobacco and tobacco products;

narcotic and psychotropic substances within the definitions of the United Nations Single Convention on Drugs of 1961 and the UN Convention on Psychotropic Substances of 1971;

residues and contaminants;

93) food product for special medical purposes - a specially designed and manufactured product that is consumed under a supervision of medical staff. This product is intended for partial or complete replacement of the usual diet of patients with limited, weakened or impaired ability to receive, digest, or absorb the usual foods or certain nutrients contained in them, or their metabolites. Food for special medical purposes may also be designated for fully or partially feeding patients with other needs specified by physicians that cannot be met by modifying the usual diet;

94) food product for weight control - a specially designed and manufactured food product intended for use in compliance with a low-calorie diet for weight reduction, which, when used in accordance with the instructions of the market operator replaces the daily diet;

95) food product of animal origin - milk, meat, fish, shellfish and crustaceans, including fresh, chilled or frozen, eggs, honey, their derivatives and other products made from animal parts, their separate organs and/or tissues intended for human consumption.

2. Other terms should be used in this Law in the meanings given to them in the Law of Ukraine "On state control over compliance with the legislation on food products, feed, animal by-products, animal health and welfare".

{Article 1 is supplemented by the second part according to Law No. 2042-VIII dated May 18, 2017}

Article 2. Safety legislation and individual food quality indicators

1. The legislation on safety and individual quality indicators of foodstuffs consist of the Constitution of Ukraine, this Law, and other legislative acts issued in accordance with it.

2. The safety legislation and individual food quality indicators must comply with the provisions of this Law. In the event of non-compliance of legislation on safety and separate quality indicators of foodstuffs, the provisions of this Law shall apply.

3. Standards for foodstuffs, research methods (tests) and sampling procedures are mandatory only in cases provided for by the Law.

4. If an international treaty of Ukraine, the consent to which has been given by the Verkhovna Rada of Ukraine, establishes rules other than those provided for by this Law, the rules of the international treaty(ies) shall apply.

Article 3. Scope of the Law

1. This Law applies to:

sanitary measures, objects of sanitary measures;

requirements for individual food quality indicators, including requirements for informing consumers about the properties of foodstuffs, including advertising foodstuffs;

market operators and establishments.

{Paragraph five of Part 1 Article 3 deleted according to the Law No. 2042-VIII dated May 18, 2017}

2. This Law shall not apply to foods designed (manufactured) for personal consumption, and supporting materials for processing and materials in contact with food, unless otherwise expressly stipulated in the Law.

Article 4. State regulation in the field of foodstuffs safety

1. State regulation in the field of foodstuffs safety is carried out in order to protect life, health and interests of consumers.

2. The state regulates safety and individual food quality indicators by:

establishing sanitary measures;

establishing requirements for individual food quality indicators;

state registration of the objects of sanitary measures specified in this Law;

issue, termination, cancellation and renewal of operating permits;

informing and outreach of market operators and consumers about safety and individual food quality indicators;

establishing health requirements for the staff;

participation in activities of relevant international organizations;

implementation of state control;

bringing market operators, their officials to responsibility in the events of violation of safety legislation and individual indicators of foodstuff quality.

Section II
POWERS OF CENTRAL AUTHORITIES IN THE FIELD OF SAFETY AND INDIVIDUAL FOOD QUALITY INDICATORS, LABORATORY STUDIES

Article 5. Central executive authorities in the field of safety and individual food quality indicators

1. The system executive authorities in the field of safety and individual food quality indicators include:

Cabinet of Ministers of Ukraine;

the central executive body, responsible for formulation and implementation of the state policy in the field of public health;

the central executive body, responsible for formulation and implementation of the state policy in the field of safety and individual food quality indicators;

the central executive body, responsible for the state policy in the field of safety and individual food quality indicators (the competent authority).

{Paragraph six of Part 1 Article 5 is deleted according to Law No. 2042-VIII dated May 18, 2017}

2. Other bodies of executive power and institutions shall not have the right to establish or otherwise regulate and/or perform the state control, including information on food, unless otherwise provided by this Law.

Article 6. Powers of the central executive body, responsible for formulation and implementation of state policy in the field of health

1. The central executive body, responsible for formulation and implementation of state policy in the field of public health:

establishes a proper level of protection of human health;

establishes a procedure for reporting food poisoning;

carries out state registration and keeps state registers of novel foodstuffs, food additives, flavorants, enzymes, and drinking mineral waters in accordance with established criteria.

2. The central executive body, responsible for formulation and implementation of state policy in the field of health, approves:

safety indicators for foodstuffs and other objects of sanitary measures;

{Paragraph 2 of Part 2 of Article 6 as amended by Law No. 2042-VIII dated May 18, 2017}

criteria for assigning drinking water to the category "potable mineral water";

{Paragraph 4 of Part 2 of Article 6 is deleted according to Law No. 2042-VIII dated May 18, 2017}

individual quality indicators of foodstuffs;

methodical guidelines and places them on its official site the next day after approval.

The central executive body, responsible for formulation and implementation of state policy in the field of public health, carries out other powers provided for by the Law.

Article 7. Powers of the central executive body, responsible for formulation and implementation of the state policy in the field of safety and individual food quality indicators

1. The central executive body responsible for development and implementation of the state policy in the field of safety and individual food quality indicators, approves:

hygienic requirements for production and circulation of foodstuffs;

the procedure for approval of export establishments, keeping the register thereof and amendments thereto;

regulations for animal slaughter.

The central executive body, responsible for formulation and implementation of the state policy in the field of safety and individual food quality indicators, exercises other powers provided for by this Law.

{Article 7 as amended by Law No. 2042-VIII dated May 18, 2017}

{Article 8 is deleted according to Law No. 2042-VIII dated May 18, 2017}

{Article 9 is deleted according to Law No. 2042-VIII dated May 18, 2017}

{Article 10 is deleted according to Law No. 2042-VIII dated May 18, 2017}

{Article 11 is deleted according to Law No. 2042-VIII dated May 18, 2017}

Section III
FUNDAMENTALS AND THE PROCEDURE FOR IMPLEMENTATION OF THE STATE CONTROL

{Article 12 is deleted according to Law No. 2042-VIII dated 18.05.2017}

{Article 13 is deleted according to Law No. 2042-VIII dated 18.05.2017}

{Article 14 is deleted according to Law No. 2042-VIII dated 18.05.2017}

Section IV
SANITARY MEASURES AND INDIVIDUAL QUALITY INDICATORS OF FOODSTUFFS

Article 15. Development, review, approval and application of sanitary measures

1. Appropriate sanitary measures are developed, reviewed and approved by the central executive body, responsible for formulation and implementation of the state policy in the field of public health, or by the central executive body, responsible for formulation and implementation of the state policy in the field of safety and individual food quality indicators within their authority and in accordance with the following requirements:

1) all sanitary measures are based on scientific principles and existing scientific substantiation, except for cases provided for in Clause 4 hereof;

2) if there are international standards, guidelines or recommendations, sanitary measures are developed on their basis, unless these international standards, guidelines or recommendations are sufficient to ensure an adequate level of human health protection;

3) in the absence or lacking international standards, instructions or recommendations to ensure an adequate level of protection of human health, sanitary measures are developed on the basis of risk assessment, taking into account the methods of risk assessment in accordance with the norms established by the relevant international organizations;

4) in the event of lacking scientific substantiation required for the risk assessment, or in the event of extraordinary circumstances that may cause or threaten to cause health problems, sanitary measures should be developed on the basis of existing relevant information received from relevant international organizations, or sanitary measures applied by interested trading partners.

2. All sanitary measures, including emergency measures, should be reviewed and updated in order to ensure that such measures are applied only to the extent necessary to protect human health if:

1) new scientific information is received;

2) significant comments from interested trade partners are received.

3. Sanitary measures should not restrict trade more than it is necessary to achieve appropriate level of human health protection, taking into account technical and economic feasibility.

4. An overview of the proposed sanitary measures and the procedure for obtaining information about them, as well as comments on their application, should be published in the mass media and on the official website of the executive body, which has developed appropriate sanitary measures.

5. All proposed sanitary measures not compliant with international standards or for which there are no international standards and which are expected to have a significant impact on export opportunities of interested trading partners should be communicated via the central executive authority to which execution of functions of the request processing center is assigned stipulated by the WTO Agreement on application of sanitary and phytosanitary measures, not less than 60 days before preparation of the final sanitary measure under the provisions of relevant international agreements.

6. Comments received as a result of notification and publication of the proposed new or changed sanitary measures should be taken into account on a non-discriminatory basis prior to adoption of such measures. Upon written request of persons or interested trade partners, the central executive authority, whose powers include the functions of the request processing center stipulated by the WTO Agreement on application of sanitary and phytosanitary measures, should provide the text of the proposed sanitary measure, indicating, if possible, the provisions that are significantly different from international standards, guidelines and recommendations.

7. In the event of an emergency, sanitary measures may be taken upon notification, provided such notification is made immediately and without delay.

8. All new and amended sanitary measures should be immediately published after their adoption in the relevant official printed media and on the official website of the executive body, which has developed appropriate sanitary measures, and enter into force not earlier than six months after the date of publication of the relevant measures.

9. In the event of emergency, as well as in the event of taking measures that reduce restrictions on import (forwarding) to the customs territory of Ukraine, sanitary measure may come into force on the date of acceptance, subject to subsequent publication in the corresponding official printed media.

10. All sanitary measures should be applied only to the extent necessary for protection of human health and without unreasonable discrimination between domestic and imported food products or between different suppliers of foodstuffs.

Article 17. Proper level of protection of human health

1. The central executive body, responsible for formulation and implementation of the state policy in the field of public health, defines the appropriate level of protection of human health from risks associated with food products.

2. The appropriate level of protection of human health is determined on the basis of:

1) general state of health of the population and risks inherent in the human environment;

2) standards, guidelines and recommendations of relevant international organizations;

3) minimizing the negative impact on international and domestic trade related to application of sanitary measures.

Article 18. Provision of information on appropriate sanitary measures

1. Upon request of any person in Ukraine or any other person of the state, the central executive authority, whose powers include the functions of the request processing center stipulated by the WTO Agreement on application of sanitary and phytosanitary measures, should provide any information on sanitary measures.

This information includes:

1) scientific substantiation of sanitary measures applied to imported and domestic foodstuffs;

2) procedures and means for assessing the risk to human health related to food products and data on assessment of such risks;

3) procedures and means of control of foodstuffs in Ukraine;

4) current instructions, requirements and procedures for inspection and control of foodstuffs;

5) information on membership and participation of Ukraine in relevant international organizations or international agreements on sanitary measures and texts of such agreements;

6) any other relevant information.

2. The provisions of the central executive authority, whose powers include the functions of the request processing center stipulated by the WTO Agreement on application of sanitary and phytosanitary measures, should be approved in accordance with the law, and the procedure for providing information and payment for conducting specified works and services should be established by the Cabinet Ministers of Ukraine.

Article 19. Rights of market operators

1. Market operators have the right to:

1) receive the following from the competent authority, in accordance with the established procedure:

duly executed documents resulting from implementation of state control of institutions and objects of sanitary measures under control of market operators, including acts of inspections, orders, protocols, and documents being the grounds for holding liable such market operators or their officials;

other information related to implementation of state control of establishments and objects of sanitary measures, managed by market operators;

2) prevent state inspectors, who did not present a certificate (referral) for carrying out an inspection measure, executed in accordance with the requirements of the law, and a document certifying the person of the state inspector before commencement of a control measure, from exercising the measure of state control.

A certificate (referral) for holding a measure should indicate:

a name of the competent authority;

a name of the market operator, and full name - for the individual entrepreneur subjected to the measure;

location of the market operator and place of residence of the individual entrepreneur subjected to the measure;

a number and date of order for implementation of the measure;

a list of officials involved in the measure, indicating their position, surname, name and patronymic;

start date and end date of the measure;

type of the measure (scheduled or unscheduled);

grounds for implementation of the measure;

subject of the measure;

information on implementation of the previous measure (type of the measure and term of its implementation). The certificate (referral) is considered valid only within a term specified therein.

Prior to commencing the measure, the officials of the competent authority are required to present to the market operator a certificate (referral) and a service certificate identifying the official of the competent authority, and provide a copy of the certificate (referral) to the operator.

An official of the competent authority without a certificate (referral) for implementation of the measure and official certificate shall not have the right to exercise state control over the market operator;

3) demand, including from state inspectors, the storage and non-disclosure of confidential information, except for cases provided by the Law;

4) challenge the results of laboratory research (tests), including arbitration;

5) order and use as evidence the results of arbitration investigations (tests);

6) challenge decisions of state inspectors;

7) apply for protection of their rights to the court;

8) demand compensation for damage caused by supply of unsuitable for consumption, improperly marked or unsafe objects of sanitary measures, provided they are used and stored in accordance with the instructions provided by the supplier of these objects of sanitary measures, or regulatory acts;

9) be dismissed by a court decision from reimbursement of losses related to unfitness for consumption and/or unsafety of objects of sanitary measures caused by violation by other persons, including consumers, of safety regulations and certain quality indicators of foodstuffs;

10) for compensation of losses caused by unlawful actions of state inspectors;

11) apply the approved guidelines;

12) for free access to legislation on safety and individual food quality indicators, in particular on official websites of the state authorities that have approved/adopted them;

13) in the absence of requirements for safety of food products to be manufactured in the normative legal acts of Ukraine, to apply the safety parameters specified in the documents of the relevant international organizations, in the absence of such parameters in the documents of the relevant international organizations - to apply the safety parameters established by law of the European Union. Compliance with the safety features indicated in this section means compliance with safety regulations and individual food quality indicators. The provisions of this clause do not apply to objects subject to state registration in accordance with the requirements of the Law.

Article 20. Duties of market operators

1. Market operators are responsible for ensuring compliance with the legislation on safety and individual food quality indicators within the activities they carry out.

2. Market operators must:

1) ensure compliance with the requirements of the Law regarding hygienic requirements for foodstuffs at all stages of their production and circulation;

2) develop, implement and apply standing procedures based on the principles of a system of analysis of hazardous factors and control at critical points, as well as provide proper training on application of standing procedures based on the principles of the system of analysis of hazardous factors and control in critical points of persons responsible for these procedures, during the production and circulation of foodstuffs;

3) notify the competent authority in cases stipulated in parts three to five of this Article and obtain operating permit(s) in cases stipulated by the Law;

4) register establishments in cases stipulated by the Law;

5) ensure compliance with safety legislation and individual quality indicators of foodstuffs in relation to individual quality indicators;

6) ensure traceability and provide information provided for in Article 22 hereof;

7) withdraw and/or recall, in cases established by the Law, foodstuffs in circulation, if these products were found to cause a harmful effect on human health;

8) provide free access to state inspectors performing state control to establishments during operation of these establishments and permit sampling of objects of sanitary measures at the above establishments, as well as provide, at request of state inspector(s), documents necessary for performance of the state control;

9) compensate harm caused to consumers as a result of consumption of food product in accordance with the law, if a court proves a causal link between this harm and actions and/or omissions of market operator, except for cases established by the Law.

3. If a market operator considers or has a reason to believe that foodstuffs it imports (forwards) to the customs territory of Ukraine, produced, processed or circulating do not meet the safety requirements, it should immediately commence a procedure for withdrawal of these foodstuffs from circulation, and within a term no more than two working days, informs in writing the competent authority. If such foods could potentially reach the consumer, the market operator should inform consumers about the reasons for withdrawal and, if necessary, recall food products, if other measures are not sufficient to achieve an acceptable level of consumer protection.

4. A market operator who retails or distributes foodstuffs, yet not packages or marks or otherwise affect the safety and integrity of food products, should initiate procedures for withdrawal from circulation of products that do not meet the safety requirements within a scope of its business. Such a market operator should promote the safety of foodstuffs, transmit the information necessary for ensuring the traceability of foodstuffs and any substances used for production of foodstuffs upon request of the persons concerned, and cooperate with market operators and/or the competent authority.

5. If the market operator has reason(s) to believe that the foods that it has brought to circulation may be harmful to human health, it should, within a period of not more than one working day, inform in writing the competent authority thereof, as well as the measures taken to prevent the risk to consumers.

6. A market operator should interact with the competent authority in measures for prevention of emergence or reduction of the risks constituted by the foodstuffs it has brought or introduced to circulation.

7. In the event of obtaining the information about non-compliance of establishments and objects of sanitary measures with established requirements of the legislation, revealed during the state control, the market operator is obliged to take necessary measures to correct such a non-compliance.

Article 21. Requirements for using standing procedures based on the principles of a system of analysis of hazardous factors and control at critical points

1. Market operators develop, implement and use standing procedures based on the principles of the system of analysis of hazardous factors and control at critical points.

2. The requirements of Part 1 of this Article shall not apply to market operators engaged in initial production and primary production, including transportation, storage and processing of primary products at the place of primary production, provided that this does not substantially changing the state of such products, as well as haulage of live animals intended for human consumption, haulage from the place of primary production to establishments manufacturing plant products, fishery products, and hunting products.

3. The principles of the system for analysis of hazardous factors and control at the critical points referred to in paragraph one of this article should cover:

1) identification of hazardous factors that should be prevented or eliminated or reduced to an acceptable level;

2) determination of critical control points at the stages at which control is critical for preventing the occurrence of hazardous factors, their elimination or reduction to an acceptable level;

3) establishment of critical boundaries at critical control points that make it possible to distinguish suitable food product from unsuitable in terms of its safety;

4) monitoring at critical control points that provide data for operational management of hazardous factors;

5) introduction of corrective actions if monitoring results suggest that a certain critical control point has come out of control;

6) development of procedures to be applied on an permanent basis in order to verify the effectiveness of measures referred to in Clauses 1-5 of part three hereof;

7) development of documents and records in accordance with a type of activity and production volumes to confirm the effective application of the measures specified in Clauses 1-6 of part three hereof.

4. Requirements for development, implementation and use of permanent procedures based on the principles of the system of analysis of hazardous factors and control at critical points allow using a simplified approach, provided that such an approach provides the same level of protection of health of consumers as in the event of introduction of the principles of a system of analysis of hazardous factors and control at critical points, as described in paragraph three hereof. The application of the simplified approach may, inter alia, include:

1) if, the results of the analysis of hazardous factors suggest the absence of critical control points, compliance with the general hygienic requirements for handling of food products specified in this Law is sufficient and introduction of a system of standing procedures based on the principles of the system of analysis of hazardous factors and control at critical points is not required. The foregoing applies to non-food establishments, namely retail establishments, including tents, kiosks, movable vehicles for trade, and catering establishments trading exclusively in beverages;

2) the possibility of partial implementing the principles of the system of analysis of hazardous factors and control at the critical points referred to in part three hereof. This applies to public catering establishments, except those specified in Clause 1 hereof, bakeries, and confectioneries;

3) the possibility of using standard plans of a system for analyzing hazardous factors and critical point control contained in methodological guides, which include information on hazardous factors,

prerequisite programs, critical checking and record keeping procedures. In this case, the use of a model plan for analysis of hazardous factors and control at critical points is possible only if the establishment meets a description contained in the methodological guidelines. This applies to slaughter, fish and dairy production establishments, establishments that carry out canning, pasteurization, and freezing foodstuffs;

4) in the event of using visual monitoring procedures, records are mede only in cases where non-compliance with established requirements is detected. Such records should include, inter alia, a description of corrections and corrective actions.

Lists of establishments specified in Clauses 1-3 hereof are not exclusive and can be expanded in the methodological guidelines.

5. In the event of changes in a quantitative and qualitative composition of food product ingredients, as well as at any production phases and circulation that may affect safety of the food product, market operators, should review and update procedures based on the principles of the system of analysis of hazardous factors and control at critical points, in order to make the necessary changes.

6. In order to carry out procedures based on the principles of a system of analysis of hazardous factors and control at critical points, market operators should:

1) provide evidence of conformity of their activities with the requirements of paragraph four hereof to the competent authority, carrying out state control, taking into account the scope of activity and volume of production, as well as simplified requirements for small establishments and establishments whose activities have a negligible degree of risk for consumers' health;

2) guarantee that documents describing the procedures developed in accordance with the requirements of this Article contain reliable information;

3) ensure storage of documents and records on implementation of the principles of the system of analysis of hazardous factors and control at critical points within three months after the end date of sale of food products, mentioned in the marking, unless otherwise provided by recommendations of the producer associations approved by the central executive body, responsible for formation and implementation of the state policy in the field of safety and individual food quality indicators.

7. Certification of standing procedures based on the principles of system of analysis of hazardous factors and control at critical points is not mandatory.

Article 22. Requirements for market operators regarding traceability

1. Market operators should be able to establish other market operators supplying them food and other objects of sanitary measures under a "one step back" principle.

2. Market operators should be able to establish other market operators to whom they supply food and other objects of sanitary measures under a "one step further" principle.

3. Requirements to market operators regarding traceability do not require them to establish connections (so-called internal traceability) between the objects of sanitary measures used during production and the objects of sanitary measures received as a result of such production.

4. In order to comply with the requirements of paragraphs 1 and 2 hereof, market operators should apply systems and procedures that ensure that such information is available to the competent authority upon request. The information must be kept for six months after the end date of the sale of the food product indicated in the marking.

Article 23. Operating permit

1. Operating permit should be obtained by market operators carrying out activities related to production and/or storage of food products of animal origin.

2. The obligation to obtain an operating permit shall not be applied in the part of relevant activity to market operators, involved in:

primary production of foodstuffs of animal origin, as well as related activities, in particular storage and handling of primary products at the place of primary production, provided the condition of such products is not substantially altered;

transportation of foodstuffs of animal origin, including those that require temperature control and cannot be stored at temperatures above 10°C, remaining suitable for human consumption;

storing foodstuffs of animal origin that do not require observation of temperature and can be stored at temperatures above 10°C, remaining suitable for human consumption;

production and/or storage of foodstuffs, the ingredients of which are exclusively plant products and/or processed products of animal origin;

operation of public catering establishments and retail establishments complying with the requirements established by the Cabinet of Ministers of Ukraine. By the time such requirements are established, this exception applies to all catering establishments and retail establishments.

{Part Two, Article 23 as amended by Law No. 2042-VIII dated May 18, 2017}

3. The persons referred to in paragraph 1 hereof are required to obtain an operating permit for each separate establishment before it is put into operation.

The operating permit is issued to establishments located at the same address (with details at the level of production line and/or foodstuffs depending on the type of operation carried out by the market operator) and identified by the market operator.

4. Operating permit is issued by a territorial office of the competent authority.

{Part Four, Article 23 as amended by Law No. 2264-VIII dated 21.12.2017}

5. In order to obtain an operating license, a market operator shall submit an application stating the name, identification code according to the Uniform state register of legal entities, individuals - entrepreneurs and public entities, place of residence or surname, name, patronymic, registration number of the tax payer's account number or series and passport number (for individuals who, because of their religious beliefs, refuse to accept the registration number of the taxpayer's registration card and have reported this to appropriate controlling authority and have a mark in the passport), the place of residence of the market operator, the name (description) of the establishment, its address, the planned activities and the list of foodstuffs planned to be produced or stored, the type of market operator by classification of economic entities defined by the Commercial Code of Ukraine (a subject of micro-, small, medium or large business). The application for issuance of the operating permit should be signed by the market operator or a person authorized by it.

{Part Five, Article 23 as amended by Law No. 2264-VIII dated 21.12.2017}

6. No later than 15 calendar days from a date of receipt by a territorial body of the competent authority of an application for issuance of an operating permit, an inspection of establishments should be carried out, the results of which determine its compliance with the requirements of the legislation.

{Part Six, Article 23 as amended by Law No. 2264-VIII dated 21.12.2017}

7. The grounds for refusal to issue an operating permit are:

1) absence of information required by law in the application for issuance of the operating permit;

2) providing of inaccurate information in the application for issuance of the operating permit;

3) establishment of non-compliance with the requirements of the legislation according to the results of inspection of the establishment;

4) failure to ensure adequate conditions for laboratory's work, in particular, failure to provide office equipped with heating, electricity, ventilation, cold and hot water supply, and sewerage, as stated by the agro-food market.

{Part Seven, Article 23 as amended by Law No. 2264-VIII dated 21.12.2017}

8. A refusal to issue an operating permit on grounds not provided for by this Law is prohibited. A decision to refuse to issue an operating permit must specify the grounds for refusal and factual circumstances that confirm the existence of such a ground.

{Part Eight, Article 23 as amended by Law No. 2264-VIII dated 21.12.2017}

9. A decision to issue or refuse to issue an operating permit shall be taken not later than 30 calendar days from the date of obtaining of relevant application of the market operator by the territorial body of the competent authority.

{Part Nine, Article 23 as amended by Law No. 2264-VIII dated 21.12.2017}

10. A copy of the decision on issuance or refusal to issue an operating permit shall be submitted (sent) to the market operator within three working days from the date of its adoption.

{Part Ten, Article 23 as amended by Law No. 2264-VIII dated 21.12.2017}

11. A decision to refuse the issue of an operating permit may be appealed to the competent authority or court.

{Part Eleven, Article 23 as amended by Law No. 2264-VIII dated 21.12.2017}

12. After eliminating the reasons for refusal to issue an operating permit, the market operator has the right to reapply with an application for issuance of the operating permit.

{Part twelve, Article 23 as amended by Law No. 2264-VIII dated 21.12.2017}

13. The establishments for which a decision has been made to issue an operating permit shall be assigned a registration number.

{Part thirteen, Article 23 as amended by Law No. 2264-VIII dated 21.12.2017}

14. For issuance of an operating permit, renewal of its action, an applicant is charged (administrative fee) in favor of the state budget a sum equal to 0.17 minimum wage established by the Law on January 1 of the calendar year in which the application for issue or renewal of the operating permit was filed. Reissue, issuance of a duplicate of the operating permit is free of charge.

{Part fourteen, Article 23 as amended by Law No. 2264-VIII dated 21.12.2017}

15. The issuance of an operating permit, its renewal should be made within two working days after obtaining of a confirmation of payment of the corresponding fee (administrative fee) by the territorial office of the competent authority.

{Part fifteen, Article 23 as amended by Law No. 2264-VIII dated 21.12.2017}

16. The validity period of operating permit is unlimited.

{Part Sixteenth, Article 23 as amended by Law No. 2264-VIII dated 21.12.2017}

17. The procedure for issuing and the form of operating permit should be approved by the Cabinet of Ministers of Ukraine.

{Part Seventeen, Article 23 as amended by Law No. 2264-VIII dated 21.12.2017}

18. Cancellation of an operating permit, its re-registration, issuance of a duplicate should be made on the grounds, in the manner and within the time limits established by the legislation on the permit system in the field of economic activity.

{Part Eighteen, Article 23 as amended by Law No. 2264-VIII dated 21.12.2017}

19. In the event of reconstruction of establishments for which an operating permit has been issued that results in a significant change of characteristics of the production facilities and technological processes or activities specified in the operating permit, the market operator must, no later than 15 calendar days before putting of the establishments to operation, apply to the territorial office of the competent authority for unscheduled inspection of the establishment. Inspection of such an establishment should be conducted within 15 calendar days from the date of obtaining relevant application from the market operator. The market operator has the right to restore the operation of the establishment after appropriate reconstruction, if the inspection results suggest the compliance of the establishment with the requirements of the legislation.

{Part nineteen, Article 23 as amended by Law No. 2264-VIII dated 21.12.2017}

20. The information contained in the operational permit should be entered in the register of market operators and establishments for which the operating permit has been issued by the competent authority in accordance with the procedure established by the central executive authority, responsible for formation and implementation of the state policy in the field of safety and individual food quality indicators.

{Part twenty, Article 23 as amended by Law No. 2264-VIII dated 21.12.2017}

21. The Competent Authority should provide free and unrestricted access to the register of market operators and establishments that have been issued an operating permit by placing it on its official website.

{Part twenty-one, Article 23 as amended by Law No. 2264-VIII dated 21.12.2017}

Article 24. Temporary suspension and renewal of operating permit

1. If a market operator fails to comply with the requirements of an order or other regulatory document for temporary cessation of the operation of the establishment or part of establishment and/or a temporary prohibition for circulation of objects of sanitary measures related to such violations within the technical feasibility period, a chief state inspector should issue a resolution on temporary cessation of operation permit (with details at the level of a production line and/or foodstuffs depending on the type of activity of the market operator).

2. In the event of a temporary cessation of an operation permit, information about it shall be entered to the relevant register and made public by the competent authority on its official website within three working days.

3. A market operator whose operation permit has been temporarily suspended shall not have the right to carry out production, sale and/or circulation of foodstuffs at such facilities.

4. A market operator, the operating permit for establishment of which has been temporarily suspended, may apply to the competent authority to renew the operating permit after eliminating the reasons that led to such a suspension.
5. An operation permit may be renewed in the order and within the terms established by Article 23 hereof.
6. A decision to temporarily suspend the operation permit may be appealed to the competent authority or court.
Article 25. State registration of establishments
1. Establishments engaged in production and/or circulation of foodstuffs, which are not required to obtain an operating permit are subject to state registration.
Vehicles used by market operator in connection with operation of another registered establishment or establishment owned by it, for which an operating permit has been issued, are not subject to state registration as a separate establishment. Vehicles used by market operators exclusively for transportation of foodstuffs, which are not related to the operation of its registered establishment or establishments, which are subject of an operating permit, should undergo cumulative state registration, for which a single application is submitted (independently of the number of vehicles concerned) and one personal registration number is assigned against the results of the application consideration. A vehicle used as an establishment for trade in foodstuffs to final consumers is subject to state registration as the separate establishment.
{Part One, Article 25 as amended by Law No. 2042-VIII dated May 18, 2017}
2. The state registration of establishments is carried out by the competent authority by entering the relevant information in the register for free. The establishments in the registry are assigned a personal registration number. The change of the name of the establishments` operator due to change of a type of the joint stock company or in connection with transformation of the joint stock company into another business entity is not a reason for operator`s appeal to the competent authority with a request to amend the register of establishments in part of the name of such an operator and not is a reason for making such changes in the registry. In the event of application of an operator whose name has been changed to the competent authority with written notification to amend the register in part of new name of such operator, the competent authority shall make such changes to the register free of charge, and report the fact in writing to the operator.
{Part Two, Article 25 as amended by Law No. 1983-VIII dated 23.03.2017}
3. Not later than 10 calendar days before the start of an establishment`s work, a market operator is obliged to submit (send) to the territorial office of the competent authority a statement on the state registration of the establishment, in which to specify the name, the identification code according to the Unified state register of legal entities, individuals – entrepreneurs and public entities, place or surname, name, patronymic, registration number of the taxpayer's account card or series and passport number (for individuals who because of their religious beliefs refuse to accept the registration number of the taxpayer's registration card and notify the relevant supervisory authority thereof and have an appropriate mark in the passport), the place of residence of the market operator, the name (description) of the establishment, its address, the planned activities, and the list of foodstuffs, production and/or circulation of which is planned, the type of market operator according to the classification of economic entities defined by the Commercial Code of Ukraine (subject of micro-, small, medium or large enterprises).
{Part Three, Article 25 as amended by Law No. 2264-VIII dated 21.12.2017}
4. An application for state registration of establishment should be certified by a signature of market operator or an authorized person thereof, and registered by the territorial office of the competent authority on the day of its receipt.
{Part Four, Article 25 as amended by Law No. 2264-VIII dated 21.12.2017}
5. The ground for refusal in the state registration of establishment is a mismatch of the application of the established form, the provision of incomplete information, or existence of previously adopted decision on the state registration of this establishment. Denial of state registration of establishments for other reasons is not allowed. The decision to refuse state registration of an establishment must contain the grounds for refusal and factual circumstances that confirm the existence of such a ground.
{Part Five, Article 25 as amended by Law No. 2264-VIII dated 21.12.2017}

6. A decision on the state registration of establishment or refusal of such registration should be taken within 10 calendar days after obtaining the corresponding statement from the market operator. A copy of the decision on the state registration of establishments or refusal of such registration should be provided (sent) to the market operator within three working days from the day of its adoption.
{Part Six, Article 25 as amended by Law No. 2264-VIII dated 21.12.2017}
7. A market operator should have the right to start operation of establishment on the principle of tacit consent, if within 15 working days after submission of the application for state registration of the establishment, a territorial office of the competent authority has failed to make a decision to refuse the state registration of the establishment, or to provide a copy of such decision to the market operator.
{Part Seven, Article 25 as amended by Law No. 2264-VIII dated 21.12.2017}
8. A market operator is obliged, within 10 working days, to inform a territorial office of the competent authority about changes in its activity, which necessitate changes in the information of the state register of enterprises of market operators, as well as termination of using the establishments.
{Part Eight, Article 25 as amended by Law No. 2264-VIII dated 21.12.2017}
9. If the results of the state control measure reveal unregistered establishment, the mandatory state registration of which is established by the Law, and sufficient information is received for its state registration, a territorial office of the competent authority should carry out state registration of such establishment on its own initiative and notify the market operator of the fact thereof.
{Part Nine, Article 25 as amended by Law No. 2264-VIII dated 21.12.2017}
10. The competent authority should provide open and free access to the state register of market operators by placing the information on its official website.
{Part Article 25 as amended by Law No. 2264-VIII dated 21.12.2017}
11. The central executive body, responsible for formulation and implementation of the state policy in the field of safety and individual food quality indicators should approve the procedure for state registration of establishments, keeping the state register of market operators, and provision of information from it to the interested parties.
{Part Article 25 as amended by Law No. 2264-VIII dated 21.12.2017}
Article 26. Approved export establishments
1. Establishments for production of foodstuffs intended for export from Ukraine (hereinafter referred to as the export establishments) should be approved by the competent authority, if required by the country of destination.
{Part One, Article 26 as amended by Law No. 2042-VIII dated May 18, 2017}
2. The competent authority should inspect export establishments for compliance with the requirements of the country of destination solely upon request of a market operator intending to export food to a destination country requiring the approval of an export establishment by the competent authority. The competent authority should approve the export establishment if the inspection results confirm its compliance with the requirements of the country of destination.
{Part Two, Article 26 as amended by Law No. 2042-VIII dated May 18, 2017}
3. The competent authority should keep a register of approved export establishments indicating the country of destination and each type of food product for which compliance with the requirements has been verified. The register is placed on the official website of the competent authority and updated not later than on the 15-th day of a current month.
Article 27. Changes to the register of approved export establishments
1. If an audit establishes that approved export establishments do not meet the declared requirements, chief state inspector should immediately inform the competent authority thereof.
2. If a non-compliance with declared requirements that does not pose a direct threat to the health of consumers is revealed during the inspection, a state inspector should be limited to warning the market operator of the need to correct such violations within a technically possible term, and make appropriate record in the act of state control. In the event of failure of the market operator to correct the detected violations specified in the act of state control, the competent authority should decide to exclude establishments referred to in paragraph one hereof or certain types of foodstuffs produced on such facilities from the register of approved export establishments.

3. A market operator may appeal a decision to exclude establishments referred to in paragraph one of this article or certain types of food products produced on such facilities from the register of approved export establishments to the court.
4. In the event of taking a decision to temporarily suspend or exclude approved export establishments or certain types of food products produced on such facilities, the competent authority of Ukraine must immediately notify the competent authority of the country of destination of the fact.
5. The competent authority of the destination country for which the compliance with the requirements has been verified by the competent authority of Ukraine should have unimpeded access to approved export establishments for the purpose of inspection of such establishments for compliance with the established requirements. The competent authority of the destination country is obliged to notify the competent authority of Ukraine of the said inspection within 48 hours.
6. If the results of inspection of approved export establishments for verifying compliance with the requirements by the competent authority of the destination country suggest that such establishments do not meet the established requirements, the competent authority of Ukraine should decide on temporary cessation of the establishments` operation or their exclusion from the register. According to this opinion, the said decision of the competent authority of Ukraine may not be subject to appeal.
{Article 28 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

Section V
STATE REGISTRATION OF OBJECTS OF SANITARY MEASURES

Article 29. State registration of objects of sanitary measures

1. It is prohibited to sell objects of sanitary measures not registered in accordance with the requirements of the Law.

2. The following items are subject to state registration:

1) novel food products;

2) food supplements;

3) flavorants, except for a separate group of flavorants, determined by the central executive body, responsible for formulation and implementation of the state policy in the field of public health;

4) enzymes;

5) auxiliary materials for processing, and materials in contact with food, which are first introduced into circulation and/or are used in the territory of Ukraine for the first time;

6) potable water, which is planned to be classified as "natural mineral water".

3. It is prohibited to require registration of objects of sanitary measures not specified in paragraph two hereof.

4. For the state registration of objects of sanitary measures, market operator or its authorized representative should submit an application of an arbitrary form accompanied by documentation in accordance with requirements of this Law, to the central executive body responsible for formation and implementation of the state policy in the field of public health.

5. The grounds for refusal of state registration of objects of sanitary measures are presence of evidence of their non-compliance with the safety legislation and individual quality indicators of foodstuffs.

6. The procedure, methods and volume of necessary research (tests) for state registration shall take into account a degree of risk posed by the objects of registration to human health, as well as the fact that the said objects of sanitary measures are approved by the relevant international organizations or the European Union.

7. The state registration of the specified objects of sanitary measures should be carried out free of charge.

8. The state registration of the objects referred to in paragraph 2 hereof, with the exception of the novel foodstuffs and food supplements, should be conducted within 30 working days after receipt of the application for such registration.

The state registration of the novel foodstuffs should be made within 180 business days of receipt of the application.

The state registration of food supplements should be made within 120 working days after receipt of the application.

9. If the state registration is not completed within the period of time specified in paragraph eight hereof, a customer should be provided with a written justification of the reasons for extending the registration period, which cannot be extended for more than 30 working days.

10. The central executive body, responsible for formation and implementation of the state policy in the field of public health, should approve the procedures for conducting state registration, keeping registers and provision of information from registers to interested parties.

11. The state registers indicated in this Article should be published on the official web-site of the central executive body, responsible for formation and implementation of the state policy in the field of public health, which should update them as new information comes, but not later than 10 working days from the day of registration of the object of sanitary measures.

Article 30. State registration of food supplements

1. Only food supplements included in the State Register of food supplements are permitted for use in circulation and production of foodstuffs.

2. The central executive body, responsible for formulation and implementation of the state policy in the field of public health, should perform state registration and keeping the State Register of Food Supplements. The State Register of Food Supplements contains, inter alia, the data on maximum allowable levels for the cases when uncertainty may endanger the health of consumers. The state register of food supplements also lists food products for production of which they are used.

The central executive body, responsible for formulation and implementation of the state policy in the field of public health, should amend the State Register of Food Supplements:

1) on its own initiative in cases of:

creation of an initial state register of food supplements;

exclusion of a food additive from the State Register of food supplements, if there is an evidence of its non-compliance with the requirements established by law;

2) upon appeal of market operators or their associations after state registration.

Food supplements recognized by the European Union as safe for human consumption are a part of the State Register of Food Supplements. Inclusion of these food supplements in the State Register of Food Supplements does not depend on approval or any other action regarding creation and/or keeping of the State Register of Food Supplements by the central executive authority, responsible for formation and implementation of the state policy in the field of public health.

3. During state registration of food supplement it is necessary to:

1) determine food products to which this supplement may be added and, if necessary, the conditions under which it may be done;

2) limit the food supplement to the lowest level of use that is necessary to achieve the desired effect;

3) take into account any allowable daily intake or amount of dietary supplement and its likely daily intake from all sources, including the possible daily consumption of food supplements by special groups of consumers.

4. A food supplement may only be registered if:

1) there is a reasonable technological need for the food supplement;

2) using the food supplement does not mislead the consumer;

3) the food supplement does not, according to available scientific data, cause a harmful effect on human health in the amount intended to be used.

5. Any market operator or association of market operators may apply for a state registration of a food supplement by submitting an application form to the central executive body, responsible for formation and implementation of the state policy in the field of public health, for state registration of the food supplement accompanied by relevant documentation, indicating that the food supplement meets the provisions of part four hereof.

If the food supplement is allowed for use by relevant international organizations, the information confirming this should be attached to the registration application. A decision to register or refuse to register the food supplement for production of foodstuffs in Ukraine or circulation of foodstuffs containing such a food supplement should be taken within 120 working days after receipt of the application.

6. A food supplement for which an application has been registered and which is allowed for use by relevant international organizations is subject to express registration procedure.

7. The express registration procedure includes a review of the report of relevant international organizations, which substantiate the possibility of using the food supplement. This review should take into account the circumstances and conditions specific to the population of Ukraine (if any), as well as technical and economic feasibility of determining the presence and/or level of use of the food supplement in food products in relation to the levels of inclusions approved by the relevant international organizations.

8. In accordance with the express registration procedure, a decision on registration or refusal to register a food supplement for production of foodstuffs in Ukraine or circulation of foodstuffs containing such a food supplement should be taken within 30 working days after receipt of the application and related documents, and should be communicated to the applicant.

Article 31. State registration of auxiliary materials for processing, materials in contact with food products, and drinking water

1. The central executive body, responsible for formation and implementation of the state policy in the field of public health, should perform state registration of auxiliary materials for processing, materials in contact with food products, and drinking water planned to be classified as "natural mineral water".

2. The reasons for the state registration are:

1) for auxiliary materials and materials in contact with food – an application of a market operator or its authorized representative in an arbitrary form and a dossier for auxiliary material and/or material in contact with food in a form approved by the central executive body responsible for formation and implementation of the state policy in the field of public health;

2) for drinking water which is planned to be classified as "natural mineral water" - an application of a market operator or its authorized representative in an arbitrary form and documentation on the results of research (tests) of water, and a description of the source from which it is obtained in a form, approved by the central executive body, responsible for formation and implementation of the state policy in the field of public health.

3. Auxiliary materials for processing and materials in contact with food circulating in Ukraine should not be a source of dangerous factors in foodstuffs in quantities exceeding the maximum residual limits.

4. The central executive body, responsible for formation and implementation of the state policy in the field of public health, defines the terms of use, the maximum limits of residues in food processing materials and materials in contact with food products.

5. State registration may be refused on the following grounds:

1) for auxiliary materials for processing and materials in contact with foodstuffs - in the event of evidence of inconsistency of these objects with the requirements of legislative acts on their safety, and in the absence of such acts – with similar requirements laid down in the regulatory documents;

2) for drinking water, which is planned to be classified as "natural mineral water" - in the event of evidence of its unsafety and/or non-compliance with the requirements of legislation on natural mineral water.

Section VI
PRODUCTION TA CIRCULATION FOODSTUFFS

Article 32. Requirements to foodstuffs

1. Food products that are in circulation in the territory of Ukraine must meet the requirements of safety legislation and individual quality indicators of foodstuffs.

In the event of evidence of harmfulness of a food product, regardless of its compliance with safety legislation and individual food quality indicators, production and circulation of such a food product must be stopped and prohibited.

2. Certification of foodstuffs is optional. This does not apply to the procedure for issuing an international certificate stipulated by the Law.

3. During production of foodstuffs, market operator can use the technical specifications, state registration of which is optional.

4. When producing foodstuffs in Ukraine it is prohibited to:

1) use food supplements that are not registered in Ukraine in accordance with the requirements of the Law;

2) use flavorings not registered in accordance with the requirements of the Law;

3) use of auxiliary materials for processing and materials in contact with foodstuffs, if they are not registered in accordance with the requirements of the Law.

5. Food products exported from Ukraine must comply with the requirements of the Ukrainian legislation on safety and individual quality indicators of foodstuffs, except for cases when:

1) such requirements to foodstuffs are established by the country to which the foodstuffs are exported; or

2) such requirements to foodstuffs are established in bilateral agreements of Ukraine with a country to which the foodstuffs are exported.

6. Enterprises included in the register of exporters are prohibited using raw materials obtained by slaughtering animals at facilities having no operating permit.

Article 33. Development, approval and application of methodological guidelines

1. Market operators may use methodical guidelines while producing foodstuffs.

2. Compliance with methodological guidelines indicates the fulfillment of the requirements specified by law.

3. Methodical guidelines are developed by associations of market operators and approved in accordance with the requirements of the Law.

4. Start of development of methodological guidelines is announced and the projected text is placed on the official web site of the state authority, which will further approve them. The draft methodological guidelines should be published on the Internet within 10 business days from the date of submission of the project to the association of market operators that has developed it.

5. The text of the announcement should contain the following information:

1) the name and contact details (telephone, postal and electronic addresses) of the association of market operators, developer of methodological guidelines;

2) the purpose of the development;

3) the provisions of the regulatory act subject to clarification.

6. A developer of methodological guidelines is obliged to work out the project, taking into account the comments and suggestions of interested parties, provided in writing, and publish their list with a shortened statement of contents and conclusions on the official web site of the state authority, which will further approve the methodical guidelines.

7. A developer of methodological guidelines should provide a revised draft and a list of comments and suggestions to the public authority, which will further approve the methodical guidelines, which should consider them within 30 working days for the purposes of:

1) conformity of the methodological guidelines with the provisions of current legislation on safety and individual food quality indicators, and in no any available - the provisions of documents of the relevant international organizations;

2) assessment of the possibility of applying the provisions of methodological guidelines in practice.

8. In the event of non-compliance of the draft guidelines with the requirements of the fifth and seventh part hereof, the draft methodological guidelines should be returned to the developer with a detailed explanation of impossibility of its approval within 10 working days.

9. After revision of the draft methodological guidelines with due account to comments, the developer of methodical guidelines may re-submit it for approval to the appropriate state authority in accordance with parts five-eight hereof.

Article 34. Slaughter of animals

1. It is prohibited to slaughter animals not accompanied by a veterinary document certifying animal health.

2. It is prohibited to slaughter domestic ungulate animals, wild mammals grown on a farm, other than hares, and slaughter of poultry and rabbits at a slaughterhouse without an operating permit. This provision does not apply to slaughter of said animals in a quantity not exceeding three units of domesticated animals or other ungulate animals per week, subject to pre-slaughter and post-mortem

inspection by a state veterinary inspector or an authorized veterinarian in accordance with the procedure approved by the central executive body, responsible for formation and implementation of the state policy in the field of safety and individual food quality indicators and in the field of veterinary medicine, as well as five poultry unit, rabbits per day.
{Paragraph one of the second part of Article 34 as amended by Law No. 2042-VIII dated May 18, 2017}

From January 1, 2025, products obtained as a result of slaughter at a slaughterhouse without an operating permit may be used exclusively for own consumption or sale on agro-food market to final consumers within 50 kilometers from the slaughter site or in the area in which it was performed.
{Part Three, Article 34 is deleted according to the Law No. 2042-VIII dated May 18, 2017}
{Part Four, Article 34 is deleted according to the Law No. 2042-VIII dated May 18, 2017}
{Part Five, Article 34 is deleted according to the Law No. 2042-VIII dated May 18, 2017}
{Part Six, Article 34 is deleted according to the Law No. 2042-VIII dated May 18, 2017}
{Part Seven, Article 34 is deleted according to the Law No. 2042-VIII dated May 18, 2017}
{Part Eight, Article 34 is deleted according to the Law No. 2042-VIII dated May 18, 2017}
{Part No, Article 34 is deleted according to the Law No. 2042-VIII dated May 18, 2017}
{Part Ten, Article 34 is deleted according to the Law No. 2042-VIII dated May 18, 2017}
{Part Eleven, Article 34 is deleted according to the Law No. 2042-VIII dated May 18, 2017}
{Article 35 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

Article 36. Circulation of foodstuffs on agro-food markets

1. Whole carcasses or parts of carcasses of ungulates and hoofed animals, poultry, rabbit and small wild game carcasses, fish, honey, eggs, unprocessed milk, home-made cheeses and plant products may be sold on agro-food markets under condition of confirmation of their fitness based on the results of research (testing) by an accredited laboratory located on the agro-food market, and/or a state inspector available on the same market. Non-domestic foods accompanied by documents that ensure traceability of products should not be subjected to the above testing.

2. The suitability mark shall be put by a state inspector working at the agro-food market on whole carcasses or parts of carcasses of ungulates and hoofed animals, poultry, rabbit and small wild game carcasses, which suitability for human consumption has been confirmed, according to the research (testing) results provided by an accredited laboratory located on the agro-food market. The state inspector should confirm the suitability for human consumption of plant products, as well as raw milk and home-made cheese against the results of research (testing) by the accredited laboratory.

3. Notches on the surface of a whole carcass, indicating inappropriateness of the product for human consumption are applied on carcasses unfit for human consumption which cannot be used for human consumption according to results of laboratory research (testing).

4. Unfit for human consumption food product, which does not pose a direct threat (low risk) to human health, is not allowed for selling and should be disposed of by the owner. The food product unfit for human consumption, which poses an immediate (high risk) threat to human health, is subject to immediate withdrawal by the owner and disposal of or destruction under control of the state inspector in accordance with the law.

5. An agro-food market is prohibited to work without an accredited laboratory available in it.

Article 37. Requirements for circulation of objects of sanitary measures

1. The following actions are prohibited:

1) circulation of foodstuffs at facilities that do not meet the requirements of sanitary measures;

2) sale of home-made foodstuffs out of agro-food markets;

3) circulation of unprocessed carcasses of ungulate animals without suitability mark on packaging;

4) circulation of foodstuffs produced at facilities failed to obtain operating permit provided for by this Law or with temporarily suspended operation permit;

5) circulation of foodstuffs produced at facilities, the notification of registration of which has not been done by a market operator according the requirements of this Law;

6) circulation of foodstuffs containing genetically modified organisms or obtained using them prior to their state registration;

7) circulation of unprocessed foodstuffs of pork for human consumption without appropriate veterinary documents in the event of confirmation of outbreaks of diseases unsafe for the health of humans or animals, by a decision of the central executive body implementing the state policy in the field of safety and individual food quality indicators .

{Part One, Article 37 is supplemented by Clause 7 according to Law No. 867-VIII dated 12/08/2015}

2. It is also prohibited to circulate objects of sanitary measures if these objects are:

1) unsafe;

2) unsuitable for consumption;

3) incorrectly marked;

4) unregistered in accordance with the requirements of the Law;

5) imported (forwarded) to the territory of Ukraine by smuggling.

Food products specified in Clauses 2 and 3 hereof are subject to withdrawal from circulation and/or recall in accordance with the requirements of the Law.

3. Objects of sanitary measures withdrawn from circulation in connection with violation of Clauses 3 and 4 of part two of this article may be returned to circulation after correction of marking or state registration in accordance with the procedure established by the Law.

4. Removed objects of sanitary measures that cannot be returned to circulation should be used for purposes other than consumption by humans, or may be destroyed in accordance with the procedure established by the Law.

5. Destruction of objects of sanitary measures, returning them to circulation for human consumption, or for other purposes should be carried out by a market operator at its expense. The procedure for destruction of objects of sanitary measures or conditions that must be fulfilled by the market operator for their return to circulation for human consumption, or for other purposes shall be established by the central executive body, responsible for forming and implementation of the state policy in the field of safety and individual food quality indicators.

6. In the event if any unsafe foodstuffs are part of a single batch or consignment with foodstuff, it is considered that all foodstuffs of this denomination in this batch or consignment are also unsafe, and their further circulation is prohibited unless further detailed assessment proves the rest of the batch or consignment is safe.

7. Unless otherwise provided by the Law, the only document to accompany the objects of sanitary measures during their transportation (forwarding), which are not related to export or import operations, should be a consignment note/waybill.

{Part Seven, Article 37 as amended by Law No. 2042-VIII dated May 18, 2017}

Article 38. Production and circulation of novel food product or ingredient

1. The novel food product or ingredient must be such that:

1) does not pose a threat to human health;

2) its characteristics do not mislead the consumer;

3) if a novel food product is designed to replace regular one, the amount of nutrients and other substances, the energy that consumers receive under normal conditions of consumption should not differ more from the values of natural variations of those obtained from the regular food product.

2. Circulation of novel food product or ingredient is prohibited in the absence of state registration to be provided by the central executive body, responsible for formation and implementation of the state policy in the field of public health.

3. The criteria that distinguish a novel food product or ingredient from a regular one are the following:

1) a food product or ingredient does not have a history of safe consumption in Ukraine and has a significant change and/or influence due to:

application of a process of animal rearing and/or plant cultivation that has not previously been used for these purposes;

production by applying a production process that has not previously been used for this type of products or ingredients;

2) A food product or ingredient does not have a history of safe consumption in Ukraine but has a history of safe consumption in other country(s) and a significant change and/or influence.

4. The term a "history of safe consumption" refers to data on consumption of a food product or ingredient as part of a normal diet of population of a country or part of the country that does not include data on the adverse effects of such a product or ingredient on human health. Such data may include, in particular, the results of scientific research and/or statistical observations.

5. The term "significant change and/or influence of a food product or ingredient" means a change and/or influence of a food product or ingredient that, according to the market operator's experience and/or according to the scientific data, exceeds more than 100 percent of the value of the regular (those occurring earlier) variations in the regular foods or ingredients, or those variations that have occurred in already registered novel foods or ingredients, with the following parameters:

1) composition, structure, nutritional value of a food product or ingredient, its physiological effect;

2) the way in which a food product or ingredient is metabolized in a human body;

3) safety of a food product or ingredient.

6. The novel foodstuffs do not include unprocessed foods that do not have a history of safe consumption in Ukraine but have a history of safe consumption in other countries or parts of the world.

7. The novel foodstuffs does not include potable water of any origin in any containers.

8. A market operator who intends to introduce novel food products in circulation in the territory of Ukraine, should apply for state registration to a central executive authority, responsible for formation and implementation of the state policy in the field of public health. The application should be accompanied by a document containing information that the novel food product meets the provisions of Part 1 hereof.

9. State registration should be made within the term specified in Article 29 hereof.

10. The exclusive cause for refusal of the state registration of novel food is a non-compliance with the requirements of the Law.

11. After state registration and introduction of a novel food product or ingredient in the Register of the novel foodstuffs or ingredients, any market operator has the right to manufacture and to bring such a food product or ingredient into circulation, subject to the provisions of the intellectual property law.

12. The provisions of this Article shall not apply to production and/or circulation of a novel food product containing, consisting of, or produced from genetically modified organisms, as well as food supplements, flavorants and enzymes.

Article 39. Requirements for marking foodstuffs

1. Foodstuffs whose marking does not meet the requirements of safety legislation and individual foodstuffs quality indicators are prohibited to circulate.

2. Marking of foodstuffs should provide consumers with information that enables them to make a choice of food product according to the needs of the consumers.

3. All food products in circulation in the territory of Ukraine shall be marked in the official language.

4. In the event of presence of genetically modified organisms (GMOs) in a food product in amounts exceeding 0.9 per cent in any ingredient of a food product containing, consisting of, or produced of genetically modified organisms, the food product marking must include the "GMO" mark.

5. The market operator may optionally include the wording "no GMO content" in the marking. In this case, the absence of GMOs in the food product should be confirmed in accordance with the requirements of safety legislation and individual quality indicators of foodstuffs. Unavailability of the data on the presence of GMO in ingredients is a sufficient evidence for application such a mark on a food product.

6. Marking of food product should be made in the state language. According to a decision taken by a market operator, a translation into other languages may be placed nearby the text in the official language.

7. The marking may indicate certain substances and their amounts without indicating the properties that a food product has due to these substances. In this case, a market operator must have

evidence of the content of these substances, which may include, inter alia, the results of research (tests) belonging to the market operator, other entities or suppliers of ingredients.

8. It is prohibited to use the following items for advertising dietary supplements:

1) statements about possible therapeutic action, painkilling effect;

2) letters of gratitude, acknowledgment, advice, if they relate to treatment or relief of condition of the disease, as well as references to such information;

3) statements that cause or contribute to emergence of a feeling of negative psychological state.

9. Requirements to marking foodstuffs defined in other regulatory acts should not conflict with the provisions of this Article.

Section VII
GENERAL HYGIENIC REQUIREMENTS CONCERNING FOOD HANDLING

Article 40. General requirements for market operators who carry out initial production and keeping records of foodstuff safety

1. In order to ensure safety of primary products during initial production, transportation, storage and other management of primary products at the place of its production and transportation of live animals, as well as health protection, market operators should take the measures concerning:

1) management of hazardous factors;

2) ensuring healthy status of plants and animals that have an influence on human health, including implementation of plans of state monitoring, control of zoonoses and their pathogens.

2. Market operators engaged in breeding, hunting animals or primary production of products of animal origin:

1) support establishments engaged in production and/or circulation of primary products and related activities, including establishments for storage and preparation of feed in cleanliness by cleaning, washing and disinfection;

2) maintain cleanliness of equipment, tools and vehicles by cleaning, washing and disinfection;

3) provide appropriate level of cleanliness of animals to be slaughtered and, if necessary, cleanliness of animals used for production of foodstuffs;

4) use potable or clean water at establishments for prevention of contamination;

5) provide access to production and/or circulation of foodstuffs of personnel whose health does not pose a threat to food safety and who has undergone a compulsory medical examination and training (preparation), which must be documented;

6) take effective measures to control pests;

7) store and remove waste and hazardous substances in the most safe way in order to prevent contamination;

8) report to the competent authority on suspicious outbreaks of diseases associated with the emergence of new animals to prevent ingress and spread of diseases transmitted to humans through a food product;

9) use results of samples` research (testing);

10) use veterinary medicines and feed additives in accordance with the requirements of the legislation.

3. Market operators engaged in harvesting or production of plant products are required to carry out actions referred to in paragraph 2 hereof in addition to actions referred to in Clauses 3, 8 and 10, as well as to use plant protection assets in accordance with the requirements of the legislation.

4. In the event of obtaining information about non-compliance of establishments with the requirements of the Law found during the state control, market operator should take all necessary measures to eliminate such non-conformities.

5. In order to ensure a high level of foodstuff safety and rapid response in the event of detecting cases that can cause a harmful effect on human health, market operators are required to:

1) keep records of measures taken to manage hazardous factors and keep them within three months after the end date of sale of food product bearing the marking;

2) provide to the competent authority or market operators who receive primary products the information referred to in this Article upon request.

6. Market operators involved in breeding, hunting animal or primary production of foodstuffs of animal origin shall keep records of:

1) type and origin of feed;

2) veterinary preparations for animals, date of their administration, waiting time, after which the use of animals and/or foodstuffs of animal origin is allowed;

3) the presence of animal diseases that may affect the safety of foodstuffs;

4) the results of research (tests) of samples obtained from animals or other samples taken for diagnostic purposes;

5) data on inspections of animal and/or food products.

7. Market operators involved in harvesting or production of plant products should keep records of:

1) the use of plant protection means;

2) the presence of harmful organisms or diseases that may affect the safety of foodstuffs of plant origin;

3) the results of relevant research (tests) of samples of plants or other samples.

Article 41. Hygienic requirements to establishments

1. Establishments at which production and/or circulation foodstuffs are carried should meet the following requirements:

1) be maintained in a clean and working condition;

2) be planned, constructed and located for proper management, cleaning and/or disinfection, preventing or minimizing any contamination, as well as taking measures required for meeting hygienic requirements, including pest control, preventing accumulation of dirt, contact with toxic substances and materials, contamination of foodstuffs, maintenance of necessary temperature regimes;

3) have proper natural or mechanical ventilation. The ventilation system should be designed in such a way as mechanical air flow from the contaminated area does not fall into the clean zone, and ensure free access to filters and other parts that need to be cleaned or replaced;

4) be provided with proper natural and/or artificial lighting of the premises required for production and/or storage of foodstuffs;

5) the floor must have sufficient drainage system, the structure of which prevents the risk of contamination. With open and/or partially open drainage channels, the waste movement must be from clean to contaminated area.

2. The provisions of this Article should not apply to market operators specified in Articles 40, 43 and 44 of the Law.

Article 42. Hygienic requirements to premises for processing or reprocessing of foodstuffs

1. The design and planning of the premises should ensure proper level of hygiene requirements for foodstuffs, including protection from contamination during and between operations with food products.

For that purposes, premises in which food products are processed and/or reprocessed must meet the following requirements:

1) non-penetrating, non-absorbing, non-toxic and washable materials, or other materials that ensure compliance with the appropriate level of hygienic requirements for protection of foodstuffs, including from contamination, during and between operations with foodstuffs, should be used for walls and floors of the premises;

2) the ceiling (or inner surface of the roof in the absence thereof) and upper anchoring elements should be constructed so that prevent accumulation of dirt, formation of undesirable mold, and drop of structural elements, reduce condensation. The surface of the ceiling, the height of which is appropriate for operation, should be smooth;

3) windows and other openings should be constructed in such a way as to prevent accumulation of dirt. Exterior windows should be equipped, if necessary, with an insect grid, easily removed for cleaning. Windows, the opening of which may lead to contamination, must be closed during the production process;

4) the surface of doors should be smooth and made of non-moisture absorbing materials. The doors should be easy to clean and disinfect, if necessary;

5) all surfaces (including the surface of equipment) in contact with foodstuffs should be kept intact, easy to clean, disinfected, if necessary, and made of smooth, stainless, non-toxic materials suitable for washing;

6) depending on type, size and activities at the facilities, the premises for cleaning, disinfection and storage of working tools and equipment should be made of stainless materials, easy to clean, be supplied hot and cold water.

2. In foodstuffs are kept in premises for acquisition of their traditional characteristics (for traditional foods), the ceilings, walls and floors of such premises may not comply with the requirements of Part 1 hereof in regard to properties of materials from which they should be made (non-penetrating and non-absorbing).

3. The provisions of this Article should not apply to market operators specified in Articles 43 and 44 of the Law.

Article 43. Hygienic requirements to movable and/or temporary establishments

1. Movable and/or temporary establishments (tents, kiosks, movable trade vehicles) must meet the following requirements:

1) to be kept clean and in good condition;

2) to provide protection from any of contamination risks, in particular from pests and rodents;

3) be equipped with means of personal hygiene;

4) the surfaces (including the surface of equipment) in contact with foods should be kept intact, easy to clean and disinfect, made of smooth, stainless, non-toxic materials, suitable for washing;

5) be supplied hot and/or cold potable water in the required quantity;

6) have appropriate means for hygienic storage of unsafe and/or inedible substances and wastes (liquid or solid), as well as means for their storage and further handling, and/or have appropriate contract for their disposal (destruction);

7) have adequate means to maintain and control the temperature required for storage of foodstuffs;

8) ensure placement of foodstuffs in such a way as to minimize the risk of contamination.

Article 44. Hygienic requirements to vehicles

1. Market operators use only vehicles that meet the following requirements:

1) the vehicles and/or containers used for haulage of foodstuffs should be clean, kept in good condition, protecting foodstuffs from contamination, and have a design that provides effective cleaning and/or disinfection thereof;

2) if the use of vehicles and/or containers for haulage of non-food products may lead to contamination of food products, for haulage of which they may be further used, they should be used solely for haulage of foods;

3) in the event of simultaneous use of vehicles and/or containers for haulage of food and non-food products, or in the event of simultaneous haulage of various foodstuffs, the separation of products to prevent their contamination should be ensured. To avoid the risk contamination, effective cleaning of these vehicles and/or containers should be provided before each subsequent use;

4) transportation of liquid, granular, powdered foods should be performed in containers and/or containers/tankers intended for carriage of solely foodstuffs. These containers and/or containers/tankers should be clearly marked in the official language, indicating their use solely for the transportation of foodstuffs, or marking "only for foodstuffs";

5) foodstuffs should be placed in vehicles and/or containers in such a way as to minimize the risk of their contamination.

Article 45. Hygienic requirements for tools and equipment

1. Market operators may use tools and equipment contacted with food that meets the following requirements:

1) to be clean and, if necessary, disinfected. Cleaning and disinfection should be carried out in such a way as to protect against any risk of contamination;

2) to be made of materials and kept in proper condition and state that reduce risk of contamination and make them possible to be cleaned and disinfected (except tare and packaging that is not returnable to market operator);

3) to be placed in such a way as to ensure cleaning of the equipment and surrounding area.

2. The equipment should be calibrated in accordance with law.

3. In the event of using chemicals to prevent corrosion of equipment and containers, such means should be used in accordance with good manufacturing practice.

Article 46. Hygienic requirements for food waste management

1. Market operators managing food waste (inedible by-products and other residues) must:

1) remove food waste from the premises with food as soon as possible;

2) keep food waste in closed containers designed to provide maximum protection and disinfection;

3) adhere to relevant provisions of legislation on storage and disposal (distruction) of food and other wastes and/or make contract(s) for their disposal (destruction).

2. Food waste should be disposed of according to the legislation.

Article 47. Hygienic requirements for water supply

1. Market operators should comply with the following water supply requirements:

1) ensure supply of potable water to establishment(s) in amount corresponding to the size and type of establishment(s);

2) clean water may be used for processing of fishery products with unaltered integrity, as well as for external washing. Pure sea water may be used for processing live bivalve mollusks, echinoderms, shells and sea gastropods. In such cases, the establishment must be designed and equipped in such a way as to enable supply of such water;

3) circulation of unpolluted water used in fire extinguishing systems, for steam production, freezing and other purposes should be provided by separate well identified water supply network. It is prohibited to connect any water pipe with technical water to water supply piping, through which the circulation of potable water occurs;

4) water used for production of foodstuffs (in technological process and/or as an ingredient) must comply with the requirements established for potable water;

5) ice in contact with food that may cause contamination of foodstuffs should be made of potable water or, if used to cool fishery products with unchanged integrity - of clean water. Ice should be produced, kept and stored in conditions that protect it from contamination;

6) steam in direct contact with foodstuffs must be free of any substances unsafe for human health and those that may cause contamination of foodstuffs;

7) in the event of heat treatment of foodstuffs in sealed containers, market operator should ensure conditions under which the water used to cool these containers is not a source of contamination of such products.

Article 48. Requirements for the hygiene of the staff working in the food processing zone

1. Market operators must comply with the following hygiene requirements for establishments operating in the food processing zone:

1) personnel is allowed to establishments, which has no contraindications to handling food products and has passed operator's training in the field of personnel hygiene confirmed by relevant records of the market operator;

2) personnel of the establishments periodically undergo training on hygienic requirements for production and circulation of foodstuffs with this market operator. The periodicity of such training should be set individually by market operators.

Article 49. Hygienic requirements to foodstuffs

1. Market operators should comply with the following requirements:

1) it is prohibited to accept objects of sanitary measures (other than live animals) used for production of foodstuffs, after processing which food products become unfit for human consumption;

2) the initial product and all ingredients stored at establishments should be kept in conditions that prevent them from being spoiled and provide protection from contamination;

3) food products must be protected from any contamination at all stages of production, processing and/or circulation;

4) effective control of pests and rodents is in progress;

5) the temperature regime, which makes it impossible to reproduce microorganisms and form toxins, is observed. This mode should be continuous. An exception to the temperature regime that makes it impossible to reproduce microorganisms and form up toxins, is possible for a limited period

of time during preparation of food product for transportation, storage, sale, serving of food products, provided this is safe for the health of consumers;

6) establishments engaged in production, processing, transportation, storage, primary packaging of processed foodstuffs must have adequate premises for storage of processed foods separately from unprocessed, including freezers of sufficient size;

7) if foods are planned to be stored or offered for consumption at low temperatures, they must be cooled as soon as possible after heat treatment or the last production phase to a temperature which does not endanger the health of consumers;

8) foodstuffs should be defrosted in such a way as to minimize the risk of reproduction of pathogenic microorganisms or formation of toxins in food products. During defrost, food should be kept at a temperature that does not pose a risk to the health of consumers. If a liquid resulting from defrosting may cause harm to human health, it should be drained in a safe way. After defrosting, food products should be kept in a way that minimizes the risk of reproduction of pathogenic microorganisms or formation of toxins;

9) unsafe and/or inedible substances, including animal feeds, should be clearly labeled and stored in separate safe containers.

Article 50. Hygienic requirements for packaging foods, including initial packaging

1. During packaging foods, including initial packaging, market operators are required to ensure compliance with the following requirements:

1) materials used for packaging, including initial packaging, should not be a source of contamination;

2) materials for primary packaging should be stored in a way that prevents its contamination;

3) packaging, including initial packaging, should be performed in such a way as to avoid contamination of the products and integrity of package.

2. Repeatedly used materials for packaging, including primary packaging, should be easy to clean and disinfect, if necessary.

Article 51. Hygienic requirements during heat treatment

1. The requirements of this Article apply to foods placed in circulation in sealed packs (containers).

2. Any heat treatment used to treat raw food or to further process treated food should:

1) contain heating of each part of the processed food product up to a defined temperature over a predetermined period of time;

2) prevent contamination of the food product during processing.

3. Market operators are obliged to ensure compliance of heat treatment processes they use with the determined results by regular checks of the established basic parameters (temperature, pressure, integrity of packaging, microbiological indicators).

Section VIII
INTERNATIONAL TRADE

Article 52. Importation of food for own consumption in Ukraine

1. Citizens of Ukraine, foreigners and stateless persons are prohibited to import foodstuffs of animal origin without packing of the producer for own consumption to the territory of Ukraine.

{Article 53 is deleted according to the Law No. 2042-VIII dated May 18, 2017}
{Article 54 is deleted according to the Law No. 2042-VIII dated May 18, 2017}
{Article 55 is deleted according to the Law No. 2042-VIII dated May 18, 2017}
{Article 56 is deleted according to the Law No. 2042-VIII dated May 18, 2017}
{Article 57 is deleted according to the Law No. 2042-VIII dated May 18, 2017}
{Article 58 is deleted according to the Law No. 2042-VIII dated May 18, 2017}
{Article 59 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

Article 60. Conditions applicable to consignments of exported foodstuffs

1. If required by the importing country, consignment with exported foodstuffs must be accompanied by originals of international certificates or other documents required by legislation of the country of destination issued by the competent authority.

2. International certificates are issued exclusively upon request of market operators and filled in Ukrainian and/or in English or in the language of the country of destination. International certificates

for consignments with certain types of foodstuffs of non-animal origin are issued in the form agreed upon by the competent authority of Ukraine and the competent authority of the country of destination, or in the form established by the country of destination. The competent authority should develop, approve and publish guidelines for export of consignments of certain types of foodstuffs of non-animal origin and the procedure of execution (filling) of relevant international certificates on its official website.

{Article 60 is supplemented with Part Two according to Law No. 2042-VIII dated May 18, 2017}

3. Unless otherwise provided by law, the amount of fee levied by market operator in favor of the competent authority for issuance of international certificate for consignment with non-animal food products is equal to 0.05 monthly minimum wage established by the Law on the date of relevant request of the market operator.

{Article 60 is supplemented with Part three according to Law No. 2042-VIII dated May 18, 2017}

4. Unless otherwise provided by law, an international certificate of consignment with non-animal food products should be issued by a state inspector not later than one business day from the date of application of a market operator to the territorial office of the competent authority (without taking into account the time required for conducting laboratory research (testing), if these are required by the country of destination, provided the compliance with the requirements of the country of destination is established under the results of the consignment testing.

{Article 60 is supplemented with Part Four according to Law No. 2042-VIII dated May 18, 2017}

Section IX
INTERNATIONAL COOPERATION

Article 61. International cooperation of Ukraine in the field of safety and individual food quality indicators

1. International cooperation of Ukraine in the field of safety and individual food quality indicators is carried out by:

1) participation in the work of relevant international organizations;

2) conclusion of international agreements, including bilateral agreements on the mutual recognition of sanitary measures;

3) harmonization of the Ukrainian legislation on safety and separate indicators of quality foodstuffs with the documents of the relevant international organizations;

4) adaptation of the Ukrainian legislation on safety and separate indicators of quality foodstuffs with the relevant legislation of the European Union.

Section X
ADMINISTRATIVE SERVICES

{Title of section X as amended by Law No. 2042-VIII dated May 18, 2017}

Article 62. List of administrative services and fees for provision thereof

{Title of Article 62 as amended by Law No. 2042-VIII dated May 18, 2017}

{Part One of Article 62 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

2. Administrative services in the field of food safety are:

1) state registration of:

novel foodstuffs;

food supplements;

flavorants, except for a separate group of flavorants, determined by the central executive body, responsible for formation and implementation of the state policy in the field of public health;

enzymes;

auxiliary materials for recycling and materials in contact with foodstuffs that are first introduced into circulation and/or are for the first time used on the territory of Ukraine;

natural mineral waters;

2) issuance of an operating permit.

{Clause 3 of the second part of Article 62 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

{Clause 4 of the second part of Article 62 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

3. Establishment of new or cancellation of existing administrative services in the scope of this Law should be carried out only by means of amendments thereto.

4. The amount of fee for provision of administrative services and the procedure for its collection should be determined by Law, taking into account its social and economic value, and should not exceed the actual value of services rendered.

{Article 63 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

Section XI
LIABILITY

{Article 64 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

{Article 65 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

Article 66. Compensation for damage (loss)

1. Inflicted damage (loss) should be compensated by market operators in accordance with the procedure established by the Civil Code of Ukraine, the Commercial Code of Ukraine, the Law of Ukraine "On liability for damage caused by defects in products", and other legislative acts.

{Part two of Article 66 is deleted according to the Law No. 2042-VIII dated May 18, 2017}

President of Ukraine	**L.KUCHMA**
Kyiv **December 23, 1997** **No. 771/97-VR**	

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